Governance of Nanotechnology and Nanomaterials: Principles, Regulation, and Renegotiating the Social Contract

George A. Kimbrell

How should we oversee new and emerging technologies and their products? What lessons can we discern from existing regulatory examples and from past mistakes? How do these lessons learned translate into informed recommendations for adequate oversight for nanotechnology to avoid repeating the mistakes of the past? The investigators of this interdisciplinary project undertook this endeavor[1] intending to answer these questions among others.

In parallel with the project team putting together this symposium, another, very different process on the oversight of nanotechnology took place. An international coalition of non-governmental organizations (NGOs) formed to address the nanotech policy dialogue. The first goal of this NGO group was to agree upon and draft fundamental principles of oversight, which it completed in 2007-08. These principles close with a call for their adoption and/or internalization by all relevant actors and bodies. In effect, they serve a function in the policy dialogue similar to that of this project's forthcoming recommendations.

Grounded in the NGO group's principles document, this article will address the difficult question, how should oversight for nanotechnology and its products be formulated? The first section of this article summarizes the principles of oversight that are necessary in the author's view to support good governance for nanotechnology and grow out of the NGO effort discussed above. The second, third, and fourth sections delve into the application of these principles in greater detail, roughly in order of potential implementation difficulty and time. Thus, the second section explains why mandatory oversight, not voluntary programs, is needed. The third section discusses the need for regulatory action and adjustment that accounts for the challenges presented by nanomaterials. The fourth outlines the larger need for legislative action to ensure regulators have the tools they need and connect nanotechnology oversight with larger governance themes. It also discusses the opportunity that nanotechnology presents to fix long-standing problems in the environmental and health oversight. Finally, the last section makes a case for precaution as the touchstone of oversight.

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One Answer to the Project's Questions: Principles for the Oversight of Nanotechnologies and Nanomaterials

In January 2007, the International Center for Technology Assessment (ICTA) and Friends of the Earth (FoE) co-hosted the first-ever Nanotechnology NGO Strategy Summit in Washington, D.C. They brought together a diverse array of public interest organizations from across North America, including but not limited to labor, environmental, women's health, consumer products safety, civil society, policy think tanks, and citizen-based grassroots organizations. The purpose was to discuss nanotechnology oversight and assessment. The views that each organization brought to the table were shaped by their experiences with past technologies and problems caused by products and processes. The first major collaborative project of the coalition was the creation of a fundamental principles document. Over the next six months, this loose coalition painstakingly developed these principles through a consultative, collaborative process, spearheaded by ICTA. The resulting 16-page declaration, *Principles for the Oversight of Nanotechnologies and Nanomaterials*,[2] outlines the eight fundamental principles necessary for adequate and effective oversight and assessment of nanotechnology. While the discussion and issue is nanotechnology specifically, the principles are those of good governance generally. They can be summarized as follows:[3]

I. A Precautionary Foundation

When an activity raises threats of harm to human health or the environment, precautionary measures should be taken, even if some cause-and-effect relationships are not fully established scientifically. Product manufacturers and distributors must bear the burden of proof to demonstrate the safety of their products. The lack of data or evidence of specific harm must not substitute for a reasonable certainty of safety. There must be independent health and safety data review as a prerequisite for market approval.[4]

II. Mandatory Nano-Specific Regulations

A modified or *sui generis* regulatory regime must be an integral aspect of the oversight of nanotechnologies. Where legal authority exists, it must be modified to adequately and effectively address the fundamentally different properties of nanomaterials and the challenges they present. These laws are even less equipped to oversee future products and processes such as active nano-systems and nano-structures currently under development. Nanomaterials should be classified as new substances and subject to nano-specific oversight mechanisms, such as data requirements and testing. Voluntary initiatives are insufficient and will only delay or forestall necessary mandatory measures.[5]

III. Health and Safety of the Public and Workers

The prevention of exposure to nanomaterials that have not been proven safe must be undertaken to protect the public and workers. The government's inadequate funding for and focus on risk research must be ameliorated. Developing worker protection measures should be paramount.[6]

IV. Environmental Protection

Manufactured nanomaterials represent a new, unprecedented class of manufactured pollutants. A full life-cycle analysis of environmental impacts — including manufacturing, transport, product use, recycling, and disposal into the waste stream — must be completed prior to nanomaterial commercialization. The current paucity of government funding for environmental impact research must be increased dramatically. Environmental protection laws, existing metrics, triggers, assessments, and implementation mechanisms must be adjusted to address the new challenges of nanomaterials.[7]

V. Transparency

Adequate oversight requires measures ensuring transparency, including installing workplace right-to-know measures, mandating product labeling, and creating a public database of health and safety information. The public's common law right to know requires the labeling of all products containing nanomaterial ingredients. Safety data must be made available for public scrutiny and strictures placed on the (mis)use of confidentiality shields.[8]

VI. Public Participation

There must be open, meaningful, and full public participation at every level. "Open" means that processes must facilitate equal input from all interested and affected parties; government-corporate alliances undermine democratic ideals. "Meaningful" means that participation must proceed and inform policy

rather than be limited to after-the-fact, one-way "education." "Full" means that participation requires democratic involvement for each stage of the technologies. Rather than beginning from false presumptions of technological inevitability and/or benefit, processes must be driven by social needs identified through informed deliberation.[9]

VII. Inclusion of Broader Impacts
Nanotechnology's wide-ranging effects, including ethical and social impacts, must be considered. Full public debate on the potential impacts of next generations of nanotechnologies — and their associated complex risks and social and ethical challenges — must begin now. Social science analyses of nanotechnology's implications must be adequately funded and take place in conjunction with the health and environmental sciences. The adverse impacts of granting patents for fundamental materials, privatizing the building blocks of the natural world, must be considered and addressed.[10]

VIII. Manufacturer Liability
All who market nano-products, including nanomaterial developers, handlers and commercial users, the makers of products containing nanomaterials, and retailers who sell nano-containing products to the public must be held accountable for liabilities incurred from their products. Those funding and engaged in commercialization are responsible for any damage to the environment stemming from their failure to take precautionary proactive measures.[11]

The signatories publicly released the *Principles* declaration on July 31, 2007 with more than 40 endorsing organizations spanning six continents.[12] Upon release, the signatories called upon all governmental bodies, policy makers, industries, organizations, and all other relevant actors to endorse and take actions to incorporate the principles. There are now more than 70 organizations as signatories.

The following three sections tease out a few of these principles' elements, discussing their application in the context of U.S. nanotech policy developments.

Mandatory, Not Voluntary, Measures

One microcosm of the overarching good governance question as applied to nanotechnology is the question of mandatory *versus* voluntary oversight measures. U.S. voluntary programs have increased in the recent past as governments moved toward more deregulation, either to supplement or replace mandatory regulation altogether. These efforts intensified under the Bush administration, becoming the favored paradigm of environmental policy.[13] The history of voluntary regulation proposals is bleak; the weight of evidence questions their worth as compared to mandatory oversight measures.[14] One major disadvantage of wholly voluntary programs is the absence of any incentive for "bad actors," or those with risky products not likely to volunteer to do health and safety testing and submit any information indicating risk. Voluntary programs also lack transparency and accountability, failings that do not give the public confidence that the government is protecting its interests.

