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Nanotechnology, Environmental Risks, and Regulatory Options

Vincent R. Johnson

St. Mary's University School of Law, vjohnson@stmarytx.edu

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Nanotechnology, Environmental Risks, and Regulatory Options

Vincent R. Johnson*

ABSTRACT

Nanotechnology is today viewed by many as a great advance in the quest for stronger and lighter materials, more effective pharmaceuticals, and better medicine. The critical question—largely unanswered—is whether this kind of science harbors destructive powers which, if fully understood, would call for restrictions or a ban on the use of certain types of nanotechnology.

Current regulations in the United States and Europe cover chemicals that may be produced in nanoform. However, those regimes are not well designed to detect the risks posed by nanotechnology because they often fail to appreciate what is unique about nanomaterials.

It is unlikely that individual countries will act to effectively address nanotechnology risks because dangers are still uncertain and the potential costs of regulation are high. Logically, nanotechnology risks should be addressed at the international level because nanomaterials cross borders and pose issues worldwide. However, there is little precedent for such regulation and many obstacles

The best course is to develop the “soft law” predicate for later “hard law” regulation. Such non-binding international norms or agreements should include codes of conduct, aspirational guidelines, statements of best practices, voluntary reporting, risk management systems, and licensing, accreditation, or certification schemes.

Soft law can be used to create expectations which, once widely endorsed, can later be translated into binding legal obligations. Minimizing the health, safety, and environmental risks related to nanotechnology requires raising the visibility of the issue, collecting reliable data, establishing prudent practices, building an international consensus, and eventually enacting and enforcing binding obligations

* Professor of Law, St. Mary's University, San Antonio, Texas. B.A., LL.D., Saint Vincent College; J.D., University of Notre Dame; LL.M., Yale University; LL.M., London School of Economics and Political Science. Member, American Law Institute.

that reflect a prudent balance between economic progress and hazard prevention.

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I. THE CHALLENGES POSED BY NEW PRODUCTS

New technologies that are initially seen as great advances in science and the quest for human progress are sometimes later viewed as exceedingly dangerous. Thus, we now know that the chlorofluorocarbons that made refrigeration, air conditioning, and aerosols possible seriously damage the earth's protective ozone layer;¹

1. See Chris Peloso, *Crafting an International Climate Change Protocol: Applying the Lessons Learned from the Success of the Montreal Protocol and the Ozone*

that lead additives can make paint durable but may poison children generations later;² that asbestos not only insulates products but destroys human respiratory systems;³ and that the fossil fuels⁴ that catalyze industry and transportation also speed climate change and its potentially destructive consequences.⁵ Nanotechnology⁶ is today viewed by many as a great advance in the quest for stronger⁷ and lighter materials,⁸ more effective pharmaceuticals,⁹ better medicine,¹⁰ and tinier machines.¹¹ The

Depletion Problem, 25 J. LAND USE & ENVTL. L. 305, 308 (2010) (“[P]rior to the Montreal Protocol, CFCs were incorporated into a variety of consumer products.”); *see also* Montreal Protocol on Substances that Deplete the Ozone Layer, Sept. 16, 1987, 1522 U.N.T.S. 3 [hereinafter Montreal Protocol].

2. *Cf.* State v. Lead Indus. Ass’n, 951 A.2d 428, 437 (R.I. 2008) (“Children under six years of age are the most susceptible to lead poisoning.”).

3. *Cf.* Timothy B. Mueller, *Tomorrow’s Causation Standards for Yesterday’s Wonder Material: Reiter v. Acands, Inc. and Maryland’s Changing Asbestos Litigation*, 25 J. CONTEMP. HEALTH L. & POL’Y 437, 440 (2009) (“Asbestos has been used in roughly four thousand commercial products.”).

4. *See* Andrew Shepherd, *The Perilous Hunt for APEC Blue: The Difficulties of Implementing Effective Environmental Regulations in China*, 6 ARIZ. J. ENVTL. L. & POL’Y 595, 600 (2016) (discussing China’s emissions).

5. *See* Veerle Heyvaert, *Governing Climate Change: Towards a New Paradigm of Risk Regulation*, 74 MODERN L. REV. 817, 818 (2011) (calling climate change the “most important environmental risk of our time”); *see also* U.N. Framework Convention on Climate Change, May 9, 1992, S. Treaty Doc. No. 102-38, 1771 U.N.T.S. 107.

