Search OCA:
Go

Get Local!
Find Local News, Events, and Green Businesses on OCA's New State Pages:
Choose Your State

OCA News Sections:

Organics
- Save Organic Standards
- Bodycare
- Clothes
- Biodynamics

Planting Peace

Environment and Climate

Health Issues
- Vitamins & Supplements
- Children's Health
- International Science Oversight Board

Genetic Engineering
- rBGH
- GE-Free Zones
- Millions Against Monsanto
- Cloning & Patenting
- Nanotechnology

Food Safety
- Mad Cow
- Irradiation
- Perchlorate

Fair Trade/Social Justice
- Buy Local Movement
- Protest Starbucks

Farm Issues

Nanotechnology: Getting it Right the First Time

By Karen Florini, Scott Walsh, John M. Balbus, and Richard Denson*
Sustainable Development Law & Policy Vol VI Issue 3, Spring 2006
Straight to the Source

INTRODUCTION Nanotechnology, the design and manipulation of materials at the atomic scale, may well revolutionize many of the ways our society manufactures products, produces energy, and treats diseases. Hundreds of large and small nanotechnology companies are developing a wide variety of materials for use in electronics, medical diagnostic tools and therapies, construction materials, personal care products, paints and coatings, environmental cleanup, energy production and conservation, environmental sensors, and many other important applications. The National Science Foundation predicts that the global market for nanomaterial products could reach $1 trillion within a decade.1

Deliberate exploitation of properties evident only at the nanoscale is central to these applications. Such properties include the large surface area of various nanomaterials, which arise from their tiny particle size, absorption and radiation of highly specific wavelengths of light, ability to penetrate cellular barriers, and high tensile strength and durability. Carefully controlled, these properties may provide highly beneficial products. However, these new and enhanced properties also raise the possibility of unintended and adverse consequences, both for human health and for the environment. For example, the same binding properties that allow nanomaterials to deliver therapeutics to cancer cells might also allow nanomaterials with these properties to deliver toxic substances to aquatic organisms. Likewise, the electrical properties that drive applications in computers may lead to oxidative damage in living tissues. It is in the best interest of companies and society that these potential harms are identified prospectively, and are addressed, ideally through material design, or alternatively, through safeguards on production, use, or disposal.

Available data, while limited in scope, clearly indicate both that some nanomaterials have hazardous properties and that growing numbers of nanomaterials are reaching the market. Unfortunately, it is far from clear whether existing federal regulatory programs will provide an effective means of addressing nanomaterial risks, particularly in the foreseeable future. As an interim measure, several voluntary initiatives to develop standards for the safe production, use, and disposal of nanomaterials are now underway. The rigor of such standards, the degree to which mandatory safeguards are adopted, and the extent to which risk-related data are generated prior to widespread dispersion of nanomaterials will jointly indicate whether previous technological mishaps will be avoided in developing nanotechnology.

WHY Â“GETTING IT RIGHT THE FIRST TIMEÂ” IS IN THE NANOTECHNOLOGY INDUSTRYÂ'S INTEREST

Environmental law is replete with illustrations of how ignorance failed to produce bliss for industry,

- Honey Bees
- Supporting Local Farmers

Politics & Democracy

OCA Action Center

OCA Campaigns

- Planting Peace: No War No Warming
- SOS: Safeguard Organic Standards
- Breaking the Chains
- GE Free Zones
- Mad Cow USA
- Children's Environmental Health
- Coming Clean
- Millions Against Monsanto
- Clothes for a Change
- Protest Starbucks
- Nutri-Con

Resources

- Buying Guide
- OCA Web Forum
- OCA Press Center
- OCA En Español
- Books We Like
- *Organic Bytes* Newsletter
- *Organic View*
- OCA Sponsors

Noticias y campañas de la OCA en español

Intern with OCA!

workers, consumers, the public, and the environment. When the harmful effects of asbestos were widely recognized, years after the material had been extensively distributed in commerce, many makers and users of asbestos products found themselves embroiled in costly litigation brought by victims and their families. As of 2002, more than half a million people had filed claims related to asbestos exposure.2 Notably, five corporations have spent more than $1 billion each on asbestos litigation; indeed, one company alone recently agreed to pay more than $4 billion to settle pending claims for asbestos exposure.3 Standard & PoorÂ's has estimated that the total cost of liability for asbestos-related losses could reach $200 billion.4

Tort liability is not the only route by which actions that are lawful today can become major headaches for industry tomorrow. In 1980, the U.S. Congress enacted the Superfund law, under which dumpsite operators, along with those who generate or transport the wastes, are legally responsible for cleaning up properties contaminated by toxic wastes, regardless of whether the contamination arose from illegal activities.5 Indeed, under SuperfundÂ's Â"joint and several liabilityÂ" provisions, a company that contributes any amount, no matter how small, to the contamination of a Superfund site may, theoretically, be held liable for the cleanup of the entire site (though the company can then seek cost-recovery against other contributors).6 To date, the industry has expended more than $20 billion in remediation and related costs.7

Even without conclusive proof linking a new technology or material to an environmental or health harm, companies may be severely penalized for failing to demonstrate the safety of their products at the onset. When European nations contested the safety of bioengineered foods, their refusal to accept imports of such foods cost U.S. farmers an estimated $300 million annually in lost crop export revenues.

Each of these examples illustrates that the failure to identify and address the risks Â– real or perceived Â– of new technologies and materials can lead to immense costs, from financial and managerial perspectives, as well as from human and environmental standpoints.8

At present, most consumers have such limited familiarity with nanotechnology that they have formed few impressions.

However, a recent study provided basic information on nanotechnology to representative groups of citizens in three locations. After reviewing that information, a substantial majority of participants said that although they anticipate major benefits from nanotechnology, they are concerned that industry is pushing products into the market without conducting adequate safety testing.9 As nanotechnology products continue to increase their presence in the market and in the news, such views may become more widespread. Indeed, although relatively few studies have been conducted on nanomaterials, the initial results have identified surprising, hazardous properties, i.e. intrinsic abilities to cause adverse effects. At the same time, the rapid pace of commercialization suggests that the potential for human and environmental exposure will grow dramatically. Available information on both of these elements of risk Â– hazard and exposure Â– is briefly summarized below. Complicating the process of both obtaining and evaluating such information is the lack of an agreed-upon system for naming and uniquely describing nanomaterials of various structures and the limited ability to detect and characterize nanomaterials in many biological and environmental media.

NANOMATERIAL HAZARDS: FLASHING YELLOW LIGHTS

The inherent nature and novel properties of certain nanomaterials, and the results from many of the relatively small number of nanotoxicity studies conducted to date, lead to concerns about nanomaterialsÂ' health and safety impacts. Many of the very properties that make nanomaterials useful also raise the potential for these materials to present novel mechanisms and targets of

toxicity. For a given mass of particles, surface area increases dramatically as the diameter of the individual particles decreases. This increased surface-area-to-mass ratio appears to be a critical feature in understanding some aspects of the toxicity of nanomaterials. For example, in a study comparing the toxicity of conventional versus nano-sized particles of titanium dioxide, the nanoparticles appeared significantly more toxic than the conventional particles when the dose was reported on a mass basis, but this distinction essentially disappeared when the dose was reported on a surface area basis.10 The higher surface area also leads to higher particle surface energy, which may translate into higher reactivity.11 Lastly, the combination of high surface area and small size may give nanoparticles unusual, catalytic reactivity, such as those seen with gold nanoparticles.12 This combination of enhanced surface area and enhanced surface activity lends far greater complexity to the characterization of nanoparticles when compared to bulk and conventional substances, and also precludes easy extrapolation about potential toxicity.

