

**NATIONAL NANOTECHNOLOGY INITIATIVE:  
CHARTING THE COURSE FOR REAUTHORIZATION**

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**HEARING**

BEFORE THE

SUBCOMMITTEE ON SCIENCE, TECHNOLOGY, AND  
INNOVATION

OF THE

COMMITTEE ON COMMERCE,  
SCIENCE, AND TRANSPORTATION

UNITED STATES SENATE

ONE HUNDRED TENTH CONGRESS

SECOND SESSION

APRIL 24, 2008

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ONE HUNDRED TENTH CONGRESS

SECOND SESSION

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## CONTENTS

	Page
Hearing held on April 24, 2008 .....	1
Statement of Senator Kerry .....	1
Statement of Senator Stevens .....	2
Statement of Senator Thune .....	33

### WITNESSES

Ferguson, Ph.D., P. Lee, Assistant Professor, Department of Chemistry and Biochemistry, University of South Carolina .....	62
Prepared statement .....	63
Goel, M.D., Ph.D., Anita, Founder, Chairman, and Scientific Director, Nanobiosym, Inc. and Founder, Chairman, and CEO, Nanobiosym Diagnostics, Inc. ....	69
Prepared statement .....	72
Heath, Jim, Elizabeth W. Gilloon Professor and Professor of Chemistry, Director, NanoSystems Biology Cancer Center, California Institute of Technology .....	76
Prepared statement .....	78
Nordan, Matthew M., President, Lux Research, Inc. ....	38
Prepared statement .....	39
Rejeski, David, Director, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars .....	47
Prepared statement .....	50
Robinson, Robert A., Managing Director, Natural Resources and Environment, U.S. Government Accountability Office .....	18
Prepared statement .....	20
Russell, Ambassador Richard M., Associate Director and Deputy Director for Technology, Office of Science and Technology Policy, Executive Office of the President .....	3
Prepared statement .....	5



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**THURSDAY, APRIL 24, 2008**

U.S. SENATE,  
SUBCOMMITTEE ON SCIENCE, TECHNOLOGY, AND  
INNOVATION,  
COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION,  
*Washington, DC.*

The Subcommittee met, pursuant to notice, at 2:49 p.m. in room 253, Russell Senate Office Building, Hon. John Kerry, Chairman of the Subcommittee, presiding.

**OPENING STATEMENT OF HON. JOHN F. KERRY,  
U.S. SENATOR FROM MASSACHUSETTS**

Senator KERRY. This hearing will come to order. Thank you all very much. I apologize for being a little bit late. I was voting on the tail end there. We thank our witnesses for their patience. We're going to try to roll right along here.

This issue couldn't be more timely as we look forward to the next generation of nanotechnology breakthroughs. In the 8 years since President Clinton first created the National Nanotechnology Initiative, it's really become clear that our ability to manipulate, engineer, and manufacture nanoparticles provides an unlimited potential for innovation and growth throughout the economy.

In 2006, an estimated \$50 billion in products worldwide incorporated some form of nanotechnology and that figure has been projected by some to reach about 2.6 trillion over the next 8 years. Scientists are using this technology to create advanced materials and systems that will obviously improve our way of life and also revolutionize the very concepts of size and scale.

The nanotechnology revolution is occurring across all sectors. In Massachusetts, my friend Dr. Robert Linares started a company in his garage after discovering a way to use nanotechnology to turn carbon powder into diamonds. I have visited one of Dr. Linares's facilities and actually watched the team that has worked to build a diamond atom by atom. His company, Apollo Diamond, is currently working with the Defense Department to develop related technologies that will reduce collateral damage, protect soldiers and citizens, and improve the capabilities of our military aircraft.

We also know that there's extraordinary potential for nanotechnology and life sciences and we'll hear later this afternoon from Dr. Goel who is CEO of Nanobiosym Diagnostics. Dr. Goel's company

is creating portable nanotechnology-enabled devices that can rapidly and accurately provide patients with real-time access to medical diagnostic information. Even better, she's working to perfect this technology in Medford, Massachusetts, a little parochialism.

As visionaries and innovators, such as Dr. Linares and Dr. Goel, work to harness this potential, the Federal Government does have a critical role to play. As we look toward reauthorizing the National Nanotechnology Initiative at the end of this Fiscal Year, there are issues and questions that have to be addressed so we can stay out in front of our global competitors, most of whom are betting big on nanotechnology right now.

We also have a responsibility to make sure we're dedicating sufficient resources toward researching the environmental health and safety impacts of these particles.

The Chairman of the Committee asked for a GAO report to assess just how much of a priority is being placed on EHS research across the 25 agencies that administer the National Nanotechnology Initiative. GAO's response is troubling.

In 2006, just 3 percent of the \$1.3 billion designated for the National Nanotechnology Initiative was used to further EHS research. Even that statistic is a little misleading because, according to the Controller General, the agencies are using a faulty reporting structure and are not receiving appropriate guidance for how to apportion funding across multiple topics.

Funding for EHS research will be a top priority as we move forward with this reauthorization process. We need to ensure a well-coordinated, well-funded governmentwide approach to performing the research that will tell us whether these particles are safe to work around, whether they're safe for the environment, and whether they're safe for consumers once they reach the shelves.

It's obviously critical to do that research upfront so we're not asking what went wrong a hundred years from now.

I look forward to discussion with these panels and working with my colleagues on the Subcommittee, including Senator Pryor, with whom I chair the High-Tech Task Force, to draft a reauthorization proposal. I hope our discussion today will be instructive with respect to that.

Senator Stevens?

**STATEMENT OF HON. TED STEVENS,  
U.S. SENATOR FROM ALASKA**

Senator STEVENS. Well, thank you very much, Mr. Chairman. I'm delighted you're holding this hearing today on nanotechnology and the reauthorization of the National Nanotechnology Initiative.

Nanotechnology is fascinating and revolutionary in many ways and it has the potential to change and improve our lives. I do think we all think about it from the golf course to the emergency room. Nanoscience is developing novel materials and devices and systems that open up new avenues of science and engineering and controlling matter at the size of 1,000ths of the diameter of the human hair creates really an interest in the public and everyone concerned with it. I think it is such an amazing new area, that it is, as I said, just plain fascinating to me.

As this nanotechnology evolves, safety becomes the topic of great interest and I think there appears to be very little evidence so far that nanotechnology is creating any serious dangers to our Nation or is unsafe. On the contrary, I'm told medicine has used nanoparticles for at least 25 years in therapeutic medicines. Magnetic resonance imaging tests already employ nanotechnology and they've not revealed any demonstrable negative impacts on human health.

So in the absence of that, I hope that Congress and the Federal Government will not, as policymakers or administrators, overestimate our role and we will conduct ourselves in the way to support the research and avoid imposing additional regulatory regimes on this developing field of science, unless we're convinced that additional regulations is really warranted.

Mr. President—Mr. Chairman, I have to leave—

Senator KERRY. I like Mr. President. It's OK.

[Laughter.]

Senator KERRY. Even if it's very fleeting.

Senator STEVENS. I had the privilege of being President of the Senate for 4 years, so I understand what you're saying.

Chairman of the Committee, Senator Inouye and I have an appointment, however, with the Chairman of the Foreign Affairs Committee of the National Peoples Congress in China, very important meeting, so I'll have to leave soon.

I want to give my apologies to my great friend Jim Heath who's here and look forward to seeing Jim. I hope he'll stop by the office before he leaves today.

Thank you very much.

Senator KERRY. Thanks so much, Senator Stevens, and thank you for your interest in this. We know that you have a huge ability to help make the right things happen on this. this. So we really appreciate your interest in it and participation.

So Mr. Russell, thank you, Director, for being here. We appreciate that, and Mr. Robinson, why don't you guys lead off? If you can summarize your statements in about 5 minutes, your full statements will be placed in the record as if read in full, so don't fear that anything will be left out of the record, and we'll have a little more chance to explore it with the panels.

Thank you.

**STATEMENT OF AMBASSADOR RICHARD M. RUSSELL,  
ASSOCIATE DIRECTOR AND DEPUTY DIRECTOR FOR  
TECHNOLOGY, OFFICE OF SCIENCE AND TECHNOLOGY  
POLICY, EXECUTIVE OFFICE OF THE PRESIDENT**

Mr. RUSSELL. Terrific. Thank you, Chairman Kerry and Vice Chairman Stevens, and when the rest of the members of the Subcommittee come, thank them as well.

I'm very pleased to appear here before you to discuss the National Nanotechnology Initiative and issues associated with its upcoming reauthorization.

First of all, I'd like to thank the Committee on behalf of the Administration and the NNI for its bipartisan support of nanotechnology research. NNI is truly an example of the successful bipartisan effort to promote one of the most important areas of science and technology currently being sponsored by the Federal Government.

The NNI was first established during the last year of the Clinton Administration. With the support of Congress and the Bush Administration, the program has more than tripled in scale, a permanent coordinating office has been established and authorizing legislation passed and signed into law. The Committee deserves great credit for its longstanding support of the program.

I have submitted detailed written testimony which I will summarize.

NNI is built on the voluntary association of 25 Federal agencies that have activities and interests related to nanoscale science and technology. The Administration believes the organization, structure and management of the NNI is appropriate and effective and, accordingly, I urge Congress to proceed with caution in considering any fundamental changes to the structure.

In Fiscal Year 2009, the Administration has requested \$1.5 billion for the program. The NNI now represents a cumulative investment of almost \$10 billion. The NNI recently released an updated strategic plan that outlines the following four basic goals for the initiative.

Goal 1. Advanced a world class nanotechnology research and development program.

The NNI has funded thousands of individual R&D projects since its inception, contributing to U.S. world leadership in nanotechnology. While identifying meaningful metrics for evaluating U.S. global leadership in nanotechnology is challenging, by many of the measures that we do have available, the United States continues to lead in both basic and applied research, nanoscale science and technology. While the U.S. leads in many important statistics, the rest of the world is hard on our heels.

In terms of both funding and research results, Europe, Asia and now Russia are matching and in some cases exceeding our nanofunding and are hoping to take over the leadership role.

Goal 2. Foster the transfer of new technologies into products for commercial and public benefit.

The NNI has put in place a number of efforts targeted to enhance the transfer of research results into practical applications and commercialization. For example, there are over 60 interdisciplinary research centers and user facilities around the country which provide collaborative environments where researchers from academia and industry can interact, increasing the likelihood of technology transfer.

Goal 3. Develop and sustain educational resources, a skilled work force, and support infrastructure and tools to advance nanotechnology.

Education is among the chief objectives of the NNI-funded university research. In addition, there are numerous specific programs targeted at K through 12 education.

Goal 4. Support responsible development of nanotechnology, something, Mr. Chairman, you were just alluding to. As potential environment, health and safety concerns about nanotechnology begin to emerge in the early years of the initiative, an interagency EHS working group was formed.

In December 2004, the NNI released a strategic plan calling out EHS research for special attention. In September 2006, the EHS

Research Needs Report was completed. It identified 75 research needs within five general categories of EHS research. Most recently, in February 2008, a comprehensive EHS strategy was released. In addition, the National Research Council is now under contract to assess the EHS strategy.

The Federal Government needs to ensure that nano-EHS research is adequately addressed. To this end, the NNI has systematically: (1) identified research needs, (2) prioritized those needs, (3) developed an associated inventory from which a gap analysis can be performed, and (4) developed a strategy for addressing and prioritizing the needs that are not currently being addressed.

The Administration believes this systematic approach is the right way to address EHS research needs. This systematic approach has led to EHS funding being more than doubled since Fiscal Year 2005, from \$35 million to \$76 million in the Fiscal 2009 request, a growth rate significantly faster than the overall growth than NNI.

As GAO points out in its report on NNI's EHS research, and I quote, "Some environmental and industry groups have advocated for a more top-down and directed approach for setting and funding Federal nanotechnology research priorities. However, such a structure and approach is generally inconsistent with the historical approaches used to set Federal research priorities and may be difficult to implement."

We agree, and the Administration does not support establishing an arbitrary top-down EHS set-aside.

In conclusion, Mr. Chairman, the NNI has been and remains a highly successful enterprise, due in large part to the unparalleled interagency coordination and collaboration which in turn has been effective because of a voluntary bottom-up nature in which all the agencies that participate benefit.

I look forward to working with the Committee as it considers how to improve upon the successful program.

[The prepared statement of Mr. Russell follows:]

PREPARED STATEMENT OF AMBASSADOR RICHARD M. RUSSELL, ASSOCIATE DIRECTOR AND DEPUTY DIRECTOR FOR TECHNOLOGY, OFFICE OF SCIENCE AND TECHNOLOGY POLICY, EXECUTIVE OFFICE OF THE PRESIDENT

### **I. Introduction**

Chairman Kerry, Ranking Member Ensign and members of the Subcommittee, I am pleased to appear before you to discuss the National Nanotechnology Initiative (NNI) and issues associated with its upcoming reauthorization. First of all, I would like to thank this Committee on behalf of the Administration and the NNI for its bipartisan support for nanotechnology research, as well as for the good working relationship the Committee has established with our office and the representatives of the NNI.

In my testimony today, I would like to provide an overview of the NNI organization, activities, and funding, and communicate the Administration's policy priorities with respect to the upcoming reauthorization of the program, in the context of the NNI's newly updated strategic plan.<sup>1</sup> I also want to go into particular detail on nanotechnology-related environmental, health, and safety (EHS) issues.

Established in 2000 to coordinate Federal nanotechnology research and development (R&D), the NNI is built on the voluntary association of 25 Federal agencies that have activities and interests related to nanoscale science and technology. The management of the NNI is led by the Office of Science and Technology Policy

<sup>1</sup>[http://www.nano.gov/NNI\\_Strategic\\_Plan\\_2007.pdf](http://www.nano.gov/NNI_Strategic_Plan_2007.pdf).

(OSTP), which oversees the National Science and Technology Council (NSTC) and the National Nanotechnology Coordination Office (NNCO). The participating agencies of the NSTC's Subcommittee on Nanoscale Science, Engineering, and Technology (NSET) coordinates the NNCO. The NNCO provides technical and administrative support to the NSET Subcommittee, serves as a central point of contact for Federal nanotechnology R&D activities, and provides public outreach on behalf of the NNI. By providing a locus for communication, cooperation, and collaboration the NNI provides effective avenues for each individual agency to leverage the resources and expertise of all participating agencies.

The NNI has become a successful model for interagency cooperation and coordination in science and technology. From the broader perspective of the U.S. Government as a whole, this cooperation and coordination creates synergy that makes the NNI greater than the sum of its parts. The coordination in addressing potential EHS implications of nanotechnology has been particularly strong, and successful: never before have regulatory and research agencies successfully communicated so effectively on a topic of common interest, and among such a large number of agencies. Through the NNI the member agencies have been working hard to understand—and to think strategically about—nanotechnology-related EHS issues in a systematic, coordinated fashion.

The NNI enterprise does come with some “overhead” expenses. As long as those expenses are relatively modest, the voluntary interagency cooperation that has been the hallmark of the NNI will continue. But in an era when so-called “discretionary funding” accounts in the Federal budget, including R&D funding, are under extreme pressure, we need to be particularly careful not to increase the overhead expenses unduly. These expenses include not just the budget for the NNCO, but also the personnel costs at each of the agencies associated with managing a complex interagency coordinated effort like this.

The Administration believes the organization, structure, and management of the NNI is appropriate and effective, and accordingly I urge Congress to proceed with caution in considering any fundamental changes in this area.

## II. Overview and Status of NNI Goals

The NNI now represents a cumulative investment of almost \$10 billion since its inception in Fiscal Year 2001, including the President's requested NNI budget for Fiscal Year 2009. The requested investment for 2009 of \$1.5 billion and the substantial growth in this investment since 2001 reflects a shared appreciation by both this Administration and Congress of the potential for nanoscale science and technology R&D. Managed under the auspices of the NNI, these investments will expand our fundamental knowledge of this field and make important contributions to national priorities such as economic competitiveness, homeland and national security, and public health. A summary of the FY 2009 NNI Budget request broken down by agency and program component area is attached in Appendix I.

The NNI recently released an updated strategic plan that outlines the following four basic goals for the initiative:

*Goal 1: Advance a world-class nanotechnology research and development program.*

Toward this goal, the NNI has funded thousands of individual R&D projects since its inception, contributing to U.S. world leadership in nanotechnology. As indicated in the recently released President's Council of Advisors on Science and Technology (PCAST) review of the NNI,<sup>2</sup> identifying meaningful metrics for evaluating U.S. global leadership in nanotechnology is challenging. But by many of the measures that we do have available, the United States continues to lead in both basic and applied research in nanoscale science and technology.

As shown in the PCAST report, U.S.-based researchers dominate in publication of nanotechnology-related papers in three of the world's premier scientific journals, *Science*, *Nature*, and *Proceedings of the National Academy of Sciences*, rising from about 60 percent at the inception of the NNI in 2000 to over 70 percent in 2006. U.S. papers also are cited far more frequently in peer reviewed journal publications than are papers from any other country—another clear indicator of the “world-class” quality of U.S. nanotechnology research. This leadership in citations has also been sustained over the initial years of the NNI, even while other nations have also substantially increased their investments in nanotechnology R&D.

Finally, and perhaps most significantly, U.S. inventors lead the world by far in nanotechnology-enabled patents, including patents filed in three or more international patent offices. This is a clear indicator of leadership in nanotechnology intellectual property, which we would expect to ultimately translate into leadership in commercialization of nanotechnology-based products.

<sup>2</sup>[http://ostp.gov/galleries/PCAST/PCAST\\_NNAP\\_NNI\\_Assessment\\_2008.pdf](http://ostp.gov/galleries/PCAST/PCAST_NNAP_NNI_Assessment_2008.pdf)

These are all strong indicators that the United States is indeed advancing a world-class nanotechnology research and development program, in large part under the auspices of the NNI. However, we must not be complacent in evaluating our international competitiveness in nanotechnology. Also as indicated in the new PCAST report, Europe as a whole leads the world in nanotechnology publications in the Science Citation Index (SCI) data base, and China and other Asian countries are rapidly gaining on the United States and Europe in SCI publications. Therefore we must continue to sustain and increase our strategic investments in this critical area of science and technology.

*Goal 2: Foster the transfer of new technologies into products for commercial and public benefit.*

The NNI has put in place a number of efforts targeted to enhance the transfer of research results into practical applications and commercialization. Examples of successful technology transfer efforts under the NNI are included in Appendix II. Specific NNI activities supporting this technology transfer/commercialization goal include the following:

- U.S. leadership in nanotechnology patenting, an essential step in commercialization. The U.S. Patent and Trademark Office (USPTO) is working hard to assure efficient and appropriate processing of nanotechnology-related patents by creating a nanotechnology patent cross reference collection, including patents and patent applications spanning the wide range of fields of science and engineering that now involve nanoscale science and technology. USPTO is also conducting training sessions for its examiners to improve their understanding of nanotechnology.
- Agency-specific programs support application and use of nanotechnology (DOD, NASA, NIH, etc.). For example, DOD has led the way in development of electronics and sensing applications of nanotechnology, as well as in development and deployment of specialized coatings, *e.g.*, to reduce wear and maintenance costs on moving parts in the Navy fleet. NASA has led in the development of nanotechnology-enabled sensors. NIH has led in funding the development of numerous biomedical applications of nanotechnology, including a number of promising novel approaches for early detection and treatment of cancer.
- Industry liaison groups and public/private partnerships. These groups assist in exchanging information on NNI research activities and industry needs and in leveraging funds for cooperative R&D. Industry liaison groups with the electronics, forest products, and chemical industries, and with the industrial research management community, are continuing, while formation of comparable groups with other sectors (*e.g.*, the construction industry) is under consideration. One successful example is the collaboration between NSF, NIST, and the industry-led Nanoelectronics Research Initiative (NRI), where industry and government representatives collaborate in setting long-term research priorities for nanoelectronics, reviewing proposals and supporting pre-competitive research. In another example, NIH is formulating a “NanoHealth Enterprise,” which is envisioned as a partnership with other Federal agencies, private industry, and international partners to address research needs for safe development of nanoscale materials and devices.
- NNI support for the development of international standards for nanotechnology. Such standards are critical to future commercialization activities. NNCO Director Clayton Teague chairs the U.S. Technical Advisory Group (TAG) to the International Organization for Standardization (ISO) Technical Committee on Nanotechnologies (ISO TC 229). NNI agencies have provided initial financial support to the American National Standards Institute’s Nanotechnology Standards Panel (ANSI–NSP) and the ANSI-accredited TAG that represents the United States on ISO TC 229. The ANSI–NSP leads the ISO TC 229 working group on EHS aspects of nanotechnology.
- Workshops facilitating technology transfer of NNI research results. Two workshops have been held to bring together representatives from state and regional nanotechnology commercialization initiatives to learn best practices and exchange information. Other workshops have been convened to discuss opportunities and priorities for nanotechnology research in specific sub-fields, where industry participants are invited to provide input, but also where they can learn about NNI-funded research that may be of interest to their companies. In particular, the NNI agencies are now organizing a series of workshops to address research priorities in specific areas of nanotechnology-related EHS.
- Research on manufacturing at the nanoscale, or “nanomanufacturing.” Nanomanufacturing will be key to the large-scale application of nanotechnology inno-

vations for commercial and public benefit. The NNI places a special emphasis on nanomanufacturing research, as one of its eight program component areas (or PCAs). For example, NSF has established a new program dedicated to nanomanufacturing supporting individual projects and the National Nanomanufacturing Network. Several workshops have been conducted to help guide the NNI nanomanufacturing research agenda and coordinate it with industry; several more are planned for the near future.

- Industry participation in NNI research. Another way in which technology transfer takes place is within the interdisciplinary research centers and user facilities around the country. In these collaborative environments, researchers from academia and industry can interact, allowing for rapid diffusion of knowledge and increasing the likelihood of innovation.

*Goal 3: Develop and sustain educational resources, a skilled work force, and the supporting infrastructure and tools to advance nanotechnology.*

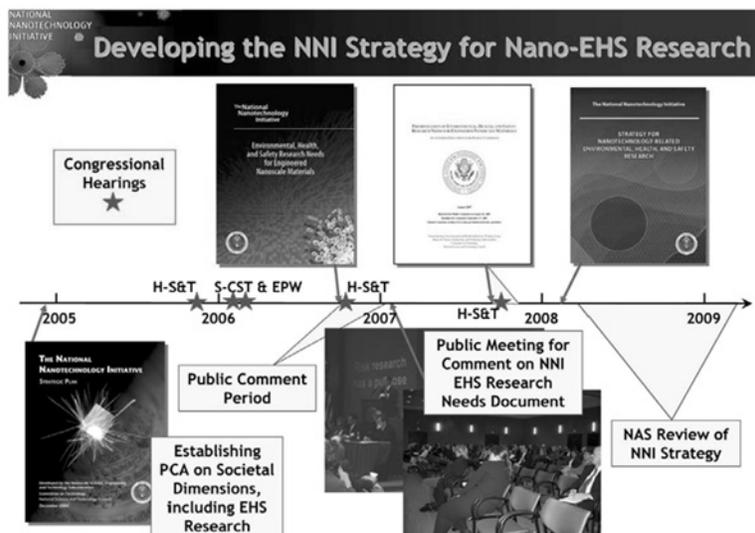
One of the chief overarching achievements of the NNI is the successful development and deployment of a unique infrastructure of nanotechnology research centers and user facilities, one that is second to none in the world. Part of the original NNI plan, this extensive network of over 60 research centers, user facilities and other infrastructure for nanotechnology research (more than 80 if you count other related centers and affiliated institutions), is now largely established. This mature infrastructure serves to accelerate nanotechnology research and development and enables researchers from across various sectors to broadly leverage their interdisciplinary intellectual and technological capital.

With respect to education and workforce development, education is among the chief objectives of NNI-funded university research. In addition, there are specific programs targeted at K–12 education, educating the public about nanotechnology, and improving nanotechnology curricula in our schools and universities. For example:

- Educational impact is among the key review criteria for NSF proposals. As a result of the NNI, thousands of undergraduate and graduate students have received training in nanoscale science and technology, providing the pipeline for nanotechnology workers and researchers that industry needs to commercialize the results of basic research in nanoscale science and technology. NSF annually supports education for about 10,000 students and teachers in the field of nanotechnology.
- The NNI has created strong incentive for interdisciplinary research at our major research institutions, and a new cadre of multi-disciplinary researchers, trained in multiple fields previously considered “diverse” and highly distinct, such as biology and solid state physics. While we retain a strong appreciation for the importance of building a solid foundation for our researchers of the future in the traditional disciplines of science and engineering, it is this “silo busting” new culture of interdisciplinary research, and the new generation of multi-disciplinary researchers emerging from the NNI-funded centers, that I consider to be one of the greatest achievements of the NNI. It is at the intersection of the traditional disciplines where we are seeing some of the most interesting and potentially beneficial applications of nanotechnology emerge.
- In addition to the general educational impact of the NNI discussed above, NNI agencies, particularly NSF, have also engaged in a number of initiatives to improve nanotechnology education, curricula, and workforce development specifically. These include the Nanotechnology Center for Learning and Teaching (NCLT) and the Nanoscale Informal Science Education (NISE) Network. Details are available in the NNI Supplement to the President’s Budget for FY 2008.
- The NNI has recently engaged the Departments of Education and Labor, and the research agencies are now working with staff from those departments to develop additional initiatives aimed at education and workforce development.

*Goal 4: Support responsible development of nanotechnology.*

The activities and issues associated with this goal have received a great deal of attention by the NNI. The original NNI implementation plan of July 2000 included a substantial section on “Societal Implications of Nanotechnology,” and requested significant resources for this activity. As potential EHS concerns about nanomaterials began to emerge in the early years of the initiative, the NNI also led the way, holding in August 2003 the first interagency meeting on this subject, which eventually led to the establishment of the formal Nanotechnology Environmental and Health Implications (NEHI) interagency working group.



In December 2004, the NNI released a strategic plan calling out EHS research for special attention, as part of a Program Component Area (PCA) on Societal Dimensions of Nanotechnology. In early 2005, the NEHI Working Group began work on a cross-agency EHS research needs document, building on an earlier effort in 2004 to inventory existing EHS research funded under the NNI. In March of 2005, the NNI released its Supplement to the President's FY 2006 Budget,<sup>3</sup> which for the first time reported EHS research investments separately. In the fall of 2005, NNI began preparation of a research needs document. The resulting document, *Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials*,<sup>4</sup> released in September 2006, identified 75 research needs within five general categories of EHS research. It also set out a plan for "next steps" for the NNI to address this issue, including further prioritization of the research needs identified in the report, evaluation of the existing NNI EHS research portfolio, a gap analysis based on a comparison of the prioritized research needs and the existing research portfolio, coordination of the NNI agencies' research programs to address the priorities, and development of a process for periodic review and updating of research needs and priorities.

The NEHI Working Group then proceeded to follow that "next steps" agenda. The research needs document was posted for public comment in the fall of 2006, followed by a public meeting to gather input on the document in January 2007. Based on this input, the NEHI Working Group in August 2007 released an interim document for public comment entitled *Prioritization of Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials*.<sup>5</sup> That document narrowed the list of EHS research needs down to five in each of the categories, for a total of 25 high-priority research needs. Based on input on that interim document and extensive further analysis by the EOP and the agencies involved, in February 2008 the NEHI Working Group released its first comprehensive *Strategy for Nanotechnology-Related Environmental, Health, and Safety Research*.<sup>6</sup>

This strategy for the NNI's EHS research presents a path for coordinated inter-agency implementation of research to address the needs identified in earlier reports. It is based in part on a detailed analysis of the Federal Government's FY 2006 nanotechnology-related EHS research portfolio, a \$68 million investment in 246 projects. Experts from the NEHI Working Group analyzed how these activities addressed the priority research needs and then proposed emphasis and sequencing for future research efforts. Agency-specific research and regulatory needs, public com-

<sup>3</sup> [http://www.nano.gov/NNI\\_06Budget.pdf](http://www.nano.gov/NNI_06Budget.pdf)

<sup>4</sup> [http://www.nano.gov/NNI\\_EHS\\_research\\_needs.pdf](http://www.nano.gov/NNI_EHS_research_needs.pdf)

<sup>5</sup> [http://www.nano.gov/Prioritization\\_EHS\\_Research\\_Needs\\_Engineered\\_Nanoscale\\_Materials.pdf](http://www.nano.gov/Prioritization_EHS_Research_Needs_Engineered_Nanoscale_Materials.pdf)

<sup>6</sup> [http://www.nano.gov/NNI\\_EHS\\_Research\\_Strategy.pdf](http://www.nano.gov/NNI_EHS_Research_Strategy.pdf)

ments on the prior documents, and considerations of the state of EHS research in the national and international nanotechnology communities all played an important role in shaping the strategy. It reflects a strong commitment among the NNI member agencies to the roles they will assume, consistent with their respective missions and responsibilities, to move the Federal efforts in nanotechnology-related EHS research forward. The comprehensive detail in the document demonstrates that the NNI is working hard to understand—and to think strategically about—nano EHS issues in a systematic, coordinated fashion. As indicated in both the initial EHS research needs document and in this new strategy document, the strategy will be updated periodically. Furthermore, as indicated in the timeline above, the National Research Council (NRC) is now under contract from the NNCO to assess the EHS strategy. Once the NRC assessment is complete, their recommendations will be incorporated, as appropriate, into an updated strategy.

