Woodrow Wilson International Center for Scholars
Project on Emerging Nanotechnologies

OVERSIGHT *of* NEXT GENERATION NANOTECHNOLOGY

J. Clarence Davies

PEN 18
APRIL 2009

ACRONYMS

CPSC – Consumer Product Safety Commission

EC – European Commission

EPA – Environmental Protection Agency

EU – European Union

FDA – Food and Drug Administration

FTE – full-time equivalent (personnel)

IBM – International Business Machines Company

IPPC – Integrated Pollution Prevention and Control (an EU directive)

MIT – Massachusetts Institute of Technology

NIOSH – National Institute of Occupational Safety and Health (U.S. Department of Health and Human Services)

NNI – National Nanotechnology Initiative

NOAA – National Oceanic and Atmospheric Administration (U.S. Department of Commerce)

OECD – Organization for Economic Cooperation and Development

OSHA – Occupational Safety and Health Administration (U.S. Department of Labor)

PEN – Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars

REACH – Registration, Evaluation, Authorization and Restriction of Chemicals (an EU regulation)

SP – sustainability plan

TSCA – Toxic Substances Control Act

UN – United Nations

USGS – U.S. Geological Survey (Department of the Interior)

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PREFACE

J. Clarence "Terry" Davies and I first became acquainted when I was appointed the first Administrator of the Environmental Protection Agency and he had just finished working on the plan that created the new agency. In the almost 40 years since then, the world has learned much about environmental problems and how to deal with them, and by many measures the environment is cleaner than it was in 1970. But, as described in Terry's report, the challenges of the 21st century are daunting and require new approaches to oversight. We need a more effective and efficient oversight system, one that can deal with nanotechnology and other scientific advances as well as the multitude of existing problems.

In this report, Terry provides some broad and innovative suggestions about what such an oversight system might look like. He describes a new Department of Environmental and Consumer Protection that would be more of a science agency than the current regulatory ones and that would incorporate more integrated approaches to oversight and monitoring. He suggests for discussion a new law that would focus on product regulation and new tools that could be used to deal with future health and environmental problems.

These suggestions are an important contribution to the dialogue that is needed to formulate a better oversight system. As Terry says, his proposals are intended to be the beginning of a discussion, not its conclusion.

Over 20 years ago at a national conference on risk assessment, I said that I do not believe technology necessarily is going to master us. We are smart enough to take advantage of the fruits of technological advances and to minimize or eliminate risks to people and the environment. But we need to learn from past mistakes and be able to anticipate future challenges. Terry's report uses the experience of the past to suggest the policy directions of the future. I share his hope that the report will spur the thinking and dialogue needed to deal with the problems that lie ahead.

— William D. Ruckelshaus

ABOUT THE AUTHOR

J. Clarence "Terry" 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. He has authored three previous reports on nanotechnology for the Project on Emerging Nanotechnologies.

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 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

Since 1980, the capability of the federal agencies responsible for environmental health and safety has steadily eroded. The agencies cannot perform their basic functions now, and they are completely unable to cope with the new challenges they face in the 21st century. This paper describes some of these challenges, focusing on next-generation nanotechnologies, and suggests changes that could revitalize the health and safety agencies.

Oversight of new technologies in this century will occur in a context characterized by rapid scientific advancement, accelerated application of science and frequent product changes. The products will be technically complex, pose potential health and environmental problems and have an impact on many sectors of society simultaneously. They may also raise challenges to moral and ethical beliefs. Nanotechnology embodies all of these characteristics as well as particular ones that challenge conventional methods of risk assessment, standard setting and oversight implementation.

The federal regulatory agencies already suffer from under-funding and bureaucratic ossification, but they will require more than just increased funding and minor rule changes to deal adequately with the potential adverse effects of the new technologies. New thinking, new laws and new organizational forms are necessary. Many of these changes will take a decade or more to accomplish, but there is an urgent need to start thinking about them now.

To stimulate discussion, this paper outlines a new federal Department of Environmental and Consumer Protection. The new agency, which would be composed largely of existing agencies, would have three main components: oversight, research and assessment and monitoring. It would be a scientific agency with a strong oversight component, in contrast to the current regulatory agencies, which are primarily oversight bodies.

The proposed agency would foster more integrated approaches, and this would require new legislation. A unified approach to product regulation is necessary to deal with current programs like monitoring and newer challenges like nanotechnology. A more integrated approach to pollution control was necessary even before the Environmental Protection Agency (EPA) was created in 1970, and since that time, the need has only increased. Integrated facility permitting, such as exists in the European Union (EU), is one avenue to pursue. Economics-based approaches, such as cap-and-trade, would also help streamline pollution control. The essential functions of monitoring the environment and analyzing the results are widely scattered throughout the government and need to be brought together. The design of the proposed new agency incorporates the proposals for an Earth Systems Science Agency and a Bureau of Environmental Statistics. The new agency would need to be able to do technology assessment, forecasting, and health and safety monitoring.

The organizational, legislative and other changes described in the paper are intended to be a starting point for discussion, not a set of fixed conclusions. Also, they are not intended to supersede or take away from the need for immediate reform, for example, for modernization of the Toxic Substances Control Act (TSCA). However, the dialogue about new approaches

needs to start now. The proposals contained in the report should help frame the discussion and give it focus.

The paper describes some of the developments that will determine the future of technology and some changes that would equip the federal government to deal with the new 21st-century science and technology. The oversight system is broken now. Revolutionary technologies like nanotechnology and synthetic biology are being commercialized now. The proposed oversight system is just a starting point for thinking about change, but change is urgently needed.

ACKNOWLEDGMENTS

I am grateful to the Project on Emerging Nanotechnologies for its support and encouragement and also to Resources for the Future for its continuing support. This paper could not have been produced without the help of people other than the author. Dave Rejeski allowed me to cover areas that were well beyond the scope of the original assignment, and he provided many useful comments and suggestions. Julia Moore's unstinting support and encouragement have made working at the Wilson Center a pleasure, and she has provided both intellectual and psychological assistance in getting this paper written. Andrew Maynard put in so much time and effort that more than once I offered him co-authorship of the report. That he declined shows how wise he is. I am very grateful to him for undertaking to make it appear as if I knew more than I really know about the science of nano. Todd Kuiken served ably as researcher, and Colin Finan helped in various ways. Three outside reviewers—Michael Rodemeyer, Munroe Newman and Mark Greenwood—provided many useful comments. As usual, my wife, Barbara, put in many hours of work on the paper. Like Andrew Maynard, she is entitled to co-authorship but was wise enough to decline. Having failed to get any co-authors, I accept all responsibility for the contents of the report.

— J. Clarence Davies

INTRODUCTION

For the first time in human history, we are close to being able to manipulate the basic forms of all things, living and inanimate, take them apart and put them together in almost any way the mind can imagine. The sophistication with which scientists are learning to engineer matter at the nanometer scale is giving us unprecedented mastery of a large part of our environment. The world of the future will be defined by how we use this mastery.

In contrast to the sweeping and dramatic possibilities of new technologies, the government agencies responsible for protecting the public from the adverse effects of these technologies seem worn and tattered. After almost 30 years of systematic neglect, the capability of federal health and safety regulatory agencies ranges from very weak to useless. The focus of regulatory reform in this period has mostly been on how to get around the existing regulatory structure rather than on how to improve it. The regulatory system was designed to deal with the technologies of the industrial age. A large gap exists between the capabilities of the regulatory system and the characteristics of what some are calling the next industrial revolution, and that gap is likely to widen as the new technologies advance.

Nanotechnology involves working at the scale of single atoms and molecules. The U.S. government defines nanotechnology as "the way discoveries made at the nanoscale are put to work" (www.nano.gov; accessed 9/19/08). The nanoscale is roughly 1–100 nanometers. For comparison, the paper on which this is printed is more than 100,000 nanometers thick. There are 25.4 million nanometers in an inch and 10 million nanometers in a centimeter.

Nanoscale materials often behave differently than materials with a larger structure do, even when the basic material (e.g., silver or carbon) is the same. Nanomaterials can have different chemical, physical, electrical and biological characteristics. For example, an aluminum can is perfectly safe, but nano-sized aluminum is highly explosive and can be used to make bombs.

The novel characteristics of nanomaterials mean that risk assessments developed for ordinary materials may be of limited use in determining the health and environmental risks of the products of nanotechnology. While there are no documented cases of harm attributable specifically to a nanomaterial, a growing body of evidence points to the potential for unusual health and environmental risks (Oberdorster 2007; Maynard 2006). This is not surprising. Nanometer-scale particles can get to places in the environment and the human body that are inaccessible to larger particles, and as a consequence, unusual and unexpected exposures can occur. Nanomaterials have a much larger ratio of surface area to mass than ordinary materials do. It is at the surface of materials that biological and chemical reactions take place, and so we would expect nanomaterials to be more reactive than bulk materials. Novel exposure routes and greater reactivity can be useful attributes, but they also mean greater potential for health and environmental risk.

Oversight consists of obtaining risk information and acting on it to prevent health and environmental damage. An underlying premise of this paper is that adequate oversight of nanotechnology is necessary not only to prevent damage but also to promote the

development of the technology. The United States and Europe have learned that oversight and regulation are necessary for the proper functioning of markets and for public acceptance of new technologies.

The application of current oversight systems to current forms of nanotechnology has been analyzed for both the United States and Europe (see, for example, Davies 2006; Davies 2007; Royal Society and Royal Academy of Engineering 2004). The existing oversight systems in the United States have been found to be largely inadequate to deal with current nanotechnology (Davies 2006, 2007, 2008; Taylor 2006, 2008; Felcher 2008; Breggin and Pendergrass 2007; Schultz and Barclay 2009). This paper looks at future generations of nanotechnology. Not surprisingly, it finds that they will present even greater oversight challenges than the current technology. And nothing less than a completely new system will suffice to deal with the next generations of nanotechnology.

The paper begins with an examination of the future of nanotechnology. It then analyzes the capacity of current oversight policies and authorities to deal with the anticipated technological developments. Concluding that the existing systems are inadequate, the major part of the paper is devoted to thinking about a more adequate oversight system for new technologies in general and for nanotechnology in particular. Failure to think about new forms of oversight perpetuates the status quo and, in the long run, invites negative effects that could undermine the promise of the new century's technologies.

1. THE FUTURE OF NANOTECHNOLOGY

Predicting the future of any major technology is difficult. On the one hand, there often is a tendency to underestimate the impact of a technology and the pace of its development. Nanotechnology development already is outpacing the predictions made when the NNI (National Nanotechnology Initiative) was created in 2000. At that time, the focus was on the impact nano might have in 20–30 years (Roco 2007). Now, the analysis firm Lux Research predicts that by 2015 nano will be incorporated in $3.1 trillion of manufactured goods worldwide (Lux Research 2008) and will account for 11 percent of manufacturing jobs globally (Lux Research 2006).