6. *See* Graeme A. Hodge et al., *Introduction: The Regulatory Challenges for Nanotechnologies* [hereinafter *Introduction*], in INTERNATIONAL HANDBOOK ON REGULATING NANOTECHNOLOGIES 3, 3 (Graeme A. Hodge et al. eds., 2010) [hereinafter *HANDBOOK*] (discussing nanotechnology’s “new scientific frontiers”).

7. *See generally* WILLIAM E. PLATTEN III ET AL., U.S. ENVTL. PROT. AGENCY, REP. NO. EPA/600/R-14/365, RELEASE OF MICRONIZED COPPER PARTICLES FROM PRESSURE-TREATED WOOD PRODUCTS (2014).

8. *See* Robert J. Aitken et al., *Regulation of Carbon Nanotubes and Other High Aspect Ratio Nanoparticles: Approaching this Challenge from the Perspective of Asbestos*, in *HANDBOOK*, *supra* note 6, at 205, 206 (noting that carbon nanotubes have “remarkable tensile strength”).

9. *Cf. In re Lupron Mktg. & Sales Practices Litig.*, No. 01-10861, 2015 WL 9412515, at *2 (D. Mass. Dec. 22, 2015) (discussing a “robust nanoparticle formulation” that “has a tumor-sensitive drug release profile”); *In re Lupron Mktg. & Sales Practices Litig.*, No. 01-10861, 2014 WL 7330815, at *6 (D. Mass. Dec. 23, 2014) (discussing targeted nanoparticles that have “the potential to overcome the toxicity and efficacy limitations associated with traditional cytotoxic agents and molecularly targeted drugs by releasing drug directly to cancer cells”).

10. *See* Marcus Widmer & Christoph Meili, *Approaching the Nanoregulation Problem in Chemicals Legislation in the EU and US*, in *HANDBOOK*, *supra* note 6, at 238 (progress is “expected” in medical treatments); Rebecca M. Hall, Tong Sun & Mauro Ferrari, *A Portrait of Nanomedicine and Its Bioethical Implications*, 40 J.L. MED. & ETHICS 763, 766 (2012) (“[N]anotechnology comprises a set of necessary enablers for personalized medicine therapeutics to become reality.”).

11. *See* Kenneth Chang & Sewell Chan, *3 Makers of World’s Smallest Machines Awarded Nobel Prize in Chemistry*, N.Y. TIMES, Oct. 5, 2016, www.nytimes.com/2016/10/06/science/nobel-prize-chemistry.html (discussing the development of “nanomachines”).

critical question—largely unanswered—is whether this new kind of science harbors destructive powers which, if fully understood, would call for restrictions or a ban on the use of nanotechnology, at least in certain contexts.

This article considers the role that regulation can play in addressing the health, safety, and environmental risks that may be associated with nanomaterials. Part II briefly surveys the history and present status of nanoscience, and the potential associated risks. Part III then considers why markets and litigation are “imperfect alternatives”¹² that cannot optimally minimize the risks related to nanotechnology. Part IV examines the challenges that impede effective regulation of nanotechnology, and the regulatory steps taken thus far by the European Union and the United States, two leaders in the scientific development and commercialization of nanotechnology. Part V then focuses on how regulation can be made more effective by broadening the domestic array of regulatory options to go far beyond traditional command-and-control mechanisms and by internationalizing regulatory efforts through the use of “soft law”¹³ instruments. Part VI offers concluding thoughts.

II. THE RISE OF NANOTECHNOLOGY

A. *Interdisciplinary Origins*

The origins and meanings of nanotechnology are unclear and disputed.¹⁴ The term “nanotechnology” was probably first used in 1974,¹⁵ and it led to a new lexicon in which there are frequent references to nanomaterials, nanoscale, and nanoparticles, as well as to nanotools, nanomanufacturing, and nanoapplications.

Nanotechnology is concerned not with one science, but many. It did not grow from a single discovery, but from contributions in numerous fields.¹⁶ Nanotechnology crosses a range of disciplines, including biology, chemistry, physics, engineering, materials science, medicine, and information technology.¹⁷ These disciplines are united by the fact that they are concerned with particles at the atomic level,¹⁸

12. NEIL K. KOMESAR, *IMPERFECT ALTERNATIVES: CHOOSING INSTITUTIONS IN LAW, ECONOMICS, AND PUBLIC POLICY* 112, 148 (U. Chi. Press 1994).

