REGULATING NANOTECHNOLOGY: A PRIVATE-PUBLIC INSURANCE SOLUTION

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ABSTRACT

Nanotechnology promises to revolutionize innovation in nearly every industry. However, nanomaterials' novel properties pose potentially significant health and environmental risks. Views in the current debate over nanotechnology regulation range from halting all research and development to allowing virtually unregulated innovation. One viable regulatory solution balancing commercialization and risk is the adoption of a mandatory private-public insurance program.

INTRODUCTION

¶1 Spurred by a strong financial commitment from the federal government and robust private investment, nanotechnology innovation is developing at a rapid pace. As investment in nanotechnology commercialization grows, several studies point to potentially serious environmental and health risks introduced by manufactured nanomaterials. The substantial benefits and risks of nanotechnology have resulted in wide-ranging debate over appropriate regulation. One viable regulatory solution balancing innovation and commercialization benefits with health and environmental concerns is the implementation of a private-public insurance program.

¶2 This iBrief will discuss nanotechnology applications and risks, review various nanotechnology regulations, and suggest a novel approach to mitigating risk while maintaining appropriate incentives for innovation. Specifically, Section I will discuss nanotechnology research and development, focusing on the benefits of nanotechnology innovation and the potential health and environmental risks posed by nanomaterials. Section II will review the current debate surrounding nanotechnology regulation, analyzing existing applicable regulatory bodies and regulations, a newly suggested law, and other proposals. Section III will consider an

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insurance solution to regulating nanotechnology, discussing challenges faced by private insurers in providing nanotechnology coverage and proposing a private-public insurance program as a potential solution.

I. NANOTECHNOLOGY BACKGROUND

¶3 Nanotechnology is a term generally used to describe the production and use of materials on a nanometer—or one billionth of a meter—scale.[2] The width of a human hair, by comparison, is approximately one hundred thousand nanometers.[3] Nanoparticles occur naturally in the environment or as byproducts of chemical reactions.[4] Manufacturing of nanoscale materials was considered as early as 1959[5] and the term "nanotechnology" was first used in the science community in 1974[6]. Until recently, however, scientists were unable to manipulate matter close to the atomic or molecular scale. Utilizing newly developed techniques, scientists can now engineer nanomaterials with desired properties.[7]

¶4 Subsection A of this section will discuss potential benefits of nanotechnology engineering. Subsection B will discuss potential nanotechnology risks.

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[2] DIVISION ON ENGINEERING AND PHYSICAL SCIENCES, COMM. FOR THE REVIEW OF THE NAT'L NANOTECHNOLOGY INITIATIVE, NAT'L RESEARCH COUNCIL, SMALL WONDERS, ENDLESS FRONTIERS: A REVIEW OF THE NATIONAL NANOTECHNOLOGY INITIATIVE 1 (2002), *available at* http://books.nap.edu/catalog/10395.html [hereinafter SMALL WONDERS].

[3] *Id.*

[4] John Balbus et al., *Getting Nanotechnology Right the First Time*, 21 ISSUES IN SCI. & TECH., July 9, 2005, at 66.

[5] *See* Francisco Castro, *Legal and Regulatory Concerns Facing Nanotechnology*, 4 CHI.-KENT J. INTELL. PROP. 140, 140 (2004) (discussing Richard Feynman's speech at the meeting of the American Physical Society).

[6] Louis M. Troilo, *Patentability and Enforcement Issues Related to Nanotechnology Inventions*, 2 NANOTECHNOLOGY L. & BUS. 36, 36 n.2 (2005) (citing N. Taniguchi, *On the Basic Concept of Nanotechnology*, PROC. INTL. CONF. PROD. ENG., Tokyo, Part II (1974)). The individual associated most with popularizing nanotechnology is Eric Drexler who explored the area in depth in his 1986 book, ENGINES OF CREATION: THE COMING ERA OF NANOTECHNOLOGY. Ivan Amato, *The Apostle of Nanotechnology*, 254 SCI. 1310, 1310 (Nov. 29, 1991).

[7] *See* Balbus *supra* note 4, at 66. *See generally* Rep. Mike Honda, *Nanotechnology Legislation in the 108th Congress*, NANOTECH. L. & BUS., Feb. 2004, at 63, 64 (noting that nanotechnology research began in NASA's Silicon Valley facility in 1996).

A. Nanotechnology Benefits

¶5 Nanoscale materials exhibit novel properties, including reactivity, electrical conductivity and changes in surface chemistry.[8] If appropriately harnessed, these novel properties may effect innovation in almost every industry.[9] For instance, scientists and engineers working on energy and environmental initiatives believe that nanotechnology will revolutionize energy production, water treatment, and environmental remediation.[10] The National Science Foundation (NSF) predicts that over the next decade the pharmaceutical and semiconductor industries will strongly rely on nanotechnology.[11]

¶6 The ability to manipulate and create nanomaterials is a relatively recent phenomenon, nonetheless the evolution of nanotechnology engineering is predicted to grow very rapidly. Linda Breggin, Senior Attorney, Environmental Law Institute (ELI), and Leslie Carothers, President of ELI, predict that nanotechnology sophistication will undergo four stages before 2020.[12] The first stage, which already passed, includes the development of passive nanostructures with a focus on manufacturing coatings, polymers and ceramics. The second stage includes the advancement of active nanostructures used in developing transistors, targeted drugs, and actuators. The third stage, which is predicted to occur in the year 2010, focuses on robotics, three-dimensional networks, and guided assemblers. The fourth stage, called the molecular nanosystems stage, includes the creation of molecules by design and the development of evolutionary systems.[13]

