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Size Matters: Regulating Nanotechnology

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SIZE MATTERS: REGULATING NANOTECHNOLOGY

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I. INTRODUCTION

For those of us susceptible to lunchroom accidents, "stain-defender" pants are nothing short of a modern miracle.[1] Indeed, one manufacturer proclaims of its spill-resistant fabric, "[c]omplications roll away like water off a duck's back . . . ."[2] Behind spill-resistant fabric and a growing number of innovative products is nanotechnology—the design, production, and application of structures and devices of a size of one hundred nanometers or less.[3] Spill-resistant pants are only the tip of the iceberg. Governments and private entities are pouring billions of dollars into nanotechnology research and development each year. According to its proponents, nanotechnology will revolutionize society's manufacturing processes and will have nearly boundless applications.

Scientists know very little, however, about the potential health and environmental effects of exposure to the engineered nanomaterials found in many new products. Nanomaterials are of interest to manufacturers precisely because their characteristics differ from those of conventional materials, and early studies indicate that many of these tiny particles have unique abilities to penetrate the body's defenses or to persist in the environment.[4] These characteristics suggest that nanomaterials may pose threats that conventional substances do not. The uncertainty and magnitude of the potential danger are sufficiently great that even the nanotechnology industry has called for far more research in this area.[5]

The public is largely unfamiliar with nanotechnology, despite its growing importance.[6] To the extent that the subject has received the attention of legal academia or the popular media, much of the focus has been on "molecular nanotechnology" ("MNT")—the potential use of self-assembly methods at the molecular level to manufacture materials.[7] Most current MNT

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[1] "Stain Defender" fabric is a registered trademark of the Dockers® line of clothing manufactured by Levi Strauss & Co. *See* Dockers, Innovations, http://www.us.dockers.com/lsco/dockers/feature/inno/d_inno_land.jsp?FOLDER%3C%3Efolder_id=2534374305317034&bmUID=1151692609035 (last visited Apr. 26, 2007) (on file with the Harvard Environmental Law Review).

[2] *See* Nano-Tex™, Resists Spills, http://www.nano-tex.com/products/resists_spills.html (last visited Apr. 26, 2007) (on file with the Harvard Environmental Law Review).

[3] A nanometer is about five times the diameter of an atom, or eighty thousand times smaller than the diameter of a human hair. *See* THE ROYAL SOC'Y & THE ROYAL ACAD. OF ENG'G, NANOSCIENCE AND NANOTECHNOLOGIES: OPPORTUNITIES AND UNCERTAINTIES 5 (2004) [hereinafter ROYAL SOC'Y], *available at* http://nanotec.org.uk/finalReport.htm.

[4] *See infra* Part II.B.

[5] *See* Robert F. Service, *Calls Rise for More Research on Toxicology of Nanomaterials*, 310 SCIENCE 1609, 1609 (2005).

[6] *See infra* note 296 and accompanying text.

[7] *See, e.g.*, RICHARD A. POSNER, CATASTROPHE: RISK AND RESPONSE 35-37 (2004); Glenn Harlan Reynolds, *Nanotechnology and Regulatory Policy: Three Futures*, 17 HARV. J.L. & TECH. 179 (2003); Jason Wejnert, *Regulatory Mechanisms for Molecular Nanotechnology*, 44 JURIMETRICS J. 323 (2004); Joel Rothstein Wolfson, *Social and Ethical Issues in Nanotechnology: Lessons from Biotechnology and Other High Technologies*, 22 BIOTECHNOLOGY L. REP. 376 (2003); Paul C. Lin-Easton, Note, *It's Time for Environmentalists To Think*

research is theoretical in nature,[8] however, and MNT "is probably decades away from even the most realizable applications."[9] Of more immediate concern are the potential risks posed by nanoscale science and engineering. This more rudimentary form of nanotechnology currently incorporates nanomaterials into an increasing number of consumer products. The policy papers and conferences that have turned to this issue generally advocate more research on the health, safety, and environmental risks that might be posed by nanomaterials.[10] Most commentators, however, suggest that existing health and environmental statutes are sufficient to address any potential risks.[11] Departing from the prevailing view, this Article concludes that such statutes are inadequate and that nanotechnology poses distinct and serious concerns that warrant legislation specific to the manufacture and use of nanomaterials. None of the existing statutes takes into account the vast uncertainty surrounding the potential adverse effects of nanotechnology, nor do any such statutes equip the government with adequate tools to address this uncertainty. Accordingly, this Article proposes a legislative framework that would promote the development and dissemination of health and safety information pertaining to nanomaterials that are introduced into commerce. Moreover, to deal with nanomaterials' uncertain effects, the proposal incorporates a bonding mechanism that would require companies that introduce certain types of nanomaterials into commerce to post a bond that would cover potential damages caused by those materials.

Part II describes nanotechnology and its growing presence in the marketplace, and explains why the potential health and environmental consequences of exposure to nanomaterials are of serious concern. Part III reviews existing statutes that could be used to analyze and manage the potential risks posed by nanomaterials, and concludes that these statutes are too weak and cumbersome to provide an adequate response. Part IV answers the argument that any regulation specific to nanotechnology should await further research

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Small—Real Small: A Call for the Involvement of Environmental Lawyers in Developing Precautionary Policies for Molecular Nanotechnology, 14 GEO. INT'L ENVTL. L. REV. 107 (2001); MICHAEL CRICHTON, PREY (2002) (fictional account warning of dangers of out-of-control molecular nanotechnology ("MNT")).

[8] *See* Lin-Easton, *supra* note 7, at 111.

[9] Wejnert, *supra* note 7, at 329.

[10] *See, e.g.*, ENVTL. PROT. AGENCY ("EPA"), NANOTECHNOLOGY WHITE PAPER (2007) [hereinafter EPA WHITE PAPER], *available at* http://www.epa.gov/osa/pdfs/nanotech/epa-nanotechnology-white-paper-final-february-2007.pdf; ENVTL. LAW INST., SECURING THE PROMISE OF NANOTECHNOLOGY: IS U.S. ENVIRONMENTAL LAW UP TO THE JOB? (2005) [hereinafter ELI]; J. CLARENCE DAVIES, MANAGING THE EFFECTS OF NANOTECHNOLOGY (2006); CTR. FOR SCI., TECH. & PUB. POLICY, THE NANOTECHNOLOGY-BIOLOGY INTERFACE: EXPLORING MODELS FOR OVERSIGHT (Jennifer Kuzma ed., 2005), *available at* http://www.hhh.umn.edu/img/assets/9685/nanotech_jan06.pdf (workshop report).

[11] *See infra* note 389 and accompanying text; *see also* Peter J. Tomasco, Note, *Manufactured Nanomaterials: Avoiding TSCA and OSHA Violations for Potentially Hazardous Substances*, 33 B.C. ENVTL. AFF. L. REV. 205, 238 (2006) (suggesting that the nanomanufacturing industry may push for voluntary testing agreements under the Toxic Substances Control Act ("TSCA")).

into the effects of exposure to nanomaterials, and explains why current circumstances create a relatively favorable opportunity for health and safety legislation specific to nanotechnology. Finally, Part V proposes a statutory scheme that would impose notification and labeling requirements on all products containing nanomaterials. For products containing nanomaterials in a "free" form, which are expected to pose greater health and environmental risks, the proposal also includes a screening process, post-marketing monitoring, and a requirement that companies introducing such products into commerce post a bond to cover potential liabilities. The proposed scheme creates an incentive to perform much-needed research on the risks posed by nanomaterials, establishes funding to redress negative effects that research may reveal, and sets the stage for further public consideration of the future role of nanotechnology.

II. Background

A. The Promise of Nanotechnology

Nanotechnology is the science of manipulating matter at the nanometer scale.[12] Broadly speaking, nanotechnology includes both traditional "top-down" manufacturing methods, such as those used to manufacture nanoscale electronic components,[13] as well as "bottom-up" methods of building things on an atom-by-atom or molecule-by-molecule basis.[14] In light of the wide range of tools, techniques, and potential applications involved, the term "nanotechnologies" is increasingly used to refer to this burgeoning field.[15] The promise of nanotechnology is that its precise methods will serve as the basis of a manufacturing technology that is cleaner and more efficient than the relatively crude, top-down methods that dominate industrial processes today.[16] Materials produced via nanotechnology—nanomaterials—are manu-

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[12] *See* Royal Soc'y, *supra* note 3, at 5.

[13] Top-down processing involves etching or milling of a larger sample of material to obtain the nanoscale material in the desired configuration. *See* Karluss Thomas & Philip Sayre, *Research Strategies for Safety Evaluation of Nanomaterials, Part I: Evaluating the Human Health Implications of Exposure to Nanoscale Materials*, 87 Toxicological Sci. 316, 316 (2005).

[14] *See* Royal Soc'y, *supra* note 3, at 25-29; K. Eric Drexler, Engines of Creation 4-5 (1986) (contrasting nanotechnology with "bulk technology" as means of manufacturing goods); Francisco Castro, *Legal and Regulatory Concerns Facing Nanotechnology*, 4 Chi.-Kent J. Intell. Prop. 140, 141 (2004); Reynolds, *supra* note 7, at 181 (contrasting nanotechnology with traditional industrial technologies, which operate from the top down). There are three basic methods of bottom-up manufacturing: chemical synthesis; self-assembly, a process analogous to that resulting in the formation of snowflakes and salt crystals; and positional assembly, in which atoms or molecules are individually positioned. *See* Royal Soc'y, *supra* note 3, at 26-28.

[15] *See, e.g.*, Royal Soc'y, *supra* note 3, at 5; Ctr. for Sci., Tech. & Pub. Policy, *supra* note 10, at 38.

[16] *See* Barbara Karn, *Overview of Environmental Applications and Implications*, *in* Nanotechnology and the Environment 2, 3 (Barbara Karn et al. eds., 2005).

factured from conventional chemical substances. What makes these materials of particular interest is that they often behave very differently from the conventional materials from which they are derived.[17] The small size and high surface-area-to-mass ratio of nanosized particles enhance the mechanical, electrical, optical, catalytic, and/or biological activity of a substance.[18] These characteristics make nanomaterials potentially desirable as drug delivery devices, chemical catalysts, and various other purposes.[19]

Nanomaterials are already being used in medical diagnosis and treatment, cosmetics, sunscreens, stain-resistant clothing, paints and coatings, electronics, tires, tennis rackets, and foods.[20] The commercial potential of nanotechnology is tremendous, with some calling it the foundation for the "next industrial revolution."[21] Funding for nanotechnology research and development is estimated at three billion dollars per year in the United States and nine billion dollars per year worldwide.[22] The global market for na-

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[17] *See* ROYAL SOC'Y, *supra* note 3, at 5; Rick Weiss, *For Science, Nanotech Poses Big Unknowns*, WASH. POST, Feb. 1, 2004, at A1. There is a wide range of nanomaterials. One-dimensional nanomaterials include nanoscale films and surfaces, whose applications include fuel cells, stain-resistant fabrics, and self-cleaning windows. *See* ROYAL SOC'Y, *supra* note 3, at 8, 10-11. Two-dimensional nanomaterials include carbon nanotubes, which possess unusual mechanical strength and thus are potentially useful in composites; and nanowires, which have potential applications in high-density data storage. *See id.* at 8-9, 12. And three-dimensional nanomaterials include nanoparticles, used in sunscreens and cosmetics; fullerenes, sometimes described as "miniature ball-bearings" that may serve as lubricants; and quantum dots, which are nanoparticles of semiconductors used in solar cells and fluorescent biological labels. *See id.* at 9-10; *see also* EPA WHITE PAPER, *supra* note 10, at 7-10 (discussing different types of nanomaterials).

[18] *See* Günter Oberdörster et al., *Nanotoxicology: An Emerging Discipline Evolving from Studies of Ultrafine Particles*, 113 ENVTL. HEALTH PERSP. 823, 835 (2005). For instance, nanoscale materials may be stronger, possess different colors, or conduct electricity more readily than the gross materials from which they are derived. *See* ROYAL SOC'Y, *supra* note 3, at 7-10.

[19] *See* Oberdörster et al., *supra* note 18, at 824.

[20] *See* ORGANISATION FOR ECONOMIC CO-OPERATION & DEVELOPMENT ("OECD"), REPORT OF THE OECD WORKSHOP ON THE SAFETY OF MANUFACTURED NANOMATERIALS 105 (2005) (listing products containing nanoscale materials available in the United States); DOUGLAS MULHALL, OUR MOLECULAR FUTURE 61-73 (2002) (discussing potential applications of nanotechnology); Oberdörster et al., s*upra* note 18, at 824-25, 836; Barnaby J. Feder, *Engineering Food at Level of Molecules*, N.Y. TIMES, Oct. 10, 2006, at C1 (describing first generation of nanotechnology-based food products now entering the market); Charles Piller, *Science's Tiny, Big Unknown*, L.A. TIMES, June 1, 2006, at A1 (reporting use of nanoparticles in weight-loss drink). Hundreds of nanotechnology products are currently on the market. *See* JANE MACOUBRIE, WOODROW WILSON CTR. FOR SCHOLARS, INFORMED PUBLIC PERCEPTIONS OF NANOTECHNOLOGY AND TRUST IN GOVERNMENT 1 (2005) ("[T]here are already over 500 products being sold that claim they are made with nanoscale or engineered nanomaterials."); Project on Emerging Technologies, A Nanotechnology Consumer Products Inventory, http://www.nanotechproject.org/index.php?id=44 (last visited Apr. 26, 2007) (on file with the Harvard Environmental Law Review) (listing at least two hundred nanotech products).

[21] Roger Allan, *Nanotechnology: Still Science Fiction or Finally Scientific?*, ELECTRONIC DESIGN, June 14, 2004, at 65; *see also* Weiss, *supra* note 17; K. Eric Drexler & Jason Wejnert, *Nanotechnology and Policy*, 45 JURIMETRICS J. 1, 9 (2004) (noting "broad economic, medical, environmental, and military implications" of nanotechnology).

[22] *See* PRESIDENT'S COUNCIL OF ADVISORS ON SCI. & TECH., THE NATIONAL NANOTECHNOLOGY INITIATIVE AT FIVE YEARS: ASSESSMENTS AND RECOMMENDATIONS OF THE NATIONAL NANOTECHNOLOGY ADVISORY PANEL 1 (2005), *available at* http://www.nano.gov/

notechnology products is currently estimated to be worth thirty-two billion dollars per year,[23] and within a decade, the market for such products is expected to top one trillion dollars in the United States alone.[24] Some observers expect nanotechnology to be more revolutionary than biotechnology or computer technology because of its potential to transform multiple sectors of the economy, ranging from energy to pharmaceuticals to manufacturing.[25] Nanotechnology applications may even benefit the environment through manufacturing processes that use less energy and generate less waste, use more efficient methods of cleaning up hazardous substances, and use more sophisticated sensors to monitor the environment.[26]

The term nanotechnology actually refers to several distinct classes of technology: nanoscale science and engineering, productive nanosystems, and replicators.[27] Nanoscale science and engineering researches the unique properties of nanomaterials—those materials at a size of one hundred nanometers or less.[28] Nanomaterials may be either fixed as integral features of larger objects (as electronic components, for instance), or used as free nanoparticles (in cosmetics or pharmaceuticals, for example).[29] Nanoscale science and engineering is the branch of nanotechnology that is now generating commercial applications,[30] and its potential risks involve the health and envi-

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FINAL_PCAST_NANO_REPORT.pdf. The federal government spends approximately one billion dollars annually on nanotechnology research and development. *See id.* at 1; 21st Century Nanotechnology Research and Development Act § 6, 15 U.S.C. § 7505 (2006) (allocating nearly $3.7 billion to nanotechnology research for 2005-2008).

[23] *See* Press Release, Lux Research, Nanotechnology in $32 Billion Worth of Products; Global Funding for Nanotech R&D Reaches $9.6 Billion (May 8, 2006), *available at* http://www.luxresearchinc.com/press/RELEASE_TNR4.pdf.

[24] *See* Rick Weiss, *Nanotechnology Precaution Is Urged: Minuscule Particles in Cosmetics May Pose Health Risk, British Scientists Say*, WASH. POST, July 30, 2004, at A2. A private research firm has projected that nanotechnology will be incorporated into $2.6 trillion's worth of products in the global marketplace by 2014. Susan R. Morrissey, *Nanotech's Safety Risks*, CHEMICAL & ENGINEERING NEWS, Dec. 5, 2005, at 46, 46-48.

[25] *See* ROYAL SOC'Y, *supra* note 3, at 7-23 (describing potential applications); Lin-Easton, *supra* note 7, at 118-19 & n.84.

[26] *See* Karn, *supra* note 16, at 5; *see, e.g.*, K.J. Klabunde et al., *Nanocrystalline Metal Oxides: A New Family of Mesoporous Inorganic Materials Useful for Destructive Adsorption of Environmental Toxins*, *in* NANOTECHNOLOGY AND THE ENVIRONMENT, *supra* note 16, at 272, 272 (identifying unique properties of nanomaterials that may make them particularly effective adsorbents and catalysts).

[27] NEIL JACOBSTEIN, FORESIGHT NANOTECH INST., FORESIGHT GUIDELINES FOR RESPONSIBLE NANOTECHNOLOGY DEVELOPMENT 2-4 (Draft Version 6, April 2006), http://www.foresight.org/guidelines/ForesightGuidelinesV6.pdf (on file with the Harvard Environmental Law Review).

[28] *Id.* at 2; ROYAL SOC'Y, *supra* note 3, at 5, 7.

[29] *See* SCIENTIFIC COMM. ON EMERGING & NEWLY IDENTIFIED HEALTH RISKS, EUROPEAN COMM'N, OPINION ON THE APPROPRIATENESS OF EXISTING METHODOLOGIES TO ASSESS THE POTENTIAL RISKS ASSOCIATED WITH ENGINEERED AND ADVENTITIOUS PRODUCTS OF NANOTECHNOLOGIES 10 (2005) [hereinafter SCENIHR].

[30] *See* JACOBSTEIN, *supra* note 27, at 2 (listing applications like pharmaceuticals, electronic memory and semiconductor devices, sensors, water purification devices, stronger fabrics and materials, security and military components, and antipollution devices).

ronmental consequences that may arise from nanomaterials' small size and unique properties.[31]

The second type of nanotechnology, productive nanosystems, seeks to produce programmable, molecular-scale systems that make other useful nanostructured materials and devices.[32] In contrast to the passive nanomaterials being developed by nanoscale science and engineering, productive nanosystems would themselves be used to build three-dimensional products in an efficient, bottom-up process.[33] Productive nanosystems are still in the early stages of development and are expected to take over a decade to develop into commercial applications.[34] Some fear, however, that the technology will enable the inexpensive manufacture of weapons, sensors, or other devices that could be used for harmful purposes[35] or that the technology will enable the production of vast quantities of environmentally destructive products.[36]

Finally, replicators, the most advanced form of nanotechnology—and the furthest from being realized—are devices that would contain a set of processing and fabrication mechanisms sufficient to replicate themselves.[37] Simply put, these nanomachines could reproduce themselves, and the instructions for their own construction, from relatively simple parts in a process akin to cell division.[38] One hypothesized danger of self-replication is that nanomachines might proliferate in an uncontrollable manner and ultimately consume the earth.[39] The term "gray goo" refers to the material resulting from such a scenario of self-replication run amok.[40]

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[31] *See id.* at 3.

[32] *See id.*

[33] *See id.* MNT refers specifically to the use of nanoscale mechanochemical fabrication methods, i.e., productive nanosystems and replicators. *See* Chris Phoenix & Eric Drexler, *Safe Exponential Manufacturing*, 15 NANOTECHNOLOGY 869, 870 (2004).

[34] *See* SCENIHR, *supra* note 29, at 3; EPA WHITE PAPER, *supra* note 10, at 12 (predicting use of nanotechnology to create guided assemblies within ten to fifteen years and molecule-by-molecule design and self-assembly capabilities after that).

[35] *See* JACOBSTEIN, *supra* note 27, at 4.

[36] *See* Phoenix & Drexler, *supra* note 33, at 871.

[37] *See* JACOBSTEIN, *supra* note 27, at 4. In the science fiction series *Stargate SG-1*, replicators are a race of self-replicating machines created using nanotechnology. These fictional replicators can absorb any superior technologies they encounter and are driven solely by their desire to create more of themselves. *See* Wikipedia, Replicator (Stargate), http://en.wikipedia.org (search for Replicator (Stargate)) (last visited Apr. 26, 2007) (on file with the Harvard Environmental Law Review).

[38] *See* POSNER, *supra* note 7, at 35-36; MARTIN REES, OUR FINAL HOUR: A SCIENTIST'S WARNING: HOW TERROR, ERROR, AND ENVIRONMENTAL DISASTER THREATENS HUMANKIND'S FUTURE IN THIS CENTURY—ON EARTH AND BEYOND 16-17 (2003) (describing nanotechnology assembly methods).

[39] *See* POSNER, *supra* note 7, at 35-36; REES, *supra* note 38, at 58 (describing as "conceivable—though still far from reality"—that nanomachines could be devised with self-assembly capability, with ultimate potential to consume all life); John Tierney, Editorial, *Homo Sapiens 2.0*, N.Y. TIMES, Sept. 27, 2005, at A25 (summarizing apocalyptic scenario resulting from out-of-control nanobots).

[40] *See* Phoenix & Drexler, *supra* note 33, at 870; DREXLER, *supra* note 14, at 172-73. The gray goo scenario is the subject of a Michael Crichton novel, *Prey*. *See* CRICHTON, *supra* note 7.

Like any significant new technology, nanotechnology offers the potential for tremendous benefits as well as risks. Some of these risks—the "gray goo" scenario, for instance—are remote and unlikely.[41] Others—in particular, the unknown effects of exposure to free manufactured nanoparticles—raise more significant concerns that confront us today.[42] It is these more immediate risks that are the focus of this article.

B. Health and Environmental Concerns

In a general sense, exposure to nanoparticles is not a new problem. Humankind has long been exposed to nanosized particles from natural sources such as forest fires and anthropogenic sources such as industrial pollution.[43] Many of these particles have a fairly short lifespan as nanoparticles because they tend to agglomerate or dissolve in water.[44] In addition, the human body has developed various mechanisms for filtering out or removing some of these particles.[45]

Only within the last twenty-five years, however, have scientists learned to manipulate nanosized particles to produce engineered nanomaterials.[46] In contrast to naturally occurring nanoparticles,[47] engineered nanomaterials tend to persist for longer periods as nanoparticles, thanks to special coatings designed to prevent agglomeration and to preserve the particles' unique properties.[48] As engineered nanomaterials come into wider use, the nature of exposure to nanomaterials will change, and the degree of exposure will in-

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[41] *See* SCENIHR, *supra* note 29, at 11 (deeming spontaneous formation of artificial living systems "highly improbable"); Phoenix & Drexler, *supra* note 33, at 870-71 (explaining that device capable of runaway replication is unlikely given difficulties of incorporating necessary characteristics of autonomous self-replication, mobility, and ability to process naturally occurring materials); Wejnert, *supra* note 7, at 329 ("MNT is probably decades away from even the most realizable applications."); Wolfson, *supra* note 7, at 382 ("[T]he risk of the inadvertent spread of nanotechnology is less of a concern in the near term because most [molecular] nanotechnology is in the early experimental or developmental stage.").

