

# An Integrated Approach to Nanotechnology Governance

*LeRoy Paddock\**

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\* LeRoy Paddock is Associate Dean for Environmental Law Studies at The George Washington University Law School.

## I.

## INTRODUCTION

The rapid emergence of nanotechnologies presents significant challenges for environmental and public health governance systems. The unique risks nanomaterials pose because of their size and reactivity, together with a lack of information about the health and environmental effects of these materials, limit the value of traditional risk assessment tools. Further, existing regulatory programs are widely seen as moving too slowly to keep up with innovations in nanotechnologies. Although some nanochemicals and nanopesticides fall under the jurisdiction of the Toxic Substances Control Act<sup>1</sup> or the Federal Insecticide, Fungicide and Rodenticide Act,<sup>2</sup> these statutes only address a small slice of the nanotechnology universe. Even if nano-specific regulatory legislation is enacted, which does not appear likely in the near term, the breadth and rapid development of nanotechnologies will require the use of governance tools in addition to traditional regulation: only this combination will achieve an appropriate balance between the societal benefits of nanotechnologies and the potential risks of at least some of these technologies. This Article suggests the need for an integrated system of environmental and public health governance that relies on a combination of approaches including: an adaptive regulatory system; wider and earlier access to information; deployment of additional public engagement mechanisms; use of voluntary programs as a transitional tool; encouraging broader adoption of corporate social responsibility (CSR) policies; adoption of voluntary codes of conduct; retention of civil liability; and informed individual decisionmaking.

In 1999, President Clinton's Council on Sustainable Development concluded "[e]nvironmental progress will depend on individual, institutional, and corporate responsibility, commitment, and stewardship."<sup>3</sup> Today's complex environmental challenges such as climate change, fisheries depletion, estuary restoration

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1. Toxic Substances Control Act of 1976, 15 U.S.C. §§ 2601-2692 (2006).

2. Federal Insecticide, Fungicide, and Rodenticide Act of 1947, 7 U.S.C. §§ 136-136y (2006).

3. PRESIDENT'S COUNCIL ON SUSTAINABLE DEV., *TOWARDS A SUSTAINABLE AMERICA: ADVANCING PROSPERITY, OPPORTUNITY, AND A HEALTHY ENVIRONMENT FOR THE 21ST CENTURY* vi (1999) (quoting PRESIDENT'S COUNCIL ON SUSTAINABLE DEV., *A NEW CONSENSUS FOR PROSPERITY, OPPORTUNITY, AND A HEALTHY ENVIRONMENT FOR THE FUTURE* (1996)), available at <http://clinton2.nara.gov/PCSD/Publications/tsa.pdf>.

and oversight of nanotechnology development cannot be solved using only regulatory tools; instead, they require all sectors—governments, companies, institutions, nongovernmental organizations (NGOs) and individuals—to assume responsibility for achieving desired outcomes. Responsibility is a simple term—the legal or ethical accountability for the care or welfare of another<sup>4</sup>—but a complex concept in the context of environmental and public health governance.

Over the last thirty plus years, responsibility for environmental and public health management has been seen as primarily a function of government. However, realizing the benefits that new technology's promise while minimizing the risk that some of these technologies may pose requires an approach that also relies on companies, universities, civil society organizations and individuals assuming some responsibilities for careful management of technology research and the life cycle impacts of products. Further, because technological developments are moving rapidly, any governance approach will have to be flexible, allowing the system to adapt as new information becomes available. The United Kingdom's Royal Commission on Environmental Pollution recently observed

[C]ontemporary society is characterized by the accelerating pace of the proliferation of new technologies. Increasingly, it will be impossible to settle questions about the environmental and human health impacts of nano- and many other new materials consistently and in a timely fashion using traditional risk-based regulatory frameworks. . .

We are therefore faced with an instance of what David Collinridge described as the "technology control dilemma." In the early stages of a technology we do not know enough to establish the most appropriate controls for managing it. But by the time the problems emerge, the technology is too entrenched to be changed without major disruptions.

The solution to this dilemma is not simply to impose a moratorium that stops development, but to be vigilant with regard to inflexible technologies that are harder to abandon or modify than more flexible ones. Thus, the key questions are how difficult would it be to remediate problems if problems arose? These considerations of trans-science, world views and the control dilemma suggest that nanomaterials, like other emerging areas of technology, require an adaptive governance regime capable of monitoring technologies

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4. See *THE AMERICAN HERITAGE DICTIONARY* 1053 (2d College ed. 1982).

and materials as they are developed and incorporated into processes and products.<sup>5</sup>

The nature of the governance system required for the nanotechnologies is not markedly different from the approach needed to address other major environmental and public health problems, such as ecosystem restoration or greenhouse gas mitigation. As Daniel Fiorino noted in his book *The New Environmental Regulation*, the European literature on social-political governance is asking the question

How can dynamic, complex, and diverse social-political systems be governed more democratically and effectively? Their answer is to think in terms of entirely new conceptions of governance, owing to the limits of traditional, hierarchical ideas about governance in a rapidly changing world. For these writers, "the growing complexity, dynamics, and diversity of our societies, as 'caused by social, technological and scientific developments,' puts governing systems under such new challenges that new conceptions of governance are needed."

Social-political governance involves new patterns of interaction among government and others in society. These patterns are not temporary, but are built into the structures and processes of governance. Distinctions between the public (the state, regulatory agencies) and the private (society, markets) are blurred as the boundaries between them become more fluid and permeable. Government acts not *on* but *with* nongovernmental and commercial entities. There is a shift from governance as one-way traffic toward two-way traffic [if we are to expect people to take on responsibility they must know why, how, they must have information, they must have a role in design and oversight] in which "aspects, qualities, problems, and opportunities" of those governing and of those being governed are considered.<sup>6</sup>

Don Kettl has identified five imperatives for a new and more effective governance strategy: (1) a policy agenda that focuses more on *problems* than on *structures*; (2) political accountability that works more through *results* than through *processes*; (3) public administration that functions more *organically*, through heterarchy, than *rigidly* through hierarchy; (4) political leadership that works more by *leveraging action* than simply by *making deci-*

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5. ROYAL COMMISSION ON ENVIRONMENTAL POLLUTION, NOVEL MATERIALS IN THE ENVIRONMENT: THE CASE OF NANOTECHNOLOGY 14-15 (Nov. 2008), available at <http://www.rcep.org.uk/reports/27-novel%20materials/27-novelmaterals.htm>.

6. DANIEL FIORINO, *THE NEW ENVIRONMENTAL PROTECTION* 161-162 (2006) (citation omitted).

sions; and (5) citizenship that works more through *engagement* than *remoteness*.<sup>7</sup>

Each of these perspectives makes clear that the nature of today's environmental and public health problems requires a fundamental rethinking of governance structures. The emergence of nanotechnologies creates particularly difficult governance challenges.

## II.

### GOVERNANCE CHALLENGES PRESENTED BY NANOTECHNOLOGIES

The rapid emergence of nanotechnologies and their penetration into the marketplace present significant governance challenges. Among the most important of these challenges are: (1) the speed at which the industry is developing and the expected scale of the industry; (2) the diversity of technologies involved; (3) the low levels of public awareness about nanotechnologies; (4) the race to be the first to the market with new products in a competitive global economy; (5) the potential extraordinary social benefits of some nanotechnologies; (6) the nature of the risks that may be created by some nanotechnologies; and (7) the ethical, legal and social issues associated with some of the technologies.

#### A. *Industry Growth*

August 2008 statistics from the Project on Emerging Technologies showed 803 nanotechnology-related products on the market, produced by 439 companies in twenty-one countries.<sup>8</sup> The majority of these products were cosmetics, personal care items, sunscreens, clothing, sporting goods and filtration devices. The nanomaterials most frequently involved are metals (silver, zinc, titanium and gold), carbon fibers, and silicon/silica.<sup>9</sup> These products are primarily passive (steady function) nanomaterials—what the International Risk Governance Council refers to as first gen-

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7. DONALD F. KETTL, *THE NEXT GOVERNMENT OF THE UNITED STATES: CHALLENGES FOR PERFORMANCE IN THE 21ST CENTURY* 8 (2005), available at <http://www.businessofgovernment.org/pdfs/KettlReport.pdf>.

8. THE PROJECT ON EMERGING NANOTECHNOLOGIES, *NANOTECHNOLOGY CONSUMER PRODUCT INVENTORY*, <http://www.nanotechproject.org/inventories/consumer/> (last visited April 13, 2010).

9. THE PROJECT ON EMERGING NANOTECHNOLOGIES, *ANALYSIS: CONSUMER PRODUCTS*, [http://www.nanotechproject.org/inventories/consumer/analysis\\_draft/](http://www.nanotechproject.org/inventories/consumer/analysis_draft/) (last visited April 13, 2010).

eration or Frame I materials.<sup>10</sup> Waiting in the development wings are second, third and fourth generation “active” or Frame II nanotechnologies. These materials could change their state during operation (second generation), could bio-assemble allowing, for example, the development of artificial organs (third generation), or could produce molecular nanosystems that function in a manner similar to natural biosystems (fourth generation).<sup>11</sup> Some second generation nanotechnologies are now reaching the market and fourth generation nanotechnologies are expected as early as 2015.<sup>12</sup> Estimates of the scale of nanotechnology market vary widely but may be as high as \$2.6 trillion<sup>13</sup> by 2015 and are, of course, affected by the current worldwide economic downturn. The International Risk Governance Council notes that

Nanotechnology has the potential to become one of the defining technologies of the 21st century. Based on the ability to measure, manipulate and organise material on the nanoscale—it is set to have significant implications—envisaged breakthroughs for nanotechnology include order-of-magnitude increases in computer efficiency, advanced pharmaceuticals, bio-compatible materials, nerve and tissue repair, surface coatings, catalysts, sensors, telecommunications and pollution control.<sup>14</sup>

By any measure, the field is growing very rapidly. In fact, J. Clarence Davies believes, “[t]wenty years from now, most products we use are likely to have some nanotechnology component.”<sup>15</sup>

The speed and magnitude of development creates difficulties for traditional approaches to regulation. In its study on *Managing the Effects of Nanotechnology*, the Project on Emerging Technologies pointed out that

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10. INTERNATIONAL RISK GOVERNANCE COUNCIL, NANOTECHNOLOGY RISK GOVERNANCE: RECOMMENDATIONS FOR A GLOBAL, COORDINATED APPROACH TO THE GOVERNANCE OF POTENTIAL RISKS 7-9 (2007), available at [http://www.irgc.org/IMG/pdf/PB\\_nanoFINAL2\\_2\\_.pdf](http://www.irgc.org/IMG/pdf/PB_nanoFINAL2_2_.pdf).

