RESEARCH ON ENVIRONMENTAL AND SAFETY IMPACTS OF NANOTECHNOLOGY: CURRENT STATUS OF PLANNING AND IMPLEMENTATION UNDER THE NATIONAL NANOTECHNOLOGY INITIATIVE

HEARING

BEFORE THE

SUBCOMMITTEE ON RESEARCH AND SCIENCE EDUCATION

COMMITTEE ON SCIENCE AND TECHNOLOGY

HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

FIRST SESSION

OCTOBER 31, 2007

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October 31, 2007

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WEDNESDAY, OCTOBER 31, 2007

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON RESEARCH AND SCIENCE EDUCATION,
COMMITTEE ON SCIENCE AND TECHNOLOGY,
Washington, DC.

The Subcommittee met, pursuant to call, at 10:00 a.m., in Room 2318 of the Rayburn House Office Building, Hon. Brian Baird [Chairman of the Subcommittee] presiding.

BART GORDON, TENNESSEE
CHAIRMAN

RALPH M. HALL, TEXAS
RANKING MEMBER

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Subcommittee on Research and Science Education

Hearing on:

Research on Environmental and Safety Impacts of Nanotechnology: Current Status of Planning and Implementation under the National Nanotechnology Initiative

October 31, 2007
10:00 a.m. – 12:00 p.m.
2318 Rayburn House Office Building
Washington D.C.

WITNESS LIST

Dr. Clayton Teague
Director
National Nanotechnology Coordination Office

Mr. Floyd Kvamme
Co-Chair
President's Council of Advisors on Science and Technology

Dr. Vicki L. Colvin
Executive Director
International Council on Nanotechnology
Professor of Chemistry and Chemical Engineering
Rice University

Dr. Andrew Maynard
Chief Science Advisor
Project on Emerging Nanotechnologies
Woodrow Wilson International Center for Scholars.

Dr. Richard Denison
Senior Scientist
Environmental Defense

Mr. Paul D. Ziegler
Chairman
Nanotechnology Panel
American Chemistry Council

HEARING CHARTER

SUBCOMMITTEE ON RESEARCH AND SCIENCE EDUCATION
COMMITTEE ON SCIENCE AND TECHNOLOGY
U.S. HOUSE OF REPRESENTATIVES

Research on Environmental and Safety Impacts of Nanotechnology: Current Status of Planning and Implementation Under the National Nanotechnology Initiative

WEDNESDAY, OCTOBER 31, 2007
10:00 A.M.–12:00 P.M.
2318 RAYBURN HOUSE OFFICE BUILDING

1. Purpose

On Wednesday, October 31, 2007, the Subcommittee on Research and Science Education of the Committee on Science and Technology will hold a hearing to review the need and motivation for research on the environmental, health and safety (EHS) aspects of nanotechnology, determine the current state of planning and implementation of EHS research under the National Nanotechnology Initiative (NNI), and explore whether changes are needed to the current mechanisms for planning and implementing EHS research. This hearing is one in a series the Committee will hold to review the administration and content of the NNI as part of the process for developing legislation to reauthorize the *21st Century Nanotechnology Research and Development Act of 2003* (P.L. 108–153) during the next session of Congress.

2. Witnesses

Dr. Clayton Teague, Director of the National Nanotechnology Coordination Office (NNCO). The NNCO serves as the focal point for and provides staff support to the Nanoscale Science, Engineering, and Technology (NSET) Subcommittee of the National Science and Technology Council. The NSET Subcommittee is responsible for the planning and coordination of the interagency NNI.

Mr. Floyd Kvamme, Co-Chair of the President's Council of Advisors on Science and Technology (PCAST). PCAST was designated by the President to act as the National Nanotechnology Advisory Panel (NNAP) in accordance with the *21st Century Nanotechnology Research and Development Act of 2003* (P.L. 108–153).

Dr. Vicki L. Colvin, Executive Director, International Council on Nanotechnology and Professor of Chemistry and Chemical Engineering, Rice University.

Dr. Andrew Maynard, Chief Science Advisor, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars.

Dr. Richard Denison, Senior Scientist, Environmental Defense.

Mr. Paul D. Ziegler, Chairman of the Nanotechnology Panel, American Chemistry Council, and Global Director, PPG Industries, Inc.

3. Overarching Questions

- How important for the advancement of nanotechnology is developing greater understanding of potential risks that the technology may introduce to the environment and human health? What impacts are environmental and safety concerns having on the development of nanotechnology-related products and their entry into the marketplace? What impact might these concerns have in the future?
- Are current federal research efforts adequate to address concerns about environmental and safety ramifications of nanotechnology? Is the EHS research

funding properly aligned with the agencies' roles and responsibilities for environmental and safety matters; is the overall level of funding adequate; have the most important research priorities been identified; and is the funding aligned satisfactorily to address those research priorities?

- What is the status of the development of a prioritized, detailed implementation plan for EHS research under the NNI? Will the plan now under development provide specific goals and timelines for achieving those goals; will it have a description of the roles and responsibilities of the participating agencies; and will it specify funding, by agency, required to reach the goals? Are the research priorities in the interim planning document appropriate?
- How can the current planning, coordination and implementation of EHS research under NNI be improved? Are alternative mechanisms needed to ensure EHS research is carried out expeditiously and on topics that will support the research needs of the agencies charged with environmental and safety regulation?

4. Brief Overview

- Nanotechnology, the science of materials and devices of the scale of atoms and molecules, has entered the consumer marketplace. Today, there are over 300[1] products on the market claiming to contain nanomaterials (materials engineered using nanotechnology or containing nano-sized particles), generating an estimated $32 billion in revenue.[2] By 2014, according to Lux Research,[3] a private research firm that focuses on nanotechnology, there could be $2.6 trillion worth of products in the global marketplace which have incorporated nanotechnology.
- There is significant concern in industry that the projected economic growth of nanotechnology could be undermined by either real environmental and safety risks of nanotechnology or the public's perception that such risks exist. Recently, some reports have indicated that these concerns are causing some companies to shy away from nanotechnology-related products and downplay nanotechnology when they talk about or advertise their products.[4] There is an unusual level of agreement among researchers, and business and environmental organizations that the basic scientific information needed to assess and protect against potential risks does not yet exist.
- The President's fiscal year 2008 (FY08) budget requests $1.4 billion for the NNI, the interagency nanotechnology research and development program. Of this amount, the budget proposes $58.6 million (4.1 percent of the overall program) for research on EHS research. This is $10.8 million above the FY07 funding level. Nearly 50 percent of this funding would go to NSF.
- In October 2003, the NSET organized an interagency Nanotechnology Environmental and Health Implications (NEHI) Working Group to coordinate environmental and safety research carried out under the NNI. The NEHI Working Group is charged with "facilitate[ing] the identification, prioritization, and implementation of research. . .required for the responsible" development and use of nanotechnology.[5]
- One of the NEHI Working Group's initial tasks was developing a prioritized plan for EHS research under the NNI. In March 2006, the Administration informed the Science Committee that this report would be completed that spring, but the document that was finally released in September 2006 was a non-prioritized list of EHS research areas. At a Science Committee hearing organized at the time of the report's release, the Chairman and Ranking Member stressed the urgency of developing the prioritized research plan.
- The latest iteration of the EHS research plan, which was released for public comment in August 2007, presents a rationale for the process of defining EHS research priorities and provides a reduced set of priorities based on the pre-

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[1] Wilson Center, Project on Emerging Nanotechnologies, "Nanotechnology: A Research Strategy for Addressing Risk" July, 2006. p. 4.

[2] Lux Research, "Taking Action on Nanotech Environmental, Health, and Safety Risks," Advisory, May 2006 (NTS–R–06–003) (hereafter cited as "Taking Action").

[3] Lux Research, "Sizing Nanotechnology's Value Chain," October 2004.

[4] Matthew Nordan testimony, Science Committee hearing, September 21, 2006, Serial No. 109–63.

[5] Terms of Reference, Nanotechnology Environmental and Health Implications Working Group Nanoscale Science, Engineering, and Technology Subcommittee Committee on Technology; March, 2005.

vious report. It also indicates that the "next steps" (with no indication of timing) include NEHI evaluating the NNI EHS research portfolio to carry out a gap analysis to compare current work to the priorities list and then develop "a strategy to address EHS research priorities", which is essentially what was promised in the plan expected in the spring of 2006.

5. Previous Hearings

The Committee held a hearing on this topic, *Environmental and Safety Impacts of Nanotechnology: What Research Is Needed?* [Serial No. 109–34], on November 17, 2005. At that hearing, witnesses from the Federal Government, industry, and environmental organizations agreed that relatively little is understood about the environmental and safety implications of nanotechnology. The non-governmental witnesses emphasized that, for the emerging field of nanotechnology to reach its full economic potential, the Federal Government must significantly increase funding for research in this area. The hearing also raised questions about the effectiveness of the coordination and prioritization of EHS research being carried out under the NNI, as well as whether the key agencies having responsibilities for regulating exposure of people and the environment to nanomaterials were fully engaged in setting the priorities and funding appropriate activities.

A second, related hearing was held by the Committee on September 21, 2006, *Research on Environmental and Safety Impacts of Nanotechnology: What Are the Federal Agencies Doing?* [Serial No. 109–63]. The witnesses were from the agencies sponsoring EHS research and participants in the NEHI Working Group, along with representatives from an industry association and an NGO. The hearing was intended to review the NEHI EHS research plan that the Committee had expected to receive earlier that year (see following section). The agency witnesses were unable to explain why the prioritized research plan had not been completed. The non-government witnesses reiterated the urgency of developing and implementing such a plan without further delay and indicated that there were deficiencies in the scale and content of the current EHS research portfolio. The hearing also raised, but did not resolve, the issue of whether the current process for planning and carrying out EHS research under NNI is viable.

6. National Nanotechnology Initiative

Fiscal Year 2008 Budget

The National Nanotechnology Initiative (NNI) is a multi-agency research and development (R&D) program authorized by the *21st Century Nanotechnology Research and Development Act* (P.L. 108–153). Currently, 13 federal agencies participate in the coordination, planning, and implementation of the research and development activities carried out under the NNI. The primary goals of the NNI are to foster the development of nanotechnology and coordinate federal R&D activities. The total NNI funding for FY 2007 is $1.35 billion and the FY 2008 request is $1.44 billion. More information on agency roles and activities under the NNI is available at *http://www.nano.gov/*.

The following table provides the FY 2008 funding proposal for each participating agency and the amount the agency has identified as supporting EHS activities:

($ in millions)

Agency	Total Spending on Nanotechnology R&D (FY08 Proposed)	Environment Health, and Safety Implications R&D (FY08 Proposed)	Percent of Total Environment, Health and Safety Implications R&D
NSF	389.9	28.8	49.1%
DOD	374.7	1.0	1.7%
DOE	331.5	3.0	5.1%
DHHS (NIH)	202.9	5.7	9.7%
DOC (NIST)	96.6	5.8	9.9%
NASA	24.0	0.0	0.0%
EPA	10.2	9.6	16.4%
USDA (CSREES)	3.0	0.1	0.2%
DHHS (NIOSH)	4.6	4.6	7.8%
USDA (FS)	4.6	0.0	0.0%
DHS	1.0	0.0	0.0%
DOJ	0.9	0.0	0.0%
DOT (FHWA)	0.9	0.0	0.0%
TOTAL	**1,444.8**	**58.6**	**100.0%**

Acronyms
CSREES = Cooperative State, Research, and Education Extension Service (within USDA)
DHS = Department of Homeland Security
DOC = Department of Commerce
DOD = Department of Defense
DOJ = Department of Justice
DOT = Department of Transportation
FHWA = Federal Highway and Works Administration (within DOT)
FS = Forest Service (within USDA)
NASA = National Aeronautics and Space Administration
USDA = U.S. Department of Agriculture

Research Plan for Environmental and Safety Implications of Nanotechnology

At the Science Committee's November 17, 2005 hearing on EHS research related to nanotechnology, Dr. Clayton Teague, Director of the National Nanotechnology Coordination Office, testified that the NEHI Working Group was "preparing a document that identifies and prioritizes information and research needs in this area. The document will serve as a guide to the NNI agencies as they develop budgets and programs and will inform individual investigators as they consider their research directions."[6] In his responses to questions for the record, Dr. Teague said the report was expected to be completed by "Spring 2006" and "is intended to be sufficiently detailed to guide investigators and managers in making project-level decisions, yet broad enough to provide a framework for the next five to ten years." The report was finally released at the time of the September 21, 2006 Committee hearing, but it was merely a listing of research topics, not a prioritized research plan with agency roles and funding levels delineated.

In August 2007, a new report was released, "Prioritization of Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials: An Interim Document for Public Comment."[7] This report, once again, is not the prioritized research plan originally anticipated for release in the Spring of 2006. It is a refined list of research priorities along with a description of a process for updating the priorities list. The document includes a "next steps" section that indicates NEHI will evaluate the NNI EHS research portfolio to carry out a gap analysis to compare current work to the priorities list and then develop "a strategy to address EHS research

[6] Clayton Teague testimony, Science Committee hearing, November 17, 2005, Serial No. 109–34.

[7] *http://www.nano.gov/Prioritization_EHS_Research_Needs_Engineered_Nanoscale_Materials.pdf*

priorities." No estimate is given for a date for completion of this EHS research program assessment and strategy document.

7. Witness Questions

Dr. Teague was asked to provide an overview of the current scope of EHS research being conducted under the NNI, including how it relates to international and private sector EHS research efforts, and to provide an update on the development of a detailed implementation plan for EHS research. He was asked to include in his testimony:

- a description of the process that is underway to develop the EHS research plan;
- a description of the tenor of the responses received during the period the NEHI Working Group report referenced above was open for public comment; and
- recommendations for ways to improve the planning, prioritization, and implementation of EHS research under the NNI.

Mr. Kvamme was asked to provide the views of the NNAP on the effectiveness, scope, and content of the current EHS research efforts under the NNI and any recommendations the NNAP may have on ways to improve the process for planning, prioritization, and implementation of EHS research under NNI. He was asked to answer the following questions:

- Has the NNAP reviewed the recent report of the Nanotechnology Environmental and Health Implications Working Group, "Prioritization of Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials"? If so, are the priorities listed in the report the right ones, and will carrying out the "next steps" described in the report result in a satisfactory detailed implementation plan for EHS research?
- Has the NNI assigned a sufficiently high priority to EHS research and are there gaps in the portfolio of NNI research now underway? What level of funding over what time period is needed to make acceptable progress in understanding the potential environmental and health risks associated with the development of nanotechnology?
- What are the optimum roles for the agencies in sponsoring or conducting EHS research? Are responsibilities and available resources currently in balance?
- Does the NNAP believe the current process is working for developing an EHS research plan under the NNI, and if not, what changes are needed?

The other witnesses were asked to provide their views on the effectiveness, scope, and content of the current EHS research efforts under the NNI and recommendations on ways to improve the process for planning, prioritization, and implementation of EHS research under NNI. They were asked to answer the following questions:

- What is your reaction to the recent report of the Nanotechnology Environmental and Health Implications Working Group, "Prioritization of Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials"? Do outside groups have a way to influence this planning process? Are the priorities listed in the report the right ones, and do you believe that carrying out the "next steps" described in the report will achieve the detailed implementation plan for EHS research that is needed?
- Has the NNI assigned a sufficiently high priority to EHS research and are there gaps in the portfolio of NNI research now underway? What level of funding over what time period is needed to make acceptable progress in understanding the potential environmental and health risks associated with the development of nanotechnology?
- What are the optimum roles for the agencies in sponsoring or conducting EHS research? Are responsibilities and available resources currently in balance?
- Can the current process for developing the EHS research plan under the NNI be made to work, and if so, what changes are needed? If not, do you have recommendations for a different approach for developing and implementing a prioritized, appropriately funded EHS research plan with well defined goals, agency roles, and milestones?

Chairman BAIRD. This morning's hearing is the third one in three years the Science Committee has held on federally sponsored research on the health and environmental risks that may arise from applications of nanotechnology. The Committee's attention to the issue reflects our view of its importance to the development of nanotechnology and to capturing the enormous promise of this technology.

The previous hearings have shown that there is wide agreement on two main points: first, nanotechnology will advance faster and receive public support if environmental, health, and safety implications of the technology are fully understood. Secondly, the interagency National Nanotechnology Initiative must include a prioritized and adequately funded research component focused on environmental, health, and safety issues, or as they are sometimes known, EHS issues.

So the question before us today is not whether EHS research is important nor whether the NNI should fund research on environment and health risks. The question is how effectively is the NNI carrying out the planning and implementation of the EHS research component of the interagency program.

With regard to the adequacy of the funding, the outside witnesses at the previous hearings either recommended that the NNI substantially increase funding for EHS research or they expressed frustration that they were unable to determine exactly what EHS research was being supported by the NNI. The basic position of most outside observers from industry and non-governmental organizations is that the funding level should be on the order of 10 percent of the total funding, rather than the current four percent.

More important than funding level is the concern that the EHS research component has not been well-planned and executed. At the Committee's November 2005 hearing, the Administration's witness indicated that an interagency working group was developing a coordinated approach to nanotech research on EHS that included input from industry and other non-governmental entities. That was back in '05 I should emphasize.

We were told that the working group was in process of producing a document that would identify and prioritize research needs to assess the risks associated with engineered nanomaterials and would be sufficiently detailed to guide researchers and research managers in making project-level decisions.

The estimated completion date for the document back in '05 was Spring of 2006. The fact that I have alluded to Halloween in 2007 suggests we have missed that date. Unfortunately, we are still waiting for that detailed implementation plan for EHS.

At the Committee's hearing last September, then-Chairman Boehlert and Ranking Member Gordon both expressed frustration at the slow pace in developing this research plan. But they were assured that the agencies were hard at work and that the plan would soon be forthcoming.

Nearly a year later, this past August, an interim report was released for public comment. Although the report makes some progress in defining research goals, once again it is not a research plan laying out goals and timelines, funding levels, and defined agency roles and responsibilities for achieving these goals. The re-

port suggests this is all coming in the "next steps," although it does not provide a target date for completion of those next steps.

Meanwhile, more and more engineered nanoparticles continue to enter the marketplace. The number of such products has doubled to 500 over the past year according to surveys by the Wilson Center's Project on Engineering Nanotechnologies. Simple prudence suggests the need for urgency in having the science of health and environmental implications catch up to or even better surpass the pace of commercialization.

The bottom line is that this is simply not an acceptable situation. We are basically still waiting for the EHS research strategy and detailed implementation plan that we were told would be available 18 months ago.

I am genuinely puzzled why more progress has not been made, hence today's hearing, to develop this research strategy and plan that everyone believes is necessary for the successful development of nanotech.

Today, I want to determine how the mechanisms in place for planning and implementing the interagency EHS research component of the NNI can be made to work better and what steps are needed to accomplish that outcome.

On the other hand, if the process is flawed or is intrinsically unable to function satisfactorily, I would invite our witnesses to suggest alternative approaches and mechanisms. I am looking for concrete suggestions that the Committee can use as it develops legislation to reauthorize NNI over the next few months. I will just interject as we look towards that reauthorization, I will keep in mind closely whether or not we have actually been able to meet some of the goals that we are now 16 months past achieving. For me it seems difficult to promote reauthorizing the program when fundamental elements of environmental health and human safety are not being well-addressed.

So I want to thank our witnesses for their attendance at today's hearing, and I look forward to our discussion of this important set of issues.

I now recognize the Ranking Member, Mr. Ehlers for an opening comment.

[The prepared statement of Chairman Baird follows:]

PREPARED STATEMENT OF CHAIRMAN BRIAN BAIRD

This morning's hearing is the third one in three years the Science Committee has held on federally sponsored research on the health and environmental risks that may arise from applications of nanotechnology. The Committee's attention to this issue reflects our view of its importance to the development of nanotechnology and to capturing the enormous promise of this technology.

The previous hearings have shown that there is wide agreement on two main points:

- First, nanotechnology will advance faster and receive public support if the environmental, health, and safety implications of the technology are understood.
- Secondly, the interagency National Nanotechnology Initiative must include a prioritized and adequately funded research component focused on environmental, health, and safety issues—or EHS issues.

So the question before us today is not whether EHS research is important nor whether the NNI should fund research on environmental and health risks. The question is how effectively is the NNI carrying out the planning and implementation of the EHS research component of the interagency program.

With regard to the adequacy of funding, the outside witnesses at the previous hearings either recommended that the NNI substantially increase funding for EHS research or expressed frustration that they were unable to determine exactly what EHS research was being supported by the NNI. The basic position of most outside observers from industry and non-governmental organizations is that the funding level should be on the order of 10 percent of the initiative's total funding, rather than the current four percent.

More important than funding level is the concern that the EHS research component has not been well planned and executed. At the Committee's November 2005 hearing, the Administration's witness indicated that an interagency working group was developing a coordinated approach to nanotechnology research on EHS that included input from industry and other non-governmental entities.

We were told the working group was in process of producing a document that would identify and prioritize research needs to assess the risks associated with engineered nanomaterials and be sufficiently detailed to guide researchers and research managers in making project-level decisions.

The estimated completion date for the document was the spring of 2006. Unfortunately, we are still waiting for that detailed implementation plan for EHS research.

At the Committee's hearing last September, then Chairman Boehlert and Ranking Member Gordon both expressed frustration at the slow pace in developing this research plan. But they were assured that the agencies were hard at work and that the plan would soon be forthcoming.

Nearly a year later—this past August—an "interim report" was released for public comment. Although this report makes some progress in defining research goals, once again it is not a research plan laying out goals and timelines, funding levels, and defined agency roles and responsibilities for achieving those goals. The report suggests this is all coming in the "next steps," although it does not provide a target date for completion of these next steps.

Meanwhile, more and more products containing engineered nanoparticles continue to enter the marketplace—the number of such products has doubled to 500 over the past year according to surveys by the Wilson Center's Project on Emerging Nanotechnologies. Simple prudence suggests the need for urgency in having the science of health and environmental implications catch up to, or even better surpass, the pace of commercialization.

The bottom line is that this is simply not an acceptable situation. We are basically still waiting for the EHS research strategy and detailed implementation plan that we were told would be available 18 months ago.

I am genuinely puzzled why more progress has not been made to develop this research strategy and plan that everyone believes is necessary for the successful development of nanotechnology.

Today, I want to determine how the mechanisms in place for planning and implementing the interagency EHS research component of the NNI can be made to work better, and what steps are needed to accomplish that outcome.

On the other hand, if the process is flawed or is intrinsically unable to function satisfactorily, I invite our witnesses to suggest alternative approaches and mechanisms. I am looking for concrete suggestions that the Committee can use as it develops legislation to reauthorize the NNI over the next few months.

I want to thank our witnesses for their attendance at today's hearing, and I look forward to our discussion of this important set of issues.

I now recognize the Ranking Member for an opening statement.

Mr. EHLERS. Thank you, Mr. Chairman. I am pleased the Committee is holding this important hearing today, but I also hope that the scary reputation of this day doesn't somehow impinge on the seriousness of the topic we're engaged in.

The promises of technology often compete for media attention with coverage of the unknown pitfalls nanotechnology products may have on human health and the environment. The nanoscale is so unexplored that we know very little about the short- and long-term environmental effects of nanomaterials in our ecosystem, and having lived through some periods of life where we did the wrong thing, for example, with pesticides and DDT and so forth, I can certainly understand the concern and perhaps even paranoia of society. At the same time, I am not sure very many people appreciate the difficulty of the work that has to be done. It is quite easy when

you conduct a human-scale, large-scale experiment such as using pesticides throughout the entire world and now observe the effects. It is quite a different matter to take an unknown effect and a relatively new scientific development and try to project what the problems might be. And I think very few people realize how difficult the work is and trying to identify the environmental effects of nanomaterials. The calm prevailing force here, of course, is the incredible benefits of nanoscale. I just read a fascinating article last week, and I am a would-be pilot and so I read a lot of aviation literature. And I found this fascinating article about nanotubes used in composite airplane construction. If you put a wire grid in, you also have the great advantage of using the nanotubes to detect cracks; but at the same time, by applying heat through the grid, you have a self-healing composite. This is a marvelous development for aviation and many other areas.

What are the bad effects? We do not yet know, but as our country invests in innovative research in nanotechnology, we must ensure that accurate risk assessments are conducted and communicated to all stakeholders. An atmosphere of trust between the nanotechnology industry and the public is necessary to allow benign products to benefit our nation and to ensure that dangerous products and byproducts never enter the market or ecosystem, a very demanding agenda.

Congress must continually assess whether nanotechnology research priorities to address unintended public health consequences of nanotechnology have been established and are being effectively implemented. As this committee prepares to reauthorize the National Nanotechnology Initiative, today's witnesses will provide valuable insights on both conducting research and sharing its results with the public.

I look forward to hearing an update from our witnesses on this most important topic, and thank you all very much for taking the time to be here.

I yield back.

[The prepared statement of Mr. Ehlers follows:]

PREPARED STATEMENT OF REPRESENTATIVE VERNON J. EHLERS

Thank you Chairman Baird. I am pleased that the Committee is holding this important hearing today, but I also hope that the "scary" reputation of today is not in any way linked with the topic at hand.

Nonetheless, the promises of nanotechnology often compete for media attention with coverage of the unknown pitfalls nanotechnology products may have on human health and the environment. The nanoscale is so under-explored that we know very little about the short- and long-term environmental effects of nanomaterials in our ecosystem.

As our country invests in innovative research in nanotechnology, we must ensure that accurate risk assessments are conducted and communicated to all stakeholders. An atmosphere of trust between the nanotechnology industry and the public is necessary to allow benign products to benefit our nation, and to ensure that dangerous products and byproducts never enter the market or ecosystem. Congress must continually assess whether nanotechnology research priorities to address unintended public health consequences of nanotechnology have been established and are being effectively implemented. As this committee prepares to reauthorize the National Nanotechnology Initiative, today's witnesses will provide valuable insights on both conducting research and sharing its results with the public.

I look forward to hearing an update from our witnesses on this important topic.

Chairman BAIRD. Thank you, Dr. Ehlers. We also are joined today by Mr. Rothman from New Jersey, and Dr. McNerney from California; and others will be joining us. As you know, we often have multiple hearings at the same time.

[The prepared statement of Mr. Lipinski follows:]

PREPARED STATEMENT OF REPRESENTATIVE DANIEL LIPINSKI

Thank you, Mr. Chairman.

I am proud to note that the State of Illinois was ranked 8th in the Nation this year by *Small Times* magazine of leading nanotechnology states. However, with success comes responsibility and nanotechnology certainly is no different as we examine potential environmental, health and safety implications.

This week's copy of *BusinessWeek* contains an article about how new nanotechnologies are helping to save vast amounts of energy simply by reducing the amount of friction in pipes throughout our economy. Innovative thin coatings and ball bearings in pipelines, as well as nanotech additives to motor oils, are helping to reduce friction by 50 percent and promote much more efficient processes. Every day, new products such as these are being introduced into the marketplace. As nanotechnology moves from a multi-billion to a multi-trillion dollar industry in just the next few years, now more than ever we must take action to identify, assess and manage potential environmental, health and safety risks.

Chairman BAIRD. In the interest of hearing what you all have to say, I will be very brief in the introductions and then we will have the panel have five minutes to speak. Dr. Ehlers and I have agreed that there are buttons we press when people go about five and one-half minutes. The chairs drop out from underneath you and you disappear into an oblivion that we will try to rescue you from at some future date.

Dr. Clayton Teague is Director of the National Nanotechnology Coordination Office. Mr. Floyd Kvamme is Co-Chair of the President's Council of Advisors on Science and Technology; Dr. Vicki Colvin, Executive Director of the International Council on Nanotechnology and Professor of Chemistry and Chemical Engineering at Rice University; Dr. Andrew Maynard, Chief Science Advisor for the Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars; Dr. Richard Denison, Senior Scientist, Environmental Defense; and Mr. Paul D. Ziegler, Chairman, Nanotechnology Panel, American Chemistry Council.

So a very, very distinguished and accomplished panel of experts. We look forward to your comments, and with that we will begin our testimony with Dr. Teague.

STATEMENT OF DR. E. CLAYTON TEAGUE, DIRECTOR, NATIONAL NANOTECHNOLOGY COORDINATION OFFICE (NNCO)

Dr. TEAGUE. Good morning, and thank you, Mr. Chairman, and other Members of the Subcommittee. Thank you for inviting me to testify at this hearing. I am pleased to have the opportunity to update the Subcommittee on the extensive efforts of the NNI to address the needs for research on the environmental, health, and safety, or EHS, aspects of nanotechnology.

Since its inception, the NNI has supported research along two paths: research toward beneficial uses of nanotechnology for society and research to protect public health and the environment. By integrating results from these two paths of research, the NNI aims to maximize the benefits of this new technology at the same time it

is developing an understanding of any potential risk and means to manage such risk.

EHS research is and has been a top priority of the Administration and the NNI. During fiscal years 2005 through 2008, the NNI agencies will have invested nearly $180 million in what we call primary purpose EHS research. This U.S. investment in such research leads all other countries by a wide margin. For 2008, the NNI agency request totaled about $59 million, an increase of 55 percent over that that was invested in 2006. We expect this trend to continue as increased knowledge informs our path forward.

Our strategic approach to prioritizing and addressing nanotechnology-related EHS research consists of four major elements: successful coordination, comprehensive planning and guidance, leveraging forefront science and collaboration, and periodic review. This four-element strategy for nanotechnology EHS research enables the NNI to identify new research needs and to pursue paths to meet those needs. By continuing to iterate these elements over the long-term, the NNI will accelerate the pace at which EHS information is developed and made available to government regulators and to industry; helping to ensure that nanotechnology enabled products are brought to the market responsibly.

The NNI is effectively coordinating government-funded research and the agency's multi-disciplinary expertise on the EHS aspects of nanotechnology. NNI agencies have expressed strong satisfaction with the coordination and collaboration opportunities stimulated by their participation in the Nanotechnology Environmental and Health Implications Working Group, or NEHI, as shown in some exemplary endorsements of the NEHI by the NNI agencies that I have provided in my written testimony. This group's outputs are developed by consensus, a process which is time consuming but ensures that the results receive strong support from all the member agencies. To provide guidance for investments in nanotechnology EHS research, we started by identifying the breadth of research necessary to support the risk assessment and risk management decision-making to inform the safe use and commercialization of nanomaterials. We narrowed the list to a set of high priority needs. We obtained a snapshot of the government portfolio of nanotechnology EHS research in 2006, and we are now comparing this list of research projects to the priority research needs in order to determine what research topics may need increased emphasis.

The important outcome of this process will be the creation of a science-based nanotechnology EHS research strategy document that provides comprehensive guidance for the planning, management, and coordination of nanotechnology-related EHS research. We hope this document's recommendations will inform and influence you in Congress, the Administration, and the agencies as they develop their annual budgets and make decisions on funding and program support. Publication of our EHS research strategy document will complete the first cycle of a long-term process. Ongoing evaluation of research needs will continue and priorities may change as new materials become candidates for use in products or as funded research yields important new results.

NNI's growing portfolio of EHS research is leveraged through collaborations among multi-disciplinary research groups, with industries, NGO's, and other governments worldwide. Significant inputs to our research strategy document have come from consultations, national and international workshops, hearings, and subsequent highly constructive public comment periods. Some 100 experts within the NNI agencies contributed to this planning process. I am confident that the EHS strategy document will facilitate the research necessary to generate the knowledge for the risk assessment, risk management, and regulatory decision-making.

Extraordinary level of multiagency coordination occurring within the NNI with respect to nanotechnology is rare, and in my own experience, unique. The NNI approach has been endorsed by reviews by the National Research Council and the President's Council of Advisors on Science and Technology. Let me assure you that we at the NNI share the importance that you, the Members of Congress, the Administration, and the research community place on nanotechnology-related EHS research. We share that view and will continue to make responsible development of nanotechnology a top priority of our research efforts.

Thank you for the attention and I am sure the extra time.

[The prepared statement of Dr. Teague follows:]

PREPARED STATEMENT OF E. CLAYTON TEAGUE

Introduction

Mr. Chairman and Members of the Subcommittee, thank you for inviting me to testify at this hearing. My name is Clayton Teague and I am the Director of the National Nanotechnology Coordination Office (NNCO). The NNCO supports the efforts of the multi-agency National Nanotechnology Initiative (NNI). I am pleased to have the opportunity to update this subcommittee on the extensive efforts underway in the NNI to address the needs for research on the environmental, health and safety (EHS) aspects of nanotechnology.

Since its inception, the NNI has supported research along two fundamental paths: research toward promising, highly beneficial uses of nanotechnology for our society and our nation's economic growth and research to protect public health and the environment. By integrating the results and new knowledge from these two paths of research, the NNI can expedite progress toward maximizing the benefit-to-risk ratio in the development of nanotechnology.

Further, EHS research is and has been a top priority of the Administration and the NNI. The Directors of the Office of Science and Technology Policy (OSTP) and Office of Management and Budget (OMB) have highlighted EHS research in each of the annual Research and Development Budget Priorities memoranda issued since 2004. During fiscal years 2005 through 2008, it is estimated that NNI agencies will have invested nearly $180 million in research whose primary purpose is to address the EHS implications of nanomaterials. With these investments, the United States leads all other countries in the world by a wide margin in support for such research. The 2008 request for this area is $58.6 million, an increase of 55 percent over 2006,[1] the last year for which we have estimates of actual funding. This growth reflects intentional and systematic program development by the NNI for nanotechnology-related EHS research.

I have been asked to describe the NNI's approach to prioritizing and addressing EHS research related to nanotechnology. Our approach—our strategy—consists of four major elements. **1) Successful coordination:** The NNI is effectively coordinating Government-funded research and the multi-disciplinary expertise of participating agencies on the EHS aspects of nanotechnology; **2) Comprehensive planning and guidance:** Through ongoing analysis of available research results by gov-

[1] See Table 6 in the NNI Supplement to the President's FY 2008 Budget, *http://www.nano.gov/NNI_08Budget.pdf,* p. 11, which shows an estimated actual R&D investment for FY 2006 of $37.7 million and the amount stated for the FY 2008 request in the PCA for research whose primary purpose was EHS implications of nanotechnology.

ernment subject matter experts, along with inputs from program managers, funding decision-makers, and the public, the NNI has published and is drafting further planning documents to provide guidance for agencies, industry, and academia on EHS research needs; **3) Leveraging forefront science through collaboration:** The NNI is supporting a growing portfolio of EHS research and is leveraging its investment through collaborations among multi-disciplinary research groups, with industry, and with other governments worldwide; **4) Periodic review:** The NNI plans to conduct periodic reviews of the state of EHS research to determine new developments or discoveries that would require changes in emphases or directions of research.

This four-element strategy for planning and implementing nanotechnology EHS research enables the NNI to adapt to the dynamic aspects of research and to pursue appropriate paths that address identified research needs. Equally, practicing these elements in an iterative long-range fashion accelerates progress toward producing the information necessary to assess safety of nanomaterials and to responsibly develop products enabled by nanotechnology.

Successful Coordination

The Nanoscale Science, Engineering, and Technology (NSET) Subcommittee's Nanotechnology Environmental Health Implications (NEHI) Working Group serves centrally and effectively to coordinate the planning and implementation of the U.S. Government's EHS nanotechnology-related research and activities. This interagency approach aligns the agencies' mandates, missions, authorities, and resident expertise with EHS research planning and implementation.

Twenty of the 26 NNI agencies participate in the NEHI Working Group. Thirteen of the agencies fund safety-related research in the field and/or have regulatory authorities to guide the safe use of nanomaterials.

The NEHI Working Group is co-chaired by Dr. Norris Alderson, Associate Commissioner for Science in the U.S. Food and Drug Administration, and Dr. George Gray, Assistant Administrator for the Office of Research and Development in the Environmental Protection Agency. Under their combined leadership, NEHI creates the framework that supports a robust, proactive process for identifying and addressing EHS research related to nanotechnology.

Starting with initial, informal meetings beginning in 2003 and formally established by the NSET Subcommittee in 2005, the NEHI Working Group has the following objectives:

- provide for the exchange of information among agencies and non-government parties that support nanotechnology research and those responsible for regulation and guidelines related to nanoproducts
- facilitate the identification, prioritization, and implementation of research and other activities required for the responsible research, development, utilization, and oversight of nanotechnology
- promote communication of information related to research on environmental and health implications of nanotechnology to other government agencies and non-government parties.

The NEHI Working Group operates on a consensus basis, thereby leading to reports and other documents that have broad approval from all member agencies. Moreover, representatives to the working group involve appropriate experts within their agencies in the development and review of any working group product. Such involvement can be time consuming, however the result is strong awareness of and support for the ultimate output. Consensus-building among key decision makers produces agency commitments to carry out their parts in generating needed information through research activity.

With this support, the NNI, through its multi-agency participation and access to the wide range of subject matter expertise, is successfully coordinating EHS research among the NNI agencies, with industry and academia, and with other nations. Doing so enables us to leverage all available resources and to accelerate the pace of progress toward generating safety-related information.

The NEHI Working Group is the most active working group of the NNI and has been described by agency representatives as the most effective interagency collaboration they have witnessed or in which they have participated. This is a clear indication of the NEHI Working Group's success.

NNI agencies have expressed strong satisfaction with the coordination and collaboration opportunities stimulated by their participation in the NNI. Some example endorsements are presented in Appendix A: *How the Interagency Process Helps Individual Agencies.* The Administration through its Budget Priorities memoranda and

Congress through the *21st Century Nanotechnology Research and Development Act* also have emphasized coordination of EHS research.

Nonetheless, some have called for a centralized office with budgetary authority to oversee the NNI's EHS research program. It is the consensus of NEHI Working Group members that such an approach would have significant detrimental effects:

- No one agency or centralized organization would have the breadth of scientific expertise and knowledge of regulatory authorities and needs currently represented by the 20 agencies participating in the NEHI Working Group.
- Creation of a new central authority would undermine the existing successful interagency coordination.
- Moving the management of all nanotechnology EHS research into a single office would likely decouple such research from related efforts within NNI agencies and from the knowledge base in the agencies that is currently networked into the NNI's EHS research effort.
- Creating a separate office would, on the one hand, give mission agencies a disincentive for doing nanotechnology-related EHS research. They would reasonably assume that another agency is responsible, and they therefore could redirect their limited resources to address other priorities. A likely result could be that the level of research would actually decrease. Conversely, creating a separate office could lead to duplicative work being funded, thereby wasting tax dollars and not optimizing progress.

Comprehensive Planning and Guidance

The NNI strategy for addressing EHS research needs for engineered nanoscale materials consist of five steps.

Step one—Identify research needs: In September 2006, the NNI published its assessment of the research needed to support risk assessment and risk management decision-making. This guidance was contained in the document, *Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials,*[2] henceforth referred to as the Research Needs document. Comments submitted during the public comment period acknowledged the comprehensiveness of the document to guide the breadth of research needed to inform safety assessment. The research needs are organized into five categories: instrumentation, metrology, and analytical methods; nanomaterials and human health; nanomaterials and the environment; health and environmental exposure assessment; and risk management methods.

Step two—Prioritize research needs: In August 2007, the NNI published a prioritization of the identified research needs on the NNI website *www.nano.gov* as an interim document for public comment. These priority needs were identified following extensive dialogue among the subject matter experts and careful analysis based on principles outlined in the *Research Needs* document and public comments received.

It is important to underscore that EHS-research planning and implementation have been taking place simultaneously for several years. The processes, like those of the research itself, are not linear. The NNI agencies have been funding basic research at increasingly higher levels and through this research have been producing information critical to this field.

Step three—Obtain a snapshot of the government portfolio of EHS research in categories identified in Step one: In order to enable a more detailed assessment of funded research in this area, OMB collected data from the NNI research agencies on all FY 2006 spending for research related to the five categories outlined in the *Research Needs* document. Note that this call captures research reported in several Program Component Areas (PCAs) as reported in the NNI Supplement to the President's 2006 Budget. For example, some research in the PCA for Instrumentation Research, Metrology, and Standards was found to be highly relevant.

Step four—Analyze data from OMB on EHS research portfolio: The NEHI Working Group is analyzing the responses to the OMB data call to perform a systematic evaluation of the NNI's EHS research portfolio. NEHI experts have retrospectively categorized research funded by NNI agencies in FY 2006 according to the priority research needs.

Preliminary results from the NEHI analysis are summarized in the following table.

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[2] *http://www.nano.gov/NNI_EHS_research_needs.pdf*

Category	*Estimated Funding*
Instrumentation, Metrology, & Analytical Methods	$27 M
Nanomaterials & Human Health	$24 M
Nanomaterials & the Environment	$13 M
Health & Environmental Exposure Assessment	$1 M
Risk Management methods:	$3 M
Totals	$67 M

NEHI's preliminary analysis indicates strong alignment of ongoing research and the priority needs. NEHI members are continuing to analyze those data as they complete this step toward drafting the NNI EHS research strategy document. While this step is not yet completed, the initial analysis indicates that many of the areas identified by experts are already receiving significant support. An initial analysis of OMB's call for data on research in the five categories of the NNI Research Needs Document is provided in Appendix B.

Step five—Provide research strategy document as guidance:

The single most important outcome of this process is the creation of a science-based EHS research strategy document that the NNI recommends to individual agencies, the Administration, and Congress for use as guidance in their decisions for funding and program support.

Within the NNI EHS research strategy document, the management of R&D programs, as with all other NNI research and funding activities, will remain within the agencies that have the appropriate jurisdiction, expert staff, and expertise to manage day-to-day research activities and funding decisions.

Agencies whose missions are reflected in a research category of the Research Needs document will be noted in the NNI EHS research strategy document to be published shortly.

Agencies will use the NNI EHS research strategy document to:

- Understand where their mission-related research fits into the overall strategy
- Identify opportunities for collaboration or cooperation
- Identify critical needs within their missions which have not gotten sufficient attention
- Understand their relationship to other agencies and their research.

We understand that some would like to have seen the initial NNI EHS research strategy document published yesterday. However, the NNI has undertaken thorough, time-consuming activities such as highly specific data collection, and the solicitation and synthesis of expert and public input to ensure that the strategy would have scientific integrity and would reflect real data and information needs and thus have the credibility to guide agencies in decisions concerning their research funding and activities. And as noted earlier, the lack of a published strategy has not delayed getting started on high priority research.

To provide some insight into the complexity of this process, it is helpful to note the range of expertise sought through consultations, a public hearing, and two highly constructive public-comment periods. World-renowned scientists from academia, industry, NGOs, and government all have provided input. Within the government alone, some 100 subject matter experts across agencies reviewed and contributed to this comprehensive document. Among those who informed the development of this strategy were experts in:

- quantum mechanical properties of engineered nanoscale materials
- characterization of the physical and biological properties of these nanoscale materials through transmission electron microscopy, dynamic light scattering, and *in vitro* and *in vivo* toxicology
- absorption, distribution, metabolism, and elimination of materials in mammalian systems
- environmental toxicology and pharmacokinetic models of toxicity
- interactions of materials with the body at the molecular, cellular, and tissue levels
- metrics for measuring exposure, fate and transport of materials in the environment

- occupational health and exposures; and risk assessment and management practices.

The road to effectively safeguarding public health is dynamic and requires attention to alternative paths for obtaining the necessary knowledge and understanding. An ongoing evaluation of the materials being considered for use in products and new research findings must continue to inform and guide our ongoing strategic planning efforts. In the coming six months, for instance, we anticipate the publication of a large number of highly informative research papers in the field, reflecting the fruits of some of the NNI's earliest investments. These research findings could possibly provide information that calls for a stronger emphasis on current areas of research or that calls for a redirection of resources to another area of inquiry. Science is not stagnant and planning for research activity cannot be either.

The NNI strategic planning process will give the agencies ongoing guidance for funding research, and it will continue to inform industry of the most important safety issues—something that industry has asked us to provide.

We expect industry-created research plans will address in greater detail important industry needs—especially with regard to product-safety testing. Many of the plans already underway are complementary to the Federal Government strategy; indeed, they were input to the formulation of the federal strategy. This underscores the fact that multiple parties will play significant roles in gaining scientific knowledge in this field. But only the NNI process addresses the breadth of information needs of the federal agencies and includes the deliberations necessary for interagency cooperation. Federal agency responsibilities for safeguarding public health cannot be delegated to any other agency or group, nor can planning for how those responsibilities will be met.

Leveraging Forefront Science Through Collaboration

The evaluation of research needs through the NNI strategic planning process has been guiding agency research efforts since the NNI was formed. Implementation of identified research activities also has been underway as has the development of partnerships to facilitate research collaborations among agencies and with partners from industry, academia and non-government organizations (NGOs).

The 2006 data provide a snapshot of EHS research investments and have already helped inform and direct future government research funding. Below are a few of the research activities and collaborations in priority areas:

- NNI agencies have issued three joint solicitations for research on potential EHS implications of nanotechnology:
  - One led by EPA that is now in its third year focuses on investigating fate, transport, transformation, and exposure of engineered nanomaterials (DOE is joining EPA and NSF in 2008).
  - A second solicitation starting in 2007 is focused on human health implications. It is led by NIH's National Institute of Environmental and Health Sciences and includes participation by five other NIH institutes as well as EPA and NIOSH.
  - Recently NSF and EPA issued a third joint solicitation for proposals to create a national Center for the Environmental Implications of Nanotechnology (CEIN) to conduct fundamental research and education on the implications of nanotechnology on the environment and living systems at all scales. The center will address interactions of naturally derived, incidental and engineered nanoparticles and nanostructured materials, devices and systems with the living world. The award is slated to be up to $5 million annually for up to five years, pending the availability of funds and successful review.
- NIH, FDA, and NIST are collaborating on work at the Nanotechnology Characterization Lab (NCL) of the National Cancer Institute (NCI), where a battery of characterization tests are being developed for pre-clinical evaluation of nanomaterials intended for cancer therapeutics.
- NIH, FDA, and NIOSH are supporting the National Toxicology Program (led by NIEHS) as it develops and carries out research and testing programs addressing health and safety issues. Collaborations are underway with NIOSH, the FDA National Center for Toxicological Research, and the NCI Nanotechnology Characterization Lab.
- NSF and EPA have issued a joint solicitation for proposals to create a national Center for the Environmental Implications of Nanotechnology (CEIN) to conduct fundamental research and education on the implications of

nanotechnology on the environment and living systems at all scales. The center will address interactions of naturally derived, incidental and engineered nanoparticles and nanostructured materials, devices and systems with the living world. The award is slated to be up to $5 million annually for up to five years, pending the availability of funds and successful review.

Identification of detailed research needs within the broader strategic framework also is taking place through various other activities and partnerships. In January 2007, NSF and NIH supported a meeting on International Nanomaterial Environmental Health and Safety Research Needs Assessment at the NIH Campus in Bethesda, Maryland. This meeting, organized and sponsored by the International Council on Nanotechnology (ICON), focused on a piece of the research framework, bringing detail to the materials in need of study. NSF supported another ICON meeting last summer that focused on research needed to inform predictive modeling of biological interactions. In addition to providing funds, government agencies sent representatives to plan and participate in each of these workshops.

NIST held a workshop in September 2007 to develop approaches for identifying standard materials for critical risk assessment and risk management and priority reference materials, among other things.

Two years ago, NIOSH released its *Approaches to Safe Nanotechnology,* a document that offers guidelines for working with nanomaterials, consistent with the best scientific knowledge. That document recently has been updated and NIOSH's work has been used as a basis in international forums toward drafting international recommendations for working with nanomaterials. Furthermore, EPA and FDA have developed policy papers guiding their mission-related research and information needs. These agencies and NIH each have established intra-agency nanotechnology task forces that coordinate across each agency and with the other NNI agencies.

International Coordination and Collaboration

Although the United States is leading the world in the level of effort aimed at EHS research, it cannot—and should not—go it alone. The U.S. Government conducts many of its planning and implementation activities in coordination with other nations and international organizations. The NEHI Working Group, with assistance from another body of the NSET Subcommittee, the Global Issues in Nanotechnology Working Group, coordinates the U.S. position and participation in international activities related to environmental, health, and safety implications of nanotechnology. For example, NNI representatives are leading national and international collaborations that ensure coordination of the U.S. strategic priorities with those of the International Organization for Standardization (ISO) and the Organization for Economic Co-operation and Development (OECD).

Standards are imperative for accurate and reliable measurement and characterization of nanomaterials, which in turn is vital for assessing exposure and its effects. NSET Subcommittee members are active participants in the ISO Technical Committee on Nanotechnologies (ISO TC229). The NSET Subcommittee has provided initial financial support to the American National Standards Institute (ANSI) accredited Technical Advisory Group (TAG) that represents the United States on the ISO TC229. The NNCO Director chairs the TAG and heads the U.S. delegation to ISO TC229. The United States holds the convener position for the ISO TC229 working group whose charter is the development of science-based standards in the areas of health, safety, and environmental aspects of nanotechnologies. The U.S. TAG also is participating actively in the working group on terminology and nomenclature and the working group on metrology and characterization.

The U.S. Government was instrumental in the formation of two nanotechnology-related working parties at the OECD, and U.S. Government representatives currently chair the bureaus of each working party. This work is not limited to the 30 OECD member countries. Non-OECD countries and regions including the European Commission, Argentina, Brazil, China, India, Israel, Russia, and Thailand are active participants, as well as the nanotechnology and chemicals industries, ISO, and NGOs.

International efforts to better understand the potential health, environmental, and safety implications of manufactured nanomaterials are being developed by the Working Party on Manufactured Nanomaterials (WPMN) under OECD's Chemicals Committee. Its objective is to promote international cooperation in health and environmental safety aspects of manufactured nanomaterials, in order to assist in their safe development. This will help ensure that approaches to assessment of hazard, exposure, and risk are of a high, science-based standard. The United States is heavily involved in all the current WPMN activities, which include:

- International coordination to assess ongoing EHS research and identify mechanisms to address future research needs
- Testing a representative set of manufactured nanomaterials in collaboration with industrial partners, in order to develop a foundation data set of their physical and chemical properties as well as their fate, safety, and health and environmental effects
- Developing guidelines for EHS-related testing of nanomaterials, building upon already developed methods where possible
- Exchanging information on risk assessment approaches for manufactured nanomaterials and making recommendations to fill gaps in current approaches
- Sharing information on voluntary data collection and regulatory activities.