[42] *See* SCENIHR, *supra* note 29, at 6 ("The concerns that nanoparticles, nanotubes, and nanofibers raise constitute the most significant ones relating to nanotechnologies within the next 3-5 years."); Drexler & Wejnert, *supra* note 21, at 20 (contending that "the big issues—for law, according to the establishment today, center around the novel properties of nanoparticles," and not around self-replicating nanosystems).

[43] *See* ROYAL SOC'Y, *supra* note 3, at 35; SCENIHR, *supra* note 29, at 34 (estimating that air in a normal room contains ten to twenty thousand nanoparticles per cubic centimeter).

[44] *See* SWISS RE, NANOTECHNOLOGY: SMALL MATTERS, MANY UNKNOWNS 13 (2004), *available at* http://www.swissre.com/INTERNET/pwsfilpr.nsf/vwfilebyIDKEYLU/ULURSYNGET/$FILE/Publ04_Nanotech_en.pdf.

[45] *See* ROYAL SOC'Y, *supra* note 3, at 38 (summarizing human defenses against small particles in the lungs, skin, and digestive tract).

[46] *See* SCENIHR, *supra* note 29, at 7.

[47] Emissions of gases from volcanoes and from plants naturally lead to the formation of nanoparticles, and human activities, such as fossil fuel combustion, welding, smelting, and other industrial processes, can generate nanoparticles as well. *See* Andrew D. Maynard & Eileen D. Kuempel, *Airborne Nanostructured Particles and Occupational Health*, 7 J. NANOPARTICLE RES. 587, 588 (2005).

[48] *See* SWISS RE, *supra* note 44, at 13.

crease.[49] Free nanoparticles are of particular concern because they are most likely to enter the body, react with cells, and cause tissue damage.[50] Even embedded nanomaterials may be released as free particles as the products into which they are incorporated wear out.[51]

Intake of engineered nanomaterials is likely to occur through various routes, including inhalation, ingestion, absorption through the skin, and injection.[52] The nature of the hazard posed by exposure to engineered nanomaterials may differ from that caused by naturally occurring nanoparticles. Engineered nanoparticles may be better able to evade the body's defenses because of their size or protective coatings.[53] Moreover, the health and environmental risks that accompany exposure to engineered nanomaterials are not well understood. At present, research efforts in nanotoxicology are just beginning, and less than 4% of all current U.S. governmental research expenditures on nanotechnology are targeted at studying effects on human health and the environment.[54] Little information on the risks is currently known,[55] and the most rudimentary toxicological data is unlikely to be available for many years.[56] Making the question particularly difficult is the wide

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[49] *See* Oberdörster et al., *supra* note 18, at 823.

[50] *See* ROYAL SOC'Y, *supra* note 3, at 36, 79-80 ("Currently we see the health, safety and environmental hazards of nanotechnologies as being restricted to discrete manufactured nanoparticles and nanotubes in a free rather than embedded form."); Gunter Oberdörster et al., *Principles for Characterizing the Potential Human Health Effects from Exposure to Nanomaterials: Elements of a Screening Strategy*, 2 PARTICLE & FIBRE TOXICOLOGY § 5.0 (2005), http://www.particleandfibretoxicology.com/content/2/1/8 (on file with the Harvard Environmental Law Review) ("Nanomaterials that are most likely to present a health risk are nanoparticles, agglomerates of nanoparticles, and particles of nanostructured materials (where the nanostructure determines behavior).").

[51] *See* ROYAL SOC'Y, *supra* note 3, at 36*;* Rick Weiss, *Nanotech Is Booming Biggest in U.S., Report Says*, WASH. POST, Mar. 28, 2005, at A6 (quoting David Rejeski (a scientist with the Woodrow Wilson International Center for Scholars) on the need to study such risks).

[52] *See* Oberdörster et al., *supra* note 18, at 823.

[53] *See id.* at 829.

[54] Service, *supra* note 5, at 1609. Figures regarding the precise amount spent on studying the potential toxicity of nanomaterials are in some dispute, as those figures often include grants that support research into the use of nanotechnology to remediate pollution sites or address other environmental problems. *See* Robert F. Service, *Nanotechnology Grows Up*, 304 SCIENCE 1732, 1734 (2004).

[55] *See* ROYAL SOC'Y & SCI. COUNCIL OF JAPAN, REPORT OF A JOINT ROYAL SOCIETY-SCIENCE COUNCIL OF JAPAN WORKSHOP ON THE POTENTIAL HEALTH, ENVIRONMENTAL AND SOCIETAL IMPACTS OF NANOTECHNOLOGIES 5-6 (2005) [hereinafter SCI. COUNCIL], *available at* http://www.royalsoc.ac.uk/displaypagedoc.asp?id=17357; Andrew D. Maynard et al., *Safe Handling of Nanotechnology*, 444 NATURE 267, 267 (2006) (identifying "five grand challenges" for nanotechnology risk research); Oberdörster et al., *supra* note 18, at 824; Weiss, *supra* note 17 ("It will be years before the first studies of nanotechnology's health and environmental impacts come together into a body of evidence."); Rick Weiss, *EPA Backs Nanomaterial Safety Research*, WASH. POST, Nov. 12, 2004, at A23 (reporting EPA award of first significant federal grants to fund studies on the potential impacts of nanoparticles on the environment).

[56] *See, e.g.*, JAMES T. BARTIS & ERIC LANDREE, NANOMATERIALS IN THE WORKPLACE: POLICY AND PLANNING WORKSHOP ON OCCUPATIONAL SAFETY AND HEALTH 7 (2006) (observing that current studies focus primarily on acute toxicity and suggesting that studies of possible chronic toxic effects would require about ten years); NANOTECHNOLOGY RESEARCH PROGRAM,

variety of nanomaterials: there are many different types and sizes, and they possess unique characteristics and different surface coatings.[57] Because the surface coatings of nanoparticles appear critical to their penetration rate and distribution in the body, toxicity may vary greatly from one type of particle to the next.[58]

Notwithstanding the lack of firm health data specific to nanomaterials, there are reasons for serious concern. First, the same properties that make nanoparticles useful for certain products and processes—their small size, chemical composition, surface structure, solubility, shape, and aggregative tendencies—may also make them harmful when taken into the body.[59] The small size of nanoparticles, for instance, corresponds to a greater surface area for a given mass of material, and hence a greater number of reactive groups at the surface.[60] Surface reactive groups, scientists believe, play an important role in toxic reactions by generating reactive oxygen species that may damage DNA, proteins, and cell membranes.[61] Consistent with this theory, experimental results suggest that tissue injury from exposure to nanoparticles is correlated with surface area rather than mass.[62] Small size also enables some nanoparticles to move into and within the body in ways that bulkier materials made of the same chemical substance cannot. When inhaled, nanoparticles are deposited more efficiently and deeply into the respiratory tract and may evade defense mechanisms that trap larger particles.[63] Nanoparticles that come in contact with the skin, such as nanomaterials incorporated into sunscreens, may penetrate the epidermis when the skin is flexed or damaged, and then pass further into the body through the lymphatic system.[64] And unlike most contaminants, nanoparticles may

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NAT'L INST. FOR OCCUPATIONAL SAFETY AND HEALTH ("NIOSH"), STRATEGIC PLAN FOR NIOSH NANOTECHNOLOGY RESEARCH 25-26, 32, 51-53 (Draft, Sept. 28, 2005), *available at* http://www.cdc.gov/niosh/topics/nanotech/pdfs/NIOSH_Nanotech_Strategic_Plan.pdf (setting out projected timeframes and targets for conducting toxicology tests on representative materials and addressing critical occupational safety and health issues).

[57] Kristen M. Kulinowski & Vicki L. Colvin, *The Environmental Impact of Engineered Nanomaterials*, *in* NANOTECHNOLOGY AND THE ENVIRONMENT, *supra* note 16, at 21, 22.

[58] Peter H.M. Hoet et al., *Nanoparticles—Known and Unknown Health Risks*, 2 J. NANOBIOTECHNOLOGY 12 (2004). The importance of surface characteristics to toxicity may make it possible to design particular nanoparticles so as to reduce their toxicity. *See* Weiss, *supra* note 55.

[59] *See* ROYAL SOC'Y, *supra* note 3, at 41-42; Andre Nel et al., *Toxic Potential of Materials at the Nanolevel*, 311 SCIENCE 622, 622 (2006); Oberdörster et al., *supra* note 18, at 824; Weiss, *supra* note 17 (discussing studies reporting deaths and abnormalities after rats were exposed to nanoparticles).

[60] The ratio of surface area to total atoms or molecules increases exponentially with decreasing particle size. *See* Oberdörster et al., *supra* note 18, at 824.

[61] *See* Nel et al., *supra* note 59, at 622-23 & 626 tbl.2. High levels of reactive oxygen species in lung tissue, for example, trigger protective or injurious responses manifested as airway inflammation and interstitial fibrosis. *Id.* at 623.

[62] *See* SCENIHR, *supra* note 29, at 35.

[63] *See* Oberdörster et al., *supra* note 18, at 829, 837.

[64] *See* Nel et al., *supra* note 59, at 625; Oberdörster et al., *supra* note 18, at 834.

cross the blood-brain barrier and enter the central nervous system through neuronal pathways leading from the respiratory tract to the brain.[65]

Health and safety concerns arise not only because of the physical characteristics of engineered nanomaterials, but also because of what we know from studies of ambient ultrafine particles. Ambient ultrafine particles differ from engineered nanoparticles in that they tend to be heterogeneous in size and more chemically complex.[66] Often derived from combustion sources, these particles have been the subject of numerous studies. Scientists have found, for example, that exposure to mineral dust particles, which are the same size as engineered nanoparticles, induces pulmonary inflammation, oxidative injury, and other damage.[67] Exposure to such particles has also been associated with heart attacks and cardiac rhythmic disturbances.[68]

The limited studies that have been done on engineered nanoparticles are similarly troubling. *In vivo* and *in vitro* studies of cells exposed to engineered nanoparticles have found adverse effects such as structural damage and oxidative stress.[69] And consistent with what we know about nanoparticles, studies in lab animals suggest that nanoparticles can penetrate the body more readily and more deeply than larger particles.[70] One study, for example, examined the effects of exposing lung tissue in mice to carbon nanotubes—engineered nanoparticles known for their strength, flexibility, and ability to conduct electricity.[71] The study found that the nanotubes pro-

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[65] *See* Gunter Oberdörster, *Effects and Fate of Inhaled Ultrafine Particles*, *in* NANOTECHNOLOGY AND THE ENVIRONMENT, *supra* note 16, at 37, 54 (reporting that ultrafine particles have been found to circumvent the blood-brain barrier in non-human primates and rodents); Oberdörster et al., *supra* note 18, at 832-33, 835. In addition, the fact that nanoparticles are more biologically active—which in some instances makes them desirable tools for delivering drugs—also suggests a greater potential to induce inflammation and other stress responses within the body. *See* Chiu-Wing Lam et al., *Toxicity of Single-Wall Carbon Nanotubes in the Lungs of Mice Exposed by Intratracheal Instillation*, *in* NANOTECHNOLOGY AND THE ENVIRONMENT, *supra* note 16, at 60, 64-65 (suggesting that carbon nanotube particles are particularly difficult to clear from the lungs and may result in lung lesions); Oberdörster et al., *supra* note 18, at 824, 836-37.

[66] *See* Nel et al., *supra* note 59, at 624; Oberdörster et al., *supra* note 18, at 823. Consequently, it is uncertain to what extent the results of these studies can be extrapolated to engineered nanomaterials. Nel et al., *supra* note 59, at 624.

[67] *See* Maynard & Kuempel, *supra* note 47, at 592-93 (discussing epidemiology and pathology studies involving nanosized particles); Nel et al., *supra* note 59, at 622.

[68] Nel et al., *supra* note 59, at 625; Oberdörster et al., *supra* note 18, at 825 (summarizing studies).

[69] Oberdörster et al., *supra* note 50, § 3.0; Noreen Parks, *New Nano-Headache?*, SCIENCENOW DAILY NEWS, June 15, 2006, http://sciencenow.sciencemag.org/cgi/content/full/2006/615/1 (on file with the Harvard Environmental Law Review) (reporting that low concentrations of ultrafine titanium dioxide particles can produce harmful free radicals in mouse brain cells).

[70] *See* Oberdörster, *supra* note 65, at 37, 54 (summarizing the unique ability of airborne ultrafine particles to pass through epithelial layers and nerve tissue to reach central nervous system and various organs).

[71] *See* Lam et al., *supra* note 65, at 60-65. Carbon nanotubes are finding widespread application in the electronics, computer, and aerospace industries because of their electrical, mechanical, and thermal properties. *See id.* at 61.

duced greater inflammation and lesions in lung tissue than quartz dust,[72] which itself is a serious occupational health hazard in chronic inhalation exposures.[73] Overall, tests of engineered carbon nanostructures in animals have yielded mixed results, depending on such factors as the particular structure being tested, the dosage, and the species being exposed.[74] Inconsistent results point to the need for standardized tests to screen nanomaterials for adverse effects.[75]

Harmful effects from real-world exposures have been difficult to track. In the most widely reported incident thus far, a bathroom cleaning product called "Magic Nano" was pulled off the market in Germany when at least 110 people reported severe respiratory problems after use.[76] It is not clear whether the product, an aerosolized cleaning spray that had not caused problems when the chemical was offered in a pump bottle, actually contained nanomaterials.[77] Scientists working with nanomaterials have not reported ill effects following nanomaterials exposure,[78] and there apparently have been no worker fatalities or injuries related to occupational exposures to engineered nanomaterials.[79] Negative effects, however, may be cumulative and require long periods to manifest.[80] Moreover, because nanomaterials are not readily detectable and because manufacturers are not required to disclose the presence of nanomaterials, consumers are ill-equipped to trace problems to nanomaterials or to take self-protective measures.

The potential environmental impacts of exposure to nanomaterials are even less well-understood than the human health effects. Research on the effect of nanoparticles on microbes, for example, has focused on the potential use of nanotechnology to remove pollutants from the environment, rather

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[72] *See id.* at 62-65. The results of the study, however, are not easily extrapolated because the nanoparticles were injected directly into the trachea rather than inhaled. *See* ROYAL SOC'Y, *supra* note 3, at 43. Other studies have suggested the risks to be less serious. *See* D.B. Warheit et al., *Lung Toxicity Bioassay Study in Rats with Single-Wall Carbon Nanotubes*, *in* NANOTECHNOLOGY AND THE ENVIRONMENT, *supra* note 16, at 67. The United Kingdom's Royal Society and Royal Academy of Engineering have nevertheless recommended that nanotubes warrant "special toxicological attention" because of similarities to asbestos and other disease-causing fibers. ROYAL SOC'Y, *supra* note 3, at 43.

[73] See 29 C.F.R. § 1910.1000 Table Z-3 (Occupational Health and Safety Act ("OSH Act") regulation setting occupational exposure limits for quartz dust.)

[74] *See* Oberdörster et al., *supra* note 18, at 826-27.

[75] *See* Oberdörster et al., *supra* note 50, § 3.0.

[76] *See, e.g.*, Piller, *supra* note 20; Rick Weiss, *Nanotech Product Recalled in Germany*, WASH. POST, Apr. 6, 2006, at A2.

[77] Piller, *supra* note 20 (reporting that German regulators released tests showing Magic Nano contained no nanoparticles); Weiss, *supra* note 76. Although the precise cause of the symptoms has yet to be determined, the symptoms suffered are consistent with a mechanism in which tiny nanoparticles clog airways or trigger immune responses. *But see* Barnaby J. Feder, *Technology's Future: A Look at the Dark Side*, N.Y. TIMES, May 17, 2006, at G4 (reporting doubts that the product contained any nanoscale ingredients).

[78] *See* Mark R. Wiesner & Vicki L. Colvin, *Environmental Implications of Emerging Nanotechnologies*, *in* ENVIRONMENTALISM AND THE TECHNOLOGIES OF TOMORROW 41, 48-49 (Robert Olson & David Rejeski eds., 2005).

[79] *See* BARTIS & LANDREE, *supra* note 56, at 13.

[80] *See* Wiesner & Colvin, *supra* note 78, at 49.

than on the ecotoxicology of nanomaterials. Nevertheless, one study did find that largemouth bass exposed to carbon fullerenes, a type of nanoparticle, suffered brain damage.[81] There is also evidence that carbon fullerenes are deadly to microorganisms.[82] The most urgent areas for future research include the fate and transport of nanomaterials, the interactions of nanomaterials with other chemicals, and the persistence of nanomaterials in the environment.[83]

Nanotechnology companies, government agencies, and public interest groups recognize the urgent need for further research in nanotoxicology.[84] Over time, such research will reduce at least some of the uncertainty of health and environmental effects. At present, however, we know very little. Risk assessment of nanotechnology is simply not possible, and evidence suggestive of potential dangers falls short of establishing that exposure to nanoparticles is harmful.[85] The critical question concerns what to do in the meantime as scientists gather risk information.

III. Existing Regulatory Authority Is Inadequate

Despite the concerns discussed in the preceding Part, the manufacture and use of nanotechnology products are not specifically regulated. The 21st Century Nanotechnology Research and Development Act of 2003,[86] the only federal statute specifically focused on nanotechnology, aims only to develop and promote nanotechnology. There is no federal law specifically regulating the health and environmental effects of nanotechnology, nor are there any specific state laws in the area.[87] In the eyes of some manufacturers, this is as it should be. Their view is that nanomaterials should be regulated no differently from the conventional substances from which they are manufactured.[88] The general health and environmental statutes that may apply to nanotechnology include the Toxic Substances Control Act ("TSCA"), Clean Air Act ("CAA"), Clean Water Act ("CWA"), and Occupational Safety and

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[81] *See* Eva Oberdörster, *Manufactured Nanomaterials (Fullerenes, C_{60}) Induce Oxidative Stress in the Brain of Juvenile Largemouth Bass*, 112 Envtl. Health Persp. 1058, 1058-62 (2004).

[82] *See* Oberdörster et al., *supra* note 18, at 827.

[83] *See* Wiesner & Colvin, *supra* note 78, at 45 (listing "key questions" to be addressed).

[84] *See Environmental and Safety Impacts of Nanotechnology: What Research Is Needed: Hearing Before the H. Comm. on Sci. and Tech.*, 109th Cong. 7–8 (2005) [hereinafter *Rejeski Testimony*] (testimony of David Rejeski, Director, Project on Emerging Nanotechnologies, noting agreement on need for further research on toxicity, exposure, epidemiology, product life cycle analysis, and other subjects); Service, *supra* note 5, at 1609; Morrissey, *supra* note 24, at 46-47 (noting broad support for studies of risk of exposure to nanomaterials).

[85] *See* Oberdörster et al., *supra* note 18, at 835 ("The lack of toxicology data on engineered [nanoparticles] does not allow for adequate risk assessment.").

[86] 15 U.S.C. §§ 7501-7509 (2006).

[87] *See* ELI, *supra* note 10, at 7 (noting lack of nanotechnology-specific regulatory structure); *id.* app. 2 (listing examples of state laws enacted to promote nanotechnology).

[88] *See infra* note 129 and accompanying text.

Health Act ("OSHA"). As explained below, a survey of these and other potentially applicable statutes reveals that such an approach would allow the introduction of many nanomaterials into commerce without further testing or approval.[89]

A. The Toxic Substances Control Act

Given its breadth and purpose, TSCA[90] is the most likely source of authority for addressing possible risks associated with nanomaterials.[91] In contrast to many other environmental laws, which govern only the release of pollutants into the environment, TSCA gives the Environmental Protection Agency ("EPA") the broad authority to regulate the entire life cycle of a chemical substance.[92] Moreover, TSCA's purpose—addressing the concern that humans and the environment are exposed to thousands of chemical substances and mixtures that may pose unknown or unreasonable risks[93]—seems well-suited to the nanotechnology challenge. Nevertheless, among the major environmental statutes, TSCA has been relatively neglected, and the difficulties encountered in its implementation stem from fundamental deficiencies in the substance of the statute itself.

TSCA provides EPA with regulatory authority in three key areas: regulating chemicals that present health or environmental risks; screening new chemicals and significant new uses of existing chemicals; and testing chemicals where risks are unknown. First, under section 6 of TSCA, EPA has the authority to regulate the manufacture, processing, distribution, use, or disposal of any chemical substance if it finds that there is a "reasonable basis to conclude" that such an activity "presents or will present an unreasonable risk of injury to health or the environment."[94] This standard requires both a factual finding of risk and a normative finding that such risk is unreasona-

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[89] *See* Oberdörster et al., *supra* note 18, at 835. Under TSCA, a new chemical substance may be manufactured so long as advance notice is provided to EPA describing the substance, the volume expected to be manufactured and used, and the available data on health and environmental effects. TSCA § 5, 15 U.S.C. § 2604 (2006); *see also* Weiss, *supra* note 17 (arguing that current regulatory scheme's focus on general questions of toxicity and volume is a poor fit for nanotechnology because substances that are nontoxic in bulk form can be deadly when produced on the nanoscale).

[90] 15 U.S.C. §§ 2601-2692.

[91] *See, e.g.*, Letter from Richard A. Denison, Senior Scientist, & Karen Florini, Senior Att'y, Envtl. Def., to Susan B. Hazen, Acting Assistant Adm'r, U.S. EPA (Sept. 2, 2004) [hereinafter Denison & Florini], *available at* http://www.environmentaldefense.org/documents/4457_NanotechLetterToEPA.pdf (requesting that EPA clarify that nanomaterials are subject to TSCA's premanufacturing notice requirements).

[92] *See* Robert V. Percival et al., Environmental Regulation 93 (2003) ("In theory, [TSCA] is the broadest source of EPA's regulatory authority . . . .").

[93] 15 U.S.C. § 2601 (statutory pronouncement of congressional findings, policy, and intent).