11. See *id.*

12. See *id.* at 7-8.

13. ELVIO MANTOVANI ET AL., FRAMING NANO, MAPPING STUDY ON REGULATION AND GOVERNANCE OF NANOTECHNOLOGIES 22 (Jan. 2009), available at <http://www.framingnano.eu>.

14. ORTWIN RENN & MIKE ROCCO, INTERNATIONAL RISK GOVERNANCE COUNCIL: WHITE PAPER ON NANOTECHNOLOGY GOVERNANCE 21 (2006) (Citation omitted), available at [http://www.nsf.gov/crssprgm/nano/reports/irgc06\\_wp.pdf](http://www.nsf.gov/crssprgm/nano/reports/irgc06_wp.pdf).

15. J. CLARENCE DAVIES, NANOTECHNOLOGY OVERSIGHT: AN AGENDA FOR THE NEW ADMINISTRATION 2 (2008), available at <http://www.nanotechproject.org/process/assets/files/6709/pen13.pdf>.

The rapid development of [nanotechnology] also means that government managers always will be operating with outdated information, and data on [nanotechnology] effects will lag behind commercial applications. Priorities for research and for regulation will need to shift constantly. We have moved into a world which is, as David Rajeski states, "dominated by rapid improvements in products, processes, and organizations, all moving at rates that exceed the ability of our traditional governing institutions to adapt or shape outcomes."<sup>16</sup>

The International Risk Governance Council (IRGC) succinctly frames the environmental governance challenge, observing "innovation in the field of nanotechnology development is far ahead of the policy and regulatory environment."<sup>17</sup>

### B. *Technological Diversity*

The applications for nanotechnologies spread across a wide range of fields. In medicine the potential uses include diagnostics, drug delivery and tissue engineering.<sup>18</sup> For foods, applications may include the delivery of bioactive food additives and new forms of packaging that have an anti-microbial effect (silver endowed materials) or that are more gas or moisture tight through the use of nanoclays.<sup>19</sup> Nanomaterials are already used in clothing to protect against stains and for anti-microbial purposes. These materials may eventually be used to strengthen fibers (nanowires) and reduce abrasion that occurs during washing.<sup>20</sup>

Nanomaterials are used in a range of cosmetics to transport nutritive and other substances through the skin. This allows the body to absorb even water-insoluble substances.<sup>21</sup> Composites are another key application with current production of several million tons per year. Nanoparticle-reinforced composite materials can resist heat, improve conduction, or exhibit a higher strength to weight ratio.<sup>22</sup> Nanoparticles are also used for coatings that resist scratching (nanoscale ceramic particles), that have

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16. J. CLARENCE DAVIES, *MANAGING THE EFFECTS OF NANOTECHNOLOGY 2* (2006), available at <http://www.wilsoncenter.org/events/docs/Effectsnanotechfinal.pdf>.

17. INTERNATIONAL RISK GOVERNANCE COUNCIL, *supra* note 10, at 13.

18. MANTOVANI ET AL., *supra* note 13, at 18.

19. *See id.*

20. *See id.*

21. *See id.* at 19.

22. *See id.*

anti-microbial properties in appliances, and that decompose organic material to make windows and roofs self-cleaning.<sup>23</sup>

The breadth of the technology creates a significant governance challenge since the various applications of nanomaterials are not regulated under a single regime as, for example, hazardous waste, but rather through a wide range of regulatory schemes. IRGC points out that “in no country is there a single regulatory structure that covers food, chemicals, personal care products, medical devices, water quality, and so on.”<sup>24</sup>

### C. *Lack of Knowledge and Public Awareness*

While increasing funding and effort are being devoted to ascertaining the health and environmental impacts of nanotechnologies, knowledge related to these issues remains seriously limited. For example, Davies and Rajeski note that a recent survey of nanotechnology firms in New England “indicates that virtually every firm—large or small—lacks clear information on the environmental and health risks of nanomaterials and is suffering from a lack of guidance from regulators. Questions remain as to what to test, the standards to apply, and where to find research on the impacts of nanoscale materials.”<sup>25</sup>

Public awareness of nanotechnologies also remains low. A 2007 nationwide survey indicated that seventy-one percent of those surveyed had heard nothing or very little about nanotechnology.<sup>26</sup> The same survey noted that fifty-one percent of the respondents indicated that they had no opinion about the risks versus benefits of nanotechnologies.<sup>27</sup>

The lack of public awareness of nanotechnologies, together with limited knowledge about the risks of some of the technologies and the absence of a clear governance system, creates the risk of public rejection of nanotechnology. Governance systems and their regulatory elements not only set management standards and punish wrongdoing, but they also help build public

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23. *See id.*

24. INTERNATIONAL RISK GOVERNANCE COUNCIL, *supra* note 10, at 8.

25. Terry Davies & David Rajeski, *Overseeing the Unseeable*, ENVTL. F., Nov.-Dec. 2007, at 36, 40.

26. *See* Peter D. Hart Research Associates, Inc., AWARENESS OF AND ATTITUDES TOWARD NANOTECHNOLOGIES AND FEDERAL REGULATORY AGENCIES 5 (Sept. 25, 2007), available at [http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Nanotechnologies/Hart\\_NanoPoll\\_2007.pdf](http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Nanotechnologies/Hart_NanoPoll_2007.pdf).

27. *Id.* at 6.

confidence in industry, especially in industries that involve significant risks.

Over the last decade, new technologies have faced public confidence challenges with varying results. In the United States, the use of bovine growth hormones (BGH) became a significant issue in the 1990s. While the controversy has largely subsided, a number of milk products are now labeled “BGH Free” to address concerns of consumers.<sup>28</sup>

Genetically modified organisms (GMOs), such as seeds that tolerate certain herbicides, have been even more controversial. Concerns include GMO “out crossing” (in which GMOs cross breed with non-GMOs and consequently change the non-GMO plant’s characteristics), fears about the potential effect of GMO foods on health, and the impact that patented GMO seeds may have on seed costs for farmers in developing countries.<sup>29</sup> Although GMO companies have overcome these concerns in the United States, public opposition in the European Union resulted in a long delay in introducing GMO seeds in Europe.<sup>30</sup> Problems of public acceptance can arise even in the absence of scientific facts substantiating the fears.<sup>31</sup>

Nanotechnologies face a similar risk, in significant part because so little is known about the effects of these technologies.<sup>32</sup> Issues have been raised in several quarters about the potential impact of nanotechnologies. For example, the Natural Resources Defense Council and Environmental Defense staff observed that the novel properties of nanotechnologies

pose new risks to workers, consumers, the public, and the environment. The few data now available give cause for concern: Some materials appear to have the potential to damage skin, brain, and lung tissue, to be mobile or persistent in the environment, or to kill microorganisms (potentially including ones that constitute the base of the food web). The trickle of data highlights how little is known

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28. See, e.g., Iowa State University Office of Biotechnology, Bovine Somatotropin (bST), [http://www.biotech.iastate.edu/biotech\\_info\\_series/bio3.html#anchor346047](http://www.biotech.iastate.edu/biotech_info_series/bio3.html#anchor346047) (last visited Apr. 13, 2010).

29. See, e.g., Wayne A. Parrot and Andrew H. Paterson, *VIEWPOINT: The GMO Controversy and the Ivory Tower*, UNIVERSITY OF GEORGIA RESEARCH, Winter 2000, available at <http://www.ovpr.uga.edu/researchnews/winter2000/viewpoint.html>.

30. Sylvie Bonny, *Why are Most Europeans Opposed to GMOs? Factors Explaining Rejection in France and Europe*, 6 ELECTRONIC J. OF BIOTECH. 50, 53 (2003).

31. Gregory N. Mandel, *Technology Wars: The Failure of Democratic Discourse*, 11 MICH. TELECOMM. & TECH. L. REV. 117, 119-120 (2005).

32. *Id.* at 119.

about the environmental and health effects of engineered nanomaterials.<sup>33</sup>

If the nanotechnology governance system does not address issues of public confidence in the technology, at least some forms of nanotechnology may suffer the same fate as that of genetically modified seed crops in the European Union: rejection of the technology as unsafe even though scientific consensus identified little risk from the use of GMO seeds.<sup>34</sup> The prospect of unfounded public rejection suggests that governance tools that create public confidence in the industry must be identified.

The risk of public rejection is especially acute in situations where scientific uncertainty is significant and where interest groups are likely to stake out strongly held positions early in the development of the technology. As Professor Mandel noted in his study of responses to risks posed by biotechnology and by nuclear power production, "individuals and interest groups do not revise their technology preferences in response to scientific and empirical information in the manner that such information appears to indicate."<sup>35</sup> Rather, a wide range of cultural factors drive and reinforce polarization. These factors include: biased assimilation of new data (Mandel notes that "individual beliefs are remarkably resilient to the introduction of new data that challenges the beliefs");<sup>36</sup> the tendency of individuals to rapidly and automatically have a positive or negative feeling when confronted with certain ideas or concepts; cognitive dissonance avoidance which leads individuals to discount information that conflicts with their perception of risks; and group dynamics that tend to perpetuate and reinforce polarization among individuals who socialize with those holding similar views.<sup>37</sup> The polarization phenomenon is aggravated by the fact that moderate voices tend to be underrepresented in debates involving technological risk because moderate voices typically do not inspire a "moderate movement."<sup>38</sup>

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33. John Balbus, Richard Denison, Karen Florini & Scott Walsh, *Getting Nanotechnology Right the First Time*, ISSUES IN SCI. & TECH., Summer 2005, at 65.