The second OECD body is the Working Party on Nanotechnology (WPN) under the Committee for Scientific and Technological Policy. The objective of the WPN is to promote international cooperation that facilitates research, development, and responsible commercialization of nanotechnology in member countries and in non-member economies. WPN activities relevant to EHS matters include evaluating the regulatory concerns of businesses utilizing nanotechnology, and public communication issues.

Conclusion

In closing, the NNI effectively coordinates EHS research planning and multi-disciplinary expertise across the 26 participating federal agencies. This ensures systematic and comprehensive planning across the broad spectrum of research programs needed to support risk assessment and risk management and to inform decision-makers.

The NNI agencies support forefront research, and leverage this research through collaborations. These research programs have generated and will continue to generate research that informs decision-makers. I am highly confident that the forthcoming NNI EHS Research Strategy will provide the needed framework for the development and support of research programs that provide new knowledge as needed for risk assessment and risk management regarding the use of nanomaterials.

Previous reviews of the NNI by the National Research Council (NRC) and the President's Council of Advisors on Science and Technology (PCAST) in its capacity as the National Nanotechnology Advisory Panel called for by the *21st Century Nanotechnology Research and Development Act,* confirm the effectiveness of our coordinated, collaborative approach. The 2006 NRC review of the NNI[3] was complimentary of the NNI's coordinated interagency approach in addressing EHS research and regulatory issues. PCAST is in the process of performing its second review of the NNI later this year. The NRC will take a comprehensive look at the NNI EHS research strategic process upon its completion.

We will of course welcome any recommendations these outside reviewers have as to how to make our strategy even more effective.

Thank you for the opportunity to speak with you on this important subject today.

[3] "A Matter of Size: Triennial Review of the National Nanotechnology Initiative," *http://books.nap.edu/openbook.php?record_id=11752&page=92*

Appendix A

How the Interagency Process Helps Individual Agencies

The effectiveness of the NNI for the participating agencies has been described by individual agencies as follows:

The Consumer Product Safety Commission (CPSC): While CPSC does not have the resources for research at this point in time, we have benefited greatly from the ability to make our research needs known to other agencies who have research funding and who share similar needs for toxicity and exposure data, etc. The concept of ensuring collaboration/communication across federal agencies to leverage limited research dollars is an important one.

U.S. Food and Drug Administration: The NNI collaboration has provided FDA the opportunity to discuss, review, and influence the priority of federally funded research organizations in their research programs. This has been particularly true in the areas of EHS needs. It is clear that the current activities of NCI/NCL, with NIST and FDA as partners, has benefited from the collaborative activities under NEHI. As a regulatory agency, FDA's research program provides the science support for current regulatory issues. Through the activities of NEHI, FDA has had the opportunity to assist in developing a research focus for issues that are a primary concern for nano-engineered materials as components of FDA regulated products. Through NEHI, FDA can leverage the resources of the funded research organizations to address those areas of concern that are shared with other regulatory agencies.

Department of Energy (DOE): DOE has included funding for new efforts in understanding the fate and transport of nanoscale materials in the environment in the FY 2008 budget request, and has joined with EPA and NSF in issuing a call for proposals in these areas. This interagency solicitation has been made possible by the interactions between DOE and the other participating agencies in the NSET and NEHI venues.

U.S. Environmental Protection Agency: The EPA is leveraging its research and development strengths by partnering with other federal agencies such as NIH, NCI, NIEHS, NIOSH, NSF, DOE, and NIST. The NEHI Working Group provides the agency with the forum and opportunity to engage in fruitful collaborative ventures. Many of our collaborative efforts have been enabled through dialogues and cooperation afforded by the NEHI Working Group and the NSET Subcommittee member meetings. The NEHI venue is especially advantageous for three critical reasons:

1. Direct communication of agency-to-agency information on engineered nanomaterial EHS issues is enabled.
2. Ways to enhance the understanding of agency-specific EHS issues are discussed.
3. Input on complex EHS issues from different agency viewpoints is provided that results in more rapid and tenable solutions.

U.S. Geological Survey: The USGS is in the planning phase of its activities with respect to nanotechnology, but has participated in the coordination activities of the NEHI Working Group and NSET Subcommittee. This involvement has given the USGS the opportunity to see where our scientific strengths will be best utilized within the set of research priorities, and to avoid duplication of effort. The involvement has also enabled us to get to know nanotechnology scientists and science leaders in other agencies in order to develop collaborative scientific projects that play to our strengths. The structure of the interagency interaction fostered by the NNCO provides forums for agencies to discuss research facilities that can be shared, thus increasing the value of the limited research dollars by enabling agencies like USGS to avoid duplicating expensive facilities.

The Nanotechnology Characterization Laboratory (NCL): The NCL at Frederick is an example of interagency coordination fostered by the NEHI Working Group. The laboratory is the result of a formal collaboration between three NEHI participating agencies: the National Cancer Institute (NCI) at the National Institutes of Health, the U.S. Food and Drug Administration (FDA), and the National Institute of Standards and Technology (NIST) within the Department of Commerce. The NCL's charter is to conduct safety testing of nanomaterials intended for medical applications; it is a resource available to investigators in academia, industry, and government

laboratories toward facilitating the rapid transition of nanotechnology-based drugs and imaging agents into commercial products.

In its three years of operation, the NCL has characterized over 100 nanoparticle types, including titanium oxide (TiO2), fullerenes, dendrimers, gold colloids, polymers, and liposomes. In collaboration with FDA and NIST, the lab has developed over 20 "best practice" protocols for characterizing these particles; several of these are now being adopted by formal Standards Developing Organizations such as ASTM and ISO.

Through its association with NEHI Working Group, the NCL also has recently engaged the National Toxicology Program (NTP); the NTP now has a seat on NCL's Scientific Oversight Committee and utilizes NCL data to inform its own nanomaterial characterization strategy and to avoid duplication of effort.

National Institute for Occupational, Safety and Health (NIOSH): NIOSH has had a good experience working with the NSET Subcommittee and NEHI Working Group for sharing information, networking, and identifying possible collaborations. This interaction also has helped provide feedback on the NIOSH Nanotechnology Program and review of NIOSH documents. NIOSH has had a broad range of collaborations with other agencies that have evolved as a result of being an early entrant into the field. Involvement with the NSET Subcommittee and the NEHI Working Group has provided an opportunity to promote and enhance some of those collaborations, including:

1. An MOU developed with OSHA regarding control banding and hazard communication
2. A collaborative arrangement with EPA to work on the Nanoscale Material Stewardship Program
3. Collaborations with DOE, DOE, and NASA to develop site-specific practices and with NIST to develop reference materials
4. Collaborations with OSHA and EPA on international conferences
5. Joint Requests for Applications with EPA, NSF, and NIH, since 2004
6. NIOSH active participation in OECD's Working Party on Nanotechnology and Working Party on Manufactured Nanomaterials (WPMN), including leadership of the WPMN's activity on Cooperation on Exposure Measurement and Exposure Mitigation.

The National Institute of Standards and Technology (NIST): Interactions with the NNI and NEHI Working Group, in particular, have supported the establishment of nanotechnology as a research direction for NIST with direct emphasis on innovation and traceable measurements, not only to advance the development of a measurement-and-standards infrastructure for nanotechnology enabled products, but also those standards necessary to support the EHS aspects of nanomaterials and products that contain them.

Examples of EHS program developments at NIST as a result of NIST–NEHI interactions include:

- 2005 Advanced Technology Program Project: Development of 2– and 3–Dimensional Analysis Methodology for Determining the Fate of Nanoparticles in Biological Tissues
- 2006 Innovative Measurement Science Program: Metrology for the Fate of Nanoparticles in Biosystems
- 2008 (if appropriated): Metrology for Nano-EHS

NIST's interactions with the NEHI Working Group member agencies has facilitated advances needed by NIST to leverage nanotechnology standards development work among other federal programs, to establish direct collaborations with other federal agencies, and to work with representatives from the risk assessment and regulatory communities representing not only government, but also academia, industry, and the international community.

National Institutes of Health (NIH): Through the NIH/National Institute of Environmental Health Sciences, active participation in the NEHI activities has provided a broad, interagency perspective that has enhanced its research program. NIH/NIEHS has worked on teams with representatives from CPSC, OSHA, and FDA, as well as funding agencies such as NIOSH, EPA and NSF. This interaction enhanced the NIH/NIEHS understanding of regulatory issues and informed the development of the NIH/NIEHS NanoHealth Initiative, the trans-NIH research strategy for environmental health and safety research. Additionally, NEHI was instrumental in providing the opportunity for NIH/NIEHS to participate in two interagency RFAs that

have addressed the interaction of engineered nanomaterials with biological systems and in international dialogue on nanotechnology health and safety issues.

National Science Foundation (NSF): NSF's mission is focused on fundamental research, education, and infrastructure that support activities in universities, industry and other agencies. The NNI coordination helps in adjusting research directions, informing NSF decisions about funding centers, and developing comprehensive infrastructure and research and education programs. A few specific collaborations that have resulted from this coordination are:

- Three joint solicitations (2005, 2007, 2008) with EPA, NIEHS, NIOSH, and DOE, respectively
- The NSF–EPA MOU and their joint support for the establishment of a Center for Environmental Implications of Nanotechnology.

Appendix B

Initial Analysis of OMB's Call for FY 2006 Data on Research in Five Categories of NNI Research Needs Document

In 2006, five agencies performed or supported research on the *Instrumentation, Metrology and Analytical Methods.* This category was cited as providing essential tools and methods for several other categories, for example to support toxicological research. It is the category with the largest 2006 investment, consistent with this enabling role. Instruments and methods are being developed to characterize a large variety of materials in pure form and in complex media, including biological environments. Additional future emphasis may be needed on instrumentation specific to the workplace and the environment. Since 2006, work has begun to develop reference materials for calibration of instruments, examination of analytical processes to assess the chemical or physical properties of such materials, and to assess the quality or comparability of results from tests designed to determine the toxicity of similar health-benefit or drug-related materials.

Six agencies funded *Nanomaterials and Human Health* research. With the most widespread investment, reported research addresses both particular nanomaterials and broad classes of materials. Effects of exposure through the lung, skin, and gastrointestinal tract are under investigation, as well as intravenous injection. Inhalation is the exposure route that is the subject of the largest number of projects. Translocation out of the exposure organ is also under study, most commonly using rodent models. As expected for a new class of materials, there is more emphasis on acute exposure than on chronic exposure. Analysis of ongoing research in this area reiterated the value that could be realized from a comprehensive database for EHS properties of nanomaterials, a concept already under development by several agencies and through our international collaborations.

Five agencies funded research in the category *Nanomaterials and the Environment.* Five broad classes of manufactured nanomaterials (metals, quantum dots, nanoceramics, carbon-based nanoparticles, and organic nanomaterials) are covered by funded projects. Studies of the effects of engineered nanomaterials on individuals of a species are underway for numerous aquatic organisms. Transport and transportation of nanomaterials in the environment are well covered. Numerous studies of physical and chemical transformation processes are underway.

Three agencies funded research on *Health and Environmental Exposure Assessment.* The investment is, in rough terms, evenly split between two categories: projects related to collecting general exposure information for workers in facilities manufacturing and using nanoscale and micro-scale titanium dioxide particles, and projects which broadly characterize and analyze factors influencing the evolution of nanoparticles emitted by production equipment in the workplace environment and its effect on the exposure potential. In 2006, this category has the smallest budget which mirrors to some extent the nascent nature of nanotechnology. Systematic collection of exposure information is hindered by the lack of standardized methods, reference materials, protocols, and affordable instrumentation for EHS measurements. The NNI has already begun to address the need for additional research in this priority area, with NIOSH directing additional funding in FY 2007 for field evaluations in partnership with various enterprises.

Four agencies funded research into *Risk Management Methods.* About one-third of the funding addresses risk-management control measures for airborne particles in the workplace with the rest of the funding addressing more general assessment of the application of risk management methods to nanomaterials. Inhalation is likely to be the most important initial exposure route during development and manufacture of particles with nanoscale features or dimensions, and is addressed by NIOSH funding for workplace exposures. Research into risk management methods for scenarios such as such as environmental releases, ecological receptors, and consumer or incidental exposures, was not funded in 2006, but the applicability of general (as opposed to nanomaterial-specific) risk management methods to these cases has also not yet been evaluated.

Biography for E. Clayton Teague

Clayton Teague is Director of the federal National Nanotechnology Coordination Office (NNCO) since April 2003. Established in 2001, the NNCO is the secretariat to the Nanoscale Science, Engineering and Technology Subcommittee of the NSTC. As such, the NNCO provides day-to-day technical and administrative support to the NSET Subcommittee and assists in the preparation of multi-agency planning, budg-

et and assessment documents. The NNCO is the point of contact on federal nanotechnology activities for government organizations, academia, industry, professional societies, foreign organizations, and others to exchange technical and programmatic information. In addition, the NNCO develops and makes available printed and other materials as directed by the NSET Subcommittee as well as maintains the NNI website.

Dr. Teague was previously Chief of the Manufacturing Metrology Division in the Manufacturing Engineering Laboratory of the National Institute of Standards and Technology (NIST).

At NIST since 1972, Dr. Teague has designed, constructed, and used precision instrumentation for ultra-high accuracy dimensional metrology of surfaces and micrometer to nanometer-scale features. Beginning with his metal-vacuum-metal tunneling work in the 1970's, he continued to work with such precision instrumentation as scanning tunneling microscopes, atomic force microscopes, displacement and phase-measuring interferometry, stylus instruments, flexure stages, and light scattering apparatus. Because the laboratory and building environments were always factors in the ultimate performance of these instruments, the subject of this workshop has been an ongoing topic of great interest.

Dr. Teague is a member of the American Society for Precision Engineering, has served twice as the Society's President, and is a fellow of the UK Institute of Physics. He served as Editor-in-Chief of the international journal *Nanotechnology* for ten years and is currently a member of the Editorial Board of the journal. He holds a B.S. and M.S. in physics from the Georgia Institute of Technology and a Ph.D. in physics from the University of North Texas. He has authored or co-authored 70 papers, has presented 50 invited talks in the technical fields described, and jointly with colleagues, has six patents. Dr. Teague has received the Gold Medal, Silver Medal, and Allen V. Astin Measurement Science Award from the Department of Commerce, the Kilby International Award by the Kilby Awards Foundation, and an IR–100 Industrial Research and Development Award for his work.

Chairman BAIRD. Mr. Kvamme.

STATEMENT OF MR. E. FLOYD KVAMME, CO-CHAIR, PRESIDENT'S COUNCIL OF ADVISORS ON SCIENCE AND TECHNOLOGY

Mr. KVAMME. Thank you, Mr. Chairman, and Members of the Subcommittee. I am pleased to have the opportunity to testify before you today.

My name is Floyd Kvamme, and I am co-chair of the President's Council of Advisors on Science and Technology, or PCAST. PCAST comprises a group from academia, industry, and other entities with experience in leading successful science and technology enterprises. My remarks today are my own but based on my conversations with fellow PCAST members. I am confident that they feel similarly on the issues under discussion today.

As part of its second review, PCAST is taking a close look at the environmental, health, and safety, or EHS, aspects of the NNI. My Co-Chair for that review is Nancy Dicciani from Honeywell Corporation, who brings years of experience in the chemical industry and the responsible development of materials. The Council has received input from a wide range of perspectives, including a technical advisory group, or TAG, made up of more than 60 leading academic and industry experts including two of my co-witnesses here today.

The main points I want to make today are, one, the NNI approach for identifying and addressing research needed to understand and manage the potential risks associated with nanotechnology appear sound and appropriate. Secondly, research to understand EHS implications should remain integrated with the broader portfolio of nanotech R&D.

It is important to note that the terms nanotechnology and nanomaterial do not refer to a single material or class of materials. Rather, they refer to a broad spectrum of engineered materials with unique size-dependent properties. Each individual nanomaterial will have a benefit-to-risk ratio that depends on the material's specific characteristics and intended application.

Federal investment in nanoscale science and engineering research remains money well spent. PCAST's assessments show that the U.S. is a leader in nanotechnology research and innovation. Solar cell technology, improved materials, energy storage, and medicine are just some of the areas sure to reap the benefits, economic and societal, from nano advances. To do so, however, there also needs to be investment in research for understanding and overcoming, that is, managing or designing out, the potential risks. As someone said in a recent PCAST discussion, we need to be cautious, not precautious. My own experience at the outset of the semiconductor industry taught me that EHS risks are part of any new technology, but they are risks that can be addressed.

Our TAG survey shows broad consensus with respect to the role of the Federal Government in supporting nanotechnology-related EHS research. The majority of respondents are eager to see the NNI continue its proactive approach and to grow research support.

Secondly, the interagency approach is effective. I reviewed the September 2006 report that outlined EHS research needs, as well as the more recently released interim document prioritizing the needs. These documents cast the wide net necessary to address the array of nanotechnology-related EHS issues and are good descriptions of the priorities. I believe the interagency process will lead to a sound research strategy.

Funding increases for EHS research across the federal agencies are of the right scale and indicate a steady increase in the capacity to conduct the necessary research. EHS research also fundamentally depends on advances in non-EHS areas such as instrumentation development and basic research on nanomaterials.

Development of nanotechnology in a responsible manner, especially at the early stages, will be expedited by integration of EHS research with broader basic and applied research. Applications-oriented research will lead to information about EHS. So rather than setting arbitrary funding levels or percentages of total spending as a guideline for the EHS budget, NNI agency should focus on addressing the identified EHS research priorities, while at the same time investing in world-class applications research. The NNI's strong interagency coordination approach is essential to optimize progress in both.

In summary, I am pleased with the extensive coordination and collaboration among the NNI agencies. Their approach appears to leverage the expertise and related efforts across the government. While there is much to be done, the process is not broken. I expect the current planning and coordination process will lead to a well-thought-out plan for nanotechnology EHS research. In fact, the coordination process used by the NNCO and the similar process used to manage networking and information technology research and development are so effective that they could well be considered models for similar coordination in fields such as K-12 education where

hundreds of programs spread over many agencies without any formal mechanism whereby the agencies might coordinate and share information. PCAST is, however, anxious to see the nanotechnology EHS research strategy document that has been referred to and strongly encourages the NEHI Working Group to complete its work as expeditiously as possible, hopefully in time for an assessment in our upcoming report which we hope to issue in January. Thank you.

[The prepared statement of Mr. Kvamme follows:]

PREPARED STATEMENT OF E. FLOYD KVAMME

Mr. Chairman and Members of the Subcommittee, I am pleased to have the opportunity to testify before you today. My name is Floyd Kvamme and I am the Co-Chair of the President's Council of Advisors on Science and Technology (or PCAST), which was designated by Executive Order as the National Nanotechnology Advisory Panel called for by the *21st Century Nanotechnology Research and Development Act of 2003.*

PCAST comprises a group from academia, industry, and other entities with experience in leading successful science and technology enterprises. My remarks today are my own, but based on my conversations with fellow PCAST members, I am confident that they feel similarly on the issues under discussion today.

As part of its second review, PCAST is taking a close look at the environmental, health, and safety (EHS) aspects of the National Nanotechnology Initiative (NMI). I co-chair the PCAST subcommittee performing that review, along with Nance Dicciani from Honeywell Corporation, who brings years of experience in the chemical industry and a personal commitment to the importance of responsible development of materials. The Council has received input from a wide range of perspectives, including from a technical advisory group (or TAG) made up of more than 60 leading academic and industry experts from a broad cross-section of disciplines related to nanotechnology, including two of my co-witnesses here today.

Based on PCAST discussions and meetings, input from the TAG, and my own talks with researchers at universities and in small and large companies, the main points I want to make in response to the Subcommittee's questions are:

1. The NMI approach for identifying and addressing research needed to understand and manage the potential risks associated with engineered nanomaterials appears sound and appropriate.

2. Research to understand EHS implications should remain integrated with the broader portfolio of nanotechnology R&D.

It is important to note that the terms "nanotechnology" and "nanomaterial" do not refer to a single material or even class of materials. Rather, the terms refer to a broad spectrum of engineered materials with unique nanoscale-dependent properties. Each individual nanomaterial will have a benefit-to-risk ratio that depends on the material's specific characteristics and intended application.

Federal investment in nanoscale science and engineering research remains money well spent. PCAST's assessments show that the U.S. is a leader in nanotechnology research and innovation. Solar cell technology, improved materials, energy storage, and medicine are just some of the areas sure to reap the benefits—economic and societal—from nano advances. To do so, there also needs to be investment in research for understanding and overcoming—that is, managing or designing out—the potential risks. As someone said in a recent PCAST discussion, we need to be "cautious, not precautious." My own experience at the outset of the semiconductor industry in the 1960s and '70s taught me that EHS risks are part of any new technology. But they are risks that can be addressed.

Already, research is shedding light on some of the questions being asked. Specifically, a study at Purdue on the environmental impact of manufactured nanoparticles on ordinary soil showed no negative effects; Georgia Tech scientists are doing similar work. Researchers at Dayton University are working on the health and safety aspects of the use of nanodiamonds as drug delivery vehicles with encouraging results. University of Oregon chemists are looking at the use of nanomaterials to clean up toxic groundwater contaminants that have until now been difficult to remove. *In vivo* tests at Rice University have found no immediate adverse health effects from carbon nanotubes injected directly into the bloodstream and that the liver seems to collect these materials effectively for excretion. These and many other studies are

increasing the body of knowledge on EHS implications and providing,useful information on the responsible use of various nanomaterials. The collection and dissemination of this research is an important essential function of the NNI, as noted in our first report.

Our TAG survey shows broad consensus with respect to the role of the Federal Government in supporting nanotechnology-related EHS research. The majority of respondents are eager to see the NNI continue its pro-active approach and expand research support.

The interagency approach is effective. I have reviewed the September 2006 report (*EHS Research Needs for Engineered Nanoscale Materials*), as well as the more recently released interim document, prioritizing the needs. These documents cast the wide net necessary to address the array of nanotechnology-related EHS issues and are good descriptions of the broad research needs. Thus, I believe the interagency process will lead to a sound research strategy. Some have called for there to be a separate office established to plan and fund EHS research related to nanotechnology. While this might provide a sense of stronger management, I do not believe that it is the best way to reduce uncertainty about potential risks to health or the environment. As I mentioned earlier, the field of "nano" is broad and the risk-benefit assessment is complex. The best way to address this complexity is by utilizing all of the expertise of the federal agencies in a coordinated fashion. The National Nanotechnology Coordination Office and the interagency NEHI Working Group appear to be the optimal approach at this time. Creating a separate office would not just add bureaucracy, it would risk losing the collaborative community of experts from agencies like EPA, FDA, NIOSH, NIST, and NIH.

Funding increases for EHS research across the federal agencies are of the right scale and indicate a steady increase in capacity to conduct the necessary research. Funding increases (from $38M in 2006 to $59M requested in 2008) are encouraging and indicate a steady increase in capacity. In general, increasing funding too rapidly does not lead to equivalent increases in high quality research. It is crucial to note that EHS research also depends on advances in non-EHS areas, such as instrumentation development and basic research on nanomaterials.

Development of nanotechnology in a responsible manner, especially at the early stages, will be expedited by integration of EHS research with broader basic and applied research. The NNI should continue to fund cutting-edge research in all areas, including for EHS. Applications-oriented research may well lead to information about EHS. Rather than setting arbitrary funding levels or percentages of total spending as a guideline for the EHS budget, NNI agencies should focus on addressing the identified EHS research priorities while at the same time investing in world-class applications research. In addition, the NNI agencies should continue their efforts to coordinate the entire portfolio of applications and implications research to leverage and optimize progress in both.

In summary, at this point in our review, I am pleased with the amount of coordination taking place among the agencies through the NNI. Their approach appears to leverage the expertise and related efforts across the government (e.g., work to assess risks of diesel, exhaust and other incidental nanomaterials).

I expect the current planning and coordination process will lead to a well thought out plan for nanotechnology EHS research across NNI member agencies. While there is much to be done, the process is not broken. In fact, the coordination process used at the NNCO and the similar process used to manage Networking and Information Technology Research and Development are so effective, they could well be considered models for similar coordination in fields such as K–12 education where spending for hundreds of programs is spread over many agencies without any formal mechanism whereby the spending agencies might be informed of activities in their sister government departments.

The Council is eager to see the final nanotechnology EHS research strategy, and strongly encourages the Nanotechnology Environmental and Health Implications working group (NEHI) to complete its work as expeditiously as possible—hopefully in time for an assessment in our upcoming report.

BIOGRAPHY OF E. FLOYD KVAMME

Floyd Kvamme is a Partner at Kleiner Perkins Caufield & Byers, a high technology venture capital firm. He is responsible for the development of high technology companies from early start-up to publicly traded phase. Mr. Kvamme currently serves on the boards of Brio Technology, Gemfire, Harmonic, National Semi-

conductor, Photon Dynamics, Power Integrations, and Silicon Genesis. Mr. Kvamme was one of five members of the team that began at National Semiconductor in 1967, serving as its General Manager of Semiconductor Operations and building it into a billion-dollar company. He served as President of the National Advanced Systems subsidiary, which designed, manufactured and marketed large computer systems. In 1982 he became Executive Vice President of Sales and Marketing for Apple Computer. While at Apple, his responsibilities included worldwide sales, marketing, distribution and support. He holds two degrees in Engineering; a BS in Electrical Engineering from the University of California at Berkeley and an MSE specializing in Semiconductor Electronics from Syracuse University.

Chairman BAIRD. Thank you, Mr. Kvamme. I want to acknowledge the presence of Ms. Hooley from Oregon who has been a strong leader in nanotechnology issues. Also welcome back to our Committee Ms. Johnson from Texas. It is good to have you back. And also I would like to at this time to ask you now for unanimous consent to the gentleman from California, Mr. Honda, to join us without objection.

Thank you. We will return to the witnesses now. Dr. Colvin, please.

STATEMENT OF DR. VICKI L. COLVIN, PROFESSOR OF CHEMISTRY AND CHEMICAL ENGINEERING; EXECUTIVE DIRECTOR, INTERNATIONAL COUNCIL ON NANOTECHNOLOGY; DIRECTOR, CENTER FOR BIOLOGICAL AND ENVIRONMENTAL NANOTECHNOLOGY, RICE UNIVERSITY

Dr. COLVIN. Thank you, Mr. Chairman, and Members of the Committee for the opportunity to speak today about the environmental, health, and safety research needs for nanotechnology. Today I am providing my individual opinions, but they have been informed by my association with the International Council on Nanotechnology, or ICON. This organization based at Rice University is a public-private partnership founded on the principle that multi-stakeholder, international collaboration is an essential ingredient for effective risk management of nanotechnology. As its executive director, it is my great honor to work with its director, Kristen Kulinowski, and our many volunteers from around the world on projects ranging from a free, searchable database of EHS research papers to a survey of current practices for nanoparticle handling in the workplace.

ICON's most recent activity has been an EHS research needs project funded in part by the National Science Foundation. We have used the global reach of our volunteers to recruit diverse stakeholders to international workshops where we asked them to assess the research needs for nano-EHS.

Given this background and my own experience as a practicing scientist and director of NSF Center for Biological and Environmental Nanotechnology, I will comment on the latest NNI document concerning nano-EHS research.

I commend the NEHI Working Group for its prioritization of the research needs in this area. I know that couldn't have been an easy process, and the deliberations were necessary. There is an urgency to nano-EHS research that affects the entire NNI investment. Innovation in nanotechnology is being threatened by the uncertainty about its risks. We need this innovation more than ever right now. Nanotechnologies offer new approaches to curing cancer and cleaning water and maybe will even enable energy independence for our

country. But fewer of these transformative technologies will make it into commerce if the technology transfer pipeline is limited by concerns about nanoproduct safety. This problem cannot be solved by increasing the inputs to the pipeline, nor should it be addressed by relaxing regulatory oversight. The only sure fix is high quality and intelligently packaged risk-related information. To create such information, researchers must start work soon and under the guidance of a federal research strategy that is in place no later than 2008.

Going from a climate of uncertainty to one of confidence in managing nanotechnology's risks is a massive undertaking that will take years to fully develop. It requires careful planning, coordination among agencies, and international cooperation. External advisors included as partners in the NNI planning process could accelerate the pace as well as make the effort more integrated internationally.

The current NNI document as is clear from its title is not a strategic plan but a collection of priority research needs. These needs are grouped by not how they connect to some end objective but by the relationship to agency missions. The cross-cutting issues of nano-EHS do not map well onto single agencies, and this presentation left me uncertain that there were any shared goals driving the federal investment. I recommend that specific research priorities be grouped so as to link them to two, maybe three concrete outcomes which have clear relevance to developing safe nanotechnology.

One example of such an outcome is the predictive model for nanotechnology risk. During our ICON workshops, we found this outcome had broad appeal to everyone, regulators, academics, and industry alike. This is because the old ways of managing risk are not easily adapted to nanotechnology. Nanomaterials can come in millions of different sizes and shapes and surfaces and chemical types. Faced with such immense variety, we can't just expect to apply new risk assessment for each new flavor of nanomaterial. Instead, we have to explore the latest tools of 21st-Century biology to move from observations of nanoparticles hazards to a paradigm that seeks to predict these hazards before a material is even created. Such predictive simulations are a long-term grand challenge for nanotechnology risk research, but to develop them requires near-term, more pedestrian activities focused on unifying researchers' terminology, methods, data structures, and even materials. I loosely refer to these as harmonization tools, and with the exception of reference materials, these needs did not make it into the top 25 list in the latest NNI analysis. At the ICON workshops, these took center stage in our discussion. Most participants felt that these tools were a prerequisite for nano-EHS research and should receive immediate priority.

To understand why this issue is so important, consider the difference between investing in applications versus risk research. In the first case, you might find five different teams to build a better battery, each with its own approach; but in the end, you help your cause even if only one team succeeds. In the second case, if you find five teams to help understand nanotube toxicity, for example, and then get five different answers, your research investment actu-

ally hurts you because it creates uncertainty rather than combating it. The bad news is that by my count, we have way over five different opinions about carbon nanotube toxicity right now. The good news is that the U.S. Government can, if it is thoughtful about the mechanisms, help researchers solve this problem and for relatively low cost.

In conclusion, I look forward to the rapid development of the NNI's strategic plan for nanotech EHS research. Breaking down risk research into several concrete outcomes, such as predictive simulations, will help to rally the scientific community and create an effective strategy. Perhaps the first step along the path will be programs that encourage researchers to adopt a common set of tools for risk research. These developments would create confidence that we are on a path towards understanding nanotechnology's risks and spread the doors open for safe nanotechnology innovation.

Thank you.

[The prepared statement of Dr. Colvin follows:]

PREPARED STATEMENT OF VICKI L. COLVIN

Summary

I am Executive Director of the multi-stakeholder International Council on Nanotechnology (ICON), and director of a federal research center in nanotechnology, and these roles have informed my opinions of the Federal Government's approach to nanotechnology risk research. I commend the Nanotechnology Environmental and Health Implications (NEHI) working group for its effort to identify and prioritize the research needs in this area. The urgency to nano-EHS research affects the entire NNI investment. This group should provide a full strategic plan within a year, and engage a broader community in authoring this document. The apparent agency boundaries that are currently used to classify the research needs should be removed, and instead these needs should be grouped and linked to larger unifying objectives—such as the development of predictive models for nanomaterial's impacts on the environment. These organizing goals should be described so that it is clear how they help transition us from a climate of uncertainty with regards to nanotechnology's risks to one of confidence. Finally, the NEHI prioritization misses the critical needs related to uniform methods, data structures and languages for nanotechnology risk researchers. There should be a clear plan to support the research harmonization activities so that the policy-makers can extract—within a few years—consensus answers to key questions in this research area. These developments would create confidence that we're on a path towards understanding nanotechnology's risks, and keep the pipeline for nanotechnology wide open for innovations.

Thank you Mr. Chairman and Members of the Committee for the opportunity to speak about the environmental, health and safety (EHS) research needs for nanotechnology. Today, I am providing my individual opinions, but they have been informed by my association with the International Council on Nanotechnology (ICON). ICON was established in 2004 by a coalition of academics, non-governmental organizations, industry and governments. This organization, based at Rice University, is a public-private partnership founded on the principle that multi-stakeholder, international collaboration is an essential ingredient for effective risk management of nanotechnology. As its Executive Director, it is my great honor to work with its Director, Kristen Kulinowski, and our many volunteers from around the world on projects ranging from a free, searchable database of EHS research papers to a survey of current practices for nanoparticle handling in the workplace.

ICON's most recent effort is an international research needs assessment project—funded in part by the National Science Foundation (NSF). We have used the global reach of our volunteers to recruit diverse stakeholders to international workshops, where we asked them to assess the research needs for nanotechnology EHS. The first step in this process is to evaluate known information about these connections and identify where resources should be directed to address knowledge gaps. The ultimate goal envisioned by this project is the design of biocompatible and environ-

mentally benign nanomaterials through the development of a framework that enables prediction of interactions based on physicochemical properties of engineered nanoparticles. The framework contains priorities to enable improved risk assessment over time as new nanomaterials or applications are developed. Armed with this knowledge, we can work together to develop safe applications of nanoscale materials or, in cases where the risks are too great, an alternative to their use.

Given this background, and my own experiences as a practicing nanotechnologist and Director of the NSF Center for Biological and Environmental Nanotechnology, I will comment on the latest National Nanotechnology Initiative (NNI) document concerning nano-EHS research needs.

I commend the Nanotechnology Environmental and Health Implications (NEHI) working group for its effort to identify the research needs in this area; however, there is an urgency to nano-EHS research that affects the entire NNI investment. Innovation in nanotechnology is being threatened by the uncertainty about its risks and how government will manage them. We need this innovation more than ever right now. Nanotechnologies offer new approaches to treating cancer and cleaning water, and may enable energy independence for our country; but fewer of these transformative technologies will make it into commerce if the technology transfer pipeline becomes clogged by concerns about nanoproduct safety. This problem cannot be solved by increasing the inputs to the pipeline, nor should it be addressed by relaxing regulatory oversight. The only sure fix is high quality and intelligently packaged risk-related information.

Going from a climate of uncertainty to one of confidence in managing nanotechnology risk is a massive undertaking that will take years to fully develop. It will also take careful planning and coordination among agencies in this government and abroad. The 2007 NEHI report is an important first step towards creating a coherent and effective strategy for nanotechnology's EHS research, but by summer of 2008 there should be a full and detailed strategic plan made available. As it makes clear in its title, this report is not a strategy. The steps proposed to getting to a strategy are reasonable and deliberative; however, I would recommend sacrificing some of them (the gap analysis for example) because of the urgency of this issue.

Break down barriers between agencies

The NEHI working group could greatly improve future documents by working to break down the apparent agency boundaries that define its approach to this area. The needs in this area are all cross-agency, and an effective strategic plan cannot look like it was created by agency silos. It appears that the various sections of the report were authored in large part by agencies working separately from one another. Section 2, for example, is clearly related to the NIST mission; section 3 to the NIH mission and section 4 to the EPA mission; sections 5 and 6 to NIOSH. Also, it is not clear that each agency should get five priorities; some agency activities need to be greater in scope in the beginning and taper towards the end of the program for example.

A missing agency in this discussion is the Department of Energy (DOE). DOE has a large investment in nanotechnology through its network of nanotechnology facilities, and is thus an immediate customer for information about risk management in a research setting. Moreover, the DOE has enormous capability for particulate and molecular contaminant transport in air, water and soil, with unparalleled experimental and computational capacity. In addition, DOE manages existing programs that seek to understand how nature both produces and uses natural nanoparticles and this perspective is of great value in risk research. For all of these reasons DOE should be a more active participant in the planning process. Like any agency, it should not receive any unfunded mandates. However, I believe that in the area of environmental exposure (fate, transport and modeling) of nanoparticles it is a key partner.

Also apparently missing is the role of the National Science Foundation in nanotechnology risk research. Currently, NSF is the single largest funder of nano-EHS research among the agencies; while risk research is not as clearly connected to NSF's mission, I would argue that this investment is an excellent one for both nanotechnology and fundamental science. In particular, the challenge of predicting the interactions of nanomaterials with the environment is one that will bring together new disciplines in computational biology and bioinformatics—disciplines nurtured in large part by the NSF.

A strategic plan needs several unifying objectives

The prioritization document provides 20,000 foot agency-specific views of this problem, but it never brings these together into a 50,000 foot view of exactly how

each research need will transition us from a climate of uncertainty to one of confidence. I believe this disconnect may exist because of the silo approach to writing this report; this division is not a general feature of the NNI and risk research, and I note with great appreciation the productive coordination among EPA, NSF, NIOSH and NIH already with respect to current funding in the area. These agencies know how to work together, they just didn't convey that fact very effectively in this current report. As a result of this, the overall document left me without a sense of the shared objectives that will drive the program. The ultimate strategic plan must be structured by two, maybe three, overarching outcomes that stakeholders agree will give us more confidence in managing risks.

During our ICON workshops, we structured debate around the shared objective of predictive models for nanotechnology risk. There was great enthusiasm for framing the problem this way among scientists with research and regulatory missions alike. Nanotechnology throws a curve ball at conventional risk assessment, which is designed to evaluate the risk of a single substance like DDT. Its basic materials can be created with millions of possible variations of different sizes, shapes, surfaces and chemical type. Faced with such variety, we can't just apply a risk tool over and over again. Instead, we have to predict based on measurable properties how nanomaterials might move into organisms, and to then use informatics models to link their presence to an impact such as toxicity. Such a concrete outcome is the best starting point for the NNI's planning process.

Engage external stakeholders in developing Grand Challenges for Nano-EHS Research

The NEHI's work would benefit greatly from a more open process that engaged external advisors not only as commenters on the document, but also as authors. This report was made available for public comment for one month, and comments were restricted to the 'principles used for prioritization,' not the actual priorities. The NEHI would benefit greatly from convening external advisors for the next stage of the process; in the least, this engagement could accelerate the drafting of the full plan. I would point to the NNI grand challenge workshops (2000–2003) as a model for this activity. These events drew researchers from all sectors together to draft the language of 'grand challenges' in area of nanotechnology related to information sciences, biology, materials and manufacturing as well as environment. Reports from these meetings often included prioritization of issues and in some cases rather detailed plans about how best to proceed with research in the area. I think especially for this topic that engagement of multiple stakeholder groups is essential. The NNI should hold 'Grand Challenge for Nanotechnology Risk Research' workshops and structure them in such a way as to directly input into their planning—and convey that structure to the participants. Engaging external advisors as real partners in the planning process should accelerate the pace of this activity and ensure the planning document is well integrated with other global efforts.

Support harmonization of language, methods and materials

Finally, there should be a clear plan to support activities devoted generally to harmonizing researchers' languages, methods and materials. These issues were mentioned in 2006, but this year only a need for reference materials made the cut. At the ICON workshops, it was hard to get participants to stop complaining about how the lack of standard terminology, data structures, methods and reference materials made their research slower and less conclusive. Overwhelmingly, participants agreed that harmonizing research methods was a critical first step in a global nano-EHS research effort.

To understand why this issue is so important consider the difference between funding applications research versus risk research. In the first case you might fund five teams to build a better battery, each with its own approach, but in the end you get what you want if only one team manages to improve the battery. In the second case, if you fund five teams to help understand nanotube toxicity and they get five different answers you are actually worse off because your research creates uncertainty rather than combating it. Unfortunately, such dissonance in the technical literature is normal for new types of science and what we are trying to measure (nanotechnology's risks) is very challenging. We researchers cannot really tackle the problem until we have a mechanism to deliberate, argue and ultimately agree on what to call nanomaterials and what protocols to follow in doing the risk research.

The harmonization that I envision will not mean that there will be consensus among the technical community on elements of nanotechnology's hazard and exposure; rather, that we will reach consensus faster because we will not be arguing through the slow channels of peer-review about methods and language. The most important features of this harmonization activity are that it must result in vol-

untary practices, designed by the active researchers in nano-EHS through a collaborative and consensus process. Top-down and mandatory instructions about how best to collect data, organize it or report would be a disaster. A great model, mentioned in the NNI's 2006 report on nano-EHS needs, are the MIAME standards for protein arrays; these are driven by researchers and NIH had the good sense to fund workshops and a website to keep them updated. To get this started for nanotechnology would require a good nano-EHS network of researchers; NSF has examples of network funding for community building in other areas. This community would convene a few workshops, use the electronic data-sharing possible via the web, and perhaps contract the services of a technical writer. Round robin tests of methods and materials would follow from any uniform practices that emerge in a Phase 2 of the harmonization program.

It is important to realize that the standardization efforts underway at ASTM and ISO are not equivalent to what I am referring to a research harmonization. I chair the ASTM E56 committee on nanotechnology and over the past few years have developed a good familiarity with international standardization. I have enormous respect for these processes, but they are poorly suited for the task I envision. First, academics are not traditionally represented in these activities. Indeed, I am one of the few academics actively involved in nanotechnology standardization and I cannot see that changing. Second, research harmonization could in principle happen over the span of nine months and several workshops; even a straightforward ASTM standard could take two years. Third, there are real issues with international participation in either ASTM or other standard developing organizations, including the International Organization for Standardization (ISO). U.S. scientists can only write standards by being on ASTM (unless they are nominated to the U.S. technical advisory group to ISO), and foreign scientists are usually expected to participate in their national standards activities—to which ASTM is a competitor. Fourth, international standardization is highly politicized and any document takes on legal and commercial scrutiny that is out of place when researchers are discussing the nitty gritty details of evaluating cell death, for example. Finally—and most problematic—standards documents from ASTM and ISO are copyrighted and expensive. The research harmonization documents need to be freely available to anyone with a computer—they have to be easy to use and access.

It may be that the research harmonization documents could serve as starting points for more formal standardization in ASTM, ISO or elsewhere. In this model, research harmonization activities would be a precursor not a competitor for formal standardization processes; in this way, they could better serve the immediate needs of the research community.

Conclusion

In conclusion, I hope that the NNI can quickly, with external input, develop a detailed strategic plan. Breaking down risk research into several concrete outcomes—such as predictive simulations—will help to rally the scientific community and create public confidence in existing and new nanoproducts. Perhaps the first step will be programs that catalyze the research community to develop and adopt common practices for nanotechnology risk research. These developments would create confidence that we're on a path towards understanding nanotechnology's risks, and keep the pipeline for nanotechnology innovation flowing.

International Nano-EHS Research Needs Assessment: A Preview of Reports from Two Workshops

ICON sponsored two workshops this year to discuss the research needed to enable prediction of nanomaterial impacts. The first workshop, held at the National Institutes of Health campus in Bethesda, MD, in January, tested whether nanomaterial composition was a reasonable way to begin classifying nanomaterials for predictive purposes and where in the life cycle of a given class of nanoparticle there might be high exposure potential. However, the dynamic nature of nanomaterials throughout their life cycle presents challenges for using physicochemical properties as predictors of biological behavior. Workshop participants identified the need for a set of screening tools to correlate the functional properties of nanomaterials—i.e., how they behave rather than what they are made of—to determine potential for bio-interaction. These tools do not exist today.

The second workshop, held at the Centre for Global Dialogue in Ruschlikon, Switzerland in June, focused on the mechanisms by which engineered nanomaterials interact with biological organisms—including oxidative stress, inflammation and immune response, protein misfolding, apoptosis and necrosis, genotoxicity and mutagenicity, and developmental effects—and interactions between engineered nanomaterials and *in vitro* and *in vivo* systems at the level of biological molecules, target cells, tissues and whole animals. Workshop participants identified a need to understand what happens to a nanoparticle when it enters a biological organism and becomes coated with biomolecules in a complex and dynamic manner that is still poorly understood. Tools for characterizing these coatings, for tracking certain types of nanoparticles throughout the body, and for correlating cell-culture studies with impacts in whole organisms are all outstanding challenges.

Some themes that cut across both workshops were the need for standard terminology, a robust library of standard reference materials for use in nano-EHS research, a set of toxicology tools that have been validated for use with nanomaterials, and a better understanding of how dose and dose rate impact toxicity for nanomaterials. All these needs were seen as limiting the research community's ability to develop predictive models for the interactions of nanomaterials with humans and the environment.

The workshops were enabled by funding from the National Science Foundation (BES–0646107) with generous in-kind support from the National Institutes of Health and the Swiss Reinsurance Company. The final report is in preparation and will be made available at *http://icon.rice.edu*.

BIOGRAPHY FOR VICKI L. COLVIN

Dr. Vicki Colvin received her Bachelor's degree in chemistry and physics from Stanford University in 1988, and in 1994 obtained her Ph.D. in chemistry from the University of California, Berkeley, where she worked under the guidance of Dr. Paul Alivisatos. During her time at the University of California, Berkeley, Colvin was awarded the American Chemical Society's Victor K. LaMer Award for her work in colloid and surface chemistry. Colvin completed her postdoctoral work at AT&T Bell Labs.

In 1996, Colvin was recruited by Rice University to expand its nanotechnology program. Today, she serves as Professor of Chemistry and Chemical & Biomolecular Engineering at Rice University, as well as Director of its Center for Biological and Environmental Nanotechnology (CBEN). CBEN was one of the Nation's first Nanoscience and Engineering Centers funded by the National Science Foundation. One of CBEN's primary areas of interest is the application of nanotechnology to the environment.

Colvin has received numerous accolades for her teaching abilities, including Phi Beta Kappa's Teaching Prize for 1998–1999 and the Camille Dreyfus Teacher Scholar Award in 2002. In 2002, she was also named one of *Discover Magazine*'s "Top 20 Scientists to Watch" and received an Alfred P. Sloan Fellowship. Her research in low-field magnetic separation of nanocrystals was named Top Five (no. 2 of 5) Nanotech Breakthroughs of 2006 by Forbes/Wolfe Nanotech Report.

Colvin is also a frequent contributor to Science, Advanced Materials, Physical Review Letters and other peer-reviewed journals, having authored/ co-authored over 75 articles, and holds patents to four inventions.

Chairman BAIRD. We have just now been joined by Dr. Bartlett. Dr. Bartlett, thank you for being here with us. Dr. Maynard?

STATEMENT OF DR. ANDREW D. MAYNARD, CHIEF SCIENCE ADVISOR, PROJECT ON EMERGING NANOTECHNOLOGIES, WOODROW WILSON INTERNATIONAL CENTER FOR SCHOLARS, WASHINGTON, D.C.

Dr. MAYNARD. Thank you, Mr. Chairman, Ranking Member Ehlers, and Members of this committee. My name is Dr. Andrew Maynard. I'm the Chief Science Advisor to the Project on Emerging Nanotechnologies which is a partnership between the Woodrow Wilson International Center for Scholars and the Pew Charitable Trusts. But of course, the views I express here are my own.

A few years ago, nanotechnology was little more than the stuff of scientists' dreams. Yet now it is being used more and more within the products we use every day, and the nanomaterials that make up these products are available for anyone to buy and use.

I want to give you an example of that and very topical after Vicki's comments. I have here a pouch of single-wall carbon nanotubes bought over the Internet. You can see they came in a USPS envelope. Anybody with a credit card can buy this product, and they can buy it in quantities from a few grams up to thousands of kilograms.

Now, we live in a society where materials like this are becoming more and more available, and the question continues to arise, are we doing enough to ensure the safety of these materials?

I just want to focus a little bit more on this particular example, so take these carbon nanotubes. If you look at the safety information which is provided by the company, the manufacturer's materials safety data sheet, this material is graphite, nothing more than the lead in my pencil. And the listed health precautions are really no more than you would have for nuisance dust. But under closer examination, these carbon nanotubes are as similar to pencil lead as the soot on my grill at home is to diamonds. Let me just read you something that a group of experts wrote in the journal *Nature* last year, and this was an article where Vicki was one of my coauthors. I am quoting here from this article. "Although it is not clear whether fiber-shaped nanoscale particles from carbon nanomaterials will behave like asbestos or not, some materials are sufficiently similar to cause concern. Any failure to pick up asbestos-like behavior as early as possible will be potentially devastating to the health of exposed people and to the future of the nanotechnology industry."

I think you can see, as this particular example eloquently demonstrates, there is a yawning knowledge gap between nanomaterials entering commerce now and what we know about their safety. And this uncertainty over how to develop nanotechnology safely is hamstringing regulators, paralyzing nanobusinesses, and confusing consumers.

So how do we bridge this gap? Well, in my written comments, I consider what we need to do to move forward and how the government's actions match up to this. But in the interest of time, let me cut to the chase here and give you the top six recommendations arising from this assessment.

First of all, we need a top-down research strategy by the end of this year at the latest, and this must respond to oversight challenges and it must be backed up with authority and resources to

ensure its implementation. As part of this strategy, we desperately need a federal advisory committee to be established to allow transparent input and review from industry, academia, non-government organizations, and other stakeholders.

Secondly, new mechanisms are needed to make a strategic plan work. These must overcome both institutional and scientific barriers and ensure resources go to where they're needed to get the job done. They must empower agencies to do what they do best, and they must prevent resources being squandered on research which is both ill-conceived and irrelevant.

Third, 10 percent of the Federal Government's nanotechnology R&D budget should be dedicated to goal-oriented nanotechnology EHS research. And looking at this, a minimum of $50 million per year should go to targeted research that directly addresses specific strategic challenges. The balance of funding should support exploratory or basic research that is conducted within the scope of a strategic research program.

Fourth, a public-private partnership should be established to address critical research questions. This should enable goal-driven research in support of government and industry oversight and a commitment of $10 million per year for the next five years sought split evenly between government and industry.