[94] *Id.* § 2605(a).

ble.[95] In determining whether a demonstrated risk is unreasonable, EPA must balance the health and environmental effects with the benefits arising from use of the substance.[96] Furthermore, under a leading judicial interpretation of section 6, EPA must evaluate the availability of substitutes for the chemical in question, it must apply only the least burdensome regulatory measure that provides adequate protection, and its decision to regulate must be supported by substantial evidence.[97]

Second, for new chemicals, section 5 of TSCA requires manufacturers to provide a premanufacture notice ("PMN") and to submit any available health and safety data to EPA.[98] EPA may take action to control unreasonable risks, but if EPA takes no action on the PMN within ninety days, manufacture of the chemical can proceed.[99] Section 5 of TSCA also gives EPA the authority to evaluate significant new uses of existing chemicals.[100] In order to determine that there is a significant new use, however, EPA must promulgate a rule pursuant to the Administrative Procedure Act.[101] A company subject to such a rule must provide a significant new use notice ("SNUN"), which is similar to a PMN.[102]

Third, although TSCA itself does not require manufacturers to conduct testing that would generate any health and safety data, section 4 of TSCA authorizes EPA to require such testing to be done.[103] EPA must make certain statutory findings—that a chemical "may present an unreasonable risk of injury to health or the environment,"[104] or that a chemical "will be produced in substantial quantities," resulting in substantial human exposure or entry of substantial quantities into the environment[105]—and EPA must promulgate a rule to require such testing.[106]

Notwithstanding TSCA's potential applicability, little attention has been paid to the statute as nanotechnology applications have come to market.[107] Hundreds of nanomaterial-containing products have become available in re-

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[95] *See* Alyson C. Flournoy, *Legislating Inaction: Asking the Wrong Questions in Protective Environmental Decisionmaking*, 15 HARV. ENVTL. L. REV. 327, 340 (1991).

[96] *See* Corrosion Proof Fittings v. EPA, 947 F.2d 1201, 1222 (5th Cir. 1991) (noting that "EPA must balance the costs of its regulations against their benefits"); PERCIVAL ET AL., *supra* note 92, at 407-08.

[97] *Corrosion Proof Fittings*, 947 F.2d at 1215-17, 1220, 1223; *see* 15 U.S.C. § 2605(a); *id.* § 2618(c)(1)(B)(i).

[98] 15 U.S.C. § 2604(a).

[99] *Id.* § 2604(a), (b). EPA takes no action on the vast majority of premanufacture notices ("PMNs"). *See* JOHN APPLEGATE ET AL., THE REGULATION OF TOXIC SUBSTANCES AND HAZARDOUS WASTES 611 (2000).

[100] 15 U.S.C. § 2604(a).

[101] *Id.* § 2604(a)(2).

[102] *See id.*; ELI, *supra* note 10, at 11.

[103] 15 U.S.C. § 2603.

[104] *Id.* § 2603(a)(1)(A)(i).

[105] *Id.* § 2603(a)(1)(B).

[106] *Id.* § 2603(a).

[107] *See, e.g.*, Tomasco, *supra* note 11, at 233 (noting that a number of popular nanomaterials, though registered under unique identifying numbers by the Chemical Abstracts Service, are not listed in EPA's TSCA Inventory).

cent years, but not until October 2005 did EPA review its first application under TSCA to make a product composed of nanomaterials.[108] Several factors explain not only why TSCA has been ignored, but also why the statute is inadequate to address the potential hazards of nanotechnology.[109] First, although TSCA is broad in scope, it leaves important regulatory gaps. Some products containing nanomaterials, such as cosmetics and sunscreens,[110] lie beyond EPA's regulatory authority under TSCA.[111] Whether agencies other than EPA have adequate authority over these items is doubtful in many instances, as will be explained below.[112]

Second, TSCA has turned out to be a very weak source of authority because of the burdens it places on EPA before EPA can limit the manufacture, processing, or distribution of a chemical substance.[113] As noted above, EPA must demonstrate the existence of unreasonable risk, it must choose the least burdensome regulatory measure that provides adequate protection, and its decision to regulate must be supported by substantial evidence.[114] This unreasonable risk standard has been deemed "a failure" by one commentator because "[i]t has imposed huge information demands, invited contention and judicial intervention, and thwarted regulatory action."[115] Given the uncertainty that tends to surround the effects of chemical exposure, the burden

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[108] *See* Juliet Eilperin, *Nanotechnology's Big Question: Safety*, WASH. POST, Oct. 23, 2005, at A11 (reporting EPA's first ruling under TSCA on a nanomaterial application, issued in September 2005).

[109] For general criticisms of TSCA, see U.S. GOV'T ACCOUNTABILITY OFFICE, CHEMICAL REGULATION: OPTIONS EXIST TO IMPROVE EPA'S ABILITY TO ASSESS HEALTH RISKS AND MANAGE ITS CHEMICAL REVIEW PROGRAM (2005); John S. Applegate, *The Perils of Unreasonable Risk: Information, Regulatory Policy, and Toxic Substances Control*, 91 COLUM. L. REV. 261 (1991); Robert B. Haemer, *Reform of the Toxic Substances Control Act: Achieving Balance in the Regulation of Toxic Substances*, 6 ENVTL. LAW. 99 (1999-2000).

[110] Cosmetics and sunscreens are nominally subject to regulation by the Food and Drug Administration ("FDA"). *See infra* Part III.E.

[111] 15 U.S.C. § 2602(2) (excluding "any food, food additive, drug, cosmetic, or device" from TSCA definition of "chemical substance").

[112] *See infra* Parts III.C-III.E.

[113] *See* Corrosion Proof Fittings v. EPA, 947 F.2d 1201, 1222 (5th Cir. 1991) (striking down bulk of EPA rule prohibiting almost all uses of asbestos, despite reliance on over one hundred studies demonstrating health risks); U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 109, at 27 (concluding that EPA "has had difficulty proving that chemicals pose unreasonable risks and has regulated few existing chemicals under TSCA"); Applegate, *supra* note 109, at 263 (stating that "[c]urrent regulatory policy [for toxic substances control] has adopted a standard of unreasonable risk and an analytical methodology known as quantitative risk assessment, both of which require enormous amounts of information and stretch the gap between available and needed data").

[114] *See supra* notes 94-97 and accompanying text.

[115] John S. Applegate, *Worst Things First: Risk, Information, and Regulatory Structure in Toxic Substances Control*, 9 YALE J. ON REG. 277, 311 (1992); *see also* Robert V. Percival, *Who's Afraid of the Precautionary Principle?*, 23 PACE ENVTL. L. REV. 21, 77 (2005) ("[T]he *Corrosion Proof Fittings* decision effectively crippled the agency's ability to conduct multisource, multi-media regulation by imposing seemingly impossible analytical preconditions on regulation.").

of proof is often too difficult to meet.[116] Furthermore, as another critic has noted, the requirement that regulatory action be supported by "substantial evidence . . . is very difficult to meet, and . . . contrasts with the much easier 'arbitrary and capricious' standard" applied under most other environmental statutes.[117] Similarly, even before EPA can require testing of a substance, it must demonstrate the existence of potential risk—yet such information may not be available if no testing has been done.[118]

Third, the implicit assumption behind TSCA is that no information on the risk of a chemical means that there is no risk.[119] Substances whose effects are uncertain are treated the same as substances that demonstrably pose no unreasonable risks.[120] This presents a particularly difficult challenge to the regulation of nanotechnology because of the vast uncertainty regarding its impact on health and safety. The difficulty of that challenge is compounded by the rapid pace of developments in the field. Given the variety of engineered nanoparticles likely to be produced, and their differing properties, it will be virtually impossible for the government to determine under TSCA whether or not each type of particle presents an unreasonable risk before products containing those particles are put on the market.[121]

Fourth, TSCA's PMN regulations contain an exemption for new chemicals or significant new uses of chemicals produced in volumes of ten thousand kilograms or less per year.[122] This threshold would exclude most nanomaterials.[123] The exemption does not apply if EPA determines that a

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[116] *See* Applegate, *supra* note 115, at 311 (attributing paucity of rules produced under TSCA to difficulty of establishing unreasonable risk); *cf.* Albert C. Lin, *Beyond Tort: Compensating Victims of Environmental Toxic Injury*, 78 S. CAL. L. REV. 1439, 1445-52 (2005) (describing difficulties faced by toxic tort plaintiffs in proving causation).

[117] *See* DAVIES, *supra* note 10, at 11.

[118] *See* TSCA § 4(a), 15 U.S.C. § 2603(a) (2006) (authorizing EPA to require safety testing). EPA's ability to order testing in order to gather toxicity or exposure data has been hampered by the requirement that it present a minimum amount of such data in the first instance. *See* Haemer, *supra* note 109, at 115-16; *see also* Tomasco, *supra* note 11, at 237 ("[T]he state of research into nanomaterials is probably not robust enough to conclude that they pose an unreasonable risk."); *cf.* Lin, *supra* note 116, at 1441 & n.2 (noting that only a small percentage of chemicals used in commerce has been subject to toxicity testing).

[119] *See* DAVIES, *supra* note 10, at 11.

[120] *See* Flournoy, *supra* note 95, at 366 (criticizing environmental standards for failing to treat uncertainty itself as a fact of regulatory significance).

[121] *See* DAVIES, *supra* note 10, at 9; CTR. FOR SCI., TECH. & PUB. POLICY, *supra* note 10, at 23 (summarizing comments of workshop participant that federal oversight process increasingly will have trouble keeping pace with nanotechnology product development and market entry); *see also* EPA WHITE PAPER, *supra* note 10, at 55 (discussing challenge of assessing toxicity of the "wide diversity and complexity of the types of materials that are available commercially or are under development").

[122] Low Volume Exemption, 40 C.F.R. § 723.50(c)(1) (2006). Another exemption is available if a manufacturer can demonstrate no or very low exposures to workers, consumers, and the general public. Low Release and Exposure Exemption, *id.* § 723.50(c)(2). In either instance, a manufacturer must specifically claim the exemption by submitting a notice of intent to manufacture at least thirty days before manufacture begins. *Id.* § 723.50(e).

[123] *See* DAVIES, *supra* note 10, at 11 (suggesting that EPA would have to amend the Low Volume Exemption in order to regulate nanomaterials).

chemical may cause serious acute, chronic, or significant environmental effects, but the regulation places the burden on EPA to make such a showing.[124]

So far, EPA has taken the position that its regulatory authority under TSCA is adequate to address any hazards posed by nanomaterials.[125] The weakness of that authority and the obstacles to exercising it, however, undermine EPA's claim. EPA officials themselves have conceded that "it is a challenge" to oversee nanotechnology under TSCA.[126] That admission understates the difficulties. EPA has not issued rules or guidance as to which nanoscale materials are "new chemical substances" or "significant new uses" such that they would be subject to TSCA's notification requirements.[127] Nor has EPA amended the regulatory exemption for new chemicals produced in low volumes. Even if EPA took these steps, legal battles would loom over whether nanomaterials are new materials or whether uses of nanomaterials are new uses for which PMNs or SNUNs must be filed.[128] On the one hand, nanomaterials are often derived from common substances that are not new, and many industry members have taken the position that nanoparticles are no different than the gross materials from which they are derived.[129] On the other hand, nanomaterials are of special interest precisely because they possess physical and chemical properties different from their parent material.[130] Even if one assumes that PMN or SNUN requirements do

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[124] 40 C.F.R. § 723.50(d).

[125] *See* CTR. FOR SCI., TECH. & PUB. POLICY, *supra* note 10, at 18 ("EPA believes that TSCA is sufficiently elastic to address nanoscale materials.").

[126] *See* Eilperin, *supra* note 108 (reporting remark by Director of the Chemical Control Division in EPA's Office of Pollution Prevention and Toxics).

[127] *See, e.g.*, Notice of Public Meeting on Nanoscale Materials, 70 Fed. Reg. 24,574 (May 10, 2005) ("Some of the nanoscale materials are new chemical substances subject to notification requirements under section 5 of [TSCA] and, therefore, are subject to review for potential human health and environmental risks before they are manufactured and enter commerce. Other nanoscale materials are existing chemical substances that may enter commerce without notification to EPA.").

[128] *See* CHRISTOPHER L. BELL ET AL., REGULATION OF NANOSCALE MATERIALS UNDER THE TOXIC SUBSTANCES CONTROL ACT 8-11 (2006), *available at* http://www.abanet.org/environ/nanotech/pdf/TSCA.pdf (noting that EPA historically has looked to a chemical substance's molecular identity, and not its physical or chemical properties, to determine whether the substance is new, but suggesting that TSCA does not require such an approach).

[129] *See* Weiss, *supra* note 17 (noting that factories that manufacture carbon nanotubes, which are made from graphite but behave very differently from ordinary graphite, submit Material Safety Data Sheets for ordinary graphite to fulfill regulatory requirements); Denison & Florini, *supra* note 91, at 2 (contending that "not a single PMN has been filed for a nanomaterial," based on the apparent assumption that nanomaterials may be treated under TSCA as if they are the same as the gross substances from which they are derived); *see also* BARTIS & LANDREE, *supra* note 56, at 9 (mentioning instances in which Material Safety Data Sheets either were incomplete or referred to controls proposed for other nanoscale or bulk materials of the same chemical composition); SWISS RE, *supra* note 44, at 36 (noting that FDA and European regulatory authorities have treated nanomaterials as substantially equivalent to conventional products).

[130] Indeed, the fact that patents have been granted for numerous products containing nanomaterials undermines the contention that engineered nanomaterials should not be treated as new materials or new uses under TSCA. *See* Citizen Petition to the U.S. Food & Drug Admin.:

apply, manufacturers need only provide data that is available; TSCA does not require manufacturers to generate any baseline data on toxicity unless EPA specifically demands it.[131] Most PMNs filed with EPA do not include test data of any type, and only about 15% include health or safety test data.[132]

The broad powers that TSCA appears to give EPA, such as the authority to demand the testing of chemicals and the filing of SNUNs, are largely illusory. In each instance, EPA must follow a cumbersome rulemaking process and make certain threshold findings that are simply impossible in the face of uncertainty.[133] All in all, the evidentiary burdens and procedural requirements that TSCA imposes on EPA, combined with its exemptions for foods, drugs, and other important classes of nanotechnology products, make the statute a poor candidate for responding to the potential dangers of nanomaterials and to the rapid pace of development in nanotechnology.[134]

B. Media-Based Environmental Statutes

Media-based environmental statutes—in particular, CAA[135] and CWA[136]—have more successful histories of implementation than TSCA and more extensive regulatory structures already in place. These statutes generally rely on permit systems to regulate pollutants at the point of their release into the environment.[137] Limitations on the release of nanomaterials could be integrated into facility permits, at least in theory. Most current and upcoming uses of nanotechnology, however, involve the deliberate incorporation of nanomaterials into products to be used by consumers. Permit limits on the release of nanomaterials by manufacturing facilities most likely would cover only those nanomaterials found in production waste streams, not nanomaterials incorporated into products. Because the use and disposal of na-

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Petition Requesting FDA Amend Its Regulations for Products Composed of Engineered Nanoparticles Generally and Sunscreen Drug Products Composed of Engineered Nanoparticles Specifically at 64-68, The Int'l Ctr. for Tech. Assessment et al., Petitioners (May 16, 2006), *available at* http://www.icta.org/doc/Nano%20FDA%20petition%20final.pdf.

[131] TSCA § 5(d), 15 U.S.C. § 2604(d) (2006); CTR. FOR SCI., TECH. & PUB. POLICY, *supra* note 10, at 32 (reporting criticisms of TSCA by nanotechnology workshop participant).

[132] *See* U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 109, at 11.

[133] 15 U.S.C. § 2604(a)(2); *id.* § 2603(a)(1); *see* Applegate, *supra* note 109, at 318-19 (suggesting that infrequent promulgation of test rules under TSCA "is best explained by the elaborate procedural barriers that confine the test rules"); *see also supra* note 118. *But cf.* BELL ET AL., *supra* note 128, at 14-16 (noting that EPA has promulgated over seven hundred significant new use rules under TSCA and that EPA has the authority to promulgate such rules for entire classes of chemicals).

[134] *See generally Rejeski Testimony*, *supra* note 84, at 6 (remarking that "the technology is developing more rapidly than our understanding of the . . . risks and our ability to respond with effective policy measures").

[135] 42 U.S.C. §§ 7401-7671q (2006).

[136] 33 U.S.C. §§ 1251-1387 (2006).

[137] *See, e.g.*, *id.* § 1342 (establishing National Pollutant Discharge Elimination System to issue permits under the Clean Water Act ("CWA")); 42 U.S.C. § 7475 (requiring preconstruction permits for "major emitting facilities" in certain areas under the Clean Air Act ("CAA")).

notechnology products are expected to be the greatest source of exposure,[138] facility permit controls would be of limited value. While it might be possible to regulate the release of nanomaterials during use, such regulation would likely be difficult, burdensome, and ineffective. It is hard to imagine, for example, restrictions on the use of a nano-sunscreen that would be effective in preventing the release of nanomaterials into the environment.[139]

Even where permit controls are feasible, application of the CAA or CWA to nanomaterials will face other hurdles. Both statutes rely heavily on monitoring,[140] which would likely require sophisticated and expensive laboratory equipment for the detection of nanoparticles.[141] In addition, similar to TSCA, these statutes generally require significant amounts of data as a prerequisite for regulatory action.[142] Such data will likely be unavailable for nanomaterials for some time.[143] Ultimately, there appear to be too many practical and legal obstacles to using the CWA or the CAA to address most potential risks of nanomaterials, particularly where those materials are purposefully incorporated into consumer products.[144]

C. Consumer Product Safety Statutes

The Consumer Products Safety Act ("CPSA")[145] focuses on protecting consumers from "unreasonable risks of injury associated with consumer

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[138] *See* DAVIES, *supra* note 10, at 14.

[139] Restrictions on disposal may be more effective than restrictions on use. The disposal of nanomaterials could be regulated by EPA pursuant to the Resource Conservation and Recovery Act ("RCRA"), 42 U.S.C. §§ 6901-6992k (2006). *See* ELI, *supra* note 10, at 14-16 (discussing potential applicability of RCRA to nanomaterials).

[140] *See* ELI, *supra* note 10, at 13.

[141] *See* DAVIES, *supra* note 10, at 14.

[142] Under the CAA, for example, EPA may establish national ambient air quality standards for pollutants based on air quality criteria specified in the statute, but only for pollutants emitted from numerous or diverse mobile or stationary sources. *See* 42 U.S.C. §§ 7408(a), 7409 (2006). Similarly, EPA may regulate hazardous air pollutants, but only upon a finding that they "present, or may present . . . a threat of adverse human health effects . . . or adverse environmental effects." *Id.* § 7412(b)(2); *see also* PAMELA E. BARKER ET AL., NANOTECHNOLOGY BRIEFING PAPER: CLEAN WATER ACT 3 (2006), *available at* http://www.abanet.org/environ/nanotech/pdf/CWA.pdf (concluding that CWA potentially gives EPA the authority to regulate nanoparticles, but that EPA first would have to demonstrate that the nanoparticles to be regulated have adverse effects on human health or the environment).

[143] *See supra* Part II.B; ELI, *supra* note 10, app. 1 at 1-2 (noting provisions of CAA and CWA potentially applicable to nanotechnologies).

[144] Statutes that focus on the cleanup of hazardous waste, such as the Comprehensive Environmental Response, Cleanup, and Liability Act ("CERCLA"), 42 U.S.C. §§ 9601-9675 (2006), may play a limited role in the regulation of nanotechnology. *See* CHRISTOPHER P. CORMACK ET AL., CERCLA NANOTECHNOLOGY ISSUES 3 (2006), *available at* http://www.abanet.org/environ/nanotech/pdf/CERCLA.pdf (concluding that "[t]he retrospective CERCLA liability framework is probably most valuable as a backup tool to deal with adverse consequences that are unanticipated or that otherwise elude environmental regulation"). Commentators generally agree, however, that because nanomaterials are likely to be difficult to clean up once released, efforts should focus on preventing exposure or release, rather than on remediation. *See, e.g.*, DAVIES, *supra* note 10, at 18.

[145] 15 U.S.C. §§ 2051-2084 (2006).

products,"[146] and so might be a logical alternative for addressing the regulatory void for nanomaterials that are being incorporated into consumer products. The authority provided by the CPSA, however, is too weak to respond to the nanotechnology challenge.

Created by the CPSA, the Consumer Products Safety Commission ("Commission") regulates consumer products through the public disclosure of information and through consumer product safety standards.[147] Under the CPSA, the Commission may ban products that create an "unreasonable risk of injury" when "no feasible consumer product safety standard" can adequately address that risk.[148] In addition, the Commission has authority under the Federal Hazardous Substances Act ("FHSA")[149] to ban or regulate substances that are hazardous and that "may cause substantial personal injury or substantial illness" as a result of consumer use.[150]

Because the Commission's regulatory authority is generally limited to consumer products not specifically regulated by another statute, its authority would not extend to many nanotechnology applications, including foods, drugs, cosmetics, pesticides, and automobiles.[151] Moreover, the CPSA and FHSA suffer from many of the same—if not greater—weaknesses as TSCA with respect to the potential regulation of nanotechnology.[152] Under the CPSA, the Commission must rely primarily on voluntary standards.[153] If such standards are inadequate, the Commission may establish mandatory standards, but only as "reasonably necessary to prevent or reduce an unreasonable risk of injury."[154] And under the FHSA, the Commission has a heavy burden of demonstrating that a substance is hazardous and that its use by consumers may cause substantial injury.[155] Thus, the thresholds for mandatory regulation are at least as difficult to meet as the standards imposed by TSCA, and would be impossible to meet with respect to nanomaterials given the paucity of existing data. Moreover, with its tiny staff and extremely limited budget, the Commission is already ill-equipped to address its current backlog of consumer product problem areas, and it has little expe-

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[146] *Id.* § 2051(b)(1).
[147] *Id.* §§ 2053-2056.
[148] *Id.* § 2057.
[149] 15 U.S.C. §§ 1261-1278 (2006).
[150] *Id.* § 1261(f)(1) (defining "hazardous substance"); *see also id.* § 1261(q) (defining "banned hazardous substance"); Treye Thomas et al., *Research Strategies for Safety Evaluation of Nanomaterials, Part VII: Evaluating Consumer Exposure to Nanoscale Materials*, 91 TOXICOLOGICAL SCI. 14, 18 (2006).
[151] 15 U.S.C. § 2052(a)(1) (defining "consumer product" under Consumer Product Safety Act ("CPSA")); *id.* § 1261(f)(2) (excluding pesticides, foods, drugs, cosmetics, and other substances from definition of "hazardous substances" under Federal Hazardous Substances Act ("FHSA")); *see also id.* § 2080(a) (listing additional limitations on jurisdiction of the Commission).
[152] *See* DAVIES, *supra* note 10, at 15 (describing the CPSA in particular as "a law with mostly hortatory powers").
[153] *See* 15 U.S.C. § 2056.
[154] *Id.*
[155] *Id.* §§ 1262(a)(1), 1261(f).

rience in carrying out the sophisticated research and analysis that would be needed to evaluate the potential dangers of nanomaterials in consumer products.[156]

D. The Occupational Safety and Health Act

Unintentional exposure to nanomaterials in significant quantities is perhaps most likely to occur among workers in the nanotechnology industry and researchers in academic laboratories.[157] Such workplace exposures are potentially governed by the Occupational Safety and Health Act ("OSH Act"),[158] which gives OSHA the authority to set and enforce "standard[s] which require[ ] conditions, or the adoption or use of one or more practices . . . reasonably necessary or appropriate to provide safe or healthful employment and places of employment."[159] OSHA implements the statute by establishing permissible exposure limits ("PELs") for each material and keeping worker exposures within PELs through administrative controls, engineering controls, and protective equipment.[160] The statute's broad language suggests its potential utility in addressing the risk of exposure to nanomaterials.

