**United States House of Representatives**
**Committee on Science and Technology**

**Hearing on:**

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

**Testimony of:**

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# Overview

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

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

In my current role as Chief Science Advisor to the Project on Emerging Nanotechnologies, I am heavily involved in working with government, industry and other groups to find science-based solutions to the challenges of developing nanotechnologies safely and effectively. The Project on Emerging Nanotechnologies is an initiative launched by the Woodrow Wilson International Center for Scholars and The Pew Charitable Trusts in 2005.[1] It is dedicated to helping business, government and the public anticipate and manage the possible health and environmental implications of nanotechnology. As part of the Wilson Center, the Project is a non-partisan, non-advocacy policy organization that works with researchers, government, industry, non-governmental organizations (NGOs), and others to find the best possible solutions to developing responsible, beneficial and acceptable nanotechnologies. The opinions expressed in this testimony are my own, and do not necessarily reflect views of the Wilson Center or The Pew Charitable Trusts.

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

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

# Executive Summary

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

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

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

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

4. **Public-Private Partnerships.** A public-private partnership should be established to address critical industry and government-research questions that fall between the gaps. A partnership model should be developed that enables goal-driven research in support of government and industry oversight, and a commitment to $10 million per year for the next five years sought; split evenly between government and industry sources.

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

science-based dialogue between stakeholders, and supporting informed decision-making by citizens, businesses, regulators, and other stakeholders.

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

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

# What is needed to make nanotechnology work?

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

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

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

Twenty-first century technologies like nanotechnology present new challenges to identifying and managing risks, and it would be naïve to assume that twentieth century assumptions and approaches are up to the task of protecting health and the environment in all cases. In the case of engineered nanomaterials, the importance of physical structure in addition to chemical composition in determining behavior is making a mockery of our chemicals-based view of risks and regulation.

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

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

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

## 1. Acknowledging the possibility of unconventional behavior

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

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

- Adverse reactions to exposure that are not predictable from the material's chemical makeup alone.[6]
- An ability to penetrate to parts of the body and the environment that are inaccessible to non-nano materials.[7]
- The emergence of physical and chemical properties that are not directly predictable from individual atoms, or the bulk material.[8]

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[4] Davies, J. C. (2006). Managing the effects of nanotechnology. Woodrow Wilson International Center for Scholars, Project on Emerging Nanotechnologies, Washington, DC.
[5] Maynard, A., D. (2007). Nanotechnology: The next big thing, or much ado about nothing? *Ann. Occup. Hyg.* 51:1-12.
[6] Oberdörster, G., Gelein, R. M., Ferin, J. and Weiss, B. (1995). Association of particulate air pollution and acute mortality: involvement of ultrafine particles? *Inhal. Toxicol.* 7:111-124.
[7] Elder, A., Gelein, R., Silva, V., Feikert, T., Opanashuk, L., Carter, J., Potter, R., Maynard, A., Finkelstein, J. and Oberdörster, G. (2006). Translocation of inhaled ultrafine manganese oxide particles to the central nervous system. *Environ. Health Perspect.* 114:1172-1178.
[8] Preining, O. (1998). The physical nature of very, very small particles and its impact on their behavior. *J. Aerosol Sci.* 29:481-495.

- A possible ability to interfere with living systems including DNA and proteins that are naturally nanoscale.[9]
- An association with diseases not conventionally associated with exposure to non-nano materials.[10]

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

## 2. Leadership in nanotechnology EHS research

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

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

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

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

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

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

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

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

## 3. An effective strategic framework

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

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

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

Broad challenges to addressing this goal include:

- Providing answers to pressing questions.

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

Many of the recommended research needs identified over the past few years by a wide range of organizations fit within these challenges, including those published by the NEHI group in 2006[11] (and the shorter list released in 2007).[12] Addressing these challenges within the context of a strategic plan will lead to progress towards the overarching goal.

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

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

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

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

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

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

[14] See *supra* note 2.

