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Nanotechnology and Society: Emerging Organizations, Oversight and Public Policy Systems

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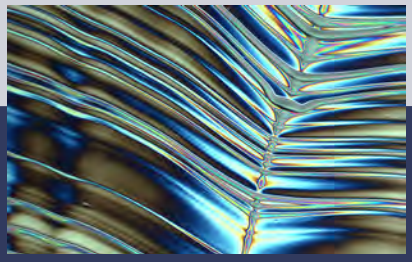
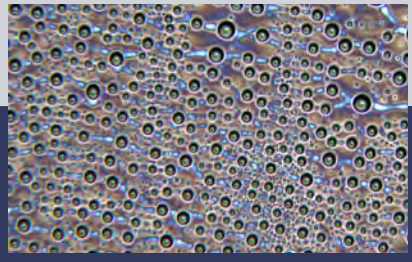

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Preface

The Center for Hierarchical Manufacturing (CHM) was launched at the University of Massachusetts Amherst (UMA) in 2006 with support from the National Science Foundation. Based in one of the world's foremost Polymer Science Departments, the CHM is a Nanoscale Science and Engineering Center (NSEC) and collaborates actively with leading industry partners and academic centers of excellence to achieve broader adoption of nanomanufacturing techniques by the nanotechnology community. The CHM fosters collaboration and cyberinfrastructure development and deployment through the National Nanomanufacturing Network (NNN) and an innovative digital library-based nanomanufacturing clearinghouse, Internano.org.

As part of its mission, the CHM supports analysis of societal implications of nanoscience and technology through a partnership with the Science, Technology and Society (STS) Initiative at UMA. The STS Initiative is a multidisciplinary research center based in the College of Social and Behavioral Sciences and the Center for Public Policy and Administration promoting collaborative research among researchers in the natural, physical, and social sciences, engineering, and public policy. The STS Initiative research projects respond to a critical global need to integrate analysis of the societal effects of emerging technologies with scientific discovery and technological advancement.

From 2006 to 2010, the STS Initiative organized three national nanotechnology and society research and policy workshops to examine: 1.) the organization and policy of innovation, 2.) networks, risk, and knowledge sharing, and 3.) public policy systems and oversight for emerging technologies. These workshops comprised part of a four-year process of inquiry and dialogue on key issues in nanotechnology and policy. The complete set of workshop reports are available at www.umass.edu/sts/nano. (See Appendix II for the workshop agendas.)

Introduction

Since 1996, the U.S. federal government has intensively invested in nanotechnology research and development to build innovation and national competitiveness. The national interest in nanotechnology was formalized in 2003 through the 21st Century Nanotechnology Research and Development Act (Public Law 108-153) which called for the creation of a national nanotechnology program to:

establish the goals, priorities, and metrics for evaluation for Federal nanotechnology research, development, and other activities; invest in Federal research and development programs in nanotechnology and related sciences to achieve those goals; and provide for interagency coordination of Federal nanotechnology research, development, and other activities undertaken pursuant to the Program.

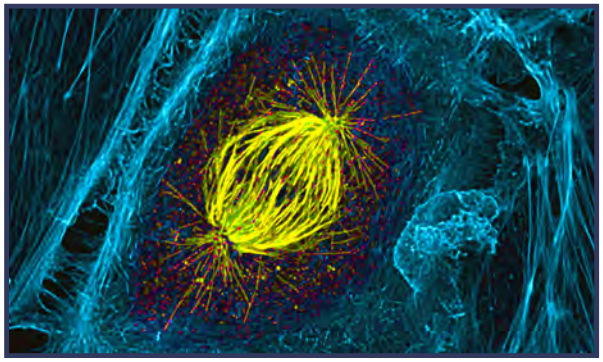


Photo credit: Patricia Wadsworth, UMass VISUAL

Although the federal government has invested substantially in nanotechnology research and development since 2003, surprisingly little federally supported activity has been undertaken to examine the regulatory processes and policies needed for this emerging science and technology domain. Absence of a single, coordinated approach to regulating nanotechnology, not unusual in U.S. science policy, has encouraged non-profits and non-governmental organizations, private firms, state-level governments, and individual federal agencies to develop their own policies. To examine the emerging patchworked landscape of approaches to nanotechnology regulation, the Science, Technology and Society (STS) Initiative, with support from the Center for Hierarchical Manufacturing (CHM), organized a national workshop, "Nanotechnology & Society: Emerging Organizations, Oversight, and Public Policy Systems," that was held on September 23-24, 2010 at the University of Massachusetts Amherst (UMA). Its goal was to examine current approaches to emerging oversight and regulations for nanotechnology research, applications, and impacts and to identify regulatory gaps that must be addressed for the nation to continue responsible development of nanotechnology. Following the National Nanomanufacturing Initiative (NNI) guidance for the responsible development of nanotechnology, workshop organizers additionally sought to "[establish] channels of communication with relevant stakeholders, in terms of both providing information and seeking input." [1]

Expert panels brought together some of the nation's leading expert, policymakers and thought leaders to focus on three broad issue areas: constructing frameworks for policymaking, international and federal policy emergence, and non-governmental organization perspectives on emerging nanotechnology oversight and regulation.[2]

[1] National Nanotechnology Initiative "Society & Safety" Accessed December 8, 2010 from http://www.nano.gov/html/society/home_society.html

[2] See Appendix I for further reading on nanotechnology regulation.

Experts and policymakers reiterated four themes throughout the workshop:

1. There is a critical need for stronger communication among policymakers, scientists, and industry professionals.
2. An ongoing challenge exists to balance processes to assure environmental health and safety (EHS) with vigorous promotion of opportunities for commercialization and competitiveness.
3. Core democratic values including transparency, disclosure, citizen engagement, and informed consent must be incorporated into regulatory discussions, specifically regarding the use of nanotechnology in consumer products.
4. Regulation of emerging technologies should incorporate societal implications of new regulations and policies.

Panel I: Constructing Frameworks for Policymaking

- Terry L. Medley, Global Director of Corporate Regulatory Affairs, DuPont, "Policy Guidance: Collaborations for the Responsible Development of Nanoscale Materials"
- Timothy Malloy, Professor of Law, University of California, Los Angeles, "Under Construction: The Many Roads to Policy"
- Jordan Paradise, Associate Professor of Law, Seton Hall University, "Developing Oversight for Nanobiotechnology: Human Drugs and Medical Devices"
- Moderator: Jane Fountain, Professor of Political Science and Public Policy and Director of the Science, Technology and Society Initiative, University of Massachusetts Amherst

The rise of nano-, bio-, and information technologies has encouraged research on policymaking in the context of emerging scientific discovery and emerging technological developments. In an environment of emergence, however, stakeholders may not be well established, issue positions may not be clearly formulated, and risks may be highly uncertain. Indeed, regulatory and oversight policies often compete with commercialization and product development, and policymakers seek to find a balance between ensuring public and worker safety, economic competitiveness, and innovation.

In spite of such ambiguity, much has been learned about robust and useful vehicles and frameworks for policymaking amid high uncertainty. This panel examined several such frameworks covering international and national responses to advances in nanotechnology.

Collaboration for Responsible Development of Nanomaterials

Successful regulation of nanotechnology requires public-private partnerships and collaboration which fosters the development of open communication channels and buy-in from diverse stakeholders.[3] Terry Medley, co-lead for the development of the Environmental Defense Fund-DuPont Nano Risk Framework,[4] explored the relative roles of public, private, and non-profit actors in creating nanotechnology development frameworks through two national initiatives: the National Nanotechnology Initiative (NNI) and the President's Council of Advisors on Science and Technology (PCAST).