As with TSCA, however, the OSH Act's broad language belies the difficulties involved in its implementation. Under case law interpreting the Act, OSHA must demonstrate a significant risk of harm in order to regulate potentially toxic substances.[161] The presence of uncertainty alone, however, is insufficient to authorize precautionary regulation under the statute.[162] Any safety standards that are adopted by OSHA must be "supported by substantial evidence in the record."[163] Furthermore, under OSHA rules, employers

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[156] The Commission's current staff of 446 is less than half its size in 1980. *See* SUSAN DUDLEY & MELINDA WARREN, GEORGE MASON UNIV. & WASH. UNIV., UPWARD TREND IN REGULATION CONTINUES: AN ANALYSIS OF THE U.S. BUDGET FOR FISCAL YEARS 2005 AND 2006, at 21 tbl.A-3 (2005), *available at* http://www.mercatus.org/repository/docLib/MC_RSP_RA-BudgetUpwardTrend_050615.pdf. The Commission's $42.5 million budget for fiscal year 1997 was less than half its budget for 1974, the year it was created. *See* U.S. GOV'T ACCOUNTABILITY OFFICE, CONSUMER PRODUCT SAFETY COMMISSION: BETTER DATA NEEDED TO HELP IDENTIFY AND ANALYZE POTENTIAL HAZARDS 4 (1997) (figures adjusted for inflation).

[157] *See* CTR. FOR SCI., TECH. & PUB. POLICY, *supra* note 10, at 23.

[158] 29 U.S.C. §§ 651-678 (2006).

[159] *Id.* § 652(8); *see id.* § 655(b).

[160] *Id.* § 655(b)(5), (7). The OSH Act also imposes a "general duty" on employers to furnish employment "free from recognized hazards that are causing or are likely to cause death or serious physical harm." *Id.* § 654(a)(1). Given current levels of uncertainty, exposure to nanomaterials does not constitute a "recognized hazard."

[161] Indus. Union Dep't, AFL-CIO v. Am. Petroleum Inst. (*Benzene*), 448 U.S. 607, 639 (1980) (plurality opinion) (stating that the Occupational Safety and Health Administration ("OSHA") can promulgate a new standard only if it demonstrates that regulation is "reasonably necessary and appropriate to remedy a significant risk of material health impairment"); Am. Textile Mfrs. Inst. v. Donovan, 452 U.S. 490, 505 n.25 (1981) (distinguishing instant case from the *Benzene* case on grounds that OSHA had demonstrated a significant health hazard).

[162] *Benzene*, 448 U.S. at 652-53.

[163] 29 U.S.C. § 655(f).

are required to identify and to warn workers only of known chemical hazards.[164]

As a result of these hurdles, many commentators have concluded that the OSH Act is an ineffective means of protecting workers.[165] OSHA has issued health regulations for only a small proportion of the substances for which regulation has been recommended.[166] Given its history, OSHA almost surely cannot keep pace with the proliferation of different types of nanomaterials in research and manufacturing settings.[167] Indeed, regulation of exposure to nanomaterials under OSHA would encounter many of the same difficulties as regulation under TSCA as the uncertainty surrounding the health and environmental effects of nanomaterial exposure would make it virtually impossible to meet the statutory thresholds for regulation.[168] Moreover, it is not clear how effective the implementation of typical workplace health standards would be. Little information is available regarding the effectiveness of engineering controls and protective equipment in controlling nanomaterial exposure,[169] and the equipment for monitoring and control may be expensive.[170]

E. Statutes Specific to Drugs and Other Products

Other statutes that offer potentially greater oversight of nanotechnology cover only specific and limited contexts. Drugs that contain nanomaterials, for example, would be subject to the extensive premarket approval process

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[164] Mary L. Lyndon, *Information Economics and Chemical Toxicity: Designing Laws to Produce and Use Data*, 87 MICH. L. REV. 1795, 1826 & n.119 (1989) (discussing OSHA regulations).

[165] *See, e.g.*, JOHN M. MENDELOFF, THE DILEMMA OF TOXIC SUBSTANCE REGULATION 100-02 (1988) (arguing that OSHA has overregulated with respect to the few substances for which it has established standards, but underregulated with respect to other substances); Thomas J. Kniesner & John D. Leeth, *Abolishing OSHA*, REGULATION, Winter 1995, at 47 (contending that there is "no indication that OSHA's actions have led to any significant reductions in injuries on the job" and that "[m]ost protection on the job comes from state workers' compensation rules and programs, and tort law"); Sidney A. Shapiro & Thomas O. McGarity, *Reorienting OSHA: Regulatory Alternatives and Legislative Reform*, 6 YALE J. ON REG. 1, 2 (1989) ("OSHA, in particular, has been a disappointment.").

[166] *See* Shapiro & McGarity, *supra* note 165, at 2-3 (noting that OSHA completed only twenty-four substance-specific regulations in the first seventeen years of its existence and that it has failed to act on hundreds of chemicals that various organizations have recommended for regulation). OSHA has increasingly suffered from limited resources. *See* DUDLEY & WARREN, *supra* note 156, at 21 tbl.A-3 (reporting decline in number of OSHA employees from 2950 to 2208 between 1980 and 2005).

[167] *See* BARTIS & LANDREE, *supra* note 56, at 8 (reporting concerns expressed at workshop that "the formal process of establishing [occupational exposure limits] would overwhelm NIOSH and OSHA capabilities").

[168] *See id.*; Shapiro & McGarity, *supra* note 165, at 4-6 (summarizing substantive constraints on OSHA). OSHA faces an additional obstacle in setting standards, compared to EPA, because the authority to research the substances OSHA is to regulate is delegated to a separate agency, NIOSH. 29 U.S.C. § 671 (2006); Shapiro & McGarity, *supra* note 165, at 7.

[169] *See* BARTIS & LANDREE, *supra* note 56, at 8.

[170] *See* DAVIES, *supra* note 10, at 12; Maynard & Kuempel, *supra* note 47, at 592-93.

that the Food and Drug Administration ("FDA") conducts for new drugs.[171] That process begins with the submission of an Investigational New Drug Application ("IND").[172] The IND, which is a prerequisite for human testing, must contain the results of pharmacological and toxicological studies of a drug in animals and/or *in vitro*, and it must describe specific testing plans.[173] Based on the IND, the FDA decides whether it is reasonably safe to proceed with clinical trials. The clinical trials involve three phases of studies in humans to determine effectiveness and toxicity,[174] and only after successful completion of the studies can the FDA approve a new drug.[175] While it is possible that the FDA may not be aware of the presence of nanomaterials in a product, the drug approval process does ensure that at least some health and safety testing has been done.[176]

Similarly, under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"),[177] new pesticides and new compositions of existing pesticides must be registered by EPA before they can be marketed.[178] Registration requires that an applicant demonstrate that the product will perform its intended function without causing unreasonable harm.[179] Accordingly, EPA demands that a battery of studies be performed on any chemical to be used as a pesticide in order to determine potential impacts on human health and the environment.[180]

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[171] Federal Food, Drug and Cosmetic Act ("FDCA") § 505, 21 U.S.C. § 355 (2006). Medical devices for which there is insufficient information to show that general or special controls (such as notification, labeling, or registration requirements) will provide a reasonable assurance of safety and effectiveness also require premarket approval. *Id.* § 360c.

[172] 21 C.F.R. § 312.20 (2007) (requiring the sponsor of a new drug to submit an Investigational New Drug Application ("IND") "if the sponsor intends to conduct a clinical investigation with an investigational new drug").

[173] *Id.* § 312.23.

[174] Phase 1 studies, conducted on a group of twenty to eighty subjects, focus on determining "the metabolism and pharmacologic actions of the drug in humans [and] the side effects associated with increasing doses," and also gather "early evidence on effectiveness." *Id.* § 312.21(a). Phase 2 studies, conducted on a group of up to several hundred subjects, are aimed at determining a drug's effectiveness for treating specific conditions. *Id.* § 312.21(b). Phase 2 studies also consider a drug's risks and common short-term side effects. *Id.* If evidence of effectiveness is shown in Phase 2, Phase 3 studies, consisting of controlled and uncontrolled trials on groups of up to three thousand patients, "gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling." *Id.* § 312.21(c).

[175] *Id.* §§ 314.1-.65 (regulations governing approval of new drugs). Once a drug is approved for marketing by the FDA, its sponsor must still monitor its safety. *See id.* § 310.303.

[176] *See* CTR. FOR SCI., TECH. & PUB. POLICY, *supra* note 10, at 21 (suggesting that the "FDA may be unaware that nanotechnology is being used in a particular product" because it "can only regulate products based on the claims of the sponsor"); Weiss, *supra* note 17 (reporting confused response of the FDA to inquiry as to whether agency had approved any nano-based products and if so, whether special safety tests had been required).

[177] 7 U.S.C. §§ 136-136y (2006).

[178] *Id.* § 136a.

[179] *Id.* § 136a(c)(5).

[180] *See* 40 C.F.R. pt. 158 (2006); *see also* Darrell D. Sumner et al., *Agricultural Chemicals: The Federal Insecticide Fungicide and Rodenticide Act and a Review of the European Community Regulatory Process*, *in* REGULATORY TOXICOLOGY 133, 137-41 (Christopher P.

Like pesticides and drugs, cosmetics and sunscreens are the subject of specific statutory authority. The use of nanomaterials in these products nevertheless has become widespread with little actual oversight.[181] The FDA has authority to regulate cosmetics under the Federal Food, Drug and Cosmetic Act ("FDCA"),[182] but the Agency has interpreted and exercised that authority in a limited manner. The FDCA prohibits "[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded."[183] The FDA has interpreted this provision to require agency approval before the marketing of certain foods, drugs, or medical devices.[184] For cosmetics products and ingredients, however, the FDA does not require premarket approval, with the exception of color additives.[185] The FDA instead places the responsibility on cosmetics manufacturers to determine the safety of their own products and ingredients before marketing.[186] Although cosmetics manufacturers may participate in voluntary programs to file data on ingredients, register manufacturing sites, and report cosmetics-related injuries to the FDA,[187] a cosmetics manufacturer may use any ingredient or market any cosmetic until the FDA demonstrates that it may be harmful—something that rarely occurs.[188]

Chengelis et al. eds., 1995) (summarizing testing requirements). Notwithstanding EPA's considerable authority over pesticides under the FIFRA, nanopesticides do raise certain issues that may warrant a reexamination by EPA of how it exercises that authority. *See* JAMES C. CHEN ET AL., THE ADEQUACY OF FIFRA TO REGULATE NANOTECHNOLOGY-BASED PESTICIDES 5-15 (2006), *available at* http://www.abanet.org/environ/nanotech/pdf/FIFRA.pdf (discussing concerns unique to nanoparticles).

[181] *See* GEORGIA MILLER, FRIENDS OF THE EARTH, NANOMATERIALS, SUNSCREENS, AND COSMETICS: SMALL INGREDIENTS BIG RISKS 4 (2006), *available at* http://www.foe.org/camps/comm/nanotech/nanocosmetics.pdf (estimating that hundreds of sunscreens, cosmetics, and personal care products currently available in the global market contain nanomaterials).

[182] 21 U.S.C. §§ 301-399 (2006).

[183] *Id.* § 331(a).

[184] MARY DEVINE WOROBEC & GIRARD ORDWAY, TOXIC SUBSTANCES CONTROLS GUIDE 69 (1989). The FDA has suggested that treating every new nanotechnology product in food as a food additive might run counter to the agency's mandate to promote innovation and might also be beyond its regulatory authority. *See* Feder, *supra* note 20; *see also* MICHAEL R. TAYLOR, REGULATING THE PRODUCTS OF NANOTECHNOLOGY: DOES FDA HAVE THE TOOLS IT NEEDS? 30-39 (2006), *available at* http://www.nanotechproject.org/file_download/110 (reviewing FDA's limited authority to regulate nanotechnology in food products).

[185] OFFICE OF COSMETICS & COLORS, FOOD & DRUG ADMIN., FDA AUTHORITY OVER COSMETICS (Mar. 3, 2005), http://www.cfsan.fda.gov/~dms/cos-206.html (on file with the Harvard Environmental Law Review); *see also* TAYLOR, *supra* note 184, at 27-30 (describing limited FDA authority over cosmetics).

[186] OFFICE OF COSMETICS & COLORS, *supra* note 185; TAYLOR, *supra* note 184, at 27-28. If the safety of a product has not been substantiated, the manufacturer must include a warning to that effect on the cosmetic product's label. 21 C.F.R. § 740.10 (2005).

[187] 21 C.F.R. pts. 710, 720 (2005); Cosmetic Regulations, 62 Fed. Reg. 43,071, 43,073-74 (Aug. 12, 1997) (revoking regulation providing for collection of voluntarily filed information on adverse reactions, but maintaining availability of adverse reaction reporting forms). Under the authority of the Fair Packaging and Labeling Act, the FDA requires that cosmetics manufacturers provide a list of ingredients. *See* Fair Packaging and Labeling Act § 5(c)(3), 15 U.S.C. § 1454(c)(3) (2006); 21 C.F.R. § 701.3 (2005).

[188] *See* WOROBEC & ORDWAY, *supra* note 184, at 76.

Sunscreens are potentially subject to greater regulation than cosmetics, but even here, FDA oversight has been minimal. The FDA considers sunscreens to be drugs because they purport to protect the skin against the harmful effects of sun exposure.[189] Although new drugs require premarket approval, as explained above, drugs that contain ingredients generally recognized as safe and effective do not.[190] In 1999, after reviewing limited toxicity data, the FDA expressed the view that "micronized" titanium dioxide is not a new drug ingredient, despite the functional differences between it and larger particles of the substance.[191] This agency pronouncement apparently has opened the door to the widespread incorporation of nanomaterials in sunscreens without further safety assessments or oversight.

F. Summing Up

Aside from laws specific to the regulation of drugs and pesticides, existing statutes leave the government poorly equipped to respond to the challenge posed by nanomaterials.[192] While the statutes discussed above might be of some use after more data is gathered and specific risks are identified, none of them offers a framework for addressing the uncertainty posed by the increasing use of nanomaterials today. These statutes generally require a material-specific demonstration of harm that is not presently available for individual nanomaterials. Moreover, given the pace of technological development, and the evidentiary burdens the statutes place on government agencies, it is unlikely that existing statutes will ever provide a complete and adequate response. The rapid spread of nanotechnology is already outpacing the government's ability to identify risks, and if left unchecked will continue to do so in the future. As members of EPA's Science Advisory Board have noted, the technology is developing so quickly that government agencies can hardly keep up with it.[193] The existing regulatory structure, as cumbersome as it is, does give agencies some oversight authority, if they are willing to

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[189] *See* Sunscreen Drug Products for Over-the-Counter Human Use, 58 Fed. Reg. 28,194, 28,195 (tentative final monograph, May 12, 1993) (explaining why sunscreens are drugs as the term is used in 21 U.S.C. § 321(g)(1) (1993)).

[190] FDCA § 201(p), 21 U.S.C. § 321(p) (2006) (defining "new drug"); *id.* § 505(a), (b), (j), 21 U.S.C. § 355(a), (b), (j) (requiring approval of new drugs).

[191] Sunscreen Drug Products for Over-the-Counter Human Use, 64 Fed. Reg. 27,666, 27,671 (final monograph, May 21, 1999) ("The agency does not consider micronized titanium dioxide to be a new ingredient . . . .").

[192] In November 2006, EPA announced its intent to regulate under FIFRA certain consumer products containing nanoparticles of silver. *See* Rick Weiss, *EPA To Regulate Nanoproducts Sold As Germ-Killing*, WASH. POST, Nov. 23, 2006, at A1. Such regulation will be the first by EPA that is specific to nanotechnology, but it apparently will be limited to products advertised as germ-killing. *See id.*

[193] *See* CTR. FOR SCI., TECH. & PUB. POLICY, *supra* note 10, at 18.

exercise it.[194] Such an approach, however, only provides a temporary and inadequate answer until a more comprehensive system can be put in place.

Existing regulation—particularly TSCA and the FDCA—provides contrasting models for dealing with risk. Under TSCA, which requires no government approval before marketing can occur, the presumption is that substances are safe unless shown to be otherwise. Given the distinctive behavior of nanomaterials and the reasonable grounds for health concerns, such a presumption is unwarranted with respect to nanotechnology. The FDCA, in contrast to TSCA, establishes a licensing scheme with extensive testing requirements. These requirements are grounded in the fact that pharmaceuticals are intended to be taken into the body and are often intended to have a toxic effect on living organisms (even if those are only microorganisms).[195] The uncertainty surrounding nanotechnology's effects on health and the environment, however, suggests that so restrictive a regulatory scheme may not be warranted. The challenge for society is to develop an intermediate approach that addresses health and environmental concerns without crippling this promising industry.

IV. The Need for a New Regulatory Approach Now

Although existing statutes are inadequate to address the uncertainties of nanotechnology, one might ask whether now is the time for a regulatory response. One alternative is to await the development of more information on the risks. Another alternative is to rely on existing statutes and voluntary guidelines to address potential risks. Drawing lessons from efforts to deal with the risks of biotechnology, this Part explains why a systematic regulatory response is needed now. Specifically, the government's limited oversight of biotechnology, combined with minimal public input regarding the appropriate amount of oversight, has led to public opposition and mistrust of the field. A more transparent and proactive approach to nanotechnology's potential risks will help to forestall potentially disastrous effects while fostering confidence in the new technology.

A. Learning from Biotechnology's Missteps

Many commentators have suggested parallels between the development of biotechnology—the use of recombinant DNA techniques to transfer ge-

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[194] *Cf. id.* at 38-39 (reporting that many participants at nanotechnology workshop supported "interim, voluntary guidelines" as they are easier to create than new regulations).

[195] *See* Michael D. Greenberg, *Information, Paternalism, and Rational Decision-Making: The Balance of FDA New Drug Approval*, 13 Alb. L.J. Sci. & Tech. 663, 665 (2003) (explaining that FDA premarket approval "protects against catastrophic risks associated with exposure to toxic products").

netic material from one species to another[196]—and the challenge presented by nanotechnology today. Although the full ramifications of the spread of biotechnology are not yet known, commentators identify the failure to anticipate the controversy surrounding genetically modified organisms ("GMOs") as a mistake for the nanotechnology industry to avoid.[197] A comparison of the two fields reveals a striking similarity in the government's approach to each: minimal oversight and a stubborn insistence on the adequacy of regulatory schemes that do not account for the unique problems posed by new technologies.

Both biotechnology and nanotechnology offer the prospect of revolutionary benefits, with advances cutting across a wide range of products and industries. Both fields, however, involve new and unpredictable technologies that have the potential for catastrophic consequences should thing go awry. The uncertainty accompanying each technology is substantial, with potentially vast and irreparable impacts on human health and the environment.[198] Furthermore, existing health and environmental statutes are an imperfect fit for addressing the unique challenges posed by biotechnology and nanotechnology because these statutes were not drafted with the potential risks of these new technologies in mind. Just as the rapid development of biotechnology has tested the regulatory system, nanotechnology threatens to overwhelm the government's ability to identify and address risks. And although the tort system is available as a backstop to deal with the shortcomings of regulatory statutes, it at best offers an incomplete solution because the negative effects of these new technologies may be latent, irreversible, and difficult to trace.[199]

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[196] *See* Gregory N. Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals*, 45 WM. & MARY L. REV. 2167, 2175 (2004).

[197] *See, e.g.*, John Balbus et al., *Getting Nanotechnology Right the First Time*, ISSUES SCI. & TECH., Summer 2005, at 65, 67 ("As demonstrated with genetically modified organisms just a few years ago, rapid commercialization combined with a failure to address risks early on can lead to product bans and closed markets . . . ."); Service, *supra* note 54, at 1732 (noting concerns that reports of negative effects of nanotechnology could spark public backlash similar to those that have hampered "agricultural biotechnology and nuclear power"); Lin-Easton, *supra* note 7, at 118 ("Parallels can be drawn between a potential controversy over nanotechnology research and the controversy surrounding DNA research . . . ."); Weiss, *supra* note 17 (quoting National Science Foundation Director saying that "[w]e can't risk making the same mistakes that were made with the introduction of biotechnology").

[198] *See* Mandel, *supra* note 196, at 2190-202 (describing potential risks, including the escape of transgenic organisms or the unintended transfer of genes to insect pests or invasive plants); *see also* Diamond v. Chakrabarty, 447 U.S. 303, 316-17 (1980) (noting arguments that "present a gruesome parade of horribles" that could result from biotechnology research and development, but suggesting that such concerns should be addressed to the political branches rather than the courts). *See supra* Part II.B (discussing health and environmental concerns associated with nanotechnology).

[199] *See* ALLIANZ GROUP & THE OECD, SMALL SIZES THAT MATTER: OPPORTUNITIES AND RISKS OF NANOTECHNOLOGIES 43 (2005), *available at* http://www.oecd.org/dataoecd/4/38/35081968.pdf (predicting that plaintiffs will have difficulty proving that illnesses were caused by exposure to nanomaterials); Mandel, *supra* note 196, at 2256 (noting that many of the risks posed by biotechnology result in latent harm and that damages caused may be too great for the

The federal government's approach to biotechnology has been largely hands-off. A 1974 report issued by a National Academy of Sciences committee called for general oversight of genetic engineering by the National Institutes of Health ("NIH").[200] In response, the NIH established an advisory committee composed primarily of scientists to review all research proposals for compliance with applicable guidelines.[201] This approach established some oversight to account for health and environmental concerns, but left the regulation of the field to the scientific community.