The result of voluntary "regulation" has been in many cases to delay or weaken mandatory regulation and forestall public involvement. U.S. action on climate change provides the perfect example of the voluntary solution myth.[15] Voluntary programs for climate change have existed since the 1990s, yet such approaches have failed to reduce greenhouse gas emissions.[16] Only since the 2007 U.S. Supreme Court's strong rebuke of the Bush administration in *Massachusetts v. EPA*,[17] where it held that the Environmental Protection Agency (EPA) decision that it did not have authority to regulate greenhouse gases pursuant to the Clean Air Act was arbitrary and capricious, has administrative and legislative mandatory climate change regulation finally moved to the fore.[18]

The main U.S. application of this debate in the nanotechnology context has been the EPA's voluntary program, the Nanoscale Materials Stewardship Program (NMSP). In the summer of 2005, EPA's Office of Pollution Prevention and Toxics (OPPT) began discussions regarding a potential voluntary pilot program for nanomaterials under its chemical authority, the Toxic Substances Control Act (TSCA).[19] The open-ended program requested that manufacturers of nanomaterials submit to EPA materials data, without any mandatory requirements. Given the then already advancing state of nanomaterial development and commercialization, the EPA voluntary program was sharply criticized by consumer and environmental advocacy groups as "inadequate and inappropriate" for the regulation of nanomaterials.[20] Although the NMSP was touted as a faster means than mandatory regulation, in practice it took EPA another two years to act. Finally, in summer 2007, EPA proposed to begin the program the following year, albeit without addressing the concerns raised by the NGO community. That community again warned that: the program lacked transparency, incentives for industry participation, and specific requirements or deadlines; would only create delay; and that mandatory oversight, or at the very least a mandatory component to the program, was instead urgently needed.[21]

The program was launched in January 2008 (to run through 2010), and as predicted, participation could

generously be called sparse: EPA's NMSP interim report showed that after a year, there were only 29 even "basic" information submissions, representing less than 10% of the unique nanomaterials EPA estimates are already commercially available, and only four companies indicated they were willing to undertake any additional nano-specific testing.[22] In sum, the participation was very low and those that did participate submitted very little actual data,[23] much of it submitted as confidential business information (CBI) and thus withheld from public review. The result was predictable from the incentives created. Why rush to give the agency data when your products are already being commercialized? Why bring greater public and regulatory scrutiny to yourself and your product? Why do more testing when not required? This thinking was encapsulated by one speaker at a 2009 food and drug law industry conference on nanotechnology: "'You can be the government's guinea pig if you turn in a lot of data,' warned George Burdock, president of the Burdock Group, an Orlando-based consulting firm. While companies should do enough safety tests of their products to show they were reasonably diligent, Burdock added, they should not overdo it. 'Don't test yourself out of a product,' he advised."[24]

Nor was the U.S. program alone as a failure in nanomaterial voluntary programs. The United Kingdom ran its own Voluntary Reporting Scheme (VRS)[25] from September 2006-September 2008 and had a grand total of eleven submissions, nine from private companies and two from academia.[26] A voluntary program conducted in Denmark yielded so little response and so little information that it did not require analysis. Scholars studying the potential success of nanomaterial voluntary programs stated in fall 2007, "We conclude that relying solely on the VEPs [voluntary environmental programs] will not be sufficient to ensure the generating of health and safety information on the hazardous properties of nanomaterials to support informed proactive risk management."[27]

That the EPA failed to heed these early lessons makes its own failure even more egregious. Moreover, the structural weaknesses of TSCA itself create a disincentive for manufacturers to provide information voluntarily: the statutory scheme assumes that no information equals no risk. If EPA does not have enough information to evaluate the health and environmental effects of a chemical, it can prohibit or limit its manufacture only if the agency can show that the chemical may present an unreasonable risk.[28] Not only does this create onerous burdens on the agency, it also creates a disincentive for manufacturers to generate information on the possible risks of a chemical.

The tide is turning toward mandatory requirements, however. In January 2009 France proposed legislation requiring that those who manufacture, import, or market nanomaterials periodically report the identity, quantity, and uses of the substances; information would be made available to the public unless damaging to national defense.[29] Stepping into the U.S. federal breach — as it has in many environmental arenas in the past — in January 2009 California's Department of Toxic Substances Control exercised its authority under the state's Health and Safety Code by requiring all companies, universities, and research facilities using carbon nanotubes or reactive nanometal oxides to submit "analytical test methods, fate and transport in the environment, and other relevant information" within one year.[30] In May 2009 the Government of New South Wales, Australia announced plans to push for mandatory labeling of nanoparticles used in workplaces.[31] And in early 2009, Canada introduced mandatory safety reporting for companies producing nanomaterials, becoming the first country to do so. Companies and institutions that manufacture or import more than 1 kg of a nanomaterial are required to submit all toxicological data they have within four months, including properties, toxicity testing, methods of manufacture, and uses.[32] The information will be used to develop a regulatory framework and inform risk assessments.[33]

With the U.S. voluntary program an unmitigated failure, it now appears the new EPA and Obama Administration may be willing to follow Canada's lead

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and make the nano-chemical data program mandatory.[34] Finding out what data companies have and what testing they are doing (and making it public) will be a significant, if belated, step in the right direction. However, even if the TSCA data program is made mandatory, without further statutory or regulatory change the amount of oversight EPA can provide pursuant to TSCA is limited. As no less than the original drafter of the statute has concluded,[35] TSCA is outdated and a relatively weak law, with numerous structural deficiencies, which are exacerbated when applied in the nanotech context.[36] These types of oversight challenges can be addressed in part by adjusting regulations to account for nano-specific considerations, as discussed in the following section.

Maximizing Existing Authority with Nano-Specific Regulatory Measures

"Nano" means more than merely tiny; it means materials that have the capacity to act in a fundamentally different way. Governments need to begin from that premise and act accordingly to provide oversight. As far back as 2004, the U.K.'s Royal Society and Royal Academy of Engineers concluded that nanomaterials need to be differentiated from other materials and treated as new substances "to take account of the enhanced or different properties that some nanoparticles (and nanotubes) may have compared with larger particles of the same chemical species."[37] In the United States, existing oversight systems have been found to be largely inadequate to deal with current nanotechnology.[38] That said, numerous federal agencies have some authority to oversee nanomaterial products and processes. In some instances, agencies can begin to address these challenges through regulatory action under existing authorities, by maximizing the nascent authority they have, but are not using. That means among other things: treating nanomaterials as new substances for assessment and regulation; tailoring regulatory risk assessment, testing, data, and thresholds to account for "nano-ness"; increasing institutional knowledge and studies; and developing cost-effective technologies for measurement and monitoring.

Addressing nanotoxicity testing is one example of a needed regulatory fix. Toxicology normally correlates health risks with the mass to which an individual is exposed, resulting in an accumulated mass as an internal dose/exposure. However, the biological activity of nanoparticles is likely to depend on physicochemical characteristics that are not routinely considered in toxicity screening studies.[39] There are many more factors affecting the toxicological potential of nanoscale materials, up to at least 16 in fact, including: size, surface area, surface charge, solubility, shape or physical dimensions, surface coatings, chemical composition, and aggregation potential — not the two or three factors normally analyzed.[40] Unless thorough investigations are performed of all variables, the toxicity and safety of various products will be unknown. Size is one of many factors, but is crucial. The relevance of the nano-size is that we cannot predict the toxicity of nanomaterials from the known properties of larger substances. In fact, nanotoxicology is an emerging field in its own right, requiring new paradigms of predictive toxicology.[41]

Agency testing methods and thresholds must be tailored to nanomaterials, a reality that U.S. agencies have been slow to acknowledge. The Food and Drug Administration (FDA) seemingly recognizes the fundamentally different characteristics of nanoparticles in its informal adoption of the U.S. National Nanotechnology Initiative (NNI) definition of nanotechnology, which includes "the creation and use of structures, devices and systems that have novel properties and functions because of their small size."[42] Yet FDA's existing testing methodologies are based on bulk material or larger particles, and the agency assumes that this battery of tests is "probably adequate" for testing the safety of manufactured nanoparticles.[43] FDA must remedy this misinformed view. The European Commission's (EC) Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) noted that "[e]xperts are of unanimous opinion that the adverse effects of nanoparticles cannot be predicted (or derived) from the known toxicity of material of macroscopic size, which obey the laws of classical physics."[44] Similarly, the U.K. Royal Society and the Royal Academy of Engineering emphasized, "Free particles in the nanometre size range do raise health, environmental, and safety concerns and their toxicology cannot be inferred from that of particles of the same chemical at a larger size."[45] And the Institute of Occupational Medicine notes, "Because of their size and the ways they are used, they have specific physical-chemical properties and therefore may behave differently from their parent materials when released and interact differently with living systems. It is accepted, therefore, that it is not possible to infer the safety of nanomaterials by using information derived from the bulk parent material."[46]

