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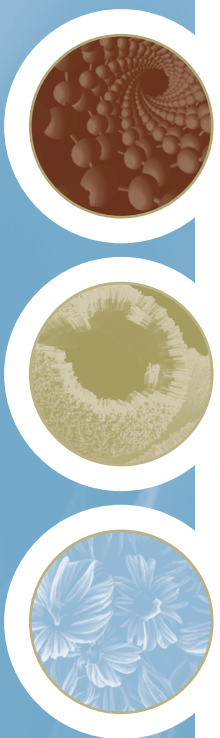
Managing the Effects of NANOTECHNOLOGY

J. Clarence Davies



Project on Emerging Nanotechnologies is supported by a grant from THE PEW CHARITABLE TRUSTS

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Preface

This paper has two purposes. The first is to describe the menu of possibilities for government action to deal with the adverse effects of nanotechnology (NT). If there are important alternatives that are not described here it is because of inadvertence or ignorance.

The second purpose is to provide evidence relevant for determining what needs to be done to manage NT. When I began this work, my initial assumption was that there was no need for new statutory authority. As I learned more about the unique aspects of NT and thought more about the weaknesses of existing statutes, I was increasingly led to the conclusion that a new law is needed. This paper, however, is not an advocacy piece for a new law. It would have been written quite differently if that were its purpose. Rather, it is a policy analysis, intended to give the reader the information relevant for thinking about a course of action. In short, the paper is intended to inform, not persuade.

A word needs to be said about the paper's title. In the coming decades, NT is likely to change many aspects of our lives, hopefully for the better. New materials and products will revolutionize the way we do many things. I do not address these kinds of effects. The time frame of the paper is the next five-to-ten years, and the primary focus is on managing potential adverse effects of NT.

I am grateful to the Project on Emerging Nanotechnologies for its generous support and encouragement, and also to Resources for the Future for its continuing support. A number of individuals have been generous in giving their time to read the paper and answer stupid questions from the author. I am particularly grateful to Julia Moore, who initiated this project, and to Dave Rejeski, Andrew Maynard, Barbara Karn and Evan Michelson, all of the Wilson Center. Among others who gave generously of their time were William K. Reilly, Mike Taylor, Mark Greenwood and Michael Rodemeyer. Jeff Porro did an excellent job editing the manuscript. The input of all these people has greatly improved this paper, but all responsibility for what it contains remains solely with the author.

Executive Summary

Nanotechnology (NT) is the production and use of materials at the smallest possible scale—100 nanometers or less. One hundred nanometers is approximately 1/800th the width of a human hair and 1/70th the diameter of a red blood cell. Materials at the nanoscale often exhibit very different physical, chemical, and biological properties than their normal size counterparts. While we know little about possible adverse effects of nanotechnology, we know enough to recognize that there needs to be some type of governmental oversight to ensure that public health and safety are not adversely affected. This paper reviews the options currently available to provide oversight, looking at the entire suite of federal government regulations, and concludes that:

Nanotechnology is difficult to address using existing regulations. There are a number of existing laws—notably the Toxic Substances Control Act; the Occupational Safety and Health Act; the Food, Drug and Cosmetic Act; and the major environmental laws (Clean Air Act, Clean Water Act, and Resource Conservation and Recovery Act)—that provide some legal basis for reviewing and regulating NT materials. However, all of these laws either suffer from major shortcomings of legal authority, or from a gross lack of resources, or both. They provide a very weak basis for identifying and protecting the public from potential risk, especially as nanotechnologies become more complex in structure and function and the applications become more diverse.

A new law may be required to manage potential risks of nanotechnology. The law would require manufacturers to submit a sustainability plan which would show that the product will not present an *unacceptable risk*, a term that is further discussed in the paper. The political obstacles to passing new legislation are very large, though not impossible, and the drawbacks of trying to fit NT under existing laws make the attempt worthwhile.

New mechanisms and institutional capabilities are needed. The paper describes several mechanisms to encourage beneficial applications of NT. These include research, tax breaks, acquisition programs, and regulatory incentives. It then outlines institutional needs in four areas: international harmonization, foresight capability, research on adverse health and environmental effects, and public participation.

If nothing specific is done to manage nanotechnology's possible adverse effects, a range of undesirable developments could emerge. The public potentially would be left unprotected, the government would struggle to apply existing laws to a technology for which they were not designed, and industry would be exposed to the possibility of public backlash, loss of markets, and potential financial liabilities. The challenges presented by nanotechnology are as many and varied as the promises that NT holds for a better life. If nanotechnology is to fulfill its promise, society must openly face the issues of whether the technology has or could have adverse effects, what these effects are, and how to prevent them in the future.

About the Author

J. Clarence (Terry) Davies

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

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

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

Characteristics of Nanotechnology

Nanotechnology (NT) is the production and use of materials with purposely engineered features close to the atomic or molecular scale. NT deals with putting things together atom-by-atom and with structures so small they are invisible to the naked eye. It provides the ability to create materials, devices and systems with fundamentally new functions and properties.

The promise of NT is enormous. It has implications for almost every type of manufacturing process and product. Potential NT applications in the next few decades could produce huge increases in computer speed and storage capacity, therapies for several different types of cancer, much more efficient lighting and battery storage, a major reduction in the cost of desalinating water, clothes that never stain and glass that never needs cleaning. While the benefits are almost limitless, they will be realized only if the potential adverse effects of NT are examined and managed.

NT is new, but the effort to understand and manage its effects will be long-term. As the world community tries to reduce the adverse effects of the technology, our understanding of these effects will steadily increase. At the same time, as the technology advances and commercial applications multiply, new challenges and problems will arise. The topics covered in this paper will be with us for decades.

Three aspects of the technology are relevant to questions of how to manage it. The first is its definition. NT covers a wide variety of processes and materials. One must consider whether it makes any more sense to talk about regulating or managing NT than it does to talk about regulating or managing things that are blue or things that are very large. The second is the rapid development of the technology. It has quickly found new applications and it will continue to expand into new materials and new uses. The third is NT's possible adverse effects. Right now, we know very little about these effects.

1. Defining NT

The definition of NT is subject to some confusion and controversy, and is complicated by the fact that there are naturally occurring nano-size materials and other nano-size particles that occur as byproducts of combustion or industrial processes. Size is critical in any definition of NT, but there are a variety of definitions in circulation. Some of the differences over definition are of only academic interest, but the way NT is defined in a regulatory context can make a significant difference in what is regulated, how it is regulated, and how well a regulatory program works.

The U.S. National Nanotechnology Initiative (NNI) defines NT as "the understanding and control of matter at dimensions of roughly 1 to 100 nanometers … nanotechnology involves imaging, measuring, modeling, and manipulating matter at this length scale" (www.nano.gov accessed 10/6/05). The Europeans tend to define it more simply as the technology dealing with applications and products with engineered structures smaller than 100 nanometers (Swiss RE 2004 p.11; The Royal Society 2004, p.5). For comparison, a single human hair is approximately 80,000 nanometers wide, and a red blood cell is approximately 7,000 nanometers wide (Royal Society 2004, p. 5).

In the context of this paper, the question of definition raises at least two important further questions: 1) Does it make sense to regulate or manage a collection of processes or materials on size alone? 2) Can a definition be formulated that allows both manufacturers and regulators to know what is included and what is not?

The basic reason that it makes sense to regulate NT as a separate category is that NT materials behave differently from conventional materials. The properties of NT materials are often not predictable from the laws of classical physics and chemistry. The laws of electricity that apply to bigger things may not hold for NT materials. A material that conducts electricity at normal size may be an electrical insulator at NT size, and vice versa. We do not know enough about the toxicity and environmental effects to know whether NT materials are also different in these respects, but it is likely, for example, that the toxicity of NT materials is more related to their surface area than to their weight (Oberdorster 2005, Maynard 2005). Certainly the direct relationship between volume of material and exposure—assumed in most chemical regulation—is not a useful guide for dealing with NT.