Controversy grew over the inadequacy of this approach, and in 1986, the federal government adopted the Coordinated Framework for the Regulation of Biotechnology.[202] The Coordinated Framework essentially declared that EPA, the FDA, and the U.S. Department of Agriculture ("USDA") already possessed adequate legal authority to regulate biotechnology.[203] Rather than calling for new regulatory authority, the Coordinated Framework established mechanisms designed to facilitate interagency coordination.[204] Undergirding the Coordinated Framework—and the determination that biotechnology could be addressed under existing statutes and regulations—were two critical assumptions: first, that the techniques of biotechnology are not riskier than traditional breeding techniques; and second, that GMOs are not fundamentally different from other organisms.[205] Supported by a scientific community that was increasingly confident about the safety of genetic engineering, the Coordinated Framework enabled the government to promote the growth of the biotechnology industry while maintaining the appearance of regulatory control.[206] The Coordinated Framework also seemed to be the easiest way to deal with what critics perceived to be a complex and rapidly developing problem. As the government admitted, "there did not appear to be an alternative, unitary, statutory approach since the very broad spectrum of products obtained with genetic engineering cut[s] across many product uses regulated by different agencies."[207] Today, the government con-

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responsible party to cover). *But see* SWISS RE, *supra* note 44, at 39 (suggesting that for certain products containing nanomaterials, tracing harmful effects to their sources "could be possible").

[200] *See* SHEILA JASANOFF, DESIGNS ON NATURE 46 (2005).

[201] *See id.* at 47-48.

[202] Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986).

[203] *Id.* at 23,303.

[204] *Id.*; *see* JASANOFF, *supra* note 200, at 52.

[205] Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23,302-03; *cf.* Emily Marden, *Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture*, 44 B.C. L. REV. 733, 738 (2003) (identifying three tenets of federal policy on biotechnology: (1) regulation would focus on products of genetic engineering rather than the process itself; (2) regulation must be grounded in verifiable scientific risks; and (3) genetically modified products are on a continuum with existing products and therefore may be regulated under existing statutes).

[206] *See* JASANOFF, *supra* note 200, at 53.

[207] Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23,303.

tinues to follow a general approach of promoting genetically modified ("GM") foods.[208]

Although a few commentators assess the government's approach to biotechnology in a positive light,[209] criticism has persisted. Scientists continue to worry about negative impacts on genetic and biological diversity, food chains, and ecological communities.[210] The unintended out-crossing of GM crops, for example, could transfer herbicide and insect resistance to weedy relatives.[211] Furthermore, many commentators have faulted the exclusion of public input from biotechnology policymaking. Professor Sheila Jasanoff contends, for instance, that "biotechnology ceased to be a matter for broad participatory politics and became instead an object of bureaucratic decision making under the guidance of technical experts."[212] The lack of public input laid the foundation for a public backlash triggered by incidents that suggested that government oversight of GM foods had been inadequate. In 2000, for example, GM StarLink corn, which had been approved for commercial use only as animal feed, was discovered in corn products sold to consumers.[213] This discovery led to cancellation of the StarLink registration, product recalls, rejection of U.S. corn shipments, and class-action lawsuits.[214] It also helped to fuel a growing grassroots movement to ban or restrict GMOs.[215]

The primary lesson that nanotechnology companies have derived from the biotechnology experience is the need to engage and educate the public early on about the relevant risks and benefits.[216] Lack of information about

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[208] *See* Marden, *supra* note 205, at 740-43 (describing policy statements that opposed imposition of regulatory burdens on biotechnology industry).

[209] *See, e.g.*, Reynolds, *supra* note 7, at 199 (contending that "the horrible scenarios envisioned by early critics . . . have neither materialized nor turned out to be a real threat").

[210] *See* Sian Mooney & David Gerard, *Using Environmental Bonds To Regulate the Risks of GM Crops: Problems and Prospects*, 2 ENVTL. BIOSAFETY RES. 25, 26 (2003).

[211] *See id.*

[212] JASANOFF, *supra* note 200, at 52; *see also* Marden, *supra* note 205, at 753-58 (describing public backlash against GM products beginning in late 1990s following absence of public discussion prior to their commercialization).

[213] *See* JASANOFF, *supra* note 200, at 135; Mandel, *supra* note 196, at 2203.

[214] *See* Mandel, *supra* note 196, at 2204-06.

[215] *See* Kimberly Geiger, *Bill Would Prevent New Bans by Counties on Modified Crops*, S.F. CHRON., July 29, 2006, at B2 (listing four California counties that prohibit planting of genetically engineered crops); Eric Bailey, *Farmers Defend Engineered Crops*, L.A. TIMES, Oct. 19, 2004, at B1 (reporting on ballot measures to ban cultivation of GM crops).

[216] *See, e.g.*, Press Release, House Comm. on Sci. & Tech., More Research on Environmental, Safety Impacts of Nanotechnology Is Critical to Success of the Industry (Nov. 17, 2005), *available at* http://gop.science.house.gov/press/109/109-165.htm (reporting testimony urging more education and engagement with the public on nanotechnology in order to avoid skepticism encountered with respect to other technologies); Lynn L. Bergeson, *Avoid Mistakes of the Past: Develop Nano Responsibly*, ENVTL. F., July-Aug. 2005, at 41, 41 ("If the right-to-know movement has taught us anything, it is that the public's perception of safety is essential and no emerging technology will survive without broad public support."); Service, *supra* note 54, at 1734 (reporting view of National Science Foundation advisor that companies should disclose which products contain nanomaterials in order to "avoid the sort of consumer backlash Monsanto suffered after it fought labeling its genetically modified crops").

health and environmental implications—and about the oversight process—tends to foster public mistrust and suspicion, and can ultimately hamper even beneficial uses of a new technology.[217] Thus, although the StarLink incident resulted from a specific failure in supervision of the agricultural supply chain,[218] it has served as a rallying point for opponents of biotechnology generally.[219] Given the relatively unformed views of the public with respect to nanotechnology and the absence, thus far, of a tragic mishap, commentators often remark that the nanotechnology industry has a unique opportunity to "get it right."[220] Making nanotechnology's growing role transparent, investigating potential risks, and addressing concerns now can reduce the likelihood of future problems and simultaneously build public support for nanotechnology.

The biotechnology experience also offers further parallels and lessons for nanotechnology that are worth noting. The Coordinated Framework rested on the questionable assumption that biotechnology's techniques and products posed risks no different in nature or degree from conventional breeding techniques.[221] The lack of regulation of nanotechnology reflects a similar assumption that nanotechnology's potential risks are no different than those posed by ordinary materials. The little that we do know about nanomaterials suggests that they are likely to pose hazards that are substantially different from those posed by conventional materials.[222] Unlike biotechnology, the potential hazards of which are primarily ecological,[223] nanotechnology's potential hazards directly threaten both human health and the environment.[224] In addition, nanotechnology will likely enable the produc-

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[217] *See* Reynolds, *supra* note 7, at 208 (reporting congressional testimony of nanotechnology researcher that failure of biotechnology industry to produce and share information with public "was a controlling factor in the industry's fall from favor"); E. Donald Elliott, *Regulate Nano Now*, ENVTL. F., July-Aug. 2005, at 43, 43.

[218] *See* Mandel, *supra* note 196, at 2207.

[219] *See* JASANOFF, *supra* note 200, at 136, 276 (noting that StarLink episode "eventually lead to stricter controls").

[220] *See, e.g.*, Press Release, House Comm. on Sci. & Tech., *supra* note 216; *Developments in Nanotechnology: Hearing Before the S. Comm. on Commerce, Sci. and Transportation*, 109th Cong. 2 (2006) [hereinafter *Davies Testimony*], *available at* http://commerce.senate.gov/pdf/davies-021506.pdf (testimony of J. Clarence Davies, Senior Advisor, Project on Emerging Nanotechnologies); Balbus et al., *supra* note 197, at 71.

[221] *Cf.* Mooney & Gerard, *supra* note 210, at 26 ("GM crops are regulated in a similar way to conventional crops in the sense that once the crop has passed *ex ante* . . . requirements, there are no statutory remedies for public or private parties that are damaged by users or manufacturers of an approved GM crop.").

[222] *See supra* Part II.B.

[223] *See* John Charles Kunich, *Mother Frankenstein, Doctor Nature, and the Environmental Law of Genetic Engineering*, 74 S. CAL. L. REV. 807, 816-22 (2001) (describing evidence that supports theories of how GM crops might result in ecological harm, while noting that possibility of health risks for consumers of GM foods "is at present only a matter of conjecture").

[224] *See supra* Part II.B.

tion of entire classes of materials whose risks could not have been anticipated when existing statutes were drafted.[225]

The attempt to regulate biotechnology under the Coordinated Framework also illustrates the difficulties involved in relying on general statutes to address the unique risks posed by emerging technologies. Various commentators have identified gaps and inconsistencies in the regulation of GM products resulting from the attempt to apply legislation enacted long before such products were conceivable.[226] Government agencies have had difficulty responding to technological advances, and the division of authority among agencies has unnecessarily exposed the public and the environment to adverse risks.[227] Attempting to regulate nanotechnology through existing statutes likely would result in similar problems. Indeed, the range of potential nanotechnology applications suggests that the difficulties will be even greater. Already, the commercial proliferation of cosmetics and other products containing nanomaterials—with little or no regulatory oversight—points to the existence of regulatory gaps and the need for an approach specific to nanomaterials.

B. Why Act Now?

1. *Paradigms for Addressing Uncertainty*

a. The Harm Principle

U.S. policy on biotechnology is typical of the approach of modern industrial societies with respect to new technologies: such technologies generally develop and come to market with little or no government oversight.[228] This, of course, is often the path of least resistance. Only when problems become obvious do we respond, if we respond at all, with prohibition or regulation.[229] Although this approach may have contributed to the rapid pace

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[225] *See* EPA WHITE PAPER, *supra* note 10, at 12 (noting that nanotechnology may lead to production of "such dramatically different technology products that the manufacture, use and recycling/disposal of these novel products . . . may prove to be a daunting task").

[226] *See, e.g.*, Rebecca M. Bratspies, *Glowing in the Dark: How America's First Transgenic Animal Escaped Regulation*, 6 MINN. J. L. SCI. & TECH. 457, 458-61 (2005) (criticizing FDA decision to allow genetically engineered GloFish to enter commerce without regulation); Mandel, *supra* note 196, at 2230-42 (listing regulatory gaps, overlaps, and inconsistencies, and examples of agencies acting outside their area of expertise).

[227] *See* Mandel, *supra* note 196, at 2172.

[228] *See* Carl F. Cranor, *Asymmetric Information, the Precautionary Principle, and Burdens of Proof*, *in* PROTECTING PUBLIC HEALTH AND THE ENVIRONMENT 74, 81 (Carolyn Raffensperger & Joel A. Tickner eds., 1999) (explaining that regulation of carcinogens in the United States is largely done by means of post-market regulatory laws).

[229] *See* Albert C. Lin, *The Unifying Role of Harm in Environmental Law*, 2006 WIS. L. REV. 897, 898-99 (2006); Percival, *supra* note 115, at 22 ("While precaution has long been an important aspiration of much of United States environmental law, in practice, regulatory policy generally has been reactive, rather than truly precautionary.").

of technological innovation,[230] it has not come without serious health and environmental costs. History is rife with examples of technologies that were first thought to be beneficial or even miraculous, but that were later found to have irreversible and catastrophic effects. For example, asbestos came into widespread use in insulation and brake linings, but ultimately caused hundreds of thousands of deaths from mesothelioma (cancer of the lining of the chest or abdomen).[231] And lead, first added to gasoline in the 1920s to reduce "engine knock," caused thousands of heart attacks annually and cognitive damage in millions of children.[232] Even biotechnology, while not linked to harms of the same magnitude, has run into problems because of the inadequate assessment and public discussion of risks. In many instances of technology gone awry, there was little hard data regarding risks when the technology was introduced.[233]

Although the "sound science" rhetoric common in political circles today may suggest otherwise,[234] neither scientific principles nor modern risk-analysis techniques require a demonstration of harm as a prerequisite for regulation.[235] Risk analysis, which plays a significant role in many environ-

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[230] *Cf.* 15 U.S.C. § 2601(b)(3) (2006) (mandating that regulation not "impede unduly or create unnecessary economic barriers to technological innovation"). *But cf.* Paul Davies, *Regulatory Challenges with Emerging Technologies*, *in* SWISS RE CTR. FOR GLOBAL DIALOGUE, NANOTECHNOLOGY: "SMALL SIZE—LARGE IMPACT?" 56, 57 (2005), *available at* http://www.swissre.com/Internet/pwswpspr.nsf/fmBookMarkFrameSet?ReadForm&BM=./vwAllbyIDKeyLu/mbui-6e7gdn?OpenDocument (arguing that stringent regulation may slow the pace of innovation in the short term, but will ultimately stimulate innovation and foster growth of new technology by engendering public confidence).

[231] *See* David Gee & Morris Greenberg, *Asbestos: From "Magic" to Malevolent Mineral*, *in* THE PRECAUTIONARY PRINCIPLE IN THE 20TH CENTURY 49, 49-63 (Poul Harremoes et al. eds., 2002); J. Peto, *The European Mesothelioma Epidemic*, 79 BRIT. J. CANCER 666, 671 (1999) (projecting 250,000 deaths in Western Europe from mesothelioma from 1995 to 2029 as a result of asbestos exposure); *see also* Balbus et al., *supra* note 197, at 67 (reporting estimated total cost of liability for asbestos-related losses could reach two hundred billion dollars).

[232] *See* PERCIVAL ET AL., *supra* note 92, at 29-31 (reporting estimated monetized benefits of eliminating lead in gasoline); Jamie Lincoln Kitman, *The Secret History of Lead: Special Report*, NATION, Mar. 20, 2000, at 11, 12 (estimating that sixty-eight million American children had toxic exposures to lead in gasoline from 1927 to 1987).

[233] *See Introduction* to THE PRECAUTIONARY PRINCIPLE IN THE 20TH CENTURY, *supra* note 231, at 3 (noting that toxic activities often are "regarded at one time as harmless by governments and others . . . until evidence about their harmful effects emerge[s]"). Lead, however, was introduced into gasoline on a widespread basis despite the existence of a fairly well-developed body of knowledge about its dangers. *See* Kitman, *supra* note 232, at 19-24; Percival, *supra* note 115, at 37-50. There was also evidence of the harmful effects of asbestos exposure long before attempts to ban it. *See id.* at 50-52.

[234] *See* Holly Doremus, *The Purposes, Effects, and Future of the Endangered Species Act's Best Available Science Mandate*, 34 ENVTL. L. 397, 415 (2004) (noting use of the term "sound science" by regulated industries and antiregulatory groups to argue that regulations should not be imposed without strong scientific justification).

[235] *Cf.* Percival, *supra* note 115, at 78 (contending that "[p]roponents of cost-benefit analysis as a regulatory decision rule" often "end up suggesting something like a precautionary approach" when asked to respond to highly uncertain but potentially catastrophic risks).

mental statutes,[236] involves two distinct modes of analysis: risk assessment and risk management. Risk assessment evaluates the sources of risk exposure, the persons or objects exposed to risk, and the extent of adverse effects likely to result from exposure.[237] Risk management is the values-driven process of making policy decisions in light of the data generated by risk assessments.[238] Risk management does not require that society respond only to those risks that threaten greater costs than benefits or only to those risks that surpass a certain threshold. Determining which risks to respond to, and how to respond, are policy judgments most properly subject to the political process.

Society's tendency to respond only to demonstrated harm is better explained by the harm principle than by risk analysis.[239] Most famously articulated by philosopher John Stuart Mill, the principle provides that harm is a necessary condition for government intervention.[240] While the harm principle has served as the "leading philosophical, political, and legal rationale" for regulation in liberal polities, it has also hindered attempts to address situations of uncertainty.[241]

The difficulty of applying TSCA to nanomaterials provides a prime illustration of the harm principle's limitations. As explained above, TSCA requires a finding of risk of harm as a prerequisite to regulatory action.[242] This is an innovation on the common law in that it permits intervention based on an assessment of future risk, rather than demanding proof of past harm.[243] But by premising regulation on demonstrated risk, TSCA shoehorns EPA into a binary choice: EPA may act if it makes a positive finding, but it may not act in all other circumstances.[244] Because the existence of uncertainty itself has no regulatory significance, situations of uncertain risk are treated as equivalent to situations of no known risk.[245] Nanotechnology presents just

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[236] AM. CHEM. SOC'Y & RES. FOR THE FUTURE, UNDERSTANDING RISK ANALYSIS 7, 13-16 (1998) [hereinafter ACS], *available at* http://www.rff.org/rff/Publications/loader.cfm?url=/Commonspot/security/getfile.cfm&PageID=14418.

[237] *Id.* at 8-9; NAT'L RESEARCH COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT 18 (1983).

[238] ACS, *supra* note 236, at 11; PERCIVAL ET AL., *supra* note 92, at 345; NAT'L RESEARCH COUNCIL, *supra* note 237, at 18-19. The distinction between risk assessment and risk management is somewhat artificial, as the application of risk assessment techniques invariably requires policy decisions more characteristic of the risk management process. *See* PERCIVAL ET AL., *supra* note 92, at 405.

[239] *See* Lin, *supra* note 229, at 921-27 (discussing harm principle).

[240] *See* JOHN STUART MILL, ON LIBERTY 80 (David Bromwich & George Kateb eds., Yale Univ. Press 2003) (1859) ("[T]he only purpose for which power can be rightfully exercised over any member of a civilised community, against his will, is to prevent harm to others."); Lin, *supra* note 229, at 921-22.

[241] *See* Lin, *supra* note 229, at 968-77.

[242] *See supra* Part III.A.

[243] *See* Lin, *supra* note 229, at 910 & n.72.

[244] *See* Flournoy, *supra* note 95, at 366 (criticizing rigid and binary nature of TSCA's decisionmaking structure).

[245] *See supra* text accompanying notes 119-120.

such a situation of great uncertainty: the data are too inadequate to support risk assessment and will continue to be inadequate for some time. Under the traditional approach, the ability to take regulatory action in the meantime is limited.

b. The Precautionary Principle

An alternative to the traditional approach involves application of the precautionary principle. The basic premise of the precautionary principle is that conclusive evidence of risk is not a prerequisite for the adoption of measures to address potential risks.[246] Contrary to caricatured descriptions,[247] the precautionary principle does not demand that all activities be proven safe before they may proceed.[248] Nor does the precautionary principle require that activities be halted based on pure speculation.[249] Rather, the principle applies only to those potential hazards sufficiently serious or irreversible that society deems them unacceptable.[250] Moreover, the precautionary principle requires plausible or scientifically tenable grounds for concern, based on a hypothesis that is consistent with background knowledge and theories.[251] Criticisms of the principle as unscientific are thus unfounded.[252]

Stated positively, the precautionary principle provides that "[w]hen human activities may lead to morally unacceptable harm that is scientifically plausible but uncertain, actions shall be taken to avoid or diminish that

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[246] *See* Christian Gollier & Nicolas Treich, *Decision-Making Under Scientific Uncertainty: The Economics of the Precautionary Principle*, 27 J. RISK & UNCERTAINTY 77, 77 (2003).

[247] Numerous variations of the precautionary principle have been articulated. *See* Per Sandin, *Dimensions of the Precautionary Principle*, 5 HUM. & ECOLOGICAL RISK ASSESSMENT 889, 902-05 (1999) (listing various formulations of the principle). Critics have tended to focus their attacks on the more extreme versions of the principle. *See* JACQUELINE PEEL, THE PRECAUTIONARY PRINCIPLE IN PRACTICE 2 (2005); *see, e.g.*, Cass R. Sunstein, *Irreversible and Catastrophic: Global Warming, Terrorism, and Other Problems*, 23 PACE ENVTL. L. REV. 3, 6 (2005).

[248] *See* Percival, *supra* note 115, at 22 (arguing that critics of the precautionary principle "are confusing the precautionary principle with the separate question of how precautionary regulatory policy should be").

[249] *See id.*

[250] WORLD COMM'N ON THE ETHICS OF SCIENTIFIC KNOWLEDGE AND TECH., UNITED NATIONS EDUC., SCIENTIFIC & CULTURAL ORGANIZATION, THE PRECAUTIONARY PRINCIPLE 13 (2005) [hereinafter UNESCO], *available at* http://unesdoc.unesco.org/images/0013/001395/139578e.pdf; *Introduction*, *supra* note 233, at 4 (noting that the precautionary principle, as originally developed, was "to be used in situations of potentially serious or irreversible threats to health or the environment").

[251] *See* UNESCO, *supra* note 250, at 13, 15.

[252] *See* David Santillo et al., *The Precautionary Principle in Practice: A Mandate for Anticipatory Preventative Action*, *in* PROTECTING PUBLIC HEALTH AND THE ENVIRONMENT, *supra* note 228, at 36, 45 ("The fundamental difference between risk and precautionary approaches is not that one uses science while the other does not, but simply the way in which scientific evidence is employed for decision making at the science-policy interface."); Daniel A. Farber, *Probabilities Behaving Badly: Complexity Theory and Environmental Uncertainty*, 37 U.C. DAVIS L. REV. 145, 170 (2003) (noting criticisms of precautionary principle, including its alleged irrationality).

harm."[253] This formulation conceptualizes the precautionary principle as modifying the harm principle, rather than rejecting it, by calling for consideration of uncertain risks. The precautionary principle is essentially a burden-shifting device that places the responsibility on industry to demonstrate lack of harm before innovations may be introduced.[254] The principle, however, does not dictate how precautionary regulatory policy should be administered.[255] Rather, the principle provides a justification for the development of intermediate options other than the binary choice between regulation and no regulation. The existence of uncertainty itself can be treated as a fact of regulatory significance that warrants an intermediate level of oversight that would be less restrictive than prohibition or strict regulation.[256]

Application of the precautionary principle to nanotechnology is appropriate because there exist scientifically tenable grounds for believing that the release of nanomaterials may result in serious harm to human health and the environment. As discussed earlier, existing information on the unique characteristics of nanoparticles and on their ability to penetrate deeply into the body, as well as experimental results suggestive of toxicity, provide a reasonable basis for concern.[257] Given the growing use of nanomaterials, decisionmakers do not have the luxury of waiting for exhaustive test results.[258] Also counseling in favor of a precautionary approach is the fact that nanoparticles are likely to be difficult to remove from the environment, meaning that negative consequences may be irreversible. Nanoparticles may be removed from drinking water, for example, only through centrifugation or ultrafiltration, neither of which is suitable for processing large volumes.[259]

2. *EPA's Current Approach*

Recognizing the need for a more proactive approach is only the first step toward deciding what that approach should be. Indeed, there are reasonable arguments against the immediate enactment of comprehensive regulation governing nanomaterials. First, comprehensive regulation may not be

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[253] UNESCO, *supra* note 250, at 14.

[254] *See* DAVID HUNTER ET AL., INTERNATIONAL ENVIRONMENTAL LAW AND POLICY 511 (3d ed. 2007) ("[M]any commentators . . . argue that the precautionary principle acts to switch the burden of proof necessary for triggering policy responses from those who support prohibiting or reducing a potentially offending activity to those who want to continue the activity.").

[255] *See* Percival, *supra* note 115, at 34.

[256] *See* Flournoy, *supra* note 95, at 387-89 (recommending that Congress reform the regulatory decisionmaking process by providing agencies with authority to undertake a range of responses upon findings of uncertainty).

[257] *See supra* Part II.B.

