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MANUFACTURED NANOMATERIALS: AVOIDING TSCA AND OSHA VIOLATIONS FOR POTENTIALLY HAZARDOUS SUBSTANCES

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Abstract: Public and private spending on nanotechnology research and development continues to increase. At the same time, government agencies around the world are spending millions to assess the potential risks to nanotechnology workers, the public, and the environment. However, innovative and opportunistic manufacturers are not waiting for test results before forging ahead. This Note focuses on the obligation of such manufacturers under the Toxic Substances Control Act (TSCA) to report and/or test nanomaterials for their effects on health, safety, and the environment prior to their release into the stream of commerce. In addition, this Note addresses the duty of manufacturers to protect workers from recognized hazards under the Occupational Safety and Health Act of 1970 (OSH Act).

Introduction

According to the 21st Century Nanotechnology Research and Development Act (Nanotechnology Act), "'nanotechnology' means the science and technology that will enable one to understand, measure, manipulate, and manufacture at the atomic, molecular, and supramolecular levels, aimed at creating materials, devices, and systems with fundamentally new molecular organization, properties, and functions."[1] As this definition implies, nanotechnology research and development aims to exploit potentially valuable differences in the physical properties of nanomaterials as compared to their "normal-sized" bulk-material counterparts.[2]

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* Solicitations Editor, Boston College Environmental Affairs Law Review, 2005–06.

[1] 21st Century Nanotechnology Research and Development Act, 15 U.S.C.A. § 7509 (West Supp. 2004).

[2] *See* Nanoscale Sci., Eng'g, & Tech. Subcomm., Nat'l Sci. & Tech. Council, The National Nanotechnology Initiative Strategic Plan iii (2004), *available at* http://www.nano.gov/NNI_Strategic_Plan_2004.pdf [hereinafter NNI Strategic Plan].

The United States government has been investing aggressively in nanotechnology for some time, spending $982 million on research and development in fiscal year 2005 alone.[3] Several states are seeking to attract a slice of the $3.8 billion that corporations spent on nanotechnology research and development worldwide in 2004.[4]

Amidst all this promise and optimism, however, are growing concerns that the health, safety, and environmental risks of nanomaterials are poorly understood.[5] Preliminary studies of carbon nanotube toxicity, for example, proved quite alarming.[6] The issue drew enough attention in 2004 for *Science Magazine* to name nanotechnology health and environmental regulation as one of seven scientific "Areas to Watch in 2005."[7]

The most extreme reaction to the perceived risks—short of an outright permanent ban—would be for the government to institute a moratorium on nanotechnology manufacturing until the risks are better understood.[8] More likely, the government will have to apply or adapt existing environmental laws and regulations to meet the chal-

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[3] *See* Nat'l Nanotechnology Initiative, Funding, http://www.nano.gov/html/about/funding.html (last visited Oct. 15, 2005).

[4] *See* M.C. Roco, *The US National Nanotechnology Initiative After 3 Years (2001–2003)*, 6 J. Nanoparticle Res. 1, 1 (2004) ("[O]ver 20 states in [the United States] have realized that nanotech has economic potential and in 2002 made a commitment for nanotechnology that is more than half the [National Nanotechnology Initiative] annual budget.") (on file with author); *Global Investment in Nanotechnology by Nations to Rise*, Wall St. J., Aug. 16, 2004, at B4.

[5] *See generally* Vicki L. Colvin, *The Potential Environmental Impact of Engineered Nanomaterials*, 21 Nature Biotechnology 1166 (2003) (outlining potential health, safety, and environmental risks). Dave Kriebel, an epidemiologist at the University of Massachusetts at Lowell, has said of nanomaterials, "'[t]he key point of concern is, because these particles are so small, they don't necessarily follow the same toxicologic principles that we understand'." Carolyn Y. Johnson, *One Million Nanotubes Could Fit Into This Period.*, Boston Globe, Feb. 15, 2005, at C1.

[6] *See* Chiu-Wing Lam et al., *Pulmonary Toxicity of Single-Wall Carbon Nanotubes in Mice 7 and 90 Days After Intratracheal Instillation*, 77 Toxicological Sci. 126, 126 (2004), *available at* http://toxsci.oupjournals.org/cgi/reprint/77/1/126 (finding that, after instilling a suspension of nanotubes directly into the lungs of mice, the nanotubes clumped together and stimulated an immune response that resulted in the scarring of lung tissue).

[7] *See Areas to Watch in 2005*, 306 Sci. 2014, 2014 (2004) ("[R]egulators in areas from consumer products, workers' health, and the environment are grappling with how best to ensure health and safety without stifling what is expected to be a major economic engine.")

[8] The environmental advocacy organization ETC Group, formerly a vocal opponent of genetically-modified foods, has turned its attention to the impact of nanotechnology and has called for a moratorium on commercial production of new nanomaterials. *See* Candace Stuart, *Watchdogs Say Stop Nanotech, Start Worldwide Dialogue*, Small Times, Jan. 31, 2003, http://www.smalltimes.com/document_display.cfm?document_id=5417.

lenge of allowing nanomaterials to be produced without significant harm to humans or the environment.[9] While the universe of potentially applicable health, safety, and environmental statutes is only as limited as the use of nanomaterials themselves, this Note focuses on the presumed toxic nature of some nanomaterials. This Note also examines some of the federal statutory and regulatory issues that would arise for a typical corporation manufacturing nanomaterials in the near-term.[10]

Part I of this Note provides an overview of nanotechnology. Parts II and III, respectively, describe federal statutes—the Toxic Substances Control Act (TSCA) and the Occupational Safety and Health Act of 1970 (OSH Act)—which take different approaches to mitigating the risks posed by substances of known and unknown toxicity. Part IV assesses the strengths and deficiencies of each statute as applied to nanomaterial manufacturing, and argues that manufacturers should adopt a precautionary approach to releasing their nanoproducts into the stream of commerce, even if certain regulatory hurdles may be overcome by perfunctory compliance with the letter of the law.

I. Nanotechnology Overview

The prefix "nano" "is derived from the Greek word *nanos*, meaning 'dwarf'. A nanometre is one thousand millionth of a metre or, in other words, one millimetre equals a million nanometres."[11] For purposes of comparison, a flea is about 1 million nanometers (nm); a red blood cell is seven thousand nm; a bacterium is one thousand nm;

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[9] *See* Ahson Wardak, Woodrow Wilson Int'l Ctr. for Scholars, Nanotechnology & Regulation: A Case Study Using the Toxic Substance [sic] Control Act (TSCA) 1–2 (2003), http://www.foresightandgovernance.org/images/nanotsca_final2.pdf.

[10] Approximately 80% of the companies pursuing nanotechnology are start-ups. *See Global Investment in Nanotechnology by Nations to Rise*, *supra* note 4. This Note is not concerned with so-called molecular nanotechnology (MNT), defined as the "purposeful manipulation of molecules and atoms to construct devices and machines." Jason Wejnert, Note, *Regulatory Mechanisms for Molecular Nanotechnology*, 44 Jurimetrics J. 323, 325 (2004). MNT is generally considered to be in the "workbench or proof-of-concept" stage, as opposed to anything likely to be mass-produced anytime soon. Glenn Harlan Reynolds, *Nanotechnology and Regulatory Policy: Three Futures*, 17 Harv. J.L. & Tech. 179, 180 (2003); *see also* Paul C. Lin-Easton, Note, *It's Time for Environmentalists to Think 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, 109 (2001) (describing the current state of MNT as comparable to "computer and information technology in the 1950s").

[11] Annabelle Hett, Swiss Re, Nanotechnology: Small Matter, Many Unknowns 5 (2004), http://www.swissre.com/INTERNET/pwsfilpr.nsf/vwFilebyIDKEYLu/ULUR-5YNGET/$FILE/Publ04_Nanotech_en.pdf.

and a ball-shaped virus is between sixty and one hundred nm.[12] Scientists reserve the "nano" prefix for materials that range in size from about 0.2 nm—the atomic level—to about 100 nm, because that range is where different or enhanced properties may be observed.[13] As experts from the United Kingdom's Royal Society and Royal Academy of Engineering explain:

> The properties of materials can be different at the nanoscale for two main reasons. First, nanomaterials have a relatively larger surface area when compared to the same mass of material produced in a larger form. This can make materials more chemically reactive (in some cases materials that are inert in their larger form are reactive when produced in their nanoscale form), and affect their strength or electrical properties. Second, quantum effects can begin to dominate the behaviour of matter at the nanoscale—particularly at the lower end—affecting the optical, electrical and magnetic behaviour of materials.[14]

Attempting to understand and exploit properties inherent in nanomaterials is in some sense not new.[15] "Nanoparticles occur naturally, and have been created for [millennia] . . . as the products of combustion and food cooking."[16] Chemists have been making polymers, composed of chains of nanoparticles, for decades.[17] What has

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[12] *Id.* One of the more well-known engineered nanoparticles, Carbon 60—also known as a "buckyball"—provides another perspective: "[T]he world is approximately one hundred million times larger than [a soccer ball], which is in turn one hundred million times larger than a buckyball." The Royal Soc'y & The Royal Acad. of Eng'g, Nanoscience and Nanotechnologies: Opportunities and Uncertainties 4 (2004), *available at* http://www.nanotec.org.uk/finalReport.htm [hereinafter Royal Society].

[13] Royal Society, *supra* note 12, at 5.

[14] *Id.* at vii. The Royal Society goes on to provide a slightly more technical explanation of the reactivity of nanomaterials:

> As a particle decreases in size, a greater proportion of atoms are found at the surface compared to those inside. For example, a particle of size 30 nm has 5% of its atoms on its surface, at 10 nm 20% of its atoms, and at 3 nm 50% of its atoms. Thus nanoparticles have a much greater surface area per unit mass compared with larger particles. As growth and catalytic chemical reactions occur at surfaces, *this means that a given mass of material in nanoparticulate form will be much more reactive than the same mass of material made up of larger particles.*

Id. at 7 (emphasis added).

[15] *Id.* at 5.

[16] *Id.* at 6.

[17] *Id.* at 5.

changed in recent years is scientists' ability to investigate, model, and manipulate matter at the nanoscale.[18] The invention of the scanning tunneling microscope (STM) in 1982, and the atomic force microscope (AFM) in 1986, have enabled scientists to use "nanoscale probes to image a surface with atomic resolution, and [also made scientists] capable of picking up, sliding or dragging atoms or molecules around on surfaces to build rudimentary nanostructures."[19] Researchers at all levels of government and academia have used these and other precision tools to investigate a variety of nanostructures, positing and delivering an impressive array of nanotechnology applications.[20]

A. *The Variety of Nanostructures*

In addition to exploiting novel properties, scientists aim to understand and make use of subtle structural differences among nanostructures[21]—differences that can have significant implications for nanomaterial manufacturers and government regulators.[22] Material properties and behavior differ, for example, depending on whether the nanomaterial is one-, two-, or three-dimensional.[23] For present purposes, materials of two and three dimensions are of most interest.[24]

Examples of two-dimensional nanomaterials include nanowires, bipolymers, inorganic nanotubes, and carbon nanotubes (CNTs).[25] CNTs are extended tubes of rolled graphene sheets that resemble chicken-wire with a unique and promising combination of physical properties.[26] "With one hundred times the tensile strength of steel, thermal conductivity better than all but the purest diamond, and electrical conductivity similar to copper, but with the ability to carry much

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[18] *See id.* at 6.

[19] Royal Society, *supra* note 12, at 6.

[20] *See id.* at 8–13 (describing the variety of nanotechnology applications).

[21] *See* Risk Assessment Unit, European Comm'n, Nanotechnologies: A Preliminary Risk Analysis on the Basis of a Workshop Organized in Brussels on 1–2 March 2004 by the Health and Consumer Protection Directorate General of the European Commission 18 (2004), http://europa.eu.int/comm/health/ph_risk/documents/ev_20040301_en.pdf [hereinafter EC Risk Assessment].

[22] *See* Royal Society, *supra* note 12, at 71.

[23] *See id.* at 8–10.

