CHAPTER 13

INNOVATIVE AND RESPONSIBLE GOVERNANCE OF NANOTECHNOLOGY FOR SOCIETAL DEVELOPMENT

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13.1 VISION FOR THE NEXT DECADE

Changes in the Vision over the Last Ten Years

Nanotechnology has been defined as "a multidisciplinary field in support of a broad-based technology to reach mass use by 2020, offering a new approach for education, innovation, learning, and governance" (Roco, Williams, and Alivisatos 1999). The governance of nanotechnology development for societal benefit is a challenge with many facets ranging from fostering research and innovation to addressing ethical concerns and long-term human development aspects. The U.S. nanotechnology governance approach has aimed to be "transformational, responsible, and inclusive, and [to] allow visionary development" (Roco 2008). Both domestically and globally, the approach to nanotechnology governance has evolved considerably in the last ten years:

- The viability and societal importance of nanotechnology applications has been confirmed, while extreme predictions, both pro and con, have receded.
- An international community of professionals and organizations engaged in research, education, production, and societal assessment of nanotechnology has been established.
- From a science-driven governance focus in 2001, there is in 2010 an increased governance focus on economic and societal outcomes and preparation for new generations of commercial nanotechnology products.
- There is greater recognition and specificity given in governance discussions to environmental, health, and safety (EHS) aspects (see Chapter 4) and ethical, legal, and social implications (ELSI) of nanotechnology. Considerable attention is being paid now to regulatory challenges, governance under conditions of uncertainty and knowledge gaps, use of voluntary codes, and modes of public participation in decision making. Overall, there is an increasing focus on "anticipatory governance."
- The vision of international and multinational collaboration and competition (Roco 2001) has become a reality and intensified since the first International Dialogue on Responsible Development of Nanotechnology was held in 2004 (NSF 2004).[46]

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Through its long-term planning, R&D investment policies, partnerships, deliberate activities to promote public engagement, anticipate the social consequences of scientific practices, and integrate the social and physical sciences, nanotechnology is becoming a model for addressing the societal implications and governance issues of emerging technologies generally (Guston 2010b). The commercialized nanotechnology innovation that accomplishes economic value for the nations that funded the research requires a supportive investment and workforce environment for manufacturing. Such environment has changed significantly in the last ten years by transfer of manufacturing capabilities from "West" to "East", and places risk in taking the nanotechnology benefits in the United States and Europe as compared to Asia.

Vision for the Next Ten Years

Nanotechnology is expected to reach mass applications in products and processes by 2020, significantly guided by societal needs-driven governance. The shift to more complex generations of nanotechnology products, and the need to responsibly address broad societal challenges such as sustainability and health, are prominent. The transition in scientific capability to complex nanosystems and molecular bottom-up nanotechnology-based components will multiply the potential for societal benefits and concerns and will require enhanced approaches to building accountable, anticipatory, and participatory governance with real-time technology assessment:

- *Emphasis is expected to increase on innovation and commercialization* for societal "returns on investment" of nanotechnology in economic development and job creation, with measures to ensure safety and public participation. An innovation ecosystem will be further developed for applications of nanotechnology, including support for multidisciplinary participation, multiple sectors of application, entrepreneurial training, multi-stakeholder-focused research, continuing science to technology integration, regional hubs, private-public partnerships, gap funding, global commercialization, and legal and tax incentives. The balance between competitive benefits and safety concerns needs to be addressed in each economy by considering international context.
- *Nanotechnology will become a general-purpose enabling technology*, which—as with such prior technologies as electricity or computing—is likely to have widespread and pervasive applications across many sectors, combining incremental improvements with breakthrough solutions. Nanotechnology will become critical to commercial competitiveness in sectors such as advanced materials, electronics, and pharmaceuticals. Precompetitive nanoscale science and engineering platforms will provide the foundation for new activities in diverse industry sectors. Multidisciplinary horizontal, research-to-application vertical, regional hubs and system-integrated infrastructure will be developed. As nanotechnology grows in a broader context, it will further enable synthetic biology, quantum information systems, neuromorphic engineering, geoengineering, and other emerging and converging technologies.
- It will become imperative over the next decade to focus not only on how nanotechnology can generate economic and medical value ("material progress"), but also on how *nanotechnology can create cognitive, social, and environmental value ("moral progress")*.
- *Nanotechnology governance will become institutionalized* in research, education, manufacturing, and medicine, for optimum societal benefits.

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[46] Also see reports of the Japan and Brussels dialogues in 2006 and 2008: http://unit.aist.go.jp/nri/ci/nanotech_society/Si_portal_j/doc/doc_report/report.pdf and http://cordis.europa.eu/nanotechnology/src/intldialogue.htm.

- *Global coordination will be needed* for international standards and nomenclature, nano-EHS (such as toxicity testing and risk assessment and mitigation) and ELSI (such as public participation in achieving both benefits and safety, and reducing the gap between developing and developed countries). An international co-funding mechanism is envisioned.

13.2 ADVANCES IN THE LAST TEN YEARS AND CURRENT STATUS

Just a decade ago, governments, academia, and industry—in the United States and elsewhere in the world—commissioned a massive expansion of research and development in nanotechnology based on a long-term science and engineering vision. Systematic investment in research on societal dimensions of nanotechnology has been undertaken in the United States since 2001, in the European Union (EU) since 2003, in Japan since 2006, and in other countries as well as by international organizations (e.g., the Organization for Economic Co-operation and Development, International Organisation for Standardization, and International Risk Governance Council) since at least 2005. Societal dimensions were included as an essential part of the vision from the beginning of the U.S. National Nanotechnology Initiative (NNI) (Roco and Bainbridge 2001). Nanotechnology has proven it has essential implications for how we comprehend nature, increase productivity, improve health, and extend the limits of sustainable development, among other vital topics.

Governance of Nanotechnology

Key challenges to nanotechnology governance have been recognized and implemented. These include developing the multidisciplinary knowledge foundation; establishing the innovation chain from discovery to societal use; establishing an international common language in nomenclature and patents; addressing broader implications for society; and developing the tools, people, and organizations to responsibly take advantage of the benefits of the new technology. To address those challenges, four simultaneous characteristics of effective nanotechnology governance were proposed and have been applied since 2001 (Roco 2008). Nanotechnology governance needs to be:

- Transformative (including a results or projects-oriented focus on advancing multi-disciplinary and multisector innovation)
- Responsible (including EHS and equitable access and benefits)
- Inclusive (participation of all agencies and stakeholders)
- Visionary (including long-term planning and anticipatory, adaptive measures)

These characteristics of nanotechnology governance continue to be important and applicable. United States examples of these four governance functions are presented in Table 13.1.

There is now an international community of scholars addressing not only research and education but also health and safety, ethics, and societal dimensions of nanotechnology. Examples of mechanisms and outputs include the National Science Foundation's "Nanotechnology in Society" network (begun in 2005), journals and publications (e.g., *Nanotechnology Law and Business* and *NanoEthics* journals, *Encyclopedia of Nanoscience and Society* (Guston 2010); and editorials in general, research-oriented journals such as *Nature Nanotechnology* and *Journal of Nanoparticle Research*, and the founding of the academic society, the Society for the Study of Nanoscience and Emerging Technologies (S.NET; http://www.theSnet.net) in 2009. From a position in 2000 where "science leaps ahead, ethics lags behind" (Mnyusiwalla et al. 2003), we are in 2010 in the process of achieving a more appropriate balance between science and ethics. A European Community (EC) "Code of Conduct for Research" has been proposed, but a common terminology and levels of national commitments have still to be reached internationally.

On EHS-related issues (Chapter 4), the international research community has been implementing integrative work that brings together physical sciences and social sciences. Voluntary reporting schemes have been introduced, albeit with limited impact (e.g., via the U.S. Environmental Protection Agency in the United States, the California Department of Toxic Substance Control, and the Department of Farming and Rural Affairs in the UK). Standardization and metrology progress is taking place (see Chapter 2). However, innovation is moving ahead of regulation, in part because regulatory bodies are waiting for standards (nomenclature, traceability methods, etc.). Two approaches are being developed in parallel in regulation of nanotechnology:

- Probing the extendibility of regulatory schemes like the Toxic Substances Control Act (TSCA) in the United States and the Registration, Evaluation and Authorization CHemicals Regulation (REACH) Act in the EU (both following a "developing the science" approach)
- Exploring (soft) regulatory and governance models that work despite insufficient knowledge for full risk assessment, including as ELSI research, voluntary codes, public engagement, observatories, public attitude surveys, and other instruments

Table 13.1 Examples of U.S. applications of nanotechnology governance functions (2001-2010)

Nanotechnology Governance Aspect	Example 1	Example 2
TRANSFORMATIVE Function		
Investment policies	Support a balanced and integrated R&D infrastructure (NNI Budget requests, 2001–2010; about 100 new centers and networks)	Priority support for fundamental research, nanomanufacturing, healthcare (NIH/NCI cancer research), and other areas
Science, technology, and business policies	Support competitive peer-reviewed, multi-disciplinary R&D programs in NNI agencies	Support for innovation in converging technologies (nano-bio-info-others) at NSF, DOD, NASA
Education and training	Introduce earlier nanotechnology education (e.g., NSF's Nanoscale Center of Learning and Teaching 2005–, Nanotechnology Undergraduate Education 2002–, and K–16 programs)	Nanotechnology informal education extended to museums and Internet (e.g., NSF's Nanoscale Informal Science and Engineering network, 2005–)
Technology and economic trans-formation tools	Support integrative nanotechnology cross-sector platforms (e.g., Nanoelectronics Research Initiative 2004–)	Establish Nanomanufacturing R&D program at NSF in 2002; NSET Nanomanufacturing, Industry Liaison & Innovation working group (NILI), 2005–
RESPONSIBLE Function		
Environmental, health, and safety (EHS) implications	U.S. Congress: Nanotechnology R&D Act of December 2003 includes EHS guidance; OSTP, PCAST, and NRC make EHS recommendations; NNI publishes national strategy for nano-EHS, 2008	Program announcements since 2001 (NSF), 2003 (EPA), 2004 (NIH); NSET Nanotechnology Environmental and Health Implications working group (NEHI), 2005–
Ethical, legal, and social issues and other issues (ELSI+)	Ethics of nanotechnology addressed in publications (Roco and Bainbridge 2001 and 2007; NGOs and UNESCO reports, e.g., UNESCO 2006)	Program announcements for nano-ELSI (NSF, 2004–); Equitable benefits for developing countries (ETC - Canada 2005; CNS-UCSB 2009)
Methods for risk governance	Risk analysis, including the social context, supported by NSF and EPA; applied in EPA, FDA, and OSHA policies	Multilevel risk nanotechnology governance in global ecological system (International Risk Governance Council (IRGC) 2009)
Regulations and reinforcement	Nanotechnology-focused regulatory groups created at EPA, FDA, and NIOSH	Voluntary measures for nano-EHS at EPA, 2008
Communication and participation	Increased interactions among experts, users, and public at large via public hearings	Public and professional society participation in the legislative process for NNI funding

INCLUSIVENESS Function		
Partnerships to build national capacity	Foster interagency partnerships (25 agencies); industry-academe-state-Federal government partnerships (NNI support for three regional-local-state workshops)	Partnering among research funding and regulatory agencies for dealing with nanotechnology implications in the NSET Subcommittee and NEHI Working Group
Global capacity	International Dialogue Series on Responsible Nanotechnology (2004, 2006, 2008) initiating new activities; Follow-up on OECD, ISO, UNESCO	International Risk Governance Council reports on all nanotechnology and on food and cosmetics (International Risk Governance Council (IRGC) 2009)
Public participation	Public input into R&D planning for nanotechnology EHS and ELSI after 2005	Combined public and expert surveys; public deliberations; informal science education (e.g., NSF)
VISIONARY Function		
Long-term, global view	*Nanotechnology Research Directions* books (1999 & 2010); these inform the strategy of the U.S., EU, Japan, Korea, China, and other countries	Long-term effect of technology on human development (*Humanity and the Biosphere*, FFF and UNESCO 2007)
Support human development, incl. sustainability	Research on energy and water resources using nanotechnology (DOE, NSF, EPA, others)	Research connecting nervous system, nanoscale physico-chemical mechanisms, brain functions, and education (NSF, NIH)
Long-term planning	Ten-year vision statements published for 2001–2010 (published in 2000) and 2011–2020 (this report, 2010)	NNI strategic plans every three years (last three in 2004, 2007, and 2010), followed by PCAST and NRC evaluations

Overall, the governance of nanotechnology has been focused on the first generation of nanotechnology products (passive nanostructures), with research and studies commencing on the next generations (see their descriptions in the chapter on Long View). Local governance innovations in places like Berkeley (CA), Cambridge (MA), Albany (NY), and in states like New York, California, Oklahoma, and Oregon, have provided “laboratories” for governance, including for regulatory and voluntary approaches. Their ideas have been modeled internationally and offer a perspective for future regional “innovation hubs” recommended later in this chapter.

Growth of Research and Outreach on Nanotechnology’s Impact on Society

The report *Societal Implications of Nanoscience and Nanotechnology* (Roco and Bainbridge 2001) called for the involvement of social scientists from the beginning of the nanotechnology enterprise in large nanotechnology programs, centers, and projects. In 2000 there was very little attention paid to nanotechnology among the community of scholars that studies science and technology from a societal perspective (Bennett and Sarewitz 2006). Research, education, and professional activities in the societal aspects of nanotechnology, supported by the NNI agencies, have made significant progress in a short period of time. Nearly half of all articles on societal dimensions of nanotechnology today have at least one author from a U.S. institution, whereas only about one-quarter of all nanotechnology articles published from 2005 to 2007 had at least one U.S. author.

An early report on converging technologies (Roco and Bainbridge 2003, xii) recommended that “Ethical, legal, moral, economic, environmental, workforce development, and other societal implications must be addressed from the beginning, involving leading … scientists and engineers, social scientists, and a broad coalition of professional and civic organizations.” There is now widespread agreement that it is better to address early the long-term EHS and ELSI issues related to converging and emerging technologies in a responsible government-sponsored framework but with broad stakeholder input, rather than having to adjust and respond to developments after the fact.