In short, the FDA is wrong that existing tests are "probably adequate." Current testing is helpful but insufficient, because it does not take into account new parameters that are necessary. FDA's established methods of safety assessment must be significantly modified in order to address the special characteristics of engineered and manufactured nanoparticles. FDA has a 2006 legal petition pending filed by a coali-

tion of non-profits (including the author's) requesting that the agency amend its regulations under the Federal Food Drug and Cosmetic Act (FFDCA) to address nanomaterials in products under its jurisdiction, including the requirement of nano-specific toxicity testing and data for products, and their classification as new substances.[47]

Regulatory thresholds are another needed adjustment. For example, EPA's current TSCA chemical notification requirements exempt several categories of chemicals, including a low-volume exemption for chemicals produced in volumes of 10,000 kilograms or less a year (or less than 11 tons a year) and a "low release/low exposure" exemption.[48] Applying such exemptions could be dangerous because nanomaterials can exhibit dramatically higher levels of activity per mass unit than conventional materials. Other environmental laws have similarly inapposite threshold levels for exposure and will also require a shift from mass/volume based measurements and limitations.[49]

Some of these adjustments can be made with political will and regulatory amendment. EPA's regulation of genetically modified microorganisms pursuant to TSCA is one example.[50] However, regulatory change in some cases is only triggered if the substance is determined to be "new." This is a major issue at the FDA. Former FDA Deputy Commissioner for Policy Michael Taylor has analyzed the FDA's preparedness and the adequacy of FDA's existing oversight framework and found it wanting. Taylor highlighted the regulatory gaps that exist in FDA's authority as applied to nanomaterials, particularly in the areas of cosmetics and dietary supplements. He recommended, among other things, that FDA take immediate steps to establish criteria for nanomaterials, including "new for legal and regulatory purposes" and "new for safety evaluation purposes."[51] Problems continue at EPA as well. Unfortunately, in summer 2007 EPA interpreted its own authority of what was a "new" material pursuant to TSCA narrowly, further limiting its regulatory authority over nanomaterials under that statute.[52] "New" chemical substances are substances not already listed in EPA's TSCA inventory,[53] and they require a premanufacture notice (PMN) and review by EPA.[54] That premarket review, in theory, allows EPA to review and assess the potential risks of a new chemical before its commercialization (and if necessary, limit or prohibit its release). Given EPA's 2007-08 determination of what is "new" and what is "existing" pursuant to TSCA,[55] which effectively ignores the new properties of materials if there is a larger substance with the same chemical structure, most nanomaterials would be "existing" and exempt from such review. The majority of nanomaterials are excluded because they have the same chemical composition and structure as some larger material even though they have new and novel properties (e.g., silver, titanium dioxide, carbon). With this policy, EPA took "an already weak statue and makes it a dead letter with respect to nanotechnology."[56] On the other hand, the Obama Administration has the opportunity to reverse it with minimal burden if it so chooses.[57] EPA has also cautioned that its actions under TSCA with regard to what is "new" do not establish a precedent for other statutory programs.[58]

Another example of recognizing and adjusting regulations to new challenges is EPA's regulation for genetically modified microbial pesticides[59] and a particular class of bioengineered pesticides, plant-incorporated protectants[60] pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). FIFRA, the federal regulatory scheme for the manufacture, labeling, sale, and application of pesticides, is in general a stronger statute than TSCA. EPA has broad premarket approval and testing authority: a pesticide must be registered with the EPA before it can be distributed or sold.[61] If a substance is found to have "unreasonably adverse effects on the environment," it cannot be registered and brought to market; approval and registration is conditioned upon use in a manner designed to prevent unreasonable adverse effects.[62] A pesticide is defined broadly as any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest.[63] This registration requirement is EPA's strongest tool for controlling the potential risks of nano-pesticides, permitting EPA to, among other things, require that manufacturers test pesticides and submit the risk data.[64] Although not as broad as TSCA, which theoretically covers all chemicals, EPA's FIFRA authority encompasses all substances with pesticidal intent. This includes the largest categories of known commercialized nanomaterials,[65] nano-silver products, which are being sold as enhanced germ-killers in a plethora of consumer products.[66] Studies have raised red flags about nano-silver's potential health and environmental impacts, particularly on aquatic systems.[67] As with FDA, a coalition of non-profits (including the author's) have provided the agency with a legal blueprint and impetus to action, filing a petition in 2008 calling on EPA to regulate nano-silver products as new pesticides under FIFRA.[68] Under FIFRA, EPA has the authority to require manufacturers undergo premarket approval and submit nano-specific data, among other requirements.

Structural Legislative Action

If used in a coordinated manner, multiple statutes provide the legal and regulatory underpinnings for

adequate regulation of some aspects of nanotechnology, in the short term. However, numerous analyses of our agencies' existing authority suggest that their application to the challenges of nanotechnology is at best problematic.[69] Trying to solve these problems through regulatory adjustments and increases in agency resources and expertise alone is somewhat akin to shuffling deck chairs on the sinking Titanic. At the end of the day, structural shortcomings must be addressed through legislation. The gaps and weaknesses in existing authority as applied to older products become large legal lacunae when dealing with nanomaterial products and their regulatory challenges. For example, FDA's authority over cosmetics and dietary supplements,[70] two significant areas of nanomaterial commercialization that create high human exposures, is extremely limited;[71] FDA has no statutory pre-market authority at all. And TSCA has numerous structural problems.[72] It assumes no data equals no risk, places the burden of production on the agency not the propriety entity, and any rule-making action by the agency must meet an exceptionally onerous standard of judicial review.[73] EPA's inability to ban asbestos under TSCA illustrates this burden well.[74] EPA carried out ten years of analysis in support of its proposed asbestos rule, and a federal Court of Appeals still struck down the rule, finding the agency's analysis insufficient.[75] Faced with this burden, EPA has banned only five chemicals since 1976. The Consumer Product Safety Commission (CPSC), the agency that theoretically oversees consumer product safety along with FDA, in reality has no power, as its statutory authority denies it the ability to impose safety standards or require pre-market testing.[76] Many of our environmental laws (Clean Air Act, Clean Water Act) are implicated by the commercialization of nanomaterials, but these statutes are in the main data-driven and here there is a dearth of data, with the onus placed on the already overburdened agencies to remedy this.[77] Accordingly, new legislation can serve two complementary and necessary ends: to properly address the challenges of nanotechnology and to remedy long-standing gaps in U.S. environmental and health regulation.