I think the NNI has made tremendous progress toward the goal of supporting responsible development of nanotechnology. Funding for EHS research in particular has more than doubled since FY 2005, from \$35 million to \$76 million in the FY 2009 request. This is only counting the narrowly defined “primary purpose” EHS R&D. Beyond just increasing the funding, the NNI agencies have come up with an excellent strategy that all the relevant agencies support, to carry forward these investments in the most effective way possible. The increasing emphasis on EHS is notable and important.

I believe the Federal Government needs to ensure that nano-EHS research needs are adequately addressed. To this end, the NNI has systematically: (1) identified research needs, (2) prioritized those needs, (3) developed an associated inventory from which a gap analysis can be performed, and (4) developed a strategy for addressing the prioritized needs that are not currently being addressed. The Administration believes this systematic approach is the right way to address EHS research needs. The Administration therefore does not support establishing an arbitrary EHS set-aside.

#### IV. Summary and Conclusions

The NNI has been and remains a highly successful enterprise, due in large part to the unparalleled interagency coordination and cooperation, which in turn has been effective because of the voluntary, “bottom up” nature of that cooperation, in which all the agencies benefit. As demonstrated above and validated by external reviews, the NNI is effectively pursuing its goals of advancing world-class nanotechnology R&D; fostering technology transfer; developing and sustaining educational resources, work force, and supporting infrastructure; and supporting responsible development of nanotechnology. The findings of the external reviews clearly indicate that the existing structure is working well, and I look forward to working with the Committee as it considers the future of this successful program.

#### APPENDIX I

##### National Nanotechnology Initiative FY 2009 Budget and Highlights

The 2009 Budget provides \$1.5 billion for the National Nanotechnology Initiative (NNI), reflecting steady growth in the NNI investment. This sustained major investment in nanotechnology research and development (R&D) across the Federal Government over the past nine Fiscal Years of the NNI reflects the broad support of the Administration and of Congress for this program, based on its potential to vastly improve our fundamental understanding and control of matter, ultimately leading to a revolution in technology and industry for the benefit of society. The NNI remains focused on fulfilling the Federal role of supporting basic research, infrastructure development, and technology transfer, in the expectation that the resulting advances and capabilities will make important contributions to national priorities, with applications across a wide range of industries including healthcare, electronics, aeronautics, and energy. Increasing investments by mission agencies in nanotechnology-related research since 2001 reflect a recognition of the potential for this research to support agency missions and responsibilities.

Table 1 provides NNI investments in 2007–2009 for Federal agencies with budgets/investments for nanotechnology R&D. Tables 2–4 list the investments by agency and by program component area (PCA). Note that the program component areas shown in these tables are those outlined in the new NNI Strategic Plan released in December 2007,<sup>7</sup> with nanotechnology-related environmental, health, and safety (EHS) research now reported for the first time in a separate PCA from education and other societal dimensions investments.

<sup>7</sup>[http://www.nano.gov/NNI Strategic Plan 2007.pdf](http://www.nano.gov/NNI%20Strategic%20Plan%202007.pdf)

The 2009 NNI budget supports nanoscale science and engineering R&D at 13 agencies. Agencies with the greatest investments are the Department of Defense (DOD—investments addressing the defense mission); the National Science Foundation (NSF—fundamental research across all disciplines of science and engineering); the Department of Energy (DOE—research providing a basis for new and improved energy technologies); the National Institutes of Health (NIH, within the Department of Health and Human Services, DHHS—nanotechnology-based biomedical research at the intersection of biology and the physical sciences); and the National Institute of Standards and Technology (NIST—fundamental research and development of tools, analytical methodologies, and metrology for nanotechnology). Other agencies that are investing in mission-related research are the National Aeronautics and Space Administration (NASA), the National Institute for Occupational Safety and Health (NIOSH/DHHS), the Environmental Protection Agency (EPA), and the Departments of Agriculture (USDA—Cooperative State Research, Education, and Extension Service, CSREES; and Forest Service, FS), Homeland Security (DHS), Justice (DOJ), and Transportation (DOT—Federal Highway Administration, FHWA).

#### **Key Points about the 2009 NNI Investments**

- The 2009 NNI budget provides increased support for research on fundamental nanoscale phenomena and processes, from \$481 million in 2007 to \$551 million in 2009.
- Increases in nanotechnology R&D funding for DOE, NIST, and NSF reflect the President's continuing commitment to significantly increase funding for physical sciences and engineering research as part of the American Competitiveness Initiative.
- The proposed budget also reflects substantial ongoing growth in funding for instrumentation research, metrology, and standards (from \$53 million in 2007 to \$82 million in 2009) and in nanomanufacturing research (from \$48 million in 2007 to \$62 million in 2009). NNI agencies are gathering input and feedback from industry and the research community on these growing investments through a series of workshops.
- EHS R&D funding in 2009 (\$76 million) is over double the level of actual funding in 2005 (\$35 million)—the first year this data was collected. The steady growth in EHS R&D spending follows the NNI strategy of expanding the capacity to do high-quality research in this field. For tables in this document, EHS R&D is defined as research whose primary purpose is to understand and address potential risks to health and to the environment posed by nanotechnology. Therefore the proposed \$76 million for 2009 does not include substantial research reported under other PCAs, *e.g.*, on instrumentation and metrology and on fundamental interactions between biosystems and engineered nanoscale materials, both of which are important in the performance and interpretation of toxicological research. An indication of the level of funding for these broader categories of nanotechnology-related EHS research may be deduced from the detailed 2006 data collected and analyzed specifically for this purpose. This data showed that the total funding for nanotechnology-related EHS research in 2006 was about \$68 million, 80 percent higher than that reported for "primary purpose research."
- A more detailed Budget Supplement will be released when data become available on funding for nanotechnology under the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs.

Table 1.—NNI Budget, 2007–2009  
[dollars in millions]

	2007 Actual	2008 Estimate*	2009 Proposed
DOD	450	487	431
NSF	389	389	397
DOE**	236	251	311
DHHS (NIH)	215	226	226
DOC (NIST)	88	89	110
NASA	20	18	19
EPA	8	10	15
DHHS (NIOSH)	7	6	6
USDA (FS)	3	5	5
USDA (CSREES)	4	6	3
DOJ	2	2	2
DHS	2	1	1
DOT (FHWA)	1	1	1
<b>TOTAL</b>	<b>1,425</b>	<b>1,491</b>	<b>1,527</b>

\*The 2008 DOD estimate exceeds the 2008 request by \$112 million but includes many Congressional earmarks that are outside the NNI plan.

\*\*Funding levels for DOE include the Offices of Science, Fossil Energy, and Energy Efficiency and Renewable Energy.

Table 2.—Actual 2007 Agency Investments by Program Component Area  
 [dollars in millions]

	Fundamental Phenomena and Processes	Nano-materials	Nanoscale Devices and Systems	Instrument Research, Metrology, and Standards	Nano-manufacturing	Major Research Facilities and Instr. Acquisition	Environment, Health, and Safety	Education and Societal Dimensions	NNI Total
DOD	210.1	86.0	120.0	4.3	7.5	22.3			450.2
NSF	145.2	58.4	52.4	14.9	26.6	30.0	26.9	34.4	388.8
DOE	52.6	68.5	9.7	11.3	0.5	92.9		0.5	236.0
DHHS (NIH)	45.7	25.4	125.7	5.9	0.8		7.7	4.2	215.4
DOC (NIST)	24.2	7.5	22.9	14.2	12.4	5.5	0.9		87.6
NASA	0.8	9.9	9.1						19.8
EPA	0.2	0.2	0.1				7.1		7.6
DHHS (NIOSH)						1.7	5.6		7.3
USDA (FS)	0.4	1.3	0.7	0.3	0.2				2.9
USDA (CSREES)	0.5	1.0	2.1		0.1		0.1	0.1	3.9
DOJ		0.1		1.6					1.7
DHS			2.0						2.0
DOT (FHWA)	0.9								0.9
TOTAL	480.6	258.3	344.7	52.5	48.1	152.4	48.3	39.2	1,424.1

Table 3.—Estimated 2008 Agency Investments by Program Component Area  
 [dollars in millions]

	Fundamental Phenomena and Processes	Nano-materials	Nanoscale Devices and Systems	Instrument Research, Metrology, and Standards	Nano-manufacturing	Major Research Facilities and Instr. Acquisition	Environment, Health, and Safety	Education and Societal Dimensions	NNI Total
DOD	258.7	68.9	119.8	8.0	5.4	24.6	2.0		487.4
NSF	138.8	62.1	50.3	16.0	26.9	31.6	29.2	33.8	388.7
DOE	51.4	77.5	13.0	12.0	2.0	92.0	3.0	0.5	251.4
DHHS (NIH)	55.6	25.4	125.8	5.9	0.8		7.7	4.6	225.8
DOC (NIST)	22.5	7.4	21.7	16.1	14.4		0.8		88.7
NASA	1.5	9.7	6.2			5.8	0.2		18.0
EPA	0.2	0.2	0.2			0.4	9.6		10.2
DHHS (NIOSH)							6.0		6.0
USDA (FS)	1.3	1.9	1.2	0.4	0.2				5.0
USDA (CSREES)	0.7	1.6	3.1		0.5		0.1	0.1	6.1
DOJ				2.0					2.0
DHS			1.0						1.0
DOT (FHWA)	0.9								0.9
TOTAL	531.6	254.7	342.3	60.4	50.2	154.4	58.6	39.0	1,491.27

Table 4.—Planned 2008 Agency Investments by Program Component Area  
 [dollars in millions]

	Fundamental Phenomena and Processes	Nano-materials	Nanoscale Devices and Systems	Instrument Research, Metrology, and Standards	Nano-manufacturing	Major Research Facilities and Instr. Acquisition	Environment, Health, and Safety	Education and Societal Dimensions	NNI Total
DOD	227.8	55.2	107.7	3.6	12.8	22.1	1.8		431.0
NSF	141.7	62.5	51.6	16.0	26.9	32.1	30.6	35.5	396.9
DOE	96.9	63.5	8.1	32.0	6.0	101.2	3.0	0.5	311.2
DHHS (NIH)	55.5	25.4	125.8	5.9	0.8		7.7	4.6	225.7
DOC (NIST)	24.5	8.5	22.7	20.9	15.3	5.7	12.8		110.4
NASA	1.2	9.8	7.7			0.2	0.1		19.0
EPA	0.2	0.2	0.2				14.3		14.9
DHHS (NIOSH)							6.0		6.0
USDA (FS)	1.7	1.3	0.7	1.1	0.2				5.0
USDA (CSREES)	0.4	0.8	1.5		0.1		0.1	0.1	3.0
DOJ									2.0
DHS			1.0						1.0
DOT (FHWA)	0.9								0.9
TOTAL	550.8	227.2	327.0	81.5	62.1	161.3	76.4	40.7	1,527.0

### Highlights of Ongoing and Planned Activities

- The extensive network of research centers, user facilities and other infrastructure for nanotechnology research, originally envisioned as a key element of the NNI strategy, is now largely complete. This mature infrastructure serves to accelerate nanotechnology research and development and enables researchers from across various sectors to broadly leverage their interdisciplinary intellectual and technological capital. NNI agencies are encouraging industrial interaction with NNI-funded research centers, and are promoting broad access to the NNI user facilities by all sectors, including small businesses. While emphasis in the near future will be on maximizing the utility and utilization of the substantial infrastructure already in place, the agencies will also consider possible new needs for the longer term.
- Industry liaison and technology transfer activities are given a high priority in the new NNI Strategic Plan released in December 2007. NNI agencies are working with industry representatives to gather input on their nanotechnology-related activities and are funding increasing numbers of nanotechnology-related SBIR and STTR awards to promote technology transfer to industry. Industry liaison groups with the electronics, forest products, and chemical industries, and with the industrial research management community, are continuing, while formation of comparable groups with other sectors (e.g., the construction industry) is under consideration. One successful example is the collaboration between NSF, NIST, and the industry-led Nanoelectronics Research Initiative, where industry and government representatives collaborate in reviewing proposals and in supporting pre-competitive research. In another example, NIH is formulating a “NanoHealth Enterprise,” which is envisioned as a partnership with other Federal agencies, private industry, and international partners to address research needs for safe development of nanoscale materials and devices.
- EHS research planning is a major activity for the NNI. In August 2007, the National Science and Technology Council’s Nanoscale Science, Engineering, and Technology (NSET) Subcommittee published a draft report for public comment prepared by its Nanotechnology Environmental and Health Implications (NEHI) Working Group entitled *Prioritization of Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials*, and, in February 2008, completed a comprehensive *Strategy for Nanotechnology-Related Environmental, Health, and Safety Research*. This is the culmination of 2 years of intensive work, including a detailed review of individual EHS research projects funded by the NNI agencies in 2006, as a guide to identification of gaps in the research portfolio compared to the designated priority research areas.
- As the NNI EHS research strategy evolves, ongoing activities to address the breadth of EHS issues proceed at an accelerating pace. A Food and Drug Administration (FDA) task force released a report in 2007 addressing scientific questions related to the application of its regulatory authorities to nanotechnology-enabled products. EPA issued a white paper on nanotechnology in 2007, and has initiated a Nanoscale Materials Stewardship Program under the Toxic Substances Control Act (TSCA) to gather and develop information from manufacturers, importers, processors and users of engineered chemical nanoscale materials. NIOSH continues to update its guidance document on best practices for safe handling of nanomaterials in the workplace, and has posted a draft document providing interim guidance on medical screening of workers potentially exposed to engineered nanoparticles. NNI agencies organized a workshop hosted by NIST in September 2007 entitled “Standards for Environmental, Health, and Safety for Engineered Nanoscale Materials.” On the research front, two joint interagency solicitations addressing potential environmental and health implications of nanotechnology continue. One (led by EPA, with NSF) addresses environmental implications, while another (led by NIH, with EPA and NIOSH) focuses on human health implications. NSF and EPA will fund a new Center for Environmental Implications of Nanotechnology (CEIN) in 2008. NSF plans to form a network around it in 2009 with collaboration from EPA and other agencies.
- International collaborations in nanotechnology are progressing, with strong NNI participation. The Organisation for Economic Cooperation and Development (OECD) Working Party on Manufactured Nanomaterials, chaired by the United States, has begun its work addressing health and safety issues. A second OECD working party formed under the Committee for Scientific and Technological Policy is addressing broader issues such as economic impact, education and training, and public communication. With respect to standards development, the National Nanotechnology Coordination Office and several NSET member agencies

represent the United States on the International Organization for Standardization (ISO) Technical Committee on Nanotechnologies (ISO TC 229), and the United States leads the ISO TC 229 working group on EHS aspects of nanotechnology.

## APPENDIX II

### A FEW EXAMPLES OF NNI SUPPORTED TRANSFERS OF NANOTECHNOLOGY

#### **Research Results from the Laboratory to Applications and Commercialization**

In addition to the examples given below, the 2007 NNI Strategic Plan<sup>8</sup> includes several examples of early NNI successes in technology transfer (pp. 14–15), as well as a number of high-impact application opportunities that are now emerging from NNI-funded laboratories (pp. 25–34). Further, the new PCAST/NNAP report includes more examples of technologies that are being transitioned from NNI-funded research into commercial applications.

- One of the original motivations for the NNI was the need for more basic research in nanotechnology-enabled electronics, photonics, and magnetics research, to keep the semiconductor industry on the “Moore’s Law” curve of continuous improvement in cost/performance of semiconductor devices that has been so important to our economic prosperity in the past 50 years. While semiconductor device design rules have been in the sub-100 nanometer range for several years now, at the time of the NNI’s inception, leaders in the industry were predicting that future progress would soon be hitting a “brick wall” where continued scaling of traditional CMOS devices would be difficult or impossible due to current leakage, heat dissipation problems, and interference by quantum effects that begin to dominate device behavior in the nanoscale size range. They called on the Government to conduct an intensified basic research program under the auspices of the NNI to address these problems, including the specific goal of developing a completely new paradigm to replace the electronic “switch” that is at the heart of both logic and memory devices. The collaboration by NSF and NIST with industry in the Nanoelectronics Research Initiative referred to above was one of the NNI responses to this problem. As a result of this and other NNI investments in nano-electronics, -magnetics, and -photonics research and infrastructure, progress in addressing this problem has been faster than had been expected previously. At a meeting of the President’s Council of Advisors on Science and Technology on January 8, 2008, George Scalise, President of the Semiconductor Industry Association, stated that, for the roadmaps the semiconductor industry has laid out, their consensus is that they are 2 years ahead of where they thought they would be just a few years ago, thanks in part to the NRI and the NNI. Dr. Scalise also said that for the next generation switch, most of the new ideas are coming from the United States, not from abroad.
- Another major thrust of the NNI that has emerged in recent years is the applications of nanotechnology related to human health—*i.e.*, to diagnosis and treatment of disease. The budget for nanotechnology research at the National Institutes of Health (NIH) has increased dramatically, from \$40 million in 2001 to a proposed \$226 million in 2009. With this NIH has established 21 new research centers focused on nanomedicine and cancer nanotechnology R&D. The range of biomedical applications of nanotechnology under investigation is extremely broad, spanning almost all of the NIH institutes. Widespread clinical application of the results of this research is likely to take many years, given the careful review and approval processes needed for such applications. But we can cite a couple of interesting examples that are nearing fruition in the cancer and regenerative medicine arenas, as follows:
  - Researchers at Northwestern University have developed a diagnostic biobarcode assay based on nanotechnology that is able to detect each of the three markers simultaneously at concentrations multiple orders of magnitude below that detectable by the standard immunoassay. The biobarcode assay can simultaneously detect trace levels of multiple biomarkers (including DNA and proteins) associated with human cancers using oligonucleotide- and antibody-coated gold nanoparticles. Nanoparticle-tagged oligonucleotide biobarcodes have been developed to detect three cancer-related protein biomarkers: pros-

<sup>8</sup>[http://www.nano.gov/NNI\\_Strategic\\_Plan\\_2007.pdf](http://www.nano.gov/NNI_Strategic_Plan_2007.pdf)

tate specific antigen (PSA); human chorionic gonadotrophin (HCG), a marker for testicular cancer; and  $\alpha$ -fetoprotein (AFP), a liver cancer marker. The ability to detect low-levels of protein biomarkers directly in serum in a multiplexed manner will enable more powerful diagnostic methods to detect early-stage malignancy. The nanotechnology biobarcode assay is being commercially developed now; so far the FDA has cleared its use for two molecular diagnostic tests associated with blood disorders.

- Another group at Northwestern has developed an engineered nanomaterial that can be injected into damaged spinal cords and could help prevent scars and encourage damaged nerve fibers to grow. The liquid material contains molecules that self-assemble into nanofibers, which act as a scaffold on which nerve fibers grow. *Researchers have reported that treatment with the material restores function to the hind legs of paralyzed mice.* A spinoff company has now been founded, with the objective of developing this therapy for humans. Initial in vitro tests have shown no apparent toxicity to human cells. The next step will be to make a material that meets FDA standards for clinical trials. This example is particularly interesting for several reasons: (1) it represents a collaboration between a materials scientist much of whose work was initially funded by the National Science Foundation and a stem cell biologist, working in a field with a strong history of NIH funding. As such it is a sterling example of both interdisciplinary collaboration and interagency collaboration that has become a hallmark of the NNI. (2) We have been hearing rumors of this work and seeing private presentations on it for several years now. Only in the past month were the results of this particular breakthrough published in the open literature. As such, we think this example is just the beginning of a flood of new biomedical applications of nanotechnology that are likely to come to light in coming years, as innovations make their way through the long pipeline between initial conception, early exploratory research, initial application experiments, in vitro safety testing, in vivo animal model safety and effectiveness testing, and finally to human clinical trials. Given this long timeline and the large potential payoffs of this type of research, it is understandable that researchers are careful about when they publish results in open literature.
- There are numerous examples of potential applications of nanotechnology in energy production, conversion, storage, transmission, and conservation. Just one of these examples addressed in the recently released PCAST report concerns the use of nanotechnology to enhance the efficiency and lower the cost of converting energy in sunlight directly into electricity, known as photovoltaics. Thin-film photovoltaic technology has improved over the last decade to a point where it can now convert sunlight to electricity as efficiently as all but the most expensive silicon-based solar cells. New low-cost production methods could help make these thin-film cells an important contributor to the Nation's energy needs. One company that has received substantial funding from NNI agencies, Nanosolar, Inc. is using printing presses instead of vacuum deposition equipment to make solar panels based on a semiconducting material called copper indium gallium diselenide (CIGS). The presses deposit nanostructured ink, which is then processed to create the light-absorbing nanoarchitecture at the heart of the solar cell. Nanosolar has recently shipped its first utility-scale panels.

Senator KERRY. Thank you very much, Director Russell. We appreciate it.

Director Robinson?

**STATEMENT OF ROBERT A. ROBINSON, MANAGING DIRECTOR,  
NATURAL RESOURCES AND ENVIRONMENT,  
U.S. GOVERNMENT ACCOUNTABILITY OFFICE**

Mr. ROBINSON. Thank you, Mr. Chairman, for this opportunity to briefly present GAO's work on this very important aspect of Federal nanotechnology research.

I would like to note for the record that today I am sitting in for Anu Mittal, who directed the work on this project but is unable to be here today because she is undergoing treatment for a very serious illness.

At the request of the full Committee and several other Members of the Congressional Nanotechnology Caucus, we examined how the NNI is addressing the potential environmental, health, and safety risks, so-called EHS risks, that may be associated with exposure to nanoscale materials.

Nanotechnology has vast potential for truly transformational innovation in virtually every industry and hundreds of products common to consumers today and others that perhaps we can only dream of. Some of what seems to be possible can only be described by someone of my age as jaw-dropping.

At the same time, the unique properties and microscale size of these materials raise questions about their risk to the human body and the environment whose answers are not fully known and where research is needed to fill the information gaps. In this context, the Committee asked us to examine: (a) the extent of Federal research on these risks in 2006 which was the latest year where data was available at the time of our review, (b) the reasonableness of Federal efforts to identify and prioritize research needs in this area, and (c) the effectiveness of Federal efforts to coordinate and collaborate on this research.

As presented in the report that you have released today, here's what we found.

First, in 2006, Federal agencies reported devoting about 3 percent or about \$38 million of the \$1.3 billion in total Federal nanotechnology research funding to EHS risks.

Our analysis, however, shows that this figure somewhat overstates the actual extent of EHS research. About 20 percent of the research that the agencies classified to us as being primarily focused on EHS actually dealt with using nanotechnology to address other kinds of environmental issues rather than on the risks associated with nanotechnology itself.

This misclassification resulted mostly from agency confusion over how to characterize this kind of research in the existing reporting structure and how to apportion research funding that addressed multiple objectives at the same time.

Given the relatively small size of research funding devoted to EHS issues and the differences of opinion about the appropriate percentage of nanotechnology funding that should be devoted to EHS risks, errors of this size are not inconsequential.

Second, the process used by NNI and the Federal agencies to identify and prioritize EHS risks and the associated research needs appeared reasonable overall. The priorities were arrived at in a collaborative, iterative, and professional fashion, and the research actually conducted was generally consistent with agreed upon priorities.

However, at the time of our review, the NNI had not yet completed its strategic EHS research plan. This plan, which has been released just a month or so ago, falls short of expectations on several levels.

Third, coordination of EHS research, among the 25 agencies participating in NNI, has been generally effective. The agencies meet frequently to identify opportunities for collaboration, jointly sponsor research workshops, have detailed staff to each other, and share the sense that a common purpose, a stable group member-

ship and mutual respect for each other's roles in an exciting mission has led to a satisfying and effective working relationship. relationship.

While presenting a generally favorable picture of Federal nanotechnology research activities, we did make one recommendation to improve them. Specifically, we believe that to clearly understand the potential EHS risks and the gaps in ongoing research, it is essential to have consistent, accurate and complete information on the extent to which agency research is designed to address those risks.

Transparency and credibility of the information presented is vitally important to ensure public confidence in the Government's efforts on this very important front.

Right now, however, the inventory of projects identified as addressing these risks is not entirely accurate. To improve the accuracy of this inventory, we recommend that the guidance provided to agencies on how to report the focus of their research activities be improved.

Mr. Chairman, let me close my prepared remarks here and we'd love to get into conversation.

[The prepared statement of Mr. Robinson follows:]

PREPARED STATEMENT OF ROBERT A. ROBINSON, MANAGING DIRECTOR, NATURAL RESOURCES AND ENVIRONMENT, U.S. GOVERNMENT ACCOUNTABILITY OFFICE

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to participate in your hearing on the future direction of the National Nanotechnology Initiative (NNI). As you know, the NNI was established in 2001 as a Federal, multiagency effort intended to accelerate the discovery, development, and deployment of nanoscale science, engineering, and technology to achieve economic benefits, enhance the quality of life, and promote national security. One of the key roles of the NNI is to coordinate the nanotechnology-related activities of 25 Federal agencies. These agencies include both those that fund nanoscale research as well as those that have a stake in the outcome of this research, such as agencies that regulate products containing nanomaterials. While the NNI is designed to facilitate intergovernmental cooperation and identify goals and priorities for nanotechnology research, it is not a research program. It has no funding or authority to dictate the nanotechnology research agenda for participating agencies or to ensure that adequate resources are available to achieve specific goals. Instead, participating agencies develop and fund their own nanotechnology research agendas, and in Fiscal Year 2006, 13 of the 25 agencies participating in the NNI allocated a total of about \$1.3 billion from their appropriated budgets to nanotechnology research and development activities. Of this total in Fiscal Year 2006, the NNI reported that \$37.7 million (or about 3 percent of the total) was used to fund research to study the potential environmental, health, and safety (EHS) risks that might result from exposure during the manufacture, use, and disposal or recycle of nanoscale materials. As you know, while the use of nanoscale materials holds much promise, the small size and unique properties of these materials raise questions about their potential EHS risks, and research is needed to fill current gaps in scientific information about their risks.