Another factor that differentiates NT materials is the importance of structure in determining their physical and biological behavior. Some experts prefer to talk about "nanostructured materials" rather than nanomaterials. In many cases, NT products start with some molecule or atom—carbon, titanium or gold, for example—shaped into a basic form such as a nanodot or nanotube. These forms are then combined into larger structures, and/or combined with other material such as textile, resin or glass. The behavior of the NT product cannot be predicted from the starting chemical, or often even from the basic NT form, because the structure of the material will be a major determinant. In this respect, chemical polymers are similar and, interestingly, the Toxic Substances Control Act (see section II) exempts polymers.

Given the above differences, the existing regulatory and management programs are not likely to be very useful in dealing with NT. This does not necessarily mean that existing statutes cannot be used, but, at a minimum, they will require adjustment and adaptation. Sections II and III of this paper discuss the application of existing authorities to NT.

When discussing the management of NT as a separate category, it may be useful to distinguish between NT processes and NT materials. The latter almost certainly will require basic changes in government regulatory programs. NT processes, on the other hand, may be more amenable to regulation under the Occupational Safety and Health Act (OSHAct) and existing environmental laws. Section II discusses this in more detail.

The answer to the definitional question—whether regulators and those regulated will be able to make a clear demarcation between what is and what isn't considered NT—will depend on the details of the definition and the technical capability for applying it. These issues cannot be resolved at the present time, but it is relevant that manufacturers across various industries seem to be in general agreement about what is considered NT.

2. Rapid Development

The current age is characterized by accelerating technological development, and NT is developing extraordinarily rapidly. The field was not identified until 1959, when Nobel physicist Richard Feynman called attention to the opportunities in the realm of the "staggeringly small" (Ratner and Ratner 2002, p.38). In 2001, *Science* magazine named NT the "breakthrough of the year." Currently, there are several hundred different commercial applications of NT. The National Science Foundation predicts that nano-related goods and services could be a $1 trillion market by 2015. (Roco and Bainbridge 2001, p.3. This often-repeated figure seems to have little analytical basis. See Miller et al 2005, p.175.)

Because of the ongoing speed of NT development, regulatory or other delays caused by government will be costly to the industry and could be deadly to small firms with little start-up capital. Government may try to avoid giving unfair advantage to any one firm or industry segment, but it will be impossible to maintain a "level playing field." Regulation inevitably will benefit some firms at the expense of others. Larger firms will have an advantage over smaller firms. Firms dependent on rapid introduction of a product will be disadvantaged in relation to those that are not so dependent.

The rapid development of NT also means that government managers always will be operating with outdated information, and that data about NT effects will lag behind commercial applications. Priorities for research and for regulation will need to shift constantly. We have moved into a world which is, as David Rejeski states, "dominated by rapid improvements in products, processes, and organizations, all moving at rates that exceed the ability of our traditional governing institutions to adapt or shape outcomes." He warns, "If you think that any existing regulatory framework can keep pace with this rate of change, think again" (Rejeski 2004, p.45.).

These consequences do not mean that government should not deal with the adverse effects of NT. Such difficulties need to be recognized and taken into account when designing and implementing an NT management system.

3. Lack of Effects Data

Given how little time has elapsed since the inception of NT, the lack of knowledge about its adverse effects is not surprising. The total number of research studies dealing with adverse effects of NT is small, but growing. (Summaries include: Maynard 2005, Oberdorster 2005, and Thomas 2005.)

Concerns about NT's potential adverse effects relate to both exposure and toxicity. The very small size of nano-structured particles poses unique problems of exposure. NT particles potentially can penetrate deep into the lungs when inhaled, may be absorbed through the skin, and may be circulated throughout the entire human body once they get into any single part of the body. Oberdorster et al (2005) note, "The biologic activity and biokinetics [of nanoscale particles] are dependent on many parameters: size, shape, chemistry, crystallinity, surface properties (area, porosity, charge, surface modifications, weathering of coating), agglomeration state, biopersistence, and dose." Once NT materials get into the ambient environment, it may be impossible to contain them. The concerns about exposure are not theoretical. Many of the current commercial applications of NT are high-exposure uses such as cosmetics, clothing and drugs.

The toxicity aspects of NT are just beginning to be explored. Maynard (2004) states that, "there are a number of quantitative indicators that nanostructured materials may present unique health risks." Particle surface area and activity may be better indicators of the pulmonary toxicity of nanoparticles than mass and bulk chemistry (ibid.). Nanoparticles may be transported from the nasal region to the brain via nerve endings (Oberdorster 2005). Carbon nanotubes may lead to significant inflammation in the lungs (Maynard 2005). A few tests on fish have shown toxic, but not lethal, effects (Oberdorster 2005). This and other fragmentary knowledge we have of the adverse effects of NT is clearly rudimentary, but it is enough to show that there are potential or actual effects that warrant concern.

Existing Regulatory Authorities

In the U.S. political system, it has never been easy to pass new laws regulating commercial products (Lazarus 2004). In the current political climate, it is close to impossible. Thus, those who see a need to address the health and environmental effects of NT have focused their attention on existing regulatory authorities. These authorities are examined below. For each of the major laws, I look at the extent to which that law can be applied to NT, and at the strengths and weaknesses of the regulatory regime if it were applied.

It is important to keep in mind that adequate legal authority is not the only requirement for a successful regulatory program. Adequate resources of personnel and money and the will to use the resources and authority also are necessary. Many of the programs discussed below do not have the resources necessary to fulfill their legal obligations. I will note some particularly egregious examples in the discussion of individual programs.

1. Toxic Substances Control Act (TSCA)

President Nixon's Council on Environmental Quality originally proposed TSCA as a way of dealing with numerous fears—founded and unfounded—related to toxic chemicals. Enacted in 1976, its primary goals were to prevent new chemicals from being marketed without adequate safeguards, and to fill gaps in the regulation of existing chemicals. The law was passed with lukewarm support by a Democratic Congress.

TSCA's coverage is quite broad, with the result that it is considered the primary vehicle for regulating NT. A broad coalition of environmental groups, including the Natural Resources Defense Council and Greenpeace, has called for regulating NT under the provisions of TSCA (comments from NRDC et al in EPA Docket OPPT-2004-0122, submitted June 9, 2005).

TSCA's coverage is broad in at least two respects. First, unlike most of the environmental statutes, it is not limited to covering one part of the environment (air, water, etc.). Thus, its regulatory reach encompasses all potential adverse effects—not just those occurring in some particular medium. This is appropriate for NT materials and products, the effects of which are not likely to be limited to a particular part of the environment.

Second, the law is directed at "chemical substances and mixtures" broadly defined as "any organic or inorganic substance of a particular molecular identity" (TSCA sec. 3(2)(A)). Types of products specifically covered by other statutes—such as pesticides, drugs, cosmetics, and medical devices—are excluded from TSCA's coverage. The environmental coalition cited above asserts that "**all** engineered nanomaterials are 'new chemical substances' under TSCA" and should be regulated as such (comments, p.2).

Even if NT materials do not meet the TSCA criterion for being new chemicals, there is another provision of the act that could bring them under its regulatory umbrella. This is the provision for "significant new use" rules (SNURs). To simplify somewhat, the EPA Administrator can declare that an existing chemical be regulated as if it were a new chemical if it is put to uses that might change its effects, for example, by increasing human exposure (TSCA sec. 5(a)). The new use provisions would not be a feasible method of regulating NT if each particular nanomaterial had to be subject to a SNUR because that approach would require an unrealistically large amount of time and resources. However, TSCA

(sec. 26(c)) provides that any action that can be taken with respect to individual chemicals also can be taken with respect to "categories" of chemicals. Categories are defined to include a group of chemicals that are similar in "physical properties" (sec. 26(c)(2)(A)), a definition that would seem adequate to cover NT materials because NT materials share similar physical properties, such as size.