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

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

## 4. Mechanisms to get the job done

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

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

Instead, mechanisms need to be implemented at the highest level that ensure an environment in which agencies with different but complementary competencies and missions can operate most effectively. Ideally, administrative structures are needed that: provide leadership in addressing research challenges across the federal government; facilitate the strategic sharing and use of information between agencies; enable interdisciplinary and interagency partnerships that are goal-oriented rather than mission-driven; simplify resource sharing between agencies; and allow for new resources to be allocated strategically across agencies to address key issues.

Mechanisms also are needed that support relevant research that is *not* constrained by bureaucratic and organizational barriers. These mechanisms will enable different

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

approaches to supporting research to be used in the best possible way to address identified research goals—including using intramural and extramural research as appropriate, and balancing applied and exploratory research. It is vital that mechanisms continue to be developed that actively encourage interdisciplinary research, and provide frameworks where ill-conceived studies resulting from inadequate interdisciplinary collaboration are the exception, rather than the norm.

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

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

- **Independence.** The selection, direction and evaluation of funded research would have to be science-based and fully independent of the business and views of partners in the organization.
- **Transparency.** The research, reviews and the operations of the organization should be fully open to public scrutiny.
- **Review.** Research supported by the organization should be independently and transparently reviewed.
- **Communication.** Research results should be made publicly accessible and fully and effectively communicated to all relevant parties.
- **Relevance.** Funded research should have broad relevance to managing the potential risks of nanotechnologies through regulation, product stewardship and other mechanisms.

As I discussed in my comments to this committee last September,[16] a number of research organizations have been established over the years that comply with some of these

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

criteria. One of these is the Health Effects Institute (HEI),[17] which has been highly successful in providing high-quality, impartial, and relevant science around the issue of air pollution and its health impacts. The Foundation for the National Institutes of Health[18] also has been successful in developing effective public-private partnerships, and the International Council on Nanotechnology (ICON)[19] is a third model for bringing government, industry and other stakeholders to the table to address common goals. The Wilson Center Project on Emerging Nanotechnologies is currently exploring these and other models as possible templates for public-private partnerships addressing nanotechnology risks.

Irrespective of which model is the best suited for nanotechnology, the need is urgent to develop such partnerships as part of the government's strategy to address nanotechnology risks. Nanotechnologies are being commercialized rapidly—going from $50 billion in manufactured goods in 2006[20] to a projected $2.6 trillion in nanotechnology-enabled manufactured goods by 2014—or 15% of total manufactured goods globally.[21] And knowledge about possible risks is simply not keeping pace with consumer and industrial applications.

## 5. Sufficient resources to address critical challenges

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

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

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

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

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

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

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

[22] See *supra* note 16.

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

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

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

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

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

Exploratory research should not be confined to these two agencies, however, as there will be instances where goal-oriented but exploratory research will fit best within the scope of mission-driven agencies, and will benefit from research expertise within these agencies. For example, researchers in NIOSH are currently engaged in exploratory research that is directly relevant to identifying and reducing potential nanotechnology risks in the workplace.[24]

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

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

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

# How do the federal government's actions match up to what is needed?

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

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

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

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

Some of the first indications that nanomaterials may present an unusual and previously unrecognized health risk came out as far back as 1990.[28] Fifteen years ago, the first

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

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

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

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

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

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

## 1. Acknowledging the possibility of unconventional behavior

In general, agencies within the federal government have made good progress in acknowledging the possibility of unconventional behavior in nanomaterials. The Office for Research and Development in EPA recognized the potential to use unconventional characteristics of nanomaterials in remediating environmental pollution some years ago. More recently, the agency has been supporting research into addressing unconventional behavior in nanomaterials that might lead to adverse environment and human health impacts.[34] NIOSH established a nanotechnology research program aimed at workplace exposures in 2004 in recognition of nano-specific challenges, and now has a successful—if sparsely funded—research portfolio spanning exploratory to applied studies.[35] The NSF recognized the need to develop a science-based understanding of nanomaterial-biological interactions early on, which led to the establishment of the Center for Biological and Environmental Nanotechnology at Rice University, and a number of other risk-relevant research initiatives.[36] NIH has encouraged an integrated approach to understanding nano-bio interactions in the development of health-related applications,

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*Sci.* 21:381-384.

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

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

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

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

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

[34] EPA (2007). US Environmental Protection Agency Nanotechnology White Paper, Environmental Protection Agency, Washington, DC. EPA 100/B-07/001. February.

