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TECHNICAL PAPER

Governance, policy, and legislation of nanotechnology: a perspective

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Abstract Nanotechnology refers to technology done at nanoscale that has applications in the real world. Unique physical and chemical properties of nanomaterials can be exploited for applications that benefit society. Nanotechnology represents a “megatrend” and has become a “general purpose” technology. An executive action of 2000, the National Nanotechnology Initiative was formalized with the 21st Century Nanotechnology Research and Development Act in 2003. Through FY2015, federal R&D investment has been about $20 billion, with annual investment in FY2015 of about $1.5B, and more than double that by the private sector. The revenues from nano-enabled products continue growing, with over $200B in FY2012 in the US alone. This represents an impressive return on investment. Reauthorization of the Initiative is needed to address concerns, including emphasis on commercialization. Research on potential safety issues of nanotechnology, development of workforce, and curriculum should be continued. In this paper, we present governance, policy, and legislation of nanotechnology.

Abbreviations

AFM	Atomic Force Microscopy
BioMEMS	BioMicroElectroMechanical Systems
BioNEMS	BioNanoElectroMechanical Systems
CPSC	Consumer Product Safety Commission
DOD	Department of Defense
DOE	Department of Energy
EHS	Environmental Health and Safety
EOP	Executive Office of the President
EPA	Environmental Protection Agency
EU	European Union
FDA	Food and Drug Administration
FS	Forestry Service
GAO	Government Accountability Office
IC	Intelligence Community
IWGN	Interagency Working Group on Nanoscience, Engineering and Technology
MEMS	MicroElectroMechanical Systems
MOEMS	MicroOptoElectroMechanical Systems
MST	Microsystems Technology
NACK	Nanotechnology Applications and Career Knowledge
NASA	National Aeronautics and Space Administration
NCMS	National Center for Manufacturing Sciences
NEMS	NanoElectroMechanical Systems
NIFA	National Institute of Food and Agriculture
NIH	National Institutes of Health
NIOSH	National Institute for Occupational Safety and Health
NIST	National Institute of Standards and Technology
NNAP	National Nanotechnology Advisory Panel
NNCO	National Nanotechnology Coordination Office
NNI	National Nanotechnology Initiative
NNIN	National Nanotechnology Infrastructure Network
NOEMS	NanoOptoElectroMecanical Systems

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NRDA	Nanotechnology Research and Development Act
NSET	Subcommittee on Nanoscale Science, Engineering, and Technology
NSF	National Science Foundation
NSIs	Nanotechnology Signature Initiatives
NSTC	National Science and Technology Council
OECD	Organization for Economic Cooperation and Development
OMB	Office of Management and Budget
OSHA	Occupational Safety and Health Administration
OSTP	Office of Science and Technology Policy
PCAST	President's Council of Advisors on Science and Technology
R&D	Research and Development
RF-MEMS	Radio Frequency MicroElectroMechanical Systems
RF-NEMS	Radio Frequency NanoElectroMechanical Systems
STM	Scanning Tunneling Microscopy
SWNT	Single Walled Nanotube
USDA	US Department of Agriculture
USPTO	US Patent and Trademark Office

"A biological system can be exceedingly small. Many of the cells are very tiny, but they are very active; they manufacture various substances; they walk around; they wiggle; and they do all kinds of marvelous things – all on a very small scale. Also, they store information. Consider the possibility that we too can make a thing very small which does what we want – that we can manufacture an object that maneuvers at that level."

(From the talk "There's Plenty of Room at the Bottom," delivered by Richard P. Feynman at the annual meeting of the American Physical Society at the California Institute of Technology, Pasadena, CA, on December 29, 1959).

1 Introduction to nanotechnology

Nanotechnology refers to any technology done on a nanoscale that has applications in the real world. It is defined as the control or restructuring of matter at the atomic and molecular levels in the size range of about 1–100 nm (Anonymous 1999, 2000). The underlying science is referred to as Nanoscience. The properties of matter at nanoscale are different from those at a larger scale. When the dimensions of a material are reduced from a large size, the properties remain the same at first, then small changes occur. Finally, when the size drops below 100 nm, dramatic changes in properties can occur. The unique physical and chemical properties of nanomaterials can be exploited for commercial applications and for novel performance that benefits society. The discovery of novel materials, processes, and phenomena at the nanoscale and the development of new experimental and theoretical techniques for research at the end of the 20th century provide fresh opportunities for the development of innovative nanosystems and nanomaterials. This field is opening new venues in science and technology (Bhushan 2010, 2012; Bhushan et al. 2014).

Nanotechnology encompasses the nanomanufacturing and application of physical, chemical, and biological systems at scales ranging from individual atoms or molecules to submicron dimensions, as well as the integration of the resulting nanostructures into larger systems. It spans across scientific fields, including chemistry, physics, material science, engineering, and manufacturing. Its impact on our society and economy in the 21st century is comparable to that of semiconductor technology, information technology, or cellular and molecular biology in the 20th century. Research in nanotechnology is leading to breakthroughs in areas such as nanomaterials and nanomanufacturing, nanoelectronics, medicine and healthcare, energy, biotechnology, information technology, and national security. Nanotechnology will continue to play a growing role in industrial applications. Nanotechnology represents a megatrend, bringing disruptive innovation. It has become a general purpose technology, being applicable across various industrial sectors.

1.1 Nanomanufacturing

Manufacturing at the nanoscale, referred to as nanomanufacturing, is accomplished by using either a "bottom-up" or "top down" approach to the production of nanomaterials, structures, devices, and systems (Bhushan 2010, 2012 Madou 2011; Bhushan et al. 2014).

In the bottom-up approach, nanoscale features are mainly built up from their elemental constituents. Elemental constituents are combined using various nanomanufacturing processes including self-assembly, chemical synthesis, molecular beam epitaxy, nanoimprint lithography, roll-to-roll processing, and dip pen lithography (see, nano.gov). Molecular self-assembly, the spontaneous self-assembly of molecular clusters, can occur from simple reagents in solution or from biological molecules (e.g., DNA) used as building blocks for the production of three-dimensional nanostructures. Chemical synthesis is carried out using gaseous precursors and solvents. These chemicals react to produce nanostructures. A variety of vacuum deposition and nonequilibrium plasma chemistry techniques are then used to produce layered nanocomposites and nanotubes. Molecular beam epitaxy is a method for deposition of thin films with a thickness of one atom on a surface. Nanoprint lithography is used to fabricate nanostructures by stamping or printing them on a surface. Roll-to-roll processing is a high volume process used to produce nanodevices on a flexible substrate. Dip pen lithography uses an atomic force microscope tip in a fluid to produce nanoscale features on a surface.

The top down approach uses lithographic and non-lithographic fabrication technologies. Lithographic technology is an underlying technology to make semiconductor chips and components. Continued improvements in lithography for use in the production of nanocomponents have resulted in line widths as small as 10 nm. The top down approach is commonly used to fabricate micro- and nanosystem components, which range in size from micro- to nanometers.

1.2 MEMS/NEMS

Micro- & nanosystems include Micro/NanoElectroMechanical Systems (MEMS/NEMS). The acronym MEMS originated in the US The term commonly used in Europe is micro/nanosystem technology (MST/NST), and in Japan it is micro/nanomachines. Another term generally used is micro/nanodevices. Advances in silicon photolithographic process technology since the 1960s led to the development of MEMS in the early 1980s. MEMS combine electrical and mechanical components to create microscopic devices that have a characteristic length between 100 and 1 mm. In the early 2000s, with the development of nanofabrication techniques, NEMS were fabricated. NEMS combine electrical and mechanical components to create nanoscopic devices that have a characteristic length of less than 100 nm. In mesoscale devices, if the functional components are on the micro- or nanoscale, they may be referred to as MEMS or NEMS, respectively. These are intelligent miniaturized systems comprised of sensing, processing, and/or actuating functions that combine electrical and mechanical components (Bhushan 2010, 2012). MEMS/NEMS terms are also now used in a broad sense and include electrical, mechanical, fluidic, optical, and/or biological function. MEMS/NEMS for optical applications are referred to as micro/nanooptoelectromechanical systems (MOEMS/NOEMS). MEMS/NEMS for electronic applications are referred to as radio-frequency-MEMS/NEMS or RF-MEMS/RF-NEMS. MEMS/NEMS for biological applications are referred to as BioMEMS/BioNEMS.

To put the dimensions and weights of nanomaterials, MEMS/NEMS, and BioNEMS in perspective, see Fig. 1 and Table 1. Examples shown are a single walled carbon nanotube (SWNT) chemical sensor (adapted from Chen et al. 2004), molecular dynamic simulations of carbon-nanotube based gears (adapted from Srivastava 2004), quantum-dot transistor (adapted from van der Wiel et al. 2003), and a digital micromirror device (adapted from Hornbeck 1999). Individual atoms are typically a fraction of a nanometer in diameter, DNA molecules are about 2.5 nm wide, biological cells are in the range of thousands of nm in diameter, and human hair is about 75,000 nm (75 μm) in diameter. The smaller length of a BioNEMS shown in the figure is about 2 nm. NEMS shown range in size from 10 to 300 nm, and the size of MEMS is on the order of 12,000 nm (12 μm). The weight of a micromachined silicon structure can be as low as 1 nN, and NEMS can be built with weight as low as 10^{-20} N with cross sections of about 10 nm. In comparison, the weight of a drop of water is about 10 μN, and the weight of an eyelash is about 100 nN.

1.3 Convergence

Roco and Bainbridge (2013) have discussed convergence of nanotechnology, biotechnology, information, and cognitive science for emerging technologies. Convergence is the process of bringing disparate technologies together into a unified field. Convergence is progressing by stages, beginning with foundational interdisciplinary research at the nanoscale during 2001–2010, followed by integration of nanoscience and nanotechnology for general purpose technology from approximately 2010 and continuing.