[258] *Cf.* PEEL, *supra* note 247, at 67 (arguing that "time constraints on health and environmental . . . decision-makers justify a more relaxed 'standard of proof' and a wider consultation of both lay and expert material in reaching a decision").

[259] *See* SWISS RE, *supra* note 44, at 31.

viable in the current political climate.[260] Second, the dearth of information on health and environmental effects suggests that regulation in a form comparable to that of existing statutes may not be possible. Existing regulatory schemes rely heavily on detailed risk assessments, which are presently infeasible for nanotechnology. While there is agreement as to the need for additional research into the risks of nanoparticles,[261] such research is not likely to generate information sufficient to perform risk assessments for at least a decade.[262] The challenge is complicated by the fact that characteristics of nanomaterials may depend on numerous factors other than size, including the type of coating found on a nanoparticle, how a particular nanomaterial was produced, and whether nanoparticles are encountered singly or as a cluster.[263]

Given these difficulties, it is not surprising that EPA, the logical candidate for taking the lead in regulating nanotechnology, has followed a largely voluntary approach thus far. In its *Nanotechnology White Paper*, released in draft form in December 2005 and finalized in February 2007,[264] EPA acknowledged the vast uncertainty regarding the environmental fate of nanomaterials, potential routes of exposure, and environmental and health effects.[265] EPA also conceded the need for greater government involvement.[266] The Agency's recommendations, however, are modest in their scope. The *White Paper*, which consists primarily of a research agenda on the environmental implications of nanotechnology,[267] recommends that potential risks from nanomaterials be addressed through voluntary efforts to improve

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[260] *See, e.g.*, ENVTL. LAW INST., COMMENTS OF THE ENVIRONMENTAL LAW INSTITUTE ON THE ENVIRONMENTAL PROTECTION AGENCY'S NANOTECHNOLOGY WHITE PAPER EXTERNAL REVIEW DRAFT 3 (Document ID EPA-HQ-ORD-2005-0504-0010.1, 2006) [hereinafter ELI COMMENTS] ("[T]he enactment of new nanotechnology legislation related to environmental, health, and safety is unlikely, at least in the near term."); ELI, *supra* note 10, at 8 (describing consensus view of conference participants that the "likelihood that new legislation would be enacted to regulate nanotechnologies in the near to medium term was remote").

[261] *See, e.g.*, Balbus et al., *supra* note 197, at 67-69 (calling for more research to identify potential risks); Rick Weiss, *Nanotechnology Regulation Needed, Critics Say*, WASH. POST, Dec. 5, 2005, at A8 ("Equally unresolved is who should pay for the additional safety studies that everyone agrees are needed.").

[262] *See* Vicki L. Colvin, *Could Engineered Nanoparticles Affect Our Environment?*, *in* NANOTECHNOLOGY: "SMALL SIZE—LARGE IMPACT?," *supra* note 230, at 19, 20.

[263] *See* EPA WHITE PAPER, *supra* note 10, at 31-32 (discussing difficulty of characterizing nanomaterials in light of their diversity and complexity); MICHAEL GRAY, AMEC EARTH & ENVTL., INC., COMMENTS ON THE NANOTECHNOLOGY WHITE PAPER 7 (Document ID EPA-HQ-ORD-2005-0504-0017.1, 2006); ROYAL SOC'Y, *supra* note 3, at 48 (emphasizing need to develop means of measuring nanomaterials, a task complicated by uncertainty regarding the physical properties that correlate most closely with toxicity).

[264] EPA WHITE PAPER, *supra* note 10; EPA, EXTERNAL REVIEW DRAFT NANOTECHNOLOGY WHITE PAPER (2005), *available at* http://www.epa.gov/osa/pdfs/EPA_nanotechnology_white_paper_external_review_draft_12-02-2005.pdf.

[265] *See* EPA WHITE PAPER, *supra* note 10, at 32-40, 42-62.

[266] *See id.* at 1 ("For EPA, nanotechnology has evolved from a futuristic idea to watch, to a current issue to address.").

[267] *See id.* at 82-89.

product design, reduce waste, and the like.[268] EPA is also considering establishment of a "voluntary pilot program" that would gather information voluntarily submitted by manufacturers about nanoproducts they are making and about any associated health or environmental risks.[269] As proposed, the program would offer two tiers of participation: participants in the "basic" program would provide existing information on an engineered nanoscale material, whereas participants in the "in-depth" program would also generate new information about hazards and risks.[270]

EPA's *White Paper* and proposed pilot program are important first steps, but they do not go far enough. The agency has focused on the critical task of information-gathering, but the voluntary pilot program provides no assurance that EPA will acquire the information it needs to identify and address the potential hazards of this rapidly developing field. Research costs, potential liability exposure, and the lack of tangible benefits from conducting health and safety research generate strong disincentives against manufacturers' gathering and disseminating such information.[271] These concerns will likely deter many members of the industry from participating in the program.[272] Furthermore, EPA's call for waste reduction and improved product design, even if heeded, does little to address risks that might be generated by nanomaterials intentionally incorporated into products such as foods or cosmetics. Voluntary private standards[273] are unlikely to be effective, either.[274] In the absence of a credible threat of regulation, voluntary programs,

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[268] *See id.* at 89-90.

[269] *See* NAT'L POLLUTION PREVENTION & TOXICS ADVISORY COMM. ("NPPTAC"), EPA, OVERVIEW DOCUMENT ON NANOSCALE MATERIALS 1 (2005), *available at* http://www.epa.gov/oppt/npptac/pubs/nanowgoverviewdocument20051125.pdf.

[270] *See* CTR. FOR SCI., TECH. & PUB. POLICY, *supra* note 10, at 18-19; INTERIM AD HOC WORK GROUP ON NANOSCALE MATERIALS OF THE NPPTAC, EPA, OVERVIEW OF ISSUES FOR CONSIDERATION BY NPPTAC 4-7 (2005), *available at* http://www.epa.gov/oppt/npptac/pubs/nanowgoverviewdocument20051109.pdf (making recommendations regarding voluntary program).

[271] *See* Wendy E. Wagner, *Commons Ignorance: The Failure of Environmental Law To Produce Needed Information on Health and the Environment*, 53 DUKE L.J. 1619, 1633-59 (2004) (discussing why actors who produce potentially dangerous products are unlikely to document or disclose adverse consequences).

[272] *See* David W. Case, *The EPA's HPV Challenge Program: A Tort Liability Trap?*, 62 WASH. & LEE L. REV. 147, 196-98 (2005) (noting that industry concerns over increased liability exposure have minimized levels of participation in EPA voluntary programs, and arguing that such concerns will limit the effectiveness of EPA's High Production Volume Challenge program, which is intended to develop toxicity information about chemicals produced in high volumes).

[273] For example, the Foresight Nanotech Institute, which describes itself as "the leading think tank and public interest institute on nanotechnology," Nanotechnology—Foresight Nanotech Institute, http://www.foresight.org (last visited Apr. 26, 2007) (on file with the Harvard Environmental Law Review), has published general "guidelines for the responsible development of productive nanotechnology by practitioners and industry." JACOBSTEIN, *supra* note 27, at 1.

[274] *See* Jennifer Nash, *Industry Codes of Practice: Emergence and Evolution*, *in* NEW TOOLS FOR ENVIRONMENTAL PROTECTION 235, 248 (Thomas Dietz & Paul C. Stern eds., 2002) (noting that empirical studies of Responsible Care, one of the most highly developed of all U.S. trade association efforts in environmental self-regulation, suggest that the program "has

whether public or private, will not generate the needed information or protective measures, nor will they foster public confidence in the regulatory system.[275]

Indeed, EPA's proposed approach to nanotechnology closely resembles the government's approach to biotechnology. The government responded to the problem of unknown risk presented by GMOs first by looking to self-regulation, and later by relying on existing statutes.[276] That approach may have been the path of least resistance, but it has not been effective in identifying or addressing risks. GM foods have become predominant in the marketplace with almost no regulatory oversight,[277] and attempts to prevent contamination of food supplies and cross-breeding have been unsuccessful.[278] The potential risks surrounding the use of nanomaterials call for a more aggressive approach.

3. *Now Is the Time*

Despite the lack of full information, it is not too early to put into place a legal framework for addressing nanotechnology that will serve as a foundation for more refined regulation in the future. As described above, commercial applications have already been making their way into the market for the past several years.[279] No longer are researchers, who have some awareness of the unusual properties of nanomaterials they work with, the only persons facing potential exposure. Millions of consumers are using—and likely ingesting, breathing, or absorbing—nanomaterials directly in cosmetics, sun-

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failed to reliably improve firms' internal management practices"); Sidney A. Shapiro & Randy Rabinowitz, *Voluntary Regulatory Compliance in Theory and Practice: The Case of OSHA*, 52 ADMIN. L. REV. 97, 135-39 (2000) (discussing evidence "that private standards do not prompt significant voluntary regulatory compliance" and that "even if there is compliance, private standards typically offer limited protection for the environment, workers, and consumers"); *cf.* Kathryn Harrison, *Challenges in Evaluating Voluntary Environmental Programs*, *in* NEW TOOLS FOR ENVIRONMENTAL PROTECTION, *supra*, at 263, 263 (contending that problems of data availability, credibility, and self-selection create a tendency to overstate effectiveness of voluntary programs).

[275] *See Davies Testimony*, *supra* note 220, at 5 ("Voluntary programs tend to leave out firms that most need to be regulated. Such programs also lack both transparency and accountability and thus do not contribute to public confidence in the regulatory system."); Alan Randall, *The Policy Context for Flexible, Negotiated, and Voluntary Measures*, *in* NEW TOOLS FOR ENVIRONMENTAL PROTECTION, *supra* note 274, at 311, 316 (arguing that effectiveness of voluntary agreements and industry codes "depend[s] on the presence of an effective regulator, at least in the background").

[276] *See supra* Part IV.A.

[277] *See* Rick Weiss, *Biotech Food Raises a Crop of Questions*, WASH. POST, Aug. 15, 1999, at A1 (noting that "gene-altered food is virtually unavoidable," and listing examples of processed foods that may contain genetically engineered ingredients).

[278] *See supra* Part IV.A; Andrew Pollack, *Lax Oversight Found in Tests of Gene-Altered Crops*, N.Y. TIMES, Jan. 3, 2006, at F2 (reporting on findings of USDA auditor that biotechnology regulators did not notice violations of their own rules, did not inspect planting sites when they should have, and did not ensure that genetically engineered crops were destroyed when field trials were completed).

[279] *See supra* Part I.

screens, and stain-resistant clothing, often without even knowing it. As these products are manufactured, broken down, washed off, and disposed of, the nanomaterials in them will enter the environment.[280] Moreover, the level of exposure and release of engineered nanomaterials will only increase as more applications are commercialized.[281] Concerns about potential toxicity will be easier to address in the present, while exposure is fairly limited.[282]

Indeed, although the overall political environment may not favor regulation,[283] current circumstances present a relatively favorable "policy window"[284] for establishing a regulatory framework specific to nanotechnology. Consumer and environmental groups have been calling for greater attention to nanotechnology's health and safety concerns, and they are not alone.[285] A congressional committee recently held hearings on the issue.[286] Insurance companies have called for safety testing, regulatory oversight, and other precautionary steps.[287] And many in the nanotechnology industry have advocated for more government-funded research on the environmental and safety implications of nanotechnology.[288]

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[280] *See* ELI COMMENTS, *supra* note 260, at 2 ("Even though nano-based industries are at an early stage of growth, it is likely that nanomaterials are already being emitted into the air, discharged into the water, disposed of, and shipped through the domestic and global economy . . . .").

[281] *See* ROYAL SOC'Y, *supra* note 3, at 69 (describing current applications as "incremental in nature," but pronouncing it "likely that progress will accelerate in the coming years").

[282] *See* Robert F. Service, *Nanomaterials Show Signs of Toxicity*, 300 SCIENCE 243, 243 (2003) (reporting comments of nanotechnology researcher that concerns about toxicity should be addressed while field is young and exposures limited).

[283] *See, e.g.*, ENVTL. LAW INST., GOVERNING UNCERTAINTY: THE NANOTECHNOLOGY ENVIRONMENTAL, HEALTH, AND SAFETY CHALLENGE 2 (2005), *available at* http://www2.eli.org/pdf/research/nanotech/eli.nano.statement.pdf (arguing for adaptation of existing laws and programs to regulate nanotechnologies because "the enactment of new nanotechnology legislation related to environmental, health, and safety, is unlikely, at least in the near term").

[284] JOHN W. KINGDON, AGENDAS, ALTERNATIVES, AND PUBLIC POLICIES 165-68 (2d ed. 1995) (defining policy windows as "an opportunity for advocates of proposals to push their pet solutions").

[285] *See, e.g.*, MILLER, *supra* note 181 (calling for moratorium on sale of personal care products containing engineered nanomaterials until adequate safety studies completed); NATURAL RES. DEF. COUNCIL, COMMENTS ON EPA EXTERNAL REVIEW DRAFT NANOTECHNOLOGY WHITE PAPER, JAN. 31, 2006, at 5 (Document ID EPA-HQ-ORD-2005-0504-0018.1, 2006) ("We reiterate the need for mandatory nano-specific regulations."); Balbus et al., *supra* note 197; Rick Weiss, *FDA Asked To Better Regulate Nanotechnology*, WASH. POST, May 17, 2006, at A14 (reporting on petition filed with FDA demanding regulation of nanoparticle-containing sunscreens and cosmetics).

[286] *See* Morrissey, *supra* note 24, at 46 (reporting November 2005 hearing of House Science Committee on the environmental, health, and safety implications of products using nanotechnology).

[287] *See, e.g.*, SWISS RE, *supra* note 44, at 47 ("In view of the dangers to society . . . and given the uncertainty currently prevailing in scientific circles, the precautionary principle should be applied whatever the difficulties. The handling of nanotechnologically manufactured substances should be carefully assessed and accompanied by appropriate protective measures."); ALLIANZ GROUP & THE OECD, *supra* note 199 (containing recommendations by insurance company for precautionary approach to nanotechnology).

[288] *See* Morrissey, *supra* note 24, at 46-47.

Reflecting on the problems encountered in biotechnology, some nanotechnology manufacturers reason that more safety data—and perhaps even public oversight—are necessary in order to gain the public trust.[289] In 2005, for instance, the Chairman and CEO of DuPont co-authored an editorial with the President of Environmental Defense, a non-profit organization, calling for "[c]urrent regulations, designed for a world before nanotechnology . . . [to] be reassessed and changed as needed to account for the novel properties of nanomaterials."[290] Large manufacturing companies in particular have expressed concerns about the liability risks associated with new nanomaterial products.[291] These firms worry that smaller companies or research labs lack the resources to perform testing to address health and safety concerns.[292] Their stated fear is that an inadequately tested product marketed by a small start-up company will cause adverse effects, thereby tarnishing the reputation of the entire nanotechnology industry and triggering an overly zealous regulatory reaction.[293] Smaller firms, by contrast, are more likely to oppose regulation because of their more limited ability to withstand regulatory delays.[294] Nevertheless, they may support a regulatory structure if it provides greater certainty that can facilitate planning and commercialization efforts.[295]

Although nanotechnology has not yet caught the public's attention, the public likely will support some form of regulation as it learns more about it. Recent national surveys found that the vast majority of respondents had heard little or nothing about nanotechnology.[296] And while respondents' expectations varied as to whether the risks of nanotechnology will outweigh the benefits, there appeared to be little confidence in business leaders or in

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[289] *See* DAVIES, *supra* note 10, at 18 ("The [nanotechnology] industry might endorse legislation as a way of assuring the public about the safety of [nanotechnology].").

[290] Fred Krupp & Chad Holliday, Editorial, *Let's Get Nanotech Right*, WALL ST. J., June 14, 2005, at B2.

[291] *See* BARTIS & LANDREE, *supra* note 56, at 5.

[292] *See id.* at 6.

[293] *See id.*; Morrissey, *supra* note 24, at 47 (reporting concern that a nanotechnology mishap "could rapidly chill investments and galvanize public opposition").

[294] *See* DAVIES, *supra* note 10, at 9 (observing that "[r]egulation inevitably will benefit some firms at the expense of others" and that "[f]irms dependent on rapid introduction of a product will be disadvantaged in relation to those that are not so dependent").

[295] *See* U.S. CHAMBER OF COMMERCE, COMMENTS ON EPA WHITE PAPER, Jan. 31, 2006, at 3, 6 (Document ID EPA-HQ-ORD-2005-0504-0017.1, 2006) (contending that lack of clarity in EPA's *White Paper* has left stakeholders without a concrete understanding of EPA's authority over the regulation of nanotechnology, thereby undermining business investment); Gary E. Marchant & Douglas J. Sylvester, *Transnational Models for Regulation of Nanotechnology*, 34 J.L. MED. & ETHICS 714, 715 (2006) (stating "tailored regulations can play a positive role in promoting a technology's growth as well as controlling its risks"); Morrissey, *supra* note 24, at 47 (noting that regulatory ambiguity may be slowing nanotechnology commercialization).

[296] *See* PETER D. HART RESEARCH ASSOCS., REPORT FINDINGS BASED ON A NATIONAL SURVEY OF ADULTS 5 (2006), *available at* http://www.nanotechproject.org/77/Hart (reporting that 69% of respondents had heard little or nothing about nanotechnology); Michael D. Cobb & Jane Macoubrie, *Public Perceptions About Nanotechnology: Risks, Benefits, and Trust*, 6 J. NANOPARTICLE RES. 395, 397 (2004) (finding that 83% of respondents had heard little or nothing about nanotechnology).

the government to protect the public from potential risks.[297] In another study, groups of citizens who were provided with background information on nanotechnology expressed a strong preference for government control rather than voluntary standards.[298] When asked to suggest ways to increase public trust in nanotechnology, participants favored the conducting of safety tests before new products come on the market and the provision of more information to support informed consumer choices.[299]

The present time is particularly opportune for the development of a framework regulatory regime because public opinion on nanotechnology is relatively unformed. To the extent that opinions already exist, they may be subject to change or persuasion.[300] If the government does not address nanotechnology now, however, initial views may become polarized and entrenched due to psychological phenomena such as the biased assimilation of new data, avoidance of cognitive dissonance, and group polarization.[301] Should the risks and benefits of nanotechnology remain uncertain for some time, as is likely to be the case, rational democratic discourse and thoughtful solutions may become less likely even as uncertainties are resolved.[302] Alternatively, the discovery of harmful effects may trigger a public backlash against nanotechnology in general or a regulatory overreaction by a Congress eager to address a problem receiving sudden media attention.[303]

V. The Proposal

The uncertainty surrounding the health and environmental effects of nanomaterials calls for an approach that promotes research, gathers and analyzes risk information, and uses the data gathered to inform regulation. Moreover, the possibility of serious health and environmental consequences—and concerns of deterrence, compensation, and fairness—suggest the need for a mechanism to ensure that potential costs are internalized by the nanotechnology industry.[304] Because society will ultimately have to make policy decisions about how to handle nanotechnology, it will also be impor-

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[297] *See* Peter D. Hart Research Assocs., *supra* note 296, at 7-8; Macoubrie, *supra* note 20, at 5 (recounting results of 2004 experimental study); Cobb & Macoubrie, *supra* note 296, at 398, 400.

[298] *See* Macoubrie, *supra* note 20, at 14 (reporting that 55% of study participants believed that government control beyond voluntary standards is necessary, 11% believed that voluntary standards would be adequate, and the rest were unsure).

[299] *See id.*

[300] *See* Gregory N. Mandel, *Technology Wars: The Failure of Democratic Discourse*, 11 Mich. Telecomm. & Tech. L. Rev. 117, 142-43 (2005).

[301] *See id.* at 159-69.

[302] *See id.* at 143.

[303] *See Davies Testimony*, *supra* note 220, at 2 (warning of the risk of public rejection of nanotechnology); Balbus et al., *supra* note 197, at 67; Reynolds, *supra* note 7, at 207.

[304] *See* James Boyd, *Financial Responsibility for Environmental Obligations: Are Bonding and Assurance Rules Fulfilling Their Promise?*, 20 Res. L. & Econ. 417, 419 (2002) (discussing purposes behind bonding and other assurance mechanisms).

tant to raise public awareness in order to inform future debate about nanotechnology. This Part describes a proposed statutory framework for regulating nanomaterials that incorporates these concerns.

As an initial matter, defining the universe of products subject to regulation will require some attention. The widely accepted description of nanomaterials as those materials having a scale of one hundred nanometers or less may provide a relatively bright line for administrative purposes.[305] Nevertheless, such a definition may not encompass all materials that possess unique properties and that may pose unique risks, and consideration of a more functional definition may be necessary.[306]

Within the universe of nanomaterials, those found in a free form, as opposed to those embedded in composite materials, pose the greatest potential for negative health and environmental effects.[307] The proposed statute would reflect this distinction by regulating products containing free nanomaterials more closely. All products containing nanomaterials would be subject to mandatory notification and labeling requirements. Products containing free nanomaterials, however, would also be subject to a screening process, post-market monitoring, and bonding requirements. These proposed requirements, which are described in further detail below, would be instituted against the backdrop of the existing tort system and would enhance its ability to achieve deterrence, compensation, and fairness goals.

A. Requirements Applicable to All Products Containing Nanomaterials

1. *Notification*

Under the proposal, all manufacturers of products containing nanomaterials, whether free or embedded, would be required to provide EPA with notice prior to the manufacture of a nanomaterial or a product containing a nanomaterial. Distributors of imported products containing nanomaterials would also be subject to these requirements. The contents of the notice would include a description of the substance, the manufacturing process, resulting by-products, and available information on health and environmental effects, as well as an estimate of the number of individuals who will be exposed to the substance and the amount to be manufactured or distributed.

For the most part, the notice would provide the same information as the PMN currently required under TSCA,[308] and thus could be implemented in part via EPA rulemaking. In such a rulemaking, EPA would make clear that all nanomaterials are to be treated as "new chemical substances" for pur-

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[305] *See supra* note 28 and accompanying text.

[306] *Cf.* TAYLOR, *supra* note 184, at 17 (recommending FDA attention to task of defining what nanomaterials should require additional safety evaluation).

[307] *See supra* notes 50-51 and accompanying text.