Research on societal implications of nanotechnology has been sponsored by the National Science Foundation (NSF) and other agencies involved in the National Nanotechnology Initiative (NNI) since September 2000, reaffirmed and strengthened by Congress (e.g., in the 21st Century Nanotechnology R&D Act of 2003) and National Research Council reports in 2002, 2006, and 2009. The second report by the President's Council of Advisors on Science and Technology on nanotechnology (President's Council of Advisors on Science and Technology [PCAST], 2005, 38) exhorted NNI agencies to "engage scholars who represent disciplines that might not have been previously engaged in nanotechnology-related research… [and ensure that] …these efforts should be integrated with conventional scientific and engineering research programs." The development of general areas of attention was impacted by NNI funding, particularly funding through the NSF Nanoscale Interdisciplinary Research Team (NIRT) projects since 2001. The two Centers for Nanotechnology in Society (CNS) at Arizona State University (ASU) and the University of California, Santa Barbara (UCSB), founded by NSF in fall 2005, together with the NIRTs at the University of South Carolina-Columbia and Harvard, constitute a network for nanotechnology in society. Table 13.4 in Section 13.8.2 illustrates the considerable NSF investment in research and outreach on nanotechnology's impact on society. In March 2010, the NNI sponsored an EHS "Capstone" workshop that incorporated ELSI into discussions of how to shape the Federal investment in research on the environmental implications of nanotechnology.

Nanotechnology Innovation and Commercialization

New forms of organization and business models may originate with nanotechnology, in support of innovation. Innovation in nanotechnology generally involves a complex value chain, including large and small companies, research organizations, equipment suppliers, intermediaries, finance and insurance, ends users (who may be in the private and public sectors), regulators, and other stakeholder groups in a highly distributed global economy (Youtie et al. 2008; Nikulainen and Kulvik 2009; Gomez-Baquero 2009). Most nanotechnology components are incorporated into existing industrial products to improve their performance.

Between 1990 and 2008, about 17,600 companies worldwide, of which 5,440 were U.S. companies, published about 52,100 scientific articles and applied for about 45,050 patents in the nanotechnology domain (Shapira, Youtie, and Kay 2010). The growth in the number of patents and publications worldwide by private and public organizations has had a quasi-exponential trend since 2000 (Chen and Roco 2009). The ratio of corporate nanotechnology patent applications to corporate nanotechnology publications increased noticeably from about 0.23 in 1999 to over 1.2 in 2008; this changing ratio indicates a shift in corporate interest from discovery to applications. While most patents in nanotechnology are filed by large companies, small and medium-sized enterprises (SMEs) have increased their patent filings. For example, the proportion of World Intellectual Property Office Patent Cooperation Treaty patents in nanotechnology filed by U.S. SMEs compared with U.S. large companies increased from about 20 percent in the late 1990s to about 35 percent by 2006 (Fernández-Ribas 2009).

The nanoscale science and engineering (NSE) patents authored by NSF grantees receiving support for fundamental research have a significantly higher citation index than all NSE patents (Hwang et al. 2005). This underlines the importance of fundamental research in the overall portfolio. Wang and Shapira (2009) identified about 230 new nanotechnology-based venture start-ups formed in the United States through to 2005, about one-half being companies that had spun off from universities.

The broad nature of nanotechnology indicates that many geographical regions will have opportunities to engage in the development of nanotechnology. For example, while leading high-technology regions in the United States (such as the areas of San Francisco-Palo Alto and Boston) are at the forefront of nanotechnology innovation, other U.S. cities and regions also have clusters of corporations engaged in nanotechnology innovation. There is an extensive corridor of corporate nanotechnology activity along the East Coast, and there are multiple companies engaged in nanotechnology innovation in other traditional industrial areas of the Northeast and Midwest. Southern California also has prominent clusters of corporate nanotechnology activities, with emergent clusters also developing in the U.S. South (Figure 13.1a).

In the period 1990-2009, twenty leading countries accounted for 93.8% of the 17,133 corporate publication/patent entries from 87 countries (Figure 13.1b). The countries of the Organisation for Economic Co-operation and Development (OECD) together accounted for the major share of the world's corporate activity in nanotechnology publications and patents during that period. All of the OECD had 14,087 entries, of which 4,330 were from European OECD members. (All of the European Union countries combined had 4,390 entries.) Of the non-OECD countries, Japan and China dominated, with Taiwan, Russia, Brazil, and India also making distinguishable contributions to the total. The United States had 5,328 entries, Japan had 2,029 entries, and China had 1,989 entries.

A key factor for commercialized innovation and economic development is the nanotechnology development and "general technology development strength" of each nation (Hwang 2010). The nations were ranked after those criteria. In nanotechnology development, the U.S. is the largest contributor followed by Japan and Germany. After the "general technology development strength", Korea, Japan, and Taiwan are best positioned, while the U.S. is close to the middle of 19 surveyed countries.

The balance between competitive benefits and safety concerns needs to be addressed in each country by considering international context. There is a risk to innovation-based prosperity and this has to be evaluated by considering the ensemble of societal effects.

Other key factors for innovation and corporate decision making in nanotechnology are recognizing consumers' values, their perceptions of the acceptability of products, and their responses to labeling. Taiwan's "nanoMark" approach recognizes legitimate applications of nanotechnology, and the labeling proposal under consideration by the EU, is focused on protecting the public against potential negative health effects. Consumer perceptions are affected by awareness education and access to information.

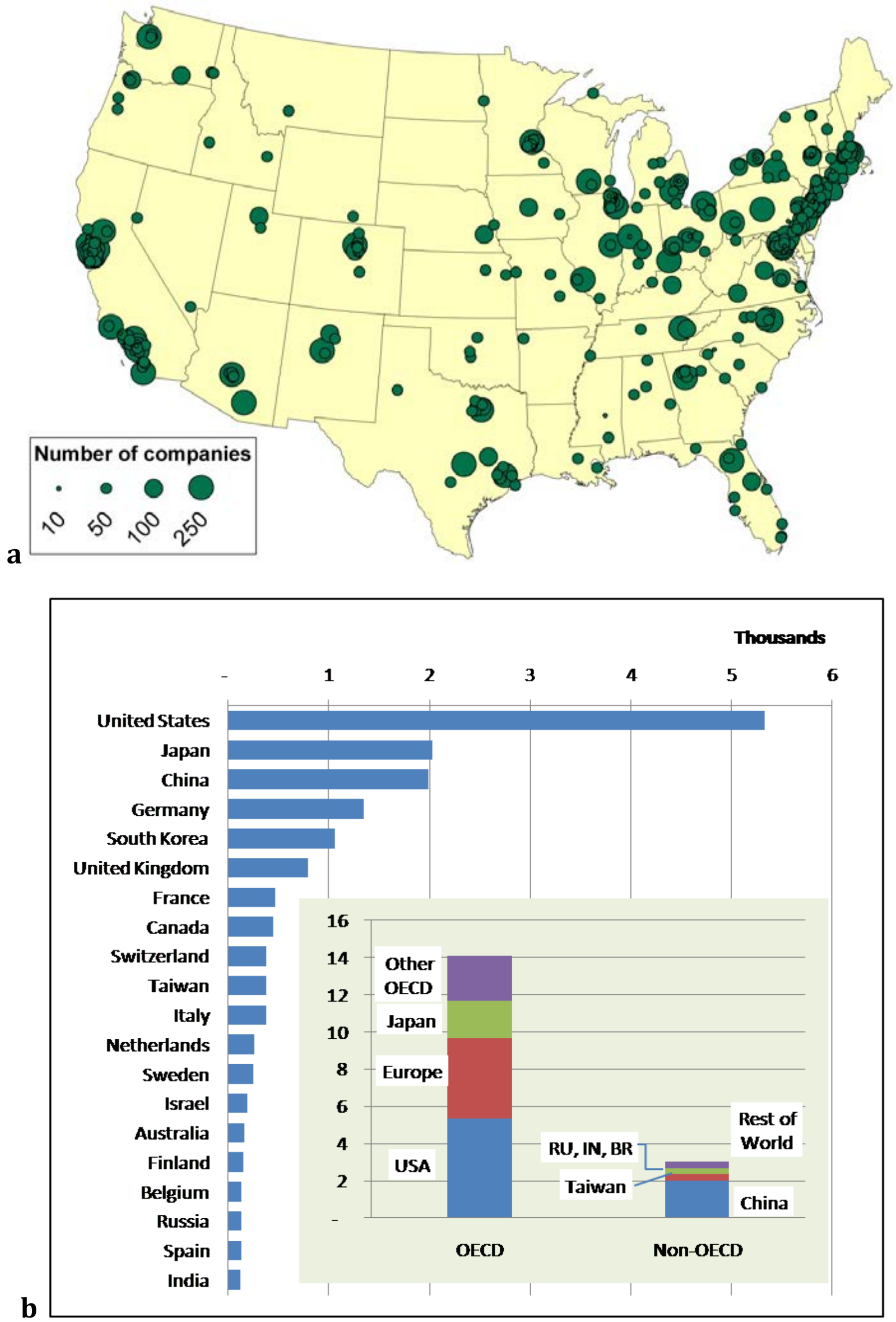


Figure 13.1. Distribution of corporate entries into nanotechnology in the United States and other leading countries, 1990-2009. Analysis of companies reporting nanotechnology publications and/or patent records (applications or grants, all patent offices, 1990-July 2008), based on Georgia Tech global database of nanotechnology publications and patents. Cities with 10 or more companies with entry into nanotechnology are mapped: (*a*) United States; (*b*) Leading countries and blocs; OECD indicates the 33 member countries of the Organisation for Economic Cooperation and Development; Europe = 20 European members of OECD with nanotechnology corporate entries; RU, IN, BR = Russia, India, and Brazil. (courtesy of Philip Shapira, Jan Youtie, and Luciano Kay.)

Public Perceptions of Nanotechnology

Surveys show that nanotechnology, when compared to other technologies, is not at the extreme, but close to biotechnology in terms of public perceptions about relative benefits and risks (Figure 13.2). A meta-analysis of 22 public surveys conducted from 2002 to 2009 in the United States, Canada, Europe, and Japan found ongoing low levels of public familiarity with nanotechnology, with benefits viewed as outweighing risks by 3 to 1, but also a large (44%) minority who had not yet made up their minds about benefits or risks (Satterfield et al. 2009).

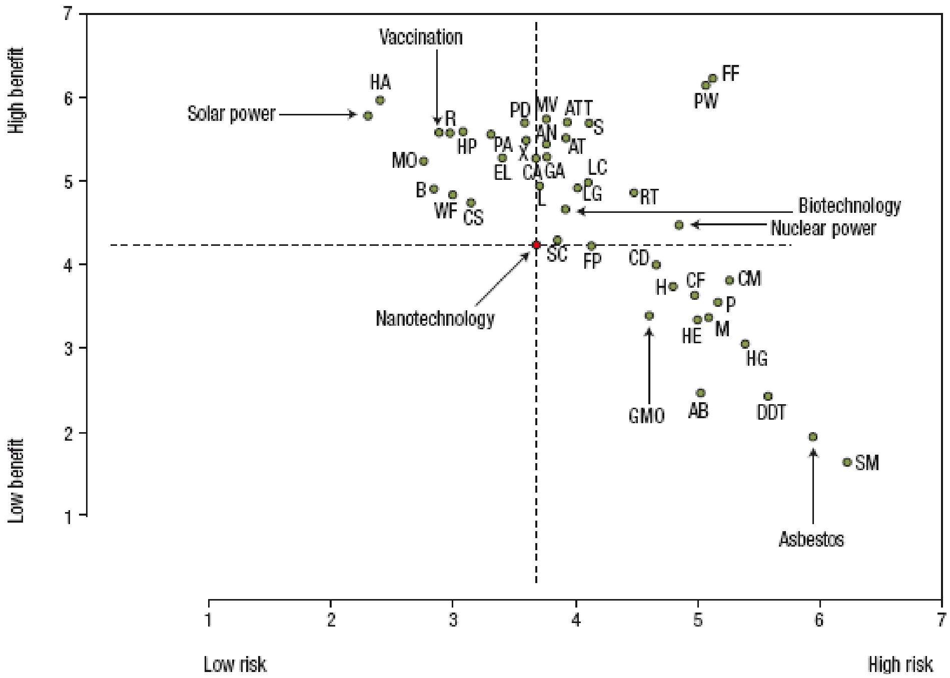
Public participation has been a central focus of an increasing amount of research. Upstream risk perception research (Pidgeon et al. 2009), small-scale informal science education activities with some engagement aspects such as science cafés, and U.S. public engagement activities around nanotechnology, such as Arizona State University's National Citizens' Technology Forum (NCTF) (Hamlett et al. 2008) and the comparative U.S.-UK and gender–focused deliberations at University of California–Santa Barbara, have been undertaken. In addition, there has been increasing use of scenarios and other foresight tools (including roadmaps, Delphi studies, etc.) in the last ten years.

Prospects for Legislation

Social sciences scholars have scrutinized extant and prospective options for environmental health and safety regulation at the national level (e.g., Bosso 2010, Kuzma et al. 2008a, Wolf et al. 2009) and in the scientific (Powell 2007) and industrial workplaces (Conti et al. 2008; the CNS-UCSB Nanotechnology and Occupational Health and Safety Conference 2007; Center for Environmental Implications of Nanotechnology industry survey 2009–2010). Davies (2009) prepared a report on legislative aspects related to new generations of nanotechnology products and processes. The Chemical Heritage Foundation commissioned a study of nanomaterials' regulatory challenges across the product life cycle, an important direction for new research (Beaudrie 2010). New legislative and regulatory initiatives are likely to focus on nanotechnology's environmental, health, and safety implications, as well as on the new generations of nanotechnology products. Such initiatives will be able to draw on this growing body of research.

Addressing Grand Challenges for Societal Development

Nanotechnology may allow us to build a sustainable, society-focused technology through up-front design rather than retroactive problem solving (see Chapters 5 and 6), use of molecular medicine and personalized health treatment (Chapter 7), increased productivity (Chapters 3 and 11), and early and continuing emphasis on multidisciplinary education (Chapter 12).



Key to acronyms

AB	alcoholic beverages	FF	fire fighting	MV	motor vehicles
AN	anesthetics	FP	food preservatives	P	pesticides
AT	air travel	GA	general aviation	PA	prescription antibiotics
ATT	automobile travel	H	herbicides	PD	prescription drugs
B	bicycles	HA	home appliances	PW	police work
CA	commercial aviation	HE	human genetic engineering	R	railroad
CD	chemical disinfectants	HG	handguns	RT	radiation therapy
CF	chemical fertilizers	HP	hydroelectric power	S	surgery
CM	chemical manufacturing plants	L	lasers	SC	stem-cell research
CS	computer display screens	LC	large construction	SM	smoking
DDT	dichloro-diphenyl-trichloroethane	LG	liquid natural gas	WF	water fluoridation
		M	motorcycles	X	x-rays
EL	electric power	MO	microwave ovens		

Figure 13.2. Survey of public perceptions of nanotechnology products by CBEN (after Currall et al. 2006).

Evaluating nanotechnology in the context of other emerging technologies is essential for overall development of societal benefit. For example, synthetic biology as an object of social study is perhaps as ill-defined today as nanotechnology was a decade ago. Research on nanotechnology applications has created many opportunities for social engagement in the process, from developing a strong understanding of the dynamics of emergent public perception and public opinion around nanotechnology to proposing new institutional modes of governance of nanotechnology development.

