United States Government Accountability Office

GAO

Report to Congressional Requesters

March 2008

NANOTECHNOLOGY

Better Guidance Is Needed to Ensure Accurate Reporting of Federal Research Focused on Environmental, Health, and Safety Risks

GAO-08-402

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Highlights

Highlights of GAO-08-402, a report to congressional requesters

Why GAO Did This Study

The National Nanotechnology Initiative (NNI), administered by the Office of Science and Technology Policy (OSTP), is a multiagency effort intended to coordinate the nanotechnology-related activities of 25 federal agencies that fund nanoscale research or have a stake in the results. Nanotechnology is the ability to control matter at the scale of a nanometer—one billionth of a meter. A key research area funded by some federal agencies relates to potential environmental, health, and safety (EHS) risks that may result from exposure to nanoscale materials. Because of concerns about federal efforts to fund and prioritize EHS research, GAO was asked to determine (1) the extent to which selected agencies conducted such research in fiscal year 2006; (2) the reasonableness of the agencies' and the NNI's processes to identify and prioritize such federal research; and (3) the effectiveness of the agencies' and the NNI's process to coordinate this research. GAO reviewed quantitative and qualitative data from five federal agencies that provided 96 percent of fiscal year 2006 funding for EHS research.

What GAO Recommends

GAO is recommending that OSTP provide better guidance to agencies regarding how to report research that is primarily focused on EHS risks. In commenting on a draft of this report, OSTP generally agreed with the findings and will review the manner in which agencies respond to current guidance.

To view the full product, including the scope and methodology, click on GAO-08-402. For more information, contact Anu Mittal at (202) 512-3841 or mittala@gao.gov.

What GAO Found

The NNI reported that in fiscal year 2006, federal agencies devoted $37.7 million—or 3 percent of the $1.3 billion total nanotechnology research funding—to research that was primarily focused on the EHS risks of nanotechnology. However, about 20 percent of this total cannot actually be attributed to this purpose; GAO found that 22 of the 119 projects identified as EHS-related by five federal agencies in fiscal year 2006 were not focused on determining the extent to which nanotechnology poses an EHS risk. Instead, the focus of many of these projects was to explore how nanotechnology could be used to remediate environmental damage or to detect a variety of hazards. GAO determined that this mischaracterization is rooted in the current reporting structure which does not allow these types of projects to be easily categorized and the lack of guidance for agencies on how to apportion funding across multiple topics. In addition to the EHS funding totals reported by the NNI, federal agencies conduct other research that is not captured in the totals. This research was not captured by the NNI because either the research was funded by an agency not generally considered to be a research agency or because the primary purpose of the research was not to study EHS risks.

Federal agencies and the NNI are currently in the process of identifying and prioritizing EHS risk research needs; the process they are using appears reasonable overall. For example, identification and prioritization of EHS research needs is being done by the agencies and the NNI. The NNI also is engaged in an iterative prioritization effort through its Nanotechnology Environmental and Health Implications (NEHI) working group. NEHI has identified five specific research priorities for five general research categories, but it has not yet completed the final steps of this process, which will identify EHS research gaps, determine specific research needed to fill those gaps, and outline a long-term, overarching EHS research strategy. GAO found that the focus of most EHS research projects underway in fiscal year 2006 was generally consistent with agency priorities and NEHI research categories and that the projects focused on the priority needs within each category to varying degrees. The anticipated EHS research strategy is expected to provide a framework to help ensure that the highest priority needs are met.

Agency and NNI processes to coordinate activities related to potential EHS risks of nanotechnology have been generally effective. The NEHI working group has convened frequent meetings that have helped agencies identify opportunities to collaborate on EHS risk issues, such as joint sponsorship of research and workshops to advance knowledge and facilitate information-sharing among the agencies. In addition, NEHI has incorporated several practices that are key to enhancing and sustaining interagency collaboration, such as leveraging resources. Finally, agency officials GAO spoke with expressed satisfaction with the coordination and collaboration on EHS risk research that has occurred through NEHI. They cited several factors they believe contribute to the group's effectiveness, including the stability of the working group membership and the expertise and dedication of its members.

Contents

Figures

Abbreviations

CPSC	U.S. Consumer Product Safety Commission
EHS	environmental, health, and safety
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
NEHI	Nanotechnology Environmental and Health Implications (working group)
NIH	National Institutes of Health
NIOSH	National Institute for Occupational Safety and Health
NIST	National Institute of Standards and Technology
NNCO	National Nanotechnology Coordinating Office
NNI	National Nanotechnology Initiative
NSET	Nanoscale Science, Engineering, and Technology (subcommittee)
NSF	National Science Foundation
NSTC	National Science and Technology Council
OMB	Office of Management and Budget
OSHA	Occupational Safety and Health Administration
OSTP	Office of Science and Technology Policy
PCA	program component area

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United States Government Accountability Office
Washington, DC 20548

March 31, 2008

The Honorable Daniel K. Inouye, Chairman
The Honorable Mark L. Pryor
The Honorable Gordon H. Smith
Committee on Commerce, Science, and Transportation
United States Senate

The Honorable Ron Wyden
The Honorable Richard Burr
Congressional Nanotechnology Caucus
United States Senate

Nanotechnology encompasses a wide range of innovations based on the understanding and control of matter at the scale of nanometers—the equivalent of one-billionth of a meter. For illustration, a sheet of paper is about 100,000 nanometers thick, a human hair is about 80,000 nanometers wide, and 2 gold atoms lying side by side are about 1 nanometer long. At the nanoscale level, some materials may exhibit electrical, magnetic, biological, and other properties that differ significantly from properties the same materials exhibit at a larger scale. For example, opaque materials, such as copper, become transparent at the nanoscale and inert materials, such as platinum and gold, become chemical catalysts. Exploiting the differences in the size and properties of materials at the nanoscale level has led to a range of commercial uses and holds the promise for innovations in virtually every industry from aerospace and energy to health care and agriculture. In 2006, an estimated $50 billion in products worldwide incorporated nanotechnology and this figure has been projected to grow to $2.6 trillion by 2014, according to an industry analyst. The Woodrow Wilson International Center for Scholars' Project on Emerging Nanotechnologies has identified over 500 consumer products that already are available to consumers that may contain nanoscale materials. For example, nanoscale materials have been embedded into clothing fabric to repel stains. Some nanoscale materials in development could greatly improve pharmaceuticals because the materials' size, structure, and behavior can be used, for example, to treat diseases by delivering drugs directly to affected cells, such as tumor cells. Food companies also are experimenting with nanoscale materials that can be incorporated into food packaging to detect spoilage or pathogens, and cosmetics companies have developed products with nanoscale materials that reportedly enable sunscreens to perform better.

While the use of nanoscale materials holds much promise for the future, the small size and unique properties of nanomaterials raise questions about potential environmental, health, and safety (EHS) effects—referred to as EHS risks—that might result from exposures during the manufacture, use, and disposal or recycle of nanoscale materials. For example, recent research suggests that nanomaterials are small enough to get inside cells and some may cross the blood-brain barrier to directly enter the central nervous system. Because nanotechnology is a relatively new science, basic information about the properties of many nanoscale materials is not fully known. Scientists are working to fill significant gaps in current knowledge about nanoscale materials so they can answer questions about potential EHS risks and help ensure the safe commercial development of these materials.

In 2001, the National Nanotechnology Initiative (NNI) was established as a federal, multiagency effort intended to accelerate the discovery, development, and deployment of nanoscale science, engineering, and technology to achieve economic benefits, enhance the quality of life, and promote national security.[1] The NNI is a mechanism to coordinate the nanotechnology-related activities of the 25 currently participating federal agencies that fund nanoscale research or have a stake in the outcome of this research, such as those agencies that may regulate products containing nanomaterials.[2] While the NNI is designed to facilitate intergovernmental cooperation and identify overarching goals and priorities for nanotechnology research, it is not a research program. It also has no funding or authority to dictate the nanotechnology research agenda for participating agencies or to ensure that adequate resources are available to achieve specific goals. Instead, participating agencies develop and fund their own nanotechnology research agendas. In fiscal year 2006, 13 of the 25 participating agencies in the NNI allocated a total of about $1.3 billion from their appropriated budgets to nanotechnology research and development activities.

[1]The creation of the NNI formalized an existing interagency dialogue on nanotechnology that began in 1998.

[2]For purposes of this report we use the term "research agency" to mean an agency whose primary mission is to conduct or facilitate scientific research, and the term "regulatory agency" to mean an agency whose primary mission is to administer regulatory programs related to environment, human health, and safety, and which may have a role in regulating products containing nanomaterials. A small number of agencies carry out both functions; we will refer to these by their primary mission.