In confronting nanotechnology, the question is not whether new legislation will be needed, the question is only when. Nanotechnology is often termed the genesis of a "revolution"[78] that will fundamentally transform technology, industry, and society.[79] A favorite quote illustrating the scope of the promises of nanotechnology, or if you prefer, the boundless hype of nanotechnology, comes from former U.S. Undersecretary of Commerce for Technology Philip Bond:

> On a human level, nano's potential rises to near Biblical proportions. It is not inconceivable that these technologies could eventually achieve the truly miraculous: enabling the blind to see, the lame to walk, and the deaf to hear; curing AIDS, cancer, diabetes and other afflictions; ending hunger; and even supplementing the power of our minds, enabling us to think great thoughts, create new knowledge, and gain new insights.
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> On a societal level, nanotechnology will deliver higher standards of living and allow us to live longer, healthier, more productive lives. Nano also holds extraordinary potential for the global environment through waste-free, energy-efficient production processes that cause no harm to the environment or human health. And nano is already showing great potential for repairing existing environmental damage as well.[80]

Today's nanomaterial products are categorized as the "first phase" or stage of nanotechnology, known as the "passive stage" because the nanostructures developed are passive parts of existing products (e.g., zinc oxide nanoparticles added to sunscreens, carbon nanotubes added to electronics, and nano-silver added to cleaning products or clothes).[81] The so-called "second stage," which was said to begin after 2005, focuses on "active" nanostructures that change their size, shape, or other properties during use (e.g., drug delivery devices).[82] Further "phases" of development predicted include systems of nanostructures including guided assembly (circa 2010) and molecular nanosystems (circa 2015).[83] In fact, the hype and promise (and it's always difficult to separate the two) predict "nothing less than complete control over the physical structure of matter — the same kind of control over molecular and structural makeup of physical objects that a word processor provides over the form and content of a text."[84] Thus, even if only a small portion of nanotechnology's predicted promises comes to pass, it is obvious that current laws are not equipped to regulate such fundamentally different products and processes. Over time, traditional regulatory frameworks, benchmarks, and distinctions will become even less useful as applied to nanotechnology's processes and applications.

In a recent ground-breaking report on "Oversight of the Next Generation of Nanotechnology," Clarence Davies tackles some of these questions, recommending a new agency created by new legislation — a new Department of Environmental and Consumer Protection to oversee product regulation, pollution control and monitoring, and technology assessment.[85] According to Davies, "Federal regulatory agencies already suffer from under-funding and bureaucratic ossification,

but they will require more than just increased budgets and minor rule changes to deal adequately with the potential adverse effects of new technologies. New thinking, new laws and new organizational forms are necessary."[86]

Creating nano-specific provisions in law alone would address only part of the problem. The question of nanotechnology oversight creates a golden opportunity to ameliorate long-festering problems in U.S. oversight structures. There is a window of opportunity for nanotechnology right now to effectuate broader reform, and it has become a major driver in larger policy decisions. Nanotechnology developments highlight how outdated our current regulatory systems are, how ill-equipped they are to deal with the issues of the 21st century. Our environmental protection laws are all approaching 40 years of age, without a significant amendment in nearly 20 years. Lacking a new generation of laws more in line with ecological and technological realities of this century, those entrusted with protecting the public health and safety are forced to continue to try and squeeze blood from the existing statutory stones.[87] The new and emerging technology dialogue provides the challenge and the opportunity to re-think existing paradigms, to re-negotiate the social contract we the people have struck with our government with regard to how we approach new products, new technologies, our own inclusion, and potential risks. As we discuss how we should regulate nanotechnology, we are also discussing how we should live as a society: What risks should the public have to bear from a product thanks to a proprietary entity wishing to commercialize it? How about those employed by the manufacturer? To what extent should we be making decisions that burden or bind future generations? What role should the public have in the decision-making process, and how much choice will they have to approve or dissent? Will nature have its own voice? Who can own these processes and their materials?

There are several existing oversight domains in which nanotechnology acts as a partner to existing issue or driver of reform: chemicals, biotechnology and genetically engineered crops and animals, food safety, cosmetics, and workplace safety, to name a few. TSCA reform[88] is the most obvious and well-documented connection; nanotechnology is already an important driver and may end up being the tail that wags the TSCA dog. This truth is visible in Washington, D.C., where nanotechnology has figured in Congressional hearings on TSCA reform.[89]

The Registration, Evaluation, and Authorization of Chemicals (REACH), the new chemical legislation on the manufacturing and commercialization of chemical substances in Europe, went into force on June 1, 2007. REACH establishes a system requiring registration and evaluation of existing and new chemical substances. Under REACH, the European Union (EU) can establish restrictions for any chemical that poses unacceptable risks and to require authorization for the use of chemicals identified as being of very high concern. REACH shifts the burden of proof to the manufacturer or industry to provide information, assess risk, and provide reasonable assurances of safety prior to marketing and use, rather than placing the burden on regulators to prove harm.[90] Under REACH, regulators can require the manufacturers provide and develop data on health and environmental impacts. In doing so, REACH will serve as a data production tool to regulators. Further, importantly for nanomaterials, REACH eliminates the "new" versus "existing" distinction that leaves the majority of nanomaterials exempt under TSCA. Instead, it simply requires that all chemicals be registered, tested, and assessed. REACH also requires manufacturers to update data on chemicals whenever there is change in composition, use, or knowledge, which a new nano-form of a substance would trigger.[91] U.S. chemical governance is now diametrically opposed to the system used in Europe, which is based on the precautionary principle, and with which U.S. companies will have to comply to sell products in Europe.[92] Although REACH has gaps and problematic thresholds for nanotechnology, with this statutory authority in place, Europe is poised to make nano-specific adjustments as needed.[93] In fact, the EU is already moving towards addressing these issues, with the Environment Committee of the European Parliament adopting a report calling for nano-specific review, testing and assessment protocols, data requirements, and labeling.[94]

In sharp contrast, a 2008 Government Accountability Office (GAO) study concluded that TSCA is badly broken; EPA lacks even basic information to say whether chemicals pose substantial health risks to the public, to say nothing of novel nanomaterials.[95] The GAO auditors found that "TSCA's regulatory framework impedes EPA's efforts to control toxic chemicals"[96] and that EPA needs additional statutory authority in order to obtain health and safety information from the chemical industry,[97] and the GAO added EPA's chemical management program to its list of "high risk" government programs.[98]

In 2008, Senator Lautenberg (D-NJ) introduced the Kid Safe Chemical Act (KSCA),[99] which, like REACH, would shift the burden for proving chemicals are safe from EPA to the chemical manufacturers.[100] Manufacturers would have to provide the EPA with the data necessary to determine if a chemical is safe and EPA would have new authority to restrict the

use of chemicals which fail to meet a new EPA safety standard.[101] Environmental organizations have made support for the act's passage a part of their message to the incoming Obama Administration,[102] and Congressional leaders are expected to re-introduce or hold further hearings as early as spring 2009. Not just EPA's, but all agencies' oversight of nanomaterials would benefit from TSCA reform. The EPA chemicals database called for by KSCA, for example, could be used to analyze ingredients in products under their respective jurisdictions. Amending TSCA to make it consistent with REACH would go a long way towards shoring up nanotechnology oversight and setting a good foundation for future nanotechnology oversight, in addition to providing needed change in our outdated and broken system of chemical regulation in general.[103]

Precaution

A librarian could fill whole reading rooms with books and articles and dissertations on the precautionary principle,[104] and a thorough examination of it is beyond the scope and intent of this article. Rather, this section will take the much less ambitious approach of deconstructing a bit why governments should apply the principle to nanotechnology and nanomaterials.