¶7 The NSF predicts that nanotechnology will represent a one trillion dollar market by 2015 and will employ two million workers.[14] Some commentators predict that by 2014, fifteen percent of all goods

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[8] Balbus *supra* note 4, at 65.
[9] See Linda Breggin & Leslie Carothers, *Governing Uncertainty: The Nanotechnology Environmental Health & Safety Challenge*, 31 COLUM. J. ENVTL. L. 285 (2006).
[10] Balbus *supra* note 4, at 65.
[11] Robin Fretwell Wilson, *Nanotechnology: The Challenge of Regulating Known Unknowns*, 34 J.L. MED. & ETHICS 704, 705 (2006).
[12] *See* Breggin & Carothers, *supra* note 9, at 291.
[13] *Id.*
[14] MIHAIL C. ROCO & WILLIAM S. BAINBRID, NAT'L SCI. FOUND., SOCIETAL IMPLICATIONS OF NANOSCIENCE AND NANOTECHNOLOGY 3 (2001), *available at* http://www.wtec.org/loyola/nano/societalimpact/nanosi.pdf. *See also* Sonia Arrison, *Nanotechnology Needs Nano-Scale Regulation*, TECHNEWSWORLD, Jan. 13, 2006, http://www.technewsworld.com/story/48272.html.

manufactured globally will involve nanotechnology.[15] The economic potential of nanotechnology is apparent from the investment therein at the federal, state and private-sector levels. The federal government committed over one billion dollars in nanotechnology funding when it enacted the 21st Century Nanotechnology Research and Development Act.[16] California is attempting to create a "Nano-Valley" in hopes of reaping benefits similar to those Silicon Valley provided to the state.[17] In 2004, venture capital funds invested almost five hundred million dollars in nanotechnology start-ups.[18] Nearly 300 nanoproducts are already commercially available,[19] and over 4,000 nanotechnology patents have been issued since 1985.[20] The United States is not alone in trying to capitalize on this technology—thirty countries have enacted initiatives to promote nanotechnology development.[21]

B. Nanotechnology Risks

¶8 The same novel properties making nanomaterials commercially appealing also pose potentially serious risks to human health and to the environment.[22] Nanoparticles can enter the human body through skin

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[15] J. CLARENCE DAVIES, WOODROW WILSON INT'L CTR. FOR SCHOLARS, EPA AND NANOTECHNOLOGY: OVERSIGHT FOR THE 21ST CENTURY 32 (2007) (citing LUX RESEARCH, THE NANOTECH REPORT iii (4th. ed. 2006)), *available at* http://www.wilsoncenter.org/index.cfm?fuseaction=events.event_summary&event_id=237810.

[16] President George W. Bush signed the 21st Century Nanotechnology Research and Development Act on December 3, 2003. Honda, *supra* note 7, at 63, 68 (appropriations totaled $809.8 million for fiscal year 2005 and $1,024.1 million for fiscal year 2008).

[17] Arrison, *supra* note 14.

[18] Wilson, *supra* note 11, at 705.

[19] *Id.* at 705; *cf.* Charles Choi, *Nano World: New Nanotech Law Called for*, PACIFIC RESEARCH INSTITUTE, Jan. 17, 2006, http://www.pacificresearch.org/press/clip/2006/clip-01-17-06sa.html (noting that approximately sixty consumer products are available on the market).

[20] Letter from Richard Denison and Karen Florini, Senior Scientist and Senior Attorney, Environmental Defense, to Ms. Ann R. Klee, General Counsel, U.S Environmental Protection Agency (May 22, 2006) (citing LUX RESEARCH, THE NANOTECH REPORT (4th. ed. 2006)), *available at* http://www.environmentaldefense.org/documents/5265_StatusofNMsUnderTSCA.pdf [hereinafter Denison Letter]; *cf.* Lindsay V. Dennis, Comment, *Nanotechnology: Unique Science Requires Unique Solutions*, 25 TEMP. J. SCI. TECH. & ENVTL. L. 87, 87 (2006) (noting that nearly 11,000 existing patents contain the words "nano" or "nanotechnology").

[21] James D. Thayer, Note, *The SPS Agreement: Can It Regulate Trade in Nanotechnology?*, 2005 DUKE L. & TECH. REV. 15 (2005).

[22] *See* Balbus, *supra* note 4, at 67.

absorption, ingestion or inhalation.[23] Once they enter the body, because of their size, nanoparticles can be carried past the blood-brain barrier into brain cells and can pass through lung and liver tissue.[24] Studies indicate that unique attributes of insoluble nanoparticles—a small diameter and large surface area—significantly increase toxicity.[25] Some nanomaterials cause oxidative stress and localized immune lesions, and may lead to other tissue and cellular damage.[26] Nanoparticles are also linked to dangerous air, soil and water pollutants.[27] A Rice University study showed that certain individual insoluble nanoparticles become very water-soluble and bacteriocidal when they aggregate.[28] The study raised concerns that nanoparticle properties can endanger ecosystems by killing bacteria constituting the base of the food chain.[29] The existing methods of filtering and removing nanoparticles from water and air are very cost intensive and generally unreliable.[30]

¶9 The environmental and health risks that nonmaterial variants pose have attracted sparse scientific attention. A report by *Lux Research* indicates that over 10,000 nanotechnology research articles were published in 2005, of those, approximately fifty focused on nanotechnology

