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Subcommittee on Science, Technology, and Innovation

Hearing on:

"National Nanotechnology Initiative: Charting the Course for Reauthorization"

Written Testimony of:

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I would like to thank Chairman Kerry, Ranking Member Ensign, and the members of the Senate Committee on Commerce, Science, and Transportation's Subcommittee on Science, Technology, and Innovation for holding this hearing on the "National Nanotechnology Initiative: Charting the Course for Reauthorization."

My name is David Rejeski, and I direct the Project on Emerging Nanotechnologies (PEN), an initiative of the Woodrow Wilson International Center for Scholars and The Pew Charitable Trusts. It is dedicated to helping business, government, and the public anticipate and manage the possible health and environmental implications of nanotechnology. As part of the Wilson Center, the Project is a non-partisan, independent policy research organization that works with researchers, government, industry, non-governmental organizations (NGOs), and others to find the best possible solutions to developing responsible, beneficial, and acceptable nanotechnologies. The opinions expressed in this testimony are my own and do not necessarily reflect views of the Wilson Center or The Pew Charitable Trusts.

Our goal is to take a long-term look at nanotechnologies, to identify gaps in nanotechnology information, data, and oversight processes and to develop practical strategies and approaches for closing those gaps and ensuring that the extraordinary potential benefits of nanotechnologies will be realized. We aim to provide independent, objective information and analysis, which can help inform critical decisions affecting the development, use, and commercialization of nanotechnologies across the globe. All research results, reports, and the outcomes of our meetings and programs are made widely available through publications and our website: http://www.nanotechproject.org.

In short, both the Wilson Center and The Pew Charitable Trusts believe there is tremendous opportunity with nanotechnology to "get it right." Societies have missed this chance with other new technologies and, by doing so, forfeited significant social, economic, and environmental benefits.

When I last appeared before the Senate Commerce Committee in May 2006, I illustrated the rapid commercialization of nanotechnology by providing analysis from the Project's then newly released inventory of nanotechnology consumer products. I also identified a number of key challenges and factors hindering nanotechnology commercialization, including lack of public engagement, lack of effective oversight and governance mechanisms, and lack of coordinated risk research strategies. Today, I would like to address what has changed since that time, what has not, and what must change if nanotechnology commercialization is to be successful in the future.

What Has Changed

I would like to begin by providing an update on the state of commercialization of nano-based consumer products and then share some observations. These products are important because consumer products will be most of the public's first experience with nanotechnology.

- **The number of nano-enabled consumer products has increased rapidly.** Two years ago, we had 212 manufacturer-identified, nano-enabled consumer products in our Consumer Products Inventory. The number now exceeds 600, a number that has doubled within the last 14 months alone.[1] Since our inventory includes only manufacturer-identified nanotechnology products, there likely are hundreds of more products on the market that are not identified as such. This number also does not take into account the hundreds of commercial and industrial current uses of nanotechnology and nanomaterials.

- **Production and distribution of nanotechnology products is increasingly global.** The products in our inventory come from 321 companies in 20 countries. All of these products are available in shopping malls or over the Internet, and we have purchased many of them on-line. Thanks to business-to-business (B2B) and business-to-consumer (B2C) e-commerce, nanotechnology products easily flow across international borders, raising control, trade, and oversight issues.

- **Silver has become the most commonly used nano-engineered material in consumer products.** The type of nano-engineered substances in these products has shifted dramatically from materials like carbon to silver, which is now used in over 140 products, primarily as an antimicrobial. However, with production costs of carbon nanotubes dropping rapidly, this mix could shift again.[2]

- **The number of children's products is on the rise**. Within the past year, an increasing number of products on sale are targeted at children, including: pacifiers, toothbrushes, baby bottle brushes, and stuffed animals. These products originate from the U.S., Australia, China, Germany, and Korea. This remains a category to watch as nanotechnology's commercialization proceeds, especially since young children and babies generally have a greater vulnerability to chemicals and other toxins.

- **Products are penetrating the market in areas where oversight regimes are weak**. For instance, as shown in Figure 1, about a half of the products in our inventory would fall under the purview of the Consumer Products Safety Commission (CPSC), an agency which, last year, according to CPSC Commissioner Thomas Moore, spent only a total of $20,000 to do a literature review on nanotechnology.[3] Other areas of high growth where

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[1] Nanotechnology Consumer Product Inventory. Washington, DC: Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, 2005. Available at http://www.nanotechproject.org/consumerproducts, accessed April 16, 2008.

[2] "Over the past two years, scale up of multi-wall carbon nanotube production has led to a dramatic price decrease down to $150/kg for semi-industrial applications. According to [*NanoSEE 2008: Nanomaterials Industrial Status and Expected Evolution*], the run for industrial CNT production plants has started in order to achieve a sustainable business with the commercialization of these high-tech materials with a mid-term price target of $45/kg." "Nanotechnology Industry is Moving from Research to Production with over 500 Consumer Nano-Products Already Available," *NanoVIP.com*. Available at http://www.nanovip.com/node/6020, accessed April 17, 2008.