Fifth, a targeted program of public engagement on nanotechnology should be established that ensures two-way communication between the developers of these technologies and the users.

And finally, top-level leadership of a single person within the Federal Government is needed to ensure appropriate action is taken in addressing these issues.

Members of the National Nanotechnology Initiative have great intentions to do the right thing, and I think we have already heard that. But considering what is at stake here, the quality of our environment, the vitality of the American economy, and the health of people like you and people like me, good intentions are simply not enough. It is vital that we take action now to ensure a world where we cannot only buy engineered nanomaterials like these carbon nanotubes, but we can also use them without fear of harm.

Thank you.

[The prepared statement of Dr. Maynard follows:]

PREPARED STATEMENT OF ANDREW D. MAYNARD

Overview

I would like to thank Chairman Bart Gordon, Ranking Republican member Ralph Hall, and the Members of the House Committee on Science for holding this hearing on *"Research on Environmental and Safety Impacts of Nanotechnology: Current Status of Planning and Implementation under the National Nanotechnology Initiative."*

My name is Dr. Andrew Maynard. I am the Chief Science Advisor to the Project on Emerging Nanotechnologies at the Woodrow Wilson International Center for Scholars. By way of background, my area of expertise is nanomaterials and their environmental and health impacts, and I have contributed substantially in the past fifteen years to the scientific understanding of how these materials might lead to new or different environmental and health risks. I was responsible for stimulating government research programs into the occupational health impact of nanomaterials in Britain towards the end of the 1990's and spent five years developing and coordinating research programs at the Centers for Disease Control and Prevention (CDC) National Institute for Occupational Safety and Health (NIOSH) that address the safety of nanotechnologies in the workplace. While at NIOSH, I represented the

agency on the Nanoscale Science, Engineering and Technology (NSET) Subcommittee of the National Science and Technology Council (NSTC), and was Co-Chair of the Nanotechnology Environmental and Health Implications (NEHI) Working Group from its inception.

In my current role as Chief Science Advisor to the Project on Emerging Nanotechnologies, I am heavily involved in working with government, industry and other groups to find science-based solutions to the challenges of developing nanotechnologies safely and effectively. The Project on Emerging Nanotechnologies is an initiative launched by the Woodrow Wilson International Center for Scholars and The Pew Charitable Trusts in 2005.[1] 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, non-advocacy policy 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.

In this testimony, I explore why we need to address the Environmental, Health and Safety (EHS) aspects of nanotechnology, and what in my perspective are key components of an effective research strategy. I then look at where current National Nanotechnology Initiative (NNI) actions and plans align with or diverge from what is needed, and draw clear recommendations on how we can get back on track to realizing the promise of nanotechnology. Finally, I draw from this assessment to address the questions specifically asked by the House Science Committee.

Executive Summary

Nanotechnology has tremendous potential to create wealth and jobs, improve standards of living and provide solutions to some of our greatest technological challenges. But this potential will not be realized unless strategic action is taken to identify, assess and manage potential risks *before* serious harm is caused. Despite a good start, the Federal Government's current approach to ensuring the development of responsible and successful nanotechnologies falls short of the mark. Action in six areas is recommended to get EHS research back on track, in support of sustainable and safe nanotechnologies:

1. **Strategy.** A top-level strategic framework should be established by the end of this year at the latest and updated every two years, that identifies the goals of nanotechnology risk research across the Federal Government, and provides a roadmap for achieving these goals. The strategy should identify information needed to regulate and otherwise oversee the safe development and use of nanotechnologies; which agencies will take a lead in addressing specific research challenges; when critical information is needed; and how the research will be funded. It should reflect evolving oversight challenges, and must be backed up with authority and resources to ensure its implementation.

2. **Mechanisms.** Mechanisms are needed to allow a strategic research framework to be implemented. These must transcend institutional and scientific barriers, and ensure resources get to where they are needed to get the job done. They must empower agencies to do work effectively within their missions, but within an overarching strategic framework. And they must prevent resources from being squandered on research that is ill-conceived and irrelevant. A federal advisory committee should be established to allow transparent input and review from industry, academia, non-government organizations and other stakeholders.

3. **Funding.** Ten percent of the Federal Government's nanotechnology research and development budget should be dedicated to goal-oriented EHS research. A minimum of $50 million per year should go to targeted research directly addressing clearly-defined strategic challenges. The balance of funding—an estimated $95 million in fiscal year 2008—should support exploratory research that is conducted within the scope of a strategic research program.

4. **Public-Private Partnerships.** A public-private partnership should be established to address critical industry and government-research questions that fall between the gaps. A partnership model should be developed that enables goal-driven research in support of government and industry oversight,

[1] For further information, see *http://www.nanotechproject.org/*. Accessed October 13, 2007.

and a commitment to $10 million per year for the next five years sought; split evenly between government and industry sources.

5. **Communication.** A targeted program of public engagement on nanotechnology should be established that ensures two-way communication between the developers and users of these technologies. This should be supported by approximately $1 million per year in funding. The program should have the fourfold aims of ensuring transparency, disseminating information, enabling science-based dialogue between stakeholders, and supporting informed decision-making by citizens, businesses, regulators, and other stakeholders.

6. **Leadership.** Top-level leadership is needed to ensure the successful development and implementation of a government-wide strategic research framework addressing nanotechnology EHS risks. One person should be appointed to oversee nanotechnology EHS research and regulation within the Federal Government, and given resources and authority to enable funding allocations and interagency partnerships that will support the implementation of a strategic research plan.

We cannot afford to drive blind into the nanotechnology future. Not only will this prevent us from seeing and navigating around the inevitable bends associated with possible risks, but it will also give those economies with the foresight to identify and negotiate the bends a very real competitive edge. Despite a good start, the U.S. is still caught up in developing new technologies within an old mindset. If emerging nanotechnologies are to be built on a sound understanding of the potential risks—and how to avoid them—new research strategies, new mechanisms of execution and new funding are all needed. These should be overseen by clear leadership and an interagency group with the authority to develop a strategic research framework and ensure its execution.

What is needed to make nanotechnology work?

Nanotechnology has the potential to turn our world upside down. The increasing dexterity at the nanoscale it provides gives us the opportunity to greatly enhance existing technologies, and to develop innovative new technologies. When you couple this capability with the unusual and sometimes unique behavior of materials that are engineered at near-atomic scales, you have the basis for a transformative technology that has the potential to impact virtually every aspect of our lives. Some of these emerging technologies will benefit individuals. Others will help solve pressing societal challenges like climate change, access to clean water and cancer treatment. Many will provide companies with the competitive edge they need to succeed. In all cases, nanotechnology holds within it the potential to improve the quality of life and economic success of America and the world beyond.

But nanotechnology also is shaking up our understanding of what makes something harmful and how we deal with that. New engineered nanomaterials are prized for their unconventional properties. But these same properties may also lead to new ways of causing harm to people and the environment.[2] Research has already demonstrated that some engineered nanomaterials can reach places in the body and the environment that are usually inaccessible to conventional materials, raising the possibility of unanticipated harm arising from unexpected exposures. And studies have shown that the toxicity of engineered nanomaterials is not always predictable from conventional knowledge.[3] For instance, we now know that nanometer sized particles can move along nerve cells; that the high fraction of atoms on the surface of nanomaterials can influence their toxicity; and that nanometer-diameter particles can initiate protein mis-folding, possibly leading to diseases.

Moving towards the nanotechnology future without a clear understanding of the possible risks, and how to manage them, is like driving blindfold. The more we are able to see where the bends in the road occur, the better we will be able to navigate round them to realize safe, sustainable and successful nanotech applications. But to see and navigate the bends, requires the foresight provided by sound science, and the ability to apply science-informed lessons.

Twenty-first century technologies like nanotechnology present new challenges to identifying and managing risks, and it would be naïve to assume that twentieth century assumptions and approaches are up to the task of protecting health and the

[2] Maynard, A.D., Aitken, R.J., Butz, T., Colvin, V., Donaldson, K., Oberdörster, G., Philbert, M.A., Ryan, J., Seaton, A., Stone, V., Tinkle, S.S., Tran, L., Walker, N.J. and Warheit, D.B. (2006). Safe handling of nanotechnology. *Nature* 444:267–269.

[3] Oberdörster, G., Stone, V. and Donaldson, K. (2007). Toxicology of nanoparticles: A historical perspective. *Nanotoxicology* 1:2–25.

environment in all cases. In the case of engineered nanomaterials, the importance of physical structure in addition to chemical composition in determining behavior is making a mockery of our chemicals-based view of risks and regulation.

Clearly, action is needed to realign how we oversee the safety of engineered nanomaterials with how these new materials might cause harm. This is a complex, but not impossible, task. A successful plan for realizing the benefits of nanotechnology while minimizing the risks depends on acknowledging the possibility of unconventional behavior, leadership, a strategic plan, mechanisms to put a research strategy into practice and sufficient resources to do this. Each of these five components are discussed below.

1. Acknowledging the possibility of unconventional behavior

Assuming that new technologies will have conventional, predictable and manageable risks is a recipe for disaster. Materials that are intentionally engineered to behave in unconventional ways will have the potential to cause harm in a manner that is not predictable from conventional understanding alone. And as a consequence, we cannot assume by default that established ways of evaluating and regulating risks will prevent these new materials from causing harm.[4] There undoubtedly will be new engineered nanomaterials and nanotechnology applications that do not impact health and the environment in an unpredictable way. Yet research has already demonstrated the ability of some engineered nanomaterials to defy convention, by getting to places inaccessible to larger scale materials, and causing harm that would not be predicted from a conventional world-view.[5]

Denying the potential for engineered nanomaterials to cause harm in unconventional ways not only flies in the face of common sense; it also prevents effective science-based decision-making. Based on the current state of knowledge, ways in which nanomaterials might demonstrate unconventional behavior include:

- Adverse reactions to exposure that are not predictable from the material's chemical makeup alone.[6]
- An ability to penetrate to parts of the body and the environment that are inaccessible to non-nanomaterials.[7]
- The emergence of physical and chemical properties that are not directly predictable from individual atoms, or the bulk material.[8]
- A possible ability to interfere with living systems including DNA and proteins that are naturally nanoscale.[9]
- An association with diseases not conventionally associated with exposure to non-nanomaterials.[10]

This knowledge needs to be tempered by the likelihood of exposure (or environmental release) occurring, which could be negligible in the case of nano-engineered electronics, but might be substantial for a range of products designed to be eaten, put on the body or dispersed in the environment.

2. Leadership in nanotechnology EHS research

Without clear leadership, the emergence of safe nanotechnologies will be a happy accident rather than a foregone conclusion.

In addressing any difficult task or challenge, progress is likely to be slow to nonexistent if no one provides vision, direction, motivation and encouragement for achieving results, and is not held accountable for results. And, ensuring the emergence of safe nanotechnologies, where the risks are uncertain and the science complex, is a fiendishly difficult challenge when seen from any angle.

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[4] Davies, J.C. (2006). Managing the effects of nanotechnology. Woodrow Wilson International Center for Scholars, Project on Emerging Nanotechnologies, Washington, DC.

[5] Maynard, A., D. (2007). Nanotechnology: The next big thing, or much ado about nothing? *Ann. Occup. Hyg.* 51:1–12.

[6] Oberdörster, G., Gelein, R.M., Ferin, J. and Weiss, B. (1995). Association of particulate air pollution and acute mortality: involvement of ultrafine particles? *Inhal. Toxicol.* 7:111–124.

[7] Elder, A., Gelein, R., Silva, V., Feikert, T., Opanashuk, L., Carter, J., Potter, R., Maynard, A., Finkelstein, J. and Oberdörster, G. (2006). Translocation of inhaled ultrafine manganese oxide particles to the central nervous system. *Environ. Health Perspect.* 114:1172–1178.

[8] Preining, O. (1998). The physical nature of very, very small particles and its impact on their behavior. *J. Aerosol Sci.* 29:481–495.

[9] Colvin, V. and Kulinowski, K. (2007). Nanoparticles as catalysts for protein fibrillation. *Proc. Natl. Acad. Sci. U.S.A.* doi:10.1073/pnas.0703194104

[10] Mills, N.L., Törnqvist, H., Gonzalez, M.C., Vink, E., Robinson, S.D., Söderberg, S., Boon, N.A., Donaldson, K., Sandström, T., Blomberg, A. and Newby, D.E. (2007). Ischemic and Thrombotic Effects of Dilute Diesel-Exhaust Inhalation in Men with Coronary Heart Disease. *New England J. of Med.* 357:1075–1082.

Leadership towards the goal of identifying, assessing and managing nanotechnology-specific risks will present many challenges. The nanotechnology community includes the Federal Government, State government, businesses, researchers, non-government organizations and consumers, as well as all their international counterparts. Each set of stakeholders brings a different set of issues to the table, and a range of abilities and skills to address those issues. Effective leadership will enable these groups to work effectively toward addressing a common goal of ensuring that emerging nanotechnologies are as safe as possible.

The Federal Government is an acknowledged leader in promoting nanotechnology research and development, and is looked to for leadership in ensuring the emergence of safe nanotechnologies. Yet the diverse makeup of the Federal Government and the different (and possibly competing) interests of agencies present real challenges to developing effective leadership. Communication and collaboration between agencies is essential if the Federal Government as a whole is to identify and address critical issues underpinning the development of safe nanotechnologies. *But committees and networks in and of themselves do not constitute leadership.*

Could an internal committee—or working group—provide the leadership necessary to ensure safe nanotechnologies? Possibly, if it was empowered to establish research directions and allocate resources. Yet even working groups are only as good as the person leading them. And while it is possible for a good committee to direct, encourage and motivate people toward addressing a common set of goals, this is more often than not a reflection of the ability of the committee's leader to direct, encourage and motivate its members. Certainly, a working group without leadership is a very ineffective device!

In short, there must be one individual within the Federal Government who is tasked with leading efforts to ensure the safety of emerging nanotechnologies, and has the resources and authority to get the job done. A key role of such a person would be to ensure agencies are able to work within their missions and competencies toward a common set of established goals. But he or she would also provide leadership to the broader stakeholder community involved—both national and international—in developing safe nanotechnologies.

3. An effective strategic framework

We are unlikely to arrive at a future where nanotechnology has been developed responsibly without a strategic plan for how to get there. Like all good strategies, this should include a clear idea of where we want to be, and what needs to be done to get there. And if we are currently lost, one of the first steps should be to find out where we are now.

Funding for research and development into nanoscience and nanotechnologies serves many purposes, including developing knowledge for its own intrinsic value, providing a platform for job and wealth creation, and improving quality of life. Research into the potential impacts of nanotechnologies supports these goals in that they are unlikely to be met if we blindly develop new technologies that might, or are perceived to, cause unacceptable harm. Yet strategically, the goals of risk-related research must be untwined from those driving nanotechnology discovery in general, if an effective research agenda is to be developed.

Later in this testimony, I will explore the goals and elements of a viable strategic framework for addressing nanotechnology EHS issues. In brief, an overarching goal for federally-funded risk-based nanotechnology research should be to develop the information necessary to identify (or predict), assess and manage risks associated with nanotechnologies. Ultimately, this means research directed towards effective oversight. A central principle of this goal is science in the service of safety, and not science for its own sake.

Broad challenges to addressing this goal include:

- Providing answers to pressing questions.
- Developing new tools and knowledge to identify the questions not currently being asked.
- Translating research results into practice, and in particular, developing new ways of predicting and managing risks.

Many of the recommended research needs identified over the past few years by a wide range of organizations fit within these challenges, including those published

by the NEHI group in 2006[11] (and the shorter list released in 2007).[12] Addressing these challenges within the context of a strategic plan will lead to progress towards the overarching goal.

Developing an effective roadmap to addressing these challenges is not as simple as prioritizing research needs. As I discovered while developing recommendations on a short-term research strategy in 2006,[13] it is necessary to work back from what you want to achieve, and map out the research steps needed to get there. This inevitably leads to complex and intertwined research threads. Yet if this complexity is not acknowledged, the result is simplistic research priorities that look good on paper, but are ineffective at addressing specific aims. And without a clear sense of context, it is all too easy to highlight research efforts that appear to be strategically important, but are in reality only marginal to achieving the desired goals.

In developing the elements of a research strategy in the earlier 2006 paper, and in a commentary published in the journal *Nature* with thirteen distinguished colleagues,[14] it became clear that an effective research strategy addressing potential nanotechnology risks will have a number of key elements. These will include:

- Goal-oriented research,
- A balance of targeted and exploratory research,
- Interdisciplinary collaboration,
- Enabling and empowering researchers and research organizations, and
- Communication and translation of information.

Building a top-down strategic nanotechnology EHS research plan around these goals, challenges and elements, is essential to providing a framework for generating the information that regulators, industry, consumers and others need to develop and use nanotechnologies as safely as possible.

As an example of what is possible, Australia recently announced the formation of an AU$36.2 million initiative to develop nanotechnologies for niche markets—the Niche Manufacturing Flagship.[15] What sets this initiative apart is an integrated approach to EHS research from the start, an approach that will lead to products that have been researched and designed with safety in mind. And while the Niche Manufacturing Flagship approach represents just one component of an effective strategic research framework, in the long run, it is products arising from programs like this that are most likely to be embraced by consumers and industry alike.

4. Mechanisms to get the job done

A strategic research plan that looks good on paper fails at the first hurdle if the mechanisms to implement it effectively are not in place.

Administrative mechanisms necessary to get the job done are largely covered by the elements of an effective research strategy already discussed, and include responsiveness to new challenges, leadership, vision, coordination and communication. But while this list is short, the challenges to developing administrative approaches that enable a top-level federal research strategy to be implemented are substantial. In many ways, it is easier to start by looking at what is not effective. Relying on individual agency-driven research plans and individual investigators to get the job done, for instance, is not effective, as leadership, vision, directed funding, coordination and communication are lost. Likewise, establishing mechanisms for communication and coordination alone is not effective, as there is no vision, no targeted resources and no leadership to apply the resulting flow of information.

Instead, mechanisms need to be implemented at the highest level that ensure an environment in which agencies with different but complementary competencies and missions can operate most effectively. Ideally, administrative structures are needed that: provide leadership in addressing research challenges across the Federal Gov-

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[11] NSET (2006). Environmental, health and safety research needs for engineered nanoscale materials. Subcommittee on Nanoscale Science, Engineering and Technology, Committee on Technology, National Science and Technology Council, Washington, DC.

[12] NEHI (2007). Prioritization of Environmental, Safety and Health Research Needs for Engineered Nanoscale Materials. An Interim Document for Public Comment, Nanotechnology Environment and Health Implications (NEHI) Working Group of the Subcommittee on Nanoscale Science, Engineering and Technology, Committee on Technology, National Science and Technology Council, Washington, DC.

[13] Maynard, A.D. (2006). Nanotechnology: A research strategy for addressing risk. Woodrow Wilson International Center for Scholars, Project on Emerging Nanotechnologies, Washington, DC.

[14] See *supra* note 2.

[15] Niche Manufacturing Flagship. *http://www.csiro.au/org/NicheManufacturingFlagshipOverview.html.* Accessed October 19, 2007.

ernment; facilitate the strategic sharing and use of information between agencies; enable interdisciplinary and interagency partnerships that are goal-oriented rather than mission-driven; simplify resource sharing between agencies; and allow for new resources to be allocated strategically across agencies to address key issues.

Mechanisms also are needed that support relevant research that is not constrained by bureaucratic and organizational barriers. These mechanisms will enable different approaches to supporting research to be used in the best possible way to address identified research goals—including using intramural and extramural research as appropriate, and balancing applied and exploratory research. It is vital that mechanisms continue to be developed that actively encourage interdisciplinary research, and provide frameworks where ill-conceived studies resulting from inadequate interdisciplinary collaboration are the exception, rather than the norm.

Where research needs fall between the gap of government and industry (because of their different goals), public-private research partnerships provide an important mechanism for bridging the gaps. Industries investing in nanotechnology have a financial stake in preventing harm, manufacturing safe products and avoiding long-term liabilities. Yet many of the questions that need answering are too general to be dealt with easily by industry alone. Perhaps more significantly, the credibility of industry-driven risk research is often brought into question by the public and NGOs as not being sufficiently independent and transparent. For many nanomaterials and nanotechnologies, the current state of knowledge is sufficient to cast doubt on their safety but lacks the certainty and credibility for industry to plan a clear course of action on how to mitigate potential risks. Getting out of this "information trap" is a dilemma facing large and small nanotechnology industries alike.

One way out of the "trap" is to establish a cooperative science organization that is tasked with generating independent, credible data that will support nanotechnology oversight and product stewardship. Such an organization would leverage federal and industry funding to support targeted research into assessing and managing potential nanotechnology risks. Its success would depend on five key attributes:

- **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 the operations of the organization should be fully open to public scrutiny.
- **Review.** Research supported by the organization should be independently and 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.

As I discussed in my comments to this committee last September,[16] a number of research organizations have been established over the years that comply with some of these criteria. One of these is the Health Effects Institute (HEI),[17] which has been highly successful in providing high-quality, impartial, and relevant science around the issue of air pollution and its health impacts. The Foundation for the National Institutes of Health[18] also has been successful in developing effective public-private partnerships, and the International Council on Nanotechnology (ICON)[19] is a third model for bringing government, industry and other stakeholders to the table to address common goals. The Wilson Center Project on Emerging Nanotechnologies is currently exploring these and other models as possible templates for public-private partnerships addressing nanotechnology risks.

Irrespective of which model is the best suited for nanotechnology, the need is urgent to develop such partnerships as part of the government's strategy to address

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[16] United States House of Representatives Committee on Science and Technology. Hearing on Research on Environmental and Safety Impacts of Nanotechnology: What are Federal Agencies Doing? Testimony of Andrew D. Maynard. September 21, 2006.

[17] For further information, see The Health Effects Institute, *http://www.healtheffects.org.* Accessed October 13, 2007.

[18] For further information, see The Foundation for the National Institutes of Health, *http://www.fnih.org.* Accessed October 13, 2007.

[19] For further information, see the International Council On Nanotechnology, *http://icon.rice.edu/*. Accessed October 13, 2007.

nanotechnology risks. Nanotechnologies are being commercialized rapidly—going from $50 billion in manufactured goods in 2006[20] to a projected $2.6 trillion in nanotechnology-enabled manufactured goods by 2014—or 15 percent of total manufactured goods globally.[21] And knowledge about possible risks is simply not keeping pace with consumer and industrial applications.

5. Sufficient resources to address critical challenges

To be effective, a nanotechnology risk-research strategic framework needs adequate funding to support proposed research, as well as sufficient expert personnel to oversee its development and implementation.

In my testimony to this committee on September 21, 2006,[22] I made the case for a minimum of $50 million per year to be spent on relevant nanotechnology risk research. This was based on an assessment of critical short-term research needs, and only covered targeted research to address these needs.[23] This estimate still stands. However, I must be clear that such an investment would need to be directed towards addressing a very specific suite of problems that regulators and industry need answers to as soon as possible. This is not envisaged as a general pot of money to be assigned to research that does not address specific and urgent nanotechnology risk goals. In other words, this is an investment that needs to be directed towards the right research.

But beyond the $50 million figure, further investment in exploratory research is needed to identify the questions we haven't thought of yet. It isn't possible to place a firm figure on how much should be spent here, but a useful rule of thumb—and one that others have advocated—is to ensure that at least 10 percent of the Federal Government's nanotechnology research and development budget is dedicated to strategic risk-related research. This would place the overall estimated EHS research budget for 2008 at $145 million—allowing for $50 million in targeted research and $95 million dedicated to exploratory research. Given the nature of exploratory research, which requires substantial investment to make significant progress, this does not seem unreasonable.

Targeted research primarily would address specific questions where answers are urgently needed to make, use and dispose of nanotechnology products as safely as possible. I would envisage that much of the necessary research would be funded by or conducted within mission-driven agencies, such as NIOSH and the Environmental Protection Agency (EPA). In addition, we must ensure that regulatory agencies, including the Food and Drug Administration (FDA) and the Consumer Product Safety Commission (CPSC), either have access to resources to fund regulation-relevant research or input to research that will inform their decision-making.

There will also be a role for science-oriented agencies such as the National Institutes of Health (NIH) and the National Science Foundation (NSF) in funding targeted research, where the missions of these agencies coincide with research that informs specific oversight questions. For example, these two agencies are ideally positioned to investigate the science behind nanomaterial properties, behavior and biological interactions in a targeted way, with the aim of predicting health and environmental impact. But ensuring that targeted research conducted within these agencies is relevant to addressing risk identification, assessment and reduction goals will be critical, and underscores the need for a robust cross-agency risk research strategy and pool of designated funds.

Exploratory research, on the other hand, primarily would be investigator-driven (within determined bounds), and so would preferentially lie within the remit of NSF and NIH. However, in ensuring effective use of funds, it will be necessary to develop ways of supporting interdisciplinary research that crosses the boundary separating these agencies, and combines investigations of basic science with research into disease endpoints, with the goal of informing oversight decisions.

Exploratory research should not be confined to these two agencies, however, as there will be instances where goal-oriented but exploratory research will fit best within the scope of mission-driven agencies, and will benefit from research expertise within these agencies. For example, researchers in NIOSH are currently engaged

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[20] Lux Research (2007). Profiting from International Nanotechnology, Report Press Release: Top nations see their lead erode. Lux Research Inc., New York, NY.

[21] Lux Research (2006). The Nanotech Report™: Investment Overview and Market Research for Nanotechnology. 4th edition, volume 1. Lux Research Inc., New York, NY.

[22] See *supra* note 16.

[23] See also: *supra* note 13.

in exploratory research that is directly relevant to identifying and reducing potential nanotechnology risks in the workplace.[24]

At present, there is no pot of "nanotechnology" money within the Federal Government that can be directed to areas of need. Rather, the NNI simply reports what individual agencies are spending. Yet if strategic nanotechnology risk research is to be funded appropriately, mechanisms are required that enable dollars to flow from where they are plentiful to where they are needed. Extremely overstretched agencies like NIOSH and EPA cannot be expected to shoulder their burden of nanotechnology risk research unaided, and regulatory agencies like FDA and CPSC currently have no listed budget whatsoever for nanotechnology EHS research. If the Federal Government is to fully utilize expertise across agencies and enable effective nanotechnology oversight, resource-sharing across the NNI will be necessary.

In addition to adequate funding, development and implementation of an effective strategic framework will only be as good as the people who develop and implement it. And this means ensuring experts within the Federal Government have the time to commit to getting such a strategy right. Such a framework is too important to be developed and implemented at the margins of peoples' responsibilities. My own experiences in co-chairing the NEHI group would suggest that, even with some of the best minds in government around the table, little progress can be made when those involved do not have the time to dedicate to the issues at hand. And nowhere is this need for time more critical than with the person charged with leading activities.

How do the Federal Government's actions match up to what is needed?

While I argue later that the Federal Government's actions on nanotechnology have so far been too little too late, it is important to recognize that the government has not been deaf to the need to address nanotechnology EHS issues. Preliminary discussions on the importance of EHS in the development of nanotechnology are evident in some of the earliest publications coming out of the NNI. For instance, quoting from an early NSET subcommittee of the NSTC document published in 2001:

> *"Although proponents of nanotechnology view it as benign, there are likely to be some unforeseen, undesirable effects.*
>
> *Even at the basic research stage, nanotechnology advocates need to inform the public about the prospects and risks. They need to engage and involve the public and the groups that represent them. While this will delay the introduction of new technologies, in the end it is likely to save time."*[25]

The NEHI working group was established in 2003 as a direct result of concerns over possible adverse impacts of technologies under development. This early awareness of the need to understand and manage risks is reflected in the 21st Century Nanotechnology Research and Development act published in 2003,[26] the NNI strategic plan,[27] annual NNI budget requests and the current efforts within the Federal Government to develop a strategic research agenda.

Yet talking about the issues is no substitute for progress, and in addressing possible harm to people and the environment, good intentions are not enough. The Federal Government may have been diligent in identifying and discussing issues, but is real progress being made towards addressing the challenges, and ensuring businesses, regulators and the public have the tools they need to make informed decisions over nanotechnology applications?

Some of the first indications that nanomaterials may present an unusual and previously unrecognized health risk came out as far back as 1990.[28] Fifteen years ago, the first concerns were raised about the potential health impacts of using carbon

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[24] NIOSH (2007). Progress towards safe nanotechnology in the workplace, National Institute for Occupational Safety and Health, Washington, DC.

[25] NSET (2001). Societal Implications of Nanoscience and Nanotechnology. NSET Workshop Report, M.C. Roco and W.S. Bainbridge, eds., National Science and Technology Council Committee on Technology, Subcommittee on Nanoscale Science, Engineering and Technology, Washington, DC.

[26] U.S. Congress (2003). *21st Century Nanotechnology Research and Development Act* (Public Law 108–153), 108th Congress, 1st session, Washington, DC.

[27] NSET (2004). The National Nanotechnology Initiative Strategic Plan, Nanoscale Science Engineering and Technology Subcommittee Committee on Technology National Science and Technology Council, ed., National Science and Technology Council, Washington, DC.

[28] Ferin, J., Oberdörster, G., Penney, D.P., Soderholm, S.C., Gelein, R. and Piper, H.C. (1990). Increased Pulmonary Toxicity of Ultrafine Particles. 1. Particle Clearance, Translocation, Morphology. *J. Aerosol. Sci.* 21:381–384.

nanotubes in commercial products.[29] I first wrote about the health and safety challenges presented by nanotechnology in 1999, in a report for the UK Health and Safety Executive.[30] In 2004, the UK Royal Society and Royal Academy of Engineering stressed the urgency with which action was needed to identify and assess the risks presented by nanoparticles,[31] and the past few years have seen an increasing number of research papers questioning conventional approaches to understanding health and environmental risks. At the same time, uncertainty over potential risks, and what is being done to minimize them, has raised barriers to businesses hoping to invest in nanotechnology,[32] and caused consumer groups to question whether people should be using nano-products.[33]

So how does the Federal Government measure up in terms of understanding what is needed to reduce uncertainty and maximize the success of nanotechnology?

1. Acknowledging the possibility of unconventional behavior

In general, agencies within the Federal Government have made good progress in acknowledging the possibility of unconventional behavior in nanomaterials. The Office for Research and Development in EPA recognized the potential to use unconventional characteristics of nanomaterials in remediating environmental pollution some years ago. More recently, the agency has been supporting research into addressing unconventional behavior in nanomaterials that might lead to adverse environment and human health impacts.[34] NIOSH established a nanotechnology research program aimed at workplace exposures in 2004 in recognition of nano-specific challenges, and now has a successful—if sparsely funded—research portfolio spanning exploratory to applied studies.[35] The NSF recognized the need to develop a science-based understanding of nanomaterial-biological interactions early on, which led to the establishment of the Center for Biological and Environmental Nanotechnology at Rice University, and a number of other risk-relevant research initiatives.[36] NIH has encouraged an integrated approach to understanding nano-bio interactions in the development of health-related applications, and has led in exploring the detailed toxicology of select nanomaterials through the National Toxicology Program—a collaboration between the National Institute of Environmental Health Sciences, NIOSH and FDA.[37] NIH also is developing an internal strategy for developing new knowledge on how nanomaterials interact with humans. FDA has recently published a paper clarifying the agency's understanding that engineered nanomaterials may take on risk-relevant properties due to their nanoscale,[38] and the CPSC and the Occupational Safety and Health Administration have both stated that nanotechnology has the potential to present new regulatory challenges. In addition, the Department of Energy, the Department of Defense and the National Institute of Standards and Technology all have research programs related to how engineered nanomaterials represent unconventional risks—and how to tackle the resulting challenges.

The reason for this long (and probably incomplete) litany is to demonstrate that the relevant agencies within the Federal Government are clear that engineered nanomaterials have the potential to behave in unconventional ways. This understanding is reflected in the laundry list of research needs to address such unconventional behavior published by the NNI in September 2006, and the rather shorter list published in 2007.

However, there is not complete accord here. A recent consultation paper from EPA on how the Toxic Substances Control Act applies to nanoscale substances did not provide a mechanism for addressing unconventional behavior in nanoscale materials, but stated that:

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[29] Coles, G.V. (1992). Occupational risks. *Nature* 359:99.

[30] Maynard, A.D., Brown, R.C., Crook, B., Curran, A. and Swan, D.J. (1999). A scoping study into ultrafine aerosol research and HSL's ability to respond to current and future research needs, health and Safety Laboratory, UK.

[31] RS/RAE (2004). Nanoscience and nanotechnologies: Opportunities and uncertainties, The Royal Society and The Royal Academy of Engineering, London, UK, 113 pp.

[32] Lux Research (2006). Taking action on nanotech environmental, health and safety risks, Lux Research Inc., New York, NY.

[33] Rock, A. (2007). Nanotechnology. Untold promise, unknown risk, Consumer Reports. July.

[34] EPA (2007). U.S. Environmental Protection Agency *Nanotechnology White Paper,* Environmental Protection Agency, Washington, DC. EPA 100/B–07/001. February.

[35] See *supra* note 24.

[36] For example, see *http://www.nsf.gov/crssprgm/nano/*. Accessed October 13, 2007.

[37] NTP Nanotechnology Safety Initiative. *http://ntp.niehs.nih.gov/files/NanoColor06SRCH.pdf.* Accessed October 13, 2007.

[38] FDA (2007). Nanotechnology. A report of the U.S. Food and Drug Administration Nanotechnology Task Force, Food and Drug Administration, Washington, DC.

> "a nanoscale substance that has the same molecular identity as a substance listed on the Inventory (whether or not reported to the Agency as being manufactured or processed in nanoscale form) is considered an existing chemical, *i.e., the nanoscale and non-nanoscale forms are considered the same chemical substance because they have the same molecular identity* [emphasis added]"[39]

EPA's paper led Barnaby Feder—a leading journalist with the *New York Times*—to write an article with the headline "EPA to Nanotech: Size Doesn't Matter."[40] Of course, as I have just laid out, size and novel properties at the nanoscale assuredly do matter when it comes to potential adverse impacts.

Overall, the Federal Government has made important strides in acknowledging the possibility that unconventional behavior in engineered nanomaterials could lead to EHS risks. However, as the recent EPA paper demonstrates, there is considerable room for improvement in linking unconventional behavior to regulatory approaches.

2. Leadership in nanotechnology EHS research

While it is generally acknowledged that engineered nanomaterials potentially present new EHS challenges, the Federal Government has not provided strong leadership in addressing these challenges. Despite a good start with the formation of NEHI, the overall Federal Government response to identifying and managing nanotechnology risks can only be described as slow, badly conceptualized, poorly directed, uncoordinated and underfunded.

In a world where unregulated and uncontrolled nanotechnology applications are appearing almost daily; where we know that there are possibilities in some cases of harm occurring to humans and the environment; where industry is calling out for greater certainty in managing the potential risks of nanomaterials; and where there are concerns that a lack of progress and transparency will undermine public confidence in emerging nanotechnologies, the Federal Government took *eleven months* to reduce a laundry list of seventy five research needs down to twenty five. To quote Barnaby Feder of the *New York Times* again, "No one can accuse them [the Federal Government] of acting rashly."[41]

And this latest Federal Government report was not even done as part of an overarching strategy, but as a precursor to developing a research strategy. By the government's own admission, it does not yet know where it is when it comes to addressing risk, and has yet to decide where it is going.[42] Yet for some time now, other countries and organizations outside the government have been mapping out what needs to be done and how.

Just as striking is the proliferation of agency-based initiatives that do not seem to form part of a coordinated interagency strategy. With one or two exceptions, there are indications that individual agencies are going their own way *because of a lack of direction from the top.* For instance, NIOSH has established an internal nanotechnology research program to address the needs of workers and industry independent of a coordinated interagency strategy, relying solely on internal resources that are not guaranteed to last. The disconnect between NIOSH's activities and other agencies' was underlined by the agency commenting publicly on EPA plans to regulate engineered nanomaterials—rather than rely on internal channels.[43] A similar indication of poor or absent leadership across federal agencies was a public submission from NIH on the recently published NEHI research priorities document—a document that NIH representatives had contributed to![44] And the recently announced Center for Environmental Implications of Nanotechnology—a joint

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[39] EPA (2007). TSCA Inventory Status of Nanoscale Substances—General Approach, Environmental Protection Agency, Washington DC.

[40] Feder, B. (2007). EPA to Nanotech: Size Doesn't Matter. Bits, *New York Times. http://bits.blogs.nytimes.com/2007/07/12/epa-to-nanotech-size-doesnt-matter/*. July 12. Accessed October 13, 2007.

[41] Feder, B. (2007). No One Can Accuse Them of Acting Rashly. Bits, *New York Times.* August 17. *http://bits.blogs.nytimes.com/2007/08/17/no-one-can-accuse-them-of-acting-rashly/*. Accessed October 13, 2007.

[42] See *supra* note 12.

[43] NIOSH (2007). Comments of the National Institute for Occupational Safety and Health on the Environmental Protection Agency Federal Register Notice Nanoscale Materials Stewardship Program and Inventory Status of Nanoscale Substances under the Toxic Substances Control Act; Notice of Availability, EPA–HQ–OPPT–2004–0122. September 7.

[44] NIH (2007). National Institutes of Health Comments on Prioritization of Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials to the NSET Subcommittee. September 17. *http://nano.gov/html/society/ehs_priorities/comments/*. Accessed October 25, 2007.

venture between EPA and NSF—does not seem to be part of any coordinated cross-agency plan.[45]

Current agency-specific initiatives do address key issues and are making an important contribution to evaluating and addressing potential nanotechnology risks. I do not want to detract in any way from their importance, or the leadership being shown by individuals within agencies to address specific challenges. But the fractured and uncoordinated approach to addressing nanotechnology risks that is emerging demonstrates a lack of overall leadership across the Federal Government, and challenges the notion that critical issues will be addressed in a strategic and timely manner, while using resources most effectively.

Such leadership across many agencies is extremely difficult, which perhaps explains NEHI's tardy response to repeated calls for action from Congress over the past two years. Yet when economic interests, people's health and the environment are on the line, to claim "it's difficult" is a poor excuse for inaction. If those responsible for the NNI have limited ability to lead effectively in ensuring the emergence of safe nanotechnologies, then this problem must be fixed if we are to find effective approaches to addressing the challenges of nanotechnology.

3. An effective strategic framework

By its own admission, the Federal Government is working towards developing a strategic research framework—and has been doing so since the House Science Committee hearing on November 17, 2005. The NEHI working group plans to follow a series of steps toward develop such a framework, although whether we will have to wait another two years for the results is unclear.

Since publication of its document *EHS Research Needs for Engineered Nanoscale Materials* in September 2006,[46] the NEHI working group has been busy countering criticisms aimed at that report and responding to invited comments. NEHI's subsequent document, *Prioritization of Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials: An Interim Document for Public Comment,*[47] further refines the prioritization principles established in the 2006 report and uses them to identify five research priority areas in each of the five categories listed in the initial report, for a total of twenty five research priority areas. Yet it remains unclear how this report or subsequent planned activities will help to provide the scientific information that industry, regulators and the public need to ensure the safe development and use of nanotechnology.

With this report, NEHI has begun to set out a systematic process for guiding agency research efforts. *But we must not mistake methodology for strategy.* While the current document focuses on prioritization, it does so without a clear understanding of context: what the overarching issues are, what is needed to address them, when results are needed and how the work will get done. Without this degree of vision, the document is in danger of being a bureaucratic reaction to criticism, rather than a proactive statement of purpose.

The stated principles for prioritizing EHS research do provide a means for sifting the many research "wants" into research "needs." But in the absence of a strategic overview, it is hard to see how application of these principles will result in an effective research plan. And while the principles appear sound individually, it is hard to see how as a group they can be used to identify a set of coherent research priorities.

The twenty-five identified research priorities provide little new information, but rather reflect many of the recommendations made by other organizations over the past few years. Comparing them with the strategic research priorities published by the Project on Emerging Nanotechnologies in July 2006,[48] there appears to be substantial agreement. But the NEHI priorities are open to broad interpretation in many cases. And so, while they reflect repeatedly articulated concerns, they present a poor basis for a strategic framework. In contrast, the Project on Emerging Nanotechnologies' research priorities are more specific and reflect the need to address clear goals.

In short, it is hard to see how following the NEHI priorities will provide the information decision-makers need to ensure the safety and sustainability of emerging nanotechnologies. Indeed, many of the priorities are so broad that they could be adequately addressed *without any progress being made towards ensuring the safety of nanotechnologies!*

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[45] See *http://www.nsf.gov/funding/pgm_summ.jsp?pims_id=503124.* Accessed October 25, 2007.

[46] See *supra* note 11.

[47] See *supra* note 12.

[48] See *supra* note 13.

On the basis of current evidence, the Federal Government is out of touch with reality and seems to be caught in a bureaucratic process that lacks the responsiveness and vision to address the questions to which nanotechnology stakeholders need answers. There is no sense of urgency to address which new research is needed, how it will be funded or the extent to which the economic success of emerging nanotechnologies will depend on this research.

4. Mechanisms to get the job done

Three mechanisms currently exist within the Federal Government to enable EHS research on nanotechnology. Firstly, individual agencies are able (within their budgetary constraints) to address specific challenges that are aligned with their own agendas and missions. Secondly, agencies are encouraged to consider priority research areas suggested by the Office of Science and Technology Policy (OSTP) and the NNI. Thirdly, information is shared between agencies within the NEHI working group. But these are weak mechanisms compared to the tasks at hand.

Certainly, these mechanisms have led to some progress—agencies are developing their own research agendas (independently of an overarching research strategy it would seem), and discussions within NEHI have undoubtedly led to a useful exchange of information. Yet taken together, they have thus far been ineffective in ensuring that relevant and coordinated research is carried out, sufficient resources are available to support this research, or that research is translated effectively into practical use by regulators, industry and others.

Clearly, the Federal Government needs a new toolkit if it is to provide answers to questions surrounding the safety of nanotechnologies. Comparing current Federal Government activities to the previously outlined actions needed to support safe and successful nanotechnologies, the Federal Government is struggling to develop and use:

- **Administrative mechanisms** that enable federal agencies to participate in an overarching strategic risk research framework, break down institutional barriers preventing collaboration and cooperation and provide leadership within the government and to stakeholders in the U.S. and the rest of the world.
- **Mechanisms** that ensure the right research funding approaches are used for the job, appropriate agencies take the lead in addressing specific questions and enable effective interdisciplinary and international research collaborations.
- **Public-private partnerships** that leverage government and industry funding to provide timely and independent answers to critical questions.
- **Funding mechanisms** that ensure agencies (and, in particular, agencies with regulatory missions) have sufficient funds to participate fully and effectively within an overarching strategic nanotechnology EHS research framework.

As a result, important research is not being funded because it falls between the cracks, because it doesn't fit within a particular agency's mandate, or because adequate funding mechanisms do not exist.

To give one example, research is needed on how atomic-level variations in structure at the surface of engineered nanomaterials influences biological interactions and potentially causes or exacerbates certain diseases. But the necessary interdisciplinary research that combines an understanding of materials properties, fundamental biological processes and disease is extremely difficult to support within the current federal research and development funding structure. And where cross-disciplinary proposals *are* considered (or where agencies attempt to fund research in unfamiliar areas), there is a danger of applying inappropriate selection criteria.

This may lead to the perception that there is a lack of competent researchers or good research proposals to address a specific challenge, whereas the reality is that those judging the proposals do not understand them, or their relevance.

Some progress has been made to correct these failings. The NSF has successfully funded a number of interdisciplinary research centers that are providing extremely valuable information on the potential risks of nanotechnologies—and how to address them. Yet these centers exist outside of an overall strategic risk framework, and remain constrained in their ability to directly relate engineered nanomaterials to potential diseases, or to inform regulation. Another partial success story is the EPA Science To Achieve Results (STAR) nanotechnology research program that has supported many projects addressing the potential health and environmental impacts of engineered nanomaterials. Yet funding for individual projects is capped at a level

too low for many researchers evaluating human and ecological toxicology to consider applying. As a result, while the research portfolio looks good on paper, in reality it is merely nibbling around the edges of the questions that need answering.

While I do not want to detract from the efforts of individuals within agencies to make a difference and develop relevant research programs, their research programs could be substantially more effective if they were given the support they need to do the job.

5. Sufficient resources to address critical challenges

The FY 2008 NNI request for nanotechnology health and safety research funding is $58.6 million[49]—less than the estimated $144 million needed for targeted and exploratory EHS research, but more than the estimated $50 million for targeted research alone. However, this figure comes with marginal information on how the money will be spent and whether it will, in fact, address strategically relevant questions, or be squandered on marginally relevant research.

Out of this request, 49 percent is to go to NSF, 20 percent to NIH and the National Institute of Standards and Technology, 16 percent to EPA and eight percent to NIOSH. In other words, despite the need for nanotechnology risk research to inform oversight and regulation, the vast bulk of the requested funding is associated with agencies that have no regulatory mission. Is this an appropriate use of funds, or does it merely reflect the spending power of the respective agencies?

The only way this question can be answered is by understanding how each agency's research will feed into an overarching strategic framework that is designed to provide answers that decision-makers need to oversee the development of safe nanotechnologies.

Unless the Federal Government is able to give a clear account of what is being invested in nanotechnology risk research, and how that investment will reduce uncertainty and enable effective risk management, there is a danger that current funding will be ineffective—no matter how impressive on paper.

In addition to questions over adequate funding, there is scant evidence that the Federal Government is investing in people to develop and implement an effective research strategy. Agency personnel addressing nanotechnology are frequently doing so at the margins of their responsibilities. Despite the acknowledged importance of EHS research, there is no single person dedicated to leading and coordinating activities across the government.

Conclusions

We cannot afford to drive blindly into the nanotechnology future. Not only will this prevent us from seeing and navigating around the inevitable bends associated with possible risks, but it will also give those economies with the foresight to identify and negotiate the bends a very real competitive edge. Despite a good start, the U.S. is still caught up in developing new technologies within an old mindset. If emerging nanotechnologies are to be built on a sound understanding of the potential risks—and how to avoid them—new research strategies, new mechanisms of execution and new funding all are needed. These should be overseen by clear, strong leadership and an interagency group with the authority to develop a strategic research framework and ensure its execution—a NEHI group with teeth.

At the beginning of this testimony, I recommended six areas where action is needed to get nanotechnology EHS research back on track, drawing from the assessment above. But the window of opportunity is fast closing. In the words of Chairman Boehlert at the September 2006 House Science Committee hearing addressing nanotechnology EHS research, which I believe expressed the sentiment of the entire Committee, "time's a wasting."[50] The stakes are too high for the Federal Government not to take appropriate action now.

Responses to specific questions

What is your reaction to the recent report of the Nanotechnology Environmental and Health Implications Working Group, "Prioritization of Environmental, Health and Safety Research Needs for Engineered Nanoscale Materials? Do outside groups have a way to influence this planning process? Are

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[49] NSET (2007). The National Nanotechnology Initiative. Research and Development Leading to a Revolution in Technology and Industry. Supplement to the President's FY 2008 Budget, Subcommittee on Nanoscale Science, Engineering and Technology, Committee on Technology, National Science and Technology Council, Washington, DC.

[50] Congressman Sherwood Boehlert (R–NY) opening statement for nanotechnology hearing. September 21, 2006. *http://gop.science.house.gov/hearings/full06/Sept%2021/sbopening.pdf.* Accessed October 14, 2007.

the priorities listed in the report the right ones, and do you believe that carrying out the "next steps" described in the report will achieve the detailed implementation plan for EHS research that is needed?

Reaction to the recent NEHI report

With this report, the NEHI working group has begun to set out a systematic process for guiding agency research efforts. But the working group is in danger of mistaking methodology for strategy. While the current document focuses on prioritization, it appears to do so without a clear understanding of context: what the overarching issues are, what is needed to address them, when results are needed and how the work will get done. Without this degree of vision, the resulting document is a *bureaucratic reaction to criticism,* rather than a *proactive statement of purpose.*

The stated principles for prioritizing EHS research do provide a means for sifting the many research "wants" into research "needs." But in the absence of a strategic overview, it is unclear how application of these principles will result in an effective research plan. And while the principles appear sound individually, it is difficult to understand how they can be applied as a group to identify a set of coherent research priorities. In particular, the second and third principles (leveraging research funded by other organizations, and adaptive management) are critical components of a research strategy, *but do not help to prioritize research in the absence of such a strategy.*

Potential for outside groups to influence the planning process

Public input has been sought on this and the previous NEHI research needs document. Responses to the most recent public consultation have yet to be published. However, it appears that the public comments on the document released in September 2006[51] led to marginal input to the following report. In order to develop a robust research strategy that addresses the needs of multiple stakeholders, more effective mechanisms are needed for soliciting expert input. Specifically, a federal advisory committee should be established to allow transparent input and review to an evolving research strategy from industry, academia, non-government organizations and other stakeholders.

Are these the right research priorities?

The research needs listed in the current and previous NEHI documents closely match those identified by other groups. Comparing the latest set of twenty-five research priorities with the strategic research priorities published by the Project on Emerging Nanotechnologies in July 2006,[52] (which draw on recommendations from a number of other groups, including the UK Royal Society and Royal Academy of Engineering, the American Chemistry Council, and the Environmental Protection Agency, EPA) there appears to be substantial overlap. But this is because the NEHI priorities are open to broad interpretation. While they reflect repeatedly articulated concerns, they present a poor basis for a strategic framework. Indeed, many of the priorities are so broad that they could be adequately addressed *without any progress being made towards ensuring the safety of nanotechnologies!*

Will the "next steps" achieve the desired goal

While the process initiated by NEHI looks logical on paper, it is hard to see how following it will provide the information decision-makers need to ensure the safety and sustainability of emerging nanotechnologies. This is a bureaucratic process that is picking at the edge of a problem from within the system, rather than starting with a clean slate and asking what needs to be done to achieve a well-defined end. The current process lacks a clear vision of what is needed to prevent people being harmed, the environment being damaged and industry being impacted by real and perceived nanotechnology risks. It lacks a sense of how research will serve effective science-based decision-making, and an appreciation for how urgently action is needed.