Alternatively, the promise of a technology and the pace of its development may be exaggerated. There are many examples of technological advances that were predicted to be imminent but that had not materialized decades, or even centuries, later. A further complication is that a technology can develop in completely unanticipated directions and be applied in ways that no one envisaged.

This section begins by reviewing several analyses of nanotechnology's future and of current nanotechnology research. It then reviews applications of the research that are likely to occur in the next 10–20 years. It concludes by distilling the attributes that are likely to characterize future technologies in general and the next generation of nanotechnology specifically.

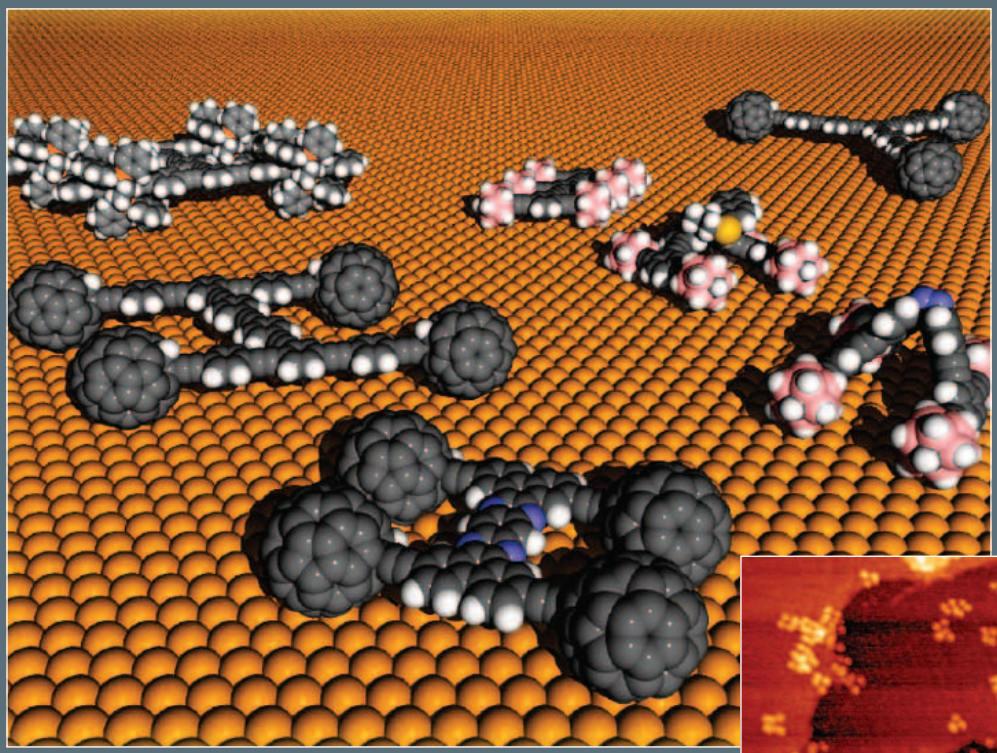
NANOTECHNOLOGY RESEARCH AND DEVELOPMENT

The major attempts to analyze the future of nanotechnology have tried to categorize the types of research being conducted and/or the types of applications of the technology. The most straightforward categorization is that used by James Tour (2007) based on work in his Rice University laboratory. He categorizes nanotechnologies as passive, active or hybrid (i.e., technologies that are intermediate between active and passive). Tour estimates the time it will take to commercialize each of these types as 0–5 years for passive nanotechnologies, 15–50 years or more for active nanotechnologies and 7–12 years for hybrids.

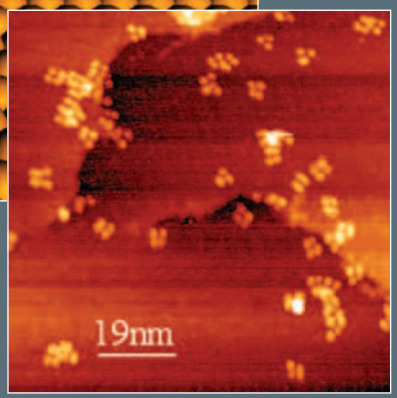
According to Tour, almost all the current applications of nano are passive, and most involve adding a nanomaterial to an ordinary material as a way of improving performance. For example, he notes that adding carbon nanotubes to rubber can greatly increase the toughness of the rubber without reducing its flexibility. Passive nanotechnology applications include using materials like carbon nanotubes, silver nanoparticles and porous nanomaterials—materials containing holes that are nanometers in diameter. These applications use nanomaterials to add functionality to products by nature of their physical and chemical form, rather than by how they respond to their environment.

Tour defines an active nanotechnology as one where "the nano entity does something elaborate." He gives the example of a "nanocar," a unique nano-engineered molecule that can be used to physically move atoms from one place to another (see illustration on "Beyond Synthetic Chemistry)". One goal of next-generation nanotechnology is to imitate nature by designing systems and devices that construct things from the bottom up, (i.e., that make things atom by atom and molecule by molecule). This means

BEYOND SYNTHETIC CHEMISTRY: An Example of Next Generation Nanotechnology



*Computer generated image of molecular "nanocars".



**Scanning Tunneling Microscope image of "nanocar" molecules. The four carbon-60 molecules making up the wheels of each "nanocar" are easily visible.

Most scientists agree that we have only scratched the surface of the full range of molecules that could be made, if only we had better tools and a more complete understanding of how things work at the nanoscale. Building on advances in science and engineering, next generation nanotechnologies will enable the design and construction of increasingly complex molecules that rival those found in biology in terms of their sophistication. For example, Dr. James Tour and his research group at Rice University are engineering an innovative new class of molecules dubbed "nanocars," that can move across a surface, and potentially ferry materials from one point to another at a nanometer scale.[1,2] Scientists are discovering that many biological processes depend on billions of molecules carrying out physical tasks, including ferrying materials around to construct, repair and fuel living cells. Mimicking these processes using artificial molecules—like the "nanocars"—may open the door to constructing sophisticated new materials and products as diverse as medicines, electronic devices and building materials.

1. Sasaki, T., Osgood, A.J., Alemany, L.B., Kelly, K.F., and Tour, J.M. 2008. Synthesis of a Nanocar with an Angled Chassis. Toward Circling Movement. Organic Letters. 10(2), 229-232.

2. Vives, G. and J. M. Tour (2009). "Synthesis of Single-Molecule Nanocars." *Acc. Chem. Res.* **42**(3): 473-487.

*Image courtesy of the American Chemical Society

**Image courtesy of the James M. Tour Group. http://www.jmtour.com/?page_id=33

that starting only with individual molecules one could make computer chips, super-strong materials, biological tissue or almost anything else. The basic methods by which this could be done are self-assembly, molecular construction or a combination of the two. Novel nanodevices such as the nanocar could be used as a basis for molecular construction. Practical applications of bottom-up construction are open to anyone's imagination, but could include repair of human tissue or the generation of energy using photosynthesis.

M. C. Roco, one of the driving forces behind the NNI, has developed a more detailed typology of nanotechnologies (Roco 2004, Roco 2007). He identifies four generations of nanotechnologies: passive nanostructures, active nanostructures, systems of nanosystems and molecular nanosystems.

Almost all the current applications and uses of nanotechnology belong to Roco's first generation, a category that is basically the same as Tour's passive category. Uses in this category most frequently entail combining a nanomaterial with some other material to add functionality or value, and the behavior of the nanomaterial does not change appreciably over time.

Roco's second generation, active nanostructures, typically involves nanometer-scale structures that change their behavior in response to changes in their environment. These changes might come about as a result of a mechanical force, a magnetic field, exposure to light, the presence of certain biological molecules or a host of other factors. Roco envisages active nanostructures as being integrated into much larger devices or systems, to make them usable in practice. Examples include new transistors and other electronic components, targeted drugs and chemicals designed for particular functions—along the lines of Tour's nanocars.

The third- and fourth-generation nanotechnologies are more abstract. According to Roco (2007, p. 28), the third generation encompasses "systems of nanosystems with three-dimensional nanosystems using various syntheses and assembling techniques such as bioassembling; robotics with emerging behavior, and evolving approaches." It includes "directed multiscale self assembling … artificial tissues … and processing of information using photons." The fourth generation "will bring heterogeneous molecular nanosystems where each molecule in the nanosystem has a specific structure and plays a different role" (*Ibid.,* p. 29). It will include macromolecules "by design," nanoscale machines and interface between humans and machines at the tissue and nervous system levels.

Even knowledgeable experts have expressed difficulty distinguishing among Roco's last three generations and understanding some of the applications that he describes. However, at a minimum, they point to future developments and uses of nanotechnology that are increasingly sophisticated, and that lead to materials and products that behave in different (even unanticipated) ways according to how they are used. These materials and products will be very different from those of the present and will have an impact on a broad spectrum of sectors and users.

A third typology was developed by Vrishali Subramanian, who conducted a comprehensive bibliographic search of research on active nanostructures for the Woodrow Wilson International Center for Scholars' Project on Emerging Nanotechnologies (PEN) (unpublished research paper). Her analysis suggests that the following categories of active nanostructures emerge from the research literature: (1) remote actuated—a nanotechnology whose active principle is remotely activated; (2) environmentally responsive—a nanotechnology that is sensitive to stimuli such as

pH, temperature, light or certain chemicals; (3) miniaturized—a nanotechnology that is a conceptual scaling down of larger devices and technologies; (4) hybrid—nanotechnology involving uncommon combinations (biotic-abiotic, organic-inorganic) of materials; and (5) transforming—nanotechnology that changes irreversibly during some stage of its use or life. She notes that active nanostructure prototypes do not necessarily fall into only one of these categories and that in fact if an innovation falls into more than one category it is likely to be more complex and dynamic.

Almost all observers predict that an important aspect of future nanotechnology will be its merging with other technologies and the subsequent emergence of complex and innovative hybrid technologies. Biology-based technologies are intertwined with nanotechnology—nanotechnology is already used to manipulate genetic material, and nanomaterials are already being built using biological components. The ability inherent in nanotechnology to engineer matter at the smallest scale is opening unexpected doors in areas like biotechnology, information technology and cognitive science, and is leading to new and transformative connections between these and other fields. Some experts, such as Mike Roco and Bill Bainbridge (2003), predict that the convergence of nanotechnology, biotechnology and information and cognitive sciences will be the defining characteristic of the 21st century. Others have gone much further, suggesting that nanotechnology is one of a suite of technologies that will precipitate a period of unprecedented life-transforming technological advances this century—the so-called technological singularity popularized by Ray Kurzweil (2006). Although these ideas may seem closer to the realm of science fiction than science fact, it is hard to avoid the sense that nanotechnology marks a tipping point from simple, chemistry-based products to sophisticated products that incorporate complex and adaptive structures at the nanoscale.