[3] Testifying before a Senate Subcommittee in 2007, CPSC Commissioner Thomas H. Moore, who has served at the agency since 1995, summed up the situation: "I do not pretend to understand nanotechnology and our agency does not pretend to have a grasp on this complicated subject either. For fiscal year 2007, we were only able to devote $20,000 in funds to do a literature review on nanotechnology." Available at: http://www.cpsc.gov/pr/moore2007.pdf, accessed April 17, 2008.

oversight is weak include cosmetics and dietary supplements, both areas where the Food and Drug Administration (FDA) has very limited regulatory authority.[4]

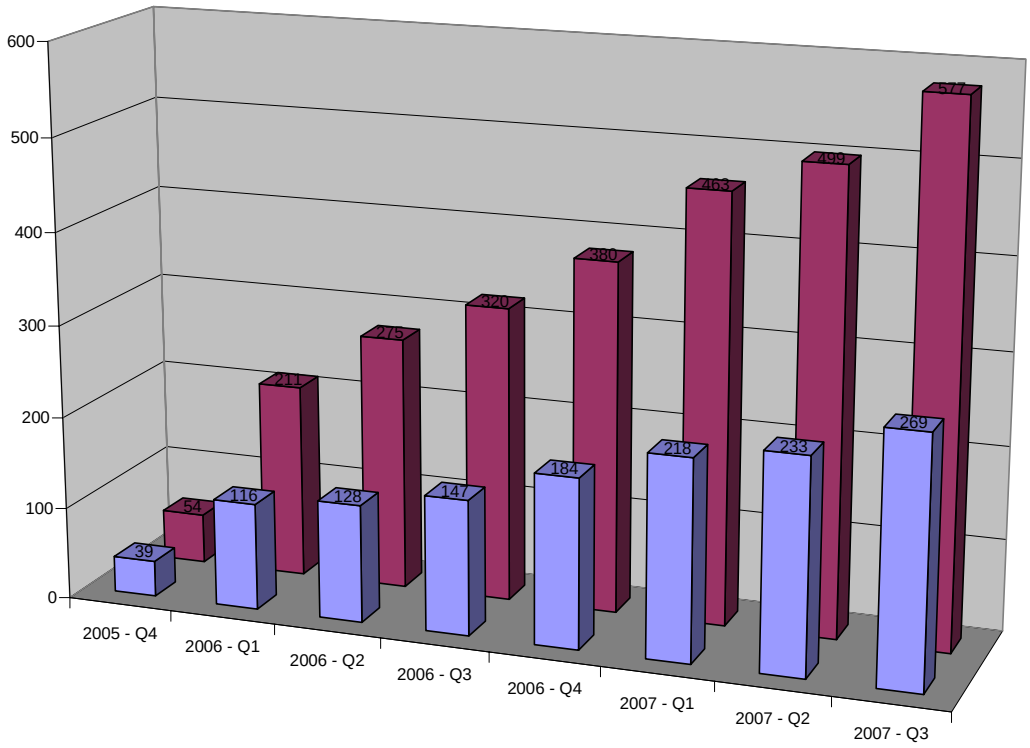

Figure 1. Growth in the number of manufacturer- identified, nanotechnology-enabled products on the market from 2005 to 2007 (in red) showing products under possible CPSC jurisdiction (in blue).

This suite of already-commercialized products tells us something about the emerging face of the nanotechnology industry and the challenges we face as we begin to introduce nanotechnology into the marketplace. These changes are signs that a set of issues related to consumer safety and health are emerging that were not as apparent when our inventory was first released. In addition, the current state of oversight regimes should raise serious concerns for policymakers tasked with the challenge of spurring nanotechnology innovation in a responsible and sustainable manner.

It is important to keep in mind that the willingness of the public to "buy nano" will be affected by changes that impact the overall climate in the commercial marketplace and influence consumer trust and confidence. Let me explore some of these changes.

Over the past year, American consumers have painfully learned that the federal oversight system is failing. The public has had to deal with lead in toys (a use that was banned 30 years

[4] Taylor, Michael. *Regulating the Products of Nanotechnology: Does FDA Have the Tools It Needs?,* Washington, DC: Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, 2007. Available at http://www.nanotechproject.org/file_download/files/PEN5_FDA.pdf, accessed April 18, 2008.

ago by the CPSC), rat poison in pet food, antifreeze in toothpaste, and *E. coli* in meat. Most recently, over 100 deaths were tied directly to a compromised blood thinner.[5]

These were equal opportunity failures involving multiple government agencies: the FDA, U.S. Department of Agriculture (USDA), and CPSC. In most cases, the agencies were not dealing with exotic toxins but ones with long histories of pernicious effects. One logical question consumers will have is: "If the government can't protect my children from lead, how will they deal with nanotechnology?"

Not surprisingly, our latest polls on public awareness of nanotechnology show declining trust in the government's ability to manage risks with emerging technologies. National surveys conducted on behalf of the Project by Peter D. Hart Research Associates in August 2006 and August 2007 indicate declining levels of confidence in the USDA and FDA, as well as businesses and companies, to maximize the benefits and minimize the risks of scientific and technological advancements (Figure 2). Considering the events of the past year, it would not be surprising to see an even greater drop in the levels of confidence in government regulatory agencies when we repeat our national survey this summer.

