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Committee on Science

Hearing on:

"Research on Environmental and Safety Impacts of Nanotechnology: What are the Federal Agencies Doing?"

Testimony of:

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I would like to thank Chairman Sherwood Boehlert, Ranking Member Bart Gordon, and the Members of the House Committee on Science for holding this hearing on "Research on Environmental and Safety Impacts of Nanotechnology: What are the Federal Agencies Doing?"

My name is Dr. Andrew Maynard. I am the Chief Science Advisor to the Project on Emerging Nanotechnologies at the Woodrow Wilson International Center for Scholars. I am an experienced researcher in the field of nanomaterials and their environmental and health impacts, and have contributed substantially in the past fifteen years to the scientific understanding of how these materials might lead to new or different environmental and health risks. I was responsible for stimulating government research programs into the occupational health impact of nanomaterials in Britain towards the end of the 1990's and have spent five of the past six years developing and coordinating research programs at the Centers for Disease Control and Prevention (CDC) National Institute for Occupational Safety and Health (NIOSH) that address the safety of nanotechnologies in the workplace. While at NIOSH, I represented the agency on the Nanoscale Science, Engineering and Technology (NSET) Subcommittee of the National Science and Technology Council (NSTC), and was co-chair of the Nanotechnology Environmental and Health Implications (NEHI) Working Group from its inception.

The Project on Emerging Nanotechnologies is an initiative launched by the Woodrow Wilson International Center for Scholars and The Pew Charitable Trusts in 2005. 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 on Emerging Nanotechnologies is a non-partisan, non-advocacy organization that collaborates with researchers, government, industry, non-governmental organizations (NGOs), and others concerned with the safe applications and utilization of nanotechnology.

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

In short, both the Wilson Center and The Pew Charitable Trusts believe there is a tremendous opportunity with nanotechnology to "get it right." Societies have missed this chance with other new technologies and, by doing so, have made costly mistakes.

As a scientist, I am awed by the vast potential of nanotechnology. I also understand the thrill of making new discoveries and turning them into societal or economic gain. But through my work in occupational health, I also understand the very real dangers of proceeding without due caution. Make no mistake, nanotechnology *is* different, and there *will* be some materials and products developed under this banner that have the potential to cause harm. The challenge we face is how to recognize and manage

this possibility ahead of time and deal with it. The stakes are high: not only are human health and the environment potentially at risk, but so is the "health" of nano-commerce. If investors and consumers reject nanotechnology through fear and uncertainty, missed opportunities in areas like medical treatment and energy production could deal a severe blow to the quality of life and the future economic well-being of this country.

Are current federal and private research efforts adequate to address concerns about environmental and safety impacts of nanotechnology? Are there gaps in the portfolio of federal research currently underway; if so, in what areas?

The long-term solution must be to reduce uncertainty about the possible health and environmental impacts of nanotechnology through systematic scientific research. Perhaps uniquely in regards to an emerging technology the federal government and industry have moved to understand the potential risks of nanotechnology at an early stage. The 21st Century Nanotechnology Research and Development Act[1] and the NEHI Working Group within NSET are testaments to the attempts of this government to act early to minimize potential risks. Yet these good intentions do not seem to have translated into hard information regarding how to avoid risks and develop safe nanotechnologies. The fact is that nanotechnology is a reality *now*—in workplaces and in the marketplace: Every day, people are asking questions like "how safe is this product?", "how do I protect myself?", and "what happens to this material in the environment?" These are questions that we do not yet have answers for, and for which we do not yet have a clear pathway to finding answers anytime soon. Our inability to provide clear and timely answers can ultimately jeopardize the ability of government and industry to reap the economic and social benefits of billions of dollars of R&D investments.

Part of the problem is that nanotechnology is complex—no single agency, research group or even scientific discipline is able to grapple with the challenges it presents without collaborating and working with others. This is not a problem we can solve piecemeal—effective solutions will require top-down direction and coordination if we are to remove the uncertainty surrounding nanotechnology and potential risk.

In a recent study, ***Nanotechnology: A Research Strategy for Addressing Risk,*** I considered what needs to happen if critical research questions are to be addressed.[2] Drawing on previously published papers from government, industry, academia and NGOs, the report—which is included with this testimony—identifies and prioritizes critical research needs and makes specific recommendations on how to develop an effective strategic research framework. In assessing the current risk research situation, it became very clear that current federal coordination of nanotechnology research is not sufficient to ensure that timely and relevant information on minimizing and managing nanotechnology's risks is being developed.

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[1] US Congress (2003). 21st Century Nanotechnology Research and Development Act (Public Law 108-153), S.189 Washington DC, 108th Congress, 1st session.

[2] Maynard, A. D. (2006). *Nanotechnology: A Research Strategy for Addressing Risk*, PEN 03 Washington DC, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars. Available at www.nanotechproject.org.

In particular, the relevant agencies are under pressure, because they are under-resourced and struggling without adequate leadership or broad strategic direction. I see no evidence of foresight; of the government looking longer-term to identify emerging risks that may appear as nanotechnology becomes more complex and converges with biotechnology. Without better foresight, there is little hope that the government will be positioned to underpin regulation with good science, or provide solid answers to questions that the public will inevitably raise about the risks of nanotechnologies. Individual agencies such as NIOSH, the Environmental Protection Agency (EPA), the National Institutes of Health (NIH) and the National Science Foundation (NSF) are doing their best to develop research programs from the bottom-up—in some cases with very limited resources. But these disconnected research programs will not make a significant difference in ensuring safe nanotechnologies without sweeping changes to the way nanotechnology risk research is directed and supported at the federal level.