34. Malcolm Grant, *2005 Kerlin Lecture*, 9 J. PACE CTR. ENVTL. LEG. STUD. 1-2 (Spring 2006), available at <http://www.pace.edu/emplibrary/Env.%20Law%20GreenLaw%20Issue%20Volume%209.pdf>.

35. Mandel, *supra* note 31, at 141.

36. *Id.* at 159.

37. *Id.* at 159-163.

38. *Id.* at 172-174.

#### D. Competitiveness

Nanotechnology development appears to have become a race in which no nation, state, university, or major company wants to be left behind. For example, the United Kingdom's Strategy for Nanotechnology concluded that "the field of nanotechnology and its applications is crucial to the future competitiveness and productivity of the UK economy, and to the well being and prosperity of its people."<sup>39</sup> And, the U.S.-based Nanotechnology Alliance observed

[T]he countries that demonstrate the highest level of innovation and capture the most value from nanotech progress will exert a very significant level of influence on the global geopolitical landscape. For us to maintain our quality of life and global leadership position, the U.S. must play, not just to participate in, but to win the international nanotechnology race.<sup>40</sup>

State after state has enacted legislation trying to secure a competitive advantage in the industry using tax credits,<sup>41</sup> emerging technology funds,<sup>42</sup> direct appropriation to university research centers,<sup>43</sup> and access to funding from Economic Development Banks.<sup>44</sup> Some countries have created cabinet level positions to help the state cultivate and expand growth industries such as nanotechnology.<sup>45</sup>

The globally competitive nature of nanotechnology development suggests the need for a multifaceted governance system, since regulatory activity in one country (such as a ban based on a precautionary approach) may simply push the development of the technology to another country. Rather, governance mechanisms will have to generate new information, engage the public and spur action (both regulatory and self-directed) wherever the technology is being developed and used.

#### E. Potential Benefits

Nanotechnologies likely will have significant impacts in many areas, including the environment, medicine, electronics, and

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39. DEP'T OF TRADE AND INDUSTRY, NEW DIMENSIONS FOR MANUFACTURING: A UK STRATEGY FOR NANOTECHNOLOGY 11 (2002), available at [http://www.innovateuk.org/\\_assets/pdf/taylor%20report.pdf](http://www.innovateuk.org/_assets/pdf/taylor%20report.pdf).

40. Nanobusiness Alliance, *Nanotechnology: A Roadmap to Leadership 2* (2006).

41. Ark. Code Ann. §15-4-2104(a) (West 2006).

42. Mass. Gen. Laws Ann. ch. 23G, §27(a), (c) (West 2006).

43. 2003 Or. ALS 725 §11(4)(b).

44. Tex. Gov't Code Ann. §489.0296(a) (Vernon 2006).

45. Va. Code Ann. §2.2-225 (West 2006).

other consumer products. Because fundamental life processes occur at the nanoscale, nanotechnology offers an ideal medium for fighting diseases.<sup>46</sup> Advanced drug-delivery systems incorporating nanotechnology would theoretically be able to direct drug molecules only to where they are needed in the body, a technique that would greatly reduce the side-effects of treatments such as chemotherapy.<sup>47</sup>

Nanotechnology is also considered one of many tools that can help address the energy crisis. Nanotechnology will be used to enhance our abilities to efficiently capture energy.<sup>48</sup> In the near-term, one of the most realistic uses of nanotechnology in the production of clean energy involves the development of more efficient solar panels.<sup>49</sup> The company Nanosolar, which is engaged in perhaps the most ambitious private effort to enhance commercial solar technology through the use of nanotechnology, has attracted millions of dollars in grants and investments.<sup>50</sup> Nanosolar's goal is to be able to mass-produce its thin-film solar panels, which are not only one hundred times thinner than traditional solar panels, but are also significantly more efficient.<sup>51</sup>

Nanotechnology could also become an important part of the cleanup of contaminated and hazardous waste sites. The EPA states that because of their enhanced reactivity, surface area, sub-surface transport, and other characteristics, nanomaterials could result in more rapid or cost-effective cleanup of wastes.<sup>52</sup> Nanotechnology is also being used to create more powerful sensors that can accurately detect contaminants in the environment at very low concentrations.<sup>53</sup> The potentially immense social benefits associated with nanomaterials are a reason so many countries and companies are pressing to rapidly develop the technologies.

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46. Lindsay V. Dennis, *Nanotechnology: Unique Science Requires Unique Solutions*, 25 TEMP. J. SCI. TECH. & ENVTL. L. 87, 94 (2006).

47. *Id.*

48. *Id.* at 94-95.

49. OFFICE OF THE SCIENCE ADVISOR, U.S. EPA, NANOTECHNOLOGY WHITE PAPER 27 (2007), available at <http://www.epa.gov/OSA/pdfs/nanotech/epa-nanotechnology-whitepaper-0207.pdf>.

50. See Nanosolar, <http://www.nanosolar.com> (last visited Oct. 1, 2009).

51. *Id.*

52. NANOTECHNOLOGY WHITE PAPER, *supra* note 49, at 22-23.

53. *Id.* at 23-24.

## F. Risks

Britain's Royal Commission on Environmental Protection well summarized the concern about the risks of nanotechnologies:

It is a matter of concern that we were repeatedly told by competent organizations and individuals that there is currently insufficient information to form a definitive judgment about the safety of many types of nanomaterials. In some cases, the methods and data needed to understand the toxicology and exposure routes of nanomaterials are insufficiently standardized or even absent. There appears to be no clear consensus among scientists about how to address this deficit.

. . . So, new toxicological and ecotoxicological protocols are required. However, and crucially, under current procedures, it can take up to 15 years for a new testing protocol to achieve regulatory acceptance. Given the rapid pace of market penetration of nanomaterials and the products that contain them, existing regulatory approaches cannot be relied upon to even detect, let alone manage, problems before the material has become ubiquitous.<sup>54</sup>

The Framing Nano Project report reinforced this concern, observing “[a] great number of studies already suggest that many nanoparticles are not inherently benign and actually can affect biological activities at the cellular, sub-cellular, and molecular level.”<sup>55</sup> Because nanomaterials are so small, they may have the ability to enter human cells and even alter biological processes on the cellular level.<sup>56</sup> Some evidence suggests the fullerenes used in cosmetics may have toxic effects on cell membranes.<sup>57</sup> A number of studies indicate that carbon nanotubes may cause “oxidative stress, inflammation, cell damage, adverse effects on cell performance, and, in a long-term perspective, pathological effects in the lungs.”<sup>58</sup> Prolonged exposure of rats to nanoscale titanium dioxide and silver dioxide has resulted in inflammation and lung tumors in some studies even though a similar effect has not been demonstrated for exposure to larger size particles of the same materials.<sup>59</sup>

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54. ROYAL COMMISSION ON ENVIRONMENTAL POLLUTION, *supra* note 5, at 9-10.

55. MANTOVANI ET AL., *supra* note 13, at 28.

56. NAT'L RESEARCH COUNCIL, A MATTER OF SIZE: TRIENNIAL REVIEW OF THE NATIONAL NANOTECHNOLOGY INITIATIVE 78-79 (2006), available at [http://books.nap.edu/openbook.php?record\\_id=11752&page=R1](http://books.nap.edu/openbook.php?record_id=11752&page=R1).

57. *Id.* at 29.

58. *Id.*

59. *Id.*

The IRGC recently observed “[w]e still have only a limited understanding of passive nanomaterials’ potential environmental, health and safety risks but active and more complex nanostructures require a far greater level of knowledge to assess potential risks.”<sup>60</sup> There is as of yet little data available about biodegradation, bioaccumulation and the possibility of accumulation of nanoparticles in the food chain. However, some investigations indicate that carbon nanoparticles can be taken up by aquatic organisms.<sup>61</sup> The Framing Nano report noted that there is “a remarkable lack of information on some key aspects of concerning the environmental impacts of manufactured nanoparticles, which currently prevents a better understanding and assessment of the toxicity and ecotoxicity of manufactured nanoparticles to the key ecosystem organisms.”<sup>62</sup> The report does point out, though, that some nanoparticles, such as titanium dioxide and silver, are used because of their antibacterial properties and raises the concern that “[t]he antifungal and antibacterial activity of manufactured nanoparticles may seriously threaten free-living nitrogen-fixing bacteria and symbiotic relationships involving fungi, bacteria, and plants. . . .”<sup>63</sup>

Both the lack of knowledge about the health and environmental impacts of nanomaterials and the research indicating some serious risks compel an approach to governance that includes an appropriate precautionary element.

### G. *Ethical, Legal and Social Issues*

Some nanotechnologies, especially active or Frame Two technologies, pose challenging ethical, legal and social issues. Among the key ethical and social issues are potential non-therapeutical, human enhancement applications of nanotechnologies, personal responsibility associated with diagnostic techniques that provide predictive information on diseases, privacy issues associated with new surveillance and medical uses of nanotechnologies, and concerns about new technologies that may fall into the hands of criminals.<sup>64</sup>

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60. INTERNATIONAL RISK GOVERNANCE COUNCIL, *supra* note 10, at 8.

61. *Id.* at 32.

62. *Id.*

63. *Id.*

64. MANTOVANI ET AL., *supra* note 13, at 35.

There are also important social issues about how priorities should be set in spending government nanotechnology research funding. These questions include:

- What percentage of research funding should be for environmental and health research?
- Should research on technologies that may pose higher risks proceed in the absence of parallel health and environmental research?
- Should research funding be focused on technologies that are likely to produce higher social benefits (perhaps at the expense of research that may lead to products that enhance competitiveness or that may be more profitable)?
- How should an acceptable trade-off between risks and benefits be determined?