1.4 Industrial applications

MEMS/NEMS and BioMEMS/BioNEMS are used in industrial, consumer, defense, and biomedical applications. Some of these applications include electromechanical, electronics, information/communication, chemical, and biological. Growth of Si-based MEMS/NEMS appears to have slowed down, while growth of nonsilicon MEMS/NEMS and BioMEMS/BioNEMS has been picking up since the first decade of the 21st century (Bhushan 2010, 2012). It is expected that nanomaterials and biomedical applications as well as nanoelectronics or molecular electronics would continue to expand. Due to the enabling nature of these systems and because of the significant impact they can have on both commercial and defense applications, both industry and national governments have taken special interest in seeing growth nurtured in this field.

The first MEMS were commercially introduced in about 1990. These were accelerometers for the deployment of an air bag in a car in the event of a crash, piezoresistive pressure sensors for manifold absolute pressure sensing for car engines, and thermal inkjet print heads. In 2015, additional examples of MEMS with large and established markets with production volumes of several hundred million units per year include piezoresistive pressure sensors for disposable blood pressure sensors, capacitive pressure sensors for

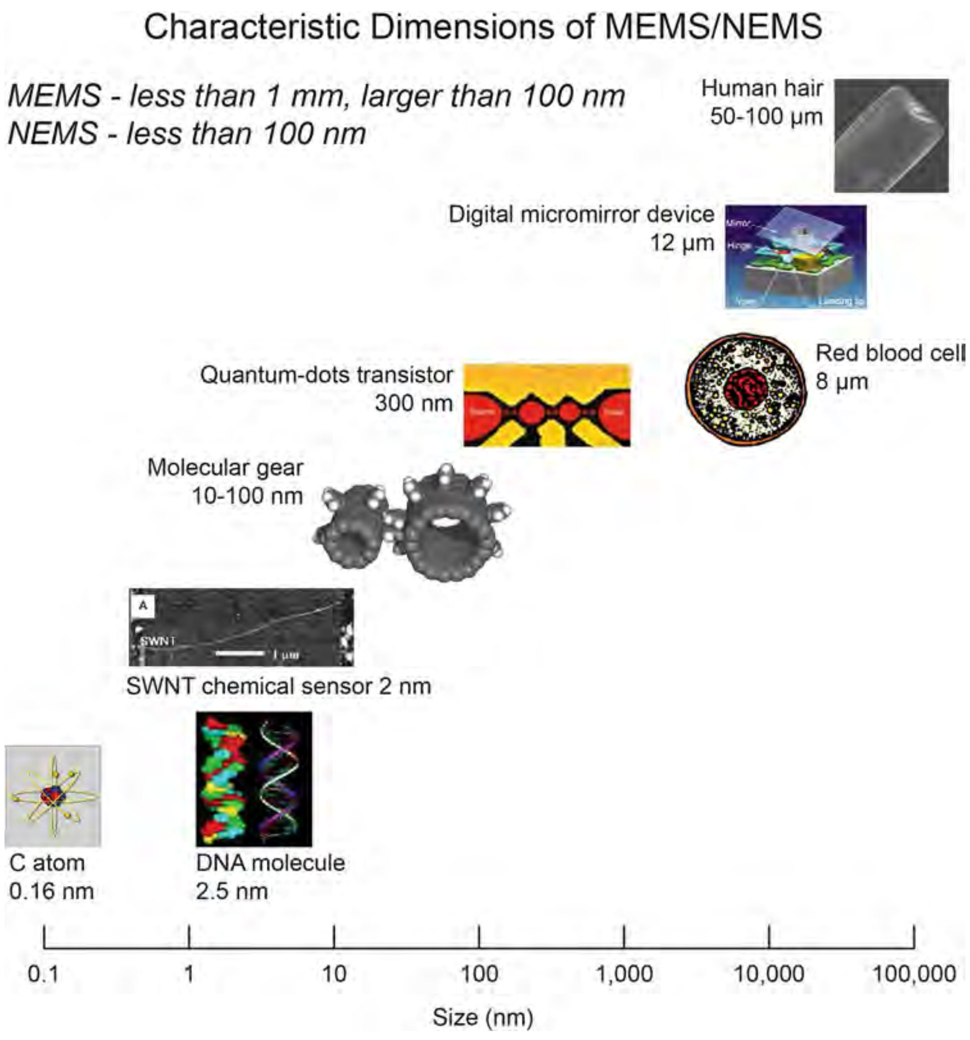


Fig. 1 Characteristic dimensions of nanomaterials, MEMS/NEMS, and BioNEMS in perspective (adapted from Bhushan 2010). Examples shown are a single walled carbon nanotube (SWNT) chemical sensor (adapted from Chen et al. 2004), molecular dynamic simulations of carbon-nanotube based gears (adapted from Srivastava 2004), quantum-dot transistor (adapted from van der Wiel et al. 2003), and a digital micromirror device (adapted from Hornbeck 1999)

Table 1 Characteristic dimensions and weights of various objects in perspective (Bhushan 2010)

(a) Characteristic dimensions in perspective
NEMS characteristic length: <100 nm
MEMS characteristic length: <1 mm and >100 nm
SWNT chemical sensor: ~2 nm
Molecular gear: ~10 nm
Quantum-dots transistor: 300 nm
Digital micromirror: 12,000 nm
Individual atoms: typically fraction of a nm in diameter
DNA molecules: ~2.5 nm wide
Biological cells: in the range of thousands of nm in diameter
Human hair: ~75,000 nm in diameter
(b)Weight in perspective
NEMS built with cross sections of about 10 nm: as low as 10^{-20} N
Micromachined silicon structure: as low as 1 nN
Eyelash: ~100 nN
Water droplet: ~10 μN

tire pressure measurements, digital micromirror arrays for digital projection display, and optical cross-connections in telecommunications. Other applications of MEMS devices include chemical/biosensors and gas sensors, microresonators, infrared detectors and focal plane arrays for earth observations, space science and missile defense applications, pico-satellites for space applications, fuel cells, and many hydraulic, pneumatic, and other consumer products.

NEMS applications include both bio and non-biological fields. Examples include: microcantilevers with integrated sharp nanotips for scanning tunneling microscopy (STM) and atomic force microscopy (AFM), quantum corral formed using STM by placing atoms one by one, AFM tips for nanolithography, dip pen lithography for printing molecules, quantum-dot transistors, nanotube based sensors, biological (DNA) motors, molecular gears made by attaching benzene molecules to the outer walls of carbon nanotubes, devices incorporating nm-thick films (e.g., in giant magnetoresistive or GMR read/write magnetic heads and magnetic media) for magnetic rigid disk and magnetic tape drives, and nanopatterned magnetic rigid disks.

Nanomaterials include nanoparticles (aggregate of 10–10^5 atoms bonded together), nanowires, nanotubes, and quantum wires. Nanomaterials have many applications. For example, nanoparticles are used in magnetic coatings for information storage devices and drug delivery, and nanotubes and nanowires are used in various sensor applications. Nanoelectronics are being developed from these nanomaterials. They are used to build computer memory using individual molecules or nanotubes to store bits of information, molecular switches, molecular or nanotube transistors, nanotube flat-panel displays, nanotube integrated circuits, fast logic gates, switches, nanoscopic lasers, and nanotubes as electrodes in fuel cells.

BioMEMS/BioNEMS are increasingly used in commercial and defense applications. They are used for chemical and biochemical analyses (biosensors) in medical diagnostics (e.g., DNA, RNA, proteins, cells, blood pressure and assays, and toxin identification), tissue engineering, and implantable pharmaceutical drug delivery. Biosensors, also referred to as biochips, deal with liquids and gases. There are two types of biosensors. The first type of biosensors are micro/nanofluidic devices. A large variety of biosensors are based on micro/nanofluidics. Micro/nanofluidic devices offer the ability to work with smaller reagent volumes and shorter reaction times, and perform analyses multiple times at once. The second type of biosensors are micro/nanoarrays, which perform one type of analysis thousands of times. Micro/nanoarrays are a tool used in biotechnology research to analyze DNA or proteins, to diagnose diseases, or discover new drugs. One microarray of silicon nanowires is used to selectively bind to and detect even a single biological molecule, such as DNA or protein. It is roughly a few nanometers in size and uses nanoelectronics to detect the slight electrical charge caused by the selective binding. Another type is a microarray of carbon nanotubes used to electrically detect glucose.

After the tragedy of Sept. 11, 2001, concern surrounding biological and chemical warfare led to the development of handheld units with bio- and chemical sensors for detection of biological germs, chemical or nerve agents, and mustard agents, as well as chemical precursors to protect subways, airports, water supplies, and the population at large. BioMEMS/BioNEMS are also being developed for minimally invasive surgery, including endoscopic surgery, laser angioplasty, and microscopic surgery. Other applications include implantable drug-delivery devices: micro/nanoparticles with drug molecules encapsulated in functionalized shells for site-specific targeting applications, and a silicon capsule with a nanoporous membrane filled with drugs for long-term delivery.

Figure 2 shows an example of (a) MEMS—a digital micromirror device (DMD) used for digital projection display (adapted from Hornbeck 1999), (b) NEMS—a single walled nanotube (SWNT) chemical sensor (adapted from Chen et al. 2004), and (c) functionalized nanoparticles for cancer detection and drug delivery (adapted from Irvine 2011).

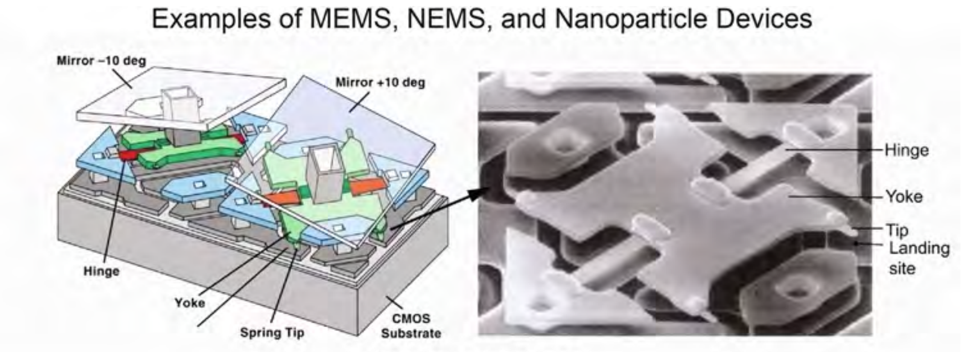
In this paper, we start with history and early research expenditures followed by governance of the National Nanotechnology Initiative, nanotechnology research and development (R&D) funding since 2001, worldwide R&D investments, and policy and legislative activities to 2014 in the US Finally, we end with a summary and outlook.