The current approach leads to some perplexing oddities. For example, it is widely accepted that research into assessing and preventing health risks in the workplace is critical to the success of nanotechnologies. However, the anticipated increase in risk-related research funding for the National Science Foundation between 2006 and 2007 (an increase of $3.6 million, from $22.1 million to $25.7 million), far exceeds the total requested nanotechnology risk research budget for the National Institute for Occupational Safety and Health in 2007 ($3 million).[3] If these figures accurately reflect the federal government's current priorities, then it is clear that ensuring safe nanotechnology workplaces is not high on the list—particularly since the mandate of NSF is basic research and not mission-driven environmental and human-health studies.

Of course, numbers alone can be misleading: What is important is the research that those numbers represent. It is obvious that without knowing where you are, you cannot plan how to get where you want to be. If federal research addressing the potential risks of nanotechnology is to be strategic, transparent and relevant, we need to know what is being done and what is being missed. Unfortunately, information as to what risk-related research is currently being carried out is not readily available from or even within the federal government. National Nanotechnology Initiative (NNI) representatives have noted that it is hard to tease out risk-related projects from the general mix of the government's nanotechnology research portfolio. However, without a more precise understanding of what U.S. government funded investigators are studying, the reported figures tell us nothing about whether the right questions are being asked—and answered—in order to ensure nanotechnology's safe management. It is important to emphasize that this research by the government is being supported by public funds and it is ultimately the public—as workers or consumers, for instance—that may bear many of the potential risks related to nanotechnology. Project-by-project data on what the

[3] NSET (2006). *The National Nanotechnology Initiative: Research and Development Leading to a Revolution in Technology and Industry Supplement to the President's FY 2007 Budget*, Washington DC, Subcommittee on Nanoscale Science, Engineering and Technology, Committee on Technology, National Science and Technology Council.

government is funding to understand and mitigate risks should be placed in the public realm now.

What should be the priority areas of research on environmental and safety impacts of nanotechnology? How should the responsibility for funding and conducting this research be divided among the federal agencies, industry, and universities?

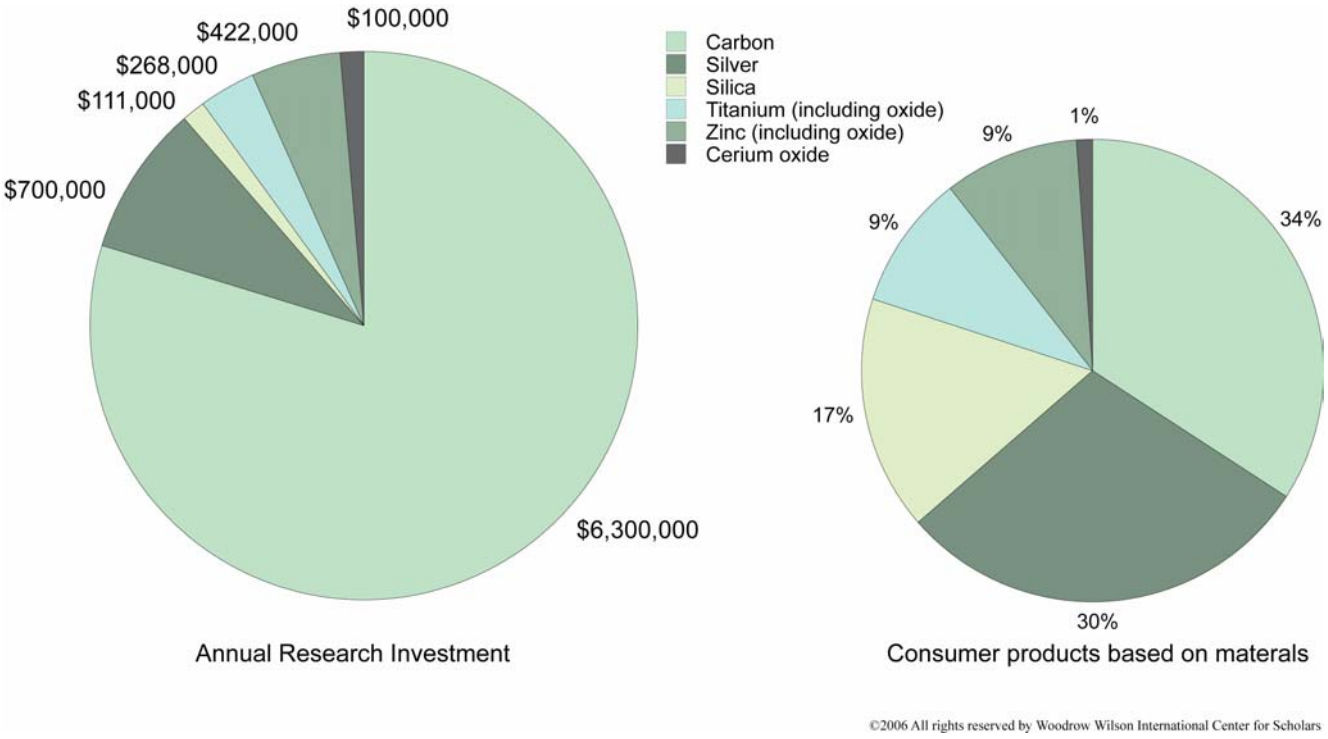
Recognizing this information gap, last year the Project on Emerging Nanotechnologies compiled and published an inventory of current nanotechnology risk-related research.[4] The inventory is publicly accessible on-line, fully searchable, and classifies research to allow a clear picture of what is currently being done. The inventory first and foremost confirms that a substantial body of research is being funded to try and understand the potential impacts of nanotechnology on human health and the environment. In 2005, we estimate that the annual U.S. federal government in research with some relevance to nanotechnology risks was over $30 million. However, it is unclear how relevant this research is to reducing the current uncertainty over nanotechnology's health and environmental impacts, providing guidance for emerging oversight regimes at agencies such as EPA and FDA, or answering increasing numbers of public questions and concerns over the safety of nanotech-related products and applications.