As an example, anyone with a credit card can purchase carbon nanotubes in powder form from a company called Cheap Tubes Inc. The nanotubes come in a sealed bag, and the accompanying safety data describes them as graphite—the same substance used to form pencil leads. Yet research has shown carbon nanotubes to be

[51] See *supra* note 11.
[52] See *supra* note 13.

potentially hazardous in ways we don't fully understand yet if inhaled.[53] If I purchased some of these carbon nanotubes today, how long will it take before someone is able to tell me how to open the package, extract the material, and use it—safely? Would it be days, months, years or even a decade? Researchers, businesses and consumers are facing similar questions every day. Yet the currently outlined "next steps" hold no hope for early answers.

Has the NNI assigned a sufficiently high priority to EHS research and are there gaps in the portfolio of NNI research now underway? What level of funding over what time period is needed to make acceptable progress in understanding the potential environmental and health risks associated with the development of nanotechnology?

EHS research priority

A continued lack of an overarching research strategy, ineffective research mechanisms and inadequate resources suggest that the NNI has *not* assigned a sufficiently high priority to EHS research. The NNI is unable to give a clear picture of the current research portfolio addressing nanotechnology risk, making it hard to gauge where the research gaps might be. An independent inventory of publicly available information on current research indicates that personal research interests, rather than overarching needs, are driving the portfolio.[54] As a result, current research is predominantly focused on novel materials like carbon nanotubes and existing areas of expertise such as inhalation toxicology, while exposure routes that include ingestion and environmental release, and materials like nanoscale silver, dendrimers and smart nanoparticles are receiving less attention.

Overall, it is possible to find research being carried out within each of the twenty-five priority areas identified by NEHI. But there are no indications that this research is sufficiently focused, or extensive enough, to come close to answering critical questions.

Funding levels

In my testimony to this committee on September 21, 2006,[55] I made the case for a minimum of $50 million per year to be spent on relevant nanotechnology risk research. This was based on an assessment of critical short-term research needs, and only covered *targeted research* to address these needs.[56] This estimate still stands. However, I must be clear that such an investment would need to be directed towards addressing a very specific suite of problems that regulators and industry need answers to as soon as possible—this is not envisaged as a general pot of money to be assigned to research that does not address specific and urgent nanotechnology risk goals. In other words, this is an investment that needs to be directed towards the *right research.*

But beyond this figure, there is a need for further investment in *exploratory research* that will identify the questions we haven't thought of yet. It isn't possible to place a firm figure on how much should be spent here, but a useful rule of thumb—and one that others have advocated—is to ensure that at least 10 percent of the Federal Government's nanotechnology research and development budget is dedicated to strategic risk-related research. This would place the overall estimated EHS research budget for 2008 at $145 million—allowing for $50 million in targeted research and $95 million dedicated to exploratory research. Given the nature of exploratory research, which requires substantial investment to make significant progress, this does not seem unreasonable.

What are the optimum roles for the agencies in sponsoring or conducting EHS research? Are responsibilities and available resources currently in balance?

Agency roles

An effective nanotechnology EHS strategic research framework will enable and empower agencies to take a lead in addressing issues that fall within their competences and missions. While top-level direction will be essential to ensuring

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[53] Cheap Tubes, Inc. *http://www.cheaptubesinc.com/*. Accessed October 19, 2007. Purchased materials are accompanied by detailed—if currently out-dated—information on published hazard studies. Yet the supplied manufacturer's safety data sheet continues to list the material as graphite, in the absence of clear guidance from regulatory authorities.

[54] Nanotechnology health and environmental implications. An inventory of current research. *http://www.nanotechproject.org/18* Accessed October 14, 2007.

[55] See *supra* note 16.

[56] See also: *supra* note 13.

success, the most effective model will not be one of command and control, but of leadership, coordination and facilitation.

An effective research framework would enable an appropriate balance between *targeted research* aimed at addressing specific questions, and *exploratory research* that helps to inform relevant questions. Targeted research would primarily address specific questions where answers are urgently needed in order to make, use and dispose of nanotechnology products as safely as possible. Much of this research would be funded by or conducted within mission-driven agencies such as the National Institute for Occupational Safety and Health (NIOSH) and EPA. An effective framework would also ensure that regulatory agencies have the resources to fund regulation-relevant research, or direct research that will inform their decision-making—including the Food and Drug Administration, the Consumer Product Safety Commission and the Occupational Safety and Health Administration.

Research agencies such as the National Institutes of Health (NIH) and the National Science Foundation (NSF) would also have a critical role in funding targeted research, *where the missions of these agencies coincide with research that informs specific oversight questions.* For example, these two agencies are ideally positioned to investigate the underlying science of nanomaterial properties, behavior and biological interactions, with the aim of predicting health and environmental impact.

Exploratory research within an effective strategic research framework would primarily be investigator-driven (within strategically determined bounds), and would preferentially lie within the remit of science-oriented agencies such as NSF and NIH. But if research funds are to be used effectively, it will be necessary to develop ways of supporting interdisciplinary research that crosses the boundary separating these agencies, and combines investigations of basic science with research into disease endpoints, with the goal of informing oversight decisions.

Exploratory research should not be confined to these two agencies; however, there will be instances where goal-oriented but exploratory research will fit best within the scope of mission-driven agencies and will benefit from the considerable research expertise within these agencies. As an example, researchers in NIOSH are currently engaged in exploratory research that is directly relevant to identifying and reducing potential nanotechnology risks in the workplace.[57]

Balancing responsibilities and resources

Responsibilities and available resources are not currently in balance across federal agencies. Examining the $58.6 million FY 2008 NNI budget request for nanotechnology EHS research, 49 percent is associated with NSF, 20 percent with NIH and the National Institute of Standards and Technology, 16 percent with EPA and just eight percent with NIOSH.[58] These figures are not supported by clear research objectives, goals and plans, so it is hard to say whether the funding will all go to nanotechnology risk-relevant research. An assessment of the 2005 Federal Government's risk research portfolio could only identify $11 million associated with highly relevant research into the potential risks of engineered nanomaterials, compared to a NNI-reported estimate of $38.5 million—a shortfall of $27.5 million![59]

Without clear information from the NNI on how requested funds will be used, it looks like that the research portfolio will be biased towards exploratory research, and away from targeted and oversight-relevant research (as reflected in NSF and NIH requesting twice as much funding for EHS research as EPA and NIOSH combined). This imbalance reflects the NNI role of simply reporting individual agency funding plans, rather than coordinating a strategic response to research needs.

The resulting budget figures reflect strategic thinking only *incidentally,* rather than by design—wealthy agencies invest more in a "hot topic" area, while poorer agencies struggle to scrape together precious resources to carry out their mandated duties. The irony in this situation, of course, is that it is the agencies without the resources to do the right research that have the clearest perspective on what needs to be done. In the FY 2008 budget request, the NSF budget for nanotechnology EHS research *increased* by $7.8 million from FY 2006 to $34.2 million—an increase of over one and a half times NIOSH's *entire request* for FY 2008 ($4.6 million). And this is in spite of most stakeholders acknowledging that addressing occupational exposure to engineered nanomaterials is a top priority.

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[57] See *supra* note 24.

[58] NSET (2007). The National Nanotechnology Initiative. Research and Development Leading to a Revolution in Technology and Industry. Supplement to the President's FY 2008 Budget, Subcommittee on Nanoscale Science, Engineering and Technology, Committee on Technology, National Science and Technology Council, Washington, DC.

[59] See *supra* note 13.

In other words, despite the need for nanotechnology risk research to inform oversight and regulation, the vast bulk of the requested funding is associated with agencies having no regulatory mission. Whether this is an appropriate use of funds, or merely reflects the spending power of the respective agencies, can only be answered by understanding how each agency's research will feed into an overarching strategic framework. But this framework does not yet exist.[60] Until it does (and mechanisms are in place to implement it), the Federal Government is unlikely to achieve a balance between agency resources and responsibilities in addressing nanotechnology risks.

Can the current process for developing the EHS research plan under the NNI be made to work, and if so, what changes are needed? If not, do you have recommendations for a different approach for developing and implementing a prioritized, appropriately funded EHS research plan with well-defined goals, agency roles and milestones?

Earlier in this testimony, I outline what is needed in my opinion to realize the benefits of nanotechnology while minimizing the risks: acknowledging the possibility of unconventional behavior; leadership; a strategic plan; mechanisms to put a research strategy into practice; and sufficient resources to do this. But overarching these steps is the goal of nanotechnology risk-related research: to develop the information necessary to identify (or predict), assess and manage risks associated with nanotechnologies—in essence to use science in support of oversight.

If the current process for developing the EHS research plan under the NNI can be made to achieve this goal—and in a timely manner—then we are on track to ensuring safe and sustainable nanotechnologies. But changes will be needed; the analysis above clearly shows that the current approach falls far short of the mark.

In reality, the NNI is not an ideal organization for addressing nanotechnology EHS risks. It is based on ideas and concepts more attuned to stimulating exploratory science and developing technology applications than providing science in support of oversight. While the NNI has effectively stimulated new research initiatives across the Federal Government, it remains primarily a forum for sharing information and reporting on agency activities. Within these functions, the NEHI working group has provided a useful forum for agency representatives to coordinate activities. Yet the NNI lacks the structure, vision and authority to ensure strategic and coordinated research in the service of effective oversight.

Nevertheless, the NNI is a useful starting point for developing a strategic Federal Government EHS research plan, if appropriate operational changes can be made. To be effective, the NNI's goals—and the terms under which it operates—will need to shift from a passive, supportive role to an active leadership role. Currently the role of the NEHI working group within the NNI is to:

- Provide for exchange of information among agencies that support nanotechnology research and those responsible for regulation and guidelines related to nanoproducts (defined as engineered nanoscale materials, nanostructured materials or nanotechnology-based devices, and their byproducts);
- Facilitate the identification, prioritization, and implementation of research and other activities required for the responsible research and development, utilization, and oversight of nanotechnology, including research methods of life cycle analysis; and
- Promote communication of information related to research on environmental and health implications of nanotechnology to other government agencies and non-government parties.[61]

Yet these roles do not enable the NNI to have the vision to develop an effective research strategy, or the authority to implement it. In my testimony above, I make six recommendations on what is needed to "make nanotechnology work":

1. A top-level strategic framework that identifies the goals of nanotechnology risk research across the Federal Government, and provides a roadmap for achieving these goals;
2. Mechanisms that will enable a strategic research framework to be implemented;

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[60] See *supra* note 12.

[61] Interagency Working Group on Nanotechnology Environmental and Health Implications (NEHI WG). *http://www.nano.gov/html/society/NEHI.html.* Accessed October 14, 2007.

3. Annual funding for nanotechnology risk-related research (targeted and exploratory) that is equivalent to approximately 10 percent of the overall Federal Government investment in nanotechnology R&D, with a minimum of $50 million per year to be dedicated to targeted research;
4. A public-private partnership between industry and the Federal Government to address specific common and critical nanotechnology research needs in a timely, transparent and credible manner;
5. An overarching communications strategy that has the fourfold aims of ensuring transparency, disseminating information, enabling science-based dialogue between stakeholders, and supporting informed decision-making by citizens, businesses, regulators, and other stakeholders; and
6. Leadership to ensure the successful development and implementation of a government-wide strategic research framework addressing nanotechnology EHS risks.

Implementation and coordination of these recommendations will require new operating terms for the NNI that allow active leadership within the Federal Government; provide authority to develop and implement cross-agency strategies; bring a goal-oriented focus to research; and facilitate the flow of resources to where they are most effectively used. In making these recommendations, I am very aware that developing an interagency group with the authority to develop and implement a cross-agency strategic plan is an enormously difficult and contentious task. As I noted earlier, the most effective model will be of leadership, coordination and facilitation, and not one of command and control. Yet the reality is that, without active leadership from the top, strategic research needs will not be met, mission-driven agencies will not have sufficient funds to do the work that is needed, and the whole nanotechnology enterprise will be jeopardized.

Annex: Goals and elements of an effective EHS strategic research framework

Strategic goals

The overarching goal for risk-based nanotechnology research can be succinctly expressed as developing the information necessary to identify (or predict), assess and manage risks associated with nanotechnologies. This is science in the service of safety, and not science for its own sake.

There are many challenges to achieving this goal, and they typically fall under three broad headings:

- **Providing answers to pressing questions.** These are questions that researchers, manufacturers and consumers are asking now, and include: How can exposure to nanomaterials be measured and controlled? How can I test my nanomaterial to determine if it is harmful? What happens if I release my nanomaterial into the environment? Am I at risk if I use personal care products containing nanomaterials? How do I dispose of waste nanomaterial and nanotechnology products that have come to the end of their life? The answers to many of these questions will require complex research, but until they are answered, they present real and immediate barriers to progress.
- **Developing new knowledge to identify the questions not currently being asked.** Many aspects of nanotechnology are so new that we do not yet know what are the right questions to ask regarding potential risks. This knowledge will not come easily from targeted research, as it is difficult to set milestones on discovering the unknown. Rather, it will be driven from the innovation researchers who are given the freedom to explore new avenues and follow interesting leads. Yet for such exploratory research to be effective in addressing risks, it must be directed within an overall risk-relevant framework, and mechanisms must be set in place to identify and follow-up on new risk-relevant information.
- **Translating research into practice: developing new ways of predicting and managing risks.** While the oversight of nanotechnology is dogged by uncertainty, it seems relatively certain that new technologies will always be one step ahead of our understanding of how they might cause harm. This lag between technology and regulation is clear as we look over the innovations of the past one hundred years. Yet as the rate of technological innovation continues to increase, it is increasingly hard to justify reactive oversight that is bogged down in bureaucratic inertia and is slow to take corrective action. In short, emerging technologies like nanotechnology challenge us to develop new, responsive and proactive approaches to identifying and managing

possible risks, so that we might prevent a lasting legacy of harm where old approaches could not keep up with new developments.

Many of the recommended research needs made over the past few years by a wide range of organizations fit within these challenges, including those published by the NEHI group in 2006 (and the shorter list released in 2007). Yet the challenges themselves are not a strategy—merely the issues that a research strategy needs to address.

Developing an effective roadmap to addressing these challenges is not as simple as prioritizing the research. As I discovered while developing recommendations on a short-term research strategy in 2006, you have to work back from what you want to achieve, and map out the research steps needed to get there. This inevitably leads to complex and intertwined research threads. If this complexity is not acknowledged, the result is simplistic research priorities that look good on paper, but are ineffective at addressing specific goals.

Key elements of a strategic framework

In developing the elements of a research strategy in the earlier 2006 paper, and in a commentary published in the journal *Nature* with thirteen distinguished colleagues, it was clear that an effective research strategy addressing potential nanotechnology risks will have a number of key elements. These include:

- **Goal-oriented research.** Whether research exploring new areas or research addressing a specific problem, an underlying principle of an effective research strategy must be science in the service of safety.
- **A balance of targeted and exploratory research.** An effective research strategy will combine research targeted to addressing specific problems, with research exploring new areas of knowledge. Both are important in the long-term to address practical issues and develop a sound understanding of what makes a new material potentially harmful, and how to avoid that harm.
- **Interdisciplinary collaboration.** Nanotechnology is inherently interdisciplinary, and effective research addressing the potential risks will be likewise. For example, early toxicity studies on nanomaterials were compromised because of a lack of understanding of the materials being used within the toxicology community, and would have benefited from stronger collaborations with materials scientists and characterization experts. Yet the disciplinary barriers faced are substantial, and cannot be broken down by researchers without help. Illustrating the problem, some seventeen years after the first toxicology studies on nanoparticles, research into nanoparticle toxicity being published now is frequently hard to interpret and compare with other studies, because the interdisciplinary barriers in place a decade and a half ago are still reasonably intact! This is just one example, but it is indicative of the need for any research strategy to break these barriers down if it is to be effective.
- **Enabling and empowering researchers and research organizations.** The effectiveness of a strategic research framework will only be as good as its ability to engage the organizations and individuals responsible for implementing it. While such a framework will of necessity be at a high level and, in the case of the Federal Government, overlay all departments and agencies associated with ensuring the safety of emerging nanotechnologies, the expertise to make it work will lie within the participating agencies, and within the broader research community. Therefore, a fine balance must be struck between controlling the direction of research and empowering agencies and researchers to lead research efforts. This balance is perhaps most important in exploratory research, where the best-positioned person to see where research is leading and its significance may be the principle investigator or research manager. Getting the balance right between providing top-down direction and enabling a degree of autonomy will be important in supporting innovative research that can be incorporated into a responsive strategy.
- **Communication and translation.** Multilateral communication of research goals, activities and findings, and translation of research into practical information and actions, are essential to the operation and implementation of an effective research strategy. These are the glue that holds an otherwise well thought-through strategic plan together.

BIOGRAPHY FOR ANDREW D. MAYNARD

Dr. Andrew Maynard is the Chief Science Advisor to the Project on Emerging Nanotechnologies—an initiative dedicated to helping business, government and the public anticipate and manage possible health and environmental implications of nanotechnology. Dr. Maynard is considered one of the foremost international experts on addressing possible nanotechnology risks and developing safe nanotechnologies. As well as publishing extensively in the scientific literature, Dr. Maynard is a well-known international speaker on nanotechnology, and frequently appears in print and on radio and television.

Dr. Maynard trained as a physicist at Birmingham University in the UK. After completing a Ph.D. in ultrafine aerosol analysis at the Cavendish Laboratory, Cambridge University (UK), he joined the Aerosols research group of the UK Health and Safety Executive, where he led research into aerosol behavior and characterization.

In 2000, Dr. Maynard joined the National Institute for Occupational Safety and Health (NIOSH), part of the U.S. Centers for Disease Control and Prevention (CDC). Dr. Maynard was instrumental in establishing the NIOSH nanotechnology research initiative, which continues to lead efforts to identify, assess and address the potential impacts of nanotechnology in the workplace. Dr. Maynard also represented NIOSH on the Nanomaterial Science, Engineering and Technology subcommittee of the National Science and Technology Council (NSET), and he co-chaired the Nanotechnology Environmental and Health Implications (NEHI) working group of NSET. Both are a part of the National Nanotechnology Initiative (NNI), the federal research and development program established to coordinate the U.S. Government's annual $1 billion investment in nanoscale science, engineering, and technology.

Dr. Maynard continues to work closely with many organizations and initiatives on the responsible and sustainable development of nanotechnology. He is a member of the Executive Committee of the International Council On Nanotechnology (ICON), he has chaired the International Standards Organization Working Group on size selective sampling in the workplace, and he has been involved in the organization of many international meetings on nanotechnology. Dr. Maynard has testified before the U.S. House Committee on Science on nanotechnology policy, and is a member of the President's Council of Advisors on Science and Technology, Nanotechnology Technical Advisory Group. Dr. Maynard holds an Associate Professorship at the University of Cincinnati, is an Honorary Senior Lecturer at the University of Aberdeen, UK, and has authored or co-authored over 90 scholarly publications.

Chairman BAIRD. Thank you. We have been joined by Mr. Reichert. Dr. Denison?

STATEMENT OF DR. RICHARD A. DENISON, SENIOR SCIENTIST, ENVIRONMENTAL DEFENSE

Dr. DENISON. Thank you very much for the invitation to present our views today.

Environmental Defense continues to believe that nanotechnology promises significant health and environmental benefits. We also believe that a robust process to address the risks of this technology is absolutely essential to ensure that those benefits are realized. We are not alone in this view. A coalition of stakeholders from large and small businesses, from academic researchers, think tanks, consumer groups, and environmental NGO's have banded together over the last two years to consistently press for a balanced approach, publicly calling for much more federal money to be spent on risk research and for a cohesive federal strategy to be developed and implemented.

Unfortunately, the Federal Government's approach under the NNI is well out of balance. To be fair, scientists at NNI and its agencies are talking and writing a great deal about the need to address the risks of this technology, and they in particular emphasize how little we know about these materials, how much work it will

take to actually fill these gaps, and how important filling those gaps is to our ability to assess and to mitigate any potential risks.

But there is a growing disparity between government scientists' words and the actions of the NNI. The problem is three-fold in our view. Too little is being spent on risk research, too little is known about what those current funds are being spent on, and the pace at which the Federal Government is moving to develop the cohesive strategy that everyone needs is bordering on glacial, although these days glaciers are moving a bit faster.

Let me address each of these in turn. The Committee and previous speakers have already detailed how little of the federal nano R&D budget is going to risk research, on the order of three to four percent, and that percentage amount has largely unchanged over the last several years. In contrast, we and many others have been calling for at least 10 percent commitment of funds to this task, yet NNI has never publicly indicated its support for such an increase.

The problem goes beyond, however, just how much is being spent. There is currently no good way to know how it is being spent, that is, what research NNI is specifically counting in its totals; and that is because NNI has never made public a listing of the projects that it is counting in its total budget figures. Some analyses suggest NNI may well be overcounting by including not only direct EHS research but also research on applications that it deems relevant to understanding risk. NNI itself has noted it has trouble drawing that line and that assessing relevance is a subjective exercise.

But much of this confusion and uncertainty could be cleared up immediately if NNI would simply disclose what specific projects are being funded. All we really know is that NNI breaks down its numbers in terms of what agencies and departments get, and this shows the National Science Foundation whose mission is funding basic research gets the lion's share of the money being spent on EHS research. While there is certainly a role for basic research, in our view, research that is meant to address health and environmental issues needs to be primarily funded through and conducted by agencies that have that as their mission: EPA, NIOSH, National Institutes of Environmental Health Sciences, and so forth.

As the Committee has noted, NNI has been promising to deliver a strategy for well over a year. It has yet to materialize, however, and the incremental process that NNI has laid out for getting there has actually led a journalist at the *New York Times* to recently quip, "No one can accuse them of acting rashly."

Unfortunately, in Environmental Defense's view, there are two structural impediments that are preventing NNI from moving faster. First, NNI lacks the overarching budgetary and oversight authority that is needed to shape and direct a research strategy undertaken by its member agencies and departments. NNI functions primarily in a facilitation and coordination role, and it simply cannot be expected to develop let alone implement such a strategy.

Second, we have become convinced that a conflict of interest has risen from the decision to house within NNI the dual, and some might say dueling, responsibilities to both develop and promote nanotechnology and at the same time to aggressively identify and mitigate its potential risks. That conflict in our view is both slow-

ing down and compromising current efforts. It manifests itself in the budget disparity, in the confusion over what NNI is actually spending, and we think it helps to explain why things are taking so long.

Even some individual agencies such as FDA and EPA are tasked with not only regulating nanotechnology but actually promoting it, sometimes even within the same office. All agency proposals pertaining to address potential risks have now to be vetted through a White House Nanotechnology Policy Group. These factors we think help to explain the disconnect between the words and the actions on the part of both NNI and its agencies.

Can the NNI approach be made to work? We think two changes are essential. First, either a new entity needs to be created or an existing entity elevated significantly and given the responsibility and authority and the resources to develop and manage the implementation of an overall risk research strategy. This entity needs to have a core health and environmental mission, and Congress should request that the National Academies assist in developing this strategy and in overseeing its implementation. Second, we believe that a stronger firewall must be established between the parts of the Federal Government whose mission is to develop and advance nanotechnology and those parts that are charged with objectively identifying and mitigating its potential risks.

To ensure that both of those goals receive comparable consideration, these responsibilities need to be assigned to different offices and staff members within those agencies.

In sum, the risk-related activities within the National Nanotechnology Initiative need to be both substantially elevated and clearly separated from those that are dedicated to promoting this technology.

Thank you very much.

[The prepared statement of Dr. Denison follows:]

PREPARED STATEMENT OF RICHARD A. DENISON

Introduction [1]

Environmental Defense continues to believe that nanotechnology promises major health and environmental benefits. We also believe that implementation of a robust process to identify and address the potential risks of engineered nanomaterials is absolutely essential to ensuring that these benefits are in fact realized. A *concurrent* and balanced approach to addressing both the applications and implications of nanotechnology is the best hope for achieving the responsible introduction of this remarkable set of new technologies.

There has been a relatively strong consensus among large and small industry, academic researchers, think tanks and consumer and environmental NGOs that this balanced approach is needed. Unfortunately, however, the Federal Government is pursuing an approach under the National Nanotechnology Initiative (NNI) that is well out of balance.

To be sure, NNI and many of its member agencies are *talking and writing* a great deal about the need to address nanotechnology's risks as well as its benefits. One need only look at their websites and reports, especially those written by their scientists. But there is a continuing, and in some ways, growing disparity between NNI's words and actions.

Over the past two years, scientists at several NNI agencies and at NNI itself have published documents elegantly describing how little we know about nanomaterials' potential hazards and exposures and how much work will be needed both to address these gaps and to adequately assess risks.[2] These documents also repeatedly draw needed attention to three critical facts:

1) Because nanomaterials have different properties than their conventional counterparts, existing information on substances' conventional forms is of limited use in elucidating the behavior and biological activity of their nano forms.
2) Methods for testing nanomaterials or for measuring their presence in environmental media or in organisms have largely yet to be developed.
3) Current approaches to predicting the hazard, exposure potential or fate of chemicals cannot be applied to nanomaterials, because they do not account for the physical as well as chemical properties that determine the latter's behavior and biological activity.

These critical gaps severely hamper our ability to apply the usual risk assessment and risk management procedures.

For example, the Nanotechnology Task Force of the U.S. Food and Drug Administration (FDA) recently released a succinct summary of the state of the science of nanomaterials falling under its jurisdiction. Reversing its earlier position that suggested nanomaterials are really nothing new, FDA now acknowledges the inability to effectively predict nanomaterials' behavior and the need for direct testing:

> "[A]t this scale, properties of a material relevant to the safety and (as applicable) effectiveness of FDA-regulated products might change repeatedly as size enters into or varies within the nanoscale range. . . .Biological interactions influenced by the particular chemistry and physical configuration of the nanoscale material might also occur in ways that are unpredictable without specific test data for the material."[3]

Likewise, the thorough *Nanotechnology White Paper* published by the U.S. Environmental Protection Agency (EPA) notes the following:

> "The diversity and complexity of nanomaterials makes chemical identification and characterization not only more important but also more difficult. A broader spectrum of properties will be needed to sufficiently characterize a given nanomaterial for the purposes of evaluating hazard and assessing risk. . . .The limited studies conducted to date indicate that the toxicological assessment of specific intentionally produced nanomaterials will be difficult to extrapolate from existing databases. The toxic effects of nanoscale materials have not been fully characterized, but it is generally believed that nanoparticles can have toxicological properties that differ from their bulk material. . . .The sheer variety of nanomaterials and nanoproducts adds to the difficulty of developing research needs. Each stage in their life cycle, from extraction to manufacturing to use and then to ultimate disposal, will present separate research challenges. Nanomaterials also present a particular research challenge over their macro forms in that we have a very limited understanding of nanoparticles' physicochemical properties."[4]

These reports also attach a considerable degree of urgency to the need to address these large and complex questions. FDA notes that "the science and applications are developing at a very rapid pace," while EPA highlights "the rapid development of nanotechnology and the increasing production of nanomaterials and nanoproducts," noting that hundreds of nanoproducts are already on the market and that "nanomaterials are already being used or tested in a wide range of products such as sunscreens, composites, medical and electronic devices, and chemical catalysts."[5]

Recognition of both the complexity of the task at hand and the urgency to get moving are widely shared beyond government. For over two years now, a coalition comprised of large and small companies, other industry groups and NGOs has publicly called for much greater attention to be paid to risk research, noting in particular the disparity between federal spending on applications versus implications research:

> "While industry, academic, and government scientists continue to vigorously explore nanotechnology's potential *applications* in a wide variety of fields, such as groundwater cleanup and cancer therapy, research on nanotechnology's potential health and environmental *implications* has failed to keep up. Federal research is essential to providing the underlying methods and tools critical to developing a fundamental understanding of the risk potential of nanomaterials and nanotechnologies—methods and tools that all producers and users can then use to fulfill their appropriate responsibility to identify potential risks of their own materials and applications."[6]

This same coalition has also called for development of a federal risk research roadmap and strategy.[7]

Unfortunately, the words in the FDA and EPA reports I referenced earlier have not translated into meaningful and sufficient actions by the Federal Government, even though they have been bolstered by the remarkable and unusual consensus among key stakeholders just noted. Too little is being spent on risk research, too little is known about what current funds are being spent on, and the pace at which the Federal Government is moving to produce a coherent risk research strategy borders on glacial. Let me address each of these concerns in more detail.

What is being spent

NNI's 2007 budget is estimated at $1.35 billion and its 2008 budget request is $1.45 billion. NNI reports that the fraction of those totals to be spent on environmental, health and safety (EHS) research and development (R&D) are 3.5 percent for 2007 and 4.1 percent for 2008[8]—a trend line that has remained nearly flat for the last several years in percentage terms and is only a modest increase in absolute dollars. In contrast, Environmental Defense has called for much more—at least 10 percent—of the federal nanotechnology R&D budget to be specifically directed, for the foreseeable future, to targeted EHS research (exclusive of applications research that may tangentially shed light on implications questions).[9] For more than two years, many others have joined us in making this call. In June 2005, the CEO of DuPont and the President of Environmental Defense co-authored an opinion editorial in the *Wall Street Journal* calling for an increase in such funding to at least 10 percent of the federal nanotechnology R&D budget.[10] Indeed, the coalition of industry and NGOs to which I just referred has also pressed Congress for a significant increase in federal appropriations. Yet NNI has never publicly called for or indicated its support for such an increase.

How current funds are being spent

NNI's budget numbers for EHS research must be considered suspect, unfortunately. There is currently no way to know what research NNI is counting when it provides its totals, because NNI has not made public any listing of the projects it includes. In addition, NNI has itself noted that it has trouble drawing the line between direct EHS implications research and applications research that it maintains is "relevant" to understanding implications. Last year, the Project on Emerging Nanotechnologies (PEN) at the Woodrow Wilson International Center for Scholars used NNI's 2005 budget numbers and its inventory of ongoing federal risk research to try to answer these questions. Of the roughly $40 million NNI said it was spending on "relevant" EHS research that year, PEN could identify as "highly relevant" only $11 million of research and about $30 million as "generally relevant."[11] While PEN's analysis has not been updated, the lack of transparency on the part of NNI as to what projects it counts in tabulating EHS spending creates unnecessary confusion and uncertainty over how much is actually being spent and on what.

To date, the only detail provided by NNI as to how this money is being spent is a breakdown by agency or department. From this breakdown, we know that the National Science Foundation (NSF), which funds basic research but has no public or occupational health or environmental mission, continues to receive the lion's share (>50 percent) of federal risk research dollars. While there is certainly a role for basic research, environmental or public health research should be conducted primarily by, and ideally directed and overseen by, federal agencies that have such missions, such as EPA, the National Institute for Environmental Health Sciences (NIEHS), or the National Institute for Occupational Safety and Health (NIOSH).

In addition, the great majority of federal risk research dollars is being spent on extramural research, through grants to academic and other institutions. Both extramural and intramural research have important roles to play, but to date too few funds have been devoted to building the needed intramural research capacity. Federal funding for both intramural and extramural research can and should reflect research priorities by more tightly focusing calls for proposals on key environmental and health research objectives. Increased funding for intramural research at federal agencies and laboratories is needed to conduct more applied research and to address specific priorities that are less likely to be efficiently addressed by academic or institutional research.

Although such federal research institutions may not have the capacity now to fully absorb the resources needed for intramural research, immediate priority should be placed on building that capacity as rapidly as possible. This capacity-building and research agenda should be viewed as an investment that will facilitate the responsible development of emerging nanotechnologies.

Need for a comprehensive federal risk research strategy—and the means to implement it

While NNI has been promising to deliver a risk research strategy that is coordinated across its agencies for well over a year, such a strategy has yet to materialize. Its issuance was just delayed again and is now projected for release in January 2008.

Based on the process NNI has laid out for developing such a strategy, it still has a considerable way to go:

- Step 1—Identify EHS research needs and priorities. This step took the form of a report issued in September 2006, which was subjected to public comment.[12] Environmental Defense's comments on this document are attached to this testimony.
- Step 2—Further prioritize research needs. This step came in a report issued in mid-August of this year, nearly a year after the first one, and was again subjected to public comment.[13] The eight-page second report was essentially a boiled-down version of the first, 60-page report.

Four more steps remain to be completed, according to NNI:

- Step 3—Evaluate in greater detail the current NNI EHS research portfolio.
- Step 4—Perform a "gap analysis" of the NNI EHS research compared to prioritized needs.
- Step 5—Coordinate and facilitate among the NNI agencies' research programs to address priorities.
- Step 6—Establish a process for periodic review of progress and for updating the research needs and priorities.

It is not clear whether each of these steps is to be taken on sequentially, with a corresponding pause for public comment. In any event, as a journalist for the *New York Times* recently put it: "No one can accuse them of acting rashly."[14]

Key impediments to progress

Unfortunately, in Environmental Defense's view, NNI has core structural impediments that prevent it from acting expeditiously to identify and address potential risks and from adopting a more balanced overall approach. The problems are twofold. First, NNI lacks any overarching budgetary and oversight authority to shape and direct the research activities undertaken by its member agencies and departments. The part of NNI that is mounting current efforts in this area is the Nanoscale Science, Engineering and Technology Subcommittee (NSET), which serves primarily in a facilitation and coordination role and simply has not been given the necessary authority to devise and implement a coherent, cross-agency risk research strategy. Additional authority to oversee and direct federal risk-related research is essential to ensure two things: a) that the right questions are asked and answered, and b) that identified risks are comprehensively assessed and do not fall through the cracks between statutes, departments and agencies.

Second, we have become convinced that a conflict of interest has arisen from the decision to house within NNI the dual functions of both seeking to develop and promote nanotechnology and its applications, while at the same time aggressively pursuing the actions needed to identify and mitigate any potential risks that arise from such applications. That conflict of interest is both slowing and compromising efforts by NNI and its member agencies and departments to effectively address nanotechnology's implications. The conflict manifests itself in the continuing budget disparity I have already discussed. It is also apparent in NNI's evident inability or unwillingness to clearly identify research activities devoted specifically to EHS concerns and sufficiently distinguish them from applications research that may incidentally yield data relevant to understanding implications. And it may help explain what's taking so long.

The conflict also appears to be manifesting itself at the individual agency level. Some NNI agencies, including FDA and EPA, are themselves charged with both promoting and regulating nanotechnology applications, sometimes even within the same office. In addition, all agency proposals pertaining to addressing nanotechnology's potential risks must now be vetted through a White House nanotechnology policy group. These factors may be responsible in part for the growing disconnect between, on the one hand, the recognition by agencies of the magnitude of and urgent need to address the risk question, and on the other hand, the tepid response of those same agencies in terms of actions to be taken.

For example, the FDA Nanotechnology Task Force's recommendations are vague and lack critical details on actions needed to close identified research and regulatory gaps. While there is a call for the agency to promote and participate in research, there is no mention of the level of resources needed, the timeframe within which this is—or needs—to be accomplished, or even an indication that there is any urgency to advance the collection of data. While the recommendations call on the agency to issue various forms of guidance for manufacturers to use on a voluntary basis, they propose that the evaluation of products continue on a case-by-case basis, which is essentially the status quo. There is no description of how the agency will or should address two key points: a) the greater uncertainties it has identified that are posed by using nanomaterials in products for which the agency has pre-market authority, or b) the considerable gaps in information for classes of products, such as cosmetics, for which the agency has no pre-market authority.

Similarly, we can look at how EPA has responded to growing public concern over the lack of nanotechnology oversight and its own scientists' identification of the enormous data gaps that must be filled if risks are to be effectively identified and addressed. EPA has taken two recent steps. First, it issued a policy decision that considers the nano forms of existing chemicals to be no different than their bulk counterparts, and by so doing effectively eliminates the only opportunity EPA has to review or require testing of such nanomaterials prior to their manufacture and use.[15] Second, it issued a "concept paper" that proposes an open-ended, voluntary program to encourage companies to submit any information they already happen to possess. EPA proposes what its own advisory committee proposed nearly two years ago—except it has removed the strict deadlines for the voluntary program and the simultaneous development of mandatory reporting rules as a regulatory backstop, which the committee had included.[16]

Recommendations: Can the NNI approach be made to work?

If NNI is to effectively address the potential risks of nanotechnology, two changes are essential.

First, a new entity needs to be created, or an existing entity elevated, and given responsibility, ample authority and resources to do the following:

- Ensure the development of an overall federal research strategy to identify, assess and address the potential risks of nanomaterials.
- Shape and direct the overall federal risk research agenda across agencies to ensure all critical needs are being addressed.
- Ensure that individual agencies have sufficient dedicated staff and resources to conduct or commission the needed research in their areas, and sufficient authority to identify, assess and address potential risks.

This entity, whether independent or housed in an existing agency, should have a core public health and/or environmental mission. Congress should also request that the National Academies' Board on Environmental Studies and Toxicology (BEST) take a lead role in developing the needed strategy, and in overseeing its implementation over a number of years. BEST has successfully played an analogous role in the formulation and execution of the U.S. Environmental Protection Agency's research strategy for assessing the risks of airborne particulate matter.[17]

The second essential step is to establish a firewall between the parts of the Federal Government whose mission is to help develop and advance nanotechnology, and those parts charged with ensuring a thorough and objective examination of its potential risks and taking the steps needed to mitigate those risks. Ensuring that both goals receive equal consideration would require, at a minimum, that the responsibility to address the two distinct goals be assigned to different offices and senior staff members, who are given parallel and comparable degrees of authority, and who report directly to the highest levels within their individual agencies and within NNI. We believe that a clear division of labor and interests is critical if public confidence in the ability of the Federal Government to facilitate the responsible development of nanotechnology is to be restored.

In sum, the activities within NNI devoted to identifying and mitigating the potential risks of nanotechnology need to be both substantially elevated in importance and clearly separated from those dedicated to promoting its development and application.

Thank you for the opportunity to present our views today. Environmental Defense stands ready to assist the Committee as it considers what changes are needed in legislation to be developed to reauthorize NNI.

Endnotes

1. A biography of Dr. Denison is attached.

2. For example, see: U.S. Food and Drug Administration, *Nanotechnology: A Report of the U.S. Food and Drug Administration Nanotechnology Task Force,* July 25, 2007, at *www.fda.gov/nanotechnology/taskforce/report2007.pdf*; and U.S. Environmental Protection Agency, *Nanotechnology White Paper,* February 2007, at *www.epa.gov/osa/nanotech.htm*; National Institute for Occupational Safety and Health, *Strategic Plan for NIOSH Nanotechnology Research: Filling the Knowledge Gaps,* at *www.cdc.gov/niosh/topics/nanotech/strat_planINTRO.html;* and National Nanotechnology Initiative, *Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials,* September 2006, at *www.nano.gov/NNI_EHS_research_needs.pdf.*
3. FDA, *op. cit.,* pp. ii, 11.
4. EPA, *op. cit.,* pp. 31, 70, 77.
5. FDA, *op. cit.,* p. 8; EPA, *op. cit.,* pp. 4, 13, 21.
6. Letter signed by 14 companies and organizations sent to Chairs and Ranking Members of the House and Senate Appropriations Committees, dated June 7, 2006, at *www.environmentaldefense.org/documents/5067_nanoappropsLetter.pdf* Emphasis in original.
7. Letter signed by 19 companies and organizations sent to Chairs and Ranking Members of the House and Senate Appropriations Committees, dated February 22, 2007, at *www.environmentaldefense.org/documents/6015_Approps_2007NASLetter.pdf*
8. *The National Nanotechnology Initiative: Research and Development Leading to a Revolution in Technology and Industry, Supplement to the President's FY 2008 Budget,* Tables 2 (p. 7) and 6 (p. 11), at *www.nano.gov/NNI_08Budget.pdf*
9. Denison R.A. "A proposal to increase federal funding of nanotechnology risk research to at least $100 million annually." Environmental Defense, Submitted to the National Academy of Sciences' Committee to Review the National Nanotechnology Initiative (April 2005), at *www.environmentaldefense.org/article.cfm?ContentID=5131*
10. See Fred Krupp and Chad Holliday, "Let's Get Nanotech Right," *Wall Street Journal,* June 14, 2005, p. B2, at *www.environmentaldefense.org/documents/5177_OpEd_WSJ050614.pdf* That same month, the American Chemistry Council's Panel on Nanotechnology and Environmental Defense issued a Joint Statement of Principles stating: "A significant increase in government investment in research on the health and environmental implications of nanotechnology is essential." At *www.environmentaldefense.org/documents/4857_ACC-ED_nanotech.pdf* And in a 2005 report on nanotechnology, Innovest, a leading investment research and advisory firm, said: "We strongly support calls by others in the investment community for increased government funding of toxicology research. The NNI's lack of priority for this issue represents a missed opportunity to minimize uncertainty." See Innovest (2005). *Nanotechnology: Non-traditional Methods for Valuation of Nanotechnology Producers.* New York, NY. Page 56. At *www.innovestgroup.com/images/pdf/final%20nano%2010-30-06.pdf*
11. Maynard, A.D. (2006) *Nanotechnology: A Research Strategy for Addressing Risk,* pp. 3, 20, at *www.nanotechproject.org/file_download/77*
12. NNI, 2006, *op. cit.*
13. National Nanotechnology Initiative, *Prioritization of Environmental, Health and Safety Research Needs for Engineered Nanoscale Materials—An Interim Document for Public Comment,* at *www.nano.gov/Prioritization_EHS_Research_Needs_Engineered_Nanoscale_Materials.pdf*
14. Barnaby J. Feder, "No one can accuse them of acting rashly," August 17, 2007, at *bits.blogs.nytimes.com/2007/08/17/no-one-can-accuse-them-of-acting-rashly/*
15. U.S. Environmental Protection Agency, "TSCA Inventory Status of Nanoscale Substances—General Approach," released for public comment on July 11, 2007, at *www.regulations.gov/fdmspublic/component/main?main=DocumentDetail&d=EPA-HQ-OPPT-2004-0122-0057*
16. U.S. Environmental Protection Agency, "Concept Paper for the Nanoscale Materials Stewardship Program under TSCA," released for public comment on July 11, 2007, at *www.regulations.gov/fdmspublic/component/main?main=DocumentDetail&d=EPA-HQ-OPPT-2004-0122-0058* The 2005 proposal made by EPA's National Pollution Prevention & Toxics Advisory Committee (NPPTAC) is at *www.epa.gov/oppt/npptac/pubs/nanowgover viewdocument20051125.pdf* Environmental Defense's comments on both of EPA's recent proposals are at

www.environmentaldefense.org/documents/7010_ED_WrittenCommentson EPANanoDocs09072007.pdf

17. Board on Environmental Studies and Toxicology, *Research Priorities for Airborne Particulate Matter: I. Immediate Priorities and a Long-Range Research Portfolio,* Committee on Research Priorities for Airborne Particulate Matter, National Research Council, 1998; and *Research Priorities for Airborne Particulate Matter: IV. Continuing Research Progress,* 2004, both at: *books.nap.edu/catalog/6131.html* and *books.nap.edu/catalog/10957.html*

Attachment 1

BIOGRAPHY FOR RICHARD A. DENISON

Dr. Denison is a Senior Scientist in Environmental Defense's Washington, DC office. With more than 20 years of experience in the environmental arena, he specializes in chemicals policy, hazard and risk assessment and management for industrial chemicals, and responsible development of nanotechnology.

Dr. Denison has managed Environmental Defense's participation in and oversight of the U.S. High Production Volume (HPV) Chemical Challenge Program, initiated by Environmental Defense, the U.S. Environmental Protection Agency and the American Chemistry Council to provide basic hazard data on the 2,200 chemicals produced in the U.S. in the largest quantities. He also represents Environmental Defense on the Chemicals Committee and on the Working Party on Manufactured Nanomaterials of the Organization for Economic Cooperation and Development (OECD). Dr. Denison was recently appointed to the Science Advisory Panel for California's Green Chemistry Initiative. Until recently, he was a member of the National Pollution Prevention and Toxics Advisory Committee (NPPTAC), which advises EPA's toxics office. Dr. Denison is part of Environmental Defense's team that worked jointly with the DuPont Corporation to develop a framework governing responsible development, production, use and disposal of nanoscale materials.

Dr. Denison has authored numerous papers and reports, and he is active in a variety of activities and forums, pertaining to chemicals and nanomaterial regulation and policy at the federal and State levels and internationally. Dr. Denison is the author of a major report, titled *Not That Innocent,* that provides a comparative assessment of existing and emerging industrial chemicals policies in the U.S., Canada and Europe.

Dr. Denison earned a Ph.D. in Molecular Biophysics and Biochemistry from Yale University in 1982. He joined Environmental Defense in 1987, after several years as an analyst and assistant project director at the Office of Technology Assessment, United States Congress.

Attachment 2

ENVIRONMENTAL DEFENSE COMMENTS[1] ON:

Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials, released September 15, 2006

JANUARY 31, 2007

Federal Register: December 8, 2006 (Volume 71, Number 236) DOC ID:FR08DE06–135

Introductory Statement

Environmental Defense appreciates this opportunity to submit comments on the National Nanotechnology Initiative's document *Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials,* which was released on September 15, 2006.

Environmental Defense is a leading national environmental nonprofit organization representing more than 400,000 members. Since 1967, we have linked science, economics, law, and innovative private-sector partnerships to create pragmatic solutions to the most serious environmental problems. Among our other activities related to nanotechnology, we are currently working with DuPont to develop a comprehensive, practical and transparent approach to proactively evaluate and address the risks of nanomaterials across their life cycle.

The National Nanotechnology Initiative's Nanoscale Science, Engineering, and Technology (NSET) Subcommittee of the Committee on Technology, National Science and Technology Council (NSTC) has requested comment on the research needs and prioritization criteria that were identified in the NSET Subcommittee document *Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials.*

We commend the NSET Subcommittee on the preparation of this report, which identifies critical research and information needs for nanoscale materials. The Subcommittee emphasizes that these research needs were not presented in any priority research order, and requests feedback on the development of criteria for establishing priority research.

Almost every research need identified in this report addresses a critical data gap. To this end we urge the U.S. Government to provide the necessary funds to implement an aggressive and broad research strategy. However, we recognize that available funds are limited and it is necessary to prioritize research needs.

The NNI proposes using a "value of information strategy" to prioritize research needs. This approach is predicated on how to assign value to different kinds of information. The NNI document identifies the following factors as indicators of research value:

- The extent to which the information will reduce uncertainty about benefits or risks.
- The extent to which information can be expected to lead to broad knowledge about the property and behavior of nanomaterials.
- The extent of expected use of the nanomaterial.
- The exposure potential for workers, consumers, or the environment.
- The potential to leverage relevant existing data.

While we agree that these are useful criteria for evaluating research priorities, we are concerned about applying some type of formal "value of information" methodology to the prioritization of nanoscale material toxicity research. At this stage, it is not possible to apply a typical "value of information" methodology to predict what type of research will optimally reduce uncertainty about risks or lead to broader knowledge and understanding of nanomaterial behavior without broadly speculating on potential risks and the types of information needed to reduce them. Value of information methodologies rely on quantifying the harms being reduced, which is not possible at this time for nanomaterial risks. Moreover, in the setting of an emerging technology such as nanotechnology, the economic consequences of obtaining or failing to obtain critical information on toxicity are in reality so unpredictable that formalizing the costs and benefits through a value of information analysis is artificial

[1] These comments are available online at *www.nano.gov/html/meetings/ehs/uploads/20070131_0752_ED_comments_on_NNI_EHS_Research_Needs_FI NAL.doc*

and potentially misleading. While some of the principles of a value of information approach are valid for prioritizing nanomaterials risks, we recommend that reference to this formal methodology be removed. In our comments below, we provide additional recommendations on how to proceed with prioritization in the face of multiple major knowledge gaps, and on the relative roles for industry and government research programs.

Based on our assessment of the report Environmental Defense would like to provide support for the EHS research portfolio, and present specific comments and recommendations pertaining to the need to prioritize the EHS research. The summary outline of EHS research needs is reproduced here, with numbering and lettering added to facilitate direct references in the text below to the research needs identified in the NNI document.

1. Instrumentation, Metrology, and Analytical Methods
    a) Methods for detection nanomaterials in biological matrices, the environment, and the workplace
    b) Methods for standardizing particle size and size distribution assessment
    c) Methods and standardized tools for assessing shape, structure, and surface area
    d) An inventory of engineered nanomaterials and their uses
2. Nanomaterials and Human Health
    a) Understanding the absorption and transport of nanomaterials throughout the body from different exposure routes—methods development
    b) Understanding the properties of nanomaterials that elicit a biological response
    c) Identification and development of appropriate *in vitro* and *in vivo* bioassays
    d) Methods to quantify and characterize exposure to nanomaterials in biological matrices
3. Nanomaterials and the Environment
    a) Evaluation of testing schemes for ecological effects
    b) Evaluation of factors affecting fate and transport
    c) Understanding the transformation of nanomaterials under different conditions
4. Health and Environmental Surveillance
    a) Understanding exposures in the workplace and factors that affect them
    b) Quantification of exposure from industrial, consumer, and other sources
    c) Establishment of environmental monitoring protocols
5. Risk Management
    a) Improve understanding of process design and engineering controls
    b) Develop "green design" techniques
    c) Determine product life cycles and potential impact on EHS
    d) Evaluate current risk communication strategies for known and anticipated risks

Below we present four overarching criteria that we believe should be used to prioritize the many research needs identified by NNI. These criteria are:

- Research that will develop the "enabling infrastructure."
- Information that will facilitate "look back" studies.
- Selection of materials should focus on key concerns related to toxicity and biological response.
- Selection of relevant materials and methods.

Criterion 1: Research that will develop the "enabling infrastructure."

