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*Project on Emerging
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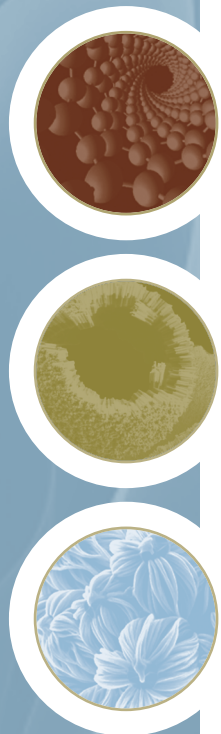
# NANOTECHNOLOGY OVERSIGHT:

## AN AGENDA FOR THE NEW ADMINISTRATION

*J. Clarence Davies*



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*by* J. Clarence Davies

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# FOREWORD

The next presidential administration will face a host of complex policy issues concerning energy, the environment, food safety, consumer products and the workplace. One issue, however, that will impact virtually all of these policy areas is nanotechnology oversight.

Nanotechnology, the science and technology of manufacturing and manipulating materials at the tiniest of scales, creates endless opportunities to address the many significant social and economic challenges facing Americans. But some new nanoscale materials may present unconventional risks to consumers, workers, and the environment. Therefore, without robust oversight mechanisms to underpin safe use, the full benefits of nanotechnology may never be realized.

Today, more than 600 manufacturer-identified consumer products are available on the market using nanotechnology. In addition, there are countless other commercial and industrial applications of which the public and policymakers are not even aware. Unfortunately, federal agencies currently have to draw on decades-old laws—many of which are woefully out of date—to ensure the safe development and use of these technologically advanced products. Federal officials need 21st century tools for cutting-edge technologies. Anything short of that is unacceptable and may leave the public unprotected from emerging risks.

Given the rate of development and commercialization of nanotechnologies, time is of the essence. In order to ensure the safe development of this rapidly advancing technology, which is projected will enable 15 percent of globally manufactured goods worth $2.6 trillion by 2014, there needs to be an increase in funding for nanotechnology risk research in the fiscal year 2009 budget to $100 million and in FY 2010 to $150 million. And through early administrative action, the next president should quickly implement new oversight mechanisms for nanotechnology. Such actions include collecting safety information on uses of nanomaterials in food production and packaging; updating federal occupational safety laws; and defining nanomaterials as "new" substances under federal laws, thereby allowing agencies such as the Environmental Protection Agency and the Food and Drug Administration to obtain more information on nanomaterials.

The author of this report, J. Clarence Davies, has invested significant thought into nanotechnology oversight issues in recent years. In this paper, he points to ways existing laws can be applied or changed, if necessary, to provide needed oversight of nanoscale materials. He also calls for an increase in resources to research the risks posed by these materials and outlines a plan for future study and oversight.

The goal of this report is to highlight the importance of creating sensible nanotechnology oversight policies and describe the actions that need to be taken by the next president. Many of the potential risks of nanoscale materials have already been identified, and for the world to realize the benefits of this technology the next administration must act swiftly and carefully. This will be a challenge, but one that could have limitless opportunities to improve the world in the 21st century. This report provides a blueprint for early action by the next White House and key regulatory agencies.

David Rejeski
Director
Project on Emerging Nanotechnologies

## ABOUT THE AUTHOR **J. CLARENCE (TERRY) DAVIES**

Dr. Davies, a senior advisor to the Project on Emerging Nanotechnologies and a senior fellow at Resources for the Future, is one of the foremost authorities on environmental research and policy. He helped pioneer the related fields of risk assessment, risk management, and risk communication, and his work has advanced our understanding of cross-media pollution, the tendency of pollutants to move across boundaries, from air to water to land, revealing shortcomings in the legal and regulatory framework.

Davies served during the first Bush Administration as Assistant Administrator for Policy, Planning and Evaluation at the U.S. Environmental Protection Agency (EPA). Earlier, he was the first examiner for environmental programs at the Bureau of the Budget (now the Office of Management and Budget). In 1970, as a consultant to the President's Advisory Council on Executive Organization, he co-authored the plan that created EPA. Dr. Davies also was Executive Vice President of The Conservation Foundation, a non-profit think tank on environmental policy; Executive Director of the National Commission on the Environment; and a senior staff member at the Council on Environmental Quality, where among other activities, he wrote the original version of what became the Toxic Substances Control Act. He has served on a number of committees of the National Research Council, chaired the Council's Committee on Decision Making for Regulating Chemicals in the Environment, chaired the EPA Administrator's Advisory Committee on Toxic Substances, and served on EPA's Science Advisory Board. In 2000, he was elected a Fellow of the American Association for the Advancement of Science (AAAS) for his contributions to the use of science and analysis in environmental policy.

Davies is the author of *The Politics of Pollution, Neighborhood Groups and Urban Renewal, Pollution Control in the United States,* and several other books and monographs addressing environmental policy issues. A political scientist by training, Davies received his B.A. in American government from Dartmouth College, and his Ph.D. in American government from Columbia University. He taught at Princeton University and Bowdoin College, and has helped mentor a generation of environmental policy researchers.

# EXECUTIVE SUMMARY

Few domestic policy areas that the new administration must address will have greater long-range consequences than nanotechnology—a new technology that has been compared with the industrial revolution in terms of its impact on society. If the right decisions are made, nanotechnology will bring vast improvements to almost every area of daily living. If the wrong decisions are made, the American economy, human health and the environment will suffer.

Nanotechnology can have a major impact on many of the most important problems facing the United States. It can reduce dependence on foreign oil, help deal with global climate change, improve the country's health system, strengthen national defense, help fight terrorism and make a major contribution to the national economy. Nanotechnology is also important as a prototype of the technological opportunities and challenges that will characterize the 21st century. The country needs to learn how to deal with potential adverse consequences of new technologies and how to make sure the technologies best serve society's needs.

The existing laws and institutions for dealing with nano and other technologies are weak and inadequate. The oversight system needs to be repaired. The regulatory agencies lack resources, some to the point of being nonfunctional. The laws have huge gaps and, more often than not, fail to protect the public. Nanotechnology highlights these inadequacies and provides an opportunity to act on them.

This report is a blueprint for what should be done about nanotechnology in the first few months of the new administration. It contains more than 35 recommendations. The following actions are necessary:

- **Maximize the use of existing laws:** Although the laws for nanotechnology oversight need to be changed, much can be done within existing authorities. Nanomaterials should be defined as "new" substances under the Toxic Substances Control Act (TSCA) and the cosmetics, food additive and food packaging provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA), thereby enabling the Environmental Protection Agency and the Food and Drug Administration to consider the novel qualities and effects of nanomaterials. The federal pesticide law should be enforced for nano anti-microbial products such as clothing and household appliances that use nanosilver. Existing regulations of the Occupational Safety and Health Administration should be used to protect workers from nanoparticles in the workplace.

- **Increase research on the risks posed by nanomaterials:** Federal spending to understand the potential risks posed by nanomaterials is inadequate. Results of the limited testing that has been done provide reason for concern: carbon nanotubes can irritate lungs in a way similar to asbestos; some nanomaterials, when tested on rats, pass from nerve endings in the nose to the brain, bypassing the blood-brain barrier; and some nanomaterials can interact with DNA. These substances could have widespread negative impacts—not only on the environment and human health but on consumer confidence as well. Risk research is essential.

- **Enact changes to existing oversight laws:** Laws such as TSCA and FFDCA, which cover adverse effects of nanomaterials,

urgently need to be strengthened. For example, under the FFDCA, two major high-exposure applications of nanotechnology, cosmetics and dietary supplements, are essentially unregulated. In fact, the current language in the law serves primarily to assure that there will *not* be adequate oversight. Other laws important for nano oversight, such as the Consumer Product Safety Act, also need radical revision.

- **Plan for the future:** Almost all the planning and debate about nanotechnology has focused on first-generation nanotechnology. The second generation of the technology is now moving from science fiction to technological fact, but society has not thought about how to deal with it or the other new technologies that are sure to follow. A commission should be named to consider oversight options for the 21st century. In addition, the government's ability to forecast technological developments needs to be greatly improved so that government and society are better prepared to manage what lies ahead.

Nanotechnology is likely to significantly change the way we live. The new administration has the opportunity to shape these changes and to ensure that the benefits of nanotechnology are maximized and the risks are identified and controlled. This is a vitally important opportunity, and this report describes how to act on it. The future of the technology is in the hands of the incoming administration. The shape of the future will depend significantly on what the new government does.