Whatever one thinks of the principle generally, for example regarding its application to all chemicals as in the EU's REACH regulation,[105] the argument in favor of applying the precautionary principle is even stronger when considering the impacts of new technological systems that we are just beginning to understand, whose long-term impacts are unknown. It is stronger because this platform technology creates new materials that have novel properties whose safety we do not fully understand how to test. It is well-known that materials engineered or manufactured to the nano-scale can exhibit radically different fundamental physical, biological, and chemical properties from their larger cousins.[106] The same new properties that excite industry (e.g., tiny size, high surface-to-volume ratio, and increased reactivity) can create associated new risks to health and the environment. Because of their tiny size, nanomaterials have unprecedented mobility for a manufactured material and the ability to get places in the human body and environment that larger particles cannot, creating novel and unanticipated exposures. Studies assessing the role of size on toxicity have generally found that nanoparticles are more toxic than larger particles of the same substance.[107] Other studies have shown that some nanoparticles are toxic in ways that cannot be attributed to particle size alone.[108] Scientists have yet to determine what physicochemical properties will be most important in determining ecological and toxicological properties of nanomaterials.[109] An increasing body of evidence indicates the potential for unusual health and environmental risks.[110]

If the precautionary principle is in part to "look before you leap," the leap into nanotechnology is of a different and unknown sort. In this way, the risks of nanotechnologies are similar to unknown risks associated with other new and emerging technologies, such as biotechnology and genetically engineered organisms, synthetic biology, and geo-engineering and climate change technologies. Yet decisions must sometimes be made in the absence of scientific information and in light of current science's limitations. Each subject carries unpredictable, unquantifiable, and possibly catastrophic risk that weighs heavily in the favor of an anticipatory, "better safe than sorry" paradigm.

Although the *Wingspread Statement* definition of the precautionary principle was used in the *Principles*,[111] another good restatement was put forth more recently by the United Nations Economic, Scientific, and Cultural Organization's (UNESCO) World Commission on the Ethics of Scientific Knowledge and Technology (COMEST) Report,[112] *The Precautionary Principle*:

> When human activities may lead to morally unacceptable harm that is scientifically plausible but uncertain, actions shall be taken to avoid or diminish that harm. *Morally unacceptable harm* refers to harm to humans or the environment that is
> - threatening to human life or health, or
> - serious and effectively irreversible, or
> - inequitable to present or future generations, or
> - imposed without adequate consideration of the human rights of those affected.
>
> The judgment of *plausibility* should be grounded in scientific analysis. Analysis should be ongoing so that chosen actions are subject to review.
>
> *Uncertainty* may apply to, but need not be limited to, causality or the bounds of the possible harm.
>
> *Actions* are interventions that are undertaken before harm occurs that seek to avoid or diminish the harm. Actions should be chosen that are proportional to the seriousness of the potential harm, with consideration of their positive and negative consequences, and with an assessment of the moral implications of both action and inaction. The choice of action should be the result of a participatory process.[113]

Under this restatement, grounds for concern to trigger the application must be "plausible or scientifically ten-

able."[114] Similarly, an earlier European Union statement held that the precautionary principle should apply when the "preliminary" evidence indicates "reasonable grounds for concern": "The precautionary principle applies where scientific evidence is insufficient, inconclusive or uncertain and preliminary scientific evaluation indicates that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the high level of protection chosen by the EU."[115] The grounds for concern regarding nanotech's potential adverse impacts to human health and the environment are both "plausible or scientifically tenable," and "reasonable."[116] Even with only a paucity of funding and research, existing studies have steadily raised red flags about nanotechnology and nanomaterials. Calls for more risk research echo seemingly daily. For example, in spring 2008-spring 2009, the studies described in Figure 1 (grouped by type of nanomaterial) were published. These studies underscore the reasonableness of the concerns about nanomaterials and the scientific plausibility of such potential harms.

In exchange for these mostly unexplored risks, what benefits are we as a society receiving by permitting unbridled commercialization? Nanotech commercialization is no longer "emerging," but moving ahead at lightning speed, with at least three to four nano-enabled consumer products hitting the market per week.

In exchange for these mostly unexplored risks, what benefits are we as a society receiving by permitting unbridled commercialization? Nanotech commercialization is no longer "emerging," but moving ahead at lightning speed, with at least three to four nano-enabled consumer products hitting the market per week.[117] Nanotechnology is quickly becoming one of the biggest areas of public and private investment in the world. In the United States, federal funding for nanotechnology has increased from approximately $464 million in 2001 to nearly $1.5 billion for fiscal year. Private industry is investing at least as much as the government, according to estimates. The only publicly available nanomaterial product inventory shows approximately 800-900 currently available on U.S. market shelves.[118] In 2007 alone, $147 billion in nano-enabled products were produced. By 2015 that figure is expected to grow to $3.1 trillion worldwide.[119] Some nano-products currently available include: paints, coatings for numerous products, "cosmetically clear" sunscreens, medical devices, sporting goods, cosmetics, stain-resistant clothing, dietary supplements, vitamins, food and food packaging, kitchen and cooking ware, light emitting diodes used in computers, cell phones, and digital cameras, film and photo development products, automotive electronics, automotive exteriors, batteries, fuel additives, and tires, computer accessories, children's toys and pacifiers, laundry detergent and fabric softeners, personal hygiene products, cleaning agents, air conditioning units, pet products, jewelry, bedding and furniture, lubricants and foams, waxes, MP3 players, and other electronics.[120] Compared to future predicted molecular assembler "nanobots" or cancer curing nano-target drug deliveries, the current applications seem mundane and their benefits marginal; yet the intertwined risks and the substantial unknowns remain the same.[121]

Finally, it is also easier to apply a precautionary approach at early stages of development, when government objectives, policies, and plans are still being determined and are not yet entrenched. In sharp contrast to commercialization, oversight in the United States continues to languish far behind the commercialization curve. In general, U.S. federal agencies have held public meetings, tried voluntary data programs, and published white papers, but have yet to engage in any meaningful regulation. Nano product manufacturers are still not required to identify nanoparticle ingredients on product labels or conduct nano-specific safety tests on these ingredients, or submit their products for approval prior to commercialization.

Policies are still being put in place to create research priorities and plans, a far cry from oversight. The NNI is the U.S. government's current hub for coordinating federal agencies' nanotechnology research and development funding.[122] The NNI's Nanotechnology Environmental Health Implications (NEHI) Working Group is the subgroup charged research of potential risks. While NEHI has produced a series of papers on risk research,[123] the results of their process has been repeatedly lambasted over the past several years[124] by Congress and the National Research Council (NRC),[125] among others, as laggard; seriously flawed; lacking an overarching vision, strategy, or plan; lacking prioritization of needs; lacking resources; lacking account-

Figure 1

Nano Risk Research Published in 2008-09

Material	Study	Finding
Carbon-based nano-material	Folkmann et al.[1]	Single-exposure in rats resulted in DNA damage in liver and lung tissue.
Carbon nano-tubes (CNT)	Centers for Disease Control[2]	CNT in mice moved through the lung lining into surrounding tissue, similar to toxic asbestos fibers.
Double-walled CNT	Scott-Fordsmand et al.[3]	Earthworms fed CNT produced fewer cocoons than normal.
Single- and multi-walled CNT	Nygaard et al.[4]	Strong allergic response when administered to mice.
Quantum Dot	King-Heiden et al.[5]	Zebrafish embryo exhibited clear toxicological impairment.
Quantum Dot	Lin et al.[6]	Accumulation in mice was toxic to vital organs and renal mitochondria.
Quantum Dot	Mahendra et al.[7]	Under normal weathering conditions, QD dissolved, releasing toxic heavy metals.
Nano C-60 (Buckminster Fullerenes)	Baun et al.[8]	In water, caused increased toxicity of a known environmental contaminant, harmful to algal cell membranes.
Nano C-60	Roberts et al.[9]	Found to be cyto- and photo- toxic to human lens epithelial cells, which could induce early-age cataracts.
Nano C-60	Zhu et al.[10]	Sub-lethal doses given to juvenile carp resulted in oxidative stress and inhibited growth.
Nano-silver	Benn and Westerhoff[11]	Leached from socks into water during washing, with wastewater and biosolid management implications.
Nano-silver	Yang et al.[12]	NS used in food storage materials were found to bind with DNA, compromising DNA replication.
Nano-silver and Nano-gold	Archer[13]	As colloids in health supplements, caused heart wall weakening and conduction system malfunction.
Nano-metals	Rogers, et al.[14]	Can significantly decrease the human blood's antioxidant capacity.
Nano-silver, Copper oxide, Zinc oxide	Anderson et al.[15]	Toxic to beneficial bacteria singly and in combination.
Iron-containing nanomaterials	Murray et al.[16]	Upon skin contact, cause inflammation and other cell damage.
Iron oxide	Pisanic et al.[17]	Toxic to nerve cells, killing some and reducing others' ability to transmit neuronal signals.
Metal oxides	Mortensen et al.[18]	Metal oxide nanoparticles can seep through skin, especially when damaged or sunburned.
Titanium Dioxide	Takeda et al.[19]	Passed from pregnant mice to offspring, caused functional and pathological disorders due to genital and cranial nerve system damage.
Titanium Dioxide	Gruden and Mileyeva-Biebesheimer[20]	Significantly hazardous to bacteria, even in extremely small doses.