We strongly recommend that federal funds be used first and foremost to **acquire fundamental knowledge that is needed to develop the "enabling infrastructure" for nanomaterial EHS, which is best addressed by the Federal Government.** This "enabling infrastructure" includes developing and standardizing, for routine application, the methods, tools (e.g., instrumentation) and basic scientific understanding needed to measure and assess:

- Physical-chemical characterization of nanomaterials;
- Sampling and analysis;
- Detection and monitoring: in workplaces, air/waterborne releases, humans and other organisms, environmental media;
- Biological and environmental fate and behavior;
- Acute and chronic toxicity; and
- Hazard, exposure and risk.

Development of the enabling infrastructure will advance industry research in risk assessment and materials design and testing of specific materials and products, and will facilitate independent researchers in pursuit of general and applied nanoscale research.

There are several lines of research discussed in the NNI document that can be included in this category. For example, we agree there is a critical need for the development of **methods to detect, quantify and characterize nanomaterials in biological matrices, the environment, and the workplace** (1a, 2d).[2] The development of these methods will facilitate a cascade of additional research pertaining to fate and transport in humans and non-human organisms from different exposure routes, and fate, transport, and transformation in the environment, which are also of high priority, and addressed in more detail below.

Another critical data need identified by the NNI is the development of **methods for the standardized characterization of nanomaterials: particle size, size distribution, shape, structure, and surface area** (1b, 1c). This will, in turn, advance government research on risk assessment, development of quantitative structure-activity relationships, and ultimately identification of the key properties of nanomaterials that elicit biological responses.

The Federal Government also needs to plays an important role in the **identification and development of key** *in vitro* **and** *in vivo* **bioassays** (2c) for acute and chronic toxicity testing, and **testing schemes for ecological effects** (3a).

A high priority should be placed on **developing methods to identify nanomaterials that exhibit environmental persistence and/or bioaccumulation potential.** These characteristics are critical indicators of concern for both environmental and human health, and nanomaterials exhibiting these properties require additional scrutiny. With such methods, research agencies could assess a broad array of materials and subsequently focus other lines of research on those materials presenting greater potential risk on the basis of their persistence and accumulation potential.

Testing protocols developed by the government can then be used by industry to demonstrate the safety of their product or to identify risks requiring mitigation. They are also the key step required for the development of robust and health protective risk assessment and risk management protocols.

The status of available assays for nanomaterials was recently reviewed in a workshop sponsored by Environmental Defense, the Center for Biological and Environmental Nanotechnology at Rice University, and the Woodrow Wilson Center, and attended by scientists from government, academia, industry, and non-profit organizations. The consensus of the attendees was the highest priority methods development needs include physical chemical characterization (structure, concentration, and surface properties, addressed above), and ADME/Translocation methods, which is equivalent to **understanding the absorption and transport of nanomaterials throughout the body from different exposure routes** (2a), particularly for *in vivo* bioassays (e.g., nanoparticles tracking, aggregation, transformation, solubility and stability, transmembrane movement, and bioaccumulation/bio persistence). The workshop proceedings are in preparation, and will be provided to the NNI upon acceptance for publication.

Although we can and should expect industry to address product-related research needs, the research listed above will be critical in generating the means by which industry can most effectively evaluate its own products. This is *not* to say that there is no role for industry prior to the development of the enabling infrastructure, as most standard apical bioassays will allow for the evaluation of potential toxicity, even in the absence of tissue quantification methods. For instance, both inhalation and instillation rodent bioassays have been very useful for elucidating toxicity for inhaled nanomaterials. Advancing research methods will require an iterative approach, measuring the outcome of new bioassays against standard apical bioassays.

[2] Numbers/letters in parentheses here and in the remainder of the text refer to items in the research outline provided above, to indicate the category and subcategory from the NNI document to which they refer.

There is certainly the potential for government-industry and other stakeholder involvement in government-led initiatives in partnerships for methods development, and industry co-funding of such research should be pursued, as long as the government retains the ability to manage and direct it.

Other considerations: Primary environmental or public health research, whether conducted intramurally or extramurally, should be directed and overseen by federal agencies that have an environmental or public health mission, such as the Environmental Protection Agency (EPA), the National Institute for Environmental Health Sciences (NIEHS), or the National Institute for Occupational Safety and Health (NIOSH). Currently, the National Science Foundation (NSF) funds and oversees more than 50 percent of the nanomaterials environmental health and safety research. NSF, which lacks any public health or environmental mission, may not be in the best position to identify and oversee such research.

Both extramural and intramural research have important roles to play, but to date too few funds have been devoted to building the needed intramural research capacity. Federal funding for both intramural and extramural research can and should reflect research priorities by more tightly focusing calls for proposals on key environmental and health research objectives. Increased funding for intramural research at federal agencies and laboratories is needed to conduct more applied research and to address specific priorities that are less likely to be efficiently addressed by academic or institutional research.

Although such federal research institutions may not now have the capacity to immediately fully absorb the resources needed for intramural research, immediate priority should be placed on building that capacity as rapidly as possible. This capacity-building and research agenda should be viewed as investment that will facilitate the responsible development of emerging nanotechnologies.

Criterion 2: Information that will facilitate "look back" studies.

The prioritization of federal research should be undertaken with the understanding that we have **critical knowledge gaps in the face of ongoing and growing exposures.** In order to lay a foundation for understanding potential risks that may only manifest themselves well after exposures start, we need to know what types of nanomaterials are present in products, who is and has been employed in production, and who may be coming into contact with nanomaterials now. As we move forward in research to fill the knowledge gaps in the laboratory, the Federal Government should also address current and emerging exposures in the workplace by **developing a registry of workers who have worked with or used nanomaterials for at least four weeks.** This will not only aid in helping to understand **"exposures in the workplace and the factors that affect them"** (4a), but will also facilitate future epidemiologic studies of workers, a critical research need that is not sufficiently emphasized in the report. In addition, **EPA, FDA and CPSC should collaborate in developing nanomaterial and nanomaterial-containing product registries and inventories, which will also facilitate additional "look back" research to the extent it is needed in the future.** This will help to meet the following research needs identified in the NNI report: **an inventory of engineered nanomaterials and their uses** (1d), and the identification and **quantification of exposure from industrial, consumer, and other sources** (4b).

Criterion 3: Selection of materials should focus on key concerns related to toxicity and biological response.

Companies can and should be expected to concentrate their environmental health and safety research and testing programs on nanomaterials used in commercial applications, where they should employ life cycle approaches to identify all known and reasonably anticipated exposure scenarios. In contrast, government sponsored research should focus more on nanomaterials that will best **elucidate general principles of toxicity and biological response** (similar to 2b), for example, seeking to understand mechanisms whereby nanomaterials may readily translocate across biological interfaces, bioaccumulate, interact with cells or specific macromolecules (e.g., the stimulation of collagen formation in fibroblasts noted with carbon nanotubes), or generate reactive oxygen species. By focusing research on those nanomaterials that exhibit these and related characteristics of biological relevance and concern, federal research will advance knowledge of the features and characteristics most associated with biological responses, and also may facilitate the development of structure-activity relationships. Acquisition of these data not only can contribute to the construction of general principles regarding nanomaterials toxicity, but will also provide nanomaterial developers with important information that can be used to design "green" nanomaterials that do not exhibit these properties.

While the costs and characteristics of some nanomaterials make the conduct of chronic bioassays or multi-generational testing challenging, in general there is likely much greater potential for nanomaterials to cause more subtle, chronic effects rather than acute toxicity—effects that may well be missed by only conducting acute testing. We therefore recommend that a number of nanomaterials with high potential for chronic exposure be tested for chronic toxicity to begin to gain understanding of potential long-term effects.

The government should also pursue and fund research in a manner that provides not only an in-depth characterization of specific categories of nanomaterial, but also fully elucidates the effects of variations (in manufacturing processes, surface modifications, etc.) among materials within those categories on key biological properties. The NIEHS has begun this process by testing at least two variations of each category of nanomaterials it is studying. Only by expanding this approach will we begin to develop the much needed *predictive capability* to interpolate or extrapolate among structurally related materials.

The NNI report indicates that government research efforts at the National Cancer Institute, National Institute for Environmental Health Sciences, National Institute for Occupational Safety and Health, the Food and Drug Administration, and the National Toxicology Program are focused on metal oxides (particularly TiO2 and ZnO), quantum dots, fullerenes, and carbon nanotubes. While it can be useful for discussion purposes to group nanomaterials into broad categories such as metal oxides, carbon-based materials, etc., the assumption that the members of such categories possess the same or similar biological properties is at this stage a hypothesis. For example production by different processes or surface modifications of the same basic material can dramatically alter the characteristics and behavior of a nanomaterial. Considerable empirical test data will be needed to test any "category hypotheses," i.e., to determine the actual extent of similarity, or the regularity and predictability of trends, among category members, with respect to both hazard and exposure characteristics.

Criterion 4: Selection of relevant materials and methods.

Research should also consider the need to test materials and applications that are now or are projected to be the **most relevant, based on likelihood of release and exposure—***examined on a life cycle basis.* As noted in the report, ". . .the exposure potential for some nanomaterials will be limited to nonexistent whereas exposure potential for other materials will exist at one or more stages of their product life cycle." Selection of the most relevant materials should be based on a systematic assessment of nanomaterials with known or reasonably anticipated human and environmental exposure potential over the life cycle of a broad array of materials.

Additional Comments: Need for public database for nanomaterial EHS data.

The development of a publicly available database containing the results of environmental health and safety testing data is an urgent need that can be readily addressed through government funding. There is precedent to make this information available. One recent example of such a database is the EPA's High Production Volume Information System (HPVIS), which is providing access to hazard data on hundreds of chemicals. Directly relevant to nanoparticles are: 1) the NIOSH Nanoparticle Information Library (*http://www2a.cdc.gov/niosh-nil/index.asp*), which includes physical chemical and toxicological data on a select number of nanomaterials, and 2) the National Cancer Institute's Nanotechnology Characterization Laboratory's publication of the results of the testing of nanomaterials, performed at the request of private companies (*http://ncl.cancer.gov/index.asp*). The reports are issued following a 90-day lag to allow for the management of confidential business information. These efforts should be consolidated and expanded to include the results of testing performed by industry laboratories to facilitate the dissemination of EHS data.

Chairman BAIRD. Mr. Ziegler.

STATEMENT OF MR. PAUL D. ZIEGLER, CHAIRMAN, AMERICAN CHEMISTRY COUNCIL NANOTECHNOLOGY PANEL

Mr. ZIEGLER. I am Paul Ziegler, Chairman of the American Chemistry Council, Nanotechnology Panel. I appreciate the invitation to address the House Committee on Science and Technology on the role of NNI in planning and implementing the environmental,

health, and safety necessary for the responsible development of nanotechnology.

ACC represents the leading companies that are engaged in the business of chemistry. In 2005, ACC formed the Nano Panel consisting of companies that manufacture, distribute, and use nanotechnology in business interests in products of nanotechnology. The panel was formed to foster the responsible application of nanotechnology, to coordinate nanotechnology EHS initiatives undertaken by member companies and other organizations, to facilitate the exchange of information among member companies and other domestic and international organizations on issues related to all aspects of nanotechnology.

In discussing federal EHS research priorities, I first would like to emphasize that improved federal coordination and support are essential for the responsible development of nanotechnology and its commercial acceptance. The Federal Government has a unique and critically important role to play in coordinating and adequately funding the research on EHS aspects of nanotechnology. It is clear, however, from the August 2007 draft report of the Nanotechnology Environmental Health Implications Working Group, "Prioritization of Environmental Health and Safety Research Needs for Engineered Nanoscale Materials" that the current priority setting process is slow and incomplete. We applaud the part of the August report that focused on EHS priorities from 75 to 25. However, the criteria for reducing these priorities was not fully articulated, nor was it clear how the 25 priorities fit together in a cohesive strategy. Moreover, the draft report does not articulate the research roles of each participating federal agency. The panel is disappointed that there is no correlation of the 25 identified research areas to risk management or urgently needed research. We encourage NEHI to complete quickly the prioritization of the identified research areas, complete the final research strategy, and initiate the top priority projects. Specific projects need to be identified with annual funding requirements and realistic deliverables and timelines. The high-quality, comprehensive, and prioritized EHS research agenda is still missing and should: one, focus on risk assessments and the generation and application of information on the continuum of exposure, dose, and response; two, promote new interdisciplinary partnerships that bring visionary thinking to research on nanotechnology; three, support better understanding of the fundamental properties of nanomaterials that have an impact in the exposure dose response paradigm; four, develop processes for establishing validated standard measurement protocols so that individual or categories of materials can be studied; five, clearly delineate the responsibilities, programs, timelines, and anticipated results of funded projects for each federal agency; six, leverage planned and ongoing work with the Organization for Economic Cooperation and Development, OECD, working party on manufactured nanomaterials, particularly in identifying ongoing or planned research projects by other companies and interpreting the results of this research and testing of representative nanomaterials using standard test methods to assess potential health or environmental hazards.

ACC has communicated at length with EPA, NIOSH, and other parties on the information that could assist by EHS research projects and would be useful in the near term. These issues include information on handling of nanomaterials in dry form and potential exposures; information on environmental releases related to production and use of nanomaterials in air, water, solid waste potential exposures unique to nanomaterials and risk management; information on the fate and transport mechanisms of nanomaterials in the environment; information on hazards of nanomaterials, basic and acute, supplemented by appropriate tiered decision-making structure for further testing; information leading to the development of workplace practices and guidelines; and finally, information on the explosion hazard potential that has been alleged with some nanomaterials.

The panel also urges as an appropriate next step the funding of an independent review by the National Research Council Board of Environmental Studies and Toxicology, or BEST, to establish EHS research priorities for manufactured nanomaterials and a substantial increase in federal funding.

On February 22, ACC along with 18 organizations requested that Congress appropriate $1 million for BEST to develop a roadmap for federal EHS projects. This would have enabled BEST to develop a roadmap and strategy for the Federal Government for EHS research needed to support safe use and development of nanoscale materials and technologies.

Until appropriate measures are developed as part of the comprehensive research to measure the results of EHS funding, a specific multi-year timetable for funding is premature. The research strategy should be sufficiently flexible to take into account results from completed research, address information gaps that may arise and be adjusted so that projects are not continually funded.

ACC and member companies of the Nanotechnology Panel strongly support EPA's planned Nanomaterials Stewardship Program. Information gained under this, along with the occupational exposure information gained by NIOSH, supporting research of other federal agencies and information from international bodies such as OECD will assist in prioritizing the EHS research projects.

In closing, I would like to emphasize the importance of significant and sustained federal funding for development and implementing comprehensive nanotechnology research strategy. ACC urges the prioritization process for EHS research to be completed expeditiously and at best be funded and complete a research roadmap and strategy. While a foundation for this important process has been established, NNI must complete its task with renewed sense of urgency. The agencies need to identify what needs to be done, what they will do, put together a timeline, and do it.

Thank you.

[The prepared statement of Mr. Ziegler follows:]

PREPARED STATEMENT OF PAUL D. ZIEGLER

Introduction

The American Chemistry Council (ACC) appreciates Chairman Gordon's invitation to address the House Committee on Science and Technology on the role of the National Nanotechnology Initiative (NNI) in planning and implementing the environ-

mental, safety, and health research necessary for the responsible development of nanotechnology.

ACC represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a $635 billion enterprise and a key element of the Nation's economy. It is one of the Nation's largest exporters, accounting for ten cents out of every dollar in U.S. exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the Nation's critical infrastructure.

In 2005, ACC formed its Nanotechnology Panel consisting of domestic producers that are engaged in the manufacture, distribution, and/or use of chemicals that have a business interest in the products of nanotechnology.[1] The Panel was formed to foster the responsible application of nanotechnology; to coordinate nanotechnology environmental, health, and safety research initiatives undertaken by member companies and other organizations; and to facilitate the exchange of information among member companies and other domestic and international organizations on issues related to applications and products of nanotechnology. The Panel supports nanotechnology products and applications that are consistent with ACC's Responsible Care® Program, and consistent with the Joint Statement of Principles the Panel and Environmental Defense issued on June 22, 2005 to help ensure that the commercialization of nanoscale materials proceeds in a way that protects workers, the public, and the environment.

I. Improved Federal Coordination and Support Are Essential for the Responsible Development of Nanotechnology and Its Commercial Acceptance

The Federal Government has a unique and critically important role to play in coordinating and adequately funding research on the environmental, health, and safety (EHS) aspects of nanotechnology. In this regard, the NNI is tasked with coordinating nanotechnology research across dozens of federal agencies. This task necessarily requires a prioritized research strategy that clearly delineates the roles of the participating federal agencies. It is clear, however, from the August 2007 draft report of the Nanotechnology Environmental and Health Implications (NEHI) Working Group, *Prioritization of Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials,* that the current priority setting process is slow and incomplete.

We applaud that part of the August 2007 NEHI Working Group's draft report that focused the EHS research priorities from 75 to a more manageable 25. However, the criteria for reducing these priorities were not fully articulated. Nor is it clear how the 25 priorities fit together into a cohesive strategy. Moreover, the draft report does not articulate the research roles of each participating federal agency.

The Panel is disappointed that there is no correlation of the 25 identified research areas to risk management or "urgently" needed research. We encourage NEHI to complete quickly the prioritization of the identified research areas, complete the final research strategy, and initiate the top priority projects. Specific projects need to be identified with annual funding requirements and realistic deliverables. At the Working Group's present pace, others will be establishing a coherent research strategy for implementation by the various federal agencies without the involvement or perspective of all NEHI members.

A high quality, comprehensive and prioritized EHS research agenda is still missing and should:

- Focus on risk assessments, and the generation and application of information on the continuum of exposure, dose and response;
- Promote new interdisciplinary partnerships that bring visionary thinking to research on nanotechnology;

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[1] Panel member companies include: Air Products and Chemicals, Inc., Arkema Inc., Arch Chemicals, BASF Corporation, Bayer Material Sciences Corporation, Cytec Industries, The Dow Chemical Company, DuPont, Eka Chemicals, Elementis Specialties, Evonik Degussa Corporation, Honeywell, Oxonica, PPG Industries, Inc., Procter & Gamble, Rohm and Haas Company, and Sasol North America, Inc.

- Support better understanding of the fundamental properties of nanomaterials that have an impact in the exposure-dose-response paradigm including the key properties of:
  1. Size and size distribution;
  2. Surface area of the primary particle;
  3. Shape of the primary particle;
  4. Chemical composition of the material;
  5. Agglomeration state in the medium used to treat the test system;
- Develop processes for establishing validated standard measurement protocols so that individual or categories of materials can be studied;
- Clearly delineate the responsibilities, programs, timelines, and anticipated results of funded projects for each federal agency. For example, the National Institute for Standards and Technology (NIST) should take responsibility for identifying what reference nanoscale materials should be developed and manage their development. EPA should be responsible for developing and evaluating methods to assess exposure to and potential effects of exposure to nanoscale materials. The Food and Drug Administration (FDA) and the National Institute for Occupational Safety and Health (NIOSH) should focus their research efforts on understanding the absorption and transport of nanoscale materials in the human body, and better utilize industry's research experience prior to making final research priority recommendations. To date, industry's role has been largely restricted to passive review of decisions already made. Industry's considerable experience could be better utilized by being actively engaged earlier in the process; and
- Leverage planned and ongoing work by the Organization for Economic Cooperation and Development's (OECD) Working Party on Manufactured Nanomaterials, particularly in identifying on-going or planned research projects by other countries and interpreting the results of this research, and the testing of representative nanomaterials using standard test methods to assess potential health or environmental hazards.

In addition, the NNI should consider compiling a list of ongoing and completed EHS research or support activities already under way such as at the International Council on Nanotechnology (ICON). This list should be updated regularly and made publicly available to ensure important research is communicated timely and accurately. The public would also benefit from the NNI ensuring that databases on consumer products believed to contain nanomaterials are accurate.

ACC has communicated at length with EPA, NIOSH, and other parties on information that could be assisted by EHS research projects and would be useful in the near term. These research issues include the following items:

- Information on the handling of nanomaterials in dry forms and potential exposures to users incorporating nanomaterials into product applications;
- Information on environmental releases related to the production or use of nanomaterials—air, water, and solid waste potential exposures unique to nanomaterials and risk management methods;
- Information on the fate and transport mechanisms for nanomaterials in the environment;
- Information on hazards of nanomaterials—basic and acute data supplemented as appropriate by a tiered decision-making structure for further testing;
- Information leading to the development of workplace practice guidelines; and
- Information on the explosion hazard potential that has been alleged with some nanomaterials.

Within the most recent NEHI report, ACC agrees with the 25 identified research areas within the five research categories identified by the Working Group. Within Category #1, the Panel specifically believes that Projects 1, 2, and 5 are high priority research areas. The Panel notes that all the projects in Category #2 were considered by the Working Group to be equal in priority. The Panel agrees with this assessment since these research areas are likely to be interrelated.

The Working Group identified five priorities for Category #3—Nanomaterials and the Environment. In its January, 2007 comments, the Panel noted the importance of research on environmental transport and fate of nanomaterials. The Panel recommends that Projects 4 and 5 dealing with transport and fate receive the highest priority. Category #4 covers health and environmental exposure assessment and includes research projects currently underway. The Panel encourages the Working

Group to consider the pilot studies underway by NIOSH that are designed to characterize worker exposure and better understand workplace processes and factors that determine occupational exposure to nanomaterials. Risk management methods are addressed in Category #5, and the Panel notes that the Working Group established priorities for each of the five identified areas. The Panel believes that all five areas are important research priorities, but notes that accurately communicating information on the hazards from and potential exposure to nanomaterials should remain a top priority.

II. The Panel Urges as an Appropriate Next Step the Funding of An Independent Review By the National Research Council Board of Environmental Studies and Toxicology (BEST) to Establish EHS Research Priorities For Manufactured Nanomaterials and a Substantial Increase in Federal Funding of EHS Programs For Manufactured Nanomaterials

The Panel believes that the National Academy of Sciences' Board of Environmental Studies and Toxicology (BEST) has an important role to play in completing the "next steps" articulated in the NEHI Working Group's report. On February 22, 2007, ACC, along with 18 organizations requested that Congress appropriate $1 million for BEST to develop a roadmap for federal EHS research projects and set priorities suitable for federal funding (letter appended to this statement). This funding would enable BEST to develop a roadmap and strategy for the Federal Government for environmental, health, and safety research needed to help support the safe development and use of nanoscale materials and nanotechnologies.

At current funding levels, only a small percentage of the NNI funds have been directed to environmental, health, and safety research. Moreover, the federal budget at other agencies with a significant interest in nanotechnology, such as EPA and NIOSH, is inadequate in light of the enormity of the task at hand. The Panel believes that a more appropriate balance is needed between the funding of potential health effects studies and environmental studies. In general, the Panel believes that approximately 5–10 percent of the overall NNI budget should be focused on EHS research projects on an annual basis. This range is consistent with the range of funding private industry devotes to research and development. Additionally, more funds should be directed to environmental exposure research.

Until appropriate metrics are developed (as part of a comprehensive research strategy) to measure the results of the EHS research funding, a specific multi-year timetable for funding is premature. The research strategy should be sufficiently flexible to take into account results from completed research, address information gaps that may arise, and be adjusted so that projects are not continually funded.

III. Identifying and Minimizing Potential Health and Environmental Risks Is Consistent With the Responsible Development of Nanotechnology

ACC's Nanotechnology Panel member companies are committed to support and actively promote the safe manufacture and use of the products of nanotechnology, consistent with the ACC's Responsible Care® program—a set of ethical principles and management systems, now nearing its 20th year, designed to improve continuously its member companies' safety, health and environmental performance. This long-established program helps guide the Panel members' approach to the development of nanotechnology, just as it does for more conventional and better understood industrial chemicals and processes.

ACC and the member companies of its Nanotechnology Panel strongly support EPA's planned Nanomaterials Stewardship Program (NMSP). Information gained under the NMSP, along with occupational exposure information gained by NIOSH, supporting research of other federal agencies, and information from international bodies such as OECD, will assist in prioritizing EHS research projects for the foreseeable future.

IV. Conclusion

In closing, ACC would like to emphasize the importance of significant and sustained federal support for developing and implementing a comprehensive nanotechnology research strategy, particularly in areas of worker safety, human health, and the environment. Federal Government support for a comprehensive EHS research agenda is essential to the sustained and responsible development of nanotechnology.

ACC urges that the prioritization process for EHS research be completed expeditiously and that BEST be funded to complete a research roadmap and strategy.

While the foundation for this important process has been established, NNI must complete its task with a renewed sense of urgency.

BIOGRAPHY FOR PAUL D. ZIEGLER

Education

1984—Program for Executives, Carnegie Mellon University

1976—Master of Science in Hygiene, University of Pittsburgh, Graduate School of Public Health

1973—Master of Public Health in Environmental Health, University of Pittsburgh, Graduate School of Public Health

1968—Bachelor of Science in Pre-Med (Biology/Chemistry), Lincoln Memorial University, Harrogate, Tennessee

Professional Experience

April 1, 2007–Present

Retired/Consultant

October 2003–April 1, 2007 (Retired this date)

Global Director Product Compliance Assurance, PPG Industries, Inc. Report to Global Director EHS, serving all PPG SBU's. Globally this position is responsible for reviewing and assessing product/process related risk, of PPG's products and businesses at an SBU and Corporate level. This includes but is not limited to three major components: 1) Risk Assessment of PPG products and SBU processes & systems; 2) Technical management of any product compliance issues, discrete enforcements events and product-related litigation in conjunction with the Law Department and outside counsel; 3) Horizon or long-term assessments relating to globally emerging product regulations and liability trends. Work closely with all appropriate functions and SBU's and keep the appropriate levels of management informed.

October 1999–October 2003

Global Director Product Stewardship, PPG Industries, Inc. Report to Corporate Vice President EHS, serving 16 SBU's on a global basis. Responsibilities include development and implementation of policies/programs to ensure products can be developed, produced, distributed, used and disposed of in a safe and environmentally sound manner and advise customers on their safe use and handling. EHS concerns will be integrated into all aspects of our businesses.

As part of the Corporate EHS Leadership Team, have duty to drive the EHS Process and Management System into the SBU's and manufacturing facilities, integrating it into each Strategic Business Unit providing technical assistance/guidance to the SBU, as they develop/tailor their requirements to meet the EHS management needs of the SBU and facilities worldwide.

Supervise a group of 32 associates, focusing on HazCom, Regulatory Compliance, Hazardous Materials Transportation, Toxicology, EHS IT, and share supervision of European Group. Also responsible for Global Emergency Response. As part of our Regulatory focus, we must deal with FDA/USDA/NSF/FIFRA issues, providing assistance to SBU's, utilizing outside counsel/technical consultants as appropriate, develop GMP/GLP documents and participate in various inspections.

Member of a number of standing committees—EHS Leadership; Management Development/Talent Review; Salary Review; Quality Council; European EHS Council; Acquisition/Divestiture Committee; Customs/NAFTA Steering Committee.

April 1987–October 1999

Director, Environmental Health Sciences for C&R Group, PPG Industries, Inc. Report to Director, C&R Manufacturing. Responsibilities involve the development and implementation of policies to protect and promote the health and safety of all individuals who might be affected by the processes, products and/or use of PPG products. Assure Group compliance with laws, rules, regulations and Company Policy/procedures for environmental, health and safety issues. This includes responsibility for personnel, products, testing, environmental concerns, and facility assets. This also involves Group, Corporate and regulatory liaisons for worldwide operations. Administer a comprehensive program covering all product safety, health, toxicology, environmental and safety issues. Act as a focal point for conveying information and coordinating health, safety/product safety, toxicology and medical activities for the C&R Group.

This position is responsible for all of the activities and responsibilities affecting the health of individuals and must be aware of safety and environmental issues, both inside and outside the Company. This covers all activities, processes and prod-

ucts of the C&R Group, including U.S., Canadian and international operations. Internationally, the incumbent is responsible for development and control of the product safety, industrial hygiene and medical activities of affiliates companies.

Supervised a group of 47 associates in EHS and a European Group of 12 associates.

July 1986–March 1987

Manager, Product Safety, Staff Group, Mobay Corporation (Plastics and Rubber, Coatings Rhein-Chemie, Fibers). Reported to the Director, Corporate Industrial Hygiene and Regulatory Compliance and had responsibility for administering a comprehensive program in the areas of health, environmental, product safety, regulatory and emergency response; coordinator for the Mobay Emergency Response Team.

1984–June 1986

Manager, Occupational and Environmental Health and Safety, Group Level, Mobay Corporation (Plastics/Coatings/Organic and Rubber Chemical/Corporate Business Development/Deerfield Urethane, Inc./Rhein-Chemie/Newark Compounding Facility/Wolff Walsrode). Reported to the Executive Vice President and had the responsibility for administering a comprehensive program in the areas of health, environmental, product safety and emergency response for those products handled by the operating units; coordinator for the Mobay Emergency Response Team.

1976–1984

Manager for the Plastics and Coatings Division of Mobay Chemical Corporation. Responsible for administering a comprehensive program covering all product safety and health considerations from research through actual marketing of the product as necessary to meet the requirements of the law and the Corporate guidelines for product safety; coordinator for the Mobay Emergency Response Team.

1974–1975

Product Manager/Noise Pollution Specialist with USC Incorporated, an environmental/engineering consulting firm in Pittsburgh, Pennsylvania.

1973–1974

Environmental Protection Specialist with the Department of Environmental Resources for the State of Pennsylvania in Pittsburgh, Pennsylvania.

Organizations/Societies

American Industrial Hygiene Association (AIHA), National and Local

Society of Chemical Hazard Communication (SCHC)

National Paint and Coatings Association (NPCA)

American Chemistry Council (ACC)

DISCUSSION

Chairman BAIRD. Thank you, Mr. Zeigler, and again, thanks to all of our witnesses. Outstanding information and very enlightening perspectives.

It is a very difficult task here because, you know, on the one hand both Dr. Ehlers and I and several other members of the panel are trained as scientists and you can't ask someone to prove the negative. It can't be done. But neither is one justified therefore in assuming the negative, and so the task before us is how can we try to predict and anticipate what might happen, while at the same time not hamstringing some potentially very, very valuable areas of research. And that is a difficult and tall order. It however is one that probably has been neglected many times in technologies in the past as Dr. Ehlers mentioned with certain pesticide applications. But very often in the history of humankind we have come up with innovations that we thought to be marvelous and they have had

adverse consequences, and only down the road do we recognize those.

So I commend all of you for what is actually fairly rare and extremely difficult matter, which is to try to anticipate something that we don't know yet what it will be. So the questions that we will ask are not in any way meant to be accusatory or condemning. I know the difficulty and the challenge. But one of the obvious questions would be, so here is this important report, prioritizing the needs, and it is now somewhat overdue to say the least. What have the hang-ups been and when might we expect it. Dr. Teague?

Dr. TEAGUE. I guess I would like to bring up or re-emphasize a couple of things that I said in my opening comments that are written in the written testimony. The first one is I think that there is a sort of a general impression that the U.S. and the Federal Government is behind what we should be doing relative to the EHS research. I think it should be really emphasized that if you look at what the Federal Government has done over the timeframe that we have been looking at nanotechnology, that the U.S. has, as I indicated, far and away invested more money in EHS research than any country in the world. We have, if you look at the publication of research in the United States that is funded mainly through the NNI, we publish far more papers in EHS research than any other country in the world. We put in place——

Chairman BAIRD. I am going to interrupt you because I have somewhat limited time and you pointed all this out in your testimony, and it is valuable. But what I am hearing from other folks and the question actually was what is the delay in the report, and what I am hearing from other folks is one, yes, there has been a lot of research conducted but it is not clear exactly what that research is. A second issue is it is not clear how that was prioritized, and those are both valid questions. My belief is that the purpose of the report is to help at least answer the second of those questions, in other words, how it is prioritized. And to say we spent a lot of money on research but it is not known exactly what the research is and it is not known how that was prioritized begs the question of when will this report be due and why has it been delayed, notwithstanding the various other things you have addressed.

Dr. TEAGUE. Okay. I will go directly to your question. This report has been in the process of developing. We have gone through the steps that I indicated. Even since the last hearing, we convened one public hearing based upon the September report to get public feedback on that. We have instituted and worked with OMB to get a data call to get a full look at the government portfolio in EHS-related research. We have those results. We are now analyzing those results, and we are comparing those against the priorities that are laid out in the August document in which we had to prioritize needs.

So we are working toward that. You say why is it taking so long? There are 20 agencies, 20 organizations involved in this, and even more particular, experts, program managers, decision-makers on funding, every aspect that is involved in trying to build consensus on how we move forward. I hope you agree that when you have that many groups involved in it, that it can take time; but we think

that the time is well-spent. If we were to, if anyone were to come forward with a plan which did not have and was not developed on the basis of consensus of the experts within the agencies, with our international collaborators—we are working very intensively with the International Standardization Organization, we are working intensively with OECD, we are working with ICON, we are working with those collaborators as input into our decision-making process.

We expect to have this report out later this year or early next year, but I assure you that going through this very deliberative process is essential. It obtains buy-in by the agencies. They are the ones who will be doing and making decisions on the funding. Our hope is that this document which we come forward with will be based upon a consensus input from the agencies, will have buy-in by the agencies. We want to work with them and not do anything to them, and to get their full buy-in you need to have much exchange, and dialogue. And the analysis of the data call that we got from OMB has been gone over and is being gone over in great detail. It has been combed and recombed to ensure that we answer some of the criticisms that I heard at the table today to make sure that when we do publish the list of projects, and we will do so, after it has been vetted with the agencies and after we try to address any confidentiality issues that might be involved in revealing projects and associated researchers.

So we think the process is working. We have a huge amount of buy-in and coordination among the agencies, and as I said, we share this. We want to do it right. We want to do it right the first time, and this aim to do well-based, well-thought-out science that has good buy-in for the agencies we think is absolutely essential to move forward.

Chairman BAIRD. I appreciate the clarifications. It is certainly understandable 20 agencies is perhaps the reason for the glacial pace. It is the equivalent to the mass of a small glacier, and I can only imagine how difficult. I think there is merit to that. However, I will in the later round of questioning—I will yield to Dr. Ehlers in a second; but I think there is also legitimacy in exploring some of the suggestions about in the future whether some alternative executive structure is needed, or agency. I am not advocating it, I just want to explore that question with the various panels.

But for now I will recognize Dr. Ehlers for five minutes.

Mr. EHLERS. Thank you, Mr. Chairman. And I would point out that Congress was always referred to as moving at a glacial pace, but I think we are really outstripping work that has been done on nanotechnology safety. So that is kind of comforting to us. We at least are moving faster than some.

Dr. Kvamme, I really appreciate your being here and your testimony and also your work on PCAST. You have done a good job there. You mentioned that funding increases for EHS, environment, health, and safety, are appropriate, but to quote you, you note it is also crucial to note that EHS research also depends on advances in non-EHS areas, and you gave as examples instrumentation development and basic research on nanomaterials. I really appreciate that because all the nanotechnology hearings we have been going through, it seems to me everyone is so intrigued with the future of nanotechnology and they are doing the developmental

research; and I am just not convinced we are doing the basic research that is necessary to achieve what we really need to know and to proceed on EHS research. So I just wondered how do you think these advances could be integrated into a strategic plan, and I will be asking Dr. Colvin a similar question in a few minutes. You can start thinking about that.

Mr. KVAMME. Sure. I think the most important thing to realize is that the interrelationship that I referred to in my testimony. Let us just take the case of bio-nano. You are trying to do a good health thing, and so obviously you don't want to hurt the patient while you are trying to deliver the therapy. So the inter-relationships of the actual application and the health and safety aspects are like this, they are tied right together. And that of course takes other things. It takes instrumentation, it takes the capability of monitoring the things. Dr. Colvin mentioned this whole aspect of predictability. I mean, that is exactly what we are looking for from, for example, the human genome project. Predictability. That will take time, but it will also take a lot of instrumentation, a lot of things of that nature. But using just that example, and that example applies to numerous other areas other than bio-nano, you have to be knowing what you are trying to do as well as its relative safety, and in that case, the health of the individual is tied into the whole thing.

Mr. EHLERS. Well, I appreciate that insight. One of the most fascinating articles I have ever read by Gerald Holton of Harvard who traced the development of high-temperature conductivity, and it just astounded me reading that, that all of the ancillary things you think that have no relationships whatsoever, which turned out to play a crucial role in the development; and I think that is the situation here, too.

Dr. Colvin, you commented that you thought the U.S. Government could fix the problem of measuring risk of nanotechnology quickly and for a relatively low cost. I appreciate your optimism. Optimism is what makes the world go 'round, what made this nation great. I have also noted it is entirely appropriate for you to be optimistic because generally the more youthful people are more optimistic. And so that is a good spirit to have, but I would like for you to try to be more specific. How can we do that? I mean, how much is your optimism——

Dr. COLVIN. Well, you took my date, so let me clarify it. I think that certainly I don't think that you can solve all of the problems. That particular comment, I regret to inform you, actually concerned what I consider to be the most immediate needs for the investments that this government is making in nano-EHS, and that is to make sure that all of the investigators funded in these programs from whatever agency agree on the basic terminology, the basic methods, and the basic way that we approach doing our science. Right now there is enormous conflict, different labs don't get the same data with apparently the same materials; and that sort of disharmony is really creating a technical literature which is not conclusive, which is typical for young science. But when that science impacts decisions, that is a problem.

So unfortunately what I was saying is that to fix that problem, to get the research community to harmonize and really come to a

rapid agreement on how they are going to do this research—just the tools—I think can be done fairly quickly and doesn't involve the kinds of longer-term research strategies that would be necessary. I think that the academic research community and the government research community needs to have, you know, the ability to create standards like the Miami standards used in approaching ray analysis for the minimal information needed to interpret quantitative biological data. There is a model for us to use. And that kind of process took under two years, was a lot of workshops, the use of the latest in electronic web communication to help create a kind of a rules to live by if you are publishing papers in the area. And that kind of investment, in that case, it was made by the NIH in their human genome work, really transformed and accelerated how quickly people could extract information from that research.

Right now I can't go to an agency and get that, even little, tiny amounts of money to hold a workshop so we can all get together and hash out, you know, what is the best way to measure toxicity for this material. And so that is the need that I see is so critical, easy to fix, but if we just sort of let it go and hope it will all work out, it will just take a lot longer. So I think that is a critical research need, and in our international workshops, every researcher was just begging their governments to set, you know, little, small amounts of money to help them communicate with each other outside the peer review channels which is what is happening now. And that is really the piece I talked about. And I am optimistic that we could do it, yes.

Mr. EHLERS. Well, as John Gardner observed years ago, you have to be optimistic because if you aren't, you will never solve the problem.

Dr. COLVIN. That is right.

Mr. EHLERS. Thank you very much.

Chairman BAIRD. Ms. Hooley, the gentlelady from Oregon and the author of the *Nanotechnology in the Schools Act.* I am sorry, Mr. McNerney is ahead of Ms. Hooley. My apologies. Dr. McNerney from California.

Mr. MCNERNEY. Thank you. You teased my good colleagues, Ms. Hooley here, but I will accept that anyway.

Dr. Colvin, I spent a lot of my career in the modeling field, and I was intrigued by your comment about developing—what did you call it—a predictive simulation tool or tools. Where are we in that effort? Just elaborate on that a little if you would.

Dr. COLVIN. It is a very exciting concept. So I think that, you know, maybe 20 years ago the field of biology really remained descriptive in nature; and what we have seen in the last decade, even the last five years, is a revolution. You know, predicting biology is not like predicting the weather anymore. We have ways of measuring the responses of organisms that are extremely sensitive. We have amazing computational tools that are now able to integrate data taken from many experiments, and there is some very exciting developments in how you might integrate that data into graphical interfaces. So you might have a virtual fish or virtual ecosystem that you could actually put an imaginary nanoparticle into and predict a response. That is not the stuff of science fiction. That is the

stuff that our Federal Government is currently funding in other areas, including nanotech.

So I want to see those kinds of capabilities that I think American science leads in drawn into this problem. So I think that some of the tools that are out there right now that weren't there are actually some of the tools of bioinformatics—the data mining technologies we have to go into vast amounts of literature and extract correlations and trends, some of the tools that are happening in predicting complex systems which are coming from areas as diverse as control theory and moving in developmental biology. These are really the cutting-edge areas of science in this country, and they are perfectly suited to addressing these problems. And I think that agencies like the National Science Foundation and others realize that enormous capability. I don't think it is a one-year program, but I think that you can begin to build these simulations, begin to have theoreticians as diverse as, you know, folks who work at the quantum mechanical level talking to people who might think on the micron level, all the way up to an ecosystem biologist who thinks about the kilometer world. And you can make those nanometer-kilometer transitions happen. And I think that that is actually one of the more exciting areas.

In our ICON workshops, we held out that vision as something to organize our theoreticians, our computational biologists, our toxicologists around it; and I think everybody got really enthusiastic and was able to also translate that enthusiasm into a very structured approach to that. So I think that in my own personal opinion, that is a very exciting area, and it is one that we could actually do that; and nanoparticles and nanotechnology are just a really good sort of first problem for that confluence of informatics biology and materials to come together.

Mr. MCNERNEY. So as far as today is concerned, there is not much resources available for that sort of process?

Dr. COLVIN. No, unfortunately it is a go-to-the-Moon kind of project, so it is not something I can sort of throw one grant in and do. It takes me working with very good modelers. A lot of good—I mean, it takes a village. So this is why I suggested it in my written testimony as one example—there are many others—of a great long-term thing that this government could actually make happen; but to do so will take a planning process that I am really hoping that they will be able to achieve. But I absolutely think it is doable and it is something that many of us in the field are trying to work towards in our own ways. But I think the Federal Government and governments world wide could do a lot to really think through how could we achieve that.

Mr. MCNERNEY. All right. Thank you. That sounds very exciting. I would like to see us follow up with that a little bit.

Dr. Denison, you mentioned the problem of insufficient oversight on the money that is being spent on EHS and also the need for single leadership position. Do you think that is achieved through legislation or through administrative means going back to the Administration?

Dr. DENISON. It is a very good question. I think the NNI, the National Coordinating Office, and the NEHI itself have struggled with this issue and have in essence had to go through a process that

was hard to direct from the top, if you will, because of the nature and the way in which that committee is structured and the overarching facilitation role that it is intended to play.

That was part of the original concept of what NNCO was supposed to be, a coordinating office. So I am not very hopeful that that kind of more directed and top-down approach that I think most people think we need, can be accomplished without some new authority, and that that authority probably does need to come through a legislative means. So there may be some ways, and I would be certainly happy to consider other ways of doing it, but I think it is certainly something that in the reauthorization process that you are starting should be given serious attention.

Mr. MCNERNEY. Thank you.

Chairman BAIRD. The Committee has been joined by Dr. Gingrey and also Dr. Lipinski. Next, Dr. Bartlett.

Mr. BARTLETT. Thank you very much. Nanotechnology is a relatively new technology, and most I think of our citizens have little understanding of what it is. They kind of know what the risks are to using explosives. When you use plastics they can smother you or mechanical things can cut you or poke you or compress you. Drugs and chemicals can affect your skin——

Chairman BAIRD. Is this a Halloween speech, Dr. Bartlett?

Mr. BARTLETT. Your brain, your kidney, and so forth. Radiation, I think they have a general understanding that these little particles go whizzing through your body and disrupt the machinery of the cells, so they can cause many and varied disruptions of the body's physiology and chemistry. What is there about nanotechnology that is unique? Are there things about nanotechnology that are different than the various categories of risk that I went through that we require new research protocols? I think the average citizen has little appreciation of the risks that nanotechnology could bring in addition to those that I have mentioned above for all of these other risks. Anybody?

Dr. MAYNARD. If I could take a stab at answering that. I think it is a very good question because of course we have got to establish whether there really is anything different and unique about nanotechnology before we begin to say we need to do lots of research into the potential risks. I think the easiest way of demonstrating that is to take an everyday object. Forget about a nanotechnology for the moment, but take something like this glass. Pretend that it was made out of glass rather than plastic, and if I asked you, well, what harm could you do with that? You would say, well, obviously you can hit somebody with it, you can throw it, you can smash it. If you have got a sharp edge, you can cut somebody with it. All of those risks are associated with the physical nature of it as well as the chemistry. We all understand that. The physical form of something is really important.

When we get down to the nanoscale, that holds true exactly the same it does for something like this. The only difference is we cannot see the nanoscale materials, so we tend to forget the physical form is important, and we think we can tell everything about it just looking at the chemistry. Of course, if I told you you could tell everything about the risk of a glass just by looking at what it is made of, which is glass, you would say, that is ridiculous. I would

also say it is ridiculous to say you can understand everything about risk of a nanomaterial just by looking at the chemicals it is made up of. That is the challenge we face, understanding that added dimension of the physical form of the materials; and we know from research that has already gone on that physical form that is important in determining how they harm either the environment or people.

Mr. BARTLETT. Yes, sir?

Dr. DENISON. May I make——

Mr. BARTLETT. Floyd, you were going to——

Dr. DENISON. Let me just add one point to that. I think Andrew is right about the physical as well as chemical makeup being essential. Part of the problem with these materials is that they tend to behave in ways that are different from ordinary chemicals that we are used to dealing with because of their physical form. So for example, particles in this nano-range can get into places that materials that are either smaller or larger can't necessarily get to. These materials are also being designed to be highly persistent, very non-able to be broken down. If those materials, as we know from other experience, get into the environment or get into people, that persistence can become a problem.

So there are certain characteristics that are being designed into these materials for functional reasons, performance reasons that have a flipside. Now, we cannot over-generalize and we cannot leap to the conclusion that all of these materials are necessarily problematic. I personally think certain applications of certain materials, a fairly narrow set, are likely to be culprits, but we can't yet identify which ones are going to be those problems because we don't yet know enough about how to correlate these properties with their biological activity.

Mr. KVAMME. I think the important thing to realize here is that this has been true for every new technology. I had the pleasure of being at the birth of the semiconductor industry in 1959, '60, '61, in that time. We worked with chemicals that were also used in San Quentin to put people to death as diffusants. You had to be very, very careful from a risk point of view. Yes, they were chemicals, yes, they were larger than what we're talking about now. But take the biofuel that I referred to before. The small molecule that goes through the blood-brain barrier, those have been, you know, researched and they are very, very difficult to figure out. We were involved in a company studying the Alzheimer's issues of what was going on in that particular barrier. So yes, there is differences, but a lot of the significant ways of looking at the problem aren't really a whole lot different in my view. However, I would say it is important to have this integration that I talked about before of application and safety risk. If you tear those apart and you create a silo for EHS only and it is not informed by the application, I will disagree with some of my fellow panelists here, I think you are making a huge mistake. You are going against the multi-disciplinary thing that we have learned in our universities is so valuable, having a cross-link of capabilities. You have to understand both to get the right answers in my view, and that is why I speak so strongly to the point of integration and the way the program is now and not

setting up some czar for EHS. I don't think that will be an informed approach.

Chairman BAIRD. The gentleman's time has actually expired, but I am going to extend it a little bit because I think it is an outstanding line of questions. So if there are others? Dr. Teague, please.

Dr. TEAGUE. Yes. I guess you were speaking of nanotechnology and within the NNI we have discussed at length the question of what is nanotechnology, and I would say the general definition that we have adopted involves the ability to work and control matter at the nanoscale. And it is that ability to control matter at the nanoscale which we say is approximately one to 100 nanometers which is very, very small. I typically say, for me to get an understanding that a sheet of paper is 100,000 nanometers thick; that helps me get a feel for how tiny the nanometer is. And I think going to Mr. Kvamme's point about the need for integration; and the point was made that at this nanoscale, there is a possibility that matter at this scale can penetrate cell walls and things of that nature. It is so important to understand that that has the potential to be a hazard to cells and to the body, but it also offers an opportunity to deliver therapies. So it is hard to say, is the ability of a nanoscaled material to penetrate cell walls and to go inside cells, is that good or bad? It could be good if you are trying to get therapy into a particular location in the body. If it happens to be that it poses a hazard, then we hope, and I think by this integration again, both trying to seek application as well as to understand their risk, if you integrate those, then you can use the control of matter at the nanoscale. If it is a hazard, we hopefully can control it and we can make it more benign with that high degree of control that we have at the nanoscale that is being offered by nanotechnology.

Mr. BARTLETT. Mr. Chairman, it might be worth just a moment for the layman who is reading this to note what the blood-brain barrier is. If you are trying to get a chemical, a drug, to the brain, it does not get there anywhere near as easily as it gets to other parts of the body. So when you are treating an infection there, an antibiotic which will treat it effectively in other parts of the body just doesn't get through this mysterious blood-brain barrier. I haven't been involved in this technology for a number of years now. Do we know what it is now?

Chairman BAIRD. Mr. Bartlett, I am going to—we are well over time for you and I want to make sure we get the other witnesses. I think the analogy we would all understand is blood-brain barrier is similar to the difficulty getting information from witnesses into the brains of the Members of the Committee. Very comparable process.

Ms. Hooley, the author of *Nanotechnology in the Schools Act.*

Ms. HOOLEY. I want to thank all of our witnesses today. I think nanotechnology holds so much promise, and there is so much we still don't know about it.

If we think five years ahead, what would be the various options, if we were determined through implication studies, that there were unintended consequences to nanotechnology? Any one of you want to answer? Go ahead.

Dr. DENISON. I think we need to always keep in mind the range and types of applications of these materials that we are addressing. And there is no question that some applications are going to be relatively easy to contain or control. They pose very little risk of exposure because of the nature of the application. Material that is imbedded in a permanent way inside of a matrix is going to be much less of a problem than something that you put into a cosmetic that you apply to your skin.

So I think one of the things we need to be prepared to do is to recognize that there may be types of applications for certain materials that we simply don't know enough about to advance significantly. And the concern I have is that we are not applying the brakes in certain places. We already have nanomaterials of a variety of types in cosmetics, in dispersive applications that are going to introduce these materials in a fairly uncontrolled way and exposing the people and the environment.