The NNI was established in 2001 to coordinate the activities of twenty-five federal agencies as they develop collaborative, long-term strategies for the future of nanotechnology in the U.S. The Initiative seeks to minimize duplication of development efforts and maximize shared resources across agencies. In its supplement to the President's Budget for fiscal year 2011, for instance, the NNI presents three key, collaboratively developed, "signature initiatives"—nanoelectronics for 2020 and beyond, sustainable nanomanufacturing, and nanotechnology for solar energy collection and conversion—as areas "ripe for significant advances through close and targeted program-level interagency collaboration." Because it effectively pools resources, encourages cross-agency communication, and actively seeks collaboration, industry leaders argue that the NNI is an excellent example of the type of collaboration needed to advance science and risk-based policy for responsible nanotechnology development.

Similarly, PCAST serves as a science and technology-based advisory board to coordinate the highest levels of strategic advice to the President. The PCAST responds to questions mandated by Congress and does not work on a consensus basis in order to preserve diversity of expertise and perspectives. Its March 2010 *Report to the President and Congress on the Third Assessment of the National Nanotechnology Initiative*[5]

[3] This section summarizes the presentation of Terry L. Medley, J.D. 2010. "Policy Guidance: Collaborations for the Responsible Development of Nanoscale Materials." Panel presentation at Nanotechnology & Society: Emerging Organizations, Oversight, and Public Policy Systems at the University of Massachusetts Amherst, Amherst MA. The video and slides of this presentation are available at http://www.umass.edu/sts/nano/2010program.html

[4] Environmental Defense-DuPont Nano Partnership. 2007. Nano Risk Framework. http://www.edf.org/documents/6496_Nano%20Risk%20Framework.pdf. See www.nanoriskframework.com

[5] See President's Council of Advisors on Science and Technology. 2010. Report to the President and Congress on the Third Assessment of the National Nanotechnology Initiative. Accessed December 8, 2010 from http://www.whitehouse.gov/sites/default/files/microsites/ostp/pcast-nni-report.pdf

calls for research evaluating the effect commercialization of nanotechnology will have on EHS concerns and ultimately advises an increase in investment in nanomanufacturing. PCAST encourages policy-makers and decision-makers to consider an incremental transition to commercialization, retention of a scientific workforce in the U.S. to maintain international competitiveness, and development of an oversight mechanism for the regulation of commercialized nanotechnology. The report, compiled by three PCAST members and twelve industry and academic professionals, offers suggestions "informed by discussions with thirty-seven government officials, industry leaders, and technical experts from a wide range of fields involving nanotechnology."[6]

While the NNI and PCAST represent two of the most important coordinated government efforts to forecast strategic needs in science and technology, a worthwhile consideration going forward involves the implementation of a proactive approach to responsible development of nanomaterials. Vital to the success of framing EHS issues is an increase in stakeholder collaboration, the incorporation of coordinated input through public-private partnerships, and the consideration of issues at a global scale. The Nano Risk Framework developed for nanomaterials by DuPont and the Environmental Defense Fund is an excellent example of stakeholder collaboration. The Framework, created during a three-year partnership, incorporates participant contributions on a global scale, receiving input from international nanotechnology leaders during multiple phases of the document's production. It is, according to its authors, "a comprehensive, practical, and flexible Nano Risk Framework—a systematic and disciplined process—to evaluate and address the potential risks of nanoscale materials."[7] However, more than a process by which risk can be assessed, the Framework is tangible proof that public-private partnerships can succeed in solicitation of open lines of communication and productively merge public and private interests.

The guidance and frameworks developed by the NNI, PCAST, DuPont, and the Environmental Defense Fund, although developed on a non-consensus basis, successfully integrate significant participation of public and private sector leaders in nanotechnology. Such guidance demonstrates the potential for cross-sector and cross-agency partnerships and can act as models for collaborative regulatory development. Indeed, PCAST recommends in its March 2010 report to "continue developing joint programs among NNI agencies that leverage expertise and resources to conduct nanotechnology EHS research and to support agency missions."[8] The creation of joint or collaborative research programs, the implementation of processes to leverage multidisciplinary resources, and targeted funding to support decision-making and risk assessment—through which the NNI will play a key role—will allow the United States to continue its global leadership and accountability in nanotechnology.

The Many Roads to Policy

One way to frame approaches to regulatory policymaking is to examine various conceptual frameworks used by researchers and policy analysts to conceptualize problem definitions and policy options.[9] With respect to regulatory policymaking for nanotechnology, for the sake of simplicity, two major types of policy options might be considered: hard law and soft law. Both attempt to answer the fundamental question: What is the proper role of government in nanotechnology policy?

Soft law refers to an environment in which government leaves it to businesses—either as individual firms or in partnerships of various kinds—to self-regulate. Soft law generally includes basic self-regulation in which companies establish their own codes of conduct. In other cases, groups of firms or an industry sector might develop shared cords of practice. For example, the DuPont risk framework presented at this workshop is a notable example of industry-led self regulation. What has been termed "enforced self regulation" has evolved to the point that government often invites companies to engage in a collaborative relationship to develop effective regulatory policies. The EPA's Stewardship Program is an example of this type of partnership. Hard law refers, by contrast, to classic or conventional regulation in which government sets standards, delineates rules and laws, monitors for compliance and enforces regulatory practices. An alternative construction to the dichotomy of hard and soft law is a hybrid and sequencing of approach developed by Malloy called "iterative regulation."

Examination of the policymaking, risk, and business literatures to map the state of the discourse on regulatory approaches for nanotechnology suggests a "policy milieu" that includes a collection of various policy tools. Some tools focus on, for example, insurance; others on information disclosure; still others are mixed approaches. Conceptualizing this milieu in narrative terms, analysts tell "stories" or present narratives about how these approaches work and how policies are produced. One of the challenges in the regulation of emerging technologies lies in simultaneous development and deployment of incentives that promote innovation and competitiveness while also

[6] *ibid*. p. vi

[7] Environmental Defense-DuPont, 2007, p. 7.

[8] PCAST, 2010, p. 41.

[9] This section summarizes the presentation of Professor Timothy Malloy. 2010. "Under Construction: The Many Roads to Policy." Panel presentation at Nanotechnology & Society: Emerging Organizations, Oversight, and Public Policy Systems at the University of Massachusetts Amherst, Amherst MA. The video and slides of this presentation are available at http://www.umass.edu/sts/nano/2010program.html. The summary draws on research from the UCLA Law and Environmental Health, Sustainable Technology Policy Program.

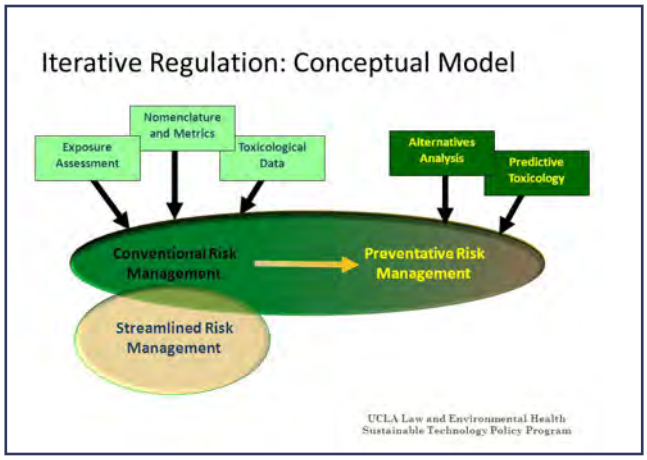
developing rules to mitigate against negative public health and environmental impacts in a highly uncertain environment.

