Falling Through the Cracks?
Public Perception, Risk, and the Oversight of Emerging Nanotechnologies

Evan S. Michelson
Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars
evan.michelson@wilsoncenter.org

David Rejeski
Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars
david.rejeski@wilsoncenter.org

Abstract

Nanotechnology is expected to be the key technology of the 21st century. Researchers are exploring ways to see and build at this scale, reengineering familiar substances like carbon and silver to create new materials with novel properties and functions. However, the emergence of nanotechnology also provides us with an opportunity to reshape how the public perceives the government's ability to manage risks posed by new technologies. As the first wave of nano-based products—including cosmetics, dietary supplements, food additives, and consumer products—enters the market, society will begin to ask questions about the health, environmental, and safety implications of these materials. The purpose of this paper is to connect the current state of such public perceptions—both with respect to nanotechnology, in particular, and to emerging technologies, in general—with the current state of nanotechnology product development and to analyze how well situated the public sector is to deal with these challenges.

1. Introduction: Nanotechnology Today and Tomorrow

When dealing with a host of immediate social, economic, and political problems, it is easy to overlook some of the potential risks posed by emerging technologies. In many cases, it is preferable to believe that novel scientific innovations are coming "down the road" and exist "way out" in the future. As has been demonstrated repeatedly in the past, operating under such a mindset can be dangerous; developments such as nuclear weapons and drug-resistant forms of infectious disease have affected society more quickly than was initially expected and, in turn, have led to myriad concerns in their own right. Unless we are careful, such mistakes could be repeated today. In particular, groundbreaking developments in nanotechnology are beginning to enter society—by way of a host of already commercialized products—much faster than is generally realized by the public.

What we see emerging in today's marketplace is the first generation of nanotechnology-based products, products that involve passive nanostructures and nanomaterials. The fact that this first wave is already here may come as a bit of a shock: only a few years ago, there were a mere handful of nanotech companies and virtually no nanotech-based products being made and marketed to consumers. However, a survey by Small Times magazine has identified that since 2000, over 1400 nanotech related companies have formed, with over 200 involved in the manufacture and distribution of nano-based products [1]. More specifically, the Project on Emerging Nanotechnologies at the Woodrow Wilson International Center for Scholars has released an inventory cataloguing over 200 nanotechnology-based consumer products that are available on the market [2], far exceeding the existing federal government accepted estimate of approximately 80 products. Additionally, according to EmTech Research, there are also more than 600 nano-based electronics components, raw materials, drug delivery technologies, and research, process, and software tools, the latter of which is used to manipulate nanomaterials and fabricate at the nanoscale [3].

The rapid pace of product innovation is not expected to slow anytime soon. In an analysis conducted by the National Center for Manufacturing Sciences of 81 manufacturing companies in the United States, 89% indicated that they expect to have nano-related products on the market in less than five years [4]. Similarly, a survey funded by the European Union of small and medium sized enterprises in eleven countries throughout the continent found that out of 380 respondents, 190 "are

1-4244-0479-7/06/$20.00

presently working with nanomaterials" and an additional 89 "mentioned that they are planning to work with nanomaterials within the next two years" [5].

This is only the beginning. The nanomaterials that are now incorporated into consumer products are, for the most part, relatively inactive. It is expected that *succeeding generations* of nano-based products will have far greater and more profound societal implications, especially as the worlds of nanotechnology, biotechnology, and information technology continue to converge and intersect with one another. It will no longer be a question of nano-based substances accidentally entering organisms or remaining there in a passive state. Instead, we could be *purposely* engineering nano-materials and nano-devices to interact with biological systems in new and novel ways, including the delivery of drugs to specific sites in the body or as assistants in *in vivo* imaging procedures. New risks to the public's health and to the environment could emerge—risks that will not only be closely tied to the properties of the engineered substances themselves, but also to their behavior, evolution, and complex interactions with other organisms, other materials, and other environmental processes.

The purpose of this paper, therefore, is to examine how public perceptions, risks, and regulations may interact as nano-based products enter the marketplace and to identify some of the key strategic issues that governments will have to address as nanotechnology grows and matures. While particular examples will be discussed in relation to the regulatory system of the United States, all nations that are looking to adopt nanotechnology as a central pillar of their 21st century economy must begin to consider these topics more fully and completely. In short, a host of new questions will emerge as developments in nanotechnology move from the fringes to the center of society, including:

- Who *does* the public trust to handle and manage the risks posed by nanotechnology?
- How is information related to nanotechnology communicated and made available?
- Are public perceptions being included and used to inform debates about proposed and pending regulations?
- What mechanisms work best to regulate nanotechnology-based products?
- Have potential chronic and long-term risks, issues, and consequences been analyzed by policymakers and government agencies?
- Have uncertainties and "domains of ignorance" been taken into account during the decision-making, policy-making, and standard-setting process, and if so, how?
- Who will be responsible, and who will be held accountable, for any unforeseen harm, ill-use, or dangerous applications of nanotechnology?

2. A Perfect Storm? The Intersection of Risk and Public Perception

2.1. The Specific Concern about Nanotechnology

One of the most illuminating conclusions resulting from the responses garnered by the National Center for Manufacturing Sciences study mentioned above is the widespread public perception that nanotechnology products are far from commercialization. The fact that companies are increasingly bringing a number of nanotechnology-based products to market—albeit with relatively little fanfare or questioning from the public—reveals the inaccuracy of the public's perception. The hope, of course, is that the advent of these new and emerging nanotechnologies will help improve the condition of human life, whether in areas of health, energy, or the environment. As the public becomes increasingly aware of these issues, experience tells us that the public will demand assurances that the inherent risks and benefits of these materials have been identified, considered, and weighed in some meaningful way by the government before being made available on the market. Moreover, it should also be worrisome—as demonstrated in a number of studies and research projects designed to measure the public's trust in the government's ability to manage successfully the risks posed by nanotechnology—that people are already voicing a lack of confidence in public sector's ability to address these issues and that they are wary of problems that may emerge for which we are unprepared to handle.

For instance, Jane Macoubrie's 2004 study, entitled "Nanotechnology: Public Concerns, Reasoning, and Trust in Government," captured the opinions of participants in three cities across the United States and found that 50% of respondents noted that they had "not much" faith or trust in government to effectively manage these hazards [6]. At first glance, this statistic may not seem that alarming in and of itself. However, when coupled with the fact that a combined 95% of participants had "heard almost nothing" or only "a little" about nanotechnology before participating in the study, it is evident that a dangerous situation is being established: a largely uninformed or under-informed public, with little to no trust in the government's ability to manage the risks of nanotechnology, will soon be exposed to and sold products that, as will be discussed later, may have undergone little regulatory inspection or oversight [6].

These results were reaffirmed in a similar study, entitled "Informed Public Perceptions of Nanotechnology

and Trust in Government," undertaken by Macoubrie in 2005, which found that even when participants were provided with information about the roles and responsibilities of government regulators, such as the United States Environmental Protection Agency (EPA), Food and Drug Administration (FDA), and Consumer Product Safety Commission (CPSC), no more than 50% of respondents believed that they could trust these agencies to regulate nanotechnology-based products accurately and successfully [7]. What is even more striking about these findings—low trust in government associated with a lack of awareness about nanotechnology—is that these trends are not limited to the United States. Another recent study conducted by the BMRB Social Research organization in the United Kingdom found that in a survey of over 1000 participants, over 80% had never heard of nanotechnology and over 90% were unable to give even the slightest definition of what the term might mean or involve [8]. Moreover, while 68% of the respondents who could provide some definition of nanotechnology replied that they believed nanotechnology "would make things better" in the future, concerns as to the government's ability to manage technological risks remained. In particular, respondents identified "the long term side effects of nanotechnology" and "whether enough was being done to establish what these were, and whether or not lessons had been learned from the past" [8].

Finally, a recent series of studies have been conducted that look at the Canadian public's perception of nanotechnology development and regulation. A number of these, including one undertaken by Edna Einsiedel, demonstrate findings similar to those reported by Macoubrie (2004 and 2005) and BMRB Social Research. Einsiedel's study, published in the collection *First Impressions: Understanding Public Views on Emerging Technologies*, found that just 17% of Canadian respondents felt confident "in the safety and regulatory approval systems governing nanotechnology" [9]. Along these lines, Jeff Walker's comparative study, released in the same volume, of Canadian and U.S. perceptions found that "there is a weakening sense of confidence in the regulatory and oversight structures in place to govern these technologies, which leads many people…to demand tighter controls and regulations of these technologies as they advance further" [10]. In short, the findings related to public perception of nanotechnology in Canada, the U.S., and the U.K. reveal a strong convergence of opinion on the subject.

What may be even more striking is that there appears to be a growing consensus as to what the public expects from the government in regards to the management of nanotechnology's potential risks. For instance, 71% of respondents in Macoubrie's 2005 study called for "increased safety tests before products go to market," along with "supplying more information to support informed consumer choices" [7]. The results of the Madison Area Citizen's Consensus Conference on Nanotechnology led to similar conclusions, with participant's suggesting that "producers should be required to prove their products are safe" and "that a method for informing the public specifically of potentially harmful effects of nanomaterials should be instituted by the government" [11]. Finally, these recommendations were echoed in the report of Nanojury UK, an independent citizen's panel, which suggests that "manufactured nanoparticles should be tested as if they were a new substance, labeled in clear English, and tested in controlled environments before release" in order to improve public confidence in the safety of these new technologies [12].