13. See Joshua A. Lance, *Equator Principles III: A Hard Look at Soft Law*, 17 N.C. BANKING INST. 175, 175 (2013) (defining “soft law” as “voluntary, informal guidelines that carry no legal obligation”).

14. *Introduction*, *supra* note 6, at 3.

15. *Id.* at 6.

16. See Chris Toumey, *Tracing and Disputing the Story of Nanotechnology*, in *HANDBOOK*, *supra* note 6, at 46, 46.

17. See *Introduction*, *supra* note 6, at 6 (listing fields).

18. *Id.* at 3 (“atomic”).

specifically the nanoscale, 10^{-9} units. Thus, a nanometer is 10^{-9} meters,¹⁹ which means one-billionth of a meter.²⁰

In nanotechnology, the defining characteristic is exceedingly minute size.²¹ Research typically involves the manipulation of matter at a scale of less than 100 nanometers.²²

B. *Forms and Uses*

Nanoparticles take many different forms, including nanospheres, nanotubes, and nanofibers.²³ Nanoparticles are today used in a wide range of consumer products, such as food and food contact items, cosmetics and skin care products, coatings such as varnishes and paints, house cleaning products, environmental remediation chemicals, communication devices, information technology, biosensors and biomedical devices, clothing, and textiles.²⁴ Silver nanoparticles are inserted into fabrics to function as antimicrobials, carbon nanotubes are used to strengthen materials, and titanium dioxide nanoparticles make sunscreens clear.²⁵

The next generation of nanotechnology will reflect the same “immense diversity,”²⁶ but will be more complex. It may involve nanoscale structures that change “in response to exposure to light, magnetic or electric fields, or the presence of specific types of molecules.”²⁷ Future applications may include targeted drug and gene delivery mechanisms, diagnostic devices, “smart” clothing and packaging, optical instruments, cloaking devices, and energy capture and storage mechanisms.²⁸ The range of products is unpredictable.²⁹

Nanotechnology may change the way wars are fought by making feasible the production of “exceptionally small, uninhabited vehicles or

19. See David Williams, *The Scientific Basis for Regulating Nanotechnologies*, in HANDBOOK, *supra* note 6, at 107, 111.

20. See Robert Falkner et al., *International Coordination and Cooperation: The Next Agenda in Nanomaterials Regulation*, in HANDBOOK, *supra* note 6, at 508, 508.

21. See Aitken et al., *supra* note 8, at 205.

22. See Falkner et al., *supra* note 20, at 508.

23. See Williams, *supra* note 19, at 108.

24. *Id.*; *Introduction*, *supra* note 6, at 17.

25. See Linda K. Breggin & John Pendergrass, *Regulation of Nanoscale Materials Under Media-specific Environmental Laws*, in HANDBOOK, *supra* note 6, at 342, 366.

26. Thomas K. Epprecht, *Producing Safety or Managing Risks? How Regulatory Paradigms Affect Insurability*, in HANDBOOK, *supra* note 6, at 163, 168.

27. Breggin & Pendergrass, *supra* note 25, at 366.

28. *Id.* at 366; Williams, *supra* note 19, at 108.

29. Karinne Ludlow & Peter Binks, *Regulating Risk: The Bigger Picture*, in HANDBOOK, *supra* note 6, at 144, 154.

weapons capable of autonomous firing decisions.”³⁰ Those same nanoapplications, in the hands of criminals and terrorists, may also revolutionize the nature and scope of illegal activity by nonstate actors.³¹ Potential military uses of nanotechnology that stand out as particularly dangerous include: small sensors, robots, missiles, and satellites; metal-free firearms; body implants; autonomous combat systems; and devices carrying chemical and biological weapons.³²

C. *Economic Stakes and Obstacles*

The economic stakes behind the nanotechnology revolution are tremendous. “Every major industrial country,”³³ including the United States,³⁴ Australia, Japan, and many Member States of the European Union,³⁵ has invested heavily in the development of nanotechnologies. Revenue from nano-enabled products grew to more than \$1 trillion in 2013.³⁶

The fact that many private interests have made substantial expenditures on nanotechnology development will undoubtedly make enactment of restrictive regulations more difficult because those enterprises are sure to lobby to protect their economic interests.³⁷ Indeed, even though there is substantial room within the WTO

30. Jürgen Altmann, *Military Applications: Special Conditions for Regulation*, in HANDBOOK, *supra* note 6, at 372, 372.

31. Susan W. Brenner, *Nanocrime?*, 1 U. ILL. J.L. TECH. & POL’Y 39, 88 (2011) (“Nanotechnology is likely to play a notable role in counterfeiting goods.”).