APPLICATIONS OF CURRENT RESEARCH

Almost every area of human activity will be affected by future nanotechnologies. Medicine, food, clothing, defense, national security, environmental clean-up, energy generation, electronics, computing and construction are among the leading sectors that will be changed by nanotechnology innovations. Here is a small sampling of research likely to result in practical applications within the next 15 years:

Smart drugs—cancer treatments. A good deal of research, involving a variety of different nanotechnologies, is being devoted to cancer detection and cure (Zhang 2007). One of the main goals of using nanotechnology for medical purposes is to create devices that can function inside the body and serve as drug delivery systems with specific targets (Pathak and Katiyar 2007). Current treatments for cancer using radiation and chemotherapy are invasive and produce debilitating side effects. These treatments kill both cancerous and healthy cells. Nanotechnology has the potential to treat various forms of cancer by targeting only the cancer cells. Researchers at Rice University have developed a technique utilizing heat and nanoparticles to kill cancer cells. Gold-coated nanoparticles designed to accumulate around cancer cells are injected into the body. Sources of radiation, similar to radio waves, are then used to transmit a narrow range of electromagnetic frequencies that are tuned to interact with the gold nanoparticles. The particles are heated by the radiation and can kill the cancer cell without heating the surrounding non-cancerous cells (O'Neal et al. 2004).

Mauro Ferrari and his research team at the University of Texas have been focusing on early detection of cancer using lab-on-a-chip technology with particles that can sort out and concentrate proteins of interest from blood samples. The same team is using injectable nanomaterials to act as carriers for drugs that are able to avoid biological barriers and target specific parts of the body (University of Texas 2006).

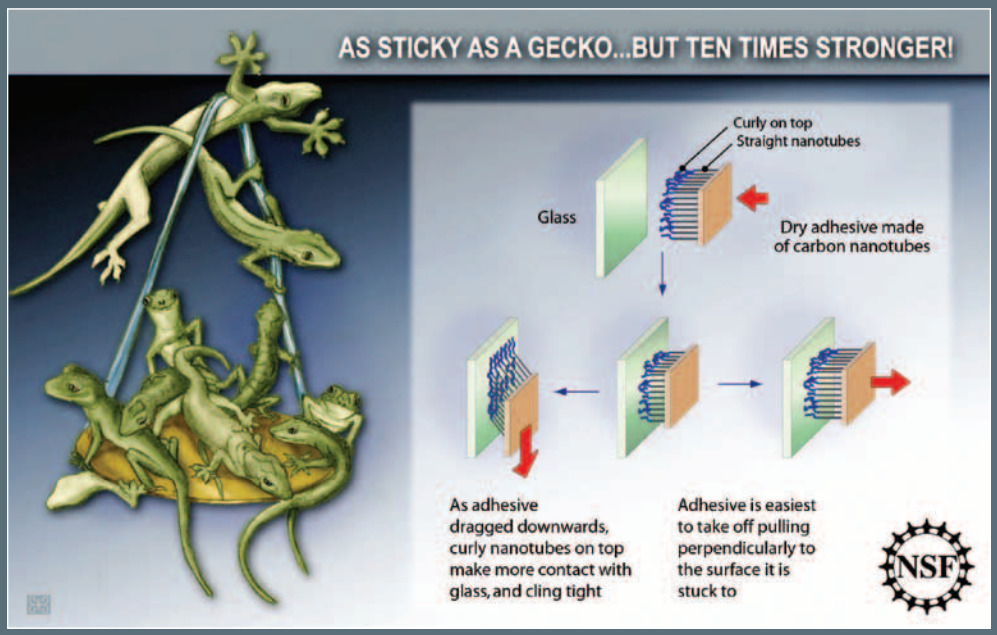
Military applications. The U.S. Army and the Massachusetts Institute of Technology (MIT) are cooperating on a large-scale program to use nanotechnology to design a new battle suit for soldiers. The goal is to create a "bullet-resistant jumpsuit, no thicker than ordinary spandex, that monitors health, eases injuries, communicates automatically and reacts instantly to chemical and biological agents" (http://web.mit.edu/isn/; accessed 11/7/08).

Next-generation computer processing. Many researchers are exploring the use of nanomaterials and nanotechnology techniques to vastly improve computers. In 2007, International Business Machines Company (IBM) researchers used self-assembling nanotechnology to improve current flow in chips by 35 percent. This new approach, called air-gap technology, is expected to quadruple the number of transistors that can be put on a chip. The natural process that forms seashells, snowflakes and enamel on teeth is used to form trillions of holes to create insulating vacuums around miles of nano-scale wires packed next to each other inside each computer chip.

Programmed biology—the smallest batteries. Battery technology is a major stumbling block for a variety of applications, ranging from electric automobiles to miniaturized implantable medical devices. One of the major limitations of current battery technology is that less than half of the space/weight of a battery is occupied by the materials that actually store the electricity. In order to increase the "energy density" of a battery the amount of inactive materials needs to be reduced. Angela Belcher and her associates at MIT have engineered a virus for use as a "programmable molecular building block to template inorganic materials growth and achieve self-assembly." These engineered viruses were used to grow nanowires of cobalt oxide, which act as the anode of a battery; cobalt oxide could significantly increase the storage capacity of lithium ion batteries and also be used to construct micro-batteries (Nam et al. 2008). Building upon this, Belcher's group genetically engineered viruses that first coat themselves with iron phosphate which can then grab hold of carbon nanotubes (acting as the cathode) creating a network of highly conductive material (Lee et al., 2009). By combining the two components (anode and cathode) the research team has developed a prototype battery about the size of a coin that has the same energy capacity of a battery that may be used in a hybrid vehicle (Trafton, 2009). Using the ability of the virus to self-assemble, Belcher's group hopes to create a fully self-assembled high performance battery that could be placed on fibers, circuits or other materials (Nam et al. 2008).

Complex materials—a super-adhesive. Scientists and engineers often look to nature to solve complex problems or to develop technologies that have the capability of mimicking nature. For example, the gecko's ability to stick to surfaces and walk up walls with ease has led researchers to design materials that can mimic the microscopic elastic hairs that line this animal's feet (see illustration on Complex Materials). Using carbon nanotubes, Liangti Qu and colleagues at the University of Dayton (Ohio) have created a material that has an adhesive force about 10 times stronger than that of a gecko's foot. These carbon nanotube materials

COMPLEX MATERIALS: An Example of Next Generation Nanotechnology



Advanced nanotechnology is enabling scientists to develop sophisticated new materials that can be used in novel ways. For instance, researchers have created a gecko-inspired adhesive with ten times the stickiness of a gecko's foot, by combining vertically aligned nanotubes with curly spaghetti-like nanotubes.

Credit: Zina Deretsky, National Science Foundation after Liangti Qu et al., Science 10/10/2008

have a much stronger adhesion force parallel to the surface they are on than that perpendicular to the surface. The result is a material that can be used to attach a heavy weight to a vertical surface, and yet be peeled off with ease. And just as a gecko is able to walk up vertical surfaces with ease, the material opens up the possibility of creating clothing that will enable humans to achieve the same feat.

Metamaterials - controlling the flow of light. A whole new field of scientific research, called transformation optics, has been made possible by the ability of nanotechnology to create new materials that bend light "in an almost arbitrary way," making possible "applications that had been previously considered impossible" (Shalaev 2008). These applications include an "electromagnetic cloak" that bends light around itself, thereby making invisible both the cloak and an object hidden inside; and a "hyperlens" that could be added to conventional microscopes allowing them to be used to see down to the nanoscale and thus to see viruses and possibly DNA molecules (*Ibid.*)

Energy generation and use. New generations of nano-based sensors, catalysts and materials have already resulted in major reductions in energy use, and further progress is certain. The ConocoPhillips oil company recently awarded a three-year, $1.2 million grant

to the University of Kansas to research the use of nanotechnology to enhance oil recovery (ConocoPhillips press release, 12/2/08). Nanoscale catalysts and nanoporous membranes are, under some circumstances, being used to facilitate production of biomass fuel. Energy transmission could potentially be made much more efficient by using engineered nanomaterials. Throughout the renewable-energy sector, nanotechnology has the potential to increase process efficiencies and process yields, decrease costs and enable energy processes that would not be attainable any other way. Nanotechnology is transforming photovoltaic cells through the development of new and less expensive manufacturing techniques and new methods of generating high-surface-area structures, optimizing sensitivity and increasing the spectral absorbency of the cells (Saunders et al. 2007). Other applications in the renewable-energy sector include using nanoscale surface properties and novel nanofabrication techniques to increase production of electricity in hydrogen fuel cells. Most renewable-energy technologies can be made more efficient using various forms of nanotechnology, at least at the laboratory scale. Whether these efficiencies translate into economic efficiencies will depend on fabrication and other costs (Saunders et al. 2007).

The timeframes within which these innovations will be commercialized will be different for different innovations and will vary depending on who is doing the estimating. For example, Tour (2007, p. 361) estimates the commercialization horizon for active nanotechnologies as 15–50 years, noting that "the truly exciting developments in nanotechnology … are often 30–50 years away, or even 100 years out." Roco (2007, p. 28), in contrast, predicts that even the most advanced of his generations will begin to be commercialized by 2015 or 2020. Roco may be overly optimistic, and the current global recession will probably delay the commercialization of new discoveries because companies and investors have less money and are more risk averse. However, accelerating paces of scientific discovery, as well as of commercial adoption, have been characteristic of nanotechnology development.

CHARACTERISTICS OF NEXT-GENERATION NANO

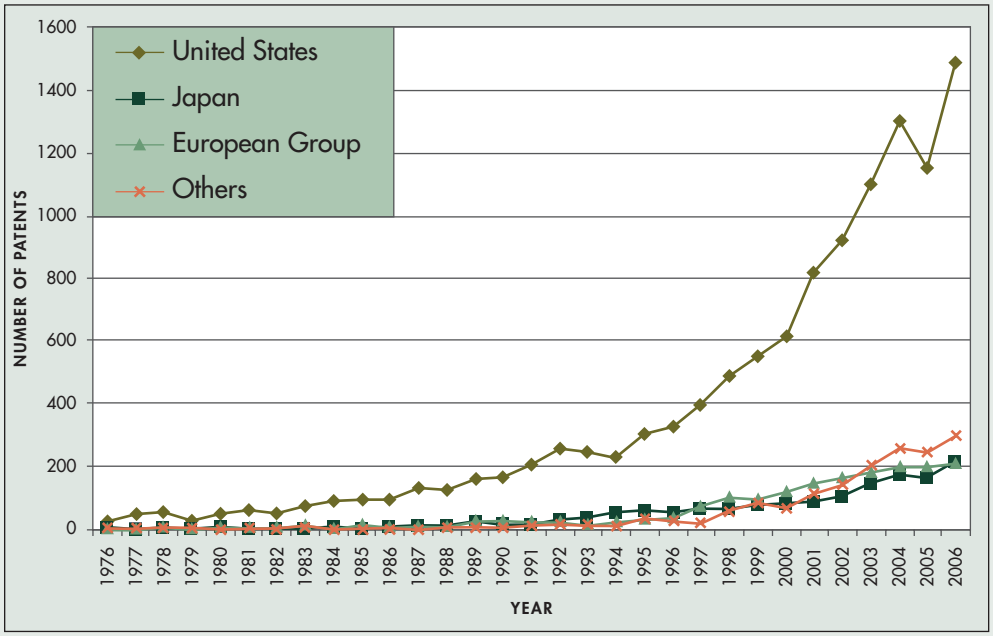
By extrapolating from the development of nanotechnology and drawing upon experience with other new technologies, one can identify a number of characteristics of next-generation nano. They divide into characteristics that are generic to most new technologies and characteristics that are unique or particularly applicable to nano.