[308] *See* TSCA § 5(d), 15 U.S.C. § 2604(d) (2006). TSCA does not require a PMN to include a description of the manufacturing process. *See id.*

poses of section 5 of TSCA.[309] Legislation to establish a notification requirement would be preferable, however, for several reasons. First, an EPA rule, unlike a new statute, would be subject to a legal challenge that the rule impermissibly expands the scope of EPA's regulatory authority under TSCA. Second, because the PMN requirement is triggered only by the manufacture of new substances, manufacturers of products containing nanomaterials similar or identical to nanomaterials already in commerce may claim that they need not submit a PMN.[310] A new statute could preclude such arguments by mandating notification for all products containing nanomaterials. Third, and perhaps most importantly, TSCA contains exemptions for foods, drugs, cosmetics, and other goods that are already incorporating nanotechnology to a significant degree. A statute containing a notification requirement for all products containing nanomaterials would enable a single government agency to keep track of all uses of nanomaterials as they spread into the marketplace. In a context where research needs are formidable, if not overwhelming, it is critical to have a coordinated approach that can gather information efficiently, look for patterns and trends, and determine research priorities.[311]

A notification requirement imposes a relatively small financial and regulatory burden on manufacturers because much of the information sought would already have been generated in the development of new products.[312] The notification will not be effective, however, without a standard system of nomenclature and metrology. Given the diversity and complexity of nanomaterials, present chemical representation and nomenclature conventions may not be adequate to identify or characterize some nanomaterials.[313] Accurate reporting and labeling of nanomaterials, let alone valid comparisons of research results, depend on standardized nomenclature conventions to avoid ambiguity and confusion.[314] It is thus essential that EPA and various organi-

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[309] *See id.* § 2604(a)(1)(A). The regulation would also need to state that potential regulatory exemptions, such as the Low Volume Exemption, are inapplicable.

[310] *See* WILLIAM F. PEDERSEN, REGULATING NANOTECHNOLOGY BY INFORMATION DISCLOSURE 3 (2005), *available at* http://www2.eli.org/pdf/research/nanotech/Presentations/pedersen.pdf (identifying concerns that have deterred EPA from asserting PMN jurisdiction over nanomaterials).

[311] *See Rejeski Testimony*, *supra* note 84, at 8-10 (calling for increased coordination and funding of risk-related research); BARTIS & LANDREE, *supra* note 56, at 17-18 (recommending "a unified federal strategy" for determining and managing the health risks of nanomaterials).

[312] *See* NAT'L POLLUTION PREVENTION & TOXICS ADVISORY COMM., *supra* note 269, at 5 (stating that "most producers, processors, users, and researchers" of nanomaterials probably have information about materials' characteristics).

[313] *See* EPA WHITE PAPER, *supra* note 10, at 31-32; *cf.* Kevin W. Powers et al., *Research Strategies for Safety Evaluation of Nanomaterials, Part VI: Characterization of Nanoscale Particles for Toxicological Evaluation*, 90 TOXICOLOGICAL SCI. 296, 301-02 (2006) (discussing nanoparticle characterization techniques).

[314] *See* EPA WHITE PAPER, *supra* note 10, at 31-32; NANOTECHNOLOGY PANEL, AM. CHEMISTRY COUNCIL, COMMENTS OF THE NANOTECHNOLOGY PANEL OF THE AMERICAN CHEMISTRY COUNCIL ON THE NANOTECHNOLOGY WHITE PAPER EXTERNAL REVIEW DRAFT 9 (Document ID EPA-HQ-ORD-2005-0504-0011.1, 2006) (noting importance of identifying and characterizing nanomaterials); SWISS RE, *supra* note 44, at 37 (explaining importance of standardization for comparison of risk assessments and for regulatory measures).

zations redouble their efforts to develop a standard terminology and nomenclature for nanomaterials.[315]

2. *Labeling*

In addition to notification, the proposed scheme would require all manufacturers and distributors of products containing nanomaterials to label their products as such, to identify the specific nanomaterial, and to provide a brief comparison of the nanomaterial with the bulk version of the material. Manufacturing facilities where nanomaterials are in use would be required to provide similar information to their employees. As noted above, the feasibility of a labeling requirement would depend in part on the development of standard terminology and nomenclature to describe nanomaterials.

A primary purpose of labeling requirements is to facilitate more efficient functioning of the market through better informed consumer choice.[316] For nanomaterials, the ability of labeling to advance that purpose would be constrained by the lack of toxicity data. Labeling promotes not only economic efficiency, however, but also personal liberty and democratic deliberation.[317] A labeling requirement for nanomaterials would enable consumers to decide whether to purchase conventional products, whose risks may be better known, or "new and improved" products containing nanomaterials, whose health effects are more uncertain.[318] Likewise, better-informed workers may demand greater safety precautions or wage premiums in exchange for occupational health uncertainty.[319] In addition, workers may monitor their health more closely, and any workers who do become ill as a result of exposure to nanomaterials will be in a better position to demonstrate that such exposure caused their illness.[320] Labeling requirements will also motivate industries to take more care regarding the safety of their products and

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[315] *See* EPA WHITE PAPER, *supra* note 10, at 32 (mentioning EPA deliberations with the American National Standards Institute, American Society for Testing and Materials, International Organization for Standardization ("ISO"), and Chemical Abstracts Service); ELI, *supra* note 10, app. C at C11 (noting that the ISO is setting up a committee "to address nomenclature and related issues").

[316] *See* Clifford Rechtschaffen, *The Warning Game: Evaluating Warnings Under California's Proposition 65*, 23 ECOLOGY L.Q. 303, 313 (1996); *see also* MENDELOFF, *supra* note 165, at 209-10 (discussing economic efficiency and rights-based rationales for information disclosure).

[317] *See* Lyndon, *supra* note 164, at 1859-60 (discussing ethical and economic justifications for disclosure requirements); Cass R. Sunstein, *Informing America: Risk, Disclosure, and the First Amendment*, 20 FLA. ST. U. L. REV. 653, 655-58 (1993) (explaining arguments for informational remedies based on grounds of liberty, economic efficiency, and democracy).

[318] *See* Rechtschaffen, *supra* note 316, at 314 ("Information promotes individual autonomy by providing individuals with knowledge of the risks involved in their choices and allowing them to decide whether or not to encounter these risks."); Feder, *supra* note 77 (reporting comment of scientist that empowering people to make choices is critical and that people "often take what appears [sic] to be riskier options").

[319] *See* Rechtschaffen, *supra* note 316, at 313-14.

[320] *See* Lyndon, *supra* note 164, at 1830-31.

processes.[321] And more generally, labeling requirements will raise public awareness of the growing presence of nanotechnology and stimulate dialogue on the future role of nanotechnology in society.[322] Such dialogue is critical because of nanotechnology's potential to have broad impacts and to cause drastic social change.[323]

As is the case with notification, a labeling requirement imposes a modest financial and regulatory burden.[324] A labeling requirement would be relatively manageable for EPA to administer as well, compared to the exhaustive analysis that would be required under a system of mandatory controls.[325] Experience with labeling requirements in other contexts, however, raises some concerns regarding their effectiveness.[326] Warnings may not be noticeable, may convey little useful information, or may be so commonplace that they lose their force.[327] Consumers may not have the time or interest to find

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[321] *See* ZYGMUNT J.B. PLATER ET AL., ENVIRONMENTAL LAW AND POLICY 539 (3d ed. 2004) (citing Rechtschaffen, *supra* note 316, at 341, 348) (concluding that California's "Proposition 65 appears to have achieved its purposes in spite of the inadequacies of many warnings" by stimulating product reformulation in industries concerned about tort liability and consumer reactions); *cf.* Jeanne Herb et al., *Harnessing the "Power of Information": Environmental Right To Know as a Driver of Sound Environmental Policy*, *in* NEW TOOLS FOR ENVIRONMENTAL PROTECTION, *supra* note 274, at 253, 257 (explaining that one of the justifications for the Toxics Release Inventory is that public disclosure of environmental performance will spur better behavior by industry).

[322] *See* PEDERSEN, *supra* note 310, at 1 (proposing that "a central authority" periodically disclose nanotechnology products or byproducts that raise some potential health or environmental concern, which may prompt affected facilities and communities to investigate more and set controls); Rechtschaffen, *supra* note 316, at 314-15 (explaining how disclosure laws advance democratic decisionmaking).

[323] *See* Michael M. Crow & Daniel Sarewitz, NANOTECHNOLOGY AND SOCIETAL TRANSFORMATION (2000), *reprinted in* AAAS SCIENCE AND TECHNOLOGY POLICY YEARBOOK 2001, at 89, 97 (A.H. Teich et al. eds., 2001) (arguing that if nanotechnology is as revolutionary as its proponents claim, it "can threaten the social structure, economic stability, and spiritual meaning that people strive in their lives to achieve").

[324] *See* PEDERSEN, *supra* note 310, at 4 (advocating information disclosure for nanotechnology products and suggesting that industry will be able to comply "at acceptable cost"); Sunstein, *supra* note 317, at 660 (arguing that regulatory schemes based on information disclosure "are generally far less expensive to implement for private industry and to enforce for government").

[325] *See* PEDERSEN, *supra* note 310, at 3-4.

[326] *See* DAVIES, *supra* note 10, at 23 ("There is not a lot of empirical evidence about the effectiveness of labeling, although the available evidence indicates that labels often do not have much impact on consumer behavior."); Lars Noah, *The Imperative To Warn: Disentangling the "Right To Know" from the "Need To Know" About Consumer Product Hazards*, 11 YALE J. ON REG. 293, 374-75 (1994) (suggesting that excessive warnings "may dilute the impact of truly important cautionary information").

[327] *See* Noah, *supra* note 326, at 365 (stating that "ambiguous warnings will undermine consumer confidence in the reliability of truly important label information"); Rechtschaffen, *supra* note 316, at 321-40 (discussing problems in implementing disclosure requirements of California's Proposition 65).

the information that is available.[328] And a poorly designed labeling requirement may generate unwarranted anxiety.[329]

The proposed labeling requirement—that manufacturers disclose that a product contains nanomaterials, identify the specific nanomaterial, and briefly compare the nanomaterial with bulk versions of the material—seeks to convey information that consumers can use to make rational decisions.[330] The requirement avoids both sensational language that might trigger an overreaction and overly detailed warnings that tend to be ignored.[331] Admittedly, consumers will not be able to make fully informed decisions because of the uncertainty surrounding the effects of exposure to nanomaterials.[332] Nevertheless, available risk data—or the fact that such data do not exist—can be posted on the Web, and labels can steer consumers to that data by providing website addresses. Because labeling increases transparency, the proposed requirement will also encourage manufacturers to weigh the potential for tort liability more seriously.[333] Finally, in light of the low social tolerance for involuntary risks and the lack of public discussion to date regarding the acceptability of nanotechnology, the labeling requirement advances the public's strong interest in simply knowing whether the products it uses contain nanomaterials.[334] Indeed, mandating public disclosure of the presence of nanomaterials would be in the long-term interests of the nanotechnology industry as well, by building a level of public trust that the biotechnology industry never established.

B. Requirements Applicable to Free Nanomaterials

Although notification and labeling requirements would apply to the manufacture and distribution of all nanomaterials and products containing nanomaterials, these requirements are limited in nature. Where nanomateri-

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[328] *See* Rechtschaffen, *supra* note 316, at 316-17 (discussing limitations of information disclosure laws).

[329] *See* Lin, *supra* note 229, at 947-48 (noting that more information about risk and uncertainty may generate more anxiety).

[330] *See* Noah, *supra* note 326, at 392 ("Ingredient declarations . . . can satisfy the disclosure function without overwhelming consumers with risk information.").

[331] *Cf.* Elise Golan et al., *Economics of Food Labeling*, 24 J. CONSUMER POL'Y 117, 139 (2001) ("Consumers are more likely to read and understand labels that are clear and concise . . . ."); Noah, *supra* note 326, at 364-65 (emphasizing importance of ensuring that warnings do not overstate or understate risks).

[332] *Cf.* Golan et al., *supra* note 331, at 140 (suggesting that consumers have a difficult time making sense of information on an issue that lacks scientific or political consensus).

[333] *See* Michael Barsa, Note, *California's Proposition 65 and the Limits of Information Economics*, 49 STAN. L. REV. 1223, 1239-43 (1997) (contending that disclosure requirements raise businesses' consciousness of possible toxic harms).

[334] *See* Lin, *supra* note 229, at 967 (contending that exposure to involuntary risks is a harm); Rechtschaffen, *supra* note 316, at 314 (explaining "right-to-know" rationale behind information disclosure laws); INT'L RISK GOVERNANCE COUNCIL, WHITE PAPER ON NANOTECHNOLOGY RISK GOVERNANCE 58 (2006) [hereinafter IRGC] (suggesting that labeling has value even if incomprehensible to an ordinary person because it conveys the message "that nothing is being withheld here").

als are found in a free form, additional requirements of screening, bonding, and monitoring would apply.

1. *Screening*

A reasonably complete characterization of the potential toxicity of each type of nanomaterial may take several years or more, assuming that the necessary resources are dedicated to such research. Rather than require extensive testing before products containing free nanomaterials can be marketed, the proposal would rely on screening tests to exclude the use of certain materials that appear most likely to be toxic.

An ideal screening test should generate reliable information on toxicity in a rapid and inexpensive manner. Techniques appear to be available to satisfy these criteria.[335] For example, *in vitro* toxicity tests, including the use of DNA chips,[336] rapidly yield fairly reliable information on the potential for reproductive hazards, genotoxicity, cancer, and organ damage.[337] Because the biological activity of nanoparticles may depend on physicochemical parameters not routinely considered in toxicity screening studies, much work will be needed to identify the specific tests to be used.[338] Nonetheless, scientists have already begun to develop a nanomaterials screening strategy that would incorporate both *in vitro* tests, such as cellular assays of tissue from the lungs, skin, liver, and other critical organs, and *in vivo* tests that would evaluate pulmonary, oral, injection, and dermal exposure.[339] Any screening test adopted for regulatory purposes should be revised on a regular basis to reflect new information about the efficacy and appropriateness of specific testing strategies.

Under the proposal, a substance that passes screening requirements could be introduced into commerce, subject to the monitoring and bonding requirements described below. A substance that fails to pass the screening

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[335] *See* Nel et al., *supra* note 59, at 626 (contending that "[o]n the basis of current understanding, the traditional study methods for testing chemical toxicity are a good starting point for [nanomaterial] testing").

[336] A DNA chip is a set of different single-stranded genetic sequences fixed to a glass slide or membrane; it is used to detect changes in gene expression resulting from exposure to a potentially toxic substance. *See* Gary E. Marchant, *Genomics and Toxic Substances: Part I—Toxicogenomics*, 33 Envtl. L. Rep. (Envtl. L. Inst.) 10,071, 10,072 (2003).

[337] *See* KATHLEEN BURNS, SCIENCECORPS, COMMENTS ON EPA DRAFT NANOTECHNOLOGY WHITE PAPER 3 (Docket ID EPA-HQ-ORD-2005-0504-0020.1, 2006) (stating that advances in low-cost *in vitro* toxicity testing and in simulation models may enable rapid initial screening of nanomaterials); Lin, *supra* note 116, at 1472-73 (discussing advances in toxicogenomics that are expected soon to allow chemicals to be screened rapidly for toxicity); Oberdörster et al., *supra* note 50, § 5.0 ("*In vitro* tests of toxicity yield data rapidly and can provide important insights and confirmations of the mechanism of *in vivo* effects.").

[338] *See* Oberdörster et al., *supra* note 50, § 1.0.

[339] *See* Nel et al., *supra* note 59, at 626 (recommending that a toxicity screening strategy include physicochemical characterization of nanomaterials, *in vitro* assays, and *in vivo* studies); Oberdörster et al., *supra* note 50, §§ 4.0-5.0 (describing possible elements of a screening strategy for nanomaterials).

would not be completely excluded from commercial use, however. For such substances, the burden would shift to the manufacturer to demonstrate through more extensive research that the substance can be used in a safe manner.

2. *Monitoring*

Any screening process can provide only a rough estimate of toxicity. In particular, rapid screening may be less effective at detecting long-term health risks, risks resulting from cumulative exposure to different nanomaterials, or risks to the environment.[340] Additional post-marketing study and monitoring will be necessary in order to detect and measure such effects. Such studies might gather further toxicological data, track the fate and transport of nanomaterials in the environment, and monitor adverse effects of exposure to nanomaterials.[341] Given the difficulty of sampling and measuring particles that are beyond the limit of detection by visible light, specific requirements may depend on technological capabilities.[342] Nevertheless, methods and technologies are available to detect and analyze nanomaterials in the environment.[343] Government agencies may need to provide specific guidance or technical assistance, particularly to small nanotechnology start-ups that may have limited access to environmental, health, and safety experts.[344]

The proposal would require monitoring results to be reported to EPA, which would have the authority to order further testing or even a moratorium on manufacture or distribution of a product if significant health or environmental impacts are found.

3. *Bonding*

The most important component of the proposal, with respect to internalizing potential costs, is the bonding requirement. Under this requirement, any manufacturer or distributor introducing into commerce a product containing free nanomaterials would be required to post a dated assurance bond

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[340] *See* BARTIS & LANDREE, *supra* note 56, at 7 (noting that current studies of health risks focus primarily on acute toxicity and that evaluation of possible chronic toxic effects may require ten years of work).

[341] Such records would be similar to those required by section 8(c) of TSCA for monitoring adverse effects on employees, public health, and the environment. 15 U.S.C. § 2607(c) (2006).

[342] *See* SCENIHR, *supra* note 29, at 18-19 (describing techniques for detecting nanoparticles in environment); *id.* at 35 (discussing difficulties in sampling nanoparticles); *id.* at 59 (noting importance of developing methodologies and equipment for measuring nanoparticles and exposure to nanoparticles in environment); Maynard et al., *supra* note 55, at 268 (suggesting time frames for developing instruments for assessing exposure to nanomaterials).

[343] *See* EPA WHITE PAPER, *supra* note 10, at 40-41; Joyce S. Tsuji, *Research Strategies for Safety Evaluation of Nanomaterials, Part IV: Risk Assessment of Nanoparticles*, 89 TOXICOLOGICAL SCI. 42, 43-44 (2006) (describing methods of measuring airborne exposures to nanomaterials).

[344] *See* BARTIS & LANDREE, *supra* note 56, at 18.

that would cover damages that may arise as a result of the company's operations for each year.[345] EPA would set the value of the bond at an amount adequate to cover the most damaging scenario deemed plausible under a worst-case analysis. Such an analysis, which would be assigned to an independent scientific advisory board, would consider factors such as possible routes and levels of exposure, and similarities between the material in question and substances with known toxicology.[346] The term of the bond would be fifteen years, or a period long enough to generate a reasonable amount of short-term and long-term toxicity information, and its value could be revised upward or downward periodically to reflect new information. The bond would be refundable in whole or part, with interest, at the end of the term if the company could demonstrate lower damages, or lower expected damages, than those estimated by EPA in setting the bond. The unrefunded portion of the bond, intended to cover expected damages that have not yet occurred, would be deposited in a trust fund that the proposal would establish.

The bonding requirement will serve two important functions: assuring the existence of funds to pay for damages that are subsequently discovered; and giving nanotechnology companies an incentive to undertake research to demonstrate that their products are safe.[347] With respect to both of these concerns, using a bonding system in conjunction with the tort system is advantageous to reliance on the tort system alone. The tort system's liability rules provide poor assurance of the availability of funds for compensation or

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[345] The bond mechanism proposed here relies significantly on the general discussion of environmental assurance bonds found in Robert Costanza & Charles Perrings, *A Flexible Assurance Bonding System for Improved Environmental Management*, 2 ECOLOGICAL ECON. 57 (1990).

[346] This analysis would be somewhat analogous to the worst-case analysis required under National Environmental Policy Act ("NEPA") regulations prior to their amendment in 1986. NEPA requires federal agencies to assess the environmental impacts of proposed federal actions. 42 U.S.C. § 4332(C) (2006). The pre-1986 regulations required, as part of the assessment, a worst-case analysis under conditions of uncertainty—specifically, if information relevant to a reasoned choice was not known and either the means of obtaining it were unknown or the cost of obtaining it was exorbitant. 40 C.F.R. § 1502.22 (1985) (superseded 1986). In the analysis, the agency was to discuss catastrophic events with low probability, as well as events of higher probability but less dramatic impact, and to weigh the need for the proposed action against the risk and severity of possible adverse impacts. Forty Most Asked Questions Concerning CEQ's National Environmental Policy Act Regulations, 46 Fed. Reg. 18,026, 18,032 (Mar. 23, 1981); DANIEL R. MANDELKER, NEPA LAW AND LITIGATION § 10.22 at 10-50 to -55 (2d ed. 1992); *e.g.*, Sierra Club v. Sigler, 695 F.2d 957, 974 (5th Cir. 1983) (mandating analysis of "informative and useful worst case scenario that reasonably limits speculation"). Although the worst-case analysis regulation was rescinded in 1986, its successor requires evaluation of "existing credible scientific evidence" relevant to assessing significant adverse impacts, including catastrophic consequences whose probability of occurrence is low. 40 C.F.R. § 1502.22 (2006); National Environmental Policy Act Regulations; Incomplete or Unavailable Information, Final Rule, 51 Fed. Reg. 15,618, 15,621 (Apr. 25, 1986).

[347] *See* Laura Cornwell & Robert Costanza, *Environmental Bonds: Implementing the Precautionary Principle in Environmental Policy*, *in* PROTECTING PUBLIC HEALTH AND THE ENVIRONMENT, *supra* note 228, at 220, 221; Costanza & Perrings, *supra* note 345, at 71; *see also* Wagner, *supra* note 271, at 1724-25 (noting that the precautionary principle creates strong incentives for the private sector to produce information about environmental harms).

cleanup, even when difficulties in proving causation can be overcome, because a firm may escape cost internalization via dissolution or bankruptcy.[348] And in situations of uncertainty, such as that presented by nanotechnology, the tort system discourages manufacturers from undertaking toxicological research because the discovery of adverse effects may lead to liability.[349] The bonding requirement, in contrast, places the responsibility on manufacturers to produce information on health risks. This is fair because manufacturers will profit directly from nanotechnology products, and it is efficient because manufacturers will tend to have the most information about the manufacturing process, their products, and the substances in those products.[350] A bonding system thus addresses critical weaknesses of the tort system while offering a promising middle road for capturing the benefits of nanotechnology.

Unlike a moratorium or a complete ban, a bonding system would allow some products containing nanomaterials to go forward into the marketplace.[351] Although a requirement that manufacturers of nanotechnology products obtain a specified amount of insurance coverage might have a similar effect, it is uncertain that the insurance industry would be willing to cover the risks.[352] At least one prominent member of the insurance industry has expressed concerns about coverage for the nanotechnology industry be-

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[348] Jeffrey Kehne, *Encouraging Safety Through Insurance-Based Incentives: Financial Responsibility for Hazardous Wastes*, 96 YALE L.J. 403, 405 (1986); Boyd, *supra* note 304, at 423.

[349] *See* Lyndon, *supra* note 164, at 1813-17 (discussing disincentives for chemical producers to identify and publicize toxic effects); Charles Perrings, *Environmental Bonds and Environmental Research in Innovative Activities*, 1 ECOLOGICAL ECON. 95, 106 (1989) (noting that "competitive markets will lead private agents to avoid investment in basic research" regarding negative externalities and that "[t]he more myopic the vision of competitive agents, the less the incentive to undertake basic experimental research").