Moreover, at least some nanoparticles can readily penetrate cell membranes, which enables them to deliver targeted drug therapies. Evidence suggests that some nanoparticles can also cross physiologic barriers (including the lung-blood, bloodbrain, and placental barriers), and can enter body compartments that neither larger particles nor smaller molecules can readily access. One study of twenty nanometer polystyrene beads suggests that they enter cells by passing directly through membranes, without requiring specific transport mechanisms. Once inside the cells, the nanoparticles distribute throughout the cytoplasm and appear to bind to a variety of key cellular structures.13

Surface modifications may allow nanoparticles to bind to cell surface receptors and potentially to interact with internal cell structures.14 Subtle variations in nanoparticle surfaces, whether due to intentional coating prior to entry into the body, unintentional surface binding, or coating degradation once inside the body, can have dramatic impacts on where and how nanoparticles gain entry into organs and cells, as well as where and how they are transported after entry. These complexities increase the difficulty of understanding nanomaterial hazards.

In addition to these inherent characteristics, the limited empirical data available adds to the concerns. As of yet, no studies on any nanomaterialÂ's reproductive toxicity, immunotoxicity, developmental toxicity, or chronic health effects, such as cancer, have been published, although some are underway.15 The limited number of short-term studies completed to date demonstrate a variety of adverse effects. Studies in which single- walled carbon nanotubes (Â“SWCNTsÂ”) were implanted into the lungs of rodents have consistently demonstrated that they cause unusual lung granulomas and have shown other signs of lung inflammation. 16 Moreover, one study found that SWCNTs also cause dosedependent, diffuse interstitial fibrosis, a form of lung disease.17 A study of multi-walled carbon nanotubes (Â“MWCNTsÂ”) showed similar lung toxicity, especially after the MWCNTs were finely ground.18 Single- and multi-walled carbon nanotubes also induce oxidative damage to skin cells, which can result in membrane damage that leads to cell death.19 These studies raise questions of potential toxicity at the beginning and end of the carbon nanotube (Â“CNTÂ”) lifecycle. This can occur through workplace exposures or when CNT-containing products undergo weathering, erosion, or grinding during recycling or disposal.

The toxicity of C60 fullerenes (commonly known as buckyballs) is particularly unclear at present. Computer modeling suggests that fullerenes can bind to DNA and have Â“negative impact on the structure, stability, and biological functions of DNA molecules.Â” 20 As a result, if fullerenes gain access to cell nuclei, they may interfere with critical cellular machinery. While fullerenes are insoluble as single particles, they can form crystalline aggregates that are readily soluble in water; these aggregates appear to be toxic to bacteria.21 In addition, studies in fish have shown that fullerenes can be transported via the gills from water to the brain, where they can cause oxidative damage to brain cell membranes.22 Uncoated fullerenes have also been found to cause oxidative stress in in vitro testing systems, i.e. cell-based systems as distinguished from whole-organism

ones.23 However, some scientists have questioned whether observed toxicity is caused by contaminants, specifically organic solvents, rather than the fullerenes themselves, and have pointed to studies that show negligible toxicity and even protective effects from pristine fullerenes that are made into water-soluble aggregates, without the use of organic solvents.24 This alternate hypothesis, however, disregards indications that the fullerene aggregates produced without solvents are significantly larger, and thus less able to penetrate cells, than those formed with solvents. This ongoing debate highlights the importance of understanding nanomaterialsÂ' physical form, as well as the limitations of current scientific understanding about nanomaterial toxicity.

Finally, quantum dots can be composed of a variety of inherently toxic materials, including cadmium and lead. Because some of the key potential applications of quantum dots include diagnostic imaging and medical therapeutics, quantum dots have been studied relatively extensively in biological systems. However, only a small portion of this research has focused on potential toxicity, and those studies performed to date have mainly been in vitro assays. While results have been somewhat inconsistent, studies that used longer exposure times were more likely to demonstrate significant toxicity.25 Inorganic elements typically make up the core of quantum dots, but these elements are generally coated with organic materials, such as polyethylene glycol, in order to enhance their biocompatibility or target them to specific organs or cells. While many coatings initially decrease toxicity by one or more orders of magnitude, the coatings might degrade when exposed to air or ultraviolet light, which could lead to toxicity increases. While the presumption has been that this cytotoxicity is caused by leakage of cadmium or selenium from the core, there is evidence that some of the molecules used as coatings may have independent toxicity.26

NANOMATERIAL EXPOSURES: A LIFECYCLE VIEW

Some nanomaterials now on the market, and others in development, can clearly result in human and environmental exposures to nanoparticles. Examples include uses in drugs and cosmetics, and remediation of groundwater contamination.

However, other products may also lead to substantial exposure, though the exposure does not necessarily occur during a productÂ's useful life. For example, nanotubes or other nanomaterials embedded within resins or other matrices may be incorporated into tennis rackets, automobile running boards, or other products. Although risk of exposure to these nanotubes (which, as noted above, have been shown to damage lung tissue)27 appears minimal during product use, pre- and post-use exposure must also be considered. Such exposure may occur during the manufacture of the product and its components, or during disposal, recycling, or reclamation. Human and environmental exposure during these other stages may be substantial. For instance, although computer users are highly unlikely to inhale carbon nanotubes bound in their computer screen, the exposure potential may dramatically increase if recyclers ultimately grind up those screens for other uses, such as road aggregate. Human exposure is most obvious for the workers doing the grinding, but may also harm road-construction workers, travelers, and neighbors as the roadÂ's surface weathers with time and traffic. Occupational exposure to researchers and students may also occur in research and development settings. In sum, it is necessary to consider a productÂ's complete lifecycle in order to understand the effects of exposure and address risks effectively.

Presently, quantitative data on exposure to nanomaterials are almost nonexistent. However, sources indicate that numerous nanomaterial- containing products are entering commerce, thus creating the potential for human and environmental exposure at various stages of their lifecycles. According to the U.S. Environmental Protection Agency (Â"EPAÂ"), Â"a survey by EmTech Research of companies working in the field of nanotechnology has identified approximately 80 consumer products, and over 600 raw materials, intermediate components and industrial equipment items that are used by manufacturers,Â" though detailed results of this survey do not

appear to be public. 28 Lux Research, a nanotechnology research and advisory firm, projected in 2004 that: Â“Sales of products incorporating emerging nanotechnology will rise from less than 0.1 percent of global manufacturing output today to fifteen percent in 2014, totaling $2.6 trillion. This value will approach the size of the information technology and telecom industries combined.Â”29 More informally, an eBay search using the word Â“nanoÂ” produces items such as golf clubs, tennis racquets, face lotions, and sun blocks; notably, however, these references may reflect marketing initiatives rather than actual nanomaterial use. Certain nanomaterials are also readily available for direct purchase, as illustrated by a Google search producing sources for nanotubes, buckyballs, quantum dots, and metal oxide nanoparticles.