The generic characteristics include:

Rapid scientific advancement. It often has been noted that most of the scientists who have ever lived are alive today. The people, tools, resources and institutions that currently exist to further scientific knowledge dwarf those of any previous period in human history (see Bowler and Morus 2005). The result is that more scientific knowledge is developed, and is being developed more rapidly, than at any other time in history. Because many of the tools and concepts have broad application, the pace of development is continually accelerating. This is illustrated by the dramatic rise in nanotechnology patents (see Fig. 1).

Rapid utilization of science. New science is put to practical application more rapidly today than at any time in the past. The line between science and technology has been completely blurred. Telecommunications, especially the computer and the Internet, allow new technologies to be rapidly disseminated throughout the world. The breakdown of traditional cultures has removed many of the

FIGURE 1. Nanotechnology-based patents*



*Adapted from Chen and Roco, 2009.

intellectual and cultural barriers to adopting new technologies.

Frequent product changes. A corollary of the rapid pace of scientific and technological development is that the characteristics of products change frequently (see Fine 2000; Mazurek 1999). The frequency with which both products and manufacturing processes change is a challenge for any oversight system because the pace of bureaucratic and regulatory procedures has not noticeably increased: indeed, it may well have slowed under the accumulated weight of procedural requirements.

Technical complexity. Nanotechnology, like most new technologies, is complex. It draws on several disciplines, including physics, chemistry and biology, and on numerous sub-specialties within those disciplines. It uses highly technical vocabulary, sophisticated mathematics and concepts that have few anchors in everyday experience. These characteristics make it difficult for even knowledgeable lay people to understand what the new technology can do. The complexity not only creates an impediment to communicating with the public but also places demands on oversight agencies to acquire new types of experts—experts who may be few in number and expensive to hire.

Potential health and environmental problems. New technologies often have unanticipated or unwanted consequences. As our knowledge of both human and ecosystem functioning has increased, we have learned more about the ways in which technology can have an impact on health and the environment. The realization that most new technologies have the potential for such impacts is the major reason for applying oversight. For example, in the 1960s and 1970s it was recognized that the

potential for adverse effects from chemicals was not limited to isolated and occasional aberrations but was something that had to be considered for all new chemicals. The realization led to passage of the Toxic Substances Control Act (TSCA) in the United States and to analogous legislation in Europe.

Broad social impact. The most important of the new technologies, such as nanotechnology and genetic engineering, transcend the categories that are usually applied to technologies. We traditionally talk about medical or transportation or energy technologies, but nano, for example, will have major impacts on all these sectors and many others as well. It is no exaggeration to say that nanotechnology will change the way we live.

Potential challenges to moral and ethical beliefs. A consequence of the broad impact of the new technologies is that they may have applications or implications that raise basic moral questions. If nanotechnology can be used to improve the functioning of the human brain, should it be used that way? And if so, for whose brains? If nanoscale materials are incorporated in foods to improve nutrition, shelf life or taste, should the food have to be labeled to show that nano has been used? If synthetic biology, using nanotechniques, can create new life forms, should it be allowed to do so? When technologies raise these kinds of questions, the general public should be an important player in the development and application of the technology. The public will play a role as consumer when the technology is marketed, but society has not yet developed institutions or mechanisms that enable the public to express its voice and be heard when the technology is still being developed. The public in its role as taxpayer should, at a minimum, have a voice in which technologies the government funds and supports. Congress obviously exercises some control over this, but only rarely is there a considered debate about the consequences of a new technology or about priorities among technologies. The technology of public-participation mechanisms lags behind the science-based technologies of the 21st century.

The characteristics of nanotechnology—especially next-generation nanotechnology—that make it particularly challenging include:

Changes in the materials. A number of nanomaterials in the advanced research stage are designed to change their characteristics under specified circumstances. Materials may change in response to an external stimulus, electromagnetic radiation, temperature or changes in pH. The change may be irreversible or temporary. Any changes in a nanomaterial over time and under different circumstances complicate oversight because the risk may change as the material changes.

Lack of risk assessment methods. Even first-generation nanotechnologies challenge traditional risk assessment methods. Multiple characteristics contribute to the toxicity of many nanomaterials; they include not just mass or number of particles but also the shape of the particles, the electrical charge at the particle surface, the coating of the particle with another material and numerous other characteristics. Science has yet to determine which of these characteristics are most important under what circumstances, and determining this will not be easy. There are thousands of potential variants of single-walled carbon nanotubes (Schmidt 2007, p. 18), and single-walled carbon nanotubes are only one of hundreds of types of nanomaterials. Next-generation nanomaterials will pose even greater problems, depending on the materials, functions, and types of applications.

Self-assembly. A number of next-generation nanotechnologies entail designing

materials that arrange themselves into complex and useful nanoscale structures with little or no additional manipulation. Engineered molecules and nanoparticles, when mixed together, naturally form into increasingly complex structures that may result in more energy-efficient manufacturing and the possibility of designing nanomaterials that can assemble in normally inaccessible places—such as within the body. Crystals are a very simple form of self-assembly: under the right conditions, atoms naturally assemble together into regular structures—often with valuable properties. Most biological systems rely on self-assembly at the nanoscale—where, under the right conditions, molecules assemble to form proteins with specific shapes and chemistries, which in turn combine to form increasingly complex systems and, eventually living organisms. Nanotechnology researchers are working on engineering advanced nanomaterials that self-assemble into useful structures in a variety of environments. Potential applications range from self-assembling templates for nanoscale integrated circuits to self-assembling biological structures that can aid nerve regeneration.

Simple self-assembly—such as crystal formation—does not raise specific new challenges. However, three aspects of self-assembly and its use in next-generation nanotechnologies potentially raise new challenges in understanding and addressing risks: (1) the in-situ transformation of materials from one form to another, with the resulting substance having a very different risk profile than that of the precursor materials; (2) the unanticipated and uncontrolled self-assembly of nanomaterials in places where they could cause harm—such as within the body or the environment; and (3) the possibility that under some circumstances self-assembly could set off a chain reaction of nanomaterial formation that could prove harmful. While at present it is by no means certain that these are valid concerns, they need careful consideration as increasingly sophisticated self-assembling nanomaterials and devices are conceived and explored.

Self-replication. Self-replication can be seen as an extension of self-assembly. Self-assembly that leads to the growth of a nanomaterial with a repeating structure is the simplest form of self-replication. More complex systems are being studied, including nanoscale systems that utilize DNA or other "blueprints" to multiply and grow in a different pattern. These systems can be designed to construct duplicates of themselves or to construct other systems. These and other approaches overlap and can be combined. Rodemeyer (2009) notes that "scientists at Arizona State University have recently reported being able to use a cell's DNA replication process to produce copies of a designed DNA nanostructure, illustrating the overlapping paths of synthetic biology and nanotechnology. Indeed … the distinction between the two disciplines is likely to disappear." Some researchers hope to break from biology completely and to create artificial (non-biological) nanoscale devices that are able to produce copies of themselves in much the same way that cells do. However, there is considerable skepticism over the likelihood of complex non-biological self-replicating systems becoming a reality in the foreseeable future.

Society has had some experience overseeing self-replicating systems in the form of genetically modified plants and organisms. But that experience probably does not provide a good model for regulating nanotechnology-based advances that combine elements of biological and non-biological systems. Fears expressed over self-replication nanotechnologies, such as the "grey goo" scenario, are almost definitely unfounded. Self-replicating systems need the right environment and the

right "food" to survive, and even if scientists were able to create artificial self-replicating nanodevices, it is highly unlikely that they could survive outside the laboratory. Nevertheless, the challenges of developing and using more realistic self-replicating systems safely need to be thought through, if potential untoward consequences are to be avoided

Within this century, the combination of nanotechnology, artificial intelligence, computer science and perhaps synthetic biology may produce a machine that is many times more intelligent than humans. Vernor Vinge, a professor of mathematical sciences, predicted in 1993 that "within thirty years, we will have the technological means to create superhuman intelligence. Shortly after, the human era will be ended" (Vinge 1993). This paper is neither predicting the end of the human era nor proposing an oversight system for self-willed robots, but it is important to be aware that some future technologies will pose challenges unlike any we have dealt with in the past.

Next-generation nanotechnologies will straddle areas of expertise and application in complex ways, and they will respond and adapt to the environment in which they are used. There is a danger that because of their invisibility, they will be treated like simple atoms and molecules from an oversight perspective. This would be as inappropriate as regulating human-scale products by the atoms and molecules of which they are made. Instead, new thinking is needed on how to ensure the safe use of nanoscale products.

2. EXISTING OVERSIGHT AND NEXT-GENERATION NANOTECHNOLOGY

A series of papers by this author and others have examined the applicability of U.S. oversight mechanisms to first-generation nanotechnologies (see cites above). All these authors have found serious gaps and inadequacies with current oversight. If there are serious problems with oversight of current technology, it should not be surprising that the problems of overseeing future technological developments will be even greater. New oversight mechanisms are needed.

This section describes the problems that may arise when the current system is applied to next-generation nanotechnologies. Although it focuses on U.S. oversight, some references will also be made to European institutions and policies. The section begins with a description of the requirements for an adequate oversight system so that the reader has a basis for evaluating the current system. It then analyzes how existing oversight programs would apply to new technologies.

REQUIREMENTS FOR AN ADEQUATE OVERSIGHT SYSTEM

An adequate oversight system must, at a minimum, be able to assess potential risks from a technology, minimize the chances that the risk will occur and maintain surveillance to identify risks that do occur. It should perform these functions while minimizing adverse impacts on technological innovation or market functions and while giving the public confidence that the system is effective and that it allows public opinion to be heard.