Another important question considers whether legislative bodies, agency officials, researchers, NGOs, and public representatives should influence the priority setting process. Increasingly, governments are being pressured to provide new “upstream” public involvement processes that allow a wider range of interests to influence research priorities.<sup>65</sup>

All of these factors suggest the complexity in creating an environmental and public health governance structure that can keep pace with the growth of the industry, deal with the very wide range of technologies that use nanomaterials, build the knowledge base needed to make better decisions and maintain public confidence, address issues of internal and international competition, and allow beneficial products to reach the market without creating excessive risk. There are, however, important lessons that can be learned from the evolving nature of environmental and public health governance involving other difficult environmental problems.

### III.

#### THE EVOLUTION OF ENVIRONMENTAL GOVERNANCE

For most of the last four decades environmental and public health governance has primarily been the domain of government. Today, governance must become a shared enterprise, anchored by government regulatory programs but fully integrating economic and values-based behavioral drivers as well. Rather than relying primarily on direct regulation to control behavior, gov-

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65. *Id.* at 39.

ernments and other organizations must employ a variety of direct and indirect measures to encourage organizations and individuals to take responsibility for their actions. These new approaches include:

- Advanced, adaptive regulations that respond to new information
- Better information that facilitates public engagement ranging from consumer decisionmaking to more informed involvement with government and businesses in designing governance approaches
- Codes of conduct and industry standards that anticipate problems and respond more quickly than government has traditionally been able to respond
- New forms of public dialogue and new channels on governance to engage the general public in the governance discussion
- A better understanding of the role of corporate social responsibility including the factors that drive businesses to take a precautionary approach in dealing with environmental and public health issues, such as reputation and investor relations, education, and consumer pressure, among others
- Retention of common law liability regimes that can temper hasty decisions to bring potentially risky products to the market and that can spur research organizations and manufactures to ensure the safety of their workers
- Government encouragement for industry performance beyond the minimums required by law

As Marian Chertow and Daniel Esty observed in their book *Thinking Ecologically*

In the past, when environmental insults were obvious and the targets of controls were big smokestack industries, making companies pay for their despoliation had a moral logic that offered wide appeal. Today, however, when many of the harms we face reflect the cumulative impact of millions of individuals and small enterprises, the enemy is "us" and the moral certainty of a crusade is harder to sustain.<sup>66</sup>

The nature of today's environmental problems and the costs to remedy those problems has dramatic consequences for the design of an effective system of environmental governance. The public can no longer simply turn over environmental problems to "expert" government agencies and expect that the problems will be

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66. Marian R. Chertow & Daniel C. Esty, *A Vision for the Future*, in *THINKING ECOLOGICALLY: THE NEXT GENERATION OF ENVIRONMENTAL POLICY* 231, 232 (Marian R. Chertow & Daniel C. Esty eds., 1997).

resolved without their involvement or commitment. And the public cannot expect these major environmental problems to be solved without committing either significant new tax or fee revenues or new sources of nongovernmental funding to the problems. Legislatures and government agencies can no longer concentrate their efforts on large public and industrial facilities and expect that major ecosystem problems will be adequately addressed. Simply writing rules, requiring and enforcing permits, and reporting to the public about how many permits have been issued and how many penalties have been imposed is an insufficient response. People want to know how safe they are and whether the environment is protected as a result of what government is doing.

Industrial facilities and service operations cannot simply outsource or offshore their environmentally damaging operations and expect that they have satisfied their environmental obligations, nor can they expect that mere compliance with a limited set of environmental standards will be sufficient to satisfy their customers' and stakeholders' expectations or demands. Both government and facility owners must recognize that members of the public want more information about environmental conditions and the opportunity to participate meaningfully in environmental decisions.

A new system of governance that includes tools other than mandatory regulations will be complex and more difficult to manage. Government "controls" much of the regulatory system but often only has the ability to influence economic and values-based environmental behavioral drivers upon which many of the new approaches rely. Thus, any new system of environmental governance will require new societal arrangements. In some cases, government will still set the standards and the rules of behavior. In other cases, new forms of stakeholder consultation will be needed where government, citizens, businesses, and NGOs work together to achieve agreed-upon environmental goals. In still other cases, companies will establish their own environmental standards driven by economic factors including cost savings and the opportunity to differentiate their products, as well as by reputation, customer demand, insurance availability, investor decisions, and other factors like corporate values. Governments' role in this area may simply be to recognize these economic forces driving corporate behavior and to not intervene in a way that would limit these forces. Or, government may be in a

position to encourage corporate “beyond compliance” behavior through incentives or by providing information to the public.

In some cases, communities will drive environmental behavior through forces such as customer demands, investment decisions, and educational campaigns. Governments’ role in these circumstances may be to provide information supporting community-based activities or to provide wider community access to government processes.

In yet other cases, NGOs will drive company behavior through negotiations, threats of public protests, or shareholder actions. Government may be able to facilitate NGO action through participation in collaborative efforts and by providing information, including scientific data. All of these possibilities surface in the context of managing nanotechnologies.

#### IV.

##### NANOTECHNOLOGY GOVERNANCE

Given the speed at which technology is developing, the imprecise fit of existing regulatory systems in dealing with nanoscale materials, the inherent limitations of regulatory systems, the global competitiveness in the nanotechnology marketplace and the unique and complex risk benefit equation for nanotechnologies, it seems clear that the regulatory system cannot and should not be relied upon, *by itself*, to manage the environmental and public health consequences of nanotechnology. Rather, regulation must be part of a broader system of governance approaches. The following section discusses the elements that should be considered in building an integrated governance system.

##### A. *Government Regulation*

Government regulation must be part of the nanotechnology governance system both to assure the environment and public health is protected and to build and maintain public confidence in the industry. Several environmental statutes, including the Federal Water Pollution Control Act,<sup>67</sup> the Clean Air Act,<sup>68</sup> the Toxic Substances Control Act,<sup>69</sup> the Federal Insecticide, Fungicide and Rodenticide Act,<sup>70</sup> the Comprehensive Environmental

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67. Federal Water Pollution Control Act, 33 U.S.C. §§ 1251-1387 (2006).

68. Clean Air Act, 42 U.S.C. §§ 7401-7671q (2006).

69. Toxic Substances Control Act, 15 U.S.C. §§ 2601-2692 (2006).

70. Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136-136y (2006).

Response, Compensation, and Liability Act,<sup>71</sup> and the Resource Conservation and Recovery Act,<sup>72</sup> may apply to nanomaterials, although each of the statutes has limitations in this context. Further, the limited ability to detect and monitor many nanoscale materials complicates the use of existing regulatory programs. And, given the pace at which the industry is evolving, reliance on traditional permitting approaches, which may take months or even years to complete for a new industrial process, could adversely affect competitiveness in the context of a rapidly developing global market and therefore may be strongly resisted.

In a recent book on nanotechnology law and policy published by the American Bar Association, Lynn Bergeson observed that the in-depth analysis of existing environmental statutes undertaken by members of the Section on Environment, Energy, and Resources pose “major challenges for environmental regulators and policymakers.”<sup>73</sup> An analysis by the Environmental Law Institute indicates that existing environmental statutes are useful, but imprecise, mechanisms for dealing with various aspects of several nanotechnologies.<sup>74</sup> Given the imprecise fit of existing regulatory programs in the context of nanotechnologies and the rapid changes within the industry, the role of regulation in managing the environmental and health impacts of nanotechnologies is likely to evolve over time.<sup>75</sup>

EPA and other federal agencies should continue examining their programs as new nanotechnologies come to the market and apply those programs to the production, use and disposal of nanomaterials as appropriate under existing legislative authority. However, because of the lack of information on the environmental and health effects of many nanotechnologies, federal agencies should begin to build a more adaptive regulatory process for nanotechnologies.

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71. Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. §§ 9601-9675 (2006).

72. Resource Conservation and Recovery Act, 42 U.S.C. §§ 6901-6992k (2006).

73. Lynn L. Bergeson, *Introduction*, in *NANOTECHNOLOGY: ENVIRONMENTAL LAW, POLICY, AND BUSINESS CONSIDERATIONS* 1, 1 (Lynn L. Bergeson, ed., 2009).

74. See Linda K. Breggin & Leslie Carothers, *Governing Uncertainty: The Nanotechnology Environmental, Health, and Safety Challenge*, 31 *COLUM. J. ENVTL. L.* 285, 311-312 (2006).

75. Glenn Harlan Reynolds, *Environmental Regulation of Nanotechnology: Some Preliminary Observations*, 31 *ENVTL. L. REP.* 10681, 10685 (2001).

### 1. Adaptive Regulations

Governments lack the information they need to make decisions for continued development of many important new technologies while minimizing the likely risks of these technologies. This situation is in some ways analogous to environmental management involving complex ecosystems. Here, too, government often does not have the knowledge base to accurately predict the outcome of regulatory interventions. In the ecosystem management context, a new approach to environmental governance emerged in the 1990s known as "adaptive management." Adaptive management is described in the Millennium Ecosystem Assessment as "[a] systematic process for continually improving management policies and practices by learning from the outcomes of previously employed policies and practices. In active adaptive management, management is treated as a deliberate experiment for purposes of learning."<sup>76</sup>

An adaptive management approach has been suggested as one method of overcoming the lack of information of many nanotechnologies without either halting technology development or risking the introduction of technologies that may have adverse environmental or health impacts: "[N]anoregulation must be regarded as a dynamic affair which must adapt to the evolution of scientific knowledge and applications and public attitude. A continuous updating must be part of the governance of nanotechnology."<sup>77</sup>

This is not a simple process for governments. Governing the development and introduction of nanotechnologies in the marketplace, like many complex environmental and health issues today, are what Don Kettl describes as "non-routine" problems.<sup>78</sup> Traditional bureaucracies are good at managing routine problems such as issuing air or water pollution permits for large industrial facilities, but hierarchical structures are far less adept at dealing with non-routine problems.<sup>79</sup> Instead, non-routine problems require "nimble organizations that can quickly adapt," "solutions based on communications and information," "different patterns of coordination for different problems," and "non-

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76. MILLENNIUM ECOSYSTEM ASSESSMENT, ECOSYSTEMS AND HUMAN WELL-BEING: POLICY RESPONSES 599 (2005), available at <http://www.millenniumassessment.org/documents/document.776.aspx.pdf>.