While there is still time to inform public perceptions about nanotechnology and to ensure that it is developed in a way that citizens—as well as the insurance industry, corporate investors, NGOs, and regulatory officials—can trust, these studies show that citizens in multiple countries share a common set of attitudes towards nanotechnologies, including:

- Little or no trust in government or industry to manage the risks associated with nanotechnologies;
- A clear set of ideas about how to build trust, which include more pre-market testing, more disclosure, and greater attention to longer-term risks and impacts to the environment; and
- The desire for greater citizen engagement in shaping how the technology is developed.

As a recent commentary in Nature magazine notes, these findings offer "governments direct public guidance on how citizens' interests must be taken into account and protected if nanotechnology is to flourish" [13].

2.2. The General Concern about Emerging Technologies

It is important to note that the public's concern regarding nanotechnology and the need for managing the risks it may pose is not an isolated event nor is it a stand-alone worry. In fact, the concerns associated with nanotechnology are well in-line with concerns expressed with the management of emerging technologies in general. The public's awareness and perception as to the benefits and drawbacks of *any* technology, including nanotechnology, is greatly influenced by their view on whether the federal regulators are seen as acting to protect the public's interests. For instance, a study conducted by Lancaster University on how the public responds to new technologies in general found that "there was widespread suspicion of [these technologies] and of the motives of those promoting them, including

government" [14]. Moreover, the authors of the study concluded that part of the explanation why such distrustful feelings are so pervasive when it comes to new technologies is that "societies' evaluation processes for such innovations…occur only at late stages in development cycles," thereby guaranteeing that any widespread concerns and worries are not addressed until the very end, when their views and opinions can have little impact [14].

A similar theme emerged during public debates in the United Kingdom over genetically-modified food, in which late-stage government attempts to gauge public perceptions on the issue found that "there is wide mistrust of government" and that such "eleventh-hour" public opinion finding sessions were "only a camouflage" designed to hide the government's "secret agendas" with respect to the development of these technologies [15]. Moreover, Walker's study of Canadian perceptions of technological governance resulted in similar findings: namely, there are concerns that "people who work in regulatory systems are not able to 'keep up' with new technologies" and that "not enough resources are dedicated to this function within government" [10]. Such responses appear to indicate that there is a great chasm between the public's perception of the government's risk management ability and what the government would have the public believe. In addition, while it is clear that nanotechnology is not the first technology to come along and question whether the public trusts the government's ability to oversee technologically innovative products, it *is* the case that since nanotechnology is effectively "next in line" to become commonplace in society and it will be in this context that these issues will be addressed. In the near-term future, the risk management capabilities of public institutions in nations around the world will become increasingly evident by how well they respond to the challenges posed by nanotechnology.

A deeper investigation into the public's anxieties regarding the introduction and management of new technologies demonstrates a consistency and commonality of concerns, thereby implying that public's reception of nanotechnology will, most likely, reflect preexisting mindsets that have emerged regarding developments in other areas of technology, such as biotechnology and information technology. In particular, a variety of studies have identified a common theme, namely, that the public is wary of the potentially negative, unintended, inadvertent, and long-term consequences of new technologies. Along these lines, a 2001 survey of public perceptions of agricultural biotechnologies in Europe noted that the respondents were concerned primarily with issues related to "formal declarations about the safety of these products, which do not acknowledge potential unforeseen impacts" and "the gap between the promises…and the first products put on the market" [16]. These issues are entirely in-line with the findings of Macoubrie's 2004 and 2005 studies about public perception of nanotechnology in the United States, in which respondents emphasized that their main concerns included "unknown risks and consequences," "unintended uses," "unforeseen, unethical and disastrous environmental or personal health consequences," "unexpected effects in the bloodstream," and the worry that "once it's out there, can you put it away" [6, 7].

Moreover, respondents to Macoubrie's 2004 nanotechnology study "scorned 'trivial' applications (such as cosmetics and wrinkle-free fabrics) and wished to encourage applications such as in water quality, medical uses to reduce human suffering, and to support alleviation of distress in developing countries" [6]. The continued appearance of these concerns across a wide spectrum of emerging technologies, in general, and nanotechnology, in particular, implies that the public has a rather common set of issues on its mind and that, primarily, it feels as if it is not being told "the whole story" about potential risks and dangers at the outset of the innovation process. Grove-White et al. highlight this point in their comparison of developments in biotechnology and nanotechnology and claim that "the deficit model of public skepticism or mistrust of science and technology is a fundamental cultural handicap for institutions charged with the regulation and assessment of new technologies" [17]. Clearly, a new approach to public engagement is required, one that can "build in more rich, more complex and nuanced, and more mature models of publics into 'upstream' modes of practice" [17].

2.3. A Once-In-A-Lifetime Opportunity

It would be unfortunate if government agencies, in the United States and elsewhere, squandered this new opportunity to change the public's perception with regards to nanotechnology oversight, in particular, and emerging technology oversight, in general. The thrust of the argument presented above is clear: nanotechnology is here and that we, as a society, are not yet fully prepared to deal with it. The encouraging point is that our collective response to the challenges posed by this emerging technology remains to be formulated, and we as a society have much experience from which to formulate a sensible and effective response. Much remains to be done, however, and we cannot assume that the "easy parts" are behind us. In fact, the opposite is true, since nanotechnology's development is expected to test the notion that innovation progresses in a linear and continuous fashion. Discoveries in nanotechnology could come in great, discontinuous leaps and, in turn, revolutionize our knowledge and understanding of the

physical world. In turn, these leaps could strain the ability of our public institutions and public infrastructure to respond in an effective and timely manner to such changes. As discussed below, these leaps of innovation could make today's issues related to product risk management appear trivial by comparison.

A significant challenge facing the regulatory system is the sheer number of areas related to nanotechnology product development warranting attention. To ensure that nanotechnology does not "fall through the cracks," a dual oversight approach must be adopted, one that supports research into nanotechnology's greatest near-term risks while, simultaneously, looking prospectively to any transformations or shifts in potential implications that may occur in the future. For instance, the main risks of today are expected to be those related to the early phases of nanotechnology and exist primarily with respect to unregulated product development and worker safety, both within the developing and developed world. Still, it is not enough simply to address these issues and disregard or ignore situations that could become even more damaging over the long-term. In particular, attention must be paid to the risks posed by nanotechnology to local ecosystems, complex agro-ecosystems, and the environment as a whole. As the report by the United Kingdom's Royal Society indicates, little information currently exists to help policymakers deal with these issues. Improved tests are needed to determine nanotechnology's long-term effects on the environment, human health, and worker safety, among many other critical needs [18].

Nevertheless, an opportunity for the successful strategic management of an emerging technology is currently at hand, one that could help direct nanotechnology along a responsible path, improve public confidence in the private and public sectors, and increase the capacity of public institutions to deal with the risks and challenges posed by cutting-edge innovation.

3. Analyzing the Risk: How Nanotechnology Can Fall Through the System

While there are already a host of sectors, from the chemical industry to consumer goods to medicine, that are beginning to be strongly influenced by developments in nanotechnology, it is difficult to determine, at this early stage, which impacts will come to be truly transformative and which will be mere footnotes along the way. Unfortunately, in the United States, there is currently a concern that the regulatory response is falling far behind the pace of technological development. In short, this country is facing a situation in which nano-based products are beginning to enter the market at precisely the points where government regulation and oversight are imperfect and imprecise. To illustrate this point, four different product categories—cosmetics, dietary supplements, food additives, and consumer products—will be examined, followed by a more detailed discussion of the difficulties associated with coordinating the regulatory system across a variety of federal agencies.

3.1. Cracks in the Dam

By identifying areas where the existing oversight system might fail, we gain a better understanding of how to strategically target our limited set of financial, human, and organizational resources. In other policy arenas, we might term this a vulnerability analysis—a systematic examination process that can be used to identify product sectors in need of additional consideration. The following criteria are used to define such "at risk" or "hot spot" [19] product areas:

1. Nanotechnology-enable products that are already on the market, and, in many cases identified as such.
2. There exists a significant chance for exposure, which is a function of exposure routes (ingestion or inhalation, for instance) and an increasing number of people exposed.
3. Little or no government requirements for pre-market testing.
4. Low or very low trust in the government agencies responsible for oversight or generally perceived as responsible for oversight.
5. The existence of various stakeholder and public interest groups committed to educating consumers about toxicity and safety issues around new products.
6. The existence of a viable market for alternatives based on explicitly "non-nano" products.

By applying these criteria to nano-based products that are already on the market, four classes emerge that seem particularly vulnerable to potential consumer backlash and may require additional oversight attention.

3.1.1. Cosmetics. To start, consider cosmetics. The Center for Food Safety and Applied Nutrition (CFSAN), a regulatory body located within the Food and Drug Administration (FDA), notes on its website that "FDA is only able to regulate cosmetics *after products are released to the marketplace*. Neither cosmetic products nor cosmetic ingredients are reviewed or approved by FDA before they are sold to the public. FDA cannot require companies to do safety testing of their cosmetic products before marketing" (italics added) [20]. In short, while the FDA requires a drug to undergo a rigorous, three-part testing regime prior to being approved for distribution, FDA has virtually no pre-market approval over cosmetics and they may be sold without any direct FDA oversight.