The starting point for any oversight system is the ability to identify the risks that a technology may pose and to assess the likelihood and the magnitude of such risks. Such an assessment requires both general scientific knowledge and data about each specific technology and product.

The relationship between science and data is complex. Without an adequate scientific framework there is no way to know what data to collect. For example, which aspects of a nanomaterial are most relevant in determining its toxicity? As noted above, more than a dozen characteristics have been suggested even for relatively simple nanomaterials. What will be needed in addition with more complex active nanotechnologies? Without better scientific knowledge we do not know what data to collect and examine. On the other hand, progress in developing the necessary scientific knowledge often depends on having a lot of data on specific materials. Only by having such data can we develop and test the needed scientific hypotheses.

Oversight cannot directly improve scientific knowledge. It can, however, make clear the need for such knowledge, frame the questions that need to be answered and, through requirements imposed on manufacturers, generate the data needed by scientists. How to apply adequate oversight when the state of scientific knowledge is not adequate is one of the basic dilemmas in developing and applying 21st-century oversight mechanisms. In most cases, the science related to risk will be primitive and uncertain, but the potential risks will be serious enough so that lack of oversight will not be an acceptable option.

Once information about the potential risks of a new material or product has been obtained, an adequate oversight system must be able to

impose requirements that prevent adverse effects from occurring or at least minimize the risks from the new product. This can be done in a variety of ways. Restrictions may be put on the product as a condition for allowing it to be marketed. Standards may be established to prevent worker or environmental exposure while the product is being manufactured, transported, stored, used or disposed of. Restrictions or requirements may be imposed on the product after it has been marketed, or the manufacturer may be required to withdraw the product from the market altogether. Additional steps can be taken to encourage green design and pollution prevention.

Because of the complexity of new technologies and the rapid pace of invention and adoption, the science will probably be inadequate to fully identify all the risks a new material or product will pose. For this reason, even more than in the past, it will be necessary to establish requirements and systems for identifying adverse effects of a product after it is in commercial use. A high degree of international cooperation will be necessary for such systems to work effectively.

These oversight requirements should be applied with a constant awareness of the need to encourage technological innovation and economic growth. The "cowboy ideology" that views regulation as antithetical to free markets has proven to be false in sector after sector. Productive markets *require* effective regulation. However, there is an undeniable tension between the two. It is unlikely that government agencies will improve their efficiency, speed and expertise sufficiently to keep pace with technological innovation. To avoid setting up large obstacles to that innovation, oversight mechanisms will have to rely more on manufacturers to assess and control risks. At the same time, oversight will have to be structured to assure that manufacturers know what information is needed, collect the information in a reliable way and do not abuse their responsibility.

Most existing oversight systems fall far short of the criteria outlined above. An examination of how specific current oversight authorities would apply to new nanotechnologies reveals many problems.

EXISTING OVERSIGHT APPLIED TO NEXT-GENERATION NANOTECHNOLOGY

Existing oversight of nanotechnology applies to three categories: substances, products and wastes. Each category poses particular kinds of problems.

Nanomaterials or substances are regulated in the United States by TSCA and in Europe by the regulation on **R**egistration, **E**valuation, **A**uthorization and Restriction of **Ch**emicals (REACH). The term *substances* is used in U.S. law; *chemicals* is used in EU law and *materials* is used in scientific and common parlance. This report uses the three terms interchangeably.

TSCA's weaknesses have been documented elsewhere (see Davies 2006, 2007; Schierow 2007). The act is unable to regulate existing substances at all. EPA has explicitly declined to consider nanomaterials as new substances unless they have a novel molecular structure, and therefore most nanomaterials are not regulated. Even manufacturers of the 30-or-so nanomaterials whose structures have been considered novel have not, with one exception, been required to submit safety data. EPA must show that the substance poses an "unreasonable risk" before it can require the data to determine whether the substance poses a risk.

TSCA was enacted in 1976 and has not been significantly changed since that time. REACH, by contrast, is a relatively new regulation; it was enacted by the European Union (EU) in 2007. It erases the distinction between new and old

substances, and it puts the burden of proof on the manufacturer to show that a substance is safe. However, many of the REACH requirements are triggered by volume of production, generally an inappropriate metric to apply to nanomaterials. Since REACH's enactment there have been ongoing discussions in the European Commission (EC) about how nanomaterials should be treated under the regulation. (For the current status of these discussions see European Commission 2008.)

As will be discussed in the next section of this paper, oversight of future nanotechnologies will probably have to focus on products rather than on substances because the same substance will have widely different impacts depending on the products in which it is used. Beyond that, the new technologies will pose major problems for both TSCA and REACH. Will a nanostructure composed of a few molecules be considered a chemical? If the nanomaterial or structure changes form when exposed to particular stimuli, which form is subject to regulation? If nanoscale substances self-assemble to create new substances, how will that be regulated? These are just some of the reasons that a focus on products is likely to be necessary. Although REACH is far superior to TSCA in its ability to protect the public, neither regulatory scheme is likely to be effective in providing oversight for new nanotechnologies.

Some regulatory programs in the United States and Europe focus on specific products. In the United States, these products include drugs, medical devices and food additives regulated by the Food and Drug Administration (FDA); pesticides and fuel additives that are registered by EPA; beef, poultry and some other farm products regulated by the Department of Agriculture; vaccines regulated by the Centers for Disease Control and Prevention; and a residual category of consumer products for which the Consumer Product Safety Commission (CPSC) is, in theory, responsible. The structure in the EU is similar in the sense that multiple product categories are regulated by a variety of agencies at both the national and EC levels. The U.S. product-focused systems vary in stringency. Most are on the more stringent end of the spectrum, placing the burden of proof on the manufacturer and requiring extensive safety testing. However, as an example at the other end of the spectrum, the CPSC is so lacking in legal authority and financial resources that most consumer products in the United States are, for all practical purposes, unregulated (see Felcher 2008). Although more than half the nanoproducts in the PEN inventory are under CPSC's jurisdiction, the commission to date has spent only $20,000 on nanotechnology (for a literature search) (*Ibid.*).

Because the specific characteristics of specific products are likely to determine the adverse effects that might occur, future oversight will need to focus primarily on products. The basic difficulty, from the oversight perspective, is the overwhelming number of products that exist and the large number of new ones that come on the market daily. Furthermore, most products do not pose serious risks to health or the environment, so trying to regulate all of them, even if possible, would be a significant waste of resources. It is neither possible nor desirable that the government regulate all products, and it will be even less possible in the future as the number and variety of products increase.

The third type of regulatory program focuses on pollution and wastes or, in the case of occupational safety and health, on places. In the United States, examples are the programs under the Clean Air and Clean Water Acts, the laws dealing with disposal of hazardous substances and the Occupational Safety

and Health Act. In the EU, pollution is dealt with primarily through the Integrated Pollution Prevention and Control (IPPC) directive. Workplaces are regulated primarily by the governments of the member nations.

For nanotechnology, and probably for other future technologies as well, both monitoring and control methods are problematic. In the absence of adequate pollution monitoring and/or control methods, prevention has to be the primary method of protecting humans and the environment. In the United States, and perhaps in Europe, waste laws focus on pollution after it is created. They are not very effective in preventing pollution. The usefulness of pollution control laws is thus likely to be limited, and greater reliance will have to be placed on product control laws.

Moreover, pollution control laws are likely to become less important because greener manufacturing methods will result in reduced pollution from manufacturing plants. This is not to say that pollution problems will disappear. In fact, a number of studies have shown that current methods of producing nanomaterials are often energy intensive and use a variety of toxic materials (Sengul et al. 2008; Kushnir and Sanden 2008; Healy et al. 2008; Eckelman et al. 2008; Singh et al. 2008). It is difficult to evaluate the results of these studies, at least for nanomaterials, because they do not take into account either the smaller mass of nanomaterials produced or the environmental efficiencies that result from nano applications. For example, one study (Kushnir and Sanden 2008) emphasizes that production of carbon nanoparticles is "2 to 100 times more energy-intensive" than production of aluminum, but the study measures energy intensity per weight of production without mentioning that, by weight, aluminum production is five orders of magnitude greater than carbon nanoparticles production.

The inadequacy of the current system to deal with new technologies is obvious. Especially in the United States, regulatory oversight has always been somewhat deficient, and over the past 30 years it has been allowed to deteriorate to the point where only major changes can rescue it. On both sides of the Atlantic, extreme free market ideologies have contributed to the erosion of oversight. Furthermore, there has been a failure to anticipate and analyze the new technologies that are being created and commercialized at an ever-increasing rate.

Gaps in the oversight system are significant. In the United States, cosmetics and dietary supplements, both product types that use nanotechnology and involve high human exposure, are subject to laws that *prohibit* effective oversight.

Two of the most important oversight problems are large and encompassing but are frequently overlooked. One problem is that no country has a comprehensive and coordinated oversight system. Both the United States and the EU have individual programs that deal with particular aspects of nanotechnology, but these programs are fragmented and uncoordinated. In the United States there is no effort to develop an overall system for nano oversight, much less for dealing with other new technologies that will shape the 21st century (see, for example, Rodemeyer 2009).

The second problem is the absence of institutions and mechanisms for dealing with the social impacts of new technologies. We do not have good ways of examining the impacts of technologies or getting public input on the impacts, and we often lack good tools for encouraging positive social impacts or discouraging negative ones.

The next section describes a new approach designed to address the problems of technology oversight.

3. THE FUTURE OF OVERSIGHT

This section explores what a more adequate oversight system might look like. The approach proposed is largely non-incremental because, in the author's view, the existing system is so deficient and the new challenges are so different from those of the past that it would be a mistake to try to deal with them by tinkering with the existing system. The political system operates incrementally except when faced with a crisis, and it is to be fervently hoped that no crisis arises with respect to nano or any other technology. However, over the long run, the political system also responds to models of what could or should exist. Goals and ideals, even if a sharp departure from the status quo, can influence the thinking of policy makers and the public. Many of the changes described below will take a decade or more to accomplish, but there is an urgent need to start thinking about them now.

The proposals set forth in this report are intended to be the start of a dialogue, not its conclusion. The purpose is to draw attention to the need for basic reform and to frame the magnitude and direction of the needed changes. If the proposals catalyze a serious discussion of oversight policies to deal with the problems of the coming decades, then this report will have achieved its purpose.

A new system requires a new organization, new legal authorities and new oversight tools. This section begins with a description of a new hypothetical organization, the Department of Environmental and Consumer Protection. Then, to describe the new authorities and tools that would be required and to flesh out the nature of the new organization, the paper discusses product regulation, pollution control, monitoring and technology assessment. Each of these would be a basic function of the new agency. Finally, the section analyzes several additional important areas that require new approaches—risk assessment, enforcement, international cooperation and public involvement. Each of these functions cuts across the basic organizational building blocks described earlier in the section.