[24] One-dimensional nanomaterials include thin films, layers, and engineered surfaces which are already widely used in fields such as electronic device manufacturing, chemistry, and engineering. Royal Society, *supra* note 12, at 8.

[25] *See id.* at 9.

[26] *See id.* at 8 fig.3.1a. There are two basic types of carbon nanotubes: single-walled, which consist of one tube, and multi-walled, which consist of several concentric tubes. *See id.* at 8.

higher currents, they seem to be a wonder material."[27] Predictions for the global impact of this nanomaterial from CNT enthusiasts are nothing short of grandiose.[28] For example, some computer memory chip manufacturers are working with CNTs "to deliver a product that will replace all existing forms of memory, such as DRAM, SRAM and flash memory, ... [and] to enable instant-on computers and to replace the memory in devices such as cell phones, MP3 players, digital cameras, and PDAs . . . ."[29] Some are less enthusiastic about the prospects for CNTs, however, preferring to work with silicon nanowires, which are similar to CNTs but are easier to manufacture, and other more typical semiconductor materials.[30]

The third category of nanomaterials is made up of spherical, three-dimensional "nanoparticles."[31] Technically, nanoparticles have always existed as natural byproducts of photochemical and volcanic activity.[32] Moreover, humans have been inhaling nanoparticles ever since they began cooking food, and more recently have been breathing in nanopollutants from vehicle exhaust.[33] This Note, however, is concerned only with deliberately manufactured nanoparticles, the human health and safety of which remains an open question.

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[27] Cientifica, Nanotubes 12 (2004) (on file with author). As the Cientifica report notes, "[t]otal global production capacity of multi-walled nanotubes is higher than 99 tons a year and [is] expected to increase to at least 268 tons annually by 2007." *Id.* at 9. Global production of single-walled nanotubes is currently estimated at 9000 kilograms per year, and should increase to approximately 27 tons by 2005, and 100 tons by 2008. *Id.*

[28] The executive summary of the Cientifica report concludes: "Despite an inevitable element of hype, the versatility of nanotubes does suggest that they might one day rank as one of the most important materials ever discovered." Cientifica, *supra* note 27, at 19. Although such claims are premature, CNT already are proving quite versatile. *See Nanotechnology Kills Cancer Cells*, BBC News, Aug. 2, 2005, http://news.bbc.co.uk/1/hi/health/4734507.stm (reporting how Stanford University researchers recently used coated CNTs to kill cancer cells under laboratory conditions, without harm to surrounding tissue).

[29] Nantero, http://www.nantero.com/index.html (last visited Oct. 17, 2005).

[30] *See* Burt Helm, *The Skinny on Nanotubes*, Bus. Wk. Online, Oct. 28, 2004, http://www.businessweek.com/technology/content/oct2004/tc20041028_4779_tc120.htm.

[31] *See* EC Risk Assessment, *supra* note 21, at 18 (discussing distinctions among nanoparticles).

[32] Royal Society, *supra* note 12, at 9.

[33] *Id.*; *see* Todd Campbell et al., *Diesel-Electric Hybrid Buses: Addressing the Technical and Public Health Issues*, Natural Res. Def. Council, Apr. 1999, http://www.nrdc.org/air/transportation/pd-ebus.asp. There is evidence that efforts aimed at reducing larger particulate matter from diesel engines have actually increased the number of harmful ultrafine and nanoparticles in the air, defined as less than 0.1 microns and 0.05 microns in diameter respectively. *Id.*

One such deliberately manufactured nanoparticle is Carbon 60, also known as buckminsterfullerene or a "buckyball."[34] "These are spherical molecules about 1 nm in diameter, comprising 60 carbon atoms arranged as 20 hexagons and 12 pentagons: the configuration of a [soccer ball]."[35] Research for buckyballs and other "fullerenes" is focused on surface lubrication, drug delivery, and electronic circuit applications.[36]

Nanoparticles may be *fixed* or *free*, and *coated* or *uncoated*.[37] Fixed nanoparticles "are embedded in a matrix and cannot move."[38] Free nanoparticles, as their name implies, can disperse widely in the environment, and, in some cases, enter living organisms—including humans—and bioaccumulate in tissues and organs.[39] Coated nanoparticles remain inert for as long as their coating lasts, and thus tend to persist longer in the environment or in the human body than uncoated nanoparticles.[40] Coated nanoparticles also present classification difficulties for health, safety, and environmental regulators, as the addition of coating to nanoparticles could cause them to behave in novel ways, rendering regulations developed for the original nanoparticles of little use.[41]

B. *Current and Future Nanomaterial Applications*

A brief survey of the many uses of nanomaterials should serve to bolster claims that nanotechnology will be "at the heart of America's 'next industrial revolution.'"[42] Current and future uses cut across sev-

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[34] *See* ROYAL SOCIETY, *supra* note 12, at 4, 9–10.

[35] *Id.*

[36] *Id.* at 10. Dendrimers comprise another class of popular deliberately manufactured nanoparticles, defined as "spherical polymeric molecules, formed through a nanoscale hierarchical self-assembly process." *Id.* Like buckyballs, dendrimers might be used as drug-delivery vehicles in the future, but current applications include use in chemical coatings and inks. *See id.* Of particular interest to environmentalists is some dendrimers' ability to trap metal ions, which could then be filtered out of contaminated water using ultrafiltration techniques. *Id.*

[37] *See* EC RISK ASSESSMENT, *supra* note 21, at 18.

[38] *Id.* Nanosized transistors, for example, can form part of a millimeter-sized chip and therefore be "fixed." ROYAL SOCIETY, *supra* note 12, at 35; *see also Infineon Shrinks Transistors with Nanotubes*, SMALL TIMES, Nov. 23, 2004, http://www.smalltimes.com/document_display.cfm?section_id=29&document_id=8452 [hereinafter *Infineon*] (describing one such CNT-based transistor).

[39] EC RISK ASSESSMENT, *supra* note 21, at 18.

[40] *See id.*

[41] *See* HETT, *supra* note 11, at 37.

[42] *See* Rick Weiss, *Nanoparticles Toxic in Aquatic Habitat, Study Finds*, WASH. POST, Mar. 29, 2004, at A2.

eral disciplines, and include:[43] sunscreens and cosmetics,[44] composites,[45] clays, coatings and surfaces,[46] cutting tools, paints, environmental remediation tools,[47] fuel cells, electronic displays, batteries, semiconductors,[48] fuel additives, chemical catalysts. lubricants, magnetic materials, medical implants, water purification,[49] and military battle suits.[50] This list is by no means comprehensive. As Horst Stormer, Nobel Laureate in Physics, has observed, "'[n]anotechnology has given us the tools to play with the ultimate toy box of nature: atoms and molecules' . . . . 'Everything is made from these, and the possibilities to create new things seem limitless.'"[51] This fact has not been lost on the international community, prompting another physics professor to remark, "'[e]very nation in the world is looking at nanotechnology as a

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[43] *See* ROYAL SOCIETY, *supra* note 12, at 10–13 (describing current and potential applications of nanomaterials).

[44] Nanosized titanium dioxide is currently used in some commercial sunscreens, as these materials are transparent but still absorb and reflect ultraviolet light. *Id.* at 10; *see* Jayne Fried, *DuPont Buys IP for Nanomaterial Seen as Hot in Cosmetics, Coatings*, SMALL TIMES, July 17, 2002, http://www.smalltimes.com/document_display.cfm?section_id=51&document_id=4173. Nan osized iron oxide, on the other hand, has properties that enable it to be used as a pigment in some lipsticks. ROYAL SOCIETY, *supra* note 12, at 10.

[45] One type of nanocomposite incorporates multi-walled CNTs to control conductivity in anti-static packaging. ROYAL SOCIETY, *supra* note 12, at 10.

[46] Nanoengineered titanium dioxide has also been used as a coating for a self-cleaning window that reduces surface tension such that waterdrops roll off so quickly that they take any dust and foreign particles with them. *Id.* at 10; *see* HETT, *supra* note 11, at 34. Researchers have also applied this concept, using silver nanoparticles, to create self-cleaning clothes. *See* John K. Borchardt, *Now, the Ever-Clean Suit*, CHRISTIAN SCI. MONITOR, Jan. 13, 2005, at 17.

[47] Several researchers have tried pumping reactive nanoparticles into soil to transform heavy pollutants—such as organic solvents or heavy metals—into less harmful substances by means of a chemical reaction. ROYAL SOCIETY, *supra* note 12, at 11; *see* HETT, *supra* note 11, at 27.

[48] *See Infineon*, *supra* note 38 ("Infineon Technologies AG . . . has created what it's calling the world's smallest carbon nanotube-based transistor, another step on the road to seeking a replacement to silicon in microelectronic devices.").

[49] Silver nanoparticles with an antibacterial effect are being tested to determine if they can effectively decontaminate drinking water. HETT, *supra* note 11, at 27; ROYAL SOCIETY, *supra* note 12, at 12–13.

[50] *See* MIT Inst. for Soldier Nanotechnologies, About ISN, http://web.mit.edu/isn/aboutisn/ (last visited Oct. 17, 2005) ("The ultimate goal is to create a 21st century battlesuit that combines high-tech capabilities with light weight and comfort. Imagine a bulletproof jumpsuit, no thicker than ordinary spandex, that monitors health, eases injuries, communicates automatically, and maybe even lends superhuman abilities.").

[51] Alissa Kaplan Michaels, *Columbia Hosts 'Nano-Day in New York,'* COLUMBIA NEWS (N.Y., N.Y.), May 4, 2004, http://www.columbia.edu/cu/news/04/05/nanoday.html.

future technology that will drive its competitive position in the world economy.'"[52]

C. *Government and Private Investment in Nanotechnology*

The United States government has been investing heavily in nanotechnology research and development for some time, sprouting something of a large nano-bureaucracy along the way.[53] The National Nanotechnology Initiative (NNI) was established in 2001 to coordinate nanotechnology research and development throughout the federal government.[54] In December 2003, Congress passed the 21st Century Nanotechnology Research and Development Act, which formalized the preexisting bureaucratic arrangement under the less formal NNI, established research centers, and appropriated the necessary funds.[55] The Nanoscale Science, Engineering and Technology (NSET) Subcommittee of the National Science and Technology Council's Committee on Technology is responsible for coordinating the research programs.[56] The National Nanotechnology Coordination Office provides day-to-day technical and administrative support for NSET activity.[57] In the first year of NNI, investment totaled $464 million for six agencies.[58] In fiscal year 2006, eleven agencies are now involved and the funding request has increased to $1.054 billion.[59]

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[52] HETT, *supra* note 11, at 6 (quoting Neal Lane, Professor of Physics, Rice University).

[53] *See* Nat'l Nanotechnology Initiative, History, http://www.nano.gov/html/about/history.html (last visited Oct. 18, 2005).

[54] Roco, *supra* note 4, at 1; *see* Nat'l Nanotechnology Initiative, *supra* note 53. Participating agencies include: the Consumer Product Safety Commission; the Departments of Agriculture, Commerce, Defense, Energy, Homeland Security, Justice, State, Transportation, and Treasury; the National Institutes of Health; Centers for Disease Control and Prevention; the National Institute for Occupational Safety and Health; the Environmental Protection Agency; the Food and Drug Administration; the Intelligence Community; the International Trade Commission; the National Aeronautics and Space Administration; the National Science Foundation; the Nuclear Regulatory Commission; and the Patent and Trademark Office. Nat'l Nanotechnology Initiative, Government Departments and Agencies, http://www.nano.gov/html/gov/home_gov.html (last visited Oct. 27, 2005).

[55] 15 U.S.C.A. §§ 7501–09 (West Supp. 2004).

[56] *See* Nat'l Nanotechnology Initiative, *supra* note 53.

[57] *Id.*

[58] NNI STRATEGIC PLAN, *supra* note 2, at iii.

[59] OFFICE OF SCI. & TECH. POLICY, EXECUTIVE OFFICE OF THE PRESIDENT, NATIONAL NANOTECHNOLOGY INITIATIVE, RESEARCH AND DEVELOPMENT FUNDING IN THE PRESIDENT'S 2006 BUDGET, http://www.ostp.gov/html/budget/2006/One-Pagers/FY06NationalNanotechnologyInitiative1-pager.pdf (last visited Oct. 27, 2005).