*The report's recommendations are summarized on pages viii-ix.*

# NANOTECHNOLOGY OVERSIGHT

## SHORT-TERM AGENDA

### Risk Research

* Increase nanotech environment, health and safety research (EHS) funding
* Strengthen National Nanotechnology Initiative (NNI) coordination

Require a peer-reviewed EHS research plan

Encourage separation of NNI promotional and oversight functions

Establish a Nanotechnology Effects Institute, similar to the Health Effects Institute (a joint undertaking of EPA and the automobile industry devoted to research on the health effects of the automobile)

### Regulatory Coordination

* Establish an Interagency Nanotechnology Regulatory Group
* Develop a nanotechnology plan within each major regulatory agency (e.g. EPA, FDA)

Improve intergovernmental coordination

### Resource Requirements

* Increase regulatory agency budgets and staffing

### Federal Agency Executive Actions

ENVIRONMENTAL PROTECTION AGENCY

* Define nanomaterials as "new" chemicals under the Toxic Substances Control Act (TSCA)
* Promote "green" nanotechnology

Promulgate a TSCA information collection rule

Expand regulation of anti-microbials under the federal pesticide law

Evaluate the application of other EPA statutes to nanotechnology

FOOD AND DRUG ADMINISTRATION

* Collect information on safety testing, forthcoming products and potential adverse effects

Establish criteria for determining which nanomaterials are "new" for regulatory purposes

Regulate cosmetics and dietary supplements

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION
AND NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

* Use existing OSHA regulations to deal with nanoparticles

Communicate to workers and firms about nanotechnology's potential health effects and measures for controlling exposure

Issue OSHA standards for nanomaterials

CONSUMER PRODUCT SAFETY COMMISSION

Hire new staff to study nanotechnology exposure

Create a Chronic Hazard Advisory Panel (CHAP) for nanotechnology products with significant exposure

### Voluntary Efforts

* Use the DuPont–Environmental Defense framework as a basis for analyzing nanotechnology risks

Issue a nanotechnology handbook for small businesses

### Public Involvement

* Give the public more information about nanotechnology

* Convene a stakeholder dialogue

Obtain the public's views about nanotechnology

## LONGER TERM AGENDA

### New Legislation

* Change TSCA to improve its effectiveness

* Amend the Federal Food, Drug, and Cosmetic Act (FFDCA) to adequately regulate cosmetics

* Give FDA regulatory authority over dietary supplements

Enact other changes to the FFDCA to give FDA authority to review safety tests on food and cosmetics

Amend the NNI act to require an EHS research plan and to provide strengthened coordination powers

### New Technologies, New Oversight

* Improve the government's forecasting ability

* Create a commission to study oversight of new technologies

* Create new forms of oversight

* *Indicates a priority recommendation*

# I. ACTION IS NECESSARY

Nanotechnology is changing the world. It promises to transform every aspect of our lives. The actions of the incoming administration will be critical in determining whether we can reap the huge potential benefits of nanotechnology and, at the same time, prevent its potentially serious dangers.

Nanotechnology has major economic and political implications. Globally, nanotechnology is expected to account for 11 percent of manufacturing jobs by 2014 (Lux Research 2006, vol. 1, p.19). Nanotechnology can help the government deal with many of the major problems it faces—energy, climate change, water supply and homeland security. Military applications of nanotechnology could change the balance of power among nations. A widespread adverse event from nanotechnology manufacturing or a nanomaterial could confront government agencies with a crisis and bring development of the technology to a halt.

Nanotechnology can result in clothes and windows that never need washing; ways of producing clean water, generating power and providing transportation that use half the energy that current methods do and at half the cost; computers with unimaginably large processing power and memory; and remedies for many of the world's illnesses. However, nanotechnology may also produce materials that could have the same effect on lungs as asbestos, damage human DNA or wipe out bacteria necessary for the functioning of ecosystems. Decisions made in the next few years will greatly influence which aspects of nanotechnology become a reality.

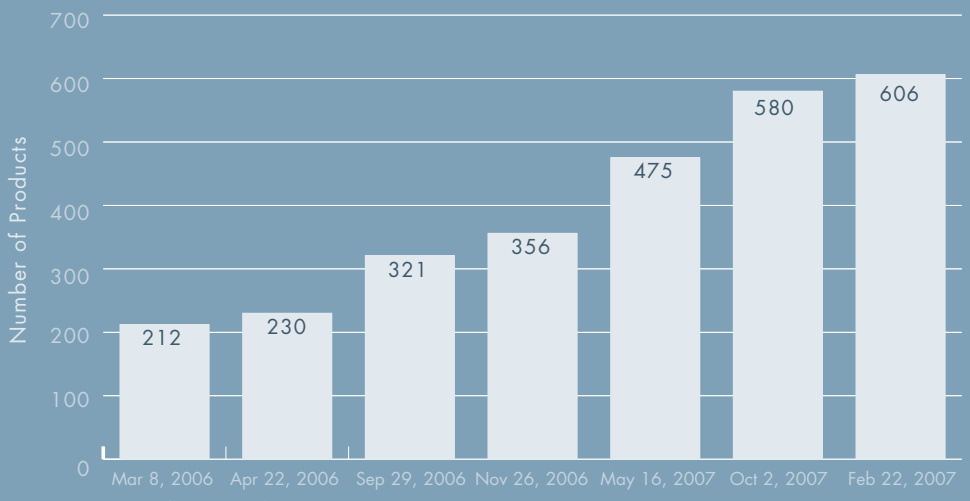
### SCOPE OF NANOTECHNOLOGY

Nanotechnology is the manipulation of matter at the scale of individual atoms and molecules. It includes processes for making materials, systems and structures, as well as the materials and structures themselves. Some types of nanomaterials exist in nature, but nanotechnology, the deliberate engineering of nanostructures and materials, largely began in the 1980s with the invention of new, more powerful types of microscopes.

Nanomaterials are usually defined as materials that have at least one dimension smaller than 100 nanometers. A nanometer is approximately 1/80,000th the width of a human hair or 1/7,000th the size of a single red blood cell. Materials at the nanoscale often exhibit physical, chemical and biological properties that are very different from those of their normal-sized counterparts.

Nanotechnology applications can be characterized as passive or active (IRGC 2007). The distinction is important because it highlights the magnitude of the technological breakthroughs still to come with nanotechnology. Passive applications are those in which the nanomaterial or structure does not change form or function. Almost all the discussions about regulating nanotechnology to date have focused on passive applications. Passive nanostructures are materials that are typically added to existing products and materials. Most of the items in the database of nanotechnology products maintained by the Project on Emerging Nanotechnologies (PEN) at the Woodrow Wilson International Center for Scholars are examples of passive nanotechnology applications. The database contained more than 600 manufacturer-identified nanotechnology consumer products as of February 2008. They included numerous cosmetics, a number of silver-based anti-microbial products (including

**FIGURE 1.** TOTAL PRODUCTS LISTED




Source: www.nanotechproject.org/consumer

food containers and no-smell socks) and other products ranging from tennis racquets to teas. The number of products in the inventory has doubled within the past 14 months (see Figure 1 ). Non-consumer nanotechnology products now on the market include electronic devices, catalysts, batteries and car bodies.

Nanostructures or nanomaterials are defined as active when they are able to change their form or function. A simple example is an anti-cancer drug in which a dendrimer (a type of nanomaterial) is designed to find cancer cells, attach itself to the cells and then release a chemical that kills them. On a more complex level, the increasing overlap between biotechnology and nanotechnology will eventually lead to nanosystems being used to assemble large systems that might include replacement limbs for humans or complex robots. The meaning of oversight in the context of active nanostructures is a challenge experts are just beginning to face. This report focuses primarily on passive nanotechnology; the question of oversight for the future is addressed in the final section.

## NEED TO ACT NOW

Nanotechnology is developing rapidly. The U.S. federal government budget for nanotechnology for fiscal year (FY) 2009 totals $1.5 billion (see Appendix B)—a 229 percent increase since 2001. Several new products are added to PEN's inventory each week, and the rate of introduction of non-consumer nanotechnology products (such as drugs, catalysts and sensors) is probably equally high. As of 2007, the Food and Drug Administration (FDA) had approved 24 nano-based drugs, and an additional 26 nanodrugs were undergoing clinical trials (Zhang, et al. 2007). China, Japan, Korea and several European nations are competing with the United States for the lead in developing the technology, and Russia recently announced a $5 billion nanotechnology research and development program (Elder 2007). Twenty years from now, most of the products we use are likely to have some nanotechnology component.

The results of tests performed to determine the adverse effects of current nanomaterials provide reason for concern: carbon nanotubes

behave in unusual, and possibly harmful, ways in animal lungs, and there are suggestions that some nanotubes could be as harmful as asbestos if inhaled; studies in rats have shown that some nanomaterials, when inhaled, pass from the nerve endings in the nose to the brain, bypassing the blood-brain barrier; and there is emerging evidence that certain nanomaterials can interfere with proteins and DNA in the human body, acting like a wrench in the works of the building blocks of life. Because of their large surface-to-mass ratio, nanoparticles are more reactive than ordinary materials. They can also be far more explosive than ordinary-sized materials—a property that the military is actively exploiting. In 2007, the Russians exploded the first bomb allegedly based on nanotechnology. It was reportedly the largest non-nuclear bomb ever tested (Elder 2007).

Nanomaterials have been used experimentally to improve the environment by cleaning up waste sites, purifying water and filtering air. Many applications of nanomaterials replace toxic substances or substitute for more energy-intensive processes (Schmidt 2007). Both the good and bad environmental effects of nanomaterials are largely unknown. On the negative side, nanomaterials will be extremely difficult or impossible to remove from the environment. Nanosilver is an example of the Jekyll-and-Hyde character of nanomaterials (see Luoma forthcoming). The antimicrobial properties of nanosilver are being used in a variety of products, but those same properties may pose a threat to the environment as well as to waste-treatment plants that clean sewage through bacterial action.