What are the incentives for business to regulate itself? The general statement is that strong incentives underlie self regulation. These include fear of liability (if people get hurt firms are subject to liability), the desire to manage the public's fear of technology (if there is a catastrophe, this will cause fear of nanotechnology and hurt development), and the "good neighbor" norm by which businesses, regardless of instrumental drivers, are attuned to the impact of their decisions on others. These normative claims should be compared to empirical practice to test their strength as regulatory vehicles.

Moreover, an examination of actual cases, Malloy argues, suggests that tort liability is not a particularly strong driver of business self-regulation. There is a long latency period before the risk of exposures is seen, thus separating cause and effect often by several years. There is limited liability of particular actors in a corporation, thus making it difficult to trace harm back to specific individuals or groups. Fear of technology seems to make sense as a driver, but other factors push back against this incentive as well.

To generalize, Malloy uses the term "incentive slippage" to specify several ways in which incentives toward self regulation are weakened and rendered ineffective.

1. Calculative slippage. This form of slippage results from behavioral tendencies of rational actors in action and in the context of conflicting norms and incentives. As business actors calculate the best course of action to produce results in a competitive environment and amid scarce resources, actions may serve to pull resources from EHS to other investment areas.
2. Routine slippage. This form of slippage focuses on gaps in coordination mechanisms—information flow, resource allocation, and allocation of authority—used in complex organizations to structure individual behavior. The business literature repeatedly demonstrates that it is very difficult to make sure the flow of information, resources, and power are allocated to ensure all relevant actors have sufficient information to make decisions informed by EHS concerns. EHS are generally weak drivers in the operating decisions of a firm, in part because it is very difficult to get the information flow in these areas right. If the firm fails in the internal management required to make the implementation of these norms effective, they slip.
3. Cognitive slippage. In this form, psychological mechanisms called norm activation barriers, such as defensive denial and norm neutralization, render norms, or good intentions, ineffectual. Individuals have a "good neighbor" norm, but also have an incentive to get products to the market, to do well competitively, and to make financial gains. These drivers underlying competition tend to drive out good neighbor norms in the actual practice of making discrete decisions.



Recognition of these various categories of incentive slippage is not meant to imply that businesses slip in every instance. The issue raised here is that there is little recognition or discussion of these forms of slippage in business law.

Counterposed to the business narrative, the regulatory narrative is typically defined in terms of a conventional regulation structure that is rigid, top-down, and a one-size-fits-all approach to highly complex regulatory challenges. The narrative continues that conventional regulatory mechanisms rely upon prescriptive, "acceptable" exposure levels and, because of this, a criticism has been that information and methodological gaps are barriers to its use. What do we find when we examine actual regulatory policies in this domain? On the structural point, it turns out that conventional regulation in EHS relies almost uniformly on performance standards built up from best practices among the best companies. So what is presented as the typical standardized policy is not actually accurate upon close examination of details. Conventional regulation does indeed tend to account for variation among industries. For example, one finds in clean air regulations that industries and firms are categorized and subcategorized at a fairly detailed level to account for diversity.

In terms of mechanisms used in government regulation of EHS in areas related to nanotechnology, conventional regulation does often set acceptable exposure levels. Yet conventional regulation is a substantially broader umbrella term encompassing information- and management-based regulation, as well as qualitative risk management.

Lack of information and uncertainties in regulatory policymaking often mean that government cannot form standards. But even in such cases, agencies can require that companies engage in

planning to mitigate risk, specifically, facility planning. Toxics use reduction planning is an example that might be applied to nanotechnology regulation, for example. Such directives are not prescriptive in the conventional sense, but they require businesses to think about information, coordination and operations. In this sense, businesses and decision-makers often engage in both quantitative and qualitative risk management. The Dupont Environmental framework, for example, is based on qualitative risk management.

In sum, government's regulatory roles and capacities are much broader than generally construed. They include information dissemination and collection; coordination of conflicting approaches to risk analysis and regulatory decision-making; quality control and enforcement; and standard setting. An iterative policy process combines the benefits of streamlined risk assessment in which business takes the lead and with a variety of tools and mechanisms to broadly analyze and mitigate against risk while the longer term, more conventional government regulatory process plays out. Government can play an oversight role in making streamlined risk management an enforceable obligation by identifying and disseminating best practices and making those that have broad applicability mandatory.

Oversight for Nanobiotechnology

Nanotechnology and nanobiotechnology have the potential to provide groundbreaking "tools for in vitro and in vivo diagnostics for much earlier detection of disease; facilitate targeted drug delivery and regenerative medical applications; supply anti-microbial coatings for implanted medical devices; and enable devices that seek, bind to, and destroy tumor cells."[10] Given this broad application and potential, industry leaders have been quick to utilize nanotechnology in pursuit of medical breakthroughs. However, regulation of such innovation has not kept pace with this research and development.

Currently, the Food and Drug Administration (FDA) is largely responsible for the oversight of clinical research, approval, and marketing of nanotechnology products. In this way, the FDA is the gatekeeper to clearance and approval of medical and health care products in the U.S. Thus, not only does the FDA have a responsibility to ensure the safety of food and drugs in the U.S., but it must do so without unnecessarily hindering the speed with which new and important breakthroughs can reach the marketplace. The very broad application of nanotechnology products and the continually evolving understanding of how

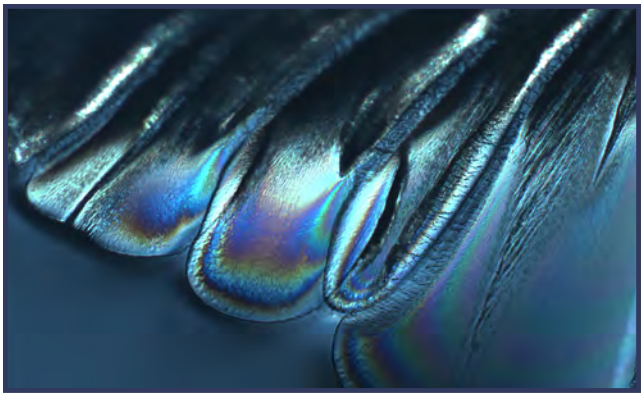


Photo credit: Jared Archer, UMass VISUAL

different nanoparticles may interact in different environments have presented unique challenges to FDA regulators as they try to balance these two objectives. On one hand, different applications of the same nanomaterial may signal different EHS issues. On the other hand, testing and retesting the same nanomaterial each time it is used in a new product is significantly time and labor intensive and therefore slows the speed with which potentially useful products can be used by the general public. To address this, the FDA implemented an accelerated approval process for treatment processes deemed to be lifesaving, based on surrogate endpoints. Conceptually, the accelerated process results in faster implementation of lifesaving products. Practically, however, this process—the same one through which the FDA classifies, reviews, and approves nanotechnology tools—has proven to be inadequate.

In a four-year collaborative, interdisciplinary research project, researchers at the University of Minnesota and Seton Hall Law School examined the effectiveness of the FDA's 510(k) approval process for class II devices.[11] This accelerated approval process necessitates "substantial equivalence" from industry that the product to be approved has the same technological characteristics or intended use as devices already cleared by the FDA. Although experts charge that this approval process may ignore any newly presented questions of safety, it is this process whereby products using nanomaterials as coating or as another component of medical devices have been approved. Moreover, data submitted through this approval process to the FDA is not currently nano-specific; the FDA uses its discretion to review this information without a formal evaluation process for nanomaterials. Thus, there is no concrete record of the number of approved nanobiotechnology products in the marketplace.