Not to be outdone, the race is on at the state level to pass favorable legislation[60] and otherwise to compete to become centers of nanotechnology research and manufacturing.[61] For example, in early 2005, New York Governor George Pataki announced that over $2.7 billion in private funds had been committed to support semiconductor and nanotechnology research and development in New York State, while Texas Governor Rick Parry unveiled his state's Nanotechnology Workforce Development Initiative, backed by a $500,000 grant.[62]

Amidst the fervid interest in nanotechnology, however, are legitimate concerns about the safety of nanomaterials.[63] The United Kingdom's Royal Society recommended "that factories and research laboratories treat manufactured nanoparticles and nanotubes as if they were hazardous . . . [and] that the use of free . . . manufactured nanoparticles in environmental applications such as remediation be prohibited until appropriate research has been undertaken."[64] A closer look at the science that influenced this conclusion tends to support this precautionary approach.

D. *Possible Adverse Health, Safety, and Environmental Impacts of Nanomaterials*

Human contact with manufactured nanomaterials may occur in various ways, including skin absorption, inhalation, and ingestion.[65] For physical harm to occur, a nanomaterial must not only contact or enter the body, but also interact with cells, causing tissue-damaging reactions.[66] For risk underwriters,

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[60] *See* Arkansas Emerging Technology Development Act of 1999, Ark. Code Ann. §§ 15-4-2101 to -2107 (2003). Section 15-4-2104 allows tax credits for locating nanotechnology facilities within Arkansas. *Id.* § 15-4-2104.

[61] *See* David Forman & Candace Stuart, *Regional Recap: States Fund, Flaunt Nano Competitiveness*, Small Times, Jan. 10, 2005, http://www.smalltimes.com/document_display.cfm?document_id=8578.

[62] *Id.*

[63] *See, e.g.*, Eva Oberdörster, *Manufactured Nanomaterials (Fullerenes, C_{60}) Induce Oxidative Stress in the Brain of Juvenile Largemouth Bass*, 112 Envtl. Health Persp. 1058, 1061–62 (2004), *available at* http://ehp.niehs.nih.gov/members/2004/7021/7021.pdf.

[64] Royal Society, *supra* note 12, at 85.

[65] Hett, *supra* note 11, at 15. Since this Note focuses on workplace and general environmental exposure, this section omits discussion of the potential implications of ingesting nanoparticles with food. *See id.* at 19–20 (discussing the possible effects of swallowing nanoparticles).

[66] Royal Society, *supra* note 12, at 36.

> [a] distinction is made as to whether a substance remains outside the body, remains on the surface of the skin or gains access to the body and gets into the blood-stream. Special attention is paid to particularly vulnerable organs such as the brain because foreign substances that are able to penetrate into such sensitive areas are considered to be particularly exposed to product liability.[67]

1. Skin Absorption

"The top layer of skin consists of calloused cells without blood supply," which constitutes a semi-permeable barrier.[68] Preliminary studies have not settled the question of whether nanoparticles can pass through the skin's layers and into the bloodstream.[69] Nanosized titanium dioxide, currently used in sunscreen, was declared safe for use as an ultraviolet filter by a European safety agency.[70] The United States Food and Drug Administration came to a similar conclusion for "micronized"—less than two hundred nm—titanium dioxide in 1999.[71] But these two tentative endorsements of one nanosubstance used in cosmetics hardly amounts to conclusive proof that nanoparticles are not capable of being absorbed through the skin, and there have been calls for additional research.[72]

2. Inhalation

If a nanomaterial is released into the air—in the workplace, for example—it may be inhaled.[73] The small size of nanomaterials ensures that inhaling a significant quantity would result in penetration deep into the lung.[74] Some studies on laboratory animals have sug-

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[67] HETT, *supra* note 11, at 15.

[68] *Id.* at 18.

[69] *See id.*; *see also* Burt Helm, *The Worries over Nano No-Nos*, BUS. WEEK ONLINE, Feb. 23, 2005, http://www.businessweek.com/technology/content/feb2005/tc20050223_6956_tc204.htm ("Scientists fear that if the metallic atoms in these lotions get into the body, they'll create free radicals and undergo oxidation reactions, literally pulling cells apart in a fashion similar to the way alcohol consumption and cigarette smoking destroy cells.").

[70] ROYAL SOCIETY, *supra* note 12, at 44.

[71] *See* Sunscreen Drug Products for Over-The-Counter Human Use, 64 Fed. Reg. 27,666, 27,671 (May 21, 1999) (codified at 21 C.F.R. pts. 310, 352, 700, & 740).

[72] *See* ROYAL SOCIETY, *supra* note 12, at 48.

[73] *Id.* at 36.

[74] *Id.* at 42. Nanoparticles are capable of passing through the cell membrane, with the possibility of disrupting key cell functions. *Id.*

gested that large doses of carbon nanotubes (CNTs) may be irrespirable.[75] In fact, perceived similarities between CNTs and asbestos fibers have led to concerns about their safety; the Royal Society, for example, has concluded "that there is sufficient concern about possible hazards to those involved in the research and early industrial development of nanotubes to control their exposure."[76] Similar concerns have been raised regarding fullerenes, with the most alarming study suggesting that fish may suffer brain damage if exposed to sufficient amounts of fullerenes.[77] The author of that study warned:

> Given the rapid onset of brain lipid peroxidation, it is important from a preventative point of view to further test manufactured nanomaterials before they are used by humans and in industrial applications. If such preventative principles had been applied to compounds such as DDT and polychlorinated biphenyls, significant environmental damage could have been avoided.[78]

Other researchers share the opinion that precautionary environmental policies ought to be adopted immediately until more is understood about the risks inherent from human contact with nanomaterials.[79]

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[75] *See, e.g.*, D.B. Warheit et al., *Comparative Pulmonary Toxicity Assessment of Single-Wall Carbon Nanotubes in Rats*, 77 Toxicological Sci. 117, 117 (2004), *available at* http://toxsci.oupjournals.org/cgi/content/full/77/1/117. Dr. Warheit's team instilled single-walled carbon nanotube soot mixture into the trachea of rats, with appropriate control groups included for comparison purposes. *See id.* at 117–18. Fifteen percent of the rats treated with carbon nanotubes suffocated to death within twenty-four hours due to clumping of the nanotubes that obstructed the bronchial passageways. *See id.* at 117. Granulomas and other inflamed-tissue reactions occurred in reaction to the foreign substance. *Id.*

[76] Royal Society, *supra* note 12, at 43. The Royal Society also noted that

> [i]t is unlikely that [CNTs] would remain as individual fibres in the air; rather, electrostatic forces probably cause them to clump into masses that are less easily inhaled to the deep lung. However, little is known of their aerodynamic properties and indeed whether they can be present in the air in sufficient numbers to constitute a risk.

Id. at 42. The Royal Society concluded, however, that "[g]iven previous experience with asbestos, we believe that nanotubes deserve special toxicological attention." *Id.* at 43.

[77] *See generally* Oberdörster, *supra* note 63.

[78] *Id.* at 1061–62.

[79] *See* EC Risk Assessment, *supra* note 21, at 107. C. Vyvyan Howard, Head of Research of the Developmental Toxico-Pathology Research Group, unequivocally stated his position:

> We are defenceless against the assimilation of nanoparticles by swallowing, inhalation or absorption through the skin. While it is easy to appreciate how this can be harnessed to positive pharmaceutical purposes, there is an urgent need to curb the generation of unnecessary nanoparticles, particularly of the

E. *Assessing the Hazard*

These safety assessments, which are part of a growing body of research into the health, safety, and environmental impacts of nanomaterials, have captured the attention of NNI. For fiscal year 2006, NNI allocated approximately $81 million for research on the health and environmental aspects of nanoscale materials.[80] But is that enough to assess the hazards of what the National Science Foundation has estimated could be a trillion-dollar industry by 2015?[81]

Given the bewildering number of permutations that can occur at the molecular level, no amount may ever be "enough" for risk assessment purposes. Rather, NNI should develop an assessment framework that works reasonably well for most substances. As Dr. Vicki Colvin, Director of the Center for Biological and Environmental Nanotechnology,[82] has pointed out, "it is far too premature to complete a formal risk assessment for engineered nanomaterials—in fact, it may never be possible with such a broad class of substances."[83]

Parts II and III of this Note describe two federal statutes—the Toxic Substances Control Act and the Occupational Safety and Health Act of 1970—which take different approaches to mitigating the risks posed by substances of both known and unknown toxicity.

> insoluble variety. There is already enough evidence available, to demonstrate that nanoparticles are likely to pose a health hazard and that human exposure in general, and in particular exposure of pregnant women and in the workplace, should be minimised on a precautionary basis. We are dealing with a potentially hazardous process. Full hazard assessments should be performed to establish the safety of each type of nanoparticle before manufacturing is licensed.

Id.

[80] Nat'l Nanotechnology Initiative, Funding for Social Dimensions, http://www.nano.gov/html/society/Funding_SocDim.htm (last visited Oct. 27, 2005).

[81] *See* Sarah Graham, *Nanotech: It's Not Easy Being Green*, SCI. AMERICAN.COM, July 28, 2003, http://www.sciam.com/article.cfm?articleID=00077C33-511E-1F20-B8E780A84189EEDF&sc=I100322.

[82] Ctr. for Biological and Envtl. Nanotechnology, Center Administration, http://cben.rice.edu/about.cfm?doc_id=5001 (last visited Oct. 27, 2005).

[83] Colvin, *supra* note 5, at 1166. Furthermore, Dr. Colvin has also noted that pressing funding managers to focus on potential drawbacks to a trendy technology can be difficult because "'[t]he immediate payback for research that demonstrates ways of using nanomaterials to cure disease . . . is greater than the reward for uncovering that nanomaterial may cause disease.'" HETT, *supra* note 11, at 29 (quoting Vicki L. Colvin).

II. The Toxic Substances Control Act

The first policy stated by Congress in the Toxic Substances Control Act (TSCA) is that "adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures."[84] But what exactly is a "chemical substance" for TSCA purposes?[85]

Section 2602(2)(A) provides:

> Except as provided in subparagraph (B), the term "chemical substance" means any organic or inorganic substance of a particular molecular identity, including—
>
> (i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature and
>
> (ii) any element or uncombined radical.[86]

Exactly in accord with congressional intent, this broad definition sweeps in a large number of potentially hazardous substances. In effect, TSCA fills the gap left by other federal environmental statutes, which for the most part do not assess the adverse effects of chemical substances on human health and the environment.[87]

A. *Classification Issues: When Is a Chemical Substance "New"?*

Under section 5(a) of TSCA, anyone who wishes to manufacture or import a "new" chemical substance must file a Premanufacture Notification (PMN) with EPA.[88] Specifically, before any new chemical substance is imported or manufactured, or any existing chemical is put to a "significant new use," PMNs require that EPA be given ninety days notice.[89] The burden is on the manufacturer or importer to de-

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[84] 15 U.S.C. § 2601(b)(1) (2000).

[85] *See* Wardak, *supra* note 9, at 3–4.

[86] 15 U.S.C. § 2602(2)(A). Mixtures, pesticides, tobacco, nuclear materials, and certain food and drugs are among the items exempted from TSCA's reporting requirements. *See id.* § 2602 (2)(B).

[87] *See* Cynthia A. Lewis & James M. Thunder, Federal Chemical Regulation: TSCA, EPCRA, and the Pollution Prevention Act 79 (1997).

[88] 15 U.S.C. § 2604(a)(1); Ginger L. Griffin, The TSCA Compliance Handbook 11 (3d ed. 1996).