International Interactions and ELSI

A strategy was proposed in 2000 to create an international scientific R&D community driven by broad human development goals (Roco 2001). Many of those goals are still valid in 2010. Several different formats for international dialogue have emerged, each with strengths and limitations. Those formats include the International Dialogues on Responsible Research and Development of Nanotechnology (2004, 2006, 2008), and the Organisation for Economic Co-operation and Development (OECD). The first International Dialogue on Responsible Nanotechnology R&D, held in 2004 (http://www.nsf.gov/crssprgm/nano/activities/dialog.jsp) in Virginia (United States), was the first truly international meeting focused on a long-term view in nanotechnology; it was followed by similar meetings in 2006 in Tokyo (Japan) and in 2008 in Brussels (EU). The 2004 meeting inspired a series of loosely coordinated activities:

- October 2004 to October 2005, Occupational Safety Group (UK, United States)
- November 2004, OECD/EHS group on nanotechnology begins
- December 2004, Meridian study for developing countries (Barker et al. 2005)
- December 2004, Nomenclature and standards (ISO, ANSI)
- February 2005, North-South Dialogue on Nanotechnology (UNIDO)
- May 2005, International Risk Governance Council (IRGC)
- May 2005, "Nano-world," Materials Research Society (materials, education)
- July 2005, Interim International Dialogue (host: EC)
- October 2005, OECD Working Party on Nanotechnology in the Committee for Scientific and Technological Policy (CSTP)
- June 2006, 2nd International Dialogue (host: Japan)
- 2006 to 2010, Growing international awareness in other national and international organizations of EHS, public participation, education for nanotechnology

Differences are noticeable today in the application of nanotechnology on a global scale (Cozzens and Wetmore 2010). Open-source "humanitarian" technology development increasingly is seen as key to nanotechnology applications in the developing world in vital, life-sustaining fields like water, energy, health, and food security (http://nanoequity2009.cns.ucsb.edu/).

The U.S. NNI agencies, followed by the EU, Japan, and Korea, have taken a multipronged approach to funding ELSI projects, which has yielded significant progress over the past decade. International perspectives reflecting opinions from over 40 countries are presented in Section 13.9 of this chapter. Table 13.2 lists a number of reference websites with ELSI materials addressing the nanoscale; in addition, various nanoscale center efforts listed in Chapter 12 include ELSI projects.

Table 13.2. Websites with ELSI content

CNS at ASU	http://cns.asu.edu
CNS at UCSB	http://cns.ucsb.edu/
NSEC network (Nanoscale Science and Engineering Centers)	http://www.nsecnetworks.org/index.php
American Chemical Society	http://community.acs.org/nanotation/
European Nanotechnology Gateway	http://www.nanoforum.org
Institute of Nanotechnology	http://www.nano.org.uk/
NanoHub	http://nanohub.org/
Nanoscale Informal Science Education Network (NISEnet)	http://www.nisenet.org
NNI Education Center	http://www.nano.gov/html/edu/home_edu.html
National Nanotechnology Infrastructure Network (NNIN) ELSI Portal	http://www.nnin.org/nnin_edu.html
ICON (especially the Good Wiki project), Rice University	http://icon.rice.edu/about.cfm

13.3 GOALS, BARRIERS, AND SOLUTIONS FOR THE NEXT 5–10 YEARS

Prepare for Mass Use of Nanotechnology

We are advancing rapidly, but time is needed to grow ideas, people, infrastructure, and societal acceptance for mass application of nanotechnology; we still have only an early understanding of the full range of nanotechnology applications. Significantly, questions about the viability of nanotechnology applications are shifting to questions about how nanotechnology can address broad societal challenges in responsible ways. Global conditions that might be addressed by mass use of nanotechnology include population increase and aging; constraints on using common resources such as water, food, and energy; the competitive challenges and opportunities created by the growth of emerging countries such as Brazil, Russia, India, and China; and convergence with other emerging technologies such as modern biology, digital information technologies, cognitive technologies, and human-centric services. Such scientific, technological, and global societal changes require deep and cross-cutting actions over the next ten years, creating the need for:

- An ecology of innovation specific to nanotechnology development
- Partnerships across disciplines, application sectors, and between and within regions
- A clear regulatory environment
- An international cross-domain informational system
- International organizations to promote common development aspects of nanotechnology R&D
- Greater cultural and political openness and commitment to international collaboration

Address Deficits in Risk Governance for the Next Generation of "Nanoproducts" as a Function of the Generation of the Product

In the next ten years, we may see the emergence of early third- and fourth-generation nanotechnology-based devices and systems (Roco 2004) (see also chapter on Long View). We have already seen the transition from first-generation passive nanotechnology products to second-generation active nanotechnology applications (Subramanian et al. 2009). These shifts will present different and increased opportunities for societal impacts. They also will require enhanced approaches for governance and risk assessment and the further integration of anticipation, accountability, and open governance into R&D and innovation policies and programs. The main risk-governance deficits for the second to fourth generations of nanoproducts (including active nanodevices, nano-bio applications, and nanosystems) are the uncertain and/or unknown implications of the evolution of nanotechnology and its potential effects on people (e.g., human health, changes at birth, understanding of brain and cognitive issues, and human evolution); environmental effects across nanomaterial life cycles; and the lack of frameworks through which organizations and policies can address such uncertainties.

Governance approaches will need to evolve for new generations of nanotechnology products and productive processes, reflecting the increases in complexity and dynamics of nanostructured materials, devices, and systems (Figure 13.3). Each product generation has its own unique characteristics: passive nanostructures, active nanostructures, complex nanosystems, and molecular nanosystems. Likewise, the four levels of risk-related knowledge shown in Figure 13.3 and the associated technologies lead to the involvement of different types of actors and anticipate particular types of discourses.

Between the first generation of nanoscale products and associated processes (referred to in Figure 13.3 as Risk Governance "Frame 1") and the following three generations ("Frame 2"), there is a natural division in the level of risk. Knowledge of nanostructure behavior is better established for Frame 1, and the potential social and ethical consequences are expected to be more transformative for Frame 2 (Renn and Roco 2006).

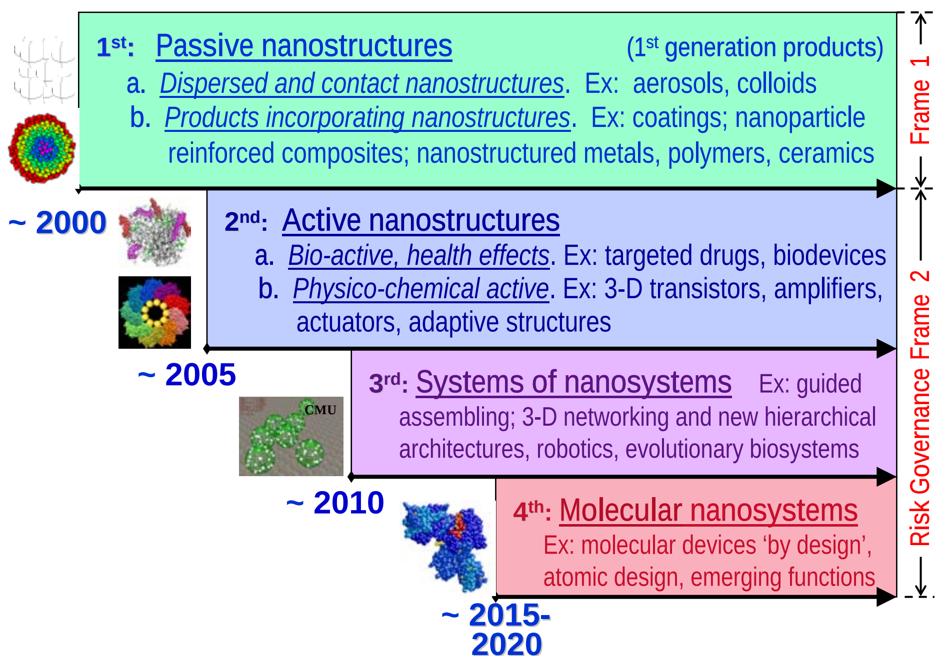


Figure 13.3. Timeline for the beginning of industrial prototyping and commercialization of nanotechnology: Four generations of products and production processes (Renn and Roco 2006).

Figure 13.4 presents an attempt to categorize the levels of governance for the responsible function, mapping them to relevant risk-governance activities. Issues related to changes within nanoscale components of larger systems used in applications (such as nanoparticles in automobile paint) typically can be addressed by adapting existing regulations and organizations to the respective systems. Issues related to changes in a technological system (such as a new family of nanobiodevices and active nanostructures) can be best addressed by creating new R&D programs, setting new regulatory measures, and establishing suitable new organizations.

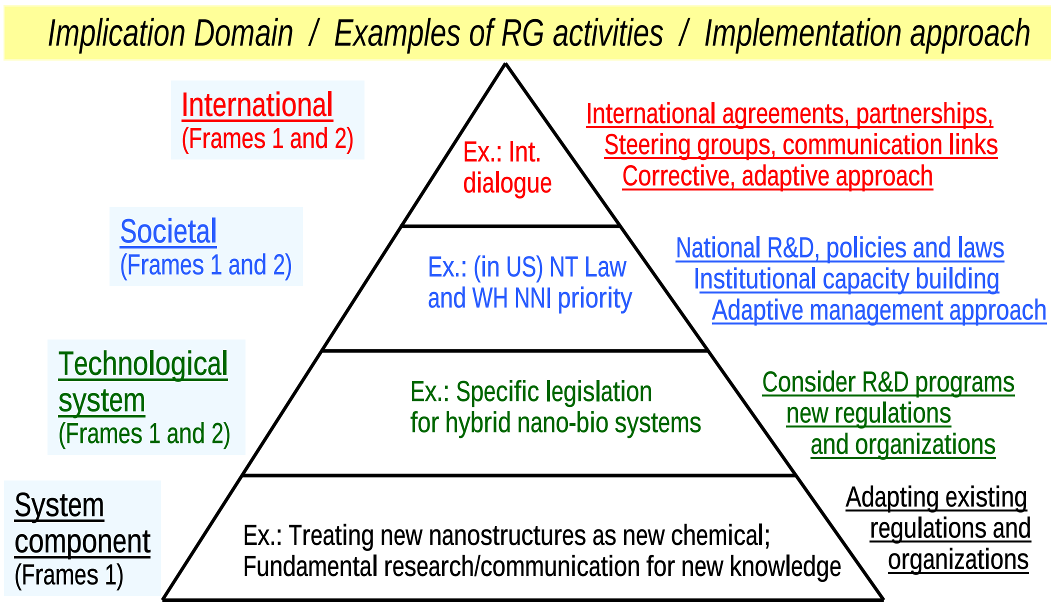


Figure 13.4. Schematic for multilevel structure of risk governance for nanotechnology (NT stands for nanotechnology, WH for White House; after Roco 2008).

At the national level, typical risk governance actions include formulation of policies and enactment of legislation, which may be considered as we advance to nanosystems. At the international level, typical actions are international agreements, collaborative projects, and multi-stakeholder partnerships, which are needed as we advance to the third and forth generations of nanotechnology-based products, systems, and processes.

Specific risk deficits are associated with the second to fourth generations (Frame 2), due to their expected complex and/or evolving behavior (Roco and Renn 2008):

- There are uncertain or unknown implications, mostly because the products are not yet fabricated.
- There is limited knowledge on hazards and exposures and specific metrology.
- The institutional deficits (societal infrastructure, political system) are related to fragmented structures in government institutions and weak coordination among key actors.
- Risk communication deficits, i.e., significant gaps exist between distinct science communities and between science communities and manufacturers, industries, regulators, NGOs, the media, and the public.

The risks in Frame 2 are primarily related to assessment of the more complex behaviors of nanomaterials and prioritization of stakeholder concerns, which rest in part on value judgments:

- Risks to human biological and societal development
- Risks due to social structures: risks may be dampened but also induced and amplified by the effects of social and cultural norms, structures, and processes

- Public perception risks
- Trans-boundary risks: the risks faced by any individual, company, region, or country, which depend not only on their own choices but also on those of others

Risk-related knowledge may be simple risk, component complexity, system uncertainty, and/or ambiguity as a function of nanotechnology generation. Roco and Renn (2008) proposed a risk management escalator (Figure 13.5) as a function of the nanotechnology product generation. This gives a broad overview of the challenges and potential solutions to risk management and governance in the coming ten years.

Create New Models for Innovation in Nanotechnology

Proposals by industry and NGOs for policy changes to facilitate innovation in the United States in nanotechnology include: increasing R&D tax credits, increasing support for precompetitive R&D, measures to provide capital for nanotechnology businesses, and changes in visa regulations to ensure access to highly-skilled technical talent (Murdock 2010; President's Council of Advisors on Science and Technology [PCAST] 2010). However, by themselves, such policies are unlikely to have major effects on the trajectories of nanotechnology innovation or to ensure that nanotechnology innovation addresses societal as well as economic objectives. To reach nanotechnology's full potential over the next decade, it is vital to combine economic support with meaningful incentives and frameworks to ensure responsible development that, besides technological and business goals, also addresses societal goals.

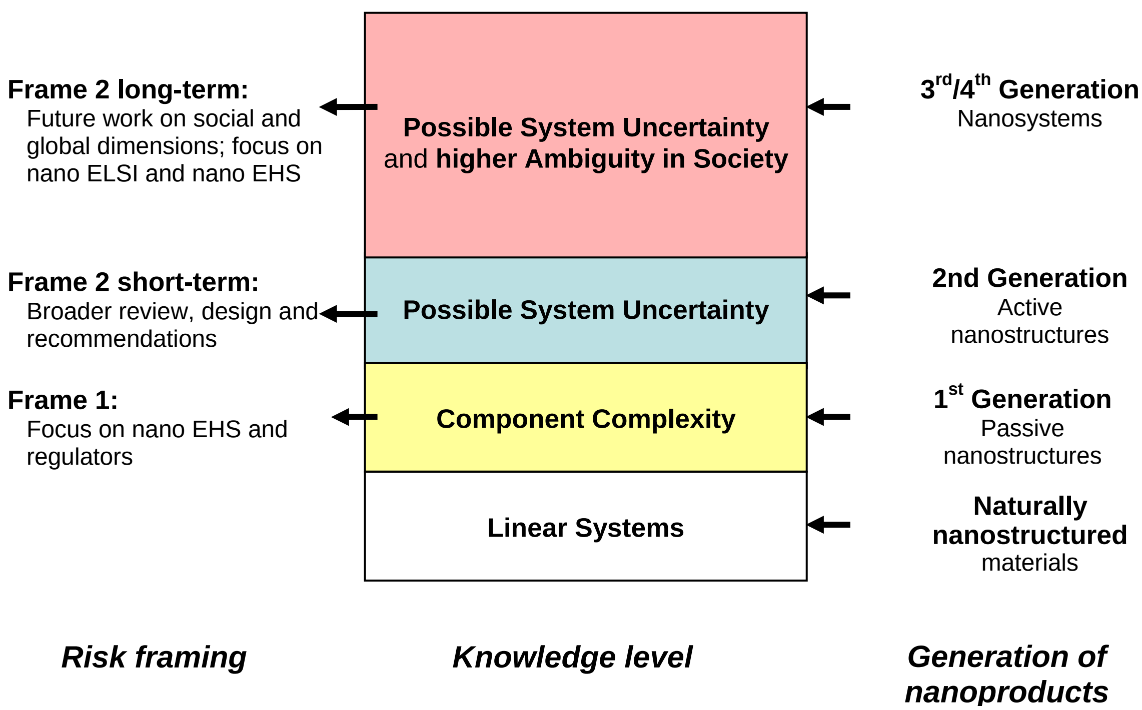


Figure 13.5. Strategies as a function of the generation of nanoscale products (Figure 13.3): Application to risk governance Frame 1 and Frame 2 (Roco and Renn 2008).