[10] This section summarizes the presentation of Professor Jordan Paradise. 2010. "Developing Oversight for Nanobiotechnology: Human Drugs and Medical Devices." Panel presentation at Nanotechnology & Society: Emerging Organizations, Oversight, and Public Policy Systems at the University of Massachusetts Amherst, Amherst MA. The video and slides of this presentation are available at http://www.umass.edu/sts/nano/2010program.html

[11] See Susan M. Wolf, Efrosini Kokkoli, Gurumurthy Ramachandran, Jennifer Kuzma & Jordan Paradise, "NIRT: Evaluating Oversight Models for Active Nanostructures and Nanosystems: Learning from Past Technologies in a Social Context," NSF grant number SES-0608791.

Although the FDA does appear open to examination of its approval process for nanomaterials, the lack of a nano-specific framework raises questions about the capacity of the current pharmaceutical approval system and highlights the ambiguity surrounding oversight for emerging technologies.

In May 2010, the FDA's Center for Drug Evaluation and Research issued an internal manual of policies and procedures containing nano-related information. Most importantly, the manual created an internal FDA database that will be used to document every application that seeks approval for nanopharmaceuticals and will establish a common location to house information on the nanoparticles' features, testing measures, and long-term tracking data. These rules acknowledge the need for centralized, consistent documentation and testing of nanomaterials. They ignore, however, the fact that nanopharmaceuticals and nanobiotechonlogy currently lack a regulatory definition of nanotechnology. Thus, while the regulations appear promising, they provide little guidance on which products must actually be recorded.

As current FDA regulations show, finding and designing appropriate methodologies for nanotechnology oversight is challenging. The current speed with which new nanomaterials are developed or utilized urgently requires the development of sound, flexible oversight frameworks. Indeed, nanotechnology regulatory processes must evolve as technology itself evolves to ensure safe and transformative nanotechnology development.

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It is critical to incorporate the public values of environmental protection, health, and safety assurance into the regulation of emerging technologies, particularly as the United States seeks to maintain its status as an international leader in nanomanufacturing. Discussion about the appropriate construction of frameworks for policymaking generates questions about the relationship between EHS funding and commercialization. What effect would policies mandating EHS research before commercialization have on innovation, the marketplace, and public or worker safety? What level of funding would be appropriate for such research? Although congressional leaders are often lobbied for increased EHS funding, it is difficult to pinpoint the specific monetary amount that would be necessary or sufficient or the appropriate length of time to limit commercialization. Government officials have a unique opportunity to simultaneously maintain the United States' global leadership in nanotechnology development while also ensuring adequate EHS standards. Finding a balance between such competing ideals, however, is difficult.

Panel II: International and Federal Policy Emergence

- Jeff Morris, National Program Director for Nanotechnology, United States Environmental Protection Agency, "Global Engagement on Nano EHS: Role of the OECD in International Governance"
- Charles L. Geraci, Jr., Coordinator, Nanotechnology Research Center, National Institute for Occupational Safety and Health, "Nanotechnology and Worker Risk: Who's At the Controls?"
- Treye Thomas, Toxicologist & Chemical Hazards Program Leader, Office of Hazard Identification and Reduction, Consumer Product Safety Commission, "Challenges in Assessing Nanomaterial Health Risks in Consumer Products"
- Moderator: Mark Touminen, Professor of Physics and co-Director of the Center for Hierarchical Manufacturing, University of Massachusetts Amherst

As countries globally develop governance mechanisms to regulate the development of nanotechnology and other emerging technologies, policy- and decision-makers must foster collaboration among international researchers, industry professionals, academics, and other stakeholders. The roles of federal agencies and international bodies in addressing EHS concerns both domestically and internationally and the processes by which regulatory decisions are made must also be made transparent.

Organizational Capacity for International Governance

For many years, countries examined and tested nanomaterials and produced nanotechnology regulations within the confines of their own borders.[12] Although information was generally freely shared across countries, active partnerships were rare. However, as Jeff Morris, National Program Director for Nanotechnology at the U.S. Environmental Protection Agency, explains, nanotechnology is a global issue, and governance, therefore, must be done within in a global construct. Morris and other government leaders encourage not only global discourse around nanotechnology, but incorporation of international, non-

[12] This section summarizes Jeff Morris. 2010. "Global Engagement on Nano EHS: Role of the OECD in International Governance." Panel presentation at Nanotechnology & Society: Emerging Organizations, Oversight, and Public Policy Systems at the University of Massachusetts Amherst, Amherst MA.

governmental voices into discussions about nanotechnology regulation and EHS concerns. The Organization for Economic Cooperation and Development (OECD) offers an effective model to mediate such international, multi-sectoral dialogue.

In 2006, the thirty members of the OECD formed the Working Party on Manufactured Nanomaterials (WPMN) as a governance mechanism to ensure chemical and nanomaterial safety issues were identified and discussed within member nations. The Working Party reviewed existing OECD testing guidelines for adequacy in addressing nanomaterials and identified where the need for new or revised testing guidelines existed. While most testing guidelines were considered appropriate to address today's needs, the WPMN identified some provisions that may necessitate adjustment for adequate analysis of nanomaterials.. For example, methodological complications were found as particles were tested in or reacted to different environments. One implication is that the process to determine and understand the characteristics of nanomaterials may not allocate enough time to make the types of regulatory EHS decisions typically made with traditional chemicals

The WPMN's success led OECD to initiate a collaborative, international effort to share the testing of an agreed set of manufactured nanomaterials selected by WPMN. Through its discussions, the WPMN aims to identify what information is needed to minimize risk, and how test guidelines can guide the development of such information ; introduce nanotechnology to new audiences, including developing nations; and evaluate the environmental impacts and social benefits of nanotechnology on a global scale. This partnership represents important progress in international nanotechnology oversight. Indeed, such knowledge sharing is critical for efficient, international regulation of nanotechnology because it prevents duplication of efforts among member states, increases the speed by which countries can be made aware of regulatory problems, and provides a centralized location for information about nanotechnology testing.

While the objectives of the WPMN result from the realities of a traditional regulatory framework, the evolution of the WPMN's activities document important dimensions to consider when developing new nanotechnology frameworks. Most notably, the WPMN shifted discourse to a focus on environmental sustainability and nanotechnology and the methods by which environmental safety is affected by consumer use of nanomaterials.

The WPMN developed as a result of concerns regarding testing guidelines and data needs, but the formal and informal collaborations resulting from the Working Party's activities are advancing nanotechnology governance globally. The role of OECD in international governance of nanotechnology-related EHS concerns reflects a larger discussion on the importance of sustainability and outreach to developing nations; this early movement toward pushing discourse as technologies are being developed and before they are ubiquitous in commerce is essential for successful governance in the future. Moreover, the international perspective of the WPMN and OECD nanotechnology oversight is a characteristic necessary for responsible development and assessment of nanotechnology globally.

Regulation of Nanotechnology Worker Risk

Nanotechnology offers an economic promise to improve many aspects of human life.[13] Its inherent uncertainty as an emerging technology, however, means that environmental and health hazards are not entirely known, and risks are not universally characterized. As nanotechnology more frequently enters the workplaces, this means that nanotechnology workers—like regulators—operate in an uncertain environment. This uncertainty remains the foremost challenge to expansion of nanotechnology commercialization in the U.S. How can the benefits of nanotechnology be realized while proactively minimizing the potential risk? How do government regulators derive benefits of commercialization that minimize predictive negative consequences? Answers to these questions are unclear, yet critical for effective management of risks associated with human health, the environment, the economy, and public trust.