Management of the NNI falls under the purview of the National Science and Technology Council (NSTC), a Cabinet-level body within the Office of the President that coordinates science and technology policy across the federal government. The NSTC's Committee on Technology has established a Nanoscale Science, Engineering, and Technology (NSET) subcommittee to help coordinate, plan, and implement the NNI's activities across participating agencies. In 2003, the NSET subcommittee further established a Nanotechnology Environmental and Health Implications (NEHI) working group.[3] The purpose of the NEHI working group, composed of representatives from 16 research and regulatory agencies, is to, among other things, coordinate agency efforts related to EHS risks of nanotechnology. As is the case with the NNI, the NEHI working group has no authority to mandate research priorities or to ensure that agencies adequately fund particular research.

In December 2003, Congress enacted the 21st Century Nanotechnology Research and Development Act.[4] The act establishes a National Nanotechnology Program to coordinate federal nanotechnology research and development. Among other things, the act directs the NSTC to establish goals and priorities for the program and to set up program component areas that reflect those goals and priorities. To implement these requirements, the NSTC has established a process to categorize research projects and activities undertaken by the various federal agencies into seven areas. Of these seven, six are focused on the discovery, development, and deployment of nanotechnology, while the seventh relates to the societal dimensions of nanotechnology that include issues such as the EHS risks of nanotechnology. Agencies also report their research funding for each area to the Office of Management and Budget (OMB) as part of the annual federal budget process. NNI's annual Supplement to the President's Budget, prepared by the NSTC, includes EHS research figures from the agencies and a general description of the research conducted by the agencies in each of the seven areas. For reporting purposes, the NSET subcommittee has defined EHS research as "efforts whose primary purpose is to understand and address potential risks to health and to the environment posed by this technology." Eight of

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

[4]Pub. L. No. 108-153 (2003).

the 13 agencies that dedicated a portion of their research budgets for nanotechnology research in fiscal year 2006 reported having devoted some resources to research that had a primary focus on potential EHS risks. However, the Woodrow Wilson International Center for Scholars has questioned the accuracy of reporting research related to EHS risks. Furthermore, some groups, including industry, environmental advocacy, and nonprofit research institutes, have raised concerns about the pace of NEHI's prioritization activities as well as the process it is using to identify research priorities and coordinate federal research.

In this context you asked us to report on (1) the extent to which selected research and regulatory agencies conducted research in fiscal year 2006 that primarily was focused on the potential EHS risks of nanotechnology; (2) the reasonableness of the processes that agencies and the NNI use to identify and prioritize federal research on the potential EHS risks of nanotechnology; and (3) the effectiveness of the processes that agencies and the NNI use to coordinate their research.

To determine the extent to which selected research and regulatory agencies conducted research that is primarily focused on studying the EHS risks of nanotechnology, we gathered data on the funding that NNI's participating agencies have used for EHS risk research. We focused our review on the Environmental Protection Agency (EPA), the National Institutes of Health (NIH), the National Institute for Occupational Safety and Health (NIOSH), the National Institute of Standards and Technology (NIST), and the National Science Foundation (NSF), because these five agencies accounted for 96 percent of the EHS research funding reported in fiscal year 2006. Of these agencies, NIH, NIOSH, NIST, and NSF are research agencies that have specific budgets to support research, including nanotechnology-related research. EPA on the other hand is a regulatory agency that also conducts research and therefore has a research budget. In addition to the agencies mentioned above, we also included in our review three regulatory agencies that do not have research budgets—the U.S. Consumer Product Safety Commission (CPSC), the Food and Drug Administration (FDA), and the Occupational Safety and Health Administration (OSHA) to determine whether these three agencies conducted any research on their own relative to EHS risks of nanotechnology. We assessed the reliability of the agencies' data and determined it was sufficient for the purposes of this analysis. To assess whether or not the primary purpose of the research conducted by these agencies addressed the EHS risks of nanotechnology, we reviewed qualitative data on all projects funded by EPA, NIH, NIOSH, NIST, and NSF in fiscal year 2006. To minimize bias and to ensure the consistency of

our evaluation, the team independently conducted project reviews by using publicly available and agency documentation, such as project abstracts or grant applications, to make our determinations. For categorization of projects that appeared questionable to us, we discussed the categorization with agency officials and modified our determination as appropriate given the additional support provided by the agency.

To determine the reasonableness of the process that the agencies and the NNI used to prioritize and coordinate federal research on studying EHS risks, we collected and reviewed documentation on research priorities, and the process used to establish these priorities, at each of the eight agencies included in our review and compared these priorities with funded research within the agency. To review the process being used by the NNI to identify and establish government-wide priorities, we reviewed NNI documents and interviewed agency officials and external stakeholder groups, including officials from groups that represent environmental and industry concerns. We compared the NNI's identified priorities with those identified by the agencies to determine whether they were consistent. We also compared the NNI's identified priorities with agency project-level data on EHS research underway in fiscal year 2006 to determine whether the projects were reflective of NNI's identified priorities. We did not determine whether the NNI's identified priorities represented a scientific consensus on the most appropriate ones. We interviewed agency officials at each of the eight agencies about the extent to which their agency's research priorities were met, either through the agency's own research or research conducted by other agencies. With regard to coordination, we discussed with agency and NNI officials how agencies coordinate research and NNI's role to facilitate that coordination, and we obtained documentation on these collaborative efforts. Furthermore, we compared the NNI's efforts to facilitate interagency collaboration with established practices that have been found to enhance and sustain collaboration among federal agencies. In addition, we interviewed stakeholders, including environmental and industry groups, to obtain views on agency coordination efforts. We conducted this performance audit from June 2007 to February 2008 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Results in Brief

Of the $1.3 billion that federal agencies allocated to nanotechnology research in fiscal year 2006, the NNI reported that about $37 million was devoted to research that primarily focused on studying the EHS risks of nanotechnology. However, based on our analysis, about one-fifth of this amount cannot actually be attributed to this purpose. Specifically, our analysis found that 22 of the 119 projects identified as EHS projects by EPA, NIH, NIOSH, NIST, and NSF in fiscal year 2006 were not primarily related to understanding the EHS risks of nanotechnology. These 22 projects, funded by NSF and NIOSH, accounted for about $7 million of the $37 million that the NNI reported as being primarily focused on EHS risks. Instead of determining the extent to which nanotechnology poses an EHS risk, the primary purpose of many of these projects was to explore how nanotechnology could be applied to remediate environmental damage or could be used to detect a variety of hazards, such as chemical or biological. The miscategorization of these 22 projects results largely from a reporting structure for nanotechnology research that does not easily allow agencies to recognize projects that use nanotechnology to mitigate environmental damage or enhance detection of environmental contaminants and from the lack of guidance available to the agencies on how to apportion funding across multiple topics, when appropriate. As a result, agency officials said they characterized these projects as being EHS-focused for lack of a more closely related category to place them in. We also determined that some federal agencies conduct research that is not reported as part of EHS research funding and is therefore not captured in the EHS totals provided by the NNI. For example, NIH has research underway to develop drug delivery mechanisms that use nanotechnology. This research also will provide relevant health and safety information on how nanomaterials interact with the body at the cellular level, but the agency's funding for this type of research is not included in the NNI's totals for EHS research because studying EHS risks was not its primary purpose. We are recommending that the Office of Science and Technology Policy (OSTP), in consultation with the NNI and OMB, provide better guidance to agencies regarding how to report research that is primarily focused on understanding or addressing the EHS risks of nanotechnology. In commenting on this report, OSTP generally concurred with the report's findings and agreed to review the manner in which agencies respond to the current guidance at future NSET meetings.

The agencies and the NNI are currently in the process of identifying and prioritizing EHS risk research needs; the process they are using appears reasonable overall. Identification and prioritization of research needs related to EHS risks takes place within individual agencies as well as within the NNI. Agencies' priorities are linked to their missions and are

generally set by intra-agency teams dedicated to nanotechnology issues. Most of the eight agencies we reviewed have established internal task forces to identify and prioritize nanotechnology research needs and to communicate these priorities to the larger research community. In addition to these agency efforts, the NSET subcommittee is currently engaged in an iterative prioritization effort through its NEHI working group. This effort began with a September 2006 report in which NEHI identified five general categories of research necessary to evaluate EHS risks and a list of 75 specific research needs, which were not prioritized at that time. Subsequently, in an August 2007 report, NEHI distilled the list of 75 specific research needs into a set of five prioritized needs under each of the five general research categories. Agency officials told us that NEHI's report generally reflects their agencies' key research priorities. NEHI has not yet completed the final steps of this process and plans to issue a report in early 2008 that will identify EHS research gaps; determine specific research needed to fill those gaps; and outline a long-term, overarching strategy to guide agency research funding decisions. Furthermore, our analysis of the 97 research projects that were underway in fiscal year 2006 that were primarily related to studying EHS risks found that the focus of these projects was generally consistent with agency priorities and NEHI's five general research categories and that the projects focused on the priority needs within each category to varying degrees. The anticipated 2008 NEHI report is expected to provide a framework to help agencies better target the highest priority research needs in the future. Also, some environmental and industry groups have advocated for a more top-down and directed approach for setting and funding federal nanotechnology research priorities. However, such a structure and approach is generally inconsistent with historical approaches used to set federal research priorities and may be difficult to implement given how federal research is currently funded.