[35] See *supra* note 24.

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

and has led in exploring the detailed toxicology of select nanomaterials through the National Toxicology Program—a collaboration between the National Institute of Environmental Health Sciences, NIOSH and FDA.[37] NIH also is developing an internal strategy for developing new knowledge on how nanomaterials interact with humans. FDA has recently published a paper clarifying the agency's understanding that engineered nanomaterials may take on risk-relevant properties due to their nanoscale,[38] and the CPSC and the Occupational Safety and Health Administration have both stated that nanotechnology has the potential to present new regulatory challenges. In addition, the Department of Energy, the Department of Defense and the National Institute of Standards and Technology all have research programs related to how engineered nanomaterials represent unconventional risks—and how to tackle the resulting challenges.

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

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

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

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

Overall, the federal government has made important strides in acknowledging the possibility that unconventional behavior in engineered nanomaterials could lead to EHS

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

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

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

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

risks. However, as the recent EPA paper demonstrates, there is considerable room for improvement in linking unconventional behavior to regulatory approaches.

## 2. Leadership in nanotechnology EHS research

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

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

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

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

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

[42] See *supra* note 12.

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

recently published NEHI research priorities document—a document that NIH representatives had contributed to![44] And the recently announced Center for Environmental Implications of Nanotechnology—a joint venture between EPA and NSF—does not seem to be part of any coordinated cross-agency plan.[45]

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

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

## 3. An effective strategic framework

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

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

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

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

[46] See *supra* note 11.

[47] See *supra* note 12.

report or subsequent planned activities will help to provide the scientific information that industry, regulators and the public need to ensure the safe development and use of nanotechnology.

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

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

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

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

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

[48] See *supra* note 13.

## 4. Mechanisms to get the job done

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

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

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

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

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

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

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

Some progress has been made to correct these failings. The NSF has successfully funded a number of interdisciplinary research centers that are providing extremely valuable information on the potential risks of nanotechnologies—and how to address them. Yet these centers exist outside of an overall strategic risk framework, and remain constrained in their ability to directly relate engineered nanomaterials to potential diseases, or to inform regulation. Another partial success story is the EPA Science To Achieve Results (STAR) nanotechnology research program that has supported many projects addressing the potential health and environmental impacts of engineered nanomaterials. Yet funding for individual projects is capped at a level too low for many researchers evaluating human and ecological toxicology to consider applying. As a result, while the research portfolio looks good on paper, in reality it is merely nibbling around the edges of the questions that need answering.

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

## 5. Sufficient resources to address critical challenges

The FY2008 NNI request for nanotechnology health and safety research funding is $58.6 million[49]—less than the estimated $144 million needed for targeted and exploratory EHS research, but more than the estimated $50 million for targeted research alone. However, this figure comes with marginal information on how the money will be spent and whether it will, in fact, address strategically relevant questions, or be squandered on marginally relevant research.

Out of this request, 49% is to go to NSF, 20% to NIH and the National Institute of Standards and Technology, 16% to EPA and 8% to NIOSH. In other words, despite the need for nanotechnology risk research to inform oversight and regulation, the vast bulk of the requested funding is associated with agencies that have no regulatory mission. Is this an appropriate use of funds, or does it merely reflect the spending power of the respective agencies?

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

The only way this question can be answered is by understanding how each agency's research will feed into an overarching strategic framework that is designed to provide answers that decision-makers need to oversee the development of safe nanotechnologies. Unless the federal government is able to give a clear account of what is being invested in nanotechnology risk research, and how that investment will reduce uncertainty and enable effective risk management, there is a danger that current funding will be ineffective—no matter how impressive on paper.

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

# Conclusions

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

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

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

## Responses to specific questions

**What is your reaction to the recent report of the Nanotechnology Environmental and Health Implications Working Group, "Prioritization of Environmental, Health and Safety Research Needs for Engineered Nanoscale Materials? Do outside groups have a way to influence this planning process? Are the priorities listed in the report the right ones, and do you believe that carrying out the "next steps" described in the report will achieve the detailed implementation plan for EHS research that is needed?**

***Reaction to the recent NEHI report***

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

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

***Potential for outside groups to influence the planning process***

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

[51] See *supra* note 11.