Currently, the Occupational Safety and Health Act of 1970 and the Occupational Safety and Health Administration (OSHA) and the National Institute for Occupational Safety and Health (NIOSH) manage most worker risk and safety issues. Since 1970, however, the type of risk to which workers may be exposed has dramatically changed and such regulations have proven inadequate. For instance, increased complexity has made regulators slow to adopt protective standards for toxic agents that are already well-known to pose significant risks. In the case of nanotechnology, workers are often exposed to nanomaterials or nanoproducts before regulations are in place or potential risks are thoroughly addressed. Thus, , expectations for rapid adoption of standards to protect workers from nanomaterials—whose risks are just emerging—are non-existent. Moreover, data on workplace hazard exposure—data which is critical for understanding where and how exposure may occur in order to rapidly put in place good interventions—is meager.

In this environment, NIOSH is the only federally funded agency to conduct research on occupational hazards. The agency uses a traditional risk management model to map concurrent research

[13] This section summarizes Charles L. Geraci, Jr. 2010. "Nanotechnology and Worker Risk: Who's At the Controls?" Panel presentation at Nanotechnology & Society: Emerging Organizations, Oversight, and Public Policy Systems at the University of Massachusetts Amherst, Amherst MA. The video and slides of this presentation are available at http://www.umass.edu/sts/nano/2010program.html

priorities and ongoing worker protection. Without enough data and resources, however, the agency is incapable of keeping pace with nanotechnology developments. Thus, a collaborative, interdisciplinary effort between researchers, business alliances, manufacturers, workers, users, risk managers, and government agencies is necessary to develop effective and scientifically informed nanotechnology oversight. A national nanotechnology partnership could share the responsibility to develop occupational safety and health guidelines to encourage prudent exposure control measures and disseminate NIOSH research to eliminate EHS risk and inform regulatory policy. The 2009-2012 NIOSH strategic plan[14] advocates for such a partnership. It moves beyond current siloed processes which require detailed knowledge of nanomaterial risks to a collaborative process which more efficiently and effectively pools nano-specific research and assessment. A formal, national nanotechnology partnership could help to fill gaps identified by NIOSH and harmonize approaches to develop exposure guidelines or standards of practice which could be used across industries. A partnership could help to generate knowledge about the nature and extent of worker risk, utilize that knowledge to develop risk control strategies to protect nanotechnology workers now, and provide an evidence base for recommendations for a mandatory nanotechnology program standard at a future date.

Assessing Health Risks in Nanomaterial Products

The Consumer Product Safety Commission (CPSC) currently maintains broad jurisdiction over 15,000 products used in or around the home; its regulatory authority extends to toys, electronic equipment, appliances, clothing, household cleaners, and building materials, among others.[15] Under the Federal Hazardous Substances Act, CPSC staff may assess a product's potential chronic health effects to consumers, which often requires new knowledge, toxicology information, and new evaluation techniques.

Like all regulatory agencies, the CPSC has examined its policies and processes in light of nanotechnology development, and, in 2005, the CPSC issued a statement regarding the potential safety and health risks of nanomaterials that could be assessed under existing CPSC statutes, regulations, and guidelines.[16] Given the rapid and dynamic development of nanotechnology, CPSC posited questions surrounding the feasibility data collection, testing, and product identification.

In is not clear whether adequate data can be collected at the nanoscale level using current facilities and techniques. Although regulatory approaches for products with nanomaterials will likely be similar to the approach used to regulate products containing other chemicals, toxicology experts charge that nanomaterials present unique testing issues because their attributes may change as the scale of their use increases. Further, their relative newness means long term impacts are unknown.

Beyond the challenges presented to testing ever-changing nanomaterials, the CPSC also questions the lack of processes to identify nanotechnology products themselves. To date, the CPSC has relied on research conducted by the Project on Emerging Technologies within the Woodrow Wilson International Center for Scholars which inventoried approximately 1,000 consumer products reported to contain nanomaterials. Those nanotechnology products which fall under CPSC regulatory authority will be classified and tested by CPSC toxicologists to determine the size distribution of particles released from products during usage. While the Woodrow Wilson list is a tremendous asset for current nanotechnology testing, the use of nanomaterials in consumer products is rapidly expanding and the list will quickly become outdated. Thus, one of the primary data needs going forward will be the identification of nanomaterial products. Moreover, once a nanoproduct is

[14] NIOSH. 2009. Strategic Plan for NIOSH Nanotechnology Research and Guidance: Filling the Knowledge Gaps. Available http://www.cdc.gov/niosh/docs/2010-105/pdfs/2010-105.pdf.

[15] This section summarizes Treye Thomas. 2010. "Challenges in Assessing Nanomaterial Health Risks in Consumer Products." Panel presentation at Nanotechnology & Society: Emerging Organizations, Oversight, and Public Policy Systems at the University of Massachusetts Amherst, Amherst MA. The video and slides of this presentation are available at http://www.umass.edu/sts/nano/2010program.html

[16] See http://www.cpsc.gov/library/cpscnanostatement.pdf

identified, CPSC will need to identify, test, and classify the specific nanomaterial used.

Utilization of the Woodrow Wilson list is a clear example of cross-sector collaboration. Collaboration among other regulatory organizations has also been useful for more efficient and appropriate identification and testing of products containing nanoparticles. For example, the CPSC recently established an interagency agreement with the NIOSH to evaluate particles generated from the use of a spray product containing titanium dioxide nanoparticles. This collaboration highlights the benefits of multidisciplinary partnerships: the CPSC was able to engage in chamber testing of nanomaterial products using a mechanical finger to spray the material into a chamber for analysis in lieu of exposing a human worker to unknown risks of the substance.

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While it is important to develop new evaluation techniques and computational methods that adequately assess nanomaterials and are adaptable to future technologies, the best process for assessing these techniques or methods remains unclear. For instance, what are the advantages and disadvantages of a substance-by-substance approach to the nanomaterials approval process? Regulatory leaders indicate that it is difficult to evaluate a material without also understanding its impact in different environments. For example, a silver nanoparticle has varying properties depending on whether it exists within a body of water. Thus, it is essential to gain full knowledge of how each nanomaterial reacts within the particles surrounding it. Such a full analysis of all nanoproducts, however, is infeasible. Instead, federal agency officials have cataloged fourteen nanoparticles as the most commonly used today. Thus, while it is daunting to evaluate each substance individually, this discrete number allows for the potential adoption of a more simplified "class approach." Although such policies will require ongoing assessment as nanotechnology continues to develop, they currently represent best practices for efficient nanotechnology assessment.

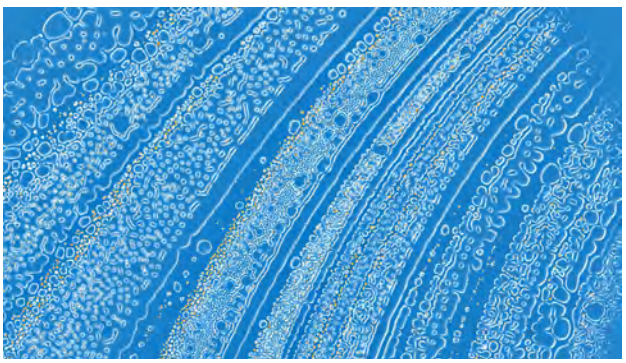


Photo credit: Scott Christensen, UMass VISUAL

Panel III: NGO Perspectives on Emerging Nanotechnology Oversight and Regulation

- Rick Reibstein, Environmental Analyst and Policy and Outreach Manager, Office of Technology Assistance, MA Executive Office of Energy and Environmental Affairs, "Anticipatory Constructive Engagement at the State Level"
- Richard Sclove, Founder and Senior Fellow, The Loka Institute, "Reinventing Technology Assessment in the U.S."
- J. Clarence Davies, Senior Fellow, Resources for the Future, "Nanotechnology and the Future of Federal Environmental Regulation"
- Moderator: Michael Ash, Associate Professor of Economics and Public Policy, University of Massachusetts Amherst