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ability; and lacking input from stakeholders, among other things.[126]

The NNI's authorizing legislation gives it no oversight authority.[127] It is a funding clearinghouse only. Nor are other agencies further along in policy making. Nanotechnology and the already extremely broad swath of commercialized nanomaterials implicate numerous U.S. federal agencies' jurisdiction. A number of laws provide bases for regulatory oversight of some aspects of nanotechnology's effects on the environment and human health. The EPA has varied regulatory authority over nanomaterials' environmental impacts pursuant to the Clean Air Act (CAA), Clean Water Act (CWA), TSCA, and FIFRA. The CPSC oversees many types of consumer products, but in practice has very little pre-market authority and even less funding. The Occupational Safety and Health Administration (OSHA) has authority over workplace health and safety issues, including the manufacturing of nanomaterials and nanoproducts. The FFDCA grants the FDA purview over the impacts of many nanomaterial products, including drugs, food and food packaging, dietary supplements, medical devices, and cosmetics. No U.S. law or regulation is specifically designed or has been amended to regulate nanotechnology and nanomaterials.

Overall, nanotechnology policy so far could be aptly summarized as "all talk, no action."[128] In 2007 EPA published a nanotechnology white paper[129] which was a good summary of nanotechnology's scientific challenges, but fell short of providing any policy guidance. FDA held its first public meeting on nanotechnology in Fall 2006,[130] and created an internal task force that drafted a report and recommendations similar to EPA's white paper.[131] The report provided a summary of the known science and recognized the fundamental different properties, uncertainties, and challenges nanomaterials present (e.g., to knowledge of risk and the way that testing is performed). It also correctly concluded that the agency needs new safety assessment tools, characterization methods, new detection/inspection tools, staff expertise, and much research to assess health effects.[132] Yet it failed to recommend any meaningful policy or oversight measures to deal with these new and fundamentally different properties, uncertainties, and challenges.[133] In 2008, FDA held yet another public meeting on nanotechnology, virtually a carbon copy of the meeting it held in 2006.[134]

The still-nascent nature of agency policy development perhaps has a silver lining — it makes precautionary approaches more politically possible.

Conclusion

Sufficient oversight of nanotechnology is predicated on principles of general good governance. The application of nanotechnology and nanomaterials to our existing regulatory frameworks spotlights their gaps and weaknesses. Formulating adequate nanotechnology regulation requires a coordinated effort to remedy the underlying systemic flaws, giving agencies the proper regulatory tools needed to address the challenges of new technological developments such as nanomaterials. As illustrated by asbestos, CFCs, DDT, leaded gasoline, PCBs, mercury, and numerous other former "wonder" substances and technologies, some nanomaterial will undoubtedly have significant and unintended negative consequences on human health and the environment. The potential impacts of nanotechnology are now foreseeable and sufficient to warrant precaution. Whether our policy makers will wait until tragedy strikes or adapt preemptively remains to be seen.

Acknowledgements

Preparation of this article was supported in part by National Science Foundation (NSF) grant no. 0608791. Any opinions, findings, and conclusions or recommendations expressed in this article are those of the authors and do not necessarily reflect the views of the National Science Foundation or the author's employer. The author thanks the project Working Group for the opportunity to participate in this project. The author also thanks his wife Colleen for her love and support.

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38. See, e.g., J. C. Davies, *Oversight of the Next Generation of Nanotechnology* (Washington, DC: Project on Emerging Technologies, 2009), *available at* <http://207.58.186.238/process/assets/files/7316/pen-18.pdf> (last visited June 1, 2009); W. Schultz and L. Barclay, *A Hard Pill to Swallow: Barriers to Effective FDA Regulation of Nanotechnology-Based Dietary Supplements* (Washington, D.C.: Project on Emerging Technologies, 2009), *available at* <http://www.nanotechproject.org/process/assets/files/7056/pen17_final.pdf> (last visited June 1, 2009) ; E. M. Felcher, *The Consumer Products Safety Commission and Nanotechnology* (Washington, D.C.: Project on Emerging Technologies, 2008), *available at* <http://www.nanotechproject.org/process/assets/files/7033/pen14.pdf> (last visited June 1, 2009); J. C. Davies, *Nanotechnology Oversight: An Agenda for the New Administration* (Washington, D.C.: Project on Emerging Technologies, 2008), *available at* <http://www.nanotechproject.org/process/assets/files/6709/pen13.pdf> (last visited June 1, 2009); L. K. Breggin and J. Pendergrass, *Where Does the Nano Go? End-of-Life Regulation of Nanotechnologies* (Washington, D.C.: Project on Emerging Technologies, 2007), *available at* <http://www.nanotechproject.org/process/assets/files/2699/208_nanoend_of_life_pen10.pdf> (last visited June 1, 2009); J. C. Davies, *EPA and Nanotechnology: Oversight for the 21st Century* (Washington, D.C.: Project on Emerging Technologies, 2007), *available at* <http://www.nanotechproject.org/process/assets/files/2698/197_nanoepa_pen9.pdf> (last visited June 1, 2009); M. Taylor, *Regulating the Products of Nanotechnology: Does FDA Have the Tools It Needs?* (Washington, DC: Project on Emerging Technologies, 2006), *available at* <http://www.nanotechproject.org/file_download/files/PEN5_FDA.pdf> (last visited June 1, 2009); L. Breggin and L. Carothers, "Governing Uncertainty: The Nanotechnology Environmental, Health, and Safety Challenge," *Columbia Journal of Environmental Law* 31, no. 2 (2006): 285-329, at 310-13; American Bar Association, Section of Environment, Energy, and Resources (ABA SEER), "Regulation of Nanoscale Materials under the Toxic Substances Control Act," June 2006, *available at* <http://www.abanet.org/environ/nanotech/pdf/TSCA.pdf> (last visited June 1, 2009); A. C. Lin, "Size Matters: Regu-

lating Nanotechnology," *Harvard Environmental Law Review* 31, no. 2 (2007): 349-408; Davies, *supra* note 36.