The combination of poorly understood risks and increasing commercial product flow led the World Economic Forum to declare the risks of nanotechnology as one of the two major technological risks facing the planet. (The second risk is an attack on or a system failure of the global information infrastructure.) (World Economic Forum 2008, p. 51). Similarly, the insurance firm Lloyd's has identified nanotechnology as a major "emerging risk" (Lloyd's 2007). A Lloyd's report notes that "nano-sized objects tend to be more toxic than their large scale form" (p. 3); there is a "lack of regulation;" "the 'wait and see' approach is increasingly becoming a dangerous way to determine the risks;" and "[i]n the past a vacuum of regulation has proved unhelpful to insurers" (p. 4). One reason for nervousness on the part of insurers and investors is the fear that some companies are not being transparent. Recently, the Investor Environmental Health Network, in collaboration with investment managers, who have more than $41 billion in combined assets, released a report raising concerns that companies are not apprising investors of potential nanotechnology risks. The report notes that "companies dealing with nanomaterials … are not disclosing the evidence of health risks of nanotechnology products, nor the lack of adequate product testing prior to their sales" (Lewis, et al. 2008).

The U.S. government needs to act now to protect the public and the environment from the potential adverse effects of nanotechnology. Many products are already on the market, and many more will follow. People are being exposed to nanomaterials every day. We know there are potential dangers. There is little or no effective oversight. Doing nothing is a dangerous option.

Oversight also needs to be strengthened to ensure that the benefits of nanotechnology are realized. Over the past 50 years, we have had

vivid examples of how adverse public opinion can block or slow the development and application of new technologies; examples include nuclear power, genetically modified crops and stem cell research. Nanotechnology could meet the same fate (Mandel 2005). The public's reactions to new technologies are determined by a variety of factors, many of them not in the realms of science or rationality; however, there is evidence that the perceived adequacy of oversight of the technology is an important consideration in shaping people's views (Macoubrie 2005). Recent surveys have indicated declining trust in both government and industry to manage the risks of emerging technologies (Hart 2007). Although there is little public support for a moratorium on nanotechnology research and development (which some non-government organizations have called for), there is likewise little support for industry self-regulation. One highly publicized adverse effect could threaten all the applications and social benefits of nanotechnology.

Many knowledgeable people think that it is premature to establish strong oversight of nanotechnology because we do not yet know enough about its possible adverse effects. Certainly we have much to learn. We do not know enough about what effects may occur outside the laboratory, we do not understand which characteristics of nanomaterials determine the toxicity of the material and we do not understand how most nanomaterials travel in the environment. Many companies involved with nanotechnology are aware of the potential risks but lack both the guidance and scientific know-how to address them. The lack of a clear road map is especially problematic for the small, innovative firms that make up much of the nanotechnology landscape (Lindberg and Quinn 2007).

Despite the large gaps in knowledge, enough is known to begin testing nanomaterials for safety. The International Life Sciences Institute has suggested a testing regime for nanomaterials, DuPont and Environmental Defense have produced a detailed framework for analyzing the possible effects of nanotechnology products and the Organization for Economic Cooperation and Development (OECD) is committed to testing several generic types of nanomaterials. Regulatory requirements are needed to amass enough test data to determine the technology's effects. To move the science of nanotoxicology forward, it is necessary to have toxicity data on a large number of nanomaterials and products. These data will not be generated or made known if companies are not required to do so.

Without an adequate oversight system we cannot protect the public when adverse effects are identified. A lack of action invites significant damage to people or the environment, and/or a public reaction that impedes development of the technology. The new administration needs to ensure that neither of these outcomes occurs.

## THE CURRENT SITUATION

Both the states and the federal government have concentrated on nanotechnology primarily as an instrument of economic development. The National Nanotechnology Initiative (NNI) is the federal structure for promoting the development and use of nanotechnology. Military applications of nanotechnology come under the NNI umbrella.

Four federal regulatory bodies—the FDA, the Environmental Protection Agency (EPA), the Consumer Product Safety Commission (CPSC) and the Occupational Safety and

Health Administration (OSHA)—have some authority, in theory, to regulate nanotechnology materials and products. However, there is a wide gap between having legal authority and actually being able to exercise oversight over nano. Exercising oversight requires that the legal authority is adequate to collect the relevant information and to take the steps necessary to prevent adverse effects, that technical and scientific information are sufficient to implement the legal authorities, that human and financial resources are sufficient and that there is the political will to take action. These requirements have, in most cases, not been met, although the adequacy of legal authority varies widely among programs.

EPA has reviewed some nanomaterials under the Toxic Substances Control Act (TSCA). It is also reviewing a nanoscale fuel additive under the requirements of the Clean Air Act and plans to use the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to review the Samsung Silver Wash washing machine, which releases ions—sub-nano-size particles of silver—as an anti-microbial. EPA's Region IX office has levied a fine of $208,000 on the manufacturer of a computer keyboard and mouse that use nanoscale antimicrobials for failing to register under FIFRA (U.S. EPA Region IX Docket #FIFRA-09-2008-0003). FDA has approved both medical devices and drugs that utilize nanomaterials. CPSC and OSHA have not taken any action on nanotechnology. The National Institute of Occupational Safety and Health (NIOSH) has sent teams to nanotechnology workplaces to document the protective measures being taken. It has also cooperated with several manufacturers to test nanotechnology monitoring and control methods.

This activity affects only a very small portion of the nanotechnology applications being used and to which people are exposed. There is no official government-wide effort to deal with the regulation of nanotechnology. The NNI has established a working group on the environmental and health implications of nanotechnology, but the group focuses on research, not oversight. An informal group, the Nanotechnology Policy Coordination Group, is led jointly by the Council on Environmental Quality and the Office of Science and Technology Policy, both part of the Executive Office of the President. Because the group's meetings and activities are not public, there is no way to know how active it is.

Part II of this paper describes actions relating to nanotechnology regulation and oversight that the government should take in the first months of the new administration. The focus is the health and safety aspects of nanotechnology because this is the most important need. The first sections contain recommendations on three subjects—research, coordination and resources—that cut across a number of agencies. Recommendations are then provided for each of the regulatory agencies. Finally, the second part of the paper covers voluntary efforts and public involvement. Part III of the paper deals with longer-term actions. In each section, the major recommendations are underlined. An asterisk indicates a priority recommendation.

# II. WHAT NEEDS TO BE DONE

Actions required to promote nanotechnology and to prevent its potential adverse effects involve numerous agencies and various kinds of efforts. Because of the gaps in our knowledge and the rapid pace at which the technology is evolving, any steps taken now will likely have to be modified in the future. However, that does not mean we should not act. It means simply that any actions we take should be flexible enough to incorporate new knowledge.

### RESEARCH

The NNI is the coordinating body for federal nanotechnology research. NNI does not have a budget of its own: the $1.5 billion that comes under its aegis for FY 2009 is the sum of the nanotechnology budgets of a dozen agencies (see Appendix B). The agency with the largest portion of that $1.5 billion is the Department of Defense (DOD) ($306 million), followed by the National Science Foundation ($247 million). In FY 2009, $76 million, about 5 percent of NNI funds, is categorized by NNI as research on the health and environmental effects of nano. An assessment of previous NNI research budgets suggests, however, that perhaps only a third of this 5 percent will support research primarily aimed at addressing the risks of nanotechnology (Maynard 2008). Most of the remaining 95 percent of NNI funds are being used to foster nanotechnology applications and to advance the science of nanotechnology.

The recommendations to improve nanotechnology research are as follows:

***1. Increase environmental, health and safety (EHS) research funding.** The most important step that can be taken in nanotechnology research is to significantly increase the dollars going to EHS research. EHS research is the greatest need, and it is the area that has been most neglected. Although still inadequate, the proposed FY 2009 level for nano EHS funding is an encouraging increase over the FY 2008 level. Also in the 2009 budget, NNI for the first time identifies EHS research in a separate category, a step that should reduce some of the controversy about what the government is actually spending.

Neither the recent NNI EHS research strategy (www.nano.gov; issued 2/14/08) nor the EPA Nanomaterial Research Strategy (draft, EPA ORD, 1/24/08) contains detailed budget estimates, which makes it hard to estimate what the federal government should be spending on nano-related EHS research. An early version of the House Committee on Science and Technology bill reauthorizing and amending the 21st Century Nanotechnology Research and Development Act required that EHS funding be at least 10 percent of total NNI funding. The 10 percent figure drew support from industry and environmental leaders but was opposed by the Bush White House. There is a question of the availability of competent researchers, but additional funds will attract researchers and encourage them to apply their expertise to nanotechnology. A reasonable target is to increase FY 2009 funding to $100 million and FY 2010 funding to $150 million.