2 History and early research expenditures

On Dec. 29, 1959 at the California Institute of Technology, Nobel Laureate Richard P. Feynman gave a talk at the Annual Meeting of the American Physical Society that has become one of the classic science lectures of the 20th century, titled, “There’s Plenty of Room at the Bottom” (Feynman 1960). He presented a technological vision of extreme miniaturization in 1959, several years before the word “chip” became part of the lexicon. He talked about the problem of manipulating and controlling things on a small scale. Extrapolating from known physical laws, Feynman envisioned a technology using the ultimate toolbox of nature; building nanoobjects atom by atom or molecule by molecule. Since the 1980s, many inventions and discoveries in the fabrication of nanoobjects have been testaments to his vision.

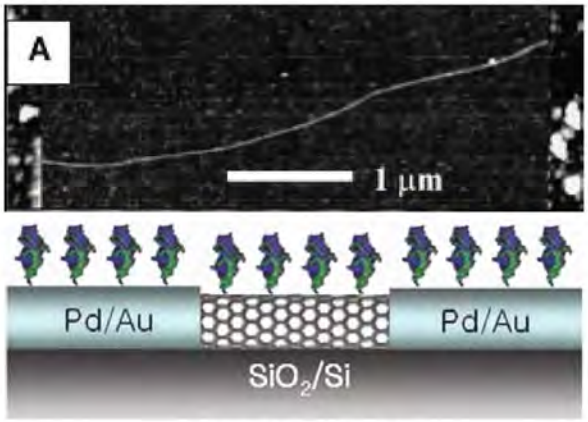
In 1998, the National Science and Technology Council (NSTC) of the White House Office of Science and Technology Policy (OSTP) created the Interagency Working Group on Nanoscience, Engineering and Technology (IWGN), recognizing the reality of the proliferation of nanotechnology. In 1999, the IWGN was elevated to the Subcommittee on Nanoscale Science, Engineering, & Technology (NSET). In a January 2000 speech also at the California Institute of Technology, President William J. Clinton talked about the exciting promise of nanotechnology and the importance of expanding research in nanoscale science and technology more broadly. Later that month in his State of the Union Address, he announced an ambitious $497 million federal, multi-agency National Nanotechnology Initiative (NNI) in the FY 2001 budget, and made the NNI a top science and technology priority (Anonymous 2000). The objective of this initiative was to form a broad-based coalition in which academia, the private sector, and local, state, and federal governments work together to push the envelope of nanoscience and nanoengineering to reap nanotechnology’s potential social and economic benefits.

Fig. 2 Examples of **a** MEMS—digital micromirror device used for digital projection display (adapted from Hornbeck 1999), **b** NEMS—SWNT chemical sensor (adapted from Chen et al. 2004), and **c** functionalized nanoparticles for cancer detection and drug delivery (adapted from Irvine 2011)



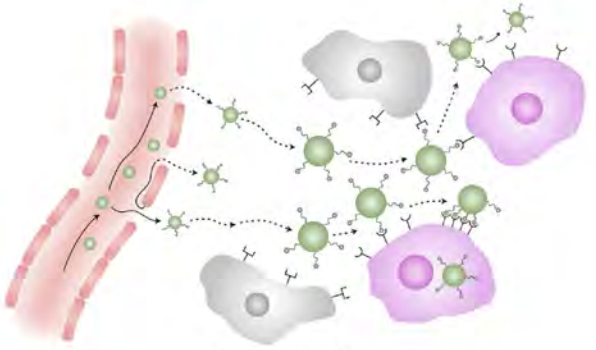
(Hornbeck, 1999)

(a)



(Chen et al., 2004)

(b)



(Irvine, 2011)

(c)

In Jan. 2003, following the creation of the NNI, the US Senate in the 108th Congress introduced a bill to establish a National Nanotechnology Program. On Dec. 3, 2003, President George W. Bush signed into law the 21st Century Nanotechnology Research and Development Act (NRDA) (Public Law 108–153). The legislation put into law programs and activities supported by the NNI. The bill gave nanotechnology a permanent home in the federal government and authorized $3.7 billion to be spent in the 4 year period beginning in October 2005. This allocation was for nanotechnology initiatives at six federal agencies: National Science Foundation (NSF), Department of Defense (DOD), Department of Energy (DOE), National Aeronautics and Space Administration (NASA), National Institute of

Standards and Technology (NIST), and the National Institutes of Health (NIH). The funds were used to provide grants to researchers, coordinate R&D across the six agencies, establish interdisciplinary research centers, and accelerate technology transfer into the private sector.

Nanotechnology R&D is directed towards understanding and controlling matter at the nanoscale. NNI has four goals (Anonymous 2014a): (a) advance world-class nanotechnology research and development; (b) foster the transfer of new technologies into products for commercial and public benefit; (c) develop and sustain educational resources, a skilled workforce, and the supporting infrastructure and tools to advance nanotechnology; and (d) support the responsible development of nanotechnology. Further details are presented in Fig. 3 (adapted from Anonymous 2014a).

Regarding international activities in early stages, the European Union (EU) made nanosciences and nanotechnologies a priority in the Sixth Framework Program (FP6) in 2002 for the period of 2003–2006. They had also dedicated small funds in FP4 and FP5 programs before. FP6 was tailored to help better structure European research and to cope with the strategic objectives set out in the Lisbon Strategy Development Plan of 2000. Japan identified nanotechnology as one of its main research priorities in 2001. The funding levels increased from $400 million in 2001 to around $950 million in 2004. In 2003, South Korea embarked upon a 10-year program with around $2 billion of public funding, and Taiwan had committed around $600 million of public funding over 6 years. Russia, Singapore, and China also started to invest on a large scale.

3 Governance of the national nanotechnology initiative

In 2001, OSTP established a National Nanotechnology Coordination Office (NNCO), and was funded by NSET. The NNCO serves as a central point of contact for Federal nanotechnology R&D activities, and provides public outreach on behalf of the NNI. The NNCO Director and Deputy Director are appointed by the White House Co-Chair of the NSTC Committee on Technology. The NNCO coordinates the preparation and publication of interagency planning, budget, and various documents, such as the NNI supplement to the President's budget. The 21st Century Nanotechnology Research and Development Act called for a National Nanotechnology Advisory Panel (NNAP), to review the NNI triennially. In 2004, PCAST was designated as that panel. In addition, the Act had called for a triennial review by the National Academies.

NNI investments are guided by an annual strategic plan published by the OSTP. Figure 4 shows the organizational structure for management of NNI; OSTP coordination and assessment of NNI efforts (adapted from Anonymous 2014a). The NNI reporting requirements overseen by OSTP include: (a) the triennial strategic plan (Year 1); (b) the triennial assessment by PCAST (Year 2); (c) the triennial assessment of the program by the National Academies (Year 3); and (d) the annual supplemental report submitted with the President's budget.