Two examples serve to highlight an apparent disconnect between the federal government's research agenda and what is needed to illuminate any hazards related to nanotechnology. The first example draws on the Project on Emerging Nanotechnologies' inventory of nanotechnology-based consumer products,[5] and compares the prevalence of nanomaterials in these products to research into their potential impacts. In figure 1, I compare research into the impact of six nanomaterials—carbon, silver, silica, titanium, zinc and cerium—to the number of consumer products known to be using these materials.

Although this is a very subjective exercise, it shows the vast majority of the *material-specific* risk research is focused—disproportionately it would seem—on carbon-based nanomaterials. At the time of the analysis, carbon-based nanomaterials accounted for just 34% of listed consumer products, while silver accounted for 30% of listed products, and silica and metal oxides such as silica, titanium dioxide, zinc oxide and cerium oxide accounted for 36% of listed products. In other words, risk research does not appear to be in step with current market realities.

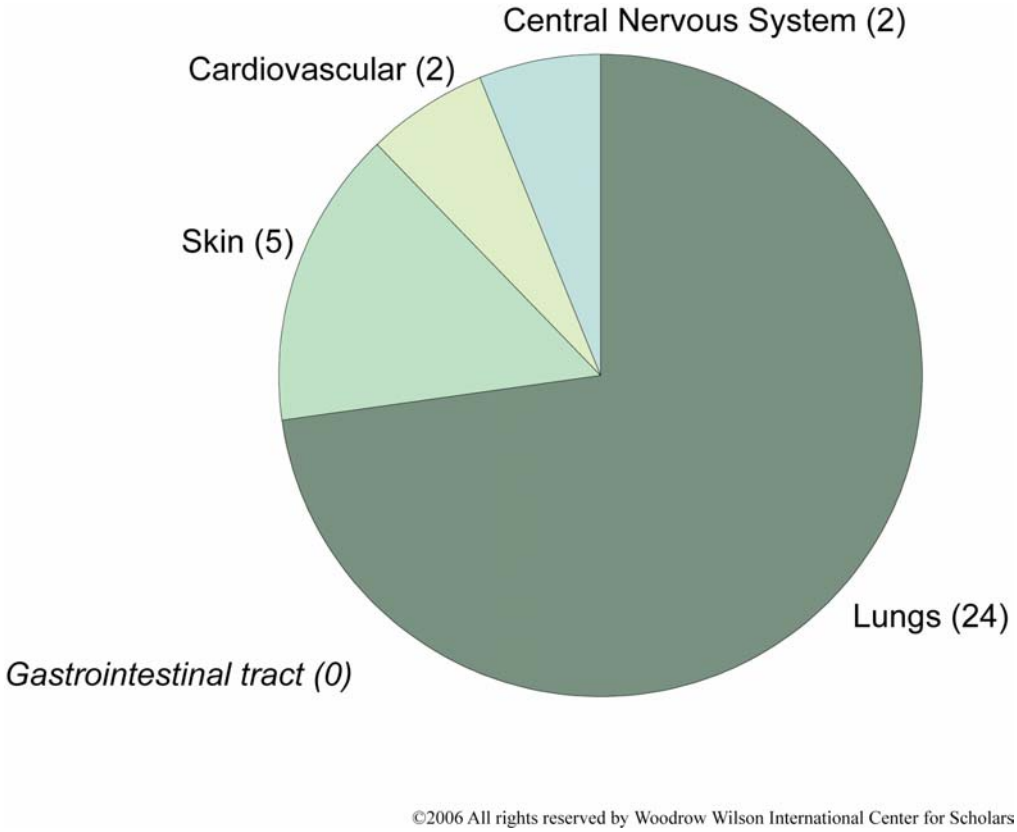
[4] Nanotechnology Health and Environmental Implications: An Inventory of Current Research. www.nanotechproject.org/18 Accessed September 12th 2006.
[5] A Nanotechnology Consumer Products Inventory. www.nanotechproject.org/consumerproducts Accessed September 12th 2006.