Perhaps the most challenging problem raised by trying to include NT materials under TSCA is the importance of structure discussed in Section I-1 above. Even assuming that NT materials are within TSCA's jurisdiction at the stage when a chemical is shaped into a basic NT form (e.g., nanodot, nanotube), the exposure and toxicity from the ultimate product cannot be predicted at that point. Thus, efforts to deal with the adverse effects of NT must focus on the stage of the ultimate product. However, it may be unreasonable and impractical to expect the manufacturers of basic NT forms to keep track of all possible uses. Furthermore, by the next stage in the process when the NT material is combined into larger structures and/or other materials, it may have lost the molecular identity that defines what TSCA covers. Labeling on the basic NT form that requires reporting of uses—as well as tracking of the NT supply chain—may provide a partial solution to this difficulty. But this is a clear example of the problems that arise when trying to apply existing legal categories to NT products.

Currently, TSCA's new chemical notification requirements exempt several categories of chemicals. The law (sec. 5(h)) authorizes the EPA Administrator to make exemptions, but **what** is exempted is defined by rules promulgated by the Administrator. The exemption most relevant to NT exempts chemicals produced in volumes of 10,000 kilograms or less per year (Code of Federal Regulations, Title 40, Ch.1, part 723.5). This is equivalent to anything less than about 11 tons a year, and would exclude almost all NT products. It clearly does not make sense if TSCA is to be applied to NT. EPA would need to amend the low-volume exemption to exclude NT materials, but crafting the exclusion would be challenging.

TSCA is a law with dramatic strengths and weaknesses. Its strengths are the flexible broadness of its coverage (see above) and the wide range of measures it allows to be taken to deal with chemical risks (TSCA sec. 6). The measures include almost any conceivable requirement the EPA Administrator would want to impose.

TSCA's strengths are, not coincidentally, balanced by hedges and obstacles that make it difficult for EPA to take action. The entire law is premised on the balancing of risks and benefits (see especially TSCA 6(c)(1)). Such balancing invites controversy and litigation. The act stacks the deck against EPA in litigation in at least three important ways.

First, the technical standard of judicial review in the act is: "supported by substantial evidence in the rulemaking record" (TSCA 19(c)(B)(i)). This standard is very difficult to meet, and it contrasts with the much easier "arbitrary and capricious" standard applied to the Clean Air Act, Clean Water Act and most other environmental statutes (see *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, para.15). The result is that it is very difficult for EPA to defend rules promulgated under TSCA.

A second weakness is that TSCA implicitly assumes that no knowledge about a chemical means that there is no risk. The most relevant section (5(e)) is the epitome of a "Catch 22." It states that if EPA does not have enough information "to permit a reasoned evaluation of the health and environmental effects of a chemical," it can delay or prohibit its manu-

facture only if it can show that the chemical "may present an unreasonable risk"—which is precisely the thing that it cannot show. There is another criterion that in theory can be used for EPA action. This is that the chemical will be produced in "substantial quantities" and that there will be significant environmental or human exposure. In practice, this criterion only rarely can be used, because most new chemicals initially are produced in small volumes, and because the likelihood of significant exposure is difficult to establish. The problem is even greater for NT materials because quantity or volume may not be a relevant indicator of potential risk.

A third problem is that the act requires EPA to meet a variety of requirements before it can regulate a chemical. The difficulty of these requirements was illustrated dramatically by the Corrosion Proof Fittings case that struck down EPA's proposed regulation of asbestos, in part because of inadequate analysis—even though EPA had spent 10 years doing the analysis to support the regulation. For example, because TSCA requires that a proposed regulation be the "least burdensome" regulation, the court criticized EPA for not analyzing the costs and benefits of all other possible ways of regulating asbestos.

These and other shortcomings contained in the act are sufficient to make TSCA a weak regulatory instrument. Furthermore, as with most government regulatory programs, there simply are not enough people in the toxic substances office to perform the tasks required by the law.

2.. Occupational Safety and Health Act (OSHAct)

The OSHAct was passed in 1970 and has been amended frequently since. The act combined the occupational safety programs housed in the Department of Labor with the occupational health functions exercised by the Department of Health, Education and Welfare (now Health and Human Services). The Department of Labor was given responsibility for administering the OSHAct.

The OSHAct's basic mechanism is for the Occupational Safety and Health Administration (OSHA) in the Department of Labor to set standards and to enforce the standards through inspections and penalties for noncompliance. An occupational safety and health standard is defined in the act (sec. 3(8)) as " a standard which requires conditions, or the adoption or use of one or more practices, means, methods, operations or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment." This language is certainly broad enough to cover NT.

The difficulties with using the OSHAct to deal with NT are the same that arise with most of the environmental statutes. Detection of NT products requires expensive and sophisticated equipment (Ratner and Ratner, 2002, pp.39–42), and it is often unclear which parameters are the relevant ones to measure from the standpoint of toxicity. For practical purposes, whether in the setting of a factory or the ambient environment, detection and control methods (e.g., filters) may not be currently available or may be too expensive or too cumbersome. (For a discussion, see Maynard 2005.)

One further OSHA weakness should be noted. Like EPA, OSHA traditionally has been starved for resources. In FY 1980 there were 2,950 OSHA employees. Twenty-five years later, with a greatly expanded economy and a larger number of workplaces, there were 2,208 OSHA employees (Dudley and Warren 2005, Table A-3, p.21). EPA has been able to perform its basic functions because state agencies do most of the labor-intensive work, such as inspections and enforcement. However, for

implementing the OSHAct, only 21 states have OSHA-approved plans that allow them to enforce OSHA standards. Three additional states have approved state plans for protecting state and local government employees only (www.osha.gov, accessed 9/7/05). There are millions of workplaces in the United States, and the chance of being visited by an OSHA inspector is not high.

3. Food, Drug, and Cosmetic Act (FDCA)

The FDCA is a one-hundred-year-old act originally passed to prevent poisonings from quack patent medicines and to clean up grossly unsanitary conditions in food processing plants. Over the years, it has been frequently amended, its scope expanding to cover an increasing number of areas.

Five types of NT applications are within the purview of the FDCA: drugs, medical devices, biologics, cosmetics and food. (Medical devices are, roughly, any mechanical thing used for treatment or diagnosis of disease.) Drugs, biologics and medical devices are regulated quite differently from cosmetics. (For a discussion of FDA and NT from an industry perspective, see Miller et al 2005, pp.83–102.)

Drugs, biologics and medical devices must receive approval from the Food and Drug Administration (FDA) before they can be sold. The approval process is time-consuming and rigorous. The burden of proof is on the manufacturer to show that the product is safe. The process has been criticized by some as too time-consuming, and by others as not sufficiently rigorous. Recently, there have been instances of political interference in FDA decisions, notably the decision to delay approval of the morning-after birth control pill. However, overall, the process for approving drugs, biologics and medical devices works reasonably well.

Cosmetics are quite a different story. Although the FDCA has a lot of language devoted to cosmetics, it is not much of an exaggeration to say that cosmetics in the United States are essentially unregulated. The FDCA prohibits the marketing of "adulterated or misbranded" cosmetics in interstate commerce. "Adulterated" is roughly defined as injurious to health. "Misbranded" means that the label is false or misleading or does not contain required information. However, manufacturers of cosmetics are not required to register with FDA, are not required to file data on product ingredients, and are not required to report cosmetic-related injuries to FDA. If by some chance FDA discovers a cosmetic that is adulterated or misbranded, it has no authority to recall the product or take action against the manufacturer. All FDA can do is ask the Justice Department to bring suit to have the product removed from the market. (see www.cfsan.fda.gov, accessed 9/17/2005.)

FDA regulation of food focuses on packaging and food additives. As with FDA's regulation of drugs, there have been some intense food-related controversies (e.g., saccharin). FDA's determination not to regulate genetically modified food as a food additive has been harshly criticized and the agency has been faulted for its inadequate monitoring of pesticide residues on food. However, FDA's legal authority under FDCA is adequate, and there is not a gross disparity between resources available and the regulatory tasks to be performed.

In light of these facts, it appears that NT-based drugs, biologics and medical devices—and probably NT-based food additives and packaging—are best regulated under the FDCA authorities. On the other hand, although it would be neater legally and

bureaucratically to regulate NT cosmetics under FDCA, the public would be better protected by regulating cosmetics under some alternative regime.