[23] Wilson, *supra* note 11, at 708.
[24] *E.g.*, J. CLARENCE DAVIES, WOODROW WILSON INT'L CTR. FOR SCHOLARS, MANAGING THE EFFECTS OF NANOTECHNOLOGY, (2006), *available at* http://www.wilsoncenter.org/events/docs/Effectsnanotechfinal.pdf; *see also Scientist Warns of Nanotechnology Dangers*, PHYSORG.COM, May 3, 2006, http://www.physorg.com/news65890257.html.
[25] Andrew D. Maynard & Eileen D. Kuempel, *Airborne Nanostructured Particles and Occupational Health*, 7 J. NANOPARTICLE RESEARCH 587, 607, (Dec. 2005).
[26] *See* Balbus, *supra* note 4, at 66. Subsequent reviews analyzing this study's use of residual organic solvents playing an important role in determining toxicity indicate that non-solvent varieties also show some toxicity to bacteria. Email from Mark Wiesner, James L. Meriam Professor of Civil and Environmental Engineering, Pratt School of Engineering, to author (Sept. 6, 2007, 01:56 EST) (on file with author).
[27] *See generally* ANNABELLE HETT, NANOTECHNOLOGY: SMALL MATTER, MANY UNKNOWNS 1, 15-29 (2004), *available at* http://www.swissre.com/resources/31598080455c7a3fb154bb80a45d76a0-Publ04_Nano_en.pdf.
[28] *See* Balbus, *supra* note 4, at 66.
[29] *Id.* at 65.
[30] *See* HETT, *supra* note 27, at 30 (discussing centrifugation and ultrafiltration as means of removing nanoparticles from water, and air-purification filters as means of removing nanoparticles from air).

environmental, health, and safety issues.[31] The dearth of academic and industry attention in studying nanotechnology risk is less surprising when one considers that federal funding for health and environmental risk research represents only four percent of the proposed federal investment.[32] Postponing research of nanotechnology risks until after health and environmental damage manifests is unwise. Indeed, if industry experience with asbestos, ammonia, methyl chloride, sulfur dioxide and chlorofluorocarbons is any indicator of the consequences of disregarding risks during the early stages of production and distribution,[33] then neglecting to adequately plan for these risks will lead to "lengthy regulatory battles, costly cleanup efforts, expensive litigation quagmires, and painful public-relations debacles."[34]

II. REGULATION DEBATE

¶10 In 2001, the federal government created the National Nanotechnology Initiative (NNI) to coordinate federal nanotechnology research and development projects.[35] Segments of over twenty-five agencies, including the National Science Foundation (NSF), the Department of Defense (DOD), the Department of Energy (DOE), the National Aeronautics and Space Administration (NASA), the National Institute of Standards and Technology (NIST), the Environmental Protection Agency (EPA), the National Institutes of Health (NIH), and the Department of Homeland Security (DHS), fall under the NNI's oversight.[36] In 2003, the 21st Century Nanotechnology Research and Development Act provided an appropriation schedule for the NNI agencies that included over a billion

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[31] MICHAEL W. HOLMAN ET AL., TAKING ACTION ON NANOTECH ENVIRONMENTAL, HEALTH, AND SAFETY RISKS, at 7 (2006) (noting that in 2000 only eleven papers focused on environmental, health, and safety issues).

[32] Fred Krupp & Chad Holliday, Editorial, *Let's Get Nanotech Right*, WALL ST. J., June 14, 2005, at B2. (noting that when private investment is factored in, funding for nanotechnology environmental and health risk research becomes "vanishingly small"). Mr. Krupp is President of Environmental Defense and Mr. Holliday is Chairman and Chief Executive Officer of DuPont.

[33] *Id*.

[34] Balbus, *supra* note 4, at 65.

[35] Honda, *supra* note 7, at 64.

[36] For a list of participating government departments and agencies see National Nanotechnology Initiative, Government Departments and Agencies, http://www.nano.gov/html/about/nniparticipants.html (last visited Jan. 21, 2008).

dollars for fiscal year 2008.[37] Further, the 108th and 109th Congresses held numerous hearings on the societal implications of nanotechnology.[38]

¶11 The strong financial commitment of the federal government, compounded by significant private investment, resulted in rapid development of nanotechnology innovation. The rapid development led to fierce debates to determine the appropriate level of nanotechnology regulation. Commentators generally discuss four regulatory approaches: (1) a complete ban on nanotechnology research, (2) strict government regulation for private research and development, (3) adjustment to the existing regulatory regimes to make them more applicable to nanotechnology, and (4) a voluntary self-regulatory regime for private research and development.[39]

¶12 This iBrief will not specifically address the merits of each regulatory approach. Rather, subsection A of this section will discuss existing regulatory bodies and regulations. Subsection B will discuss a proposal for a new nanotechnology-specific law, and subsection C will examine other regulatory proposals.

A. Existing Regulatory Bodies and Regulations

¶13 Currently no regulations exist applying specifically to nanomaterials.[40] Statutes most relevant to nanotechnology regulation

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[37] Honda, *supra* note 7, at 68.

[38] Breggin & Leslie, *supra* note 9, at 296, n. 47-50 (noting the many hearings before Congress concerning nanotechnology); *see, e.g.*, *Societal Implications of Nanotechnology: Hearing on H.R. 766 Before the H. Comm. on Science*, 108th Cong. (2003); *Environmental and Safety Impacts on Nanotechnology: What Research is Needed?: Hearing Before the H. Comm. on Science*, 109th Cong. 1 (2005); *Developments in Nanotechnology: Hearing Before the Senate Comm. on Commerce, Science and Transportation*, 108th Cong. (Feb. 2006) (statement of Sen. Ted Stevens, Chairman, Sen. Comm. on Commerce, Science and Transportation); Press Release, Senate Environment and Public Works Committee, Senator Jeffords' Statement on Nanotechnology (Apr. 6, 2006), *available at* http://epw.senate.gov/pressitem.cfm?party=dem&id=253725; *Promoting Economic Development Opportunities Through Nano Commercialization: Hearing Before the Senate Comm. on Trade, Tourism, and Econ. Dev.*, 108th Cong. (May 4, 2006).