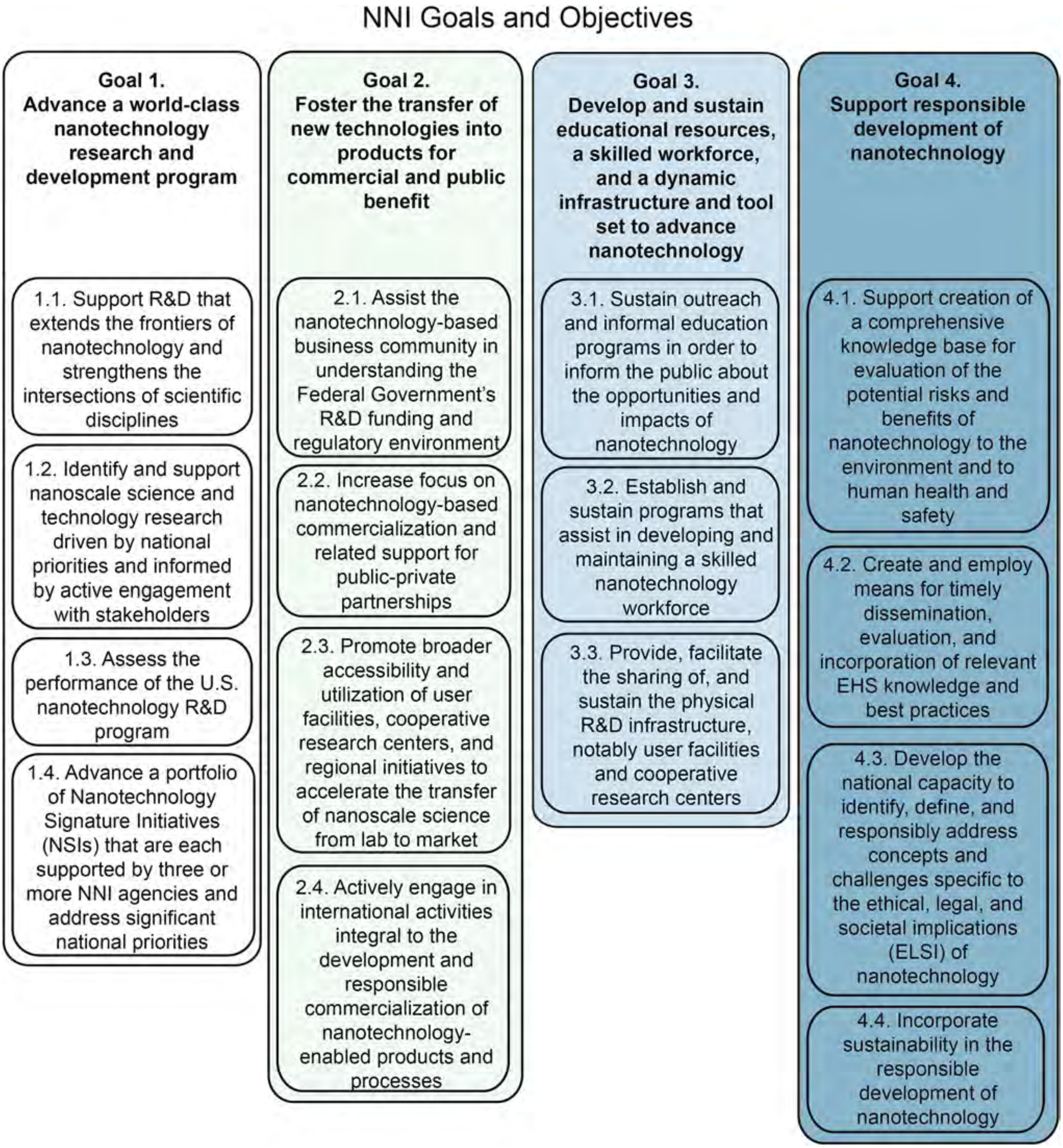
4 Nanotechnology R&D funding since 2001

Since 2001, the US Congress has appropriated about $20 billion for nanotechnology R&D through FY 2015, with about $1.5 billion spent in FY 2015 alone. Figure 5 shows NNI funding growth from FY 2001 through FY 2015 (adapted from Anonymous 2014d). Twenty top-level federal agencies (27 including all subsidiary sub-agencies) fund NNI related research, as shown in Table 2 (Anonymous 2014a). Table 3 shows the breakdown of the NNI budget by agency for the period of FY 2001 to FY 2015 (Anonymous 2014d). About 93 % of the funding is spent by five agencies –NIH (28.7 %), NSF (26.8 %), DOE (22.3 %), DOD (9.4 %), and NIST (5.4 %). US private sector R&D funding, presented in Table 4 is more than double that of federal and state funding with a focus on translating fundamental research into commercial products (adapted from Anonymous 2014d; Flynn 2014).

The NNI strategic plan for FY 2015 was published in February 2014 by OSTP (Anonymous 2014a). In this plan, priorities for NNI funding by Program Component Area were (a) Foundational Research (35 % of NNI funding); (b) Applications, Devices, and Systems (24 %); (c) Signature Initiatives (19 %); (d) Infrastructure & Implementation (16 %); and (e) Environment, Health, and Safety (EHS) (7 %).

Five areas, called Nanotechnology Signature Initiatives (NSIs), were identified for targeted program-level interagency collaboration. These NSIs were intended to enable the rapid advancement of selected science and technology in the service of national security, economic, and environmental goals by focusing resources on critical challenges and R&D gaps (Anonymous 2014a, b). These areas were:

- *Nanotechnology for solar energy collection and conversion: contributing to energy solutions for the future* This NSI will utilize the unique physical phenomena that occur on the nanoscale to help overcome current performance barriers and substantially improve the collection and conversion of solar energy. Participating agencies include: DOE, NIST, NSF, DOD, Intelligence Community (IC), and US Department of Agriculture (USDA), and the National Institute of Food and Agriculture (NIFA).



NNI Goals and Objectives

Goal 1. Advance a world-class nanotechnology research and development program

1.1. Support R&D that extends the frontiers of nanotechnology and strengthens the intersections of scientific disciplines

1.2. Identify and support nanoscale science and technology research driven by national priorities and informed by active engagement with stakeholders

1.3. Assess the performance of the U.S. nanotechnology R&D program

1.4. Advance a portfolio of Nanotechnology Signature Initiatives (NSIs) that are each supported by three or more NNI agencies and address significant national priorities

Goal 2. Foster the transfer of new technologies into products for commercial and public benefit

2.1. Assist the nanotechnology-based business community in understanding the Federal Government's R&D funding and regulatory environment

2.2. Increase focus on nanotechnology-based commercialization and related support for public-private partnerships

2.3. Promote broader accessibility and utilization of user facilities, cooperative research centers, and regional initiatives to accelerate the transfer of nanoscale science from lab to market

2.4. Actively engage in international activities integral to the development and responsible commercialization of nanotechnology-enabled products and processes

Goal 3. Develop and sustain educational resources, a skilled workforce, and a dynamic infrastructure and tool set to advance nanotechnology

3.1. Sustain outreach and informal education programs in order to inform the public about the opportunities and impacts of nanotechnology

3.2. Establish and sustain programs that assist in developing and maintaining a skilled nanotechnology workforce

3.3. Provide, facilitate the sharing of, and sustain the physical R&D infrastructure, notably user facilities and cooperative research centers

Goal 4. Support responsible development of nanotechnology

4.1. Support creation of a comprehensive knowledge base for evaluation of the potential risks and benefits of nanotechnology to the environment and to human health and safety

4.2. Create and employ means for timely dissemination, evaluation, and incorporation of relevant EHS knowledge and best practices

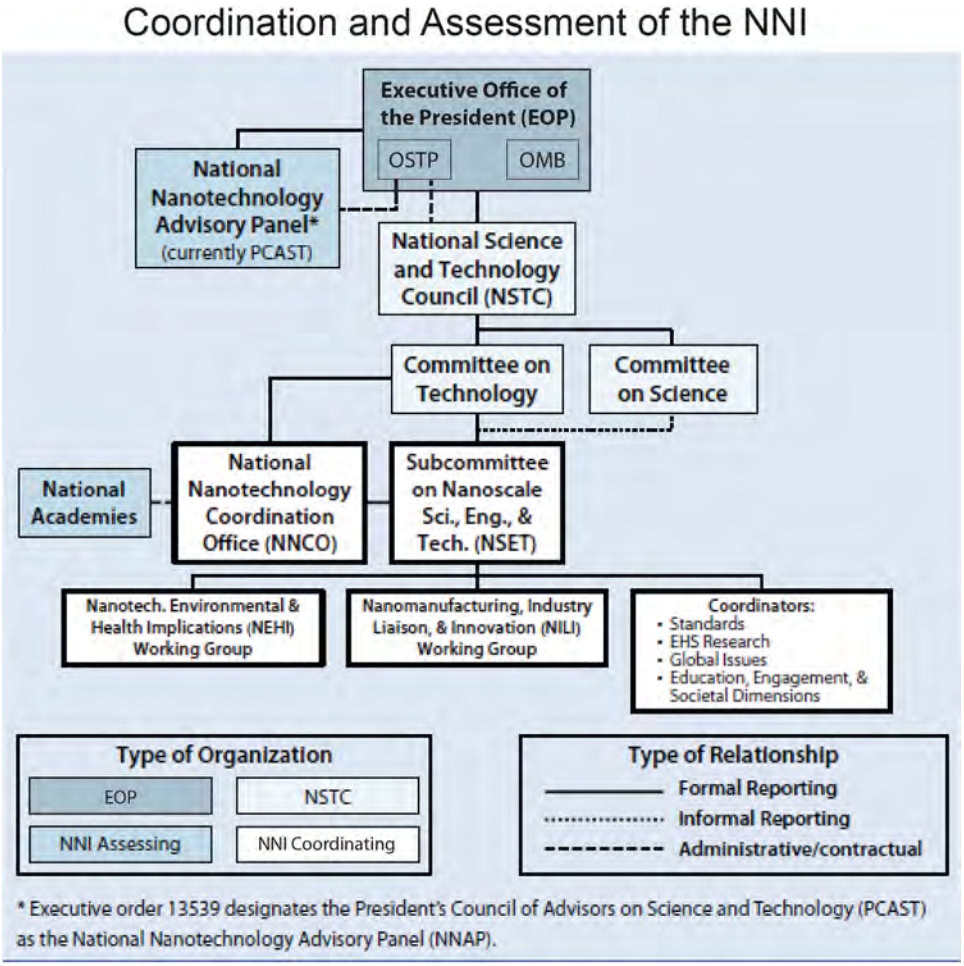
4.3. Develop the national capacity to identify, define, and responsibly address concepts and challenges specific to the ethical, legal, and societal implications (ELSI) of nanotechnology

4.4. Incorporate sustainability in the responsible development of nanotechnology

Fig. 3 A Summary of NNI goals and objectives from the 2014 NNI Strategic Plan (adapted from Anonymous 2014a)

- *Sustainable nanomanufacturing: creating the industries of the future* This NSI will establish manufacturing technologies for economical and sustainable integration of nanoscale building blocks into complex, large-scale systems by supporting product, tool, and process design informed by and adhering to the overall constraints of safety, sustainability, and scalability. Participating agencies include: NIST, NSF, DOE, Environmental Protection Agency (EPA), IC, NIH, National Institute for Occupational Safety and Health (NIOSH), Occupational Safety and Health Administration (OSHA), and USDA/Forestry Service (FS).
- *Nanoelectronics for 2020 and beyond* This NSI is aimed at discovering and using novel nanoscale fabrication processes and innovative concepts to produce revolu-

Fig. 4 Organizational structure for management of NNI (adapted from Anonymous 2014a)



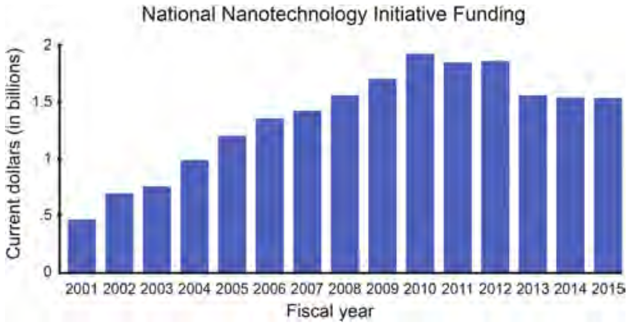


Fig. 5 US National Nanotechnology Initiative Funding, FY 2001–2015 (based on Anonymous 2014d)

tionary materials, devices, systems, and architectures to advance the field of nanoelectronics. Participating agencies include: NSF, DOD, NIST, DOE, and IC.

- *Nanotechnology knowledge infrastructure (NKI): enabling national leadership in sustainable design* This NSI will coordinate the nanoscale science, engineering, and technology communities around the fundamental, interconnected elements of collaborative modeling, a cyber-toolbox, and data infrastructure that will capitalize on American strengths in innovation, shorten the time from research to new product development, and maintain US leadership in sustainable design of engineered nanoscale materials. Participating agencies include: Consumer Product Safety Commission (CPSC), DOD, DOE, EPA, Food and Drug Administration (FDA), NASA, NIOSH, NIST, NSF, OSHA.
- *Nanotechnology for sensors and sensors for nanotechnology: improving and protecting health, safety, and the environment* This NSI has considerable potential for nanotechnology to open the door to the development of inexpensive, portable devices that can rapidly detect, identify, and quantify biological and chemical substances. Participating agencies include: CPSC, DOD, EPA, FDA, NASA, NIH, NIOSH, NIST, NSF, USDA.