At the request of the full committee and Members of the Congressional Nanotechnology Caucus, we just completed a report that is being released today on the NNI's and Federal agencies' efforts to study the potential environmental, health, and safety risks of nanotechnology.<sup>1</sup> My testimony is based on the findings of this review and will cover the following three areas: (1) the extent to which selected research and regulatory agencies conducted research in Fiscal Year 2006 that primarily was focused on the potential EHS risks of nanotechnology; (2) the reasonableness of the processes that agencies and the NNI use to identify and prioritize Federal research

<sup>1</sup>GAO, *Nanotechnology: Better Guidance Is Needed to Ensure Accurate Reporting of Federal Research Focused on Environmental, Health, and Safety Risks*, GAO-08-402 (Washington, D.C.: Mar. 31, 2008).

on the potential EHS risks of nanotechnology; and (3) the effectiveness of the processes that agencies and the NNI use to coordinate their research. For our review, we collected data from five Federal agencies that provided 96 percent of Fiscal Year 2006 funding for EHS research—the Environmental Protection Agency (EPA), the National Institutes of Health (NIH), the National Institute for Occupational Safety and Health (NIOSH), the National Institute of Standards and Technology (NIST), and the National Science Foundation (NSF). We also contacted three regulatory agencies—the U.S. Consumer Product Safety Commission (CPSC), the Food and Drug Administration (FDA), and the Occupational Safety and Health Administration (OSHA)—that do not have specific research budgets to determine whether they conducted any research on their own relative to potential EHS risks. We conducted this performance audit from June 2007 to February 2008 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our finding and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

In summary we found the following:

- About 20 percent of the over \$37 million in Fiscal Year 2006 research expenditures that the NNI reported as being primarily focused on the EHS risks of nanotechnology cannot actually be attributed to this purpose. We found that 22 of the 119 projects identified as EHS-related by EPA, NIH, NIOSH, NIST, and NSF in Fiscal Year 2006 were not primarily related to understanding the extent to which nanotechnology poses an EHS risk. These 22 projects, funded by NSF and NIOSH, accounted for about \$7 million of the \$37 million that the NNI reported as being primarily focused on EHS risks. The focus of many of these projects was to explore how nanotechnology could be used to remediate environmental damage or to detect a variety of hazards unrelated to nanotechnology. We determined that this mischaracterization was the result of the current reporting structure that does not allow these types of projects to be easily categorized in another more appropriate category, and also the lack of guidance for agencies on how to apportion research funding across multiple topics, when appropriate. To address this issue, we recommended that the Office of Science and Technology Policy (OSTP), in consultation with the NNI and the Office of Management and Budget (OMB), provide better guidance to agencies regarding how to report research that is primarily focused on understanding or addressing the EHS risks of nanotechnology. In commenting on this report, OSTP asserted that it already provides extensive guidance, but it agreed to review the manner in which agencies respond to the current guidance.
- In addition to the EHS funding totals reported by the NNI, we found that Federal agencies conduct other EHS research that is not captured in the NNI totals. This research was not captured by the NNI because either the research was funded by an agency not generally considered to be a research agency or because the primary purpose of the research was not to study EHS risks. Because the agencies that conduct this research do not systematically track it as EHS-related research, we could not establish the exact amount of Federal funding that is being devoted to this additional EHS research.
- Federal agencies and the NNI were, at the time of our review, in the process of identifying and prioritizing EHS risk research needs; overall, we believe that the process they were using was reasonable. For example, identification and prioritization of EHS research needs was being done by the agencies and the NNI collaboratively. The NNI was also engaged in an iterative prioritization effort through its Nanotechnology Environmental and Health Implications (NEHI) working group. As a result of this effort, NEHI had identified five general research categories that should be the focus of Federal research efforts and five specific research priorities under each general category. Our analysis of the 97 research projects that were underway in Fiscal Year 2006 that were primarily related to studying EHS risks found that the focus of these projects was generally consistent with agency priorities as well as NEHI's five general research categories. However, we did find that, while agency funded research addressed each of the five general research categories, it focused on the priority needs within each category to varying degrees. As our report was in production, NEHI released a new EHS research strategy on February 13, 2008, which is intended to provide a framework to help ensure that the highest priority EHS research needs are met.
- Agency and NNI processes to coordinate activities related to potential EHS risks of nanotechnology have been generally effective. The NEHI working group

has convened frequent meetings that have helped agencies identify opportunities to collaborate on EHS risk issues, such as joint sponsorship of research and workshops to advance knowledge and facilitate information-sharing among the agencies. These types of exchanges, according to most agency officials we spoke with, have helped advance knowledge and facilitated information-sharing among the agencies. In addition, NEHI has incorporated several practices that we have previously identified as key to enhancing and sustaining interagency collaborative efforts, such as defining a common outcome and leveraging resources, but it had not, at the time of our review, completed its overarching strategy to help better align agencies' EHS research efforts. Finally, all agency officials we spoke with expressed satisfaction with the coordination and collaboration on EHS risk research that has occurred through NEHI. They cited several factors they believe contribute to the group's effectiveness, including the stability of the working group membership and the expertise and dedication of its members. Furthermore, according to these officials, this stability, combined with common research needs and general excitement about the new science, has resulted in a collegial, productive working environment.

### Background

Nanotechnology encompasses a wide range of innovations based on the understanding and control of matter at the scale of nanometers—the equivalent of one-billionth of a meter. To illustrate, a sheet of paper is about 100,000 nanometers thick and a human hair is about 80,000 nanometers wide. At the nanoscale level, materials may exhibit electrical, biological, and other properties that differ significantly from the properties the same materials exhibit at a larger scale. Exploiting these differences in nanoscale materials has led to a range of commercial uses and holds the promise for innovations in virtually every industry from aerospace and energy to health care and agriculture. In 2006, an estimated \$50 billion in products worldwide incorporated nanotechnology and this figure has been projected to grow to \$2.6 trillion by 2014. One research institute estimates that over 500 consumer products already available to consumers may contain nanoscale materials.

The National Nanotechnology Initiative (NNI) was established in 2001 as a Federal, multiagency effort intended to accelerate the discovery, development, and deployment of nanoscale science, engineering, and technology to achieve economic benefits, enhance the quality of life, and promote national security. Management of the NNI falls under the purview of the National Science and Technology Council (NSTC) that coordinates science and technology policy across the Federal Government. The NSTC is managed by the Director of the Office of Science and Technology Policy (OSTP), who also serves as the Science Advisor to the President. The NSTC's Committee on Technology established the Nanoscale Science, Engineering, and Technology (NSET) subcommittee to help coordinate, plan, and implement the NNI's activities across participating agencies. In 2003, the NSET subcommittee further established a Nanotechnology Environmental and Health Implications (NEHI) working group.<sup>2</sup> The purpose of the NEHI working group, composed of representatives from 16 research and regulatory agencies, is to, among other things, coordinate agency efforts related to EHS risks of nanotechnology. Similar to the NNI, the NEHI working group has no authority to mandate research priorities or to ensure that agencies adequately fund particular research.

In December 2003, Congress enacted legislation to establish a National Nanotechnology Program to coordinate Federal nanotechnology research and development.<sup>3</sup> Among other things, the act directs the NSTC to establish goals and priorities for the program and to set up program component areas that reflect those goals and priorities. To implement these requirements, the NSTC has established a process to categorize research projects and activities undertaken by the various Federal agencies into seven areas. Six of the seven focus on the discovery, development, and deployment of nanotechnology, while the seventh relates to the societal dimensions of nanotechnology that include issues such as the EHS risks of nanotechnology.

As part of the annual Federal budget process, agencies also report their research funding for each area to OMB. The NNI's annual Supplement to the President's Budget, prepared by the NSTC, includes EHS research figures from the agencies and a general description of the research conducted by the agencies in each of the areas. For reporting purposes, the NSET subcommittee has defined EHS research

<sup>2</sup>As of December 2007, a total of four working groups exist within the NSET subcommittee: (1) Global Issues in Nanotechnology; (2) Nanotechnology Environmental and Health Implications; (3) Nanomanufacturing, Industry Liaison, and Innovation; and (4) Nanotechnology Public Engagement and Communications.

<sup>3</sup>The 21st Century Nanotechnology Research and Development Act, Pub. L. 108–153 (2003).

as efforts whose primary purpose is to understand and address potential risks to health and to the environment posed by nanotechnology. Eight of the 13 agencies that funded nanotechnology research in Fiscal Year 2006 reported having devoted some of those resources to research that had a primary focus on potential EHS risks.

Under the NNI, each agency funds research and development projects that support its own mission as well as the NNI's goals. While agencies share information on their nanotechnology-related research goals with the NSET subcommittee and NEHI working group, each agency retains control over its decisions on the specific projects to fund. While the NNI was designed to facilitate intergovernmental cooperation and identify goals and priorities for nanotechnology research, it is not a research program. It has no funding or authority to dictate the nanotechnology research agenda for participating agencies.

The NNI used its Fiscal Year 2000 strategic plan and its subsequent updates to delineate a strategy to support long-term nanoscale research and development, among other things. A key component of the 2000 plan was the identification of nine specific research and development areas—known as “grand challenges”—that highlighted Federal research on applications of nanotechnology with the potential to realize significant economic, governmental, and societal benefits.

In 2004, the NNI updated its strategic plan and described its goals as well as the investment strategy by which those goals were to be achieved. Consistent with the 21st Century Nanotechnology Research and Development Act, the NNI reorganized its major subject categories of research and development investment into program component areas (PCA) that cut across the interests and needs of the participating agencies. These seven areas replaced the nine grand challenges that the agencies had used to categorize their nanotechnology research. Six of the areas focus on the discovery, development, and deployment of nanotechnology. The seventh, societal dimensions, consists of two topics—research on environmental, health, and safety; and education and research on ethical, legal, and other societal aspects of nanotechnology.

PCAs are intended to provide a means by which the NSET subcommittee, OSTP, OMB, Congress, and others may be informed of the relative Federal investment in these key areas. PCAs also provide a structure by which the agencies that fund research can better direct and coordinate their activities. In response to increased concerns about the potential EHS risks of nanotechnology, the NSET subcommittee and the agencies agreed in Fiscal Year 2005 to separately report their research funding for each of the two components of the societal dimensions PCA. The December 2007 update of the NNI's strategic plan reaffirmed the program's goals, identified steps to accomplish those goals, and formally divided the societal dimensions PCA into two PCAs—“environment, health, and safety” and “education and societal dimensions.”

Beginning with the development of the Fiscal Year 2005 Federal budget, agencies have worked with OMB to identify funding for nanoscale research that would be reflected in the NNI's annual Supplement to the President's Budget. OMB analysts reviewed aggregated, rather than project-level, data on research funding for each PCA to help ensure consistent reporting across the agencies. Agencies also relied on definitions of the PCAs developed by the NSET subcommittee to determine the appropriate area in which to report research funding. Neither NSET nor OMB provided guidance on whether or how to apportion funding for a single research project to more than one PCA, if appropriate. However, representatives from both NSET and OMB stressed that the agencies were not to report each research dollar more than once.

#### **Almost One-Fifth of Reported EHS Research Projects Were Not Primarily Focused on Studying the EHS Risks of Nanotechnology**

About 18 percent of the total research dollars reported by the agencies as being primarily focused on the study of nanotechnology-related EHS risks in Fiscal Year 2006 cannot actually be attributed to this purpose. Specifically, we found that 22 of the 119 projects funded by five Federal agencies were not primarily related to studying EHS risks. These 22 projects accounted for about \$7 million of the total that the NNI reported as supporting research primarily focused on EHS risks. Almost all of these projects—20 out of 22—were funded by NSF, with the two additional projects funded by NIOSH. We found that the primary purpose of many of these 22 projects was to explore ways to use nanotechnology to remediate environmental damage or to identify environmental, chemical, or biological hazards not related to nanotechnology. For example, some NSF-funded research explored the use of nanotechnology to improve water or gaseous filtration systems. Table 1 shows our

analysis of the nanotechnology research projects reported as being primarily focused on EHS risks.

Table 1.—GAO Analysis of the Number and Dollar Value of Nanotechnology Research Projects Reported by Selected Agencies as Being Primarily Focused on Environmental, Health, and Safety Risks, Fiscal Year 2006

[Dollars in millions]

Agency	Projects reported by agencies as being primarily focused on EHS		Projects determined by GAO to be primarily focused on EHS		Projects determined by GAO not to be primarily focused on EHS	
	Number	Dollar Value <sup>a</sup>	Number	Dollar Value	Number	Dollar value
EPA	10	\$3.6	10	\$3.6	0	\$0
NIH	18	\$5.6	18	\$5.6	0	\$0
NIOSH	23	\$4.3	21	\$4.2	2	\$0.1
NIST	2	\$2.4	2	\$2.4	0	\$0
NSF	66	\$21.1	46	\$14.7	20	\$6.4
Total	119	\$37	97	\$30.5	22	\$6.5

Source: GAO analysis of agency obligations data.

<sup>a</sup> Figures differ slightly from those reported by the NNI in the Supplement to the President's FY2008 Budget due to rounding error or modifications made to the project-level data after they were reported by agencies to the NNI.

We found that the miscategorization of these 22 projects resulted largely from a reporting structure for nanotechnology research that does not easily allow agencies to recognize projects that use nanotechnology to improve the environment or enhance the detection of environmental contaminants, and from the limited guidance available to the agencies on how to consistently report EHS research. From Fiscal Years 2001 to 2004, the NSET subcommittee categorized Federal research and development activities into nine categories, known as “grand challenges,” that included one focused on “nanoscale processes for environmental improvement.” Agencies initiated work on many of these 22 projects under the grand challenges categorization scheme. Starting in Fiscal Year 2005, NSET adopted a new categorization scheme, based on PCAs, for agencies to report their nanotechnology research. The new scheme eliminated the research category of environmental improvement applications and asked agencies to report research designed to address or understand the risks associated with nanotechnology as part of the societal dimensions PCA.

The new scheme shifted the focus from applications-oriented research to research focused on the EHS implications of nanotechnology. However, the new scheme had no way for agencies to categorize environmentally focused research that was underway. As a result, NSF and NIOSH characterized these projects as EHS focused for lack of a more closely related category to place them in, according to program managers. Furthermore, neither NSET nor OMB provided agencies guidance on how to apportion the dollars for a single project to more than one program component area, when appropriate. This is especially significant for broad, multiphase research projects, such as NSF's support to develop networks of research facilities. Of the five agencies we reviewed, only NSF apportioned funds for a single project to more than one PCA.

In addition to research reported to the NNI as being primarily focused on the EHS risks of nanotechnology, some agencies conduct research that is not reflected in the EHS totals provided by the NNI either because they are not considered Federal research agencies or because the primary purpose of the research was not to study EHS risks. For example, some agencies conduct research that results in information highly relevant to EHS risks but that was not primarily directed at understanding or addressing those risks and therefore is not captured in the EHS total. This type of research provides information that is needed to understand and measure nanomaterials to ensure safe handling and protection against potential health or environmental hazards; however, such research is captured under other PCAs, such as instrumentation, metrology, and standards. Because the agencies that conduct this research do not systematically track it as EHS-related, we could not estab-

lish the exact amount of Federal funding that is being devoted to this additional EHS research.

**Processes to Identify and Prioritize Needed EHS Research Appear Reasonable and Are Ongoing but a Comprehensive Research Strategy Has Not Yet Been Developed**

All eight agencies in our review have processes in place to identify and prioritize the research they need related to the potential EHS risks of nanotechnology. Most agencies have developed task forces or designated individuals to specifically consider nanotechnology issues and identify priorities, although the scope and exact purpose of these activities differ by agency. Once identified, agencies communicate their EHS research priorities to the public and to the research community in a variety of ways, including publication in agency documents that specifically address nanotechnology issues, agency strategic plans or budget documents, agency websites, and presentations at public conferences or workshops. We determined that each agency's nanotechnology research priorities generally reflected its mission. For example, the priorities identified by FDA and CPSC are largely focused on the detection and safety of nanoparticles in the commercial products they regulate. On the other hand, EHS research priorities identified by NSF reflect its broader mission to advance science in general, and include a more diverse range of priorities, such as the safety and transport of nanomaterials in the environment, and the safety of nanomaterials in the workplace.

In addition to the efforts of individual agencies, the NSET subcommittee has engaged in an iterative prioritization process through its NEHI working group. Beginning in 2006, NEHI identified but did not prioritize five broad research categories and 75 more specific subcategories of needs where additional information was considered necessary to further evaluate the potential EHS risks of nanotechnology. NEHI obtained public input on its 2006 report and released another report in August 2007, in which it distilled the previous list of 75 unprioritized specific research needs into a set of five prioritized needs for each of the five general research categories. The NEHI working group has used these initial steps to identify the gaps between the needs and priorities it has identified and the research that agencies have underway. NEHI issued a report summarizing the results of this analysis in February 2008.

Although a comprehensive research strategy for EHS research had not been finalized at the time of our review, the prioritization processes taking place within individual agencies and the NNI appeared to be reasonable. Numerous agency officials said their agency's EHS research priorities were generally reflected both in the NEHI working group's 2006 research needs and 2007 research prioritization reports. Our comparison of agency nanotechnology priorities to the NNI's priorities corroborated these statements. Specifically, we found that all but one of the research priorities identified by individual agencies could be linked to one or more of the five general research categories. According to agency officials, the alignment of agency priorities with the general research categories is particularly beneficial to the regulatory agencies, such as CPSC and OSHA, which do not conduct their own research, but rely instead on research agencies for data to inform their regulatory decisions.

In addition, we found that the primary purposes of agency projects underway in Fiscal Year 2006 were generally consistent with both agency priorities and the NEHI working group's research categories. Of these 97 projects, 43 were focused on Nanomaterials and Human Health, including all 18 of the projects funded by NIH. EPA and NSF funded all 25 projects related to Nanomaterials and the Environment. These two general research categories accounted for 70 percent of all projects focused on EHS risks.

Furthermore, we determined that, while agency-funded research addressed each of the five general research categories, it focused on the priority needs within each category to varying degrees. Specifically, we found that the two highest-priority needs in each category were addressed only slightly more frequently than the two lowest-priority needs.

Moreover, although the NEHI working group considered the five specific research priorities related to human health equally important, 19 of the 43 projects focused on a single priority—"research to determine the mechanisms of interaction between nanomaterials and the body at the molecular, cellular, and tissular levels." Table 2 shows a summary of projects by agency and specific NEHI research priority.

Table 2.—Research Primarily Focused on the Environmental, Health, and Safety Risks of Nanotechnology by Agency and Specific Nanotechnology Environmental and Health Implications Working Group Research Priority

	EPA	NIH	NIOSH	NIST	NSF	Total
<i>Instrumentation, Metrology, and Analytical Methods</i>	0	0	1	2	8	11
1. Develop methods to detect nanomaterials in biological matrices, the environment, and the workplace				1	7	8
2. Understand how chemical and physical modifications affect the properties of nanomaterials						0
3. Develop methods for standardizing assessment of particle size, size distribution, shape, structure, and surface area			1	1		2
4. Develop certified reference materials for chemical and physical characterization of nanomaterials						0
5. Develop methods to characterize a nanomaterial's spatio-chemical composition, purity, and heterogeneity					1	1
<i>Nanomaterials and Human Health</i>	4	18	10	0	11	43
1. Develop methods to quantify and characterize exposure to nanomaterials and characterize nanomaterials in biological matrices <sup>a</sup>	1	1	4		2	8
2. Understand the absorption and transport of nanomaterials throughout the human body <sup>a</sup>	1	1			2	4
3. Establish the relationship between the properties of nanomaterials and uptake via the respiratory or digestive tracts or through the eyes or skin, and assess body burden <sup>a</sup>		5	3		1	9
4. Determine the mechanisms of interaction between nanomaterials and the body at the molecular, cellular, and tissular levels <sup>a</sup>	1	10	3		5	19
5. Identify or develop appropriate in vitro and in vivo assays/models to predict in vivo human responses to nanomaterials exposure <sup>a</sup>	1	1			1	3
<i>Nanomaterials and the Environment</i>	5	0	0	0	20	25
1. Understand the effects of engineered nanomaterials in individuals of a species and the applicability of testing schemes to measure effects	1				2	3
2. Understand environmental exposures through identification of principle sources of exposure and exposure routes					1	1
3. Evaluate abiotic and ecosystem-wide effects					6	6
4. Determine factors affecting the environmental transport of nanomaterials	2				9	11
5. Understand the transformation of nanomaterials under different environmental conditions	2				2	4
<i>Health and Environmental Exposure Assessment</i>	0	0	3	0	2	5
1. Characterize exposures among workers			2		1	3

Table 2.—Research Primarily Focused on the Environmental, Health, and Safety Risks of Nanotechnology by Agency and Specific Nanotechnology Environmental and Health Implications Working Group Research Priority—Continued

	EPA	NIH	NIOSH	NIST	NSF	Total
2. Identify population groups and environments exposed to engineered nanoscale materials						0
3. Characterize exposure to the general population from industrial processes and industrial and consumer products containing nanomaterials						0
4. Characterize health of exposed populations and environments						0
5. Understand workplace processes and factors that determine exposure to nanomaterials			1		1	2
<i>Risk Management Methods</i>	<i>1</i>	<i>0</i>	<i>7</i>	<i>0</i>	<i>5</i>	<i>13</i>
1. Understand and develop best workplace practices, processes, and environmental exposure controls			4		2	6
2. Examine product or material life cycle to inform risk reduction decisions	1				1	2
3. Develop risk characterization information to determine and classify nanomaterials based on physical or chemical properties			1		2	3
4. Develop nanomaterial-use and safety-incident trend information to help focus risk management efforts						0
5. Develop specific risk communication approaches and materials			2			2
<i>Total</i>	<i>10</i>	<i>18</i>	<i>21</i>	<i>2</i>	<i>46</i>	<i>97</i>

Source: GAO analysis of agency data.  
<sup>a</sup>Priorities given equal weight.

### Coordination Processes Have Fostered Interagency Collaboration and Information-Sharing

Agency and NNI processes to coordinate research and other activities related to the potential EHS risks of nanotechnology have been generally effective, and have resulted in numerous interagency collaborations. All eight agencies in our review have collaborated on multiple occasions with other NEHI-member agencies on activities related to the EHS risks of nanotechnology. These EHS-related activities are consistent with the expressed goals of the larger NNI—to promote the integration of Federal efforts through communication, coordination, and collaboration. The NEHI working group is at the center of this effort.

We found that regular NEHI working group meetings, augmented by informal discussions, have provided a venue for agencies to exchange information on a variety of topics associated with EHS risks, including their respective research needs and opportunities for collaborations. Interagency collaboration has taken many forms, including joint sponsorship of EHS-related research and workshops, the detailing of staff to other NEHI working group agencies, and various other general collaborations or memoranda of understanding.

Furthermore, the NEHI working group has adopted a number of practices GAO has previously identified as essential to helping enhance and sustain collaboration among Federal agencies.<sup>4</sup> For example, in 2005 NEHI clearly defined its purpose and objectives and delineated roles and responsibilities for group members. Furthermore, collaboration through multiagency grant announcements and jointly sponsored workshops has served as a mechanism to leverage limited resources to achieve increased knowledge about potential EHS risks.

Finally, all agency officials we spoke with expressed satisfaction with their agency's participation in the NEHI working group, specifically, the coordination and col-

<sup>4</sup> GAO, *Results-Oriented Government: Practices That Can Help Enhance and Sustain Collaboration among Federal Agencies*, GAO-06-15 (Washington, D.C.: Oct. 21, 2005).

laboration on EHS risk research and other activities that have occurred as a result of their participation. Many officials described NEHI as unique among interagency efforts in terms of its effectiveness. Given limited resources, the development of ongoing relationships between agencies with different missions, but compatible nanotechnology research goals, is particularly important. NIH officials commented that their agency's collaboration with NIST to develop standard reference materials for nanoparticles may not have occurred as readily had it not been for regular NEHI meetings and workshops. In addition, NEHI has effectively brought together research and regulatory agencies, which has enhanced planning and coordination. Many officials noted that participation in NEHI has frequently given regulators the opportunity to become aware of and involved with research projects at a very early point in their development, which has resulted in research that better suits the needs of regulatory agencies.

Many officials also cited the dedication of individual NEHI working group representatives, who participate in the working group in addition to their regular agency duties, as critical to the group's overall effectiveness. A number of the members have served on the body for several years, providing stability and continuity that contributes to a collegial and productive working atmosphere. In addition, because nanotechnology is relatively new with many unknowns, these officials said the agencies are excited about advancing knowledge about nanomaterials and contributing to the informational needs of both regulatory and research agencies. Furthermore, according to some officials, there is a shared sense among NEHI representatives of the need to apply lessons learned from the development of past technologies, such as genetically modified organisms, to help ensure the safe development and application of nanotechnology.

In closing, Mr. Chairman, while nanotechnology is likely to affect many aspects of our daily lives in the future as novel drug delivery systems, improved energy storage capability, and stronger, lightweight materials are developed and made available, it is essential to consider the potential risks of this technology in concert with its potential benefits. Federal funding for studying the potential EHS risks of nanotechnology is critical to enhancing our understanding of these new materials, and we must have consistent, accurate, and complete information on the amount of agency funding that is being dedicated to this effort. However, this information is not currently available because the totals reported by the NNI include research that is more focused on uses for nanotechnology, rather than the risks it may pose. Furthermore, agencies currently have limited guidance on how to report projects with more than one research focus across program component areas, when appropriate. As a result, the inventory of projects designed to address these risks is inaccurate and cannot ensure that the highest-priority research needs are met.

Mr. Chairman, this concludes my prepared statement. I would be happy to respond to any questions that you and other Members may have.

Senator KERRY. Well, that's great. I'd like to pick up on it.

Senator Stevens has to run in a few minutes. Do you want to ask or are you OK?

Senator STEVENS. I'm OK.

Senator KERRY. OK. Thanks. Let me follow up on what you just said about the testimony. Maybe I can get you guys playing off each other a little bit.

Director Robinson, you say that you found this process of prioritizing the research reasonable but you also found that it falls short of the expectations, and on your score, Director Russell, you say that the NNI Working Group has been comprehensive enough and we don't need something further. So there's a slight divergence here and we're trying to figure out where to go on that path.

Can you elaborate, Director Robinson, on your views of the strategy document and why you don't think it provides sufficiently prioritized guidance, and then the second part of the question, how, because of the lack of sufficient guidance, that could have an impact on this discipline and on the future?

Mr. ROBINSON. Yes, Senator. Again, the process itself, it's hard to argue with. I mean, the folks are working together quite well. They sat down. They hashed out priorities across their agencies.

They arrived at a set of 25 needs. There doesn't seem to be a huge amount of contention that these encompass the most important research needs facing this subject.

The document itself, I've got to tell you, the strategy paper itself is a little hard to follow. I mean, when you sit down to try to go through that, it's not easy to get through.

But on one of the more important fronts, however, it doesn't lay out who's responsible for what, who's accountable for delivering what, and hold them responsible for delivering the research that they're supposed to do to add up to this collective whole. Secondly, it lays out 25 or so priorities and essentially provides them equal weight.

So it would be more helpful to know what is the most important of the most important in a true budget scarcity environment. Something has to be sacrificed.

Senator KERRY. What's the impact of not knowing?

Mr. ROBINSON. Well, at the end of the day, I don't think you can be absolutely certain or the public can be absolutely certain by looking at that document that the Federal Government has a full thorough systematic effort in place to ensure that nanotechnology risks are being fully and completely addressed and that—

Senator KERRY. Can I stop you there? Let me stop you there.

Director Russell, what do you say to that?

Mr. RUSSELL. So a couple of things.

Senator KERRY. Can you pull the mike up a little?

Mr. RUSSELL. Sure. I've got to turn it on, too. A couple things. One is that there's no question that we can continue to improve the process by which we identify from a bottom-up approach which areas need to be researched and how much money we have to spend in each area.

The strategic document, which I actually think is well put together, is fairly lengthy and quite specific, but it is not a roadmap, and I think that's maybe where there's a difference between what GAO is saying and what we're saying.

The strategy is how we're going to move forward. I think what Director Robinson is suggesting is what they would love to see as an actual roadmap. That is something that we certainly can look at and try to figure out what makes the most sense going forward.

One of the things that we have done is we've asked the National Research Council to actually review the strategic document and give us recommendations and so we're waiting for that review and—

Senator KERRY. When will that be forthcoming?

Mr. RUSSELL. I don't know—March of next year is when we're going to get that.

Senator KERRY. Not till next year?

Mr. RUSSELL. It takes the NRC awhile to actually—this was published—this document here, which we are discussing, was published in February of this year and then the NRC has a very specific series of reviews that it does which takes some time.

Senator KERRY. Go ahead.

Senator STEVENS. I've got to go but I wanted to ask just two questions.

Mr. Russell, I'm reminded of Norm Augustine's report that indicated that in India, they're producing 700,000 engineers and China 400,000 engineers and we're producing 70,000 engineers.

Now, do we have—how does the amount we're spending on nanotechnology compare to China and India?

Mr. RUSSELL. Well, we're spending more than both China and India on nanotechnology, although Asia, as a whole, is increasing and, roughly speaking, Asia's spending about the same amount now we are spending on nanotechnology. So Asia as a whole as opposed to those specific two countries.

Senator STEVENS. So our lack of educational activities for more people is not shorting us as far as our basic research in nanotechnology?

Mr. RUSSELL. Compared today to India and China, that's true. Now, I would assume, because China is spending more money generically on R&D and ramping up faster than we are over time on R&D, that at some point, they probably will end up spending more. So that's clearly something that we need to be cognizant of.

Senator STEVENS. I think you ought to give us annual reports on that.

Mr. Robinson, let me ask you this. In terms of your report and this idea of transparency, do you believe that every one of these research projects ought to have a set-aside of money to go into the aspects of safety and health as related to the research project?

Mr. ROBINSON. No, I wouldn't suggest that. My main point is that if we say we're spending X millions of dollars on EHS research, let's make sure that the money's actually going in that direction and that it will be transparent for what the actual purpose of the research is.

Senator STEVENS. Who is—are we supposed to have another agency look into the safety and health aspects of nanotechnology?

Mr. ROBINSON. No, we don't call for that, Senator, no.

Senator STEVENS. You don't—

Mr. ROBINSON. We didn't call for that. We didn't—

Senator STEVENS. Who's going to do it? That's what I'm saying.

Mr. ROBINSON. Well, the NNI Program, I think, right now is doing a credible job of assembling the research needs and attacking most of them. I'm not sure—

Senator STEVENS. Including health and safety?

Mr. ROBINSON. Short of saying how—whether the dollars are adequate, I would say the process that's used to arrive at and undertake the research that's to be undertaken certainly is not open to substantial challenge, I don't think.

Senator STEVENS. All right. Thank you.

Senator KERRY. Yes, Mr. Russell?

Mr. RUSSELL. I was just going to jump in. I think the answer is that there are a number of different agencies that are all doing this research and when you put them all together as coordinated by the NNI, in the case of Fiscal Year 2009 request, you get roughly \$75 million.

Senator KERRY. Why the resistance to doing what people would call a roadmap/comprehensive strategy? Thanks, Ted.

Mr. RUSSELL. I don't think there's—it's a matter of a resistance in terms of doing it.

Senator KERRY. Why would there be the automatic instinct that everybody's got to know where to go here? I mean, this is the EHS concern is real.