Other information suggests that nanomaterial uses and exposures in the United States are about to increase significantly. For example, the PresidentÂ's Council of Advisors on Science and Technology concluded in a 2005 report that the United States is the world leader in nanotechnology by a variety of measures, including public and private spending, numbers of start-up companies, and numbers of scientific research articles. The NanoBusiness Alliance states that there are 613 companies involved with nanotechnology within the United States, while noting that Â“it is notoriously difficult to track commercial developments in nanotechnology, so [the Alliance] cannot be precisely sure.Â”30 Likewise, the dramatic growth in the number of nanotechnology patents issued by the U.S. Patent Office suggests that increasing numbers of nanomaterials are being introduced into the market.31 With the commercialization of more products containing nanomaterials comes the risk for more human and environmental exposure, which lends urgency to the need for understanding the potential hazards of nanomaterials. It also raises the questions of whether, and how carefully, regulators are reviewing the lifecycle impacts of these new materials before they reach the market.

NANOMATERIAL RISKS: WILL EXISTING REGULATORY PROGRAMS PROTECT WORKERS, THE PUBLIC, AND THE ENVIRONMENT?

Effectively managing nanomaterialsÂ' potential risks will prove to be a challenge for existing occupational and environmental regulatory frameworks for at least five reasons. First, in most of the current regulatory programs, standards and their exemptions are based on mass and mass concentration. Because of their high surface-area-to-mass ratios, and enhanced surface activity, nanomaterials are likely to prove potent at far lower concentration levels than envisioned when these thresholds were initially set.

Second, although regulators can often reasonably predict at least some types of toxicity for new conventional materials based on extrapolation from conventional materials having a similar chemical structure, too little is currently known about nanomaterials to enable such extrapolation.

Third, it appears that many nanomaterials are being developed in a decentralized fashion, with a significant percentage of production coming from small, dispersed facilities. As a result, the sheer number of facilities involved will hamper the gathering of information on which materials are produced, and the purpose and specific applications of the materials, as well as directing compliance and enforcement efforts to where they are needed. Additionally, much of the production, processing, and use of these materials will take place in facilities that may lack the expertise and resources to understand and comply with environmental and occupational safeguards.

Fourth, some potential nanotechnology applications may fall through the cracks among the jurisdictions of multiple regulatory programs. For example, the Food and Drug Administration (Â“FDAÂ”) reviewed sunscreens using nanoparticles of titanium dioxide for potential of immediate health effects on consumers. 32 However, neither the FDA nor the EPA appears to have reviewed how titanium dioxide nanoparticles could affect aquatic ecosystems once these sunscreens wash

off.

Lastly, the pace of the regulatory process lags far behind the speed at which nanomaterials are being introduced into the market. While substances marketed as pesticides,33 fuel additives,34 or drug or food additives35 regularly receive significant scrutiny when first introduced, most other substances do not.36 As a result, occupational and environmental protections are generally developed only after problems are identified or strongly suspected in regulatory proceedings that typically take several years to complete. A more detailed discussion of specific regulatory issues under key U.S. laws follows.

U.S. Occupational Safety and Health Act

Under the Occupational Safety and Health Act (Â“OSHActÂ”),37 four types of regulatory mechanisms are available for protecting workers from overexposure to chemicals: substance-specific standards, general respiratory protection standards, hazard communication standards, and the Â“general duty clause.Â” Each is examined below.

As a practical matter, substance- specific occupational standards are unlikely to be set in the absence of extensive toxicology data. Currently, the vast majority of standards adopted have been based on findings of human epidemiological studies, which follow widespread exposure and take years, or even decades, to conduct. Given the relative paucity of health data on nanoparticles, it is unlikely that any nanoparticle-specific standards will be established in the reasonable future. In their absence, inhalable nanoparticles will automatically be covered by the 5 micrograms per cubic meter (Â“mg/m3Â”) standard that applies to Â“particulates not otherwise regulated,Â” sometimes called Â“nuisance dust.Â”38 Unfortunately, these mass-based standards, developed for conventional particles, are unlikely to protect workers from adverse effects of nanoparticle exposures; indeed, one study has suggested that exposure to carbon nanotubes at 5 mg/m3 for several weeks would be analogous to exposure levels found to cause lung granulomas and inflammation in rats.39

Second, the respiratory protection standard requires employers to provide workers with respirators or other protective devices when engineering controls are not adequate to protect health.40 The standard provides guidance in selecting specific personal protective equipment and in implementing workplace respiratory protection programs. Only respirators certified by the National Institute of Occupational Safety and Health may be used, and employers must assess the effectiveness of the respirators they supply. The current lack of validated means to measure and characterize the form and size of nanoparticles in the air, as well as the uncertainties regarding respirator performance, especially in relation to particles between 30 and 70 nanometers and potential agglomerates around 300 nanometers, will complicate implementation of this standard.41

Third, OSHActÂ’s hazard communication standard42 stipulates that all producers or importers of chemicals are obligated to develop Material Safety Data Sheets (Â“MSDSsÂ”), which are intended to provide workers with available information on hazardous ingredients in products they handle and educate them on safe handling practices. However, even when accurate and upto- date, MSDSs have significant limitations; most notably, there is no requirement to either generate data on potential hazards or disclose the absence of any data. Moreover, in some instances, a nanomaterialÂ’s MSDS has simply adopted the hazard profile for a presumedly-related bulk material. For example, an MSDS for carbon nanotubes identifies the primary component as graphite, and cites information on the hazards of graphite, without acknowledging any dissimilarity between the two substances. 43 From a scientific perspective, this makes no more sense than considering carbon nanotubes equivalent to diamonds. While graphite, diamonds, and carbon nanotubes are all composed of carbon, the physical and chemical properties of these three

substances are quite distinct, reflecting their radically different molecular structures.

Finally, OSHActÂ's general duty clause44 is intended as a backstop to protect workers from certain exposures that are widely known to result in toxic effects but are not addressed specifically by an OSHA standard. The general duty clause, however, applies only to Â"recognizedÂ" hazards, a difficult criterion to meet in light of the current paucity of toxicity data on specific nanomaterials.

U.S. Toxic Substances Control Act

Beyond the occupational realm, the array of potential environmental regulatory authorities initially appears impressive. These include the Clean Air Act, the Clean Water Act, the Resources Conservation and Recovery Act, which addresses management of hazardous and other solid wastes, and the Toxic Substances Control Act (Â"TSCAÂ"), which covers commercial chemicals other than those used as drugs, food additives, cosmetics, fuel additives, and pesticides. Yet, most existing regulations under these statutes are not directly relevant to nanomaterials. Moreover, adopting new standards would require that the EPA launch lengthy, data-intensive rulemaking processes that would take years to complete.45

Certain provisions of TSCA, however, currently apply and may be the most immediate way for the EPA to regulate at least some nanomaterial applications. Enacted in 1976, TSCA authorizes the EPA to regulate chemicals that are processed, imported, manufactured, distributed in commerce, used, or disposed of in the United States upon finding that they pose an Â"unreasonable risk.Â"46 As further discussed below, TSCA also has certain provisions under which the EPA can review the safety of new chemicals before they enter commerce. Â"NewÂ" chemicals, as defined by the TSCA, are those not included in the initial Inventory of Chemicals in Commerce completed in 1980, or subsequently added to the Inventory after going through the new-chemical review process.47 As of 2005, the EPA had reviewed more than 40,000 new chemicals prior to their introduction into commerce, and had restricted or otherwise regulated 1,600, or four percent, of these chemicals.48