So I think what we need to do is go cautiously in those types of applications, and we have every reason to expect they are going to be dispersive or directly expose people until we know more about these materials and their properties and whether they in fact pose risks. That is the major piece of advice I would offer.

Ms. HOOLEY. Anyone else want to tackle that?

Mr. ZIEGLER. Yes. I certainly agree with what Dr. Denison just said. You really need to understand along the life cycle of any chemical where are the potential exposures, and some of the basic stuff that certainly that I look for at the grass roots, being a practicing industrial hygienist, is what is the exposure in production. If I am dealing with a powder, it can be pretty high. The risk is significant. The potential hazard is great, but if I can get that into a matrices, into a resin, or into a solution, that hazard and risk is still there but it goes way down. And I think that is something that really helps us understand how we need to control this or approach it. It is quite common with any chemical that we develop that we have to understand what the exposure is going to be along the manufacture, incorporation into products, and then at the end-use level. That certainly is one of the gaps that I think exists that we don't have a good way to get an exposure. Fortunately, most of the manufacturing is closed-system; and we try to get it into some matrices before it is just put into the environment so the next level of use has a lot more control of the exposure.

Ms. HOOLEY. Cadmium is currently used in a lot of new nanotechnology applications, but it is a heavy metal, similar toxicity problems as mercury or lead. In light of the recent concerns about lead in consumer products, what is to prevent these nanotechnology applications that use cadmium from being the next type of consumer product that cause safety concerns?

Dr. TEAGUE. Let me take a shot at that.

Ms. HOOLEY. All right.

Dr. TEAGUE. I am aware that cadmium is used in some of the quantum dot products, cadmium selenide and some of the other ones because of its fluorescent properties. I am not too much aware of it being used in other products. In general, the view that we have is that the current regulatory system that is in place from EPA, from FDA, from CPSC, from OSHA are such that they are

appropriate for handling any of these new materials. They have each taken special attention to any of the new nanomaterials. Each one of the agencies that I have mentioned have formed task forces within their agencies to pay special attention to nanomaterials and to consider how their regulatory authorities would apply to such materials. The other aspect of this issue is that it is the responsibility of the manufacturers to ensure that any materials, any products which come on the market, are safe. The regulatory agencies are there to make sure that that is true, but it is the manufacturers' responsibility to ensure that products, materials, devices are safe when they come to the marketplace, and we feel confident, I feel confident, that that is the case with respect to nanomaterials.

So in the case of cadmium, that particular one, and I think those are being sold in relatively small quantities, mostly for experimental applications, at this particular point. Some of it is being used as a means of quick diagnosis because they have the nice fluorescence, better than natural fluorescent materials.

Ms. HOOLEY. Anyone else? Dr. Denison.

Dr. DENISON. Yes, I think you raise an important point that I think highlights the importance of designing the materials from the start to avoid potential problems downstream. Using materials that we know to be highly toxic like cadmium in applications where we either don't know or we can expect some release to happen is not a good principle to start with. So there is quite a bit of talk about green nanotechnology——

Ms. HOOLEY. Right.

Dr. DENISON.—which one element of that is designing out the potential toxicity or later risk of these materials from the beginning. While I think Clayton is right that the current uses of these are relatively limited, quantum dots including cadmium-based quantum dots are being looked at for a lot of other applications and may be much higher in volume and so forth. And the problem with our current regulatory structure is that for many of the application areas for nanomaterials they do not provide a sufficient look at those materials before they hit the market. They either don't meet the thresholds of tonnages of materials that trigger an assessment or they go in applications that are regulated by agencies that only have post-market authorities, to look at a problem only after it has arisen, like the Consumer Product Safety Commission, like the FDA with cosmetics.

So for those uses in particular, we need to be very careful about using materials that we have any reason to expect are inherently toxic.

Chairman BAIRD. May I comment? We are expecting votes at 11:30, and in order to make sure that all Members of the Committee have the chance to ask questions, I am going to shorten this.

Ms. HOOLEY. I just want to—five seconds. I would hope that we do everything we can. Nanotechnology has such great importance I think to our future, and I would hope that we would do everything we can as we see materials being used that are toxic materials, that we figure out a way to get rid of them before we even start.

Chairman BAIRD. The gentleman from Georgia, Dr. Gingrey.

Mr. GINGREY. Mr. Chairman, I thank you. You are on such a Halloween roll today, I probably ought to yield my time to you, but I do have one question I want to ask and one statement I would like to make, too. We have passed through this committee and thanks to the Chairman and my colleagues on both sides of the aisle, passed green chemistry legislation. We passed it in the last Congress as well, and hopefully we will get our buddies in the other body to help us get that through; and here Dr. Denison just mentioned green nanotechnology. It is amazing, but we need to do on the growth scale, if you will, we need to move forward with that.

I am going to ask my question to Dr. Maynard, but hopefully there will be enough time some of the others can weigh in as well. Dr. Maynard, you described the Federal Government's leadership role in nanotechnology EHS research, I think you said, as slow, badly conceptualized, poorly directed, uncoordinated, and underfunded.

Dr. MAYNARD. Did I really say that?

Mr. GINGREY. Why don't you tell us what you really think? My question is how would you make NEHI more effective? If you could address that for us I would appreciate it.

Dr. MAYNARD. Well, first of all, let me acknowledge that though I agree with that statement, people in the Federal Government, Clayton Teague and others, have actually been working very hard to try to make this work, and I applaud their efforts. But as I said in my testimony, trying hard is not good enough.

If you look at NEHI at the moment, it is hamstrung in a number of ways. It is hamstrung because people just do not have the time to do the work that needs to be done. Everybody is very, very thinly stretched in that committee. They need the time to do the right work. It is also hamstrung because they have little or no authority. They can coordinate activities but they really can't get what needs to be done to ensure things like this are safe, rather than just talking about what needs to be done. They are hamstrung because they don't have a clear perspective of what the goals are they are trying to achieve.

And getting back to a point Floyd made earlier about collaboration between different areas to ensure nanotechnology succeeds. I applaud that. That is essential that we get the people developing nanotech applications and working with the people understanding risks. But if you are going to develop these things safely, you have got to address specific risk-based questions. You have got to understand what those questions are and what you have got to do to address them, and what we have at the moment is we have an applications-driven attitude where the people setting the questions really don't understand how risk science works; and to solve that, you have got to have somebody in leadership that understands the risk-based issues, the oversight issues, and the regulatory issues. If you don't have that, I cannot see progress being made.

Dr. TEAGUE. May I respond to that as well?

Mr. GINGREY. Please.

Dr. TEAGUE. I would say that in general among the NEHI Working Group, by and large no one believes that a nano-EHS czar is a good idea. In fact, they think it is a bad idea. And the reason that I think everyone feels so strongly that it is a bad idea is that

no one agency, I don't think even any centralized organization, would even come close to having the breadth and the depth of the expertise represented both in the applications research as well as in the toxicology and other fields needed as is present in all of the NNI agencies. The 20 agencies I referred to by and large are not just the research agencies, they are all the regulatory agencies as well. And one of the reasons that some of those things come to play as much as they do is that one needs to do a lot of careful planning and analysis to do good research. A lot of the research that was done early on was certainly not coordinated from the Federal Government. I think that is why some of it did produce some very premature results and a lot of wrong conclusions were drawn from it. By the careful planning and by tapping into the depth of experts within the Federal Government and our collaboration with others outside, I think that we have by far the best approach to trying to carry out appropriate research in a careful, deliberately planned way. If one doesn't do that, the result is typically bad research and research that leads to premature and often poor results, poor understanding, and leading to, I think, a lot of misleading conclusions that have already been drawn because the research was not planned, not well-conducted.

Mr. GINGREY. Mr. Chairman, if the other witness can respond very briefly. I know we are running out of time.

Mr. KVAMME. I would just make the point that I think the real struggle here is do you do this top-down or bottom-up? The way we looked at it from a PCAST point of view is there is a lot of stuff bottoms-up that is happening, and I think it is very, very good stuff. I invite you to go onto Dr. Colvin's website. A lot of good stuff is coming up, and we are learning a lot. And I would only say that is the way the semiconductor industry got started, and we have been pretty successful at it. That is the way the Internet industry came in, that is the way the micro-computer came on. I think if you top-down this too much at this early stage, you are making a mistake.

Chairman BAIRD. I thank the gentleman, and Dr. Gingery is being modest when he referred to this committee passed the green chemistry bill. It was his bill.

Mr. Honda has been a leader and well at the forefront of the nanotech issue, introduced House Res. 3235 I believe it was, and Mr. Honda, thanks for joining the Committee and welcome.

Mr. HONDA. Thank you, Mr. Chairman, and I thank you for inviting me. Just very quickly, I appreciate this kind of conversation because that bill does address some of the issues that our blue-ribbon task force that we formed in Silicon Valley and some of the questions and directions are being addressed in some of your conversations; and permeating through a lot of the recommendations was the issue of ethics, and I think that that is something that as a schoolteacher I would be always looking for. But I am assuming that that is part of your value system anyway.

A couple of quick questions, and if the bell rings, then I will ask if you could respond in writing; but you were talking about modeling and terminology on modeling, and I guess the question I have is that when we get to a certain scale in the nanoparticle activities, the chemistry and the physics all change. In the modeling area,

how do you become predictive in an area that is not known and unpredictable? And I guess my second question would be nanoparticles have always existed. It is nothing new. As a science teacher, I always wondered, then how did we handle nanoparticles up to now naturally? What are the differences between a natural-occurring and manipulated nanoparticles versus man or human manipulated particles? Those are the two kinds of questions that have been plaguing me.

Dr. COLVIN. Let me quickly do this so I can give my other panelists a chance to speak. So the predictive models are possible. We actually are pretty good at predicting, for example, the changing colors of quantum dots from fundamental principles of quantum mechanics. So we actually know that part. How we are going to do it I think in the EHS arenas—you know, I live in Houston, Texas, and when the hurricanes head to us, there are all these predictive models. But they don't say one track; they give us a direction with a range. So I think a lot of the predictive modeling that is developed is actually statistical. It is not saying exactly what is going to happen. It is saying likely to happen and with what confidence. So that would be one comment on predictive modeling.

Mr. HONDA. Almost like human variabilities?

Dr. COLVIN. Right, and that is a very important point because I think humans tend to want certainty, and there will be ranges. And as we get better, we will narrow up those models and make them more precise; but that is how we will start.

The second part on the natural nanoparticles, that is a fascinating question. They are out there. It doesn't mean that all nanoparticles will be safe. There are plenty of natural things that are not safe, but it does mean that biological organisms probably have developed ways of processing them. And in fact, there is already clear evidence that a lot of *in vivo* animal studies of nanoparticle interaction shows that our immune system is quite capable of addressing particular oxidative stress that is introduced by particles that you don't see in organisms that are single cellular, for example. So that is a really important point, and I would just say there is a lot we need to do to bring that out.

Dr. TEAGUE. I guess one thing that is very important about your question, and I think sometimes it is a misconception, and that misconception is that sometimes at the nanoscale some of our science is new. As Dr. Colvin just indicated, quantum mechanics doesn't change at this scale. We have the basic fundamental science to undergird what we are doing, and with the new computational power, new particular algorithms that are being developed, we can actually compute from what scientists call an ab inito calculation, just direct quantum mechanics, and can predict many other properties up to reasonable sized nanostructures. We run out of steam at about 10,000–100,000 atoms—but at this size we can predict the properties quite well. I would also, going back to something you mentioned earlier, point out that predictive toxicology is something that the NNI has focused on some and very happy to hear the subject of modeling brought up in this discussion. We have worked with Vicki on some of this. But there is a center that is driving some of this in EPA at the Research Triangle Institute. There is a center for predictive toxicology that is focusing on mod-

eling toxicology—now they are turning their attention toward the predictive toxicology of nanomaterials. And I would just endorse what she said about your second question.

Dr. MAYNARD. Can I just very briefly address that second question? You are exactly right. As you are sitting there, you are breathing in at least 10 billion nanoparticles per minute, and you look reasonably healthy. We have all to deal with these. There are two but's here. The first but is we know historically people breathe in nanoparticles; some people die. They are not safe. The second thing is, we have evolved to deal with certain types of nanoparticles. If you introduce a brand-new type of nanoparticle to people, we cannot predict that it will be as safe as the ones we are breathing all the time.

Chairman BAIRD. Dr. Denison, one final comment?

Dr. DENISON. Yes, very quickly. I would just want to amplify that one of the reasons that the risk part of nanotechnology started getting attention is precisely because we know that small particles in that range that are incidentally produced, primarily through combustion, diesel exhaust particles, and the like, do in fact have major health problems. They cause health concerns in people that are exposed to them. So that is part of the motivation for recognizing that there is a potential here for engineered materials to have similar risks.

Mr. HONDA. Thank you. Mr. Chairman, thank you in the name of Robin Williams, nano-nano.

Chairman BAIRD. Dr. Lipinski and we have about 10 minutes left, five minutes and we will have to wrap it up. Dr. Lipinski.

Mr. LIPINSKI. Well, I will probably make this less than five minutes, although I just ran out. I had a resolution in the Transportation Committee, and by the time I had got there it had already passed. That teaches me that maybe you are better off not being there.

If I could only find my questions here. First thing, I would like to thank the Chairman for holding this hearing, and I want to emphasize Chairman Baird is the only one that I allow to call me doctor. But as a former chemical engineer, especially as someone who is very interested in helping to make this a more green world, it is good to see this article here in *Business Week* about saving energy by fighting friction, about use of nanotechnology to make anything that has a fluid flow more efficient through nanotechnology. I think it is very important that especially since we hear about all these issues right now with the safety of consumer products, especially for children's toys, but other things that are not really getting the attention that they deserve. I believe when they are going out to the public, I think it is very important that as nanotechnology really more and more—there are nanotech products out there, and as the world moves more toward using more nanotech in our products, I think it is very important that we look at these issues. I thank the Chairman for holding this hearing.

One thing I wanted to ask, are we right now looking at comparatively the new nanotech products? Are we comparing those to products that may already be out there that they are replacing because some of the products that they may be replacing already have, you know, concerns, safety problems with them. Is that really going on?

Is that type of comparison going on or is it just a comparison to an ideal of something that we have no problems with it? Because I hate to say that but there is a trade-off there. Dr. Maynard.

Dr. MAYNARD. Many of the first generation of products that are appearing are really just extensions of existing products. So nanotechnology is what I refer to as nowhich technology. You take something which you have already got and you make it better using nanotechnology. And so if you look at Consumer Products, that is where most people are going to come face to face with nanotechnology. But of course as you look to the future, there are going to be brand-new nanotechnology solutions to challenges, and that I think is where you are going to see brand-new technologies develop.

So there is a little bit of mix of both. But certainly as far as the everyday person in the street goes, the things that we keep coming into contact with now and over the next few years are just going to be extensions of conventional technologies and material.

Mr. ZIEGLER. I would like to make a comment here to your question. I think in some cases the answer is a resounding yes. The work that is going on with nanotechnology today is replacing something that is a problem. For instance, chrome-6, chrome-3, the chromates. For corrosion resistance, I do know there is work going on. It is not going on at a rapid pace, but it is going on and there are going to be some trials and then there has got to be a lot of testing and probably three or four years on certain pieces of equipment so that we know that it will perform; but it is based on nano. It is a much safer product than having the chromates in the workplace or in landfills or in the air. So I think it is not just an extension of products in every case that we are accustomed to today.

Dr. TEAGUE. I would like to add very much the same comment. I think that quite soon nanotechnology-based products will be replacing some that are on the market. I think one of the ones that is probably most imminent, and I am not sure if we are talking five or 10 years, but in that neighborhood, one could very well see nanotechnology-based light bulbs; which again are using the quantum dots that we talked about earlier as fluorescent agents. Using the nanotechnology-based light bulbs, one is talking about increasing efficiency by 50 percent above what the fluorescent lights are so that you could have a huge impact not only in terms of energy efficiency, it also turns out if you look at it very carefully; you compare the metals and the elements that are being used in the nanotechnology based light bulbs which have been demonstrated in the laboratory already and in some of them in early products; you reduce even the mercury which is present in fluorescent light bubs. So if you look at it in terms of the balance between products and what impact they might have in terms of long life cycle analysis, the nanotechnology-based products are typically more efficient and have a lot less of the toxic elements in their actual manufacture and in their use.

Mr. LIPINSKI. Thank you. Thank you, Dr. Chairman.

Chairman BAIRD. Very interesting and appropriate line of questioning to finish with, an exciting enterprise but also one that we want to make sure we do right; and I thank all the panelists for their efforts. We have about five minutes for my colleagues on the

panel here to make the vote, so with this we are going to adjourn the hearing but I wanted to express my deep appreciation for all the Members who offered their outstanding testimony today; and we will look forward to the report when it comes out and to further progress in this important field.

Thank you, and with that the hearing stands adjourned.

[Whereupon, at 11:40 a.m., the Subcommittee was adjourned.]

Appendix:

Answers to Post-Hearing Questions

ANSWERS TO POST-HEARING QUESTIONS

Responses by E. Clayton Teague, Director, National Nanotechnology Coordination Office (NNCO)

Questions submitted by Chairman Brian Baird

Q1. Is the environmental, health and safety research (EHS) funded and planned for funding under the National Nanotechnology Initiative coordinated with related research being carried out abroad? Are there formal mechanisms available to help coordinate EHS research internationally? How does the funding under the NNI in this area compare to foreign research support levels?

A1. The EHS research funded and planned for funding under the NNI is coordinated with related research being carried out abroad through three formal mechanisms: first, participation and leadership on the Organization for Economic Cooperation and Development (OECD) Working Party on Manufactured Nanomaterials (WPMN) and OECD's Working Party on Nanotechnology; second, participation and leadership on the International Organization for Standardization (ISO) Technical Committee on Nanotechnologies (TC229) Working Group on Environmental and Health Aspects of Nanotechnologies; and third, close coordination between solicitations for EHS research by U.S. research agencies and their equivalents of the European Union. Additional information follows.

- The Unites States currently chairs the OECD WPMN. The working party has a number of projects focused on EHS research including the gathering, sharing, and prioritization of information on research and research needs among member countries and regions participating in the working party. Other projects include cooperation on voluntary schemes and regulatory programs, co-operation on risk assessment, and information sharing regarding national strategies and policies for managing EHS research regarding nanomaterials. One project has recently selected a set of representative nanomaterials for extensive testing, while another is evaluating the applicability of existing international testing protocols to nanomaterials.
- The ISO TC229 has participation by 27 member nations and offers excellent means for communication among member nations about EHS research through the introduction, selection, and formulation of new work items. New work items leading to international documentary standards for the TC and its Working Group are based on results of research and needs for standardization as the research results are moved from the laboratory into commercial products.
- At the agency level, the current U.S. solicitation supporting investigations of fate, transport, transformation, and exposure of engineered nanomaterials (jointly funded by EPA, NSF, and DOE) is closely coordinated with a parallel solicitation by the European Community. In addition, at the country-to-country level, U.S. agencies are seeking appropriate partners for nano-EHS research under bilateral science and technology agreements.

Even with some reasonably focused efforts to obtain information about the funding levels for EHS research for nanomaterials by other countries, we have only limited anecdotal information. The information we have suggests that the U.S. funding for this research is, by amount and by percentage of national funding for nanotechnology R&D, significantly larger than any other country. Most other countries and regions have only begun funding of EHS research on nanomaterials in the last year or so, whereas the U.S. began funding of this research at the NNI's inception in 2001 and since then has been increasing the level of funding at a high rate.

Q2. Dr. Maynard has suggested a mechanism for the government to partner with industry to fund EHS research that would support the needs of government in formulating a regulatory framework for nanomaterials and the needs of industry on how to develop nanotechnology safely. The idea is to use the Health Effects Institute model, which studies the health effects of air pollution. Do you believe this would be a good model for developing a government/industry research partnership for EHS research related to nanotechnology?

A2. Government/industry partnerships are already a valuable part of ensuring the vigor and quality of programs to address nanotechnology EHS research needs. There are several avenues for supporting such partnerships, for example, the NIH/NCI Nanotechnology Characterization Laboratory and Cooperative R&D Agreements between individual companies and federal agencies. Further, NIH, working with sev-

eral other agencies, is exploring how the Foundation for the National Institutes of Health might be used to support such research with funding being jointly provided by the Federal Government and by industry. Thus, as the NNI moves forward in exploring collaborative work with industry, the Health Effects Institute (HEI) model might offer some additional insights for developing a government/industry research partnership for EHS research related to nanotechnology.

In assessing the appropriateness of the HEI model for supporting EHS nanotechnology research there are several major differences between the avenues being explored by federal agencies for nanotechnology EHS research and that of the HEI model that need to considered. First, research funded through the HEI is for materials which are not proprietary while at this early stage in nanotechnology's development engineered nanomaterials typically are proprietary. Second, while the HEI model is based on joint efforts between one agency and one industrial sector (EPA—primarily, with some special projects involving one to two other agencies, and the worldwide motor vehicle industry), nanotechnology EHS research engages a large number of agencies (over 20) and multiple industry sectors. Third, the HEI model examines health effects associated predominantly with air pollution originating from mobile sources and therefore only examines one route of exposure, that of inhalation. Fourth, challenges associated with nanotechnology EHS research arise from a number of factors such as the diversity of classes and types of engineered nanomaterials and their applications in many areas, e.g., biomedical, consumer products, food, energy, and environmental sectors. Further, the number of application areas is continuing to grow at a rapid pace. Therefore, it is not clear that the HEI model offers advantages over the avenues already being pursued individually and jointly by the agencies under the NNI.

The NNI operating through the NSET Subcommittee, the NEHI Working Group, the NNCO, the NNI member agencies, and their formalized interactions with industrial liaison groups for various industrial sectors provides a broad-based model for planning and conducting nanotechnology EHS research in collaboration with industry. This model enables the required multidisciplinary approach and provides a means by which the research can be guided by the missions and responsibilities of federal agencies. Further, this model provides a mechanism to integrate and leverage the expertise that exists across the Federal Government and the broad cross section of research efforts underway in government, academia, and industry. Finally, the model provides federal programs with information that not only meets their needs in a timely and cost-effective manner but also addresses private sector needs/guidance on nanotechnology EHS from a wide range of industries. For example, the NNI document released in September of 2006, "Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials" and the more recently released draft EHS research priorities document were both based in part on substantial input from two of the industrial liaison groups that the NNI has been working with, representing the chemical and electronics/semiconductor industries, respectively. These two groups collaborated in formulating a list of recommended EHS research priorities, in close coordination with the NNI agencies.

Q3. Mr. Ziegler and Dr. Denison recommended that the National Academy of Sciences be tasked to take a lead role in developing the EHS research strategy and assessing its implementation over time. What is your view of this recommendation?

A3. The need for a nanotechnology EHS research strategy was recognized by the NNI agencies and a completed EHS research strategy document is imminent. Therefore, tasking the National Academy of Sciences to develop such a strategy at this time would be duplicative. Assessing the research strategy and the effectiveness of its implementation over time is an appropriate role for the National Academy of Sciences. The NSET Subcommittee already has contracted with the NAS to evaluate the NNI's EHS research strategy that will be published in the next couple of months. In general such targeted external review by the NAS can be considerably more helpful to the NNI agencies than a broad assessment that attempts to address many diverse aspects. The NNAP provides broad oversight; the NAS can be most helpful by offering more narrowly focused reviews.

The NSET members believe that employing agency expertise in assessing both regulatory and scientific needs for nanotechnology EHS research has resulted in a rigorous research strategy and has appropriately integrated agency expertise and responsibilities into the strategy.

Q4. One of the key aspects of carrying out EHS research is to have agreed terminology and standards for characterization of nanomaterials;

Q4a. Is this getting sufficient attention under the NNI? What is the role of NIST in this area?

A4a. Under the NNI, development of an appropriate terminology (and nomenclature) is receiving a high level of attention. Many of the NNI member agencies are participating in the ISO Technical Committee on Nanotechnologies (ISO TC229) Working Group on Terminology and Nomenclature, and the Director of the NNCO is Chair of the ANSI Technical Advisory Group (TAG) to ISO TC229. NIST, several branches of DOD, DOE, EPA, NIOSH, NASA, and the National Cancer Institute are active members of the ANSI TAG. Some NNI agencies are also engaged in standards development efforts by ASTM, IEEE, and SEMI. All these standards development organizations and ISO TC229 are also very active in developing documentary standards for the measurement and characterization of nanomaterials and for many aspects of the exposure and potential hazards of nanomaterials.

With respect to physical reference standards, NIST is in the process of producing "standards" relevant to nanotechnology EHS. These include:

- RM 8011–8013 gold nanoparticles in three mean particle sizes 10 nm, 30 nm, and 60 nm
- RM 8281 single wall carbon nanotubes with long and short lengths in solution

In addition NIST is currently working with NIOSH, NIEHS, and the NTP on the development of other standards for nanotechnology EHS needs. NIST hosted an NNI Workshop on Standards for EHS Research Needs for Engineered Nanoscale Materials on September 12–13, 2007. The purpose of the workshop was to develop guidance on what physical and documentary standards are required to enable sound risk assessment and risk management of engineered nanomaterials. In the longer-term, the workshop will facilitate the development of standards needed for understanding and managing occupational exposure to engineered nanomaterials; nanomaterial fate and transport in the environment; and nanomaterial potential impacts on human health and the environment.

Q4b. Is there a role for NNI to provide direct assistance to nanotechnology companies, particularly small companies, to help them characterize new nanomaterials, which will thereby assist the companies in assessing the potential environmental and health risks of the new materials?

A4b. In general, the Federal Government does not assist companies in characterizing new chemical substances, whether or not they are nanoscale materials. Nevertheless, there are definitely roles for the NNI to provide direct assistance to small and large nanotechnology companies to assist them in assessing potential EHS risks of new nanoscale materials. Some examples already underway follow.

The Nanotechnology Characterization Laboratory jointly supported by NCI, FDA, and NIST offers services to characterize new nanomaterials and is also developing and publishing recommended protocols for assessing the potential health risks of new nanomaterials.

The NNI-established user facilities offer small and large businesses access to state-of-the-art instrumentation and facilities that can be used for characterizing new nanomaterials and studying their interactions with biosystems. (A list of these user facilities is provided in the NNI Supplement to the President's 2008 Budget.)

NIOSH offers "Programs for Nanotechnology in the Workplace" to provide companies with guidance for implementation of engineering controls, use of personal protective equipment, and management practices for working with nanomaterials. NIOSH also conducts Health Hazard Evaluations to find out whether there are health hazards to employees caused by exposures or conditions in the workplace, including concerns related to nanotechnology. Finally, NIOSH has an interdisciplinary field team of researchers that partners with employers and others in conducting field studies to observe and assess occupational health and safety practices in facilities where nanotechnology processes and applications are used.

FDA, EPA and CPSC have all announced that they will work with businesses to guide them regarding their use of specific nanomaterials in products.

Questions submitted by Representative Vernon J. Ehlers

Q1. Please tell us more about how the agencies are working together on nanotechnology in general and specific to EHS issues, especially in areas where there may be some overlap. How are you making sure that efforts are not being duplicated?

A1. In general the NNI member agencies work together to coordinate both their intramural and extramural funding for nanotechnology R&D. Numerous interagency activities are detailed in the 2004 NNI Strategic Plan and in the annual NNI Supplements to the President's Budgets. To support the advancement of this broad and complex field, the NNI creates a framework for a comprehensive nanotechnology R&D program by establishing shared goals, priorities, and strategies for agencies to leverage their expertise and resources. Duplicative work is less likely at the outset of any program, but with time and growth of R&D efforts attention needs to be paid, both within and across agencies to ensure duplication is avoided. However, differences in agency missions decrease the likelihood that identical research will be funded by more than one agency.

This NNI framework is implemented for nanotechnology EHS research primarily through the NEHI Working Group. This working group provides a forum for the sharing and reviewing project-specific information for coordination. Such communication and collaboration among agencies also minimizes the potential for undesirable duplication. Joint solicitations typically involving two to five agencies are specifically designed to avoid duplication of efforts among the participating agencies.

Three statements from the NNI member agencies illustrate the effectiveness of this approach for nanotechnology EHS research. Others for more general nanotechnology research are provided in the Appendix to my written testimony.

From the EPA: The U.S. EPA's, Office of Research and Development (ORD) and the National Toxicology Program, as well as the National Institute for Occupational Health and Safety, have initiated collaborative interactions in their intramural (in-house) and extramural nanomaterials health effect research efforts. These interactions have their origins in the development of the NNI, NSET, "Environmental, Health, Safety Research Needs for Engineered Nanoscale Materials" document. These interactions have been further enhanced through invitations by EPA's ORD to the National Toxicology Program and the NIOSH nanomaterials health effects lead scientists to visit ORD's National Health and Environmental Effects Laboratory to present their research activities and to identify areas where common interests and complementation could be pursued with minimal duplication of efforts. These activities have led to the following collaborative interactions with ORD's intramural nanomaterials health effects research:

- NIOSH scientists are collaborating with ORD's intramural investigators to apply unique cell biology technology and gene expression profiling at EPA to compare the molecular pathology of granulomas induced by asbestos fibers or carbon nanotubes to identify common or different mechanisms of injury.
- EPA, NIOSH, and NIEHS have collaborated in generating and funding extramural grants addressing nanomaterials health effects research needs. The results of these activities are communicated amongst the participating federal agencies in their annual grantees meeting.
- A final example of EPA's work with the National Toxicology Program is provided in the response to Question 1 from Congressman Lipinski.

From the USDA Forest Service: For the USDA Forest Service, which has no in-house expertise in nanotechnology EHS but is charged with advancing new uses for forest-derived nanomaterials and incorporating nanomaterials developed in other industry sectors into forest products, the NNI is providing: 1) extremely valuable advice and counsel on the priority issues for EHS; 2) information and coordination on how nanomaterials must be categorized and characterized with respect to EHS risks; 3) leadership with engaging public groups and entities on EHS issues and concerns; and 4) contact points in other agencies who have capabilities in EHS who can help identify risks with respect to forest-derived nanomaterials.

From NIST: Through the efforts of the NEHI Working Group and the NNCO like the September 2006 "Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials" document and the NNI/NIST Workshop mentioned above, as well as others organized by the various agencies, the agencies interact at multiple levels, which minimizes overlap and at the same time allows for considerable exchange and communication between agencies. While there is no one way to develop a research strategy, we believe that the one developed by the NNI is the best one for the agencies because—if for no other reason—the agencies participated in its development and have a commitment to it. Call it buy-in or ownership, if you will, but it's essential to creating a research agenda that the agencies themselves will support and thus fund.

Q2. On the issue of stovepiping EHS research versus integrating it into all research, do all current NNI grants currently include an EHS component? If not, should they? Why or why not?

A2. For clarification, the only "NNI grants" are through the NNI member agencies. Agency missions drive the way in which EHS research may or may not be incorporated into grants for nanomaterial and nanotechnology research and whether EHS research is an implicit or explicit component. Of the NNI's 25 participating federal agencies, 13 fund safety-related research and/or have regulatory authority to guide safe use of nanomaterials.

In some cases, the model better suited to the science is having scientists with the experience, facilities, and understanding conduct EHS research, rather than adding an EHS component to all research. But when the research effort brings interdisciplinary efforts together, EHS is clearly a part. One model is NIH grants for medical applications and pharmacological research in which EHS is not a separately funded component, but by necessity is an integral part of the research. A different model is DOD sensor work, in which EHS is a component, but the grant does not directly fund EHS research. For their parts, DOE and NSF do include an EHS requirement in their grants.

Stepping back a moment, it is important to keep in mind that the state of scientific understanding of how engineered nanoscale materials of various compositions interact with biological systems is incomplete. So government-funded basic and applied research toward understanding the EHS impacts of nanomaterials broadly falls into three areas: not only (1) research to develop instrumentation and methods for measuring, characterizing, and testing nanomaterials and for monitoring exposure and (2) research contributing to safety assessments of nanomaterials and nanomaterial-based products, but also (3) research to expand knowledge and further the understanding of how nanomaterials behave.

The very breadth and multidisciplinary nature of nanotechnology and the collaborative focus of the Nanotechnology Environmental and Health Implications (NEHI) working group expands the capabilities of agency missions.

Although not all grants by NNI member agencies include EHS components, certainly for some types of research, biomedical applications research in particular, the government is actively encouraging researchers to address safety and effectiveness issues as early as possible in the innovation cycle. Many NIH-funded research projects include safety testing as a part of routine procedures as the research progresses. As another example, one of the objectives of FDA's Critical Path Initiative is to encourage researchers to incorporate into their research, at the earliest possible stages, procedures that will help them later in the process of satisfying FDA requirements for demonstrating safety and effectiveness of the final products that might eventually emerge as a result of that research.

Questions submitted by Representative Daniel Lipinski

Q1. Much of the EHS research to date has focused on exotic materials with unrealistic exposure-scenarios. While that is useful in establishing information on an upper bound of the hazard, the context is rarely communicated and it creates fear. What is critical is that we make sure nano-enabled products are as safe or safer than what we use today.

As I understand it, the hazard of a nanomaterial often depends upon much more than the size and type of material, but also surface properties, purity, etc. that relate to how it is made. How is the toxicology work underway controlling for this? Are researchers using standardized, well characterized materials? If not, how can we make use of the research findings?

A1. Much of the EHS research to date has been focused on several of the engineered nanoscale materials being produced in the largest quantities, e.g., TiO2, and single- and multiple-walled carbon nanotubes. The current stage for producing many engineered nanoscale materials is such that the chemical composition and physical characteristics of manufactured nanomaterials can vary substantially between batches and vendors. Because of this variability and general poor characterization of materials used, research findings from much early toxicology research on engineered nanomaterials are difficult to interpret. Many studies are having to be repeated with better-characterized materials in order to establish a better understanding of the correlation of a particular biological response to a specific engineered nanoscale material. Recognizing the importance of the need for well characterized materials for the conduct of toxicology studies, the NNI agencies are funding and conducting research to develop a suite of reference materials and improved instrumentation to analyze and characterize nanomaterials, both as raw materials and as materials in biological systems. A suite of reference nanomaterials—stable materials for which the chemical and physical properties are rigorously characterized to verify the composition or properties of their products—are being developed to overcome

these problems. Within workshops and standards committee considerations NNI agencies are participating in expert discussions on what might comprise a minimum set of measurements that would enable consistency among materials used and reported on by researchers and accepted means to specify nanomaterials for efficient commerce.

Due to the numerous types of reference materials needed for different groups or classes of nanomaterials, a coordinated, interagency research effort is required to support the significant and necessary level of R&D. Pure samples are needed and instruments with the ability to determine the elemental composition, accurate dimensions, location, and chemical state of all atoms in nanomaterials must be developed. The critical and relevant physical parameters (size, shape, composition) must be identified. Reliable methods for distributing these standards also must be established. While NIST will have a major role in developing and validating instrumentation and methods, multiple NNI agencies will need to be involved. NASA and DOD will play a key role in identifying materials and processes likely to be used in the composites industry. Contributions from agencies such as the EPA and NIOSH will be essential to describing the use of these materials in environmental and workplace monitoring settings. The expertise of the NIH and FDA will be critical for identifying the relevant parameters to be characterized for health and safety research.

The National Toxicology Program (NTP) has provided and shared with EPA's intramural health and ecological effects investigators well characterized engineered/manufactured nanomaterials of common interest to both EPA and NTP in order to examine cellular models of toxicity to complement NTP's animal toxicology studies in an effort to: 1) identify alternative test methods and approaches to assess/predict the toxicity of nanomaterials; 2) develop an enhanced health effects database that could be integrated and used for health risk assessment of nanomaterials; and 3) assist or guide subsequent sub-chronic and/or chronic animal toxicity studies of engineered/manufactured nanomaterials of interest for both agencies/programs. This format using and sharing well characterized identical nanomaterials of common interest will be pursued in future NTP and EPA nanomaterials toxicological studies.

Q2. It seems that most of the early uses of nanotechnology and nanomaterials are for existing products and processes, many of which are far from ideal from a health and environmental safety perspective. What is being done to systematically compare the risks and benefits of the nanoscale alternative against the conventional approach in use today so that we accelerate the substitution of nanomaterials where they are superior (e.g., when replacing a known toxin)?

A2. The "green" potential of nanotechnology—the capacity to reduce pollution through the redesign of industrial processes and the replacement of toxic solvents, poisonous metals, and corrosive chemicals with less hazardous nanomaterials—is widely acknowledged to be great. NNI agencies funding research in green chemistry include the National Science Foundation, the Department of Energy, and the Environmental Protection Agency. EPA's recent Pollution Prevention through Nanotechnology Conference (held September 25–26, 2007) brought together representatives from industry, academia, non-governmental organizations, and government to discuss current practices and potential research in three major areas where nanotechnology can contribute to pollution prevention:

a. Products: Less toxic, less polluting, and wear-resistant.
b. Processes: More efficient and waste-reducing.
c. Energy and Resource Efficiency: Processes and products that use less energy and fewer raw materials because of greater efficiency.

Inputs from this workshop will provide guidance for both intramural and extramural funding of nanotechnology research by EPA.

Q3. The discussion around nanomaterials tends to focus on "engineered" nanomaterials which are roughly defined as those that are purposefully created. However, the volume of naturally occurring and ultrafine particles produced by combustion, as well as those used as fillers in rubber tires or plastics is many orders of magnitude greater than the newly engineered nanomaterials. What are we doing to ensure that we leverage the body of EHS knowledge on these particles? Are we missing the forest from the trees by emphasizing only "engineered nanomaterials"? What efforts are there to assess the comparative hazard posed by engineered nanomaterials against incidental or naturally occurring nanomaterials?

A3. Existing knowledge about EHS implications of ultrafine particles is being leveraged to address potential EHS concerns regarding nanomaterials, both naturally oc-

curring and engineered nanoparticles. NIOSH and DOE, for example, have drawn upon existing knowledge bases to provide guidance about workforce safety and engineered nanomaterials. Other agencies are focusing on understanding the behaviors of nanomaterials, incidental and engineered, in biological systems and the environment. Many of the analytical methods being used for characterization of engineered nanomaterials are ones that have been developed and applied to ultrafine particles. Examples include electron microscopy, dynamic light scattering, gas absorption measurements of surface area, etc. Limited research has been conducted to date that explores the comparison of effects of incidental or natural nanoscale particles with those of engineered nanomaterials.

The EPA *Nanotechnology White Paper,* Feb. 2007, recognized the paucity of data for engineered nanomaterials health effects relative to the amount of data available for ultrafine particles from emission sources. The *White Paper* also recognized the need to query existing ultrafine particle toxicity databases in order to determine the extent to which they could provide insight into the engineered nanomaterials hazard identification, mechanism(s) of injury, and mode(s) of action relative to ultrafine particles present in ambient air. These comparisons are critical to determining whether there are potentially unique health effects, and to understanding mechanisms of injury, related to the novel physicochemical properties of engineered nanomaterials. EPA's Office of Research and Development (ORD) intramural engineered nanomaterials health effects research, supported through its Nanotechnology Initiative, has started toxicology studies comparing the pulmonary and cardiovascular toxicity, hazard identification, and mechanism of injury of specific combustion particles and engineered nanomaterials. Proposals to continue the comparative toxicological assessment of environmental ultrafine particles and engineered nanomaterials are being considered by ORD for continued research support within its developing multi-year plans.

In terms of missing the forest from the trees by emphasizing only "engineered nanomaterials," research funded under the NNI has focused primarily on engineered nanomaterials, their properties, and their interactions with biosystems. However, if one takes a perspective in terms of the quantity of the two types of materials to which the general population is exposed or the quantity introduced into the environment, engineered nanomaterials are a small part of the forest. (The quantity of ultrafine particles to which the general population is and has been exposed is much greater than that for engineered nanomaterials.)

Much understanding of the implications of ultrafine particles interactions with biosystems also may be gained from studies using engineered nanomaterials since they are typically far more uniform than, for example, PM combustion byproducts in their physical and chemical properties, e.g., size distribution, chemical composition, atomic and molecular structure, than are those of ultrafine particles. These more uniform properties and the degree of control of matter at the nanoscale offered by nanotechnology are enabling major advances in our understanding of the interactions of all nanomaterials with biosystems.

Some specific examples follow of research being conducted and information being provided about working with engineered nanomaterials, built on the knowledge of working with ultrafine particles.

- EPA's Particulate Matter research program is the lead federal program examining health and environmental effects associated with exposure to airborne particulate pollution in order to support the National Ambient Air Quality Standard for Particulate Matter. A critical research goal within EPA's Particulate Matter research program is linking particulate health effects from ultrafine particles generated from the combustion of fossil fuels. EPA's Particulate Matter research will provide potentially important information regarding the dosimetry/translocation, hazard identification, and health effects of inadvertently produced ultrafine particles.
- NIOSH's experience in researching and defining characteristics, properties, and effect of ultrafine particles such as welding fumes and diesel particulates provide a strong foundation for its current nanotechnology research activities. Existing studies on human or animal exposure to ultrafine and other respirable particles provide a basis for generating hypotheses about the possible adverse health effects from exposures to similar materials on a nanoscale. The studies of ultrafine particles may provide useful data to generate hypotheses for further testing. The studies in cell cultures provide information about the cytotoxic properties of nanomaterials that can guide further research and toxicity testing in whole organisms.
- Based on leveraged research and the limited amount of information about the potential risks from handling nanomaterials in workplaces and laboratories,

NIOSH has issued its "Guidance for Handling Nanomaterials and Precautionary Measures for Employees and Workers Handling Engineered Nanomaterials" document, which is in wide circulation and has been proposed for adoption by ISO TC–229.

- Current NIOSH research includes a five-year multi-disciplinary study into the toxicity and health risks associated with occupational nanoparticle exposure. Another study examines ultrafine particle intervention studies in automotive plants.
- Within DOE, preliminary research suggests that some controls used in conventional laboratory settings will work effectively as guidance for handling engineered nanoparticles and nanostructured porous materials. Based on the available science, DOE has issued an "Approach to Nanomaterial Environmental Safety & Health" document, which compiles recommended practices for laboratory staff and information about the safety and health effects related to nanomaterials, particle measurement, and control effectiveness.
- Several of the leading researchers in the toxicology of ultrafine particles have received major grants to do nanotechnology-related toxicology research. These grants were awarded by a variety of agencies, including DOD, NSF and EPA to support research directed explicitly towards the understanding of EHS aspects of engineered nanomaterials/nanoparticles.
- Nanotechnology—specific EHS work has been done in the EPA health laboratory in rats and various in vitro systems, including human cells, and in mice. This research has in one way or another been predicated on work with basic comparisons of engineered versus other ultrafine particles.

Q4. To what extent is the toxicity research relevant to "real world" situations? To what extent are federally funded efforts using the routes of exposure or formulations that emulate the nanomaterials being used in available products?

A4. NNI member agencies are funding toxicity research they consider highly relevant to "real world" situations. For example, research is being funded to understand better the potential for exposure to engineered materials during manufacturing processes and during use of products containing engineered nanomaterials. Research is also underway aimed at improving our understanding of what happens to engineered nanomaterials as they may be introduced into the environment throughout the full life cycle of the materials and products containing these materials. Potential hazards of these materials are the other half of the potential risks posed by these materials. Research on potential hazards due to the introduction of these materials into biosystems—from the cellular level to the full system level—is also underway.

As the National Academies concluded in their 2006 assessment, it is not possible to draw general conclusions on engineered nanomaterials since not all nanomaterials are alike. There is still science to be done in this area. Research results already indicate that certain nanomaterials are safe as used in products today, while other nanomaterials cannot be safely used in living systems in unmodified form. While there are research questions still to answer, the prospects for the safe use of many, if not most, nanomaterials are great.

We know that some early research on potential toxicity of nanomaterials, including some with highly publicized results showing potential negative health effects, did not reflect "real world situations" with likely exposure dosages, pathways, or even pure samples of the materials in question. In fact, it has been shown that initial toxicity observed for carbon nanotubes in one study was due to metal contaminants in the tested samples (Ni, FE, Co)—materials used as a catalyst during the production process. In another study the mice being tested suffocated from the "instillation" (injection into the throat or lungs) of a large quantity of carbon nanotubes—not from material-specific toxic effects.

Appropriate prioritization of the Federal Government's research on potential toxicity of nanomaterials is underway through the interagency process I described in my testimony, which does factor in the need to conduct such research in a way that is relevant to real-world conditions and to focus first on the most likely exposure routes.

Q5. The NNI Authorization Act requires that a strategic plan for program activities be prepared and updated at three-year intervals. The next update is due in December 2007. Will the updated plan be released on time?

A5. Yes. Work to update the NNI Strategic Plan has been underway since early 2007 and delivery of the updated Strategic Plan to Congress as called for in the *NNI Authorization Act* is expected to be on or before December 30, 2007.

ANSWERS TO POST-HEARING QUESTIONS

Responses by E. Floyd Kvamme, Co-Chair, President's Council of Advisors on Science and Technology

Questions submitted by Chairman Brian Baird

Q1. Progress in understanding the risks of nanotechnology will require balance among fundamental research and research that is more directed and product specific. NSF funds basic environmental, health and safety (EHS) research, and at present, its research portfolio comprises 50 percent of the total federal effort in EHS research. Has PCAST reviewed the funding balance among agencies contributing to EHS research and does PCAST believe the current funding allocation represents the correct balance?

A1. PCAST's review of the NNI is ongoing, and as part of that process I met recently with NIST, FDA, NIOSH, EPA and NSF agency representatives personally to get an updated understanding of the overall approach and infrastructure for nanotechnology EHS research. The current nanotechnology EHS funding allocation among federal agencies does appear to be effectively coordinated via the NNI and naturally balanced in a manner consistent with individual agency's mission, expertise, and capacity. Through the NNI, the agencies have undertaken a number of joint solicitations and other jointly funded activities relevant to nanotechnology EHS research. The increases in basic and applied EHS research appear to be matched to the increase in capacity for high quality research. If there is one area that should receive greater funding, it is the area of metrology and standards. This area is the focus of NIST, which plans to direct a portion of its increased funding under the American Competitiveness Initiative toward nanotechnology EHS-related research (if the FY 2008 appropriation bill for NIST is passed).

Q2. PCAST was given the responsibility to serve as the statutorily created advisory committee for the National Nanotechnology Initiative. The statute requires the advisory committee to assess all aspects of the management, coordination, implementation, and content of the NNI and to report on its findings every two years to the President and Congress. The last report was released in May of 2005. What is the status of the next report, which is due this year, and when will it be made available?

A2. The PCAST anticipates reviewing the findings and recommendations from its review at its meeting on January 8, 2008. We have intentionally delayed this report somewhat to allow the council to include a review of the updated NNI strategic plan, which is to be completed by the end of the year. In my testimony presenting our first review of the NNI, I recommended that PCAST's reviews of the NNI be changed to once every three years, consistent with the period for updating the strategic plan and for the triennial reviews by the National Research Council, both of which are to be assessed in the NNAP review. It was my understanding at that time that the members viewed this quite favorably and we have, therefore, worked to this timeframe. In your reauthorization of the NNI, we would suggest that this formal change in the legislation be made.

Q3. Is PCAST satisfied that the NNI is adequately coordinating EHS research with related foreign research efforts?

A3. As called for in our last report, the NNI is taking a leadership role in coordinating EHS activities internationally, particularly within the Organization for Economic Cooperation and Development (OECD) and the International Standardization Organization (ISO). The OECD Working Party on Manufactured Nanomaterials, which is chaired by Jim Willis of the EPA, is the body that is leading efforts to share EHS information and coordinate the collaborative development of information that is needed by governments and industries worldwide. Also, Clayton Teague chairs the U.S. ANSI-accredited Technical Advisory Group and heads the U.S. delegation to the ISO technical committee on nanotechnologies, which is working to develop standards for instrumentation, reference materials, test methods, and EHS practices. ISO standards often are adopted widely and PCAST endorses the NNI's continued participation and leadership in these activities. As a result of this international work, PCAST is very pleased with the increase in international coordination that has occurred since our first report.

Q4. Dr. Maynard has suggested a mechanism for government to partner with industry to fund EHS research that would support the needs of government in formulating a regulatory framework for nanomaterials and the needs of industry on

how to develop nanotechnology safely. The idea is to use the Health Effects Institute model, which studies the health effects of air pollution. Do you believe this would be a good model for developing a government/industry research partnership for EHS research related to nanotechnology?

A4. As a general model for government-industry partnership, the Health Effects Institute is centered primarily on one area (air pollution) and essentially one industry (automakers). This model does not translate easily to the much broader area covered by nanomaterials and the diversity of nanomaterial-related EHS risks and benefits, which cannot be confined to one industry. Moreover, unlike in the case of the HEI, the information of interest and use to industry would likely be considered proprietary. Furthermore, it is not clear who would shoulder the burden and what incentives may be applied. Nonetheless, PCAST is pleased that the NNI has been reaching out to the private sector through consultative advisory boards and has reached agreement with the semiconductor, chemicals, and forest products industries. These agreements focus on strengthening government-industry interactions with respect to nanotechnology development, including the need to understand potential EHS risks. It is very possible that in our upcoming report, we will call for extending this type agreement to additional industry groups.

Q5. Mr. Ziegler and Dr. Denison have recommended that the National Academy of Sciences be tasked to take a lead role in developing the EHS research strategy and assessing its implementation over time. What is your view of this recommendation?

A5. As mentioned above, the NAS is already responsible for assessing the NNI as a whole on a triennial basis. The PCAST welcomes this review and is taking NAS recommendations from its first report into consideration in completing its current updated review of the program. According to the NNI agencies, an interagency-developed plan for EHS nanotechnology research is near completion. Therefore, it seems duplicative to ask the NAS to begin work on such a plan. Rather, it would be helpful if the Academy were asked to assess the NNI plan and provide expert review and feedback to ensure it is complete and scientifically sound. PCAST intends to review the NNI EHS research strategy when it becomes available. Subsequent review by the NAS of the strategy would be welcomed.