77. MANTOVANI ET AL., *supra* note 13, at 8.

78. KETTL, *supra* note 7, at 20.

79. *Id.* at 19-21.

routine solutions” produced by “innovative problem solvers driven by information.”<sup>80</sup> Instead of hierarchy, solving non-routine problems require heterarchy—“pluralistic structures that rely heavily on the initiative of their members, who seek to learn quickly and effectively about how to best handle uncertain futures.”<sup>81</sup> In the case of nanotechnologies, regulators are part of the heterarchy, but so are NGOs, businesses, researchers and many others. Adaptive regulation will require early and regular engagement of all of these parties if the process is to succeed, an approach that government has not often used.

Further, most regulatory programs are premised on the development of uniform rules that often remain in place for many years. The administrative and public consultation procedures associated with rulemaking create an inherently slow process. In the case of a fast moving nanotechnology industry, new approaches to regulation likely will be needed. In order to maintain trust and speed up the adaptation process, these approaches will have to rely on close consultation among government officials, companies and the stakeholders affected by particular technologies. Adaptive changes in regulation will have to be monitored, again through some form of stakeholder process, to assess the effectiveness of the regulatory approach and to adjust the process should it not be effective in dealing with the identified risks or if new information becomes available.

## 2. Information Requirements

The information needed to make adaptive regulatory decisions for most nanotechnologies is not readily available. Many companies do not have detailed environmental and health effects data for the nanomaterials with which they are working. Information disclosures under the existing regulatory programs, both mandatory and voluntary, as they apply to nanomaterials, have been limited. Further, companies may avoid disclosure by producing nanomaterials in quantities below thresholds requiring disclosure. For example, even the advanced toxics information disclosure system under the European Union’s Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) directive requires information disclosure only for

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80. *Id.* at 20.

81. *Id.* at 20-21.

chemicals produced above a one ton threshold.<sup>82</sup> Early in 2009, press reports indicated that Canada was planning to close this gap through a mandatory reporting system that would require companies and institutions that manufacture or import more than 1kg of nanomaterials to submit all of the information they have on the physical and chemical properties, toxicological data, and manufacturing methods and uses of the materials.<sup>83</sup> However, to date, the regulations have not been released.

The United Kingdom and the United States have experimented with voluntary nanotechnology reporting systems, but these approaches have met with only limited success. The United Kingdom launched its Voluntary Reporting Scheme in 2006 to gather information on health, environmental and safety issues and to help the government develop appropriate regulations for nanomaterials. At the time the program concluded in September 2008, the government had received submissions from only nine industries and two universities.<sup>84</sup>

EPA's Nanoscale Materials Stewardship Program began in January 2008 with the objective of assembling existing data from manufacturers and processors of nanoscale materials and encouraging the use of risk management practices in developing nanoscale materials. The Stewardship Program also seeks to promote the development of test data and supporting responsible development of nanomaterials.<sup>85</sup> The Stewardship Program includes a basic and an in-depth program. Under the basic program, EPA asks organizations to submit information and data on nanomaterials, such as physical and chemical properties, hazards, exposure, use and risk. The in-depth program focuses on collaborations for the development of risk assessment data on specific nanomaterials. As of September 2008, twenty-two organizations working with ninety-three nanomaterials had submitted information to EPA under the basic program.<sup>86</sup> Only four companies have agreed to participate in the in-depth program, however.<sup>87</sup>

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82. Council Regulation 1907/2006, Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), 2006 O.J. (L 396) (EC), available at <http://eur-lex.europa.eu/LexUriServ/LexUriSer.do?uri=OJ:L:2006:396:0001:0849:EN:PDF>.

83. See Victoria Gill, *Nano-Regulation Creeps Closer*, ROYAL SOCIETY OF CHEMISTRY, Feb. 25, 2009, <http://www.rsc.org/chemistryworld/news/2009/february/25020901.asp>.

84. MANTOVANI ET AL., *supra* note 13, at 90.

85. See U.S. EPA, Nanoscale Materials Stewardship Program, <http://www.epa.gov/oppt/nano/stewardship.htm> (last visited Oct. 1, 2009).

86. MANTOVANI ET AL., *supra* note 13, at 91.

87. See Gill, *supra* note 83.

Although these voluntary programs are producing some additional information, it does not appear that they will provide for more elaborate information regulation. A recent study of voluntary programs related to nanotechnologies found that relying *solely* on 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,”<sup>88</sup> but a voluntary program that becomes mandatory after a period of no more than three years “would allow companies to adapt and develop methodologies for generating health and safety information with increasing information exchange with regulators.”<sup>89</sup>

An effective nanotechnology regulatory system must generate more information on the risks associated with the technologies. This may require an information collection system such as REACH but with a lower threshold, such as one kilogram for some nanomaterials, that triggers compliance requirements, perhaps phased in after a two or three year long voluntary reporting period. Information obtained through a more robust information collection process can then serve as the basis for adaptive decisionmaking. To be successful, an adaptive management approach will require new modes of stakeholder engagement that will allow stakeholders and organizations to become as informed about environmental and public health issues as government agencies in order to respond quickly to new risks.

## B. *Public Engagement*

### 1. A National Nanotechnology Governance Dialogue

Engaging the public, both through representational stakeholder organizations and the general public, in the oversight of nanotechnologies is central to effective nanotechnology governance. The Framing Nano report prepared for the European Union points out

Public involvement, or participation, has a twofold purpose:

- Increase public awareness on a technology supporting the building of opinions and positions based more on facts than on

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88. Steffen Foss Hansen & Joel A. Tickner, *The Challenges of Adopting Voluntary Health, Safety and Environment Measures for Manufactured Nanomaterials: Lessons from the Past for More Effective Adoption in the Future*, 4 NANOTECHNOLOGY L. & BUS. 341, 359 (2007).

89. *Id.*

speculative claims. Helping to distinguish between perceived and real risks;

- Increase the level of interface and confidence among those developing and regulating nanotechnology and the public (citizens and consumers using nanotechnology). This is pivotal to help defining proper, acceptable, trade-offs of risks and benefits of nanotechnology.

In the words of the European Group on Ethics in Science and New Technologies (EGE): "*Public participation is of vital concern in democratic states.[. . .]This raises wider issues of trust and confidence building between the scientific community and the public, including the need to promote proper debate (in particular on uncertainties), and ultimately leads to issues of deliberative democracy, including questions about who draws the lines between what is allowed, acceptable, and what is not; and who overviews those who draw the lines.*"<sup>90</sup>

Public involvement related to nanotechnology is needed at several levels to assure public confidence—in setting research priorities, in identifying risk management approaches, and in keeping the public informed.

Public dialogue should play a central role in creating the nanotechnology governance framework and overseeing the implementation of that framework. The Royal Society and Royal Academy of Engineering issued a call for public dialogue and debate on nanotechnology issues in its groundbreaking 2004 study of the industry:

The general case for wider societal dialogue about novel technologies, and with it greater openness about science policy, rests upon three broad sets of argument . . . The normative argument proposes that dialogue is a good thing in and of itself and as such forms a part of the wider democratic processes through which controversial decisions are made . . . The instrumental argument suggests that dialogue, as one means of rendering decision-making more open and transparent, will increase the legitimacy of decisions and through this generate secondary effects such as greater trust in the policy-making process . . . Finally, the substantive argument is that dialogue will help to generate better quality outcomes. In the field of environmental risk, non-technical assessments and knowledge have been shown to provide useful commentary on the validity or otherwise of the assumption made in expert assessments.<sup>91</sup>

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90. MANTOVANI ET AL., *supra* note 13, at 38 (emphasis in original).

91. THE ROYAL SOC'Y & THE ROYAL ACAD. OF ENGINEERING, NANOSCIENCE AND NANOTECHNOLOGIES: OPPORTUNITIES AND UNCERTAINTIES 63 (2004).

The Royal Society noted that with many mature technologies public dialogue has often arrived “too little too late” to be effective.<sup>92</sup> With nanotechnology there is still a unique, but unfortunately narrowing opportunity to avoid the problem of too little, too late.

A workshop convened by the Agrifood Nanotechnology Project observed that of the “many lessons learned [about the controversy surrounding biotechnologies], perhaps the greatest consensus centered on the perceived failure to engage diverse stakeholders and other potentially affected groups in a dialogue as standards for agricultural biotechnologies were being promulgated.”<sup>93</sup> The IRGC has also suggested a stakeholder-based dialogue,<sup>94</sup> and the Natural Resources Defense Council and Environmental Defense have called upon both government and industry to do a better job of “engaging the broad array of stakeholders outside government and industry—labor, health organizations, consumer advocates and environmental NGOs—whose constituencies stand to be both beneficiaries of this new technology and those most likely to bear any risks that arise.”<sup>95</sup>

There are a number of models that could be used in designing an ongoing, stakeholder-based dialogue on nanotechnology governance including:

- EPA’s National Advisory Council for Environmental Policy and Technology that, since 1988, has advised the Agency on a range of policy, technology and management issues.<sup>96</sup>
- EPA’s National Environmental Justice Advisory Committee created in 1993 to bring together representatives of community, academia, industry, environmental, indigenous, as well as state, local, and tribal government groups “to create a dialogue that can define and ‘reinvent’ solutions to environmental justice problems.”<sup>97</sup>

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92. *Id.* at 64.

93. INSTITUTE FOR FOOD AND AGRICULTURAL STANDARDS, AN ISSUES LANDSCAPE FOR NANOTECHNOLOGY STANDARDS: REPORT OF A WORKSHOP 6 (2007), available at <http://ifas.msu.edu/NSWorkshopReport.pdf>.

94. INTERNATIONAL RISK GOVERNANCE COUNCIL, *supra* note 10, at 18-19.

95. ENVIRONMENTAL DEFENSE, GETTING NANOTECHNOLOGY RIGHT THE FIRST TIME 4 (July 7, 2005), available at [www.edf.org/documents/4533\\_EDnanopersp.pdf](http://www.edf.org/documents/4533_EDnanopersp.pdf).

96. See National Advisory Council for Environmental Policy and Technology, Cooperative Environmental Management, <http://www.epa.gov/ocem/naccept> (last visited Oct. 1, 2009).