In the international context, Federal investment in FY 2014 and 2015 by the US of about $1.5B per year is slightly higher than that by the EU or Japan. In 2014, the EU launched Horizon 2020 (2014–2020) after the conclusion of the EU FP7, with a total budget of €77B. In Horizon

Table 2 Federal departments and agencies participating in the NNI (Anonymous 2014a)

- A: Eleven Federal Departments and Independent Agencies and Commissions with Nanotechnology R&D Budgets
  - Consumer Product Safety Commission (CPSC)
  - Department of Commerce (DOC)
    - National Institute of Standards and Technology (NIST)
  - Department of Defense (DOD)
  - Department of Energy (DOE)
  - Department of Health and Human Services (DHHS)
    - Food and Drug Administration (FDA)
    - National Institute for Occupational Safety and Health (NIOSH)
    - National Institute for Health (NIH)
  - Department of Homeland Security (DHS)
  - Department of Transportation (DOT)
    - Federal Highway Administration (FHWA)
  - Environmental Protection Agency (EPA)
  - National Aeronautics and Space Administration (NASA)
  - National Science Foundation (NSF)
  - US Department of Agriculture (USDA)
    - Agricultural Research Service (ARS)
    - Forest Service (FS)
    - National Institute of Food and Agriculture (NIFA)
- B: Nine Other Participating Departments and Independent Agencies and Commissions
  - Department of Education (DOEd)
  - Department of the Interior (DOI)
  - US Geological Survey (USGS)
  - Department of Justice (DOJ)
    - National Institute of Justice (NIJ)
  - Department of Labor (DOL)
    - Occupational Safety and Health Administration (OSHA)
  - Department of State (DOS)
  - Department of the Treasury (DoTreas)
  - Intelligence Community (IC)
    - Office of the Director of National Intelligence (ODNI)
  - Nuclear Regulatory Commission (NRC)
  - US International Trade Commission (USITC)
- C: Also participating from the Department of Commerce (DOC), listed above
  - Bureau of Industry and Security (BIS)
  - Economic Development Administration (EDA)
  - US Patent and Trademark Office (USPTO)

2020, the EU identified six key areas: nanotechnology, advanced manufacturing, advanced materials, nanoelectronics, photonics, and biotechnology, and allocated €6.6 B for these areas over a 6 year period; about €1.1B per year. An additional €5B was planned for public–private partnerships. It should be noted that, in addition to EU expenditure, individual countries within the EU invest additional money on research. In 2014, Japan planned to spend ¥550B over the following 5 year period on nanotechnology, which translates to about $1B per year. Japanese companies are reported to invest about 90 % of total R&D in nanotechnology.

5 Worldwide R&D investments and output

5.1 R&D investments

Figure 6 shows Federal R&D funding from FY 1997 to FY 2009 for the US, EU, Japan, and others (adapted from Roco 2011). The funding has steadily grown for all countries. The US and the EU have made comparable investments, followed by Japan, China, Korea, and Taiwan. A substantial change in global investment rate is observed in about 2000 after introduction of the NNI and about 2006 due to the introduction

Table 3 NNI investments for various funding agencies from FY 2001 to FY 2015 (request)

National Nanotechnology Initiative Investments by Agency
FY 2001–2015 (dollars in millions)

FY	**2001**	**2002**	**2003**	**2004**	**2005**	**2006**	**2007**	**2008**	**2009**[†]	**2010**	**2011**	**2012**	**2013**	**2014**[††]	**2015**[†††]	**Total**[a]
CPSC	0	0	0	0	0	0	0	0	0.2	0.5	1.8	2.0	1.3	2.0	2.0	9.7
DHS	0	2	1	1	1	1.5	2.0	3.2	9.1	21.9	9.0	18.7	14.0	24.0	32.4	140.7
DOC/NIST	**33**	**77**	**64**	**77**	**79**	**77.9**	**87.6**	**85.6**	**93.4**	**114.7**	**95.9**	**95.4**	**91.4**	**97.8**	**82.6**	**1252.3**
DOD	**125**	**224**	**220**	**291**	**352**	**423.9**	**450.2**	**460.4**	**459**	**439.6**	**425.3**	**426.1**	**170.1**	**175.9**	**144**	**4786.4**
DOE	**88**	**89**	**134**	**202**	**208**	**231**	**236**	**244.7**	**332.6**	**373.8**	**346.2**	**313.8**	**314.2**	**303.3**	**343.1**	**3759.7**
DOJ	1	1	1	2	2	0.3	1.7	0.1	1.2	0.2	0	0	0	0	0	10.5
DOT	0	0	0	0	0	0.9	0.9	0.9	0.9	3.2	1.0	1.0	2.4	2.0	1.5	14.7
EPA	5	6	5	5	7	4.5	7.6	12.1	11.6	17.7	17.4	17.5	14.6	15.5	16.8	163.3
DHHS (tot)	40	59	78	106	168	195.4	222.7	311.4	356.0	472.6	428.6	479.6	485.4	469.5	469.6	4341.7
FDA	0	0	0	0	0	0	0	0	6.5	7.3	9.9	13.6	16.1	17.0	17.0	87.4
NIH	**40**	**59**	**78**	**106**	**165**	**191.6**	**215.4**	**304.5**	**342.8**	**456.8**	**408.6**	**456.0**	**458.8**	**441.5**	**441.5**	**4165.4**
NIOSH	0	0	0	0	3	3.8	7.3	6.9	6.7	8.5	10.0	10.0	10.5	11.0	11.1	88.8
NASA	22	35	36	47	45	50	19.8	17.4	13.7	19.7	17	18.6	16.4	17.9	13.7	389.2
NSF	**150**	**204**	**221**	**256**	**335**	**359.7**	**388.8**	**408.6**	**408.6**	**428.7**	**485.1**	**466.3**	**421.0**	**410.6**	**412.4**	**5355.8**
USDA (tot)	0	0	0	2	3	6.2	6.8	10.1	15.3	20.3	20.0	18.3	19.5	19.1	18.8	159.4
ARS	0	0	0	0	0	0	0	0	0	0	0	2.0	2.0	2.0	2.0	8.0
FS	0	0	0	0	0	2.3	2.9	4.6	5.4	7.1	10.0	5.0	5.0	4.0	4.0	50.3
NIFA	0	0	0	2	3	3.6	3.9	5.5	9.9	13.2	10.0	11.3	12.5	13.1	12.8	101.1
Total[†]	464	697	760	989	1200	1351.3	1424.1	1554.5	1701.5	1912.8	1847.3	1857.3	1550.2	1537.5	1536.9	20,383.4

Data provided by NNCO (Anonymous 2014d)

About 93 % of the funding is spent by the five agencies are highlighted in bold

[†] NOT including American Recovery and Reinvestment Act funds for NSF ($101 M), DOE ($239 M), NIST ($43 M), and NIH ($73 M)

[††] FY ’14 estimated based on 2014 enacted levels and may shift as operating plans are finalized

[†††] FY ’15 Request

[a] Totals may not add due to rounding

Table 4 R&D funding data across all industrial sectors in various regions in 2012, data collected by Lux research (adapted from Anonymous 2014d; Flynn 2014)

US	
Federal and state	$2.1 B
Industry	$4.0 B
Venture capital investors	$0.5 B
Total	$6.6 B
Worldwide	
Federal, state, industry, and venture capital investors	$18.5 B

of second generation nanotechnology products. The figure also shows the specific Nano R&D 2008 in dollars per capita. The numbers for the US, EU, and Korea are comparable, with Japan being higher. Figure 7 shows industrial spending for various countries in 2012 (adapted from Roco 2014). The US spent far more than other countries. However, the rest of

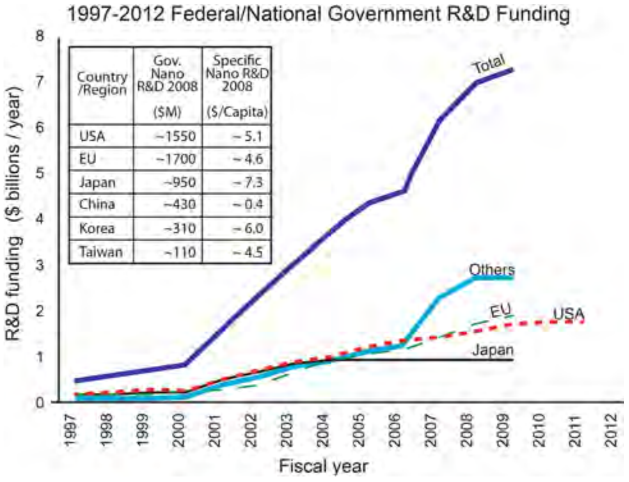


Fig. 6 FY 1997–2009 Federal/national government R&D funding. Specific nanotechnology R&D per capita is based on the national nanotechnology expenditures and effective expenditure for all other R&D programs (adapted from Roco 2011)

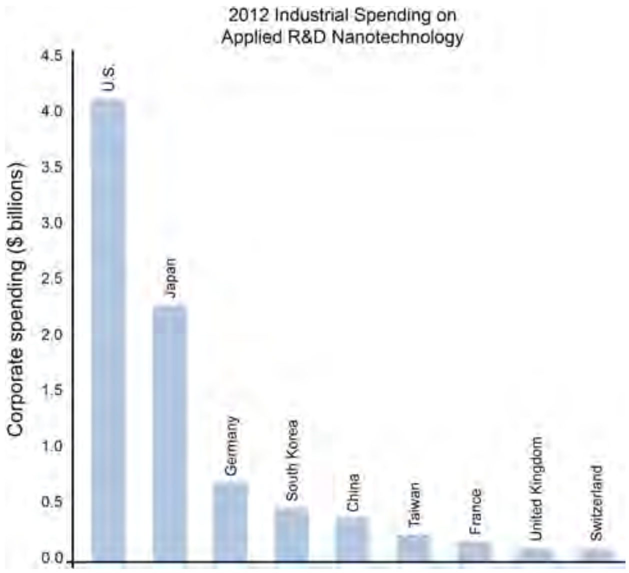


Fig. 7 Industrial R&D spending in 2012 for industry focused on applied R&D for first & second generations of nanotechnology products (based on Roco 2014)

the world, particularly emerging economies such as China, have been increasing their funding both at the national government and industrial levels at a rapid rate.