[350] *See* ROBERT L. GLICKSMAN ET AL., ENVIRONMENTAL PROTECTION LAW AND POLICY 764 (4th ed. 2003) (explaining that shifting the cost of generating toxicity data to those who manufacture and use chemicals is efficient and equitable); Applegate, *supra* note 109, at 308 (contending that the burden of proof regarding toxicity (or lack thereof) should be placed on manufacturers if they "can develop toxicology information more cheaply than EPA, or if the cost [of such research] is more efficiently or equitably borne by them and their customers"); Wagner, *supra* note 271, at 1738-39.

[351] *See* Peter Bohm & Clifford S. Russell, *Comparative Analysis of Alternative Policy Instruments*, *in* 1 HANDBOOK OF NATURAL RESOURCE AND ENERGY ECONOMICS 395, 432 (A.V. Kneese & J.L. Sweeney eds., 1985); Jason F. Shogren et al., *Limits to Environmental Bonds*, 8 ECOLOGICAL ECON. 109, 113 (1993); *see also* Frank Wätzold, *Efficiency and Applicability of Economic Concepts Dealing with Environmental Risk and Ignorance*, 33 ECOLOGICAL ECON. 299, 308 (2000) (suggesting that environmental bonds are more appropriate "when the number of polluters is relatively low," given the administrative costs involved in collecting bonds, monitoring polluters, and returning the money).

[352] *See* ALLIANZ GROUP & THE OECD, *supra* note 199, at 42-43 (noting that the insurance industry, by providing coverage, is contributing to the commercialization of nanotechnology, but warning of the need for close scrutiny of risks as nanotechnology becomes more prevalent). *See generally* Costanza & Perrings, *supra* note 345, at 67-68 (recommending that bond schemes be used "wherever future costs [are] uninsurable commercially—where actuarial risks cannot be calculated from historical data"); Lin, *supra* note 229, at 975 ("For truly uncertain events, insurance is unavailable.").

cause of the "unforeseeable nature of the risks it entails and the recurrent and cumulative losses it could lead to."[353] To counter this concern, commentators have suggested government-sponsored nanotechnology insurance or liability protection akin to that provided to the nuclear industry by the Price-Anderson Act.[354] Under such a scheme, private liability would be capped, and the government would provide indemnification for damages exceeding the cap.[355] Even a partial shield against liability, however—whether through insurance coverage or a liability cap—would create a moral hazard for nanotechnology companies to take inefficient risks, as risks of liability or harm are shifted to insurance companies, the government, or potential victims.[356] Nanotechnology companies would face weaker incentives to conduct research on the health and safety effects of nanomaterials than under a bonding system.[357] And thanks to indemnity limits, deductibles, conditions, exclusions, and other policy limitations, insurance—if available—almost invariably does not compensate for all losses.[358]

The bonding system proposed here builds on similar incentive-based mechanisms used to protect the environment. Deposit-refund schemes, for example, promote recycling and reduce litter.[359] And bonding mechanisms are used widely in the mining industry to ensure site reclamation.[360] The Surface Mining Control and Reclamation Act ("SMCRA"),[361] for instance, mandates the use of performance bonds to guarantee reclamation of coal

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[353] SWISS RE, *supra* note 44, at 40; *see also* Kenneth S. Abraham, *Environmental Liability and the Limits of Insurance*, 88 COLUM. L. REV. 942, 946 (1988) ("[I]nsurance deals best with risk, or predictable probabilities, and not with uncertainty, or unpredictable probability of loss.").

[354] *See* David M. Berube, *Regulating Nanoscience: A Proposal and a Response to J. Clarence Davies*, 3 NANOTECHNOLOGY L. & BUS. 485, 499, 503-04 (2006) (looking to Price-Anderson Act as possible model for addressing potential liability of nanotechnology industry); GEORGE J. MANNINA, JR., NANOTECHNOLOGY: DON'T DELAY LIABILITY RISK ASSESSMENTS AND SOLUTIONS (21 Legal Backgrounder, No. 37, 2006), *available at* http://www.wlf.org/upload/120806lbmannina.pdf (suggesting creation of a "Nanotechnology Insurance Fund" funded by surcharges on nanotechnology products or nanotechnology companies, and/or congressional appropriations); *see also* Price-Anderson Act, 42 U.S.C. § 2210 (2006); Duke Power Co. v. Carolina Envtl. Study Group, Inc., 438 U.S. 59, 64-67 (1978) (summarizing provisions of Price-Anderson Act).

[355] *See* Berube, *supra* note 354, at 504.

[356] *See id.*; *see also* Benjamin J. Richardson, *Mandating Environmental Liability Insurance*, 12 DUKE ENVTL. L. & POL'Y F. 293, 304 (2002) (noting that "availability of insurance may reduce incentives to be careful," but suggesting that in at least some circumstances, insurers can reduce moral hazard through risk assessment and risk classification techniques, deductibles, policy exclusions, and enhanced monitoring).

[357] *Cf.* Costanza & Perrings, *supra* note 345, at 71 (describing research incentives created by bonds).

[358] *See* Richardson, *supra* note 356, at 328; *see also* Berube, *supra* note 354, at 498 (noting that nanotechnology is not specifically excluded in most policies today, but acknowledging that such exclusions could readily be added upon policy renewal).

[359] *See* Cornwell & Costanza, *supra* note 347, at 222.

[360] *See* David Gerard, *The Law and Economics of Reclamation Bonds*, 26 RESOURCES POL'Y 189, 189 (2000).

[361] 30 U.S.C. §§ 1201-1328 (2006).

mining sites.[362] Each bond is set at an amount that reflects the "worst case scenario"—"the cost of reclaiming the site if the permittee forfeits the bond at the point of maximum reclamation cost liability."[363] As mining proceeds, the bond amount may be adjusted to account for unforeseen costs, such as the cost of treating water polluted by mine discharges.[364] Although government agencies sometimes fail to enforce such bonding requirements, those requirements can be an effective tool for promoting reclamation when they are set adequately and enforced.[365]

Environmental bonds have some limitations. The most serious concerns relevant to this proposal involve moral hazard, liquidity constraints, observability, adequacy, and administrative costs. Commentators suggest that moral hazard—the temptation to behave differently because of the existence of insurance or other incentives—may arise in government regulators because the manufacturer has the burden of demonstrating that it is entitled to refund of the bond at the end of the bond term.[366] This burden, it is suggested, gives regulators an incentive to confiscate the bond regardless of the firm's level of precaution.[367] Such concerns, however, are misplaced with respect to the instant proposal. Because funds confiscated from the bond will be placed in a trust fund, rather than retained by EPA, any incentive to improperly retain funds will be modest. Furthermore, concerns that EPA may confiscate funds without reason will be lessened by data from the presence or absence of legitimate tort claims by private individuals harmed by nanotechnology. Procedural mechanisms can also be put in place to limit the potential for abuse: the ultimate determination of whether a manufacturer is entitled to a refund could be entrusted to an independent committee of scientists outside EPA, and such determinations could be made subject to judicial review.[368]

The requirement of posting a bond is likely to slow the commercialization of nanotechnology applications that involve free nanomaterials. It could

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[362] SMCRA § 509, 30 U.S.C. § 1259 (2006); *see also* Cornwell & Costanza, *supra* note 347, at 236-38 (discussing present uses of bonds as regulatory instruments); Lisa A. Kirschner & Edward B. Grandy, *Mining and the Vanishing Surety Bond Market*, 17 NAT. RESOURCES & ENV'T 152, 152 (2003) (discussing financial guarantee obligations applicable to mining industry); Shogren et al., *supra* note 351, at 120-21 (discussing use of environmental bonds to ensure restoration after surface coal mining).

[363] OFFICE OF SURFACE MINING, U.S. DEP'T OF THE INTERIOR, HANDBOOK FOR CALCULATION OF RECLAMATION BOND AMOUNTS 6 (2000), *available at* http://www.osmre.gov/directives/directive882a.pdf.

[364] *See* 30 U.S.C. § 1259(e); Craig B. Giffin, *West Virginia's Seemingly Eternal Struggle for a Fiscally and Environmentally Adequate Coal Mining Reclamation Bonding Program*, 107 W. VA. L. REV. 105, 125-28 (2004) (describing exercise of authority to adjust bonding requirements).

[365] *See* Gerard, *supra* note 360, at 194-95 (discussing audits of bonding programs that regulated surface mining sites in the western United States).

[366] *See* Shogren et al., *supra* note 351, at 114.

[367] *See id.*

[368] *See* Boyd, *supra* note 304, at 446 (explaining that risk of government confiscation of bonds is low as long as criteria for return of bonds are interpretable by the courts).

also create liquidity problems, particularly for smaller nanotechnology start-ups.[369] This is especially true because of the degree of uncertainty regarding health and environmental effects; the costs associated with a worst-case scenario could be quite high.[370] While it is possible that insurance markets might develop so that firms can pool their risk and insure against forfeiture of their bond, insurers may be reluctant to enter the market because of difficulties in assessing risks.[371] Thus, one effect of a bonding requirement may be to favor larger nanotechnology companies with greater access to capital over smaller companies.[372] This will not necessarily quash all innovation, however, nor will it necessarily eliminate start-up companies from the industry. The pharmaceutical industry provides a potentially apt comparison: thanks to the lengthy process and high costs involved in identifying, developing, and seeking FDA approval for new drugs, smaller companies often partner with larger companies in developing or marketing new drugs.[373] One can envision the formation of similar partnerships in the nanotechnology industry; in particular, large companies that can afford to post bonds may tend to be more involved in the manufacture of goods for the marketplace, while smaller companies may focus on research and development, which will not be subject to the bonding requirement.[374] Another possible effect of a bonding requirement would be to favor nanotechnology applications of greater economic value—and thus more likely to attract investment—over those applications of lesser economic value. Such a filtering effect could be desirable if the economically more valuable applications tend to offer greater social benefits as well.[375]

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[369] *See* Shogren et al., *supra* note 351, at 115-18 (discussing liquidity constraints).

[370] *See id.* at 116 ("When confronting potential environmental damages, the costs may well be in the hundreds of millions of dollars."). For comparison purposes, hard-rock mining operations in the western United States sometimes operate with bond amounts of twenty million dollars or more. *See* Gerard, *supra* note 360, at 193-95.

[371] *See* Shogren et al., *supra* note 351, at 116-17. *But cf.* Boyd, *supra* note 304, at 438-39 (contending that opponents of financial assurance requirements often express unwarranted fears of mass disruption and insurance unavailability).

[372] *See* Cornwell & Costanza, *supra* note 347, at 231 ("Bonding requirements could create cost and underwriting barriers to entry for some market participants, particularly small businesses."); Peter Huber, *The Old-New Division in Risk Regulation*, 69 VA. L. REV. 1025, 1035 (1983) ("[S]creening systems favor big-ticket products and operations.").

[373] *See* Amy Barrett et al., *More Bitter Pills for Big Pharma*, BUS. WK., Jan. 10, 2005, at 112, 114 (noting pressure for large pharmaceutical companies to pursue licensing or acquisition deals with smaller companies).

[374] *Cf.* Mooney & Gerard, *supra* note 210, at 28 (proposing use of environmental bonds to regulate risks of GM crops, and recommending that manufacturers, rather than individual producers, be required to post bonds because manufacturers have deeper pockets and are fewer in number).

[375] *Cf.* Jonathan M. Gilligan, *Flexibility, Clarity, and Legitimacy: Considerations for Managing Nanotechnology Risks*, 36 Envtl. L. Rep. (Envtl. L. Inst.) 10,924, 10,925 (2006) (suggesting that "a more risk-acceptant position would be appropriate" for nanotechnology applications with "truly important and revolutionary benefits," and a more precautionary approach for applications involving minor improvements to existing products).

money now devoted to nanotechnology research, imposing an application fee on companies subject to bonding requirements, or by taxing the nanotechnology industry. Ultimately, such costs constitute the modest price of ensuring that this new and potentially lucrative technology develops in a responsible manner.

The requirements discussed here would apply generally to products containing free nanomaterials. To the extent that drugs and pesticides undergo more stringent premarketing review under other regulatory regimes, such products could be exempted from screening requirements. Because new drugs are subject to an extensive premarketing approval process that includes clinical trials, new drugs could be exempted from bonding requirements as well. Notification requirements should apply even to these products, however, so that EPA can serve as a clearinghouse for risk information on nanomaterials.

C. Addressing Workplace Exposures

The proposal, as discussed thus far, focuses on general risks to the public arising from the commercialization of nanotechnology products. Many elements of the proposal would benefit not only the general public, but also workers in manufacturing facilities who may be exposed to nanomaterials. For example, information subject to the labeling requirement would also be provided to workers, and funds secured by the bonding requirement would be available to compensate workers injured by exposure.

Given the weaknesses of the OSH Act and the potential for high levels of exposure in the workplace,[383] however, additional protective measures will be necessary. Monitoring requirements for workplaces will need to be especially rigorous and systematic, and manufacturers should be required to conduct physical examinations of employees on a regular basis. The resulting data, which would be submitted to EPA and to OSHA, will be invaluable in assessing potential toxicity.[384] Whether specific measures to limit worker exposure should be required is a more difficult question. The nanotechnology industry has expressed interest in sharing information and cooperating with the government in evaluating best practices for controlling workplace exposures.[385] Because of the uncertainty surrounding the effectiveness of personal protective equipment, filtration systems, and other control methods, however, it may not be possible to determine what measures

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[383] *See supra* Part III.D.

[384] *See* BARTIS & LANDREE, *supra* note 56, at 7 (discussing "need for protocols and surveillance strategies for observing worker health in the near term in order to be able to assess the possible long-term chronic toxic effects").

[385] *See id.* at 14 (discussing cooperative efforts between government and industry concerning workplace safety).

should be adopted—or if necessary, mandated—for some time.[386] The history of occupational illnesses involving coal dust, asbestos fibers, and other tiny particles counsels that manufacturers take reasonable precautions, such as manufacturing and using nanomaterials in closed systems, to the extent possible.[387] Ultimately, if the data suggest the presence of unaddressed occupational hazards, OSHA may need to be given greater authority to act in the face of uncertain dangers.

D. Comparison with Other Proposals

There are few proposals to regulate nanomaterials other than the one made here.[388] Most interested parties instead advocate increased research and more vigorous use of existing regulatory authority.[389] One regulatory proposal, however, was made by J. Clarence Davies, an EPA official in the first Bush Administration and now Senior Advisor to the Woodrow Wilson Center's Project on Emerging Technologies.[390] Davies' proposal contains testing, labeling, and reporting elements,[391] but differs from the present proposal in critical ways. The central element of Davies' proposal is a sustainability plan that manufacturers of nanotechnology products would have to submit to EPA.[392] The sustainability plan would have six components: "1) a life cycle analysis of the material or product; 2) testing results; 3) proposed future reporting requirements; 4) proposed labeling . . . ; 5) proposed restrictions, if any . . . ; and 6) an explanation of why the product risk . . . is acceptable."[393] EPA would review the sustainability plan and approve it if EPA determines that the product does not pose "unacceptable risks."[394]

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[386] *See id.* at 9; Maynard & Kuempel, *supra* note 47, at 606-07; *see, e.g.*, IRGC, *supra* note 334, at 51 (noting that traditional respiratory protection may not be effective for particles smaller than fifteen nanometers and that even the most efficient facemasks have not been tested with nanoparticles).

[387] *See* SCI. COUNCIL, *supra* note 55, at 6 (noting that "[n]anomaterials are generally produced in closed systems to avoid combustion of hydrogen or oxidation of nanomaterials and to minimise hazards from waste gas").

[388] In December 2006, the city of Berkeley, California, passed an ordinance requiring researchers and manufacturers within the city to report what nanotechnology materials they were working with. *Berkeley Puts Nanotechnology Under Hazardous Materials Law*, L.A. TIMES, Dec. 14, 2006, at C2.

[389] *See, e.g.*, Tomasco, *supra* note 11, at 245 (arguing that manufacturers should undertake some safety testing before mass production, but acknowledging that "perfunctory compliance with TSCA and OSH Act provisions is certainly possible"); Kevin Bullis, *Can Nanotech Be Regulated?*, TECH. REV., Jan. 23, 2006, http://www.technologyreview.com/read_article.aspx?id=16322 (on file with the Harvard Environmental Law Review) (reporting comments of senior scientist at Environmental Defense suggesting that it is premature to enact new legislation regulating nanotechnology).

[390] *See* DAVIES, *supra* note 10, at 5.

[391] *See id.* at 19.

[392] *See id.*

[393] *Id.*

[394] *Id.*

Such a regulatory scheme may make sense at a future date when more is known about the risks of nanotechnology. But given the present uncertainty and the length of time necessary to begin to resolve that uncertainty, a meaningful life-cycle analysis may not be possible.[395] It is also unlikely that manufacturers would be able to generate the testing results necessary to determine whether unacceptable risks exist. Furthermore, without a bonding mechanism, Davies' proposal gives less assurance that adequate funds will be available to rectify or compensate for adverse effects that later arise.

Davies' proposal also differs from the present one in that it would not distinguish explicitly between products containing free nanomaterials and those containing embedded nanomaterials, and it would not apply retroactively to nanotechnology products already on the market.[396] Davies' proposal to require a sustainability plan for all products containing nanomaterials, not just free nanomaterials, would generate a more thorough analysis of possible negative effects, but would impose a significant regulatory burden on manufacturers of nanotechnology products that appear to pose little risk. And although the grandfathering of products already on the market might be politically attractive and less burdensome on regulatory agencies,[397] there is little reason to assume that products already on the market are any safer than those likely to be introduced. In contrast to other contexts in which grandfathering has been incorporated into regulation,[398] the retroactive application of regulatory requirements here would not disturb the settled expectations of manufacturers or other interested parties.[399] The nanotechnology industry is relatively young, manufacturers are well aware of the uncertainty surrounding the health effects of exposure to nanomaterials, and there are reasonable arguments that nanomaterials already on the market should have been treated as new substances or as significant new uses under TSCA.

A more drastic alternative to the present proposal would be a moratorium, or even a ban on products containing nanomaterials.[400] The promising potential of nanotechnology and the lack of data on nanomaterials' health

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[395] *See* SCI. COUNCIL, *supra* note 55, at 6 (noting that "life cycle analysis can only assess known impacts").

[396] *See* DAVIES, *supra* note 10, at 18-19.

[397] *See id.* at 19.

[398] *See, e.g.*, Ann Brewster Weeks, *Advising Nature: Can We Get Clean Air from the Old Dirties?*, 33 NEW ENG. L. REV. 707, 711-15 (describing the grandfathering of older power plants under the New Source Performance Standards program and the New Source Review program of the CAA).

[399] *See* Huber, *supra* note 372, at 1027 ("New risks . . . may be regulated with less direct disruption of settled expectations."); *id.* at 1064 (noting that "transition costs are largely absent when new products are regulated").

[400] *See, e.g.*, DAVIES, *supra* note 10, at 22 (mentioning call for moratorium by the Action Group on Erosion, Technology, and Concentration, a Canadian organization); MILLER, *supra* note 181, at 5 (calling for "moratorium on the further commercial release of personal care products that contain nanomaterials, and the withdrawal of such products currently on the market").

effects undermine the appeal of this possibility, however.[401] Even if prohibition were desirable, a complete ban would be politically and practically impossible. The public is unlikely to support a ban, and the billions of dollars pouring into nanotechnology research and development make it highly unlikely that a moratorium or ban would be enacted.[402] Moreover, a ban would likely drive nanotechnology research and manufacturing to other countries, depriving the United States of the tremendous potential benefits of nanotechnology and potentially impacting our economic and military security.[403]

Finally, the current proposal assumes implementation in the United States through federal legislation. An analogous scheme could be adopted by other nations individually or by international agreement. The history of international agreements to regulate technologies, however, suggests that such cooperation typically follows the demonstration of serious and imminent harm.[404] The uncertainty surrounding nanotechnology likely does not provide a sufficient impetus for nations to invest the effort, time, political capital, and resources necessary to reach an international agreement with significant substantive commitments at this time.[405] However, a framework convention involving limited substantive commitments from countries involved in nanotechnology, which is more likely, can lay the groundwork for information generation and future international cooperation.[406] Moreover, insurance requirements of multinational corporations, certification programs, and worldwide information-sharing efforts all may play a role in facilitating global cooperation on this critical issue.[407]

VI. Conclusion

Nanotechnology promises immense benefits in manufacturing processes, energy efficiency, and innovative products. Nanotechnology applications are already becoming widespread even at this relatively early stage of the basic science. Like many technologies of the past, however,

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[401] *Cf.* Royal Soc'y, *supra* note 3, at 77 (rejecting call for moratorium because the scientific evidence does not "warrant such a major intervention").

[402] *See* Macoubrie, *supra* note 20, at 8.

[403] *See* Phillip J. Bond, *Responsible Nanotechnology Development*, *in* Nanotechnology: "Small Size—Large Impact?," *supra* note 230, at 7, 7 (noting potential benefits of nanotechnology and declaring that "nanotechnology is coming, and it won't be stopped"); Drexler & Wejnert, *supra* note 21, at 15-16 (arguing that suppressing development of nanotechnology "will not work" because development will proceed in other countries, and suggesting that "opting out of nanotechnology would relegate a nation to no longer being a player in technological civilization").

[404] *See* Marchant & Sylvester, *supra* note 295, at 722.

[405] *See id.*

[406] *See* Kenneth W. Abbott et al., *A Framework Convention for Nanotechnology?*, 36 Envtl. L. Rep. (Envtl. L. Inst.) 10,931, 10,931 (2006) (advocating an international framework convention for nanotechnology).

[407] *See* IRGC, *supra* note 334, at 62-64.

nanotechnology is being adopted without thoughtful consideration of potential health, environmental, or even societal effects. The need for research on such effects is widely recognized, but additional research alone will not be enough. As we await the results of such research, advances in the basic science will continue, the number and variety of nanotechnology products will multiply, and exposure to nanomaterials will increase, along with health and environmental uncertainty.

The proposal made here tackles the uncertainty through a bonding requirement that gives companies using nanotechnology an incentive to conduct health and safety research and assures the existence of funding to cover damages that may later arise. While the bonding mechanism is by no means a perfect solution, it is a superior alternative to the status quo and to the conventional approach of responding only to demonstrated harm. In addition, the proposal's notification, labeling, and monitoring requirements begin to address the distinct but related problem of governance: how should society handle a suite of technologies with such potential for tremendous benefits and tremendous risks? There are no easy answers to this question, of course. Society will never have all the information it needs to make decisions without some uncertainty. But adopting the instant proposal will stimulate the development of more of the desired information, make that information more widely available, and better equip society to respond to unforeseen challenges.