97. See National Advisory Council for Environmental Policy and Technology, Environmental Justice, <http://www.epa.gov/environmentaljustice/nejac/index.html> (last visited Oct. 1, 2009).

- The U.S. Climate Action Partnership, an extended collaboration among major businesses and leading environmental organizations that has developed a comprehensive proposal for strong national climate legislation.<sup>98</sup>
- President Clinton's Council on Sustainable Development multi-year, multi-stakeholder dialogue designed to create policies to support sustainable development in the United States.<sup>99</sup>

Open, representative stakeholder processes are a proven approach to more inclusive models of governance. The National Nanotechnology Initiative, one of its member agencies, or a non-profit organization should convene a national nanotechnology governance dialogue as soon as possible to help develop an integrated nanotechnology governance strategy. Such a dialogue would facilitate the creation and use of adaptive management strategies and allow the integration of non-regulatory governance approaches that together could foster public confidence, help avoid high risk situations, and speed the development of technologies with high societal benefits.

## 2. Upstream Public Involvement

Recently, calls have increased for what is known as “upstream” public engagement in technology development, that is, engagement at the research and development stage. A report on communication outreach in nanotechnology observed that “*Generally speaking*, ‘direct dialogue with the public on science should move from being an optional add-on to science-based policy making and to the activities of research organisations and learned institutions, and should become a normal and integral part of the process,’”<sup>100</sup> Upstream public engagement does not involve the public telling scientists what to do. Rather, it should render scientific cultures

more self-aware of their own taken-for-granted expectations, visions, and imaginations of the ultimate ends of knowledge, and rendering these more articulated, and thus more socially accountable and resilient, is a radically different kind of role for the social

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98. See United States Climate Action Partnership, <http://www.us-cap.org> (last visited Oct. 1, 2009).

99. See President Clinton's Council on Sustainable Development, <http://clinton2.nara.gov/PCSD/> (last visited Oct. 1, 2009).

100. Working Paper Resulting from the Workshop on Strategy for Communication Outreach in Nanotechnology 10 (Matteo Bonazzi ed., 2007), [ftp://ftp.cordis.europa.eu/pub/nanotechnology/docs/nano\\_outreach\\_final.pdf](ftp://ftp.cordis.europa.eu/pub/nanotechnology/docs/nano_outreach_final.pdf) (citing Science & Society report, S&T House of Lords Committee, 2000 & 2002).

sciences. This, we argue, lies in science's own best interest, as it would provide the grounds for a public legitimacy that its patrons and exploiters are so anxiously seeking.<sup>101</sup>

The European Union's (EU) new recommended Code of Conduct for Responsible Nanosciences and Nanotechnologies Research provides

Governance of N&N research activities should be guided by the principles of openness to all stakeholders, transparency and respect for the legitimate right of access to information. It should allow the participation in decision-making processes of all stakeholders involved in or concerned by N&N research activities.<sup>102</sup>

The National Nanotechnology Initiative (NNI) has given some consideration to the idea of stakeholder dialogue related to its research program. "Goal 4" of the Initiative's Strategic Plan focuses on supporting responsible development of nanotechnology:

Responsible development of nanotechnology also entails establishing channels of communication with relevant stakeholders, in terms of both providing information and seeking input. Such communications allows the public and the NNI agencies to make well-informed decisions and builds trust among all stakeholders. Implicit in this approach is the recognition that public acceptance of nanotechnology and its applications are necessary components of successful commercialization.<sup>103</sup>

NNI should put this goal into operation and follow the lead of the EU Code of Conduct by creating an ongoing stakeholder dialogue that works with the NNI agencies to establish priorities for research and helps address the environmental, legal, and social issues associated with nanotechnology research and development.

### 3. Engaging Citizens

Dialogue engages surrogates for the general public, but it is also important to find ways to directly engage the interested public. Public education is an important element of a new public dialogue on nanotechnology. Education in this context cannot simply be a one-way effort to convince the public that na-

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101. Phil Macnaghten, Matthew B. Kearnes & Brian Wynne, *Nanotechnology, Governance, and Public Deliberation: What Role for the Social Sciences?*, 27 SCI. COMM. 268, 278 (2005).

102. *Commission Recommendation on a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research*, at 6, COM (2008) 424 final (July 2, 2008).

103. THE NATIONAL NANOTECHNOLOGY INITIATIVE, STRATEGIC PLAN 19 (2007), available at [http://www.nano.gov/NNI\\_Strategic\\_Plan\\_2007.pdf](http://www.nano.gov/NNI_Strategic_Plan_2007.pdf).

nanotechnology has important societal benefits and is safe. Instead, the education process must be part of the dialogue, requiring "innovative approaches to information provision, ones that involve a genuine two-way engagement between scientists, stakeholders and the public."<sup>104</sup>

The Project on Emerging Nanotechnologies at the Woodrow Wilson International Center for Scholars<sup>105</sup> is an excellent source of information on nanotechnologies, but its reach is limited. Educational tools like the Museum of Science, Boston's six DVD<sup>106</sup> set on nanotechnology can also help inform the public on the nature of nanotechnologies and its benefits and risks. However, as the data cited earlier on public awareness of nanotechnologies indicate, much more needs to be done to provide the level of information that will support an informed discussion on nanotechnologies.

Effective use of the Internet offers intriguing possibilities for a new form of two-way dialogue with the broader public. Such a dialogue could start with a web site that regularly posts the best and most credible information on the developments in nanotechnology. This could include up-to-date information on both the risks and benefits of nanotechnologies, information about developments in government regulations, and information about industry standards and self-regulation approaches. The broader public could use the site to comment on proposed regulations or on issues that could be addressed by members of the industry.<sup>107</sup>

Credibility and responsiveness are key issues for this idea to succeed. A government-managed site is one option, but given the role governments are playing in supporting nanotechnology development and the skepticism among many about government, this may not be the best option. Other options include a non-profit organization with experience in nanotechnology such as the Project on Emerging Technologies, or a combination of well-

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104. THE ROYAL SOC'Y & THE ROYAL ACAD. OF ENGINEERING, *supra* note 91, at 66.

105. See The Project on Emerging Nanotechnologies, <http://www.nanotechproject.org> (last visited Oct. 1, 2009).

106. See The Project on Emerging Nanotechnologies, Nanotechnology and the Consumer, [http://www.nanotechproject.org/news/archive/talking\\_nano](http://www.nanotechproject.org/news/archive/talking_nano) (last visited Apr. 13, 2010).

107. AMERICAN BAR ASS'N SEC. ON ENV'T, ENERGY & RESOURCES., EMS/INNOVATIVE REGULATORY APPROACHES 16 (2006), <http://www.abanet.org/environ/nanotech/pdf/EMS.pdf>.

regarded NGOs and broadly representative industry groups working together. One small-scale model of the latter type of arrangement can be found in the innovative website jointly maintained by the Minnesota Center for Environmental Advocacy (MCEA) and Flint Hills Resources, a large oil refiner, on which emissions data is available to the public. Members of the public have the opportunity to comment directly to both MCEA and Flint Hills about information found on the site.<sup>108</sup>

Engaging the public through representative stakeholder dialogues both on governance approaches and upstream on research priorities will be important in obtaining the consensus needed to create an integrated governance system for nanotechnology that relies on mechanisms other than traditional regulation. It will also be important in directing societal resources to research projects with the highest benefit and to minimizing risks from new technologies. But broader engagement of the general public is also critical to maintain public confidence in both the governance system and in understanding the risk/benefit trade-offs associated with new technologies.

### C. *Corporate Responsibility*

Corporate accountability or corporate social responsibility (CSR) has been a rapidly growing force in corporate governance over the last several years. McBarnet in *The New Corporate Accountability* observes “Typically, CSR policies involve a commitment by corporations, usually expressed in their statements of business principles or corporate-specific codes of conduct, to enhanced concern for the environment, human rights, fairness to suppliers and customers, and opposition to bribery and corruption.”<sup>109</sup> Since CSR is often seen as simply a voluntary activity that corporations undertake to build or protect their reputations, it is not an approach that can be depended upon to drive corporate behavior. Critics of CSR argue that if specific behavior is needed to protect the public, the behavior needs to be required

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108. See Flint Hill Resources and Minnesota Center for Environmental Advocacy, Environmental Reporting Made Easy, <http://www.fhrpinebend.com/> (last visited Apr. 13, 2010).

109. Doreen McBarnet, *Corporate Social Responsibility Beyond law, Through Law, for Law: The New Corporate Accountability*, in *THE NEW CORPORATE ACCOUNTABILITY: CORPORATE SOCIAL RESPONSIBILITY AND THE LAW* 10 (Doreen McBarnet, Aurora Voiculescu & Tom Campbell eds., 2007).

by statute or regulation rather than as part of a corporate commitment to social responsibility.<sup>110</sup>

These arguments ignore two important factors, however: the limits of what can be accomplished by regulation or statute, and developments that increasingly make CSR more than unenforceable volunteerism. While the regulatory system is critically important and will need to play a larger role in the management of nanotechnologies over the next few years, it is constrained. These limitations include the absence of international legal regimes even though businesses are increasingly global, the ability of corporate interests to soften legal controls through lobbying efforts, limited enforcement resources or weak penalties, and the incentives for companies to narrow regulatory restraints through “creative” approaches to compliance.<sup>111</sup>

One of the most notorious examples of creative compliance has been “life extension projects” used by large industrial facilities in the United States to avoid the need to invest in expensive new pollution control equipment that would otherwise be required under the New Source Review provisions<sup>112</sup> of the Clean Air Act.<sup>113</sup> The Clean Air Act grandfathered many large existing air emission sources at the time of its passage allowing them to continue to operate without upgrading to state-of-the-art air pollution control technology. However, the Act required facilities to upgrade their pollution control equipment when a facility is modified. The expectation was that allowing upgrades to be deferred until a facility was being modified for other reasons would reduce the cost of pollution control upgrades. This was especially true of power plants that often are shut down for several weeks for modifications.