Agency and NNI processes to coordinate activities related to the potential EHS risks of nanotechnology have been generally effective. The NEHI working group has convened frequent meetings, augmented by informal discussions among agencies, that have helped agencies identify opportunities to collaborate on EHS risk issues. These interagency collaborations have taken many forms including joint sponsorship of EHS-related research and workshops and detailing staff to work at other NEHI participating agencies. These types of exchanges, according to most agency officials we spoke with, have helped advance knowledge and facilitated information-sharing among the agencies. In addition, NEHI has incorporated several practices that we have previously identified as key to enhancing and sustaining interagency collaborative efforts, such as

defining a common outcome and leveraging resources, but has not completed an overarching strategy to help better align agencies' EHS research efforts. Finally, all agency officials we spoke with expressed satisfaction with both the coordination and the collaboration on EHS risk research that has occurred through NEHI. These officials cited several factors that they believe have contributed to the working group's effectiveness, including the expertise, dedication, and low turnover rate of its members. Furthermore, according to these officials, this stability, combined with common research needs and general excitement about the new science, has resulted in a collegial, productive working environment.

Background

Nanotechnology is generally defined as the ability to understand and control matter at the nanoscale (between 1 and 100 nanometers), in order to create materials, devices, and systems with fundamentally new properties and functions specific to that scale. For example, opaque materials, such as copper, become transparent at the nanoscale and inert materials, such as platinum and gold, become chemical catalysts. With the capacity to control and manipulate matter at this scale, nanotechnology promises advances in areas such as new drug delivery systems, more resilient materials and fabrics, stronger materials at a fraction of the weight, more efficient energy conversion, and dramatically faster computer chips.

To guide federal development of this technology, the National Nanotechnology Initiative (NNI) was established in fiscal year 2001 to support long-term research and development aimed at accelerating the discovery, development, and deployment of nanoscale science, engineering, and technology. The NNI is a multiagency program involving nanotechnology-related activities of the 25 federal agencies currently participating, including the National Science Foundation (NSF), the Department of Defense, the Department of Energy, the National Institutes of Health (NIH), and the National Institute of Standards and Technology (NIST). See table 1 for a complete listing of federal agencies participating in the NNI as of December 2007.

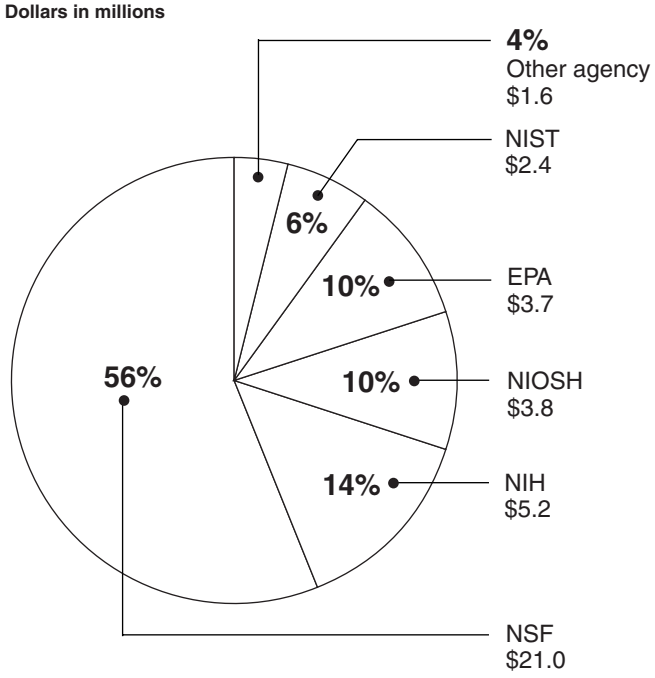
Table 1: Federal Agencies Participating in the National Nanotechnology Initiative, as of December 2007

Federal Agencies with Budgets Dedicated to Nanotechnology Research and Development	Other Participating Agencies
• Cooperative State Research, Education, and Extension Service	• Bureau of Industry and Security
• Department of Defense	• Department of Education
• Department of Energy	• Department of Labor
• Department of Homeland Security	• Department of State
• Department of Justice	• Department of the Treasury
• Department of Transportation	• Food and Drug Administration
• Environmental Protection Agency	• International Trade Commission
• National Aeronautics and Space Administration	• Intelligence Advanced Research Projects Activity
• National Institute of Standards and Technology	• Nuclear Regulatory Commission
• National Institute for Occupational Safety and Health	• U.S. Consumer Product Safety Commission
• National Institutes of Health	• U.S. Geological Survey
• National Science Foundation	• U.S. Patent and Trademark Office
• U.S. Forest Service	

Source: NNI.

Federal support for nanotechnology research totaled about $1.3 billion in fiscal year 2006. Cumulatively through fiscal year 2006, federal agencies have devoted over $5 billion to nanotechnology research since the NNI's inception. While not all of the NNI's participating agencies conduct or sponsor research, in fiscal year 2006, 13 agencies had budgets dedicated to nanotechnology research and development. Eight of these 13 agencies devoted some of their research resources to studying the environmental, health, and safety (EHS) risks of nanotechnology. Of these eight agencies, five—EPA, NIH, NIOSH, NIST, and NSF—accounted for almost 96 percent of the research focused on EHS risks in fiscal year 2006. NSF alone accounted for about 56 percent of all federal EHS risk research in fiscal year 2006. See figure 1 for a break out of research funds used by agency.

Figure 1: Nanotechnology EHS Research by Agency, as Reported by the National Nanotechnology Initiative, Fiscal Year 2006



Source: GAO analysis of NNI budget data.

A number of research and regulatory agencies support research to advance knowledge and information about the potential EHS risks of nanotechnology:

- The National Institute for Occupational Health and Safety (NIOSH) is a research agency within the Department of Health and Human Services (HHS) that concentrates its research on topics related to human health. NIOSH's research results in recommendations for preventing work-related injuries, illnesses, and death. It therefore focuses on studies that will improve scientists' ability to identify potential adverse occupational health effects of nanomaterials.

- At NIH, another HHS research agency that concentrates on human health, nanotechnology research is generally focused on the development of medical applications and the protection of public health, including research to examine the interaction of nanomaterials with biological systems.

- Consistent with its mission to advance measurement science, standards, and technology to enhance economic security and improve our quality of life, the National Institute of Standards and Technology (NIST), an agency in the Department of Commerce, develops the measurement techniques required to better characterize potential impacts of nanotechnology.

- The National Science Foundation (NSF) has the broadest research portfolio relative to nanotechnology and supports research to help meet its mission to promote the progress of science and engineering. With regard to EHS risks, NSF sponsors research to develop new methods to characterize nanoparticles and investigate the environmental implications and toxicity of nanomaterials. In addition, NSF sponsors a network of research centers that focus on a range of EHS issues including occupational safety during nanomanufacturing and the interaction of nanomaterials and cells.

In addition to these research agencies, a number of regulatory agencies also have an interest in developing information about the potential EHS risks of nanotechnology:

- The Environmental Protection Agency (EPA), which is both a research and regulatory agency, is tasked with protecting human health and the environment. As a result, EPA determined that it needed to develop a better understanding of the potential human health and environmental risks from exposure to nanoscale materials and is therefore focusing its research efforts in this area, among others.