Mr. RUSSELL. No, absolutely. Not only is it—

Senator KERRY. Don't we want people in the public to have as much information and sense of where we're heading as possible?

Mr. RUSSELL. Yes, absolutely, and as I was saying, what has been done to date, every year the NNI has been putting out more detailed and more specific EHS reports and in this case just in February came up with a strategic plan.

Creating a roadmap obviously is an additional step and an additional work activity and it's something that we can certainly look into doing. It is—

Senator KERRY. Do you agree that it is the appropriate group to do it?

Mr. RUSSELL. The NNI? I think—

Senator KERRY. Yes. NNI.

Mr. RUSSELL. So the NEHI, which is a subgroup of the Subcommittee that's responsible for dealing with the Nanotechnology Program is indeed the right working group to be working on these issues and has been very active in working on these issues. So absolutely.

Senator KERRY. Fair enough. How effectively in your judgment, Mr. Russell, are we sharing and coordinating this effort with other countries?

Mr. RUSSELL. Actually, I think we're doing that well. As a matter of fact, I think we are doing more than almost all other countries, especially and specifically about EHS, but let me give you an example.

Just this week, the OECD is holding a meeting on this specific issue. EPA is chairing that meeting. It's on Nanotechnology and specifically EHS Issues and so we're working very hard to coordinate with the rest of the world, not just on EHS, though, because EHS is just one issue with nano.

Obviously one of the things we want to make sure is that we win the commercialization battle as well and there we're working very hard internationally on issues like standards where it's really critical that we end up with the world adopting standards that are beneficial to our companies just as much as they are good for the world in terms of new nanotechnology products.

Senator KERRY. Now let me come to the structure of this thing. The Nanotechnology Research and Development Act originally called for a National Nanotechnology Advisory Panel to the President and to the whole NNI.

President Bush fought for that authority to be put into the PCAST, the President's Council of Advisors on Science and Technology.

My question to you is isn't their mandate so broad as a whole that it just doesn't have the kind of specific expertise and knowledge that you want with respect to the nanotechnology sector?

Mr. RUSSELL. Let me answer that in two ways. One is, one of the reasons the President very much wanted PCAST, which is the panel you just described, to advise him on nanotechnology is that he actually meets with PCAST on an ongoing basis.

PCAST is made up of leading CEOs of tech companies and presidents of universities, very prestigious people. They actually have a group that advises them, what's called a TAG, an advisory group specific to nanotechnology. Those are nanotechnology scientists and so those nanotechnology scientists as a fairly large group of people are directly advising presidents of universities, the head of the National Academy of Engineers, for example, now soon to be our head of the Smithsonian, who is currently head of Georgia Tech, as well as venture capitalists and presidents of large corporations, who are on PCAST, and so really having PCAST review and speak to nano really helps in terms of its status within the policymaking process.

So I think it's a very useful function to have PCAST doing that.

Senator KERRY. Does it stifle it in any way? Does it cut it off?

Mr. RUSSELL. I don't think so. I think it has exactly the opposite effect.

Senator KERRY. How would you say PCAST has guided and advised the NNI thus far?

Mr. RUSSELL. Well, it has actually very directly interacted with the NNI and directly given advice, written a report. It's done a very good report on the state of technology, nanotechnology, in terms of the U.S. and the rest of the world, which has been a very valuable document.

Senator KERRY. The National Research Council's 2006 review suggested otherwise a little bit. Are you familiar with it?

Mr. RUSSELL. I am familiar with it. I haven't looked at that recently.

Senator KERRY. They found that the NNI does not have the benefit of access to an independent standing technical advisory panel, even though there is. I'm quoting them, "ongoing national need for such a body," and they recommended the establishment of an independent advisory panel with specific operational expertise in nanoscale science and engineering.

Why wouldn't we want to follow that counsel?

Mr. RUSSELL. Because I think what you will lose by doing that—the way the system works now, and I really think it's been working very well, is you have that specific expertise, the expertise that the Academy is talking about which is part of what's called the TAG, which is the advisory council, that specific nanotechnology scientists, to PCAST.

So you have a large number of nano experts talking directly to very well-respected people, like Norm Augustine, who are on PCAST. Having Norm Augustine and others like him talking to the President about nanotechnology really helps nano. I think we would lose a lot if we broke that chain.

Senator KERRY. Mr. Robinson, do you want to comment?

Mr. ROBINSON. Senator, this topic is a little bit beyond the scope of our initiative, so I wouldn't have any more to add.

Senator KERRY. OK. That's fair. Let me ask either of you if you'd like to comment on this concept that has been suggested to the Committee that part of the problem with the way that the program is currently constituted is that the agencies don't have a clear sense of how to work together in order to maximize their budgets, maximize their resources, and make sure there's a clear cut government-wide strategy for forwarding nanotechnology research.

Is there anything specific about the current structure that you think, as we think about the reauthorization, that ought to be changed? Either of you?

Mr. RUSSELL. I must say, and obviously I work with a lot of different types of interagency programs, and of the various programs that have many agencies involved and in this case we have 25 separate agencies, nano is one of the best coordinated programs that we have in the science arena, and I actually think the GAO report really echoes that and so I don't think—you can always make improvements, no question, but I think we want to be really careful that we don't blow up what has really been a successful model and a long-term model.

I mean, you know, we've now been with this model for 8 years and under this model, we've seen a tripling of the budget. We've seen the establishment of a national coordinating office. We've seen the passage of legislation which this Committee put forward. So I think it's been a successful model.

Mr. ROBINSON. One thing I would add to that is I would agree that, among my 35 years of doing this, this is one of the situations when we look at collaboration and where we'd have to say this is pretty good by Federal standards. Not the least of which, it is important to mention that research bodies and regulatory bodies are sort of working together, crossing normal sort of barriers and this is a real advantage to this particular operation.

The thing that we would want to bring to the dance, however, is that at the end of the day, there's nobody ensuring that all the work that's supposed to be done is orchestrated in a systematic fashion to reach conclusion at the same point and address all the barriers and all the knowledge gaps that the public probably expects from its government; that it's going to protect itself from any potential unintended "I Am Legend" kind of consequences that I think some folks probably have in their minds.

Senator KERRY. Thank you very much. Senator Thune?

**STATEMENT OF HON. JOHN THUNE,  
U.S. SENATOR FROM SOUTH DAKOTA**

Senator THUNE. Thank you, Mr. Chairman. I want to thank you for holding the hearing and thank both the panels that are testifying, one now and one later, for their testimony, and I think it's important that to keep our country competitive, we always push the boundaries of science in accordance with reasonable ethical standards and public safety measures.

Nanotechnology is the frontier of the scientific community and the U.S. National Nanotechnology Initiative is an important part of fully actualizing the benefits of this very exciting technology, and as our witnesses, I think, are highlighting, nanotechnology is already playing a part, an important part in our everyday lives.

Over the past 14 months, the number of nano-enabled consumer products has doubled. Consumers across the country are benefiting from this research, even if in many cases they're unaware of its origins.

So thanks to the investment of public and private sector resources and the ingenuity of America's scientists, the influence and the benefits of nanotechnology are going to continue to lift the

standard of living for Americans and for individuals around the world.

As we move forward with reauthorizing the National Nanotechnology Initiative, I think we need to encourage greater focus on safety and greater transparency within the National Nanotechnology Initiative and I would also encourage my colleagues on the Committee to consider an increased role for renewable energy within the National Nanotechnology Initiative, and I again want to thank our witnesses for their testimony, and I look forward to working with my colleagues on the Committee as we strengthen this very important initiative.

I guess I'd like to just ask a couple of questions, if I could, related to agricultural and energy issues. Agriculture is obviously very important in my state and advances in biotechnology have greatly increased the yields and efficiency of producing many of our crops, and I guess my question has to do with what advances do you see being made in nanotechnology in the agricultural field? How far off are these advances?

Given the food shortages that are being caused by increasing demand for food abroad? Do you think we should be directing more funding toward the research of nanotechnology that will promote agriculture?

Mr. RUSSELL. I can talk to the energy field a little more easily than I can talk directly to agriculture. Clearly, there are benefits associated with nanotechnology, and I would think where you might see that particularly is in things like improved fertilizers and improved utilization of nano to create new types of crops.

But let me give you an energy example that is real and that could make a huge difference for all of us and that's with lighting.

Senator THUNE. What's that?

Mr. RUSSELL. Lighting. Nano-enabled LEDs can be twice as efficient as fluorescent light bulbs and they have none of the real problems associated with them and if you look at overall energy consumption in this country, lighting is a massive piece of the puzzle and so there, you're really seeing where nanotechnology can make a truly significant difference.

One of the problems with LEDs is getting white light and through nanotechnology, we can solve that problem and that would be a real increase in efficiency and a real decrease in our energy need for the country.

Senator THUNE. My assumption, based on the answer to that question, though, is there hasn't been a lot of thought given to how nanotechnology might impact crop production and biotechnology.

Mr. RUSSELL. I wouldn't actually say that. I'm just less familiar with that area, but I'm happy to get you examples for the record because there is work ongoing in that area as well.

[The information referred to follows:]

The NM supports extensive nanotechnology R&D in biotechnology and agriculture. For example, the USDA program on Nanoscale Science and Engineering for Agriculture and Food Systems aims to develop nanoscale detection and intervention technologies for enhancing food safety and agricultural biosecurity; effective delivery of micronutrients and bioactive ingredients in foods; and product identification, preservation, and tracking. The program also supports social science researches to address public perception and acceptance of nanotechnology applications in agriculture and food systems.

The NMI is also supporting research using nano-fabricated surfaces to study how certain bacteria affect the water-transporting tissues in plants. The nanotechnology approach enables the study of the plants without destroying them, allowing collection of more and better data. Understanding how bacteria colonize these nano-structured vessels is leading to development of novel plant disease control strategies.

Senator THUNE. Coming back to your response about the energy issue, one of the greatest challenges, I think, that our country faces right now is this dangerous dependence that we have on foreign sources of energy and I also believe that ethanol made from crops and that sort of thing is an immediate solution to this problem and one that we need to continue to develop, and I think we have to commercialize cellulosic ethanol as soon as possible to meet that growing demand for fuel.

There's a certain—there's a cap on what we can generate from corn. That varies. Most people think somewhere in the 15 billion gallon range and we use about a 140 billion gallons of fuel in this country every year. So we're at about 7.5 billion gallons of production right now. So even if we max out what we can do in corn, we're still a long ways from having significant impact.

On the other hand, when you start getting into the cellulosic field, which is advanced biofuels made from other types of biomass, switch grass, wood chips, those sorts of things, you can dramatically increase the amount of renewable energy that we can produce, and one of the technological obstacles to producing cellulosic ethanol is perfecting the enzymatic reactions that break down cellulose to usable sugars that can make ethanol.

So I guess the question I have is, is there a role for nanotechnology in perfecting that process, and has the initiative focused on fuel production, in addition to some of the things that you referenced with regard to light?

Mr. RUSSELL. Again, Senator, I'm happy to get you for the record the specifics of what the Department of Energy is doing. The Department of Energy is one of the significant contributors to the Nano Initiative and there is absolutely no question that nanotechnology—one of the real breakthroughs by using nano is to reduce, for example, expensive catalysts associated with reactions and the reason for that is pretty clear.

[The information referred to follows:]

In order to convert cellulosic biomass (*e.g.*, wood, switchgrass, corn stover, and wheat straw, and other agricultural and forest residues) into biofuels, complex enzymes must break down the cell walls of the feedstock plants. Optimization of these enzymes depends on a detailed understanding of how they interact with the plant cells at the nanoscale. As result, the three new DOE Bioenergy Research Centers are using many of the same tools used by nanoscience researchers for this aspect of their research, including a range of powerful new capabilities for imaging matter at the nanoscale. This nanoscale imaging is integrated into a systems approach that also utilizes a range of other tools, including rapid genomic sequencing and high-throughput screening, metagenomics, and other techniques that are specific to genomics-based systems biology. Nanotechnology tools are helpful in investigating cell-wall physical and chemical properties, how they function, and how certain structural features inhibit or facilitate enzymatic interactions and subsequent conversion to sugar (for eventual conversion by microbes to ethanol as well as to hydrocarbons, including "green" gasoline, diesel, and even jet fuel). Specifically, researchers do not have a good understanding of the solution physics and thermodynamics that govern the protein-domain biological functions at the nanometer scale. The new tools of nanotechnology can help develop system-level descriptions of these processes, including the biomolecular mechanics that govern interactions at the cellulose surface. For example, DOE is using nanotechnology tools to help design enzymes (biocata-

lysts) that can more efficiently break down cellulosic feedstock into sugar, which can then be processed by microbes into ethanol and other fuels, including hydrocarbons. This research is being conducted by DOE's three Bioenergy Research Centers (<http://genomicsgtheenergy.gov/centers/index.shtml>), which are led by ORNL, LBNL, and Univ. of Wisconsin (in close collaboration with Michigan St.).

Obviously when you can distribute chemicals at the nanoscale, you can dramatically reduce the amount of either the toxic or the expensive catalysts you need for individual reactions.

So nanotechnology has generically proven very valuable in these kind of reactions in terms of making them cost effective, which obviously is a huge part of the equation when you're talking about cellulosic. It's not that we don't know how to do cellulosic, it's hard to do it at scale, it's hard to do it at a reasonable cost.

Senator THUNE. In your reference to—I know the DOE's real involved with this initiative which I think is a good thing because I think that the energy applications are very real and can be very meaningful.

How would you rate the coordination among the Federal agencies that are involved with the effort? Are there things that can be done to improve that?

Mr. RUSSELL. Well, generically and this is largely because they've all bought into the effort itself, it's excellent. As I stated in my testimony, we have 25 agencies who are voluntarily participating and the reason that's important is they all think they're getting something out of it and since they think they're getting something out of it, they actually are actively participating in the program rather than simply being forced to participate.

So for that very reason, actually the interaction is excellent and you don't see the kind of problems you see with coordination where agencies think that they're either being forced to do something or that another agency might be stealing their budget and so that's really a differentiator in this case and I think it's worked very well.

Senator THUNE. Thank you. Thank you, Mr. Chairman. Thank you for your testimony.

Senator KERRY. Thank you very much, Senator Thune. Just a last question quickly. Tell America what you think. What are we looking at here? What do you see the future of nanotechnology conceivably providing? Are there areas where you see the most impact, perhaps the products and types of things that will be most exciting to Americans?

Mr. RUSSELL. Well, I think there will be a variety of areas and that's one of the wonderful things about nanotechnology because it really crosscuts almost all the areas you can imagine in terms of commercializable products.

Clearly, today, biomedical is an amazing and a growing field. Just today in the *Washington Post*, in the Business section, they had a very interesting article about cancer fighting drugs that can be targeted through nanoparticles directly at just the cancer.

You're seeing similar breakthroughs with replacing bones, making bone screws out of actual bone, and other advances in the biomedical field, and in other areas, like coatings, there is tremendous current work going on where you're seeing much stronger and better and longer-lasting coatings.

Also in the environmental field, and this goes to GAO's point that about \$7 million of pro-environment research was categorized as environmental impacts, nanotechnology, because it can reduce the waste stream, because we can use less of dangerous products, not just expensive products, in terms of how we manufacture things can make a real difference in terms of the amount of waste that's produced that's produced when we are producing things.

So I think those are some of the many areas you're going to see breakthroughs. The other is in materials and having stronger, lighter materials which again saves energy and allows us to do all sorts of interesting things is clearly an area where nanotechnology has really taken off.

Mr. ROBINSON. And I would agree, you know, beyond the biomedical front, obviously the energy potential, if you can develop these nano-based thin photovoltaics that essentially can be incorporated into windows, paints, roofs that make every house its own energy generator, I mean phenomenal potential there.

But referencing back to Senator Thune's point, one of the things that we want to make sure in our work which was indeed concentrated on EHS issues, we want to make sure that we don't have a repeat similar to biotech crops where the public's confidence or at least other potential buyers' confidence was shaken and it damaged our ability to enter the marketplace and that is sort of at the root of this effort.

We need to make sure that everything's aboveboard, transparent and, as best we can determine, all the risks are identified and attacked in the most systematic efficient way possible, and that's at the root of our testimony today.

Senator KERRY. Well, I appreciate it. We appreciate your testimony today. I'm going to leave the record open for a couple of weeks in the event any other colleagues have any questions they want to submit in writing, but we thank you for coming today. Thank you for the analysis. Thank you, Director Russell, for your help in understanding this as we go forward.

Mr. RUSSELL. Thank you, Mr. Chairman.

Senator KERRY. Could we ask for the second panel to come forward right away and we'll get started? Appreciate that.

Mr. Matthew Nordan, the President of Lux Research, Incorporated; Mr. David Rejeski, Director, Foresight and Governance Project, Project on Emerging Nanotechnologies, Woodrow Wilson Center; Dr. P. Lee Ferguson, Assistant Professor, Department of Chemistry and Biochemistry, University of South Carolina; Dr. Anita Goel, Nanobiosym, Incorporated; and Dr. James Heath, Nanosystems Biology Cancer Center at the California Institute of Technology.

We welcome you all. Thank you for being here. Why don't we just begin with you, Mr. Nordan? We'll run right down the line here and we welcome your testimonies. Again, all your testimonies will be placed in the record in full. If you could summarize in 5 minutes, that would be great.

**STATEMENT OF MATTHEW M. NORDAN, PRESIDENT,  
LUX RESEARCH, INC.**

Mr. NORDAN. Good afternoon, Mr. Chairman. Lux Research advises corporations and investors on the unique perspective—

Senator KERRY. Advises about the unique perspectives of nanotechnology?

Mr. NORDAN. Commercialization.

Senator KERRY. Commercialization.

Mr. NORDAN. On the basic measure of scientific output, the NNI has been a great success. The \$7.2 billion that it has channeled since launch has funded prodigious research in areas ranging from noninvasive cancer therapies to high-efficiency solar panels, but more than this, the NNI has catalyzed a virtuous cycle of innovation.

The NNI has excited corporate interest in nanotech. It helped spark \$2.4 billion in private R&D spending on the topic last year which exceeded government funding by 23 percent. Stimulated by the NNI, venture capitalists have opened their checkbooks. Last year, VC funding for U.S.-based nanotech startups totaled \$632 million. That's four times the figure in the year before the NNI, and finally, NNI-funded initiatives have sparked new enthusiasm about the physical sciences broadly among students, from the post-graduate level down to high school.

Nanotechnology is now having a significant commercial impact. Because nanotech is a toolkit that's being deployed behind the scenes in virtually every manufacturing industry, it can seem invisible. There's an all-too-commonly held misperception that all we have to show for our nanotech funding is stain-resistant pants but this view is dead wrong.

From the billions of dollars in nano-enabled pharmaceuticals sold last year by the likes of Abbott to the nanocomposites in coatings, the chip in millions of vehicles from General Motors, nanotech is on track to exceed my firm's projection of enabling \$2.6 trillion in goods sold by 2014, about 15 percent of manufacturing output.

Nanotech is also creating new companies and new jobs. In my home state of Massachusetts, the Arsenal Complex in the City of Watertown was 750,000 square feet of empty crumbling space in the mid 1990s, but now its biggest tenant is A1-2-3 Systems which manufactures high-performance batteries with nano-structured electrodes based on research by Yet Ming-Chiang at MIT, precisely the type of work that the NNI funds. In four short years, A1-2-3 has gone from a few dozen employees to more than 1,000 and it's helped to shift the center of battery innovation from East Asia to the U.S.

Now my company conducts an annual assessment of international competitiveness in nanotech. We rank 19 nations worldwide. On an absolute basis, the U.S. remains the world leader, but the U.S. does not lead and not by a long stretch when the size of our economy is taken into account.

For instance, when you look at government funding on an absolute basis, the U.S. topped the charts last year, but when the same figures are considered on a per capita basis at purchasing power parity, the U.S. takes eighth place with funding half that of Taiwan and behind Germany, Sweden and France.

Other nations are gaining rapidly. Nanotech funding is growing in the EU at twice our rate. Russia recently funded a state nanotechnology corporation with \$5 billion of public financing and the citation rate of nanotech journal articles in China, which is a measure of their quality, has doubled in the last decade.

Now with these facts in mind, the NNI should certainly be reauthorized but as nanotech shifts from discovery to commercialization, change is required. Most of the changes that will help transition NNI-funded research to market really have nothing to do with nanotechnology in particular. They address broader issues. This should come as no surprise given nanotech's diversity and breadth. For example, rapidly growing companies need skilled human capital. This means major new investment in science and technology training for U.S. students, as Senator Stevens referred to, but it also requires easing the visa process for foreign nationals and expanding the H1V program.

Recall A1-2-3 Systems. Had Yet Ming-Chiang returned to his native country, its 1,000 employees might well be in Taiwan. Startups that want to access public markets face immense administrative costs to comply with regulations like Sarbanes-Oxley. Reducing these costs will unshackle them. We should note that of 14 nanotech startups that have gone public to date, most of them have done so on foreign exchanges where the cost of doing business is much lower.

Finally, Congress can introduce financial mechanisms that help small companies collaborate with big ones. This is particularly important in nanotech by, for example, enabling small firms to transfer their net operating losses to corporate partners.

There are, however, a number of smaller changes specific to nanotech that are also necessary. I'll focus on two. First, a reauthorized NNI should fund not just basic research but also precompetitive R&D into nanomaterials application development and manufacturing scale-up.

The Department of Energy's Nano Manufacturing Initiative is a model case study for this.

Second, a reauthorized NNI must address potential environmental health and safety risks as we've discussed much more aggressively, bringing regulatory clarity to companies that are begging for it and presenting a comprehensive interagency roadmap for EHS research.

I appreciate your inviting me here to speak. I'm confident that with your informed decisions the next 7 years of the NNI will be even brighter than the first seven.

I'm pleased to answer any questions.

[The prepared statement of Mr. Nordan follows:]

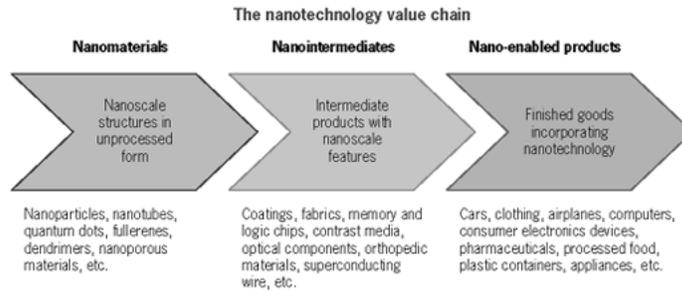
PREPARED STATEMENT OF MATTHEW M. NORDAN, PRESIDENT, LUX RESEARCH, INC.

The National Nanotechnology Initiative (NNI) is a great success; it has not only funded prodigious fundamental research, but has also catalyzed a virtuous cycle of innovation manifested in corporate R&D and venture capital. The landscape is different today than when the NNI commenced in 2001, however. Nanotech's discovery phase has given way to commercialization—tens of billions of dollars worth of products now incorporate nanotech—and other nations are eroding the U.S.'s dominant position. As the NNI is reauthorized, its focus should shift to application development and manufacturing scale-up—and its approach to environmental, health, and safety (EHS) issues must be overhauled.

**The NNI Has Catalyzed a Virtuous Cycle of Innovation**

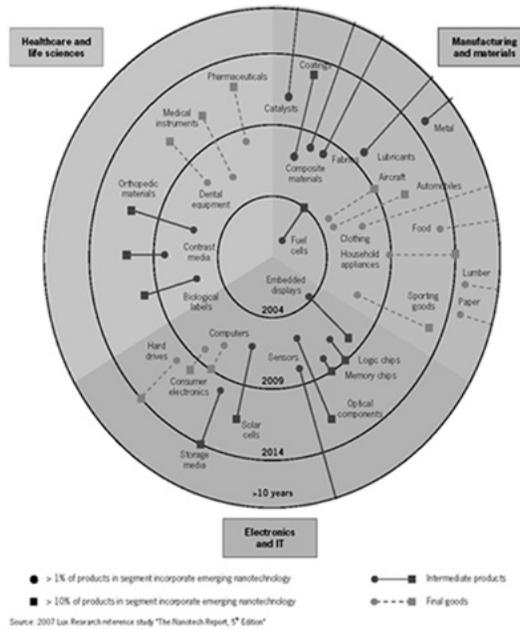
Nanotechnology is the purposeful engineering of matter at scales of less than 100 nanometers (nm) to achieve size-dependent properties and functions. Nanotech is not a new industry or market, but rather an enabling set of technologies that impact a wide variety of industries through a nanotech value chain. This value chain starts with nanomaterials like carbon nanotubes and dendrimers, which are incorporated into intermediate products like memory chips and drug delivery systems, which are in turn used to make enhanced final goods like mobile phones and cancer therapies (see Figure 1). Lux Research projects that new, emerging nanotechnology applications will affect nearly every type of manufactured product through the middle of the next decade, becoming incorporated into 15 percent of global manufacturing output totaling \$2.6 trillion in 2014 (see Figures 2 and 3).<sup>1</sup>

**Fig. 1: Nanotech Adds Value across Industry Value Chains in Three Stages**



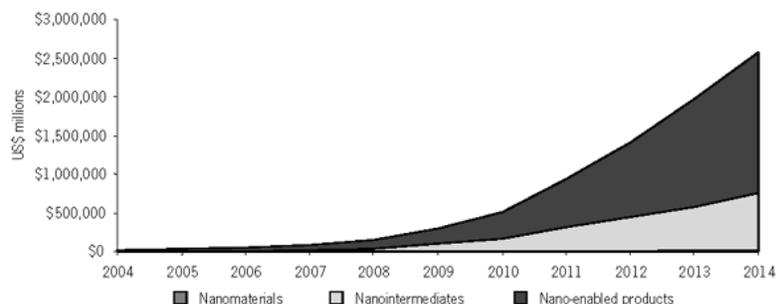
Source: 2007 Lux Research reference study "The Nanotech Report, 5<sup>th</sup> Edition"

**Fig. 2: Product Categories Are Incorporating Emerging Nanotechnology at Different Rates**



<sup>1</sup>Source: October 2004 Lux Research report "Sizing Nanotechnology's Value Chain."

**Fig. 3: Global Sales of Products Incorporating Emerging Nanotechnology, by Value Chain Stage, 2004 to 2014**



Source: 2007 Lux Research reference study "The Nanotech Report, 5th Edition"

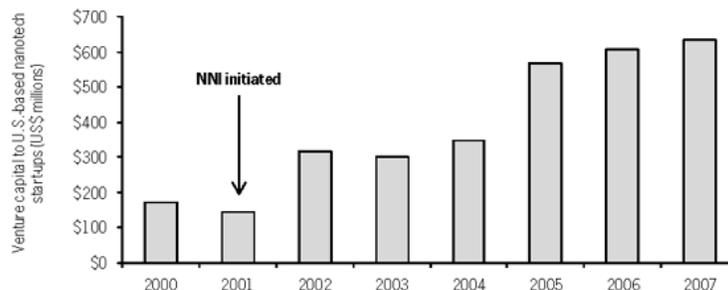
Introduced in 2001 and signed into law in 2003, the U.S. National Nanotechnology Initiative is the Federal Government's coordinating program for publicly-funded nanotechnology research, which has inspired similar efforts in countries worldwide from Germany to South Korea. By the core measure of scientific output, the NNI has been a great success—U.S. scientists have published 55,661 journal articles on nanoscale science and engineering since 2001, 27 percent of the world's total. But in addition to this, the very presence of the NNI has catalyzed a virtuous cycle of innovation, manifested in:

- *Corporate R&D spending.* Large U.S. corporations from GE to Motorola spent \$2.4 billion in nanotechnology R&D in 2007, up 22 percent from 2006 and 557 percent from 2000, the year before the NNI's introduction. The 2007 figure was 23 percent higher than U.S. Government nanotechnology funding at the Federal and state level combined.<sup>2</sup> These efforts include in-house research like GE's Nanotechnology Advanced Technology Program, broad collaborations like Cabot Corporation's Fine Particle Network, and joint ventures like DA Nanomaterials, created by DuPont and Air Products. Without the NNI as a widely-publicized focusing mechanism for nanotechnology research, it's unlikely that this intense corporate focus on nanoscale science and engineering would have materialized.
- *Venture capital (VC) funding.* Venture capitalists are always on the lookout for compelling investment themes, as well as non-dilutive sources of financing that can help sustain the companies they invest in through notoriously rocky early stages. The NNI has provided both, serving as a validator that has helped open VCs' wallets to materials science investments in a fashion never before seen. In 2007 VC firms put \$632 million into U.S.-based nanotech start-ups in 2007, more than four times the figure in the year before the NNI was initiated (see Figure 4).<sup>3</sup>

<sup>2</sup>Source: 2007 Lux Research reference study "The Nanotech Report, 5th Edition."

<sup>3</sup>Source: March 2008 Lux Research report "How Venture Capitalists Are Misplaying Nanotech."