Figure 1.
Nanotechnology Environmental Safety and Health research funding for six classes of engineered nanomaterials, compared to consumer products using those materials (based on 2005 data)



The second example considers the number of research projects that are probing the potential effects of nanomaterials on different parts of the body—the lungs, the skin, the central nervous system, the cardiovascular system and the gastrointestinal tract. Figure 2 indicates that current human hazard research appears to focus heavily on nanomaterials in the lungs (24 projects), while no projects are specifically addressing the potential effects of nanomaterials in the gastrointestinal tract. Given the large number of current and future nano-products that are intended to be eaten—such as food and nutritional supplements—this is a curious and serious omission.

Figure 2.
Nanotech-risk research projects on specific areas of the body (based on 2005 data)



These examples indicate that current federally funded research is not addressing the general range of risks that ***may already be present in the market*** and that risk research is not guided by a careful consideration of needs—today or tomorrow. Why is there so little research on nanomaterials in use now? Is the emphasis on lung impacts due to careful consideration of relative risks, or because pulmonary toxicologists are more active in this field?

Having cataloged information on current risk-research, the Project on Emerging Nanotechnologies (PEN) was able to go back and check the validity of published government funding figures. Comparing estimates of federal spending on nanotechnology risk research from our research inventory to figures published by NSET tells an interesting story. Table 1 compares the NSET figures with PEN-estimated annual funding for research which is *highly relevant* to understanding risk and research which has *some degree of relevance*.

Table 1.
U.S. federal government annual spending on nanotech-risk R&D ($millions)[6]

Agency	NNI-estimated risk-related annual R&D	PEN-estimated risk-related annual R&D (all relevant research)	PEN-estimated risk-related annual R&D (highly relevant research)
NSF	24.0	19.0	2.5
DOD	1.0	1.1	1.1
DOE	0.5	0.3	0
HHS (NIH)	3.0	3.0†	3.0†
DOC (NIST)	0.9	1.0	0
USDA	0.5	0.5	0
EPA	4.0	2.6	2.3
HHS (NIOSH)	3.1	3.1††	1.9†††
DOJ	1.5	0	0
Totals	38.5	30.6	10.8

Annual spending estimated from the National Nanotechnology Initiative, and the Project on Emerging Nanotechnologies (PEN). Highly relevant research (right hand column) is specifically focused on health and environmental risks associated with engineered nanomaterials, and is included in the broader analysis of all relevant research (middle column). NNI figures are estimated budgets for October 2005 – September 2006, while PEN figures are estimated expenditure for January – December 2005. †Estimate, based on research within the National Toxicology Program. ††Based on aggregated funding reported by NNI. †††Estimated from the percentage of projects highly relevant to engineered nanomaterials.

Highly-relevant research covers projects with the specific aim of understanding the potential risks of nanotechnology, and includes areas such as using a life-cycle approach to evaluate the impact of future nanotechnologies (EPA), and evaluating assessment methods for nanoparticles in the workplace (NIOSH). On the other hand, *research with some degree of relevance* includes projects that are not focused on nanotechnology risk, but nevertheless have the potential to shed some light on our understanding of risk. Examples include studying the formation of nano-droplets (NSF), developing biosensors for metals (EPA) and controlling exposure to welding fumes (NIOSH).

There is close agreement between the NSET estimate for *highly-relevant* risk research and the Project on Emerging Nanotechnologies estimate of research with *some degree of relevance*. When the Project on Emerging Nanotechnologies estimate of research that is *highly relevant* to engineered nanomaterials is compared to the NSET estimate, the gap widens considerably. Based on all available information, we estimate that only $11 million per year is being spent on research that is *highly relevant* to nanotechnology risks, compared to NSET's estimate of $38.5 million per year. That gap is too large to be explained by the different reporting periods or a lack of agency disclosure.

[6] Maynard, A. D. (2006). *Nanotechnology: A Research Strategy for Addressing Risk*, PEN 03 Washington DC, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars. Available at www.nanotechproject.org.

What elements should the forthcoming report on research needs produced by the National Nanotechnology Environmental and Health Implications Working Group contain to adequately guide federal research investment in this area? What additional steps are needed to improve management and coordination of federal research on the environmental and safety impacts of nanotechnology?

The evidence before us strongly suggests that current federal research efforts are not adequate to address concerns arising about the environmental, health and safety impacts of nanotechnology. There are clear gaps in the research portfolio in determining potential hazard, evaluating exposure, controlling releases of nanomaterials, determining potential impact and managing risk. But I am more concerned over the lack of an apparent top-down strategy that couples risk research to real information needs. Without such a strategy, it is next to impossible to identify clearly where the gaps are and how best to address them. Implicit in a strategy is the setting of hard priorities, the linking of these priorities to actual multi-year funding levels, and the development of metrics to measure results over time. There is a large difference between a strategy and a list of research needs.

A government strategy must also consider and integrate industry issues and, ultimately, enable collaborative funding. Much less information is available on industry-based risk research and testing programs. Some initiatives shine out, such as the research consortium led by DuPont to develop measurement methods and research supported by the International Council On Nanotechnology (ICON) into good workplace practices. But these are the exception—most nanotechnology industries are looking to the government for guidance on what should be done and are coming up against a brick wall. This means that we not only lack a coherent government strategy, but we lack a coherent public-private sector strategy, and we certainly have no international strategy to address risks in a timely manner.