Nevertheless, cosmetics advertised as containing nanomaterials are already on the market. A simple search

of the United States Patent and Trademark Office (USPTO) database leads to a number of cosmetic and personal care product companies, including L'Oreal, Unilever, and Colgate-Palmolive, that have applied for patents for the use of engineered nano-substances in a variety of cosmetics, including skin creams, nail polishes, hair conditioners, and deodorants [21]. In particular, a search of the Nanotechnology Consumer Product Inventory shows that L'Oreal is promoting its Plenitude Revitalift cosmetic line that contains nanotechnology-enhanced exfoliating treatments designed to penetrate beneath the skin surface [2]. By incorporating vitamin A molecules inside a polymer "capsule," this line of cosmetics claims to introduce nanomaterials within the underlying, base layers of skin. Moreover, the inventory contains the Australian firm Advanced Nanotechnology Limited, which has created a series of nanoscale powders, known as Alusion, for use in lipstick and face powders, along with a transparent version of sunscreen, known as ZinClear, that is reported to contain nano-sized particles of the broad-spectrum ultraviolet absorber zinc oxide [2]. Similar to L'Oreal's Plenitude Revitalift, ZinClear reportedly uses nanomaterials in a product that is applied to the skin. Since both products are cosmetics, neither is required to undergo any form of product testing prior to entering the market in the United States.

A handful of efforts are underway that are attempting to learn more about these materials. While pre-market approval is not required for these materials, the FDA has recently introduced a voluntary reporting system, the Voluntary Cosmetic Registration Program (VCRP), with the hopes that cosmetic manufacturers will voluntarily submit information about both their production sites and ingredients [22]. However, it remains unclear as to how many companies that produce nano-based cosmetics will participate in this program, and it is not evident that there is enough incentive for such firms to do so, especially if participation may lead to more stringent oversight. Once located, the FDA does have the authority, under Section 704 of the Federal Food, Drug, and Cosmetic Act (FFDCA), to inspect manufacturers for cosmetics, but the ability of field offices to identify such firms has been limited [23]. Additionally, there is an initial round of basic research being conducted by a public-private sector initiative that is attempting to determine the toxicity of these, and other, nanotechnology related products. Researchers at Rice University, in conjunction with FDA's CFSAN are "evaluating the effects" of quantum dots and nano-sized titanium dioxide particles on "human and pig skin" [24]. Such work is preliminary, but a useful first-step in determining the long-term health risks, if any, posed by the use of nanoscale engineered materials in cosmetics. However, gaps in the research still remain: for example, none of the existing studies address the life cycle impacts of cosmetics after their use and disposal, such as the impact of nano-scale metal oxide based sunscreens on aquatic life and habitats. Conceivably, negative health or environmental effects reported to be caused by these cosmetics based on their nanotechnology component could create a public backlash. Such a response would not only negatively impact the nanotechnology industry, but it would also reinforce public mistrust and undermine confidence in the government's ability to manage new technologies in an effective manner.

In short, cosmetics may become the initial battleground where consumer interests clash with the long-term plans of industry. Large numbers of consumers already apply these products directly to their bodies, including hair, face, and skin. In addition, there already exists a well-developed and defined market for cosmetics that eschew chemicals in favor of more natural ingredients. Companies operating in this market could easily adapt a "non-nano" label as a competitive positioning strategy and, in turn, raise implicit questions in the mind of the public about the risks involved with nano-based ingredients. This would obviously put companies using nanotechnologies on the defensive. Finally, civil society groups such as the Coalition for Safe Cosmetics and the Environmental Working Group remain vigilant watchdogs monitoring the behavior of the cosmetics industry [25]. These groups have a wide reach, both domestically and globally, with linkages to other groups concerned with the environment, breast cancer, and public health in general.

3.1.2. Dietary supplements. Second, consider dietary supplements. Under the Dietary Health and Education Act, Congress defined dietary supplements as "product taken by mouth that contains a 'dietary ingredient' intended to supplement the diet," including substances such as "vitamins, minerals, herbs or other botanicals, [and] amino acids" [26]. Under this Act, "a firm is responsible for determining that the dietary supplements it manufactures or distributes are safe and that any representations or claims made about them are substantiated by adequate evidence to show that they are not false or misleading. The burden of proving safety under the Act is not on FDA, but rather the firm manufacturing or distributing the dietary supplement. This means that dietary supplements *do not need approval from FDA* before they are marketed" (italics added) [26]. Companies are thus not required to seek FDA approval and may bring products containing nanomaterials to market without any meaningful government oversight.

For example, Health Plus International has already developed a product known as Spray for Life, a dietary and health supplement advertised to deliver vitamins faster and more evenly into the body through the use of

nanomaterials [2]. While this new delivery system may allow for an increase in the bioavailability of active ingredients when compared to conventional pills, tablets, capsules, or liquids, any potential side effects remain unknown because no approval process requiring a demonstration of safety was required as a condition of pre-market approval due to the product's status as a dietary supplement. Despite the lack of rigorous testing, there remains a large market for alternative remedies. Many consumers have put their trust in these alternatives versus the costly—and highly hyped—commercial pharmaceuticals. As one executive from Bayer recently stated, "We're losing the battle for consumer trust" [27].

3.1.3. Food additives. Third, consider food additives. While the application of nanotechnology to the food industry—by way of additives, production, processing, and packaging—may sound far-fetched, the market share of these uses is expected to grow from a $7 billion business in 2006 to a $20.4 billion business by 2010 [28]. Moreover, the number of companies working in this area is expected to rise from "69 in 2002 to 2004 to several thousands by 2010" [28].

To address issues related to food additive safety, both from nanotechnology and other sources, the FDA recently opened its Office of Food Additive Safety (OFAS), designed to handle all requests for approval for food additives, food colors, and food packaging. In order for a product containing an additive that is *directly* added to food to obtain approval, OFAS notes that "a manufacturer must first petition FDA" and "provide convincing evidence that the proposed additive performs as it is intended" [29]. However, the clearance for an indirect food additive—for example, one that is not intended to become part of food but that may be involved in food packaging and production—is less stringent and raises questions as to how much of the substance might migrate into the food, be consumed by the public, and potentially end up being detrimental to human health. From the public's perspective, such worries could become linked to a long history of concerns over the presence of chemicals and engineered ingredients in the food supply. Evidence of such a mindset is apparent in that the organic food sector has grown at nearly 20 percent per year since 1990 and now accounts for over $15 billion in sales globally per year [30,31]. Clearly, there is a growing segment of the public that does not want their food "engineered"—bio, nano, or otherwise—and there are dozens of civil society groups organizanied to look over the shoulder of transnational food product companies.

Nevertheless, the application of nanotechnology to food packing has already begun. The United States Department of Agriculture (USDA), for example, is currently funding research focused on such projects as "SBIR II: Nano- and Micro Encapsulation of Food Additives" [32]. The private sector reportedly is also investing heavily in this area, with companies like Nestle working in nanotechnology to "make the molecules in ice cream more uniform in size' [33]. As companies move toward commercialzing such projects, the FDA must be mindful of the possible human health implications of these developments. At least food additives require a degree of demonstration of safety under the FFDCA, which distinguishes them, from a regulatory perspective, from cosmetics and dietary supplements which, as noted earlier, require little to no pre-market approval. The rationality of this fundamental distinction under current regulatory regimes is questionable, especially since all three applications allow nanomaterials to enter the body in some fashion. Without a consistent set of reporting requirements, the novelty associated with such nano-based products implies that neither the manufacturer nor the government may possess enough systematic information to understand the material's cumulative, and potentially harmful, effects.

3.1.4. Consumer products. Finally, consider consumer products. In the United States, the Consumer Product Safety Commission (CPSC) is "charged with protecting the public from unreasonable risks of serious injury or death from more than 15,000 types of consumer products under the agency's jurisdiction" [34]. Primarily, CPSC manages the recall of products once they have been found to be unsafe, either by way of manufacturer's testing or a consumer complaint. However, numerous problems remain associated with the organization's ability to implement its mandate. First, while the agency can implement specific labeling requirements, the fact is that CPSC is more reactive, rather than proactive, when it comes to protecting the public's safety. Second, it has little legislative authority to block potentially dangerous products from coming to market, let alone manage the risks associated with a product that employs any kind of new technology, such as nanotechnology. Finally, CPSC suffers from a lack of human resources: the total staff is below 500 people, less than half the number of people it had in 1980 [35].

Nevertheless, as was mentioned earlier, a host of consumer products containing nanomaterials have already reached the market and are being purchased and used by consumers, many of whom may be unaware that these products are nano-engineered or contain nanoscale materials. A search of the Nanotechnology Consumer Products Inventory [2] can provide numerous examples, including:

- paint, such as Behr Premium Plus and Deletum 5000—a version of anti-graffiti paint that coats a surface with nanomaterials and is capable of

guarding against other pollutants, including dust, grease, or dirt;
- glass and lens coatings, marketed by NanoFilm and designed to protect such surfaces from scratching and residue;
- sporting goods, such nanomaterial-based ski wax, made by Cerax, and designed to improve ski and snowboard performance;
- entertainment devices, such as children's toys, a sector that is expected to grow at a rate of 15% per year, leading to a $146 million market by 2015 for toys that employ innovations in self-cleaning nanomaterials and nano-electronics [36].

