chemistry, biology, and physics of nanoscale material interactions at the molecular and cellular level through *in vitro* and *in vivo* experiments and simulation models.

The Department of Defense is supporting a Multidisciplinary University Research Initiative (MURI) program to create predictive models for celluar response to nanoparticles of varying size, shape, charge, and composition and their influence on the cellular, sub-cellular, and biomolecular levels. This research is creating a significant body of knowledge of reactions between nanoscale materials and biological materials.

All material stuff around us, either natural or man-made, has structure at the nanoscale. All living cells, for instance, interact with nanostructures when they feed, breed or are touched by viruses. Thus, facilitated by new investigative methods, development of knowledge at the nanoscale is a natural trend in science and engineering. This knowledge may prepare us to address unexpected risks of human activity, such as encountering unknown viruses and bacteria. The knowledge also might help us to address challenges raised by nanostructures themselves, particularly new functions of the same chemical composition and more reactive surfaces of nanostructures.

NNI research is developing new knowledge regarding environmental, health and safety issues through the more than 120 projects underway at the end of 2003, including several centers at the University of California, Davis (nanoparticles in the environment); Worcester Polytechnic Institute (air pollution); University of Illinois at Urbana-Champaign (water purification); Rice University (nanostructures in the environment); and University of Notre Dame (nanoparticles in soils). Researchers are addressing such questions as: What is different about artificially created nanostructures? How would those nanostructures behave differently from bulk if released in the environment? Nanotechnology will develop in the areas where potential advantages will exceed the impact of potential risks and where the potential risks are limited and can be addressed. Current approaches are attempting to address nanotechnology impacts in research or production within the existing system applications such as biology, chemistry or electronics.

The key questions asked by technology users and the public concern economic development and related issues, such as commercialization, education, infrastructure, and environmental, health, ethical, and legal aspects. We have the responsibility to increase productivity, better use natural resources, reduce poverty and hunger, improve healthcare, and enhance human resources. We also must address health and environmental risks and related efforts to reduce them. The public policy response must be balanced between public benefit and risk. Considering the opinions of individual groups—at times different from the largest majority and sometimes conflicting with scientific facts—must occur in the context of broader societal goals.

The vision of few intelligent nanometer robots mentioned in science fiction literature (for example, the novel *Prey* by Michael Crichton) leads to immediate criticism by some groups that are concerned that such robots would take over the world and damage the environment. This criticism ignores input from researchers who note that basic laws of mass and energy conservation may not lead to infinitely multiplying material objects, and that only a complex system of presumably already known living systems may be able to multiply and be intelligent.

The government's role is to provide R&D support for knowledge development, identify possible risks for health, environment, and human dignity, and inform the public with a balanced approach about the benefits and potential unexpected consequences of nanotechnology.

The NSF prepared a report entitled *Societal Implications of Nanoscience and Nanotechnology* in September 2000 and published it for broader public distribution in 2001 [9]. The proceedings were followed by various program solicitations and the assignment to the National Nanotechnology Coordination Office (NNCO) in 2001 of a monitoring role for potential unexpected societal implications. The NNCO also has the role of communicating with the public.

In 2003, a subgroup of the NSET Subcommittee, the Nanotechnology Environmental and Health Implications (NEHI) working group, was established to address environment, health, and safety (EHS) issues. Among those issues are identification and prioritization of EHS research needs and communication of information pertaining to the EHS aspects of nanomaterials to researchers and others who handle and use nanomaterials.

In another follow-up to the 2000 *Societal Implications* report, NSF has made support for social, ethical, and economic research studies a priority by (a) including this as a new theme in the NSF annual program solicitations since 2000; (b) requiring its nanotechnology research and education centers to address societal implications of the research performed in the respective center; and (c) conducting a study on the impact of technology and converging technologies from the nanoscale [10].

NSF has pursued the research and education themes "Nanoscale processes in the environment" and "Societal and Educational Implications of Nanotechnology" as part of its NNI programs since July 2000 (annual program solicitations NSF 00-119, 01-157, 02-148, 03-043, 03-044), and 100 examples of awards made in this area are posted on www.nsf.gov/nano, listed under Solicitations and Outcomes. Examples of projects supporting societal implications are given in Table 2.3. EPA has had annual program announcements in the STAR program with focus on nanotechnology and

Table 2.3
Examples of NNI Projects Supporting Social Implications Research

Project	Agency	Institution
Nanotechnology and its publics	NSF	Pennsylvania State University
Public information and deliberation in nanoscience and nanotechnology policy (SGER)	Interagency	North Carolina State University
Social and ethical research and education in agrifood nanotechnology (NIRT)	NSF	Michigan State University
From laboratory to society: developing an informed approach to nanoscale science and engineering (NIRT)	NSF	University of South Carolina
Database and innovation timeline for nanotechnology	NSF	UCLA
Social and ethical dimensions of nanotechnology	NSF	University of Virginia
Undergraduate exploration of nanoscience, applications and societal implications (NUE)	NSF	Michigan Technological University
Ethics and belief inside the development of nanotechnology (CAREER)	NSF	University of Virginia
All centers, NNIN and NCN have a societal implications components	NSF, DOE, DOD, and NIH	All nanotechnology centers and networks

the environment since 2002; in FY 2003, 22 awards were made and, in 2004, about 12. DOE has included nanoscience in environmental research performed at several National Laboratories, such as Oak Ridge in Tennessee and the Environmental Molecular Sciences Laboratory in Washington State. Additional Small Business Innovation and Research/Small Business Technology Transfer Program (SBIR/STTR) awards were made at NSF after 1999 when nanotechnology was specifically targeted in the respective program announcements. EPA will have an SBIR solicitation on "Nanomaterials and Clean Technology" with a deadline in May 2004. FDA, EPA and other regulatory agencies are following very closely the research results.