With the right leadership from the federal government, effective research programs and partnerships can be developed that will lead to safe nanotechnologies. In the attached report, I make a number of recommendations on what needs to be done in the next two years. Here, I would like to focus on three specific recommendations for developing a strong federal research agenda that simultaneously reduces uncertainty as fast as possible and serves the needs of regulators, industry and other stakeholders:

- **Develop a top-down strategic risk-research framework within the federal government;**

- **Adequately fund strategic risk-focused research, with an investment of *at least* $100 million, over the next two years; and**

- **Support a joint government-industry funded cooperative science organization, with a five-year plan to systematically address the human health impacts of engineered nanomaterials through independent, targeted research.**

Although not comprehensive, I believe making advances in each of these three areas, as I will explain in more detail, will lead to effective research programs that serve the needs of various end-users.

Develop a top-down strategic risk-research framework within the federal government.

Nanotechnology is no longer confined to the laboratory; it is a commercial reality now.[7] As our ability to make new materials, devices and products through nanoscale engineering becomes increasingly sophisticated, researchers, workers and the public are raising real concerns over what the possible impacts to their health and the environment will be. These are concerns that can only be addressed through systematic, targeted and coordinated research.

Bottom-up, or investigator and agency-driven research, is highly effective at generating new knowledge. However, it will never have the context and perspective to holistically address issues arising from technology development and implementation. Instead, a top-down approach is essential, one that maps out necessary areas of research, prioritizes critical needs and provides support and direction for research agencies. In effect, a top-level framework is needed that enables scientists and research agencies to do their job as effectively as possible, to the best of their ability.

Where resources are limited, a top-down approach is the only way of ensuring that the necessary research is done within budgetary constraints and in a timely manner. The danger of not coordinating direction and resources from the highest levels is that research becomes unfocused and untargeted—and ultimately ineffective. It is irresponsible to spend millions of dollars on building a better microscope in the name of risk research when we cannot tell workers how effective their respirators are when working with nanomaterials!

An effective top-down strategic framework must identify and prioritize critical research needs within the context of oversight and regulation. But it must also have teeth—it must have the authority to ensure that research priorities can be met through the provision of sufficient resources, the support of key agencies and the use of effective and relevant research and development mechanisms. It also must enable collaboration and partnerships between researchers, agencies and other organizations. As I have mentioned previously: nanotechnology is complex, and progress will only be made by working together.

While the NEHI Working Group has been effective in getting research agencies talking about risk, it has shown little evidence of leadership in setting and implementing a

[7] An on-line Project on Emerging Nanotechnologies inventory identifies nearly 300 nanotechnology-based consumer products (www.nanotechproject.org/consumerproducts). These represent the tip of the commercial nanoproduct iceberg. Lux Research estimates that $32 billion worth of nanotechnology-enabled products were sold in 2005 (www.luxresearchinc.com/press/RELEASE_TNR4.pdf).

strategic research agenda. Although the NEHI Terms of Reference focus on supportive roles of information sharing and communication,[8] the Working Group has no clear authority to direct research from the top down. To be truly effective in removing uncertainty surrounding the potential impacts of nanotechnologies, a new interagency oversight group should be established with authority to set, implement and review a strategic risk research framework. This group would be responsible for developing a top-level strategic framework that would serve as a guide for the coordination and conduct of risk-related research in relevant agencies. It would have the authority to set and implement a strategic research agenda and assure that agencies are provided with appropriate resources to carry out their work. The group would direct efforts to provide a strong scientific basis for regulatory decisions, thus bridging the existing gap between the need for oversight and our poor technical understanding of nanotechnology risks. It would also ensure that the results of risk-relevant research are put to practical uses, including education and outreach programs. In addition, the group would ensure that risk-related research is coordinated between industry and government and between the U.S., other countries and international organizations.

In order to establish a long-term research agenda, the group must draw on the expertise of stakeholders, as well as government and non-government experts. I would strongly recommend that the National Academies are commissioned to conduct an independent, rolling review of research needs and priorities, which informs the strategic risk research framework.

Adequately fund strategic risk-focused research, with an investment of at *least $100 million*, over the next two years.

Once a research strategy is in place, it must be funded at realistic levels if it is to be successful. In my analysis of short term strategic needs, I estimated the minimum level of funding needed to address critical questions by estimating the cost of the most important immediate research areas. From this analysis, a minimum of $100 million should be invested in targeted, highly relevant nanotechnology risk research over the next two years if significant progress is to be made. This is a substantial increase in the estimated $11 million per year currently being spent on risk-specific research.[9] Funding should be tied to a top-level strategic risk research framework, and it should support agencies with missions and competencies to assess and reduce harm to people and the environment, such as NIOSH, EPA and the National Institute of Environmental and Health Sciences (NIEHS). But, it should also leverage the research expertise and facilities of agencies such as the Department of Energy (DOE) and NSF.

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[8] Interagency Working Group on Nanotechnology Environmental and Health Implications (NEHI WG): www.nano.gov/html/society/NEHI.htm Accessed September 12th 2006.

[9] Maynard, A. D. (2006). *Nanotechnology: A Research Strategy for Addressing Risk*, PEN 03 Washington DC, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars. Based on data published in the Project on Emerging Nanotechnologies inventory of nanotechnology EH&S research (www.nanotechproject.org/18). This figure does not include recent increased EPA investment in nanotechnology risk research.