32. See Altmann, *supra* note 30, at 382 (listing uses); Hitoshi Nasu, *Nanotechnology and the Future of the Law of Weaponry*, 91 INT’L L. STUD. 486, 487 (2015) (discussing potential use in hostilities).

33. Kenneth W. Abbott, Douglas J. Sylvester & Gary E. Marchant, *Transnational Regulation of Nanotechnology: Reality or Romanticism*, in HANDBOOK, *supra* note 6, at 525, 525.

34. *Nanotechnology Update: Corporations Up Their Spending as Revenues for Nano-Enabled Products Increase*, LUX RESEARCH (Feb. 17, 2014), https://www.nsf.gov/crssprgm/nano/reports/LUX14-0214_Nanotechnology%20StudyMarketResearch%20Final%2017p.pdf (“The United States maintained its lead over all other governments, with \$2.1 billion of federal and state funding in 2012.”).

35. See Breggin & Pendergrass, *supra* note 25, at 343.

36. See *Market Report on Emerging Nanotechnology Now Available*, NAT’L SCI. FOUND. (Feb. 25, 2014), https://www.nsf.gov/news/news_summ.jsp?cntn_id=130586 (“[R]evenue from nano-enabled products grew worldwide from \$339 billion in 2010 to \$731 billion in 2012 and to more than \$1 trillion in 2013. Revenue from the United States alone was \$110 billion, \$236 billion and \$318 billion those same years, respectively.”).

37. Cf. Altmann, *supra* note 30, at 373 (“[T]he economic competition between countries can act as a barrier [to nanotechnology regulation] because better safety features tend to make production more expensive”); Vincent R. Johnson, *Regulating Lobbyists: Law, Ethics, and Public Policy*, 16 CORNELL J.L. & PUB. POL’Y 1, 10 (2006) (“From a business standpoint, hiring a lobbyist is often the smart thing to do.”).

international economic order for states to take action to protect the environment,³⁸ governments that have invested heavily in promoting nanotechnologies will be reluctant to adopt measures that might interfere with the prosperity of the nanotech sector.³⁹ Because nanotechnology developments move at a rapid pace, any regulatory interruption has the potential to seriously impede innovation and profitability.⁴⁰

D. *Inadequate Information About Risks*

The health, safety, and environmental risks associated with nanotechnology are largely unknown⁴¹ because the relevant science is still evolving. Nanomaterials have been commercially used in products and services for only a relatively short period of time. There is a “dearth of information” relating to several key aspects of nanoscale materials.⁴²

The uncertainties relate not merely to health, safety, and environmental effects, but such basic matters as how to classify nanomaterials and define nanotechnology.⁴³ The latter is particularly important because clear and accurate definitions are essential if empirical studies are to be useful and the ambit of regulatory obligations intelligently articulated.⁴⁴ The value of early studies of nanotechnology was compromised by a lack of terminological coordination,⁴⁵ and a history of inconsistent definitions continues to cause patent-granting authorities great difficulties in identifying relevant prior art.⁴⁶

38. See Steve Charnovitz, *The WTO's Environmental Progress*, 10 J. INT'L ECON. L. 685, 688–90 (2007) (describing the WTO system).

39. See Andrew D. Maynard, Diana M. Bowman & Graeme A. Hodge, *Conclusions: Triggers, Gaps, Risks and Trust*, in HANDBOOK, *supra* note 6, at 573, 579 (“Governments have a strong interest in their considerable investments in nanotechnologies leading to economic stimulation . . .”).

40. J. Clarence Davies, *From Novel Materials to Next Generation Nanotechnology: A New Approach to Regulating the Products of Nanotechnology*, in HANDBOOK, *supra* note 6, at 545, 547.

41. U.S. ENVTL. PROT. AGENCY, *Nanotechnology and Nanomaterials Research 1*, (last visited June 5, 2016), <https://www.epa.gov/sites/production/files/2013-12/documents/nanotechnology-fact-sheet.pdf> (“Nanomaterials are very useful, but there is little research about how they affect human and ecosystem health.”).

42. Breggin & Pendergrass, *supra* note 25, at 355.

43. *Id.* at 356; John Miles, *Nanotechnology Captured*, in HANDBOOK, *supra* note 6, at 83, 94 (discussing the current “working definition”).

44. Williams, *supra* note 19, at 109–11 (“a great deal will depend on the borderline between the nanoscale and the microscale”).