One promising model is development of regional multidisciplinary translational nanotechnology innovation hubs. These would undertake activities and develop networks to combine corporate and public sector users, researchers, EHS experts, and other stakeholders in strategies to stimulate, qualify, and diffuse nanotechnology innovation to meet societal goals. These hubs should also exploit complementary opportunities to engage traditional industries in nanotechnology-enabled innovation strategies, also involving manufacturing extension centers, universities, and other technology deployment capabilities. There may be regional opportunities to integrate translational nanotechnology innovation hubs with efforts to foster "nanoclusters" and "nanodistricts"; take an urban and regional systems approach to facilitate responsible innovation; and foster workforce training and development. There will be needs for informed decision making, clarity, anticipation, and coordination in regulatory processes to reduce uncertainty that will constrain nanotechnology innovation, yet also to ensure responsible and prudent development if those applications that may raise EHS concerns. At the same time, there will be opportunities for international and transnational collaboration to harmonize standards that will be helpful to the development of international markets for nanotechnology applications.

It is also vital to support the development of regional and state models for nanotechnology innovation. Since the establishment of the NNI in 2001, numerous state, regional, and local partnerships have been established, solely or as part of broader initiatives, to support and advance nanotechnology innovation and commercialization. (Seven major categories of partnerships, with representative examples, are noted in Section 13.8.1.) In addition, there are some cross-state consortia backed by both academia and industry that are focused on advancing specific nanotechnology applications, such as the Western Institute of NanoElectronics. During the next ten years, there will be a much greater emphasis on developing new models to support nanotechnology-based innovation and commercialization, on the societal returns to investment in nanotechnology, as well as on new measures to ensure safety. Establishment of public-private partnerships not only provides support for technical and commercial advances but also provides new means to engage the public in development of applications that are fundamentally translational; these emerging models may solve many problems of communicating with the public.

There will be multiple pathways through which nanotechnology innovation will be deployed and have impacts in and for industry between now (2010) and 2020. Nanotechnology is emerging as a general purpose technology, as initially proposed in the 1999 *Nanotechnology Research Directions* report and confirmed by later developments (Youtie et al. 2008). Early forecasts held that nanotechnology would contribute to approximately 10 percent of global manufacturing output by 2015 (Roco and Bainbridge 2001; Lux Research 2004). The 2008–2010 global financial crisis and economic slowdown is temporarily dampening the current pace of nanotechnology's growth (Lux Research 2009), but is not changing the underlying trajectory of development. In the near term, many of the innovations induced by nanotechnology are leading to both incremental improvements of existing products and, increasingly over time as we get closer to 2020, they are expected to lead to revolutionary architectures and functions.

Prepare Workers and the Public at Large for Nanotechnology Development

As the scale and scope of nanotechnology innovations picks up over the coming decade, there will be significant implications for employment and training (addressed in detail in Chapter 12). The pervasive, general-purpose nature of nanotechnology means that impacts will be seen across all industry sectors. Whether in mature sectors such as plastics or packaging or in leading-edge industries such as electronics or aerospace, companies that lag in awareness, understanding, and applications of nanoscale materials, processes, and devices to their current and future lines of products and services are apt to be at a competitive disadvantage, with consequent risks to business survival and employment. At the same time, new jobs are likely to be created in enterprises of any size that can best identify and exploit the commercial opportunities that nanotechnology presents.

In this context, access to workers who have the skills to develop, acquire, produce, and manage nanotechnology-enabled innovations will be vitally important. It is important to ensure that those who will develop, apply, manage, and oversee innovations in nanotechnology are not only technically well-trained but also well-prepared to anticipate and address broader implications. Employees in corporate public, legal, and regulatory affairs and areas other than R&D will need increased knowledge of nanotechnologies as well.

Advance R&D Related to Ethics and Understanding of Societal Dimensions of Nanotechnology

The principal needs in the next 5–10 years relating to ethics and understanding of societal dimensions of nanotechnology are:

- A comprehensive understanding of nanotechnology in society, investigated by including "what goes into nanotechnology" (economic and social drivers, public expectations, cultural values, aspirations, etc.), in addition to "what comes out of nanotechnology" (applications and their effects)
- Integration of nanotechnology ELSI considerations into educational processes, including in-depth school curricula for interested students and establishing ELSI relationships to the processes of innovation and assessment (safety by design, responsible innovation)
- Global harmonization of traceability of measurement methods in standards and metrology; coordination of regulatory standards
- Integration of "life-cycle approaches" to materials testing (based on pre- and post-market product-testing, rather than predominantly on pre-production testing) (Chapter 4)
- Implementation of "principles of green nanotechnology"—design principles for sustainability in light of life-cycle considerations (Chapter 5)

Integrate Research for Applications and Implications of Nanotechnology

The approaches to nano-EHS and nano-life (such as biology, medicine, technology) science research need to be unified under the single objective of obtaining a rich understanding of the interactions of well-characterized engineered nanomaterials with biological systems. Integration of transformative and responsible aspects of nanotechnology in a unified R&D program is a priority.

Make Moral Progress

In the future, technological and economics decision making should consider larger issues of "moral progress."[47] Research on ethical, legal, and social issues is vital to understanding how to create social and environmental value in the development of science and technology (e.g., see Hamlett et al. 2008; Pidgeon et al. 2009; Satterfield et al. 2009; Scheufele and Corley 2008; Corley and Scheufele 2010), which includes development of processes to address the diversity of views across different publics.

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[47] Term coined by Susan Neiman, as quoted in "Why is the modern view of progress so impoverished?" (Onwards and Upwards section), *The Economist*, 19 December, 2009.

Build a Network for Anticipatory, Participatory, and Adaptive Technology Assessments

Aspects of technology assessment have been initiated since 2000, under the long-term planning and implementation of the NNI and open to the participation of major stakeholders. That long-term vision has been credited for the national and then global focus on nanotechnology R&D.

Participatory technology assessment is essential to responsible nanotechnology development. It has been proposed to establish a network to conduct participatory technology assessment activities that:

- Harness education, deliberation, and reflection to give a voice to everyday citizens who otherwise have minimal representation in the politics of science and technology
- Enable decision makers to take into account the informed views of their constituents regarding emerging developments in science and technology

A participatory nanotechnology assessment network would work with decision makers to identify timely and relevant topics for assessment, engage experts and the public nation-wide, facilitate in-depth learning and deliberative processes for thousands of participants, and disseminate the results to a general public audience of millions and to key decision makers. The home for this network could be a nonpartisan, policy research institution that can serve as an institutional link to government, eliciting input on technology assessment topics and functioning as a venue for disseminating results. The network would incorporate university participants who bring strengths in conceptual and methodological development in technology assessment methods, contributing to technical and social analysis, organizing participatory technology assessment exercises, and evaluating technology assessment projects. The network should also incorporate organizations (including science museums, science cafes, and citizen groups) that have capabilities in citizen engagement, collaboration with schools, and broad public education concerning science, technology, and society issues.

13.4 SCIENTIFIC AND TECHNOLOGICAL INFRASTRUCTURE NEEDS

Nanotechnology infrastructure needs will change as a function of external conditions such as developments in other emerging technologies, increased requirements for sustainable development in a more crowded world, health and particularly aging, and globalization. A single top-down centralized investment approach may not be able to address such complexity. Several new infrastructures are needed, for both producers and users of nanotechnology, to enhance participation of the general public in decision making, inform policies, and expand international context. It will be necessary to assess business-to-consumer and business-to-business public nanotechnology product inventories, and create and test models of stakeholder engagement using emerging alternatives to the newspaper such as social media and Web 2.0 platforms. Other needs include:

- Horizontal integration of institutes and laboratories in safety, metrology, and societal implications research
- Establishment of platforms for international exchange on best practices, such as formal international traceability of measurement infrastructure, including an accreditation system
- Support for activities and infrastructure to connect the Global South to nanotechnology advancements to create better economic, health, and living conditions for the world's poor

13.5 R&D INVESTMENT AND IMPLEMENTATION STRATEGIES

Changing the focus of nanotechnology research from the Bohr and Edison quadrants in 2001–2010 to the Pasteur quadrant after 2010 (quadrants defined by Stokes 1997) has direct implications for R&D strategies:

- Platforms for R&D and innovation in nanotechnology need to be strengthened via:
  - Short and long-term framework policies and strategies to address manufacturing, healthcare, sustainable development, communication, and other societal needs
  - Regional capabilities and opportunities bringing together different stakeholders
  - Linking innovation with society and equity in access and distribution of benefits
  - Cross-discipline, cross-sector information system on research, innovation and production
- Infrastructure for commercialization needs to be strengthened via:
  - Federal Government and state R&D investment and coordination
  - Regional partnerships
  - Public-private partnership platforms for precompetitive R&D and innovation in nanotechnology
- Continuity of investment for fundamental and applied research in this long-term initiative, and institutionalizing the R&D programs and funding mechanisms for nanotechnology
- Increased international exchanges, based on mutual benefit, to address opportunities for global R&D collaboration and competition
- Shift of ELSI work in the direction of probing citizens' expectations of the prosperity enabled by innovation contrasted with fears and objections to the means (land use, factories, tax/regulatory policy, someone might get rich) of accomplishing the necessary "economic value capture" from that innovation
- Development of improved assessment metrics

Table 13.3 gives several suggested strategies for R&D investment and implementation strategies, grouped by the four basic governance functions discussed earlier (e.g., see Table 13.1).

13.6 CONCLUSIONS AND PRIORITIES

A strong focus is needed in the next ten years on improving anticipatory and participatory governance for nanotechnology that integrates the four basic functions of being transformative, responsible, inclusive, and visionary.

Improving open-innovation environments and creating better innovation mechanisms for nanotechnology has to be addressed with priority in the next decade as nanoscale science and engineering have established stronger foundations and expectations of societal outcome increase:

- Strengthening an *innovation ecosystem conductive to economic and safe application of nanotechnology*. This includes support for multidisciplinary participation, access to a diverse manufacturing base and multiple sectors of application, encouraging private-public partnerships and integration of capabilities, entrepreneurial training, multi-stakeholder-focused research, R&D platforms with continuing integration from research to technology application, regional hubs, research to commercialization gap funding, facilities for global commercialization, an outcome-drive culture encouraging creativity and innovation, and legal and tax incentives. The balance between competitive benefits and safety concerns needs to be addressed in each country by considering international context.

- Create and sustain *mechanisms of innovation* for establishing nanotechnology infrastructure, economic development, job creations, quality of life, and national security. Several examples are:
  - Programs for public-private funding of *industry inspired fundamental and precompetitive research.* Previous examples in the U.S. are the NSF's Industry-University Cooperative Research Centers (IUCRC, since 2001), the Nanoelectronics Research Initiative (NRI, since 2004) partnering the Semiconductor Research Corporation with NSF and more recently NIST), and NSF and Industrial Research Institute (IRI, in 2010-) program
  - *Focused research programs* where interdisciplinarity and partnering with industry is required (e.g., Nanotechnology Signature Initiatives, NNI, 2011–). Coordinate such programs across the breath and expertise of multiple agencies, through a variety of complementary funding mechanisms
  - *Funding innovation opportunities supplements* to research projects based on the research results obtained in the first half of the respective projects. A previous example in the U.S. is the NSF program solicitation "Grant Opportunities for Academic Liaison with Industry" (GOALI) combined with supplements offered by "Accelerating Innovation Research" (AIR) in 2010.
  - Creation and sustaining of regional public-private partnerships such as university-industry--government-local organizations research centers. Regional partnership models in U.S. are listed in Section 13.8.1
  - Support R&D multidisciplinary/multi-sector platforms with a long-term vision and planning (such as technology roadmaps). For example, in the U.S. the electronic, chemical industry and wood and paper industries have their own nanotechnology roadmaps
  - Support and maintain nanomanufacturing user facilities and education programs. Examples in the US are National Nanotechnology Infrastructure network (NNIN) and Sandia National Laboratory (SNL), and National Nanomanufacturing Network (NNN)
  - "High Tech Extension" is the direct connection of nanotechnology infrastructure to existing businesses, helping them improve existing products, develop new products, and expand employment (Section 13.8.1)
  - "Gap Funding," is accelerated commercialization assistance to entrepreneurial ventures (e.g., SMEs, university and/or corporate spinouts) in the form of technology transfer and early-stage funding on favorable terms (Section 13.8.1)
  - Provide nano-EHS regulatory assistance to companies, especially small and medium size.
  - Support access of industry to data bases, research projects, user facilities and international collaboration
  - Provide education and supporting tolls for the introduction of nanotechnology for economical benefit and better paying jobs, to increase penetration of nanotechnology in both emerging and traditional industries.

Priority actions in nano-EHS and ELSI for the next decade include the following:

- Integrate social science and humanities work with NSE research.

- Enhance public participation via ongoing, two-way/multi-way dialogues between nanotechnology community and organizations and civic organizations and lay publics. Articulate a new public engagement strategy, including reaching those least educated and those most dependent on Internet sources of information. Organize integrative activities for a broad set of NSE and societal dimensions researchers as well as various publics, including but not limited to scenario development workshops and informal science education. Make NSE experts accessible to policymakers for input.
- Provide more support for co-education of NSE and social science graduate students to develop interdisciplinary institutional cultures and national exchange networks; provide more opportunities to institutionalize and disseminate such practices.
- Develop structured (institutionalized) contexts for two-way communication between the public and researchers, as an important step in educating scientists and engineers about the legitimate bases for public concerns (and ongoing public support for science), as well as in educating the public about science and engineering and nanotechnology.
- Support research on the projected future "nano" workforce and on demographics for key nodes of nanotechnology-based industry development in United States and abroad.
- Give priority to evidence-based nanotechnology risk communication based on public and expert mental models and risk perception research, media studies, and multi-pathway decision risk analysis.
- Adopt an anticipatory, participatory, real-time technology assessment and adaptive governance model for nanotechnology so as to prepare the people, tools, and organizations for responsible development of nanotechnology. Evaluate how well social actors and regulatory institutions are prepared to deal with challenges from nanotechnology developments, e.g., new generation of products, dealing with knowledge gaps, and assignment of drug/device classifications.