Critical research is needed that addresses risk assessment, environmental impact, human health impact and hazard prediction. In table 2, I outline the highest research priorities—based upon my previously published analyses of research needs—and identify agencies that are ideally placed to lead these research efforts.

Table 2.
Short-term nanotechnology environmental, safety and health implications research priorities, lead agencies and estimated costs[10]

Lead Agency	Short Term Research Goals	Estimated Funding†
Cross Agency	• Develop research methodologies to proactively address risk • Begin developing appropriate risk assessment tools • Preliminary development of informatics systems for nanomaterials	7
EPA	• Identify sources and routes of exposure and release - environment • Develop and evaluate environmental measurement methods • Preliminary development of appropriate methods for evaluating ecotoxicity • Preliminary development of life cycle analysis tools for engineered nanomaterials • Preliminary investigation of ecotoxicity mechanisms • Preliminary investigation of nanomaterial release into the environment • Begin to study dispersion, transformation, fate, persistence and bioaccumulation in the environment	20
NIH	• Begin to evaluate the toxicity of representative nanomaterials • Preliminary development of appropriate toicity testing endpoints • Preliminary development of appropriate toxicity testing methods • Begin developing predictive toxicology capabilities • Begin developing computational toxicology for engineered nanomaterials • Preliminary investigation of nanomaterial structure activity relationships	24
NIOSH	• Develop and evaluate human exposure measurement methods • Develop guidance on best possible working practices • Develop and evaluate personal protective equipment • Develop and evaluate respiratory protective equipment • Develop and evaluate process-based controls • Identify sources and routes of exposure and release - workplaces • Develop instrument-based exposure metrics • Develop and evaluate appropriate toxcity screening tests • Develop a preliminary understanding of organ-specific dose • Preliminary research exploring associations between nanomaterials exposure and human health outcomes • Begin to develop methods to control and manage spills • Study the role and significance of routes of entry into the body • Preliminary investigations of nano-specific safety issues • Begin studying transport, transformation and fate in the body • Preliminary evaluation of risk reduction through material substitution	46
NIST	• Preliminary development of appropriate nanomaterials characterization methods • Begin developing measurement and characterization standards • Begin developing standards for terminology and reference materials	9
Total		**106**

Proposed lead agencies and minimum targeted federal funding levels to address identified short-term research goals. Estimated funding is in $millions over a two-year period, and includes intramural and extramural funding of risk-specific research. Research goals addressing immediate, medium-term and long-term areas are shaded from dark to light. †Estimated funding over 2 years.

[10] Maynard, A. D. (2006). *Nanotechnology: A Research Strategy for Addressing Risk*, PEN 03 Washington DC, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars. Available at www.nanotechproject.org.

Support the formation of a joint government-industry funded cooperative science organization, with a five-year plan to systematically address the human health impact of engineered nanomaterials through independent, targeted research.

The success of a strategic risk research framework for nanotechnology will depend critically on the mechanisms used to implement research. Federally funded research must be systematic and targeted, if it is to answer questions being asked by industry and the public. But progress will also depend on collaborating and partnering with other stakeholders—particularly industry.

Industries investing in nanotechnology have a financial stake in preventing harm, manufacturing safe products and avoiding long-term liabilities. Yet, with a few exceptions, most of the questions that need answering are too general to be dealt with easily by industry alone. Perhaps more significantly, the credibility of industry-driven risk research is often brought into question by the public and NGOs as not being sufficiently independent and transparent. It seems that the current state of knowledge is sufficient to cast doubt on the safety of some nano-industries and products, but current information lacks the credibility for industry to plan a clear course of action on how to mitigate potential risks. Getting out of this "information trap" is a dilemma facing large and small nanotechnology industries alike.

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

> **Independence.** The selection, direction and evaluation of funded research must be science-based and must be fully independent of the business and views of partners in the organization.
>
> **Transparency.** The research, reviews and the operations of the organization must be fully open to public scrutiny.
>
> **Review.** Research supported by the organization must be independently and transparently reviewed.
>
> **Communication.** Research results must be made publicly accessible and fully and effectively communicated to all relevant parties.

A number of research organizations have been established over the years that comply with some of these criteria. Yet, perhaps the organization most successful and relevant to nanotechnology is the Health Effects Institute (HEI).

HEI was established in 1980 as a non-profit research institution focused on providing "high-quality, impartial, and relevant science" around the issue of air pollution and its health impacts.[11] The Institute is committed to supporting risk-relevant research through anticipating the needs of policymakers and scientists and by identifying the underlying questions propping up policy arguments and research priorities. Additionally, the production of timely scientific evidence is crucial to allow for decisions to be made within appropriate product development cycles.

The HEI research model is unique in a number of ways. New research projects are chosen based on a *competitive proposal process*. This project selection process is similar to those employed by NSF and NIH, but it includes added attention to the policy relevance of scientific research. Once projects are selected for support, HEI issues *contracts*—not grants—to investigators. This is a unique component of the HEI process, and it allows the organization to benefit from the most creative proposals from the science community but still have much greater control over the scope of work and the final products to ensure their relevance to decisions. Close control over research enables HEI to aggressively manage investigations by monitoring progress and terminating projects that are not meeting established standards.