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46. C. L. Tran et al., "A Scoping Study to Identify Hazard Data Needs for Addressing the Risks Presented by Nanoparticles and Nanotubes," *Institute of Occupational Medicine,* December 2005, at 34, *available at* <http://randd.defra.gov.uk/Document.aspx?Document=CB01072_3060_FRP.doc> (last visited June 1, 2009).
47. See generally ICTA et al., "Petition Requesting FDA Amend Its Regulations for Products Composed of Engineered Nanoparticles Generally and Sunscreen Drug Products Composed of Engineered Nanoparticles Specifically," FDA Docket # 2006P-0210, May 16, 2006, *available at* <http://www.icta.org/doc/Nano%20FDA%20petition%20final.pdf> (last visited June 1, 2009).
48. TSCA Regulations, Premanufacture Notice Exemptions, 40 C.F.R. § 723.5 (2009) (Chemical substances manufactured in quantities of 10,000 kilograms or less per year, and chemical substances with low environmental releases and human exposures).
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51. See Taylor, *supra* note 38, at 4.
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56. Public Comment Docket for NMSP Concept Paper, "Comments of J. Clarence Davies," EPA-HQ-OPPT-2004-0122-0059.1; see also EPA, "TSCA Nanoscale Materials Inventory Paper: Public Comments with EPA Responses", December 20, 2007.
57. See, e.g., *FCC v. Fox Television Stations*, 129 S. Ct. 1800 (2009) (holding that agency changes in policy must be reviewed under the same standard as new policies, and do not require a different or more substantive rationale); Davies (2008), *supra* note 38, at 12 (recommending reversal).
58. See EPA, *supra* note 55, at 1.
59. See 40 C.F.R. Part 172, Subpart C (2009) (experimental use permits); 40 C.F.R. §§ 158.690, 158.740 (2009) (data registration requirements).
60. 40 C.F.R. Part 174 (2009).
61. 7 U.S.C. § 136a(a) (2009).
62. *No Spray Coalition, Inc. v. City of New York,* 351 F.3d 602, 604-05 (2d. Cir. 2003) (*citing* 7 U.S.C. § 136a(C)(5)(D)).
63. 7 U.S.C. § 136(u)(1) (2009).
64. 7 U.S.C. § 136a (2009).
65. Woodrow Wilson International Center for Scholars, Project on Emerging Nanotechnologies, "Analysis of Inventory of Nanotechnology-Based Consumer Products," August 2008, *available at* <http://www.nanotechproject.org/inventories/consumer/analysis_draft/> (last visited May 20, 2009).
66. R. Weiss, "Groups Petition EPA to Ban Nanosilver in Consumer Goods," *Washington Post*, May 2, 2008, at A4.
67. See generally S. Luoma, *Silver Nanotechnologies and the Environment: Old Problems or New Challenges*? (Washington, D.C.: Project on Emerging Technologies, 2008), *available at* <http://www.nanotechproject.org/process/assets/files/7036/nano_pen_15_final.pdf> (last visited June 1, 2009); C. Baker et al., "Synthesis and Antibacterial Properties of Silver Nanoparticles," *Journal of Nanoscience and Nanotechnology* 5, no. 2 (2005): 244-249.
68. ICTA et al., "Petition for Rulemaking Requesting EPA Regulate Nano-Silver Products As Pesticides," EPA Docket # EPA-HQ-OPP-20080650, May 1, 2008, *available at* <http://www.icta.org/nanoaction/doc/CTA_nano-silver%20petition__final_5_1_08.pdf> (last visited June 1, 2009); EPA, "Petition for Rulemaking Requesting EPA Regulate Nanoscale Silver Products as Pesticides; Notice of Availability," 73 *Federal Register* 69644-69646 (November 19, 2008) (opening public docket); EPA, "Petition for Rulemaking Requesting EPA Regulate Nanoscale Silver Products as Pesticides; Extension of Comment Period," 74 *Federal Register* 2072 (January 14, 2009) (extending public docket).
69. See *supra*, note 38.
70. See Schultz and Barclay, *supra* note 38.
71. FDA's regulation of cosmetics and cosmetic ingredients does not include premarket approval, besides the addition of color additives. FDA, Center for Food Safety and Applied Nutrition,

"FDA Authority Over Cosmetics," *available at* <http://www.cfsan.fda.gov/~dms/cos-206.html> (last visited May 20, 2009). FDA protects the public's health and safety by prohibiting the adulteration or misbranding of cosmetics and has the authority to require warning labels. 21 C.F.R. §§ 740.1 (Misbranding); 740.10(a) (Labeling of cosmetic products for which adequate substantiation of safety has not been obtained) (2009). FDA can also pursue enforcement actions against cosmetics manufacturers in violation of the law and request product recalls. 21 C.F.R. §§ 7.40-7.59 (2009).

72. Government Accountability Office (GAO), "Chemical Regulation: Options for Enhancing the Effectiveness of the Toxic Substances Control Act," February 26, 2009, *available at* <http://www.gao.gov/new.items/d09428t.pdf> (last visited June 1, 2009); see also Lin, *supra* note 38, at 362-66.
73. *Id.* See, e.g., Davies (2006), *supra* note 38, at 10-12.
74. *Corrosion Proof Fittings v. EPA,* 947 F.2d 1201 (5th Cir. 1991).
75. *Id.* at 1215 (concluding that EPA had failed to carry its burden because it did not consider all evidence and did not give enough weight to the statutory directive to promulgate the least burdensome regulation required to adequately protect the environment).
76. See Felcher, *supra* note 38, at 3-4, 17-19.
77. See, e.g., Lin, *supra* note 38, at 367-368.
78. See, e.g., R. Weiss, "Nanotech Raises Worker-Safety Questions", *Washington Post* April 8, 2006, at A1 ("To tour the gleaming offices of Altair Nanotechnologies Inc. is to see why the U.S. Commerce Department calls nanotech "the next industrial revolution" – a revolution not of smelters and smokestacks but of precision-engineered carbon "buckyballs" one-ten-thousandth the size of the head of a pin and microscopic nanospheres that can pack the power of a car battery in a napkin-thin wafer. What could be more 21st-century?"); C. Piller, "Science's Tiny, Big Unknown," *Los Angeles Times,* June 1, 2006, at A1 ("Nanotechnology has the potential to create revolutionary change across multiple, key areas of human endeavor, according to trade group NanoBusiness Alliance. To maintain its global economic lead and to keep the U.S. homeland secure, we must win the nanotech race.").
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80. P. J. Bond, Undersecretary of Commerce for Technology, U.S. Department. of Commerce, Technology Administration Remarks as Prepared for Delivery, World Nano-Economic Congress, Washington, D.C., September 9, 2003, *available at* <http://web.archive.org/web/20040110043144/http://www.technology.gov/Speeches/p_PJB_030909.htm> (last visited June 1, 2009).
81. See generally M. C. Roco, National Science Foundation and National Nanotechnology Initiative, "Governance of Nanotechnology for Human Development," Presentation, Science and Technology for Human Future, April 28, 2006; M. C. Roco, "Nanotechnology's Future," *Scientific American*, August 2006, *available at* <http://www.scientificamerican.com/article.cfm?id=nanotechnologys-future> (last visited June 4, 2009).
82. See Roco, *supra* note 81.
83. *Id.*
84. G. Reynolds, "Nanotechnology and Regulatory Policy: Three Futures," *Harvard Journal of Law and Technology* 17, no. 1 (2003): 179-210, at 185.
85. See Davies (2009), *supra* note 38.
86. *Id.*
87. See G. Torriano, *Second Alphabet* (London: 1662) ("To go about to fetch bloud out of stones, viz. to attempt what is impossible.").
88. See e.g., M. Greenwood, "TSCA Reform Building a Program That Can Work," *Environmental Law Report News & Analysis* 39, no. 1 (2009): 10034-10041.
89. U.S. House of Representatives, Committee on Energy & Commerce, Subcommittee on Commerce, Trade, and Consumer Protection, "Revisiting the Toxic Substances Control Act of 1976," February 26, 2009, *available at* <http://energycommerce.house.gov/index.php?option=com_content&task=view&id=1505&Itemid=95> (last visited May 20, 2009). See, e.g., Committee Testimony of C. Davies, *available at* <http://energycommerce.house.gov/Press_111/20090226/testimony_davies.pdf> (last visited June 1, 2009); Committee Testimony of M. Wright, *available at* <http://energycommerce.house.gov/Press_111/20090226/testimony_wright.pdf> (last visited June 1, 2009).
90. See, e.g., GAO, "Testimony Before the Subcommittee on Commerce, Trade, and Consumer Protection, Committee on Energy and Commerce, House of Representatives Chemical Regulation: Options for Enhancing the Effectiveness of the Toxic Substances Control Act," February 26, 2009, at 4, *available at* <http://www.gao.gov/new.items/d09428t.pdf > (last visited June 1, 2009).
91. EC, "Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee: Regulatory Aspects of Nanomaterials," SEC (2008) 2036, June 17, 2008, at 4, *available at* <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0366:FIN:EN:PDF> (last visited June 1, 2009).
92. See, e.g., L. Layton, "Chemical Law Has Global Impact," *Washington Post*, June 12, 2008, at A1.
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96. *Id.*, at 9. See also Government Accountability OfficeGAO, GAO No. 05-458, "Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program," (June 2005), *available at* <http://www.gao.gov/new.items/d05458.pdf> (last visited June 1, 2009).
97. *Id.*, at 2.
98. GAO, "High-Risk Series: An Update," Report to the Congress, January 2009, at 2, *available at* <http://www.gao.gov/new.items/d09271.pdf> (last visited June 1, 2009).
99. S. 3040, 110th Congress (2008) ("To amend the Toxic Substances Control Act to reduce the exposure of children, workers, and consumers to toxic chemical substances"). An earlier version was introduced in 2005. See Child, Worker, and Consumer-Safe Chemicals Act of 2005, S. 1391, 109th Congress (2005).
100. See, e.g., Senator Boxer Opening Statement, "Oversight on EPA Toxic Chemical Policies," April 29, 2008, *available at* <http://epw.senate.gov/public/index.cfm?FuseAction=Majority.PressReleases&ContentRecord_id=9abd162f-802a-23ad-4c49-b0f6d51c9c42&Region_id=&Issue_id=> (last visited May 20, 2009) ("The overall toxic chemicals law, the Toxic Substances Control Act, or 'TSCA,' was adopted in 1976 and was supposed to help assure that toxic chemicals would be restricted or banned if they were hazardous. But in essence, TSCA puts the burden on the government to prove a toxic chemical is a risk. That is unlike the European program,