At first blush, TSCA appears to provide the EPAwith a fairly broad authority to regulate new chemicals. As noted in the Conference Report accompanying TSCAÂ's enactment:

[T]he most desirable time to determine the health and environmental effects of a substance, and to take action to protect against any potential adverse effects, occurs before commercial production begins. Not only is human and environmental harm avoided or alleviated, but also the cost of any regulatory action in terms of loss of jobs and capital investments is minimized. For these reasons the conferees have given the Administrator broad authority to act during the [premanufacture] notification period.49

Specifically, section 5 of TSCA requires the producer of a Â"newÂ" chemical substance to send EPA a Â"Pre-Manufacture NotificationÂ" (Â"PMNÂ") before beginning to produce a substance. At least in theory, PMNs allow the EPA to review and assess the potential risks of a new material before it reaches the market and, if necessary, to require that a producer provide further information, or limit the chemicalÂ's use.

Unfortunately, there are no baseline data requirements for PMNs, and 85 percent of PMNs are submitted without any health data.50 Although the EPA can request additional data, it rarely does so; instead, it typically conducts its review based on use of structure-activity relationship models. This model estimates the toxicological properties of an unstudied substance, based on the extent of molecular structural similarity to substances with known toxicological properties. Existing models have little applicability to nanomaterials, because the models are based on the properties of bulk forms of conventional chemical substances, and because nanomaterialsÂ' novel and enhanced properties result from characteristics other than their molecular structure, e.g. size or shape. It

remains to be seen whether the EPAwill require actual toxicity data on nanomaterials to be submitted as part of the PMN review process.

Other key questions also remain unresolved, including the extent to which nanomaterials qualify as Â“newÂ” chemicals, which is necessary to trigger PMN requirements. Under TSCA, a Â“newÂ” chemical is one that is not already listed on the TSCA Inventory of chemicals in commerce and is of Â“a particular molecular identity.Â” 51 Although it is obvious that a nanomaterial constitutes a Â“newÂ” chemical if its molecular formula is not already on the TSCA Inventory, some parties assume that a nanomaterial qualifies as Â“existing,Â” i.e. not new and therefore not subject to PMN review, if its molecular structure is identical to a substance already on the Inventory. By this logic, carbon nanotubes would not require PMNs, because graphite is already listed on the TSCA Inventory. As of January 2006, only about ten PMNs or PMN exemption requests had been submitted to the EPA, even though a much larger number of nanomaterials appear on the market in the United States.52 Of these, the EPA had approved only one: a low-release/low-exposure PMN exemption for a carbon nanotube, 53 under which the manufacturer typically must submit a full PMN once production exceeds a specified volume.

Environmental Defense has urged the EPA to clarify that nanomaterials with existing molecular structures still constitute Â“newÂ” substances unless their chemical and physical properties are demonstrably identical to those of the conventional substance. This definition is based on the grounds that only substances with the same properties, as well as the same molecular structure, share Â“a particular molecular identity.Â”54

Environmental Defense also urged the EPA not to apply massbased, or other exemptions in the PMN program, unless the underlying scientific rationale is appropriate when applied to nanomaterials.55 In addition to its pre-manufacture review provisions, TSCA also provides for certain information-gathering authorities. For example, section 8(a) authorizes the EPA to require that manufacturers provide use and exposure information; section 8(e) requires manufacturers to submit any information indicating that a substance may pose a Â“significant riskÂ” to health or to the environment; and section 8(d) authorizes the EPA to require manufacturers to submit all toxicity-related studies already in their possession. As further discussed below, the EPA is currently conducting a multi-stakeholder process on nanomaterial risks in order to design a voluntary initiative and consider possible uses of TSCA authorities.

Finally, section 6 of TSCA theoretically authorizes the EPA to restrict the manufacture, processing, distribution in commerce, use, and disposal of chemical substances if Â“there is a reasonable basis to concludeÂ” that its manufacture, distribution in commerce, use, or disposal Â“presents or will present an unreasonable risk of injury to health or the environment.Â”56 However, as a practical matter, the procedural requirements associated with section 6 are so complex that these provisions have seldom been used.57

Federal Consumer Products Laws

As noted above, TSCAdoes not cover certain chemical substances. In particular, TSCA does not cover pesticides, which the EPA regulates under the Federal Insecticide, Fungicide, and Rodenticide Act. TSCA additionally does not cover food, food additives, drugs, cosmetics, or medical devices, which the FDA regulates under the Federal Food, Drug, and Cosmetic Act. However, although cosmetics are excluded from TSCA, they are not subject to FDA pre-market approval authority.58 As also is noted above, fuel additives, including a nanomaterial-based additive now under review by the EPA,59 are covered by specific provisions of the Clean Air Act.

Unlike TSCA, the other programs require companies to submit specified data on the safety of new products before they are introduced into commerce. By definition, however, only nanomaterials

used for these specific types of applications are covered by these particular programs. Moreover, the FDA acknowledges that, even if a product involving nanotechnology falls within its ambit, the agency may not even be aware that the product contains a nanomaterial, Â“if the manufacturer makes no nanotechnology claims regarding the manufacture or performance of the product.Â”60

Finally, the Consumer Product Safety Act (Â“CPSAÂ”), like TSCA, does not require pre-market testing of new products.61 As a practical matter, the U.S. Consumer Product Safety Commission, which administers the CPSA, focuses largely on injuries and poisonings, rather than chronic toxicity issues.62

ADDRESSING NANOMATERIAL RISKS: NEXT STEPS

Given the limitations of existing regulatory tools and policies, three distinct kinds of initiatives are urgently needed: first, a major increase in nanomaterial risk research; second, rapid development and implementation of voluntary standards of care, pending development of adequate regulatory safeguards; and third, updates of existing policies to address the shortcomings described above in addressing nanomaterial risk management. A wide array of stakeholders must be involved in all components of these processes, including labor groups, health organizations, consumer advocates, community groups, environmental organizations, as well as large and small businesses and the academic community.

INCREASE GOVERNMENTAL INVESTMENT IN RISK RESEARCH

The U.S. government, as the largest single investor in nanotechnology research and development, needs to spend more time and money to assess the health and environmental implications of nanotechnology, and to ensure that the critical research needed to identify potential risks is conducted expeditiously. Through the National Nanotechnology Initiative, the federal government spends more than $1 billion annually on nanotechnology research and development.63 Of this amount, environmental and health implications research accounted for only $8.5 million (less than one percent) in fiscal year (Â“FYÂ”) 2004.64 This funding is expected to increase to $38.5 million (less than four percent) in FY 2006.65

The U.S. government should spend at least $100 million annually on risk research for the next several years. While an annual expenditure of $100 million represents a significant increase over current levels, it is still less than ten percent of the overall federal budget for nanotechnology development. Moreover, this amount is a modest investment compared to the potential benefits of risk avoidance and the $1 trillion role that nanotechnology is projected to play in the world economy by 2015.