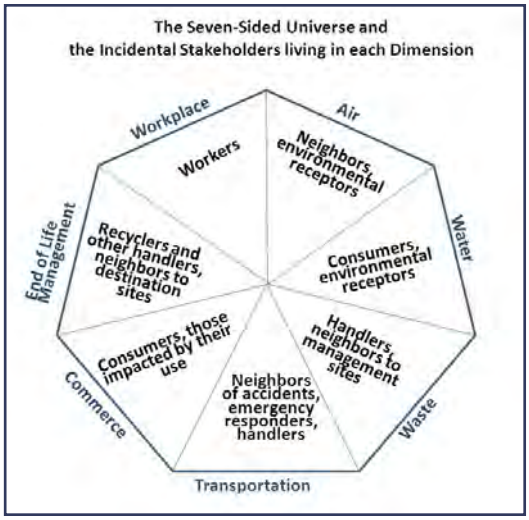
Nanotechnology and other emerging technologies present a unique opportunity for collaboration among a spectrum of stakeholders. Non-governmental organizations play a critical role in contributing to the policy dialogue regarding oversight and regulation of nanotechnology, especially in the incorporation of public participation with the current discourse. The following panelists provide insight into key aspects necessary for successful oversight of nanotechnology.

Rick Reibstein, Environmental Analyst and Policy and Outreach Manager at the Office of Technology Assistance in the Massachusetts Executive Office of Energy and Environmental Affairs discusses the promotion of public input in the state-level regulatory process. Next, Dr. Richard Sclove, Founder and Senior Fellow at the Loka Institute, presents findings on the substantial benefits of participatory technology assessment in the United States and abroad. Finally, J. Clarence Davies, Senior Fellow at Resources for the Future, offers suggestions for more efficient federal regulation of emerging technologies.

Nanotechnology and State Level Engagement

The Office of Technical Assistance and Technology (OTA) within the Massachusetts Executive Office of Energy and Environmental Affairs has visited nearly 2,000 facilities throughout the past twenty years to provide free and confidential guidance to implementing safe and sustainable technology. [17] OTA focuses

[17] This section summarizes Rick Reibstein. 2010. "Anticipatory Constructive Engagement at the State Level." Panel presentation at Nanotechnology & Society: Emerging Organizations, Oversight, and Public Policy Systems at the University of Massachusetts Amherst, Amherst MA. The video and slides of this presentation are available at http://www.umass.edu/sts/nano/2010program.html



on reducing risks at the source through better process and product design to promote safe and green nanotechnology in Massachusetts. Concerted assistance to complement existing enforcement is a "two-handed approach" to environmental protection, combining soft and hard law in ways that strengthen both. OTA's interaction with companies helped the Commonwealth of Massachusetts to articulate the goal of the safe development of nanotechnology, an approach that is aimed at avoiding both Type I (over regulation) and Type II (under regulation) errors.

The precautionary principle requires regulators to protect the public from potential harm even when it is not completely understood. The reasons for regulatory action can be made clear, and the value of precaution without full information about risk can be widely acknowledged and shared. For example, no one questions posting warnings about unsafe ice skating on ponds when temperatures are high, even when no cracks in the ice are visible.

Massachusetts environmental, health and safety agencies have worked together to seek input from the wide range of stakeholders who may be potentially affected by nanotechnologies (either positively or negatively). These stakeholders are identified, briefly, in Figure 1 and categorized according to seven key dimensions under OTA's purview. They have utilized transparent, public dialogue to inform policy instead of behind-the-scenes decision-making. Public discussion on nanotechnology involving business, technical, and legal experts and public advocates has highlighted the importance of articulating clear and simple concepts when addressing this complex issue. The policy discussion must be framed in a way that all stakeholders can grasp, so that it can encompass the widest set of perspectives. Avoidance or explanation of jargon is essential, and key assumptions must be reviewed so that different populations with different concerns will use terms and concepts the same way.

Fostering democratic participation provides the best chance for the successful development and acceptance of implementable strategies for safe and sustainable nanotechnologies. Some "simple, but not simplistic" concepts which can be applied to this task include: 1.) adopting a holistic, life-cycle perspective of nanotechnology; 2.) understanding the value of recognizing rights to information; 3.) employing the role of empathy in considering warnings and preventive design; and 4.) recognizing the clear difference between free, releasable nanoparticles and those that are embedded until end-of-life.

Technology Assessment in the United States

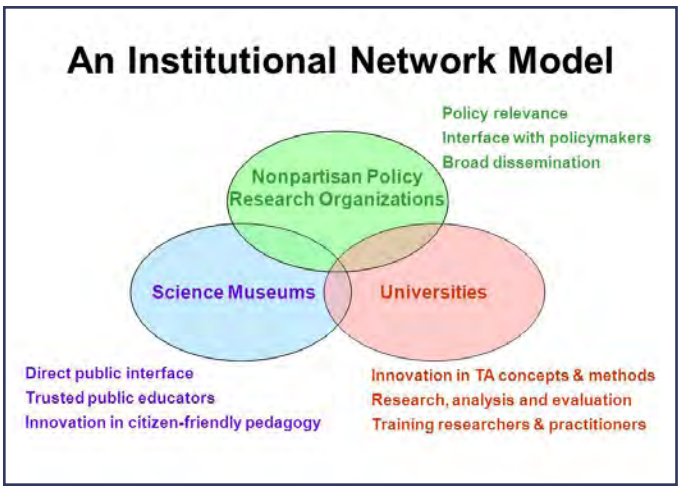
Ramifications of scientific and technological transformations are often not understood until society is already well-entrenched in utilizing the inventions or innovations. [18] At that point, it is difficult to change processes and societal implications may be severe or irreversible. Technology assessment offers a method to enhance societal understanding of emerging technologies before the innovations become institutionalized and to encourage public participation in agenda-setting and policy-making that may directly or indirectly affect their lives.

Technology assessment generally stands counter to current policy-making methodologies. Yet, the process incorporates traditional, accepted democratic values of transparency and participation. Nonetheless, the history of technology assessment in the federal government illustrates a reluctance to embrace fully participatory policy-making. In 1972, the U.S. launched the federal Office of Technology Assessment (OTA); the office was closed by Congressional action in 1995, and repeated attempts to reopen the office have failed. In 2008, Congress asked the Governmental Accountability Office (GAO) to establish permanent technology assessment capacity in the form of GAO studies and reports, the number of reports produced annually is occurring at less than ten percent of the original OTA rate.

Participatory technology assessment methods have been adapted and demonstrated at least sixteen times in the U.S., primarily in universities as research and demonstration projects (e.g., the Boston Consensus Conference on Biomonitoring[19]).

[18] This section summarizes Richard Sclove. 2010. "Reinventing Technology Assessment in the U.S." Panel presentation at Nanotechnology & Society: Emerging Organizations, Oversight, and Public Policy Systems at the University of Massachusetts Amherst, Amherst MA. The video and slides of this presentation are available at http://www.umass.edu/sts/nano/2010program.html

[19] See http://www.biomonitoring06.org/



Such methods have been pioneered in a number of western European nations. For instance, since 1987, twenty-two participatory technology assessments have been held in the form of consensus conferences[20] organized by the Danish Board of Technology (Denmark's office of technology assessment), each of which included panels of diverse lay participants that exclude experts and other members of stakeholder groups. During Danish consensus conferences, the layperson panels hear expert and stakeholder testimony before they deliberate and deliver a written report intended to inform parliamentary and public discussions. Such a process is considered successful by the Danish Board of Technology not as a substitute for collaboration, but because the consensus agreement produced by conference participants represents a broader diversity of societal views on technological innovations. Moreover, this method of public engagement allows for participation of citizens who do not have a direct stake in the issue at hand and whose voices typically may be trivialized in traditional regulatory discourse.