**2. Require a peer-reviewed EHS research plan.** The effectiveness of EHS research is a function not only of the quantity of dollars spent but also of the quality and relevance of the research undertaken. As Andrew Maynard of PEN (2006, p.5) has said, "The federal government needs to assume top-down,

* *Priority*

authoritative oversight of strategic risk-based research." The 21st Century Nanotechnology Research and Development Act of 2003 requires that NNI issue a general strategic research plan and update that plan every three years. The act should be amended to similarly require an EHS strategic plan and to require that the plan be developed with stakeholder input, be peer reviewed and be subject to public comment before being made final. The EHS strategic plan must have clear goals and a workable road map for how to achieve those goals. The House bill referenced above would require NNI to issue an EHS plan. An EHS research plan issued voluntarily by NNI in 2007 was widely condemned as inadequate by both congressional lawmakers and scientists. A revised plan, issued in February 2008, was somewhat improved but still lacked details about how the goals would be accomplished.

***3. Strengthen National Nanotechnology Initiative (NNI) coordination.** For the research plan to be effective, NNI needs to have greater ability to direct and coordinate agency expenditures. At present, it relies on cajoling the agencies and on whatever influence it can exert over the Office of Management and Budget (OMB). OMB acts as the president's agent in putting together the federal budget, and thus is the only real source of power with regard to budgeting. The president should direct OMB to ensure that individual agency nanotechnology EHS budget requests are consistent with the NNI EHS plan. During the annual budget review, NNI should be authorized to make recommendations to OMB for switching funds among agencies and programs. Consideration should be given to providing a lump sum of money that NNI could use to jump-start high-priority research projects. Another option would be to require that one associate director in the White House Office of Science and Technology Policy (OSTP) be responsible for NNI coordination. OSTP's associate directors are among the few positions in the Executive Office of the President that require Senate confirmation and are therefore subjected to congressional oversight.

**4. Encourage separation of NNI promotional and oversight functions.** More than 90 percent of NNI funds are spent on development and promotion of nanotechnology, and encouraging the growth of the technology has been the focus of NNI's efforts. Some environmental groups have claimed that this promotional function interferes with the function of assuring adequate research on and oversight of potential adverse effects of nanotechnology. Responding to this criticism, the NNI, in its 2007 Strategic Plan, established EHS as a separate program component (National Science and Technology Council 2007). The establishment of a separate interagency regulatory coordinating group (see page 9) and a separate EHS research plan (see page 7) should prevent the NNI's promotional function from interfering with an aggressive program to identify any EHS problems with nanotechnology.

**5. Establish a Nanotechnology Effects Institute.** The federal government and the nanotechnology industry have a joint stake in improving scientific knowledge about the effects of nanotechnology. This shared interest could be embodied in the creation of a scientific research institute devoted to understanding the effects of nanotechnology. The institute would be modeled on the Health

Effects Institute, a joint undertaking of EPA and the automobile industry devoted to research on the health effects of the automobile. EPA and/or the National Institute of Environmental Health Sciences (part of the National Institutes of Health) should initiate discussions with major firms involved in nanotechnology to explore creation of such an institute.

### REGULATORY COORDINATION

Many federal agencies are involved in nanotechnology policy, and many federal laws either are being applied or could be applied to nanotechnology. The multiplicity of authorities can lead to overlaps, gaps and unnecessary duplication. However, if properly coordinated, the work of the agencies can be mutually reinforcing and can save taxpayers' money. This report makes three proposals for improving coordination.

***1. Establish an Interagency Nanotechnology Regulatory Group.** The president should establish by executive order an interagency nanotechnology regulatory group (INREG). The group should be charged with (1) formulating an interagency plan for applying existing regulatory authorities to nanotechnology, (2) identifying needs for new authority, (3) exchanging information about regulatory activities and (4) coordinating with the NNI on research needs of the regulatory agencies. Unlike NNI, both the mandate and the membership of INREG would reflect a focus on regulation, whereas NNI is focused on research. The group should be composed of senior-level regulators from EPA, CPSC and the Departments of Health and Human Services, of Labor and of Agriculture. Chairmanship of INREG should rotate among the agencies. Oversight of biotechnology has been handled primarily through coordination among the regulatory agencies. Some have argued that nanotechnology should be dealt with in the same way (see Davies 2006, p.16).

***2. Develop a nanotechnology plan within each agency.** Most of the major regulatory agencies have multiple components that are or should be concerned with nanotechnology. If actions are to be coordinated among the agencies, they must first be coordinated within the agencies. This can best be done if each agency formulates a nanotechnology action plan. The plans would delineate how the different parts of the agency will work together when dealing with nanotechnology and would provide a basis for researchers to give regulators the scientific information they need. EPA and FDA have already taken initial steps to formulate agency nanotechnology plans, although both plans, especially EPA's, did not demonstrate a sufficiently strong link between research and regulatory functions.

**3. Improve intergovernmental coordination.** Many states have programs to promote nanotechnology as part of their economic development. Some of these programs are large; for example, the College of Nanoscale Science & Engineering at the University at Albany - State University of New York has 2,300 employees (Bandhold 2008). Many state programs are partially based on federal funding. Also, several states and localities are considering regulation of nanotechnology. The city of Berkeley in California passed an ordinance in 2006 requiring reporting by nanofacilities. Better coordination among the federal agencies involved in nanotechnology and state and local nano efforts could benefit all parties. The federal government should

make sure that state and local oversight efforts are properly evaluated and that the lessons learned are used to inform federal action. NNI should designate a person to track state development efforts, and INREG should assign someone to monitor and interact with state and local regulatory efforts. These functions could expand if they proved useful.

### RESOURCE REQUIREMENTS

In recent years, most of the EHS regulatory agencies have been deprived of the resources needed to perform their basic functions. Therefore, when considering initiatives needed to deal with a new challenge such as nanotechnology, it is necessary to understand the already serious constraints on agency resources and to take steps to enable the agencies to take on new responsibilities. It is necessary to:

***1. Increase regulatory agency budgets and staffing.** A major increase in the budgets and staffing of the regulatory agencies is essential if they are to address the problems of nanotechnology.

FY 2007 budgets (the latest year for which there are final budget numbers) for the regulatory agencies are as follows: EPA—$7.7 billion; FDA—$1.8 billion; OSHA—$487 million; and CPSC—$63 million. In the abstract, this is a lot of money. However, it is minimal in the context of the federal budget or when weighed alongside the agencies' responsibilities. Table 1 puts the agency budgets in two other perspectives. It shows how the agency budgets have fared over time, and it controls for inflation. When controlled for inflation, since 1980 OSHA's budget has remained about the same, FDA's has doubled and EPA and CPSC budgets have been reduced by nearly half .

There are major disparities among the agencies. The EPA budget is 100 times as large as the CPSC budget. The disparities are due not only to the varying missions of each agency but also to the vagaries of history and politics.

**TABLE 1.** REGULATORY AGENCY BUDGETS IN CONSTANT DOLLARS[a]
(budget authority in millions of 1982 dollars)

| | 1980 | 1990 | 2000 | 2007 | 2009[b] |
|---|---|---|---|---|---|
| EPA | 6001 | 4310 | 4486 | 3817 | 3385 |
| OSHA | 239 | 210 | 226 | 241 | 238 |
| FDA | 418 | 471 | 622 | 875 | 845 |
| CPSC | 57 | 28 | 31 | 31 | 38 |

a. Actual budget authority, adjusted by Consumer Price Index (CPI-U) for January of the relevant year.
b. 2009 from the president's proposed budget (proposed, not actual), adjusted for January. 2008 CPI-U.

Source: Office of Management and Budget

EPA is by far the largest of the four agencies. Its budget is larger than that of FDA, OSHA and CPSC combined. EPA also has the broadest mandate of any of the four agencies, but even more relevant is that EPA, unlike the other regulatory agencies, has major functions in addition to its regulatory activities. EPA has a large science component that does both applied and basic research. It provides funding and technical assistance for construction of waste-treatment facilities and for the operation of state pollution control agencies. It has 10 regional offices. Although EPA's responsibilities have expanded, its budget, as illustrated in Table 1, has shrunk. In constant dollars, EPA's budget is significantly less than it was in the early 1970s, before it was given such major responsibilities as TSCA, the Superfund program and implementation of the 1990 Clean Air Act amendments.

FDA's budget, unlike the budgets of the other three agencies, has increased in recent decades. However, most of that increase is attributable to user fees, which are dedicated to pre-market reviews of drugs and other products. As Michael Taylor, a former FDA official and now a professor at George Washington University, has observed, "FDA lacks the resources it needs to build its own nanotechnology expertise, to develop the safety testing protocols and detection methods needed to evaluate new nanotechnology products, to conduct its own risk research, to gather the necessary pre-market data required to get ahead of commercialization and to oversee products after they have entered the market" (Taylor 2006, p. 7). Taylor notes that for FDA to be able to do what it was doing in 1996 and to continue the new activities mandated for it since then, the agency's 2007 budget would have to be more than 50 percent greater than it is (ibid.).