45. See Oliver Tassinari, Jurrón Bradley & Michael Holman, *The Evolving Nanotechnology Environmental, Health, and Safety Landscape: A Business Perspective*, in HANDBOOK, *supra* note 6, at 177, 179.

46. See Gregory N. Mandel, *Regulating Nanotechnology Through Intellectual Property Rights*, in HANDBOOK, *supra* note 6, at 388, 393.

Sound science is the key to charting a safe course through the potential risks posed by nanotechnology. That precondition depends on the use of appropriate and widely agreed upon definitions that are able to draw a reliable boundary “between the products of nanotechnology and everything else.”⁴⁷

E. *The Uncertain Risk Profile*

In principle, efforts to minimize health, safety, and environmental risks should be based on a risk profile for the particular technology that takes into account the kind of harm to which the risk pertains, the severity and scale of the risk if it comes to fruition, and the probability of the risk materializing.⁴⁸ However, in the case of nanotechnologies, it is extremely difficult to produce reliable risk assessments because those judgments turn upon a careful review of exposure- and hazard-related data, both of which are now surrounded by considerable uncertainties.⁴⁹ There are “huge gaps” in the relevant scientific knowledge.⁵⁰ In addition, new technological developments more than a few years out are “inherently unpredictable.”⁵¹

F. *Special Scientific Rules Apply*

The seemingly well-established scientific principles that regulate ordinary life do not apply to nanoparticles. “[N]anotechnologies exploit the specific properties that arise from matter at the nanoscale that are characterized by the interplay of classical physics and quantum mechanics, where the properties are often difficult to predict *a priori*.”⁵²

Nanoparticles may not be “sufficiently alike to afford general statements about their toxicological properties” in the products and locations where they may end up.⁵³ Thus, it might never be scientifically possible to offer assurances that all products containing nanotechnology are safe. General conclusions about the nanotechnology health-effects

47. Williams, *supra* note 19, at 122.

48. Roger Brownsword, *The Age of Regulatory Governance and Nanotechnologies*, in HANDBOOK, *supra* note 6, at 60, 70.

49. *Introduction*, *supra* note 6, at 3, 13–14.

50. *Id.* at 16; Quasim Chaudhry, Hans Bouwmeester & Rolf F. Hertel, *The Current Risk Assessment Paradigm in Relation to the Regulation of Nanotechnologies*, in HANDBOOK, *supra* note 6, at 124, 139 (noting “critical knowledge gaps”); Ludlow & Binks, *supra* note 29, at 149 (noting “current lack of knowledge”).

51. Breggin & Pendergrass, *supra* note 25, at 366.

52. See Williams, *supra* note 19, at 108.

53. Alfred Nordmann, *Philosophy of Technoscience in the Regime of Vigilance*, in HANDBOOK, *supra* note 6, at 41.

on large, well-defined classes of things may prove to be beyond the reach of human knowledge.⁵⁴

Nanotechnology is described by some as a “wicked” public policy problem posing challenges so great as to rank with climate change and synthetic biology.⁵⁵ A large part of those challenges results from the fact that nanoscience is interdisciplinary, and consequently there is no “small body of knowledge” that will yield all the answers about the risks of nanotechnology.⁵⁶ Yet regulators need “a profound level of knowledge” if they are to be able to establish prudent nanotechnology regulations.⁵⁷

G. *Specter of Asbestos*

In many minds, the potential risks of nanotechnology are linked with the sad history of asbestos.⁵⁸ Once viewed as a miracle material,⁵⁹ asbestos was later unmasked as a lethal killer. Some scholars argue that the risks posed by nanofibers should be evaluated bearing in mind the carcinogenic effects of asbestos fibers.⁶⁰

The idea of a possible connection between asbestos and nanoparticles is reinforced by the fact that for humans, such as workers in nanotechnology plants,⁶¹ inhalation is the most likely route of exposure to nanoparticles.⁶² Inhaled nanoparticles that reach the blood stream may travel to the liver, heart, and blood cells.⁶³ It is therefore not surprising that some scholars argue that it is “imperative” that regulators

54. *See id.* at 25, 41.

55. *See Introduction, supra* note 6, at 4.

56. Toumey, *supra* note 16, at 57.

57. Widmer & Meili, *supra* note 10, at 241.

58. *Introduction, supra* note 6, at 7; Aitken et al., *supra* note 8, at 211–29 (discussing the health risks and eventual regulation of asbestos).