To avoid having to process permits for minor modifications, EPA interpreted the statutory requirement to exclude routine maintenance, repairs or modifications.<sup>114</sup> Companies and their lawyers pushed this narrow window wide open using a creative interpretation of the exception, frequently justifying significant changes in regulated facilities as simple life extension projects characterized as no more than routine maintenance, repair or

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110. *Id.* at 27-29.

111. *Id.* at 45-47.

112. See NAT'L ACAD. OF PUB. ADMIN., A BREATH OF FRESH AIR: REVIVING THE NEW SOURCE REVIEW PROGRAM 36-44 (2003).

113. 42 U.S.C. § 7411 (2006).

114. A BREATH OF FRESH AIR, *supra* note 112, at 36-44.

modification. This approach was facilitated by the fact that these facilities were under no obligation to report their “life extension” projects to EPA. The practice continued for several years until EPA launched an enforcement initiative aimed at examining whether life extension projects actually involved significant modifications. These reviews and a number of subsequent lawsuits changed the industry practice but only after years of excess emissions.

This is one of many circumstances that clearly demonstrate the limitations of an approach that relies solely on regulation and enforcement. As McBarnet noted, “changing the law can make creative compliance more difficult but it cannot eradicate it.”<sup>115</sup> “The result is that changes to the law alone cannot easily tackle creative compliance, because creative compliance is the product not just of the limits in the law but of a mind-set which seeks to exploit those limits, and, crucially, which sees this exploitation as perfectly legitimate.”<sup>116</sup> McBarnet suggests that actions taken voluntarily pursuant to an organization’s social responsibility program are less likely to be construed using a narrow “compliance” lens.

While this may be true, the public need not rely on the beneficence of the organization as the sole reason to carry out organizational commitments. Organizational commitments can be formally enforced through contracts with vendors and suppliers (supply chain requirements) and procurement requirements. The commitments may also establish a standard of care that courts could take into account in nuisance or tort litigation. They may also be a factor in false advertising litigation as was the case in *Kasky v. Nike, Inc.*<sup>117</sup> In *Kasky*, Nike had claimed that

workers who make Nike products are protected from physical and sexual abuse, that they are paid in accordance with applicable local laws and regulations governing wages and hours, that they are paid on average double the applicable local minimum wage, that they receive a ‘living wage,’ that they receive free meals and health care, and that their working conditions are in compliance with applicable local laws and regulations governing occupational health and safety.<sup>118</sup>

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115. McBarnet, *supra* note 109, at 48.

116. *Id.*

117. *Kasky v. Nike, Inc.*, 45 P.3d 243 (Cal. Sup. Ct. 2002) *aff’d* by 539 U.S. 654 (2003).

118. *Id.* at 248.

While a decision was not reached on the merits, the California Supreme Court did find that “when a corporation, to maintain and increase its sales and profits, makes public statements defending labor practices and working conditions at factories where its products are made, those public statements are commercial speech that may be regulated to prevent consumer deception.”<sup>119</sup> This decision indicates that, at least in some states, corporate responsibility statements could be enforceable under laws that prohibit false advertising or other types of false statements by companies.

Internal economics that drive organizations to adopt corporate social responsibility policies also have an impact on whether these policies have a real impact on an organization’s operations. These internal corporate economic drivers include reputation, customer desires, insurance availability, license to operate, investor preferences, lender concerns, SEC reporting requirements, government and public relations, access to markets, product differentiation, green procurement standards, international environmental standards such as ISO 14000, supply chain requirements, employee morale and recruiting, and operational efficiency. All of these factors have economic implications for companies that may be affected by environmental performance. While government does not control these economic motivators, it may be able to exercise some influence over them, and can certainly take them into account in designing governance systems and setting priorities.

As Marc Allen Eisner pointed out,

Future gains in environmental quality may be impossible without a fundamental reconsideration of regulatory design. This reconsideration must take the form of incorporating advances in corporate self-regulation, associational regulation, and standards into the regulatory system and thinking creatively about how public policies can be used to reinforce incentives or compensate for their absence.<sup>120</sup>

In short, “being more responsible may help corporations out compete rivals by staying ahead of tightening regulations, reducing usage of increasingly costly inputs, and attracting investment dollars from concerned consumers.”<sup>121</sup>

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119. *Id.* at 262.

120. MARC ALLEN EISNER, GOVERNING THE ENVIRONMENT: THE TRANSFORMATION OF ENVIRONMENTAL REGULATION 282 (2007).

121. *Id.* at 276.

A second factor in the evolution some companies have undergone is pressure from stakeholders, although the decision to implement environmental initiatives is ultimately linked to the bottom-line. The growing push from stakeholders has caused companies to consider building a reputation for corporate responsibility. In doing research for the book *Green to Gold*, Esty and Winston were surprised at how often executives said the reason for launching an environmental initiative was because it was the "right thing to do."<sup>122</sup> However, building a good reputation is not just the right thing to do, it is also a point of competitive advantage because "doing the right thing attracts the best people, enhances brand value, and builds trust with customers and other stakeholders."<sup>123</sup> Esty and Winston conclude: "The logic of corporate environmental stewardship need not stem from a personal belief that caring for the natural world is the right thing to do. If critical stakeholders believe the environment matters, then it's the right thing to do for your business."<sup>124</sup>

Perhaps the most important new set of stakeholders are banks and insurance companies, which may require environmental assessments for major loans and give lower lending rates to companies with carefully constructed environmental management plans.<sup>125</sup> Insurance companies, in particular, have closely watched the development of nanotechnologies to assess the risk they may present for existing or new policies.<sup>126</sup>

Community pressure is also important. In their research on the pulp and paper industry, Gunningham, Kagan, and Thornton found firms were motivated to go beyond compliance because of

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122. DANIEL C. ESTY & ANDREW S. WINSTON, *GREEN TO GOLD: HOW SMART COMPANIES USE ENVIRONMENTAL STRATEGY TO INNOVATE, CREATE VALUE, AND BUILD COMPETITIVE ADVANTAGE* 13-14 (2006).

123. *Id.* at 14.

124. *Id.*

125. *Id.* at 9, 11. See also Eric Assadourian, *The State of Corporate Responsibility and the Environment*, 18 *GEO. INT'L ENVTL L. REV.* 571, 575 (discussing the pressure banks and insurers put on companies to become more responsible and noting that Swiss Re alters its insurance rates based on a company's environmental impacts and associated risks).

126. See LLOYD'S EMERGING RISKS TEAM REPORT, *NANOTECHNOLOGY RECENT DEVELOPMENTS, RISKS AND OPPORTUNITIES* (2007), available at [http://www.nanet.nu/upload/centre/nanet/nyheder/lloydsemergingrisksteamreport\\_nanotechnology\\_report.pdf](http://www.nanet.nu/upload/centre/nanet/nyheder/lloydsemergingrisksteamreport_nanotechnology_report.pdf); HILARY SUTCLIFFE & SIMON HODGSON, *AN UNCERTAIN BUSINESS: THE TECHNICAL, SOCIAL AND COMMERCIAL CHALLENGES PRESENTED BY NANOTECHNOLOGY* (2006), available at [http://www.insightinvestment.com/global/documents/riliterature/367922/an\\_uncertain\\_business\\_report.pdf](http://www.insightinvestment.com/global/documents/riliterature/367922/an_uncertain_business_report.pdf).

pressures from the “social license.”<sup>127</sup> The social license can be enforced by enhancing or reducing of the firm’s reputation, by putting pressure on regulators to enforce existing regulations more vigilantly, by filing of citizen suits, by lobbying for tighter regulations, and by market pressures such as boycotts.<sup>128</sup> The authors found that pulp and paper mill firms were generally highly motivated to stay ahead of environmental regulations so that they could remain in the public’s good graces.<sup>129</sup>

The factors that motivate large firms to go beyond compliance may not, however, have the same impact on smaller businesses. David Williamson and Gary Lynch-Wood found that the social license does not inspire small firms to go beyond compliance because the main motivations of the social license, stakeholder pressure and reputation, do not affect them in the same way they affect large firms.<sup>130</sup> The authors identify five factors that influence a firm’s environmental behavior: (1) the environmental impact of the firm’s products and processes; (2) customer power; (3) customer interest; (4) corporate/brand visibility; and (5) community pressure.<sup>131</sup> They found that two or more factors must have a “high pull rating” before a firm would be motivated to go beyond compliance.<sup>132</sup> Thus, it is important for government, in looking at the factors that motivate corporate behavior, to be thoughtful about whether particular companies or particular industries are more or less likely to be motivated to perform beyond what the law requires.

In order to achieve optimum results with the limited resources available to them, government agencies must continue to develop their understanding of how these internal economic factors affect corporate environmental decisionmaking and use this understanding to design management systems and set priorities. McBarnet sums up the situation as follows:

Law is not just a tool of government, and government regulation is not the only way to try to control business through law. Civil society organisations too are increasingly deploying legal mechanisms to constrain business. What is more, they are deploying law to *en-*

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127. Neil Gunningham et al., *Social License and Environmental Protection: Why Businesses Go Beyond Compliance*, 29 *LAW & SOC. INQUIRY* 307, 339 (2004).

128. *Id.* at 319-20.

129. *Id.*

130. Gary Lynch-Wood & David Williamson, *The Social Licence as a Form of Regulation for Small and Medium Enterprises*, 34 *J.L. SOC’Y* 321, 339 (2007).

131. *Id.* at 331-32.

132. *Id.* at 332.

*force*, rather than just to encourage, commitments by business to ethics, human rights, and social and environmental responsibility. At the same time, governments are using the market through their procurement power, and facilitating market and NGO pressures with enhanced disclosure. Business organisations are not only adopting internal CSR policies but are themselves exercising legal and market control over other businesses, as well as lobbying and organising (especially when stung by NGO attention themselves) to raise industry standards on CSR and level the playing field. International organisations, both public and private, are setting standards. NGOs and businesses are working in partnership, with NGOs advising rather than criticising business.