OSHA's problems are largely due to politics. Protecting workplace safety is essential, but OSHA has been largely beholden to one constituency—labor unions—a constituency tied to one of the country's two major political parties, the Democrats. In recent decades, neither the unions nor the Democrats have fared particularly well, and neither has OSHA. If OSHA is to take on the task of protecting workers from excess exposure to nanomaterials, it will need more resources, regardless of which party wins in 2008.

CPSC does not have the money, expertise or regulatory tools to deal with nanotechnology. At present, its main function is to serve as an excuse for not regulating consumer products. Legislation now moving through Congress would help CPSC and may include funding earmarked to deal with nanotechnology. But the legislation is only a band-aid on a gaping wound. The new administration and Congress will have to decide whether they are serious about the safety of consumer products. If they are, they must enact legislation that gives the agency greater authority to prevent the marketing of dangerous products rather than to recall them after they are in people's homes. The commission form of agency rule is a prescription for cumbersome decision making and muddled responsibility. CPSC will also require greatly increased resources.

It is beyond the scope of this paper to suggest what the budgets of the regulatory agencies should be. It is important to point out, however, that the actual dollars consumed by the agencies are a very small part of the federal budget. The combined total FY 2009 proposed budgets for the four agencies are about 10 percent of the budget of the Department of Agriculture. The total of the budgets of all four agencies equals 3 percent of the cost *over-*

*run* of DOD weapons procurement (see GAO 2008). Nanotechnology is a very small portion of the EPA and FDA budgets, and OSHA and CPSC are currently spending almost no money on nano.

There are many needs beyond resources. There are specific actions that should be taken by each of the regulatory agencies. These are described below, starting with EPA.

### ENVIRONMENTAL PROTECTION AGENCY

EPA is central to nanotechnology oversight in part because it administers TSCA, the only law that, at least potentially, could provide oversight for nanotechnology in general .

TSCA is intended to oversee all chemical substances, and nanomaterials are chemical substances. However, the act has a number of serious defects and badly needs to be amended (see Section III). It has been characterized as "toothless" and "gutless," but it still has some functioning parts that can be usefully applied to nano.

***1. Define nanomaterials as "new" chemical substances under TSCA.** One of the notable weaknesses of TSCA is that most of its authority to regulate existing chemical substances (as contrasted with new chemical substances) has been rendered inoperative by court decisions and by the language of the act. If nanomaterials are not defined as new chemical substances, they are not, in practical terms, subject to most of the TSCA regulatory authorities.

In 2007, EPA issued a policy paper announcing that the agency would not take size into account when deciding what substances were new chemicals. Since size is the factor that defines a nanomaterial, and it is size that makes nanomaterials behave differently, and perhaps more dangerously, than normal-size substances, the EPA announcement amounted to saying that there would not be a TSCA nanotechnology program. Two points should be noted, however. First, the agency's interpretation of how TSCA defines a new chemical may be legally correct: the act's definition talks only about molecular structure and not about any other defining characteristics. Second, because the molecular structure of some nanomaterials is unique, some of them will be included in the new chemicals category. However, the majority of nanomaterials will not be included because they have the same chemical composition and structure as some larger material (e.g., silver, titanium dioxide, carbon).

Nanomaterials must be defined as new chemical substances if TSCA is to serve as the vehicle for dealing with their potential adverse effects. There are two ways in which this could be done. First, the new administration could submit to Congress legislation amending TSCA's definition of "chemical substance." There would probably be some industry opposition to this, but how much is not clear. If, for political or other reasons, legislation seems undesirable, an alternative would be for the administration to promulgate a "significant new use rule" (SNUR) under TSCA. The act gives broad authority to cover categories of chemicals under such a rule and, once covered, the chemicals are essentially considered to be new chemicals. The disadvantage of such a rule is that it would almost certainly be tested in the courts, which might cause a lengthy delay in implementing the rule.

Neither the legislative amendment nor the SNUR option is a perfect solution, but the central importance of TSCA for nanotechnol-

ogy oversight makes it urgent to take one action or the other. Failure to do so would mean that there was no existing law that could be used as a general oversight mechanism for nanotechnology.

**2. Promulgate a TSCA information collection rule.** In January 2008, EPA initiated a voluntary program to collect from nanotechnology manufacturers information about the kinds of materials they are producing, what types of practices they are using to prevent adverse effects, and what is known about the effects of the materials. EPA stated that it needs such information to decide what kind of regulatory program, if any, it should institute to deal with nanomaterials.

The goals of the EPA voluntary program are laudable, but it is not clear how many firms will participate, how representative of the industry they will be or how much information participants will choose to submit. EPA would be much more likely to get the needed information by promulgating a section 8 rule under TSCA. TSCA section 8(a) allows EPA to require manufacturers to report on the uses, risks, amount manufactured, by-products and other information about a chemical or category of chemicals.

Despite its drawbacks, the voluntary program should be retained for at least two reasons. First, it will encourage more open informal discussions between EPA and manufacturers than if the manufacturers were only responding to a rule. Second, TSCA section 8(a) excludes small manufacturers. Thus, the voluntary program could serve as a vehicle to get information from small nanotechnology firms.

EPA is responsible for implementing other laws that are either already being used to regulate specific uses of nanomaterials or will have to deal with specific aspects of nanotechnology in the near future. Recommendations regarding these are discussed below.

**3. Expand regulation of anti-microbials under the federal pesticide law.** FIFRA regulates anti-microbials, among other things. Last year, EPA reversed a previous decision and announced that it would require the Samsung Silver Wash washing machine to register under the act. The machine releases ions—sub-nano-size particles of silver—into each wash load in order to kill bacteria and other microbes. However, the EPA decision was phrased in the narrowest possible terms, thereby excluding the many other nano-utilizing anti-microbial products now on the market. These products may involve significant human exposure and should be reviewed in the same way as other anti-microbials are. Such an action would require only implementation of the existing law; no new legislation would be needed.

***4. Promote "green" nanotechnology.** Nanotechnology can improve the environment in many ways. It can save energy by making materials lighter or processes less energy intensive; it can improve the effectiveness and efficiency of environmentally useful products such as solar panels and car batteries; it can substitute safer materials for more toxic chemicals; and it can be used for environmental remediation and pollution control. PEN has outlined a variety of measures to promote green nanotechnology (Schmidt 2007), including launching a "Green Nano Awards" program, using federal facilities as test beds and employing federal procurement to increase demand for green nano products. EPA should take the lead in many of these areas. The NNI should exam-

ine whether it can give greater priority to the development of green nanotechnology and should publicize what it has done to foster such development.

**5. Evaluate the application of other EPA statutes to nanotechnology.** Many EPA laws in addition to TSCA and FIFRA potentially apply to nanotechnology. The disposal of nanomaterials and products containing them comes under the purview of the Resource Conservation and Recovery Act (RCRA) and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) (see Breggin and Pendergrass, 2007). The Clean Air and Clean Water Acts will have to be employed to avoid adverse environmental effects from nanotechnology, although at the present time the lack of information about effects and the lack of detection and control technologies make it difficult to use these acts to deal with nanotechnology. EPA should analyze the short-term possible uses of the air and water permitting processes to foster disclosure and to encourage use of good management practices for nanomaterials.

EPA will need to make many internal changes to address the environmental problems of the 21st century (see Davies 2007). It will need to better integrate its existing programs and to develop a forecasting capability so that it can prepare for problems and develop strategies for dealing with them. Section III contains a further discussion of this subject.

### FOOD AND DRUG ADMINISTRATION

The FDA has broad regulatory authority over a range of products, including drugs, food, medical devices, dietary supplements and cosmetics. Nanomaterials are now in products in all these categories, and the application of nanotechnology to these areas is likely to grow rapidly in the coming years. There are at least three major steps that FDA should take to deal with the increasing use of nanotechnology in the products it regulates. Each will require additional resources. The three recommendations are as follows:

**1. Establish criteria for determining which nanomaterials are "new" for regulatory purposes.** Similar to TSCA, many important FDA regulatory authorities are triggered by a substance being categorized as "new." FDA needs to establish criteria and provide guidance to the industry about when nanomaterials are not the same as materials that are already listed in FDA's GRAS (generally recognized as safe) food additive and food packaging regulations or that have been reviewed under the Cosmetic Ingredient Review (Taylor 2006, p. 8). The agency criteria clarifying what is "new" for legal and regulatory purposes "presumably would include functional properties that relate to the likelihood that the safety profile of the nanotechnology version would be different from the conventional one. Such criteria would be helpful for all categories of FDA-regulated products as a guide to decisions about the need for toxicity testing beyond what already exists on the conventional form" (ibid.).

***2. Collect information on safety testing, forthcoming products and adverse events. At present, there are major gaps in FDA's authority to require that regulated industries provide the information it needs to assess safety risks.**

**These deficiencies need to be remedied.**

FDA may be able to obtain some of the information it needs on a voluntary basis. For example, an existing FDA regulation requires cosmetic companies to compile safety substantiation data on their ingredients, but it does not give FDA access to those data. FDA should ask the companies to voluntarily submit their safety data on all cosmetic products making nanotechnology claims or containing nanomaterials (Taylor 2006, p. 9). Similarly, FDA should work with the food industry to obtain safety data on food uses of nanotechnology.