59. Anna Linetskaya, Note, *Asbestos Lawsuits in Russia: Bring One If You Can*, 22 CARDOZO J. INT’L & COMP. L. 399, 400 (2014) (“Once known as a miracle material used by emperors and priests to entertain the crowds with its nonflammable qualities, asbestos is now known as a toxic material that causes cancer.”).

60. *See Williams, supra* note 19, at 119.

61. *See Aitken et al., supra* note 8, at 208 (indicating there is “almost no information” on worker exposure); *but see* Katie Miller, Note, *Nanotechnology: How Voluntary Regulatory Programs Can Both Ease Public Apprehensions and Increase Innovation in the Midst of Uncertain Federal Regulations*, 8 IND. HEALTH L. REV. 435, 444 (2011) (“[I]n August 2009, the deaths of two female factory workers in China were allegedly linked to adverse effects of nanotechnology at a factory that produced paint containing nanomaterials. The two girls died from lung damage similar to that seen in asbestos-related mesothelioma victims The precise reason for the deaths has not yet been released, but the possibility that nanoparticles could cause these kinds of effects is cause for alarm.”).

62. Williams, *supra* note 19, at 119.

63. *Id.*

allow wider safety margins for products and applications that are likely to give rise to significant human exposure to nanoparticles.⁶⁴

Health risks may be created by free nanoparticles generated during production processes and negligently released into the environment or intentionally delivered to persons via nanotechnology-based products. The exposure of persons to nanoparticles that have characteristics not previously encountered may overwhelm their immune and inflammatory defense mechanisms.⁶⁵

Special attention has focused on one particular kind of nanoparticle, the carbon nanotube. A new form of carbon molecule, carbon nanotubes are “considered to be many times stronger than steel yet only one sixth its mass,” and to have “unique electronic properties.”⁶⁶ Research has suggested that some carbon nanotubes may cause serious health problems because they may exhibit toxic properties similar to asbestos.⁶⁷ However, nanotubes come with a variety of physical and chemical characteristics,⁶⁸ and not all are equally hazardous.⁶⁹ Some scholars say the risks are “manageable at this time.”⁷⁰

III. NONREGULATORY ALTERNATIVES

It would be unnecessary to address nanotechnology risks through regulation if product markets and liability regimes were capable of ensuring that a proper balance is struck between the competing public interests in innovation and accident prevention. However, as the following sections explain, those alternatives fall far short of such a lofty goal.

A. *The Inadequacies of Markets*

1. Lack of Information

Consumers are poorly positioned to protect their own interests from the potential dangers posed by nanotechnology. Much industry-supported research on nanotechnology is not available to the public,⁷¹

64. Chaudhry et al., *supra* note 50, at 140.

65. See Williams, *supra* note 19, at 116.

66. See Aitken et al., *supra* note 8, at 205–06.

67. See *id.* at 206, 229 (“[T]he parallels . . . are remarkable . . .”).

68. See Tassinari et al., *supra* note 45, at 194 (discussing carbon nanotubes of varying lengths and diameters, including multi-walled, single-walled, and double-walled nanotubes).

69. See Aitken et al., *supra* note 8, at 231.

70. Tassinari et al., *supra* note 45, at 195.

71. See *id.* at 183 (“Much of the industry supported research is not available to the public.”).

and what is available is often shrouded in the complexities of science. While some products tout that they contain nanoparticles,⁷² many do not.⁷³ Even when the presence of nanoparticles is disclosed, as is required by the European Union Cosmetics Regulation,⁷⁴ consumers receive little or no information about the risks of those materials.

Efforts to bring greater transparency to nanotechnology products have been met with only partial success. Of the 1,814 consumer products listed on the Nanotechnology Consumer Products Inventory (2015), 49% of the products (889) do not disclose the composition of the nanomaterial used in them.⁷⁵ Unlike many countries in Europe, the United States is skeptical about the usefulness of enacting requirements that mandate the labeling of products containing nanomaterials but do not notify consumers of specific risks.⁷⁶ In the American view, merely knowing that a product contains nanoparticles is not useful.

Presumably, intelligent consumer decisions about products produced with nanotechnology would have to be made on an individual product basis, rather than based on a crude assessment that all nanoparticles are bad, or that all nanoparticles are good. However, products containing nanoparticles are becoming widespread, and may become pervasive. It is unrealistic to expect consumers to engage in a careful weighing of the risks and alternatives if they purchase nanotechnology-related goods and services several times a year, or a week, or a day. There must be a less burdensome, more reliable, means of guarding against the risks that may be associated with nanoparticles and nanoapplications.