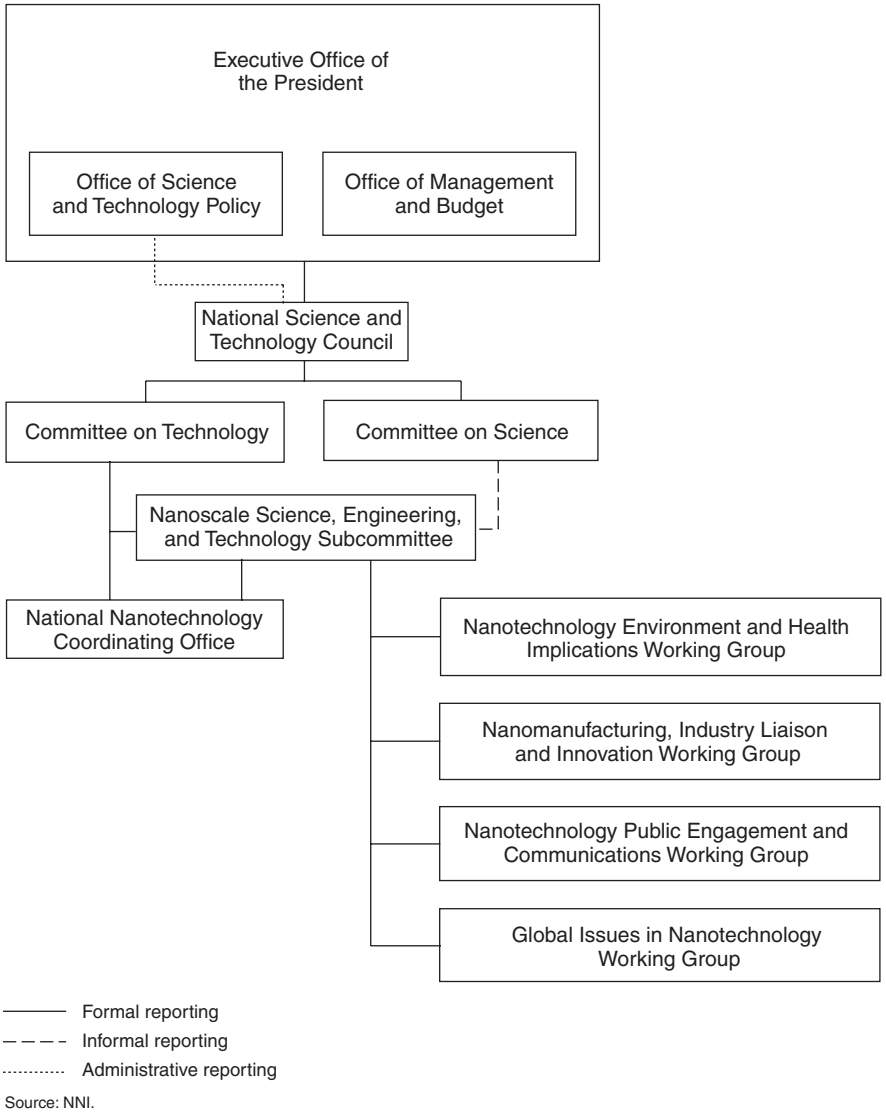
- The Food and Drug Administration (FDA), another HHS agency, is generally responsible for overseeing the safety and effectiveness of drugs and devices for humans and animals, and of biological products for humans. The agency also is generally responsible for overseeing the safety of color additives, cosmetics, and foods, including food additives and dietary supplements. As a result, FDA is interested in understanding the potential risks posed by nanomaterials used in products under its jurisdiction.

- The Occupation Safety and Health Administration (OSHA) is a Department of Labor agency whose mission is, in part, to ensure the safety and health of workers by setting and enforcing standards and encouraging continual improvement in workplace safety and health. OSHA is interested in information that would aid in the application of existing health standards—including hazard communication, respiratory protection programs, and laboratory standards—to nanotechnology operations and help determine the need for new standards or guidance products.

- The mission of the U.S. Consumer Product Safety Commission (CPSC) is to protect the public from unreasonable risks of serious injury or death from more than 15,000 types of consumer products, including some that may be manufactured with nanomaterials.

The NNI is managed within the framework of the National Science and Technology Council's (NSTC) Committee on Technology. The NSTC is an organization through which the President coordinates science and technology policies across the federal government. The NSTC is managed by the Director of the Office of Science and Technology Policy (OSTP), who also serves as the Science Advisor to the President. The NSTC's Committee on Technology established the Nanoscale Science, Engineering, and Technology (NSET) subcommittee to coordinate communication between the federal government's multiagency nanoscale research and development programs. The NSET subcommittee is composed of representatives from any agencies that choose to participate in the NNI (as of January 2008, 25 agencies are involved) and serves as the primary interagency coordination mechanism for nanotechnology-related research. Supporting the NSET subcommittee, the National Nanotechnology Coordinating Office (NNCO) provides day-to-day technical guidance and administrative assistance to prepare multiagency planning, budget, and assessment documents. In addition, the NSET subcommittee has established a number of working groups to help better focus interagency attention and activity on specific issues, such as the Nanotechnology Environmental and Health Implications (NEHI) working group. This group was designed to provide for exchange of information among participating agencies; facilitate the identification, prioritization, and implementation of research; and promote communication to other federal and nonfederal entities. The NEHI working group also coordinates U.S. participation in international activities, including the programs of the Organisation for Economic Co-operation and Development. Currently, NEHI membership consists of 16 research and regulatory agencies. See figure 2 for the NNI's structure.

Figure 2: National Nanotechnology Initiative Structure



Source: NNI.

Under the NNI, each agency funds research and development projects that support its own mission as well as the NNI's goals. While agencies share information on their nanotechnology-related research goals with the NSET subcommittee and NEHI working group, each agency retains control over its decisions on the specific projects to fund. While the NNI was designed to facilitate intergovernmental cooperation and identify goals and priorities for nanotechnology research, it is not a research program. It has

no funding or authority to dictate the nanotechnology research agenda for participating agencies.

The NNI used its fiscal year 2000 strategic plan and its subsequent updates to delineate a strategy to support long-term nanoscale research and development, among other things. A key component of the 2000 plan was the identification of nine specific research and development areas—known as "grand challenges"—that highlighted federal research on applications of nanotechnology with the potential to realize significant economic, governmental, and societal benefits.[5] Examples of potential breakthroughs cited in this strategic plan included developing materials that are 10 times stronger, but significantly lighter, than steel to make vehicles lighter and more fuel efficient; improving the speed and efficiency of computer transistors and memory chips by factors of millions; and developing methods to detect cancerous tumors that are only a few cells in size using nanoengineered contrast agents.

In 2004, the NNI updated its strategic plan and described its goals as well as the investment strategy by which those goals were to be achieved.[6] Consistent with the 21st Century Nanotechnology Research and Development Act, the NNI established major subject categories of research and development investment, called program component areas (PCA), that cut across the interests and needs of the participating agencies.[7] These seven areas replaced the nine grand challenges and other nanotechnology investment areas that the agencies had previously used to categorize their nanotechnology research. Six of the seven areas are focused on the discovery, development, and deployment of nanotechnology. The seventh, societal dimensions, consists of two

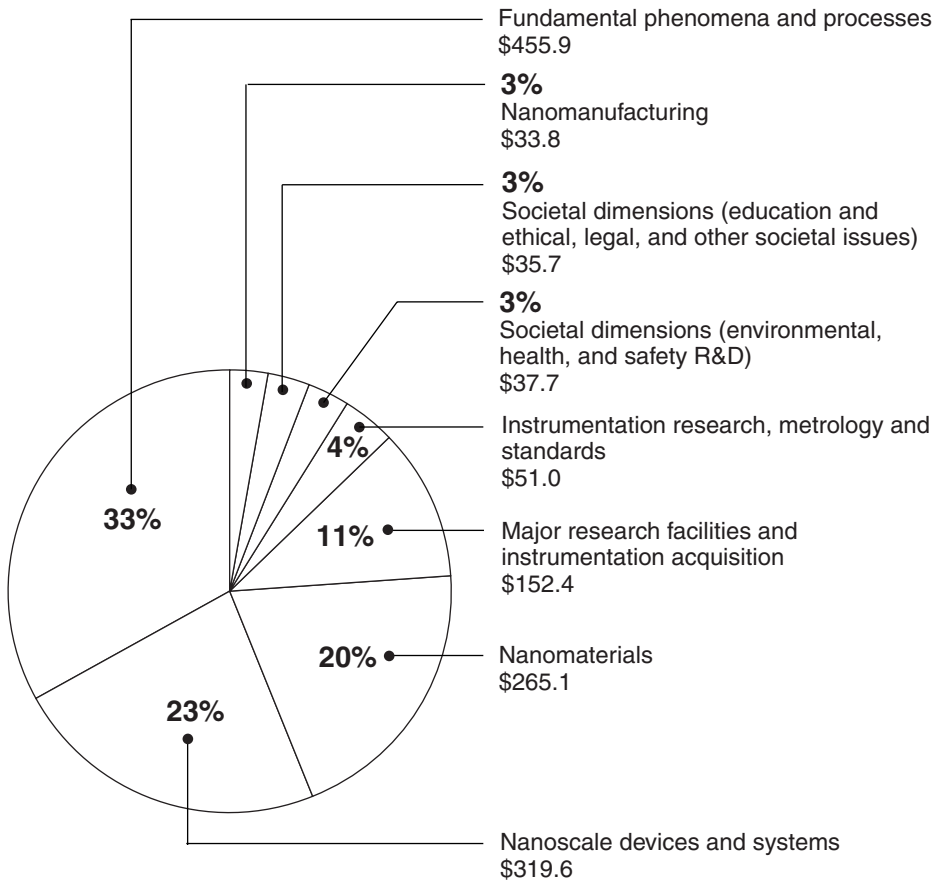
[5]The nine grand challenges were as follows: nanostructured materials by design; manufacturing at the nanoscale; chemical-biological-radiological-explosive detection, and protection; nanoscale instrumentation and metrology; nano-electronics, -photonics, and -magnetics; healthcare, therapeutics, and diagnostics; efficient energy conversion and storage; microcraft and robotics; and nanoscale processes for environmental improvement.