called REACH. REACH puts the burden on the chemical industry – where it should be – to show that their chemicals are safe.").

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103. See generally R. Dennison, "Ten Essential Elements of TSCA Reform," *Environmental Law Reporter* 39, no. 1 (2009): 10020-10028.
104. See generally P. Harremoes et al., *The Precautionary Principle in the 20th Century: Late Lessons from Early Warnings* (London: Earthscan Publications, 2002).
105. See, e.g., D. Bowman and G. Val Calster, "Reflecting on REACH: Global Implications of the European Union's Chemicals Regulation," *Nanotechnology Law & Business* 4, no. 3 (2007): 375-384, at 381.
106. See, e.g., NNI, *supra* note 42; EC, SCENIHR, "Risk Assessment of Products of Nanotechnologies" (adopted January 19, 2008), at 13, *available at* <http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_023.pdf> (last visited June 1, 2009) ("It must be noted that nanotechnology as introduced nanoparticulate forms of chemicals, of which properties, behavior and effects are largely unknown, and hence, of concern.").
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110. See, e.g., Maynard et al., *supra* note 40; Oberdorster et al., *supra* note 40.
111. Science and Environmental Health Network, "Wingspread Consensus Statement on the Precautionary Principle," January 26, 1998, *available at* <http://www.sehn.org/wing.html> (last visited June 1, 2009) ("When an activity raises threats of harm to the environment or human health, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically.")
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113. *Id.*, at 14, Box 2.
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115. EC, "Communication from the Commission on the Precautionary Principle," February 2000, at 2, *available at* <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2000:0001:FIN:EN:PDF> (last visited June 1, 2009).
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121. R. Weiss, "For Now, Nanotechnology Means Little More Than Better Golf Ball," *Washington Post*, March 10, 2006, at A3 ("They promised robots the size of blood cells, able to crawl through the body in search of disease. Featherweight aircraft parts stronger than steel. Solar-charged batteries better and cheaper than oil. Those and other revolutionary products may yet emerge from nanotechnology, the nascent but quickly maturing field of molecular-scale engineering in which scientists are harnessing the power of the very small. But for now, it turns out, people will have to settle for odor-eating shoe inserts, livelier golf balls, age-defying nano-nutritional supplements and – for those with a hankering for a really small treat – nanotech chocolate chewing gum. Such are the products emerging at the intersection of exotic science and prosaic consumerism, as outlined in the first comprehensive inventory of nanoproducts, out today.").
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125. National Research Council (NRC), *Review of Federal Strategy for Nanotechnology-Related Environmental, Health, and Safety Research* (Washington, D.C.: National Academies Press, 2008).
126. *Id.*, at Executive Summary.

127. See generally J. Sargent, "CRS Report to Congress, The National Nanotechnology Initiative: Overview, Reauthorization, and Appropriations Issues," February 29, 2008, *available at* <http://ftp.fas.org/sgp/crs/misc/RL34401.pdf> (last visited June 1, 2009).
128. See generally B. Feder, "Teeny-Weeny Rules for Itty-Bitty Atom Clusters," *New York Times*, January 16, 2007, at 45, *available at* <http://www.nytimes.com/2007/01/14/weekinreview/14feder.html> (last visited June 4, 2009) ("Federal and state regulators...have so far been happy to sponsor meetings and studies that call for regulation but notably reluctant to engage in any. A very small fraction of the billions of dollars being invested in nanotechnology research is being used to ferret out potential risks.").
129. See EPA, *supra* note 107.
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131. FDA, "Nanotechnology, A Report of the U.S. Food and Drug Administration Nanotechnology Task Force," July 25, 2007, *available at* <http://www.fda.gov/nanotechnology/> (last visited June 1, 2009).
132. See, e.g., FDA Task Force Report, supra note 131, at 14, 17-18.
133. *Id.*, at 4, 11, 12, 13 ("There may be a fundamental difference in the kind of uncertainty associated with nanoscale materials compared to conventional chemicals, both with respect to knowledge about them and the way testing is performed."); *id.*, at 15 ("Also as discussed above, there may be general differences in properties relevant to evaluation of safety and effectiveness (as applicable) of products using nanoscale materials compared to products using other materials."); *id.*, at 17 ("[B]ecause many of these tests were developed for molecular forms of materials, and nanoscale materials may behave differently, the ability of these tests to support decisions about biological effects or further testing requirements need to be evaluated."); *id.*, at 18 ("Currently, ability to detect nanoscale materials in the body or in products regulated by FDA is limited and...may require substantial effort."); *id.*, at 18 ("[M]aterials in the nanoscale range may present particular challenges, for example relating to tests that assess product stability or development of potentially hazardous byproducts."); *id.*, at 18 ("Standard approaches for handling materials for testing will also need to be evaluated and may need to be modified...."); *id.*, at 20 ("As discussed in the State of the Science section, the Task Force believes that nanoscale materials will present regulatory challenges that are similar to those posed by other new technologies that FDA has dealt with in the past, such as biotechnology products, but also some potentially new challenges."); *id.*, at 30 ("As discussed in the State of the Science section, although the science of nanotechnology is continuing to evolve, it is known that the size of a particle can affect its properties such that versions of the same substance with differing particle sizes can have different properties....To appropriately assess the safety...it will be important in some cases for FDA or the manufacturer to take into account whether the product contains nanoscale materials."); *id.*, at 32 (Because nanoscale materials can behave differently than other versions of the same materials, it will be important for FDA to obtain relevant information about the characteristics of products containing nanoscale materials."); *id.*, at 32 ("[T]he presence of nanoscale materials may change the regulatory status/regulatory pathway of products.")
134. FDA, "Consideration of FDA-Regulated Products That May Contain Nanoscale Materials; Public Meeting," 73 *Federal Register* 46022-46024 (August 7, 2008).