**Fig. 4: The NNI Sparked Venture Capital Interest in Nanotechnology**



Source: March 2008 Lux Research report "How Venture Capitalists Are Misplaying Nanotech"

- *New companies and new jobs.* Consider A123Systems, which uses nanostructured lithium iron phosphate electrodes to make advanced batteries now being evaluated for use in electric vehicles like GM's Chevy Volt. In the mid-1990s, the Arsenal complex in the City of Watertown, Massachusetts was 750,000 square feet of empty, crumbling space. Now, A123Systems is its biggest tenant, commercializing battery devices based on research by Yet-Ming Chiang at MIT—precisely the type of research that the NNI funds. In just 4 years, A123 has gone from a few dozen employees to more than 1,000—and helped to shift the center of battery innovation from east Asia to the United States.

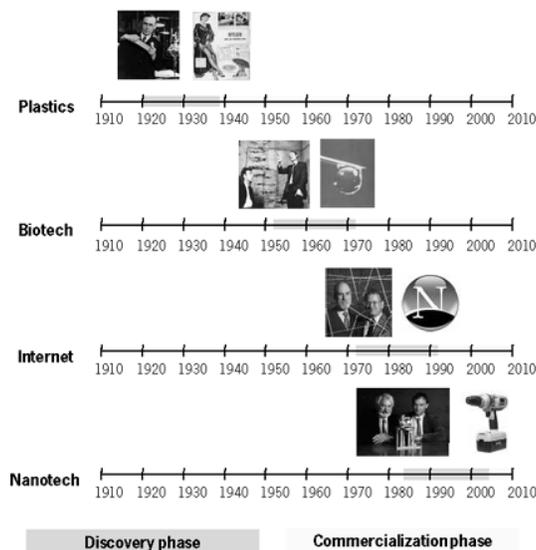
#### **The Nanotech Landscape Is Very Different Today than When the NNI Launched**

When the NNI took shape in 2001, nanotechnology activity focused on early-stage laboratory research with little commercial impact, and the U.S. was alone in the world in having a nationwide coordinating program for nanotech. Today, both factors have changed. Nanotechnology has shifted from its discovery phase into its commercialization phase—and at the same time, the dominant competitive position of the United States has been eroded by other nations.

##### *Nanotech Commercialization is Eclipsing Discovery*

In the last 7 years, emerging nanotechnology has increasingly become a fact of life and of business, as the technology has shifted from an era of *discovery* to one of *commercialization*. In this fashion, nanotechnology follows the example of other world-changing technologies like polymer science and biotechnology. For these emerging technologies, everything starts with the discovery phase—a period of basic research and application development—which has a characteristic time span, give or take a bit, of about 20 years. It's then that a tipping point gets reached, triggering the commercialization phase—where the technology's long-term impact is manifested (see Figure 5).

Fig. 5: Nanotech's Shift from Discovery to Commercialization Follows a Familiar Pattern



Source: 2007 Lux Research reference study "The Nanotech Report, 5<sup>th</sup> Edition"

For instance, plastics' discovery phase started in the 1920s, when scientist Wallace Corrothers at DuPont began work on synthesizing nylon. In 1937, he was issued his patent on the material. Two years afterward—about 20 years after discovery began—American women bought 64 million pairs of nylon stockings; once the commercialization threshold was reached, it took off fast. In biotechnology, James Watson and Francis Crick characterized DNA in 1953, and 20 years later, right on cue, Stanley Cohen and Robert Boyer applied genetic engineering techniques to synthesize insulin for the first time. Genentech, the first biotech start-up, was founded in 1976, and commercialization has since skyrocketed: In 2006, revenues of publicly-traded biotech companies topped \$65 billion. In information technology, Vint Cerf and Robert Kahn proposed the Internet protocol in 1974. The number of Internet users grew gradually to the single-digit millions up through 1993, but began to skyrocket in about 1994, the year Netscape's browser was released—reinventing communication and commerce in the process.

Nanotech's discovery phase started in the mid-1980s with the invention of scanning probe microscopes that enabled scientists to visualize matter at the nanoscale for the first time. Innovations have reached the market in electronics, as AI23Systems' nanostructured battery electrodes appeared on store shelves in Black & Decker's Dewalt line of power tools; in healthcare, as nanoparticulate drug reformulations like Abbott's cholesterol drug Tricor have found their way into doctors' repertoire; and in materials and manufacturing, as PPG's coatings have improved the performance of millions of automobiles. According to our research, approximately \$88 billion in manufacturing output worldwide incorporated emerging nanotechnology in 2007.

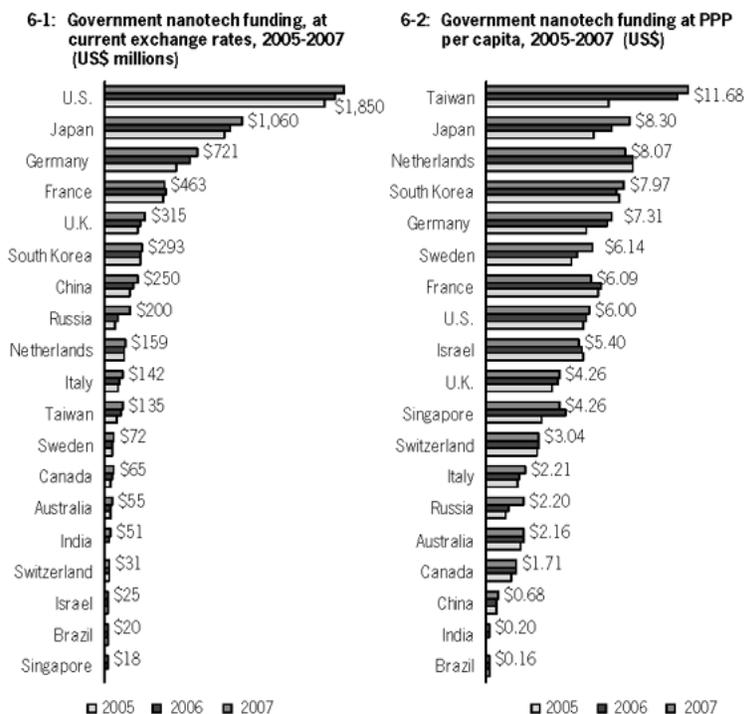
#### *The Dominant Position of the U.S. Is Being Eroded*

Each year, Lux Research conducts an annual assessment of international competitiveness in nanotechnology, ranking 19 nations worldwide on their nanotechnology activity and technology commercialization strength. On an absolute basis, the U.S. remains the world leader in nanotech. Two factors, however, should give U.S. policy-makers pause:

- *The U.S. does not lead on a relative basis.* Relative to our population and the size of our economy, the U.S. pales in comparison to other countries when it comes to nanotechnology activity. For example, when government funding is considered on an absolute basis, the U.S. topped the charts in 2007. However,

when the same figures are considered on a per capita basis at purchasing power parity, the U.S. takes eighth place, with funding half that of Taiwan, and behind Germany, Sweden, and France (see Figure 6).<sup>4</sup>

**Fig. 6: U.S. Government Nanotech Funding Lags Other Nations on a Relative Basis**



Note: Data labels in above figures refer to 2007 data

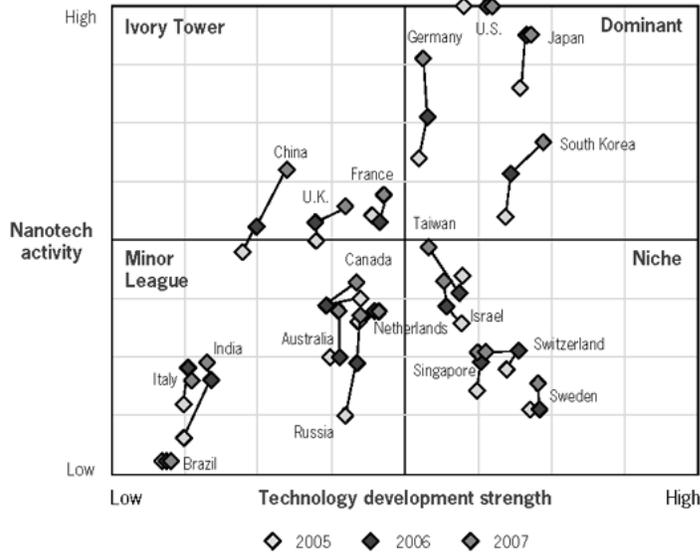
Source: December 2007 Lux Research report "International Activity Drives Nanotechnology Forward"

- *Other countries are catching up.* Since we began performing our international competitiveness rankings in 2005, the position of the U.S. has remained static while other countries have vaulted upwards in their nanotechnology activity (see Figure 7). For example, nanotech funding is growing in the EU at twice the rate in the United States, putting the EU on track to claim the mantle of nanotechnology leadership due to a renewed focus on nanoscale science and engineering in the 7th Framework Programme for research. Russia recently funded a state nanotechnology corporation with \$5 billion of public financing. And scientists in China published nearly as many scientific journal articles on nanoscale science and engineering in 2007 as those in the U.S. did, at 7,282 to 7,528 (see Figure 8). While the quality of these publications has been suspect in the past, the citation rate of nanotech journal articles from China—a measure of their quality—has doubled in the last decade.<sup>5</sup>

<sup>4</sup> Source: December 2007 Lux Research report "International Activity Drives Nanotechnology Forward."

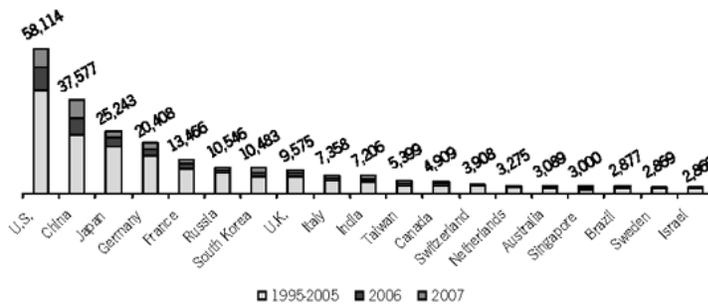
<sup>5</sup> Source: Science Citation Index as of December 10, 2007; search terms (country), (year), and (quantum dot OR nanostruc\* OR nanopartic\* OR nanotub\* OR fulleren\* OR nanomaterial\* OR nanofib\* OR nanotech\* OR nanocryst\* OR nanocomposit\* OR nanohorn\* OR nanowir\* OR nanobel\* OR nanopor\* OR dendrimer\* OR nanolith\* OR nanoimp\* OR nano-imp\* OR dip-pen).

Fig. 7: Other Nations Are Gaining on the U.S. in Nanotechnology



Source: December 2007 Lux Research report "International Activity Drives Nanotechnology Forward"

Fig. 8: Journal Articles on Nanoscale Sciences and Engineering Topics, 1995 to 2007



\*2007 data as of December 10, 2007

Source: December 2007 Lux Research report "International Activity Drives Nanotechnology Forward"

**A Commercially-Dominated Landscape Requires Change to Unlock the NNI's Value**

Clearly, the NNI should be reauthorized. But in the context of growing nanotech commercialization and increased international competitiveness, the onus is on Congress to eliminate roadblocks to market introduction for nanotechnology applications. Most of these changes are not specific to nanotech, although a few key ones are.

*Nanotech's Pervasiveness Means that Most Required Changes are General*

Many of the changes that will help transition NNI-funded research to market have nothing to do with nanotechnology specifically, but address broader issues in technology commercialization. Given nanotechnology's diversity, and the breadth of product categories that it touches, this is to be expected: As goes technology in general, so goes nanotech. These changes include:

- *Attracting U.S. students to science and engineering, and retaining foreign ones.* Funding for nanotechnology R&D will amount to nothing without a steady stream of trained scientists and engineers entering the work force. The U.S. should strengthen programs designed to inspire students with wonder for the physical sciences in K–12 and undergraduate education to nurture homegrown talent. But it should also reconsider the effect of visa tightening on the inflow of foreign science and technology graduate students, and expands H1-B visa programs to allow students that have earned advanced degrees in science and engineering in the U.S. to remain here—rather than repatriating taking with them the skills they acquired in the U.S. The lesson of A123Systems is instructive: Had Yet Ming-Chiang returned to his native country, its 1,000 employees would likely be in Taiwan.
- *Reducing the cost of doing business for start-ups seeking public markets.* Start-up companies looking to make initial public offerings (IPOs) on the public markets face immense administrative costs to comply with regulations such as Sarbanes-Oxley. Easing these burdens will unshackle them. It's important to note that of the 14 nanotech start-ups that have gone public, most have done so on foreign exchanges where the cost of doing business is lower.
- *Introducing financial mechanisms to encourage collaboration between small and large firms.* Nanotechnology commercialization has followed a pattern similar to biotech, in which small, innovative companies develop breakthrough technologies that incumbent corporations bring to market: Silver nanoparticle antimicrobial company Nucrust Pharmaceuticals relied on wound care dressing maker Smith & Nephew to get to market, while A123Systems found its partner in Black & Decker. Congress can grease the wheels of nanotechnology commercialization by creating financial mechanisms that help small firms to collaborate effectively with large ones. One example of such a measure would be enabling small companies to transfer their net operating losses to their corporate partners—allowing those partners to reap the tax benefits of research investments, which the loss-making smaller companies can't claim.

#### *A Few Nanotech-Specific Changes Are Necessary*

In addition to these general reforms, a smaller number of changes specific to nanotech are also required. There are two specific actions we think Congress should take now:

- *Shift some of NNI's focus to application development and manufacturing scale-up.* A reauthorized NNI should focus on not just on basic research, but also on precompetitive R&D into nanomaterials application development and manufacturing scale-up. Currently the technical challenges that are limiting nanotech commercialization are not as much in synthesizing nanomaterials or understanding their fundamental properties as in learning how to integrate them into products and manufacturing them economically in large volumes. The Department of Energy's Nanomanufacturing initiative, run out of its Industrial Technology Program, is a model case study—it aims to introduce shared Nanomanufacturing centers as pilot facilities on the model of the NNI's existing user centers for nanoscale analytical equipment.
- *Take a completely different approach to environmental, health, and safety (EHS) issues.* In our work with companies looking to take advantage of nanotech innovation, the single concern that comes up more than any other is potential EHS risks of nanomaterials. While it's of course incumbent on companies developing nano-enabled products to test their own products to ensure safety, there's an important role for government to play in resolving these concerns—by funding basic research on nanomaterials EHS risk that no individual firm can afford, and by establishing clear regulatory guidelines for companies working with nanomaterials.

On the first point, the NNI should be generously funding basic research on the EHS risks of nanomaterials—just as NNI-funded research on nanoscience has supported deployment of real-world nanotech applications, the results of NNI-funded EHS work would help companies complete their own EHS evaluations. Unfortunately, funding levels remain too low to have the desired impact, and, even more critically, the NNI has never effectively addressed EHS issues surrounding nanotech with a comprehensive, interagency plan for required EHS research. The Nanotechnology Environmental and Health Implications (NEHI) Working Group report on EHS issues has not filled this gap—it fails to prioritize specific materials and applications for research, avoiding the tradeoffs that are inherent in any meaningful strategy—and the EPA's internal review of its own nanomaterials EHS activities, by definition, does not cross agencies.

This lack of coordination is hampering development, and must change. The best way to move forward on this front would be to execute the nanomaterials EHS strategy by the National Academies' Board on Environmental Studies and Toxicology—Congress has already appropriated funds for this study, but the work has not yet been started.

Second, ambiguity surrounding how nanomaterials will be regulated must be dispelled. It's still often not clear how current regulations apply to nanoparticles or whether and when agencies will issue new ones—leaving firms that work with nanomaterials confused about how to plan for regulatory rulings. The companies we speak with are actually eager for appropriate regulatory guidance about nanomaterials, to ensure a level playing field and to help them guarantee the safety of workers, consumers, and the environment. While companies are generally pleased about how the EPA, for example, has communicated with them so far, they're also frustrated by how slow those agencies have been to set specific guidance, as witnessed by the glacial pace of the EPA's voluntary Nanoscale Materials Stewardship Program. Seven years after the NNI's launch, it's still unclear to most commercial entities when and how the materials they work with will be treated under the EPA's Toxic Substances Control Act—forming a real commercialization gating factor.

At Lux Research, we applaud the efforts that have taken place so far under the National Nanotechnology Initiative, which have made the U.S. a world leader in nanotechnology and are bringing real economic benefits to our Nation. We're confident that a renewed NNI, with adjustments like those outlined above, will increase these benefits—and enable nanotechnology to help address the challenges the country faces in combating disease, moving toward energy independence, and sustaining economic growth.

Senator KERRY. Thank you very much, Mr. Nordan. Very helpful. Mr. Rejeski?

**STATEMENT OF DAVID REJESKI, DIRECTOR, PROJECT ON  
EMERGING NANOTECHNOLOGIES, WOODROW WILSON  
INTERNATIONAL CENTER FOR SCHOLARS**

Mr. REJESKI. Chairman Kerry, I'd like to thank you for the invitation to talk directly to you and also to the Committee.

I appeared before this Committee about 2 years ago and today what I would like to do is address what's changed since that time I appeared here, what hasn't and what I believe must if nanotechnology commercialization is going to be successful in the future.

Let me begin by providing an update on the state of commercialization of nano-based products. Two years ago, we had 230 manufacturer-identified nano-enabled consumer products in our inventory. The number is now exceeding 600. It's doubled in the last 14 months with products from essentially 320 companies and 20 countries.

The main nano-engineered material in these products is now silver which is used in over a 140 products, such as this nano-silver toothpaste, which is from Korea and we bought in Gaithersburg. I would not use this because I don't really know what the risks are and I'll guarantee you nobody in our Government knows.

The other thing that's happened is the—

Senator KERRY. What kind of toothpaste?

Mr. REJESKI. —nano-silver.

Senator KERRY. What is nano-silver?

Mr. REJESKI. Essentially the toothpaste has been—there's nano-silver in this and it's nanoscale that's introduced as an antimicrobial. So it's designed to have significant antimicrobial powers once it's put in your mouth. It obviously raises issues about what

does it do when you swallow it. If I have periodontal disease, you know, is it going to into the bloodstream, et. cetera?

Senator KERRY. Does it say on the tube what it is?

Mr. REJESKI. Well, it's in Korean.

Senator KERRY. It's in Korean?

Mr. REJESKI. Yes. That presents a problem.

Senator KERRY. You bought it where?

Mr. REJESKI. Gaithersburg. And, you know, we've got—right now, there are nine toothpastes that contain nano-engineered materials in the U.S. marketplace.

Senator KERRY. What are they, just out of interest? Do you know?

Mr. REJESKI. It's largely antimicrobial silvers and also whitening calcium peroxide, but again, you know, the issue is obviously who's tested this, you know, what are some of the risks. It's out there. Consumers can buy it.

Senator KERRY. Well, that applies to about 75,000 chemicals that are in the marketplace.

Mr. REJESKI. Right. Yes. We're just adding nano to the long list of other chemicals that we know very little about.

Senator KERRY. Would that fall under TOSCA?

Mr. REJESKI. This probably would fall partially under FDA regulation, though the actual chemical inputs would fall under TOSCA.

Senator KERRY. It's an interesting question as to where that liability lies, but we'll look at that. Go ahead.

Mr. REJESKI. Let me just continue with some other observations.

I'd say that the area where the largest market penetration is are also areas where we have the weakest—

Senator KERRY. Your smile is radiating, I want you to know.

Mr. REJESKI. Well, we can pass this around.

Senator KERRY. Geiger counter.

Mr. REJESKI. So a lot of the products are penetrating in areas where we really don't have significant oversight, such as the Consumer Product Safety Commission, which spent about \$20,000 last year doing a literature research on nanotech. That's out of our \$1.5 billion NNI.

I think the other thing I want to talk about is the fact that the American consumer learned a painful lesson last year and that's that the oversight system in this country is failing. The public's had to deal with lead in toys that was banned 30 years ago, rat poison in pet food, antifreeze additives in toothpaste, E.coli in meat. These are not novel toxins. So consumers are nervous, our surveys show it, and so are other people that are going to be, I think, critical to nanotech commercialization.

The financial community is taking another look at nanotech. A number of insurance companies have now placed nanotechnology in their top category of emerging risks. I talked last month to people at Lloyd's of London and they basically said there are two things that are critical to reducing risks with nanotech: transparency and oversight and regulation. We have none of those.

State and local governments are moving to provide their own guidance to nanotech firms. We've seen that in Berkeley, California. We're going to see it shortly in Cambridge, Massachusetts, and the State of Wisconsin is doing some work.

I think NGO positions are hardening. A recent report by Friends of The Earth called for a total moratorium on the use of nano in all foods and food packaging. I think if there was ever a honeymoon with the NGO's, it is over, and I think that's something that the Government has squandered over the past 2 years.

Finally, the actual firms, especially small firms, are nervous because they lack clear guidance from the Government. One senior safety manager at a Massachusetts corporation told us, "At this time, we don't understand what regulatory requirements may be uniquely applicable to nanotech."

These problems do not bode well for nanotech commercialization. So let me talk a little bit about what hasn't changed and I think what needs to be done as the Congress turns their attention to the reauthorization of what I hope they will call the 21st Century Nanotechnology R&D and Commercialization Act because that's what it's all about now.

The three areas are critical. The first, the GAO mentioned, is transparency. The reauthorization bill must make the NNI fully transparent and accountable in terms of investments to address the risks. Public confidence in nanotech can't be built on hidden agendas or exaggerated numbers and we believe a separate external advisory board needs to be essentially established to provide guidance and oversight for the NNI.

Strategy. We need a comprehensive strategy, Congress has been waiting few years for this, that addresses existing and emerging risks, sets governmentwide priorities, ties funding levels to priorities and ensures that the right that the right risks are being addressed by the right agencies at the right time in the R&D commercialization cycle.

The strategy also needs a minimum funding level for nano-related EHS research, order of magnitude increases for EHS funding at our key regulatory agencies. That includes EPA, FDA, USDA, and the Consumer Product Safety Commission.

We need to provide public-private partnerships and we need funding and a strategy for clean and green nanotech.

The final area is engagement. Public awareness of nanotech is stuck at a low level. We haven't moved the awareness meter or nanometer in the past few years compared to basically where we started.

The Federal Government has no strategy to engage the public at a wider level and fill the knowledge gaps about nanotech and I think that's going to have serious implications essentially for long-term success. This needs to be remedied—

Senator KERRY. What do you think is the most responsible entity for that?

Mr. REJESKI. I think it's government-wide, but I think the coordination again has to come from the top level. I think the Government needs to think about potentially bringing in an external entity that really knows how to do this.

Let me conclude with sort of one following recommendation. I think the greatest challenge we're facing is basically how do we develop effective governance systems for 21 Century technology, one that's going to work with nanotech and all the technologies beyond, such as things like synthetic biology?

So I think it's time to actually do a high-level commission, something that could be set up by the National Academies of Science and Public Administration, to establish them and actually have them undertake this larger task so that we aren't sitting here in another 3 years having the same discussion with the next technology, and I think there's simply too much at stake here.

I'd like to thank the Committee for giving me an opportunity to address you.

[The prepared statement of Mr. Rejeski follows:]

PREPARED STATEMENT OF DAVID REJESKI, DIRECTOR, PROJECT ON EMERGING NANOTECHNOLOGIES, WOODROW WILSON INTERNATIONAL CENTER FOR SCHOLARS

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

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

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

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

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

#### **What Has Changed**

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

- *The number of nano-enabled consumer products has increased rapidly.* Two years ago, we had 212 manufacturer-identified, nano-enabled consumer products in our Consumer Products Inventory. The number now exceeds 600, a number that has doubled within the last 14 months alone.<sup>1</sup> Since our inventory includes only manufacturer-identified nanotechnology products, there likely are hundreds of more products on the market that are not identified as such. This

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

number also does not take into account the hundreds of commercial and industrial current uses of nanotechnology and nanomaterials.

- *Production and distribution of nanotechnology products is increasingly global.* The products in our inventory come from 321 companies in 20 countries. All of these products are available in shopping malls or over the Internet, and we have purchased many of them on-line. Thanks to business-to-business (B2B) and business-to-consumer (B2C) e-commerce, nanotechnology products easily flow across international borders, raising control, trade, and oversight issues.
- *Silver has become the most commonly used nano-engineered material in consumer products.* The type of nano-engineered substances in these products has shifted dramatically from materials like carbon to silver, which is now used in over 140 products, primarily as an antimicrobial. However, with production costs of carbon nanotubes dropping rapidly, this mix could shift again.<sup>2</sup>
- *The number of children's products is on the rise.* Within the past year, an increasing number of products on sale are targeted at children, including: pacifiers, toothbrushes, baby bottle brushes, and stuffed animals. These products originate from the U.S., Australia, China, Germany, and Korea. This remains a category to watch as nanotechnology's commercialization proceeds, especially since young children and babies generally have a greater vulnerability to chemicals and other toxins.
- *Products are penetrating the market in areas where oversight regimes are weak.* For instance, as shown in Figure 1, about a half of the products in our inventory would fall under the purview of the Consumer Products Safety Commission (CPSC), an agency which, last year, according to CPSC Commissioner Thomas Moore, spent only a total of \$20,000 to do a literature review on nanotechnology.<sup>3</sup> Other areas of high growth where oversight is weak include cosmetics and dietary supplements, both areas where the Food and Drug Administration (FDA) has very limited regulatory authority.<sup>4</sup>

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

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

<sup>4</sup>Taylor, Michael. *Regulating the Products of Nanotechnology: Does FDA Have the Tools It Needs?*, Washington, DC: Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, 2007. Available at [http://www.nanotechproject.org/file\\_download/files/PEN5\\_FDA.pdf](http://www.nanotechproject.org/file_download/files/PEN5_FDA.pdf), accessed April 18, 2008.

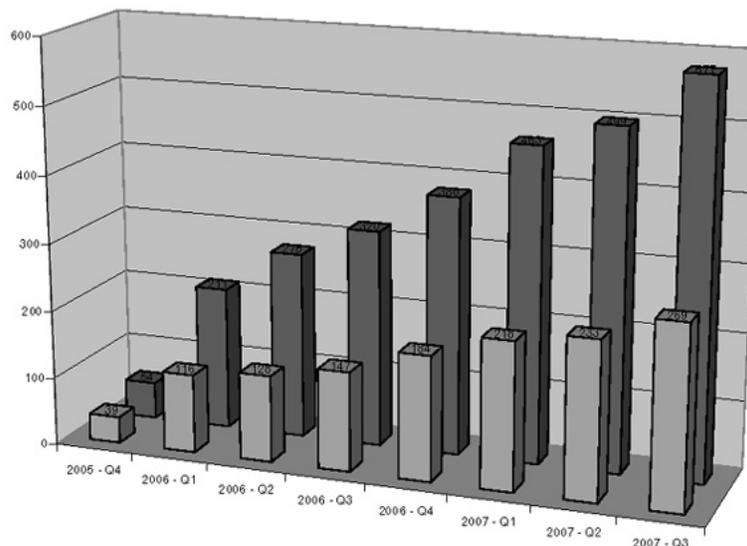


Figure 1. Growth in the number of manufacturer-identified, nanotechnology-enabled products on the market from 2005 to 2007 (in red) showing products under possible CPSC jurisdiction (in blue).

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

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

Over the past year, American consumers have painfully learned that the Federal oversight system is failing. The public has had to deal with lead in toys (a use that was banned 30 years ago by the CPSC), rat poison in pet food, antifreeze in toothpaste, and *E. coli* in meat. Most recently, over 100 deaths were tied directly to a compromised blood thinner.<sup>5</sup>

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

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

Public trust is the “dark horse” in nanotechnology’s future. If government and industry do not work to build public confidence in nanotechnology, consumers may reach for the “No-Nano” label in the future. Public perceptions can have large eco-

<sup>5</sup>“FDA Links More Deaths to Blood Thinner.” *Associated Press*, April 8, 2008. Available at: <http://ap.google.com/article/ALeqM5iT7Y6m5N3h8XK-CDe9bU7wuYNCcQD8VTUN600>, accessed April 18, 2008.

conomic impacts. The European Union's (EU) *de facto* moratorium on the approval of new genetically modified food products, driven largely by public concerns, is costing American farmers an estimated \$300 million per year in lost sales.<sup>6</sup>

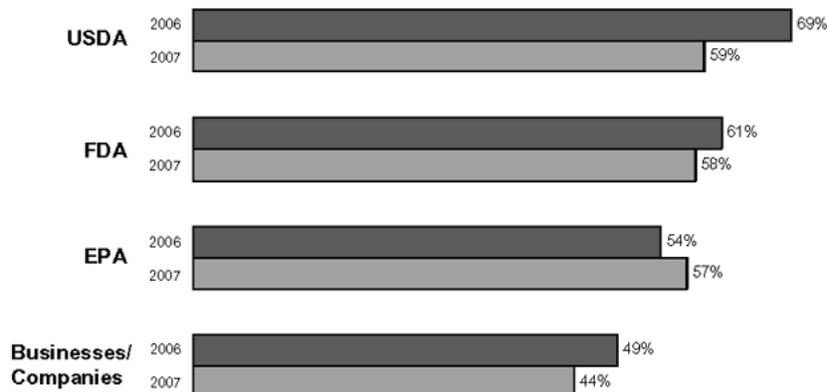


Figure 2. Percentage of respondents with “Great deal/fair amount of confidence” in each to maximize benefits and minimize risks of scientific/technological advancements. Results are from surveys conducted in August 2006 and August 2007. Each survey had 1,014 respondents and margin of error of  $\pm 3.1$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

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

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

#### NanO Bio-Sim

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



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

<sup>7</sup>Additional claims can be found on product website. Available at [http://www.fulvic.org/html/nano\\_bio-sim.html](http://www.fulvic.org/html/nano_bio-sim.html), accessed April 22, 2008.