The NNI annual investment in research and education with relevance to environment has increased progressively since 2000. Other programs dedicated to environmental implications of nanotechnology abroad were announced in March 2003 by the European Community and in November 2003 by Taiwan—about three years after the NSF first called for proposals in that area.

One should not sidetrack the efforts for sustainable development by delaying or halting the creation of new knowledge in the field. At the international "Nanotech 2003 and Future" conference in Japan on February 26, 2003, I made an international appeal to researchers and funding organizations "to take timely and responsible advantage of the new technology for economic and sustainable development, to initiate societal implications studies from the beginning of the nanotechnology programs, and to communicate effectively the goals and potential risks with research users and the public" [11]. Since then, I've had discussions with representatives from the European Commission, Asia-Pacific Economic Cooperation, Switzerland, UK, Taiwan, China, Australia, and other countries about this topic. International collaboration is necessary in a field that does not have borders, where the products are sold internationally, and the health and environmental aspects are of general interest.

Nanotechnology is still in the precompetitive phase in most areas where applications are foreseen, and international collaboration is beneficial. Nanotechnology has the long-term potential to bring revolutionary changes in society and harmonize international efforts towards a higher purpose than just advancing a single field of science and technology or a single geographical region. A global strategy guided by broad societal goals of mutual interest is envisioned.

Appendix: Laws and Regulations that Apply to Nanotechnology Development

On December 3, 2003, the President signed into law the 21st Century Nanotechnology Research and Development Act [6]. A section of that law is dedicated to societal implications.

Congress issues authorization laws and funding appropriations for nanotechnology R&D to Federal agencies participating in NNI each year. The number of participating agencies has increased from six agencies in FY 2001 to 10 agencies in FY 2002 and 22 agencies in FY 2005.

These organizations have primary responsibility for implementing regulations and guidance in areas relevant to nanotechnology materials and products:

- Environmental Protection Agency (EPA)
- Food and Drug Administration (FDA)
- National Institute for Occupational Safety and Health (NIOSH)
- Occupational Safety and Health Administration (OSHA)
- U.S. Department of Agriculture (USDA)

- Consumer Product Safety Commission (CPSC)
- U.S. Patent and Trademark Office (USPTO)

Research to establish the knowledge base that is used by regulatory agencies to inform their decision-making process may be performed by Federal agencies, such as NSF, NIH, NIST, EPA, FDA, NIOSH, OSHA, USDA, DOE, and DOD, or may be performed by industry or other private sector research institutions.

The materials and products based on nanotechnology are regulated today within the existing network of statutes, regulations, rules, guidelines, and other voluntary activities. Nanostructures are evaluated by various groups and in different countries as "chemicals with new uses" or as "new chemicals." In some cases, pre-market review and approval are required (e.g., drugs, food packaging, and new chemical compounds). In other cases, post-market surveillance and monitoring apply (e.g., cosmetics and most consumer products). The existing regulatory network will be modified, if necessary. Examples of regulatory laws and standards applicable to nanoparticles and other nanostructures include the following:

- In the environment (in air, water, soils):
  - Toxic Substances Control Act (TSCA), administered by the EPA
  - Clean Air Act for ultrafine particles, administered by the EPA
  - Waste disposal acts, administered by the EPA
- In the work place (aerosol-based standards based on existing health risk data):
  - Permissible Exposure Limits (PELs), established by the Occupational Safety and Health Administration (OSHA)
  - Recommended Exposure Limits (RELs), established by the National Institute of Occupational Safety and Health
  - Threshold Limit Values (TLVs), established by the American Conference of Government Industrial Hygienists (ACGIH)
  - Personal Protective Equipment to reduce exposure, established by the OSHA and ASTM (American Society for Testing and Materials)
- Nanoparticles for drugs to be metabolized in the human body, to be used as diagnostics or therapeutic medical devices (such as quantum dots); regulated by the FDA.
- Nanostructured particles/substances to be incorporated into food; the FDA and USDA share regulatory authority (such as food additives, food coloring).
- Substances incorporated into consumer products; regulated by the Consumer Product Safety Commission (CPSC) under the Federal Hazardous Substances Act. A focus is on protection of children, who are more susceptible and who sometimes put objects in their mouth that were not intended for that purpose.

Under NEHI coordination, the EPA, FDA, CPSC, OSHA, NIOSH, NIST, USDA, and other agencies are reviewing existing rules and procedures to determine how to use the existing statutes and regulations to review products of nanotechnology, as these products are developed. Where new nanotechnology