Public trust is the "dark horse" in nanotechnology's future. If government and industry do not work to build public confidence in nanotechnology, consumers may reach for the "**No-Nano**" label in the future. Public perceptions can have large economic impacts. The European Union's (EU) *de facto* moratorium on the approval of new genetically modified food products, driven largely by public concerns, is costing American farmers an estimated $300 million per year in lost sales.[6]

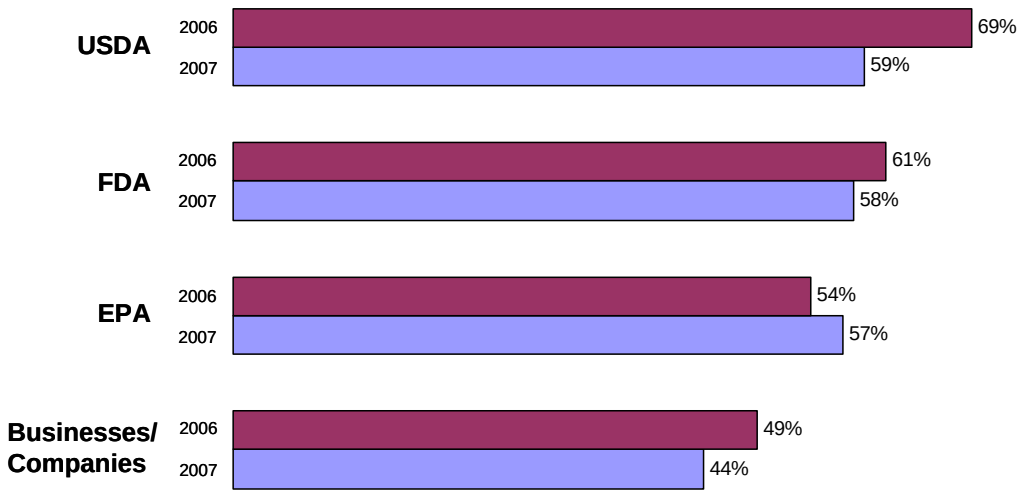

Figure 2. Percentage of respondents with "Great deal/fair amount of confidence" in each to maximize benefits and minimize risks of scientific/technological advancements. Results are from surveys conducted in August 2006 and August 2007. Each survey had 1,014 respondents and margin of error of ± 3.1 percentage points.

[5] "FDA Links More Deaths to Blood Thinner," *Associated Press*, April 8, 2008. Available at: http://ap.google.com/article/ALeqM5iT7Y6m5N3h8XK-CDe9bU7wuYNCcQD8VTUN6O0, accessed April 18, 2008.

[6] Estimate according to Biotechnology Industry Organization. Available at: http://www.bio.org/foodag/background/eumoratorium.asp, accessed April 18, 2008.

Consumer confidence will be further undermined if companies continue to make claims about nanotechnology in their products that cannot be supported. Last month, the Environmental Protection Agency (EPA) fined a California company $208,000 for making unsubstantiated claims involving the anti-bacterial benefits of a nano-silver coating for computer mice and keyboards. Since that time, the claim about the use of nanomaterials has been removed from the manufacturer's web site, though the product appears to have remained unchanged. This phenomenon is one that has been seen with other products, including food storage containers and stuffed animals.

In addition to disappearing product labels, the nanotechnology commercial landscape is awash with hyperbolic product claims so obtuse that no consumer could possibly unravel their meaning. Companies are creating a literal nanotechnology "Tower of Babel." Here are a few examples from our Consumer Products Inventory:

NanO Bio-Sim

" This product is essential for one's optimum health. The elimination of Candida, parasites, worms, yeast, fungi, and amoebas from the body is the fundamental base of any cure that will return health to the body…Once ***Bio-Sim*** *is absorbed by the body, the sugar and the vinegar begin* ***attracting the parasites, fungi, Candida, worms, and amoebas from their hiding places****. Then, the NanO silica* ***act as cutting knives*** *on the intruders. Fortunately, this action only affects the pathogens and leaves the healthy body intact because of the perfect sizing of the diatomaceous earth."*[7]

Eczemel Nano-Cream

"Due to their specific composition, nanoparticles have a very high affinity to the ***horny layer of the skin*** *and are used as transport systems which help the different active agents to penetrate the skin more readily. The capsules of nanoparticles consist of* ***monolayers of phosphatidylcholine****, a naturally occurring substance that nature uses for the basic structure of the membranes of each cell. Nanoparticles contain within their nucleus the* ***active substances****, which are gradually released in the skin."*[8]

MesoPlatinum®

"Promotes increased mental focus and concentration. Promotes enhanced mental acuity. ***Supports healthy tissue regeneration*** *of the heart tissue, thymus and the entire endocrine system. Promotes increased* ***creativity****.*

[7] Additional claims can be found on product website. Available at http://www.fulvic.org/html/nano_bio-sim.html, accessed April 22, 2008.

[8] This and other claims are available in the Project's Consumer Products Inventory. Available at http://www.nanotechproject.org/consumerproducts, accessed April 16, 2008.

*Promotes very **vivid dreams**. Promotes **improved memory**. Supports DNA repair. Promotes increased libido in both males and females."*[9]

Discussions about nanotechnology should not be just about the risks, but also about benefits. Most nano-enabled products carry a price premium over their non-nano counterparts. What, exactly, are consumers getting for their money, and who can help sort this out?

The developments I have outlined do not bode well for nanotechnology commercialization. American consumers are nervous – so are other people who matter to the long-term success of nanotechnology, including insurers and investors, state and local governments, NGOs, other countries, and nanotechnology companies. Let me summarize some of these concerns.

Insurers and Investors: The financial community is taking another look at nanotechnology. The Lloyd's of London Emerging Risks Team just issued a report on nanotechnology that noted that "due to the potential impact to the insurance industry if something were to go wrong, nanotechnology features very highly in Lloyd's top emerging risks."[10] When I talked recently to staff at Lloyd's, they said that two things are critical to the insurance sector in terms of reducing risks: transparency and regulation. We have neither at the moment and the federal government is doing little to remedy this problem. Similar to Lloyd's, Zurich Insurance's Canadian office ranked nanotechnology in the top tier of emerging global risks (along with climate change and deteriorating infrastructure).[11] A recent UK exercise involving 35 representatives from government, NGOs, and academia also identified nanotechnology as the top risk to ecosystems (above climate change and the possible impact of novel pathogens).[12]

One reason insurers and investors are nervous is the fear that some companies are not being transparent. Last week, the Investor Environmental Health Network, in collaboration with investment managers, who have more than $41 billion in combined assets, released a report raising concerns that companies are not apprising investors of potential nanotechnology risks. The report notes that, "…companies dealing with nanomaterials…are not disclosing the evidence of health risks of nanotechnology products, nor the lack of adequate product testing prior to their sales."[13]

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[9] Ibid.