FDA should not, however, have to rely on voluntary industry compliance in order to obtain data on the safety of the products that it regulates. The agency needs legal authority to require disclosure of specified information, including safety information, on emerging technologies and products that are under its jurisdiction. It should be given rule-making authority to establish interim pre-market notification mechanisms to address emerging and novel technologies. Its inspection authority should be expanded to include access to all safety information (Taylor 2006, p. 10).

FDA and the other regulatory agencies also need to have legal authority to obtain health and safety data regarding a product after it has been marketed. Even the most thorough pre-market testing and review can miss important adverse effects, as demonstrated by recalls of drugs and medical devices, which undergo rigorous pre-market review. FDA should have authority to require post-market monitoring and surveillance of products under its jurisdiction. It also should have broad authority and adequate resources to devise mandatory adverse event reporting systems that are appropriate for each product category and are the least burdensome approach necessary to achieve the oversight purpose (Taylor p.10).

**3. Regulate cosmetics and dietary supplements.** Cosmetics and dietary supplements are important applications of nanotechnology that are of specific concern to FDA because they involve high exposure to people and are largely unregulated for safety. Section III discusses legislation to deal with these products.

### OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION AND NATIONAL INSTITUTE OF OCCUPATIONAL SAFETY AND HEALTH

In theory, NIOSH is supposed to provide the scientific and technical information that OSHA uses for its regulations. In practice, OSHA has often ignored NIOSH. However, NIOSH, conceptually a scientific organization, has become a quasi-regulatory body because its guidelines and recommendations are frequently used in litigation and have thereby acquired much the same force as regulations. The NIOSH-OSHA relationship is important in part because NIOSH has devoted considerable attention to nanotechnology, whereas OSHA has largely ignored the subject.

**1. Communicate to workers and firms about nanotechnology.** OSHA should use its Web site, publications and other materials to communicate information about nanotechnology's potential health effects and measures for controlling exposure. The OSHA Web site should link to NIOSH's information about nanotechnology. OSHA should include nanotechnology as one of the

subjects to be covered in its training grants to unions, universities and employers. In many workplaces, Material Safety Data Sheets (MSDSs), an important form of communication with workers, do not distinguish between the macro form of the material and the nanotechnology form (e.g., the MSDS for silver is used when a worker is actually exposed to nanosilver). This practice is misleading and deceptive and should be discontinued. MSDSs in nanotechnology workplaces should be required to be specific to nanomaterials.

***2. Use existing OSHA regulations to deal with nanoparticles.** The hazard communication standard can be used to require MSDSs for nanomaterials. The laboratory safety standard should be extended to include nanomaterials. The respirator standard may be applicable under certain circumstances. When practical equipment becomes available, OSHA should require monitoring of nanoparticle levels in the workplace.

**3. Issue OSHA standards for nanomaterials.** The standards should include exposure limits for nanoparticles and good practices for preventing worker exposure. Enough information is available from NIOSH, international organizations and European practice to make the standards feasible and defensible. In fact, NIOSH has already issued draft exposure limits for titanium dioxide nanoparticles and is working on additional standards (see www.cdc.gov/niosh/review/public). OSHA also could require medical surveillance of workers who are exposed to nanoparticles, but the lack of knowledge about what adverse effects to look for probably makes this suggestion premature.

## CONSUMER PRODUCT SAFETY COMMISSION

About half of the products in PEN's inventory of nanotechnology consumer products fall under the jurisdiction of CPSC (Felcher, forthcoming, from which much of this section is drawn). However, CPSC has been rendered almost incapable of doing anything, and certainly incapable of coping with a complex technology that is used in a broad range of products and whose effects are largely unknown. The Consumer Product Safety Act, passed in 1972, has been crippled with amendments that, among other things, prohibit the agency from imposing mandatory safety standards if the industry agrees to write its own voluntary standards and from saying anything to the public about a product without the approval of the manufacturer. The agency has no authority to require pre-market testing and must therefore rely on post-market recalls. The commission's ability to police the market and enforce its regulations has been severely compromised over the past few decades. The number of products sold in the United States, many of them manufactured overseas, has proliferated, while CPSC's resources have dwindled. CPSC's budget was cut in half between 1977 and 1983 and has stayed at roughly the 1983 level. The staff, which was 900 in FY 1981, had been reduced to 393 by FY 2007.

Legislation pending in Congress would reverse some of the erosion in the agency's authority, and it is likely that the agency will receive significantly more money in the FY 2009 budget. The Senate version of the CPSC Reform Act of 2008 (S. 2663) authorizes $1 million for research on the safety of nanotechnology in products. Using its new resources, CPSC should take at least two steps.

**1. Hire new staff to study nanotechnology exposure.** CPSC has focused primarily on acute hazards, in part because it lacks the scientific expertise to deal with chronic hazards. With respect to nanotechnology products of concern, such as infant pacifiers and teething rings, CPSC should analyze whether there is likely to be exposure to nanomaterials from such products and, if so, what short- and long-term health effects are associated with the exposure.

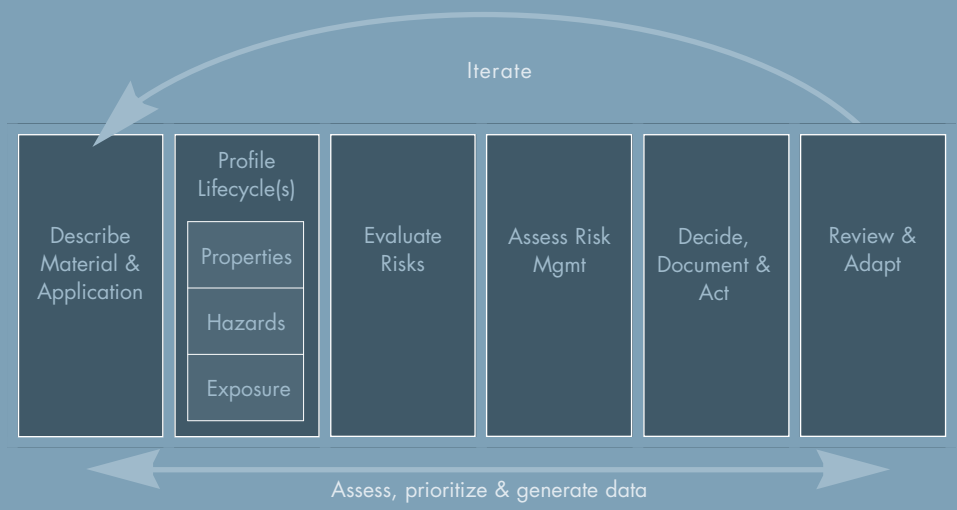
**2. Create a Chronic Hazard Advisory Panel (CHAP) for nanotechnology products with significant exposure.** The Consumer Product Safety Act prohibits CPSC from promulgating a safety rule related to a chronic hazard without first establishing a CHAP. A CHAP consists of seven experts drawn from a list of nominees compiled by the National Academies. The CHAP advises CPSC about the risk of the products in question. If CPSC finds that there is significant exposure to nanomaterials from certain products, it should convene a CHAP to give an opinion about the risk from these products. If the CHAP advises that the risk is unreasonable, CPSC can either take action itself or request that EPA take action under TSCA.

### VOLUNTARY EFFORTS

The success of nanotechnology and the prevention of its adverse effects ultimately rest with the private sector. No amount of government policing will work without cooperation from nanotechnology firms. However, it would be a mistake to rely totally on the free market. Past history and current evidence show that there are always some irresponsible firms, and that even the most responsible firms benefit from government regulation. Voluntary efforts are a supplement to, not a substitute for, government oversight.

***1. Use the DuPont–Environmental Defense framework as a basis for analyzing nanotechnology risks.** A solid basis for voluntary cooperation by the private sector has been established by DuPont and Environmental Defense. The two organizations, in consultation with many others, for-

**FIGURE 2.** ENVIRONMENTAL DEFENSE - DUPONT NANO RISK FRAMEWORK




Source: www.nanoriskframework.com

mulated a detailed framework for examining the health and environmental effects of a nanoproduct. The framework (see Figure 2) was tested on several products made or used by DuPont, and DuPont has made its use mandatory in the development of new nanoscale materials within the company.

The framework should be embraced by the NanoBusiness Alliance and be incorporated into the Responsible Care program of the American Chemistry Council. The Department of Commerce could meet with these organizations and encourage them to use the framework.

In addition, the insurance industry should consider making adoption of the framework a condition for insuring nanomanufacturers. The insurance industry has, for the past several years, shown leadership in expressing concern about the potential adverse effects of nanotechnology. Important reports about nano have been issued by Swiss Re (2004) and by Lloyd's (2007). The new administration should meet with insurers and perhaps with state insurance regulators to explore how the insurers can best deal with nano and how the federal government could support their efforts.

**2. Issue a nanotechnology handbook for small businesses.** Many of the companies involved with nanotechnology are small start-up companies, often springing from university research efforts. These companies need help in thinking about testing requirements, legal constraints and life-cycle analysis of nanotechnology products. There also may be opportunities for encouraging small companies to invest in green nano. The Small Business Administration, working with EPA and trade associations, should produce and disseminate a handbook dealing with these matters. The handbook should be aimed at small nanotechnology firms and should be available on the Internet.