What is emerging in the arena of CSR is a complex interaction between government, business and civil society, private law, state regulation and self-regulation, at national and international levels, with social, legal, ethical and market pressures all being brought to bear in ways that cut across traditional pigeon-holes, and which . . . interrelate with and foster each other.<sup>133</sup>

Commitments pursuant to corporate social responsibility programs should be considered as one element of a governance system for nanotechnologies. Government agencies and NGOs can encourage organizations to adopt corporate social responsibility policies recognizing both the value of self-motivated behavior and the enforceable or quasi-enforceable nature of CSR commitments. Organizations certainly can adopt CSR policies on their own recognizing the wide range of economic value that they may gain from the policies in addition to any ethical statement that the organization may wish to make through the policies. This is most easily done if the governance system is overseen by a multi-stakeholder group that can understand and appreciate the value of corporate commitments as part of the overall approach to governance.

#### D. *Codes of Conduct*

Codes of conduct and industry self-regulation have a similar, but typically narrower impact as CSR policies. In the absence of government regulation, codes can help build public confidence, reduce reputational risk, improve government and community relationships, and reduce the risk of private litigation. These codes and self-regulatory mechanisms are important governance

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133. McBarnèt, *supra* note 109, at 55-56.

tools, especially if the codes or self-regulatory mechanisms increase the amount of information available to the public.

Modern industry environmental codes trace their origin to the Coalition for Environmental Responsible Economies (CERES) and its CERES Principles adopted in response to the Exxon Valdez disaster.<sup>134</sup> The American Chemistry Council (ACC, then the Chemical Manufacturers Association) adopted its Responsible Care<sup>®</sup><sup>135</sup> program at least in part to deal with increasing public concern about the chemical industry growing out of the Bhopal disaster and disclosure of the role of discarded chemicals in groundwater contamination during the 1980s. Responsible Care is a mandatory program for all ACC members and is practiced in 53 national associations.<sup>136</sup> The German chemical industry has specifically committed to “sustainable and responsible” development of nanomaterial under the core principles of Responsible Care.<sup>137</sup>

Given the likely limitations on the government’s ability to respond to nanotechnology, codes of conduct and self-regulation are important to avoiding potential adverse impacts from nanotechnology and to building public confidence in the industry. Both the Natural Resources Defense Council and Environmental Defense have recognized the importance of corporate standards of care

Even under the most optimistic scenario, it appears unlikely that federal agencies will put into place adequate provisions for nanomaterials quickly enough to address the materials now entering or poised to enter the market. Out of enlightened self-interest, industry must take the lead in evaluating and managing nanomaterial risks for the near term, working with other stakeholders to quickly establish and implement life cycle-based “standards of care” for nanomaterials.

These standards should include a framework and a process by which to identify and manage nanomaterials’ risks across the product’s full life cycle, taking into account worker safety, manufacturing releases and wastes, product use, and product disposal . . . Such

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134. See Ceres, <http://www.ceres.org/Page.aspx?pid=416> (last visited Apr. 13, 2010).

135. See American Chemistry Council, *Responsible Care*, [http://www.americanchemistry.com/s\\_responsiblecare/sec.asp?CID=1298&DID=4841](http://www.americanchemistry.com/s_responsiblecare/sec.asp?CID=1298&DID=4841) (last visited Apr. 13, 2010).

136. *Id.*

137. See VCI, *Implementing Responsible Care® for a Responsible Production and Use of Nanomaterials*, <http://www.vci.de/default2~rub~0~tma~0~cmd~shd~docnr~122292~nd~.htm> (last visited Apr. 13, 2010).

standards should be developed and implemented in a transparent and accountable manner, including publicly disclosing the assumptions, processes, and results of risk identification and risk management systems.<sup>138</sup>

### E. *Liability*

Organizations that produce products containing nanomaterials will face the threat of legal liability under nuisance, negligence, or strict liability theories if exposure to nanomaterials causes harm to public health or the environment. The civil liability system plays a critical role in tempering corporate decisions to prematurely introduce potentially risky products into the market.

Companies can mitigate their liability exposure through a number of mechanisms that are part of the proposed environmental and public health governance structure.<sup>139</sup> Liability can be mitigated by a robust regulatory regime that encourages courts to view compliance with the regulatory scheme as establishing reasonable care on the part of the industry. This may be especially true of a transparent adaptive system that regularly gathers new information and adjusts the regulatory regime based on such new information. Courts, in these circumstances, may see the information generation and rule adjustment process as an indication that reasonable care is used in dealing with potential risks.

The risks of civil liability can also be minimized by increased transparency. The worst-case scenario for companies is demonstrated by the fate of the asbestos industry and, more recently, by litigation related to anti-inflammatory drugs. A key factor in both liability situations is that information about the adverse impact of asbestos and the drugs was available to the manufacturer but was not disclosed to the public or regulatory authorities. Prompt disclosure of information about adverse impacts of a product does not immunize a company from legal liability. However, it can reduce the potential of legal liability in several ways.

First, the prospect of disclosure can provide the impetus for a company to modify its product, withhold it from the market, or temporarily remove it from the market until the impact is better understood or the public is clearly warned. Second, disclosure

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138. John Balbus et al., *Getting Nanotechnology Right the First Time*, 21 ISSUES SCI. & TECH 70 (2005).

139. Mark Stallworthy, *Environmental Liability and the Impact of Statutory Authority*, 15 J. ENVTL. L. 3 (2003).

can prompt regulatory action including additional studies, product warnings, or market restrictions. Third, disclosure allows consumers to make more informed choices in the use of a product. Finally, wider stakeholder involvement with access to more complete information early in the approval process may raise issues or problems that could be resolved before a product reaches the market, thus avoiding potential mishaps.

The prospect of liability for harm to public health or the environment will be an important governance tool for the nanotechnology industry. Of equal importance is industry's opportunity to minimize that liability by employing mechanisms such as public reporting and early public involvement.

#### F. *Individual Decisionmaking*

Consumer decisions about nanotechnologies could play an important role in driving markets for nano products. For this to happen, consumers will need much more information on the benefits and the risks of nano-enhanced products. This paper has recommended that the federal government, either directly through the National Nanotechnology Initiative or through other organizations, should significantly expand both the information available to the public on nanotechnologies and the medium through which that information can be obtained. An alternative would be to increase the funding to a program as the Center for Emerging Technologies to expand its existing information base and information dissemination efforts to reach a much wider audience. Consumers would then be in a much better position to make an informed decision about whether to use nano-enhanced products and to support additional regulation of nanomaterials.

It may also be time to introduce a labeling program that allows consumers to determine whether nanoscale materials are contained in the products they buy and research the effects of the nanoscale materials. This labeling program should also direct consumers how to properly dispose of items containing potentially harmful nanoscale materials. Those who oppose mandatory labeling requirements argue that labeling can be expensive and can raise concern that labeled products are *per se* hazardous without conveying much useful information. Proponents of labeling assert that the public has a right to know about the materials in the products they buy, especially if there are unknown but potentially significant risks associated with such materials. Further, they assert that labeling is the only way con-

sumers can make informed choices about their purchases and informed decisions about disposing of the products.

The Royal Commission on Environmental Pollution concluded that labeling of products containing nanomaterials “is unlikely to provide useful information about the impacts on health or the environment.”<sup>140</sup> As a result, the Commission declined to recommend labeling for nanomaterials. This conclusion appears based on a narrow view of the value of labeling. Some labels, such as nutritional labels on food, do provide data on the package. Others provide less direct information but can still be valuable. For example, labels, such as the Forest Stewardship Council’s seal, simply indicate a product meets a detailed set of standards that can be found on the FSC website. Similarly, the “organic” food label provides a quick reference to a set of standards for what constitutes organically grown food. Other labels such as those that accompany hazardous materials use only key words such as “flammable” or “combustible” accompanied by a number that allows first responders to quickly look up the nature of the hazard associated with a leak or spill.

Labeling in the context of nanotechnologies could be limited to certain types of products such as those that will be applied to the skin, those that might come in contact with food, and those that may pose a health issue if disposed of in an improper manner. Labels could be as simple as “contains nanoscale zinc oxide,” or contains “carbon nanotubes.” These labels would allow curious customers to further research the particular material involved and make a more informed purchasing, use or disposal decision. This approach seems especially important in light of the lack of information about health and environmental impacts of nanoscale materials. The fact that a number of products are currently touted based on the use of nanomaterials indicates that nanolabeling would not necessarily deter consumers from buying a labeled product. Labeling would, however, allow consumers to take some responsibility for the purchase, use and disposal of at least some types of nano-based products. Again, a multi-stakeholder dialogue would be a good forum to initially raise the question of the role of labeling in nanotechnology governance.

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140. ROYAL COMMISSION ON ENVIRONMENTAL POLLUTION, *supra* note 5, at 19.

V.  
CONCLUSION

The evolving nature of nanotechnologies, the speed at which new nanoproducts are being introduced in to the marketplace, the internationally competitive nature of the sector, the lack of knowledge about the environmental and health impacts of many nanomaterials, the potentially high societal benefits of many of the technologies and the growing evidence of risk from exposure to at least some nanomaterials all indicate that nanotechnology governance needs much more attention. It is clear not only from the fact that nanotechnology development is outpacing the ability of the regulatory system to respond, but also from the limitations of the traditional regulatory system in dealing with other difficult environmental and public health problems, that a more integrated system of governance is needed to effectively deal with nanotechnology. Such an integrated system will require organizations at all levels and individuals to take responsibility for their role in research, production, use and disposal of nanomaterials. It will also require a combination of new forms of government regulation, better information, new means of public engagement, voluntary programs that can produce early results and a bridge to new regulatory programs, understanding and leveraging of the role that corporate social responsibility can play in environmental and health governance, the introduction of codes of conduct and self-regulatory mechanisms, continued exposure to legal liability and providing the public with information and tools such as labels that allow them to make decisions related to the purchase, use and disposal of products that contain nanomaterials.

The first, and perhaps most important, step in this process is convening a national nanotechnology dialogue that will serve as the focal point for integrating these various approaches to nanotechnology governance so that the benefits of nanotechnologies can be realized without creating unacceptable environmental and public health risks.