[10] Lloyd's Emerging Risks Team. *Nanotechnology: Recent Developments, Risks and Opportunities*, 2007. Available at http://www.lloyds.com/Lloyds_Market/Tools_and_reference/Exposure_Management/Emerging_risks.htm, accessed April 17, 2008.

[11] Zurich's view was covered in the following article: "Nanotechnology, climate change, infrastructure among top risks," *Canadian Underwriter*, November 22, 2007. Available at http://www.canadianunderwriter.ca/issues/ISArticle.asp?id=76768&issue=11222007, accessed April 17, 2008.

[12] "Scanning the risk horizon for emerging threats," *Lloyd's.com*, 8 April 2008. Available at http://www.lloyds.com/News_Centre/Features_from_Lloyds/Scanning_the_risk_horizon_for_emerging_threats090408.htm, accessed April 17, 2008.

[13] Lewis, Esq., Sanford, Richard Liroff, Ph.D., Margaret Byrne, M.S., Mary S. Booth, Ph.D., and Bill Baue. "Toxic Stock Syndrome: How Corporate Financial Reports Fail to Apprise Investors of the Risks of Product Recalls and Toxic Liabilities," *IEHN*, April 2008. Available at: http://www.iehn.org/publications.reports.toxicstock.php, accessed April 18, 2008.

State and Local Governments: Tired of waiting for federal action, municipal governments are moving to provide specific guidance to nanotechnology firms in places like Berkeley, CA, and, soon, in Cambridge, MA. Interestingly, when Cambridge passed the world's first biotechnology ordinance in the mid-1970s, companies did not flee. The city provided a unique location where the rules of the road were known and the public was comfortable with established safety precautions. It is now home to 55 biotechnology firms.[14] Last year, the state of Massachusetts established an Interagency Nanotech Council to discuss nanotechnology issues[15] and, most recently, a state lawmaker in Wisconsin has sought answers from state officials about potential reporting requirements for firms involved with nanotechnology. Also, a recent analysis by our Project indicates that five states with significant nanotechnology activities (CA, MA, NY, NJ, MI) could take a more proactive approach to nanotechnology oversight based on legal authorities that go beyond those of the federal government.[16] This is not an optimal solution (since it could disaggregate markets), but history has shown that state action is often a prerequisite for federal movement on emerging environmental and public health issues. As Justice Brandeis once noted, the states are the "laboratories of democracy," and they often drive public policy innovation.

NGOs: During the last year, the positions taken by NGOs have hardened. A recent report by Friends of the Earth called for a complete moratorium on the use of nanotechnology in all foods and food packaging until more is known about the risks to humans and the environment.[17] In early April, the Silicon Valley Toxics Coalition called for "new comprehensive state and federal regulatory policies that adequately address the potential hazards posed by nanotechnology."[18] Increasingly, NGOs are growing impatient with a lack of transparency by government and slow action on oversight. If there ever was a honeymoon with the NGO community, it is over.

Other Countries: Countries are responding to this evolving commercialization climate differently, which generates its own set of issues. Internationally, the EU is clearly moving in the direction of a more precautionary approach to nanotechnology oversight raising the potential of a three-tiered governance system at a global level – reflecting diverging approaches by the EU, the U.S., and countries like China. Large disparities in nanotechnology oversight systems at a global level would be highly counterproductive and create an uneven playing field for U.S. companies who want to operate in the global marketplace. Variations in oversight also open the door to potentially dangerous products flowing across our borders, as we have seen in the case of substandard products from China.

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[14] Lipson, Sam 2004. "The Cambridge Model of Biotech Oversight," at: http://www.gene-watch.org/genewatch/articles/16-5lipson.html

[15] The group recently issued its first workshop report with a second now being planned. The report is available at: http://www.mass.gov/dep/toxics/sourcest.htm#ec, accessed April 22, 2008.

[16] Keiner, Suellen. "Room at the Bottom? Potential State and Local Strategies for Managing the Risks and Benefits of Nanotechnology." Washington, DC: Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, 2007. Available at http://www.nanotechproject.org/process/assets/files/6112/pen11_keiner.pdf, accessed April 16, 2008.

[17] "Nanotech Exposed in Grocery Store Aisles," Friends of the Earth, March 11, 2008. Available at: http://action.foe.org/pressRelease.jsp?press_release_KEY=343, accessed April 21, 2008.

[18] "SVTC Nanotech Report: Regulating Emerging Technologies in Silicon Valley and Beyond," Silicon Valley Toxics Coalition. Available at: http://www.etoxics.org/site/PageServer?pagename=svtc_nanotech, accessed April 21, 2008.