[89] Griffin, *supra* note 88, at 11; *see* 15 U.S.C. § 2604(a).

termine whether or not a substance is new.[90] To determine this, a manufacturer would look first to the TSCA Chemical Substance Inventory (Inventory).[91]

The Inventory contains both public and confidential portions; EPA maintains the confidential portion in order to protect proprietary chemical information.[92] If the substance is already listed on the public portion of the Inventory, it is an existing chemical, and the manufacturer is free to begin producing the chemical and has no obligation to submit a PMN pursuant to section 5.[93] If it is not in the public portion of the Inventory, a manufacturer would have to file a Bona Fide Intent to Manufacture with EPA—a process that can take up to thirty days—to determine if the substance is in the confidential portion.[94] Assuming the chemical is not in the Inventory, the manufacturer or importer will have to consider filing a PMN, unless any of a number of statutory exemptions can be invoked.[95]

B. *Statutory Exemptions*

A number of statutory exemptions to a PMN filing are available.[96] First, exempted completely from TSCA regulation are entire classes of materials that are regulated elsewhere, including: pesticides, tobacco products, nuclear material, firearms and ammunition, food and food additives, drugs and medical devices, and cosmetics.[97] No PMN is required for impurities and by-products without a separate commercial use, nor is a PMN required for "mixtures" that result from combining two chemicals that are already in the Inventory.[98] Other common ex-

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[90] GRIFFIN, *supra* note 88, at 11.

[91] *Id.* "There are approximately 75,000 chemical substances, as defined in Section 3 of the TSCA, on the Inventory at this time." EPA, New Chemicals Program, What Is the TSCA Chemical Substance Inventory?, http://www.epa.gov/opptintr/newchems/invntory.htm (last visited Oct. 20, 2005). Before a chemical would appear in the TSCA Chemical Substance Inventory (Inventory), it probably must be given a Chemical Abstracts Service Registry Number (CASRN). *See* WARDAK, *supra* note 9, at 10. CASRNs are unique identifying numbers, which are given to virtually every new chemical and are internationally recognized. CAS Registry, http://www.cas.org/EO/regsys.html (last visited Oct. 20, 2005). The Chemical Abstracts Service Registry contains over 26 million organic and inorganic substances and 56 million chemical sequences. *Id.*

[92] *See* GRIFFIN, *supra* note 88, at 13.

[93] *Id.*

[94] *Id.* at 13–14.

[95] *Id.* at 14.

[96] *See* WARDAK, *supra* note 9, at 11–12.

[97] 15 U.S.C. § 2602(2)(B) (2000).

[98] GRIFFIN, *supra* note 88, at 15.

emptions include: the Research and Development Exemption (R&D), the Solely-for-Export Exemption, the Low-Volume Exemption, the Low-Release and Exposure Exemption (LoREx), and the Test-Marketing Exemption.[99]

The R&D and the Test-Marketing exemptions can only be invoked if small quantities of chemicals will be produced.[100] R&D activities include synthesis of, or research on, new chemical substances.[101] The Low-Volume and LoREx exemptions can only be invoked if the manufacturer intends to produce less than ten thousand kilograms—or about twenty-two thousand pounds—of chemicals per year.[102]

C. *The Premanufacture Notification Process*

Assuming the PMN process cannot be circumvented, a chemical manufacturer has a number of potential issues to address.[103] TSCA section 5(a) mandates that if a manufacturer is going to produce or import a new chemical, it must notify EPA of its intention to do so ninety days in advance.[104] The manufacturer also must provide EPA with "data which the [submitter] . . . believes show[s] that . . . the manufacture, processing, distribution in commerce, use, and disposal of the chemical substance . . . will not present an unreasonable risk of injury to health or the environment."[105] The purpose of submitting a PMN is to give EPA an opportunity to screen the chemical for health and environmental risks.[106] If EPA does not use this opportunity to screen the chemicals, the production may go forward despite the lack of testing.[107] Most importantly, if a company has no toxicity data for a given chemical, the manufacturer is only required to submit data that already exists elsewhere,[108] or may simply rely on information for

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[99] *See* WARDAK, *supra* note 9, at 11–12; LEWIS & THUNDER, *supra* note 87, at 50.

[100] *See* GRIFFIN, *supra* note 88, at 15–16.

[101] *Id.* at 16.

[102] *Id.* at 17.

[103] *See* Premanufacture Notification, 40 C.F.R. § 720 (2004) (mandating procedures for PMN compliance); s*ee also* GRIFFIN, *supra* note 89, at 11–34 (providing step-by-step overview of the PMN process).

[104] *See* 15 U.S.C. § 2604(a) (2000).

[105] *Id.* § 2604(b)(2)(B).

[106] JOHN S. APPLEGATE ET AL., THE REGULATION OF TOXIC SUBSTANCES AND HAZARDOUS WASTES 611 (2000); *see* 15 U.S.C. § 2604(e)(1)(A).

[107] *See* APPLEGATE ET AL., *supra* note 106, at 611.

[108] *See* GRIFFIN, *supra* note 88, at 23, 28.

chemicals that are structurally analogous to the one being reviewed.[109]

EPA can also seek to delay production if it finds that additional data is necessary to understand a chemical's risk-profile.[110] If in EPA's estimation the PMN information reveals unreasonable risk, EPA may issue a proposed rule that becomes effective immediately.[111] EPA may have to go to court to prevent production if it finds that the chemical "may present" an unreasonable risk; however, EPA may act on its own if it finds that the chemical "presents or will present" an unreasonable risk.[112]

One key advantage to not filing a PMN is that a manufacturer would be exempt from producing or offering studies describing the material's safety.[113] If subject to the PMN process, the manufacturer must provide copies of all health and environmental effects test data relating to the substance that are in its possession or control.[114] The manufacturer must also provide descriptions of all other health and environmental effects data that it knows about or can reasonably ascertain.[115]

The term "known to or reasonably ascertainable" covers "all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know."[116] The cost and burden to the submitter in obtaining information is considered by EPA in determining whether such information is known or reasonably ascertainable by a manufacturer.[117] Thus, what is reasonable to a large company with a sizable research budget would not necessarily be reasonable to a small startup.[118] Regulators have also sought to curb abuse of shell corporation setups by defining "possession or control" to mean "in possession or control of the submitter, or of any subsidiary, partnership . . . [or] parent company."[119]

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[109] *Id.* at 28.
[110] *See* 15 U.S.C. § 2604(e).
[111] *See id.* § 2605(d).
[112] *Id.* § 2604(e)(1)(A), (f); Applegate et al., *supra* note 106, at 611.
[113] *See* 15 U.S.C. § 2604(b); Griffin, *supra* note 88, at 22.
[114] 15 U.S.C. § 2604(d)(1)(B).
[115] *Id.* § 2604(d)(1)(C).
[116] Premanufacture Notification, 40 C.F.R. § 720.3(p) (2004).
[117] Griffin, *supra* note 88, at 23.
[118] *Id.* at 23.
[119] 40 C.F.R. § 720.3(y).

D. *The Fate of Filed Premanufacture Notifications*

However, despite the ominous statutory language, a closer look at the fate of filed PMNs reveals that being forced to submit a PMN might not be so disagreeable after all. For example, in 1983, the Office of Technology Assessment reported that approximately fifty percent of PMNs included no toxicity information at all, and less than twenty percent provided figures on long-term toxicity.[120] Three thousand PMNs were filed in 1988; twenty-three hundred in 1995; and fifteen hundred in 1997.[121] In fiscal year 1987–88, EPA stated that it took no action on ninety percent of PMNs; in 1995, EPA took no action on *ninety-eight percent* of PMNs.[122]

E. *The Toxic Substances Control Act Section 8 Reporting Requirements*

Section 8(a) of TSCA requires chemical manufacturers to keep records and make certain reports to EPA.[123] Section 8(a)(2) specifies that EPA may require reports on a chemical substance containing the substance's chemical identity, trade name, molecular structure, proposed use, amounts manufactured or processed, resultant by-products, "[a]ll existing data concerning the environmental and health effects of such substance," the number of persons exposed, and the method of disposal.[124] In addition, section 8(d) essentially mandates manufacturers, processors, and distributors to provide EPA with access to unpublished studies that EPA would not know about otherwise.[125]

F. *The Toxic Substances Control Act Section 4 Testing*

In contrast to the screening function of section 5 PMNs, and the information-gathering function of section 8, section 4 allows EPA to require that manufacturers generate new test data in the face of unreasonable risk or substantial human exposure.[126] After an initial screen of chemical safety based on existing data, if EPA finds that not enough information exists to determine whether a chemical poses an

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[120] Applegate et al., *supra* note 106, at 611.

[121] *Id.*

[122] *Id.*

[123] *See* 15 U.S.C. § 2607 (2000); Griffin, *supra* note 88, at 53.

[124] 15 U.S.C. § 2607(a)(2).

[125] Griffin, *supra* note 88, at 55; *see* Premanufacture Notification, 40 C.F.R. § 720.3(k)(1).

[126] *See* 15 U.S.C. § 2603(a).

unreasonable risk, it may list the chemical for testing consideration.[127] The multi-agency Interagency Testing Committee (ITC) also recommends chemicals for testing through its Priority Testing List (PTL).[128] If either by its own determination or on recommendation from ITC EPA determines that a chemical needs testing, it may promulgate a formal test rule or enter into a voluntary testing consent agreement with the manufacturer.[129]

1. When Will EPA Take Action Under the Toxic Substances Control Act Section 4?

Section 4(a)(1)(A) allows EPA to take action if:

> (i) [T]he manufacture . . . of a chemical substance . . . may present an unreasonable risk of injury to health or the environment,
>
> (ii) there are insufficient data and experience upon which the effects of such manufacture . . . of such substance . . . on health or the environment can reasonably be determined or predicted, and
>
> (iii) testing of such substance . . . is necessary to develop such data . . . .[130]

In addition, Congress has enacted the so-called "B-policy" of TSCA testing, which empowers EPA to take action if:

> (i) [A] chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (II) there is or may be significant or substantial human exposure to such substance or mixture, [and there are insufficient data and a need to develop such data, as in subsection A].[131]

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[127] GRIFFIN, *supra* note 88, at 35.

[128] *See id.* at 36–37; *see, e.g.*, Fifty-Fifth Report of the TSCA Interagency Testing Committee to the Administrator of the Environmental Protection Agency, 70 Fed. Reg. 7364, 7366 (Feb. 11, 2005); Fifty-Fourth Report of the TSCA Interagency Testing Committee to the Administrator of the Environmental Protection Agency, 69 Fed. Reg. 33,528, 33,530 (June 15, 2004). The list may not exceed fifty chemicals at one time, which arguably limits the PTL's effectiveness and shortens the list of chemicals under serious scrutiny. *See* 15 U.S.C. § 2603(e)(1)(A).

[129] GRIFFIN, *supra* note 88, at 35.

[130] 15 U.S.C. § 2603(a)(1)(A).

[131] *Id.* § 2603(a)(1)(B).

Both the courts and EPA have struggled to define the basis for an "unreasonable risk" to health, to the indisputable detriment of the TSCA testing regime.

2. Defining "Unreasonable Risk" and "Substantial and Significant Exposure"

The D.C. Circuit Court of Appeals in *Chemical Manufacturers Ass'n v. EPA* interpreted TSCA to hold EPA to less than the common law's "preponderance of evidence" test in finding an unreasonable risk under section 4(a)(1)(A)—what the court called a "more-than-theoretical basis" for finding an unreasonable risk.[132] As for substantial and significant exposure, in a Fifth Circuit Court of Appeals decision concerning a test rule on the chemical cumene, the court struggled to understand what EPA meant by "substantial" exposure.[133] For example, the court analyzed EPA's stated rationale for when it will make the required findings under subsections A and B of section 4(a)(1) by examining the following language from EPA's *Federal Register* notice for a proposed test rule on Chloromethane and Chlorinated Benzenes:

> "While there is a need to show a potential for exposure in order to make a Section 4(a)(1)(A) finding, the exposure threshold is much lower than that under Section 4(a)(1)(B). This is because the former . . . finding was intended to focus on those instances where EPA has a scientific basis for suspecting potential toxicity and reflects that the potential for risk to humans may be significant even when the potential for exposure seems small as, for example, when the chemical is discovered to be hazardous at very low levels. In contrast, the 4(a)(1)(B) finding was intended to allow EPA to require testing, not because of suspicions about the chemical's safety, but because there may be substantial or significant human exposure to a chemical whose hazards have not been explored."[134]

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[132] *See* Chem. Mfrs. Ass'n v. EPA (*CMA I*), 859 F.2d 977, 979 (D.C. Cir. 1988) ("The probability of infrequent or even one-time exposure to individuals can warrant a test rule, so long as there is a more-than-theoretical basis for determining that exposure in such doses presents an 'unreasonable risk of injury to health.'").