Once projects are funded, *strict quality control* is followed. Both HEI staff and independent investigators audit and review project quality. HEI's strict adherence to their quality control guidelines and rigorous peer reviews serves as potent defense against possible detractors. While this quality control does come at the cost of burdening investigators with more numerous reviews, it also serves to strengthen the validity of the data when applied in the policy realm and has raised HEI to a place among the most respected research organizations in the world.

Finally, supported research undergoes *independent peer review and policy relevance critique*. This process allows for thorough review prior to publication of a comprehensive report by HEI. The findings of any dissenting critiques are published along with final reports. In turn, all results are openly published in HEI's reports, both positive and negative, so that industry professionals and policymakers can better understand how the investigators reached their conclusions.[12] Since these results are presented in a highly transparent manner and are available at varying levels of detail, they are accessible to a wide variety of audiences. In addition, after reports are released, HEI monitors their use and strives to ensure that the full range of conclusions is considered by decision makers in order to maintain their scientific integrity.[13]

HEI has funded over 250 studies in North America, Europe and Asia on a variety of topics, including carbon monoxide, air toxics, nitrogen oxides, diesel exhaust, ozone and particulate matter. The organization credits its success to five key factors: effective governance, joint industry-government funding, quality science, no advocacy and

[11] Health Effects Institute (HEI) Website. "What is the Health Effects Institute." Available at www.healtheffects.org/about, accessed July 27th 2006.
[12] HEI Annual Report 2005, p. 6.
[13] HEI Annual Report 2005, p. 6.

communication. Members constituting the HEI Board of Directors are chosen based upon their independence of any interests that could constitute bias, and this level of independence is extended down through the committees and staff. Individuals selected to the board are dually approved by stakeholders on both sides. The board of directors is charged with screening for potential conflicts of interest, overseeing staff, appointments to panels and the selection of researchers.

The HEI model is ideally suited to generating the credible and relevant information necessary to develop safe nanotechnologies. Developing a program using such a model would complement federal research into the potential risks of nanotechnology and would provide industry and regulatory agencies with needed information on managing possible health and environmental impacts. HEI could well be used as a template for establishing a separate "Nanotechnology Effects Institute." But it would be more expedient to develop a nanotechnology risk research program within HEI. For this to occur, four conditions would need to be met:

- **Commitment by HEI to develop a nanotechnology risk research program.**
  Informal discussions with HEI have indicated a willingness to consider extending the Institute's research portfolio to addressing nanotechnology and potential risks. Successful development of such a research program will depend on long-term funding commitments from government and industry and a targeted, relevant research agenda.

- **Commitment from the federal government to jointly fund research.**
  A successful program will depend on matched federal-industry funding, over a minimum of five years. Federal funding levels of at least $10 million over that time frame will be needed to ensure a coherent, relevant and influential research program and to attract industry funding. Currently, most government funding for HEI comes from EPA, with one half from the research arm and one half from the program/regulatory side. This allows for a tight link between research and regulation and the provision of a solid scientific underpinning for oversight. This approach can be followed for nanotechnology but should be expanded to consider research needs of agencies beyond EPA, such as FDA.

- **Commitment from industry to jointly fund research.**
  Likewise, establishing a successful research program will depend on a matching financial commitment from industry of at least $10 million over the next five years. Provisions should be made to integrate research issues from small business and start-up firms.

- **A relevant and robust strategic research agenda.**
  The success of a HEI-based nanotechnology risk research program will depend on identifying research areas that complement federal research, while responding directly to industry needs. Based on my analysis of critical research needs, I would propose that the initial emphasis of such a research agenda should focus on understanding and reducing the potential toxicity of engineered nanomaterials in

humans. Table 3 lists a suite of research projects, along with estimated funding levels, which could form the backbone of a credible five-year research program. Of course, an expert oversight committee convened by an organization like HEI could—with broad input from the science and regulatory communities—review these priorities rapidly and finalize a set of targeted priorities to be sought in a first Request for Applications.

It must be emphasized that this proposed program would complement, and not replace, either federal or industry research programs and that the estimated $20 million over five years is in addition to funding levels recommended for government-specific research.

Table 3.
Proposed components of a five-year cooperative government-industry nanotechnology risk research program

Thematic Area	Goals	Estimated funding (5 years, $ millions)
Begin to evaluate the toxicity of representative nanomaterials		
	Ascertain the applicability of the fiber paradigm to high aspect-ratio engineered nanomaterials	$2M
	Develop a preliminary ranking of the toxicity of commercially available nanomaterials, compared to non-nano benchmark materials	$2M
	Develop a systematic understanding of preferential protein adsorption on representative nanoparticles in biological systems, and evaluate subsequent impact on biological activity	$1M
Preliminary development of appropriate toxicity testing methods		
	Develop and validate a suite of in vitro tests for evaluating the potential toxicity of new engineered nanomaterials	$2M
Preliminary investigation of nanomaterial structure activity relationships		
	Systematically evaluate the association between discontinuous particle size-dependent properties (such as quantum confinement) and toxicity	$2M
	Evaluate the range of biological responses associated with physical and chemical perturbation within classes of nanomaterials in commercial production. Specifically consider variations in surface coatings and treatments, crystallinity and suspension liquid within nanomaterial classes	$2M
Develop and evaluate appropriate toxicity screening tests		
	Develop and validate a suite of acellular tests for screening potential nanomaterial toxicity	$1M
Develop a preliminary understanding of organ-specific dose		
	Investigate the relationship between geometric and biologically active surface area as a function of particle size, shape and chemistry	$2M
Study the role and significance of routes of entry into the body		
	Investigate whether transport along the olfactory nerves is a significant exposure route in humans, and what the potential impact on the central nervous system might be	$2M
	Establish boundaries on factors that influence nanoparticle penetration through the skin, and study potential health impact as a function of key parameters	$2M
Begin studying transport, transformation and fate in the body		
	Develop pharmacokinetic models of nanoparticle transport and partitioning in the body, through various routes of exposure	$2M
TOTAL		$20M