[39] *E.g.*, Satya Thallam, Commentary, *Nanotech*, MERCATUS REPORTS, Fall 2006, at 4-5, *available at* http://www.mercatus.org/repository/docLib/20061108_Regulation_Fall_2006.pdf.

[40] Scott Segal, *Environmental Regulation of Nanotechnology: Avoiding Big Mistakes for Small Machines*, 1 NANOTECH. L. & BUS. 290, 295 (2004); Holman, *supra* note 31, at 12.

include the Toxic Substances Control Act[41] (TSCA), the Occupational Safety and Health Act[42] (OSHA) and the Food, Drug and Cosmetic Act [43](FDCA).[44]

¶14 The EPA attempts to regulate nanomaterials under the TSCA, which was enacted to ensure that adequate safeguards are put in place before new chemicals are marketed to consumers.[45] Chemical substances manufactured at the nanoscale level are arguably subject to regulation under either the Section 5(a)(1) requirements for new chemical substances or the Section 5(a)(2) requirements for existing chemical substances.[46]

¶15 There are challenges to TSCA's effectiveness in regulating nanotechnology.[47] For instance, although tiny amounts of nanoparticles can be toxic, the TSCA excludes certain chemicals made in relatively small quantities.[48] Also, under Section 5(a)(1), new chemicals are grouped based on their toxicity similarities to existing chemicals, but such groupings may be inappropriate for nanomaterials.[49]

¶16 The EPA issued six broad initiatives in February 2007 to underline its role in nanotechnology regulation, more than two years after the federal government's first round of funding.[50] Among the initiatives is the Voluntary Stewardship Program, which encourages nanotechnology developers to provide the EPA with research data that can be used to develop best practices.[51] The Voluntary Stewardship Program has come

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[41] 15 U.S.C. §§ 2601-2692 (2006).
[42] 29 U.S.C. §§ 651-678 (2006).
[43] 21 U.S.C. §§ 300-399 (2006).
[44] Other laws that are possibly applicable to nanotechnology regulation include: the Clean Air Act (CAA), the Clean Water Act (CWA), and the Resource Conservation and Recovery Act (RCRA). DAVIES, *supra* note 24, at 10-14 (arguing that even if these laws apply to nanotechnology, their only practical effect in many situations is the imposition of a ban on particle release into the environment).
[45] *Id.* at 13.
[46] Christopher L. Bell et al., *Regulation of Nanoscale Materials under the Toxic Substances Control Act*, 2006 A.B.A. SEC. ENV'T., ENERGY, AND RESOURCES 7, 13, *available at* http://www.abanet.org/environ/nanotech/pdf/TSCA.pdf.
[47] *E.g.*, Davies, *supra* note 24, at 10-12 (arguing that TSCA only applies to macro particles, which is a generic term referring to non-nanoparticles).
[48] Kevin Bullis, *New Nano Law?*, TECH. REV., Jan. 17, 2006, http://www.technologyreview.com/article/16323.
[49] *See generally* Denison Letter, *supra* note 20.
[50] ENVTL. PROT. AGENCY, NANOTECHNOLOGY WHITE PAPER (2007), *available at* http://www.epa.gov/OSA/pdfs/nanotech/epa-nanotechnology-whitepaper-0207.pdf.
[51] *Id.* at 68, 89-90.

under strong criticism, and commentators exhibit doubt whether the program creates sufficient incentives for industry participation.[52]

¶17 In May 2007, the Woodrow Wilson International Center for Scholars issued a report proposing more than twenty-five actions that the EPA can take to improve oversight of nanotechnologies. Central recommendations include increasing federal government focus on researching the health and environmental effects of nanotechnology, as well as specific ways of changing the TSCA to cover nanoparticles.[53]

¶18 The OSHA, which is implemented by the Department of Labor (DOL), sets standards for hazardous airborne particles. However, the OSHA's determination of an acceptable quantity of toxic airborne substances applies to macro-particles. Most commentators agree that even if OSHA can be expanded to cover nanoparticles, the agency's current under-funding makes regulation almost impossible.[54]

¶19 The Food and Drug Administration (FDA) implements the FDCA, which regulates drugs, medical devices, biologics, cosmetics and food.[55] The FDA classifies nanoparticles as a variation of their base macro substance and only requires new substances to be registered.[56] The FDA claims that existing regulations are sufficient for nanomaterials despite not requiring pre-market approval for products such as cosmetics.[57]

¶20 In 2002, the NNI agencies and the White House National Economic Council formed a review committee to evaluate interagency coordination efforts, the suitability of federal investments, and risk coordination.[58] The committee made ten general recommendations, none of which dealt with monitoring or establishing risk guidelines. Further, the EPA's Science Advisor, Paul Gilman, noted that none of the agencies focus on the convergence of nanomaterial jurisdiction across agencies.[59]

B. A Proposal for a New Nanotechnology-Specific Law

¶21 Clarence Davies, a senior advisor to the Project on Emerging Nanotechnologies at the Woodrow Wilson International Center for Scholars, recently suggested a new law as the appropriate regulatory response.[60] Davies argues that existing laws and agencies have significant

[52] *See, e.g.*, Breggin & Carothers, *supra* note 9, at 295.
[53] DAVIES, *supra* note 24, at 5-6.
[54] *E.g.*, *id.* at 12.
[55] *Id.* at 13.
[56] HETT, *supra* note 27, at 36.
[57] HOLMAN, *supra* note 31, at 12-13.
[58] SMALL WONDERS, *supra* note 2, at 1.
[59] Segal, *supra* note 40, at 301.
[60] DAVIES, *supra* note 24, at 3.