Firms: Increasingly, nanotechnology firms, especially small firms, are nervous because government has failed to provide a clear and predictable path to compliance. A new report by Ernst & Young on strategic business risks identified regulatory and compliance risk as the number one risk companies face today and will likely face in the future.[19] Recently, our Project released the results of a New England focused survey, conducted by researchers at University of Massachusetts-Lowell, that investigated how nanotechnology firms (especially small- and medium-size firms) are dealing with environmental, health and safety (EHS) management and what information they need to address risks proactively.[20] The survey produced two key findings. The first is that most nanotechnology firms recognize the existence of potential risks. The second, however, is that the firms (especially small firms) feel that they lack (a) information on the health and environmental risks of nanomaterials and (b) the necessary guidance from suppliers, industry, governmental regulatory bodies, and others to manage risks associated with these materials and processes. As one senior safety manager in a Massachusetts corporation said, "At this time, we don't understand what regulatory requirements may be uniquely applicable to nanotechnology and nanoparticles." Compliance is hard if the compliance criteria are unknown.

Interestingly, the one entity that thinks things are fine is our federal government – specifically, the National Nanotechnology Initiative (NNI) – which has provided continued public reassurances that risk research is more than sufficient and existing oversight systems adequate for nanotech. As Congress approaches the reauthorization of the 21st Century Nanotechnology Research and Development Act, they need to carefully weigh the evidence for and against the federal government's position and the ultimate cost of a miscalculation.

What Has Not Changed and What Needs to Change

Let me now talk about what has not changed over the past two years and what needs to be remedied as the Congress turns its attention to the reauthorization of the 21st Century Nanotechnology Research and Development Act and looks beyond. Three issues must be addressed by the Act: transparency, strategy, and engagement.

1. Transparency: The Reauthorization Bill must make the NNI fully transparent and accountable in terms of its investments and strategy to address the risks of nanotechnologies.

During a three-year period, our Project has spent between $50,000 and $60,000 in staff time analyzing and making public federal government expenditures that address nano-related risks to workers, consumers, and the environment. It has not been an easy task, but, more importantly, it should never have been necessary. The federal government's data on risk

[19] This report identified regulatory and compliance risk as its number one risk. Obviously, this has high relevance to any industry using nanotechnology. Source: Ernst & Young (in collaboration with Oxford Analytica). *Strategic Business Risk 2008 - The Top 10 Risks for Business*, 2008.

[20] John E. Lindberg and Margaret M. Quinn. *A Survey of Environmental, Health and Safety Risk Management Information Needs and Practices among Nanotechnology Firms in the Massachusetts Region*. Washington, DC: Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, 2007. Available at http://www.nanotechproject.org/file_download/226 ,226, accessed April 16, 2008.

research, including spending levels, detailed project descriptions, and all assumptions driving the analysis, should have been on-line and transparent from the very beginning of the NNI.

Unfortunately, the recent study by the Government Accountability Office (GAO) has failed to remedy this problem since the detailed data that the GAO collected for their analysis is also not being made publicly available.[21] The existing lack of transparency undermines public trust, undercuts our ability to build workable public-private partnerships, raises suspicions among NGOs, and weakens the basis for international collaboration on risk research. It also makes any form of accountability to the Congress, for instance, virtually impossible. Finally, a strong risk strategy cannot be built on a weak quantitative foundation that cannot be validated by external stakeholders. Secrecy about the data underlying the government's approach to risk compromises our national investments in nanotechnology. As the late Senator Patrick Moynihan was fond of saying: "Secrecy is for losers."[22]

Our analyses consistently show that the federal government is inflating investments in risk analysis and management by orders of magnitude and, by doing so, distorting the perceptual environment where nanotechnology investment and commercialization takes place. These assurances of large investments in risk research (combined with statements of adequate oversight) provide a false sense of confidence and actually shift risks onto consumers, workers, investors, and, ultimately, onto insurers and re-insurers.

The Act must require that a comprehensive, public, on-line EHS research database be created and also mandate annual updates. This should be done within six months following the passage of the Act. Collaboration with international organizations, such as the OECD, should be supported to expand the collection and on-line publication of EHS research data internationally. Finally, the collection, analysis, and publication of other data key to understanding nanotechnology commercialization should be undertaken by the Department of Commerce, such as data on industry structure, venture capital investments, job creation, and domestic and international market growth.

Increased transparency must be combined with increased oversight. The existing reviews of the NNI through the President's Council of Advisors on Science and Technology (PCAST) are inadequate. PCAST is already stretched too thin and lacks the depth and breadth of knowledge necessary to review the critical EHS component of the NNI along with other areas crucial to the successful commercialization of nanotechnology.

Given the size of our investments in the NNI and its implications for economic growth, a separate external advisory board (independent of PCAST) should be created that has broad representation from the nanotechnology community, including universities, NGOs, investors, and a range of businesses, especially small businesses, which often lack a voice in our policy deliberations. Finally, the NNI should fully support the external review of the EH&S risk research strategy by the National Academies' Board on Environmental Studies and Toxicology (BEST). This review has received broad support from a variety of stakeholders including the

[21] We have compared the GAO findings with both the NNI numbers and our Project's inventory and included that analysis in the Appendix to this testimony.
[22] Moynihan, D.P. 1998. *Secrecy: The American Experience*, New Haven, CT: Yale University Press.

American Chemistry Council, Dupont, Evonik (formerly Degussa), the NanoBusiness Alliance, and the Environmental Defense Fund. Given the existing lack of transparency regarding the government's risk related research, reviews by independent entities are critical to maintaining accountability.

2. Strategy: After four years of waiting, the Congress has still not received a comprehensive, top-down strategy to address existing and emerging nanotechnology risks.