While CPSC has issued a statement recognizing the growing use of nanomaterials in various consumer product sectors, J. Clarence Davies has noted that due to a shortage of personnel and a lack of "individuals with the appropriate expertise to deal with nanotechnology" it remains unclear how well CPSC would be to respond to the potential challenges that may be associated with such developments [37,38]. Moreover, as the commercialization of nanotechnology consumer products becomes a global phenomenon—as they enter markets throughout North America, Europe, and East Asia [39]—it is not clear whether a regulatory action taken against a product in the United States would have any impact on products that are exported and sold in countries overseas. Nevertheless, it is reasonable to assume the implications of a product recall or ban in the United States would have global implications that would be adverse to future developments in nanotechnology around the world.

3.1.5. Overview: regulatory gap analysis. In terms of oversight by the federal government in the United States, this investigation of emerging consumer products makes clear that the level of pre-market regulatory review is dependant upon the type of product being made and is unrelated to the potential hazard the product may pose. Importantly, two products may contain the same nanomaterial or be the result of the same nanotechnology process, but because of jurisdictional limitations, one product may be subject to significant pre-market review (pharmaceuticals), while other products are not subject to such pre-market testing (cosmetics, dietary supplements). Emerging developments related to products in medicine, electronics, and food could further blur the boundaries of regulatory responsibility.

While some agencies do have bureaucracy in place to address such cross-over effects, such as FDA's Office of Combination Products, they are still mostly reliant on information provided by the manufacturer as to the potential hazards of the nanomaterial in question. Without an overarching strategic plan to organize and direct research into the potential implications of nanotechnology, federal agencies may find it difficult to generate such toxicology information internally. Overall, as FDA notes in its publicly available statement on nanotechnology regulation, "few resources currently exist to assess the risks that would derive to the general population from the wide-scale deployment of nanotechnology products" [40].

For a mostly uninformed public, these regulatory gaps can create a confusing and perplexing situation. Who exactly is responsible for oversight? And, more broadly, is there any effective government oversight? As Table 1 illustrates, three possible answers to these questions exist. In the first case, consumers must heed the old adage of *caveat emptor*, as they are left to decide for themselves what is and what is not safe. With little or no publicly available consumer information and a lack of labeling requirements, consumers may not even know which products contain engineered nano-substances are on the market. In the second case, regulators may have the tools in place to begin to address these issues, for example, EPA's authority under the Toxic Substance Control Act (TSCA) to review a pre-manufacturing notice submitted by a manufacturer when it intends to begin production of new nanoscale materials consisting of a chemical substance. However, these authorities will only be effective if exercised and employed carefully and consistently. Finally, recent events associated with the third case, that of pharmaceuticals, are a sobering reminder that even if established oversight processes are in place, and even if significant pre-market testing is required, products capable of causing harm and injury

Table 1. Gaps in the oversight system: governance challenges posed by nanotechnology

Product Categories	Agency	*Caveat Emptor* (Buyer Beware)	Potential Control (If Exercised)	Pre-Market Approval
Cosmetics	FDA	✓		
Dietary Supplements	FDA	✓		
Food Additives	FDA		✓	
Consumer Products	CPSC		✓	
Chemicals	EPA		✓	
Pharmaceuticals (Drugs)	FDA			✓

still have the potential to enter the market, affecting millions of consumers. While these events may occur rarely, their widespread impacts and visibility in the press create public mistrust and suspicions that can linger for years.

3.1.6. Overview: vulnerability analysis. As Table 2 illustrates, by applying the "at risk" criteria presented at the beginning of this section to the four product areas analyzed above, it is possible to assemble an overall risk management matrix that can highlight the "hot spot" points at which potential problems or public backlash could emerge with respect to various product categories. For each criterion, a qualitative ranking can be produced (high, moderate, or low) that can help indicate the degree of potential impact of various classes of nano-based products on society.

1. *Nanotechnology-enable products that are already on the market, and, in many cases identified as such.*

A cursory analysis of the four product areas indicate that there is a relatively high degree of cosmetics and consumer products are already on the market—in the form of eye cream, deodorant, and toothpaste for the first case and in the form of hockey sticks, television displays, tennis rackets, and clothing in the second case. Moreover, because the Consumer Products Inventory released by the Project on Emerging Nanotechnologies only contains nano-based products that are self-identified by the manufacturer, advertised on the Internet, and described in English, there clearly could be many more such products available on the market from various countries around the world.

2. *There exists a significant chance for exposure, which is a function of exposure routes (ingestion or inhalation, for instance) and an increasing number of people exposed.*

Due to the direct nature of exposure (i.e. ingestion) for food additives and dietary supplements and the multiple routes of exposure (i.e. ingestion, dermal, and inhalation) for cosmetics, these applications could come to have a high impact on a large number of consumers. Along these lines, the aerolsolization of a nanotechnology related cleaning product from Germany appears to have caused a number of adverse health effects and has led to a widespread recall of these items [77]. However, use of nanomaterials in other categories of consumer products, such as sporting goods, electronics, and clothing, could have moderate exposure potential, as these materials are expected to remain embedded in the object.

3. *Little or no government requirements for pre-market testing.*

As the regulatory gap analysis indicated, there are little to no government requirement for pre-market testing in the realms of cosmetics, dietary supplements, and consumer products.

4. *Low or very low trust in the government agencies responsible for oversight or generally perceived as responsible for oversight.*

Macoubrie's 2005 study found that trust in the FDA—the main agency responsible for overseeing cosmetic, dietary supplement, and food additive regulation—dropped, though not precipitously, after citizens learned about federal regulatory responsibilities for nanotechnology, thereby leading to a moderate ranking [7]. This report also indicated that trust in CPSC increased after participants learned more about the agency, leading to a designation of "low" in terms of public perception risk [7].

5. *The existence of various stakeholder and public interest groups committed to educating consumers about toxicity and safety issues around new products.*

There exist a number of organizations, such as a The Campaign for Safe Cosmetics, Environmental Working Group, and Organic Consumers Association that have become organized around the issues of both cosmetics and food additives and, to a lesser extent, dietary

Table 2. Nanotechnology in Society: A Comparative Vulnerability Analysis

Criteria	Cosmetics	Dietary Supplements	Food Additives	Consumer Products
Products on market	High	Low	Low	High
Exposure potential	High	High	High	Moderate
Lack of pre-market testing	High	High	Moderate	High
Low trust in regulator	Moderate	Moderate	Moderate	Low
Stakeholder/Public Interest groups	High	Moderate	High	Moderate
Existing market for alternatives	High	Moderate	High	Moderate
OVERALL RISK	**High**	**Moderate**	**Moderate**	**Moderate/Low**

supplements. Organizations like Consumers Union and the Consumer Federation of America focus on consumer products as well, though with more of a focus on product comparison and evaluation.

6. *The existence of a viable market for alternatives based on explicitly "non-nano" products.*

The existence of viable, explicitly "non-nano" industries could be similar to those related to cosmetics and food, where natural ingredient cosmetic alternatives, provided by companies like Aveda Corporation, and organic food alternatives, provided by companies like Whole Foods Market, have captured large segments of the consumer population. The viability of well defined, alternative, "non-nano" markets is less clear for dietary supplements and consumer products.

3.2. The Interaction of Complex Regulatory Systems

3.2.1. A shifting regulatory landscape. The complexity of these public perception and governance issues is compounded by the fact that if a nano-based product comes to have multiple adverse effects and impacts on, for example, the environment, responsibility for the management of the problem at the federal level may shift. For instance, consider the situation that would arise if either the nano-based ski wax or the nano-based glass coatings mentioned above are found to have an adverse environmental impact. In such an occurrence, the burden of oversight could conceivably shift from the CPSC to the EPA, making it the lead agency responsible for analyzing and managing such risks. However, as a recent General Accountability Office (GAO) report notes, such shifts and regulatory hand-offs bring about their own difficulties, as federal agencies tend to "carry out programs in a fragmented, uncoordinated way, resulting in a patchwork of programs that can waste scarce funds, confuse and frustrate program customers, and limit the overall effectiveness of the federal effort" [41].

As new nano-based products are developed, similar kinds of nanomaterials will be employed in a variety of ways, to the point that there may be significant overlap and confusion with respect to their oversight. For example, consider nano-based anti-microbial products, which are expected to have multiple applications across a variety of industries and sectors. In some cases, these products may be used in the next generation of wound dressings, which fall under the jurisdiction of the FDA. In some cases, these products may be used in new kinds of meat and food packaging, which fall under the jurisdiction of the USDA. In some cases, these products may be used in pesticides, which fall under the jurisdiction of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which EPA and FDA both implement. Without effective means of communication and coordination between and among federal agencies—as well as their state counterparts—different sections of government run the risk of adopting different regulatory standards for nano-based anti-microbials, thereby creating a motley, confused, and uneven regulatory landscape. This confusion could blunt innovation at the front end and undermine the prevention of risk at the back end.