flaws making them inapplicable to nanotechnology. His most ardent criticisms of existing regulatory laws include: (1) inability to account for the uniqueness of nanomaterial behavior, (2) shortcomings in legal authority to monitor nanotechnology adequately, and (3) under-funding by the federal government of enforcement and measurement mechanisms.[61]

¶22 The proposed law focuses on products rather than the environment, and shifts the burden from the regulatory agencies to the manufacturers. The law requires manufacturers to prove that newly developed nanomaterials are safe to consumers and manufacturers.[62] Davies concedes that an effective, coordinated, intra-agency program, similar to the framework established for biotechnology, may be viable.[63] He notes, however, that given the current political climate, passing a new law or adjusting existing laws regulating commercial products is highly unlikely.[64] His proposal is not without substantive opposition, with many arguing that it could harm small businesses and hinder innovation.[65]

C. Other Regulatory Solutions

¶23 Nanotechnology proposals run the gamut from completely banning nanotechnology production to eliminating all regulation. Suggestions include creating a new federal department overseeing all emerging technologies,[66] approaching regulation from a transnational perspective,[67] and regulating *ex post* by relying on traditional tort or workers' compensation remedies.[68]

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[61] *Id.* at 3, 8. These criticisms are grounded in the challenge to create appropriate nomenclature for nanomaterials. For instance, "if C60 [bucky balls] is not toxic, but aggregates of C60 are toxic, then what [level] of aggregate is toxic . . . [or] do you regulate the initial C60 . . . if so does that include all derivatives of C60?" Email from Mark Wiesner, James L. Meriam Professor of Civil and Environmental Engineering, Pratt School of Engineering to author (Sept. 6, 2007, 01:56 EST) (on file with author).
[62] DAVIES, *supra* note 24, at 18.
[63] *Id.* at 16.
[64] *Id.* at 10.
[65] *E.g.*, Choi, *supra* note 19.
[66] *See* Dennis, *supra* note 20, at 112.
[67] Although this iBrief does not address international and cross-border approaches to nanotechnology regulation, *see* Gary E. Marchant & Douglas J. Sylvester, *Symposium Article: Part III, How Do We Develop Regulatory Policy in the Context of Limited Knowledge about Risks?: Transitional Model for Regulation of Nanotechnolgy,* 34 J.L. MED. & ETHICS 714 (2006); *see also* Thayer, *supra* note 21.
[68] *See generally* W. Kip Viscusi, *The Interaction Between Product Liability and Workers' Compensation as Ex Post Remedies for Workplace Injuries*, 5 J. LAW, ECON. & ORG. 185, 186 (1989).

¶24 Overall, dozens of non-governmental organizations have opined on nanotechnology regulation.[69] Some argue that manufacturer self-regulation coupled with the existing light federal regulatory framework is the best approach to ensuring that nanotechnology's full market and social potential is attained.[70] Several consortia of private nanotechnology research and development companies have taken proactive steps by outlining potential self-regulation approaches and setting standards.[71] Commentators in favor of self-regulation argue that mere perception of risk, rather than actual risk, should not serve as a basis for government intervention.[72] Also, they point to biotechnology, where restraint in regulatory intervention has led to significant innovative breakthroughs with almost no danger to public safety.[73]

¶25 Opposing those arguing for manufacturer self-regulation are those arguing in favor of a slowdown of, or even a complete ban on, nanomaterial production until environmental and health risks are appropriately ascertained. These groups included the Natural Resources Defense Council, the Center for Technology Assessment, and Greenpeace.[74]

¶26 Many commentators urge that a comprehensive, multi-pronged approach that "include[s] elements of regulatory and voluntary programs under existing environmental statutes; corporate stewardship; tort liability; federal, state, and local legislation; voluntary standards; disclosure; liability

[69] Some of the prominent non-governmental organizations include: Action Group on Erosion, Technology and Concentration (ETC Group); Center for Biological and Environmental Nanotechnology (CBEN); Center on Nanotechnology and Society (Nano & Society); Center for Nanotechnology in Society (CNS); Center for Responsible Nanotechnology (CRN); Environmental Law Institute (ELI); Friends of the Earth (FOE); International Risk Governance Council (IRGC); Meridian Institute; and Woodrow Wilson International Center for Scholars' Project on Emerging Nanotechnology. Breggin & Carothers, *supra* note 9, at 299-303.
[70] Choi, *supra* note 19.
[71] Breggin & Carothers, *supra* note 9, at 298 (noting that the industry groups include the American Chemistry Council's Chemstar Nanotechnology Panel, the NanoBusiness Alliance, and the Nanoparticle Benchmarking Occupational Health, Safety and Environment Program); Edward Rashba et al, *Standards in Nanotechnology*, 1 NANOTECH. L. & BUS. 185, 188 (2004) (noting that the industry groups include the Institute of Electrical and Electronics Engineers ("IEEE") and the American Society for Mechanical Engineers ("ASME")).
[72] *See, e.g.*, HOLMAN, *supra* note 31, at 3. For a general discussion of risk perception, see Howard Kunreuther, *Risk Analysis and Risk Management in an Uncertain World*, 22 RISK ANALYSIS 257 (2002).
[73] Arrison, *supra* note 14. Ms. Arrison is the director of Technology Studies at the California-based Pacific Research Institute.
[74] Thallam, *supra* note 39, at 5.

insurance; and international measures" is the best way to balance innovation and commercialization benefits with health and environmental risk concerns.[75] Perhaps the best attempt at setting nanotechnology development standards is spearheaded by the American National Standards Institute (ANSI), whose members include government agencies, organizations, companies, and academic and international bodies.[76]

III. INSURANCE SOLUTION

¶27 When faced with uncertain risks, the government may choose to set regulation anywhere along the *ex post* to *ex ante* precautionary spectrum.[77] Because government regulations strongly influence enterprise decisions, regulatory uncertainty adversely affects manufacturer productivity.[78] Uncertainty disables enterprises from making the cost-benefit calculations necessary to determine appropriate risk-optimizing behavior.[79] As nanotechnology manufacturers await—possibly indefinitely—a regulatory response, a tension arises between the need to quickly capitalize on market opportunities and the need to guard against possible liability exposure.