5.2 Output

Limited current US data exits on the return on investment in nanotechnology as it relates to scientific output, the number of jobs created, and product revenues (Roco 2011, 2014; Chen et al. 2013; Arora et al. 2013; Flynn 2014; Li et al. 2014). The European Commission Research Directorate General, Brussels, and the US organization for economic cooperation and development (OECD) have published some data on these subjects, though individual US federal agencies have not published much data themselves. These data are critical for tracking performance and for planning purposes. They are also critical for Congress to make educated decisions on reprioritization and total investments in nanotechnology R&D. In this section, we present an overview of the US data that exists in the public domain.

Figure 8a shows the number of nanotechnology publications in archival journals in the SCI database between 1990 and 2013 for the US and other countries (adapted from Roco 2014), and Fig. 8b, c show the number of nanotechnology patents published for the US and other countries (adapted from Anonymous 2014d). There is a steady growth in the number of publications for each country, although unevenly distributed among the various countries.

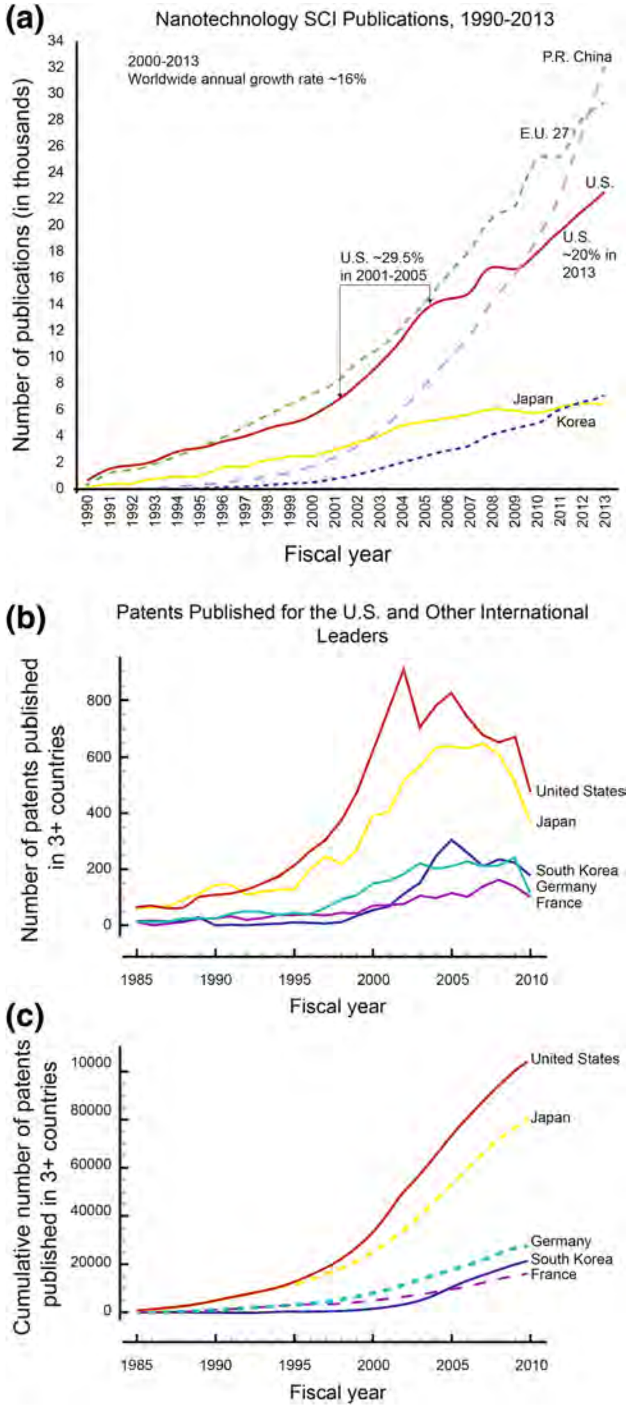
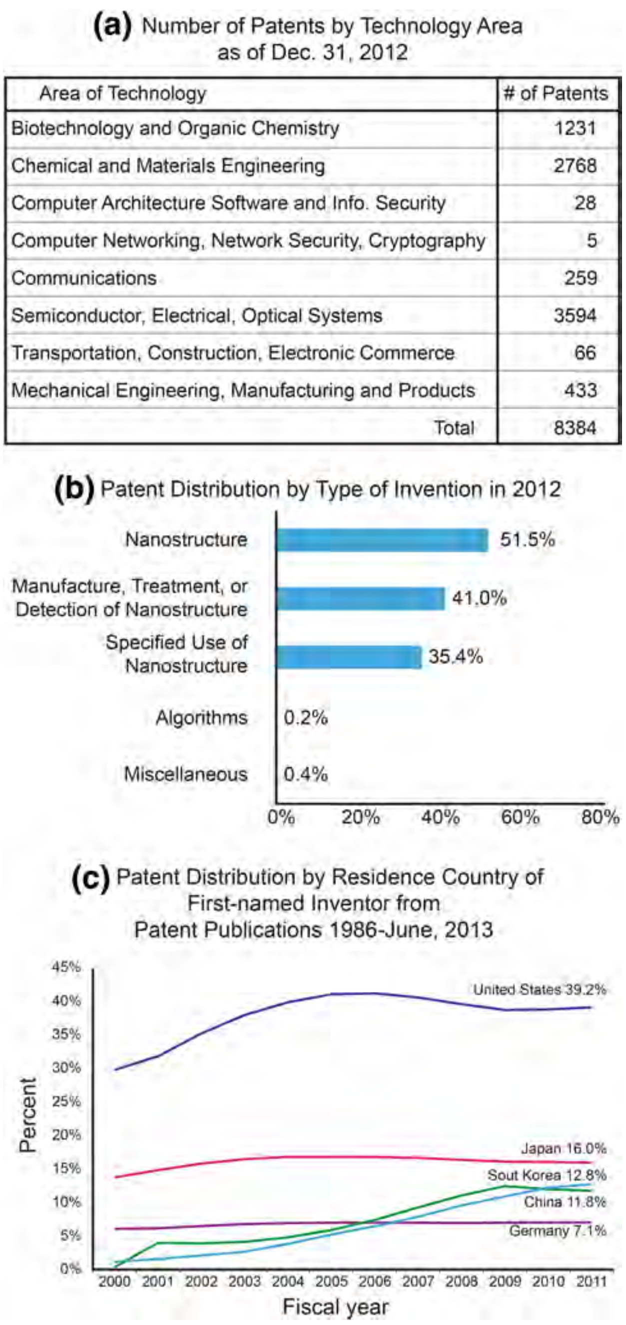


Fig. 8 **a** Number of nanotechnology SCI publications from 1990 to 2013. Data was generated from an online search in the Web of Science using a "title-abstract" search in the SCI database for nanotechnology by keywords (adapted from Roco 2014). **b**, **c** Number of nanotechnology patents published from 1985 to 2010 for the US and other countries. The metrics of patents published in three or more countries is a more representative indicator of significance (adapted from Anonymous 2014d)

The metrics of patents published in three of more countries is a more representative indicator of significance compared to those patents published in just one or two countries. It should be noted that although the rate of patents published has decreased over the past decade, the cumulative growth has continued. Additional data are provided by Roco (2011), and Chen et al. (2013). Figure 9 gives the breakdown of the number of patents issued by the US Patent and Trademark Office (USPTO) by technology area as of December 31, 2012, type of invention in 2012, and by country of residence of the first-named inventor from 1986 through June 2013 (adapted from Lorengo 2013).


(a) Number of Patents by Technology Area as of Dec. 31, 2012

Area of Technology	# of Patents
Biotechnology and Organic Chemistry	1231
Chemical and Materials Engineering	2768
Computer Architecture Software and Info. Security	28
Computer Networking, Network Security, Cryptography	5
Communications	259
Semiconductor, Electrical, Optical Systems	3594
Transportation, Construction, Electronic Commerce	66
Mechanical Engineering, Manufacturing and Products	433
Total	8384

Fig. 9 The breakdown of the number of patents issued by the USPTO based on **a** technology area, as of December 31, 2012, **b** type of invention in 2012, and **c** residence—country of first-named inventor, 1986-June 2013 (adapted from Lorengo 2013)

R&D funding breakdown and nano-enabled product revenues for various regions in 2012 are presented in Tables 4 and 5 (adapted from Flynn 2014; Whitman 2015). In 2012, for the US alone, nano-enabled product revenues were $236 billion for a modest annual federal R&D investment of $1.5 billion, or a total public/private investment of $6.6 billion. This represents an impressive return on investment.

Table 6 presents a summary of six key indicators of nanotechnology R&D investment and output in the world and the US between 2000 and 2010 (adapted from Roco 2014). The key indicators include (1) R&D funding (public and private), (2) venture capital, (3) SCI papers, (4) patent applications, (5) people—primary workforce, and (6) final products market. The growth rate of the key nanotechnology indicators of 16–33 % is observed. It is noted that the global market for nanomaterials has been reported to be tens of billions of dollars in FY 2015 with a rapid growth rate. The global revenues of nano-enabled products and nanomaterials are approaching $1 trillion.

Figure 10 shows the primary applications markets for nano-enabled products based on reviews gathered from 300 respondents in a 2014 survey project conducted by the National Center for Manufacturing Sciences (NCMS), Ann Arbor, Michigan (adapted from Mehta 2015). The data shows that some industries pursue simultaneous pathways for penetrating multiple markets and end users for their products. The largest application markets are listed below in decreasing order of response rate (percentage):

- Healthcare, pharmaceuticals, biomedical applications, and biotechnological applications,
- Electronics,
- Energy and energy storage,
- Chemical and processes,
- Automotive,
- Sensing and environment, and
- Aerospace.