Several overall possibilities for improving the governance of nanotechnology in the global self-regulating ecosystem are recommended (refer also to the examples in Table 13.3):

- Use open-source and incentive-based models
- Build a global, sustainable nanotechnology through up-front design rather than corrective actions
- Empowering stakeholders and promoting partnerships among them
- Implement long-term planning that includes international perspectives
- Institutionalize nanotechnology in research, education, and production processes
- Combine science-based voluntary and regulatory measures for nanotechnology governance and in particular for risk management (Fiorino 2010; Hodge at al. 2010)
- Support an international co-funding mechanism for maintaining databases, nomenclature, standards and patents

13.7 BROADER IMPLICATIONS FOR SOCIETY

This chapter already covers this topic in its main sections. One may underline that governance of nanotechnology is essential in realizing the benefits of the new technology, limiting its negative implications, and enhancing global collaboration. Further, nanotechnology development is interdependent and synergistic with other emerging technologies. Besides its key transformative effects in discovery, innovation, and specific applications, nanotechnology governance affects society at large and international interactions.

13.8 EXAMPLES OF ACHIEVEMENTS AND PARADIGM SHIFTS

13.8.1 Regional Partnerships in Nanotechnology

Contact person: Skip Rung, Oregon Nanoscience and Microtechnologies Institute (ONAMI)

Since the establishment of the NNI in 2001, numerous state, regional, and local partnerships have arisen, dedicated completely or in part to the advancement of nanotechnology. These partnerships may be grouped into seven major categories:

- State-backed organizations to enhance nanotechnology research capacity and state-funded programs to grow startup companies, with significant, but not exclusive, focus on nanotechnology (e.g., ONAMI and the Oklahoma Nanotechnology Initiative)
- State-funded programs to grow startup companies, some exclusive (e.g., Albany Nanotech) and other with significant, but not exclusive, focus on nanotechnology (e.g., Ben Franklin Technology Partners)
- Academically oriented infrastructure investments by states, including cost-share support from private sources (e.g., California NanoSystems Institute)
- Member-funded state/local trade associations (e.g., Colorado Nanotechnology Alliance)
- Member-funded national/international nanotechnology trade associations (e.g., NanoBusiness Alliance and the Silver Nanotechnology Working Group)
- Industry-sponsored academic-industry consortia (e.g., Western Institute of NanoElectronics)
- Industry-inspired fundamental research for an industry sector (e.g., Nanoelectronics Research Initiative involving NSF since October 2003 and NIST since 2007)

Funding, sustainability, and operational success for these kinds of partnerships can only occur in strong alignment with important stakeholder objectives that are able to out-compete other initiatives seeking public or voluntary private support. In the case of state investment (the majority of cases), the sole motive is economic development, requiring credible results in terms of jobs (ideally) or at least financial leverage. There is increasing pressure for such initiatives to become "self-supporting" (although with private and Federal funds), even in the case of activities for which the state economy is the primary beneficiary.

In the next ten years, as the NNI increases its emphasis on commercialization, two regional/state initiative activities can be expected to grow in importance. The first activity, "High Tech Extension" (Figure 13.6) is the direct connection of nanotechnology infrastructure to existing businesses, helping them improve existing products, develop new products, and expand employment. Easy and economical access to resources such as nanoscale materials characterization can expand the impact of nanoscience to a broader swath of the economy.

Table 13.3. Suggested function increases for future nanotechnology governance

TRANSFORMATIVE Function	Emphasize policies to develop focused, system-oriented R&D programs in nanomanufacturing, sustainability, and other priority areas
	Enhance the nanotechnology tools and facilitate the innovation cycle from discovery to invention to business models and to societal needs
	Strengthen priority investment in nanotechnology for human health, regenerating the human body, and maintaining working capacity while aging
	Investigate nanotechnology for sustainable natural resources (water, energy, food, clean environment)
	Develop new organizational and business models, including support for nanoinformatics
	Expand university and community college curricula supporting nanotechnology and converging emerging technologies (e.g., NSF's Nanoscale Center for Learning and Teaching)
	Foster nanotechnology research, education, and production clusters and regional hubs for various application areas to reduce the delay between inventions, technological development, and societal response
	Construct horizontally, vertically, and system-wide integrated infrastructure with open access
	Improve the metrics applicable to all projects and agencies in the United States
	Enhance international information systems to provide all researchers timely information
	Develop and implement informatics tools for nanomaterials, devices, and systems
	Create accreditation boards for traceability (reference materials, laboratories)
RESPONSIBLE Function	Establish research and regulations for the new (third and fourth) nanotechnology generations
	Implement/complete a predictive approach for toxicity of nanomaterials; establish user facilities to implement it
	Build a sustainable nanotechnology through up-front design rather than retro corrections
	Develop new systemic knowledge for a life-cycle approach to nanotechnology products
	Integrate nano-EHS and -ELSI considerations into the research process
	Develop an integrated, validated scientific platform for hazard, exposure, and risk assessment at a scale commensurate with technology growth (see Chapter 4)
	Sustain and expand the NSF's Nanotechnology in Society Network and create additional infrastructure within other NNI lead agencies
	Develop new methods, such as multicriteria decision analysis (e.g., Linkov et al. 2007; Tervonen et al. 2009)
	Investigate nanotechnology for the poor (Barker et al. 2005)
	Institutionalize coordination of regulatory agencies and research organizations
	Use social science, history, philosophy, and ethics knowledge-base to research nano-ELSI rather than support actions subsidiary to outreach goals, e.g., draw on available theories & analysis of ongoing innovation trajectories
INCLUSIVENESS Function	Create public-private partnerships among Federal government, states, industry sectors, academe, and research foundations
	Address social issues of interest to many stakeholders, such as workforce displacement
	Develop a common information exchange domain for industry, researchers, regulators, consumers, general public
	Continuous contribution to OECD working groups on nanotechnology and related emerging technologies
	Global, cross-sector, and open source collaboration in the area of nano-EHS will be essential factors in the introduction of nanotechnology as a general purpose technology.
	To enhance participatory governance, increase the use of public and expert surveys and of emerging platforms of communication such as social media and Web 2.0 platforms
	Fund evidence-based nanotechnology risk communication based on public and expert mental models and risk perception research, media studies, and multi-pathway decision risk analysis

Table 13.3, continued

VISIONARY Function	Study changing societal interactions due to converging and emerging technologies
	Develop operational aspects of anticipatory and participatory governance (e.g., Roco, 2008; Barben et al. 2008; Satterfield et al. 2009; Sclove, 2010)
	Forecast long-term potential effects of nanotechnology on global warming; the next 1000 years (FFF/UNESCO 2007)
	Prioritize development of nanotechnologies for renewable energy, clean water, public health infrastructure, urban sustainability, and agricultural systems
	Prepare ten-year vision (2011–2020) (this report)
	Transition from a research-centric to a demand/user/application-centric focus

Figure 13.6. Nanoscience facilities and equipment can best benefit technology development when they are conveniently located and easy to use by businesses. Such access is especially important to the small and medium size enterprises that are critical for early-stage commercialization. State and regional economic development field staff can serve as "high-tech extension" agents.

The second activity, known as "Gap Funding," is accelerated commercialization assistance to entrepreneurial ventures (e.g., SMEs, university and/or corporate spinouts) in the form of technology transfer and early-stage funding on favorable terms. While SBIR and STTR awards are vital tools in this regard, locally managed capital with an emphasis on launching growth companies is a necessary addition to the portfolio of commercialization programs, and one which lends itself well to Federal partnerships with state/regional initiatives. Federal and state partnerships for the "gap funding" of new ventures that commercialize NNI-funded technology R&D could accelerate commercialization by 2–4 years and ensure a focus on economic returns and job creation. The "gap" to be traversed with proposed short-term funding assistance is also known as the "valley of death" between business startup and commercial profitability, a particularly risky interim phase for advanced-technology businesses.

Table 13.4. Examples of NSF-sponsored projects supporting social implications inquiry, 2001-2010

Project*	Institution
Nanotechnology and its Publics	Pennsylvania State University
Public Information and Deliberation in Nanoscience and Nanotechnology Policy (SGER)	North Carolina State University
Social and Ethical Research and Education in Agrifood Nanotechnology (NIRT)	Michigan State University
From Laboratory to Society: Developing an Informed Approach to NSE (NIRT)	University of South Carolina
Intuitive Toxicology and Public Engagement (NIRT)	North Carolina State University
Data base and innovation timeline for nanotechnology	University of California Los Angeles
Social and ethical dimensions of nanotechnology	University of Virginia
Undergraduate Exploration of Nanoscience, Applications and Societal Implications (NUE)	Michigan Technological University
Ethics and belief inside the development of nanotechnology (CAREER)	University of Virginia
All NNIN and NCN centers have societal implications components	All 28 NSF nanotechnology centers and networks
NSEC: Center for Nanotechnology in Society at Arizona State University	Arizona State University
NSEC: Center for Nanotechnology in Society at University of California, Santa Barbara	University of California, Santa Barbara
NSEC: Nanotechnology in Society Project, Nano Connection to Society	Harvard University
NSEC: Center for Nanotechnology in Society: Constructive Interactions for Socially Responsible Nanotechnologies	University of South Carolina
CEIN: Predictive Toxicology Assessment and Safe Implementation of Nanotechnology in the Environment	University of California Los Angeles
CEIN: Center for Environmental Implications of Nanotechnology	Duke University
NNIN: National Nanotechnology Infrastructure Network (10%)	Cornell University
NIRT; Nanotechnology in the Public Interest: Regulatory Challenges, Capacity and Policy Recommendations	Northeastern University
Collaborative Grant: Bringing Nanotechnology and Society Courses to California Community Colleges	University of California, Santa Barbara

* Key to abbreviations of project types (in order of appearance):

SGER: Small Grant for Exploratory Research
NIRT: Nanoscale Interdisciplinary Research Team
NUE: Nanotechnology Undergraduate Education in Engineering
CAREER: Faculty Early Career Development Award
NNIN: National Nanotechnology Infrastructure Network
NCN Network for Computational Nanotechnology
NSEC: Nanoscale Science and Engineering Center
CEIN: Center for the Environmental Implications of Nanotechnology

13.8.2 Examples of Research Projects on Societal Implications Established by NSF

Contact person: Mihail C. Roco, National Science Foundation

Table 13.4 (previous page) lists the many projects established by the National Science Foundation through 2010 to support research on societal implications of nanotechnology research, development, and commercialization. (A number of these projects also support outreach to inform the American public regarding nanotechnology issues and involve them in governance discussions.)

13.8.3 Center for Nanotechnology in Society at ASU

Contact person: David Guston, Arizona State University

The Nanoscale Science and Engineering Center/Center for Nanotechnology in Society at Arizona State University (NSEC/CNS-ASU; http://cns.asu.edu) was established on October 1, 2005, with funding from the National Science Foundation. CNS-ASU combines research, training, and engagement to develop a new approach to governing emerging nanotechnology. The center uses the research methods of "real-time technology assessment" (RTTA) and guides them by a strategic vision of anticipatory governance. The anticipatory governance approach consists of enhanced foresight capabilities, engagement with lay publics, and integration of social science and humanistic work with nanoscale science and engineering research and education (Guston 2008; Wetmore et al. 2008). Although based in Tempe, Arizona, CNS-ASU has major partnerships with the University of Wisconsin–Madison and the Georgia Institute of Technology, plus a network of other collaborators in the United States and abroad.

CNS-ASU has two types of integrated research programs, as well as educational and outreach activities (which are themselves integrated with research). Its two thematic research clusters, which pursue fundamental knowledge and create linkages across the RTTAs, are "Equity, Equality and Responsibility" and "Urban Design, Materials, and the Built Environment." The Center's four RTTA programs are:

- Research and Innovation Systems Assessment, which uses bibliometric and patent analyses to understand the evolving dynamics of the NSE enterprise
- Public Opinion and Values, which uses surveys and quasi-experimental media studies to understand changing public and scientists' perspectives on NSE
- Anticipation and Deliberation, which uses scenario development and other techniques to foster deliberation on plausible NSE applications
- Reflexivity and Integration, which uses participant-observation and other techniques to assess the center's influence on reflexivity among NSE collaborators

The center's major conceptual-level achievement has been validating anticipatory governance as a richly generative strategic vision. Its three major operations-level achievements are: (1) completing the "end-to-end" assessment to create novel insights in a study of nanotechnology and the brain; (2) deepening the integration of NSE researchers into CNS-ASU; and (3) building collaborations for informal science education (ISE) on the societal aspects of NSE. Programmatic achievements include establishing an internationally adopted definition of nanotechnology to assemble and mine bibliographic and patent databases; conducting two national public opinion polls and a poll of leading nano-scientists; conducting the first National Citizens' Technology Forum on nanotechnology for human enhancement (Figure 13.7); demonstrating that interactions between NSE researchers and social scientists can generate more reflexive decisions; sustaining an international research program on NSE and equity; and laying the foundations for a new research program in urban design, materials, and the built environment.

Figure 13.7. Participants in the first National Citizens' Technology Forum on Nanotechnology and Human Enhancement, conducted by CNS-ASU in March 2008 (courtesy of David Guston).

The center's principal intellectual merit derives from the large-scale, interdisciplinary ensemble that underpins it. The ability to embrace and facilitate interactions among disparate approaches to understanding nanotechnology, and to build complementary capacities to tap that knowledge for governance, is the critical intellectual contribution to which CNS-ASU aspires. Both in terms of publications and citations, the center's work has a substantial impact on scholarship. For broader impact, the center has coupled research, education, and outreach activities exceptionally well by training significant numbers of new scholars from the social sciences and nanoscience-based physical sciences, incorporating forefront research in new courses and ISE opportunities, and returning lessons learned and techniques developed for outreach back to the classroom. CNS-ASU has broadened the participation of under-represented groups by cultivating junior scholarship and raising issues of equity, gender, and disability as objects of programmatic study. The center has enhanced the infrastructure for research and education by organizing community-defining conferences, producing community-defining sources of knowledge, serving as an international hub for dozens of scholars, sharing data and instruments widely, and disseminating its results aggressively to its academic peers as well as to public, scientific, industry, and policy audiences.

13.8.4 Center for Nanotechnology in Society at UCSB

Contact person: Barbara Harthorn, University of California, Santa Barbara

The Center for Nanotechnology in Society at the University of California, Santa Barbara (CNS-UCSB), promotes the study of societal issues connected with emerging nanotechnology in the United States and around the globe. It serves as a national research and education center, a network hub among researchers and educators concerned with innovation and responsible development of nanotechnology, and a resource base for studying these issues in the United States and abroad. The work of the CNS-UCSB is intended to include multiple stakeholders in the analysis of nanotechnology in society and in discussion through outreach and education programs that extend to industry, community, and environmental organizations, policymakers, and diverse publics.