[133] *See* Chem. Mfrs. Ass'n v. EPA (*CMA II*), 899 F.2d 344, 359 (5th Cir. 1990).

[134] *Id.* at 358 n.20 (quoting Chloromethane and Chlorinated Benzenes Proposed Test Rule, 45 Fed. Reg. 48,524, 48,528 (July 18, 1980)).

The Fifth Circuit, not satisfied with this and other explanations, ultimately remanded the test rule to EPA to refine what is meant by "substantial" exposure to a chemical.[135]

EPA responded by issuing "TSCA Section 4(a)(1)(B) Final Statement of Policy," which defines "substantial production" and "substantial release." in addition to "substantial and significant human exposure."[136] "Substantial production" was defined to be a "threshold value of 1 million pounds" for all manufacturers of a chemical.[137] One million pounds was chosen in part because it "narrows the 'universe' of chemicals potentially subject to TSCA section 4 testing . . . to 11 percent of the TSCA inventory."[138] EPA defined the human exposure criteria guidelines with respect to three categories of persons affected: the general population, consumers, and workers.[139] For the general population, exposure to 100,000 people is considered "substantial," while exposure to a lesser number of people would be considered "significant" if those people were exposed "more directly or on a routine or episodic basis."[140] The same framework applies to consumers and workers, except the quantitative threshold for consumers is ten thousand people, while the threshold for workers is one thousand people.[141] EPA also reserves the right to dispense with the numerical thresholds when necessary, if "additional factors" weigh in favor of testing under the B-policy:

> In some cases, however, where the thresholds are not met, it may be more appropriate to use a case-by-case approach for making findings by applying other considerations. . . . [Thus,] EPA may consider "additional factors" for making findings for substances which do not meet the numerical thresholds articulated herein for evaluating existing chemicals under TSCA section 4(a)(1)(B).[142]

However, although consideration of additional factors gives EPA a certain degree of freedom to order testing under the B-policy, the procedure for ordering testing remains formal and rigid. For example, the

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[135] *See id.* at 360.

[136] TSCA Section 4(a)(1)(B) Final Statement of Policy, 58 Fed. Reg. 28,736, 28,746 (May 14, 1993).

[137] *Id.*

[138] *Id.* at 28,740.

[139] *Id.* at 28,746.

[140] *Id.* at 28,746 tbl.1.

[141] *Id.*

[142] TSCA Section 4(a)(1)(B) Final Statement of Policy, 58 Fed. Reg. at 28,746.

plaintiffs in *Physicians Committee for Responsible Medicine v. Leavitt* attempted to prevent EPA from implementing its High Production Volume (HPV) Challenge Program, whereby chemical manufacturers would volunteer to gather data and test certain HPV chemicals.[143] The plaintiffs argued that EPA had a non-discretionary duty to initiate formal rulemaking and testing under the B-policy because EPA had made "*de facto* . . . findings of substantial production, substantial release and/or substantial human exposure."[144] The plaintiffs based the contention that the requisite findings had been made on EPA's unsupported statements published in the *Federal Register* and made in presentations to Congress.[145] For example, EPA made the commonsense assertion in the *Federal Register* that "[i]t is generally accepted that chemicals having a high level of production have an increased potential for exposure in comparison to low production volume chemicals."[146] The *Leavitt* court found, however, that the plaintiffs "proffered no evidence to indicate that the general statements made by EPA were the product of an analysis that in any way approximates, or can be substituted for, the type of analysis that would be required for a formal finding of substantial release and/or substantial exposure."[147] As a result, the court sided with EPA, preserving EPA's alternative testing arrangement with industry.[148]

A glance at the "type of analysis required" goes a long way in explaining why EPA would prefer alternative testing arrangements to formal rulemaking.[149] Promulgation of formal test rules is not only

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[143] *See* 331 F. Supp. 2d 204, 204 (S.D.N.Y. 2004).

[144] *Id.* at 205.

[145] *Id.* at 205–06.

[146] Data Collection and Development on High Production Volume (HPV) Chemicals, 65 Fed. Reg. 81,686, 81,688 (Dec. 26, 2000).

[147] 331 F. Supp. 2d at 207.

[148] *Id.*

[149] *See id.* The court explains the quintessentially bureaucratic analysis required:

> [F]ormal proceedings on this issue would normally have involved: (a) the establishment of a workgroup within EPA's Office of Pollution Prevention and Toxics ("OPPT") to conduct a review regarding which HPV Program chemicals satisfy the statutory requirements for rulemaking, what data exist to support the making of Section 4 findings and the development of proposed test rules to fill in data gaps for HPV Program chemicals; (b) the presentation of information from the OPPT workgroup to the OPPT Office Director, whose task it would then be to make a recommendation to the Assistant Administrator for the Office of Prevention, Pesticides and Toxic Substances ("OPPTS"), who is the only EPA official (besides the Administrator) authorized to make Section 4 findings . . . .

Id.

time-consuming, but expensive.[150] Thus, EPA and industry will often enter into testing consent agreements instead.[151] These agreements are entered into by EPA with individual manufacturers, or groups of manufacturers that have formed consortiums to share costs.[152] A formal test rule would apply to all manufacturers, while a consent agreement can allow testing to commence without having every conceivable constituent involved.[153] In addition, some manufacturers have benefited from taking the lead in suggesting testing methods that EPA has neither the time nor the inclination to oppose aggressively.[154]

G. *The Toxic Substances and Control Act Penalties*

Section 16 identifies the penalties for TSCA violations.[155] EPA is authorized to impose a civil penalty of up to twenty-five thousand dollars per violation, with each day of violation constituting a separately punishable act.[156] In addition, any person who "knowingly or willfully" violates a TSCA provision may be subject to an additional criminal penalty of twenty-five thousand dollars per day for each violation, imprisonment up to one year, or both.[157]

III. The Occupational Safety and Health Act of 1970

As discussed in Part II, the main function of TSCA is to place a reporting burden on manufacturers and importers of chemical substances. The Occupational Safety and Health Act of 1970 (OSH Act), on the other hand, imposes two broad duties on all employers, regardless of an employer's line of business.

The first duty, known as the "general duty clause" mandates that each employer "furnish to each of his employees employment and a place of employment which are free from recognized hazards that are

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[150] *See* Applegate et al., *supra* note 106, at 618 (noting that proposed test rules on glycidols would cost $18 million and estimates for fluoroalkane testing ranged from $4.8 to $9 million).

[151] *See id.* at 619–20. If ITC has recommended a chemical for testing, however, use of voluntary testing consent agreements is unlawful absent a showing that formal testing is not necessary. *See* Natural Res. Def. Council, Inc. v. EPA, 595 F. Supp. 1255, 1261, 1262 (S.D.N.Y. 1984).

[152] *See* Griffin, *supra* note 88, at 42.

[153] *See id.* at 42–43.

[154] *See id.* at 46 (noting that some chemical manufacturers have found that a "proactive approach" to negotiations with EPA is "most effective").

[155] 15 U.S.C. § 2615 (2000).

[156] *Id.* § 2615(a).

[157] *Id.* § 2615(b).

causing or are likely to cause death or serious physical harm to his employees."[158] The general duty clause was enacted to deal with hazards to which no specific standard applies.[159]

The second broad duty requires each employer to "comply with occupational safety and health standards promulgated under this chapter," and enforced by the Occupational Safety and Health Administration (OSHA).[160] The Hazard Communication Standard (HCS)—a worker's "right-to-know" law—is arguably the most important OSHA regulation:

> The purpose of [HCS] is to ensure that the hazards of all chemicals produced or imported are evaluated, and that information concerning their hazards is transmitted to employers and employees. This transmittal of information is to be accomplished by means of comprehensive hazard communication programs, which are to include container labeling and other forms of warning, material safety data sheets and employee training.[161]

A. *The General Duty Clause*

The absence of a chemical-specific OSHA rule does not mean a manufacturer may be lax in its investigation of chemical safety.[162] A manufacturer can receive a citation under OSH Act's general duty clause for failing to render its workplace free of a recognized hazard.[163] The courts have applied a number of tests to determine whether a hazard is "recognized."[164]

Some courts have held that a hazard is considered "recognized" if in the employer's industry it is common knowledge, or if the employer had knowledge of the hazardous condition.[165] In *National Realty & Construction Co. v. Occupational Safety & Health Review Commission*, the D.C.

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[158] Occupational Safety and Health Act of 1970 § 5(a)(1), 29 U.S.C. § 654(a)(1) (2000).

[159] Mark A. Rothstein, Occupational Safety and Health Law 178 (3d ed. 1990).

[160] 29 U.S.C. § 654(a)(2).

[161] Hazard Communication, 29 C.F.R. § 1910.1200(a)(1) (2004); Jennifer C. Silk et al., Hazard Communication Compliance Manual 1 (Jennifer C. Silk & Martha B. Kent eds., 1995).

[162] *See* Rothstein, *supra* note 159, at 178.

[163] *See id.* at 179.

[164] *See, e.g.*, Am. Smelting & Refining Co. v. Occupational Safety & Health Review Comm'n, 501 F.2d 504, 511 (8th Cir. 1974); Nat'l Realty & Constr. Co. v. Occupational Safety & Health Review Comm'n, 489 F.2d 1257, 1265 n.32 (D.C. Cir. 1973).

[165] Rothstein, *supra* note 159, at 185.

Circuit Court of Appeals held that whether a hazard is recognized by an industry is determined by "the common knowledge of safety experts who are familiar with the circumstances of the industry or activity in question."[166] In *American Smelting & Refining Co. v. Occupational Safety & Health Review Commission*, the Eighth Circuit Court of Appeals held that a recognized hazard is not limited to hazards that are readily detectable by human senses, but also covers hazards that can only be monitored through instrumentation.[167] Finally, standards developed by the American National Standards Institute may also be used to prove industry recognition.[168]

An employer's duty to render the workplace free from recognized hazards extends beyond mere perfunctory compliance with promulgated standards.[169] The D.C. Circuit has gone as far as to impose a penalty under the general duty clause where a manufacturer knew that compliance with a certain standard for a recognized hazard was inadequate to protect worker safety: "[I]f . . . an employer knows a particular safety standard is inadequate to protect his workers against [a] specific hazard . . . he has a duty under section 5(a)(1) to take whatever measures may be required by the Act . . . to safeguard his workers."[170]

B. *The Hazard Communication Standard*

The primary purpose of the HCS is to ensure that manufacturers seek out and evaluate all the available scientific information on a material, which is then made available to anyone in the stream of commerce.[171] The starting point for hazard evaluation is two lists of chemicals: "Threshold Limit Values for Chemical Substances and Physical Agents in the Work Environment", adopted by the American Conference of Governmental Industrial Hygienists (ACGIH); and a list of chemicals created and maintained by OSHA.[172] This group of chemicals is only the "floor" of the universe of all potentially hazardous

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[166] 489 F.2d at 1265 n.32.

[167] 501 F.2d 504, 511 (8th Cir. 1974).

[168] *See* St. Joe Minerals Corp. v. Occupational Safety & Health Review Comm'n, 647 F.2d 840, 845 n.8 (8th Cir. 1981). ANSI "is a private, non-profit organization . . . that administers and coordinates the U.S. voluntary standardization and conformity assessment system." Am. Nat'l Standards Inst, About ANSI Overview, http://www.ansi.org (follow "About ANSI" hyperlink) (last visited Oct. 27, 2005).

[169] *See* ROTHSTEIN, *supra* note 159, at 179.

[170] UAW v. Gen. Dynamics Land Sys. Div., 815 F.2d 1570, 1577 (D.C. Cir. 1987).

[171] SILK ET AL., *supra* note 161, at 11.