4. Environmental Laws

There are many more environmental laws than most people realize—at least several hundred, even using a narrow definition of "environmental." The vast majority deal with very specific, narrow subjects, or they are minor amendments to existing laws. The three major environmental statutes are the Clean Air Act (CAA), the Clean Water Act (CWA) and the Resource Conservation and Recovery Act (RCRA).

The basic mechanism of CAA and CWA is to set standards and to enforce them through permits issued to pollution sources. The CAA standards are mostly ambient and emission standards, and the CWA standards are mostly technology-based. But RCRA is different. Instead of regulating pollution sources, it sets technology standards for disposal sites and establishes a "cradle-to-grave" reporting system for hazardous wastes.

The preceding one-paragraph description of three very long (CAA is 448 pages) and complex laws is obviously a gross oversimplification. However, it is hard to imagine how these laws could be used to manage the adverse effects of NT products. As was noted above in the section on the OSHAct, it is difficult to detect nanomaterials except with sophisticated laboratory equipment. If these materials cannot be detected, the provisions of the environmental laws are inoperable. Furthermore, even if these materials can be detected, the only practical control in many situations would be to impose a complete ban on their release into the environment. Such a ban probably could be better handled through a product-oriented law like TSCA. The technology-based parts of the environmental statutes would be inoperable because there is no agreed-upon best available technology (BAT) for the removal of NT particles from air, water, or waste streams.

The processes used to manufacture NT materials present a different situation. A recent study (Robichaud in press; also see Lekas 2005) examined the potential risks from manufacturing five types of nanomaterials, and compared the risks with those from a half dozen non-nano processes ranging from petroleum refining to wine making. The risks from the two types of processes (nano and non-nano) were found to be in the same general range—a finding that is not surprising given that the manufacture of NT materials uses inputs and processes similar to those in other industries. The study excluded risks attributable to the nanomaterials themselves. While existing environmental laws presumably can handle ordinary emissions from plants manufacturing NT materials, it is not clear whether those laws can deal with emissions of NT materials.

It may be necessary to invoke the environmental laws if disposal or leakage from manufacturing facilities is a significant source of NT materials in the environment. (Environmental Law Institute 2005 discusses how these laws might be used.) From what we know now, use and disposal of NT **products** is probably a much greater source of environmental exposure. This brings us back to TSCA-like statutes. TSCA section 6 authorizes the EPA Administrator to prohibit or otherwise regulate "any manner or method of disposal" of a hazardous substance or mixture "by its manufacturer or processor or by any other person who uses, or disposes of, it for commercial purposes." But this is probably only a theoretical point. In fact, because of other provisions in TSCA, it is unlikely that the provision would be invoked or, if it were, that it would be upheld in the courts.

There also are releases of nanoparticles that are not related to NT products. For example, the burning of diesel fuel creates nano-sized particles (Goldman and Coussens 2005, p.30). These sources will have to be regulated under the environmental laws, although detection and control will be difficult. The focus of this paper, however, is on engineered nanoscale materials, not on natural or incidental nanoparticles.

The one environmental law provision that has been considered in the NT context is the CAA standard for fine particulates. This standard sets limits on the amount of particulates less than 2.5 micrometers in diameter that can be present in the ambient air. (2.5 micrometers is equal to 2.5 thousand nanometers. In other words, a 100-nanometer-wide particle, the largest NT particle by the usual definition of NT (see above), is 1/25 of the small particle CAA standard.) The CAA standard, like almost all environmental standards, is premised on a direct relationship between volume or concentration on the one hand, and risk on the other. This relationship may not be valid for NT. In any case, volume and concentration may not be useful measures if NT is lumped together with larger-sized matter, because the volume and concentration will be dominated by the larger-sized material.

5. Other Laws

There are a number of other laws that are relevant for NT. If NT materials are used in pesticides, then the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) comes into play. If NT materials are used to filter drinking water, the Safe Drinking Water Act may apply. Some NT applications could involve radioactive materials, in which case the laws regulating nuclear and atomic energy matters are relevant. If NT is used in relation to food, there are several laws in addition to FDCA that deal with food safety and purity.

As its name indicates, The Consumer Product Safety Act, administered by the Consumer Product Safety Commission (CPSC) is responsible for ensuring consumer products are safe. It is, however, a law with mostly hortatory powers. The total staff of CPSC is 446, less than half the number of people it had in 1980. And even in 1980, its staff was inadequate to keep track of the millions of consumer products (Staff numbers from Dudley and Warren 2005, table A-3, p.21). Applications of NT in consumer electronics equipment, or in other items like tennis balls, would come under the purview of the CPSC.

None of these laws has the central importance in NT regulation that TSCA, OSHAct and FDCA have. As we have discussed, there are major problems even with TSCA, OSHAct and FDCA. The next section will consider whether some of these problems can be addressed within the NT context.

Applying Existing Authorities

Several kinds of incremental steps could be taken to manage NT within the existing legal framework. This section explores three approaches: coordinating existing laws; amending existing laws to deal with NT; and strengthening existing laws. These are in no way mutually exclusive.

1. Coordinating Mechanisms

A coordinated and comprehensive program for dealing with the effects of NT that is based on existing laws would: clarify which laws would govern in particular circumstances; specify how different laws would relate to one other if more than one applied; and ensure that there were no gaps or significant duplications in coverage.

Regulation of biotechnology provides relevant experience for establishing such a program. On June 26, 1986, the President's Office of Science and Technology Policy (OSTP) issued a "Coordinated Framework for Regulation of Biotechnology" (Federal Register, vol. 51, #123, pp. 23302-23350). The framework delineates the policies and responsibilities of six different agencies with respect to regulating biotechnology research and products. It allocates jurisdiction and responsibility among the agencies both for approving commercial biotechnology products and for conducting biotechnology research. Wherever possible, it gives responsibility to a single agency for reviewing product safety. Where this is not possible, it designates a lead agency, and mandates consolidated or coordinated reviews.

As part of the same effort, the White House established an OSTP-chaired Biotechnology Science Coordinating Committee consisting of representatives from each of the agencies. Among other things, the committee helped get some agreement on consistent definitions of the genetically engineered organisms subject to review—a key element in any coordinated approach. The committee also established the principle that agencies should use scientific reviews of comparable rigor (ibid. p.23303).

The biotech Coordinated Framework has been in place for 20 years, and, as noted by a 2004 comprehensive review (Pew 2004, p.3), "The adequacy of the Coordinated Framework has been a matter of disagreement from the beginning." Interestingly, the review report notes that, "While the policy remains that genetically engineered products should receive the same regulatory treatment as similar, conventionally produced products, in practice agencies have developed a hybrid system that effectively treats biotechnology products differently. In part, this evolution has resulted from the difficulty of fitting biotechnology products into pre-existing legal categories…and in part due to the perceived public interest in affording GE [genetically engineered] products greater scrutiny" (ibid. p.10). The same evolution could take place with NT products.

In theory, a framework for NT could be established similar to the biotechnology framework. However, NT probably covers an even broader array of types of products than does biotech. Also, it is too early to know the types of products that will incorporate NT, so an agreement might be more difficult. A greater obstacle is the difference—with respect to physical and biological behavior—between NT products and larger-scale products of the same molecular composition. EPA cannot regulate carbon nanotubes as if they were just small amounts of carbon compounds, because

the nanotubes behave quite differently in the environment, and probably in the human body as well. The same is true of other types of NT products. This means that an effective regulatory mechanism must involve internal changes within each of the agency programs and not just allocate responsibilities among agencies.

The current federal coordinating mechanism for NT is the Nanoscale Science Engineering and Technology (NSET) subcommittee of the National Science and Technology Council Committee on Technology (see www.nano.gov). NSET has established a Nanotechnology Environmental and Health Implications Working Group. The subcommittee and the working group have focused on research and development. NSET could evolve to deal with regulatory and policy issues as well as research, but it does not have the membership or authority to do so now.