Though the NNI strategy for addressing risks has improved, it still lacks a clear set of government-wide priorities tied directly to funding levels, which would ensure that the right agencies are focused on the right risks at the right time in the research and development and commercialization cycle. The recent GAO report praised the level of collaboration between agencies involved in the NNI, but collaboration between agencies is an insufficient condition for success. Like soccer, moving the ball down the field as a team does not necessarily result in a goal – for that you need strategy and leadership. In short, what the NNI currently calls a strategy is really a collection of what individual agencies "can" do and not what they "should" do.

Any risk strategy also needs appropriate funding to work. I support a 10 percent floor for EHS funding because PEN's extensive analyses indicate that funding for highly-relevant risk research has been exaggerated for at least the past three years, and this underinvestment needs to be corrected, especially as more nanotechnology products flow into the marketplace and raise questions about public safety and challenges for government regulators. A PEN analysis of current research projects listed in the NNI's "Strategy for Nanotechnology-Related Environmental, Health, and Safety Research" found that only 62 of the 246 projects listed were highly relevant to addressing EHS risks of nanotechnology.[23] These 62 projects accounted for an estimated $13 million in research and development funding for 2006—far lower than the $68 million cited by the NNI document as being focused on EHS research.[24] In fact, our analysis now shows that the EU is spending almost twice the U.S. investment in highly-relevant EHS risk research.[25]

Research programs like the NNI do not automatically guarantee an optimal allocation of public money. Sometimes, key constituents or topics are left unfunded or under addressed. Recognizing this problem, the government has set minimal funding requirements. The federal government does this with small businesses in our set-asides for Small Business Innovation Research grants and with the Human Genome Project by dedicating five percent of all Project research spending to examine ethical, legal, and social implications that the policy community knew would accompany the development and application of genomics. The reauthorization

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[23] Project specific data underpinning this analysis can be found in the Project on Emerging Nanotechnologies Environment, Health and Safety Research Inventory. This inventory is in the process of being adopted and updated by the Organization for Economic Cooperation and Development, Working Party on Manufactured Nanomaterials. Available at: http://www.nanotechproject.org/inventories/ehs/, accessed April 15, 2008.

[24] Further independent assessment of research funded in 2006 reveals funding for highly-relevant risk research was closer to $20 million. The discrepancy appears to be due to relevant research that that the NNI missed in their analysis—another indicator that the government is not on top of what research is being funded, and lacks sufficient transparency for effective accountability. Available at: http://www.nanotechproject.org/inventories/ehs/, accessed April 8, 2008.

[25] Press release and additional information on analysis is available at: http://www.nanotechproject.org/news/archive/ehs-update/, accessed April 21, 2008.

proposal to set aside 10 percent of the total NNI budget for nanotechnology EHS research has received support from a wide range of stakeholders including the NanoBusiness Alliance, American Chemistry Council, and NGOs, including the Environmental Defense Fund. As Sean Murdock, director of the NanoBusiness Alliance, said in his recent testimony before the House Science and Technology Committee, "…we believe that 10 percent of the total funding for nanotechnology research and development is a reasonable estimate of the resources that will be required to execute the strategic plan…"[26]

The strategy must also increase, by orders of magnitude, the funding available for risk research at agencies with oversight missions such as the EPA, FDA, USDA, and CPSC. Our analysis has found that only $4.5 million for 36 projects at the EPA, $5.1 million for 45 projects at the National Institute for Occupational Safety and Health, and $56,501 for 9 projects at the USDA is dedicated to projects focusing on the risks of nanotechnology for FY2006.

Government oversight based on weak science is not acceptable. In some of these agencies, there may also be a lack of human resources and the scientific expertise needed to assess nanotechnology risks. Consequently, the federal risk research strategy must involve a human resources component, including an analysis of expertise gaps and plans on how they will be funded and filled. The recent assessment of the FDA's scientific capacity by their own science board uncovered a number of limitations that are directly relevant to nanotechnology:

- The development of medical products based on "new science" cannot be adequately regulated by the FDA.
- There is insufficient capacity in modeling, risk assessment, and analysis.
- The FDA science agenda lacks a coherent structure and vision, as well as effective coordination and prioritization.[27]

The strategy should support specific mechanisms to facilitate public-private partnerships focused on closing knowledge gaps in nanotechnology risk assessment and management and leveraging scarce funds across sectors. The NNI should evaluate a number of models for public-private partnerships using the following criteria:

- **Independence**. The selection, direction, and evaluation of funded research would have to be science-based and fully independent of the business and views of partners in the organization.
- **Transparency**. The research, reviews, and operations of the organization should be fully open to public scrutiny.
- **Review**. Research supported by the organization should be independently and

[26] Full quote from testimony reads, "While we believe that 10 percent of the total funding for nanotechnology research and development is a reasonable estimate of the resources that will be required to execute the strategic plan, we also believe that actual resource levels should be driven by the strategic plan as they will vary significantly across agencies." From testimony for hearing on "The National Nanotechnology Initiative Amendments Act of 2008," April 16, 2008.

[27] *FDA Science and Mission at Risk: Subcommittee on Science and Technology*, November 2007. Available at: http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_01_FDA%20Report%20on%20Science%20and%20Technology.pdf, accessed April 21, 2008.

transparently reviewed.

- **Communication**. Research results should be made publicly accessible and fully and effectively communicated to all relevant parties.
- **Relevance**. Funded research should have broad relevance to managing the potential risks of nanotechnologies through regulation, product stewardship, and other mechanisms.[28]

Two models should be adapted, funded, and evaluated over the next three years.