### PUBLIC INVOLVEMENT

The basic problem with public involvement is the scarcity of people who want to listen. Most officials do not really want to listen to the public, most members of the public are not really interested in listening to officials or experts, and representatives of interest groups are much more interested in being heard than in listening. One of the great virtues of democratic elections is that they give politicians an incentive to listen to the public. The listening problem will not be fixed in 100 days, and probably not in 100 years, but there are steps that can and should be taken to involve the public in nanotechnology policy.

***1. Give the public more information about nanotechnology.** More than three-quarters of the American public know almost nothing about nanotechnology. There is no guarantee that knowing more about the technology will make the public more supportive of it (Kahan, et al. 2008), but knowing more could make their views more reasoned and less subject to bias and misinformation. The National Science Foundation (NSF) has invested in museum programs and other methods of informing the public about nanotechnology, and it should increase its efforts, using television, the Internet and other appropriate media. NSF should also consider working with organizations such as America Speaks, which have experience in engaging the public on important policy issues.

Two more specific ways of informing the public are labeling and use of the Toxics Release Inventory (TRI). Some consumer

groups have urged the government to require that products containing nanomaterials be labeled to show that they contain nanomaterials. If such labeling were required, consumers would be able to know which products contain nanomaterials. Buyers who wanted to avoid exposure to nanomaterials would be better able to do so, and if adverse effects were produced by a nanomaterial there would be a better chance of detecting it. On the other hand, determining what should be labeled, enforcing the labeling requirement and responding to questions arising from the labels would be costly for manufacturers and the government. Manufacturers worry that labeling would discourage buyers from purchasing their products. The new administration should convene an interagency group to investigate the feasibility and desirability of labeling nanotechnology products. The group should report its findings within one year.

The TRI was established in 1986 as part of the Emergency Planning and Community-Right-to-Know Act. It requires that owners and operators of certain facilities annually report the amounts of certain listed toxic chemicals they release to the environment. Approximately 650 chemicals are on the TRI reporting list. EPA makes these reports public. A recent PEN report (Breggin and Porter 2008) examined the applicability of TRI to nanomaterials and concluded that TRI would be applicable to nanomaterials, while also observing that "it is quite possible … that other mechanisms would be preferable to TRI as a vehicle for disclosure about nanomaterials" (ibid. p. 3).

The usefulness and feasibility of applying TRI to nanomaterials should be tested by applying such a provision to all or selected federal facilities. A number of federal facilities that use nanomaterials are covered by TRI (see ibid. p. 6). The idea of using federal facilities, especially DOD facilities, as a way of testing nanotechnology policies may have wide applicability. Methods for monitoring, control and disposal of nanomaterials could be tried at federal facilities, and the results could be used to formulate policies applicable to the private sector.

**2. Obtain the public's views about nanotechnology.** Many of the policies for dealing with new technologies entail questions of ethics and values. The experts on these subjects are members of the general public, so it is important to obtain their views. Also, as noted earlier, the public is in a position to block development of new technologies, so it is necessary for policy makers to know what people are thinking and to give the public an opportunity to express opinions and to be heard.

The old ways of engaging the public, such as public hearings, never worked very well and probably work less well today. Experimentation and creative thinking about new forms of public participation are necessary and are taking place to some extent. For example, Arizona State University, with funding from NSF, is convening six citizen panels to consider how best to manage nanotechnology and other new technologies. The panels will engage in Web dialogues with experts and face-to-face meetings with each other. PEN also has experimented with a Web-based dialogue on nanotechnology. In any form of public participation, it is important that there be some route by which the policy makers receive the views of the public.

***3. Convene a stakeholder dialogue.** Many of the initiatives described in this paper would benefit from focused review and discussion by the major stakeholder groups—big and small nanotechnology firms,

environmental and consumer groups, labor unions, scientists and public officials. Stakeholder dialogues could improve the quality of the proposals, facilitate their implementation and produce new recommendations.

In late 2007, PEN, in conjunction with the Meridian Institute, interviewed nanotechnology stakeholders to ascertain their interest in a dialogue on nanotechnology oversight. The general response in the interviews was a willingness to participate in a dialogue but a lack of intensity or commitment. The absence of any pressure or deadline to drive the dialogue contributed to the lukewarm response. This attitude likely would change if the new administration endorsed a dialogue and provided both an agenda and some deadlines. If the stakeholders were convinced that the government might act on their recommendations, a dialogue could make a major contribution to nanotechnology policy.

# III. THE LONGER TERM

This report has outlined a variety of initiatives that can and should be taken when a new administration takes office. Some of the initiatives, such as increasing the resources of the regulatory agencies, will have a short-term impact but will require several years to reach full fruition. Two other kinds of initiatives that are inherently longer term will also require the attention of the transition team and the new administration. These are enacting new legislation and preparing for the next generation of nanotechnology and other technologies.

### NEW LEGISLATION

It is often said that the American system is a government of laws, and in fact laws are what drive the actions of the government agencies. Most of the U.S. laws dealing with environment, health and safety are antiquated and weak. The last major environmental law was enacted almost 20 years ago. TSCA, the only law applying generally to nanomaterials, has not been significantly changed in more than 30 years. As a result, the United States is trying to deal with 21st-century problems using mid-20th-century tools. Current laws are not adequate to deal with nanotechnology or with many of the other environment, health and safety problems the nation faces.

One option for improving nanotechnology oversight would be to adopt legislation focusing exclusively on nanotechnology. In many ways, it would be neater and perhaps more effective to try to enact such legislation. What such a law might contain has been outlined elsewhere (see Davies 2006). However, it would take time to enact such a law, and the problems of committee jurisdiction in both chambers of Congress would be formidable. Thus, the discussion that follows deals with individual laws aimed at specific subjects, not a comprehensive nanotechnology law. It does not deal with drugs, pesticides and other products adequately covered by existing law.

The legislation recommended below focuses on nanotechnology, but it is impossible to make recommendations for nanotechnology without dealing with the general shortcomings in individual existing laws. For example, it is almost impossible for EPA to require adequate risk information for new chemicals under TSCA. This problem requires a general fix that is applicable to all new chemicals; it would make no sense to fix the problem for nanomaterials alone.

#### *1. Toxic Substances Control Act.

Some argue that TSCA is so flawed that it cannot be salvaged. We disagree. The statute went through a tortuous gestation, marked by opposition from within the administration that proposed it and from outside groups, and by a lack of any strong support. We believe that TSCA can be a valuable tool for dealing with nanotechnology and other new technologies if some of the scars of its gestation are fixed. It is the only broad environmental statute that transcends the flawed air-water-land basis for dealing with environmental problems.

In the EPA section we recommended either enacting a significant new use rule or amending the legislative authority relating to TSCA to make clear that nanomaterials are covered as new substances. Appendix C gives specific legislative language for doing this and other changes recommended here.

Other changes in TSCA are necessary. The first is to remove the catch-22 that requires

EPA to show that a new chemical poses a risk before the agency can obtain enough information to determine whether it actually poses a risk. The second change is to remove the conditions and requirements that guarantee that EPA can never regulate an existing substance. The American legal tradition requires that regulatory actions be fair, justified and applied with due process. However, the TSCA conditions applicable to regulating existing substances were put into TSCA not to make it fair and legal but to make it impotent.

One set of needed TSCA changes, those concerning confidential business information (CBI) and data sharing, may command broad support. The current language of TSCA makes it easy for manufacturers to label data "Confidential" and severely constrains EPA's ability to share CBI data with other entities. As a result, much information submitted under TSCA is not available to states, other countries or the public. The remedy is described in Appendix C.

***2. Cosmetics.** The portion of the FFDCA providing FDA with regulatory authority over cosmetics is an empty vessel. Indeed, its basic purpose is to provide a justification for not regulating cosmetics. The industry maintains a registry that, according to the industry, contains test data showing the safety of the active ingredients used in cosmetic products, but this information is not provided to FDA. The FFDCA should be amended to require that the data in this registry be submitted to and reviewed by the FDA. FDA should also be authorized to forbid marketing of any cosmetic containing an ingredient that is not safe or for which adequate test data are not available. This should not impose any significant additional burden on the industry if, as the industry maintains, such testing already is being performed.

Another needed change in the FFDCA is to make clear where and how to draw the line between a drug and a cosmetic. That line is blurry now and is likely to be further blurred by the use of nanomaterials.

***3. Dietary Supplements.** In 1994, Congress passed the Dietary Supplement Health and Education Act (DSHEA). The act is another example of anti-regulation law masquerading as something different. Facing intense political pressure from the dietary supplement industry, with the passage of DSHEA Congress prohibited FDA from imposing premarket testing or approval on dietary supplements (vitamins, herbs, etc.) and placed the burden of proof on FDA to prove that a supplement is unsafe. Some supplements are being developed using nanotechnology that may allow them to reach the brain, the placenta or other vulnerable parts of the body. Toxicity research on these products has not been done, so it is not known what results might ensue from the use of such products, but a potentially hazardous situation exists (Schultz and Barclay, forthcoming).