Q6. One of the key aspects of carrying out EHS research is to have agreed terminology and standards for characterization of nanomaterials.

Q6a. Is this getting sufficient attention under the NNI? What is the role of NIST in this area?

Q6b. Is there a role for NNI to provide direct assistance to nanotechnology companies, particularly small companies, to help them characterize new nanomaterials, which will thereby assist the companies in assessing the potential environmental and health risks of the new materials?

A6a,b. Establishing standards (in terms of materials, methods, minimum data sets for characterization, etc.) is the right area to focus attention. NIST is expanding its nanotechnology efforts here (again largely under the increased funding provided for by the ACI) and is expanding collaborations with other agencies (e.g., NCI, NCL) and industry in the process. All the agency representatives I have met have pointed to the central role of NIST in characterization and standard setting for nanotechnology. NIST recently hosted a workshop focused on nanomaterials EHS. Such work will facilitate responsible nanotechnology development across the board, including in industry and small companies, and represents some of the best assistance the NNI can provide to "raise all boats." PCAST may suggest broader roles for the NNI in future reports in this all important area of standard setting and characterization for each of the many potential suppliers of nanotechnology based products.

Questions submitted by Representative Vernon J. Ehlers

Q1. On the issue of stovepiping EHS research versus integrating it into all research, do all current NNI grants currently include and EHS component? If not, should they? Why or why not?

A1. Many current NNI grants have components relevant to nanotechnology EHS, as appropriate or related to the specific research aims. It is essential that these efforts are not separated from applications research or institute them artificially, which risks waste and redundancy in research funding. On the other hand, it would not be prudent to require that every research grant or project include an EHS com-

ponent. Some researchers do not have the capacity to do such work. Rather, all researchers should have the ability to access and share EHS information with the nanotechnology research community broadly. As PCAST completes its next review, we will, undoubtedly discuss this important area of balance between applications and EHS research and the interplay between them.

Questions submitted by Representative Daniel Lipinski

Q1. Much of the EHS research to date has focused on exotic materials with unrealistic exposure scenarios. While that is useful in establishing information on an "upper bound" of the hazard, the context is rarely communicated and it creates fear. What is critical is that we make sure nano-enabled products are as safe or safer than what we use today.

As I understand it, the hazard of a nanomaterial often depends upon much more than the size and type of material, but also surface properties, purity, etc. that relate to how it is made. How is the toxicology work underway controlling for this? Are researchers using standardized, well characterized materials? If not, how can we make use of the research findings?

A1. Although some early studies were done using nanomaterials that were poorly characterized, researchers are increasingly aware of what constitutes well-characterized samples. Scientists are in the process of identifying the relevant parameters to include to sufficiently characterize a specific nanomaterial, including size, aspect ratio, surface chemistry, and charge, for example. However, nanomaterials are extremely diverse and controlling parameters will vary for different materials. This highlights again the importance of NIST in establishing standard reference materials, methodologies, and tools to help guide the research and development community as it continues to build a knowledge base that will inform future research. As I will comment on below in response to Ranking Member Hall's question, each generation of tests will improve our knowledge of what input parameters are critical to understanding outcomes of tests.

Q2. It seems that most of the early uses of nanotechnology and nanomaterials are for existing products and processes, many of which are far from ideal from a health and environmental safety perspective. What is being done to systematically compare the risks and benefits of the nanoscale alternative against the conventional approach in use today so that we accelerate the substitution of nanomaterials where they are superior (e.g., when replacing a known toxin)?

A2. Risk vs. benefit comparisons occur on an application-specific basis (e.g., sunscreens, nanocrystalline formulations of approved drugs). To my knowledge, this process doesn't differ from the normal process of evaluating new and improved approaches for any application, whether they are nano-enabled or not.

Q3. The discussion around nanomaterials tends to focus on "engineered" nanomaterials which are roughly defined as those that are purposefully created. However, the volume of naturally occurring and ultra-fine particles produced by combustion, as well as those used as fillers in rubber tires or plastics is many orders of magnitude greater than the newly engineered nanomaterials. What are we doing to ensure that we leverage the body of EHS knowledge on these particles? Are we missing the forest from the trees by emphasizing only "engineered nanomaterials"? What efforts are there to assess the comparative hazard posed by engineered nanomaterials against incidental or naturally occurring nanomaterials?

A3. The NNI agencies are indeed leveraging experience and knowledge of the EHS implications from studies of naturally occurring and ultra-fine particles. This is a prime example why a separate entity to oversee the entire federal nanotechnology EHS research effort is not advisable, as it would create a new "stovepipe" and inevitably limit input from the expertise resident in the agencies. Furthermore, a number of structures already exist and are working along this line. For example, EPA has extensive experience dealing with particulate matter in its Office of Air and Radiation.

Q4. To what extent is the toxicity research relevant to "real world" situations? To what extent are federally funded efforts using the routes of exposure or formulations that emulate the nanomaterials being used in available products?

A4. The relevance of a given work in toxicity research to the real-world varies by study and the investigators' specific aims, and again, as mentioned earlier, current research is helping to inform future research. The National Toxicology Program,

which incorporates expertise from NIEHS, EPA, and FDA, is leading the way in systematically evaluating a number of classes of nanomaterials in commercially available products, including carbon nanotubes, gold- and silver-based particles and metal oxides.

Questions submitted by Representative Ralph M. Hall

Q1. With your semiconductor industry background, you have great experience in bringing new technologies to market. How is nanotechnology different from other technologies? How did you deal with new technology uncertainty when the semiconductor industry was in its infancy?

A1. Each new technology seems to bring its own set of challenges but, generally speaking, they are similar in that there are unknowns that must be understood and which do not tend to be discovered in an ordered fashion. Specifically, when looking at the early days of the semiconductor business, we were blessed in that the earliest text on the mechanisms at work in a semiconductor (Electrons and holes in semiconductors, with applications to transistor electronics by Dr. William Shockley—circa 1948) was a very accurate description of semiconductor phenomena. But knowing which processes would be most effective and manufacturable took a couple of decades. In the early days, we worked in germanium, silicon, gallium arsenide, as well as other materials. Germanium was most common in that it was easiest to work with. Silicon posed many problems in that its surface characteristics were difficult to understand. Years of experiments, of course, paid off in the eventual understanding of the many nuances of the material. One of the most important lessons learned was that with each succeeding series of experiments, one needed to do more characterization of the input materials to assure the accuracy of the output. Without fail, when early experiments were completed, a desire to have made additional measurements before the experiment started was present. But progress was made as each generation of data gathering used knowledge earned from the previous work. Today, in nanotechnology, a similar process is taking place. Some are critical of early experiments were of limited value because certain parameters were not specified or input materials were poorly characterized. But, if that early work informs the next set of experiments, progress is made and knowledge of what parameters and characterizations are needed in future work is established. The other essential is to share results. Published papers, conferences and other mechanisms were used in the early semiconductor days. The International Solid State Circuits Conference held each year in Philadelphia was a major meeting point. This is partly why I feel that measuring the number of publications and conferences is an important part of measuring progress at this early stage in nanotechnology development.

ANSWERS TO POST-HEARING QUESTIONS

Submitted to Vicki L. Colvin, Professor of Chemistry and Chemical Engineering; Executive Director, International Council on Nanotechnology; Director, Center for Biological and Environmental Nanotechnology, Rice University

These questions were submitted to the witness, but were not responded to by the time of publication.

Questions submitted by Chairman Brian Baird

Q1. Dr. Maynard has suggested a mechanism for government to partner with industry to fund environmental, health and safety (EHS) research that would support the needs of government in formulating a regulatory framework for nanomaterials and the needs of industry on how to develop nanotechnology safely. The idea is to use the Health Effects Institute model, which studies the health effects of air pollution. Do you believe this would be a good model for developing a government/industry research partnership for EHS research related to nanotechnology?

Q2. Is there a satisfactory level of international collaboration and coordination of EHS research? What is the role here of non-governmental organizations, such as the International Council on Nanotechnology?

Q3. The President's Council of Advisors on Science and Technology (PCAST) was assigned by the President to serve as the statutorily created outside advisory committee for the National Nanotechnology Initiative. How useful is PCAST as a means for private sector organizations to provide input to the planning and prioritization process for EHS research under the NNI? Are there other mechanisms available for stakeholders to have a voice in this process?

Q4. Mr. Ziegler and Dr. Denison have recommended that the National Academy of Sciences be tasked to take a lead role in developing the EHS research strategy and assessing its implementation over time. What is your view of this recommendation?

Q5. One of the key aspects of carrying out EHS research is to have agreed terminology and standards for characterization of nanomaterials.

a. Is this getting sufficient attention under the NNI? What is the role of NIST in this area, and do you have recommendations for how progress in these standards setting activities can be accelerated?

b. Is there a role for NNI to provide direct assistance to nanotechnology companies, particularly small companies, to help them characterize new nanomaterials, which will thereby assist the companies in assessing the potential environmental and health risks of the new materials?

Questions submitted by Representative Vernon J. Ehlers

Q1. With regard to the tools that you say are needed "to correlate the functional properties of nanomaterials," can you speak to where we are on our research to develop these tools?

Q2. On the issue of stovepiping EHS research versus integrating it into all research, do all current NNI grants currently include and EHS component? If not, should they? Why or why not?

Questions submitted by Representative Daniel Lipinski

Q1. Much of the EHS research to date has focused on exotic materials with unrealistic exposure scenarios. While that is useful in establishing information on an "upper bound" of the hazard, the context is rarely communicated and it creates fear. What is critical is that we make sure nano enabled products are as safe or safer than what we use today.

As I understand it, the hazard of a nanomaterial often depends upon much more than the size and type of material, but also surface properties, purity, etc. that relate to how it is made. How is the toxicology work underway controlling for this? Are researchers using standardized, well characterized materials? If not, how can we make use of the research findings?

Q2. It seems that most of the early uses of nanotechnology and nanomaterials are for existing products and processes, many of which are far from ideal from a health and environmental safety perspective. What is being done to systematically compare the risks and benefits of the nanoscale alternative against the conventional approach in use today so that we accelerate the substitution of nanomaterials where they are superior (e.g., when replacing a known toxin)?

Q3. The discussion around nanomaterials tends to focus on "engineered" nanomaterials which are roughly defined as those that are purposefully created. However, the volume of naturally occurring and ultrafine particles produced by combustion, as well as those used as fillers in rubber tires or plastics is many orders of magnitude greater than the newly engineered nanomaterials. What are we doing to ensure that we leverage the body of EHS knowledge on these particles? Are we missing the forest from the trees by emphasizing only "engineered nanomaterials"? What efforts are there to assess the comparative hazard posed by engineered nanomaterials against incidental or naturally occurring nanomaterials?

Q4. To what extent is the toxicity research relevant to "real world" situations? To what extent are federally funded efforts using the routes of exposure or formulations that emulate the nanomaterials being used in available products?

Questions submitted by Representative Ralph M. Hall

Q1. Please share your thoughts on the idea of establishing a separate program office to oversee EHS research. Why is such an office needed for nanomaterials versus other materials? What authorities would such an office need to have? What are the possible pitfalls of such an approach? How would you prevent the perception of adding another level of federal bureaucracy to the mix? As an alternative to creating a new office, how can we improve the mechanisms we currently have in place to achieve the same goals?

ANSWERS TO POST-HEARING QUESTIONS

Responses by Andrew D. Maynard, Chief Science Advisor, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, Washington, D.C.

Questions submitted by Chairman Brian Baird

Q1. Mr. Ziegler and Dr. Denison have recommended that the National Academy of Sciences be tasked to take a lead role in developing the environmental, health and safety (EHS) research strategy and assessing its implementation over time. What is your view of this recommendation?

A1. Two years ago, I would have strongly recommended such an action, as long as it included a strong work plan that enabled the development of a robust multi-stakeholder strategy, with a planned series of reviews and revisions. However, the U.S. Government has run out of time to develop such strategies, and needs to start taking action on doing the relevant risk research as soon as possible.

A number of reports and reviews over the past few years have identified the short-term research needed to support safe nanotechnology development.[1,2,3,4,5,6] With hundreds of commercial and consumer products making nanotechnology claims currently on the market and nanomaterials easily available for online purchasing (as I exhibited during my testimony), there is little excuse for not taking action on these research needs and questions now.

However, looking to the future, there is a need for a long-term plan of action. I would therefore recommend that the government put in place a strategy for dealing with short-term issues as soon as possible, and that the National Academy of Sciences (NAS), or a similar independent body, take a lead role in developing, reviewing and revising a longer-term research strategy. To be effective, this would require publication of a strategic plan within 12 months, followed by periodic reviews over the subsequent five years.

Commitment to a robust review/revision process is essential in order to respond adequately to the evolving development path of nanotechnologies, especially as new information on nanomaterial health and safety becomes available. In addition, *any strategic plan must be accompanied by the will, mechanisms and resources to enact it.*

Thus, my recommendation is for parallel tracks of government taking action on a short-term strategy now, with NAS or a similar organization taking the lead on longer-term planning, implementation and review of an EHS research strategy. Both tracks should have multi-stakeholder involvement, and should facilitate international coordination of research strategies and actions.

Q2. You suggested in your testimony the need for an individual to be designated to take a leadership role for EHS research under the NNI. Could you elaborate on the characteristics and functions of this leadership role and suggest how to implement the proposal?

A2. First, let me stress that any effective approach to addressing nanotechnology EHS issues must involve multiple agencies and must engage key decision-makers in the respective agencies.

However, effective leadership is imperative for this approach to succeed. A highly capable person with the time, responsibility, authority and desire to work with agencies across the Federal Government should fill this leadership role, so as to develop and enact workable solutions to the EHS nanotechnology challenges. This person would need a clear understanding of the issues involved in developing a cross-

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[1] RS/RAE (2004). Nanoscience and nanotechnologies: Opportunities and uncertainties, The Royal Society and The Royal Academy of Engineering, London, UK, 113 pp.

[2] Denison, R.A. (2005). "A proposal to increase federal funding of nanotechnology risk research to at least $100 million annually," Environmental Defense, Washington, DC.

[3] NIOSH (2005). Strategic plan for NIOSH Nanotechnology Research, National Institute for Occupational Health and Safety. Draft.

[4] Maynard, A.D. (2006). Nanotechnology: A research strategy for addressing risk, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, Washington, DC.

[5] NSET (2006). Environmental, health and safety research needs for engineered nanoscale materials. Subcommittee on Nanoscale Science, Engineering and Technology, Committee on Technology, National Science and Technology Council, Washington, DC.

[6] EPA (2007). U.S. Environmental Protection Agency *Nanotechnology White Paper,* Environmental Protection Agency, Washington, DC. EPA 100/B–07/001. February.

agency EHS research program, as well as the respect of researchers and decision-makers within the agencies.

As I envision this much-needed oversight position, the individual in this leadership role would have the assigned authority to engage and collaborate with agencies at the levels where decisions are made and to bring people to the table to find mutual solutions to hard problems. Such problems may entail identifying ways to share resources across agencies, to coordinate and integrate research activities, to work in a collaborative manner to address broad challenges, and to break down institutional barriers.

To create this proposed leadership role, it is my personal and professional opinion that Congress could include a provision in the *Twenty First Century Nanotechnology Research and Development Act* reauthorization that either establishes this authority, or requires the National Nanotechnology Initiative (NNI) to establish this authority. I recommend that Congress provide sufficient funding for this position on an annual basis.

Q3. The President's Council of Advisors on Science and Technology (PCAST) was assigned by the President to serve as the statutorily created outside advisory committee for the National Nanotechnology Initiative. How useful is PCAST as a means for private sector organizations to provide input to the planning and prioritization process for EHS research under the NNI? Are there other mechanisms available for stakeholders to have a voice in this process?

A3. PCAST draws on input from a wide range of people, through the Nanotechnology Technical Advisory Group (NTAG)—on which I serve. However, NTAG and the process of engagement and input are not transparent.

While the NTAG provides input to the review of the NNI, it is not a mechanism that is well-suited for transparent and multi-stakeholder input to the process of planning and prioritizing EHS research. Alternative mechanisms currently do not exist to achieve this, beyond the occasional public meetings and consultations held by NSET. These public meetings and consultations are not strategically effective in engaging stakeholders.

A robust review and assessment process—whether undertaken by the NAS or another organization—would lead to a significant increase in stakeholder input. But this process is too slow and cumbersome to guide strategic research and policy decisions on a regular basis. In my testimony, I propose establishing a federal advisory committee that would allow transparent input from and review of an evolving research strategy by industry, academia, non-government organizations and other stakeholders.

Q4. One of the key aspects of carrying out EHS research is to have agreed terminology and standards for characterizing nanomaterials.

- *Is this getting sufficient attention under the NNI? What is the role of NIST in this area?*
- *Is there a role for NNI to provide direct assistance to nanotechnology companies, particularly small companies, to help them characterize new nanomaterials, which will thereby assist the companies in assessing the potential environmental and health risks of new materials?*

A4. Terminology and characterization standards are essential for effective EHS research. But there are dangers in standards work unnecessarily delaying EHS research. In the first instance, it is incorrect to assume that no research can proceed until global standards are in place—research is about exploring the unknown and will frequently set the agenda for standards development, rather than being subject to it. Secondly, there is a danger in assuming that standards developed to support the commercial development and use of nanotechnologies are also suitable for governing EHS research. But there is not a one-size-fits-all solution here.

In the short-term, good research practices are needed to ensure new data can be interpreted effectively.

In the long-term, researchers need as much help as they can get in understanding the characteristics of nanomaterials, in a way that will allow for the cross-comparison and most effective use of studies.

NIST is the lead U.S. agency in developing characterization methods and has a critical role in leading in and facilitating the development of applicable standards. The NNI has supported NIST's role, but further support is needed. In addition, other agencies with EHS expertise need to be empowered to participate in the standards process, with staff time and resources made available to do the job effectively.

A central nanomaterials characterization facility focused on EHS characterization would strongly support small companies. For such a facility to be effective it must:

1. be developed within an overarching strategy for EHS research;
2. complement other approaches to materials characterization, and provides a service to developers/companies lacking the resources to do the necessary work; and
3. focus specifically on EHS-relevant characterization methodologies.

Questions submitted by Representative Vernon J. Ehlers

Q1. To date, there is no evidence of any harm from a product which uses nanotechnology. Are you worried about nanotechnology in products? Are we doing a good job of prioritizing our research efforts between final products and other byproducts of nanoproduction?

A1. The short answer to this question is: yes. I am worried about the widespread and uncontrolled use of engineered nanomaterials in products, and I do not believe we are doing a good job prioritizing research to understand the risks of either these materials, or their byproducts.

We have a great opportunity here to learn from past mistakes; to avoid significant harm and halt the development of a legacy of adverse health and environmental impacts that emerge only years or decades after consumers (including children) have been using products and exposed to unknown risks. The reality is that new engineered nanomaterials are entering the market now, with little understanding of how they will impact on health and the environment. We are aware of over 570 manufacturer-identified nanotechnology consumer products,[7] and these represent just the tip of the engineered nanomaterial iceberg. If we are to understand how to use these materials safely and wisely, we need action now.

The current research portfolio is not prioritized to address and manage the impact of these materials—or their byproducts. As I noted in my testimony, carbon nanotubes are being sold and used now, with the assumption that they are as safe as graphite. But the toxicity data—while inconclusive—suggests the material could be much more harmful. This is just one example. In the meantime, other materials, including titanium dioxide, nano silver and other nanomaterials, are being used with increasing frequency. We are doing a poor job of responding to the fact that they may present a different risk to what conventional thinking would tell us. Not all of these materials will be harmful. But without good information, is this a risk we are willing to take?

In addressing potential risks, a life cycle approach is needed—as I and a number of colleagues have highlighted in the journal *Nature*.[8] This means looking at the byproducts of production and use as well (whether they are nano or not), and the end-of-life impacts. Such an approach is fundamental to a strategic research program, and yet it is not in evidence.

Q2. On the issue of stovepiping EHS research versus integrating it into all research, do all current NNI grants currently include an EHS component? If not, should they? Why or why not?

A2. Not all federally funded nanotechnology research includes an EHS component, although an increasing number of large programs do. Yet I believe the keys here are collaboration and partnership across programs, not necessarily integration of EHS research into all aspects of research. Understanding the potential impacts of engineered nanomaterials is complex, and progress will only be made through interdisciplinary collaboration that includes the developers of materials, as well as those equipped to address potential harm.

Attempts to integrate EHS research into applications-focused projects can lead to divisive battles for resources between applications and implications research. This could lead to inexperienced researchers doing EHS research in a way that does not progress the state of knowledge. It also runs the danger of addressing very specific EHS challenges, while leaving other equally important challenges untouched. Of the majority of instances that I am aware, integrated research programs have a primary

[7] Maynard, A.D. and E. Michelson. (2007). A Nanotechnology Consumer Products Inventory." Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, Washington, DC. Available at: *http://nanotechproject.org/consumer* (accessed November 14, 2007).

[8] Maynard, A.D., R.J. Aitken, et al. (2006). "Safe handling of nanotechnology." *Nature* 444(16):267–269.

focus on developing applications, with risk-based research forming a relatively small component of the research portfolio. This does have the disadvantage of marginalizing risk research—implying that it is not as important or as worthy as the applications research. Yet if we want the highest quality of research into understanding potential adverse impacts, it must be given the same respect as any other scientific endeavor.

On the other hand, well-executed integrated programs can and do encourage close collaboration and partnerships between researchers developing applications and understanding risks. We are seeing this in some of the National Science Foundation-funded nanotechnology research centers. The Niche Manufacturing Flagship in Australia is also following this model,[9] where applications and implications researchers are working toward a common goal of developing safe and successful applications.

The bottom line is that an integrated approach can work well, but is not always the best way to address every important EHS issue. Rather, mechanisms and funding are needed that enable strong partnerships and collaborations between applications and implications researchers, either within or outside research programs.

Questions submitted by Representative Daniel Lipinski

Q1. Much of the EHS research to date has focused on exotic materials with unrealistic exposure scenarios. While that is useful in establishing information on an "upper bound" of the hazard, the context is rarely communicated and it creates fear. What is critical is that we make sure nano-enabled products are as safe or safer than what we use today.

As I understand it, the hazard of a nanomaterial often depends upon much more than the size and type of material, but also surface properties, purity, etc., that relate to how it is made. How is the toxicology work underway controlling for this? Are researchers using standardized, well characterized materials? If not, how can we make use of the research findings?

A1. The attributes underlying nanomaterial hazard are complex, and we are just beginning to learn what is important. As others and I have noted in previous publications, we need to explore somewhat artificial (i.e., not necessarily commercially relevant) nanomaterials, to understand what attributes are important and why. But we also need more targeted research that addresses materials that are in or will enter commercial production. Both approaches are complementary.

I do not believe that EHS research that explores how well-defined (but not necessarily commercially relevant) nanomaterials behave necessarily creates fear, any more than basic research into how the world works creates false hope. However, it is possible that people sometimes miscommunicate or misunderstand such research. In this case, rather than limiting important research from fear of how people will react to the findings, there needs to be greater education and engagement on nanotechnology between policy-makers, industry and the public, to enable informed decision-making. This is a recommendation I make in my written testimony.

Regarding the challenges of characterizing materials used in investigations, it is essential that researchers adequately describe the materials and study protocols they use, if studies are to be interpreted and compared effectively. This is not an easy task: researchers are having to learn new techniques and protocols, and we are not yet sure how we should be characterizing nanomaterials in toxicity or exposure studies. A number of groups are currently working on this, including the International Council On Nanotechnology (ICON) and the American Chemistry Council nanotechnology panel. But it is researchers in academia and industry, who are frustrated by the lack of guidance and progress from the Federal Government on nanomaterial characterization approaches, who are driving current efforts.

Q2. It seems that most of the early uses of nanotechnology and nanomaterials are for existing products and processes, many of which are far from ideal from a health and environmental safety perspective. What is being done to systematically compare the risks and benefits of the nanoscale alternative against the conventional approach in use today so that we accelerate the substitution of nanomaterials where they are superior (e.g., when replacing a known toxin)?

A2. There is some work underway to compare the risks and benefits of nanoscale alternatives against conventional materials; however, a clear systematic approach has not yet been established. Many manufacturers of new commercial nanoproducts

[9] Niche Manufacturing Flagship. Available at: *http://www.csiro.au/org/NicheManufacturingFlagshipOverview.html* (accessed October 19, 2007).

make claims about the benefits of their products as compared to conventional products; however, it is unclear the extent to which they are systematically evaluating the risks of the nanomaterials or nanoproducts they create or use to comparable products made with larger-scale materials. Yet, in recent years, conferences, papers, and researchers have encouraged the incorporation of life cycle assessment (LCA) or life cycle thinking into nanomaterial and product design and development to create products that are safer and greener during production, use and at end-of-life.

Green nanotechnology approaches encourage the replacement of existing products with new nanoproducts that are more environmentally friendly throughout their life cycles, among other risk mitigation goals. Ultimately, green nano may help accelerate the substitution of nanomaterials where they are superior as well as safe.

A number of scientists are engaging in this area as described in the Project on Emerging Nanotechnologies' *Green Nanotechnology* report.[10] These scientists are applying the lessons from green chemistry and green engineering to nanotechnology in their laboratories and incorporating life cycle thinking into the design and production of new nanomaterials and products. These chemists and engineers seek to design processes that are as clean and efficient as possible, use both benign and less toxic material inputs, and prevent waste.

Efforts to develop systematic approaches to evaluating the risks and benefits of nanomaterials include (a) a recent study by researchers at the Oregon Nanoscience and Microtechnologies Institute applying the principles of green chemistry to nanoscience,[11] and (b) a nanotechnology life cycle assessment workshop of international experts convened in October 2006 by the European Commission's Nano & Converging Science and Technologies Unit, EPA's Office of Research & Development, and the Project on Emerging Nanotechnologies. This collaboration resulted in a joint report on nanotechnology and life cycle assessment.[12] This report provides recommendations for moving forward with assessing the life cycle impacts of nanotechnologies without near-perfect data. EPA is actively studying the positive environmental uses of nanotechnology, as compared to existing technologies and materials. The agency's National Center for Environmental Research is funding grants for research in green nanotechnology.

As laudable as these initiatives are, they will be ineffective if not pursued within the context of a strategic plan. Nanotechnology cannot be seen in isolation, and the potential impacts of developing and using specific nanotechnology solutions need to be balanced against the risks of not pursuing these technologies. Yet this does not give *carte blanche* to implementing nanotechnology solutions that look good, but have not been fully evaluated. The prudent approach is to develop these technologies with as clear an understanding of the science-based pros and cons as possible. This will only happen within the context of a top-down research strategy.

Q3. The discussion around nanomaterials tends to focus on "engineered" nanomaterials which are roughly defined as those that are purposely created. However, the volume of naturally occurring and ultra-fine particles produced by combustion, as well as those used as fillers in rubber tires or plastics is many orders of magnitude greater than the newly engineered nanomaterials. What are we doing to ensure that we leverage the body of EHS knowledge on these particles? Are we missing the forest from the trees by emphasizing only "engineered nanomaterials"? What efforts are there to assess the comparative hazard posed by engineered nanomaterials against incidental or naturally occurring nanomaterials?

A3. In addressing the potential impact of engineered nanomaterials, there is much we can learn from the impacts of incidental nanomaterials on human health and the environment. But nanotechnology also provides the tools to create new nanoscale materials to which our bodies have not been exposed before, and have not necessarily evolved to deal with. While it is often useful to discuss incidental and engineered nanomaterials as separate issues, a strong research strategy should integrate knowledge on both areas.

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[10] Schmidt, K. (2007). "Green nanotechnology: It's easier than you think." PEN 08. Washington, DC, Woodrow Wilson International Center for Scholars, Project on Emerging Nanotechnologies. Available at: *http://www.nanotechproject.org/file_download/187* (accessed November 15, 2007).

[11] Dahl, J.A., B.L.S. Maddux, and J.E. Hutchison. 2007. "Toward Greener Nanosynthesis." *Chem. Rev.* 107(6):2228–2269.

[12] PEN and EC. (2007). "Nanotechnology and Life Cycle Assessment: A Systems Approach to Nanotechnology and the Environment. Synthesis of results obtained at a workshop in Washington, DC, October 2–3, 2006." Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, and European Commission. Available at: *http://www.nanotechproject.org/fileG5–download/168* (accessed November 15, 2007).

EHS research is conducted to protect people and the environment, irrespective of the type of harmful agent. Thus, having a strategic research plan that enables a free flow of information from where it resides to where it is needed—regardless of how the technologies or the materials are classified—is essential. In developing the Project on Emerging Nanotechnologies' publicly accessible EHS research database,[13] we recognized the importance of having access to information on all types of nanomaterials. For this reason, we include and categorize research addressing both incidental and naturally occurring nanomaterials.

But the bottom line is that engineered nanomaterials present unique potential threats to our health and the environment; while we can and must learn from associated research areas, we need a strategy that clearly articulates the nanotechnology-specific questions that need answering, and how they are to be answered.

Q4. To what extent is the toxicity research relevant to "real world" situations? To what extent are federally funded efforts using the routes of exposure or formulation that emulate the nanomaterials being used in available products?

A4. Strategic research is needed both on fundamental mechanisms of action of nanomaterials in humans and the environment—which will help predict the behavior of new nanomaterials and develop new understanding of what makes them harmful—and on specific nanomaterials in commerce. But without a clear strategy, there will be no coordination of these complementary approaches, and no hope of making systematic progress. This is the situation we find ourselves in now.

In my analysis of the research portfolio last year, it was clear that a bottom-up approach to EHS research (i.e., one where the researchers dictate the agenda) has led to a preponderance of scientifically interesting studies of questionable relevance, and major gaps in the research portfolio for addressing commercially relevant materials and significant routes of exposure. For instance, much research has focused on carbon nanotubes and inhalation exposure. Yet relatively little research is being carried out on prevalent, although perhaps less scientifically stimulating, materials like silver nanoparticles, and other exposure routes such as ingestion.

The only way of redressing the balance is to complement bottom-up driven research with a top-down strategy, that enables goal-oriented targeted and exploratory research with the aim of providing relevant answers that industry and regulators can use.

Q5. You and Dr. Denison call for ten percent or more of the Federal Government's nanotechnology research and development budget be dedicated to goal-oriented EHS research. As pointed out by Dr. Denison's testimony, only 4.1 percent of NNI's 2008 budget is to be spent on EHS R&D. Would you please elaborate on this and explain how you came up with this 10 percent figure? Would the other panelists please comment on this recommendation?

A5. As I argue in my testimony, research funding must be tied to a research strategy, which will allow for a systematic allocation of funds and the review of progress towards clear goals. Targeted research goals arise from specific questions that need to be answered if we are to develop safe ways of using the current generation of engineered nanomaterials. In my July 2006 analysis,[14] I evaluated how much it would cost to address the most pressing questions and attained an estimate of $50 million per year. In addition to this targeted research, exploratory research (including basic research) is needed to develop the knowledge needed to ask and address longer-term questions. This research should still be goal-oriented, but its exploratory nature precludes attaching definite dollar figures to the cost of generating new knowledge. As an example, the goal of developing methods to predict the toxicity of new engineered nanomaterials requires the generation of new knowledge through exploratory research, but it is impossible to tell how much this research will cost to yield results. Yet a line must be drawn somewhere on how much funding will be allocated to such research.

The figure of 10 percent of the NNI budget for both targeted and exploratory EHS research will enable valuable research to proceed without unduly biasing the funding portfolio towards risk-based research. With less than 10 percent, exploratory re-

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[13] PEN (2007). Nanotechnology Environmental and Health Implications Inventory of Current Research. Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, Washington, DC. Available at: *http://nanotechproject.org/18* (accessed November 14, 2007)

[14] Maynard, A.D. (2006). Nanotechnology: A research strategy for addressing risk, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, Washington, DC.

search becomes starved and thus prevents the generation of new knowledge essential to tackling future problems. With more than 10 percent, it becomes hard to justify EHS research funding to managing possible (and even speculative) risks arising from associated nanotechnology research.

Assigning 10 percent of the nanotechnology R&D budget to risk research also makes a number of very clear statements: risk research and risk researchers have a credible and a critical role to play; the Federal Government is dedicated to supporting the commercial development of nanotechnology with the knowledge necessary to use it safely; and the Federal Government are committed to a transparent and accountable plan for ensuring the safe development of nanotechnology.

Questions submitted by Representative Ralph M. Hall

Q1. Please share your thoughts on the idea of establishing a separate program office to oversee EHS research. Why is such an office needed for nanomaterials versus other materials? What authorities would such an office need to have? What are the possible pitfalls of such an approach? How would you prevent the perception of adding another level of federal bureaucracy to the mix? As an alternative to creating a new office, how can we improve the mechanisms we currently have in place to achieve the same goals?

A1. I have not suggested that a separate program office is needed to oversee EHS research, but rather that *leadership* is needed (together with a strategic plan, and the resources and means to implement it) to ensure that the right research is done to underpin the development of safe nanotechnologies—and to support the U.S. Government's significant investment in nanotechnology research and development.

The current approach to ensuring the right research is done is clearly not working. I demonstrated this in my testimony with the example of carbon nanotubes—a material that anyone can purchase online and use. The questions we need to answer in order to use this material safely are not rocket science: Does exposure occur in the workplace? How can we measure it? How toxic is the material? Does it behave like asbestos? How much will be released into the environment? And so on. Yet current research plans do not seem geared to addressing pressing questions like these in a timely manner. The question is, therefore, what does it take to fix the system?

In my written testimony, I make several recommendations on actions that are needed if we are to provide industry, regulators and the public with the answers they need to develop and use the products of nanotechnology safely. From these recommendations, it is very clear that leadership with authority is needed to enable research, oversight and regulatory agencies to work within their respective authorities toward the common goal of ensuring the safety of emerging nanotechnologies. It is also clear that EHS research needs a champion—a person who understands its relevance and value; a person who can counter misconceptions that risk research is somehow a poor cousin of basic and applications-focused research; and a person who understands how risk research works.

Such leadership could reside within the current NNI structure. But to be effective, this appointed person would need to be given authority to engage agencies at the highest level in order to lead a coordinated and strategic response to the challenges raised by emerging nanotechnologies. This champion would also need the authority to channel strategic research to addressing regulatory oversight issues.

ANSWERS TO POST-HEARING QUESTIONS

Responses by Richard A. Denison[1], Senior Scientist, Environmental Defense

Introduction

Before addressing Subcommittee Members' specific questions, Environmental Defense wishes first to elaborate on the recommendations we offered in our testimony on changes needed for the NNI to effectively identify and address the potential risks of nanoscale materials, as our recommendations bear directly on many of these questions. We also wish to address what we believe to be serious mischaracterizations of our positions provided by two other witnesses at the hearing. Finally, we describe a *federal precedent and potential model for restructuring the NNI.* This model directly addresses our and others' mounting concern that nanotechnology's potential risks are not being sufficiently addressed because the same entity has been charged with both promoting and providing oversight of this technology. The restructuring we suggest would help to ensure that nanotechnology's risk implications get the attention they need, even as federal investment in nanotechnology development proceeds.

Our two main recommendations are as follows: First, we recommend creating a new entity, or elevating an existing entity, with the responsibility to develop and oversee a federal research strategy to identify, assess, and address the potential risks of nanomaterials. This entity should be provided with ample budgetary and independent management authority and sufficient resources, and should have a core public health and/or environmental mission. Second, we recommend establishing a clearer and stronger separation in decision-making and management between the parts of the Federal Government whose mission is to help develop and advance nanotechnology, and those parts charged with ensuring a thorough and objective examination of its potential risks and taking steps needed to mitigate those risks.

Hearing witnesses Dr. Clayton Teague and Mr. Floyd Kvamme inaccurately depicted Environmental Defense's recommendations in their prepared statements and in response to Subcommittee Members' questions. They repeatedly and incorrectly stated or implied that we and other witnesses critical of their efforts (a) are calling for appointment of an EHS research "czar" and (b) intend for EHS research to be conducted in isolation (in a "silo"), wholly removed from research on nanotechnology applications. Neither is the case.

Environmental Defense is indeed very concerned about the NNI's continuing lack of sufficient direction, leadership, and authority to develop and implement an effective and coherent risk research strategy across the Federal Government. This lack of focus is not the result of happenstance, in our view, but rather it is embedded in the origins and management structure of the NNI itself.

With apologies for the "alphabet soup," note that the National Nanotechnology Coordination Office (NNCO, headed by Dr. Teague) is managed under the Nanoscale Science Engineering and Technology (NSET) Subcommittee of the Committee on Technology (CoT), which is part of the National Science and Technology Council (NSTC). The NSTC is advised by the President's Council of Advisors on Science and Technology (PCAST, co-chaired by Mr. Kvamme). PCAST has been designated as the National Nanotechnology Advisory Panel (NNAP), which is charged with reviewing the federal nanotechnology research and development program.

The core mission of all of these entities is the advancement of technology in the U.S. The NNCO staff, the NSET and CoT chairs, and the PCAST/NNAP membership are populated almost entirely with *technologists*—individuals trained in materials sciences or with technology development expertise and experience.[2] From a historical perspective, this makeup is not surprising, as the NNI was created with the primary aim of advancing nanotechnology. (Of the eleven areas of activity delineated for the national nanotechnology program called for under the *21st Century Nanotechnology Research and Development Act of 2003,* only a small part of one of them addresses health or environmental implications; the other ten focus on advancing nanotechnology applications.[3])

Although the staffing and membership composition described above is quite appropriate for the NNI's work to develop and promote nanotechnology *applications,* it is entirely inappropriate when it comes to addressing nanotechnology's *implications—it potential risks.* Scientists trained and experienced in understanding health or environmental risks, rather than technologists, need to direct and implement the NNI's efforts to identify and address nanomaterial hazards and exposure potential. Delivering the right expertise is crucial, as is providing some distance from, and an effective counterbalance to, the inevitable boosterism of technologists charged with a promotional role.

The effect of the current imbalance is evident in the hearing statements of technologists Mr. Kvamme and Dr. Teague, defending the NNI's risk-related efforts. Even as they professed that the NNI is serious about addressing nanotechnology's potential risks, both witnesses claimed or implied that concerns about nanotechnology's risks are overblown. In his written statement, Mr. Kvamme stated the following:

> "Already, research is shedding light on some of the questions being asked. Specifically, a study at Purdue on the environmental impact of manufactured nanoparticles on ordinary soil showed *no negative effects;* Georgia Tech scientists are doing similar work. Researchers at Dayton University are working on the health and safety aspects of the use of nanodiamonds as drug delivery vehicles *with encouraging results.* University of Oregon chemists are looking at the use of nanomaterials to clean up toxic groundwater contaminants that have until now been difficult to remove. *In vivo* tests at Rice University have found *no immediate adverse health effects* from carbon nanotubes injected directly into the bloodstream and that the liver seems to collect these materials effectively for excretion." (emphases added)[4]

This "summary" of the available risk research on nanomaterials is highly selective and biased, as it over-generalizes findings and highlights only "exonerative" results while ignoring many other studies that indicate potential concerns. It is also entirely at odds with the far more balanced rendition of the facts provided by NNI Agency health and environmental scientists.[5]

Dr. Teague, in response to a Subcommittee Member's question, stated the following:

> "A lot of the research that was done early on, even though it was certainly not coordinated and from the Federal Government, and I think that is why some of it did produce some very premature results and a lot of wrong conclusions were drawn from it. By the careful planning and by tapping into the depth of experts within the Federal Government, and our collaboration with others outside, I think that we have, by far, the best approach to trying to carry out appropriate research in a careful, deliberately planned way. If one doesn't do that, the result is typically bad research and research that leads to premature and often poor results, poor understanding and leading to, I think, a lot of misleading conclusions that have already been drawn there often, because the result was not planned, not well-conducted."[6]

While we certainly have no quarrel with the need for more and better coordinated research, Dr. Teague's implication that only "bad" research has indicated the potential for risks again reflects a very biased view of the available literature. It also is not indicative of what any good health or environmental scientist in the field would state to be the case.

Indeed, a review just published in *Nanotoxicology* found that the "vast majority" of nearly 430 journal papers reporting on toxicity testing of various nanoparticles identified adverse effects in laboratory animals or cell lines.[7]

What concerns Environmental Defense most about these statements, however, is that senior NNI and PCAST members seem to believe it is their role to downplay evidence that suggests that engineered nanomaterials may pose risks to health or the environment.

The mechanism the NNI is using to address nanotechnology's potential risks is the Interagency Working Group on Nanotechnology Environmental and Health Implications (NEHI). NEHI's stated mission is to:

- provide for *exchange of information* among agencies that support nanotechnology research and those responsible for regulation and guidelines related to nanoproducts (defined as engineered nanoscale materials, nanostructured materials or nanotechnology-based devices, and their byproducts);
- *facilitate* the identification, prioritization, and implementation of research and other activities required for the responsible research and development, utilization, and oversight of nanotechnology, including research methods of life cycle analysis; and
- *promote communication* of information related to research on environmental and health implications of nanotechnology to other Government agencies and non-Government parties.[8]

Environmental Defense agrees with the importance and necessity of such "bottom-up" functions of interagency information exchange, facilitation, and communication,

but we believe they are not enough to produce and effectively implement a risk research strategy. We think the record speaks for itself: a string of unmet promises to deliver the strategy, and near-universal disappointment in the scope and quality of the interim documents delivered to date by NEHI.[9]

We support retaining and continuing to use the "bottom-up" approach to gain input from the full range of agencies and individuals with expertise in relevant fields. This approach needs to be supplemented, however, with a "top-down" capacity, designating a smaller group of senior health and environmental scientists with the authority to direct and oversee both the EHS research budgets and associated activities within and across NNI agencies. These scientists should be drawn from NNI agencies with missions to protect human health and/or the environment and related research capabilities. *Whether situated within the current NNI structure or outside of it, this executive body needs to have decision-making authority that is independent of those parts of NNI charged with advancing nanotechnology development.* (Our written testimony elaborates further on why this separation of roles is needed.)

With regard to the claim of other witnesses that Environmental Defense favors somehow isolating implications research from applications research, we absolutely do not. We fully recognize both the need for and the benefits of "cross-fertilization," as well as the importance of simultaneously pursuing and sharing the results, from different lines of research. It would clearly be counterproductive to obstruct such opportunities for synergism or to impede the free flow of research ideas and results. Our point instead is that addressing risk implications requires conducting research that is both intended and directly targeted to answer specific risk-relevant questions. Such research should also be undertaken and directed by—and judgments as to its adequacy, quality and interpretation made by—scientists trained in the health or environmental sciences who work at agencies charged with the pursuit of health or environmental missions. It is equally important that the specifics of the projects and amount of funding spent on such research be transparently and clearly identified and accounted for separate from applications research, some of which may well yield findings relevant to understanding risk.

A federal precedent—and potential model—for our recommended approach

Our nation has faced similar situations in the past, when mounting concern that a technology's potential risks received insufficient attention because the same entity had been charged with both promoting and providing oversight of that technology. The Atomic Energy Commission (AEC), for example, first established by the *Atomic Energy Act of 1946,* was explicitly assigned the functions of both encouraging the use of nuclear power and regulating its safety. Concerns about this dual charge grew among both proponents and critics of nuclear power, coming to a head in the mid-1970s, when Congress abolished the AEC. Congress then assigned the oversight functions of the AEC to a new entity, the Nuclear Regulatory Commission (NRC), and shifted federal nuclear energy research and development to the U.S. Department of Energy (DOE).[10]

The NRC's mission and work specifically includes risk research: "As part of its regulatory program, the NRC conducts an extensive research program to provide independent information and expertise to support its safety decision-making."[11] This research is conducted through the NRC's Office of Regulatory Research, which "[p]rovides leadership and plans, recommends, manages and implements programs of nuclear regulatory research." The Office also engages in considerable cooperative research with "DOE and other federal agencies, the nuclear power industry, U.S. universities, and international partners."[12] However, it operates and is managed independently, and the NRC has in place extensive guidelines and procedures intended to assure it avoids conflicts of interest (COI) that could arise from its use of DOE laboratories for technical assistance and research,[13] or from its hiring contractors who have also worked on or are competing for DOE contracts.[14]

Hence—far from operating in a "silo" and being unable to take advantage of the "cross-fertilization" arising from research conducted on applications—the NRC has established an approach intended to allow for safety research to be conducted in a manner that transparently manages COI, while also maintaining its independent decision-making. While we make no representation as to the NRC's performance, we believe the Committee should seriously examine the NRC example as a precedent and potential model for the kinds of changes that may be needed to reform the NNI. Such reform would, in our view, help to ensure that nanotechnology's risk implications get the attention they need, even as federal investment in nanotechnology development proceeds.

Our specific responses to Questions for the Record follow.

Questions submitted by Chairman Brian Baird

Q1. Dr. Maynard has suggested a mechanism for government to partner with industry to fund environmental, health and safety (EHS) research that would support the needs of government in formulating a regulatory framework for nanomaterials and the needs of industry on how to develop nanotechnology safely. The idea is to use the Health Effects Institute model, which studies the health effects of air pollution. Do you believe this would be a good model for developing a government/industry research partnership for EHS research related to nanotechnology?

A1. We agree that the Health Effects Institute (HEI) provides a good model for governing public-private research partnerships, for several reasons. First, because the research findings have implications for needed regulatory controls that may be controversial, it would be beneficial to have an objective, scientifically excellent third party, which neither makes nor is a stakeholder in policy-making (i.e., is outside of government and the regulated industry), conduct such research. Second, given the considerable technical demands of the research, the HEI model—which employs the finest academic scientists as research planners, performers and peer reviewers—will help assure high-quality and credible research results. Third, situating this research in a high-quality independent institution will help foster the development of a focused and consistent research strategy in a way that may be more difficult to achieve with multiple competing government agencies. Finally, HEI employs a number of governance and operational procedures to help ensure transparency, credibility and integrity in its research; these include a commitment to release all research results (positive or negative), reliance on governance and advice by independent expert committees, and insulation of the review and release process from sponsor influence.

Q2. The President's Council of Advisors on Science and Technology (PCAST) was assigned by the President to serve as the statutorily created outside advisory committee for the National Nanotechnology Initiative. How useful is PCAST as a means for private sector organizations to provide input to the planning and prioritization process for EHS research under the NNI? Are there other mechanisms available for stakeholders to have a voice in this process?

A2. As noted in our Introduction, PCAST, like the NNI itself, has as its core mission the advancement of technology in the U.S. Not surprisingly, PCAST's membership is therefore made up almost entirely of *technologists*—individuals trained in materials sciences or with expertise and experience in the area of technology development.[15] Only three of the 36 PCAST members have health science or environmental science expertise, and none has a risk science background. This mission and composition, while appropriate for overseeing NNI's primary goals related to developing and promoting nanotechnology *applications*, are in appropriate when it comes to overseeing or judging how well the NNI is addressing nanotechnology's *implications*—its potential risks. Scientists trained and with extensive experience in understanding health or environmental risks—not technologists—need to oversee and advise NNI's efforts to identify and address nanomaterial hazards and exposure potential. In our view, PCAST's ability to effectively execute its assigned advisory tasks is impeded by the same problem we have identified within the NNI itself: insufficient separation between the promotional and oversight roles it is being expected to play.

In addition to this structural or compositional constraint, the only mechanism PCAST seems to have developed for gaining outside input—its Nanotechnology Technical Advisory Group (NTAG)—operates virtually entirely out of sight. No description of the NTAG—its members, its mission or charge, its operating guidelines, whether or when it meets—is available on the PCAST website.[16] (In the interest of full disclosure, Environmental Defense was extended but declined an invitation to join the NTAG primarily because we were concerned that it appears to operate largely out of public view.) This approach is in marked contrast to the manner in which federal advisory committees are structured and operate, pursuant to the *Federal Advisory Committee Act* (FACA).

Q3. Dr. Maynard suggested the need for an individual to be designated to take a leadership role for EHS research under the NNI. Do you agree with this recommendation, and if so, how would you define the characteristics and functions of this leadership role and how could the proposal be implemented?

A3. We agree with the need for more centralized and independent leadership and increased decision-making authority sufficient to direct and oversee federal nanotechnology risk research, although we think that designation of a small group

of experienced individuals with a somewhat diverse set of backgrounds and expertise in health and environmental fields, rather than a single individual, may be preferable. In our Introduction, we have described in some detail the characteristics, functions and authorities such an entity would need to effectively direct a federal risk research program. We have also suggested that the Nuclear Regulatory Commission and its Office of Nuclear Regulatory Research provide both a precedent and potential model. Most important, such an executive body needs to have decision-making authority that is independent of those parts of NNI charged with advancing nanotechnology development.

Q4. One of the key aspects of carrying out EHS research is to have agreed terminology and standards for characterization of nanomaterials.

a. Is this getting sufficient attention under the NNI? What is the role of NIST in this area?

b. Is there a role for NNI to provide direct assistance to nanotechnology companies, particularly small companies, to help them characterize new nanomaterials, which will thereby assist the companies in assessing the potential environmental and health risks of the new materials?

A4a,b. While deciding on terminology and standards for characterization has proven challenging both domestically and internationally, we believe the NNI is devoting sufficient attention to these important matters. Because terminology and standards for characterization must be agreed upon by a variety of industry sectors, academic researchers, and government bodies in different countries, there is only so much the NNI can do to help the parties come to agreement. The National Institute of Standards and Technology (NIST) has an important role to play in both helping to set the standards and then developing and making available reference materials for those standards. To our knowledge, NIST is adequately engaged in these processes.

The Federal Government, through entities such as NIST and the Nanomaterial Characterization Laboratory of the National Cancer Institute, has been assisting both private sector and academic groups with nanomaterials characterization. This is indeed an important and useful role for the government to play, and the NNI should encourage its member agencies to assist with characterization. The NNI itself does not have the facilities to carry this out.

Questions submitted by Representative Vernon J. Ehlers

Q1. On the issue of stovepiping EHS research versus integrating it into all research, do all current NNI grants currently include and EHS component? If not, should they? Why or why not?