Table 5 Nano-enabled product revenues data across all industrial sectors in various regions in 2012, data collected by Lux research (adapted from Flynn 2014; Whitman 2015)

US	$236 B
Europe	$235 B
Asia	$213 B
Rest of the world	$47 B
Total	$731 B

Table 6 Summary of six key indicators of nanotechnology R&D investment and output in the world and the US during 2000–2010 and projections for 2015 (adapted from Roco 2014) (Venture Capital estimations were made by Lux research)

World/US	R&D funding (public & private)	Venture capital	SCI papers	Patents applications	People—primary workforce	Final products market
2000	~$1.2B/$0.37B	~$0.21B/$0.17B	18,085/5342	1197/405	~60,000/25,000	~$30B/ $13B
2010	~$18B/$4.1B	~$1.3B/$1.0B	78,842/17,978	~20,000/5,000	~600,000/220,000	~$300B/$110B
2000–2010 (average growth)	~31 %/~27 %	~30 %/~35 %	~16 %/~13 %	~33 %/~28 %	~25 %/~23 %	~25 %/~24 %
2015 (projected)					~2,000,000/800,000	~1,000B/$400B

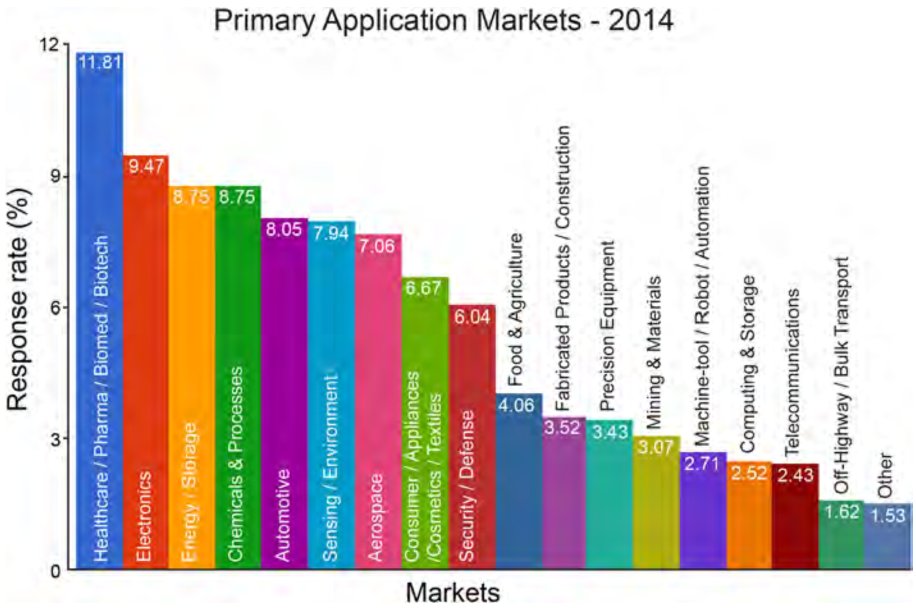


Fig. 10 Primary application markets—2014 for nano-enabled products based on reviews as ranked in a survey (adapted from Mehta 2015)

In summary, the US remains a global leader in both investments and output, as measured by the number of publications and patents, jobs, and nano-enabled product revenue. However, other countries are slowly catching up and competing with the US, including China which is rapidly increasing its share of investment.

6 NNI policy and legislative activities to 2014 in the US

6.1 Introduction of bills

Since the enactment of the Nanotechnology Act on Dec. 3, 2003, *it has not been reauthorized by Congress*. Reauthorization is necessary to address various concerns that have arisen in carrying out the goals of the NNI. Two bipartisan reauthorization bills were passed by the House in the 110th and 111th Congress; yet the Senate did not take any action on these bills. One bill was introduced by the Senate in the 111th Congress and it died in the committee process.

- 110th Congress, 2nd session, H. R. 5940, National Nanotechnology Initiative Amendments Acts of 2008, bipartisan.
- 111th Congress, 1st session, H. R. 554, National Nanotechnology Initiative Amendments Acts of 2009, bipartisan.
- 111th Congress, 1st session, S. 1482, National Nanotechnology Initiative Amendments Act of 2009, introduced by Democrats.

The following bills were introduced in the 113th Congress:

- 113th Congress, 1st session, H.R. 394, Nanotechnology Advancement and New Opportunities Act, introduced by Democrats and not refereed to committee.
- 113th Congress, 1st session, H. R. 4159, and 113th Congress, 2nd session, S. 2757, The America Competes Reauthorization Act of 2014.

NNI reauthorization was included as one of the titles in these two bills introduced by Democrats. They both died in committee.

For completeness, we make a few comments on the legislative process (White and Carrey 2011; Bhushan 2015). A bill takes a complex path before it becomes law. A bill with an identical language must pass by both chambers and be signed by the President to become law. Appropriations Committees of both Houses authorize funding of laws.

6.2 Hearings in 2013–2014

The author co-organized various nanotechnology hearings that were held in the 113th Congress in 2013–2014, while he was serving as an ASME Science & Technology Policy Fellow for the Subcommittee on Research and Technology, Committee on Science, Space, and Technology in US Congress in Washington, D.C. The following two information hearings were held:

- "Nanotechnology: From Laboratories to Commercial Products" on May 20, 2014, Organized by House Committee on Science, Space, and Technology
- "Nanotechnology: Understanding How Small Solutions Drive Big Innovation" on July 29, 2014, Organized by House Committee on Energy and Commerce.

One legislative hearing was held on a bill:

- "Frontiers in Innovative Research, Science, and Technology (FIRST) Act (H.R. 4186) which reauthorizes funding for NSF, NIST, OSTP and Interagency STEM Programs" on Nov. 13, 2013. This bill included a NNI component.

These hearings did not lead to any legislation in 2014.

6.3 NNI policy and the need of a reauthorization of the bill to address various concerns

Various concerns regarding the NNI have been raised in several reports on the mandated NNI Triennial Reviews. The National Academies report on the Triennial Review in 2013 (National Research Council 2013a) stated that five crosscutting recommendations should be implemented within 6 month:

- NNI should address the lack of information at the project level on who is performing research, where, and on what, as this has many implications.
- NNI should enhance planning, management, and coordination by developing and implementing interagency plans for focused areas, i.e., the signature initiatives and the working groups. Their absence implies lack of technology transfer.
- NNI should revise online resources, such as www.nano.gov, to effectively serve all the various stakeholder groups.
- NNI should develop test metrics for assessing progress toward goals and for informing program leadership using current advances in technology and methods, for example, in data collection and social network analysis.
- NNI should identify, share, and implement best practices, such as those described in the National Academies Report, especially relating to technology transfer and commercialization, as there are benefits to be gained by all.

At the request of Chairman of the House Science, Space, and Technology Committee, the Government Accountability Office (GAO) conducted a study and issued a report in 2014 entitled "Nanomanufacturing: Emergence and Implications for US Competitiveness, the Environment, and Human Health" (Anonymous 2014c). It examined current issues related to nanotechnology and nanomanufacturing. This report also identified various concerns in the NNI implementation, including the valley of death—gaps in funding or support for technology development and manufacturing development, for a schematic, see Fig. 11 (Bhushan 2015).

Research and some development occurs in academic labs, primarily funded by federal and state investments. Translational research is funded jointly by federal/state and private funding. Product launch is then carried out by startups and funded by venture capitalists or industry. Federal R&D agencies and public–private partnerships need to invest in technology transfer and developing research into a successful product. Technology transfer will drive the economy and facilitate in multiplying the investment in basic research. The idea that we "invest here and manufacture there" exists because the US economy is not able to provide the necessary investments and incentives for venture capitalists and industries (Bhushan 2015). The report also stated that there is a lack of participation in setting standards for nanomanufacturing and nanotechnology, a lack of national vision for nanomanufacturing capability, and a need for integrated framework to help assess and address the EHS implications.

The PCAST report on the Triennial Review issued in 2014 (Anonymous 2014d) reiterated many critiques advanced by the National Academies and GAO reviews. It stated that the NNI has reached a turning point. Although continued support of fundamental research in nanotechnology is critical, the transition toward commercialization is encouraged to translate the technologies and investments into commercial products and revenues. This may affect a range of technology areas, including drug

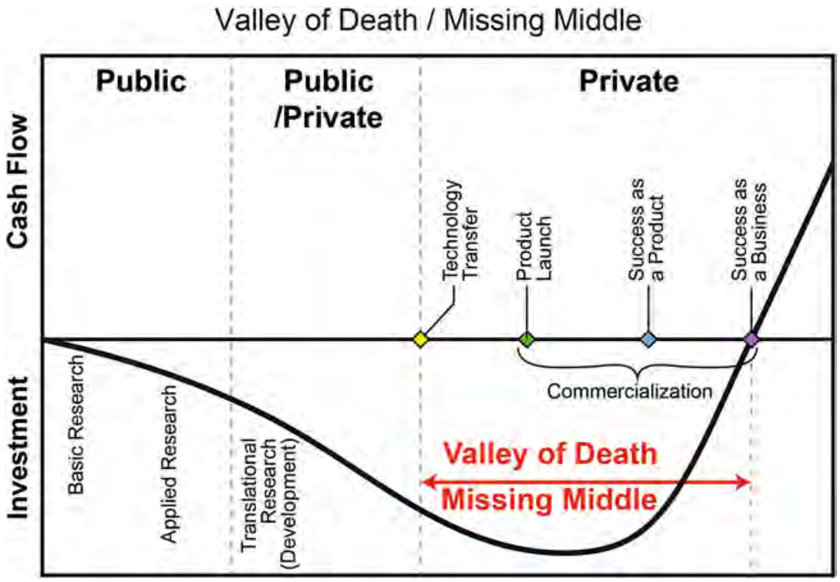


Fig. 11 Schematic showing the "valley of death" scenario (Bhushan 2015)

delivery, energy technology, smart sensors, clean water, and quantum computing.