Given the wide-ranging set of research issues that need to be addressed, and the significant uncertainties associated with the anticipated results, there is no single Â“magic number,Â” nor precise method to determine the right dollar figure that should be expended. Nevertheless, $100 million per year represents a reasonable, lower-bound estimate of what is needed. Experts broadly agree that addressing the potential risks of nanotechnol- ogy will be an unusually complex task. Despite its name, nanotechnology is anything but singular; it is a potentially limitless collection of technologies and associated materials. The sheer diversity of potential materials and applications, which is a source of nanotechnologyÂ’s enormous promise, also poses major challenges with respect to characterizing potential risks.

A wide range of stakeholders are calling for increased research. In a rare example of convergence from sectors that often have highly divergent views, representatives from the environmental, manufacturing, investment, and insurance communities have all advocated dramatic increases in federal funding on the health and environmental implications of nanotechnology. For example, in

June 2005, the CEO of DuPont and the President of Environmental Defense coauthored an Op-Ed in the Wall Street Journal, calling for an increase in such funding.66 That same month, the American Chemical CouncilÂ's Chemstar Panel on nanotechnology and Environmental Defense issued a Joint Statement of Principles, stating that Â"[a] significant increase in government investment in research on the health and environmental implications of nanotechnology is essential.Â"67 A recent report on nanotechnology by Innovest, an investment research and advisory firm, Â"strongly support[ed] calls by others in the investment community for increased government funding of toxicology research,Â" and noted that the National Nanotechnology InitiativeÂ's Â"lack of priority for this issue represents a missed opportunity to minimize uncertainty.Â"68 Additionally, several of the worldÂ's largest insurance firms, including Swiss Re,69 Munich Re,70 and Allianz,71 have called for greater scrutiny of the potential risks of nanotechnology.

ExpertsÂ' assessments, testing costs associated with hazard characterization programs for conventional chemicals, and comparison to the research budgets for a roughly analogous risk characterization effort on risks of airborne particulate matter further buttress the call for greatly expanded health and environmental research spending.72

Current federal initiatives on nanotechnology have made significant achievements in accentuating and accelerating the enormous potential benefits of nanomaterials. To date, however, federal agencies have not fulfilled their equally critical role in identifying, managing, and ideally avoiding the potential downsides. A far better balance between these two roles must be struck if nanotechnology is to deliver on its promise, without delivering unintended and unforeseen adverse consequences.

But the U.S. government should not be the sole, or even the principal, funder of nanomaterial risk research. Other governments are also spending heavily to promote nanotechnology research and development, and they too should allocate some portion of their spending to address nanotechnology risks. Indeed, the United KingdomÂ's Royal Society and Royal Academy of Engineering, in its seminal July 2004 report, Nanoscience and Nanotechnologies: Opportunities and Uncertainties, calls for the U.K. government to devote Â£5-6 million (US $9.5-11.3 million) per annum for ten years, to do its part to develop the methodologies and instrumentation needed to set the stage for actual testing of nanomaterials.73

Although government risk research plays a critical role in the development of basic knowledge and methods for characterizing and assessing the risks of nanomaterials, private industry should fund the majority of the research and testing on the products they are planning to bring to the market. In turn, governments should focus on providing the Â"enabling infrastructureÂ" for nanotechnology research. Such research cuts across a broad range of disciplines, and will have broad impacts on society. In particular, the government can mobilize the research industry to create a database of representative, model nanomaterials. The government can also develop methods and tools needed to characterize, detect, and measure nanomaterials; to assess their biological fate and behavior; and to assess acute and chronic toxicity. Most importantly, the government can coordinate this research, and disseminate the results, thereby increasing efficiency and reducing redundancy. Clearly, all parties involved will benefit if governments and industry coordinate their research to avoid redundancy and optimize efficiency.

DEVELOP VOLUNTARY STANDARDS OF CARE

Given that federal agencies are unlikely to develop and implement adequate regulatory programs for nanomaterials quickly enough to address the products now entering or poised to enter the market, voluntary Â"standards of careÂ" for nanomaterials must play a role in guiding the safe use of nanomaterials in the near term. These standards should include a framework and a process by

which to identify and manage nanomaterialsÂ' risks across a productÂ's full lifecycle, taking into account worker safety, manufacturing releases, product use, and product disposal. In addition, these standards should incorporate feedback mechanisms, including environmental and health monitoring programs, to check the accuracy of judgments made about a nanomaterialÂ's risks, and the effectiveness of risk management practices. Such standards should be developed and implemented in a transparent and accountable manner, including public disclosure of the assumptions, processes, and results of the risk identification and risk management systems.

Several voluntary programs are currently at various stages of evolution, though their eventual outputs are still far from clear. In November 2005, a workgroup of an EPAadvisory committee proposed a framework for a voluntary program aimed at producers, processors, and users of nanomaterials. The group also recommended using certain TSCA regulatory authorities to address nanomaterial risks.74

In addition, both ASTM International75 and the American National Standards Institute (with the International Standards Organization)76 have recently initiated multi-stakeholder efforts to develop voluntary standards for nanotechnology. Both initiatives are at an early stage, and have not yet produced substantive drafts.

Finally, Environmental Defense and DuPont are working together to design and demonstrate a framework for the responsible development, production, use, and disposal of nanoscale materials. While the project will initially pilot-test the framework on specific nanoscale materials, or on applications of interest to DuPont, the organizations intend to develop a framework that can be adapted for use by a broad range of stakeholders.

But voluntary standards by themselves are only a temporary expedient; in the longer term, regulatory programs will be essential to securing long-term public confidence and support for nanotechnology. Here again, a wide range of stakeholders believe that a nanotechnology regulatory scheme is needed. In a survey conducted by the Wilson Center, 55 percent of the 1,250 respondents stated that government control beyond voluntary standards was necessary, while only eleven percent felt that voluntary standards were adequate.77 According to a recent report on nanotechnology by Innovest, Â"[a] significant portion of the more than 60 companies we interviewed indicated an interest in having some sort of standards in place. In many cases, they felt that science-based regulation would provide a more level playing field.Â"78 In a Joint Statement of Principles submitted to the EPA, both Environmental Defense and the Nanotechnology Panel of the American Chemistry Council stated that the responsible regulation of nanomaterials Â"will best assure that nanomaterials are being developed in a way that identifies and minimizes potential risks to human health and the environment.Â"79 In an Op-Ed in the Wall Street Journal, Environmental DefenseÂ's President, Fred Krupp, and DupontÂ's Chairman and CEO, Chad Holliday, agreed that Â"both public and business interests will inevitably compel regulatory protection to ensure product safety and to create a level playing field for business.Â"80

CONCLUSION

As recently noted by a columnist for the Motley Fool investment newsletter, Â"the scientific community will inevitably determine that at least some nanoscale materials pose unnecessarily high risks.Â"81 If the public, however, were to discover that companies knowingly hid or downplayed the risks, it could not only lead to lawsuits, but might also create a serious backlash against all things nano. The best-case scenario might be overregulation, while the worst case may be that many nanotechnology- related products are banned altogether. In an ideal world, adequate data on nanomaterialsÂ' hazards and exposure would already exist, allowing governments to establish appropriate safeguards through a transparent public process that would generate long-term public confidence in nanotechnology. In reality, such data are extremely limited, and

regulatory programs are undeveloped. Substantially greater amounts of government and corporate support for research into the health and environmental effects of nanomaterials are urgently needed, along with rapid development of voluntary standards of care that can help address the issues until meaningful regulations can be put into place.