72. See Md. Ershadul Karim & Abu Bakar Munir, *Nanotechnology: Sketching the Next Big Thing in Malaysian Context*, 12 NANOTECHNOLOGY L. & BUS. 161, 163 (2015) (explaining that hundreds of products use the word “nano” in the product name”).

73. See Catherine Morris Krow, *CNTS, Nano-Tio2, and Nanosilver: Assessing Risk and Investing in Safety*, 11 NANOTECHNOLOGY L. & BUS. 146, 154 (2014) (discussing labeling of products containing nanoscale titanium dioxide in the United States).

74. See Lucas Bergkamp et al., *Nanotechnology Regulation in Europe: From REACH and Nano-Registries to Cosmetics, Biocides, and Medical Devices*, 11 NANOTECHNOLOGY L. & BUS. 93, 96 (2014) (Under the Cosmetics Regulation, “the nano-form must be clearly identified as such in the list of ingredients on the label; any such nano-form is to be followed by the word ‘nano’ in brackets.”).

75. Marina E. Vance et al., *Nanotechnology in the Real World: Redeveloping the Nanomaterial Consumer Products Inventory*, 6 BEILSTEIN J. NANOTECHNOLOGY 1769, 1769 (2015), <http://www.beilstein-journals.org/bjnano/single/articleFullText.htm?publicid=2190-4286-6-181>.

76. Falkner et al., *supra* note 20, at 519–20.

2. Lack of Clear Expectations

To be sure, consumers may have preferences for or against nanotechnology (Americans are generally pro,⁷⁷ and Europeans con⁷⁸). However, those preferences are shaped more by the media and deeply engrained cultural values⁷⁹ than by any careful weighing of the risks and alternatives. It is “doubtful” whether the media provides consumers with an objective picture of nanotechnology issues.⁸⁰

In most situations, consumers have no clear expectations about the safety or dangerousness of products containing nanoparticles. It was precisely that type of concern that caused the American Law Institute to virtually abandon, in the *Restatement (Third) of Torts*, the “consumer expectation test” as a standard for determining whether a product is defective.⁸¹ Consumer expectations are certainly no more reliable in assessing nanotechnology than in evaluating whether ordinary products, such as cars,⁸² are designed in a manner that is unreasonably dangerous.

3. Risks to Workers

Workers who serve in nanotechnology laboratories and related operations may be even less able than consumers to protect their own interests due to fear that they will lose their jobs or otherwise be

77. See Ludlow & Binks, *supra* note 29, at 151 (“at least for the US public, ‘a majority is convinced that the benefits outweigh the risks’ in regard to nanotechnology although they know little about the technology”) (footnote omitted) (internal citations omitted); but see Emilee S. Preble, Note, *Preemptive Legislation in the European Union and the United States on the Topic of Nanomedicine: Examining the Questions Raised by Smart Medical Technology*, 7 IND. HEALTH L. REV. 397, 412 (2010) (“Though nanotechnology and nanomedicine have many supporters there are other groups in the United States that are opposed to nanotechnology research and development.”).

78. Cf. Falkner et al., *supra* note 20, at 519 (noting that, unlike the US, the EU regulates nanotechnology related to cosmetics).

79. Cf. *id.* at 509 (noting the relevance of “societal risk perceptions”).

80. Thorsten Weidl, Gerhard Klein & Rolf Zollner, *The Role of Risk Management Frameworks and Certification Bodies*, in HANDBOOK, *supra* note 6, at 462, 475.

81. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2(b) cmt. g (AM. LAW INST. 1998). The Restatement retains consumer expectations for some special situations. For example, “[w]hether . . . a fish bone in a commercially distributed fish chowder constitutes a manufacturing defect . . . is best determined by focusing on reasonable consumer expectations.” *Id.* at cmt. h. In addition, the Restatement holds sellers of used products strictly liable for manufacturing (and occasionally other) defects in the products only when the seller’s marketing practices would cause reasonable buyers to think that the product in question is no riskier than if it were new. *Id.* § 8(b).