In fact, one can imagine a situation where nano-based anti-microbials are approved for use by the FDA and not by the USDA or the EPA, thereby allowing such products to enter and spread through the market one way when they are not allowed to enter and spread through the market by another. While EPA and FDA do work fairly closely on these matters to ensure that such overlap does not occur, the intersection of responsibility between federal agencies could become a more acute problem in the future as the applications of nanotechnology become more widespread and pervasive. Of course, determinations related to whether or not such products should be approved for distribution will require a finer analysis of any potential human health and environmental risks, and it may be the case that there is a good reason to allow them to be used in wound dressings and not in meat packaging or as pesticides. However, once these products make it "out there"—regardless of how they entered the market in the first place—there is always a chance that the undesired impacts, which were being guarded against by one agency, occur because approval for use has been granted by another agency.

Only a concerted effort between different parts of the regulatory system will be able to overcome the challenges posed by the development of nano-based products and ensure that consistent regulatory regimes and safety standards are developed that can effectively deal with these oncoming challenges. For instance, as J. Clarence Davies has noted, a new law or set of laws may be needed to address the current system's deficiencies. [42]. Additionally, without such intra-governmental organization, communication, and coordination, it is conceivable that many of these questions and issues will, in the end, land in the courts and in the realm of the insurance industry, as disputes over potential accidents and mishaps become mired in lawsuits and liability claims. The hope is that while such possibilities loom, they can be avoided by taking a proactive approach to nanotechnology oversight. As the Swiss Reinsurance report, *Nanotechnology: Small Matter, Many Unknowns*, predicts, "claims for compensation may certainly be expected in the event of health impairment. The more time passes before the harmful effect is realized, the greater the cumulative claim for compensation will be" [43].

3.2.2. The shape of the emerging response. Regardless of the complex nature of the current regulatory scheme, there have been a number of recent attempts, by a wide range of individuals, non-profit, and governmental institutions, to develop policies and formulate a coherent management agenda to help the government handle emerging challenges and risks posed by nanotechnology. To start, the state of science is evolving rapidly. Major reviews have been published that focus on various facets of nanotechnology's implications: Gunter Oberdorster, Eva Oberdorster, and Jan Oberdorster have released an article that summarizes the body of knowledge in the nascent field of nanotoxicology [44]; Andrew Maynard and Eileen Kuempel have produced a similar review with an eye toward the effects of airborne nanoparticles and occupational health [45]; and researchers from Rice University and XL Insurance have undertaken a comparative, quantitative risk analysis of the production of manufactured nanomaterials [46]. Additionally, the International Life Sciences Institute's Nanomaterial Toxicity Screening Working Group—composed of a number of researchers from academia, industry, and government—have assembled the "elements of screening strategy" that will offer guidance as to characterize "the potential human health effects from exposure to nanomaterials" [47].

Moreover, policy analysis from academic and other non-governmental organizations, in both the United States and Europe, is increasing as well. For instance, in addition to the Royal Society report of 2004, The National Academies in the United States is currently involved in an ongoing assessment of the National Nanotechnology Initiative [48]. The Environmental Law Institute recently released a report, based on a key stakeholder meeting it hosted in May 2005, on the subject of how existing environmental regulation can be applied to the governance of uncertainty in the realm of nanotechnology [49]. Both the University of Minnesota and Michigan State University have hosted conferences that highlight the "lessons learned" from biotechnology oversight and their application to nanotechnology oversight [50, 51]. In Europe, nanotechnology governance issues are being addressed through the work of Nanologue, a network of institutions located throughout the continent; in particular, this group has provided an overview of current research on the ethical, legal and social aspects of nanotechnology, with a main focus on the food industry [52, 53]. Relevant reports have also emerged from The Innovation Society [54], aimed at establishing "a multi-stakeholder-dialogue-approach towards a sustainable regulatory framework for nanotechnologies and nanosciences," and the International Risk Governance Council (IRGC), which conducted a worldwide survey of various government-initiated activities associated with nanotechnology risk governance [55].

The response of the United Sates government to the risk management of nanotechnology has been expanding as well. Along these lines, the National Nanotechnology Initiative (NNI) "formally established the Nanotechnology Environmental and Health Implications (NEHI) Working Group," primarily to allow for the "exchange of information among agencies that support nanotechnology research and those responsible for regulation and guidelines related to nano-products" [56]. Additionally, the EPA has prepared and recently released for comment a draft White Paper that "explore[s] research and risk assessment needs" related to nanotechnology [3].

In a similar proactive move, the Interim Ad Hoc Work Group on Nanoscale Materials of EPA's National Pollution Prevention and Toxics Advisory Committee (NPPTAC) has held a number of public meetings in conjunction with the development of their proposed Nanoscale Materials Voluntary Program (NVP) [57]. An Overview of Issues document was submitted to EPA Administrator Stephen Johnson on November 22, 2005, and is expected to provide the foundation for the NVP. The EPA has also engaged in intra-governmental collaboration on this subject through the sponsorship of extramural grants by way of a joint solicitation with NSF and the National Institute for Occupational Safety and Health (NIOSH) for research investigating the environmental and health effects of manufactured nanomaterials [58]. The National Institute of Health's National Institute of Environmental Health Sciences (NIEHS) has joined the subsequent version of this request for proposals [59].

Outside the EPA, a number of other agencies are working to develop strategies designed to manage nanotechnology's potential challenges. To address the need for an increased level of public engagement with nanotechnology, the NSF has funded and created the Nanoscale Informal Science Education Network and two new Centers for Nanotechnology in Society, thereby greatly expanding its partnerships with science museums and universities in a coherent effort to assess the implications of nanotechnology for society as a whole [60]. Additionally, because of its historical experience handling cutting-edge technologies, the USPTO has become a leader in adjusting to the onset of this new technology. In particular, this organization has created "a new cross-reference digest for nanotechnology," a first step in its "multi-phase nanotechnology classification project" that will eventually lead to more detailed, cross-reference classifications for nanotechnology, all with the aim of developing a database of nanotechnology related patents and assisting its examiners in the evaluation of

claims put forth by corporations working in the field [61, 62].

Additionally, the National Toxicology Program (NTP) of the National Institutes of Health (NIH) has begun "researching the toxicity of four common classes of nanomaterials" in order to help "EPA and other policymakers shape policies for the emerging technology" [75]. NIOSH has also released two draft documents that provide an overview of the agency's approach to nanotechnology risk management. The first, *Strategic Plan for NIOSH Nanotechnology Research: Filling the Knowledge Gaps* [76], aims "to provide a tool for coordinating nanotechnology research across the Institute and to provide a guide for enhancing the developments of new research efforts that will respond to the challenges of working with a new technology." The second summary document, entitled *Approaches to Safe Nanotechnology*, discusses procedures for handling nanomaterials in the workplace and warns that "if engineered nanomaterials involve the same characteristics that seem to be associated with ultrafine particles, they may raise the same concerns" [66]. Such analyses, with an explicit focus on occupational health, are timely and needed, especially since a higher degree of risk currently exists for some segments of the population—such as workers in laboratories and production sites—because of their interaction with and close proximity to manufactured nanomaterials. These groups may end up being the first negatively affected by the hazards associated with nanotechnology, and, in order to avoid a mishap, they will need guidance to ensure for their personal protection and special training in regards to waste management and accident containment.

Finally, a number of information cataloguing projects are underway to help organize and track research into the environmental, health, and safety implications of nanotechnology. For instance, NIOSH is working to develop an fully searchable, web-accessible Nanoparticle Information Library (NIL) that is "intended to help occupational health professionals, industrial users, worker groups, and researchers organize and share information on nanomaterials, including their health and safety-associated properties" [63]. The information contained in NIL will act as a complement to the two other existing, on-line inventories that track both previously completed and ongoing research related to the environmental, health, and safety implications of nanotechnology: the Inventory of Nanotechnology Environment, Health and Safety Research by the Project on Emerging Nanotechnologies [64] and the International Council on Nanotechnology (ICON) Environmental, Health and Safety Database [65].

4. The Regulation of Novelty: A Look into the Future

Even considering the various oversight efforts mentioned above, an important question remains: to what degree are governments, both in the United States and abroad, prepared to handle the unique challenges posed by nanotechnology and nano-based products as the technology moves through successive generations of development? For example, in the wake of numerous scandals that have plagued the pharmaceutical industry—scandals that have greatly reduced the public's trust in government oversight of potentially harmful technologies—it is clear that a number of holes exist with respect to the government's ability to manage technological risk and that the coming onslaught of nano-based products could further expose these gaps, thus further diminishing the public's confidence. Presently, worries over nanotechnology have yet to become as widely publicized and popularized as the recent Vioxx or defibrillator debacles. There is the real possibility that as products containing nanomaterials begin enter the market at ever faster rates, similar high-profile cases could emerge that would have the effect of tarnishing the image of this nascent industry. In this event, it is important to stress the "blurring" and cross-over of concerns on the part of the public: they may not differentiate between harms emerging from different nanotechnology sectors, let alone from different nanotechnology applications.