INSTITUTIONAL FRAMEWORK

A new oversight system is urgently needed both because of the pitiful state of the current system and because of the nature of the new challenges presented by technological change.

The characteristics of the new technology have been described above. The current oversight system was designed to deal with the problems of steam engine technology in the context of a pre-computer economy. It was based on assumptions that most problems are local, that programs can be segmented and isolated from each other, that technology changes slowly and that all the important problems have been identified. All of these concepts are no longer valid, if they ever were.

The antiquated conceptual basis of the system has been made more evident by the massive erosion of money and manpower from a system that always suffered from inadequate resources. However, resources alone are not what is needed. New concepts, new types of organizations and new tools are necessary to provide the knowledge and flexibility for effective oversight.

A new structure for 21st-century oversight requires more integrated approaches at every level. The current fragmented system was tolerable as long as the problems were limited in scope and localized in scale. This is no longer

the case. The problems of the 21st century have a potentially broad impact that is not limited to any single geographic area. They do not and will not fit into the compartments delineated by current legislation.

At the level of individual programs, fragmentation hinders effectiveness now. There are almost more pollution control programs than anyone can count, and pollution control and prevention are handicapped because current government regulations focus narrowly on air pollution, water pollution or various forms of disposal. In another area, environmental monitoring is inefficient and unsatisfactory because of the multiple agencies trying to monitor interconnected parts of the environment, each agency doing it in its own way.

At a broader level, regulation of different kinds of products can benefit from drawing on the same risk research or the same systems for monitoring adverse effects. Different types of research can benefit from a single source of monitoring data. There are many such synergisms.

Another pressing need is for scientific support that is based on high-quality research and that is relevant to the needs of oversight. In the United States, both EPA and FDA have had the advantage of in-house scientific support, but the amount of support is inadequate. A recent report by a subcommittee of the FDA Science Board stated, "The FDA cannot fulfill its mission because its scientific base has eroded and its scientific organizational structure is weak" (U.S. FDA 2007, p. 3). FDA and EPA have had problems attracting and retaining good scientists because most scientists would prefer to work for a science agency than for an oversight agency.

Unlike the current EPA and FDA, which are oversight agencies with a scientific component, the new agency would be a scientific agency with an oversight component. Both the research and assessment component and the monitoring component of the new agency would focus on science, and each of these components probably would be larger than the oversight component. The scientific complexity of 21st-century problems requires oversight agencies that have strong scientific competence.

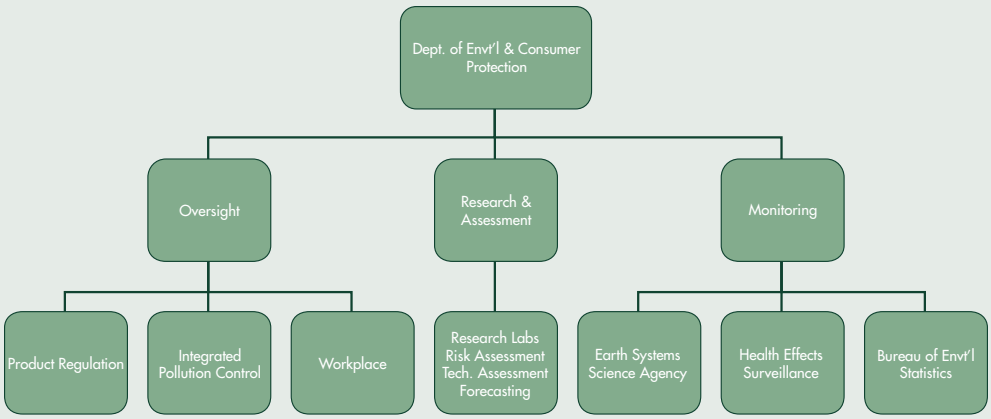
An additional need is for laws and organizations that are flexible enough to respond to the characteristics of technology described in the first part of this paper. The existing U.S. federal oversight agencies have generally been too small to have much flexibility. All their resources are devoted to survival and to the performance of the minimal required functions; they have limited ability to anticipate and respond to new problems or to consider new ways of doing things.

Meeting these needs would require both new laws and a new organization. This short paper does not cover new laws in any detail, although some suggestions are included in the discussion below. A new organization that would provide more integration, better science and more flexibility is outlined in Figure 2.

The organization depicted in Figure 2 could provide a more adequate basis for oversight than the current system does. It would focus oversight on products, pollution and the workplace, and do so in a more integrated way. In addition to an oversight function, the organization would have major components devoted to monitoring and research. The research function would also deal with technology assessment and forecasting.

A new agency would make many synergisms possible among the different functions and programs shown in Figure 2 and would facilitate integration of closely related programs. Although this paper focuses on nanotechnology,

FIGURE 2. Hypothetical Department of Environmental and Consumer Protection



the reorganization would improve the government's ability to handle almost all major environmental and consumer programs. For example, it would allow climate change research and modeling to be brought together under one agency (under the research and monitoring functions). The same agency would be responsible for controlling greenhouse gases (under the oversight function), and the head of the agency could formulate overall climate policy with the benefit of advice from both the scientific and regulatory components of the agency.

The new agency would incorporate six existing agencies: EPA, the U.S. Geological Survey (USGS), the National Oceanic and Atmospheric Administration (NOAA), the Occupational Safety and Health Administration (OSHA), the National Institute of Occupational Safety and Health (NIOSH) and CPSC. New units would have to be established for risk assessment, forecasting, technology assessment, health monitoring and the Bureau of Environmental Statistics.

The appendix provides some dollar and personnel estimates for the hypothetical agency. The estimates are based on the current size of the component agencies plus some additional dollars and personnel based on estimated need. The proposed agency would be among the smaller federal cabinet departments but not the smallest. In terms of full-time equivalent (FTE) personnel, for example, it would be ten times larger than the Department of Education and four times larger than the Department of Housing and Urban Development. However, it would be half the size of the Treasury Department and a quarter the size of the Department of Homeland Security.

The new agency would be significantly larger than the current EPA or any of the other federal oversight agencies. The oversight functions should be housed in a larger organization not only because of the relationship between size and flexibility noted above but also because the current small size of the regulatory agencies makes them vulnerable to becoming even smaller. The "large getting larger" seems to be the organizational analogue of the rich getting richer. Smaller agencies have less influence and are less able to influence policy than larger agencies are. Aside from this political point, the small size of the oversight agencies prevents them from being able to devote resources to new problems, and in the 21st century new problems will arise frequently.

Large size can have the disadvantage of encouraging slow and rigid decision-making and discouraging innovation and creativity. To reduce these disadvantages, many of the components of the new agency would be allowed to operate with a good deal of independence. The success of the new organization would depend greatly on the degree to which it could strike a good balance between integration and independence of the components.

Other functions could be added to the new agency. For example, food-safety programs, currently scattered among four federal agencies, could be consolidated in the proposed department. However, this function and other functions are not included here because they are subject to other legislative proposals or other considerations beyond the scope of this paper. Consideration should be given to creating a commission to consider the composition of the new agency as well as possible new oversight laws and tools.

PRODUCT REGULATION

A central question for oversight is whether it should focus on materials or products. The answer will determine many of the most important parameters of the oversight system. The current oversight systems focus on both materials and products. Materials are regulated by TSCA and REACH; various kinds of products, (e.g., drugs, pesticides and beef), are regulated under a variety of other laws.

Materials are substances with particular characteristics. TSCA defines them as substances with a particular molecular composition, although size or form should be added as a relevant defining characteristic to deal with nanotechnology. Other characteristics of a material, such as radioactivity, may also be relevant for oversight.

Products are items that are sold to public consumers, manufacturers or others. A product may go through multiple stages, each stage being a separate product. For example, carbon nanotubes (one product) can be combined with plastic in a compound used for car bodies (a second product), and that compound is incorporated in a finished automobile (a third product). A material is usually a product, and the same material can be incorporated in many products.

An oversight system based only on products would be better than the current mixed system. The way in which the material is used, the way it is combined with other materials, and other factors are critical for determining whether adverse effects will occur (Royal Commission on Environmental Pollution 2008). Therefore, materials by themselves do not provide a good basis for evaluating risk. If some types of carbon nanotubes can cause asbestos-type problems, for example, these problems can be avoided by combining the nanotubes with other materials, by using them only in closed systems or by making minor changes in the form of the nanotubes. Regulation of products will capture these differences—regulation of the material will not. Whether it is possible to establish an oversight system based on products rather than materials will depend on what the system looks like.

At least two principles should underlie oversight of products. First, oversight should encompass the life cycle of the product—manufacture, use and disposal. Transportation is also part of the life cycle, but it can be regulated separately by the Department of Transportation. Second, the degree of oversight, i.e., the stringency of regulatory requirements, should be related to the anticipated harm the product will cause. This is a function of the severity of anticipated harm and the likelihood that it will occur.

The government is not likely to have detailed and current information about the

composition of a product, its intended use or its anticipated effects. Only the manufacturer will be able to know or obtain this information on a timely basis. Thus, the government inevitably must depend on the manufacturer to reliably test the product and to accurately report relevant information to the government. The penalties for distorting, concealing or failing to obtain required data must be sufficiently great to deter such behavior.

A previous report (Davies 2006, p. 19) suggested that the information required of the manufacturer be incorporated in a sustainability plan (SP) that the manufacturer would compile. A plan would be required for each product. The plan would contain a summary of known information about the components of the product, the adverse effects of the product, a life-cycle analysis of the product describing its use and manner of disposal and an explanation of why the product would not cause any undue risk. The government would define as precisely as possible what data are required and what constitutes undue risk. Risk would include mechanical risks (e.g., from chainsaws or collapsing baby cribs) as well as chemical and biological risks. It seems reasonable to require every manufacturer of a product to know this information before selling the product. The government could require additional information for particular categories of products. The SP would have to be updated if the manufacturer became aware of new information that affected the product's risk.

A number of firms have voluntarily produced statements similar to a sustainability plan. For example, Apple issued an environmental report on its MacBook Air laptop computer (images.apple.com/environment/resources/pdf/MacBook-Air-Environmental-Report.pdf). The report includes sections on climate change, energy efficiency, material efficiency, restricted substances and recycling. DuPont, in cooperation with Environmental Defense, developed a framework for analyzing the risks of nanomaterials (www.nanorisk-framework.com). The framework is applied to all new DuPont nanoproducts. For many chemicals, the SP would resemble the chemical safety assessments required under REACH.

Because every product (except those exempted) would have to have an SP, manufacturers would be able to know the potential risks of components they use by requiring their suppliers to provide them with the SPs for the components. This would be a major benefit to manufacturers of complex products like automobiles. At present, auto manufacturers may be legally liable for problems caused by components they use, but they may have no practical way to find out what the risks of the components are. REACH (Article 34) requires risk information to be passed on from any actor in the supply chain to the next actor or distributor up the supply chain.