Participatory technology assessment provides one foundational component for a nascent U.S. institutional network (ECAST, the Expert and Citizen Assessment of Science and Technology network) that will involve universities, science museums, and nonpartisan policy research organizations in organizing both expert and participatory technology assessments. Such an institutional network model can broaden public discussion and dissemination of research and evaluation findings and build public trust. ECAST will incorporate expertise from trusted public educators, researchers, and policy-makers and ensure a broad and informed approach to research on emerging technologies. Such a framework could be adapted to nanotechnology discussions and act as a model to develop more socially- and environmentally-conscious nanotechnology oversight. Indeed, participatory technology assessment enhances the social and ethical analysis of emerging technologies by including individuals who are traditionally excluded from policy and regulatory discourses and should be further developed to be included in the nanotechnology regulatory policy dialogue.

[20] See http://www.loka.org/TrackingConsensus.html

The Future of Federal Environmental Regulation

Strong and experienced voices in the advocacy community claim that the current U.S. federal regulatory system is "badly broken" and ill-equipped to regulate nanotechnology effectively.[21] Declines in funding and staffing for the U.S. EPA and the CPSC have made it difficult to catalogue and assess nanomaterials, leaving several consumer products under-regulated, including cosmetics, vitamins, herbs, and dietary supplements. Moreover, considerable evidence reveals that federal laws are outdated and inadequate to address the EHS concerns presented by rapid development of nanotechnology.

Furthermore, nanotechnology is not unique. It is a harbinger of future environmental problems and in many ways represents the environmental health and safety challenges of the future: Nanotechnology is global. It requires international oversight and collaboration and raises questions about the transnational diffusion of ideas and products. Nanotechnology is multi-media, appearing in a variety of forms and blurring traditional boundaries. Its issues are multi-sector, thereby affecting many aspects of the economy. It is multi-disciplinary. Nanotechnology issues require collaboration of lawyers, chemists, engineers, social scientists, and others; single disciplinary approaches are irrelevant. Finally, nanotechnology is fast-moving. New science is developing at an accelerating pace, and the product turn-over rate is astounding. Adequate technological policies require scientific understanding unparalleled in regulatory climates of the past. These rapid changes and increased complexities are symbolic of the challenges experts anticipate for future technological advances.

In contrast with the rapid pace of nanotechnology development, government regulation of emerging technologies is becoming slower and falling further behind. The EPA's budget is about half of what it was in the 1970s. The CPSC has about 200 fewer staff members than in the 1980s. The FDA scientific capacity is limited, and the agency reviews less than 1% of imported foods in the U.S. and a similarly small percentage of imported active drug ingredients. Additionally, only about 3% of the NNI budget

[21] This section summarizes J. Clarence Davies. 2010. "Nanotechnology and the Future of Federal Environmental Regulation." Panel presentation at Nanotechnology & Society: Emerging Organizations, Oversight, and Public Policy Systems at the University of Massachusetts Amherst, Amherst MA. The video and slides of this presentation are available at http://www.umass.edu/sts/nano/2010program.html

is devoted to health and safety studies. Without new regulatory institutions, frameworks, and tools, capable of adapting to emerging nano and environmental technologies, the current regulatory system is at risk of becoming irrelevant.

One method to improve the regulatory capacity for nanotechnology may be the creation of a new department of environmental and consumer protection, which would incorporate more emphasis on monitoring and evaluation. It would integrate the existing EPA, OSHA, NIOSH, National Oceanic and Atmospheric Administration (NOAA), CPSC, part of the FDA, and the U.S. Geological Survey (USGS).

Focus on such federal agencies is critical because, while state, international, and private sector self- regulations are important, federal policies remain the most susceptible to general influence.

Regardless of what agency controls nanotechnology, four criteria must be considered as new regulations are developed: 1.) Is the legal authority adequate to the regulatory challenges at hand, specifically to those related to nanotechnology? 2.) Does government have the resources to implement adequate regulatory provisions? 3.) Does government have the scientific and technical information to implement laws to protect its citizens and the environment? 4.) Does the political will exist to take action to remedy these deficiencies in an increasingly technological society and economy? Many advocates and regulatory experts would argue that the existing federal system fails on all four criteria.

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The foregoing raises provocative and important questions. For example, by what methods might federal agencies better incorporate public participation in policy- and regulatory-making discussions? It is important to invest time prior to a period of public input to construct specific framework addressing what input will be solicited and how it will be consequently addressed. As seen in previous participatory technology assessment sessions, an effective method for demonstrating accountability to the public is ensuring that the agency responds to participants. Furthermore, avoidance of technical jargon and understanding of the homogeneity of the population will further encourage fruitful public participation. Should environmental advocacy organizations serve as the "conscience of society" by helping the public understand the legal system? Why is the current regulatory system inadequate to address many emerging technologies?

Conclusion

Complexities inherent in regulation of nanotechnology and other emerging technologies require cross-sector, long-term collaboration. To achieve such collaborative goals, communication pathways between policymakers, scientists, and industry professionals must be created and sustained. The models, frameworks, and processes presented in this report represent some of the best practices to date for encouraging such partnerships, but they are not representative of all successful models.

Further, even those frameworks discussed here--for example laws and policies currently in place within government and industrial firms--must be regularly reviewed in light of ever-changing and emerging technologies. As inadequacies are identified, democratic processes must shape the pathways through which informed and effective rules are designed.

Development of new rules and oversight processes for nanotechnology must strive to keep pace with rapid technological developments. However, policymakers must seek a clear balance between adequately addressing EHS concerns while still encouraging innovation and commercialization. Withstanding pressures encouraging such quick consensus or final decisions, requires clear, straightforward frameworks, and development of such frameworks requires continued investment in multi-disciplinary and cross-sector research.

Appendix I: Selected Further Reading

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Appendix II: Workshop Agendas

Nanotechnology and Society: The Organization and Policy of Innovation

May 17, 2007
University of Massachusetts Amherst

8:00 - 8:30 Registration

8:30 - 8:45 Jane Fountain, Professor of Political Science and Public Policy and Director of the Science, Technology and Society Initiative

8:45 - 9:00 Paul Kostecki, Vice Provost for Research at UMass Amherst

9:00 - 10:30 Panel I: Technology Innovation and Dispute Resolution

- "Re-thinking scientific teams: Competition, conflict and collaboration"
  Howard Gadlin, Ombudsman, National Institutes of Health, Office of the Ombudsman, Center for Cooperative Resolution
- "Nanotechnology Innovation--Two Aspects"
  Jay P. Kesan, Professor and Director, Program in Intellectual Property & Technology Law, University of Illinois College of Law
- Moderator: Ethan Katsh, Professor of Legal Studies and Director of the Center for Information Technology and Dispute Resolution, UMass Amherst

10:30 - 10:45 Break

- Podcast - Nanotechnology: Wave of the Future?
  A podcast produced by undergraduate students in the Advanced Issues in Information Technology class (Communication 497T) at UMass Amherst.