2. Amending Existing Laws

Some of the aforementioned problems—and questions about whether particular laws (e.g., TSCA) cover NT—could be addressed by amending individual statutes to make clear that they do cover NT. While this would avoid a lot of litigation, winning the approval of numerous congressional committees and the executive branch for such legislation would be a formidable challenge.

There also would be the major substantive problem of deciding how to define what is covered. Is it possible to define NT just by the size of the material? What if the NT material is combined with a non-NT material? If one manufacturer makes carbon nanotubes and another manufacturer makes a textile that incorporates the tubes, do you regulate both? If the nanotubes are used in a medical device, what role would FDA play? What happens in the future when NT is combined with genetic engineering? While it might be possible to arrive at reasonable answers to these kinds of questions, it would require a lot of time, effort and foresight.

3. Strengthening Existing Laws

Even assuming that existing laws could be amended to clarify and make explicit their coverage of NT—and that the patchwork of existing laws could be stitched together in a coordinated framework that would perform better than it has for biotech—one still would be left with the weaknesses contained in these laws. Section II delineated some of these weaknesses. TSCA still would lack authority to require risk data. FDA still would not be able to review and regulate the ingredients of cosmetics. OSHA still would lack resources.

In the current political climate, it is inconceivable that these weaknesses could be remedied. It would be easier, politically and substantively, to draft and enact a new law focused on NT. I turn to an outline of such a law in the next section.

Even if there is agreement that there should be a new law, it will take months—and probably years—before a new law is enacted. In the interim, regulators would have to use existing laws in the best possible way. Thus, how the current laws can be applied to NT, and what resources will be required to effectively apply them, are inescapable and important issues.

A New Law

Given all the difficulties of using existing laws to address the potential adverse effects of NT, there is much to be said for considering a completely new law. New legislation could be tailored specifically to take account of the current characteristics of NT as well as characteristics we expect to emerge in the next decade or two. A new law also could take advantage of what we have learned about regulation in the past four decades.

The wide spectrum of products and materials included in NT means that the law would have to be broad enough to cover all of these products and materials. At the same time, the law would have to allow for broad categories of exemptions—perhaps up to 80 or 90 percent of NT products—if resource demands were not to become prohibitive. The rapid development of NT would require a regulatory structure that is flexible and that does not unduly impede development of the technology. The lack of data about the adverse effects of NT means that the law would have to be structured to provide incentives for developing effects data and making it available.

Section II noted the near impossibility of passing new regulatory legislation (including strengthening of existing laws) in the current political climate. However, this could change. The political climate could shift because of changes in the nation or the global competitive climate. A dramatic event or crisis affecting some aspect of the environment—or involving NT directly—could create an opportunity or a demand for new legislation (see Kingdon 1984). A broad consensus, perhaps fed by disparate state and local regulatory action, could emerge to favor NT legislation. The insurance companies, concerned about the liability of their industry customers (see Swiss Re 2004), and the European Union, which has been more active about regulation than the United States, are constantly pressing for action on NT. The NT industry might endorse legislation as a way of assuring the public about the safety of NT.

Because of these possibilities, and because thinking about NT legislation is itself a mechanism for reaching agreement about what should be done, this section of the paper outlines what a new NT legislative initiative might look like.

1. Description

I begin with the assumption that a new law would focus on products, not on the environment, because once NT materials get into the environment, it is probably too late to take remedial measures. The law should focus on prevention, not cleanup, for the same reason. Thus, the general framework looks something like TSCA or FIFRA, or the drug part of FDCA.

Given the lack of NT effects data, it would be necessary to place the burden on the manufacturer to show that the proposed product is safe. As more is learned about classes of NT products, it may be possible to carve out categories of exemptions, or types of products that require less information.

The process that the law would prescribe can be envisioned in four stages: ground rules, sustainability plan, review and follow-up.

In the first stage, EPA (assuming EPA is the lead agency) would have to define the law's coverage. Providing a workable definition of NT products will not be easy. It does seem clear that all **products** containing NT materials will have to be covered, not just the basic NT materials. The reason is that both exposure

and toxicity are not predictable from the NT material alone. The exposure and toxicity of a carbon nanotube or a titanium nanoparticle, for example, will depend on what structure it is shaped in, what other materials it is used with, and how it is used. Regulations probably should require labels on NT materials stating that any product using the material must be registered with and reviewed by EPA.

There are at least two further definitional issues. The first is: Should the coverage exclude products covered by other laws? I think the answer is yes, provided that the coverage of the law is really adequate to protect the public. Thus, drugs, biologics, medical devices, food additives, pesticides and nuclear materials all would be excluded. However, cosmetics, for example, would not be excluded because there is no regulatory review of cosmetic products. The second issue is: What do we do about NT products already on the market? Should the law be applied retroactively? I think probably not, because the resource burden on both the regulating agency and the manufacturers would be unmanageable. However, the law should contain provisions for restricting products already on the market if it is discovered that they are having an adverse effect.

EPA also would have to establish testing and reporting requirements. The requirements should be coordinated internationally and, ideally, would be the same in all nations. This would benefit manufacturers as well as governments. The International Life Sciences Institute (ILSI) has developed the elements of a detailed screening strategy for human health effects of nanomaterials (ILSI 2005).

The testing requirements would build on a set of protocols that describe how each type of test should be done. What tests are required would be based on the type of product and the results of previous tests (a decision tree). The testing requirements also could be tiered over time, although it is not clear what the basis of the tiers would be. Current EU chemicals law requires more testing as the volume of the chemical produced increases. However, this is probably not a good basis for tiering the testing of NT materials.

The reporting requirements, which also could be coordinated with other nations, should place as small a burden as possible on the manufacturer, but provide enough continuing information to alert the government if a problem arises. At a minimum, the manufacturer should be required to report results of any tests conducted on adverse effects, as well as any information received about adverse effects occurring. Less information could be required of companies with good health and environmental records.

In the second stage, the manufacturer would submit a sustainability plan (SP) to EPA, preferably in electronic format. The SP would have six components: 1) a life cycle analysis of the material or product; 2) testing results; 3) proposed future reporting requirements; 4) proposed labeling of the product; 5) proposed restrictions, if any, on the product; and 6) an explanation of why the product risk, if any, is acceptable. The burden of proof for showing that the product does not pose unacceptable risks belongs to the manufacturer.

In the third stage, the government would initiate a review process, the endpoint of which is to approve the SP, approve it with changes, or disapprove it. The criterion for approval is that the product will not create any "unacceptable risks," a term which the law would have to define with great care. (In my view, unacceptable risk is no more or less stringent than "unreasonable risk." I have avoided the latter term because I would like to encourage a more flexible definition than has been given to unreasonable risk.)

There are several, not necessarily mutually exclusive, approaches that could be taken to defining unacceptable risk. First, and most obvious, the manufacturer might have to anticipate likely risks from the product and show either that they would not occur if reasonable steps were taken to prevent them, or that, if they occurred, the actual damage would be very small. A second possibility is to take a rough cost-benefit approach. That is, some risks would be deemed acceptable if the benefits of the product clearly outweighed the risks. If the product cured cancer, for example, some risk of death in unusual cases would be acceptable. A third approach is based on comparative risk. A product's risk might be acceptable if it could be shown clearly that it would substitute for a material that had greater risks. Some combination of these approaches, as well as other possibilities, needs to be considered.

A review stage should strike a balance between allowing a sufficient amount of consultation with interested parties and minimizing the time taken to approve or disapprove the SP. The general public needs to have an opportunity to comment, and administrative law usually requires that the public be given at least 60 or 90 days to make comments. If a public hearing is requested or required, however, the time consumed by public review will be considerably greater. And while other nations also should be consulted, this could be very time consuming, even when aided by electronic communications.

At present, there is no institutional structure to formulate or facilitate international regulation. The amount of time and degree of detail necessary for international consultation will depend on how much agreement there is on the basic regulatory framework. Ideally, there would be complete consistency among major nations, so that approval of a product in one country constituted approval globally. However, if this were the case, other countries might have to be given enough time to review the SP themselves. Protection of confidential business information is another important consideration that must be incorporated into the review process.