¶28 Manufacturers may rely on third-party insurance to overcome this tension. Insurance significantly reduces transaction costs by establishing beforehand the party responsible for damages if an accident occurs.[80] A properly functioning insurance market allocates risk and thereby creates appropriate incentives for responsible behavior, spreads economic consequences of loss, compensates victims, and prevents over-deterrence.

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[75] Breggin & Carothers, *supra* note 9, at 310; Krupp & Holliday, *supra* note 32, at B2.

[76] *See* Press Release, American National Standards Institute ("ANSI"), ANSI-NSP Releases Priority Recommendations Related to Nanotechnology Standardization Needs (Nov. 17, 2004), http://www.ansi.org/news_publications/news_story.aspx?menuid=7&articleid=817; *see also* Press Release, ANSI, Nanotechnology Survey Launched to Assess Industry Needs, Apr. 25, 2006, http://www.ansi.org/news_publications/news_story.aspx?menuid=7&articleid=1202.

[77] *See* Jonathan Wiener, *Precaution in a Multi-Risk World*, *in* HUMAN AND ECOLOGICAL RISK ASSESSMENT: THEORY AND PRACTICE 1509, 1513 (Dennis D. Paustenbach ed., 2002).

[78] *See* W. Kip Viscusi, *Frameworks for Analyzing the Effects of Risk and Environmental Regulations on Productivity*, 73 AM. ECON. REV. 793, 793 (1983).

[79] *See* Kenneth S. Abraham, *Environmental Liability and the Limits of Insurance*, 88 COLUM. L. REV. 942, 944 (1988).

[80] Benjamin J. Richardson, *Mandating Environmental Liability Insurance*, 12 DUKE ENVTL. L. & POL'Y F. 293, 295 (2002).

¶29 However, when the insurance market is not functioning properly, private insurers behave similarly to risk-averse policyholders and are deterred from underwriting risk.[81] The world's largest re-insurance company, Swiss Re, notes that the existence of a viable insurance market depends on four factors:

1. *Accessibility*: Probability and severity of losses must be quantifiable to allow pricing.
2. *Randomness*: Time of the insured event must be unpredictable and occurrence independent of the will of the insured.
3. *Mutuality*: Exposed persons must join together to build a community to share and diversify risk.
4. *Economic feasibility*: Insurers must be able to charge a premium which is commensurate with the risk, giving them a fair chance to write the business profitably in the long run.[82]

¶30 Subsection A of this section will discuss considerations that surround insuring nanotechnology by relying solely on the private insurance market.[83] Subsection B will argue that, given the unique risks and short history of nanotechnology, a private-public insurance program is the optimal solution for regulation.

A. Private Insurance Considerations

¶31 Insurance policies do not specifically exclude nanotechnology-related risk.[84] As a result, private insurers recently expressed concerns over the uncertain risks posed by nanotechnology.[85] To exist, insurers must be able to diversify their risk portfolio among various policyholders as well as

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[81] Abraham, *supra* note 79, at 947.
[82] Swiss Re, Nanotechnology—The Insurers' Perspective, *available at* http://www.swissre.com (search keywords "nanotechnology insurers' perspective" and select first link) (last visited Jan. 21, 2008) [hereinafter Insurers' Perspective].
[83] This iBrief does not address risks associated with non-nanotechnology aspects of nanomaterial production, for more information see generally Christine Robichaud et al., *Relative Risk Analysis of Several Manufactured Nanomaterials: An Insurance Industry Context,* 39 ENV'T SCI. TECH. 8985 (Aug. 28, 2005), *available at* http://pubs.acs.org/cgi-bin/abstract.cgi/esthag/2005/39/i22/abs/es0506509.html.
[84] Walter R. Stahel, *The Insurability of Emerging Technologies*, *in* NANOTECHNOLOGY: "SMALL SIZE—LARGE IMPACT?" 33 (Annabelle Hett ed., 2005), *available at* http://www.swissre.com-nanotechnology_report.pdf.
[85] Wilson, *supra* note 11, at 706.

among various events. Swiss Re points to three factors making diversification impossible for nanotechnology:

1. Probability and severity of risks are impossible to assess.
2. Many companies, industry sectors and geographical regions are affected simultaneously.
3. Predicting the magnitude of a possible event exceeds the capacities of the private insurance industry.[86]