The intellectual aims of CNS-UCSB are twofold: to examine the emergence and societal implications of nanotechnology with a focus on the global human condition in a time of sustained technological innovation; and to apply empirical knowledge of human behavior, social systems, and history to promote the socially and environmentally sustainable development of nanotechnology in the United States and globally. These aims motivate research from many theoretical and methodological perspectives, provide the basis for industry-labor-government-academic-NGO dialogues, and organize the mentoring of graduate, undergraduate, and community college students and postdoctoral researchers.

CNS-UCSB researchers address a linked set of social and environmental issues regarding the domestic U.S. and comparative global creation, development, commercialization, consumption, and regulation of specific nano-enabled technologies for energy, water, environment, food, health, and information technology. The center addresses questions of nanotechnology-related societal change through research that encompasses three linked areas:

- Historical context of nanotechnology
- Nanotechnology and globalization, with an emphasis on East and South Asia
- Nanotechnology risk perception and social response studies among experts and publics; media framing of nanotechnology risks; and methods for engaging diverse U.S. publics in upstream deliberation about new technologies

CNS-UCSB has close ties with the internationally prominent nanoscience researchers at UCSB who are connected with the university's California NanoSystems Institute, Materials Research Laboratory, and National Nanotechnology Infrastructure Network; with ecotoxicology researchers in the UC Center for Environmental Implications of Nanotechnology (UC CEIN); and with social science research centers focused on relations among technology, culture, and society. These ties are enhanced by wider collaborations in the United States and abroad. U.S. collaborators are based at UC Berkeley, Chemical Heritage Foundation, Duke University, Quinnipiac University, Rice University, State University of New York (SUNY) Levin Institute, SUNY New Paltz, University of Washington, and University of Wisconsin. Collaborators abroad are based at Beijing Institute of Technology, Cardiff University, Centre National de la Recherché Scientifique, University of British Columbia, University of East Anglia, University of Edinburgh, and Venice International University.

CNS-UCSB's novel graduate educational program co-educates societal implications and nanoscale science and engineering students. UCSB graduates in nanoscale science and engineering participate in CNS-UCSB research on, for example, science policy analysis, media coverage analysis, public deliberation, expert interviews on risk and innovation, Chinese patent analysis, and comparative state R&D policies.

13.8.5 Governance toward Sustainable Nanotechnology

Contact person: Jeff Morris, U.S. Environmental Protection Agency

One objective of U.S. EPA's Nanomaterial Research Program is to shift thinking and behavior from managing risk to preventing pollution. Preventing pollution is one of main themes in the EPA *Nanomaterial Research Strategy* (http://www.epa.gov/nanoscience), while other themes directly support EPA research to understand what properties of different nanoscale materials may cause them to be, among other things, mobile, persistent, and/or bioavailable. This and other exposure-related information, together with research on what specific nanomaterial properties may influence toxicity, can inform the use of green chemistry and other approaches to foster the responsible design, development, and use of nanomaterials, including nanotechnology uses that directly or indirectly advance environmental protection. In addition to ensuring that existing nanomaterials are environmentally sustainable, EPA also needs to look for creative ways to develop nanomaterials in a sustainable manner.

The environmentally friendly research by EPA seeks to demonstrate how toxic chemicals can be avoided while producing nanoparticles and has been applied to one promising application: technology for cleaning up pollution that uses nanoscale zero valent iron (NZVI) to promote the breakdown of contaminants in ground water. The EPA team began by making NZVI by mixing tea with ferric nitrate. This process did not use any hazardous chemicals, such as sodium borohydride, which is commonly used to make nanoparticles. Not only did the process eliminate the use of hazardous chemicals, but the nanoparticles showed no significant signs of dermal toxicity. The researchers next used grape extract to make high-quality nanocrystals of gold, silver, palladium, and platinum (Nadagouda et al. 2010). The message behind this example is that moving toward sustainable nanotechnology means incorporating new thinking into materials research and development. The EPA research may or may not lead to "green nano" materials that can be commercialized. Nevertheless, it demonstrates that it is feasible to synthesize nanoparticles using nontoxic inputs, and that the real limits to the development and application of green chemistry approaches for nanotechnology lie in our own ingenuity.

13.8.6 Public Participation in Nanotechnology Debate in the United States

Contact person: David Berube, North Carolina State University

Public participation in science and technology debate has been convincingly shown to matter for normative, instrumental, and substantive purposes, and indeed this "participatory turn" is now evident in many countries (Harthorn 2010). In particular, effective public participation can serve a vital instrumental role in development of trust—essential in the nanotechnology case given the uncertainties about safety, extent of benefits, and longer term social risks. The NNI, through the NSF, has supported a number of efforts to include the public in science and technology policy decision making through a number of different formats and programs (see Guston 2010). Activities range from informal science outreach at museums (NISEnet), to science café–type informal community discussions at a number of sites, to longer-term informal "citizen schools" (e.g., at the University of South Carolina), and to multi-sited national engagement consensus conferences (CNS-ASU) and comparative cross-national public deliberations (CNS-UCSB). CNS's Public Communication of Science and Technology is conducting engagement activities on public perception of risks of nanoscience and on nanotechnology and food.

CNS-ASU's National Citizens' Technology Forum was modeled after Danish consensus conference but distributed across six U.S. locales. The NCTF on "nanotechnology and human enhancement" demonstrated that a high-quality deliberative activity can be organized at a national scale in the United States, and that a representative selection of lay citizens can come to discerning judgments about nanotechnology developments while they are still emergent (Hamlett et al. 2008). CNS-UCSB's 2007 comparative U.S.-UK public deliberations were modeled on UK upstream deliberation efforts and included a between-groups design to compare deliberations on nanotechnology applications for energy and for health in the two countries (Pidgeon et al. 2009). More recently CNS-UCSB in 2009 conducted an additional set of workshops, in deliberative groups, to examine more closely the role of gender differences, a consistent factor in diverging public views on risks.

About 53% of the public in the United States perceives little to no risk from nanotechnology (Berube and Cummings 2010). The only nanotechnology applications to which the public regularly applies high negative EHS footprints are food-related. Important variables determining public perceptions of risk seem to be educational levels and socioeconomic categories more than cultural or religious identifiers, though culture and religion can be correlated to education and socioeconomic status.

There is a growing population of "newsless" Americans who do not seek out news from either traditional sources or digital media sources. Also, there is a growing body of Americans known as "net-newsers" who get most of their news information from Internet resources (Pew Research Center for People and the Press 2010). While some net-newsers clearly draw from traditional news that has migrated to the web, a growing number are turning to resources associated with the term "Web 2.0." These two phenomena pose special challenges for engaging the public in effective nanotechnology governance discussions. We must find new and creative ways to reach the newsless, and we must find creative ways to use social media engagement platforms to reach those individuals who are net-newsers. The swing toward net-newsing also means that much of what social science knows about the amplification of risk, which traditionally has been drawn from newspapers and television, will likely need to be reexamined.

13.8.7 Scenarios Approach: The NanoFutures Project

Contact person: Cynthia Selin, Arizona State University

The future of nanotechnology is not preordained and can therefore not be predicted. There are critical uncertainties surrounding both the technological pathways and the societal implications of discoveries on the nanoscale. The development of nanotechnology depends on choices made today, choices that occur throughout society in the boardroom, within the laboratory, in the legislature, and in shopping malls. There are numerous complex, interrelated variables that impinge upon what nanotechnology will ultimately look like in ten years' time.

Future-oriented methods like scenario planning provide a means to structure key uncertainties driving the coevolution of nanotechnology and society (Selin 2008). These critical uncertainties range from the health of the U.S. economy, to regulatory frameworks, to public opinion, to the actual technical performance of many of nanotechnology's projected products. Anticipation and foresight, as opposed to predictive science, provide means to appreciate and analyze uncertainty in such a way as to maximize the positive outcomes and minimize the negative outcomes of nanotechnology (Barben et al. 2008, Youtie et al. 2008). The value of scenario development in particular is to rehearse potential futures to identify untapped markets, unintended consequences, and unforeseen opportunities.

Three application areas are important to assess the prospective benefits and risks of nanotechnology:

- *Health and medicine*: Nanotechnology promises many breakthroughs in cancer treatment, drug delivery, and personalized medicine. The CNS has looked systematically at emerging diagnostic technologies and determined that critical choices revolve around the reliability and security of the data produced by the device and how well the device is managed and integrated within the larger medical system. If portable, fast, and reliable medical diagnostics are to yield positive societal benefits, questions regarding access must be adequately addressed.

- *Climate and natural resources*: Nanotechnology's development can be directed towards overcoming many of the planet's most urgent ills by generating products and processes that focus on conserving, protecting, and extending natural resources. One CNS-ASU scenario focused on generating drinkable water from air, which could enable off-the-grid survival and begin to address global demands for clean water.
- *Energy and equity*: Nanotechnology has much to offer towards producing greater efficiencies and cost savings in the energy domain. One particular scenario examined using nanotechnology-enhanced coolants to boost nuclear power generation. Describing such a future technology as a scenario provides a means to assess the broader barriers to and carriers of the innovation.

These anticipation and foresight approaches may take a variety of forms from traditional scenario planning to experiments with virtual gaming, simulation modeling, deliberative prototypes, and training modules. Such tools enable the scientific enterprise to become more responsive to shifting societal, political, and economic demands to produce more robust and relevant discoveries that address contemporary and future needs proactively.

13.8.8 Large Nanotechnology Firms as the Primary Source of Innovation and Under-Commercialization

Contact person: N. Horne, University of California, Berkeley

A small number of large multinational firms are responsible for a significant portion of nanotechnology patenting activity, yet competitive strategies artificially reduce their ability to commercialize products. New policies can change this trend.

Since 2000, nanotechnology discovery and innovation have flourished; nanotechnology has now reached the broad diffusion point of a general-purpose technology (Graham 2010). Large multinational enterprises (LMEs) remain the locus of most nanotechnology innovation relative to small and medium enterprises (SMEs) and universities, with moderate relative change over time (Table 13.5). Innovation occurs within LMEs due to the clustering of capital, including equipment and technically proficient labor, combined with deep market knowledge that maximizes application development.

Patenting is more concentrated in 2010 as compared to 2000, with over a quarter of all U.S. nanotechnology patents issued held by only twenty entities. And as of 2008, private R&D investment is now larger than public R&D investment. Moreover, LMEs now represent the largest source of capital annually, with less than 5% of total funding coming from the generally recognized source of innovation, venture capital. While this balance of relatively higher private funding is desirable, it further underscores the dominance of LMEs and the importance of ensuring high commercialization efficiencies for broader economic good.

Private firms are both effective commercialization drivers and a significant source of commercialization inefficiency. In all technology areas, at least one-third of technology products fully vetted through technical and market testing are not launched to market. Consistent findings of significant suppression rates emerge from empirical data across multiple applied nanotechnology market sectors sharing similar characteristics in the overall nanotechnology market, including longer exit periods and high initial capital investment requirements. The percentage of technically and market-ready products not released to the market is on average between 40 and 50 percent (for technology products, see Cooper 2001; for pharmaceutical products, see Carrier 2008). The impact of regulatory review on pharmaceutical suppression is higher, of course, than for technology products. Policies to drive out sleeping patents are common in many industrialized nations via compulsory licensing and march-in clauses. These policies have been shown empirically to be ineffective due to significant underuse; firms do not use licenses because first-moving firms bear the costs, whereas subsequent firms would benefit financially (Carlton and Perloff 2000).

Table 13.5. Top nanotechnology patent holders*

2004				**2010**		
Rank	**Entity**	**Type**	**# U.S. nano patents**	**Entity**	**Type**	**#U.S. nano patents**
1	IBM	LME	171	IBM	LME	257
2	UC Regents	Univ.	123	Canon	LME	164
3	U.S. Navy	Govt.	82	Samsung	LME	137
4	Kodak	LME	72	UC Regents	Univ.	112
5	Minnesota Mining	LME	59	HP	LME	112
6	MIT	Univ.	56	Hitachi	LME	78
7	Xerox	LME	56	Seiko	LME	80
8	Micron	LME	53	Olympus	LME	71
9	Matsushita	LME	45	Rice U.	Univ.	70
10	L'Oreal	LME	44	Nantero	SME	68
Total patents, top 10			761			1149
Percentage of total U.S. nanotechnology patents held by top 10 nanopatent assignees			14%			19%
Total patents, 2nd 10			309			496
Percentage of total U.S. nanotechnology patents held by next 10 nanopatent assignees			6%			8%
Percentage of total U.S. nanotechnology patents held by top 20 patent assignees			20%			27%

* From Li et al. 2007 and Graham 2010; the table cites data as originally published.

The implications for 2020 are significant. Under current trends, continued government investment in basic and applied R&D combined with general economic recovery will create continued patenting and spin-out growth over the mid-term, despite a short-term shortage of venture capital funding. At the same time, a significant number of nanotechnology patents will be concentrated to a smaller set of actors. As a result, a limited number of large firms will continue to serve as both a significant source of intellectual property and under-commercialization in the near- and mid-terms. New policies to effectively drive out sleeping patents can increase nanotechnology's broader economic impact. Specifically, auctions across multiple-sector firms will offset the underuse of compulsory licensing; auctions should be carefully constructed to avoid distortions.

The goal of nanotechnology patent auctioning is to incentivize firms to release unused intellectual property (IP) by providing short- and mid-term profit for patents. With compulsory licensing, the number of potential bidders, and therefore the short-term valuation of intellectual property, are lower as compared to an open-auction market. Auctioning eliminates the weakness of compulsory licensing, as first-moving firms assume both the costs and the financial rewards of IP reassignment. Two factors determine the type of auction that would create the greatest efficiency: *private value*, in which bidding firms may have relevant IP that would significantly increase the value of an auctioned IP, and *information asymmetry*, in which bidding firms may have knowledge of the auctioned IP that would affect valuation. Given that nanotechnology products generally require many patents to create a final product, the withholding of a single patent critical to the success of a product could produce artificially high bids relative to the real value of the patent, simply due to timing. Concurrent rather than subsequent auctioning would prevent the overvaluation of such critical patent technology. Therefore, a uniform-price auction, otherwise known as a second-price sealed bid or Vickrey auction of multiple nanotechnology patents, would produce the most efficient reallocation of patents.