### *Are these the right research priorities?*

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

### *Will the "next steps" achieve the desired goal?*

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

As an example, anyone with a credit card can purchase carbon nanotubes in powder form from a company called Cheap Tubes Inc. The nanotubes come in a sealed bag, and the accompanying safety data describes them as graphite—the same substance used to form pencil leads. Yet research has shown carbon nanotubes to be potentially hazardous in ways we don't fully understand yet if inhaled.[53] If I purchased some of these carbon nanotubes today, how long will it take before someone is able to tell me how to open the package, extract the material, and use it—safely? Would it be days, months, years or even a decade? Researchers, businesses and consumers are facing similar questions every day. Yet the currently outlined "next steps" hold no hope for early answers.

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[52] See *supra* note 13.

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

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

### *EHS research priority*

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

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

### *Funding levels*

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

But beyond this figure, there is a need for further investment in *exploratory research* that will identify the questions we haven't thought of yet. It isn't possible to place a firm figure on how much should be spent here, but a useful rule of thumb—and one that others have advocated—is to ensure that at least 10% of the federal government's nanotechnology research and development budget is dedicated to strategic risk-related research. This would place the overall estimated EHS research budget for 2008 at $145

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

[55] See *supra* note 16.

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

million—allowing for $50 million in targeted research and $95 million dedicated to exploratory research. Given the nature of exploratory research, which requires substantial investment to make significant progress, this does not seem unreasonable.

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

***Agency roles***

An effective nanotechnology EHS strategic research framework will enable and empower agencies to take a lead in addressing issues that fall within their competences and missions. While top-level direction will be essential to ensuring success, the most effective model will not be one of command and control, but of leadership, coordination and facilitation.

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

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

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

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

### *Balancing responsibilities and resources*

Responsibilities and available resources are not currently in balance across federal agencies. Examining the $58.6 million FY2008 NNI budget request for nanotechnology EHS research, 49% is associated with NSF, 20% with NIH and the National Institute of Standards and Technology, 16% with EPA and just 8% with NIOSH.[58] These figures are not supported by clear research objectives, goals and plans, so it is hard to say whether the funding will all go to nanotechnology risk-relevant research. An assessment of the 2005 federal government's risk research portfolio could only identify $11 million associated with highly relevant research into the potential risks of engineered nanomaterials, compared to a NNI-reported estimate of $38.5 million—a shortfall of $27.5 million![59]

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

The resulting budget figures reflect strategic thinking only *incidentally,* rather than by design—wealthy agencies invest more in a "hot topic" area, while poorer agencies struggle to scrape together precious resources to carry out their mandated duties. The irony in this situation, of course, is that it is the agencies without the resources to do the right research that have the clearest perspective on what needs to be done. In the FY2008 budget request, the NSF budget for nanotechnology EHS research *increased* by $7.8 million from FY2006 to $34.2 million—an increase of over one and a half times NIOSH's *entire request* for FY2008 ($4.6 million). And this is in spite of most stakeholders acknowledging that addressing occupational exposure to engineered nanomaterials is a top priority.

In other words, despite the need for nanotechnology risk research to inform oversight and regulation, the vast bulk of the requested funding is associated with agencies having no regulatory mission. Whether this is an appropriate use of funds, or merely reflects the spending power of the respective agencies, can only be answered by understanding how each agency's research will feed into an overarching strategic framework. But this

[57] See *supra* note 24.

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

[59] See *supra* note 13.

framework does not yet exist.[60] Until it does (and mechanisms are in place to implement it), the federal government is unlikely to achieve a balance between agency resources and responsibilities in addressing nanotechnology risks.

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

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

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

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

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

- Provide for exchange of information among agencies that support nanotechnology research and those responsible for regulation and guidelines related to nanoproducts (defined as engineered nanoscale materials, nanostructured materials or nanotechnology-based devices, and their byproducts);

[60] See *supra* note 12.