[172] *See id.* at 18; *see also* 29 C.F.R. pt. 1910, subpt. Z (2004).

chemicals, however.[173] For all other chemicals, the manufacturer is required to determine if a chemical is a physical or a health hazard by conducting tests and searching for relevant scientific studies.[174] Crucially, the HCS only requires that there be one scientific study addressing a material's adverse impact to deem it a "health hazard" that demands hazard communication to affected parties.[175]

A full hazard communication is effected by the combination of three essential components: labeling, a Material Safety Data Sheet (MSDS), and employee training.[176] The label provides a summary of the chemical's hazards and warns the employee to take precautions if necessary.[177] The MSDS is more extensive and has been described as a "one-stop shopping document for the user," providing information on a chemical's properties, hazards, and appropriate protective measures.[178] The final component, employee training, ensures that employees or other handlers understand the risks and precautionary measures identified on the label and MSDS.[179] This provides assurance that employees actually respond appropriately when confronting a potential or known hazard.[180]

C. *Emergency Temporary Standards and Substance-Specific Standards*

OSHA is permitted to adopt an Emergency Temporary Standard (ETS) when it appears "that employees are exposed to grave danger from exposure to substances or agents determined to be toxic or physically harmful or from new hazards."[181] There must be "more than some possibility" of a grave danger, but absolute certainty is not required.[182]

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[173] *See* SILK ET AL., *supra* note 161, at 19.

[174] *Id.* at 20.

[175] According to the HCS,

> "Health hazard" means a chemical for which there is statistically significant evidence based on at least one study conducted in accordance with established scientific principles that acute or chronic health effects may occur in exposed employees. The term "health hazard" includes chemicals which are carcinogens, toxic or highly toxic agents, reproductive toxins, irritants, corrosives, sensitizers . . . and agents which damage the lungs, skin, eyes, or mucous membranes.

Hazard Communication, 29 C.F.R. § 1910.1200(c) (2004).

[176] *See* SILK ET AL., *supra* note 161, at 12.

[177] *See id.* at 13.

[178] *Id.*

[179] *See id.* at 14.

[180] *See id.*

[181] 29 U.S.C. § 655(c) (2000).

[182] *See* Dry Color Mfrs. Ass'n v. Dep't of Labor, 486 F.2d 98, 104 (3d Cir. 1973).

Also, when evidence of harmful effects on humans is not available, evidence from animal studies is permitted to suggest possible carcinogenic effects in humans.[183]

In addition, an ETS is not subject to the rulemaking requirements of the Administrative Procedure Act due to the presumed immediate, grave danger involved.[184] An ETS, however, may only be issued for a six-month period; thereafter, a permanent specific standard must be promulgated.[185] In practice, courts are disinclined to order OSHA to issue an ETS both because of courts' traditional reluctance to substitute their judgment for that of administrative agencies,[186] and the diversion of resources from other, arguably more pressing rulemaking that such an order would impose.[187]

When OSHA does promulgate a specific standard, it has significant leeway to determine the threshold amount of evidence required to trigger rulemaking. In *Industrial Union Department v. American Petroleum Institute*, a case concerning the permissible exposure limit (PEL) of benzene, the Supreme Court explained that:

> OSHA is not required to support its finding that a significant risk exists with anything approaching scientific certainty. Although the Agency's findings must be supported by substantial evidence . . . a reviewing court [is required] to give OSHA some leeway where its findings must be made on the frontiers of scientific knowledge.[188]

This holding effectively allows OSHA to err on the side of caution when promulgating a PEL, as long as the standard is supported by a body of "reputable scientific thought."[189]

However, as John M. Mendeloff explains, even a cautious approach to promulgating PELs will not always adequately protect worker safety.[190] Mendeloff argues that there are actually four catego-

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[183] *See* Synthetic Organic Chem. Mfrs. Ass'n v. Brennan, 503 F.2d 1155, 1160–61 (3d Cir. 1974).

[184] Rothstein, *supra* note 159, at 53.

[185] *Id.*

[186] *See* Pub. Citizen Health Research Group v. Auchter, 702 F.2d 1150, 1153 (D.C. Cir. 1983) (finding that "the district court impermissibly substituted its evaluation for that of OSHA" in ordering the issuance of an ETS within twenty days).

[187] Rothstein, *supra* note 159, at 71.

[188] 448 U.S. 607, 656 (1980).

[189] Rothstein, *supra* note 159, at 84.

[190] *See* John M. Mendeloff, The Dilemma of Toxic Substance Regulation: How Overregulation Causes Underregulation at OSHA 78 (1988) (noting how disease may result even when OSHA has promulgated a PEL).

ries of occupational diseases that are caused by exposure to toxic substances in the workplace: diseases resulting from exposure that exceed an OSHA PEL; diseases resulting from exposure below an existing OSHA PEL; diseases resulting from exposure to substances for which there is no PEL but for which ACGIH or other groups have proposed exposure limits; or diseases resulting from exposure to existing substances for which neither OSHA nor anyone else has proposed exposure limits.[191]

In part because of this inevitable element of uncertainty, OSHA has significant latitude to determine the methods of compliance with promulgated PELs. OSHA has stated its preference "that engineering and work practice controls be used as the primary method of complying with PEL's."[192] Engineering controls include "material substitution, process or equipment redesign, process or equipment sealing, enclosure, or isolation, local exhaust ventilation, and employee isolation."[193] OSHA specifically disfavors respirators as an engineering control, advising that they be "relied on only as a means of last resort because they simply do not provide a comprehensive and reliable method of employee protection, are uncomfortable and may themselves create safety and health hazards."[194]

IV. The Toxic Substances Control Act, the Occupational Safety and Health Act, and Manufactured Nanomaterials

Part IV considers the intersection of the two federal statutes discussed above—TSCA and OSH Act—with manufactured nanomaterials, paying special attention to the opportunities and pitfalls that await those who choose to mass-produce nanomaterials.

A. *The Toxic Substances Control Act and Nanomaterials*

Since TSCA principally regulates chemical substances, it is first necessary to ask whether certain nanomaterials are "chemical substances" within the meaning of TSCA. Section 2602(2)(A) sweeps in much of the atomic universe with its expansive definition: "the term 'chemical substance' means any organic or inorganic substance of a

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[191] *Id.*

[192] Identification, Classification and Regulation of Potential Occupational Carcinogens, 45 Fed. Reg. 5001, 5222 (Jan. 22, 1980) (codified at 29 C.F.R. pt. 1990).

[193] *Id.* at 5223.

[194] *Id.* at 5222.

particular molecular identity, including—(i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and (ii) any element or uncombined radical."[195] Thus, it seems that most manufactured nanomaterials would be considered chemical substances within the meaning of TSCA.[196]

1. Nanomaterials and Filing a Premanufacture Notification

One issue that needs to be considered is whether a smaller version of an already existing material is "new" for TSCA classification purposes.[197] A manufacturer must look to see if the substance manufactured is already listed in the TSCA Inventory.[198] Listed substances are existing chemicals, for which a manufacturer need not submit a premanufacture notice (PMN).[199]

Before a chemical would appear in the Inventory, it likely would need a unique identifying number from the Chemical Abstracts Service—called a Chemical Abstracts Service Registry Number (CASRN)—which is given to almost every new chemical and is internationally recognized.[200] A number of popular nanomaterials have CASRNs: "carbon buckytubes," 1333-86-4; "fullerenes, tubular," 308068-56-6; "carbon fibers, nanotubes," 308068-63-0.[201] Despite having a CASRN, none of these substances are currently in TSCA's Inventory.[202]

An interesting problem arises when a manufacturer seeks to make a nanosized version of a chemical already in the Inventory. At present, no mechanism exists to prevent a manufacturer from simply extrapolating toxicity information from the bulk-sized toxicity data on file.[203] However, the very nature of a nanomaterial belies such simple

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[195] 15 U.S.C. § 2602(2)(A) (2000). Mixtures, pesticides, tobacco, nuclear materials, and certain food and drugs are among the items exempted from TSCA's reporting requirements. *Id.* § 2602(2)(B).

[196] *See* WARDAK, *supra* note 9, at 4–5.

[197] *See supra* Part II.A.

[198] *See supra* text accompanying note 91.

[199] GRIFFIN, *supra* note 88, at 11, 13. EPA, however, is in the process of reviewing this policy, so manufacturers should proceed cautiously if a bulk counterpart to a nanomaterial already appears in the Inventory. *See* Nanoscale Materials; Notice of Public Meeting, 70 Fed. Reg. 24,574 (May 10, 2005) (providing notice of a public meeting to discuss a possible voluntary pilot reporting program for certain existing nanoscale materials).

[200] *See supra* note 91.

[201] WARDAK, *supra* note 9, at 10.

[202] *See id.* To be certain that a substance is not already in the public or confidential portions of the Inventory, consultation with EPA is advised. *See* GRIFFIN, *supra* note 88, at 14.

[203] *See* HETT, *supra* note 11, at 36; s*ee also supra* text accompanying note 108.

analogy.[204] The distinguishing feature of nanomaterials is that they do not necessarily behave like their larger counterparts when operating at the nanoscale.[205] Thus, toxicity data that is on record for bulk-sized titanium dioxide, for example, will not necessarily apply to titanium dioxide nanoparticles.[206] Theoretically, nothing—besides corporate conscience, fear of product liability lawsuits, and EPA and citizen vigilance—stands in the way of a manufacturer commencing production of a nanosized version of an Inventory chemical with completely novel, inadequately tested, and potentially hazardous properties.

TSCA's statutory exemptions may provide another route around the PMN requirement for creative CEOs of both the smallest start-ups and the largest multinational corporations.[207] TSCA's "solely-for-export" exemption allows a manufacturer to avoid the PMN process if the chemical is produced for exportation only.[208] Assuming a recipient country did not require extensive health and environmental effects data, a particularly skittish manufacturer could export a nanomaterial while awaiting results from U.S. government-funded health-effects research.[209]

Alternatively, a manufacturer could seek the protection of TSCA's Low-Volume Exemption or Low-Release and Exposure Exemption (LoREx) by producing less than ten thousand kilograms per year.[210] This allows a large company to at least "get in the game" while the research trickles out and investors get more comfortable with nanotechnology and its risks. This strategy also limits liability should nanomaterials turn out to be more harmful than most suspect at the moment.

At the same time, ten thousand kilograms per year might represent one hundred percent of a smaller company's output. Indeed, currently, very few American companies appear to possess even this capability.[211] While some American companies have begun construc-

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[204] *See* HETT, *supra* note 11, at 36.

[205] *See id.*

[206] *Id.*

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

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

[209] *See* Nat'l Inst. for Occupational Safety & Health, NIOSH Safety & Health Topic: Nanotechnology, http://www.cdc.gov/niosh/topics/nanotech/ (last visited Oct. 23, 2005) (describing the NIOSH Nanotechnology and Health & Safety Research Program as"[a] five-year multidisciplinary study into the toxicity and health risks associated with occupational nanoparticle exposure").

[210] *See supra* note 102 and accompanying text.

[211] *See* Matt Kelly, *Fullerenes Flourish, and Nano-C Can Make Them by the Ton*, SMALL TIMES, Oct. 27, 2003, http://www.smalltimes.com/document_display.cfm?document_id=6825 (describing comparatively low American fullerene output).

tion on multitonnage capable facilities. Japanese manufacturers have been less reluctant to churn out nanomaterials by the ton.[212] The National Science Foundation, perhaps conscious of this manufacturing gap, recently announced awards to establish the Center for High Rate Nanomanufacturing at Northeastern University, the Center for Affordable Nanoengineering of Polymer Biomedical Devices at Ohio State University, and the Center for Templated Synthesis and Assembly at the Nanoscale at University of Wisconsin–Madison.[213]

For companies unable or unwilling to wait for academic and government research to yield helpful results, production of potentially hazardous new nanomaterials will commence after the filing of a PMN.[214] When filing a PMN, a manufacturer is required to produce all environmental and health effects studies in the manufacturer's "possession or control," as well as descriptions of all other health and environmental effects data that the manufacturer knows about or can reasonably ascertain.[215]

It must be emphasized that submitting a PMN does not require a manufacturer to produce new data or to conduct studies.[216] Therefore, a manufacturer that proposed to mass-produce fullerenes or carbon nanotubes (CNTs) would not necessarily be forced to test those substances.[217] However, the manufacturer would be obliged to disclose that large concentrations of fullerenes have been shown to cause brain damage in fish,[218] or that large quantities of inhaled CNTs cause pulmonary problems and death in lab rats.[219]

Moreover, while a company can treat a large amount of proprietary information as Confidential Business Information under TSCA, EPA generally will not honor requests to keep health and safety studies confidential.[220] Thus, if a new nanomanufacturer is set to produce a substance that is sufficiently similar to a nanomaterial that has already been subjected to the PMN process, the new company is permit-

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[212] *See id.* Frontier Carbon Corp., a Japanese company, can currently manufacture forty tons of fullerenes per year, and expects to increase production to 300 tons by 2007. *Id.*

[213] *See* Press Release, Nat'l Sci. Found., NSF Announces Six New Centers for Nanoscale Research, (Sep 21, 2004), http://www.nsf.gov/news/news_summ.jsp?cntn_id=100443&org=NSF&from=news.