There is a need for coordination among U.S. agencies for all decisions regarding a particular material or product, as well as for general policies on matters such as risk assessment and labeling. Any new statute should mandate coordinated policies and decisions and should establish an interagency group to implement the mandate.

The review stage may provide companies additional incentives for developing environmentally beneficial products (see Section V below). If there were tax incentives for developing such products (see Section V-2), EPA could decide whether the product qualified for a tax benefit, or could provide input for such a determination by the Treasury Department. Also, the approval process could be speeded up in various ways for products that had major health or environmental benefits.

The follow-up stage would have to include provisions for dealing with new uses of a product, and for requiring further testing if new evidence comes to light. Again, the law would need to be balanced between giving the government the information it would like but not imposing on manufacturers burdens that would stifle entrepreneurship. Another tradeoff involves enforcement and judicial review. TSCA has been rendered almost inoperative because of the difficulties of enforcing the law and defending against attacks in the courts. However, the rights of the regulated parties and the general public also need protection. A balance should be struck. Any new law would have to deal with a variety of other issues such as imports, exports, national defense and citizen lawsuits.

2. Advantages and Disadvantages

A new law focused on NT would have two major advantages, especially in light of the problems outlined in Section II: It could avoid some of the pitfalls of previous regulatory laws, and it could be tailored to the particular characteristics of NT. By being able to define NT and nanomaterials in a legal context, a new law would avoid the distortions and problems that come with trying to shoehorn NT into the definitions (e.g., "chemicals") in existing law. The task of enacting major new legislation, however, requires mustering political strength and wisdom. The political strength for that task may not materialize unless an extraordinary consensus—one involving industry, environmental groups and regulators—emerges.

Compared to the existing laws, the type of legislation outlined above could provide greater protection for the public. It also might place a greater burden on manufacturers, especially small start-up companies. The choice between protecting public health versus protecting small business and technological innovation can be very stark, but in the context of NT, it may be less so. While much of the commercial innovation in NT comes from small start-up companies, a discussion of the structure of the NT industry notes that, "Most nanotechnology start-ups will not attempt to develop and market their own commercial products. Rather, they will seek to partner with large companies in industries that can utilize nanotechnology to improve their commercial products" (Miller et al 2005, p.37). Also, the government can take various steps to ease the burden on smaller companies, such as establishing an office devoted to assisting small business. It also can provide templates, guidebooks and other technical assistance.

A new law could strike a different balance between safety and innovation than the one outlined above. Two simple, but far-reaching, changes could fundamentally shift the balance of the legislation. First, the burden of proof could be placed on the government to show that there is unacceptable risk. While this would remove any incentive for manufacturers to develop information about their products, it would be more consistent with much of American law. Second, in tandem with this shift in burden, the law could set a time limit on the government's review, so that after a given time, such as 90 days, a company could market its product unless the government took legal action to prevent or delay marketing. With these changes, the new law would look much like TSCA, with many of the same weaknesses with regard to public health and environmental protection.

From the perspective of the regulating agency, the advantage of getting adequate information is somewhat offset by the problems of reviewing and managing a large amount of data. The experience with TSCA is instructive. EPA generally has not pursued the avenue of requiring test data for new chemicals, mostly because of the weakness of the law's provisions allowing it to do so, but also because it feared that its limited resources would not allow it to review most of the submitted test data. Given that there is an expectation that a large number of NT products and applications will materialize in the coming years, the regulators' workload and capacity will have to be considered in the regulatory regime.

3. Other Options

The major alternatives to new legislation include: working within the existing statutory framework, creating a voluntary program, or imposing a ban on NT commercialization. Sections II and III discussed the possibilities of working within the existing laws.

EPA proposed a voluntary program for NT in September 2005 (U.S. EPA 2005). The program would ask producers of engineered nanoscale materials to submit to EPA, for materials chosen by the producer, information on: 1) material characterization; 2) hazard information; 3) use and exposure potential; and 4) risk management practices. If basic information on material characterization (such as surface area, solubility or chemical composition) were missing, the voluntary program participant would be expected to generate the information, but there is no expectation that any other information would be generated for the program. A separate "in-depth" program would focus on a more limited number of materials, and would ask participants to generate and report risk information specified by EPA. That information is intended to allow the agency to conduct a full risk assessment of the identified materials and associated uses. Both programs are designed to help EPA develop a permanent (and, presumably, non-voluntary) regulatory program for NT.

A key question to ask about any voluntary program is: What incentives are there for people to join the program and comply with its requirements? (See the essays by Mazurek and by Harrison in Dietz and Stern 2002.) For example, the 33–50 program, one of the first major voluntary efforts initiated by EPA, asked companies to volunteer to make major reductions in toxic air emissions. Many companies voluntarily made the reductions, but they were encouraged to do so by the fact that in a few years they almost certainly would be forced to do so by enforcement of the Clean Air Act.

The primary incentives for joining the voluntary EPA NT program are that it would provide companies "a concrete means to demonstrate their individual and collective commitment to responsible nanotechnology development," and that it would give participants "an opportunity to help determine the best ways to evaluate and address the potential risks" of NT (US EPA 2005). Many companies involved in NT fear a public reaction against NT, which might be fed by a lack of regulation. They also fear the possibility of over-regulation by EPA and other regulatory agencies. Thus, the incentives offered by the EPA program have some appeal, and may be sufficient to motivate companies to participate. Because the demands of the proposed program are fairly modest, non-compliance from those who do participate should not be a problem. An exception may be the withholding of existing negative risk information.

A major disadvantage of voluntary programs is that they may leave out the people who most need to be included. In the case of NT, small firms making risky products and large firms with small consciences are not likely to volunteer to do health testing or to give EPA information that might indicate a significant risk.

The other major option to new legislation is a ban either on commercialization of NT products or on NT research. ETC, the Action Group on Erosion, Technology, and Concentration, a Canadian-based organization, has stated: "Given the concerns raised over nanoparticle contamination in living organisms, Heads of State … should declare an immediate moratorium on commercial production of new nanomaterials and launch a transparent global process for evaluating the socio-economic, health and environmental implications of the technology (ETC Communique, Issue 76, May/June 2002). This is, as far as I know, the only organization that has called for a ban on NT. Focus groups convened by the Project on Emerging Nanotechnologies indicate that only a small minority of the general public support a ban (Macoubrie 2005, p.17).

The British Royal Society (2004, p.8) did recommend that: "Until more is known about environmental impacts … the releases of manufactured nanoparticles and nanotubes into the environment should be avoided as far as possible." It also recommended prohibiting "the use of free (that is, not fixed in a matrix) manufactured nanoparticles in environmental applications such as remediation" until more is known about the risks and benefits of such use (ibid.).

A ban is consistent with the "precautionary principle" which, in one of its simplest forms, says you will not undertake any action unless you know that it will not have any unacceptable consequences. (There are many versions of the precautionary principle and many discussions of it. For a good overview, see Durant in Durant et al 2004.) The wisdom of a ban depends on weighing the potential benefits of continued development of NT against the severity and likelihood of any adverse consequences resulting from the technology. Most knowledgeable observers believe that the benefits of NT will outweigh the adverse consequences, especially if steps are taken to minimize adverse effects.

Another option is labeling. Some have argued that consumers are entitled to know if products contain nanomaterials. Labeling also can benefit manufacturers by allowing them to determine the contents of supplied goods and/or the supplier's conformance with good practices. While labeling is a supplement, rather than a substitute, for the broader programs outlined above, it could be important. For example, if NT product review were not made retroactive, products already on the market might be labeled to indicate that they had not been reviewed by the government. There is not a lot of empirical evidence about the effectiveness of labeling, although the available evidence indicates that labels often do not have much impact on consumer behavior (see Lutzenhiser and also Thogersen in Dietz and Stern 2002).

State pilot programs are yet another option. NT development is concentrated in fewer than a dozen states, and, in theory, a state could initiate a program at least to collect data on NT uses and effects. Given the intense interstate competition to attract high-tech industry, it seems doubtful that any state would have much incentive to take such an initiative. Several states have initiated programs to encourage NT as part of their economic development efforts (see, for examples, www.watechcenter.org; www.ccst.us). Washington State has called the competition to attract nano companies "one of the most intensely competitive technological races in history" (www.watechcenter.org, p.1, accessed 11/2/05).