[6]The NNI's four goals are to (1) maintain a world-class research and development program aimed at realizing the full potential of nanotechnology; (2) facilitate transfer of new technologies into products for economic growth, jobs, and other public benefit; (3) develop educational resources, a skilled workforce, and the supporting infrastructure and tools to advance nanotechnology; and (4) support responsible development of nanotechnology.

[7]The seven program component areas are fundamental nanoscale phenomena and processes; nanomaterials; nanoscale devices and systems; instrumentation research, metrology, and standards for nanotechnology; nanomanufacturing; major research facilities and instrumentation acquisition; and societal dimensions.

subareas—research on environmental, health, and safety; and education and research on ethical, legal, and other societal aspects of nanotechnology. The EHS portion of the societal dimensions PCA accounted for over $37 million in fiscal year 2006. See figure 3 for a break out of research funds used, by PCA.

Figure 3: Nanotechnology Research Funding by Program Component Area, Fiscal Year 2006



Source: GAO analysis of NNI budget data.

PCAs are intended to provide a means by which the NSET subcommittee, OSTP, the Office of Management and Budget (OMB), Congress, and others may be informed of the relative federal investment in these key areas. PCAs also provide a structure by which the agencies that fund research

and development can better direct and coordinate their activities. In response to increased concerns about the potential EHS risks of nanotechnology, in fiscal year 2005, the NSET subcommittee and the agencies agreed to separately report their research funding for each of the two components of the societal dimensions PCA. The December 2007 update of the NNI's strategic plan reaffirmed the program's goals, identified steps to accomplish those goals, and formally divided the societal dimensions PCA into two separate PCAs—"environment, health, and safety" and "education and societal dimensions."

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

Almost 20 Percent of EHS Research Projects Were Not Primarily Focused on Studying the EHS Risks of Nanotechnology

Although the NNI reported that federal agencies in fiscal year 2006 devoted $37.7 million—or about 3 percent of the total of all nanotechnology research funding—to research that primarily focused on studying the EHS risks of nanotechnology, we found that about 18 percent of the EHS research reported by the NNI cannot actually be attributed to this purpose. This was largely due to a reporting structure that did not lend itself to categorizing particular types of projects and limited guidance provided to the agencies by the NNI on how to consistently report EHS research. In addition to research reported as being primarily focused on the EHS risks of nanotechnology, some agencies conduct research that is not reflected in the EHS totals provided by the NNI either because they are not considered federal research agencies or because the primary purpose of the research was not to study EHS risks.

EHS Research Constituted about 3 Percent of Federal Nanotechnology Research Funding in Fiscal Year 2006

Overall, 3 percent—or $37.7 million—of the approximately $1.3 billion dedicated for nanotechnology research funding in fiscal year 2006 was reported as being devoted to studying the EHS risks of nanotechnology. Our review of data on agency funding for 119 projects that were underway in fiscal year 2006 largely confirmed the figures reported by the NNI. Specifically, all but one of the five individual agencies reported the same or greater funding to us than what the NNI reported for fiscal year 2006. EPA reported slightly less to us than it did to the NNI. Largely these discrepancies resulted from timing differences in the date the NNI needed the data and the date agency officials finalized their review of fiscal year spending. For example, NIOSH reported $470,000 more to us because it had not included funding for a few projects in its report to the NNI, according to agency officials. Other differences resulted from rounding.

As would be expected, our review of the descriptive information on EHS projects found that those agencies with missions directly related to protecting the environment or human health and safety devoted a greater percentage of their nanotechnology research budgets to studying EHS risks. For example, in fiscal year 2006, NIOSH reported devoting 100 percent of its fiscal year 2006 nanotechnology research funds to support 23 projects to study EHS risks. These projects focused primarily on worker safety and exposure, such as gathering data on workplace exposure to nanomaterials and evaluating the extent to which particle size affects the toxicity of inhaled nanomaterials. Similarly, EPA reported devoting 82 percent of its nanotechnology research budget to study EHS risks. This research included human health-focused projects to examine the toxicity of manufactured nanomaterials at the molecular and cellular level, as well as environmentally focused projects to evaluate how nanomaterials disperse and change under different environmental conditions and the extent to which nanomaterials accumulate in the bodies of various animal species.

In contrast, we found that agencies with broader missions devoted a smaller portion of their nanotechnology research funds to study EHS issues. For example, NIST, an agency oriented toward measurement science and standards, dedicated 3 percent of its nanotechnology research budget to EHS risks in fiscal year 2006. The majority of its research funding focused on such PCAs as fundamental phenomena and processes; nanoscale devices and systems; and instrumentation research, metrology, and standards. Similarly, NSF dedicated 6 percent of its fiscal year 2006 nanotechnology research funds on research related to EHS risks as compared with 41 percent focused on fundamental phenomena and processes.

In fiscal year 2008, funding for both EHS-related research and nanoscale research in general is projected to grow. Overall nanotechnology research is projected to increase in fiscal year 2008 to about $1.4 billion, or an increase of 20 percent over fiscal year 2005 figures. Funding for EHS-related research is expected to increase to approximately $59 million, an increase of 68 percent over fiscal year 2005 levels. As a result, EHS research would grow to about 4 percent of projected nanotechnology research in fiscal year 2008.

Current Reporting Structure and Limited Guidance Contribute to Inaccurate Reporting of EHS Risk Research

About 18 percent of the total research dollars reported by the agencies as being primarily focused on the study of nanotechnology-related EHS risks in fiscal year 2006 cannot actually be attributed to this purpose. Specifically, our analysis found that 22 of the 119 projects funded by five federal agencies were not primarily related to studying EHS risks. These 22 projects accounted for about $7 million of the total that the NNI reported as supporting research primarily focused on EHS risks. Almost all of these projects—20 out of 22—were funded by NSF, with the two additional projects funded by NIOSH. See table 2 for our analysis of the nanotechnology research projects reported as being primarily focused on EHS risks.

Table 2: GAO Analysis of the Number and Dollar Value of Nanotechnology Research Projects Reported by Selected Agencies as Being Primarily Focused on Environmental, Health, and Safety Risks, Fiscal Year 2006

(Dollars in millions)

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

Source: GAO analysis of agency obligations data.

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

We found that the primary purpose of many of these 22 projects was to explore ways to use nanotechnology to remediate environmental damage or to identify environmental, chemical, or biological hazards. For example, a number of NSF projects explored the use of nanotechnology to improve water or gaseous filtration systems. In other cases, NSF-funded research was targeted toward developing nanotechnology-based applications to remediate soil or water contamination. In addition, many of the projects NSF reported as having a primary purpose to study EHS risks were part of its efforts to build a national research infrastructure capable of supporting a wide range of nanotechnology-related research. Specifically, NSF sponsors 16 Nanoscale Science and Engineering Centers, many of which devote a portion of their research efforts to EHS risk-related projects. In these cases, NSF apportioned a segment of the Center funding to the EHS category to account for this research. At NIOSH, both projects that we identified as not being primarily focused on studying EHS risks were focused on using nanotechnology to mitigate workplace risks, such as developing advanced sensors that incorporate nanotechnology to detect the presence of toxic gases in the workplace.

We found that the miscategorization of these 22 projects resulted largely from a reporting structure for nanotechnology research that does not easily allow agencies to recognize projects that use nanotechnology to improve the environment or enhance the detection of environmental contaminants, and from the limited guidance available to the agencies on how to consistently report EHS research. From fiscal years 2001 to 2004, the NSET subcommittee categorized federal research and development activities into nine categories, known as "grand challenges," that included one focused on "nanoscale processes for environmental improvement." Agencies funded and researchers initiated work on many of these 22 projects under the grand challenges categorization scheme. Starting in fiscal year 2005, NSET adopted a new categorization scheme for agencies to report their nanotechnology research. The new scheme, which was based on PCAs, eliminated the environmental improvement applications research category. Instead, agencies were asked to fund and report research designed to address or understand the risks associated with nanotechnology, as part of the societal dimensions PCA. In essence, the new scheme shifted the focus from applications-oriented research to research focused on the EHS implications of nanotechnology. However, under the new scheme, agencies no longer had a way to categorize environmentally focused research that had been initiated. As a result, NSF and NIOSH characterized these projects as EHS focused for lack of a more closely related category to place them in, according to program managers. Furthermore, neither NSET nor OMB provided agencies guidance on to

how to apportion the dollars for a single project to more than one program component area, when appropriate. This is especially significant for broad, multiphase research projects, such as NSF's support to develop networks of research facilities with the capability to address a range of nanotechnology-related topics. Of the five agencies we reviewed, only NSF apportioned funds for a single project to more than one PCA.