[214] *See supra* Part II.C. (describing the PMN process).

[215] 15 U.S.C. § 2604(d)(1) (2000).

[216] *See* GRIFFIN, *supra* note 88, at 23.

[217] *See id.*

[218] *See* Oberdörster, *supra* note 63, at 1060–62.

[219] *See supra* note 75.

[220] *See* GRIFFIN, *supra* note 88, at 59.

ted to use the data already on file.[221] Given the cost of conducting health and safety studies, this loophole offers significant cost savings to the late-coming freerider, and represents a significant penalty for the pioneering company.[222]

2. Nanomaterials and Section 4 Testing

The recent spike of government and university research into the potential adverse effects of nanomaterials on human health and the environment[223] could—assuming the results are negative—accelerate a growing perception that nanomaterials may be unsafe. This would prompt EPA to assert its authority under section 4 of TSCA to promulgate test rules or enter into testing consent agreements.[224] However, EPA is only permitted to force testing under certain conditions.[225]

One such condition arises when the Interagency Testing Committee (ITC) recommends testing of a material by placing it on its Priority Testing List (PTL).[226] A check of two recent PTLs. however, showed no chemicals that were obviously nanomaterials.[227] In fact, both PTLs contain chemicals that were first placed onto the list in 1993, calling into question the speed with which chemicals move on and off the PTL.[228] Thus, if EPA were to order section 4 testing for nanomaterials, it is more likely that the impetus would come from within EPA than from ITC.[229]

In order to compel testing of nanomaterials, section 4(a)(1)(A) requires a showing of "unreasonable risk," while section 4(a)(1)(B)—the B-policy—allows EPA to act in the face of unknown hazards if certain conditions are met.[230] In order to find an unreasonable risk, EPA

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[221] *See id.* at 23, 28.

[222] *See* APPLEGATE ET AL., *supra* note 107, at 618 (noting the cost of chemical testing).

[223] *See supra* Part I.E.

[224] *See* 15 U.S.C. § 2603(a) (2000).

[225] *See supra* Part II.F. (describing section 4 testing).

[226] *See* GRIFFIN, *supra* note 88, at 36–37.

[227] *See* Fifty-Fifth Report of the TSCA Interagency Testing Committee to the Administrator of the Environmental Protection Agency, 70 Fed. Reg. 7364, 7366 (Feb. 11, 2005); Fifty-Fourth Report of the TSCA Interagency Testing Committee to the Administrator of the Environmental Protection Agency, 69 Fed. Reg. 33,528, 33,530 (June 15, 2004).

[228] *See* Fifty-Fifth Report of the TSCA Interagency Testing Committee to the Administrator of the Environmental Protection Agency, 70 Fed. Reg. at 7366; Fifty-Fourth Report of the TSCA Interagency Testing Committee to the Administrator of the Environmental Protection Agency, 69 Fed. Reg. at 33,530.

[229] *See* GRIFFIN, *supra* note 88, at 35 (describing EPA's power to order testing on its own initiative).

[230] *See* 15 U.S.C. § 2603(a) (2000).

must make a showing of potential exposure and be armed with a scientifically justifiable suspicion that the risk to humans may be significant—usually brought on by evidence that the chemical is discovered to be hazardous at very low levels.[231] At present, while there is some hard evidence of potential health hazards from animal studies, the state of research into nanomaterials is probably not robust enough to conclude that they pose an unreasonable risk.[232] As Andrew Maynard of the National Institute for Occupational Safety and Health (NIOSH) has commented, "'[n]obody is saying here it's a minor threat or a major threat—we just don't know.'"[233]

When faced with substances of unknown toxicity with the potential for substantial human exposure, the B-policy can provide justification for ordering chemical studies.[234] However, with the nanomaterial industry in its infancy, very few, if any, manufacturers produce enough nanomaterials to surpass the 1 million pound threshold required for the B-policy to take effect.[235] For example, current combined global production for both single-walled and multi-walled nanotubes is approximately 109 tons.[236] Total global production capacity of multi-walled nanotubes may increase to 268 tons annually by 2007, while production of single-walled nanotubes is expected to reach one hundred tons by 2008.[237] Frontier Carbon, a Japanese corporation funded by Mitsubishi and the first mass-producer of fullerenes in the world, fabricates 40 tons of fullerenes per year and expects to increase production to three hundred tons by 2007.[238] Thus, in the next few years, there very well may be what the layperson would consider a "substantial" amount of nanomaterial production, but from TSCA's standpoint, the production level does not meet the substantial threshold to merit testing.[239]

Absent any rapid decision to lower the substantial production threshold significantly just for engineered nanomaterials, might EPA

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[231] *See* Chloromethane and Chlorinated Benzenes Proposed Test Rule, 45 Fed. Reg. 48,524, 48,528 (July 18, 1980).

[232] *See supra* Parts I.D–E.

[233] Helm, *supra* note 69 (quoting Andrew Maynard, Nat'l Inst. of Occupational Safety & Health).

[234] *See* Chloromethane and Chlorinated Benzenes Proposed Test Rule, 45 Fed. Reg. at 48,528.

[235] *See* TSCA Section 4(a)(1)(B) Final Statement of Policy, 58 Fed. Reg. 28,736, 28,746 (Mav 14, 1993).

[236] *See* CIENTIFICA, *supra* note 27, at 9.

[237] *Id.*

[238] *See* Kelly, *supra* note 211.

[239] *See* TSCA Section 4(a)(1)(B) Final Statement of Policy, 58 Fed. Reg. at 28,746.

order testing under section 4 anyway? The Final Statement of the B-policy allows EPA to consider "additional factors" for substances that "do not meet the numerical thresholds" set by the B-policy.[240] Given the high degree of uncertainty surrounding the safety and toxicity of nanomaterials, the impending boom in nanomaterial production, EPA's apparent inability to respond meaningfully to a filed PMN,[241] and the complicating factor that a given nanomaterial may behave differently depending on whether it is coated or uncoated, fixed or free, or one-, two-, or three-dimensional, EPA would be well within reason if it decided to order formal test rules for certain engineered nanomaterials in order to ensure a modicum of safety.[242]

However, the strongest push for testing might—and arguably should—come from the nanomanufacturing industry itself through voluntary testing consent agreements.[243] First, testing consent agreements allow the manufacturer to circumvent certain reporting, recordkeeping, exportation, penalty, and iudicial review requirements otherwise imposed by section 4 testing.[244] Second, fears of EPA and industry striking a backroom deal without public input and appropriate controls appear to be unfounded.[245] The public is allowed an opportunity to participate in all phases of the negotiation and implementation of any agreement as "interested parties."[246] On the other hand, all signatories waive their right to challenge the consent agreement on the basis that it is not a "rule" under section 4, significantly reducing delays brought on by judicial review.[247] Finally,

> [u]se of a testing consent agreement in lieu of a formal test rule should not be viewed as indicating any intent to relax the requirements relating to the actual testing conducted on the chemical. The data derived from chemical testing are expected to be of the same quality, regardless of whether the testing results from a rule or a consent agreement. The only

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[240] *Id.*

[241] In fiscal year 1995, EPA took no action on ninety-eight percent of filed PMNs. APPLEGATE ET AL., *supra* note 106, at 611.

[242] *See* discussion *supra* Part II.F.

[243] *See* ROYAL SOCIETY, *supra* note 12, at 50 (urging industry to test new nanoparticles to minimize human exposure).

[244] APPLEGATE ET AL., *supra* note 106, at 619.

[245] *See* Nanoscale Materials, 70 Fed. Reg. 24,574 (May 10, 2005) (providing notice of a public meeting to discuss a possible voluntary pilot reporting program for certain existing nanoscale materials).

[246] GRIFFIN, *supra* note 88, at 46.

[247] *Id.* at 47.

differences are in the formality of the procedures that lead up to testing.[248]

If the decision in *Physicians Committee for Responsible Medicine v. Leavitt* is any guide, the courts are beginning to respect EPA's discretionary authority to seek alternative arrangements to the formal testing scheme.[249] Indeed, as the U.S. District Court for the Southern District of New York has observed, "negotiation to determine appropriate test protocols as well as other relevant criteria certainly is not only permissible but indeed preferable to blind, often impractical, bureaucratic blundering."[250] Thus, nanomaterial manufacturers would do well to heed the advice of veteran chemical companies, who advocate a proactive approach to negotiations and exhort manufacturers to "lead the way" in suggesting testing methods.[251] The Chemical Manufacturers Association, for one, has gone a step further and is in the midst of a self-imposed, multi-year, $67 million program of "basic research on the potential carcinogenic, endocrine disruption, and respiratory effects of industrial chemicals."[252] In a similar fashion, reliance on government and academic research for health and safety data should decrease as the nanotechnology sector matures and funds suitable research similar to other developed industries.[253]

B. *The Occupational Safety and Health Administration and Nanomaterials*

"The National Science Foundation has estimated that 2 million workers will be needed to support nanotechnology industries worldwide within 15 years."[254] In the short-term, the Royal Society believes that "[t]he greatest potential for exposure . . . over the next few years will be in the workplace, both in industry and in universities."[255] Although NIOSH is in the process of producing a "best practices" document for working with nanomaterials, nanomaterial manufactur-

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[248] *Id.* at 45.

[249] *See* 331 F. Supp. 2d 204, 208 (S.D.N.Y. 2004); *see also supra* text accompanying notes 143–48 (discussing *Leavitt*).

[250] Natural Res. Def. Council v. EPA, 595 F. Supp. 1255, 1262 (S.D.N.Y. 1984) (holding that negotiated testing agreements were unlawful when ITC recommends a chemical for testing and EPA does not eventually engage in formal rulemaking).

[251] *See* GRIFFIN, *supra* note 88, at 46.

[252] APPLEGATE ET AL., *supra* note 106, at 620.

[253] *See id.*

[254] Nat'l Nanotechnology Initiative, Frequently Asked Questions, http://www.nano.gov/html/facts/faqs.html (last visited Oct. 23, 2005).

[255] ROYAL SOCIETY, *supra* note 12, at 42.

ers still need to be aware of the many OSHA compliance issues which will arise in the production of potentially hazardous nanomaterials.[256]

Currently, there are no nanomaterial-specific OSHA rules or Permissible Exposure Limits (PELs).[257] Nor has the American Conference of Governmental Industrial Hygienists (ACGIH) proposed any exposure limits.[258] But, to borrow John Mendeloff's rubric, occupational disease may still arise from "exposures from existing substances for which neither OSHA nor anyone else has proposed exposure limits."[259] The key is whether a given nanomaterial would be considered a "recognized hazard" within the meaning of the general duty clause.[260] Since the American National Standards Institute has not yet developed standards,[261] the issue reduces to whether it is the common knowledge of safety experts in the field that a given nanomaterial is hazardous.[262]

This test would probably look to official statements from NIOSH for guidance. In this regard, NIOSH has thus far offered only noncommittal, conservative statements, like the following from its official website:

> Occupational health risks associated with manufacturing and using nanomaterials are not yet clearly understood. . . .
> . . . .
> Workers within nanotechnology-related industries have the potential to be exposed to uniquely engineered materials with

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[256] *See* Sandy Smith, *Howard: Nanotechnology Represents an "Exciting Challenge" for EHS*, Occupational Hazards, May 7, 2004, http://www.occupationalhazards.com/articles/11779.

