Order Code RS20589
Updated August 2, 2007

CRS Report for Congress

Manipulating Molecules: Federal Support for Nanotechnology Research

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Summary

The Bush Administration requested $1.447 billion for nanotechnology research in FY2008, a $56 million increase over the estimated $1.391 billion for FY2007. (See **Table 1**.) Nanotechnology is a newly emerging field of science where scientists and engineers are beginning to manipulate matter at the molecular and atomic levels in order to obtain materials and systems with significantly improved properties. Ten nanometers is equal to one-ten thousandth the diameter of a human hair. Proponents of this technology argue that nanotechnology will lead to a new industrial revolution in the 21st century. Scientists note that nanotechnology is still in its infancy, with large scale practical applications 10 to 30 years away. Congressional concerns include the distribution of Program Component Area funding levels, the potential environmental and health concerns associated with the development and deployment of nanotechnology, and the role of the Food and Drug Administration as nano products move into the marketplace.

Introduction

As indicated in **Table 1**, the Administration requested $1,447 billion for nanotechnology research in FY2008, a 4% increase over the FY2007 estimated funding level of $1.391billion. Nanotechnology[1] is the creation and utilization of materials, devices, and systems with novel properties and functions through the control of matter atom by atom, or molecule by molecule. Such control takes place on a scale of a fraction of a nanometer to tens of nanometers. Ten nanometers is equal to one-ten thousandth the diameter of a human hair. Academic and industry scientists working in this field contend that research in nanoscience will lead to revolutionary breakthroughs in such areas as medicine, manufacturing, materials, construction, computing, and telecommunications. Within a short period of time, nanotechnology has expanded from an obscure research

[1] For purposes of this report, the term "nano" can be applied to technology, measurement, science, or other research fields. The size of an average virus is equal to one nanometer (nm).

obsession to a worldwide scientific and industrial enterprise. According to the National Science Foundation (NSF), by 2015 nanotechnology will have grown to a $1 trillion enterprise, with over 500 marketed products made at the nanoscale or with engineered nanomaterials. The marriage of nano and biotechnology has been projected to create a whole new generation of drugs, biomedical devices, and other solutions to some of our most challenging medical problems.[2] However, according to F. Mark Modzelewski, founder of the Nano Business Alliance, what researchers can do to control and manipulate atoms and molecules is still limited. Nevertheless, despite being at the early stages of nano development, more than 1200 companies conduct nanotechnology Research and Development (R&D). They vary from startups such as Nano-Tex, a company that developed anti- wrinkle chemicals for textiles, to large corporations like General Electric and Hewlett-Packard. Recent developments in nano have helped IBM develop computer hard drives that store one hundred times more data than older models. Another company has discovered a process to develop cheaper and easier-to-use solar cells, while still another firm is utilizing nanoparticles to improve screens for phones. Matthew M. Nordan, President of Lux Research Inc., noted that sales of products that incorporate nanotech amounted to $32 billion in 2005.[3]

In September of 2006, the National Research Council (NRC) released its first triennial evaluation of the National Nanotechnology Initiative. The report noted that the federal R&D programs are intended to advance the boundaries of the knowledge and development technologies that address government and national needs. The committee concluded that the development of the goals articulated in the NNI's strategic plan, and establishment of the related program component areas are an important outcome of the NNI that has had a positive impact on the allocation of federal support to the fields and disciplines that make up nanotechnology initiative.[4]

Nanotechnology and the Federal Role

In FY2004, the Bush Administration designated the National Nanotechnology Initiative (NNI) as a multi-agency research initiative aimed at maximizing the return on the federal investment in nanoscale R&D through coordination of funding, research, and infrastructure development activities at individual agencies. As indicted in **Table 1,** since President Bush took office in 2001, funding for the federal NNI has increased from $453 million in FY2001 constant dollars, to an estimated $1.167 billion in FY2008, a 158% increase in real dollars.

The coordination of the NNI occurs at two different levels within the federal government. With the enactment of P.L. 108-153 (The 21st Century Nanotechnology

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[2] Jane Macoubrie, *Informed Public Perceptions of Nanotechnology and Trust in the Government*, Woodrow Wilson International Center for Scholars, September 8, 2005, p. 1.

[3] Matthew M. Nordan, President of Lux Research Inc., Testimony before the House Science Committee, September 21, 2006.

[4] For more details see, *A Matter of Size*: Triennial Review of the National Nanotechnology Initiative, Committee to Review that National Nanotechnology Initiative, National Materials Advisory Board, Division on Engineering and Physical Sciences, National Research Council, September 27, 2006.