ENDNOTES: Getting it Right the First Time

1 M.C. ROCO, THE FUTURE OF THE NATIONAL NANOTECHNOLOGY INITIATIVE (2003), http://www.nano.gov/html/res/slides.pdf (last visited Mar. 8, 2006).

2 Michelle J. White, Fifteenth Annual Corporate Law Symposium: Corporate Bankruptcy In The New Millennium: Why The Asbestos Genie WonÂ't Stay In The Bankruptcy Bottle, 70 U. CIN. L. REV. 1319, 1320 (2002).

3 CBS News, Halliburton OKÂ's $4B Asbestos Payment (Dec. 18, 2002), http://www.cbsnews.com/stories/2002/12/18/national/main533512.shtml (last visited Mar. 20, 2006).

4 STANDARD & POORÂ'S, INSURANCE: PROPERTY-CASUALTY INDUSTRY SURVEY (2005), see http://sandp.ecnext.com/coms2/gi_0260- 226/Insurance-Property-Casualty-Industry-Survey.html.

5 U.S. Environmental Protection Agency (Â"EPAÂ"), CERCLA Overview, http://www.epa.gov/superfund/action/law/cercla.htm (last visited Mar. 6, 2006).

6 NATÂ'L ACAD. OF SCI. RPT. ON SUPERFUND AND MINING MEGASITES, LESSONS FROM THE COEUR DÂ'ALENE RIVER BASIN; FINAL PUBLICATION (Dec. 2005), at 416-17, available at http://www.epa.gov/superfund/ reports/pdfs/coeur/ch9.pdf (last visited Mar. 6, 2006).

7 U.S. GENERAL ACCOUNTING OFFICE, SUPERFUND PROGRAM: CURRENT STATUS AND FUTURE FISCAL CHALLENGES 17 (2003), http:// www.gao.gov/new.items/d03850.pdf, at 3 (last visited Mar. 6, 2006).

8 Plant Biotechnology Research and Development in Africa: Challenges and Opportunities: Before the Subcomm. on Research of the H. Comm. on Science, 108th Cong. (2003) (statement of J. Dennis Hastert, Speaker, H. R.), http://www.house.gov/science/hearings/research03/jun12/ hastert.htm (last visited Mar. 6, 2006).

9 JANE MACOUBRIE, INFORMED PUBLIC PERCEPTIONS OF NANOTECHNOLOGY AND TRUST IN GOVERNMENT (2005), http://www.wilsoncenter.org/news/ docs/macoubriereport.pdf (last visited Mar. 6, 2006).

10 GÃ¼nter OberdÃ¶rster et al., Nanotoxicology: An Emerging Discipline Evolving from Studies of Ultrafine Particles, 113 ENVTL. HEALTH PERSP.823, 823-839 (2005).

11 GÃ¼nter OberdÃ¶rster et al., Principles for Characterizing the Potential Human Health Effects from Exposure to Nanomaterials: Elements of a Screening Strategy, 2 PARTICLE & FIBRE TOXICOLOGY 8 (2005).

12 M. C. Daniel & D. Astruc, Gold Nanoparticles: Assembly, Supramolecular Chemistry, Quantum-size-related Properties, and Applications toward Biology, Catalysis, and Nanotechnology, 104 CHEM. REV. 293, 293-346 (2004).

12 M. Edetsberger et al., Detection of Nanometer-sized Particles in Living Cells Using Modern Fluorescence Fluctuation Methods, 332 BIOCHEMICAL AND BIOPHYSICAL RES. COMM. 109, 109-116 (2005).

14 A. K. Gupta & A. S. Curtis, Lactoferrin and Ceruloplasmin Derivatized Superparamagnetic Iron Oxide Nanoparticles for Targeting Cell Surface Receptors, 25 BIOMATERIALS 3029, 3029-40 (2004).

15 Woodrow Wilson Center Project on Emerging Nanotechnologies, Nanotechnology Environmental and Health Implications: An Inventory of Current Research, http://www.nanotechproject.org/index.php?id=18 (last visited Mar. 6, 2006).

16 Chiu-Wing Lam et al., Pulmonary Toxicity of Single-wall Carbon Nanotubes in Mice 7 and 90 Days after Intratracheal Instillation, 77 TOXICOLOGICAL SCI. 126, 126-134 (2003); D. B. Warheit et al., Comparative Pulmonary Toxicity Assessment of Single-wall Carbon Nanotubes in Rats, 77 TOXICOLOGICAL SCI. 117, 117-25 (2004); A. A. Shvedova et al., Unusual Inflammatory and Fibrogenic Pulmonary Responses to Single-walled Carbon Nanotubes in Mice, 289 AM. J. PHYSIOLOGY, LUNG CELL AND MOLECULAR PHYSIOLOGY 698, 698-708 (2005).

17 Shvedova, id.

18 J. Muller et al., Respiratory Toxicity of Multi-wall Carbon Nanotubes, 207 TOXICOLOGY & APPLIED PHARMACOLOGY 221, 221-31 (2005).

19 N. A. Monteiro-Riviere et al., Multi-walled Carbon Nanotube Interactions with Human Epidermal Keratinocytes, 155 TOXICOLOGY LETTERS 377, 377-384 (2005); S. Manna et al., Single-walled Carbon Nanotube Induces Oxidative Stress and Activates Nuclear Transcription Factor- kb in Human Keratinocytes, 5 NANOTECH. LETTERS, 1767, 1676- 1684 (2005); A. A. Shvedova et al., Exposure to Carbon Nanotube Material: Assessment of Nanotube Cytotoxicity Using Human Keratinocyte Cells, 66 J. TOXICOLOGY & ENVTL. HEALTH 1909, 1909- 1926 (2003).

20 Xiongce Zhao et al., C60 Binds to and Deforms Nucleotides, 89 BIOPHYSICAL J. 3856, 3856Â–3862 (2005).

21 J. D. Fortner et al., C60 in Water: Nanocrystal Formation and Microbial Response, 39 ENVTL. SCI. & TECH. 4307, 4307-16 (2005).

22 OberdÃ¶rster, supra note 11.

23 Christie M. Sayes et al., The Differential Cytotoxicity of Water-Soluble Fullerenes, 4 AM. CHEM. SOC. 1881, 1881-1887 (2004); Christie M. Sayes et al, Nano-C60 Cytotoxicity is Due to Lipid Peroxidation, 26 BIOMATERIALS 7587, 7587-7595 (2005).

24 G. Andrievsky et al., Is C60 fullerene molecule toxic? 13 FULLERENES, NANOTUBES, AND CARBON NANOSTRUCTURES 363, 363-376 (2005); Gharbi N., M. Pressac, M. Hadchouel, H. Szwarc, S. Wilson & F. Moussa, Fullerene Is a Powerful Antioxidant in Vivo with No Acute or Subacute Toxicity, 5 NANO LETTERS 2578, 2578-2585 (2005).