A mishap with respect to nanotechnology in the environment—whether in the United States or abroad—could potentially negatively affect the public's willingness to apply nanotechnology to biomedicine or information technology. It is possible that the recall of the German-based cleaning product mentioned in a previous section could have such an effect. In fact, even though the adverse health effects may not have been due to nanomaterials, this incident highlights the public perception difficulties that could emerge, as it has already garnered significant attention from the press and a variety of public interest groups [78, 79]. Nanotechnology companies, regardless of their products and sectors, have a vested interest in making sure no mishaps occur. As these technological fields continue to converge, fears based on past incidents of mismanagement—from genetically modified foods to nuclear power to the widespread release of toxic chemicals—may re-emerge and reinvigorate concerns about safety and decision-making transparency.

Part of the reason why this unease may re-appear is that the current drive to manipulate matter at the nanoscale is designed to create substances that are fundamentally different from anything that has existed thus far. It is the explicit goal of the National Nanotechnology Initiative (NNI) to support research and

create novelty—in other words, to create products, structures, and systems "where *unique phenomena enable novel applications*" (italics added) [67]. The very use of the phrases "unique phenomena" and "novel applications" is significant, for it denotes a mindset prevalent within this field of study that actively looks to innovate and create materials that have no historical precedent. Moreover, many federal agency planning documents reinforce this notion of nanotechnology as a transformative technology by making a point to describe it as revolutionary, paradigm-changing, and disruptive.

The notion elucidated here is that nanotechnology is planned disruption. As Michael Roukes of the California Institute of Technology notes, "the theory of nanoscience is still in its infancy. It makes relatively simple assumptions based upon fundamental physical science, but the parallel operation of hundreds or thousands of nanoscale processes will introduce huge oceans of unknown interactions and consequences that we haven't yet faced" [68]. Science at this scale will provide us with an endless stream of surprises, many of which will be pleasant and beneficial to humanity, not to mention lucrative for companies and individuals. However, science at this scale may also create numerous unintended consequences for which we may be poorly prepared as a society to handle, manage, and govern.

Long-term developments in nanotechnology are also expected to be punctuated by a number of shifts, each involving a change in products, stakeholders, risks, and benefits, thereby further complicating an already complex risk management and regulatory situation. As mentioned earlier, products containing passive nanostructures will give way to products containing active nanostructures. Eventually, as Roco notes, "systems of nanosystems" could be designed that are capable of rudimentary levels of self-assembly and lead to the emergence of robotics that would be guided by a distributed network of intelligent nanomaterials [69]. Ultimately, innovations in nanotechnology may reach the point at which molecular nanosystems will become "smart" enough to design themselves and change in a manner that mimics natural evolution.

The problem is that although our human and financial investments are designed to create these very shifts, we are only just beginning to explore the regulatory and risk implications of these technological transformations. Until even more attention is directed toward the potential pitfalls of nanotechnology and nano-based products, limitations on our understanding may allow dangerous issues to emerge well beneath the radar screen of intense scrutiny, thereby limiting our ability to detect emerging problems until too late in the oversight process. To avoid such an undesirable situation, there needs to be a more complete consideration of how the unique developments of nanotechnology will impact both government and society as a whole.

Part of the reason why oversight concerns must be addressed early in the nanotechnology product development cycle is that once this new technology begins to mature it can be expected to proceed down wholly unexpected pathways—pathways that can create a new set of challenges in and of themselves. For this reason, as James Wilsdon and Rebecca Willis argue in their book *See-Through Science* [70] and as Einsiedel notes in her introduction to *First Impressions* [71], the public needs to become aware of and engaged with these issues much earlier in "the innovation trajectory." Once nanotechnology becomes a locked-in, "general purpose technology," like the Internet, electricity, or steam power, it may be "too late" to engage the public in an effective and constructive manner [72]. As a general purpose technology, its growth will come to have broad impacts across multiple industrial sectors and products, some of which may be difficult to predict beforehand. Consider, for example, the number of ingenious ways people are using the Internet today versus during its period of initiation and incubation in the early 1990s. It would have been nearly impossible to imagine the manner in which people would be conducting their lives on-line—which can range from filing taxes to buying cars to sending letters—and it would have been even more difficult to imagine how certain sectors of the economy, such as consumer goods and transportation, would have to adjust and amend its behavior in response to this new tool.

While the variety of applications associated with *any* technology will expand over time, current nanotechnology research may result in a situation in which surprising developments—in low-oversight realms, such as cosmetics, dietary supplements, food additives, and consumer products—become more of the rule than the exception. Such disruptive changes pose great challenges for public policy. While the governance system may be able to play adequate "catch-up" as technology undergoes rapid, incremental change, it can become overwhelmed when the technology frontier "jumps" to a new level and shifts radically [73]. The key question is: *can policy adjust accordingly?* At this point, the answer is unclear, though the question remains important given the disruptive changes expected from developments in nanotechnology. For this reason, even at this early stage, it is important to conceptualize where, when, and how some of these transformations may occur, if only to help regulators and policymakers get an early start on what issues they will have to address in the near and long-term future. The hope is that by casting a broad net and keeping a close watch on a variety of impacted economic and industrial sectors, the entire range of nanotechnology's far-reaching developments will begin

to become open and available to close scrutiny and analysis.

5. Conclusion: The Path Forward

In conclusion, it is clear that some degree of work is underway by government agencies to ensure that nanotechnology-related problems do not creep up on society and occur without forewarning. In particular, government agencies like FDA, CPSC, and EPA are beginning to make a concerted effort to address these issues and establish effective guidelines that detail how nanomaterials and nano-based products should be reviewed, approved, and monitored. NIOSH's development of *Approaches to Safe Nanotechnology* and the formation of their new field research team to assess nanotechnology processes, USPTO's designation of a specific, nanotechnology related patent digest, and the EPA *Nanotechnology White Paper* are welcomed steps in this direction. Similarly, the NSF is beginning to respond to calls for more public engagement and non-governmental organizations are continuing to provide useful and insightful analysis to help inform the decisions made by policymakers.

One area in need of further investigation in the United States is closer collaboration with regulatory and oversight agencies in other countries with respect to nanotechnology. As regulators in Europe, Asia, and elsewhere begin to deal with the increasing number of nano-based products hitting the market, new international approaches to the governance of this emerging technology will be needed. Along this line, a number of reports have recently emerged in Europe that not only discuss differing regulatory approaches but that also offer new insights into how such oversight could progress and evolve [74]. As these foreign systems are analyzed, natural areas for partnerships may surface, allowing for the most useful and constructive aspects of each governance system to become more widely adopted.

A window of opportunity is at hand, one that could lead to increased trust in private and public institutions to manage potential technical risks—but only if they respond accordingly. Unfortunately, as Macoubrie's 2005 study showed, the low trust associated with the government's ability to handle the risks posed by nanotechnology currently appears to be matched by an associated low level of trust in industry's ability to watch over itself. To combat such sentiments, a contingent, detailed management plan needs to be developed to help ensure that, in the event of a "nano-Three Mile Island," public outrage and fear over nanotechnology does not escalate to a crisis point. To do so will require, as the report *Governing at the Nanoscale* illuminates, new ways of engaging with the public and "a more open model of innovations…in which imaginaries are opened up to greater scrutiny and debate" [80]. Such endeavors will be needed in order to avoid a dive in public trust before the technology gets completely "off the ground." For instance, the nanotechnology industry as a whole may wish to consider taking the prospect of self-regulation seriously. Over time, such actions could begin to signal to the public that the industry as a whole is interested in protecting society from the potential unwanted, unwelcome, and ill effects that may arise from the potential applications of nanotechnology.

Whatever the solution, it is imperative that the longer term issues related to the development of nanotechnology are not lost in the shuffle of the more immediate, near-term applications. The coming and expected transition from passive to active nanotechnologies could radically shift the nature of the risks posed to public health, worker health, and the environment. Moreover, the convergence of nanotechnology, biotechnology, and information technology could result in an entirely new class of risks that are as-of-yet unforeseen and unanticipated. In the end, only coordinated and increased vigilance by government regulators, individual citizens, and the public as a whole will ensure that a suitable path emerges—one that consciously addresses these complex and intricate questions and helps ensure that nanotechnology leads to a safe and secure future.

Acknowledgements

We would like to thank Lynn Bergeson and Michael Cole for their assistance in reviewing earlier drafts of this article. Material from this article was previously presented at "The Nanotechnology-Biology Interface: Exploring Models for Oversight," University of Minnesota, Minneapolis, MN, September 15, 2006 and at "Environmental and Safety Impacts of Nanotechnology: What Research is Needed?" United States House of Representatives, Committee on Science, Washington, DC, November 17, 2006.

References

[1] "Commercialization and Profits on the Rise, Nano Leaders Will Here in Chicago," *Small Times*, September, 29, 2004, accessed February 3, 2006 <http://www.smalltimes.com/document_display.cfm?document_id=8322>.

[2] The Project on Emerging Nanotechnologies, "A Nanotechnology Consumer Products Inventory," Woodrow Wilson International Center for Scholars, Washington, DC, accessed March 22, 2006 <http://www.nanotechproject.org/consumerproducts>.