- Facilitate the identification, prioritization, and implementation of research and other activities required for the responsible research and development, utilization, and oversight of nanotechnology, including research methods of life-cycle analysis; and
- Promote communication of information related to research on environmental and health implications of nanotechnology to other government agencies and non-government parties.[61]

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

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

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

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

not be met, mission-driven agencies will not have sufficient funds to do the work that is needed, and the whole nanotechnology enterprise will be jeopardized.

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

***Strategic goals***

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

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

- **Providing answers to pressing questions.** These are questions that researchers, manufacturers and consumers are asking now, and include: How can exposure to nanomaterials be measured and controlled? How can I test my nanomaterial to determine if it is harmful? What happens if I release my nanomaterial into the environment? Am I at risk if I use personal care products containing nanomaterials? How do I dispose of waste nanomaterial and nanotechnology products that have come to the end of their life? The answers to many of these questions will require complex research, but until they are answered, they present real and immediate barriers to progress.

- **Developing new knowledge to identify the questions not currently being asked.** Many aspects of nanotechnology are so new that we do not yet know what are the right questions to ask regarding potential risks. This knowledge will not come easily from targeted research, as it is difficult to set milestones on discovering the unknown. Rather, it will be driven from the innovation researchers who are given the freedom to explore new avenues and follow interesting leads. Yet for such exploratory research to be effective in addressing risks, it must be directed within an overall risk-relevant framework, and mechanisms must be set in place to identify and follow-up on new risk-relevant information.

- **Translating research into practice: developing new ways of predicting and managing risks.** While the oversight of nanotechnology is dogged by uncertainty, it seems relatively certain that new technologies will always be one step ahead of our understanding of how they might cause harm. This lag between technology and regulation is clear as we look over the innovations of the past one hundred years. Yet as the rate of technological innovation continues to increase, it is increasingly hard to justify reactive oversight that is bogged down in bureaucratic inertia and is slow to take corrective action. In short, emerging technologies like nanotechnology challenge us to develop new, responsive and proactive approaches to identifying and managing possible risks, so that we might prevent a lasting legacy of harm where old approaches could not keep up with new developments.

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

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

### *Key elements of a strategic framework*

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

- **Goal-oriented research.** Whether research exploring new areas or research addressing a specific problem, an underlying principle of an effective research strategy must be science in the service of safety.
- **A balance of targeted and exploratory research.** An effective research strategy will combine research targeted to addressing specific problems, with research exploring new areas of knowledge. Both are important in the long term to address practical issues and develop a sound understanding of what makes a new material potentially harmful, and how to avoid that harm.
- **Interdisciplinary collaboration.** Nanotechnology is inherently interdisciplinary, and effective research addressing the potential risks will be likewise. For example, early toxicity studies on nanomaterials were compromised because of a lack of understanding of the materials being used within the toxicology community, and would have benefited from stronger collaborations with materials scientists and characterization experts. Yet the disciplinary barriers faced are substantial, and cannot be broken down by researchers without help. Illustrating the problem, some seventeen years after the first toxicology studies on nanoparticles, research into nanoparticle toxicity being published now is frequently hard to interpret and compare with other studies, because the interdisciplinary barriers in place a decade and a half ago are still reasonably intact! This is just one example, but it is indicative of the need for any research strategy to break these barriers down if it is to be effective.

- **Enabling and empowering researchers and research organizations.** The effectiveness of a strategic research framework will only be as good as its ability to engage the organizations and individuals responsible for implementing it. While such a framework will of necessity be at a high level and, in the case of the federal government, overlay all departments and agencies associated with ensuring the safety of emerging nanotechnologies, the expertise to make it work will lie within the participating agencies, and within the broader research community. Therefore, a fine balance must be struck between controlling the direction of research and empowering agencies and researchers to lead research efforts. This balance is perhaps most important in exploratory research, where the best-positioned person to see where research is leading and its significance may be the principle investigator or research manager. Getting the balance right between providing top-down direction and enabling a degree of autonomy will be important in supporting innovative research that can be incorporated into a responsive strategy.
- **Communication and translation.** Multilateral communication of research goals, activities and findings, and translation of research into practical information and actions, are essential to the operation and implementation of an effective research strategy. These are the glue that holds an otherwise well thought-through strategic plan together.

# Biography of Andrew Maynard

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

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

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

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