25 Ron Hardman, A Toxicological Review of Quantum Dots: Toxicity Depends on Physico-chemical and Environmental Factors, 114 ENVIRON. HEALTH PERSP. 165, 168-69 (2005), available at http://ehp.niehs.nih.gov/ members/2005/8284/8284.pdf (last visited Mar. 6, 2006).

26 Hardman, id. at 168-70.

27 See Edetsberger, supra note 13; see also Woodrow Wilson Center Project on Emerging Nanotechnologies, supra note 15.

28 EPA, Nanotechnology White Paper Â– External Review Draft, at 3 (2005), http://www.epa.gov/osa/pdfs/EPA_nanotechnology_white_paper_ external_review_draft_12-02-2005.pdf (last visited Mar. 6, 2006). EmTech Research is a division of Small Times Media, which also publishes Small Times, a leading magazine on the nanotechnology industry; see also, Nanotechnology Now, http://www.nanotech-now.com/currentuses. htm (last visited Mar. 6, 2006) (describing current nanotechnology applications).

29 Press Release, Lux Research, Revenue From Nanotechnology-Enabled Products To Equal IT And Telecom by 2014, Exceed Biotech By 10 Times, (Oct. 25, 2004) (on file with author), available at http:// www.luxresearchinc.com/pressb.html (last visited Mar. 6, 2006).

30 Hearing Before the Research Subcomm. of the H. Comm. on Sci, 109th Cong. 9 (2005) (written testimony of Sean Murdock, NanoBusiness Alliance Executive Director).

31 Vivek Koppikar et al, Current Trends in Nanotech Patents: A View from Inside the Patent Office, 1 NANOTECH. L. & BUS. 24, 24-30 (2004).

32 Food and Drug Administration, Sunscreen Drug Products For Over- The-Counter Human Use; Final Monograph, 64 Fed. Reg. 27,666, 27,671 (May 21, 1999), available at http://www.cfsan.fda.gov/~lrd/ fr990521.html (noting that FDA reviewed Â“acute animal toxicity, irritation, sensitization, photoirritation, photosensitization, and human repeat insult patch and skin penetration studies,Â” but giving no indication that any other testing was done or reviewed).

33 See generally, EPA, Pesticides, http://www.epa.gov/pesticides (last visited Mar. 6, 2006). Pesticides are regulated by the Environmental Protection Agency under the Federal Insecticide, Fungicide, and Rodenticide Act, which include pre-market testing and approval provisions..

34 See generally, EPA, Fuels and Fuel Additives, http://www.epa.gov/ otaq/additive.htm (last visited Mar. 6, 2006). Under Â§ 211 of the Clean Air Act, the EPA has issued regulations requiring that each manufacturer or importer of gasoline, diesel fuel, or fuel additives, have its product registered by the EPA prior to its introduction into commerce. Registration involves providing a chemical description of the product as well as certain technical, marketing and health-effects information.

35 See generally, Food and Drug Administration, FFDCA, http://www.fda.gov/opacom/laws/fdcact/fdctoc.htm (last visited Mar. 6, 2006). The Federal Food, Drug, and Cosmetics Act (Â“FFDCAÂ”) requires pre-market testing and approval of drugs and food additives. Similar provisions apply to medical devices; however, pre-market approval is not required for cosmetics.

36 See generally, EPA, Toxic Substances Control Act (Â“TSCAÂ”), http://www.epa.gov/Region5/defs/html/tsca.htm (last visited Mar. 6, 2006). The TSCA governs chemical uses other than those regulated under FFDCA, the Federal Insecticide, Fungicide, and Rodenticide Act, and the Clean Air ActÂ’s fuel-additives provisions.

37 See U.S. Department of Labor, Occupational Safety and Health Administration, http://www.osha.gov/pls/oshaweb/owasrch.search_ form?p_doc_type=OSHACT (last visited March 5, 2006).

38 29 C.F.R Â§ 1910.1000 table Z-1 (2005), available at http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS& p_id=9992 (last visited Mar. 6, 2006).

39 Lam, supra note 16. 40 See 29 C.F.R Â§ 1910.134(a)(2) (2005), available at http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS& p_id=12716 (last visited Mar. 6, 2006).

41 A. Balazy et al., Manikin-Based Performance Evaluation of N95 Filtering-Facepiece Respirators Challenged with Nanoparticles, THE ANNALS OF OCCUPATIONAL HYGIENE 1, 1Â–11 (2005).

42 See 29 C.F.R. Â§ 1910.1200 (2005), available at http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10 099 (last visited Mar. 6, 2006).

43 Carbon Nanotubes, Inc., Material Safety Data SheetÂ—CNI Carbon Nanotubes (2004), http://www.cnanotech.com/pages/buckytube_properties_ uses/5-0_buckytube_properties_uses.html (follow Â“Buckytube MSDsÂ” hyperlink; then follow Â“Buckytube MSDsÂ” hyperlink) (last visited Mar. 6, 2006).

44 See 29 C.F.R. Â§ 1903.1 (2005).

45 Linda K. Breggin, Environmental Law Institute, Securing the Promise of Nanotechnology: Is U.S. Environmental Law Up to the Job? (2005), available at http://www.elistore.org/reports_detail.asp?ID=11116 (last visited Mar. 6, 2006). In addition, it is possible that some discarded nanomaterial products or nanomaterial-containing wastes could be regulated under existing Resource Conservation and Recovery Act (Â“RCRAÂ”) or Clean Water Act regulations. However, existing RCRA would apply only to the extent that nanomaterial wastes happen to exhibit one of the four narrowly defined Â“characteristicsÂ” of a hazardous waste, or happen to meet a description for a listed waste such as, e.g. a solvent waste. Most nanomaterial wastes probably will not fall within those parameters.

46 EPA, Toxic Substances Control Act, available at http://www.epa.gov/Region5/defs/html/tsca.htm (last visited March 6, 2006).

47 U.S. GOVERNMENT ACCOUNTABILITY OFFICE, NO. GAO-06-217R, CHEMICAL REGULATION: APPROACHES IN THE UNITED STATES, CANADA, AND THE EUROPEAN UNION, (2005), available at http://www.gao.gov/ htext/d06217r.html (last visited Mar. 6, 2006).

48 Fortner, supra note 21 (noting that a Â“similar number [of new chemicals] have been withdrawn by the manufacturer, often in the face of EPA action).

49 Conf. Rep. No. 1679 65 (1976), reprinted in LEGISLATIVE HISTORY OF THE TOXIC SUBSTANCES CONTROL ACT (1976).

50 U.S. GOVERNMENT ACCOUNTABILITY OFFICE, NO. GAO-05-458, OPTIONS EXIST TO IMPROVE EPAÂ'S ABILITY TO ASSESS HEALTH RISKS AND MANAGE ITS CHEMICAL REVIEW PROGRAM 11 (2005), available at http://www.gao.gov/htext/d05458.html (last visited Mar. 6, 2006).

51 15 U.S.C. Â§ 2602(2) & 2602(9) (2005).

52 P. Phibbs, Outlook 2006Â—Toxic Substances: Industry Expects Pivotal Year For Regulation of

Chemicals by EU, International Body, BNA DAILY ENVIRONMENT REPORT, Jan. 20, 2006, p. B-37.