A1. The choice need not be between either incorporating an EHS component into every research grant or stovepiping risk research into a completely separate program. Environmental Defense does not believe it makes sense to compel all researchers to add EHS research questions into their projects, as—many of them may lack the relevant EHS expertise. Rather, there ought to be a mechanism to ensure that federally funded investigators pursuing basic or applications-oriented research projects, which may provide insight into EHS questions (e.g., how nanomaterials interact with biologic systems), at least share their findings with EHS researchers. They should also coordinate their studies wherever possible (e.g., by conducting testing on the same materials, utilizing the same reference materials or methods for nanomaterial characterization).

As described in our Introduction, maximizing research coordination and sharing of results among investigators conducting applications and EHS implications research is highly beneficial and should be encouraged. However, in addressing EHS implications, it is essential to conduct research that is both intended and targeted to answer specific risk-relevant questions. Scientists trained in the health or environmental sciences who work at agencies charged with the pursuit of health or environmental missions should undertake and direct this research, and they should be the judges of its adequacy, quality and interpretation. It is equally important that the specifics of the projects and amounts spent on such EHS-targeted research be transparently and clearly identified and accounted for separate from applications research, even while fully acknowledging that some applications research will yield findings relevant to understanding risk.

Questions submitted by Representative Daniel Lipinski

Q1. Much of the EHS research to date has focused on exotic materials with unrealistic exposure scenarios. While that is useful in establishing information on an "upper bound" of the hazard, the context is rarely communicated and it creates fear. What is critical is that we make sure nano-enabled products are as safe or safer than what we use today.

A1. We will address the question of "upper bound hazard" and "unrealistic exposure scenarios" under the related Question 4 below.

We do not agree that current EHS research on nanomaterials is focusing on exotic materials. Most studies to date have focused on a range of engineered nanomaterials that are either already in commerce in significant amounts (e.g., titanium dioxide) or are now subject to considerable research interest and poised to enter commerce in the near future (e.g., carbon nanotubes). Some less common engineered nanomaterials (e.g., quantum dots) are confined mostly to biomedical research applications, but they are also being examined for use in a broader range of applications (e.g., photovoltaic cells, LED displays).[17]

Q1a. As I understand it, the hazard of a nanomaterial often depends upon much more than the size and type of material, but also surface properties, purity, etc. that relate to how it is made. How is the toxicology work underway controlling for this? Are researchers using standardized, well characterized materials? If not, how can we make use of the research findings?

A1a. There is currently substantial variation in the degree and quality of physicochemical characterization performed on nanomaterials used in toxicology studies.[18] The questioner is correct in suggesting that the results of studies with poor characterization are of limited use. Efforts to develop a scientific consensus are underway both domestically and internationally, and the government laboratories are setting a high standard for physicochemical characterization in their own work. The development of international voluntary standards and characterization requirements for publication in scientific journals are both underway. Lastly, NIST and its international counterparts are developing and promoting the use of standardized reference nanomaterials. All of these efforts will improve the credibility and usefulness of research results.

One obstacle to sharing characterization data is the fact that manufacturers frequently consider such information to be Confidential Business Information (CBI), which greatly impedes the ability of the government, nanomaterial users, third-party researchers, and the public to independently conduct adequate toxicity testing or interpret the results. Ultimately, fully addressing the characterization issue will require both an understanding of the types of information that are most important for nanomaterials, as well as an agreement on what information needs to be released to strike the right balance between the need to sufficiently inform and to protect legitimate CBI.

Q2. It seems that most of the early uses of nanotechnology and nanomaterials are for existing products and processes, many of which are far from ideal from a health and environmental safety perspective. What is being done to systematically compare the risks and benefits of the nanoscale alternative against the conventional approach in use today so that we accelerate the substitution of nanomaterials where they are superior (e.g., when replacing a known toxin)?

A2. We agree that most current nanomaterial applications represent incremental modifications of existing products and processes. We are not aware of evidence or analysis, however, indicating that such modifications have typically yielded any significant health or environmental benefits over the processes and products they are intended to replace. Indeed, most of the nanomaterialcontaining products introduced onto the market to date have been intended to provide other consumer benefits (e.g., stain resistance, scratch resistance, strength enhancement, etc.), not to provide direct health or environmental benefits or replace of a specific toxic chemical. (Some producers may argue that the slew of recently introduced nanosilver-containing products claiming antimicrobial activity provide health benefits, but that assertion is far from established, in our view, and could easily be offset by the harm they could cause to beneficial microbes.) Nonetheless, there is no question that considerable nanotechnology research and development is underway that is intended to deliver products and processes that offer health or environmental benefits. Nanotechnology holds significant promise in this regard.

Determining whether and to what extent risks are reduced and environmental or health benefits are realized is complex. Virtually all experts agree that a systematic comparison will require considering the full life cycles of the materials being com-

pared, and that much of the information needed to perform such comparisons may be unavailable or difficult to compile. In many cases there may also be tradeoffs: reduced energy consumption of a nano-enabled product during use might be offset by increased production energy, for example.

Proponents of Green Chemistry are already mounting efforts to ensure that its principles[19] are fully understood and applied by developers of nanomaterials.[20] While it cannot be assumed that nano-enabled products and processes will be inherently safer or yield health or environmental benefits, the potential for these outcomes exists and will be more likely to be realized through conscious design decisions.

Q3. The discussion around nanomaterials tends to focus on "engineered" nanomaterials which are roughly defined as those that are purposefully created. However, the volume of naturally occurring and ultrafine particles produced by combustion, as well as those used as fillers in rubber tires or plastics is many orders of magnitude greater than the newly engineered nanomaterials. What are we doing to ensure that we leverage the body of EHS knowledge on these particles? Are we missing the forest from the trees by emphasizing only "engineered nanomaterials"? What efforts are there to assess the comparative hazard posed by engineered nanomaterials against incidental or naturally occurring nanomaterials?

A3. Newly engineered nanomaterials have both similarities and major differences with natural or incidental combustion particles and industrial ultrafine particles that have been around for decades or longer. Several points need to be made. First, there should be no assumption that non-engineered nanoparticles to which we are exposed, or even engineered nanoparticles that have been in use for some time, are "safe." It is precisely our recognition that inhaled ultra-fine combustion particles can traverse the lungs and cause damage not only to the lungs but also elsewhere in the body (including to the cardiovascular system) that prompted much of the initial concern about engineered nanomaterials. The considerable literature and methods available on ultrafine combustion particles are indeed being used extensively to inform our efforts to understand the potential risks of engineered nanomaterials.

Second, in many cases, little or no testing of even large-volume "existing" engineered nanomaterials has been required as a condition to remain on the market, and for some of these so-called "legacy" nanomaterials, very few studies have been conducted. We would welcome greater scrutiny of such materials, as well as newer engineered nanomaterials, as well as comparisons among them.

Third, while it may be viewed as inequitable to hold newly engineered nanomaterials to a higher threshold of safety than older engineered nanomaterials, it would be an even more serious mistake to fail to ascertain the potential toxicity of newly engineered nanomaterials out of a belief that exposures will never be significant compared to more familiar materials. Some nanomaterials are being considered for use or already used in applications that will widely disperse them in the environment. For example, EPA's Office of Air and Radiation is evaluating an application for use of nano cerium oxide as a fuel additive. This application is eerily reminiscent of our experience with leaded gasoline, where initial assumptions that the lead would never be released from motor vehicle tailpipes in sufficient quantities to cause meaningful exposure or harm turned out disastrously wrong. We should not repeat this mistake with insufficiently tested nanoparticle fuel additives.

Samsung's washing machines, which claim to infuse nanosilver particles into the washwater[21] (which then go down the drain), raised objections from operators of municipal wastewater treatment facilities, who were concerned about potential environmental effects of the resulting wastewater treatment plant influents and effluents, given that silver exhibits significant ecotoxicity.[22] Other nanomaterial applications already on the market entail direct human exposure, most notably sunscreens and cosmetics; the latter are not subject to any pre-market review despite the certainty of human exposure.[23]

Fourth, the precise and highly homogeneous composition of most engineered nanomaterials, and their intended use in specific applications, could well lead to exposures of a wholly different nature and magnitude than those associated with natural or incidental nanomaterials.

Q4. To what extent is the toxicity research relevant to "real world" situations? To what extent are federally funded efforts using the routes of exposure or formulations that emulate the nanomaterials being used in available products?

A4. This question, like the preface to Mr. Lipinski's questions, is essentially asking whether the laboratory conditions used in toxicity testing realistically simulate conditions under which actual exposures occur.

There are important scientific and policy justifications for the approaches used to characterize the potential hazards of a substance, independent of how or in what form someone might be exposed to it. First, hazard characterization is intentionally conducted independent of exposure characterization (which are typically then combined to characterize risk); the former is used to identify the *inherent* hazards of a material, while the latter step is when factors affecting the nature and extent of exposure—e.g., form of the material, likely dose, etc.—are taken into account.

Second, the goal of hazard identification is to characterize the full extent of potential adverse affects that could be associated with exposure to a substance across an entire population. The exposed population will exhibit a range of responses even to the same exposure. In order to ensure that the most susceptible or vulnerable members of society are protected, hazard identification must be able to identify upper bound effects.

Third, toxicologists' obvious need to rely on animal rather than human studies requires, for sound scientific reasons, that they employ what the lay person may think are "unrealistic" exposure scenarios. Consider the very high doses typically used in animal studies. Certain adverse health effects, such as malignant tumors, are typically relatively infrequent events. Under "realistic" exposures, an effect seen in a human population at a frequency, say, of one in ten thousand to one in a million, would nevertheless be considered to occur at a high incidence.

Given that it is unrealistic and unethical to use ten thousand or a million laboratory animals in a study, we must rely on high-dose exposures to increase the chances that we will observe these rare events, should they be associated with the chemical being tested, in a much smaller number of laboratory animals, within a reasonable time span. We can then extrapolate the observed effects to predict what would occur in humans at much lower doses or over longer periods of time.

This is the risk-based approach to public health protection that has evolved over the last 60 years. Laboratory techniques have been developed to provide useful information for predicting toxicity in the "real world." While the resulting information is not perfect, and examples of inaccuracies are available, overall the information generated using validated, standardized laboratory tests allows scientists and policymakers to make informed decisions about the relative safety of different materials. All of these challenges inherent in developing a basis for predicting the effects of real world exposures apply equally to nanomaterials. They are among the reasons we are calling for more federal investment in, and a more strategic approach to, nanomaterial risk research.

With regard to our ability to know or predict what real world exposures will be, it is important to first recognize the complexity in defining what constitutes the "real world" for a class of materials like nanomaterials, the fate and behavior of which are presently poorly understood. Many nanomaterials are likely to take multiple forms when one considers the full value chain or life cycle, from production through end use and disposal or post-use management. At each stage, the potential for releases into the environment or exposures to workers, consumers or the public are possible. Clearly, there is no single "real world" situation.

Seeking to limit testing at this early stage to only certain routes of exposure or certain formulations rests on the questionable assumption that we know exactly how these materials are produced, used and disposed of, now and for the foreseeable future. Most of this information is not available, and is almost certain to change. Before C60 fullerenes ("buckyballs") started showing up in skin creams offered for sale, few would have ever predicted such a use or the associated routes of exposure. Under our current regulatory system, except in limited circumstances, even new nanomaterials can be produced and used in any number of ways without the producer or user having to inform the government or gain its approval. There is essentially no tracking of the production and use of nanomaterials. This is another reason why it is so important to gain an understanding of the inherent hazard of a material, which is relevant no matter how it may be used or encounter people or the environment.

It is also premature to assume we know or can predict how nanomaterials behave in the body or the environment. As just one example, consider the conventional wisdom has been that, once released to the environment, nanomaterials would always aggregate and lose their "nano-ness." This assumption is already proving to be wrong. Because aggregation reduces or interferes with functionality and performance, developers of these materials are finding ways to modify or treat nanomaterials to better maintain them in a dispersed state. And recent studies of carbon nanotubes have revealed that mixing them with natural river water actually leads to a stable suspension of individual CNTs, due to their interaction with humic acids present in the water.[24]

Q5. You and Dr. Maynard call for ten percent or more of the Federal Government's nanotechnology research and development budget be dedicated to goal-oriented EHS research. As pointed out in Dr. Denison's testimony, only 4.1 percent of NNI's 2008 budget is to be spent on EHS R&D. Would you please elaborate on this and explain how you came up with this 10 percent figure? Would the other panelists please comment on this recommendation?

A5. Our call to devote at least 10 percent of the Federal R&D nanotechnology budget to direct EHS research for the foreseeable future is based on an assessment of the scope, magnitude and complexity of the needed research.[25] It is also informed by reference to a number of analogous or related cost benchmarks, which are briefly noted below. Our full analysis and associated documentation is included here as Attachment 1; we prepared this analysis at the request of the National Academies' Committee to Review the National Nanotechnology Initiative.

Benchmarks we used to derive the minimum 10 percent figure include the following:

- Government and non-government experts' assessments of the costs of conducting the needed research—including basic material characterization, development of the needed infrastructure (e.g., methods, tools, instrumentation), and assessment of risks in specific exposure settings (e.g., workplaces). Each of these tasks by itself is estimated to require at least a major fraction of the 10 percent EHS investment we call for.
- Actual testing costs for identifying the hazard potential of conventional chemicals, which indicate the potential for testing costs *per substance to* extend into the millions of dollars.
- The budget—averaging $60 million annually—for a roughly analogous research program to characterize the risks of airborne particulate matter (PM), which EPA undertook based on a strategy developed and overseen by the National Academies' Board on Environmental Studies and Toxicology (BEST) between 1998 and 2004. As noted by BEST, this budget covered only a portion of EPA's and the Nation's research needs to understand the risks of airborne PM. This task, while complex, is considerably more restricted in scope than what is expected to be needed to assess potential risks of nanomaterials.

Q6. You mentioned in your testimony that over the past two years scientists at several NNI agencies and at NNI itself have published documents describing how little we know about nanomaterials' potential hazards and exposures and how much work will be needed both to address these gaps and to adequately assess risks. Yet everyday new nanotechnologies are entering the marketplace. Would you like to comment further on this finding? Would the other panelists care to address this issue?

A6. My written statement addresses this issue in considerable detail, and provides examples of the agencies' recognition of the magnitude of the research and regulatory task at hand, contrasted with the rather tepid actions being taken by those same agencies. These responses illustrate the growing disconnect between what most stakeholders—industry included—believe government should be doing in the face of nanotechnology's rapid commercialization, and what it is actually doing. This situation is at or near the point putting at risk the public's confidence in both government and industry's ability or willingness to responsibly address the development of this technology. That, in turn, puts public acceptance—and the success—of nanotechnology itself at risk.

Questions submitted by Representative Ralph M. Hall

Q1. Please share your thoughts on the idea of establishing a separate program office to oversee EHS research. Why is such an office needed for nanomaterials versus other materials? What authorities would such an office need to have? What are the possible pitfalls of such an approach? How would you prevent the perception of adding another level of federal bureaucracy to the mix? As an alternative to creating a new office, how can we improve the mechanisms we currently have in place to achieve the same goals?

A1. The Introduction to this document addresses these questions in detail.

Endnotes

1. My colleagues Drs. John Balbus and Caroline Baier-Anderson assisted in preparing our answers to these questions for the record.

2. See *www.nano.gov/html/about/nnco.html* (NNCO); *www.nano.gov/html/about/nsetmembers.html* (NSET); *www.ostp.gov/nstc/html/G5−committees.html#cot* (CoT); and *www.ostp.gov/PCAST/membership2.html* (PCAST). Only three of the 36 members of PCAST have a health science or environmental science expertise, and none has a risk science background.
3. See Section 2(b) of the Act, available at *frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=108G5−congG5−publicG5−laws&docid=f:publ153.108*
4. Statement of Mr. Floyd Kvamme, Co-Chair of the President's Council of Advisors on Science and Technology, House Science Committee hearing held on 10/31/07, page 2, available at *democrats.science.house.gov/Media/File/Commdocs/hearings/2007/research/31oct/Kvamme—testimony.pdf*
5. For example, see: U.S. Food and Drug Administration, *Nanotechnology: A Report of the U.S. Food and Drug Administration Nanotechnology Task Force,* July 25, 2007, at *www.fda.gov/nanotechnology/taskforce/report2007.pdf*; and U.S. Environmental Protection Agency, *Nanotechnology White Paper,* February 2007, at *www.epa.gov/osa/nanotech.htm*; National Institute for Occupational Safety and Health, *Strategic Plan for NIOSH Nanotechnology Research: Filling the Knowledge Gaps,* at *www.cdc.gov/niosh/topics/nanotech/stratG5−planINTRO.html*
6. Transcribed from the webcast of the hearing, starting at approximately one hour 29 minutes, available at science.edgeboss.net/real/science/scitech07/103107.smi.
7. See Hansen, Steffen Foss, Larsen, Britt H., Olsen, Stig I. and Baun, Anders, "Categorization framework to aid hazard identification of nanomaterials," *Nanotoxicology,* published online November 13, 2007.
8. See *www.nano.gov/html/society/NEHI.htm*
9. See testimony of non-government witnesses at the Committee's hearings held on November 17, 2005 (*science.house.gov/publications/hearingsG5−markupsG5−details.aspx?NewsID=979*); September 21, 2006 (*science.house.gov/publications/hearingsG5−markupsG5−details.aspx?NewsID=1186*); and October 31, 2007 (*science.house.gov/publications/hearingsG5−markupsG5−details.aspx?NewsID=2021*).
10. See "NRC—Regulator of Nuclear Safety" (*www.nrc.gov/reading-rm/doc-collections/nuregs/brochures/br0164/r4/*) and "Our History" (*www.nrc.gov/about-nrc/history.html*) on the NRC's website.
11. See "Regulatory Research" (*www.nrc.gov/about-nrc/history.html*) on the NRC's website.
12. See webpage for the Office at *www.nrc.gov/about-nrc/organization/resfuncdesc.html*
13. See NRC memoranda titled "Organizational Conflict of Interest Regarding Department of Energy Laboratories" dated January 6, 1998 (*www.nrc.gov/reading-rm/doc-collections/commission/secys/1998/secy1998-003/1998-003scy.html*) and February 5, 1999 (*www.nrc.gov/reading-rm/doc-collections/commission/secys/1999/secy1999-043/1999-043scy.html*).
14. See NRC memorandum titled "Memorandum Report: Audit of NRC Oversight of Its Federally Funded Research and Development Center," May 28, 2002 (*www.nrc.gov/reading-rm/doc-collections/insp-gen/2002/02a-011.pdf*).
15. See *www.ostp.gov/PCAST/membership2.html*
16. This situation with the NTAG is in partial contrast to PCAST itself, whose members and meeting agendas are posted at *ostp.gov/pcast/pcast.html*
17. See, for example, Evident Technologies, the self-described "leader in quantum dot product development" (*www.evidenttech.com/applications.html*).
18. One review just published in *Nanotoxicology* of nearly 430 nanoparticle toxicology papers found that, while the vast majority showed evidence of adverse effects, there was also a serious lack of characterization of the tested materials. See Hansen et al., 2007, *op. cit.*
19. See "12 Principles of Green Chemistry," *www.epa.gov/greenchemistry/pubs/principles.html*, originally developed by Paul Anastas and John Warner, *Green Chemistry: Theory and Practice* (Oxford University Press: New York, 1998).
20. See, e.g., Paul Anastas and Julie Zimmerman (2007). "Green Nanotechnology: Why We Need a Green Nano Award & How to Make it Happen." Washington, DC: Project on Emerging Nanotechnologies, Woodrow Wilson International Cen-

ter for Scholars, at *www.nanotechproject.org/fileG5−download/206*; and other information at *www.nanotechproject.org/tags?tag=green*

21. See *ww2.samsung.co.za/silvernano/silvernano/washingmachine.html*
22. See letter dated January 26, 2006 to Jim Jones, Director, EPA Office of Pesticide Programs, from Chuck Weir, Chair, Tri-TAC (a technical advisory group for Publicly Owned Treatment Works (POTWs) jointly sponsored by the California Association of Sanitation Agencies, the California Water Environment Association, and the League of California Cities), at *www.tritac.org/documents/letters/2006G5−01G5−27G5−EPAG5−SamsungG5−SilverG5−Wash.pdf*
23. Sunscreens qualify as over-the-counter (OTC) drugs, and as such are required by FDA to meet more extensive requirements than are cosmetics, though considerably fewer than for prescription drugs. With respect to pre-market approval, if a new active ingredient is used in a sunscreen, some testing is required for both efficacy and dermal effects before such a product can be marketed. Use of an already reviewed active ingredient does not require such approval. One point of remaining ambiguity, however, is the extent to which FDA will consider nano versions of active ingredients they have already reviewed in their larger forms to be new active ingredients. See U.S. Food and Drug Administration, 2007, *op. cit.*
24. Hyung H, Fortner J.D., Hughes J.B., Kim J. 2007. Natural organic matter stabilizes carbon nanotubes in the aqueous phase. *Environ. Sci. Technol.* 41(1):179–184.
25. In addition to the information and sources provided in Attachment 1, more recent reports by federal agencies have elaborated further on the broad scope of research needed. See reference in Endnote 5.

Attachment 1

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

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

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

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

Context for judging risk research spending

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

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

These initial studies only highlight how little is known about the health and environmental effects of engineered nanomaterials. Despite the uncertainty, the rapid development of nanomaterial applications is outpacing efforts to understand their implications—let alone ensure their safety. Thousands of tons of nanomaterials are already being produced each year,[5] and hundreds of products incorporating nanomaterials are already on the market.[6] The global market for nanotechnology products is expected to reach at least $1 trillion over the next decade.[7] Given the length of time it will take to develop an adequate understanding of the potential risks posed by a wide variety of nanomaterials, and to apply this knowledge to inform appropriate regulation, it is imperative that we dedicate substantial funding for comprehensive risk research programs now.

The National Nanotechnology Coordination Office (NNCO) estimates that fiscal year 2004 spending for environmental and health implications research stood at only $8.5 million, less than one percent of the total NNI budget.[8] Since then, such spending appears to be rising somewhat: Requested funding for FY 2006 from federal agencies under the NNI for health and environmental research totals $38.5 million, just under four percent of the total FY 2006 nanotechnology development budget for these agencies of $1.05 billion.[9] While an annual expenditure of $100 million represents an additional significant increase over the current level, it is still a small fraction of the more than $1 billion now being directed annually towards nanotechnology development through the National Nanotechnology Initiative (NNI).

Moreover, it is a modest investment compared to the potential benefits of risk avoidance and to the $1 trillion or more that nanotechnology is projected to provide to the world economy by 2015.[10]

Complexity of defining nanomaterial risks

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

- many fundamentally different types of materials (e.g., metal oxides, quantum dots, carbon nanotubes), and hundreds or thousands of potential variants of each;
- many novel properties potentially relevant to risk (e.g., size, structure, reactivity, surface chemistry, electrical and magnetic properties)
- many potential types of applications (e.g., fixed in a matrix vs. freely available, captive vs. dispersive use);
- many categories and types of uses (e.g., medical devices, pharmaceuticals, environmental remediation, and consumer products ranging from cosmetics to electronics);
- multiple points of potential release and exposure over the full life cycle of a given material/application (e.g., during production, use, disposal);
- multiple potential means of release (e.g., in emissions, in wastes, from products);
- multiple potential routes of exposure (e.g., inhalation, dermal, oral);
- multiple potentially exposed populations (e.g., workers, consumers as well as public); and
- potential to cause environmental as well as human health-related impacts.

Scope of needed research

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

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

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

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

Among the types of risk research needed are the following:

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

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

Benchmarks for risk research spending

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

Experts' assessments:

- Experts from a variety of fields have declared that NNI's current funding for nanotechnology risk research needs to be significantly increased. Invited experts to a workshop sponsored by the Nanoscale Science Engineering, Science and Technology Subcommittee (NSET) of the NNI, held in September 2004, called for at least a 10-fold increase in federal spending on nanotechnology risk-related research, relative to the approximately $10 million spent in FY 2004.[11]
- At that same workshop, a representative of the Nanotechnology Initiative at the National Institute for Occupational Safety and Health (NIOSH) provided an estimate of the investment needed just to begin to address workplace safety issues—which accounts for only one of the numerous settings where release and exposure to nanomaterials may occur. That estimate, which is based on an internal analysis conducted by NIOSH researchers, is that an investment of $10–20 million per year for at least 10 years will be needed—assuming the funds are able to be directed at targeted research to address specific predetermined issues. The representative further indicated that the investment necessary to identify the issues to target and to more broadly address nanotechnology implications in the workplace as the technology matures will be significantly larger.[12] (NIOSH's current funding level for this research is considerably lower, $2–3 million per year. In 2004, NIOSH initiated a five-year program to assess the toxicity of ultrafine and nanoparticles, funded at about $1.7 million in FY 2004 and about $2.3 million in FY 2005.[13] According to NNI, NIOSH has requested $3.1 million for FY 2006 for this type of work.[14])
- At a briefing held on March 22, 2005, to preview the findings of an upcoming report by the President's Council of Advisors on Science and Technology (PCAST) that has been charged with reviewing the NNI, John H. Marburger III, Science Adviser to the President and chief of the White House Office of Science and Technology Policy, noted that the toxicity studies now underway are "a drop in the bucket compared to what needs to be done."[15]
- The chemical industry has also concluded that nanotechnology risk research should be highly prioritized and highly funded relative to other activities by the NNI. In a nanotechnology development roadmap requested by the NNI, the industry identifies an essential need to increase our "understanding of the fundamental scientific principles operating at the nanoscale, including interdependent structure-property relationships." The roadmap highlights as critical research needs the following:

- development of characterization tools, including real-time characterization methods and tools and the associated infrastructure for their development and use; and
- environment, health and safety, including assessment of human health and environmental impact hazards, determination of exposure potentials for nanosized materials, and handling guidelines for operations involving nanomaterials.

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

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

Hazard endpoint testing costs:

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

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

Below we discuss several available hazard testing cost estimates.

- At one end of the spectrum is the so-called Screening Information Data Set (SIDS), developed by the Chemicals Program of the Organization for Economic Cooperation and Development (OECD), which consists of about 20 data elements and—as its name indicates—represents the minimum hazard information considered necessary to screen chemicals in order to set priorities for further scrutiny. SIDS focuses primarily on short-term toxicity to mammals (as models for human toxicity) and aquatic species (as a subset of indicators of potential ecological toxicity). The U.S. Environmental Protection Agency, which employs the SIDS in its High Production Volume (HPV) Challenge,[17] estimates the cost of producing a full set of SIDS data at $250,000 per chemical,[18] which is generally consistent with an industry estimate of up to $275,000 per chemical.[19] While SIDS is useful in setting priorities for further action among conventional chemicals, the information it provides is too limited to be sufficient to characterize the risks posed by nanomaterials.
- Testing cost estimates have been prepared in a Business Impact Assessment document prepared for the European Commission's Enterprise Directorate in support of the European Union's chemical policy proposal called REACH (for Registration, Evaluation and Authorization of Chemicals). REACH proposes different levels of testing that depend primarily on the production tonnage of a chemical. At the lowest production volumes, a base set of test data—roughly equivalent to the SIDS discussed above—would be required, the generation of which is estimated to cost -151,700 (about $198,000). The most extensive test battery applicable to the highest-volume substances—and considered generally sufficient to inform a full risk assessment—is estimated to cost -1,664,260 (about $2,170,000).[20]
- An even more extensive test battery (and perhaps a more appropriate one for characterization of many nanomaterials, at least initially) is that required of pesticides under the *Federal Insecticide, Fungicide and Rodenticide Act* (FIFRA). This hazard-only test battery consists of up to 100 individual data elements,[21] with the actual requirements varying by factors such as use

and volume of use. When supplemented with detailed exposure information, EPA generally considers this dataset sufficient to conduct a risk assessment for a pesticide. An upper estimate of $10 million per chemical for testing costs has been indicated by the Agricultural Research Service for a pesticide proposed for major food crop use, with costs for most pesticides being "significantly less."[22]

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

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

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

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

- are comprised of many entirely novel classes of materials;
- will be applied and used in ways that will create the potential for release and exposure through many more pathways (e.g., oral, dermal; via drinking water);
- in addition to being present in air emissions, may be present in wastes, water discharges and a wide array of products;
- through incorporation into products, may result in exposure of consumers, as well as the general public and workers; and
- pose potential environmental as well as human health risks that need to be considered.

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

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

Actual EPA expenditures during the first six years of the research program (FY 1998–2003) were relatively similar to the recommended amounts, as reported by NRC in its 2004 report:

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

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

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

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

Conclusion

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

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

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

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

Endnotes

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

2. See Environmental Defense's written statement submitted to the National Academies' Committee to Review the National Nanotechnology Initiative at its March 24–25, 2005 Workshop on Standards for Responsible Development of Nanotechnology, Washington DC; and letter dated November 15, 2004 from Environmental Defense to Dr. Mihail Roco, Chair, NSTC Subcommittee on Nanoscale Science, Engineering and Technology (also attached to our written statement).
3. Standard & Poor's, *Insurance: Property-Casualty Industry Survey,* July 15, 2004.
4. To assist the Committee, we attached a bibliography of references and associated abstracts of risk-related research studies on nanomaterials to our written statement provided to the Committee's at its March 24–25, 2005 workshop reviewing the National Nanotechnology Initiative.
5. See The Royal Society and the Royal Academy of Engineering, *Nanoscience and nanotechnologies: Opportunities and uncertainties,* London, July 2004, pp. 26-7, available online at *www.nanotec.org.uk/finalReport.htm.* This estimate is provided for the 2003–2004 timeframe, with rapidly escalating quantities projected thereafter.
6. See, for example, an unofficial list of nanomaterial-containing products compiled by EPA as of July 2004, posted by the ETC Group online at *www.etcgroup.org/documents/nanoproductsG5−EPA.pdf;* and a description of current nanotechnology applications at *www.nanotech-now.com/current-uses.htm*
7. See, for example, Lux Research, Sizing Nanotechnology's Value Chain, October 2004, summary available online at *www.luxresearchinc.com/press/RELEASEG5−SizingReport.pdf* "Sales of products incorporating emerging nanotechnology will rise from less than 0.1 percent of global manufacturing output today to 15 percent in 2014, totaling $2.6 trillion." Also see National Science Foundation, *Societal Implications of Nanoscience and Nanotechnology,* March 2001, p. 3, available online at *www.wtec.org/loyola/nano/NSET.Societal.Implications/nanosi.pdf* ". . .projected total worldwide market size of over $1 trillion annually in 10 to 15 years. . ."
8. E. Clayton Teague, *Responsible Development of Nanotechnology,* National Nanotechnology Coordination Office, April 2, 2004, available online at *www.technology.gov/OTPolicy/Nano/04/0402G5−Teague-Infocast.pdf*
9. National Science and Technology Council, Nanoscale Science, Engineering and Technology Subcommittee of the Committee on Technology, *The National Nanotechnology Initiative: Research and Development Leading to a Revolution in Technology and Industry: Supplement to the President's FY 2006 Budget,* March 2005, p. 38.
10. See endnote 7.
11. Phibbs, P., Daily Environment Report, 9/13/04, p. A-3, "Federal Government Urged to Boost Spending on Managing Risks Posed by Nanotechnology," quoting experts invited to NSET's Research Directions II workshop held in Washington, DC on 9/8–9/04.
12. Phibbs, P., *ibid.,* quoting NIOSH scientist Andrew Maynard's statement at NSET's Research Directions II workshop held in Washington, DC on 9/8–9/04; and A. Maynard, personal communication, 4–20–05.
13. See National Nanotechnology Initiative, "NNI Environment and Health Safety Research," available online at *www.nano.gov/html/facts/EHS.htm*
14. National Science and Technology Council, *op. cit.*
15. R. Weiss, "Nanotech Is Booming Biggest in U.S., Report Says," *Washington Post,* March 28, 2005, p. A6, available online at *www.washingtonpost.com/wp-dyn/articles/A5221-2005Mar27.html*
16. The Royal Society and the Royal Academy of Engineering, *op. cit.*, p. 48.
17. See EPA's website for the U.S. HPV Challenge, *www.epa.gov/chemrtk/volchall.htm*
18. See *www.epa.gov/chemrtk/hpvq&a.pdf*
19. See the American Chemistry Council's summary of the U.S. HPV Challenge, online at *memberexchange.americanchemistry.com/randt.nsf/unid/nnar-4dfn3h*
20. Risk & Policy Analysts Ltd, Revised Business Impact Assessment for the Consultation Document, Working Paper 4, prepared for the European Commission Enterprise Directorate-General, October 2003, Annex 1, available online at *www.rpaltd.co.uk/tools/downloads/reports/reachrevisedbia.pdf* Figures cited here assume that all listed tests are required to be conducted, that none of the

tests have previously been conducted, and that no estimation techniques are allowed as a substitute for testing.

21. Requirements are summarized at *www.epa.gov/pesticides/regulating/data.htm*. Regulations specifying testing requirements are at 40 CFR Part 158.
22. See "EPA and Pesticide Registration Issues," USDA Agricultural Research Service, available online at *www.ars.usda.gov/is/np/mba/jan97/epa.htm*
23. Board on Environmental Studies and Toxicology, *Research Priorities for Airborne Particulate Matter: I. Immediate Priorities and a Long-Range Research Portfolio,* Committee on Research Priorities for Airborne Particulate Matter, National Research Council, 1998, available online at *books.nap.edu/catalog/6131.html*
24. Board on Environmental Studies and Toxicology, *Research Priorities for Airborne Particulate Matter: IV. Continuing Research Progress,* Committee on Research Priorities for Airborne Particulate Matter, National Research Council, 2004, available online at *books.nap.edu/catalog/10957.html*
25. Board on Environmental Studies and Toxicology, 1998, *op. cit.*, Table 5.1, page 101. Amounts include research management, including research planning, budgeting, oversight, review, and dissemination, cumulatively estimated by the committee at 10 percent of project costs.
26. Board on Environmental Studies and Toxicology, 2004, *op. cit.*, Table S–1, page 6.

ANSWERS TO POST-HEARING QUESTIONS

Responses by Paul D. Ziegler, Chairman, American Chemistry Council Nanotechnology Panel

Questions submitted by Chairman Brian Baird

Q1. What do you see as the relative roles of the government and industry related to research on environmental, health and safety (EHS) aspects of nanotechnology?

A1. The Panel believes that the Federal Government and industry each have distinct but interrelated roles in EHS research pertinent to nanotechnology. The government has the primary role of identifying and conducting basic EHS research. The Federal Government is plainly in the best position to identify and coordinate government-funded research and the multi-disciplinary expertise of the many participating agencies engaged in the EHS aspects of nanotechnology. Federal research is essential to providing the underlying methods and tools critical to developing a fundamental understanding of nanoscale materials and nanotechnologies. These methods and tools can be used by all nanotechnology producers and users to fulfill their role in the responsible development of nanotechnology. Industry also has several critically important roles. First, industry should assist with and comment upon the government's identification of research priorities as industry is well-positioned to help inform the government's understanding of which nanotechnology product platforms are nearing commercialization or are commercially important. Together, the government, industry, and other stakeholders can identify research priorities that will best correlate with real world realities and challenges. Second, once equipped with the tools and methods critical to developing an understanding of nanomaterials, industry is best able to discharge its responsibility of assuming the primary role of characterizing the EHS implications of specific types of nanoscale materials or technologies that enable specific types of manufactured products.

Q2. You note in your testimony that industry's role in developing research priorities to date has been "largely restricted to passive review of decisions already made." Do you have recommendations on how to address this? Does industry have a voice through the outside advisory process for the NNI that is currently handled by the President's Council of Advisors on Science and Technology (PCAST)?

A2. The Panel believes that industry's role in the identification and communication of research priorities could be given better expression if industry were engaged earlier in the process. While PCAST provides some limited opportunity for the expression of stakeholder views in this area, it is not clear how industry's participation in PCAST (and comment upon various National Nanotechnology Coordination Office (NNCO) Nanotechnology Environmental Health Implications (NEHI) research prioritization initiatives) actually translate into the identification of research priorities. Industry's role traditionally has been one of passive comment on the *product* of a deliberative process in which it is not engaged. The Panel believes that the product of this process would be substantively enhanced and more reflective of industry's significant expertise in this area if industry were more substantively engaged in the deliberative process itself, as opposed merely to commenting upon the result of that process.

Q3. Through what mechanisms could government and industry work more collaboratively to address risk-research needs for nanotechnology? How does the American Chemistry Council's Nanotechnology Panel coordinate with federal activities?

A3. There are multiple mechanisms that facilitate collaboration between the government and industry to address effectively risk-research needs pertinent to nanotechnology. First, and as noted above, the Panel believes it could add significant value if it were more substantively engaged earlier in the deliberative process in identifying research priorities. Second, the Panel is supportive of public-private partnerships that enable both the government and industry collaboratively to fund strategically important research in targeted EHS areas. Third, the Panel has been very active in supporting the concept of and helping to build the foundational elements of the U.S. Environmental Protection Agency's (EPA) voluntary Nanoscale Materials Stewardship Program (NMSP). The Panel participated in the National Pollution Prevention Toxics Advisory Committee (NPPTAC) as a member of the *Ad Hoc* Work Group on Nanoscale Materials, and has consistently supported EPA's efforts to design and implement a voluntary program designed to collect and generate information and data on nanoscale materials. The Panel is also engaging in exten-

sive outreach to other stakeholders to help ensure the NMSP, once commenced, is successful and attracts robust participation. The Panel also has signed-on to multiple letters to Congress expressing the views of diverse stakeholders including industry, researchers, and non-government organizations, urging greater funding for EHS nanotechnology research and the funding of a National Academies' Board of Environmental Studies and Toxicology (BEST) initiative to develop and monitor implementation of a comprehensive, prioritized EHS nanotechnology research roadmap for all federal agencies. These letters are attached for your information and review.

Q4. Dr. Maynard has suggested a mechanism for government to partner with industry to fund EHS research that would support the needs of government in formulating a regulatory framework for nanomaterials and the needs of industry on how to develop nanotechnology safely. The idea is to use the Health Effects Institute model, which studies the health effects of air pollution. Do you believe this would be a good model for developing a government/industry research partnership for EHS research related to nanotechnology?

A4. The Panel believes that the Health Effects Institute (HEI) model is one of several models that may potentially serve as a suitable model for structuring government/industry research partnerships. The Panel is engaged with other stakeholders in identifying suitable models based on existing public-private partnership models. The Panel believes, however that the process of identifying a suitable model is an iterative one. More discussion is needed to identify the unique aspects of EHS nanotechnology research needs before the elements of existing models, including the HEI model, the Foundation for the National Institutes of Health model, and other relevant models, can be assessed to ensure the appropriate elements of a construct suitable to nanotechnology EHS research are identified. Once this foundational work is completed, stakeholders will be better able to build a model appropriate for EHS nanotechnology public-private partnerships. The Panel is open to considering all appropriate models, but believes that it is premature now to conclude that any one existing model, including the HEI model, is appropriate for EHS nanotechnology research purposes.

Q5. The President's Council of Advisors on Science and Technology (PCAST) was assigned by the President to serve as the statutorily created outside advisory committee for the National Nanotechnology Initiative. How useful is PCAST as a means for private sector organizations to provide input to the planning and prioritization process for EHS research under the NNI? Are there other mechanisms available for stakeholders to have a voice in this process?

A5. PCAST is, of necessity, very high-level. As such, it cannot be expected to deal explicitly with research needs at a useful level of detail. PCAST has sought external advice from stakeholders on several occasions. The pathway to more industry involvement may be elsewhere, as discussed in the response to Question 1. If desired, PCAST could be augmented with industry representatives with nanotechnology expertise.

Q6. One of the key aspects of carrying out EHS research is to have agreed terminology and standards for characterization of nanomaterials.

Q6a. Is this getting sufficient attention under the NNI? What is the role of NIST in this area?

A6a. As best as the Panel can discern, NNI's role in terminology and standards development has been expressed principally, if not exclusively, in participating in the ANSI TAG and ISO 229 standards development process. The Panel welcomes NNI's participation, and believes that it is a critical partner in these important standards setting initiatives. The Panel urges NIST and other agencies, as appropriate, to become more engaged in initiatives intended to prioritize, discuss, and help define and resolve morphology issues.

Q6b. Is there a role for NNI to provide direct assistance to nanotechnology companies, particularly small companies, to help them characterize new nanomaterials, which will thereby assist the companies in assessing the potential environmental and health risks of the new materials?

A6b. The Panel believes there is considerable merit in the suggestion that NNI has a role in providing nanotechnology companies assistance in characterizing nanomaterials with a view toward better identifying, characterizing, and mitigating potential environmental and health risks posed by nanoscale materials. The Panel would be interested in working with NNI and other interested stakeholders in exploring how best NNI could provide such assistance.

Questions submitted by Representative Vernon J. Ehlers

Q1. How does the chemical industry deal with new technology uncertainty in the development of new products?

A1. The chemical industry has a well documented and distinguished history of addressing proactively and thoroughly the implications of new technology. All Panel member companies support and promote the safe use and manufacture of products and applications of nanotechnology, as well as any new technology, consistent with the Responsible Care® Program. Responsible Care® is a global initiative of the international chemical industry that is practiced currently in 52 countries, and has been for over two decades. Participating entities share a common commitment to advancing the safe and secure management of chemical products and processes. Specific Responsible Care® practices may vary from country to country as they are determined by each country's laws and national industry association. Participating in Responsible Care® is mandatory for ACC member companies, all of which have made CEO-level commitments to uphold these program elements: measuring and publicly reporting performance; implementing the Responsible Care Security Code; applying the modern Responsible Care® management system to achieve and verify results, and obtaining independent certification that a management system is in place and functions according to professional standards.

Since 1988, ACC members have significantly improved their environmental, health, safety, and security performance through the Responsible Care Program. This commitment requires a third-party certified management system that incorporates the following product stewardship elements: ensure that health, safety, security, and environment and resource conservation are considered for all new and existing products and processes; provide information on health, safety, security, and environmental risks and pursue protective measures for employees, the public, and other key stakeholders; and support education and research on the potential health, safety, environmental effects of its products and processes. More information on the Responsible Care Program is available at *http://www.responsiblecare.com*.

The Panel has also prepared and conducted a survey on practices followed by Panel member companies who participated in the survey. In addition to workplace practices, the Panel survey collected information on potential exposures (which were found to be exceedingly trivial), confirmed the existence and implementation of exposure control programs for nanomaterials handling, and related information pertinent to nanomaterials use and risk mitigation measures used in the workplace. The summary of this survey is available at *http://www.americanchemistry.com/nanotechnology*.

Q2. On the issue of stovepiping EHS research versus integrating it into all research, do all current NNI grants currently include an EHS component? If not, should they? Why or why not?

A2. To the best of the Panel's information and belief, not all NNI grants include an EHS component. The Panel believes that while not all NNI grants may be explicitly relevant to EHS issues, all NNI grants should include a component that explicitly seeks consideration of the EHS implications of the actions contemplated under the grant.

Questions submitted by Representative Daniel Lipinski

Q1. Much of the EHS research to date has focused on exotic materials with unrealistic exposure scenarios. While that is useful in establishing information on an "upper bound" of the hazard, the context is rarely communicated and it creates fear. What is critical is that we make sure nano-enabled products are as a safe or safer than what we use today.

As I understand it, the hazard of a nanomaterial often depends upon much more than the size and type of material, but also surface properties, purity, etc. that relate to how it is made. How is the toxicology work underway controlling for this? Are researchers using standardized, well characterized materials? If not, how can we make use of the research findings?

A1. The Panel strongly advocates that all physical/chemical considerations be included in toxicology studies. As you may know, several prominent national and international symposia and workgroups convened over the past several years have strongly suggested that certain physical characteristics of study substances must be determined and reported by investigators conducting toxicological studies on nanomaterials. One set of recommendations published by Oberdöerster et al., 2005

in *Particle and Fibre Toxicology,*[1] strongly suggests specific physical properties of nanomaterials, including median size, size distribution, zeta potential, surface chemistry, surface topography, shape, etc., be characterized in conjunction with any investigation of their potential hazards. The Panel strongly suspects that research findings presented on nanomaterials that are not well characterized along the lines noted above may well distort the hazard potential of nanomaterials to the point of invalidating the findings. Research findings can be utilized to the maximum by ensuring that the subject materials are well characterized along the lines outlined above.

Q2. It seems that most of the early uses of nanotechnology and nanomaterials are for existing products and processes, many of which are far from ideal from a health and environmental safety perspective. What is being done to systematically compare the risks and benefits of the nanoscale alternative against the conventional approach in use today so that we accelerate the substitution of nanomaterials where they are superior (e.g., when replacing a known toxin)?

A2. The Panel does not necessarily agree with your statement that "many" early uses of nanotechnology are "far from ideal from a health and environmental safety perspective." That said, you raise a good point about the need to develop strong risk/benefit principles and practices to help ensure that the substitution of macro-scale materials with nanoscale materials reaps EHS benefits. The Panel is a supporter of lifecycle analyses (LCA) approaches, and believes that the application of well defined LCA tools and programs will assist innovators and others in assessing the comparative benefits of nanoscale materials over their macroscale counterparts. LCA for nanomaterials includes the assessment of potential risk throughout the product's life cycle or planned life cycle. LCA considerations include considerations from material sourcing, through production and use, to end-of-life disposal or recycling. LCA considerations should also include how the material's properties, hazards, and exposures may change during the material's life cycle (for example, because of physical interactions during manufacturing or use, or from chemical changes that may occur as it breaks down after disposal).

EPA's Design for the Environment (DfE) has been a leader in identifying the pollution prevention opportunities offered by nanotechnology. EPA recently convened a symposium, *Pollution Prevention Through Nanotechnology, http://www.epa.gov/oppt/nano/nanopconfinfo.htm*, in which many applications of nanoscale materials and structures were identified as having compelling pollution prevention benefits. The Panel supports continued research in LCA and related areas.

Q3. The discussion around nanomaterials tends to focus on "engineered" nanomaterials which are roughly defined as those that are purposefully created. However, the volume of naturally occurring and ultrafine particles produced by combustion, as well as those used as fillers in rubber tires or plastics is many orders of magnitude greater than the newly engineered nanomaterials. What are we doing to ensure that we leverage the body of EHS knowledge on these particles? Are we missing the forest from the trees by emphasizing only "engineered nanomaterials"? What efforts are there to assess the comparative hazard posed by engineered nanomaterials against incidental or naturally occurring nanomaterials?

A3. We concur that the volume of naturally occurring nanoscale materials and those produced through combustion products dwarf the volume of engineered nanomaterials. A key difference between engineered and non-engineered materials is that non-engineered materials may be poorly defined in a variety of ways including size and purity. Any EHS impacts are difficult to attribute to a particular property. Many engineered nanomaterials can be well defined using available tools making it easier to correlate potential EHS impacts to specific properties. Using existing LCA information from naturally occurring nanomaterials or nanomaterials that are produced incidentally is accomplished through "bridging."

Q4. To what extent is the toxicity research relevant to "real world" situations? To what extent are federally funded efforts using the routes of exposure or formulations that emulate the nanomaterials being used in available products?

A4. The Panel agrees with the implicit concern in this question, that being there may be a disconnect between ongoing federal research and near-term research needs

[1] Oberdörster G., Maynard A., Donaldson K., Castranova V., Fitzpatrick J., Ausman K., Carter J., Karn B., Kreyling W., Lai D., Olin S., Monteiro-Riviere N., Warheit D., Yang H., Principles for characterizing the potential human health effects from exposure to nanomaterials: elements of a screening strategy, *Part Fibre Toxicol* Oct. 6;2:8.

relevant "to 'real world' situations," or at the least concerned that we lack a high degree of confidence that there is a correlation between ongoing research and research results that serve real world situations. It is because of this concern the Panel has urged Congress, as set forth in the attached letters, to consider funding the NAS/BEST to prepare and implement a comprehensive federal EHS nanotechnology research roadmap.

Questions submitted by Representative Ralph M. Hall

Q1. It is our understanding that responsible manufacturers and users of nanomaterials, including presumably some of your members, are generating information about their properties that could be relevant to understanding their biological and environmental behavior. How can that information be shared so that risk assessment and risk management in general can be improved and so that developers can design more benign materials and avoid pitfalls?

A1. The Panel intends to share information through its participation in the EPA NMSP. An noted above, the Panel has been a strong and consistent supporter of the NMSP, and believes that Panel members and many other stakeholders will participate in this important voluntary program. Additionally, industry is encouraging all OECD participating countries to help develop an EHS research database as part of the ongoing efforts of the OECD's Working Party on Nanomaterials Steering Group (SG) 1 project. The objective of SG 1 is to develop a global resource that identifies research projects that address environmental, human health, and safety issues associated with manufactured nanomaterials. The database will include projects that are planned, underway, or completed, and build upon the database of the Woodrow Wilson International Center for Scholars: *Nanotechnology Health and Environmental Implications: An Inventory of Current Research.*

Industry is required to inform users of the hazards of any product, whether or not they are nanoscale materials, on Material Safety Data Sheets and labels as required by OSHA's Hazard Communication Standard. We are also required to inform EPA of any previously unknown Unreasonable Risks under the requirements of TSCA Section 8(e) for industrial chemicals and under FIFRA Section 6(a)(2) for pesticides.

Q2. Are companies holding back on the development of nanotechnology products because of a lack of regulations? Do you feel that actual nanotechnology products are being mislabeled in order to stem public concern?

A2. The Panel is unaware of any of its members "holding back" on nanotechnology innovation due to the perceived "lack of regulations." Panel members companies and many other business stakeholders are well aware of the panoply of federal and State regulations that apply to the manufacture of products, including the products of nanotechnology. The Panel thus believes that the perception that there is a "lack of regulations" is a misperception. The Panel is unaware of any specific products that are being "mislabeled" to stem public concern.

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