Agencies Conduct Additional Research that Also Helps Advance Scientific Knowledge of Potential EHS Risks

In addition to research reported to the NNI as being primarily focused on the EHS risks of nanotechnology, some agencies conduct research that is not reflected in the EHS totals provided by the NNI either because they are not considered federal research agencies or because the primary purpose of the research was not to study EHS risks. For example, FDA, which does not have a specific research budget and does not generally track nanotechnology research spending, used a portion of its operating funds in fiscal years 2004 through 2007 to undertake 15 research projects to evaluate the potential health risks of nanomaterials in the products that it regulates. One such project focused on sunscreens that contain nanosized particles of titanium dioxide to better understand their potential to be absorbed into the body through the skin. Another project is designed to study the toxicological and immunological responses to nanoparticles that may be used in therapeutic drugs. A fundamental understanding of potential risks will help FDA develop guidance and make future regulatory decisions regarding the manufacture and use of FDA-regulated products using these materials, according to program managers.

In addition, as noted in the NNI's annual Supplement to the President's Budget, some agencies conduct research that results in information highly relevant to EHS risks but that was not primarily directed at understanding or addressing those risks and therefore is not captured in the EHS total. For example, NIH has research underway to develop drug delivery mechanisms that use nanotechnology. While the primary purpose of such research is to develop medical applications using nanotechnology, the research also provides information on how toxic the nanomaterials are, whether they accumulate in body tissues, and how they interact with the body at the cellular and molecular level. Agencies report funding data for such research in other PCAs, such as nanoscale devices and systems, rather than the EHS area. In addition, NIST conducts an array of nanotechnology research to accurately quantify the properties of nanomaterials and determine their size, shape, and chemical composition. This type of information is needed to understand and measure nanomaterials to ensure safe handling and protection against potential health or environmental hazards. However, NIST reports the funding data

for such research under other PCAs such as instrumentation research, metrology, and standards.

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

Ongoing agency and NEHI working group efforts to identify and prioritize needed research related to the potential EHS risks of nanotechnology appear reasonable but have not as yet resulted in a comprehensive research strategy to guide EHS research across agencies. We found that the EHS risk research undertaken in fiscal year 2006 addressed a range of EHS topics, was generally consistent with both agency- and NEHI-identified research priorities, and focused on the priority needs within each category to varying degrees.

Agencies Have Identified Their EHS Research Priorities

We determined that each agency's nanotechnology research priorities generally reflect its mission. For example, the priorities identified by FDA and CPSC are largely focused on the detection and safety of nanoparticles in the commercial products they regulate. On the other hand, EHS research priorities identified by NSF reflect its broader mission to advance science in general, and include a more diverse range of priorities, such as the safety and transport of nanomaterials in the environment, and the safety of nanomaterials in the workplace.

All eight agencies in our review have processes in place to identify and prioritize the research they need related to the potential EHS risks of nanotechnology. Most agencies have developed task forces or designated individuals to specifically consider nanotechnology issues and identify priorities, although the scope and exact purpose of these activities differ by agency. EPA, for example, formed a Nanomaterial Research Strategy Team to craft a long-term, focused plan to guide all of the agency's nanotechnology research. The strategy, which identifies EPA's research priorities around four key themes and seven scientific questions, is based in part on the agency's 2007 "Nanotechnology White Paper" that described scientific issues the agency should consider to help ensure safe development of nanotechnology and to understand the potential risks. At other agencies, particularly those that have little or no funding for nanotechnology research, specific individuals throughout the agency have

been tasked to identify and prioritize EHS research needs. For example, CPSC has assigned individual staff responsible for different aspects related to consumer product safety, such as health scientists, to monitor trends in the use of nanomaterials in such products, which helps inform the agency's nanotechnology research priorities. Once identified, agencies communicate their EHS research priorities to the public and to the research community in a variety of ways, including publication in agency documents that specifically address nanotechnology issues, agency strategic plans or budget documents, agency Web sites, and presentations at public conferences or workshops.

NNI's Efforts to Prioritize Research Needs Are Ongoing

In addition to the efforts of individual agencies, the NSET subcommittee has engaged in an iterative prioritization process through its NEHI working group, although this process is not yet complete. First, in 2006, NEHI identified but did not prioritize five broad research categories and 75 more specific subcategories of needs where additional information was considered necessary to further evaluate the potential EHS risks of nanotechnology.[8] The report identified these five general research categories as (1) Instrumentation, Metrology, and Analytical Methods; (2) Nanomaterials and Human Health; (3) Nanomaterials and the Environment; (4) Health and Environmental Exposure Assessment; and (5) Risk Management Methods.[9] Second, following efforts to obtain public input on its 2006 report, NEHI released another report in August 2007,[10] in which it distilled the previous list of 75 unprioritized specific research needs into a set of five prioritized needs for each of the five general research categories.[11]

[8]NSTC, Committee on Technology, Subcommittee on Nanoscale Science, Engineering, and Technology, "Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials," Sept. 20, 2006.

[9]The Health and Environmental Exposure Assessment category was initially named Health and Environmental Surveillance.

[10]NSTC, Committee on Technology, Subcommittee on Nanoscale Science, Engineering, and Technology, NEHI Working Group, "Prioritization of Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials: An Interim Document for Public Comment," Aug. 16, 2007.

[11]The five specific needs for the Nanomaterials and Human Health category were all afforded the same top priority.

The NEHI working group has used these initial steps to identify the gaps between the needs and priorities it has identified and the research that agencies have underway. According to agency and NNI officials, once this gap analysis is complete, NEHI will formulate a long-term, overarching EHS research strategy. According to the August 2007 report, the proposed strategy will list NEHI's final research priorities, describe current federal EHS research, document the unmet needs, identify opportunities for interagency collaboration, and establish a process for periodic review. As envisioned, the EHS research strategy will serve as guidance for individual agencies as they develop their own research agendas and make funding decisions. NEHI plans to complete this overarching research strategy and issue a report in early 2008, according to NNI officials.

Agencies' and the NNI's Prioritization Processes Appear Reasonable

Despite the fact that a comprehensive research strategy for EHS research has yet to be finalized, the prioritization processes taking place within individual agencies and the NNI appear so far to be reasonable. Numerous agency officials said their agency's EHS research priorities were generally reflected both in the NEHI working group's 2006 research needs and 2007 research prioritization reports. Our comparison of agency nanotechnology priorities to the NNI's priorities corroborated their statements. Specifically, we found that all but one of the research priorities identified by individual agencies could be linked to one or more of the five general research categories. For example, OSHA's need for toxicity data and information related to exposure is reflected in the two general research categories of Health and Environmental Exposure Assessment and Nanomaterials and Human Health. According to agency officials, the alignment of agency priorities with the general research categories is particularly beneficial to the regulatory agencies, such as CPSC and OSHA, which do not conduct their own research, but rely instead on research agencies for data to inform their regulatory decisions.

In addition, we found that the primary purposes of agency projects underway in fiscal year 2006 were generally consistent with both agency priorities and the NEHI working group's research categories. Of these 97 projects, 43 were focused on Nanomaterials and Human Health, including all 18 of the projects funded by NIH. In addition, EPA, NIOSH, and NSF each undertook research for this general research category. EPA and NSF funded all 25 projects related to Nanomaterials and the Environment. These two general research categories accounted for 70 percent of all projects focused on EHS risks. Reflective of its relatively large EHS research budget and broad mission, NSF sponsored projects in each of the five general research categories. In contrast, all the research projects NIST

sponsored were related to Instrumentation, Metrology, and Analytical Methods.

Agency research addressed each of the five general research categories and focused on the priority needs within each category to varying degrees. With the exception of the Human Health category, for which all specific needs were considered a top priority, 43 percent of projects addressed the two highest-priority needs in each category and 37 percent addressed the two lowest-priority needs. For example, 8 of the 11 projects in the Instrumentation, Metrology, and Analytic Methods category focused on the highest-priority need to "develop methods to detect nanomaterials in biological matrices, the environment, and the workplace." In contrast, of the 25 projects related to Nanomaterials and the Environment, 3 addressed the highest-priority need in the category—"understand the effects of engineered nanomaterials in individuals of a species and the applicability of testing schemes to measure effects"—and 11 addressed the fourth-ranked priority—"determine factors affecting the environmental transport of nanomaterials." Moreover, although the NEHI working group considered the five specific research priorities related to human health equally important, 19 of the 43 projects focused on a single priority—"research to determine the mechanisms of interaction between nanomaterials and the body at the molecular, cellular, and tissular levels." See table 3 for a summary of projects by agency and specific NEHI research priority.