Conclusions

Nanotechnology is a reality now, and our ability to produce ever-more sophisticated materials, processes and products by engineering at the nanoscale will only increase over the coming years. Yet our understanding of the potential environmental, safety and health impacts of these emerging technologies is rudimentary at best.

Government and industry have been commendably astute in recognizing the possibility of new risks arising from emerging nanotechnologies at an early stage. But over a decade after the first indicators of nanostructured material-specific hazards were published, risk-based research remains poorly focused and under funded. Current federal research programs are unlikely to provide answers where they are most needed, and needed they are—especially since a proper understanding of risks is the only way to assure the emergence of economically viable technologies that do not harm people or the environment.

In this testimony, I have examined where current research strategies are lacking, and what can be done to ensure that future research is effective in reducing uncertainty surrounding the safety of nanotechnologies. In particular, I highlighted the need to develop a top-down strategic risk-research framework within the next six months and the need to adequately fund risk research—with an investment of at least $100 million over the next two years. I also proposed establishing a five-year, $20 million joint government-industry risk research partnership through the Health Effects Institute that will complement federal research initiatives.

As the recommendations presented above begin to be implemented, it is clear that a host of questions remain to be addressed, including:

- How are federal agencies ensuring that nanotechnology risk research information is being made widely available to the public, researchers, and small businesses?
- How can the risk-related research needs of small nanotechnology businesses and start-ups be integrated into a comprehensive government-industry strategy?
- How is the federal government translating risk-based research into effective guidance on working with and using nanotechnology-based products as safely as possible?
- What plans does the federal government have to closely coordinate risk research at a global level?
- What processes are in place that will allow the government to better anticipate and address future risks, especially as nanotechnology becomes more complex and converges with biotechnology?
- How much is the federal government spending to design and engineer risks out of nanotechnology processes and products (rather than just addressing them after the fact)?

In closing, let me say that I have tremendous respect for the researchers who are working to understand the potential impacts of nanotechnology on human health and the environment. It is through their efforts that we now know many of the key issues that need to be addressed in order to make nanotechnology safe. However, for these researchers and research directors to be effective, they must be better supported with the necessary financial, human and strategic resources that they need. By taking action now, we have the opportunity to realize the full potential nanotechnology has to offer, without creating a legacy of harm to human health and the environment.

Biography of Andrew Maynard

Dr. Andrew Maynard serves as the Science Advisor to the Project on Emerging Nanotechnologies. He is internationally recognized as a research leader and lecturer in the fields of aerosol characterization and the implications of nanotechnology to occupational health. He trained as a physicist at Birmingham University (UK), and after completing a Ph.D. in ultrafine aerosol analysis at the Cavendish Laboratory, Cambridge University (UK) joined the Aerosols Research Group of the UK Health and Safety Executive.

In 2000, Dr. Maynard joined the National Institute for Occupational Safety and Health (NIOSH), part of the U.S. Centers for Disease Control and Prevention (CDC). At NIOSH, he established a groundbreaking research program in ultrafine aerosol analysis, and was instrumental in developing NIOSH's nanotechnology research program. This research was at the forefront of international scientific efforts to better understand the occupational health implications of nanomaterials, and to develop guidance on workplace exposures in this burgeoning industry. While at NIOSH, Dr. Maynard was a member of the Nanomaterial Science, Engineering and Technology subcommittee of the National Science and Technology Council (NSET). He also co-chaired the Nanotechnology Health and Environment Implications (NEHI) working group of NSET. Both are a part of the National Nanotechnology Initiative (NNI), the federal research and development program established to coordinate the U.S. government's annual $1 billion investment in nanoscale science, engineering, and technology.

Dr. Maynard was co-chair of the first two international conferences on nanotechnology and occupational health, and is affiliated with many organizations and initiatives exploring the responsible and sustainable development of nanotechnology. He is a member of the Executive Committee of the International Council On Nanotechnology (ICON), and until recently, chaired the International Standards Organization Working Group on size selective sampling in the workplace. He holds an Associate Professorship at the University of Cincinnati (OH), and is an Honorary Senior Lecturer at the University of Aberdeen (UK). His expertise covers many facets of scientific research and policy, from occupational aerosol sampler design to recommendations on strategic nanotechnology research, as reflected in over 70 professional publications. Dr. Maynard is a regular international speaker on nanotechnology, and frequently appears in print and on radio and television.