13.8.9 Decision Making with Uncertain Data

Contact person: Jeff Morris, U.S. Environmental Protection Agency

The history of regulation of industrial chemicals shows that regulatory agencies such as EPA have been unable to keep pace, in terms of acquiring and evaluating risk-related information, with the introduction of chemicals into society.[48] Yet it seems to be accepted by many government, industry, and NGO stakeholders that the appropriate path for nanotechnology governance is to follow the regulatory science model that has been used for decades for industrial chemicals.[49] This acceptance has important implications for the U.S. regulatory agencies under whose mandates nanotechnology risk issues fall. Christopher Bosso (2010) has identified *institutional capacity* as a major issue arising from nanotechnology stakeholders' agreements that large amounts of data will be needed to inform decisions related to nanotechnology's environmental implications. Given the inability of regulatory agencies to adequately address the assessment needs of traditional industrial chemicals, it seems unlikely that regulators will have the capacity to keep up with nanotechnology's regulatory demands unless they adopt new approaches to governing the introduction of new substances, including but not limited to nanoscale materials, into society.

Related to institutional capacity is another issue raised by Bosso (2010), the trade-off between taking action to anticipate risks and acquiring sufficient information to make defensible decisions about risks. Regulatory agencies traditionally have needed a large body of evidence to make decisions on chemical risks. It will take years, if not decades, to develop hazard and exposure databases as large as currently exist for such substances as asbestos.[50] The dilemma, therefore, is *how to instill anticipatory, risk-preventative behavior in governance institutions when little regulatory science data exist*. If those responsible for environmental decision making embrace the existing chemical assessment model as the principal approach

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[48] There are more than 84,000 chemical substances on the TSCA Chemical Substances Inventory; for only a small fraction of those has EPA received sufficient data to make risk determinations in accord with EPA's own risk assessment guidelines. On average, about 700 new substances are added every year. Information on the TSCA inventory may be found at http://www.epa.gov/oppt/newchems/pubs/invntory.htm. Also see U.S. Government Accountability Office (GAO) 2005.

[49] For discussion on regulatory science and its use in environmental decision making, see Jasanoff 1990.

[50] EPA's 1989 attempt to ban asbestos from products was overturned in 1991 by the Fifth Circuit Court of Appeals because, in essence, the court determined that EPA had not provided a sufficient regulatory science justification for the ban. See http://www.epa.gov/asbestos/pubs/ban.html. For a concise summary of the issue, see Environmental Working Group, "The Failed EPA Asbestos Ban," http://www.ewg.org/sites/asbestos/facts/fact5.php.

to nanotechnology governance, the balance between being anticipatory and generating robust risk-information databases likely will become increasingly difficult and contentious.

The idea of *anticipatory technology evaluation* for nanomaterials fits within a larger national and global movement toward sustainable chemical, material, and product development and use. The people who invent, design, synthesize, fabricate, incorporate into products, use, regulate, and dispose of or recycle chemicals and other materials—including nanoscale materials—in many cases do not have adequate information (including but not limited to physical-chemical and/or material properties, life cycle, hazard, fate, exposure) to make decisions that lead to those chemicals or materials being designed, created, and managed in an environmentally sustainable manner. Nor do they often have information on the inputs (e.g., energy, starting materials) that go into, and the emissions that are released from, the fabrication of these substances. Without such information, environmental decision makers will not be able to overcome the current backlog of unassessed chemicals (including, increasingly, nanomaterials), let alone address the impacts of new materials from emerging technologies, such as nanoscale materials. The recent introduction of a TSCA reform bill in the United States, together with the European Community's progress toward implementing REACH, adds impetus to the need for innovative solutions to assessment approaches oriented toward the green design of chemicals, materials, and products.

13.8.10 Penetration of Nanotechnology in Therapeutics and Diagnostics

Contact person: Mostafa Analoui, The Livingston Group, New York, NY

The past decade has witnessed a strong surge in research and product development around utilization of nanotechnology in life sciences (see Chapter 7). During 2000-2010, nanotechnology publications and patents have shown a steady growth, while for nanobiotechnology the trend is showing a much faster growth, reflecting additional scientific investment both by public and private sectors (Delemarle et al. 2009). This steady increase in scientific output and creation of intellectual properties, however, has not been matched with a similar pattern in investment, product development and commercialization (Business Insights 2010). This discrepancy in evolution of knowledge and market introduction is a common characteristic of innovative and emerging technologies.

An overwhelming level of investment is currently focused on reformulation and novel delivery of existing chemical and molecular entities. Consistently, more than 60% of nanomedicine R&D is allocated to this segment. There are several outstanding and successful developments. Perhaps the hallmark of such activities can be summarized in the journey that Abraxis took for development of nano-albumin formulated of paclitaxol (product known as Paclitaxel), one of the most cytotoxic agents. Abraxane has promised a safe therapy at much higher doses. Abraxane received FDA clearance for metastatic breast cancer in January of 2005. Since then, Abraxane has been prescribed to an increasing number of patients, with expanding indications. This product had more than $350 million sales in 2009 and was cornerstone for acquisition of Abraxis by Celgene for $2.9 billion. This is the largest merger and acquisitions deal to date in the nanomedicine field.

Examples of nano-formulated drugs approved and in the market are listed in Table 13.6, showing a market size of more than $2.6 billion in nanotechnology-based therapeutics in 2009, with no product in the market in 2000.

Table 13.6. Selected nano-based therapeutics and their 2009 sales (*represents 2008 sales)

Product	Particle type	Drug /Application	Technology by /Licensed to	Status	2009 Sales ($M)
TriCor	Nanocrystal	Fenofibrate	Elan/Abbott	Marketed	1,125.0
Rapamune	Nanocrystal	Sirolimus	Elan/Wyeth	Marketed	343.0
Ambisome	Liposomal	Amphotericin B	Gilead Sciences	Marketed	258.6
Abraxane (since 2005)	Nanoparticle	Paclitaxel	American Bioscience	Marketed	350
Doxil *	Liposomal	Doxorubicin	ALZA	Marketed	227.0
Emend	Nanocrystal	Aprepitant	Elan/Merck	Marketed	313.1
Abelcet	Liposomal	Amphotericin B	Elan	Marketed	22.6
Triglide	Nanocrystal	Fenofibrate	SkyePharma Pharmaceuticals	Marketed	28.0
Amphotec *	Liposomal	Amphotericin B	ALZA/Three Rivers Pharmaceuticals	Marketed	3.7
Total					**$2,671M**

With more than $120 billion pharmaceutical products losing their patent protection between 2009 and 2014, this has started an avalanche of R&D and investment, which should come to fruition for patients and investors during 2010–2020. Perhaps the most promising products yet to come or new chemical/molecular entities based on a rational nanoscale-design addressing major chronic diseases such as Alzheimer's disease (AD), osteoarthritis and rheumatoid arthritis (OA/RA) and major improvement therapeutics for ophthalmic diseases such as Age-related Macular Degeneration (AMD) and Diabetic Macular Edema (DME). With current pipeline and increased R&D investment, some landscape-shifting management of such diseases via nanomedicine products is anticipated.

Nanotechnology-based diagnostics has gone through a significant landscape shift since 2000, when key promising areas (as a combination of ongoing research and blue-sky thinking) included nano-based contrast agents, nano-arrays for label-free sequencing, highly sensitive and specific assays and passive sensors. Quantum dots (QDs) received broad attention as a promising optical contrast agent for *in vitro* and *in vivo* biological imaging. Despite significant progress in R&D on QDs, concerns with toxicity have prevented utilization of this product for human imaging. Nevertheless, there has been a significant program in enhancing several *in vivo* contrast agents (for CT and MR imaging), as well as in the introduction and validation of new class of agents that is expected to find their ways in clinical practice in next decade. Additionally, nano-based arrays and assays are gradually coming out of research laboratories into clinical markets. More than 50 companies are developing nanoparticle-based medicines for treating, imaging and diagnosing cancer in 2010 in the U.S. alone (Service, 2010).

An example of such development is ultrasensitive detection of protein targets, using nanoparticle probe technology developed by Nanosphere, Inc. Nanosphere is using its patented gold nanoparticle probe technology to develop rapid, multiplexed clinical tests for some of the most common inherited genetic disorders, including certain types of thrombophilia, alterations of folate metabolism, cystic fibrosis, and hereditary hemochromatosis. Also, it must be noted that Nanosphere is a recent, pure-play nanodiagnostic company, which went public through IPO in 2007.

Currently nanodiagnostics concepts focus around utilization of nanoscale properties for:

- Ultrasensitive biomarker development/measurement
- Multi-assay for real-time *in vitro* assessment
- Clinical nano-tracers and contrast agents for establishing disease stage, drug PK/PD and monitoring therapy

Successful development of such ensembles of therapeutics and diagnostics for drug development will eventually lead to more effective utilization in clinical practice, with the promise of moving toward "personalized medicine." Figure 13.8 compares historical and future market size for therapeutics and diagnostics products.

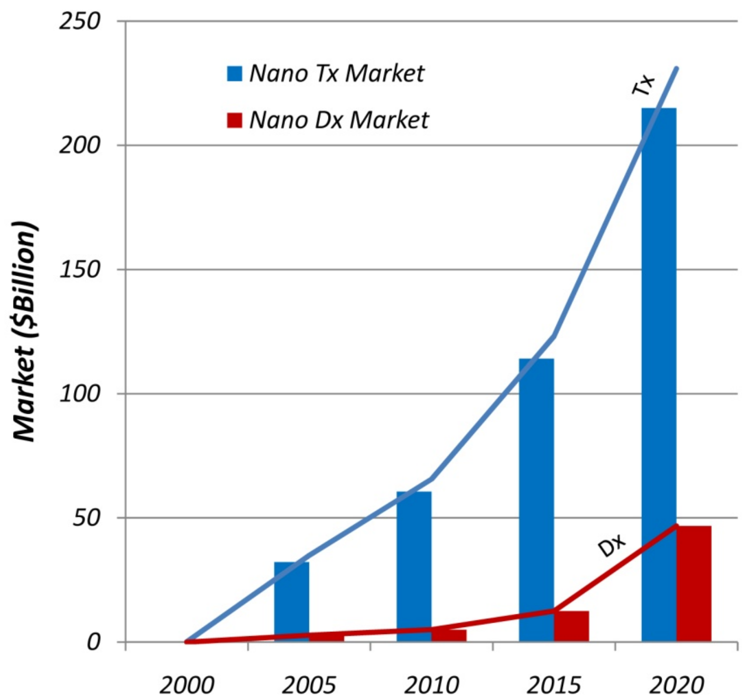

Figure 13.8. Historical and projected markets for nanotherapeutics (Tx) and nanodiagnostics (Dx) (Baseline data and compounded annual growth rates are based on BCC Research 2010).

While we are not at a stage to claim availability of "personalized medicine" today (although depending on a chosen definition, one may claim this has been practiced in medicine for quite some time), we have certainly come a long way since 2000. In the next 10 years, nanotechnology is projected to make even greater contributions compared to the past 10 years (Table 13.7). Convergence of nanodiagnostics and nanotherapeutics, along with better understanding of the etiology of diseases, should provide game-changing solutions for prevention of disease, more effective patient management, and enhancing quality of life globally.

Table 13.7. Major trends and projection in nanotherapeutics and nanodiagnostics 2000–2020

	2000	2010	2020
Therapeutics			
Reformulation	Academic Research	Several products approved and in the market	Fully developed market & deep pipeline of compounds with recent patent expiration
Novel Delivery	None	Several compounds in clinical trials	Multiple products in the market
Nano-based drug	None	Early stage R&D	Nano "blockbusters" addressing AD, OA/RA, CVD, DME/AMD
Diagnostics			
Assays and Reagents	None	Initial market entry	Main stream marketed products
In vitro Dx	None	A few approved/marketed products, more under development	Fully developed market. Multi-assay and hyper-sensitive solutions requiring minimal biological sample.
In vivo Dx	None	*In vivo* contrast agents under clinical trials	A few marketed products and deep pipeline
Theranostics (Tx+Dx)	None	Early stage R&D	A few game-changers paving the way toward personalized medicine. Significant steps toward nanobiosystem medicine.

13.8.11 Products Enabled with Nanotechnology Generated $254 Billion in 2009

Contact person: Jurron Bradley, Lux Research

Since the U.S. National Nanotechnology Initiative sparked a boom of interest in the early 2000s, nanotechnology has enticed entrepreneurs, financiers, and corporate leaders with its potential to create value in a wide range of products and industries. For example, in 2009 businesses generated $254 billion in revenue from products touched by emerging nanotechnology, which is defined as the purposeful engineering of matter at scales of less than 100 nanometers to achieve size-dependent properties and functions.

There are three stages of the nanotech value chain, including nanomaterials (raw materials that make up the base of the nanotechnology value chain), nanointermediates (intermediate products—neither the first nor the last step in the value chain—that either incorporate nanomaterials or have been constructed from other materials to have nanoscale features) and nano-enabled products (finished goods at the end of the value chain that incorporate nanomaterials or nanointermediates). About 88% of 2009 revenue came from nano-enabled products, which are in big ticket markets like automobiles and construction (Figure 13.9). The nanomaterials and nanointermediates portion *of the value chain supplied the other 12%, namely nanomaterials like zinc oxide, silver, and carbon nanotubes and nanointermediates like coatings and composites.*

In terms of sector, the manufacturing and materials sector—which includes industries like chemicals, automotive, and construction—accounted for 55% of the revenue in 2009, and the electronics and IT sector—which is dominated by computer and consumer electronics—contributed 30%. The healthcare and life sciences sector—primarily made up of pharmaceuticals, drug delivery, and medical devices—and the energy and environment sectors—comprised of energy applications like solar cells and alternative batteries—contributed 13% and 2%, respectively. In terms of region, the U.S. and Europe provided 67%

of the revenue, followed by 37% from Asia and the remainder from the rest of the world (Figure 13.9).

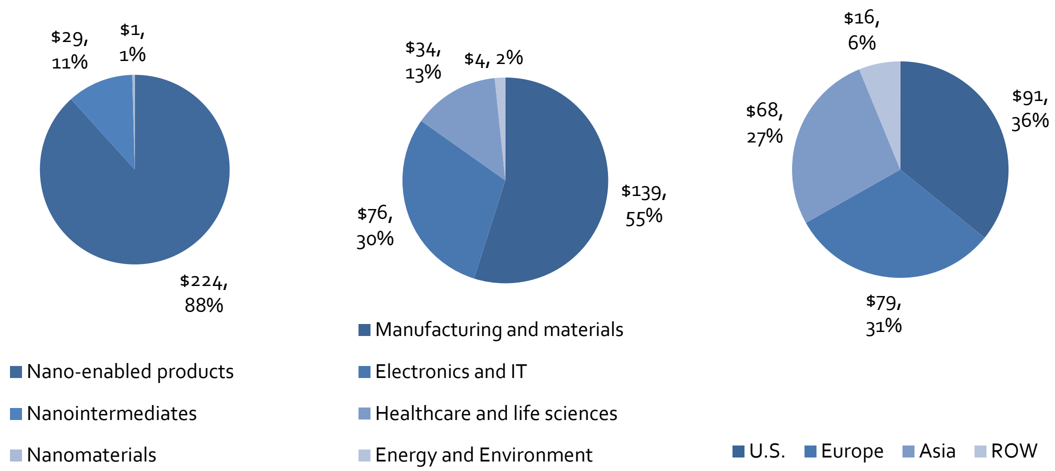

Figure 13.9. Products touched by nanotechnology generated $254 billion in 2009.