The report presented four general constraints to technology commercialization (Anonymous 2014d). It stated that first-time academic entrepreneurs have little training or experience in moving a technical innovation out of the research lab and into a company. The second constraint has to do with a lack of marketing knowledge, i.e., how their innovation might address strategic goals of a company or could be translated into a successful product. Third, given that venture capitalists prefer to back experienced entrepreneurs, fund raising for newcomers becomes more difficult. Finally, an academic may not be allowed by the peer review process to pursue high-risk, high-return ideas. The report made recommendations to address all these constraints.

The report argued that the NSIs being used are shaped by coordination of three or more federal agencies around a topic. Instead, it recommends creation of "Grand Challenges," which are large, outward-facing efforts with specific, measurable goals. A Grand Challenge has a well-defined technical goal and it addresses an issue of significant societal impact. It has a measurable end-point with clear milestones en route.

The report recommended that the NNI redirect its vision. Significant recommendations are summarized below:

- NNI should transition its activities towards facilitating commercialization by directing the formulation of specific nanotechnology Grand Challenges. The Grand Challenge framework—a partnership between public and private sectors—can drive scientific advances to revolutionary commercialized products.
- Establish a process to identify the Grand Challenges and program-management changes to ensure their success.
- Federal R&D commercialization funding should be assessed through a formal system of metrics.
- Develop the next generation National Nanotechnology Infrastructure Network (NNIN).
- Define potential nanomanufacturing innovation institutes dedicated to nanotechnology.
- Expand NSF Innovation Corps with a focus on entrepreneurship in nanotechnology.
- Implement tools like innovation prizes and public/private partnerships to accelerate progress and commercialization.
- Establish an annual nano-focused economic development forum designed to bring together academic researchers, the venture capital community, and industry to enhance the possibility to create business partnerships.
- Execute a process to establish a common set of evaluation metrics to quantify and report impact on workforce, productivity, and scientific knowledge in nanotechnology.
- Continue work on EHS to ensure safe new technologies and develop public trust. Develop a multidisciplinary nanotechnology EHS ecosystem that will expedite safety assessment, decision, making, and commercialization.
- Develop comprehensive nanotechnology EHS standards.
- Support nanoscale research centers and infrastructure networks to ensure effective training of a new generation of interdisciplinary scientists and engineers.
- Develop new National Security Science and Engineering Faculty Fellowships-style research grants in nanotechnology to encourage US researchers to go abroad for a time.

- Identify ways to attract and ultimately to keep scientists and engineers in the US in order to sustain the research infrastructure.
- Align congressionally mandated reviews conducted by the National Academies and PCAST in order to reduce the burden on the NNI.

It should be noted that some in NNI management believe that there are excessive reporting requirements, presented in the section on Governance. The Senate Democratic bill (S. 2757, 113th Congress, 2nd session) introduced in July 2014, proposed that the frequency of reports should be decreased to every 4 years.

To expand on the importance of EHS focus, the use of nanotechnology products, particularly nanomaterials, is perceived to have potential EHS risks when exposed during manufacturing, use, or disposal. Established tools and techniques to study EHS risks do not exist for nanotechnology products. In addition, it is difficult to assess risks because nanomaterials may differ in size, shape, and surface chemistry. NIOSH is responsible for developing recommended exposure limits and necessary protective actions for nanomaterials (NIOSH 2009, 2013a, b; National Research Council 2013b).

Public understanding and attitudes may also affect the environment for R&D, reputation, and market acceptance of nanotechnology products (Sargent 2013). It is an important area and it requires funding. There are few efforts in various museums to educate and inform the public at large of the benefits of nanotechnology products (Crone 2006). A major effort has been carried out at the Boston Museum of Science, led by curator Larry Bell. They have developed various exhibits with nanotechnology objects which can be used by visitors of all ages.

A trained nanotechnology workforce needs to be developed. It is critical to attract and educate students in the growing field of nanotechnology. Curriculum development focusing on science and technology of nanotechnology should be continuously developed for various levels, including K-12, 2-year engineering and technology programs, university level for undergraduate and graduate students, and continuing education for practicing professionals. As an example, an effort in the US led by Pennsylvania State University is carried out by the Nanotechnology Applications and Career Knowledge (NACK) network to develop curriculum and assist 2-year community colleges, as well as to train practitioners.

6.4 Need for a workshop?

There is a concern on the efforts of the NNI, including technology transfer and Grand Challenges, as well as questions as to whether funding should be reprioritized and reallocated. There have been many workshops and studies, though none has been done under the umbrella of OSTP/NNCO or another unbiased organization. Congress needs reliable, quantitative data on various metrics, including the number of companies started, number of jobs created, and overall scientific and economic impact. This information must come from a reliable source—OSTP/NNCO—rather than from a third party. Thus, there is a need for a workshop done under the auspices of OSTP/NNCO bringing together policy legislators, experts, and practitioners to address many concerns in the execution of the NNI.

The following is a suggested scope for a workshop:

- *Economic benefits* Collect concrete data on the number of companies started, number of jobs created, and scientific and economic impact. How can we quantify and measure the effect of federal R&D funding on the creation of jobs, innovation, and industry?
- *Nano priorities* What are the Grand Challenges both in terms of research and applications? What are the global challenges in research and applications? Do we still need support to basic research or shall we move to applications and/or do we focus on a few basic areas and/or areas of national and economic importance? Is nanomanufacturing an important area for a significant focus, and what is the best path forward to encourage this area?
- *Federal coordination* How well is NNCO coordinating activities among the 27 federal agencies funding NNI activities to avoid duplication? Are appropriate metrics being implemented to monitor output and impact? Are all stakeholders being served?
- *Technology transfer* To facilitate translation/commercialization, identify areas where federal agencies and national labs can work with startups. Should we develop a consortium consisting of industry, national labs, federal agencies, and universities? Do we need a different venture capital (VC) model for nano—i.e. longer lead time, high investment, ramp-up period? How shall we implement tools such as innovation prizes and public–private partnerships to accelerate innovation and technology transfer?
- *Science, technology, engineering, and mathematics (STEM) education* How well have we done in education and outreach? Is there adequate public outreach? How should we attract and train nano workforce—activities aimed at K-12 students, museum exhibits, targeted doctoral fellowships? What is the role of nanotechnology in STEM education issues?
- *EHS* What are potential risks of nanomaterials and how to address them? Are the EHS concerns based on scientific evidence? Would focusing on these issues take away research funding for basic nano R&D?

- *International cooperation* Are there benefits of international cooperation? What would be appropriate and do we have enough? How can we encourage more international cooperation?

The data collected from the workshop can guide future NNI policies.

7 Summary and outlook

Nanotechnology refers to any technology done on a nanoscale that has applications in the real world. The properties of matter at the nanoscale are different from those at a larger scale. The unique physical and chemical properties of nanomaterials can be exploited for commercial applications that benefit society. The discovery of novel materials, processes, and phenomena at the nanoscale and the development of new experimental and theoretical techniques for research at the end of the 20th century, provide fresh opportunities for the development of innovative nanosystems and nanomaterials. Nanotechnology represents a "megatrend," and has become a "general purpose" technology.

The NNI was launched in the US in 2000 with a $497 million investment in the FY 2001 budget. In 2003, a 21st Century Nanotechnology R&D Act became law in the US, with $3.7 billion to be spent in the 4 year period beginning in October 2005 over six federal agencies. Through FY 2015, about $20 billion was spent by 20 federal agencies, with about $1.5 billion for FY 2015. Twenty top-level federal agencies (27 including all subsidiary and sub-agencies) fund NNI-related research with about 93 % of the funding being spent by five agencies (NIH, NSF, DOE, DOD, and NIST). The US private sector R&D investment is estimated to be twice that of public funding, with a focus on translating fundamental research into commercial products.

NNI is governed by an intricate organizational structure overseen by OSTP. NNCO has the responsibility to coordinate R&D activities among various federal agencies. Congress mandates various Triennial Review reports, including an external triennial assessment by the National Academies and another by PCAST, which reports to OSTP.

The US and the rest of the world continue to make significant investments. As of FY 2015, the US and the EU have made comparable government investments, followed by Japan, China, Korea, and Taiwan. US private industry has spent far more than other countries. However, the rest of the world, particularly emerging economies such as China, are increasing funding at a rapid rate. Based on key indicators of nanotechnology development, which include R&D funding, venture capital, SCI papers, patent applications, primary workforce, and final product market, a significant growth rate in all of these indicators is observed worldwide. The revenue from nano-enabled products continues to grow, with over $200 billion in 2012 in the US alone. This represents an impressive return on R&D investment.

Regarding legislative activities in the US, after the enactment the NNI in 2003, it has not been reauthorized by Congress. The 2013 report on the Triennial Review by the National Academies raised various concerns. Major concerns include lack of information at the project level on who is performing research and its implications; poor planning, management, and coordination; lack of metrics for assessing progress; and lack of official data on return on investments. A GAO report on nanomanufacturing released in 2014 identified various concerns, including the lack of investment in commercialization, resulting in the "valley of death." It also stated a lack of national vision in nanomanufacturing. It stressed the need for a lack of participation in setting standards for nanomanufacturing and nanotechnology. PCAST, in their report on the Triennial Review, also stated that NNI should transition its activities towards facilitating commercialization. They suggested development of the Grand Challenge framework to drive scientific advances to revolutionary commercial products. They emphasized the need for research on EHS-related issues to protect public life and environment, development of nanotechnology workforce, curriculum development, continued education of the public of the benefits of nanotechnology and changing attitudes should be continued. Reauthorization should address these various concerns.

As an outlook, NNCO needs to develop metrics to assess progress towards goals. Data on research and economic output should be collected regularly to show lawmakers the impact of federal investments on the economy to guide future policies. There appears to be a lack of investments in technology transfer. Since 2001, as expected, the major focus has been on foundational research, which has been broadly based. NNI is believed to have reached a turning point. One should assess the scientific progress made and its economic impact. Based on this detailed analysis, scientific focus may need to be on only a few areas of economic importance. In addition, the NNI needs to develop strategies for investment in translational research to facilitate commercialization. Finally, research on EHS related issues to protect public life and environment, development of nanotechnology workforce and curriculum development, programs to educate the public of the benefits of nanotechnology and to change attitudes toward nanotechnology should be continued.

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