### **Eczemel Nano-Cream**

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



### **MesoPlatinum®**

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

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

*Insurers and Investors:* The financial community is taking another look at nanotechnology. The Lloyd's of London Emerging Risks Team just issued a report on nanotechnology that noted that “due to the potential impact to the insurance industry if something were to go wrong, nanotechnology features very highly in Lloyd's top emerging risks.”<sup>10</sup> When I talked recently to staff at Lloyd's, they said that two things are critical to the insurance sector in terms of reducing risks: transparency and regulation. We have neither at the moment and the Federal Government is doing little to remedy this problem. Similar to Lloyd's, Zurich Insurance's Canadian office ranked nanotechnology in the top tier of emerging global risks (along with climate change and deteriorating infrastructure).<sup>11</sup> A recent UK exercise involving 35

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

<sup>9</sup>*Ibid.*

<sup>10</sup>Lloyd's Emerging Risks Team. *Nanotechnology: Recent Developments, Risks and Opportunities, 2007*. Available at <http://www.lloyds.com/LloydsMarket/Toolsandreference/ExposureManagement/Emergingrisks.htm>, accessed April 17, 2008.

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

representatives from government, NGO's, and academia also identified nanotechnology as the top risk to ecosystems (above climate change and the possible impact of novel pathogens).<sup>12</sup>

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

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

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

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

<sup>12</sup>"Scanning the risk horizon for emerging threats," *Lloyd's. com*, 8 April 2008. Available at [http://www.lloyds.com/News\\_Centre/Features\\_from\\_Lloyds/Scanning\\_the\\_risk\\_horizon\\_for\\_emerging\\_threats0904\\_08.htm](http://www.lloyds.com/News_Centre/Features_from_Lloyds/Scanning_the_risk_horizon_for_emerging_threats0904_08.htm), accessed April 17, 2008.

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

<sup>14</sup>Lipson, Sam 2004. "The Cambridge Model of Biotech Oversight," at: <http://www.genewatch.org/genewatch/articles/16-5lipson.html>

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

<sup>16</sup>Keiner, Suellen. "Room at the Bottom? Potential State and Local Strategies for Managing the Risks and Benefits of Nanotechnology." Washington, DC: Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, 2007. Available at [http://www.nanotechproject.org/publications/archive/room\\_at\\_bottom/](http://www.nanotechproject.org/publications/archive/room_at_bottom/).

<sup>17</sup>"Nanotech Exposed in Grocery Store Aisles," Friends of the Earth, March 11, 2008. Available at: <http://www.foe.org/nanotech-exposed-grocery-store-aisles>.

<sup>18</sup>"SVTC Nanotech Report: Regulating Emerging Technologies in Silicon Valley and Beyond," Silicon Valley Toxics Coalition. Available at: [http://www.etoxics.org/site/PageServer?page\\_name=svtc\\_nanotech](http://www.etoxics.org/site/PageServer?page_name=svtc_nanotech), accessed April 21, 2008.

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

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

#### **What Has Not Changed and What Needs to Change**

Let me now talk about what has not changed over the past 2 years and what needs to be remedied as the Congress turns its attention to the reauthorization of the 21st Century Nanotechnology Research and Development Act and looks beyond. Three issues must be addressed by the Act: transparency, strategy, and engagement.

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

During a three-year period, our Project has spent between \$50,000 and \$60,000 in staff time analyzing and making public Federal Government expenditures that address nano-related risks to workers, consumers, and the environment. It has not been an easy task, but, more importantly, it should never have been necessary. The Federal Government’s data on risk research, including spending levels, detailed project descriptions, and all assumptions driving the analysis, should have been online and transparent from the very beginning of the NNI.

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

Our analyses consistently show that the Federal Government is inflating investments in risk analysis and management by orders of magnitude and, by doing so, distorting the perceptual environment where nanotechnology investment and com-

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

<sup>20</sup>John E. Lindberg and Margaret M. Quinn. A Survey of Environmental, Health and Safety Risk Management Information Needs and Practices among Nanotechnology Firms in the Massachusetts Region. Washington, DC: Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, 2007. Available at <http://www.nanotechproject.org/process/assets/files/5921/file.pdf>.

<sup>21</sup>We have compared the GAO findings with both the NNI numbers and our Project’s inventory and included that analysis in the Appendix to this testimony.

<sup>22</sup>Moynihan, D.P. 1998. *Secrecy: The American Experience*, New Haven, CT: Yale University Press.

mercialization takes place. These assurances of large investments in risk research (combined with statements of adequate oversight) provide a false sense of confidence and actually shift risks onto consumers, workers, investors, and, ultimately, onto insurers and re-insurers.

The Act must require that a comprehensive, public, on-line EHS research database be created and also mandate annual updates. This should be done within 6 months following the passage of the Act. Collaboration with international organizations, such as the OECD, should be supported to expand the collection and on-line publication of EHS research data internationally. Finally, the collection, analysis, and publication of other data key to understanding nanotechnology commercialization should be undertaken by the Department of Commerce, such as data on industry structure, venture capital investments, job creation, and domestic and international market growth.

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

Given the size of our investments in the NNI and its implications for economic growth, a separate external advisory board (independent of PCAST) should be created that has broad representation from the nanotechnology community, including universities, NGO's, investors, and a range of businesses, especially small businesses, which often lack a voice in our policy deliberations. Finally, the NNI should fully support the external review of the EH&S risk research strategy by the National Academies' Board on Environmental Studies and Toxicology (BEST). This review has received broad support from a variety of stakeholders including the American Chemistry Council, Dupont, Evonik (formerly Degussa), the NanoBusiness Alliance, and the Environmental Defense Fund. Given the existing lack of transparency regarding the government's risk related research, reviews by independent entities are critical to maintaining accountability.

2. *Strategy*: After 4 years of waiting, the Congress has still not received a comprehensive, top-down strategy to address existing and emerging nanotechnology risks.

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

Any risk strategy also needs appropriate funding to work. I support a 10 percent floor for EHS funding because PEN's extensive analyses indicate that funding for highly-relevant risk research has been exaggerated for at least the past 3 years, and this underinvestment needs to be corrected, especially as more nanotechnology products flow into the marketplace and raise questions about public safety and challenges for government regulators. A PEN analysis of current research projects listed in the NNI's “Strategy for Nanotechnology-Related Environmental, Health, and Safety Research” found that only 62 of the 246 projects listed were highly relevant to addressing EHS risks of nanotechnology.<sup>23</sup> These 62 projects accounted for an estimated \$13 million in research and development funding for 2006—far lower than the \$68 million cited by the NNI document as being focused on EHS research.<sup>24</sup> In

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

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

fact, our analysis now shows that the EU is spending almost twice the U.S. investment in highly-relevant EHS risk research.<sup>25</sup>

Research programs like the NNI do not automatically guarantee an optimal allocation of public money. Sometimes, key constituents or topics are left unfunded or under addressed. Recognizing this problem, the government has set minimal funding requirements. The Federal Government does this with small businesses in our set-asides for Small Business Innovation Research grants and with the Human Genome Project by dedicating 5 percent of all Project research spending to examine ethical, legal, and social implications that the policy community knew would accompany the development and application of genomics. The reauthorization proposal to set aside 10 percent of the total NNI budget for nanotechnology EHS research has received support from a wide range of stakeholders including the NanoBusiness Alliance, American Chemistry Council, and NGO's, including the Environmental Defense Fund. As Sean Murdock, director of the NanoBusiness Alliance, said in his recent testimony before the House Science and Technology Committee, ". . . we believe that 10 percent of the total funding for nanotechnology research and development is a reasonable estimate of the resources that will be required to execute the strategic plan . . ." <sup>26</sup>

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

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

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

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

- *Independence.* The selection, direction, and evaluation of funded research would have to be science-based and fully independent of the business and views of partners in the organization.
- *Transparency.* The research, reviews, and operations of the organization should be fully open to public scrutiny.
- *Review.* Research supported by the organization should be independently and 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.<sup>28</sup>

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

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

<sup>27</sup> FDA Science and Mission at Risk: Subcommittee on Science and Technology, November 2007. Available at: [http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b\\_02\\_01\\_FDA%20Report%20on%20science%20and%20Technology.pdf](http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_01_FDA%20Report%20on%20science%20and%20Technology.pdf), accessed April 21, 2008.

<sup>28</sup> See Dr. Andrew Maynard's testimony for hearing on "The National Nanotechnology Initiative Amendments Act of 2008," April 16, 2008. Available at: [http://www.nanotechproject.org/process/assets/files/6689/maynard\\_written\\_april08.pdf](http://www.nanotechproject.org/process/assets/files/6689/maynard_written_april08.pdf), accessed April 21, 2008.

Two models should be adapted, funded, and evaluated over the next 3 years.

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

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

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

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

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

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

### Conclusions

Let me close by putting forth a greater challenge to the Committee and our government. For the commercial success of any emerging technology, we need a better

<sup>29</sup> Jim Hutchinson’s technique is able to create a gram of gold nanoparticles for \$500, down from the \$300,000 per gram cost for traditional methods. Schmidt, Karen. *Green Nanotechnology: It’s Easier Than You Think*, Washington, D.C.: Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, 2007. Available at: [http://www.nanotechproject.org/publications/archive/green\\_nanotechnology\\_its\\_easier\\_than/](http://www.nanotechproject.org/publications/archive/green_nanotechnology_its_easier_than/), accessed April 18, 2008.

<sup>30</sup> Rejeski, David. “How About An X-Prize for Green Nanotechnology?” *Nanotechnology Now*, 2007. Available at: <http://www.nanotech-now.com/columns/?article=134>.

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

We need to bring together the best minds in the Nation to develop a governance system for 21st century technologies, a system that will work with nanotechnology and the technologies beyond. A high-level commission (organized by the national academies of Science and Public Administration) should be established to undertake this task.

Finally, let me say that I applaud the Committee for focusing our attention on issues affecting the successful commercialization of nanotechnology. Nanotechnology is no longer just a large government research project. Products are moving out of the lab into the market and onto store shelves. This is success, but it is not guaranteed forever. The next two to 3 years will be critical to ensuring that our investments pay off, and the structure and functions of the NNI will play an important role in making sure we can maximize the benefits of nanotechnology while minimizing the risks.

#### APPENDIX

### Comparison of Nanotechnology Risk-Research Funding for 2006

#### Definitions of risk-relevant research used in funding assessments:

##### *NNI*

In the context of this comparison, the given NNI definition of EHS-relevant research is “research whose primary purpose is to understand and address potential risks to health and the environment posed by this technology.”<sup>31</sup>

##### *GAO*

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

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

##### *PEN*

PEN defines highly relevant research as:

“Research that is specifically and explicitly focused on the health, environmental and/or safety implications of nanotechnology. Also included in this category are projects and programs where the majority of the research undertaken is specifically and explicitly focused on the health, environmental and/or safety implications of nanotechnology. Examples of research in this category would in-

<sup>31</sup>“Environmental, health and safety research needs for engineered nanoscale materials,” *The National Nanotechnology Initiative*, September 2006. Available at: [http://www.nano.gov/NNI\\_EHS\\_research\\_needs.pdf](http://www.nano.gov/NNI_EHS_research_needs.pdf), accessed April 22, 2008.

<sup>32</sup>“Nanotechnology. Better guidance is needed to ensure accurate reporting of Federal research focused on environmental, health and safety risks,” U.S. Government Accountability Office, 2008. Acronyms—NIH: National Institutes of Health; NIOSH: National Institute for Occupational Safety and Health; NIST: National Institute of Standards and Technology.

clude research to understand the toxicity of specific nanomaterials, research into exposure monitoring and characterization to further understand potential impact, research into biological interactions and mechanisms that is focused on answering specific questions associated with potential risk. Examples of research that would not be included in this category would include exploratory research into biological mechanisms outside the context of understanding impact, general instrument development, and research into therapeutics applications which also incorporate an element of evaluating impact.”<sup>33</sup>

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

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

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

Agency	NNI-assessment of EHS-relevant projects <sup>35</sup>	GAO-assessment of EHS-relevant projects <sup>35</sup>	PEN-assessment of highly relevant EHS projects listed by the NNI
EPA	3.6	3.6	1.3 <sup>A</sup>
NIH	5.6	5.6	0.8 <sup>B</sup>
NIOSH	4.3	4.2	4.9
NIST	2.4	2.4	NA
NSF	21.1	14.7	1.4 <sup>C</sup>
DOD	—	—	1.4
DOE	—	—	0
USDA	—	—	0.1
Total	\$37 million	\$30.5 million	\$9.9 million (\$13 million) <sup>37</sup>

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

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

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

Senator KERRY. We're delighted. Thank you. Very helpful.  
Dr. Ferguson?

<sup>33</sup> Maynard, Andrew. Testimony for U.S. House of Representatives Committee on Science and Technology Hearing on: The National Nanotechnology Initiative Amendments Act of 2008, April 16 2008. Available at [http://www.nanotechproject.org/process/assets/files/6689/maynard\\_writing\\_april08.pdf](http://www.nanotechproject.org/process/assets/files/6689/maynard_writing_april08.pdf), accessed April 21, 2008.

<sup>34</sup> Acronyms—DOD: Department of Defense; DOE: Department of Energy.

<sup>35</sup> "Nanotechnology. Better Guidance Is Needed to Ensure Accurate Reporting of Federal Research Focused on Environmental, Health and Safety Risks," U.S. Government Accountability Office, 2008.

<sup>36</sup> Numbers in parentheses represent the number of projects where finding information is available. This assessment was carried out on projects listed in the document "Strategy for nanotechnology-related environmental, health and safety research," The National Nanotechnology Initiative, 2008. Available at: [http://www.nano.gov/NNI\\_EHS\\_Research\\_Strategy.pdf](http://www.nano.gov/NNI_EHS_Research_Strategy.pdf), accessed April 22, 2008.

<sup>37</sup> Number in parentheses represents estimated annual funding, accounting for missing budget data.

**STATEMENT OF P. LEE FERGUSON, Ph.D., ASSISTANT  
PROFESSOR, DEPARTMENT OF CHEMISTRY AND  
BIOCHEMISTRY, UNIVERSITY OF SOUTH CAROLINA**

Dr. FERGUSON. Good afternoon. I wish to thank you, Senator Kerry and the other members of the Subcommittee, for inviting me to testify today.

I'm Lee Ferguson, an Assistant Professor at the University of South Carolina.

Since 2003, I have led a team of researchers investigating the fate and effects of nanomaterials in the environment. I feel strongly about the need to continue and to expand this research and I'm happy to talk with you today about it.

My primary point is that development and commercialization of nanotechnology may present unforeseen hazards to environmental and human health. It is therefore essential that scientific research be continued to address this issue.

Since the initial authorization of the National Nanotechnology Initiative, the Federal Government has supported scientific research into the environmental and health impacts of nanotechnology. There now exists a growing body of work addressing the risks associated with nanomaterials. However, it is clear that we have much to learn.

The current state of the science with respect to environmental health and safety issues of nanotechnology can be summarized briefly. We have learned that nanomaterials are very difficult to measure accurately in environmental and biological systems. It has become clear that existing analytical methods are simply inappropriate or insufficient to make these measurements.

We've also learned that nanomaterials may be transported in the environment in ways that are not necessarily predictable from existing scientific models and that nanomaterials may interact directly with pollutants of concern, such as PCBs and heavy metals.

Finally, there are indications of risks associated with exposure of humans and ecosystems to nanomaterials. These risks include direct toxicity and uptake of nanomaterials into biological tissues.

Through the NNI, the Federal Government has developed a strategy aimed at prioritizing research needs with respect to environmental health and safety issues of nanotechnology. This prioritization is essential so that an organized effort can be made to address environmental and health impacts of nanotechnology as this technology is developed. This last point is critical. We cannot afford to wait until nanotechnology is fully developed to begin assessing its risks and hazards to human health and the environment.

I wish to highlight specific areas of research that I believe deserve particular attention. Without methods for detecting and characterizing nanomaterials in the environment and in human tissues, nanomaterial exposure assessment is impossible.

Research into analytical methods and metrology of nanomaterials is a top priority and support for this work should be accelerated within the NNI.

With respect to research on environmental and human health effects of nanomaterials, I stress the need to develop standardized testing methods that are appropriate to assessing toxicity and bio-

logical uptake of nanomaterials and their manufacturing byproducts.

There's a critical need to assess the human and ecological exposure after release of nanomaterials into the ambient environment. We still have very limited knowledge of the treatability of nanotechnology waste as well as the routes by which nanomaterials may enter and move within our air and water.

Finally, our ability to assess and predict risk of emerging nanotechnologies to human and environmental health depends on understanding the mechanisms by which nanomaterials act on biological systems. This understanding represents a grand scientific challenge and will require a significant and well-supported effort.

During reauthorization of the NNI, I ask you to consider the resources that are needed now and in the future for addressing these concerns. As you've heard, between 2005 and 2009, expenditures within the NNI on EHS research have increased from 3 percent to approximately 5 percent of the total NNI budget.

A significant increase in our scientific understanding of the environmental and health impacts of nanotechnology will require a more substantial investment. A realistic target in the very near term should be to increase the level of funding for EHS research on nanotechnology to exceed 10 percent of the NNI budget.

I wish to close by saying that we have a unique opportunity now. Through the NNI, we have begun to address the EHS risks of nanotechnology simultaneously with the development of this technology. We have only to look at the lessons learned from PCBs and other legacy chemical contaminants to realize the dangers of waiting until new technologies mature to assess their environmental and health risks.

I urge this Committee to consider these concerns during the reauthorization of NNI.

Thank you for considering my testimony.

[The prepared statement of Dr. Ferguson follows:]

PREPARED STATEMENT OF P. LEE FERGUSON, PH.D., ASSISTANT PROFESSOR,  
DEPARTMENT OF CHEMISTRY AND BIOCHEMISTRY, UNIVERSITY OF SOUTH CAROLINA

#### **Oral Testimony**

Good afternoon. I wish to thank Senator Kerry and the other members of the Subcommittee for inviting me to testify today. I am Lee Ferguson, an assistant professor at the University of South Carolina. Since 2003, I have led a team of researchers investigating the fate and effects of nanomaterials in the environment. I feel strongly about the need to continue and expand this research, and I'm happy to talk with you about it.

*Primary point:* Development and commercialization of nanotechnology may present unforeseen hazards to environmental and human health—it is essential that scientific research be continued to address this issue.

Since the initial authorization of the National Nanotechnology Initiative in 2003, the Federal Government has supported scientific research into the environmental and health impacts of nanotechnology.<sup>1</sup> There exists now a growing body of work addressing the risks associated with nanomaterials; however, it is clear that we still have much to learn.

*What we know:* The current state of the science with respect to environmental, health, and safety issues of nanotechnology can be summarized briefly.

<sup>1</sup> For example, since 2003 the U.S. EPA National Center for Environmental Research has coordinated extramural funding efforts among EPA, NSF, DOE, NIOSH, and NIEHS to address environmental and health effects of nanomaterials (<http://es.epa.gov/ncer/nano/index.html>).

- We have learned that nanomaterials are very difficult to measure accurately in environmental and biological systems. It has become clear that existing analytical methods are simply inappropriate or insufficient to make these measurements.
- We also have learned that nanomaterials may be transported in the environment in ways that are not necessarily predictable from existing scientific models and that nanomaterials may interact directly with pollutants-of-concern such as PCBs and heavy metals.
- Finally, there are indications of risks associated with exposure of humans and ecosystems to nanomaterials. These risks include direct toxicity and uptake of nanomaterials into biological tissues.

*Federal prioritization:* Through the NNI, the Federal Government has developed a roadmap aimed at prioritizing research needs with respect to environmental, health, and safety issues of nanotechnology.<sup>2</sup> This prioritization is essential so that an organized effort can be made to address environmental and health impacts of nanotechnology as this technology is developed. This last point is critical—we cannot afford to wait until nanotechnology is fully developed to begin assessing its risks and hazards to human health and the environment.

*Future research needs:* I wish to highlight specific areas of research that I believe deserve particular attention:

- Without methods for detecting and characterizing nanomaterials in the environment and in human tissues, nanomaterial exposure assessment is impossible. Research into analytical methods and metrology of nanomaterials is a top priority and support for this work should be accelerated within the NNI.
- With respect to research on environmental and human health effects of nanomaterials, I stress the need to develop standardized testing methods that are appropriate to assessing toxicity and biological uptake of nanomaterials and their manufacturing byproducts.
- There is a critical need to assess routes of human and ecological exposure after release of nanomaterials into the ambient environment. We still have very limited knowledge of the treatability of nanotechnology wastes as well as the routes by which nanomaterials may enter and move within our air and water.
- Finally, our ability to assess and predict risk of emerging nanotechnologies to human and environmental health depends on understanding the mechanisms by which nanomaterials act on biological systems. This understanding represents a grand scientific challenge and will require significant and well-supported effort.

During reauthorization of the NNI, I ask you to consider the resources that are needed now and in the future for addressing these concerns. Between 2005 and 2009, expenditures within the NNI on EHS research have increased from 3 percent to approximately 5 percent of the total NNI budget. A significant increase in our scientific understanding of the environmental and health impacts of nanotechnology will require a more substantial investment. A realistic target in the very near term should be to increase the level of funding for EHS research on nanotechnology to exceed 10 percent of the NNI budget.

I wish to close by saying that we have a unique opportunity now—through the NNI we have begun to address the EHS risks of nanotechnology *simultaneously* with the development of this technology. We have only to look at the lessons learned from PCBs and other legacy chemical contaminants to realize the dangers of waiting until new technologies are mature to assess their environmental and health risks. I urge this Committee to consider these concerns during the reauthorization of the NNI. Thank you for considering my testimony.

<sup>2</sup>The five primary research categories identified for priority research consideration are: (1) Instrumentation, Metrology, and Analytical Methods; (2) Nanomaterials and Human Health; (3) Nanomaterials and the Environment; (4) Human and Environmental Exposure Assessment; and (5) Risk Management Methods. These categories and the associated research strategies are outlined in three documents: National Science and Technology Council 2006, *The National Nanotechnology Initiative: Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials*, [http://www.nano.gov/NNI\\_EHS\\_research\\_needs.pdf](http://www.nano.gov/NNI_EHS_research_needs.pdf); National Science and Technology Council 2007, *Prioritization of Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials*, [http://www.nano.gov/Prioritization\\_EHS\\_Research\\_Needs\\_Engineered\\_Nanoscale\\_Materials.pdf](http://www.nano.gov/Prioritization_EHS_Research_Needs_Engineered_Nanoscale_Materials.pdf); and National Science and Technology Council 2008, *The National Nanotechnology Initiative: Strategy for Nanotechnology-Related Environmental, Health, and Safety Research*, [http://www.nano.gov/NNI\\_EHS\\_Research\\_Strategy.pdf](http://www.nano.gov/NNI_EHS_Research_Strategy.pdf).

### Written Statement

I wish to thank Senator Kerry and the other members of the Subcommittee for inviting me to testify about the current status and future needs of research into the environmental, health, and safety issues of nanotechnology. I am Lee Ferguson, an assistant professor of chemistry and biochemistry at the University of South Carolina. Since 2003, I have led a team of researchers at USC, funded by the U.S. EPA Science to Achieve Results (STAR) program<sup>3</sup> and organized within the USC Nano-Center investigating the fate and health effects of nanomaterials in the environment. Our overall goal is to elucidate the potential for manufactured nanomaterials to be transported within the aquatic environment and the associated hazards of such transport to both aquatic and human life. I feel strongly about the need to continue and expand this research, and I'm happy to talk with you about it.

*Primary point:* Development and commercialization of nanotechnology may present unforeseen hazards to environmental and human health—it is therefore essential that scientific research be conducted to address this issue.

Since the initial authorization of the National Nanotechnology Initiative in 2003, the Federal Government has continuously supported intramural and extramural scientific research into the environmental and health impacts of nanotechnology.<sup>4</sup> As a consequence, there exists now a growing body of work addressing the risks associated with nanomaterials; however, it is clear that we still have much to learn.

*What we know:* The emergence of nanotechnology is an exciting opportunity that could result in significant contributions to the treatment of disease, development of more effective polymer composites, fuel cells and capacitors, and clean-up of polluted groundwater. Although the use of nanoparticles may allow for significant advances in science and technology, assessment of potential negative health and environmental impacts on humans, non-human biota, and ecosystems is imperative before their widespread production and use. The same properties that make these particles desirable, may also contribute to their toxic potential and extensive studies to address both the acute and chronic effects of nanoparticles are necessary to determine if negative health and environmental impacts outweigh the potential benefits. In humans, a concerning route of exposure is via direct inhalation, both in the workplace where these particles are manufactured and used, and from the innate environment contaminated with particles released from anthropogenic and natural sources.<sup>5,6</sup> Other routes of exposure that are currently a concern include dermal and dietary. The current state of the science with respect to environmental, health, and safety issues of nanotechnology can be summarized briefly.

- We have learned that nanomaterials are very difficult to measure accurately in environmental and biological systems—this greatly complicates assessment of occupational and environmental exposure as well as occurrence and fate of these materials in the environment. It has become clear that existing analytical methods (*e.g.*, those designed for detecting and quantifying chemical contaminants) are simply inappropriate or insufficient to make these measurements.<sup>7</sup>
- We also have learned that nanomaterials may be transported in the environment in ways that are not necessarily predictable from existing models for more conventional contaminants, and that nanomaterials may interact directly with pollutants-of-concern such as PCBs and heavy metals, potentially leading to mobilization and enhanced toxicity.<sup>8</sup>
- Finally, there are clear indications of risks associated with exposure of humans and ecosystems to nanomaterials. These risks include direct toxicity and uptake

<sup>3</sup>U.S. EPA STAR Program: Chemical and biological behavior of carbon nanotubes in estuarine sedimentary systems. Award # RD-83171601 P. Lee Ferguson, PI.; G. Thomas Chandler; and Walter A. Scrivens, University of South Carolina, Columbia, SC.

<sup>4</sup>For example, since 2003 the U.S. EPA National Center for Environmental Research has coordinated extramural funding efforts among EPA, NSF, DOE, NIOSH, and NIEHS to address environmental and health effects of nanomaterials (<http://es.epa.gov/ncer/nano/index.html>).

<sup>5</sup>Maynard AD, Baron PA, Foley M, Shvedova AA, Kisin ER, Castranova V. Exposure to carbon nanotube material: aerosol release during the handling of unrefined single-walled carbon nanotube material. *J Toxicol Environ Health A* 2004; 67: 87–107.

<sup>6</sup>Nel A, Xia T, Madler L, Li N. Toxic potential of materials at the nanolevel. *Science* 2006; 311: 622–627.

<sup>7</sup>U.S. Environmental Protection Agency. 2007. Nanotechnology White Paper. Washington, D.C. EPA/100/B-07/001. p. 40–41.

<sup>8</sup>Ferguson PL, Chandler GT, Templeton RC, DeMarco A, Scrivens WA, Englehart, B. Influence of sediment-amendment with single-walled carbon nanotubes and diesel soot on bioaccumulation of hydrophobic organic contaminants by benthic invertebrates. *Environ. Sci. Technol.* 2008; in press.

<sup>9</sup>Lam CW, James JT, McCluskey R, Hunter RL. Pulmonary toxicity of single-wall carbon nanotubes in mice 7 and 90 days after intratracheal instillation. *Toxicol Sci* 2004; 77: 126–134.

of nanomaterials into biological tissues.<sup>9,10</sup> However, the mechanisms by which nanomaterials exert biological effects are poorly known and there is a clear need for basic research directed at new methods for assessing “nanotoxicology”.

*Federal prioritization:* Through the NNI, the Federal Government has developed and refined a roadmap aimed at identifying and prioritizing research needs with respect to environmental, health, and safety issues of nanotechnology.<sup>11</sup> The five primary research categories identified are: (1) Instrumentation, Metrology, and Analytical Methods; (2) Nanomaterials and Human Health; (3) Nanomaterials and the Environment; (4) Human and Environmental Exposure Assessment; and (5) Risk Management Methods.