Research and Development Act), the National Science and Technology Council (NSTC)[5] Committee on Technology (CT) is now responsible for setting priorities and coordinating joint research activities among the agencies participating in the NNI. The NSTC requested the President's Council of Advisors on Science and Technology (PCAST), to conduct a review of the NNI as called for in P.L. 108-153. The NSTC Committee on Technology also directed the Nanoscale Science, Engineering and Technology (NSET) committee (consisting of the agencies involved in the NNI) to assist PCAST with its review of the NNI. Further, with the passage of the Bob Stump, National Defense Authorization Act for Fiscal Year 2003 (P.L. 107-314, Sec. 246), the NSTC is responsible for the coordination of DOD's nanotechnology activities.

Table 1. Estimated Funding for Nanotechnology FY2008

($ millions)

	FY2005 Enacted	FY2006 Enacted	FY2007 Estimate	FY2008 Request
NNI Total	**1,200**	**1,303**	**1,391[a]**	**1,447**
NSF	335	344	373	390
DOE	208	207	293	332
NASA	37	45	25	24
DOC (NIST)	63	79	89	97
EPA	5	7	9	10
DOD	315[c]	352[d]	417	375
DHS (TSA)	1	1	1	1
USDA	1	3	7	6
USDA/FS[b]	0	0	2	2
NIOSH[e]	3	3	3	3
Department of Justice	2	2	1	1
Transportation	0	0	1	1
HHS (NIH)	80	165	170	205

Note: Agencies in italics are included in P.L. 108-153, the National Nanotechnology Program.

a. The revised FY2006 funding levels are contained in the President's Supplement to the FY2007 budget request released in July of 2006.
b. U.S.D.A./Forest Service
c. Includes $148 million in earmarks, according to DOD.
d. Includes $130 million in earmarks, according to DOD.
e. National Institute of Occupational Safety and Health (within CDC).

[5] The NSTC is a Cabinet-level Council, chaired by the President, which coordinates science, space, and technology and the diverse parts of the federal research and development enterprise. Membership consists of the Vice President, Assistant to the President for Science and Technology, Cabinet Secretaries, and Agency Heads with significant science and technology responsibilities, and other White House officials.

At the second level the NSTC established the National Nanotechnology Coordinating Office (NNCO) in October 2000. In addition to being responsible for the day-to-day management of the NNI, the NNCO assists the Committee on Technology with identifying funding priorities, establishing budgets, and evaluating current NNI activities. The five agencies included in P.L. 108-153 are NSF, the Department of Energy (DOE), the National Aeronautics and Space Administration (NASA), the National Institute of Standards and Technology (NIST) within the Department of Commerce (DOC), and the Environmental Protection Agency (EPA). Further, reflecting committee jurisdiction, the NNI authorization legislation does not include nanotechnology research activities in six other agencies which also fund nanotechnology research. These include the Departments of Defense (DOD), Homeland Security (DHS), Agriculture (USDA), Justice (DOJ), the National Institutes of Health (NIH), and the National Institute for Occupational Safety and Health (NIOSH).

The FY2007 Strategic Plan

After the enactment of P.L. 108-153, the NSTC, Committee on Technology (CT) became responsible for developing a strategic plan for the NNI. The NSTC is required to update the plan every three years. According to the Administration, the FY2007 strategic plan articulates a vision for the NNI in which the ability to understand and control matter on the nano scale will lead to a revolution in technology and industry. The revised strategic plan focuses on four cross-cutting goals. They are:

1. Maintain a world class research and development program aimed at realizing the full potential of nanotechnology. Long-term basic research is considered essential to establishing a fundamental knowledge of nanoscale phenomena. Research activities performed by individual researchers, as well as interdisciplinary research teams, are to focus on fundamental understanding and synthesis of nanometer-size building blocks with potential breakthroughs in a number of scientific and engineering disciplines.

2. Facilitate the transfer of new technology into products for economic growth, jobs, and other public benefits. The second goal focuses on ensuring that breakthroughs in federally sponsored nanotechnology research are quickly transferred to the private sector. The strategic plan highlights a number of current mechanisms utilized by the NNI to transfer research outcomes to the private sector. They include the establishment of the NSET industry liaison group with various commercial sectors to promote the exchange of information on NNI research programs and industry needs that relate to nanotechnology.

3. Develop educational resources, a skilled workforce, and supporting infrastructure and tools to advance nanotechnology. Within this goal, the NNI's primary objective is to ensure the education of the next generation of researchers and innovators. In addition, it also requires the development of a workforce with technical skills needed to work in a nano environment. Further, in addition to human resources, the government maintains a number of research user facilities outside the NNI that support nano research.

4. Support responsible development of nanotechnology. According to the strategic plan, responsible development of nanotechnology means that the federal

government supports the previous three goals of the initiative, but concomitantly endorses concerns about the potential societal concerns associated with the development and deployment of nanotechnology. Nanotechnology societal dimensions include a range of issues such as equitable access to benefits arising from nanotechnology, possible health or environmental effects, and privacy concerns associated with distributed nanotechnology-based sensors.