[257] *See* Juliana Gruenwald, *Researchers Discuss Safety Guidelines for Handling Nanomaterials*, Small Times, May 19, 2004, http://www.smalltimes.com/document_display.cfm?document_id=7922.

[258] *See* Press Release, American Conference of Governmental Industrial Hygienists (ACGIH®), ACGIH® Board Ratifies 2005 TLVs® and BEIs®: 2005 TLVs® and BEIs® Substances and Agents Listing, https://www.acgih.org/resources/press/TLV2005list.htm (last visited Oct. 23, 2005) (listing substances with Threshold Limit Values (TLVs) and Biological Exposure Indices (BEIs), but never specifically listing any chemical using the "nano" prefix).

[259] Mendeloff, *supra* note 190, at 78.

[260] Occupational Safety and Health Act of 1970, § 5(a)(1), 29 U.S.C. § 654(a)(1) (2000).

[261] *See* Am. Nat'l Standards Inst., Nanotechnology Standards Panel, http://www.ansi.org/standards_activities/standards_boards_panels/nsp/overview.aspx?menuid=3 (last visited Oct. 23, 2005) (describing American National Standards Institute, Nanotechnology Standards Panel's mission to develop nanotechnology standards, including: "nomenclature/terminology; materials properties; and testing, measurement and characterization procedures").

[262] *See* Nat'l Realty & Constr. Co. v. Occupational Safety & Health Review Comm'n, 489 F.2d 1257, 1265 n.32 (D.C. Cir. 1973).

> novel sizes, shapes and physical and chemical properties, at levels far exceeding ambient concentrations. To understand the impact of these exposures on health, and how best to devise appropriate exposure monitoring and control strategies, much research is still needed. Until a clearer picture emerges, the limited evidence available would suggest caution when potential exposures to nanoparticles may occur.[263]

While accurate, this is not the most helpful statement for a manufacturer producing nanomaterials today—what should they do to protect their workers from injury and their corporation from liability?

First, if an employer is in possession of data that unequivocally demonstrates that a particular nanomaterial is "likely to cause death or serious physical harm to . . . employees," then the employer has a duty to mitigate the threat of that hazard.[264] Likewise, if a substance shows carcinogenic effects in lab animals, OSHA is empowered to issue an Emergency Temporary Standard under section 6.[265] Nanomaterials currently pose a unique problem because it is too early for anyone to say with any degree of scientific certainty that occupational exposure to nanomaterials poses a health hazard.[266] However, it would be disingenuous of anyone, particularly a manufacturer concerned about the potential of product liability lawsuits, to say—in the absence of health effects data to the contrary—that his or her nanomaterial is definitely safe; the literature abounds with cautionary statements that imply the opposite.[267] Thus, the prudent course of action is to proceed as if the material in question is actually hazardous, obligating the manufacturer to engage in adequate hazard communication.[268]

Consider, in this respect, the United Kingdom's response to the Royal Society's report on nanomaterials:

> The Government accepts that chemicals in the form of nanoparticles or nanotubes can exhibit different properties to

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[263] Nat'l Inst. for Occupational Safety & Health, *supra* note 209.

[264] 29 U.S.C. § 654(a)(1).

[265] *See* Synthetic Organic Chem. Mfrs. Ass'n v. Brennan, 503 F.2d 1155, 1160–61 (3d Cir. 1974).

[266] The HCS regulations define health hazard as "a chemical for which there is statistically significant evidence based on at least one study conducted in accordance with established scientific principles that acute or chronic health effects may occur in exposed employees." Hazard Communication, 29 C.F.R. § 1910.1200(a)(1) (2004).

[267] *See supra* Parts I.D–E.

[268] *See supra* Part III.B. (describing HCS).

> the bulk form of the chemical; sometimes this is beneficial and sometimes it may be potentially hazardous. The Government also accepts that safety testing on the basis of a larger form of a chemical cannot be used to infer the safety of the nanoparticulate form of the same chemical and that therefore individual regulations within the existing framework will need to be reviewed to reflect the possibility that nanoparticulate material may have greater toxicity than material in the larger size range.[269]

However, the current practice in preparing information for a Material Safety Data Sheet (MSDS) appears to be precisely what the Royal Society and United Kingdom consider ill-advised.[270]

The MSDS for titanium dioxide nanopowder, for example, contains the same information as the regular titanium dioxide MSDS.[271] Even though this information might be wholly inapplicable and inadequate, "the safety data sheet for nano-titanium dioxide powder still recommends that a dust respirator be worn while handling this substance, although such masks are known to offer only limited protection."[272]

While referring the user to the safety information for titanium dioxide is somewhat helpful, reliance on the safety measures in place for bulk-sized titanium dioxide are at best misleading, and at worst dangerous. Such reliance could be dangerous because of a fifth category of occupational disease caused by toxic substances that Mendeloff did not specifically identify—diseases resulting from a substance which has been assigned an inappropriate PEL.[273] A bulk-sized PEL automatically assigned to any nanomaterial is potentially an inappropriate designation. Nevertheless, a manufacturer is entirely within its rights in taking that step under the current OSHA scheme.[274]

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[269] HM Gov't, Response to the Royal Society and Royal Academy of Engineering Report: 'Nanoscience and Nanotechnologies: Opportunities and Uncertainties' 6 (2005), *available at* http://www.ost.gov.uk/policy/issues/nanotech_final.pdf.

[270] *See supra* text accompanying notes 176–80.

[271] Hett, *supra* note 11, at 33.

[272] *Id.*

[273] *See* Mendeloff, *supra* note 190, at 78; *see also supra* text accompanying note 191 (describing four categories of occupational disease caused by toxic substances in the workplace).

[274] The HCS specifically allows a manufacturer the discretion to choose the appropriate PEL by requiring that each material safety data sheet include "[t]he OSHA permissible exposure limit, ACGIH Threshold Limit Value, and any other exposure limit used or recommended by the chemical manufacturer, importer, or employer preparing the material safety data sheet, where available." Hazard Communication, 29 C.F.R. § 1910. 1200(g)(2)(vi) (2004).

To prevent the widespread use of bulk-sized information for nanomaterial MSDSs, OSHA could attempt to curb the practice by making an example of one manufacturer. OSHA could achieve this by issuing an Emergency Temporary Standard (ETS) under section 6 for a hazardous nanomaterial of its choosing.[275] An ETS is particularly appropriate when dealing with substances of unknown toxicity—as is the case with most nanomaterials—since all that is required is "more than some possibility" of danger; no absolute certainty is required.[276] Moreover, if evidence of a nanomaterial's carcinogenicity in animals were to surface, OSHA could act immediately to protect humans working with the substance.[277] However, since an ETS is only effective for six months and a permanent standard must be promulgated soon thereafter, OSHA would be more likely to develop nanomaterial-specific PELs than to issue a slew of ETSs in response to adverse health data.[278]

When OSHA does promulgate nano-specific regulations and PELs, it need not be intimidated by the inexact state of research. As the Supreme Court explained, OSHA is entitled to "some leeway where its findings must be made on the frontiers of scientific knowledge."[279] However, employers should take care that any work practice mandated by OSHA actually protects their workers from known hazards. As the D.C. Circuit Court of Appeals held in *UAW v. General Dynamics Land Systems Division*: "[I]f . . . an employer knows a particular safety standard is inadequate to protect his workers against [a] specific hazard . . . he has a duty under section 5(a)(1) to take whatever measures may be required by the Act . . . to safeguard his workers."[280]

Consider in this respect an informational note produced by the United Kingdom's Health and Safety Executive (HSE).[281] In line with American practice, the HSE note emphasizes the importance of mitigating risk through adequate environmental control measures before resorting to the use of personal protective equipment, such as respira-

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[275] *See supra* Part III.C. (describing ETS procedure).

[276] *See* Dry Color Mfrs. Ass'n v. Dep't of Labor, 486 F.2d 98, 104 (3d Cir. 1973).

[277] *See* Synthetic Organic Chem. Mfrs. Ass'n v. Brennan, 503 F.2d 1155, 1160–61 (3d Cir. 1974).

[278] *See* ROTHSTEIN, *supra* note 159, at 53.

[279] Indus. Union Dep't, AFL-CIO v. Am. Petroleum Inst., 448 U.S. 607, 656 (1980).

[280] 815 F.2d 1570, 1577 (D.C. Cir. 1987).

[281] HEALTH & SAFETY EXECUTIVE, PARLIAMENTARY UNDER SECRETARY (WORK AND PENSIONS) (LORDS), NOTE NO. HSIN1, HORIZONS SCANNING INFORMATION (2004), *available at* http://www.hse.gov.uk/pubns/hsin1.pdf.

tors and facemasks.[282] HSE adds, however, that "[i]f your control measures are based on pre-existing standards then you should ensure that these standards are relevant for nanoparticles. . . . [E]ngineering solutions should be sought, such as containment or effective and appropriate local exhaust ventilation eg [sic] fume cupboards."[283] If engineering solutions prove ineffective, resorting to personal protective equipment is permissible.[284] However, HSE warns that all respirator filters should be checked with the manufacturer to ensure that they will prevent nanoparticles from passing through.[285] Finally, HSE advises that "[f]or the highest levels of protection, [self-contained breathing apparatus] having a correctly fitted full-face mask and positive demand compressed air supply will be required."[286]

C. *Lessons for the Nanomaterial Manufacturer*

Under both TSCA and OSH Act statutory schemes, there is ample opportunity for a nanomaterial to slip virtually unnoticed out of the chemical plant and into the stream of commerce. TSCA currently allows nanomaterial manufacturers to analogize to bulk materials already in the Inventory and to use the test data previously generated.[287] In addition, nano-sized versions of Inventory chemicals technically may be produced without filing a PMN.[288] TSCA also contains a number of statutory exemptions to filing a PMN.[289] Even if a PMN must be filed, EPA may never take action on it.[290]

As for OSH Act, there is a strong argument that nanomaterials would not currently be considered a "recognized" hazard within the meaning of the general duty clause.[291] Current industry practice also seems to condone the use of PELs developed for bulk-sized materials on nanomaterial MSDSs.[292] These MSDSs in turn recommend the use of work practice controls that potentially provide inadequate protec-

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[282] *See id.* at 2; *see also supra* text accompanying notes 192–94.
[283] HEALTH & SAFETY EXECUTIVE, *supra* note 281, at 2.
[284] *See id.*
[285] *Id.*
[286] *Id.*
[287] *See* GRIFFIN, *supra* note 88, at 23, 28.
[288] *Id.* at 13.
[289] *See supra* Part II.B.
[290] *See supra* Part II.D.
[291] *See supra* Parts III.A, IV.B.
[292] *See supra* text accompanying note 272.

tion against worker inhalation, ingestion, and skin absorption of nanomaterials.[293]

Nevertheless, while perfunctory compliance with TSCA and OSH Act provisions is certainly possible and will provide a certain amount of insulation from liability, the risk that a given nanomaterial will turn out to be toxic argues in favor of some form of manufacturer-initiated testing before mass-production.[294] The exact level of testing to undertake depends on the individual manufacturer's tolerance for risk, including the possibility of protracted, costly litigation. The testing arrangements described herein appear to be the most palatable option for the manufacturer interested in protecting workers, the public, and the bottom line.[295]

Conclusion

Nanotechnology promises untold benefits for the future. But scientific progress with respect to manufactured nanomaterials and their myriad applications may be outpacing appreciation of the environmental, safety, and health risks associated with these materials. TSCA and OSH Act provide part of the existing regulatory framework that will be used to address and mitigate hazards that may be posed by these substances. A manufacturer that fails to investigate and test the safety of a nanomaterial before its release into the stream of commerce—based on manipulation of statutory exemptions and clever interpretation of statutory language—does more than expose itself to liability, it reveals its lack of concern for the welfare of both its workers and the public.

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[293] *See supra* text accompanying notes 271–78.

[294] *See supra* Part IV.A.2.

[295] *See supra* Part IV.A.2.