[3] "Nanotechnology White Paper," United States Environmental Protection Agency, Washington, DC, December 2, 2005, accessed March 12, 2006

<http://www.epa.gov/osa/pdfs/EPA_nanotechnology_white_paper_external_review_draft_12-02-2005.pdf>.
[4] National Center for Manufacturing Sciences, "Nanomanufacturing Industry in the U.S.—Survey 2003," National Center for Manufacturing Sciences, Ann Arbor, MI, May 12, 2004.
[5] "European Survey on Success Factors, Barriers and Needs for the Industrial Uptake of Nanomaterials in SMEs," nanoRoadSME, Karlsruhe, Germany, July 2005, accessed February 3, 2006 <http://www.nanoroad.net/download/sme_survey.pdf>.
[6] Jane Macoubrie, "Nanotechnology: Public Concerns, Reasoning, and Trust in Government," not published, 2004.
[7] Jane Macoubrie, "Informed Public Perceptions of Nanotechnology and Trust in Government," Woodrow Wilson International Center for Scholars, Washington, DC, September 2005.
[8] BMRB Social Research, "Nanotechnology: Views of the General Public," BMRB Social Research, United Kingdom, January 2004, accessed February 3, 2006 <http://www.nanotec.org.uk/Market%20Research.pdf>.
[9] Edna Einsiedel, "In the Public Eye: The early landscape of nanotechnology among Canadian and US Publics" in *First Impressions: Understanding Public Views on Emerging Technologies*, Government of Canada, Ottawa, CA, 2005, pp. 99-117, accessed February 3, 2006 <http://www.biostrategy.gc.ca/CMFiles/CBS_Report_FINAL_ENGLISH249SFD-9222005-5696.pdf>.
[10] Jeff Walker, "Report on a Study of Emerging Technologies in Canada and the U.S.: Prevailing Views, Awareness, and Familiarity," in *First Impressions: Understanding Public Views on Emerging Technologies*, Government of Canada, Ottawa, CA, 2005, pp. 6-19, accessed February 3, 2006 <http://www.biostrategy.gc.ca/CMFiles/CBS_Report_FINAL_ENGLISH249SFD-9222005-5696.pdf>.
[11] "Report of the Madison Area Citizen Consensus Conference on Nanotechnology," University of Wisconsin-Madison, Madison, WI, April 24, 2005, accessed February 3, 2006 <http://www.lafollette.wisc.edu/research/Nano/nanoreport42805.pdf>.
[12] "Nano jury 'verdict' calls for more public say and clarity on nanotechnology," Greenpeace, London, UK, September 26, 2005, accessed February 3, 2006 <http://www.greenpeace.org.uk/contentlookup.cfm?CFID=1292997&CFTOKEN=81325448&ucidparam=20050926143910>.
[13] "Value-free nanotech?" *Nature* 437, September 22, 2005, pp. 451-452.
[14] Robin Grove-Wright, Phil Macnaghten, and Brian Wynne, *Wising Up: The Public and New Technologies,* Lancaster University, Lancaster, UK, November 2000.
[15] Richard Heller of Clarity, ed., *GM Nation? The Findings of the Public Debate,* Department of Trade and Industry, London, UK, September 2003, accessed February 3, 2006 <http://www.gmnation.org.uk/docs/gmnation_finalreport.pdf>.
[16] Clair Marris, Brian Wynne, Peter Simmons, and Sue Weldon, "Public Perceptions of Agricultural Biotechnologies in Europe," PABE Research Project, December 2001, accessed February 3, 2006 <http://www.lancs.ac.uk/depts/ieppp/pabe/docs/pabe_finalreport.pdf>.
[17] Robin Grove-White et al., "Bio-to-Nano? Learning the Lessons, Interrogating the Comparison," Lancaster University and Demos, Lancaster, UK, June 2004, accessed February 3, 2006 <http://www.demos.co.uk/projects/currentprojects/ESRCnanotech/outputs>.
[18] The Royal Society, "Nanoscience and nanotechnologies: opportunities and uncertainties--Summary," The Royal Society, London, UK, July 2004, accessed February 3, 2006 <http://www.nanotec.org.uk/report/summary.pdf>.
[19] Todd Hylton, "Developments in Nanotechnology" Oral Testimony, United States Senate Committee on Commerce, Science, and Transportation, Washington, DC, February 15, 2006.
[20] "FDA Authority Over Cosmetics," United States Food and Drug Administration, Rockville, MD, March 3, 1995, accessed March 12, 2006 <http://www.cfsan.fda.gov/~dms/cos-206.html>.
[21] "Patent Full Text and Full-Image Databases," United States Patent and Trademark Office, Washington, DC, accessed February 3, 2006 <http://www.uspto.gov/patft>.
[22] "Voluntary Cosmetic Registration Program (VCRP)," United States Food and Drug Administration, Rockville, MD, December 1, 2005, accessed March 22, 2006 <http://www.cfsan.fda.gov/~dms/cos-regn.html>.
[23] "Federal Food, Drug and Cosmetic Act," United States Food and Drug Administration, Rockville, MD, accessed February 3, 2006 <http://www.fda.gov/opacom/laws/fdcact/fdcact7a.htm>.
[24] Nakissa Sadrieh, "FDA Perspective on Nanomaterial-Containing Products," presented at Nanobusiness 2005, New York, NY, May 2005, accessed March 25, 2006 <http://www.fda.gov/nanotechnology/powerpoint_conversions/May05_files/800x600/slide1.html>.
[25] "Skin Deep," Environmental Working Group, Washington, DC, accessed March 15, 2006 <http://www.ewg.org/reports/skindeep>.
[26] "Overview of Dietary Supplements," United States, Food and Drug Administration, Rockville, MD, January 3, 2001, accessed February 3, 2006 <http://www.cfsan.fda.gov/~dms/ds-oview.html#what>.
[27] Rob Walker, "Cold Call," *New York Times Magazine*, New York Times, New York, NY, January 8, 2006.
[28] "Study: Nanotechnology in Food and Food Processing Industry Worldwide 2003-2006-2010-2015," Helmut Kaiser Consultancy, Tuebingen, Germany, 2005, accessed February 3, 2006 <http://www.hkc22.com/nanofood.html>.
[29] "Food Additives," United States Food and Drug Administration, Rockville, MD, January 1992, accessed February 3, 2006 <http://www.cfsan.fda.gov/~lrd/foodaddi.html>.
[30] Catherine Greene and Carolyn Dimitri, "Organic Agriculture: Gaining Ground," *Amber Waves*, United States Department of Agriculture, Washington, DC, February 2003, accessed March 21, 2006 <http://www.ers.usda.gov/amberwaves/feb03/findings/organicagriculture.htm>.
[31] Nanette Hansen, "Organic Food Sales See Healthy Growth," MSNBC.com, December 3, 2004, accessed March 10, 2006 <http://msnbc.msn.com/id/6638417>.