The Nanoscale Science, Engineering, and Technology (NSET) subcommittee of the National Science and Technology Council (NSTC) has done a commendable job of focusing the disparate interests of the Federal agencies party to the NNI such that an organized effort can be made to address environmental and health impacts of nanotechnology *as this technology is developed*. This last point is critical—we cannot afford to wait until nanotechnology is fully integrated within our commercial enterprises to begin assessing its risks and hazards to human health and the environment.

*Future research needs and challenges:* Nanomaterials have not been well characterized in terms of their environmental occurrence, behavior, and toxic potential even though they may contribute to occupational and general air/water pollution through manufacturing and waste disposal as well as through inclusion in drug delivery and therapeutic applications. Large data gaps exist with regard to our basic understanding of the potential for manufactured nanoparticles to cause deleterious effects on human as well as ecological systems.

In assessing possible health and environmental effects of manufactured nanomaterials, it is important to study their impact in relevant model systems and in chemical forms reflective of occupational/environmental exposures. There are many different types of nanoparticles/nanomaterials and each of these will have a behavior (for example toxicity or transport) dictated by chemical and physical factors unique to the material. Below, I comment on specific areas of research within the framework outlined by the NSET subcommittee that I believe deserve particular attention:

- Without methods for detecting and characterizing nanomaterials in the environment and in human tissues, exposure assessment and environmental occurrence and fate studies are impossible. I wholeheartedly agree with the NSET subcommittee that research into analytical methods and metrology of nanomaterials is a top priority and support for this work should be accelerated within the NNI.
- With respect to research on environmental and human health effects of nanomaterials, I stress the need to develop standardized testing methods that are appropriate to assessing toxicity and biological uptake of nanomaterials.
- It is clear from my own work as well as that of others that we must consider not only the health and environmental risks of manufactured nanomaterials but also that of byproducts generated during manufacturing. This is a relatively unexplored area of research and should be considered.
- There is a critical need to assess routes of human and ecological exposure after release of nanomaterials into the ambient environment. We still have a very limited knowledge base regarding the treatability of nanotechnology wastes as well as the routes by which nanomaterials may enter and move within our air and water. This should be a top priority for EHS research within the NNI.

<sup>9</sup>Lam CW, James JT, McCluskey R, Hunter RL. Pulmonary toxicity of single-wall carbon nanotubes in mice 7 and 90 days after intratracheal instillation. *Toxicol Sci* 2004; 77: 126–134.

<sup>10</sup>Templeton RC, Ferguson, PL, Washburn, KM, Scrivens, WA, Chandler, GT. Life-cycle effects of single-walled carbon nanotubes (SWNTs) on an estuarine meiobenthic copepod. *Environ. Sci. Technol.* 2006; 40: 7387–7393.

<sup>11</sup>This strategy is outlined in three documents: National Science and Technology Council 2006, *The National Nanotechnology Initiative: Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials*, [http://www.nano.gov/NNI\\_EHS\\_research\\_needs.pdf](http://www.nano.gov/NNI_EHS_research_needs.pdf); National Science and Technology Council 2007, *Prioritization of Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials*, [http://www.nano.gov/Prioritization\\_EHS\\_Research\\_Needs\\_Engineered\\_Nanoscale\\_Materials.pdf](http://www.nano.gov/Prioritization_EHS_Research_Needs_Engineered_Nanoscale_Materials.pdf); and National Science and Technology Council 2008, *The National Nanotechnology Initiative: Strategy for Nanotechnology-Related Environmental, Health, and Safety Research*, [http://www.nano.gov/NNI\\_EHS\\_Research\\_Strategy.pdf](http://www.nano.gov/NNI_EHS_Research_Strategy.pdf).

- Finally, our ability to accurately assess and predict risk of emerging nanotechnologies to human and environmental health is critically dependent on our understanding of the mechanisms by which nanomaterials act on biological systems at the cellular and molecular level. This understanding represents a grand scientific challenge and will require significant and well-supported effort.

As you look to reauthorization of the NNI, I ask you to consider the resources that are critically needed now and in the future for addressing these emerging concerns. In 2005, expenditures through the NNI budget on nanotechnology-related EHS research totaled approximately \$35 million or 3 percent of the total NNI budget. As of today, the NNI budget request for 2009 allocates \$76 million or approximately 5 percent of the total request to research on EHS issues of nanotechnology. It is very clear that a significant increase in our collective scientific understanding of the environmental and health impacts of nanotechnology will require a more substantial investment. A realistic target in the very near term should be to increase the level of funding for EHS research on nanotechnology to meet or exceed 10 percent of the NNI budget.

I wish to close by saying that we have a unique opportunity now—through the efforts of the NNI we have begun the process of addressing EHS risks of nanotechnology *simultaneously* with the development of this technology. We have only to look back at the lessons learned from PCBs and other legacy chemical contaminants to realize the dangers of waiting until new technologies are mature to assess their environmental and health risks. I urge this Committee to consider these concerns during the reauthorization of the NNI. Thank you for considering my testimony. In the Appendix below I have included a summary of the research currently being conducted at the University of South Carolina on environmental and human health issues in nanotechnology.

#### **Appendix: Ongoing Research at the University of South Carolina on the Environmental Fate and Health Effects of Manufactured Nanomaterials**

*Research Team:* Dr. Lee Ferguson, Dr. Tara Sabo-Attwood, Dr. G. Thomas Chandler, Dr. John Ferry, Dr. Tom Vogt, Dr. Gene Feigley, Dr. Alan Decho, Dr. Sean Norman, Dr. Lee Newman, and Dr. Shosaku Kashiwada

Although the use of nanomaterials may allow for significant advances in science and technology, assessment of potential negative health and environmental impacts on humans, non-human biota, and ecosystems is imperative. The same properties that make these particles desirable, may also contribute to their toxic potential. Our research team at USC is studying the potential toxic effects that various nanoparticles have on humans, microbial communities, and aquatic ecosystems. This is an interdisciplinary effort which involves cooperation among chemists, physicists, biologists, toxicologists, and microbial ecologists, among others. The focus of our research efforts are described below. For more information, please visit <http://www.nano.sc.edu/thrust—nanoenvir.asp>.

#### **Subproject #1: Pulmonary Toxicity of Nanomaterials**

*Project leaders:* Tara Sabo-Attwood and Gene Feigley

In humans, the dominant route of exposure is suspected to occur via direct inhalation, both in the workplace where these particles are manufactured and used, and from the environment contaminated with particles released from anthropogenic and natural sources. Health-effects studies of air exposure to nanomaterials will require design of novel inhalation toxicology facilities and filtration technologies not available presently in the United States. Our group is uniquely qualified to design, build and test a small-scale prototype facility to assess aerosol generation, fate and transport. Construction of this prototype will lead to the development of inhalation exposure protocols for relevant animal models to assess the toxicological impacts of nanoparticles. In addition, we have already established complimentary *in vitro* studies that reveal toxic effects of single-walled carbon nanotube (SWNT) in human lung cells, and are currently exploring the molecular mechanisms responsible for this toxicity.

### **Subproject #2: Environmental Fate, Transport and Toxicity of Carbon Nanomaterials in Aqueous Systems**

*Project leaders: Tom Chandler, Lee Ferguson, Shosaku Kashiwada*

Project Focus:

*Synthesis of unique radioisotope-labeled nanomaterials for toxicological, fate and environmental transformation studies*

Single-walled carbon nanotube (SWNT) fate in aquatic/sedimentary systems is still largely under-explored. The USEPA has supported research by our team at USC aimed at elucidating the toxic effects and environmental fate and transport behavior of SWNT in estuarine environments. Our results have shown that manufacturing byproducts of SWNT are toxic to estuarine meiobenthic copepods and that copepods ingest but do not bioaccumulate SWNT from sediments. In addition, we have shown that SWNT are highly sorptive to hydrophobic organic contaminants such as PCBs and PAHs, and that organisms ingesting SWNTs with associated organic contaminants can bioaccumulate the associated organics in their tissues. Studies on environmental fate of SWNT under simulated estuarine conditions reveal that SWNT materials aggregate strongly and agglomerate to natural particles (*e.g.*, clay and sand) in the presence of high ionic strength solutions (*e.g.*, seawater), but that this behavior is inhibited by the presence of high concentrations of dissolved organic matter.

As part of our EPA-funded research, we have been developing a repository of pure, radio-labeled carbonaceous nanomaterials for national environmental toxicology and chemistry uses. With our collaborator Research Triangle Institute, Inc. we have custom synthesized single-walled carbon nanotubes. We are using these materials to perform experiments aimed at uptake/bioaccumulation and linked acute/chronic toxicity of SWNTs in at least two model invertebrate systems, fish and marine invertebrates (copepods). The <sup>14</sup>C-SWNT materials are also being used to study particulate sorption, aggregation, transport in porous media, and biophototransformation in a laboratory setting.

### **Subproject #3: Microbial Applications and Degradation of Nanomaterials**

*Project leaders: Alan Decho, Sean Norman, John Ferry*

Biofilms consist of bacteria cells attached to a surface that produce a large network of extracellular polymeric secretions (EPS). In doing so, bacterial cells are able to protect themselves against antimicrobial agents, and manipulate their local environment. Biofilms commonly occur in natural and engineered environments. However, their presence often incurs multibillion dollar costs for hospitals (*e.g.*, most hospital-acquired infections are biofilms), industry (*e.g.*, cause metal corrosion and biofouling, reduce heat transfer efficiency), potable water system maintenance (*i.e.*, protect pathogenic bacteria against chlorination), as well as being important in natural environments. Our research focuses on using nanoparticles to detect and monitor biofilms, study how the nanoparticles are captured and sequestered, and determine if the bacteria degrade these particles in various settings.

- *Biofilm Nanosensors*: Understanding biofilm processes, and controlling their costly effects is important has important economic, health, and environmental implications. The development of specific Nanosensors for monitoring bacterial processes within biofilms is an important step in the in-situ detection and monitoring of biofilm processes. Our studies aim to develop specific sensors that can be 'captured' by a biofilm, then provide important physical/chemical/metabolic information regarding processes occurring within the biofilm.
- *Capture and Sequestration of NanoParticles by Biofilms*. Bacterial biofilm are an efficient filter for particulates, colloids and dissolved molecules. They are likely important in the capture and concentration of nanoparticles under different Environmental conditions. We strive to: (1) understand how biofilms sequester nanoparticulates, and (2) manipulate biofilms to enhance capture efficiency.
- *Biofilm Test Systems*: This phase involves the development of biofilm culture systems that accurately mimic natural biofilm populations. Such systems will be coupled to CSLM, Raman/CSLM, and other analysis instrumentation for precise testing of antimicrobial approaches on living and engineered nanosurfaces.

#### *Microbial Interactions and Degradation*

This project is directed at determining the influence of nanomaterials on environmental microbial activity. Nanomaterials have unique antimicrobial properties that may be exploited in environmental disinfection and/or infection control. There are

also therapeutic applications for this research relative to artificial implants, prostheses, etc.

*Specific Goals:* Particular attention will be paid to questions such as: Do the materials in question support or inhibit the formation of biofilm communities? Are microbial communities capable of affecting the structure of associated nanomaterials (*i.e.*, metabolically transforming them)? Do nanomaterials exert selective population pressure on microbial communities (*i.e.*, selectively targeting one particular type of microbe vs another in mixtures)?

We will develop 'nanoprobes' (fluor-, SERS-based) for biofilm investigations in environmental studies. We will also develop/build biofilm flow-through cells and bioreactors for live culturing, and observation, of biofilms in the presence/absence of nanomaterials using our new confocal (CSLM) and Raman-confocal systems in ENHS.

#### **Subproject #4: Photocatalysis of Reactions Mediated by Nanomaterials**

*Project leaders: John Ferry, Tom Vogt*

Project Focus:

Development of nanostructured materials with applications for environmental modification or remediation is the focus of this project. We are primarily interested in developing mixed metal oxide visible light activated photocatalysts for effecting sunlight activated oxidation in the aqueous phase. The materials focus will be active catalysts (nanoparticulate metal oxides) that engage in direct electron transfer with substrates and passive materials that may exhibit catalytic properties by promoting close association (such as various nanocarbons). We will monitor the degradation of catalytically active nanomaterials in environmental matrices, using microscopic and molecular techniques. We will assay the catalytic activity of the material during degradation, which is an exploratory evaluation of the structure activity relationship. We will assay the physico-chemical behavior of the material upon exposure to environmental conditions (*e.g.*, aggregation, adsorption of "poisons" that affect catalyst activity, etc). We will explore application venues for materials that are effective photoactivated oxidants (drinking water and surface disinfection, biomedical applications, etc).

#### **Subproject #5: Plant Interactions with Nanoparticles**

*Project leaders; Lee Newman, Tara Sabo-Attwood, Jason Unrine, Cathy Murphy*

Project Focus:

Plant uptake and response to nanoparticles will have significance on many levels. First and foremost is to understand the parameters of plant uptake of the particles; what types (*i.e.*, chemical composition) of particles are taken up, is there a size limit or shape preference, do the chemicals used to cap the particles impact uptake? Could plant compounds affect the bioavailability of particles in a natural system? In independent studies, we have already exposed the model plant, *Nicotiana glauca*, to several different sized gold nanosphere, gold nanospheres with different capping chemicals, and silver nanospheres. Through simple light microscopy we have identified spheres of 3–5nm within the vascular tissue of the roots of the plants, and aggregation of larger spheres on the outside of the roots. We have observed enhanced precipitation of the particles when exposed to root exudates. We have also had a plants analyzed by one the using the beam lines at Brookhaven National Laboratory's Synchrotron Light Source, and had XANES collected for selected areas of the plants analyzed. We found that the particles were retained as gold, and not gold salts within the plant, and that the pattern of accumulation differed within the plant tissues.

Senator KERRY. Thank you, Dr. Ferguson.  
Dr. Goel?

**STATEMENT OF ANITA GOEL, M.D., Ph.D., FOUNDER,  
CHAIRMAN, AND SCIENTIFIC DIRECTOR, NANOBIOSYM, INC.  
AND FOUNDER, CHAIRMAN, AND CEO,  
NANOBIOSYM DIAGNOSTICS, INC.**

Dr. GOEL. Thank you, Chairman Kerry and members of the Subcommittee, for inviting me to share this testimony with you.

My name is Dr. Anita Goel. I'm the Chairman and CEO of Nanobiosym, Inc., and Nanobiosym Diagnostics. Nanobiosym fo-

cuses on creating innovation at the nexus of physics, medicine and nanotechnology. Nanobiosym Diagnostics is focused single-mindedly on commercializing a chip technology we've developed out of that nexus which will enable a future cell phone-like device in which you could put a drop of blood or saliva on a chip, stick it into the device and within a few minutes be able to diagnose what kind of infectious disease a person has.

This has, of course, many markets in the developed world, but we're also looking at commercializing this in the developing world. I want to share with the Committee a few aspects of our experience in doing that.

Taking the ability of diagnosing disease out of a pathology lab and the basement of a hospital and putting it into people's own hands will have a transformative effect on healthcare globally, because it will bring the ability to diagnose disease into doctors' offices, patients' bedsides, people's homes, or even into rural remote villages around the world.

My own background for the past 5 years I've been a nanotechnology entrepreneur and over 15 years have been a scientist in the field of nanotechnology, originally beginning at Stanford before the word "nanotechnology" became a buzzword and then at Harvard and MIT where I did my Ph.D. in Physics and an M.D. in medicine, two fields which traditionally haven't talked to each other but in my own mind come together at the nanoscale.

The National Nanotechnology Initiative has been critical to my company. It has not only helped us in terms of direct funding but it has been instrumental in creating the landscape and the infrastructure for innovation and that's been important in creating the environment that was needed for what we did.

I believe that the next 5 years could be even more profound if we make the right decisions, because as a Nation, we're really poised at the juxtaposition or a junction between basic R&D and commercialization. At Nanobiosym, we are not only commercializing our research by translating these basic insights into products, but also seeking to maximize the impact these insights can have on global challenges.

From our experience in bridging the gamut from basic R&D innovation to establishing proof of concept to commercializing products and also penetrating into emerging global markets, I believe there are four key lessons that we have learned that I would like to suggest to this Committee to consider as they build the roadmap for the NNI reauthorization.

Number (1) Let's talk about education. Obviously we need a qualified work force, but more than that, we need to think about the kind of people we are creating. We need to look at transcending conventional boundaries in our educational system, the boundaries between different academic disciplines, the boundaries between academia and corporate training programs, and even between the United States and international training programs.

Just like other countries send their students and people to train in our country, I think we need to send our people worldwide not only to train about nanotechnology but also to learn about the broader global context.

Number (2) Bridging the gap between fundamental research and products and commercialization. There are programs like the SBIR and the TIP Program which are very instrumental in bridging that valley of death, if you will, but, you know, there are other countries that are investing very heavily into very concentrated areas as a strategy, economic development strategy, if you will, to leapfrog themselves into a major player in the nanotechnology economy.

I think an analogy can be drawn with the automobile industry where, as you know, many countries can focus on building the best bumper or the best headlight. As Americans, however, we're uniquely positioned to create an entire nanotechnology economy. Just as we created the automobile economy that enabled us to capitalize on its mobility and create a whole system of jobs and infrastructure.

I think we need to focus on how nanotechnology works at the systems level, not only in basic research but also bridging into commercial products and solving global problems.

Number (3) The third key lesson is the broader impact nanotechnology can have on global challenges, whether it be the energy crisis, the environmental problem or healthcare.

Because it's such an interdisciplinary field where many fields come together in one melting pot and it has impact across various sectors, it really provides unique fresh approach to create, if you will, disruptive solutions to existing global challenges.

In my company, for example, not only are we looking at taking our technology to impact the way healthcare is practiced here and around the world but we are seeing that the same platform technology has impact on food testing, water safety testing, environmental testing, even crop pathogen testing.

So the same platforms can have many different kinds of applications. We need to think more broadly and more holistically in terms of how we leverage what we have. There's a lot of concern these days about the potential negative impacts on safety or on the environment of nanotechnology. I think that nanotechnology can help be part of the solution, not the problem, if we broaden our view.

Number (4) Fourth, I think there's a historically unique opportunity right now to bring emerging technologies into emerging global markets. I think that fields like nanotechnology are going to force us to think and even act globally.

In our company, for example, we follow the precedent of the cell phone industry. In the telecom field, you saw a paradigm shift when communications and computing devices became portable. You saw even poor villagers and beggars in developing world countries starting to use cell phones once the cost came down. Part of it is they didn't have the land line infrastructure to displace.

We envision driving a similar paradigm shift in the healthcare industry where the ability to diagnose disease can be taken out of a hospital and put into people's own hands and even transported to remote areas of the world. I believe the key to doing that is cutting the cost, making it affordable, but also forming global partnerships.

Part of our strategy as a company has been, and I would propose the Committee consider this as part of their roadmap, is that we

as Americans should engage other global partners in addressing global challenges and adopting some of the developing world problems as part of our own because part of those problems help stimulate new solutions.

Finally, I would like to thank you, Chairman Kerry, as well as the members of the Committee. Let me end by saying I believe we are uniquely poised to harness nanotechnology to fuel and revitalize our own economy if we think about it in a more global fashion.

Thank you very much.

[The prepared statement of Dr. Goel follows:]

PREPARED STATEMENT OF ANITA GOEL, M.D., PH.D., FOUNDER, CHAIRMAN, AND SCIENTIFIC DIRECTOR, NANOBIOSYM, INC. AND FOUNDER, CHAIRMAN, AND CEO, NANOBIOSYM DIAGNOSTICS, INC.

Chairman Kerry, Ranking Member Ensign, and members of the Subcommittee, I would like to thank you for the opportunity to testify on the reauthorization of the National Nanotechnology Initiative.

My name is Dr. Anita Goel, and I am the Founder, Chairman, and Scientific Director of Nanobiosym, Inc. and the Founder, Chairman, and CEO of Nanobiosym Diagnostics, Inc. Nanobiosym was founded as an idea lab and research institute to innovate at the convergence of physics, medicine and nanotechnology. Nanobiosym, and its commercial partner Nanobiosym Diagnostics, have been privately developing *Gene-RADAR*<sup>®</sup>, a portable nanotechnology-enabled platform that can rapidly and accurately detect genetic fingerprints from any biological organism. The company's vision is to give patients worldwide real-time access to their own diagnostic information via low-cost handheld devices. We are based in Medford, Massachusetts.

I first began working as a scientist in the field of nanotechnology over fifteen years ago at Stanford University—well before the term “nanotechnology” had become a buzz word. I simultaneously trained as both a physicist and physician, with my PhD in Physics from Harvard University and my MD from the Harvard-MIT Joint Division of Health Sciences and Technology (HST). For almost 5 years now, I have been a nanotechnology entrepreneur as the Founder, Chairman, and CEO of Nanobiosym and Nanobiosym Diagnostics. We are developing commercial products targeted for global markets—in both the developed and developing worlds.

#### **What is Nanotechnology?**

Nanotechnology to me is the ability to probe and control matter and systems on increasingly finer scales, at the nanoscale ( $10^{-9}$  m) and smaller. This is important because it gives us a new level of control over matter. Nanotechnology is a platform science which combines several traditional fields such as physics, chemistry, biology, and medicine. The applications that stem from these capabilities likewise cut across several different sectors from medicine and energy to the environment and materials science. For example, the ability to control the assembly and arrangement of atoms and molecules in a nanomaterial could give it the durability of steel and the weight of plastic.

Nanotechnology provides a platform for innovation across conventional boundaries of science, technology, and commerce. Furthermore, by its intrinsic multidisciplinary nature, it fosters collaboration across conventional political and economic boundaries.

#### **Nanobiosym and the National Nanotechnology Initiative**

Nanobiosym has been the direct beneficiary of the National Nanotechnology Initiative. Without the resources that the Initiative brought to bear—not only funding, but also coordination and a sense of national priority—Nanobiosym would not be where it is today. We have been fortunate to work with several of the agencies participating in the Initiative, and have received multiple rounds of competitive funding grants from DARPA, AFOSR, Phase I and Phase II SBIR funding from DOE, and now more recently were awarded a defense contract from DTRA as some of our technology platforms transitioned from the pure R&D stage to the more applied or prototyping stage.

As the Subcommittee considers how best to update and improve the Initiative, I hope that our experience as an emerging nanotechnology company (in moving across the gamut from science and technology innovation, to proof of concept development

and developing commercial products for global markets) will help identify what has worked well and what could be improved to encourage other companies like us.

### **The Need for Reauthorization**

As Congress begins to consider reauthorizing the National Nanotechnology Initiative, it is important to understand that because the original authorization was so successful, the Nation's nanotechnology landscape dramatically changed in the last 5 years. The 21st Century Nanotechnology Research and Development Act focused primarily on basic research. This led to dynamic growth in America's nanotechnology research infrastructure primarily in academic settings, and sowed the seeds of nanotechnology commercialization throughout the country.

Today, 5 years later, we are beginning to see the results of this initial investment, as nanotechnology-enabled products start to enter the marketplace across the spectrum of industry sectors, from water purification to materials engineering to healthcare. While the success of the first 5 years gives us great hope, however, I cannot impress upon the Subcommittee enough that the growth of the next 5 years could be exponential. Building on the success of the National Nanotechnology Initiative's first 5 years, the United States has a historic opportunity to drive nanotechnology to maximize its impact on global challenges, including health, environment, energy, and even building the new global economy.

The reauthorization of the National Nanotechnology Initiative should focus on four new areas in addition to basic research:

1. improving nanotechnology education, which will supply a qualified workforce for the American and global nanotechnology economy;
2. bridging the gap between research and commercialization, which will help America drive the global nanotechnology revolution;
3. addressing environmental, health, safety, and other global challenges, which will ensure that we can enjoy the many benefits of nanotechnology while addressing any risks that may arise; and
4. bringing emerging technologies into emerging global markets.

Each of these four areas has a direct impact on my company. Progress in each will enable Nanobiosym to bring its lifesaving products to market faster, to expand and provide quality jobs for more people, and to market our products to global markets in both the developed and developing world.

## **A Roadmap for Harnessing Nanotechnology to Drive the New Global Economy**

### *1. Nanotechnology Education*

If America is going to compete effectively in the global nanotechnology revolution, we need a highly skilled and qualified work force. We need scientists, engineers, and technicians who have a vision for nanotechnology, seek to innovate with it, and are capable of working at the nanoscale. We need professors and teachers who can educate about the nano world and we need business professionals who can turn the scientists' work into useful products. It is already difficult to meet the demand for PhDs with nanotechnology backgrounds, and that demand will only increase in the coming years.

We need to spark interest in nanoscience, starting in grade school. We need to build a nanotech pipeline in education which will allow for a steady stream of qualified personnel to supply our labs and companies.

Nanotechnology education, like nanotechnology research, is necessarily multidisciplinary. Because nanotechnology spans physics, materials science, chemistry, and biology, it needs to be taught throughout the science curriculum. And like other subjects, nanotechnology is best learned by doing. Programs that improve access to basic nanotechnology tools will help inspire a new generation of students to pursue careers in science because they will be able to see firsthand nanotechnology's potential.

Our education system must start transcending conventional boundaries between academic disciplines, between academic and corporate training programs, and between U.S. and international training experiences. I would suggest the creation of more international exchange programs. Just as other countries send their students here, we should start sending our people around the world to be trained not only in nanotechnology but its broader international context.

The reauthorization bill will be an excellent investment in America's future if it promotes nanotechnology education from grade school through graduate school. If it does not, we will continue to rely in the short term on foreign science students

who will often end up returning to their home countries to compete against us after completing their studies.

### *2. Bridging the Gap Between Nanotechnology Research and Commercialization*

As the Members of this Subcommittee know, America's competitiveness in the global market is being tested in the field of nanotechnology, where Russia, China, Japan, the European Union, and other nations are making major investments in translating basic research into marketable nanotechnology products. Often, foreign governments are pursuing a strategy of letting American researchers do the basic science, then using their resources to commercialize that research and gain the economic benefit. Having invested in the early days of nanotechnology research and innovation, we should not miss the opportunity to fully commercialize our own research.

Programs such as Small Business Innovation Research, Small Business Technology Transfer, and the new Technology Innovation Program are vital mechanisms for bringing technology out of the lab and into the marketplace. They provide needed resources and expertise to emerging small businesses, and they help bring new technology and new jobs into existence. They bridge the "valley of death" that lies between basic research funding and late-stage commercial funding—a valley that would otherwise swallow many more promising companies. As the Subcommittee drafts the reauthorization legislation, I urge you to ensure that these programs play a major part in the bill.

In my own experience, programs like SBIR have enabled companies like ours to stay focused on more disruptive innovations even when they are not the lowest hanging fruit in terms of revenue generation. In practice, such programs keep American innovation at the cutting edge as we continue to meet real-time market needs.

Rapid commercialization is important, but goal-oriented research also will help accelerate the path to market for nanotech companies. Many emerging countries are focusing on this strategy to leapfrog themselves into significant roles in the global economy. For example, countries like Taiwan have determined that, although they may not be able to challenge the United States across the board, they can compete effectively if they concentrate their resources. By conducting goal-oriented research in a key area such as electronics or display technologies, they can achieve a strong position in those markets.

We can do the same thing. Already, we have had tremendous success with goal-oriented research in cancer treatment and other health-related areas. Identifying and pursuing other key goals, such as nanomedicine, energy, electronics, or water purification, will help ensure that we are getting the most for our research money.

As someone who practically embodies the concept of "multidisciplinary research," I would encourage the Subcommittee to see to it that goal-oriented research centers cross traditional scientific and agency boundaries. The National Science Foundation and the Department of Energy should be working together; NIST should be working with EPA; and so forth. I have seen the beginnings of such multidisciplinary research under the current National Nanotechnology Initiative, and the results are indeed encouraging. I see this in my own company every day, and I know it works.

Goal-oriented work and cooperation will go far to expedite commercialization and provide a more efficient path to market for many businesses and products. I caution the Committee, however, not to get trapped by lesser goals while losing sight of the bigger picture. It is one thing to make products based on nanotechnology research; it is another to build a nanotechnology economy. The goal-oriented nanotech research of competing economies is understandable given their resources. But it is one thing to be simply the supplier of a bumper, or a headlight, or a mechanical part for an automobile; it is another thing to build an economy based on the mobility the automobile enabled, which spawned multiple new industries and employed millions. So it could be with nanotechnology.

It is true that goal-specific research will be important, as will support for commercialization and collaboration between agencies. It will be this understanding of the nano-based economy that will differentiate us from our competitors and allow us to make the best decisions about where to invest our resources. This understanding will also enable us to take a fresh approach to American leadership in the new global economy.

### *3. The Broader Impact of Nanotechnology on Environmental, Health, Safety and other Global Challenges*

A comprehensive, strategic approach to understanding the environmental, health, and safety effects of nanotechnology is a necessary component of any Federal plan at this point. With nanotechnology products entering the commercial market, it is

important that we know how nanoparticles behave in the body and in the environment. Just as important is the need to communicate with consumers so that they understand the efforts that are underway to determine and address any risks that may exist. The last thing that any nanotechnology company wants is for a lack of safety data to scare consumers into staying away. The field has learned the lessons of the genetically-modified food debacle.