Finally, there is still not enough attention being paid to engineering the risks out of nanotechnology manufacturing and products. Recent research at the Massachusetts Institute of Technology (MIT) has shown that carbon nanotubes may contain high concentrations of toxic impurities like chromium and lead – if we continue down this path, the nanotechnology revolution risks being a dirty one, not a green one. We have the ability to enable "green" nanotechnology production and products – reducing toxic inputs, energy use, emissions, end-of-life impacts, and ultimately financial liabilities – but presently we lack a coherent strategy and the resources to do this. University of Oregon researcher Jim Hutchinson has been able to create gold nanomaterials through "green" synthesis that is not only safer and faster than traditional means but also much less expensive.[29] The longer the government and industry delay investments in "greening" the nanotechnology production infrastructure, the more we may have to invest to manage risks after the fact. Based on PEN analysis, I recommend dedicating $20-30 million annually to establish at least one major university center on "green" nanotechnologies and a prestigious and highly-visible award to spur green nanotechnology innovation.[30] The goal should be to make the U.S. the world's leader in "green" nanotechnology.

3. Engagement: Public awareness of nanotechnology is stuck at a low level. The same surveys mentioned earlier have actually shown a decrease in the number of Americans who have "heard a lot" about nanotechnology from August 2006 to August 2007. Despite an annual U.S. public and private sector investment of over $4 billion in nanotechnology research and development, 80-90 percent of Americans have heard "very little" or "nothing" about nanotechnology. The original 21st Century Nanotechnology Research and Development Act specified that the government provide:

*"…through the National **Nanotechnology** Coordination Office…for public input and outreach to be integrated into the Program by the convening of regular and ongoing public discussions, through mechanisms such as citizens' panels, consensus conferences, and educational events, as appropriate;…"*

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[28] See Dr. Andrew Maynard's testimony for hearing on "The National Nanotechnology Initiative Amendments Act of 2008," April 16, 2008. Available at: http://www.nanotechproject.org/process/assets/files/6689/maynard_written_april08.pdf, accessed April 21, 2008.

[29] Jim Hutchison's technique is able to create a gram of gold nanoparticles for $500, down from the $300,000 per gram cost for traditional methods. Schmidt, Karen. *Green Nanotechnology: It's Easier Than You Think*, Washington, DC: Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, 2007. Available at: http://www.nanotechproject.org/process/assets/files/2701/187_greennano_pen8.pdf, accessed April 18, 2008.

[30] Rejeski, David. "How About An X-Prize for Green Nanotechnology?" *Nanotechnology Now*, 2007. Available at: http://www.nanotech-now.com/columns/?article=134.

Unfortunately, this mandate came with no funding, and the National Nanotechnology Coordination Office has not fulfilled this mission.

At this critical juncture, the federal government has no strategy to engage the public and fill the knowledge gap about nanotechnology, which could have serious implications for nanotechnology's long-term success. Significant resources and ingenuity need to be committed to this area. An essential element missing from previous efforts has been genuine citizen engagement. We are still talking to the American public about nanotechnology through TV shows, web sites, and museum exhibits — this is not public engagement. Some experiments on engagement have been run by various National Science Foundation-funded nanotechnology centers, but there is no effort being made to scale these up to reach significant numbers of people nationwide (we need to engage thousands, not dozens).

As the commercialization of nano-based products accelerates, how the public learns about nanotechnology, from whom, and with what message will be critical to assuring public confidence in the applications and support for further government funding. We need large-scale education and citizen deliberation on how to balance the opportunities and risks presented by nanotechnology that engages the diverse perspectives of the American public, helps identify a collective public agenda, generates buy-in from stakeholders, and raises awareness about the issues. For nanotechnology to succeed, the strategy for public engagement will be as critical as the strategy for risk assessment and management and will require adequate funding and top-level attention. It cannot be approached piecemeal or as an afterthought. The NNI should bring in an outside entity with proven capabilities in running large multi-stakeholder dialogues on key national policy issues and provide adequate funding to run a one-year, national dialogue on nanotechnology.

Conclusions

Let me close by putting forth a greater challenge to the committee and our government. For the commercial success of any emerging technology, we need a better approach to governance that can support strategic risk research, provide adequate oversight, and engage the broader public in our technological future. With nanotechnology, industry and government are struggling to balance science, innovation, and the pressures for rapid commercialization with a need to address risks and public concerns early and proactively. This situation does not surprise people who were part of the debates around agricultural biotechnology in the 1990s or watched the tortuous path of nuclear power through the 1950s and 60s. The recurrence of issues around risk assessment, oversight, and public dialogue – irrespective of the technology involved – indicates that these challenges have deeper origins that will not respond to quick fixes. The government is not organized for the tasks at hand, and the challenges we face will only grow more complex as nanotechnology and biotechnology increasingly converge and new scientific fields, such as synthetic biology, emerge.

We need to bring together the best minds in the nation to develop a governance system for 21st century technologies, a system that will work with nanotechnology and the technologies

beyond. A high-level commission (organized by the national academies of Science and Public Administration) should be established to undertake this task.

Finally, let me say that I applaud the committee for focusing our attention on issues affecting the successful commercialization of nanotechnology. Nanotechnology is no longer just a large government research project. Products are moving out of the lab into the market and onto store shelves. This is success, but it is not guaranteed forever. The next two to three years will be critical to ensuring that our investments pay off, and the structure and functions of the NNI will play an important role in making sure we can maximize the benefits of nanotechnology while minimizing the risks.