Program Component Areas

The 21st Century Nanotechnology Research and Development Act directed the NSTC to establish Program Component Areas (PCAs), with specific priorities and technical goals, which reflect the priority goals established for the entire nanotechnology program. While the NNI goals embody the vision of the initiatives, the PCAs relate to areas of investment that are critical to accomplish the goals.[6] These areas cut across the interests and needs of the participating agencies and indicate where advancements may be enhanced through the coordination of multiple agencies. According to NSET, PCAs provides a structure by which the agencies funding R&D can better direct and coordinate their research activities.[7] The seven PCAs are: (1) Fundamental nanoscale processes, (2) Nanomaterials, (3) Nanoscale devices and systems, (4) Instrumentation research, metrology[8] and standards, (5) Manufacturing, (6) Major research facilities, and instrumentation acquisition, and (7) Social dimensions. In FY2006, the first three PCAs, which primarily fund basic research, accounted for 76% of all PCA funding.

Congressional Issues

Nanotechnology Environmental and Health Concerns. A report written by Andrew Maynard, chief science advisor for the Project on Emerging Nanotechnology at the Woodrow Wilson International Center for Scholars, has called on the federal government to make major changes in the handling of nanotechnology risk research. The report's principal conclusions are that "the federal government needs to assume top-down, authoritative oversight of strategic risk-based research, and that nanotechnology risk research should be carried out by federal agencies with a clear mandate for oversight and for research on the environment, safety and health (ESH) issues."[9] Without such an approach, Maynard argues, significant knowledge gaps which currently exist in all areas of nanotechnology risk assessment will persist.

According to Maynard, the level of funding for ESH may be lower than what was reported by the agencies participating in the ESH initiative. For example, the author noted the NNI planned to spend $37.5 million on ESH research in FY2006. However,

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[6] The National Nanotechnology Initiative, Research and Development Leading to a Revolution in Technology and Industry, Supplement to the President's FY2006 Budget, p. 5.

[7] The PCAs are Fundamental nanoscale phenomena, Nano-materials, Nanodevices and systems, Instrumentation, Nano-manufacturing, Research facilities and instrumentation, and Societal dimensions.

[8] Metrology is the study of measurement.

[9] Andrew D. Maynard, Chief Science Advisor, NANOTECHNOLOGY: A Research Strategy for Addressing Risk, The Woodrow Wilson International Center for Scholars, July 2006, p. 5.

Maynard notes that the two agencies (EPA and NIOSH) mandated to sponsor research in support of protecting human health and the environment accounted for an estimated $6.9 million, or 18% of total ESH funding in FY2006. Further, even if the federal spending levels are accurate, according to the author, one still cannot determine how well coordinated and effective the research might be because there is no information on what research is being done and what is not.[10] According to Clayton Teague, the Director of the NNI Coordination Office, regulatory agencies, such as EPA and FDA, believe their current regulatory options are adequate to cover nano-engineered products.

The Food and Drug Administration Task Force Report. In July of 2007, the Food and Drug Administration (FDA) released a report that addresses the scientific issues, as distinct from regulatory policy issues, in recognition of the importance science will play in the development of nanotechnology regulatory policy.[11] According to the report, rapid developments in the field mean that attention to emerging science is needed to enable FDA to predict and prepare for different types of nano products the agency may see in the near future. The Tasks Force's initial recommendation relating to scientific issues focuses on improving scientific knowledge of nanotechnology to help ensure the agency's regulatory effectiveness, particularly with regards to products not subject to premarket authorization requirements. The report also addresses the need to analyze whether tools available to describe and evaluate nanoscale materials are sufficient.

A general finding of the report is that nanoscale materials present regulatory challenges similar to those posed by products using other emerging technologies. However, according to FDA, challenges may be magnified both because nanotechnology can be used in, or to make, any FDA-regulated product, and because at this scale properties of materials relevant to the safety and (as applicable) the effectiveness of FDA-regulated products may change repeatedly as size enters into or varies within the nanoscale range. In addition, the emerging and uncertain nature of the science and the potential for rapid development of applications for FDA-regulated products highlight the need for timely development of a transparent, consistent, and predictable regulatory pathways.

The Task Force concluded that the Agency's authorities are generally comprehensive for products subject to premarket authorization requirements, such as drugs, biological products, devices, and food and color additives, and that these authorities give FDA the ability to obtain detailed scientific information needed to review the safety and, as appropriate, the effectiveness of products. The Task Force has made various recommendations to address regulatory challenges that may be presented by products that use nanotechnology, especially regarding products not subject to premarket authorization requirements, taking into account the evolving state of the science in this area. In addition a number of recommendations deal with requesting data and other information about effects of nanoscale materials on safety and, as appropriate, the effectiveness of products.

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[10] Ibid., p. 18.

[11] Nanotechnology, A Report of the U. S. Food and Drug Administration Nanotechnology Task Force, July 25, 2007. For additional information see [http://www.fda.gov/nanotechnology/nano_tf.html].