¶32 Nanotechnology presents serious concerns across all three of these factors. First, while most previous technological leaps have been in areas where a degree of knowledge and experience was available, here sparse exposure and toxicology research, a lack of nano-related accident history, and the breadth of nanotechnology applications leave insurers without reasonable means to classify the risk posed by nanomaterials.[87] Second, because many countries, industries, government agencies, academic institutions, large multi-national corporations and small start-ups currently participate in nanomaterial research and development, there is significant concern that a nanotechnology-related accident could affect multiple classes of policyholders simultaneously.[88] Even among individual policyholders, nanotechnology risk exists in multiple lines of business and could lead to multiple levels of damage—product liability, product recall, workers' compensation claims, director and officer liability, and negative publicity.[89] The number and type of possible claim permutations makes it difficult to separate claim processing. Finally, the extent of potential claims is impossible to accurately predict. Insurers are concerned that "[t]he examples of accidents and individual claims frequently mentioned in connection with nanotechnology are only the tip of the iceberg."[90] If third-party liability insurers cannot assess the magnitude of risk, under-coverage may financially cripple the policyholder's business.[91] Nanomaterial manufacturers also find it difficult to ascertain deductibles, as well as determine conditions, exclusions, payout triggers, and indemnity limitations.[92]

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[86] Insurers' Perspective, *supra* note 82.
[87] *See* HETT, *supra* note 27, at 40.
[88] Christopher Lauterwasser, *Dealing with Risks and Opportunities of New Technologies*, *in* NANOTECHNOLOGY: "SMALL SIZE—LARGE IMPACT?, *supra* note 84, at 37.
[89] *Id.*
[90] HETT, *supra* note 27, at 39.
[91] *See* Richardson, *supra* note 80, at 295.
[92] *Id.* at 328.

¶33 The inability to screen nanotechnology manufacturers through risk assessment, to classify nanomaterial risk and to determine which risks are excludable from coverage will undoubtedly result in problems with adverse selection and moral hazards.[93] Specifically, if private insurers are unable to appropriately determine deductible and premium levels because they possess less information than their policyholders, a disproportionate number of high-risk nanotechnology manufacturers will aim to obtain coverage, while low-risk manufacturers will elect to remain uninsured.[94] Further, because the insurer is likely to accurately assess risk only after nanotechnology-related accidents occur, the policyholder's incentive to avoid losses is eliminated.[95] The problem with inappropriate risk-mitigating incentives is compounded for judgment-proof enterprises, whose insurance coverage and other ability to pay for damages is less than their potential nanotechnology-related liabilities.[96] Currently, victims of nanotechnology-related accidents have no recourse for damages inflicted by judgment-proof enterprises.

B. Private-Public Insurance Proposal

¶34 A private-public insurance program is a possible solution for balancing the nanotechnology enterprises' dual interests of capitalizing on market opportunities and limiting liability exposure with the public policy interest of stimulating responsible innovation. Currently a private-public insurance scheme exists to address the low-probability, but high-loss, area of nuclear accidents.[97] Nuclear accident insurance is covered by the Price-Anderson Act,[98] which provides an excellent template for approaching nanotechnology accidents.[99]

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[93] *See* Abraham, *supra* note 79, at 946-47.
[94] *Id*. at 946.
[95] *Id*.
[96] Richardson, *supra* note 80, at 327.
[97] *See* Robin M. Hogarth & Howard Kunreuther, *Ambiguity and Insurance Decisions*, 75 THE AM. ECON. REV. 386, 389 (1985).
[98] Pub. L. No. 85-256, 71 Stat. 576 (codified as amended in 23 U.S.C. §§ 2210, 2039 (2006)).
[99] Since its enactment, the Price-Anderson Act has been continuously challenged. The Act withstood a constitutional challenge and was upheld by the Supreme Court in *Duke Power Co. v. Carolina Entl. Study Group*, 438 U.S. 59 (1978). Today many organizations including The Cato Institute, Greenpeace, Taxpayers for Common Sense and Green Scissors continue to oppose the Price-Anderson Act. *See* Barry P. Brownstein, *The Price-Anderson Act: Is It Consistent with a Sound Energy Policy?*, THE CATO INSTITUTE, Apr. 17, 1984, http://www.cato.org/pubs/pas/pa036.html; Public Citizen, Price-Anderson Reauthorization in H.R.6: An Insurance Scam for the Nuclear Industry, http://www.citizen.org/cmep/energy_enviro_nuclear/electricity/energybill/article

¶35 The Price-Anderson Act was passed in 1957 and was recently extended through 2025 by the Energy Policy Act of 2005.[100] The Price-Anderson Act requires power reactor licensees to obtain the maximum level of private sector insurance and, in the event of an accident, contribute annually to a secondary insurance fund.[101] Currently, all such primary and secondary insurance coverage totals over ten billion dollars.[102] All losses above those covered by the primary and secondary insurance pools are handled by the government.[103] The Price-Anderson Act indemnifies nuclear power reactor licensees from tort liability and precludes victims of nuclear accidents from claiming punitive damages.[104]

¶36 Inaccurately perceived risks and other externalities cause private insurance markets to break down and require government intervention.[105] Private sector insurance providers underwriting nanotechnology initiatives confront concerns similar to those faced by private sector nuclear power reactor licensees—inability to accurately assess both probability and magnitude of loss.

¶37 A mandatory insurance program, similar to that required by the Price-Anderson Act, would significantly reduce adverse selection problems. By requiring insurance as a precondition of nanotechnology research and development, a diverse pool of risk-seeking policyholders would be created. Although the insurers' inability to set appropriate premium and deductible levels would persist, setting fees at a level that precludes the least responsible enterprises from coverage would alleviate moral hazard problems. A starting point for determining pricing levels may be based on insurers' experience with the biotechnology or chemical industries. Further, indemnification from tort liability for nanotechnology participants in the private-public insurance program would create the necessary incentives for high-risk enterprises to adjust their behavior and avoid being uninsurable. Mandatory insurance forces manufacturers of nanomaterials to prove that their initiatives are safe enough to be insurable.

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s.cfm?ID=10322 (last visited Jan. 21, 2008); Green Scissors, Nuclear Bailout: Price-Anderson Act, http://www.greenscissors.org/energy/price-anderson.htm, (last visited Jan. 21, 2008).