Special efforts will be needed to inform small businesses about the requirements and to provide these businesses with technical assistance to help them meet the requirements. A variety of programs can be used to do this. Small businesses should not be exempted from oversight because some of the most dangerous products are made by small manufacturers, and it is not unreasonable to expect them to assess whatever dangers their products might pose.

What would be done with the sustainability plan and what additional information, if any, it would have to contain, would depend on the harm the product might cause. A possible typology is as follows:

Category 1: This category would be for products that have a very low probability of having adverse effects. There would be no oversight; the SP would simply be retained by

the manufacturer, or, if there were clearly no significant risks, the product manufacturers might be exempted from the SP requirement altogether. Examples of category 1 products are books, furniture and some industrial tools—probably 70–90 percent of all products in commerce. There is always the possibility that new evidence will move a category 1 product to a different category.

Category 2: This category would be for products for which risk-communication measures should be sufficient to avoid adverse effects. The manufacturer would be required to use the SP as the basis for a product safety data sheet to be given to users and/or for labeling for consumers. Examples of products in this category would include some household cleaning products and industrial catalysts that are consumed in the manufacturing process.

Category 3: Post-market review of the SP by government. This category would consist of category 1 or 2 products suspected of causing adverse effects after having been sold. The government would be empowered to halt manufacture and/or distribution of the product pending a review of its safety.

Category 4: This category would be for products that have some probability of causing adverse health or environmental effects. There would be pre-market review of the product. Products in category 4 would include pesticides, fuel additives and products containing designated types of materials (e.g., persistent organic pollutants).

The government would define the categories and decide which products belong in which categories. To the extent possible, the government would assign broad classes of products to particular categories. If a manufacturer wanted to produce a product that was not included in one of the previously assigned classes, it would have to submit a request to the government to designate which category the product belonged in.

For categories 3 and 4, the burden of proof would be on the manufacturer to demonstrate that the data in the SP were valid and adequate and that they supported the conclusion that the product would not or did not pose undue risk. The government might have to show some cause for categorizing a product as category 3.

As noted above, the major challenge in regulating products is the enormous number of products on the market at any given time. For example, CPSC oversees 15,000 types of products, and each type contains numerous individual products. Inevitably, the number of products placed in each category would, to some extent, be determined by the resources available to the government oversight agency. The first two categories would require only spot checking by government, and category 3 probably would apply to only a relatively small number of products. Category 4 would require intensive use of government resources. Consideration should be given to paying for product approval through fees, as is now done for drug registration by FDA, although steps would need to be taken to avoid some of the problems with the FDA system. Consideration should also be given to making public on a regular and timely basis whatever gap may exist between resources and oversight requirements. This could be done by requiring the agency to regularly publish the number of products that should be reviewed but for which resources were not available to do the review.

INTEGRATED POLLUTION CONTROL

Pollution control is control or prevention of harmful wastes. *Pollutants* are unwanted by-products of manufacture or use. Unlike materials or products, they have no value and the oversight goal can be to reduce pollutants to

the smallest amount possible. This goal is not applicable to materials or products because, since they have value, the benefits of the product to society must be weighed against the cost of its adverse effects. Even with respect to toxic materials it is necessary to consider the benefits they provide. Pollutants that can be recycled become, strictly speaking, products because someone will pay for them and therefore they have a value.

The dividing lines into which pollution control has been segmented are a significant handicap in dealing with present and future problems. For example, control of nanoparticles released during manufacture must be based on preventing the releases from occurring. Trying to deal with the problem by separately regulating releases to the air or the water or land, as current law does, will not work.

In Europe, integrated pollution control is a reality (U.S. EPA 2008). In 1996, the EU approved the IPPC directive. The directive mandated that each EU member nation establish a system based on an integrated pollution permit for each facility. The EU set up a mechanism to assist the countries with such a system, in particular by defining sector-specific Best Available Technology, the standard to be incorporated in each permit. The IPPC permits cover not only disposal to air, water and land, but also such matters as energy and water use, noise and odors, accidents and facility decommissioning.

As stated in a comprehensive U.S. government report on IPPC permits in the United Kingdom, "the U.S. does not have a corresponding, all-inclusive environmental statute to address emerging challenges on a comprehensive, ongoing, and straightforward basis." (U.S. EPA 2008, p. xi). A U.S. facility typically must have dozens of environmental permits (Davies 2001). Each federal program (air pollution control, etc.) requires several different types of permits, and in addition to the federal permits there are state and local permits. A large facility will require several filing cabinets (or many megabytes of computer space) for the contents of the different permits it holds. The system not only results in bureaucratic duplication and confusion but also makes permitting opaque to the public. Moreover, because of the fragmentation, it fails to control a significant portion of a facility's environmental impact (*Ibid.*). Although the EU's IPPC system operates in a political and cultural context different from that of the United States, the United States would benefit from adopting an approach more like the EU's.

The linkage between oversight of products and control of pollution (wastes) has not been adequately explored on either side of the Atlantic. Regulation of materials and products may, in some cases, be the most effective and efficient way of preventing or reducing wastes. In the United States, the linkage is recognized—TSCA authorizes the EPA Administrator to, among other things, regulate the manufacture, use and disposal of a substance that presents or will present an unreasonable risk (TSCA sec. 6(a)). However, these authorities have rarely been used. In the 30-year history of TSCA, EPA has used these authorities to regulate a total of six existing chemicals (Schierow 2007, p. 17). It is likely that to deal with future problems, the product control laws will need to become a more significant part of environmental protection.

TECHNOLOGY OVERSIGHT AND ASSESSMENT

A *technology* can be defined either as a body of scientific knowledge and its application or as the practical application of a particular body of scientific knowledge. To the extent that

the definition includes scientific knowledge, it probably would be impossible to regulate this kind of knowledge and, even if it were possible, it would be counterproductive. Oversight focuses on the applications of a technology. However, the line between the science and its applications may be difficult to draw, especially when dealing with the social implications of technology. Would a new material that enabled the human brain to grow additional neurons be considered science or the application of science? Focusing on particular applications may miss the overall impacts of a technology, and by the time the implications of the applications become clear it may be too late to effectively influence the direction the technology takes. With only a few exceptions (e.g., nuclear power) technology as such is not and should not be regulated in the same sense that products and wastes should be regulated. However, oversight can take forms other than regulation.

The impacts of new technologies on society in the 21st century will be huge. We can deal with these impacts to some extent by regulating products, materials and wastes. But many of the most important impacts will not be captured within these categories. When one thinks of the impacts of the automobile on society, air pollution does not seem to be among the biggest, important as it is. Three things are needed for oversight of technology: (1) an assessment of the technology's impacts, especially unintended impacts; (2) ways for the public to understand the technology's impacts and register its views; and (3) ways for the government to translate the public's views into actions. None of these requirements is being satisfactorily met.

In one sense, technology assessment is done all the time. Measuring pollution from various sources, modeling the impact of climate change and estimating future sales of computers are all elements of technology assessment. However, what is needed is a capability to consider the overall impacts of major new technologies and to do so while there is still time to deal with the impacts. This requires a forecasting capability as well as an assessment capability. The techniques for doing forecasting and assessment have not received the attention they need. Not coincidentally, the institutions for making forecasts and conducting assessments are weak or non-existent (see Davies 2008, pp. 23-24).

Involving the public in the evaluation of new technologies poses many difficulties. It should be understood that the public *will* become involved, politically and economically, as protestors or boosters or customers. However, the involvement is mostly after the technology has become established. The future of the world's people will be shaped by new technologies, but there is usually no opportunity for people to consider which technologies should be promoted, which should be discouraged and how to deal with the consequences and impacts of any particular technology before the impacts occur.

How the government should influence the direction of new technology is also a knotty question. The government exerts a major influence now through financial support for private research and development, appropriations for defense and other science-intensive government programs and regulations (or the absence of regulations) on various activities. All these actions usually are taken piecemeal, without any coherent strategy for the overall technological future of the world or even for the future of any particular technology.

Consideration should be given to using "social impact statements" analogous to the environmental impact statements required of

government projects. The statements would provide a vehicle for the public to learn about new technologies and for both the public and the government to consider what steps, if any, should be taken to maximize the beneficial impact of the technology and to minimize its adverse effects. Who would prepare the statements, when would they be prepared, what would be their scope and level of detail and how they would be disseminated are all questions that would need to be answered.

Individual government agencies need to become more aware of their impact on technological development and of the impact of technologies on society. The foremost example is the military, which has given us a large number of significant technologies ranging from DDT to the Internet. The Department of Defense should establish a Defense Technology Review Board to weigh the civilian as well as the military consequences of new military technology. Board members would have to be privy to all aspects of defense research and development. The board would provide advice both to the military departments and to the President's Science Advisor.

MONITORING

Monitoring is an essential part of oversight. It provides the link between government actions and the real world. The institution outlined in Figure 2 would do two types of monitoring—environmental and human.

Environmental monitoring in the United States includes a broad set of functions conducted by a number of agencies. Recently, a distinguished group of science policy experts proposed combining the two largest agencies, NOAA and USGS, into a single, independent Earth Systems Science Agency (Schaefer et al. 2008). NOAA has a budget of nearly $4 billion and 12,000 employees. USGS has a $1 billion budget and 8,500 employees (*Ibid.*). The structure in Figure 2 would adopt the experts' proposal but would make the Earth Systems Science Agency a semi-independent part of the proposed Department of Environmental and Consumer Protection. The monitoring part of the department also would include the EPA monitoring functions and a Bureau of Environmental Statistics, analogous to the Bureau of Labor Statistics. The bureau proposal has been around for 20 years and has several times come close to becoming law, but has never quite made it usually because of extraneous factors.

In addition to the Earth Systems Science Agency, there should be a human-health monitoring component. Given the uncertainties of risk assessment for new technologies, some adverse consequences of new products will probably be missed when the product is first commercialized. These consequences will not be identified unless there is an extensive surveillance system that spots abnormal health phenomena such as an excess number of cases of a given disease or a spike in emergency room admissions. It is beyond the scope of this paper to provide details about such a system, but it should be coordinated with other domestic and international health reporting systems and it should be as unobtrusive as possible.

RISK ASSESSMENT

The above discussion provides some detail about the major components shown in Figure 2. Four functions cut across most of the components: risk assessment, enforcement, international cooperation and public involvement. Each of these will be discussed in the context of 21st-century technologies.

Adequate oversight of new technologies will depend on our ability to forecast the risks the technologies pose. Forecasting the risk

involves basic scientific information about the technology, test data on specific products and risk assessment. Each of these components has a different source and different characteristics.