APPENDIX

Comparison of Nanotechnology Risk-Research Funding for 2006

Definitions of risk-relevant research used in funding assessments:

NNI

In the context of this comparison, the given NNI definition of EHS-relevant research is "research whose primary purpose is to understand and address potential risks to health and the environment posed by this technology."[31]

GAO

From the GAO assessment of EHS-relevant research, it appears that the same definition of relevance was used as established by the NNI (see above). From the GAO report:

"To assess whether or not the primary purpose of the research conducted by these agencies addressed the EHS risks of nanotechnology, we reviewed qualitative data on all projects funded by EPA, NIH, NIOSH, NIST, and NSF in fiscal year 2006. To minimize bias and to ensure the consistency of our evaluation, the team independently conducted project reviews by using publicly available and agency documentation, such as project abstracts or grant applications, to make our determinations. For categorization of projects that appeared questionable to us, we discussed the categorization with agency officials and modified our determination as appropriate given the additional support provided by the agency."[32]

PEN

PEN defines highly relevant research as:

"Research that is specifically and explicitly focused on the health, environmental and/or safety implications of nanotechnology. Also included in this category are projects and programs where the majority of the research undertaken is specifically and explicitly focused on the health, environmental and/or safety implications of nanotechnology. Examples of research in this category would include research to understand the toxicity of specific nanomaterials, research into exposure monitoring and characterization to further understand potential impact, research into biological interactions and mechanisms that is focused on answering specific questions associated with potential risk. Examples of research that would not be included in this category would include exploratory research into biological mechanisms outside the context of understanding impact, general instrument development, and research into therapeutics applications which also incorporate an element of evaluating impact."[33]

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[31] "Environmental, health and safety research needs for engineered nanoscale materials," *The National Nanotechnology Initiative*, September 2006. Available at: http://www.nano.gov/NNI_EHS_research_needs.pdf, accessed April 22, 2008.

[32] "Nanotechnology. Better guidance is needed to ensure accurate reporting of federal research focused on environmental, health and safety risks," *U.S. Government Accountability Office*, 2008. Acronyms - NIH: National Institutes of Health; NIOSH: National Institute for Occupational Safety and Health; NIST: National Institute of Standards and Technology

[33] Maynard, Andrew. *Testimony for United States House of Representatives Committee on Science & Technology Hearing on: The National Nanotechnology Initiative Amendments Act of 2008*, April 16 2008. Available at http://www.nanotechproject.org/process/assets/files/6689/maynard_written_april08.pdf, accessed April 21, 2008.

Assessment of Projects Primarily Focused on Addressing Nanotechnology ESH Implications
Number of Active Projects, 2006

Agency[34]	NNI-assessment of EHS-relevant projects[35]	GAO-assessment of EHS-relevant projects[4]	PEN-assessment of highly relevant EHS projects listed by the NNI[36]
EPA	10	10	10 (10)
NIH	18	18	11 (5)
NIOSH	23	21	21 (21)
NIST	2	2	4 (0)
NSF	66	46	10 (10)
DOD	-	-	7 (2)
DOE	-	-	0
USDA	-	-	2 (1)
Total	**119**	**97**	**65**

Assessment of Projects Primarily Focused on Addressing Nanotechnology ESH Implications
Estimated Funding of Active Projects, 2006

Agency	NNI-assessment of EHS-relevant projects[4]	GAO-assessment of EHS-relevant projects[4]	PEN-assessment of highly relevant EHS projects listed by the NNI
EPA	3.6	3.6	1.3[A]
NIH	5.6	5.6	0.8[B]
NIOSH	4.3	4.2	4.9
NIST	2.4	2.4	NA
NSF	21.1	14.7	1.4[C]
DOD	-	-	1.4
DOE	-	-	0
USDA	-	-	0.1
Total	**$37 million**	**$30.5 million**	**$9.9 million ($13 million)[37]**

Notes:

A. EPA funding reported by NNI and GAO represents funding for a 3-year period. PEN figures are an estimate of annual funding for 2006.

B. The PEN assessment found many National Institutes of Health (NIH) research projects to have some relevance to addressing nanotechnology risks, but the majority of these projects were not primarily focused in risk-related research.

C. Many of the NSF projects were found to have a degree of relevance to nanotechnology risk, but few were specifically focused on addressing environment, health and safety issues.

[34] Acronyms - DOD: Department of Defense; DOE: Department of Energy
[35] "Nanotechnology. Better guidance is needed to ensure accurate reporting of federal research focused on environmental, health and safety risks," *U.S. Government Accountability Office*, 2008.
[36] Numbers in parentheses represent the number of projects where finding information is available. This assessment was carried out on projects listed in the document "Strategy for nanotechnology-related environmental, health and safety research," *The National Nanotechnology Initiative*, 2008. Available at: http://www.nano.gov/NNI_EHS_Research_Strategy.pdf, accessed April 22, 2008.
[37] Number in parentheses represents estimated annual funding, accounting for missing budget data.

Biography of David Rejeski

David Rejeski directs the Project on Emerging Nanotechnologies. Launched by the Woodrow Wilson International Center for Scholars and The Pew Charitable Trusts in 2005, the Project is dedicated to helping business, government, and the public anticipate and manage possible health and environmental implications of nanotechnology. For the past six years, he has also served as the Director of the Foresight and Governance Project at the 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 the Environmental Protection Agency (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 research and development 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 EPA. 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 organization 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. He 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 National Science Foundation's Advisory Committee on Environmental Research and Education; the Committee on Science, Engineering, and Public Policy of the American Association for the Advancement of Science (AAAS); the National Council of Advisors of the Center for the Study of the Presidency; the *Journal of Industrial Ecology*, the Greening of Industry Network, and the University of Michigan's Corporate Environmental Management Program. He has graduate degrees in public administration and environmental design from Harvard and Yale.