10:45 - 12:15 Panel II: Forming Public Opinion and Informing Public Policy on Emergent Technologies: the Role of the Media

- "Investment and interpretation: Nanotechnology, financial journalism and practical epistemology"
  Geoff Cooper, Senior Lecturer, University of Surrey Department of Sociology (UK)
- "Predicting the Future: How Ordinary People Make Sense of Emerging Nanotechnologies"
  Susanna Hornig Priest, Associate Professor and Director of Research, College of Mass Communications and Information Studies, University of South Carolina
- Moderator: Jarice Hanson, Professor of Communication, UMass Amherst

12:30 - 2:00 Luncheon Panel: Visual Perception of Nanoscale Phenomena

- Welcome and Introduction

  Janet Rifkin, Dean, College of Social and Behavioral Sciences, UMass Amherst
- "Perceiving Nanoscale Phenomena: Interpreting and Disseminating Nanoscale Images"
  Otávio Bueno, Professor of Philosophy, University of Miami
- Moderator: Kyle Cave, Professor of Psychology, UMass Amherst

2:00 - 4:00 Panel III: Organization and Economics of the Nanotechnology Research and Development Enterprise

- "Nanotechnology, Development and Public Policy"
  John Armstrong, Vice President, UMass Amherst Foundation, UMass Amherst; Center for Hierarchical

Manufacturing External Advisory Board member; Vice President for Science and Technology, IBM (retired); National Science Board (1996-2002)

- "The Culture of the American University in the Age of Neoliberalism"
  Daniel Lee Kleinman, Professor, University of Wisconsin, Department of Rural Sociology
- "Why Managing Research is Not Managing Science"
  David Rejeski, Director of the Project on Emerging Nanotechnologies and the Foresight and Governance Project, Woodrow Wilson International Center for Scholars
- Moderator: Jane Fountain, Professor of Political Science and Public Policy and Director, Science, Technology and Society Initiative, UMass Amherst

Nanotechnology and Society: Emerging Opportunities and Challenges Networks, Risk, and Knowledge Sharing

October 3, 2008
University of Massachusetts Amherst

8:00 – 8:30 Registration and Continental Breakfast

8:30 – 9:00 Opening Remarks and Welcome

9:00 – 10:30 Panel I: Nano, Innovation and Networks

- "Categorizing a Field – The Use of the Nanotechnology Label across Communities"
  Professor Stine Grodal, Strategy and Policy, Boston University
- "Nanotechnology Collaboration, Information Transfer, and Field Structure"
  Professor Emily Erikson, Sociology, UMass Amherst
- "Local Ecologies of Knowledge, National Systems of Innovation, and Nanotech Research in the Global South"
  Dr. Geri Augusto, Public Policy, Taubman Center For Public Policy and American Institutions, Brown University
- Moderator: Professor Donald Tomaskovic-Devey, Chair, Sociology, UMass Amherst

10:30 – 11:00 Break

11:00 – 12:30 Panel II: Nano, Innovation and Risk

- "Bounding Nanotechnology: Deconstructing the Drexler-Smalley Debate"
  Professor Sarah Kaplan, Management, Wharton School, University of Pennsylvania
- "Nanotechnology Collaboration, Information Transfer, and Field Structure"
  Dr. Erik Fisher, Center for Nanotechnology in Society and Consortium for Science, Policy, and Outcomes
- "A Mirror of Social Development: Industry decisions regarding new technologies"
  Jennifer Hill Geertsma, Sociology, UMass Amherst
- Moderator: Douglas Anderton, Associate Dean for Research, College of Social and Behavioral Sciences, Professor of Sociology, and Director of the Social and Demographic Research Institute, UMass Amherst

12:30 – 2:00 Luncheon Keynote

- Advancing the Science of Science and Innovation Policy: Current Approach and Next Steps
  Dr. Julia Lane, Program Director, Science of Science & Innovation Policy, NSF

2:00 – 3:30 Panel III: Nano, Innovation and Diffusion of Knowledge

- "Inventor Mobility and Knowledge Transmission in Nanotechnology"

Professor Gerald Marschke, Department of Economics and Department of Public Administration & Policy, SUNY Albany

- "The National Nanomanufacturing Network"
  Mark Tuominen, Professor of Physics and Co-Director of the Center for Hierarchical Manufacturing (CHM) and MassNanoTech, UMass Amherst
- "Nano Social Science: An Emerging Specialization"
  Professor Alan L. Porter, Industrial & Systems Engineering and Public Policy, Georgia Tech; co-director of the Technology Policy and Assessment Center; Director of R&D for Search Technology, Inc.
- Moderator: Mark Tuominen, Professor of Physics and Co-Director of the Center for Hierarchical Manufacturing (CHM) and MassNanoTech, UMass Amherst

3:30 – 4:00 Discussion and Closing

- Jane Fountain, Professor of Political Science and Public Policy and Director, Science, Technology and Society Initiative, UMass Amherst

Nanotechnology & Society: Emerging Organizations, Oversight, and Public Policy Systems

September 24, 2010
Lincoln Campus Center, 10th Floor
University of Massachusetts Amherst

8:00 – 8:30 Registration & Continental Breakfast

8:30 – 9:00 Welcome & Opening Remarks

- Michael Malone, Vice Chancellor for Research & Engagement, UMass Amherst
- Jane Fountain, Professor of Political Science and Public Policy; Director, Science, Technology and Society Initiative, UMass Amherst
- MV Lee Badgett, Director, Center for Public Policy and Administration and Professor, Economics, UMass Amherst

9:00 – 10:30 Panel 1: Constructing Frameworks for Policymaking

- "Policy Guidance: Collaborations for the Responsible Development of Nanoscale Materials"
  Dr. Terry L. Medley, Global Director of Corporate Regulatory Affairs, DuPont
- "What's the Problem with Nanotechnology?"
  Timothy Malloy, Professor of Law, UCLA
- "Developing Oversight for Nanobiotechnology: Human Drugs and Medical Devices"
  Jordan Paradise, Associate Professor of Law, Seton Hall University
- Moderator: Jane Fountain, Professor of Political Science and Public Policy and Director of the Science, Technology and Society Initiative, UMass Amherst

10:30 – 10:50 Break

10:50 – 12:20 Panel 2: International and Federal Policy Emergence

- "Global Engagement on Nano EHS: Role of the OECD in International Governance"
  Jeff Morris, National Program Director for Nanotechnology, US Environmental Protection Agency

- "Nanotechnology and Worker Risk: Who's At the Controls?"
  Charles L. Geraci, Jr., Coordinator, Nanotechnology Research Center, National Institute for Occupational Safety and Health (NIOSH)
- "Challenges in Assessing Nanomaterial Health Risks in Consumer Products"
  Treye Thomas, Toxicologist & Chemical Hazards Program Leader, Office of Hazard Identification and Reduction, Consumer Product Safety Commission
- Moderator: Mark Touminen, Professor of Physics and co-Director of the Center for Hierarchical Manufacturing, UMass Amherst

12:20 – 1:45 Lunch

1:45 – 2:00 The Center for Hierarchical Manufacturing, University of Massachusetts Amherst

- Mark Touminen, Professor of Physics and co-Director of the Center for Hierarchical Manufacturing, UMass Amherst

2:00 – 3:30 Panel 3: NGO Perspectives on Emerging Nanotechnology Oversight and Regulation

- "Anticipatory Constructive Engagement at the State Level"
  Rick Reibstein, Environmental Analyst and Policy and Outreach Manager, Office of Technology Assistance, MA Executive Office of Energy and Environmental Affairs
- "Reinventing Technology Assessment in the U.S."
  Richard Sclove, Founder and Senior Fellow, The Loka Institute
- "Nanotechnology and the Future of Federal Environmental Regulation"
  J. Clarence Davies, Senior Fellow, Resources for the Future
- Moderator: Michael Ash, Associate Professor of Economics and Public Policy, UMass Amherst

3:30 – 4:00 Discussion & Closing