Venture capital funding increased steadily until 2008, but it experienced a significant decline during the 2009 economic crisis (Table 13.8).

Table 13.8. Venture capital funding for nanotech totaled $792 million in 2009

(US$ million)	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
U.S.	$ 171	$ 145	$ 318	$ 301	$ 366	$ 566	$ 654	$ 683	$ 1,159	$ 668
Europe	$ 23	$ 34	$ 37	$ 25	$ 78	$ 69	$ 73	$ 54	$ 144	$ 108
Asia	$ -	$ 48	$ -	$ -	$ 16	$ 6	$ 10	$ 2	$ -	$ 5
Rest of world	$ 12	$ 27	$ 11	$ 44	$ 16	$ 19	$ 50	$ 35	$ 58	$ 12
Total	$ 206	$ 254	$ 366	$ 371	$ 476	$ 659	$ 787	$ 774	$ 1,360	$ 792

13.9 INTERNATIONAL PERSPECTIVES FROM SITE VISITS ABROAD

The following are summaries from the international WTEC "Nano2" workshops held in Germany, Japan, and Singapore, with a focus on international convergence in governance.

13.9.1 United States-European Union Workshop (Hamburg, Germany)

Panel members/discussants

Alfred Nordmann (co-chair), Technical University of Darmstadt, Germany
Mike Roco (co-chair), U.S. National Science Foundation
Rob Aitken, Institute of Occupational Medicine; SAFENANO, Edinburgh, UK
Richard Leach, National Physical Laboratory, UK
Ilmari Pyykkö, University of Tampere, Finland
Nira Shimoni-Eyal, Israel
Georgios Katalagarianakis, EU support, Greece
Christos Tokamanis, EU support

It was noted in this session that nanotechnology research amounts to a socio-political project. In the spirit of the "Nano2" study, this formulation underscores the desire to look beyond nanoparticles and other advances in nanomaterials to some of the more long-term prospects and ambitions of nanotechnology. The topics for the group included regulation, standardization, ethical, and societal dimensions. For each of these areas of inquiry, there is something different to report about international convergence.

From the point of view of regulation and the knowledge that is required to establish regulatory thresholds and procedures, progress in regard to nomenclature, measurement, characterization, standardization, and testing procedures appears painfully slow and lags behind the speed of commercial development and the introduction of products into the marketplace. While such a lag is not unusual in and of itself, there looms in this case the question whether the lack of progress owes to formidable systematic difficulties and the level of complexity. If so, this might prove to be a major obstacle for extending available regulatory methodologies in the near, medium, or even long term even to "first generation" nanomaterials.[51] The last ten years saw the emergence of an at least two-pronged approach, and the next ten years will see its further development:

- On the one hand, there is close attention being paid to the requirements for an adequate extension of existing regulatory frameworks, such as the need for the development of internationally standardized traceability methods. Greater effectiveness might be achieved by a greater cohesion among international funding schemes.
- On the other hand, numerous analyses and institutional innovations are focusing on the development of expanded soft-law regulatory schemes that can serve a stop-gap role in the absence of proper risk-assessment and classical regulatory monitoring. These institutional innovations comprise soft-law codes of conduct or certifications, observatories, public engagement exercises, and consumer conferences, ELSI research, and platforms for the exchange of best practices.[52] All of these largely informal institutions serve to observe what social scientists have analyzed as a collective experiment with emerging technologies. Here, another avenue of research would integrate EHS and materials researchers more strongly with social scientists or regulators in order to explore together how far the notions of "safety by design," "precautionary science," "green nanotechnology," or "responsible innovation" can be developed.[53] Finally, it is in the arena of the collective experiment that epidemiology and a pre- and post-market product-testing approach receive greater attention than the ambition to determine pre-market and pre-production the toxicological properties of more or less generic nanomaterials. This includes increased emphasis on life-cycle analysis/assessments (LCA) and the development and improvement of LCA methodologies.

The call for international coordination and harmonization is loud and clear, and there are international working parties in a variety of venues. If international standards and the harmonization of traceability methods are not forthcoming, this is due partly to the duplication of research efforts and partly to the intractabilities of the problems at hand. The question of international convergence looks different in regard to ethical and societal

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[51] It is the case, of course, that nanomaterials are already covered by, for example, the REACH regulatory framework—at the cost of either not considering sufficiently or *de facto* exempting the specificities arising from their nanoparticulate or nanostructured character.

[52] In this regard, the NanoCap project suggested the introduction of safety notes as a standard element of research publications, alongside the methods section. The note would merely describe what safety measures were actually taken in the laboratory and would thus contribute to best practices and the evolution of shared standards.

[53] Integrated approaches are visible in exemplary studies like Lawton, J. (ed.). 2008. *Novel materials in the environment: The case of nanotechnology*. London: Royal Commission on Environmental Pollution, also in studies of the IRGC.

dimensions. Here there is an initial emphasis on specific cultural values and citizens' attitudes at the national and European Union levels. Recognition of these differences is an important prerequisite for the international diffusion of nanotechnological products and processes.[54]

One can speak of a two-pronged approach related to ELSI:

- On the one hand, there is a proactive and anticipatory approach that consists of first imagining potential or likely future applications of nanotechnology in society and then to appreciate and evaluate their impacts. Here, prospects of human enhancement through use of nanotechnology are currently proving to be divisive.
- On the other hand, there are attempts to understand nanotechnology as a socio-political project—in other words, to see what societal and technological trajectories are continued and intensified by nanotechnology, to appreciate and assess the visionary dreams and societal expectations that drive nanotechnology research, and to seek out just where currently funded nanotechnology research is proving to be disruptive.[55] In the context of this approach, there remains much to be questioned that is now taken for granted.

The perceived division of moral labor ("ethical considerations are important but they should be delegated to advisory committees") has been and will continue to be challenged, as for example, by the Code of Conduct for Nanotechnology Research that has been proposed by the European Commission.

A society that observes itself in an experimental mode must repeatedly ask itself, "How are we doing?" Since answering this question involves judgments, interventions, and calls for action, this kind of assessment of how we are doing regarding nanotechnology goes beyond the role of nanotechnology observatories as they are currently conceived, and it will open up in the next decade new requirements for the inclusion of social science and humanities scholarship.

13.9.2 United States-Japan-Korea-Taiwan Workshop (Tokyo/Tsukuba, Japan)

Panel members/discussants

Tsung-Tsan Su (co-chair), Industrial Technology Research Institute, Taiwan
Mike Roco (co-chair), U.S. National Science Foundation
Yoshio Bandou, National Institute for Materials Science, Japan
Toshiyuki Fujimoto, National Institute of Advanced Industrial Science & Technology (AIST), Japan
Ivo Kwon, Ewha Women's University, Korea
Mizuki Sekiya, AIST, Japan

The vision has changed in the last ten years:

- The initial focus was only on technical issues; now we also are addressing broader societal implications issues from economical outcomes and innovation to regulatory aspects.

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[54] Here, internationalization of the debate is moved forward by academics through venues like the S.NET society or the Springer journal *NanoEthics*.
[55] This does not necessarily involve a consideration of long-term nanotechnological developments. Nanoparticles are already proving disruptive because they are so hard to classify and therefore do not fit classical assessment schemes. The use of biological properties in the construction of nanomaterials (virus-like structures as nanotechnological building blocks) may well prove even more disruptive.

- There has been a partial transition from science-driven policies to user-driven policies, e.g., applications-driven R&D. Some countries have always had a strong emphasis on applications-driven research. There is an increased emphasis now on "return on investment"—how many jobs can you create?
- Both EHS and ELSI are now addressed more realistically and with specificity.
- There is more emphasis now on a common international vision; more communication and acceptance of common approaches and goals, addressing global issues like lowering CO_2, energy, and the environment.
- Both negative and positive hype experienced initially have receded; extreme negative predictions of the early 2000s have not come to pass.

The vision for the next ten years:

- Nanotechnology will be built into systems, e.g., nanotechnology to solve photovoltaic systems issues; use in transportation systems such as electric cars; biological applications such as in drug delivery, food, and agriculture, etc.; these will enable ubiquitous computing, communication, and sensing systems.
- Look to mass use of nanotechnology; many new products will emerge.
- Nanoscale science and engineering will be included in standards of learning by 2020.
- Nanotechnology will enable sustainable development.
- Nanotechnology may help to solve the world's problems, but there is concern of increasing the technological gap between developed and developing countries.
- Development of international activities will be institutionalized regarding nomenclature, standards, and patents related to nanotechnology, as well as in developing a common lexicon and improved toxicity evaluation, risk assessment, and mitigation.

The main goals for 2020:

- Clear regulatory environment to enable commercialization, protect consumers and general public; this should include internationally acceptable, harmonized regulations.
- Promotion by international organizations (e.g., ISO, *International Electrotechnical Commission*) of professionalism in nanotechnology R&D; easy communication internationally will accelerate exchanges of opinions among people in different countries concerning nanotechnology and support for common standards for valid research methodologies.
- Shift to a new generation of nanotechnology-enabled products, including preparation of enabling manufacturing and monitoring tools and regulations.
- Reduction in cultural, political barriers (e.g., to international collaboration, acceptance of nanotechnology-enabled products).
- Creation of an international information system; databases, information sources for broad access from researchers, industry, regulators, political system, including different categories and lists of funded research projects.
- Training of young scientists internationally to understand societal implications of nanotechnology.

Main infrastructure needs:

- Institutional mechanisms for international collaboration
- Ongoing support for ISO/TC229, IEC/TC113, OECD WPN; currently these are not permanent activities and serve only in advisory capacities.

- Fill the technology gap between developed and developing countries through international collaboration, e.g., the United Nations Environment Programme, United Nations Ethics Programme (UNESCO, 2006), Asia Nanotechnology Forum (ANF).
- Infrastructure to address long-term sustainable development through nanotechnology: CO_2 problem, nano-geo-engineering, water filtration and desalinization; this may require establishing a new international organization.
- International mechanism(s) to support nano-ELSI aspects; better coordination of existing national institutes; leverage individual countries' efforts.

Suggested R&D strategies:

- Create an international open source network to promote nanotechnology R&D and applications for sustainable development, other common problems, through precompetitive research (EHS, ELSI; climate change solutions; water filtration; energy and sustainable development technologies) (this might be difficult; it is very competitive now).
- Continue to allocate a portion of R&D projects to EHS and ELSI research and education, and to integrating EHS and ELSI with core R&D.
- Employ standard definitions and research protocols in EHS and ELSI research internationally, i.e., implement ISO, IEC, OECD recommendations.

Several emerging issues have been identified:

- Labeling is becoming an international issue; there is a contrast between the EU proposed approach aiming to address safety and Taiwan's "nanoMark" approach aimed at addressing authenticity of nanotechnology products.
- Public engagement is now a common interest internationally.

13.9.3 United States-Australia-China-India-Saudi Arabia-Singapore Workshop (Singapore)

Panel members/discussants

Graeme Hodge (co-chair), Monash University, Australia
Mike Roco (co-chair), U.S. National Science Foundation
Salman Al Rakoyan, King Abdullah Institute for Nanotechnology, Saudi Arabia
Freddy Boey, Nanyang Technical University, Singapore
Craig Johnson, Department of Innovation, Industry, Science and Research, Australia
John Miles, National Measurement Institute, Australia
Murali Sastry, Tata Chemicals Innovation Centre, India
Yuliang Zhao, Institute of High Energy Physics, Chinese Academy of Sciences, China

Key changes of the nanotechnology vision in the last ten years:

- Huge progress has been made in putting together building blocks for international governance: International Dialogue on Responsible Development of Nanotechnology (Arlington 2004, Bruxelles 2006, Tokyo 2008), IRGC (2006), UNEP, ISO, and OECD.
- International communities and networks of professionals have formed, in nanotechnology and societal implications, with a significant collaborative effort.
- Nanotechnology has moved from being a science and technology dream to a social reality.

Several major changes that are needed in the next decade:

- A common international language for nanotechnology and related studies, e.g., ISO standards to be adopted worldwide; characterization (Richman and Hutchison 2009).
- International joint funding mechanisms to support international standards activities, health and safety testing, other areas of common interest in "precompetitive" research. An alternative would be better coordination, more international co-funding, and leveraging of individual nations' R&D efforts.
- Different countries' interests need to be respected, e.g., developing countries.

Main scientific/engineering advancements and technological impacts in the last ten years:

- Development of capabilities to do nanoscale science and engineering research around the world.
- Beginning of scaled-up manufacturing capabilities at the nanoscale.
- Evolution from focus on multidisciplinary science and engineering to new multifaceted enabling technologies
- Move from science-only focus in nanotechnology to science and technology for society and the development of beneficial applications.

Key goals for the next 5-10 years:

- Scientific communities, industry, and governments should take the lead in undertaking meaningful and proactive public engagement, including better public appreciation/education of the value of the nanotechnology investments and how potential risks are being addressed.
- Open access, collaborative knowledge system(s) for strengthened investment and governance.
- Continued/increased international collaboration in nanotechnology investment; leveraging, sharing of facilities, best use of existing resources.
- Explicit system for incorporating ethical, legal, and other societal issues (ELSI) into nanotechnology governance, such as real-time technology assessment. Although this is not necessarily an issue unique to nanotechnology, and is essentially a broader science issue, nanotechnology could nonetheless set the example.

Needs for scientific and technological infrastructure include:

- Some participants suggested a new international agency for "precompetitive" collaborative R&D.
- An alternative is just better coordination (e.g., following the example of OECD Working Party on Manufactured Nanomaterials [WPMN] in EHS testing).

Emerging topics and priorities for future nanoscale science & engineering research and education:

- Need for ongoing regulatory review: e.g., incorporation of nanomaterials in existing approved products raises new regulatory issues (Breggin et al. 2009)
- Strengthening of international governance of nanotechnology
- Assessment of societal impacts and regulatory issues for next generations of nanotechnology-enabled products (Renn and Roco 2006)
- International harmonization of patent policies

Several characteristics of the implications of nanotechnology R&D on society:

- Nanotechnology is a lightning rod for debate over the impact of science on society more generally, and to some critics, is a symbol of everything that's wrong in the world
- Potential exists for nanotechnology to further divide the world into haves and have-nots—create a "nano divide" (Sparrow 2007); *or*, nanotechnology might have the potential to help bridge the divide between north and south (Singer et al. 2005; Salamanca-Buentello et al. 2005; Hodge et al. 2007).

13.10 REFERENCES

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