[100] Pub. L. No. 109-58, §§ 601-610, 119 Stat. 594 (2005).

[101] AM. NUCLEAR SOC'Y, PRICE-ANDERSON ACT: BACKGROUND FOR POSITION STATEMENT 54, 1-2, (Nov. 2005), http://www.ans.org/pi/ps/docs/ps54-bi.pdf, (noting that as of 2005 the maximum level of primary insurance is $300 million, and total individual secondary contributions will add up to $95.8 million, capped at $15 million per year) [hereinafter PRICE-ANDERSON ACT BACKGROUND].

[102] *Id*.

[103] Hogarth & Kunreuther, *supra* note 97, at 389.

[104] PRICE-ANDERSON ACT BACKGROUND, *supra* note 101, at 2.

[105] *See, e.g.*, Richard J. Zeckhauser & W. Kip Viscusi, *The Risk Management Dilemma*, 545 ANNALS OF THE AM. ACAD. OF POL. & SOC. SCI. 144, 144 (1996).

¶38 The pooling of insurance fees is another important aspect of the private-public insurance program. After accounting for management and other expenses, all collected nanotechnology-related insurance premiums and deductibles would be pooled across insurers. A cross-insurer or independent enterprise would have management and investment responsibility for the pool. In the event of an accident, claimants would receive damages from this pool. If possible, this pool would be broken down into several categories including environmental and employment-related liability. Unlike other suggested regulations, the pooling function of the mandatory private-public insurance program would eliminate the concerns arising from judgment-proof enterprises. Also, the pool would be composed of premiums and deductibles, factors that are directly correlated with the level of risk associated with each nanotechnology initiative.

¶39 If the magnitude of loss from nanotechnology-related accidents exceeded an insurance pool's coverage level, remaining liability would be covered by the federal government. Even though government intervention creates an unavoidable moral hazard, the premium and deductible levels should be set high enough to prevent the highest risk nanotechnology manufacturers from becoming initially insured and therefore from operating. Barring very expensive and persistent nanotechnology accidents, the private sector would provide the majority of insurance coverage, freeing government nanotechnology expenditures to be applied to research, development and risk assessment.

¶40 A possible criticism of the private-public nanotechnology insurance program is that it does not focus on eliminating nanotechnology-related accidents, but rather focuses on after-the-fact compensation. Indeed, the private-public insurance program assumes that nanotechnology innovation is an essential step in technological evolution and is socially beneficial. Therefore, the program's goal is to prevent the over-deterrence of innovation and to take steps to address the nanotechnology-related accidents that most commentators perceive to be inevitable. Although the private-public insurance program prevents victims from pursuing tort claims, it may wind up benefitting victims on balance, as it would replace the risk of the tort remedy with the predictability of a no-fault compensation scheme. While filing a lawsuit does not ensure the right or ability to collect damages,[106] a strict liability standard eliminates the need for victims to show either causation or fault (tort elements that are difficult to prove given

[106] PRICE-ANDERSON ACT BACKGROUND, *supra* note 101, at 2; *see also* Richard Murray, *Liability Regimes in a Changing Risk Landscape*, *in* NANOTECHNOLOGY: "SMALL SIZE—LARGE IMPACT?", *supra* note 84, at 40.

the current sparse research on nanomaterial risk) and allows for predictable recovery of damages.[107]

¶41 Another criticism of the private-public nanotechnology insurance program is that, as with any regulation, it raises the price of market participation above what small and start-up businesses can endure. But unlike many previous technological innovations, nanotechnology research and development does not occur in entrepreneurs' garages. Rather, most small and start-up nanotechnology companies are associated with large businesses, universities and venture capital funds. If a small start-up business' nanotechnology innovation is truly promising, that company should not have trouble finding appropriate funding for insurance coverage from financial sponsors.

¶42 This insurance scheme also does not address the concern that in a global environment the risk of nanoparticle dispersion transcends national boundaries. With nanotechnology production, as with any global economic initiative, the threat of developers and manufacturers racing to establish laboratories and plants in low regulatory regimes is high. Although the private-public nanotechnology insurance program is United States-focused, it provides a starting point for expanding nanotechnology regulation internationally.

¶43 Lastly, the private-public insurance program does not eliminate difficulties with classifying nanotechnology research and risk. It creates a derivative question of who is a nanomaterial manufacturer for regulation purposes. However, mandating private-public insurance creates appropriate incentives for manufacturers, insurers and the federal government to collaborate on establishing appropriate research, development and risk standards.

CONCLUSION

¶44 The same novel nanomaterial properties that are predicted to create a one trillion dollar market by 2015 are also likely to create significant health and environmental risks. The benefits and dangers associated with nanomaterials stimulated fierce debates over appropriate nanotechnology regulation. Commentators and interest groups have proposed a wide range of possible regulatory solutions. This iBrief argues that a viable regulatory solution exists in the insurance market. A hybrid private-public insurance program resolves the current difficulties insurers face with accurately assessing the probability and magnitude of nanotechnology-related loss. Further, the private-public insurance program allows for collaboration

[107] Richardson, *supra* note 80, at 301.

among manufacturers, insurers and the federal government in establishing standards.

¶45 To create appropriate incentives, the private-public nanotechnology insurance program requires: (1) mandatory participation as a precondition to research and development, (2) creation of a cross-insurer pool of premiums and deductibles to use for claimant payouts, (3) federal government coverage of losses exceeding coverage provided by a cross-insurer pool, and (4) indemnification from tort liability of program participants. Although the private-public insurance program does not resolve many existing nanotechnology obstacles, it is a way to balance commercialization and risk concerns.