Some would say that the most likely option always is to do nothing, taking no initiatives to deal with NT's adverse effects. But that would serve no one's interest. The public would be left unprotected, the government would struggle to apply existing law to a technology for which it was not designed, and industry would be exposed to the possibility of public fear and outrage over a powerful, mysterious, and potentially dangerous new technology.

Incentives for Environmentally Beneficial Technology

An important aspect of managing NT is to encourage its application to environmentally beneficial uses. Most applications of NT are environmentally beneficial in that they reduce the amount of material necessary for a particular purpose. However, there are more specific environmental benefits that NT may make possible. For example, NT materials already have been used to remove toxic materials from soil at contaminated sites (Oberdorster 2005, p.4).

Government initiatives to encourage environmentally beneficial NT also should be used to encourage applications that benefit public health. In fact, failure to treat NT public health and environmental applications equally would be morally and politically untenable. This section discusses four mechanisms that can be used to encourage applying NT to environmental protection and public health: research, tax breaks, acquisition programs and regulatory advantages. While each of these is worth considering, each has significant problems.

1. Research

The most direct way for government to encourage beneficial NT is for the government (usually federal, but possibly state or local) to conduct the research itself. Alternatively, the government can pay for research, but let others do the actual work under contract. A third possibility—one in which the government has less control over the research—is for the government to award research grants.

In 2000, President Clinton started the National Nanotechnology Initiative (NNI), which included $422 million of funds from various agencies. The 21st Century Nanotechnology Research and Development Act (P.L.108-153), enacted in 2003, provided a statutory base for the NNI. (The text of the act and description of the program can be found at www.nano.gov.) The NNI is an interagency effort under the general direction of the National Science and Technology Council. The NNI included $989 million for research contained in the budgets of 11 agencies in FY 2004. In 2005, the amount is estimated to increase to $1.08 billion. The President's budget requests $1.05 billion in FY 2006. Of the 2006 request, $230 million is in the Defense Department budget. EPA is requesting $5 million. Overall, 4 percent of the federal funds go to research on the health and environmental effects of NT and another 4 percent goes to "education-related activities and research on the broad implications of nanotechnology for society" (www.nano.gov).

Several U.S. states have appropriated money for NT research as part of the competition for economic growth. In 2000, California allocated $95 million toward a Nano-Systems Institute at the University of California Los Angeles and Santa Barbara. In 2003, Oregon appropriated $21 million to launch a Nano/Micro Institute, and New York contributed $50 million to a Nanotech Center at SUNY Albany (Washington Nanotechnology Initiative, www.wanano-tech.org, p.3, accessed 11/2/05).

Many other national governments are funding NT research. The European Union is spending significant amounts. In 2004, scientists in China published more articles on nanoscience and nanotechnology than scien-

tists in the United States, and China now ranks third behind the United States and Japan in NT patents (Hassan 2005). A recent survey (Choi 2005) found the United States, Japan, Germany and South Korea to be the dominant nations in NT research and development.

The effectiveness of this research for encouraging environmentally beneficial NT is unknowable now and may never be known. (Miller et al 2005, pp. 115–130, analyze the NNI program and consider it successful.) Dramatic successes and failures of government R&D programs are widely publicized, but overall evaluations of such programs are rare. In the United States, it is hard to know what portion of government R&D funds go to NT technologies that are directly or indirectly beneficial to health and the environment. This should be a continuing concern of the NNI.

2. Tax Breaks

Tax benefits have been an important tool for protecting the environment. The Byzantine U.S. tax code contains a variety of incentives for environmentally beneficial behavior such as energy conservation.

Tax penalties to discourage pollution or other socially undesirable behavior have been used in the United States, but are more common in European countries. For example, gas taxes are much higher in most OECD (Organization for Economic Cooperation and Development) countries than in the United States (Davies and Mazurek, 1998, p.211).

Although one can argue that any imaginable provision can find its way into the U.S. tax code, there are at least two significant obstacles to using taxes to encourage environmentally beneficial NT.

One obstacle is that there has never been strong support for such use of the tax system. In particular, environmental groups have been cool to economic incentives of any kind. The tax-writing committees in Congress, especially the powerful House Ways and Means Committee, most frequently have taken the position that taxes should be used only to raise general funds for running the government and have opposed using taxes for social purposes. The Treasury Department usually has supported the committees in this opposition. The fact that some large corporations are engaged in NT research and development does provide a potential base of support for tax subsidies.

The other obstacle lies in defining which expenditures would be eligible for tax subsidies or tax penalties. The definition of which products or processes are NT is not altogether clear, and defining which NT efforts are environmentally desirable is much more problematic. The need to make economically important decisions about poorly delineated categories leads to confusion at best, and to corruption at worst.

3. Acquisition Programs

The federal and state governments are major consumers of a broad variety of goods and services. This characteristic has occasionally been used to promote social goals. For example, the Clean Air Act (section 248) says that the General Services Administration (GSA) should underwrite the incremental cost of purchasing clean fuel vehicles for use in federal agency fleets. In theory, the government could be required to purchase environmentally beneficial NT products. Such a mandate would raise the same definitional problems as tax breaks. More fundamentally, it would raise a dilemma that has characterized most acquisition proposals, one of cost versus social goal. Government agencies generally behave like rational consumers, searching for the lowest price for a given product. If the products mandated to be purchased are less expensive than comparable products, agencies will buy them

in any case and the legislation is unnecessary. If the mandated products are more expensive, the agencies will be reluctant to spend their budget money to fulfill a purpose that is not part of their mission, and the acquisition program gets quietly undermined by the resistance of purchasing agents in individual agencies. To the extent that government purchasing is done centrally by the GSA, the chances of acquisition programs succeeding are slightly better, but the basic dynamic remains.

4. Regulatory Incentives

There have been a few instances of using regulatory incentives to encourage particular types of technologies. For example, FDA accelerates the review and approval of certain types of drugs that address unmet medical needs (see www.accessdata.fda.gov). It would be possible for FDA to give some advantage to NT drugs and medical devices if this were considered desirable. It also would be possible to do this under new legislation dealing with NT, such as the proposal outlined in Section IV above. TSCA does not lend itself to such incentives because there is a set time limit (90 days, extendable to 180 days) for EPA to make a decision about a chemical. At the end of the time period, the chemical can be manufactured unless the agency has taken steps to ban or limit its manufacture.

How much of an incentive a regulatory provision is depends on how much capital has been invested in the product before the regulatory decision, and on how much time is saved by the regulatory advantage. In the case of something like a new drug, where the development expense typically is large and the regulatory delay could be lengthy, a regulatory leg up can be an important incentive.

New Institutional Capabilities

Dealing successfully with NT's adverse effects will require the establishment of new institutions or institutional mechanisms. While necessary to deal with NT, these institutions and mechanisms also are necessary for dealing with a wide variety of other problems and policies. Although they are discussed in the context of NT, their broader relevance should be kept in mind. The four most important functions that require institutional strengthening and innovation are international harmonization, foresight capability, research and public participation.

1. International Harmonization

Any effort to address NT must be international in scope. Every aspect of the new technology is international. As noted above, research on NT is being conducted in a large number of countries. Research and development are not limited to OECD nations—South Korea, China, India and Brazil, among others, are major players. Furthermore, most of the firms marketing or likely to market NT products engage in international outsourcing, licensing of firms in other countries, and other actions across national boundaries that make the notion of "country of origin" seem quite outdated.

A regulatory regime for NT should have international coordination built into it. The failure of the U.S. TSCA to do this is one of its many weaknesses. The section of this paper that discussed creation of a new law described some ways this might be done. Additional ideas are needed.