Basic scientific information comes primarily from university and government laboratories. The motives for developing the information include scientific curiosity, the possibility of obtaining grants and contracts and the possibility of making money through patents and/or start-up companies. Meeting societal needs, such as identifying the risks of new technologies, is often not a major consideration in setting the basic science agenda. This is one reason why it is important for government oversight agencies to have their own scientific resources.

Testing of specific products is done primarily by their manufacturers, either in-house or through contract laboratories. It is beyond the resources of government agencies to test the multitude of products and, in any case, the manufacturer will be most knowledgeable about the products it is making.

Testing for new kinds of products can be problematic. For example, it is often not known what end points (e.g., cancer, asthma, fish mortality) to look for when testing nanomaterials nor is it understood which characteristics of the material are associated with adverse effects. In the absence of testing, conclusions about the safety of a product or material are often based on analogous materials that have been tested. However, by definition, new types of materials and products do not have exact analogues that have been tested. When technologies are evolutionary, as many nanotechnologies are, analogues may help predict behavior, but they are still generally not an alternative to testing. The technology of testing is itself changing, and there has been progress in developing tests that are much faster and cheaper than current tests that rely on laboratory animals (Service 2008).

The type of risk assessment usually done by the government has evolved into a highly sophisticated set of procedures. Risk assessment must be used if government decision makers are to make rational decisions.

Risk assessment was developed to meet the needs of decision makers. It did not grow out of any scientific questions, and assessments typically are not scientific products; they are a way of organizing and analyzing data about a particular substance or product. They are not scientific because only in unusual cases can they be empirically verified. The typical risk assessment may result in a finding that substance X will produce Y number of additional cancer cases per million people exposed. However, whether Y is zero or 1,000 in reality will never be known and typically is unknowable because there are too many other causes of cancer. Regulatory decisions almost always must be taken based on the weight of the available evidence. Conclusive scientific proof is usually not to be had, although the better the available science the easier it is to do a risk assessment and the more accurate the assessment is likely to be.

Because decisions typically must be based on balancing the available evidence, the default assumption about who has the burden of proof is critically important. Rodemeyer (2009) has observed that "in many cases information about risks of a new technology is simply unavailable or uncertain. In such cases, the regulatory decision depends upon the default policy assumptions about the inherent safety of the technology. In turn, the default policy assumption is shaped by the framing of the new technology in relation to existing technologies." (Also see Jasanoff 2005.)

REACH primarily puts the burden on the manufacturer to prove safety, whereas TSCA

puts it on the government to prove risk. This makes REACH a more effective oversight law. Industry occasionally argues that the burden should be on the government because it is not possible to prove safety, but this is a fallacious argument. It is not possible to conclusively prove the safety of a product just as it is usually impossible to conclusively prove the risk. Risk and safety are both operationally defined by required tests, and it is equally difficult to prove either one.

ENFORCEMENT

Enforcement has two related dimensions—incentives and compliance. The stronger the incentives the better the compliance, but the two dimensions involve different considerations.

The increasingly rapid pace of technological innovation and the diversity of the innovations have made it difficult to apply many of the older enforcement approaches. Newer approaches have emphasized economic incentives and flexibility. Liability has been used as the major incentive in one U.S. waste law (the Comprehensive Environmental Response, Compensation, and Liability Act of 1980), and it might be possible, for example, to make manufacturers legally liable for failure to develop a sustainability plan or for any adverse consequences that could reasonably have been foreseen but that were not included in the plan. A downside to using liability and litigation in implementing regulatory oversight is that government employees might have to spend large amounts of time giving testimony in court, making depositions and participating in litigation in other ways. This might seriously affect their ability to perform their primary duties (Mark Greenwood, personal communication).

Cap-and-trade programs, such as the one used in the U.S. regulation of sulfur dioxide emissions from power plants, have been proposed as a substitute for much of the existing pollution control structure (see http://www1.law.nyu.edu/conferences/btl/index.html; accessed 11/11/08). Effluent fees and charges have also been used in a few situations and have been suggested as an approach that could be used more widely. It is not clear whether these kinds of approaches could be used for oversight of useful products (as contrasted with wastes) and, at the least, caution must be exercised when proposing that incentives developed for curbing wastes be applied to useful products.

Insurance is another incentive that can be important. It can be used either negatively or positively. Negatively, one insurance company has already refused to insure for any damage connected with nanotechnology (Rizzuto 2008), citing the lack of adequate risk information. If other companies follow suit, this could be a major incentive for more research and more testing of products by private firms. Insurers could deny insurance to manufacturers that did not have a sustainability plan. On the positive side, insurance could be given to manufacturers against tort suits if the manufacturer had an adequate sustainability plan and had implemented that plan, and the tort suit covered a subject that was included in the plan.

With respect to compliance, the key question probably is the extent to which voluntary compliance can be relied upon. The answer depends on the cultural context and may differ between Europe and the United States. At least for the United States, oversight in many contexts has shown voluntary compliance to be undependable. Legally enforceable requirements, vigorously implemented, are necessary to deal with the usually small, but important, percentage of firms that are not good corporate citizens.

INTERNATIONAL COOPERATION

The combination of a worldwide economy and near-instantaneous communication among

all nations has made technology oversight an international issue. Every oversight function, from research to enforcement, now has important international dimensions. The challenge is how to embody the international dimensions in effective institutions.

A web of international organizations exists. The EU is itself an international organization. The Organization for Economic Cooperation and Development (OECD), which includes most of the industrialized nations, has taken a variety of initiatives related to new technology. It has agreed to test 14 generic nanomaterials for health and environmental effects, and has established a database for sharing research information on potential adverse effects of manufactured nanomaterials (http://www.oecd.org/document/26/0,3343,en_2649_37015404_42464730_1_1_1_1,00.html). The United Nations has several components relevant to oversight including the World Health Organization, the UN Environment Program, and the International Labor Organization. Many non-governmental international organizations, including international trade associations and mixed public-private organizations such as the International Organization for Standardization, play a part in oversight efforts.

In the long run, an international regime for product oversight may develop to match the international trade in products. At the least, the U.S. and European regulatory approaches should be made consistent (see Breggin and Falkner 2009). In the interim, the emphasis should be on information sharing.

At least three types of information should be made available internationally: (1) research results on adverse effects of a technology; (2) standards, regulations and other oversight policies and decisions applied to a product or technology; and (3) reports of any adverse health or environmental effects that occur and that could be attributed to a product. The OECD has made a start on the first two. The third is an important function that needs to be supported, perhaps by a joint effort of the World Health Organization and the UN Environment Program. An international system for reporting adverse effects would have to draw heavily on existing surveillance systems.

As this is written, the worldwide economic crisis and the collapse of the Doha round of international trade talks have made the future of all international efforts uncertain. One outcome of the current crisis could be a stronger set of international institutions, even perhaps including the basis for an internationalized system for dealing with new technologies and products.

PUBLIC INVOLVEMENT

Transparency should be the hallmark of oversight activities. Without it, the public interest tends to get submerged beneath the interests of bureaucrats, politicians and special interests. Transparency becomes even more important in the context of new technologies because if the public senses that secrets are being kept and motives are being hidden it may reject a new technology regardless of its benefits. As the International Risk Governance Council (2007, p. 8) has noted, the new technologies will require more public involvement because their "social, economic and political consequences are expected to be more transformative." The challenge, as expressed by the Royal Commission on Environmental Pollution (2008, p. 72), "is to find the means through which civil society can engage with the social, political and ethical dimensions of science-based technologies, and democratize their 'license to operate'… a challenge of moving beyond the governance of risk to the governance of innovation."

The 21st Century Nanotechnology Research and Development Act, the law governing nano research in the United States, requires the National Nanotechnology Coordination Office to provide "for public input and outreach to be integrated into the [National Nanotechnology] Program by the convening of regular and ongoing public discussions, through mechanisms such as citizens' panels, consensus conferences, and educational events, as appropriate" (PL 108-153, sec. 2(b)(10)(D)). The National Science Foundation has experimented with some of these techniques, but overall, little effort has gone into implementing this part of the law. Other countries have also experimented with new public participation mechanisms to deal with technology (see, for example, Jones 2008).

In the context of new technology oversight, the public can be thought of as three groups: (1) the insiders—industry representatives, non-governmental organizations, academic experts, labor union representatives; (2) the somewhat informed general public; and (3) the bystanders. The majority of the population falls in the category of bystanders. They do not know about or understand the new technologies and they do not follow what the government does or says about them. However, even the bystanders may influence oversight through their role as consumers, and the products they buy may be influenced by the opinions of the insiders.

A goal of public policy has been to move people from the bystander category to the informed category. This is consistent with a Jeffersonian view of democracy and is an important way of reducing the chances that the public will react against a technology based on propaganda or misinformation. How successful efforts to inform the public can be, what methods can be used and how to draw the line between information efforts and propaganda are important subjects that are beyond the scope of this paper.

THE PATH AHEAD

This is a short paper that covers a broad range of topics. A previous report (Davies 2008) laid out the steps that can be taken in the short run to improve nanotechnology oversight. This paper broadens the coverage in that the suggestions for new oversight mechanisms cover all technologies, not just nanotechnology. It also stretches the timeframe—the focus is technologies and policies over the next several decades. The paper is an exercise in both technology forecasting and policy envisioning. If the forecasts are even roughly accurate, then thinking about new policies is urgently needed.

APPENDIX – APPROXIMATE DOLLARS AND PERSONNEL IN NEW DEPARTMENT

Agency	Oversight		Research		Monitoring		Total	
	$s	FTEs	$s	FTEs	$s	FTEs	$s	FTEs
EPA	6,600	14,800	600	1,900	300	600	**7,500**	**17,300**
CPSC	65	400					**65**	**400**
OSHA	500	2,000					**500**	**2,000**
NOAA			1,750	5,500	1,500	6,800	**3,250**	**12,300**
USGS			500	3,300	1,000	5,200	**1,500**	**8,500**
NIOSH			265	1,409			**265**	**1,409**
Other	1,000	1,000	3,025	500	1,050	200	**5,075**	**1,700**
Total	$8,165	18,200	$6,140	12,609	$3,850	12,800	**$18,155**	**43,609**

Notes: For abbreviations see list of acronyms. Dollar figures are given in millions. All figures are author's approximations based on current strength of agencies that would be included in the new department, except for the "other" category which is based on need rather than on existing agencies.

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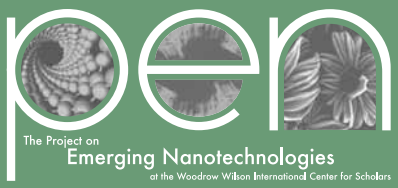

Woodrow Wilson International
Center for Scholars

One Woodrow Wilson Plaza
1300 Pennsylvania Ave., N.W.
Washington, DC 20004-3027

T 202.691.4000
F 202.691.4001
www.wilsoncenter.org/nano
www.nanotechproject.org

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