Table 3: Research Primarily Focused on the Environmental, Health, and Safety Risks of Nanotechnology by Agency and Specific Nanotechnology Environmental and Health Implications Working Group Research Priority

	EPA	NIH	NIOSH	NIST	NSF	Total
Instrumentation, Metrology, and Analytical Methods	**0**	**0**	**1**	**2**	**8**	**11**
1. Develop methods to detect nanomaterials in biological matrices, the environment, and the workplace				1	7	8
2. Understand how chemical and physical modifications affect the properties of nanomaterials						0
3. Develop methods for standardizing assessment of particle size, size distribution, shape, structure, and surface area			1	1		2
4. Develop certified reference materials for chemical and physical characterization of nanomaterials						0
5. Develop methods to characterize a nanomaterial's spatio-chemical composition, purity, and heterogeneity					1	1
Nanomaterials and Human Health	**4**	**18**	**10**	**0**	**11**	**43**
1. Develop methods to quantify and characterize exposure to nanomaterials and characterize nanomaterials in biological matrices[a]	1	1	4		2	8

	EPA	NIH	NIOSH	NIST	NSF	Total
2. Understand the absorption and transport of nanomaterials throughout the human body[a]	1	1			2	4
3. Establish the relationship between the properties of nanomaterials and uptake via the respiratory or digestive tracts or through the eyes or skin, and assess body burden[a]		5	3		1	9
4. Determine the mechanisms of interaction between nanomaterials and the body at the molecular, cellular, and tissular levels[a]	1	10	3		5	19
5. Identify or develop appropriate *in vitro* and *in vivo* assays/models to predict in vivo human responses to nanomaterials exposure[a]	1	1			1	3
Nanomaterials and the Environment	**5**	**0**	**0**	**0**	**20**	**25**
1. Understand the effects of engineered nanomaterials in individuals of a species and the applicability of testing schemes to measure effects	1				2	3
2. Understand environmental exposures through identification of principle sources of exposure and exposure routes					1	1
3. Evaluate abiotic and ecosystem-wide effects					6	6
4. Determine factors affecting the environmental transport of nanomaterials	2				9	11
5. Understand the transformation of nanomaterials under different environmental conditions	2				2	4
Health and Environmental Exposure Assessment	**0**	**0**	**3**	**0**	**2**	**5**
1. Characterize exposures among workers			2		1	3
2. Identify population groups and environments exposed to engineered nanoscale materials						0
3. Characterize exposure to the general population from industrial processes and industrial and consumer products containing nanomaterials						0
4. Characterize health of exposed populations and environments						0
5. Understand workplace processes and factors that determine exposure to nanomaterials			1		1	2
Risk Management Methods	**1**	**0**	**7**	**0**	**5**	**13**
1. Understand and develop best workplace practices, processes, and environmental exposure controls			4		2	6
2. Examine product or material life cycle to inform risk reduction decisions	1				1	2
3. Develop risk characterization information to determine and classify nanomaterials based on physical or chemical properties			1		2	3
4. Develop nanomaterial-use and safety-incident trend information to help focus risk management efforts						0
5. Develop specific risk communication approaches and materials			2			2
Total	**10**	**18**	**21**	**2**	**46**	**97**

Source: GAO analysis of agency data.

[a]Priorities given equal weight.

Despite the fact that the NEHI working group's priorities reflect individual agency priorities, some environmental and industry groups have called for a more top-down and directed approach to the NNI's prioritization efforts. In various congressional testimonies and in written comments on the NEHI working group's draft reports, some groups have suggested that the NNI adopt a stronger, more autonomous role in setting the federal EHS research agenda. Some of these groups suggest that the NNI should have the authority to direct participating agencies to undertake research in specific EHS areas, its own budget authority, and the ability to shift EHS research dollars among the agencies. Proponents believe that this more centralized approach would help ensure that a cohesive EHS research strategy is implemented in a timely manner and that sufficient resources are dedicated to the highest-priority research.

However, such a strategy may not be consistent with historical approaches used to set federal research priorities and would be difficult to implement given how federal research currently is funded. Federal expenditures for research and development are regular budget items and are contained, along with other types of expenditures, within the budgets of more than 20 federal agencies. For some of these agencies, research is a major activity, and for others, it is a smaller part of a much larger set of programs. Centralizing nanotechnology research expenditures in a single existing agency or new agency would be difficult to achieve. In addition, agency officials we spoke with were generally satisfied with the current bottom-up, consensus-based approach. Moreover, they said the process has benefited from the in-depth expertise each agency has developed. For example, NIH played a large role in shaping the priorities for Nanomaterials and Human Health; NIST was heavily involved with Instrumentation, Metrology, and Analytical Methods; and NIOSH was a major contributor to the development of priorities for Health and Environmental Exposure Assessment. Some officials acknowledged that while the current approach has limitations, it benefits from the input of a broader range of stakeholders. According to one official, information bubbles up through the NNI structure and is utilized to inform and create a top-down vision, which then serves to guide agency funding decisions.

Coordination Processes Have Fostered Interagency Collaboration and Information-Sharing

Agency and NNI processes to coordinate research and other activities related to the potential EHS risks of nanotechnology have been generally effective, and have resulted in numerous interagency collaborations. In fact, all eight agencies in this review have collaborated on multiple occasions with other NEHI-member agencies on activities related to the EHS risks of nanotechnology. These EHS-related activities are consistent with the expressed goals of the larger NNI—to promote the integration of federal efforts through communication, coordination, and collaboration. The NEHI working group is at the center of this effort. Regular NEHI working group meetings, augmented by informal discussions, have provided a venue for agencies to exchange information on a variety of topics associated with EHS risks, including their respective research needs and opportunities for collaborations.

Interagency collaboration has taken many forms, including joint sponsorship of EHS-related research and workshops, the detailing of staff to other NEHI working group agencies, and various other general collaborations or memoranda of understanding. For example, FDA, NIST, and NIH's Nanotechnology Characterization Laboratory have initiated formal agreements to collaborate on research to characterize the physical and biological properties of nanomaterials used in cancer diagnosis and treatment.[12] An FDA official said that this arrangement was developed primarily through discussions that occurred as a result of the agencies' participation in NEHI. Participation in NEHI has helped facilitate other types of interagency collaborations including a 2007 memorandum of understanding between EPA and NSF to create and fund research at a virtual Center for the Environmental Implications of Nanotechnology, detailing a CPSC toxicologist to a research laboratory office at EPA, and sponsoring international conferences on nanotechnology and occupational health by all NNI agencies, led by NIOSH, in 2005, 2006, and 2007. See table 4 for more examples of interagency collaboration.

[12]The Nanotechnology Characterization Laboratory is part of NIH's National Cancer Institute.

Table 4: Examples of Agency Collaborations Related to Potential EHS Risks of Nanotechnology

General Collaborations
• NIH's National Characterization Laboratory, in partnership with FDA and NIST, is developing characterization methods to evaluate nanomaterials intended for cancer treatments.
• EPA and NSF signed a memorandum of understanding to create and fund research at a virtual Center for the Environmental Implications of Nanotechnology.
• CPSC, FDA, NIH, and NIOSH have participated collaboratively on the Toxicological Evaluation of Nanoscale Materials program within the National Toxicology Program.
• NIOSH and OSHA have collaborated to develop guidelines for working with engineered nanomaterials.
• NIH and NIST have collaborated to characterize properties of nanoparticles commonly used in sunscreen lotions.
• Staff from NIST and CPSC have been detailed to other NNI agencies.
Grant Solicitations
• EPA, NIH, NIOSH, and NSF have issued interagency competitive grant announcements through EPA's Science to Achieve Results program to address various environmental and health implications of nanotechnology.
• EPA, NIH, and NIOSH have developed an interagency Funding Opportunity Announcement to investigate the biocompatibility and toxicity of industrial nanomaterials in mammals.
• EPA and NIOSH have funded research on the dispersion of nanoscale particulate aerosols.
Workshops
• NIOSH and other NNI agencies have sponsored international conferences on nanotechnology and occupational health in 2005, 2006, and 2007.
• NSF has facilitated meetings for NSF grantees on the EHS aspects of nanotechnology with participation from other NNI agencies.

Source: GAO.

Furthermore, the NEHI working group has adopted a number of practices GAO has previously identified as essential to helping enhance and sustain collaboration among federal agencies.[13] For example, NEHI's 2005 "Terms of Reference" clearly defined its purpose and objectives and delineated roles and responsibilities for group members. Furthermore, collaboration through multiagency grant announcements and jointly sponsored workshops has served as a mechanism to leverage limited resources to achieve increased knowledge about potential EHS risks. Despite the general effectiveness of its collaboration efforts, the NEHI working group has not yet completed an overarching strategy to help align the agencies' EHS research efforts. A completed strategy, combined with the results of the research needs prioritization process, also will serve as a means to monitor, evaluate, and report on the progress of meeting EHS research needs. In the meantime, the NNI's annual Supplements to the President's

[13]GAO, *Results-Oriented Government: Practices That Can Help Enhance and Sustain Collaboration among Federal Agencies*, GAO-06-15 (Washington, D.C.: Oct. 21, 2005).

Budget have described the agencies' activities related to EHS issues, among other things, and provided a mechanism to reinforce agency accountability and performance.