An international coordinating body would greatly strengthen national efforts to manage NT. One possibility is for OECD to establish an International Council on the Effects of Nanotechnology (ICEN). Membership would not be limited to OECD countries and should include UNEP (United Nations Environment Program) and WHO (World Health Organization). The council would have three major functions: 1) sharing and disseminating information on the health and environmental effects of NT; 2) making non-binding recommendations for government actions to manage NT's effects; and 3) evaluating the actions taken by member states to address the effects of NT. The last function would be analogous to OECD's evaluations of national environmental programs (see, for example, OECD 1996, OECD 2000).

The current international mechanisms for dealing with environmental and technological problems are a crazy-quilt of small, mostly inadequate, institutions and staffs. An international coordinating body for NT could be just an interim step. At some point, the need for a single strong international body to manage all of the environmental treaties, agreements and understandings will become imperative. The need to deal internationally with NT will add one more reason for nations to create such a body.

2. Foresight Capability

The U.S. EPA, the National Research Council (NRC) and others have called for the development of an improved technology forecasting ability to identify potential environmental impacts of emerging technologies, to interact with business in the early stages of technology development to help design out negative impacts, and to support environmentally positive applications (Olson, B. and Rejeski, D., "The Challenge Ahead" in Olson and Rejeski 2005; also see Brewer and Stern 2005, pp. 104–107).

There has been a long, on-going debate about the ability to do forecasting. If the goal is accurate prediction of the future, then most forecasting is doomed to failure. However, thinking about the future allows one to consider likely options, identify important determinants of the future of a technology, and get a jump on creating relevant policies. The rapid pace of NT makes improved foresight capability a necessity.

Several kinds of initiatives are needed. First, EPA and other agencies should establish offices explicitly charged with forecasting—and with encouraging their agency to use forecast results. Second, NSF, EPA and others should fund academic centers dedicated to research that will improve forecasting ability. A lot of research on how to improve forecasting is needed (Brewer & Stern 2005, pp.230–245; Ascher 1978), but forecasting is inherently interdisciplinary, and for this and other reasons, it has been almost entirely neglected by academics. The availability of funding for research —and the existence of institutions that would use the results—would help remedy this neglect. As the NRC has said, many reasons exist to motivate forecasting activities. Among them is the desire to increase the lead time for making decisions in order to allow more careful analysis of various options, and to increase the chance for broad public participation in decision making (Brewer and Stern, 2005 p.104). In managing NT's effects, these reasons are particularly relevant.

Congress also needs to have the ability to foresee and evaluate new technological developments. In 1995, the Republican Congress eliminated the Congressional Office of Technology Assessment (OTA), the only effective institution it had for fulfilling these tasks. It eliminated OTA as a budget-cutting measure, although the total OTA budget was a modest $22 million. Rebuilding Congress' foresight capability is essential if the legislature is to operate effectively in the modern world (see Morgan and Peha 2003; Goldman and Coussens 2005, p.10).

3. Research

Section V-1 discussed the role of research in encouraging environmentally beneficial NT. However, there is also a need for research focusing on adverse effects of NT, monitoring instruments, and control methods to prevent adverse effects. Much of the research on effects is either done or paid for by the government.

NT presents a variety of unique challenges. It is not clear whether there are good ways to detect NT materials in the ambient environment, or, if they cannot be detected, whether there are ways environmental controls can be imposed. It is not clear which, if any, of the usual control methods will be effective in dealing with NT materials. Following these avenues often leads back to the primary importance of prevention. The only way to deal with potential adverse effects of NT in most cases will be to design the product or tailor the use of the material so that the NT material does not get into the environment or the human body in the first place.

Rejeski has suggested that EPA needs an advanced research capability similar to the military's Defense Advanced Research Projects Agency (DARPA) to develop breakthrough solutions for the "really hard problems" (Olson and Rejeski 2005, p.172). EPA's track record with research of this kind is not good, but creation of a new office with incentives to attract outstanding researchers could change this.

It will remain a continuing challenge to identify and analyze the adverse effects of NT. With government funds, some new institutions at universities already have been established to do research on these effects. Much of the research on effects is cross-disciplinary—a

major handicap in enlisting the discipline-oriented universities to undertake the research. It also is a handicap in enlisting individual researchers who may not get academic rewards for working on interdisciplinary, applied problems. The question of how to create incentives for the private sector to conduct testing and do research on NT adverse effects is a different kind of institutional challenge. Holding manufacturers responsible for the adverse effects of their products is clearly a major incentive for such testing and research.

There is broad agreement that current government spending to determine the health and safety effects of NT is inadequate. At a Nov. 17, 2005, hearing before the House Committee on Science, industry, environmental and research organizations called for federal spending of at least $100 million annually—more than three times current expenditures —on health and safety research (Couillard 2005). Some witnesses also called for a more actively managed, strategically targeted, and carefully coordinated approach to determine what adverse effects, if any, NT may create.

Recently, the Project on Emerging Nanotechnologies at the Woodrow Wilson Center released a comprehensive inventory of NT-related environmental, health and safety research (Maynard 2005b). The inventory covered information on 208 research projects, in 6 countries and regions, accounting for $38 million of research annually. 169 projects, accounting for $27 million, were in the United States. However, within the United States, only $6 million of federal research was considered to be of "high relevance" to determining the environmental, health and safety implications of engineered nanomaterials.

4. Public Participation

The involvement of members of the general public is crucial for dealing with NT's adverse effects in two different ways. First, as the Royal Society (2004, p.62) states, "some of the social and ethical concerns that certain applications of nanotechnologies are likely to raise stretch well beyond the basic science or engineering of the matter" (see also Roco and Bainbridge 2001). Social values, apart from scientific questions, are an inextricable part of assessing risks (Stern and Fineberg 1996), and the public needs to be involved in assessing NT's risks, as well as in defining the measures to be taken to deal with the risks.

The social value questions that NT is likely to raise transcend the risks of individual technologies or applications. A study comparing the controversy over biotechnology with what might be expected in relation to NT noted that the issues many people saw as being involved in the biotechnology controversy included "Global drives towards new forms of proprietary knowledge; shifting patterns of ownership and control in the food chain; issues of corporate responsibility and corporate closeness to governments; intensifying relationships of science and scientists to the worlds of power and commerce; unease about hubristic approaches to limits in human understanding; conflicting interpretations of what might be meant by sustainable development…" (Grove-White 2004, p.19). As the authors point out, these kinds of concerns cannot be accommodated within a framework of risk assessment of individual NT products.

The second way the public needs to be involved is as consumers both of information about NT and of NT products. The tremendous potential of the technology will not develop without the public having a realistic view of the intended and unintended effects of NT. In its scope and diversity of applications, NT often has been compared with biotechnology. The lessons learned from biotechnology about the consequences of a poorly

informed public should not be lost on those dealing with NT. Some institutions have risen to this challenge. For example, DuPont has joined with the non-governmental organization Environmental Defense to define a process for identifying and reducing potential health, safety and environmental risks of nanoscale materials, and to test the process on specific DuPont materials or applications.

A study by the Woodrow Wilson Center's Project on Emerging Nanotechnologies (Macoubrie 2005) showed more trust in regulatory agencies than might have been expected. Almost half the sample believed that EPA, OSHA and other regulatory agencies would effectively manage risks from nanotechnology, while about 40 percent believed the agencies could not be trusted. Of the 177 participants in the study, 55 percent said that voluntary standards applied by industry would not be sufficient to deal with NT risks. When asked for their top choice of how government and industry could increase public trust, 34 percent selected increased safety tests before products are marketed, and 25 percent chose supplying more information to support informed consumer choices (ibid. p.19).

New and better institutions for public participation are needed (Beierle and Cayford 2002, p.74; Brewer and Stern 2005, p.37). Going through the motions of a public hearing where nobody listens, or launching a slick public relations campaign will not suffice. The public needs to be educated, not brainwashed. It needs to be seriously listened to, not tolerated. And there needs to be real participation. New forms of participation are being tried, for example, using the Internet, and NT provides a good opportunity to use and experiment with these new methods.

The challenges presented by NT are as many and varied as the promises that it holds for a better life. If the new technology is to fulfill its promise, society must openly face the issues of whether the technology has or could have adverse effects, what these effects are, and how to prevent them. I hope that this paper will move that effort forward.

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