This problem requires a legislative fix, which would include greater regulatory authority for FDA, greater information about the dietary supplement products being developed and more resources for FDA to carry out its mission in this regard. A forthcoming PEN study provides detailed recommendations (ibid.).

**4. Other Changes to the FFDCA.** In the FDA section above, we outlined other changes that need to be made in FDA's authority. These include giving FDA authority to review safety tests on food and cosmetic ingre-

dients and to require post-market monitoring and surveillance of many types of products.

**5. NNI.** The budget authorizations in the 21st Century Nanotechnology Research and Development Act of 2003, which is the statutory basis for the NNI, expire in October 2008. It is likely that the act will be reauthorized before the new administration takes office. Whether or not it has been reauthorized, the act should be amended to include a requirement for an EHS research plan and to strengthen NNI's coordination powers (see #2 and #3 under Research in Section II above).

### NEW TECHNOLOGIES, NEW OVERSIGHT

In the 21st century, technological innovation will almost certainly accelerate from its already rapid pace. Neither the U.S. government nor any government elsewhere in the world is prepared to deal with the adverse effects and unanticipated consequences of the new technologies. If we do not prepare ourselves, we run a high risk of doing irreversible damage to humankind and to our planet, and of ending up not with a world made better by technology but with lives threatened and impoverished by the world we have created. Nanotechnology provides both the necessity and the opportunity to start addressing these questions.

***1. Improve the government's forecasting ability.** At present we have only a vague picture of the technological developments that lie a decade or two ahead. Agencies such as EPA, the Department of Commerce and the Department of Agriculture need to create and nurture offices that have the specific mission of identifying technological trends. This would give government and society some lead time to think about what the trends mean and what needs to be done to ensure that the new technologies bring the maximum benefit and the fewest adverse effects to society.

Second, Congress needs better ways to evaluate and anticipate scientific and technological developments. The congressional culture is dominated by lawyers, who have little or no training in science. This makes it especially important that the Congress have access to sources whom it trusts and who have the responsibility to tell the legislators what they need to know about scientific and technological developments.

Congress once had such an organization, the Office of Technology Assessment (OTA). Unfortunately, in a move of breathtaking stupidity, in 1995 the Congress removed all funding for OTA, thus ending its existence (see Morgan and Peha 2003). Congress should either revive OTA by providing the modest funding (approximately $20 million per year) used by the OTA when it was operational or create a new agency to perform the functions that OTA used to perform.

**2. Create new forms of oversight.** The existing forms of oversight are outdated and inadequate. The contrast between the inflexible, compartmentalized oversight systems of the past century and biotechnology, climate change, nanotechnology and other challenges of the 21st century is stark.

Proposals for new types of oversight have been heavily influenced by the free market ideology of the 1980–2007 era. They largely entail giving more responsibility and flexibility to private firms (see, for example, Fiorino 2006 and Kamarck 2007). There is much that is useful in these proposals, but they are not

adequate to deal with the technological challenges of the 21st century. Given the potentially great impact of a failure to identify and control an adverse effect of nanotechnology, should we really leave its identification and control in the hands of those who are producing it?

***3. Create a commission on oversight of new technology.** The president should appoint a commission to formulate a blueprint for new forms of oversight. Commission members should include scientists, policy makers, business representatives, consumers, and environmentalists. It should have a fixed life span, perhaps three years. Its report should provide guidance for government oversight over the next few decades. The commission should have a broad mandate to allow it to consider all forms of technology and all forms of change—new legislation, institutional changes and private sector initiatives.

The commission will need to address the functions entailed in oversight, including how to identify the universe of concern, how to narrow the subjects of oversight to a manageable number, how to collect information on the targets of oversight (risks and benefits), how to manage potential dangers from new technologies, how to get public input into decisions about technologies and how to structure surveillance activities so that new findings about a technology can be rapidly identified and acted upon.

Commission members will need to be open to new approaches and ideas. Can oversight be linked to the patent system? Can manufacturers take the initiative to propose restrictions, labels and other ways of managing a technology? What would an international surveillance system look like? Do we need a new technology oversight agency? Should EPA and the Congress jettison the air-water-land approach to environmental protection? Are there market-based incentives to encourage greener products?

* * * * *

Scientists have given and will continue to give us vast marvels, capable of producing technologies of great power. Each of these marvels, including nanotechnology, comes in a treasure chest of riches and a Pandora's box of evils. The challenge of the new century and to the new administration is to use the treasure while keeping shut the lid on the Pandora's box. It is a daunting challenge, but one that can be met.

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## **APPENDIX B:** PLANNED 2009 NNI BUDGET BY PROGRAM COMPONENT AREA (dollars in millions)

| | FUNDAMENTAL PHENOMENA & PROCESSES | NANOMATERIALS | NANOSCALE DEVICES & SYSTEMS | INSTRUMENT RESEARCH, METROLOGY, & STANDARDS | NANO-MANUFACTURING | MAJOR RESEARCH FACILITIES & INSTR. ACQUISITION | ENVIRONMENT, HEALTH, AND SAFETY | EDUCATION & SOCIETAL DIMENSIONS | NNI TOTAL |
|---|---|---|---|---|---|---|---|---|---|
| DOD | 227.8 | 55.2 | 107.7 | 3.6 | 12.8 | 22.1 | 1.8 | | 431.0 |
| NSF | 141.7 | 62.5 | 51.6 | 16.0 | 26.9 | 32.1 | 30.6 | 35.5 | 396.9 |
| DOE | 96.9 | 63.5 | 8.1 | 32.0 | 6.0 | 101.2 | 3.0 | 0.5 | 311.2 |
| DHHS (NIH) | 55.5 | 25.4 | 125.8 | 5.9 | 0.8 | | 7.7 | 4.6 | 225.7 |
| DOC (NIST) | 24.5 | 8.5 | 22.7 | 20.9 | 15.3 | 5.7 | 12.8 | | 110.4 |
| NASA | 1.2 | 9.8 | 7.7 | | | 0.2. | 0.1 | | 19.0 |
| EPA | 0.2 | 0.2 | 0.2 | | | | 14.3 | | 14.9 |
| DHHS (NIOSH) | | | | | | | 6.0 | | 6.0 |
| USDA (FS) | 1.7 | 1.3 | 0.7 | 1.1 | 0.2 | | | | 5.0 |
| USDA (CSREES) | 0.4 | 0.8 | 1.5 | | 0.1 | | 0.1 | 0.1 | 3.0 |
| DOJ | | | | 2.0 | | | | | 2.0 |
| DHS | | | 1.0 | | | | | | 1.0 |
| DOT (FHWA) | 0.9 | | | | | | | | 0.9 |
| **TOTAL** | 550.8 | 227.2 | 327.0 | 81.5 | 62.1 | 161.3 | 76.4 | 40.7 | 1,527.0 |

Source: National Nanotechnology Initiative, available at www.nano.gov

## APPENDIX C: PROPOSED LEGISLATIVE CHANGES IN TSCA

(Detailed conforming provisions are omitted.)

1. Include nanomaterials as new chemicals.

Add to section 3(2)(A) the following: "(iii) any material produced in a form where one or more dimensions is less than 100 nanometers and where physical, chemical, or biological properties differ significantly from similar materials with the same chemical identity due to its nanometer structure, even if such material has the same molecular identity as a chemical already on the inventory, unless a substantially identical nanomaterial is already on the inventory."

2. Allow EPA to obtain information to determine the risk of new chemicals.

Delete section 5(e)(1)(A)(ii).

Delete section 5 (e)(1)(C).

3. Remove unrealistic constraints on EPA's rulemaking ability.

At the end of the first paragraph of section 6(a) delete "using the least burdensome requirements."

Delete second paragraph of section 6(c)(1) ("If the Administrator determines that a risk of injury to health or the environment could be eliminated or reduced to a sufficient extent by actions taken under another Federal law … ").

Delete section 9 ("Relationship to Other Federal Laws").

Modify the procedural requirements of sections 6(c)(2) and (3).

Delete section 19 (c)(B) ( "substantial evidence in the rulemaking record").

4. Modify the constraints imposed by the CBI provisions.

Add to section 14(a) a new paragraph: "(5) may be disclosed to any state government, foreign nation, or international governmental organization provided that it has safeguards deemed by the Administrator to be adequate for the protection of the information and subject to such other conditions as the Administrator may impose."

Amend section 14 to require that information labeled CBI be accompanied by a certification, signed by a responsible official of the submitting firm, that the confidentiality is necessary and justifiable and setting forth the specific and particular reasons for the confidentiality.

The **PROJECT ON EMERGING NANOTECHNOLOGIES** was launched in 2005 by the Wilson Center and The Pew Charitable Trusts. It is dedicated to helping business, governments, and the public anticipate and manage the possible human and environmental implications of nanotechnology.

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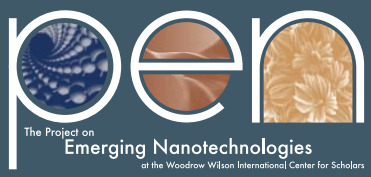


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