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

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

Conclusions

Nanotechnology is likely to affect many aspects of our daily lives in the future as novel drug delivery systems, improved energy storage capabilities, and stronger, lightweight materials are developed and made available to the public. However, for a technology that may become

ubiquitous, it is essential to consider the potential risks of using nanotechnology in concert with its potential benefits. The first steps are to identify what is not known about the properties of nanomaterials and what must be known about how these materials interact with our bodies and our environment. The NNI, through its NEHI working group, has begun a process to identify and prioritize both the research needed to better understand potential EHS risks and the gaps between what research is underway and the highest-priority needs. Essential to this process is consistent, accurate, and complete information on the amount of agency research designed to address and understand EHS risks. However, this information is not currently available because the totals reported by the NNI include research that is more closely related to uses of nanotechnology, rather than the risks nanotechnology may pose. Furthermore, agencies currently have limited guidance on how to report projects with more than one research focus across program component areas, when appropriate. As a result, the inventory of projects designed to address these risks is inaccurate and cannot ensure that agencies direct their future research investments appropriately.

Recommendation for Executive Action

We recommend that the Director, OSTP, in consultation with the Director, NNCO, and the Director, OMB, provide better guidance to agencies regarding how to report research that has a primary focus to understand or address environmental, health, and safety risks of nanotechnology.

Agency Comments and Our Evaluation

We provided CPSC, FDA, EPA, NIH, NIOSH, NIST, NSF, OSHA, and OSTP with a copy of this report for review and comment. OSTP generally concurred with the report's findings and agreed to review the manner in which agencies respond to the current guidance at future NSET meetings. In addition, the Department of Health and Human Services, on behalf of FDA, NIH, and NIOSH, said that the report clearly addressed the three charges that GAO was given and they provided technical comments which we incorporated as appropriate. In its comments, NIST said the report was fair and balanced. EPA, CPSC, NSF, and OSHA neither agreed nor disagreed with our report, and EPA and CPSC provided technical comments that we incorporated as appropriate. See appendices I, II, and III for agency comment letters from OSTP, HHS, and NIST, respectively.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to interested congressional

committees and Members of Congress, the Secretary of Commerce, Secretary of Health and Human Services, the CPSC Commissioner, the EPA Administrator, the FDA Commissioner, the NIH Director, the NIOSH Director, the NIST Director, the NSF Director, the OSHA Administrator, and the OSTP Director. We will also make copies available to others upon request. In addition, the report will be available at no charge on the GAO Web site at http://www.gao.gov.

If you or your staffs have questions about this report, please contact me at (202) 512-3841 or mittala@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix IV.

Anu K. Mittal
Director, Natural Resources and Environment

Appendix I: Comments from the Office of Science and Technology Policy

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF SCIENCE AND TECHNOLOGY POLICY
WASHINGTON, D.C. 20502

March 3, 2008

Ms. Anu Mittal
Director of Natural Resources and Environment
U.S. Government Accountability Office
441 G. Street N.W.
Washington, D.C. 20548

Dear Ms. Mittal:

Thank you for the opportunity to comment on the GAO's proposed report on Federally supported nanotechnology-related environmental, health, and safety research (GAO-08-402).

Generally, the Office of Science and Technology Policy (OSTP) agrees with the report's findings and is pleased that the GAO found interagency coordination and prioritization of nanotechnology EHS research to be effective and reasonable. OSTP is particularly pleased that the GAO noted one of the strengths of the government's interagency coordination lies in the knowledgeable and dedicated Federal employees that work in this area.

With respect to GAO's finding that a fraction of NNI-identified EHS research projects is not primarily focused on EHS risks, OSTP acknowledges that this budget cross-cut is open to reasonable, different interpretations. These illustrate the challenges associated with attempting to categorize fundamental, knowledge-creating research and to determine to what degree such research is related to EHS. Nonetheless, while GAO's presumption in the process recommendation—that more accurate reporting will better support program planning and policy development—is correct in principle, it does not follow that marginal differences in individual agency reporting negatively affect interagency coordination and prioritization or agency-level implementation of nanotechnology EHS research. This is borne out by GAO's own findings in this report.

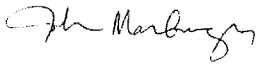
OSTP, the Office of Management and Budget (OMB), and the National Nanotechnology Coordinating Office (NNCO) already provide extensive detailed guidance for reporting nanotechnology research, particularly for EHS—more guidance, in fact, than perhaps any other area of Federally-funded research and development. This guidance is based directly on program component area designations established in the National Nanotechnology Initiative Strategic Plan by the interagency Subcommittee on Nanoscale Science, Engineering, and Technology (NSET) of the National Science and Technology Council. As with all agency reporting, we fundamentally rely on the expert judgment of the program managers at the agency level.

Ms. Anu Mittal – Page 2

In the aggregate, the data that are currently reported provide sufficient and clear perspective and are just one of many key inputs to guide coordination, program planning and future directions. Therefore, OSTP does not agree that more detailed reporting guidance will result in better coordination of nanotechnology EHS research. However, given the GAO's findings, OSTP will discuss the manner in which agencies respond to current guidance at future NSET meetings.

Thank you for the opportunity to comment. OSTP appreciates GAO's efforts to fully understand the NNI and NSET interagency coordination process, and generally agrees with the report's overall assessments.

Sincerely,



John H. Marburger, III
Director

Appendix II: Comments from the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Assistant Secretary for Legislation

Washington, D.C. 20201

FEB 29 2008

Ms. Anu Mittal
Director, Natural Resources
and Environment
U.S. Government Accountability Office
Washington, DC 20548

Dear Ms. Mittal:

Enclosed are the Department's comments on the U.S. Government Accountability Office's (GAO) draft report entitled: Nanotechnology: Better Guidance Is Needed to Ensure Accurate Reporting of Federal Research Focused on Environmental, Health, and Safety Risks (GAO 08-402).

The Department appreciates the opportunity to review and comment on this draft report before its publication.

Sincerely,

for Jennifer R. Cleary

Vince Ventimiglia
Assistant Secretary for Legislation

GENERAL COMMENTS OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE U.S. GOVENRMENT ACCOUNTABILITY OFFICE'S DRAFT (GAO) DRAFT REPORT ENTITLED: "NANOTECHNOLOGY: BETTER GUIDANCE IS NEEDED TO ENSURE ACCURATE REPORTING OF REDERAL RESEARCH FOCUSED ON ENVIRONMENTAL, HEALTH, AND SAFETY RISKS "(GAO-08-402)

The report clearly addresses the three charges that GAO was given, but in finding that there were some misclassifications of "applications" projects as "implications," the report could have focused more on the adequacy of funding for research on environmental and occupational health and safety implications. Additionally, the report does not distinguish funding derived from NNI allocations and funding resulting if an agency reprograms non NNI internal funds.

The report does not discuss the activities of OSHA regarding occupational health risks.

Appendix III: Comments from the National Institute of Standards and Technology

UNITED STATES DEPARTMENT OF COMMERCE
National Institute of Standards and Technology
Gaithersburg, Maryland 20899-0001
OFFICE OF THE DIRECTOR

FEB 2 1 2008

MEMORANDUM FOR Anu Mittal
Director, Natural Resources and Environment
Government Accountability Office

From: James M. Turner, Ph.D.
Acting Director

Subject: Comments on Government Accountability Office (GAO) Draft Report Entitled "NANOTECHNOLOGY: Better Guidance is Needed to Ensure Accurate Reporting of Federal Research Focused on Environmental, Health, and Safety Risks" (GAO-08-402)

This is in response to your draft report dated March 2008 entitled "NANOTECHNOLOGY: Better Guidance is Needed to Ensure Accurate Reporting of Federal Research Focused on Environmental, Health, and Safety Risks." Thank you for the opportunity to review and comment on this draft.

Overall, the draft report is fair and balanced. The report does not, however, explicitly incorporate changes requested by the National Institute of Standards and Technology (NIST) to elucidate the relatively large size of nanotechnology Environmental Health and Safety (EHS) - *enabling* NIST research compared to the small size of explicitly nanotechnology EHS - *focused* Program Component Area (PCA) 7A research.

The report accurately notes that "Some agencies conduct research that results in information highly relevant to EHS risks but that this research was not primarily directed at understanding, or addressing, those risks and therefore is not captured in the EHS total." Further, the report gives two detailed examples of research resulting in information highly relevant to EHS risks, and included NIST in these examples. I appreciate the recognition of this situation and agree with the findings.

I am committed to ensuring that NIST continues to provide technically sound and timely standards support to the National Nanotechnology Initiative (NNI).

We are looking forward to receiving your final report. Please contact Steve Willett on (301) 975-8707 should you have any questions regarding this response.

NIST

Appendix IV: GAO Contact and Staff Acknowledgments

GAO Contact

Anu Mittal, 202-512-3841 or mittala@gao.gov

Staff Acknowledgments

In addition to the contact person named above, Cheryl Williams (Assistant Director), Nancy Crothers, Elizabeth Erdmann, David Lutter, and Rebecca Shea made key contributions to this report.

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