That said, however, Nanobiosym's experience represents a different part of the issue. Amid the concern about potential negative environmental, health, and safety impacts, it is easy to forget that nanotechnology can be much more of an environmental, health, and safety solution than a problem. For example, Nanobiosym's products will improve health both here and in the developing world by rapidly diagnosing infectious disease. Soon, we plan to expand into water and food testing. When it hits its stride, my company will be an environmental, health and safety solution, not a problem.

Although I am proud of our technology and the contribution it will make, many other nanotechnology companies are making similar contributions to environmental, health, and safety issues. From fuel cells to LED lights, from cancer treatments to antibacterial surfaces, and from strong composite materials to aircraft metal fatigue sensors, nanotechnology products are beginning to clean up the environment, cure people and keep them healthy, and save lives by preventing accidents. These trends will only accelerate as nanotechnology becomes more widespread.

#### *4. Bringing Emerging Technologies into Emerging Global Markets*

I envision that the new global economy will take shape as the economies of major nations become more interdependent and intertwined via science, technology, and commerce. Nanotechnology by its very multidisciplinary and international nature is thus likely to play a major role in driving the new global economy.

Nanotechnology will spur American entrepreneurs to think and act even more globally. As Americans, we should take a bold step toward global leadership in the nanotechnology revolution by engaging other players around the world and also by embracing global challenges (such as the energy crisis, global health, and the environment) as our own including those of the developing world. Together we should focus on using our best scientific and technological tools to solve real-world problems.

For example, at Nanobiosym we have developed a technology platform that has both biodefense applications and clinical diagnostic markets here in the U.S. as well as in the developing world. The very nature of the way innovation and commercialization is proceeding in nanotech enables us to reach out to a global market. For example our product, because of its portability and small size, has a large potential in the developing world. Similar to the cell phone industry which has made a disruptive impact on telecommunications in emerging markets, there are six billion people on Earth and everybody gets infected at some point in their life. If we can make our products cheap enough we can improve global healthcare as well as cater to the needs of a growing multibillion-dollar market.

#### **Conclusion**

I would like to thank you, Chairman Kerry, Ranking Member Ensign, and the members of the Subcommittee once again for the invitation to testify today, and for your leadership in working to ensure that America can harness the nanotechnology revolution to not only revitalize its economy but also drive and help shape the new global economy. Building on the success of the National Nanotechnology Initiative's first 5 years, the United States has a historic opportunity to drive nanotechnology to maximize its impact on global challenges. The economic and humanitarian benefits of driving this nanotechnology revolution will be tremendous, and the reauthorization of the National Nanotechnology Initiative will go a long way toward putting America at the forefront of this global revolution.

As the CEO of an emerging nanotechnology business with global aspirations, I am certainly grateful for the support.

Senator KERRY. Thank you very much, Dr. Goel.  
Dr. Heath?

**STATEMENT OF JIM HEATH, ELIZABETH W. GILLOON  
PROFESSOR AND PROFESSOR OF CHEMISTRY; DIRECTOR,  
NANOSYSTEMS BIOLOGY CANCER CENTER, CALIFORNIA  
INSTITUTE OF TECHNOLOGY**

Dr. HEATH. Senator Kerry and colleagues, about a decade ago, the late Rick Smalley sat before this very same Senate Committee when it was considering the National Nanotechnology Initiative. Rick won the 1996 Nobel Prize in Chemistry for his discovery of  $C_{60}$ , known as Buckminsterfullerenes and the class of all carbon molecules known as the fullerenes—molecules which in many ways have become the poster children of nanotechnology.

I also had a part in that discovery. It was my dissertation work and Rick was my Ph.D. advisor and thus it's a special honor to be here today.

Senator KERRY. Can you pull the microphone closer to you?

Dr. HEATH. How's that?

Senator KERRY. Thanks.

Dr. HEATH. Anyway, thus it's a special honor to be here today and I want to recall a little bit of Rick's testimony from a decade ago.

He said, and I quote, "I sit before you here today with very little hair on my head." That's obviously a quote. "As a result of chemotherapy. I'm not complaining. Twenty years ago, I would already be dead, but 20 years from now, we will no longer have to use this blunt tool. Nanotechnology will have given us engineered drugs which are nanoscale cancer-seeking missiles, a molecular technology that specifically targets just the cancer cells and leaves everything else blissfully alone. I may not live to see it but I am confident it will happen."

Well, Rick was prophetic on both accounts. He didn't live to see it but it's happening now and it's happening faster than he envisioned it happening.

One example comes from my colleague at Caltech, Mark Davis. Mark is a member of the Cancer Center I direct. It was one of the few nanotechnology-based cancer centers the NCI founded a few years ago. Mark developed a nanotherapeutic that begins to mimic Rick's cancer-seeking nanotech missiles. He put this into a Phase I trial and a patient came into this Phase I trial that had late-stage metastatic pancreatic cancer.

I know there's a lot of—probably a number of folks in this room that have had cancer but if you had had late-stage metastatic pancreatic cancer, you probably wouldn't be here today. The survival rate for that disease is almost zero.

In these Phase I trials, the patients that come in are ones that have failed every other type of therapy. They're on their last hope basically, and this patient had two to 3 months left to live. Well, as of today, and this is 2 years later, this patient is still living, is cancer free, and went through the entire trial without even hair loss. That's a stunning result.

Now the chemotherapy was actually a typical chemotherapeutic drug. It was one that would lead to side effects, such as hair loss or cardiac arrest, but the nanotherapeutic, which was the delivery system that delivered that drug, basically permitted the dose to be

lowered twenty-fold and therefore lowering the toxicity. It also directed more effective delivery of the drug to the cancer.

The scientific foundation for that drug is what the National Nanotechnology Initiative has delivered. Each of the nanoparticles, for example, is designed to look friendly to the immune system, to stay in the blood for days until it finds the tumor, and not to release their drug payload until the nanotherapeutic is actually inside the cancer cells. None of this is by accident.

In fact, a lot of the research that went into making that happen we might think of as Environmental Health and Safety kind of research but it would never be classified as such because you actually have to do it to make the stuff work. This I would argue that in many ways we're vastly underestimating the amount of money that's going into EH&S-type work because it accompanies a lot of this type of research.

We are faced with some staggering scientific and technological problems today, ranging from energy and healthcare and the environment, and nanotech solutions are virtually at the forefront of every single one of these problems. For example, in my own lab, we have developed a technology that goes from a finger prick of blood to 50 protein diagnostic measurements, all within the time scale that's actually faster than the blood clotting.

Now that we're beginning to harness that technology for use in our soldiers in Afghanistan and Iraq but we're also using it within our cancer center. In Afghanistan and Iraq, there's many instances where this technology can be utilized to help dramatically shorten the time between diagnosis and treatment after trauma. The therapy can help save lives. This is an emerging and really interesting issue. I hope someone asks me about it.

Now is not the time to further regulate this field. The therapeutics and the diagnostic devices that I've just talked about go through very demanding procedures, the same FDA approval procedures that anything else goes through, and these procedures are the gold standard. They work.

The NSF and the NIH have both taken very seriously the aspects of the health impact of nanotech and they've launched major initiatives in these areas. However, the example of a nano drug vastly reducing side effects, not increasing them, has been the story when the foresight and the resources are available to ensure that the science is done correctly. Right now that part is working.

I want to conclude with what I think is probably a looming crisis. In fact, I know it's a looming crisis. I was recently at a meeting where a bunch of experts were bemoaning the fact that drug trials, clinical trials of drugs are now becoming an offshore endeavor.

Well, I'm here to tell you that every aspect of that process, from the basic science to the engineering to the product testing to the manufacturing is becoming an offshore endeavor. This is not just for drugs, but for many fields.

We are in serious danger of losing our competitive advantage in a number of high-tech arenas. We achieve world scientific and technological leadership by taking on high-risk, high pay-off goals and sticking with those goals. However, our scientific enterprise, I believe, is becoming risk-averse.

Other countries see this chink in our armor and are challenging us. The National Nanotechnology Initiative constitutes one of our high-risk, high-yield investments and it's working, but in other areas, we are losing our edge.

I think our great country has a history of achieving its goals by combining bold scientific visions, strong political leadership, effective public education and significant and sustained investment in our scientific foundation. Through that, we have maintained our global technological and economic leadership. I think finding ways to sustain that mix rather than finding ways to regulate an emerging and fragile field should be the focus of this debate.

Thank you.

[The prepared statement of Dr. Heath follows:]

PREPARED STATEMENT OF JIM HEATH, ELIZABETH W. GILLOON PROFESSOR AND PROFESSOR OF CHEMISTRY; DIRECTOR, NANOSYSTEMS BIOLOGY CANCER CENTER, CALIFORNIA INSTITUTE OF TECHNOLOGY

Senator Kerry, Members of the Committee, and Colleagues:

Nearly a decade ago the late Rick Smalley sat before a Senate committee that was considering the National Nanotechnology Initiative. Rick won the 1996 Nobel Prize in Chemistry for his part in the discovery of C<sub>60</sub> and the fullerenes. I also had a part in that—it was my dissertation work, and Rick was my Ph.D. advisor. Thus, it is a special honor to be testifying here today, and I want to recall a bit of Rick's testimony from a decade ago.

*"I sit before you today with very little hair on my head . . . a result of chemotherapy . . . I'm not complaining. Twenty years ago . . . I would already be dead. But twenty years from now . . . we will no longer have to use this blunt tool. . . . Nanotechnology will have given us . . . engineered drugs which are nanoscale cancer-seeking missiles, a molecular technology that specifically targets just the . . . cancer cells . . . , and leaves everything else blissfully alone . . . I may not live to see it, but . . . I am confident it will happen."*<sup>1</sup>

Rick was prophetic on both accounts. He didn't live to see such advances, but they are happening now. One example comes from my Caltech colleague, Mark Davis. Mark is a member of a cancer center that I direct. It is one of a few innovative cancer centers that the NCI funded a few years ago to develop nanotechnology tools for battling cancer.<sup>2</sup> Mark's lab developed a nanotherapeutic that begins to mimic Rick's nanoscale cancer-seeking missiles.<sup>3</sup> I'll begin with a story about a patient from a Phase I clinical trial of this drug. Phase I trials are a last recourse for those who have failed everything else, and this patient came to Mark's trial with late-stage, metastatic pancreatic cancer, and a prognosis of 2-3 months left to live. There are several cancer survivors in this room. However, if any of you had had metastatic pancreatic cancer, it is unlikely you would be here today. The survival rate for this terrible disease is almost zero. That patient entered the trial almost 2 years ago, and is still alive, cancer free, and went through the entire trial without even hair loss. That is a stunning result—the drug itself was a typical chemotherapeutic with toxic side effects that range in severity from hair loss to cardiac arrest. However, the delivery agent, which was a nanotechnology, permitted the dose to be lowered 20-fold, and directed more effective drug delivery to the cancer.

The scientific foundation for this drug is what the national nanotechnology initiative has delivered. Each of Mark's nanoparticles is designed to look friendly to the immune system, to stay in the blood for days until they find the tumor, and to not release their drug payload until they are inside a cancer cell.

This is just the beginning.

<sup>1</sup>Richard E. Smalley testimony before the Senate Committee on Commerce, Science and Transportation, May 12, 1999.

<sup>2</sup>The NanoSystems Biology Cancer Center is one of a few Cancer Centers for Nanotechnology Excellence (CCNEs) that the National Cancer Institute funded starting in late 2005.

<sup>3</sup>M. E. Davis and M. E. Brewster, "Cyclodextrin-based pharmaceuticals: Past, present, future," *Nat. Rev. Drug. Disc.*, 3, 1023 (2004).

We are faced with some staggering scientific challenges today—ranging from energy to health care to the environment. For virtually all of these problems, nanotechnology-enabled solutions are at the forefront of the scientific search for answers.

In my lab we have developed a nanotechnology-enabled chip that carries out almost 50 diagnostic measurements from a fingerprick of blood—all before the blood even clots.<sup>4</sup> This chip has applications for our soldiers in Iraq and Afghanistan where shortening the time between injury, diagnosis, and treatment can save lives. It also has applications to routine health care.

Now is not the time to further regulate this field. Mark's therapeutics and our diagnostic devices go through the same demanding FDA approval processes as standard drugs and health care technologies—that process sets the global standard, and it works.

The NSF and the NIH are taking seriously the tasks of understanding the environmental and health impacts of nanotechnologies—both agencies have established significant programs to understand those risks.

However—the example of a nanodrug vastly reducing toxic side effects—not increasing them, has been the story when the foresight and resources are available to ensure that the science is done correctly. Right now, that part is working.

Finally, I want to turn to a looming crisis. I was recently at a meeting where various experts were bemoaning the fact that clinical drug trials are increasingly off-shore endeavors. In fact, the entire process, from the basic science of discovery, to engineering, product testing, and manufacturing, is moving off shore—and not just for drug discovery. We are in serious danger of losing our competitive advantage in a number of high tech arenas. We achieve world scientific & technological leadership by taking on high risk, high payoff goals, and sticking with those goals. However, our scientific enterprise is becoming risk averse. Other countries see this chink in our armor, and are challenging us. The National Nanotechnology Initiative constitutes one of our high risk/high yield investments. It is clearly working, although it is a serious struggle to stay ahead of the curve. In other areas, we are losing our edge.

Our great country has a history of achieving goals by combining bold scientific vision, strong political leadership, effective public education, and significant and sustained investment in our scientific foundation. That is how we have maintained our global technological and economic leadership. Finding ways to sustain that mix, rather than finding ways to regulate an emerging and fragile field, should be the focus of this debate.

Thank you.

Senator KERRY. Thank you very much, Doctor. That was a very interesting, provocative, and thoughtful testimony.

Let me ask you. When you suggest, as you did, that we should not, I think you used the word “interfere,” am I correct, and therefore not interrupt this chain of important research which you're doing and it is important and I understand that, how do you respond to the other testimony and to others who are suggesting that we don't know what some of the impacts of these nanoparticles are and some of the uses that are out there? How do you balance this non-interference and obvious need to be competitive and move down the road with need of the rights, the public's right to know, and adequate protection for the public against the product like that where you may be brushing your teeth with something that you learn in 10 years actually does you great harm?

Dr. HEATH. Well, I would argue that the vast amount of nanotechnology that's investigated today is done on a very small scale in the lab where we've never gone in and interfered with the science and it's probably not appropriate to do so because that's not a place where it's going to have an impact.

<sup>4</sup>Rong Fan, Ophir Vermesh, Alok Srivastava, Brian K.H. Yen, Lidong Qin, Habib Ahmad, Gabriel A. Kwong, Chao-Chao Liu, Juliane Gould, Leroy Hood, and James R. Heath. “Integrated Blood Barcode Chips,” under review to *Nature Biotechnology* 4/08.

Whenever any of these technologies actually make it out into the commercial arena, the very nature of that process mandates that these things are investigated very thoroughly. I can tell you mostly from the healthcare arena that it's a demanding process. I was at a meeting where a bunch of people doing nanotech are staggered by these regulations.

Senator KERRY. Staggered by?

Dr. HEATH. By the regulations of trying to—it's what every drug has to do to go through FDA or—

Senator KERRY. You're talking about a drug and drugs indeed have a certain protocol and a higher standard. What about other products that come into the market? I mean obviously this toothpaste doesn't.

Dr. HEATH. Right.

Senator KERRY. There are countless other products. My wife and I just wrote a book, she wrote the chapter on toxins and, you've got these extraordinary numbers of toxins that are in products that people aren't even aware of. Whether it's phthalates in plastic that we now know is carcinogenic, bisphenol, or other things that kids suck on and are in toys or elsewhere, and people really don't know the consequences.

Dr. HEATH. Well, I think that we have some issues in terms of products that get released that we don't have very much oversight on. I don't think that's a nanotechnology problem. I think if you compared what happens in the cosmetic industry where people are applying all kinds of things to the body,—

Senator KERRY. That's crazy.

Dr. HEATH.—you don't have near the amount of oversight over that industry. Nanotech is—

Senator KERRY. We actually have none.

Dr. HEATH. Yes. That's right. If we single out nanotech, right now it's a very fragile field. It's young. I know we talked about these major things going into products.

Senator KERRY. Well, wouldn't you say—

Dr. HEATH. It's small potatoes.

Senator KERRY. When you say single it out, I'm not sure we're singling it out, but given its potential to be in so many different products and the extraordinary power within the marketplace that it may well have, doesn't it behoove us to try to get this right up-front?

Dr. HEATH. Absolutely, and I would say just like—you know, several years ago, when the AIDS crisis hit, our knowledge of the human immune system went up dramatically because of that crisis.

At the moment, because of National Nanotechnology Initiative, we know a tremendous amount of what nanotechnology matters and materials and et. cetera do inside the human body and the environment that we never would have known otherwise.

I think we're learning this and we haven't had a uniform way to maybe categorize it, although I believe there are some agencies that are beginning to do that, but if we made a regulation now, it'd be based upon ignorance, I believe. But I do believe it's a good time to try to begin categorizing it in a rational way.

Senator KERRY. I mean what if the regulation is a reaction to ignorance in a sense in that it is requiring a certain protocol to be

followed before X, Y or Z product is placed out there? Is that so onerous?

Dr. HEATH. No. In fact, I think that's done now.

Senator KERRY. Should we demand a transparent protocol by which something is coming to the market?

Dr. HEATH. At least in all the commercial endeavors I've been involved in, that is exactly what happens now because of the current standards and practices.

Senator KERRY. Except for those 75,000. I think we only have 6,000 FDA-approved chemicals that are out in the marketplace out of some 82,000 that I know are "out in the marketplace," some of them to a lesser or greater degree than others, obviously. Cosmetics is an example where estrogenic substances have been used in some of these products which wind up in fact potentially giving people cancer.

Hair straighteners, for instance, have been shown to be particularly malicious among African American young women who wind up with a greater incidence of breast cancer and other things. Nobody has done a complete linkage, but there's a lot of evidence now about endocrine disruptors and other impacts out there. Books are being written by researchers, oncologists, and others that are all looking at this.

It seems to me the warning signs are flashing and we ought to just be careful. That's all. Nobody wants to interfere.

Anybody else want to respond to this? Yes, Dr. Goel?

Dr. GOEL. Yes. I would like to add that I think that it's not a matter of whether to apply regulations or not, it's about where to apply the regulations and when to apply them.

I think what Dr. Heath said at the level of the basic science innovation, that's probably not the best place to apply the restrictions.

Senator KERRY. Are we trying to? Is anybody trying to apply it there?

Dr. GOEL. I think that the hype that gets created about the negative aspects of nanotechnology may tend to discourage certain kinds of funding to basic science nanotechnology which could have an adverse effect.

Senator KERRY. So we should be wary of that and wary of interfering at the basic level, correct?

Dr. GOEL. In terms of a mentality. I think the other thing is one must be clear that not all kinds of nanotechnology are this general—the same kind of bad consequence. Maybe you're referring to nanomaterials or nanochemicals. Nanotechnology is broader than that.

Senator KERRY. Agreed.

Dr. GOEL. And what it defines and refers to is much broader than that and so I think it's a very narrow projection of what nanotechnology is.

Senator KERRY. How would you define it?

Dr. GOEL. Nanotechnology?

Senator KERRY. Yes.

Dr. GOEL. I love to define it.

Senator KERRY. What?

Dr. GOEL. In my mind, it really is the ability to probe and control matter at increasingly finer scales, 10 to the minus 9 meters and

beyond and smaller, and why that's important is because when we can learn to control and manipulate matter and probe matter on that level, we can effect the properties of systems and nanomaterials is one example.

In our example, we control the molecules which improves the precision and accuracy with which we can read out information.

Senator KERRY. Where are you in that process? Do you actually have an ability to—

Dr. GOEL. We have a prototype.

Senator KERRY. A prototype?

Dr. GOEL. Yes.

Senator KERRY. Which is bigger than what you're holding in your hand?

Dr. GOEL. No, this is the chip.

Senator KERRY. That's the prototype chip?

Dr. GOEL. Yes.

Senator KERRY. What's the read-out?

Dr. GOEL. The read-out is bigger than our Blackberry I show here.

Senator KERRY. So that is yet to come?

Dr. GOEL. Yes, exactly.

Senator KERRY. Dr. Ferguson.

Dr. FERGUSON. Yes, I would comment—

Senator KERRY. Let me just give you all a heads up. I have a meeting I've got to run to before too long. So I may have to truncate this a bit but we'll try to keep going.

Dr. FERGUSON. Senator Kerry, I would say that the examples that Dr. Heath highlighted about biomedically relevant nanoparticles certainly would be well understood by the time they get to the point they'd be used in biomedicine from lots of study by the FDA and the developers, but I would say that your example of, for example, at Tuskalis with 75,000 compounds that are out there in our environment is a great example of why we should be spending the effort upfront right now to study and understand at the scientific level the behavior in both environmental systems as well as biological systems of as broad a range of nanomaterials as possible.

The big problem here is that for nanotechnology, we're really talking about a very, very broad scientific field that encompasses lots of different materials with different chemistries and different surface properties and so it's very difficult to say whether nanotechnology, nanomaterials in general are dangerous, are not dangerous, are safe or not safe.

Senator KERRY. Well, let's come back to the panel's original discussion then. Does that say something about what ought to be required in terms of a strategy or roadmap? Where do you all come out on that?

Dr. FERGUSON. I think that's essential. I think that there should be some rational prioritization of the types of nanomaterials and the types of nanotechnologies that are assessed in terms of environmental and human health safety and so I think of this as a chemist and the ideal would be to come up with models that we can fit new nanomaterials into as they become available where we have some applicable—some idea of how these new materials will behave with reference to materials we've studied in the past.

That's the best way, I think, to leverage our scientific knowledge.  
 Senator KERRY. Mr. Rejeski.

Mr. REJESKI. I think one of the most important things we can actually do is provide adequate resources to some of these agencies that provide oversight. I mean the FDA an incredibly powerful brand for people that are trying to bring products into the market.

The FDA's own science board just did a fairly extensive examination of their capacities and one of the things they said was the development of new medical products based on what they said was new science, which would include genomics nanotech, cannot be adequately regulated by the FDA at this moment.

I mean, basically, we've just witnessed over a hundred deaths on an FDA-approved product, a blood thinner. So I think, you know, one of the things that we're looking at, and it's a much wider area, is just making sure that these agencies, such as the FDA, the Consumer Product Safety Commission, EPA, have the resources. They are totally starved under the NNI because 60 percent of the environmental health and safety research is going to the NSF.

NSF is a phenomenal agency but NSF will not answer any of the questions that we're going to have to answer around this product. Meanwhile, all the agencies that really are required to provide oversight and the science that's behind oversight because we don't want oversight built on inadequate science are starved, and I think that's part of the strategy that we haven't gotten right yet and it's critical now as we move more of these products, whether they're medical applications, whether they're cosmetic, whatever it is, into the commercial realm.

So I think part of it is actually doing something that we need to do generally in the government and obviously the Congress has been holding hearings about consumer product safety, about the EPA, but I think a strong FDA helps in the long run because the entire world cares about the FDA's clinical trial process.

Senator KERRY. I'm going to come to you, Mr. Nordan, in just a minute, but who was it, Dr. Ferguson or Dr. Goel, who mentioned the negative hype? That's what I thought, Dr. Goel.

It seems to me the only way to push back against the negative hype is going to be to do the scientific research and develop a kind of transparent accountable understanding of the American people of what they're dealing with, isn't it?

Dr. GOEL. I agree, yes. I think that—

Senator KERRY. Can you do that adequately without running into the problem that I think Dr. Heath appropriately raises, which is, scaring everybody away and creating such an albatross of a process that you reduce innovation?

Dr. GOEL. I think absolutely.

Senator KERRY. What's the key to that?

Dr. GOEL. The key to that is letting the research happen, remove the shackles around the creative research process, let that happen.

Senator KERRY. Right.

Dr. GOEL. Once the research tries to, as he said, get out of the lab and go into the marketplace and starts to cross the gamut, then bring in the regulatory thresholds that you would apply to any other product.

Senator KERRY. Does that work for you, Dr. Heath?

Dr. HEATH. I think if those regulatory bars you have to jump over are carefully thought out, absolutely.

Senator KERRY. But if they come after the initial research steps—

Dr. HEATH. It's kind of nice to know what's down the road so that you, you know, focus your efforts in—

Senator KERRY. Was that any different from where you are now?

Dr. HEATH. No, I would say for the drugs—so let me be very clear. I believe for anything that's nanotherapeutic or drug-related, we have a great process. We do not need to step into new regulations.

Senator KERRY. Right.

Dr. HEATH. For other stuff that may not be certain things you ingest, it could be a chemical, could be a face powder, could be a solar cell, we may need to have a certain level of standards that we establish.

Senator KERRY. Good line to draw. I accept that. Mr. Nordan.

Mr. NORDAN. To give some insight from how the business community views this, we work with a large number of corporations across a large number of industries, from electronics through to chemicals and also in life sciences.

I would tell you that we should not conflate in this discussion laboratory research and regulation of manufactured goods that are manufactured to large scale. I don't think there is anyone who is calling for or deeply focused on setting limits, as we've seen, for example, with stem cell research, on what scientists can and cannot do in the nanoscale regime in the laboratory.

It's a very different issue when you come to manufactured goods, and I think what's unique in nanotechnology is that you have both large companies, like Dupont, as well as small ones, like Alta Nanotechnologies, that are asking for regulatory clarity.

Normally you think of this as trying to duck regulations and duck red tape and in this case, you have folks at large chemical companies, electronics firms, medical products companies who are simply asking not for new regulations but for regulatory clarity on what currently applies.

A client of ours that I spent some time with recently, a CTO of a billion dollar, multibillion dollar chemicals, multinational chemicals company on the East Coast, and sat down with him, went through some nanotechnology research. We were batting some questions back and forth. He said, "You know what, Matthew? It's amazing to me that 7 years after the introduction of the National Nanotechnology Initiative, I don't know whether TOSCA applies to my products or not."

You would not suit up and go into a football game if you didn't know what the rules were and when someone could tackle you and businesses are very concerned about bringing products to market, that in some cases their rivals in Europe and in East Asia are doing that well ahead of them, not because they're concerned about the consequences of regulation but because they don't know what the rules of the game are.

Senator KERRY. Fair enough. That's very important. That's a very important view obviously for us to factor in as we think about this.

How about the foreign competition piece? Will this work if we have a fairly commonsensical but nevertheless accountable and transparent system but the Chinese don't?

Mr. NORDAN. Well, if I could take a shot at that, I think that there are places in the world where there are straightforward commonsense mechanisms that might be considered more onerous than the United States where there is actually much more active nanotechnology research and development, at least on behalf of large corporations.

We normally think of Europe as being a generally more cautious and more precautionary group of societies when it comes to new chemicals, new materials. Regulations like REACH, for example, is a very broad-ranging chemical regulation in the EU or an example of that. Yet when you compare the Dows and Duponts and GE Plastics of the world with their rivals in Europe, companies like Salve and BASF and DSM, you actually find that the European companies have been much more aggressive in conducting research on nanoparticles and being very straightforward and transparent with the public on how they're being used and launching products that are actively pitched for their nanobenefits, nanobenefits, and I think that comes down to regulatory clarity.

I don't think there is an incompatibility between straightforward common sense application of regulatory regimes and aggressive commercial activity in nanotech. I think the European example argues that they can come together.

Senator KERRY. Well, folks, regrettably, I've got to be over in the Capitol for a briefing on Syria and North Korea and what's going on. I apologize for breaking up, but as I said, I'll leave the record open.

I appreciate all of you coming here. This is really very, very helpful. We obviously want to get this thing reauthorized and do this well and if you have further thoughts you would like to share with the Committee, the record is open. We welcome your further comments based on what you've heard today or if you think you'd like to extrapolate a little bit, we'd welcome that.

It's an interesting topic. I regret more people weren't able to be here, but Thursday afternoon, having just had our last vote sort of affects what happens here a little bit, I apologize for that. Everybody has pretty intensive schedules.

But this is a topic everybody is intrigued by and learning more about. We've clearly learned around here to try as hard as we can not to get in the way and I think we're getting better at that, not to overreach but to come up with something that's really thoughtful and workable. We'll do our best here to be able to try to do that because we want this sector to flourish.

I'm convinced that this, together with a few other things, like artificial intelligence, robotics and communications and so forth, are the future for us in terms of high value-added jobs and technology advances and so forth, life sciences obviously, bio, but this is a big deal for us.

So we want to try to get it right and I hope you'll help us do that. You certainly have to a great degree today.

So all the way from California and elsewhere, thanks so much for coming in. We really appreciate it.

We stand adjourned.  
[Whereupon, at 4:25 p.m., the hearing was adjourned.]