[32] "SBIR II: Nano- and Mirco-Encapsulation of Food Additives," United States Department of Agriculture Current Research Information System, Washington, DC, accessed February 3, 2006 <http://cris.csrees.usda.gov/cgi-bin/starfinder/4398/crisassist.txt>.
[33] Mark Baard, "Little Things Could Mean A Lot," *Wired*, March 10, 2004, accessed March 21, 2006, accessed <http://www.wired.com/news/technology/0,1282,62602,00.html>.
[34] "Home Page—About," United States Consumer Product Safety Commission, Bethesda, MD, March 22, 2006, accessed March 22, 2006 <http://www.cpsc.gov/about/about.html>.
[35] Susan E. Dudley and Melinda Warren, *Upward Trend in Regulation Continues: An Analysis of the U.S. Budget for Fiscal Years 2005 and 2006*, Regulator's Budget Report 27, Mercatus Center, George Mason University, Arlington, VA, June 2005, accessed February 3, 2006 <http://www.mercatus.org/regulatorystudies/article.php/1246.html>.
[36] "Study: Smart Toys, Nano Toys, Computerized Toys & Electronic Toys Market Worldwide 2005-2010-2015," Tangull America LLC, New York, NY, accessed February 3, 2006 <http://www.tangull.com/NanoToysStudy.html>.
[37] "CPSC Nanomaterial Statement," United States Consumer Product Safety Commission, Bethesda, MD, accessed March 22, 2006, <http://www.cpsc.gov/LIBRARY/CPSCNanoStatement.pdf>.
[38] J. Clarence Davies, "Developments in Nanotechnology" Written Testimony, United States Senate Committee on Commerce, Science, and Transportation, Washington, DC, February 15, 2006, accessed March 22, 2006 <http://commerce.senate.gov/hearings/testimony.cfm?id=1736&wit_id=4997>.
[39] Andrew Maynard and Evan Michelson, "The Nanotechnology Consumer Product Inventory," Woodrow Wilson International Center for Scholars, Washington, DC, accessed March 23, 2006 <http://www.nanotechproject.org/index.php?s=file_download&id=38>.
[40] "FDA Regulation of Nanotechnology Products," United States Food and Drug Administration, Rockville, MD, accessed February 6, 2006 <http://www.fda.gov/nanotechnology/regulation.html>.
[41] *Results-Oriented Government: Practices That Can Help Enhance and Sustain Collaboration among Federal Agencies,* GAO-06-15, United States Government Accountability Office, Washington, DC, October 2005, accessed February 3, 2006 <http://www.gao.gov/new.items/d0615.pdf>.
[42] J. Clarence Davies, *Managing the Effects of Nanotechnology*, Woodrow Wilson International Center for Scholars, Washington, DC, 2006.
[43] Annabelle Hett, *Nanotechnology: Small Matter, Many Unknowns*, Swiss Reinsurance Company, Zurich, Switzerland, 2004.
[44] Gunter Oberdorster, Eva Oberdorster, Jan Oberdorster, "Nanotoxicology: An Emerging Discipline Evolving form Studies of Ultrafine Particles," *Environmental Health Perspectives* 113 (7), pp. 823-839.
[45] Andrew Maynard and Eileen Kuempel, "Airborne Nanostructured Particles and Occupational Health," *Journal of Nanoparticle Research,* 2005 (7), pp. 587-614.
[46] Christine Ogilvie Robichaud, Dicksen Tanzil, Ulrich Weilenmann, and Mark Wiesner, "Relative Risk Analysis of Several Manufactured Nanomaterials: An Insurance Industry Context," *Environmental Science and Technology,* 39 (22), pp. 8985- 8994.
[47] Gunter Oberdorster, Andrew Maynard, Ken Donaldson, Vincent Castranova, Julie Fitzpatrick, Kevin Ausman, Janet Carter, Barbara Karn, Wolfgang Kreyling, David Lai, Stephen Olin, Nancy Monteiro-Riviere, David Warheit, Hong Yang, "Principles for Characterizing the Potential Human Health Effects from Exposure to Nanomaterials: Elements of a Screening Strategy," *Particle and Fibre Toxicology,* 2 (8), accessed February 3, 2006 <http://www.particleandfibretoxicology.com/content/pdf/1743-8977-2-8.pdf>.
[48] "Review of the National Nanotechnology Program," The National Academies, Washington, DC, accessed March 22, 2006 <http://www8.nationalacademies.org/cp/projectview.aspx?key=289>.
[49] *Securing the Promise of Nanotechnology: Is U.S. Environmental Law Up to the Job? A Dialogue,* Environmental Law Institute, Washington, DC, October 2005.
[50] Jennifer Kuzma, ed., *The Nanotechnology-Biology Interface: Exploring Models for Oversight*, Center for Science, Technology, and Public Policy, University of Minnesota, Minneapolis, MN, September 15, 2005, accessed March 22, 2006 <http://www.hhh.umn.edu/centers/stpp/nanotechnology.html>.
[51] "First International IFAS Conference on Nanotechnology: What Can Nano Learn from Bio? Lessons from the Debate over Agrifood Biotechnology and GMOs," Michigan State University, East Lansing, MI, accessed March 22, 2006 <http://www.carrs.msu.edu/nanoconference>.
[52] "Nanologue Mapping Study," Nanologue, September 2005, accessed March 22, 2006< http://www.nanologue.net/custom/user/Downloads/NanologueMappingStudy.pdf>
[53] "Nanologue Background Paper," Nanologue, September 2005, accessed March 22, 2006 <http://www.nanologue.net/custom/user/Downloads/NanologueBackgroundPaper.pdf>.
[54] Cristoph, Meilie, *Nano-Regulation*, The Innovation Society, Ltd., St. Gallen, Switzerland, March 2006.
[55] IRGC Working Group on Nanotechnology, *Survey on Nanotechnology Governance: Volume A. The Role of Government*, International Risk Governance Council, Geneva, Switzerland, January 2006.
[56] "NNI Environment Health and Safety Issues," National Nanotechnology Initiative, Washington, DC, accessed February 3, 2006 <http://www.nano.gov/html/society/EHS.htm>.
[57] "Overview of Issues for Public Discussion and Consideration by NPPTAC," Interim Ad Hoc Work Group on Nanoscale Materials, National Pollution Prevention and Toxics Advisory Committee (NPPTAC), United States Environmental Protection Agency, Washington, DC, September 21, 2005.
[58] "$5 Million Awarded to Study Health and Environmental Effects of Nanotechnology," United States Environmental Protection Agency, Washington, DC, March 16, 2006, accessed March 23, 2006

<http://yosemite.epa.gov/opa/admpress.nsf/0/6D536A255F4416848525713300520F80>.
[59] "Nanotechnology Research Grants Investigating Environmental and Human Health Effects of Manufactured Nanomaterials: a Joint Research Solicitation-EPA, NSF, NIOSH, NIEHS," United States Environmental Protection Agency, Washington, DC, December 20, 2005, accessed March 23, 2006 <http://es.epa.gov/ncer/rfa/2005/2005_star_nano.html#AWARD_ADMINISTRATION>.
[60] "New Grants Are Awarded to Inform the Public and Explore the Implications of Nanotechnology," National Science Foundation, Arlington, VA, October 6, 2005, accessed February 3, 2006 <http://www.nsf.gov/news/news_summ.jsp?cntn_id=104505&org=olpa&from=home>.
[61] "New Cross-Reference Digest for Nanotechnology," Unites States Patent and Trademark Office, Alexandria, VA, March 8, 2005, accessed February 3, 2006 <http://www.uspto.gov/web/patents/biochempharm/crossref.htm>.
[62] Vance McCarthy, "USPTO Poised to Ring in a New Era of Simplified Search and Better Visibility for Nano Patents," Nano Science and Technology Institute, Cambridge, MA, December 2, 2005, accessed March 22, 2006 <http://www.nsti.org/news/item.html?id=35>.
[63] "Nanoparticle Information Library (NIL)," National Institute of Occupational Safety and Health, Washington, DC, accessed March 23, 2006 <http://www2a.cdc.gov/niosh-nil/index.asp>.
[64] The Project on Emerging Nanotechnologies, "Nanotechnology Health and Environment Implications: An inventory of current research," Woodrow Wilson International Center for Scholars, Washington, DC, accessed March 23, 2006 <http://www.nanotechproject.org/index.php?id=18>.
[65] International Council on Nanotechnology, "ICON EHS Database," Rice University, Houston, TX, accessed March 23, 2006 <http://icon.rice.edu/research.cfm>.
[66] *Approaches to Safe Nanotechnology: An Information Exchange with NIOSH,* National Institute for Occupational Safety and Health, Washington, DC, October 1, 2005, accessed February 3, 2006 <http://www.cdc.gov/niosh/topics/nanotech/pdfs/Approaches_to_Safe_Nanotechnology.pdf>.
[67] "What is Nanotechnology?" National Nanotechnology Initiative, Washington, DC, accessed March 23, 2006 <http://www.nano.gov/html/facts/whatIsNano.html>.
[68] Michael Roukes, "The Vast Potential of Very Small Things," *BusinessWeek online*, October 19, 2004, accessed March 23, 2006 <http://businessweek.com/bwdaily/dnflash/oct2004/nf20041019_8591.htm>.
[69] M.C. Roco, "Nanoscale Science and Engineering: Unifying and Transforming Tools," *AIChE Journal* 50 (5), pp. 890-897.
[70] James Wilsdon and Rebecca Willis, *See Through Science: Why Public Engagement Needs to Move Upstream*, Demos, London, UK, 2004.
[71] Edna Einsiedel, "Introduction: Making Sense of Emerging Technologies," in *First Impressions: Understanding Public Views on Emerging Technologies*, Government of Canada, Ottawa, CA, 2005, pp. 2-5, accessed March 22, 2006 <http://www.biostrategy.gc.ca/CMFiles/CBS_Report_FINAL_ENGLISH249SFD-9222005-5696.pdf>.
[72] Martin LaMonica, "Nanotech Creeping in, bit by tiny bit," *CNET News.com*, October 25, 2005, accessed February 3, 2006 <http://news.cnet.co.uk/gadgets/0,39029672,39193470,00.htm>
[73] Clayton M. Christensen, *The Innovator's Dilemma*, Harvard Business School Press, Cambridge, MA, 1997.
[74] Evan Michelson, "Analyzing the European Approach to Nanotechnology," Woodrow Wilson International Center for Scholars, Washington, DC, November 2004, accessed March 22, 2006 <http://www.environmentalfutures.org/Images/Nanotec1.pdf>.
[75] "NIH Research Into Nanotech Toxicity May Help Shape Federal Policies," *Inside EPA*, Inside Washington Publishers, Washington, DC, March 27, 2006.
[76] *Strategic Plan for NIOSH Nanotechnology Research: Filling the Knowledge Gaps*, National Institute for Occupational Safety and Health, Washington, DC, September 28, 2005, accessed March 28, 2006 <http://www.cdc.gov/niosh/topics/nanotech/strat_planINTRO.html>.
[77] "Exercise caution when using 'nano-sealing sprays' containing a propellant!" Federal Institute for Risk Assessment, Berlin, Germany, March 31, 2006, accessed April 10, 2006 <http://www.bfr.bund.de/cms5w/sixcms/detail.php/7699>.
[78] Rick Weiss, "Nanotech Product Recalled in Germany," *The Washington Post,* April 6, 2006, page A02.
[79] "Nanotech Product Recall Underscores More Need for Nanotech Moratorium: Is the Magic Gone?" ETC Group, Ottawa, CA, April 7, 2006, accessed April 10, 2006 <http://www.etcgroup.org/article.asp?newsid=559>.
[80] Matthew Kearnes, Phil Macnaghten, James Wilsdon, *Governing at the Nanoscale*, Demos, London, UK, 2006.