53 C. Auer, Director of EPAÂ's Office of Pollution Prevention and Toxics, Presentation to a Workshop sponsored by the Org. for Econ. Cooperation and Dev.: Recent Experience of the U.S. on Nanotechnology (Dec. 7, 2005).

54 Letter from Richard A. Denison, Ph.D., Senior Scientist, and Karen Florini, Senior Attorney, Environmental Defense to Susan B. Hazen, Acting Assistant Administrator, EPA Office of Prevention, Pesticides and Toxic Substances (Sept. 2, 2004), available at http://www.environmentaldefense. org/documents/4457_NanotechLetterToEPA.pdf (last visited Mar. 6, 2006).

55 Denision, id.

56 15 U.S.C. Â§ 2605(a) (2005), available at http://www.law.cornell.edu/ uscode/html/uscode15/usc_sec_15_00002605Â—Â—000-.html (last visited Mar. 6, 2006).

57 U.S. GOVERNMENT ACCOUNTABILITY OFFICE, supra note 48.

58 Food and Drug Administration, Center for Food Safety and Applied Nutrition, FDA Authority Over Cosmetics (2005), http://www.cfsan.fda.gov/~dms/cos-206.html (last visited Mar. 6, 2006).

59 EPA, supra note 38, at 29.

60 Food and Drug Administration, FDA Regulation of Nanotechnology Products, http://www.fda.gov/nanotechnology/regulation.html (last visited Mar. 6, 2006).

61 15 U.S.C. Â§Â§ 2051?2084 (2005).

62 See, e.g., U.S. Consumer Product Safety Commission, Database of Consumer Product-related Statistics, http://www.cpsc.gov/about/ about.html (last visited Mar. 6, 2006).

63 U.S. OFC. OF SCI. & TECH. POLICY. NATIONAL NANOTECHNOLOGY INITIATIVE - RESEARCH AND DEVELOPMENT, FUNDING IN THE PRESIDENTÂ'S 2006 BUDGET, http://www.ostp.gov/html/budget06.html (follow Â"FY 2006 One PagersÂ" to Â"National Nanotechnology InititiaveÂ" hyperlink) (last visited Mar. 6, 2006).

64 National Nanotechnology Initiative, Responsible Development of Nanotechnology, Apr. 2, 2004, http://www.technology.gov/OTPolicy/ Nano/04/0402_Teague-Infocast.pdf (last visited Mar. 6, 2006). Specifically, Teague indicates that environmental and health implications research accounted for 8% of $105.8 million, or a total of $8.5 million. See also Hardman, supra note 25.

65 NANOSCALE SCI., ENGÂ'G AND TECH., NATIONAL NANOTECHNOLOGY INITIATIVE: RESEARCH AND DEVELOPMENT LEADING TO A REVOLUTION IN TECHNOLOGY AND INDUSTRY: SUPPLEMENT TO THE PRESIDENTÂ'S FY2006 BUDGET 38 (2005), available at http://www.nano.gov/NNI_06Budget.pdf (last visited Mar. 21, 2006).

66 F. Krupp & C. Holliday, LetÂ's Get Nanotech Right, WALL ST.J., June 14, 2005, at B2.

67 ENVTL. DEF. & AM. CHEMISTRY COUNCIL NANOTECHNOLOGY PANEL, DOCKET OPPT-2004-0122, JOINT STATEMENT OF PRINCIPLES, (2005), available at http://www.environmentaldefense.org/documents/ 4857_ACC-ED_nanotech.pdf (last visited Mar.

20, 2006).

68 INNOVEST, NANOTECHNOLOGY: NON-TRADITIONAL METHODS FOR VALUATION OF NANOTECHNOLOGY PRODUCERS 56 (2005).

69 Swiss Re, Nanotechnology: Small Matter, Many Unknowns (May 10, 2004), http://www.swissre.com/ (last visited Mar. 6, 2006).

70 Munich Re, Nanotechnology Â– What is in store for us? (2002), http://www.munichre.com/publications/302-03534_en.pdf?rdm=81727 (last visited Mar. 6, 2006).

71 Allianz, Small Sizes that Matter: Opportunities and risks of Nanotechnologies. Report in Co-Operation with the OECD International Futures Programme (June 3, 2005).

72 Richard A. Denison, A Proposal to Increase Federal Funding of Nanotechnology Risk Research to at Least $100 Million Annually (2005), available at http://www.environmentaldefense.org/documents/4442_ 100milquestionl.pdf (last visited Mar. 6, 2006) (responding to a request from the National Research CouncilÂ's Committee to Review the National Nanotechnology Initiative).

73 THE ROYAL SOC. AND ROYAL ACAD. OF ENGÂ'G, NANOSCIENCE AND NANOTECHNOLOGIES: OPPORTUNITIES AND UNCERTAINTIES 48 (2004), available at http://www.nanotec.org.uk/finalReport.htm (last visited Mar. 6, 2006).

74 NATÂ'L POLLUTION PREVENTION & TOXICS ADVISORY COMM. (Â"NPPTACÂ"), INTERIM AD HOC WORK GROUP ON NANOSCALE MATERIALS. OVERVIEW OF ISSUES FOR CONSIDERATION BY NPPTAC (2005). available at http://www.epa.gov/oppt/npptac/pubs/nanowgoverviewdocument20051125. pdf (last visited Mar. 6, 2006).

75 ASTM INTÂ'L. COMM. E56 ON NANOTECHNOLOGY (2005).

76 AM. NATÂ'L STANDARDS INST., NANOTECHNOLOGY STANDARDS PANEL (2005).

77 Macoubrie, supra note 9.

78 INNOVEST, supra note 68.

79 ENVTL. DEF. AND AM. CHEMISTRY COUNCIL NANOTECHNOLOGY PANEL, supra note 67.

80 Krupp & Holliday, supra note 66, at B2.

81 J. Uldrich, DuPont: The Truth Helps Nanotech, MOTLEY FOOL (Dec. 22, 2005), http://www.fool.com/news/commentary/2005/commentary05122219. htm (last visited Mar. 6, 2006).

* Karen Florini is a Senior Attorney with Environmental Defense, a leading environmental advocacy organization. Scott Walsh, M.B.A., is a Project Manager with Environmental Defense. John M. Balbus, M.D., M.P.H., is the Health Program Director with Environmental Defense. Richard Denison, Ph.D., is a Senior Scientist with Environmental Defense. The assistance of Nicole Buffa in preparing an earlier draft of this article is gratefully acknowledged. Portions of this article are adapted from another article by the same authors, Â"Getting It Right the First Time: Developing

Nanotechnology While Protecting Workers, Public Health and the Environment,Â" Ann. NY Acad. Sciences (forthcoming 2006). This article is reprinted with permission from 3.1 NANOTECHNOLOGY LAW & BUSINESS Â©2006, http://www.nanolabweb.com, with minor modificiations.

Add a Comment

Comment on this story in the OCA Forum and your comment will also be added here. Requires a valid OCA Forum username and password.

OCA Forum Username:

OCA Forum Password:

Register | **I Forgot My Password**

Make Comment

Organic Consumers Association - 6771 South Silver Hill Drive, Finland MN 55603
E-mail: **Staff** · Activist or Media Inquiries: 218-226-4164 · Fax: 218-353-7652
Please support our work. **Send a tax-deductible donation to the OCA**