82. See *Pannu v. Land Rover N. Am., Inc.*, 120 Cal. Rptr. 3d 605, 617 n.11 (Ct. App. 2011) (“Is it within the reasonable consumer’s expectation that . . . drastic steering maneuvers will not result in a rollover of a sports utility vehicle? The answer is not obvious.”).

punished for raising health and safety issues.⁸³ Workers also often lack information about the risks to which they are exposed.⁸⁴ Scholars contend there is an “urgent need” for monitoring the health of workers (including academics) who are routinely exposed to nanotubes.⁸⁵

B. *The Inadequacies of Liability Litigation*

1. Litigation Follows Innovation

In the United States, innovation is frequently followed by litigation because new practices often cause personal injuries or property damage.⁸⁶ The widespread production of cars, marketing of consumer goods, and use of computerized data⁸⁷ all led to lawsuits because they caused harm, often to innocent persons.⁸⁸ Such tort litigation serves a useful purpose because it forces enterprises to internalize the costs of their activities and to make an honest calculation of whether the benefits of those practices outweigh the risks.⁸⁹ That type of assessment helps to produce a reliable determination of whether precautions should be employed, activity levels reduced, or certain practices ended.⁹⁰

2. Obstacles to Recovery

However, there are numerous reasons why tort claims related to nanotechnology may fail. Negligence and strict liability claims related to products are likely to be defeated by widely recognized “state of the art” defenses.⁹¹ In addition, it is often difficult to prove that a particular defendant caused a plaintiff’s harm, especially where many years have

83. See Brooke E. Lierman, “To Assure Safe and Healthful Working Conditions”: Taking Lessons from Labor Unions to Fulfill OSHA’s Promises, 12 *LOY. J. PUB. INT. L.* 1, 15 (2010) (noting “fear of retaliation”).

84. *Id.* at 15 (noting “lack of information about hazards”).

85. Aitken et al., *supra* note 8, at 232.

86. See Vincent R. Johnson, *Standardized Tests, Erroneous Scores, and Tort Liability*, 38 *RUTGERS L.J.* 655, 668 (2007).

87. See Vincent R. Johnson, *Cybersecurity, Identity Theft, and the Limits of Tort Liability*, 57 *S.C. L. REV.* 255, 256 (2005) (“When an unauthorized user hacks or otherwise improperly accesses information contained in computerized databases, the consequences can be devastating for the persons to whom the information relates.”).

88. See Johnson, *supra* note 86, at 669–70 (discussing cars, consumer goods, and databases).

89. See Vincent R. Johnson, *Credit Monitoring Damages in Cybersecurity Tort Litigation*, 19 *GEO. MASON L. REV.* 113, 114 (2011) (“By requiring data possessors to cover credit-monitoring costs, courts will deter breaches of cybersecurity.”); *id.* at 151 (discussing deterrence).

90. See *id.* (“[T]he risk of liability influences both the choice of precautions and activity levels.”).

91. Ludlow & Binks, *supra* note 29, at 158 (discussing Australia).

passed, scientific evidence is uncertain, or the plaintiff has been exposed to other potential causes. In most countries, absent a showing of but-for causation, a tort claim will not succeed.⁹²

In rare cases—such as the DES (diethylstilbestrol) lawsuits in which daughters were harmed by a drug taken by their pregnant mothers more than a decade earlier—American courts have shifted the burden of proof on causation to drug manufacturers and have imposed liability in proportion to their market share.⁹³ However, only a few jurisdictions have followed that course.⁹⁴ Those that have done so have insisted that the plaintiff sue enough manufacturers so that a substantial share of the market is represented, prove that all of the manufacturers were negligent, and demonstrate that the injurious product was produced in a generic form that makes identification of the responsible manufacturer impossible.⁹⁵ The theory of market-share liability is unlikely to aid nanotechnology plaintiffs for several reasons: namely, lack of fungibility (since producers may use nanotechnology in different ways) and lack of negligence. It would presumably not be feasible to prove that nanotechnology manufacturers were negligent if the risk that they failed to avoid was *unforeseeable*.⁹⁶ Moreover, if those manufacturers conformed to the customs in the industry, and those customs were reasonable, those practices would likely be treated as evidence that the manufacturers did not act negligently.⁹⁷ Manufacturers may also be able to successfully invoke “the bulk supplier defense, the learned intermediary defense, and the sophisticated user doctrine.”⁹⁸

Nanotechnology tort claims may fail for reasons related to statutes of limitations,⁹⁹ *forum non conveniens*,¹⁰⁰ comparative fault,¹⁰¹ or bias on

92. See, e.g., RESTATEMENT (THIRD) OF TORTS: PHYSICAL & EMOTIONAL HARM § 26 (AM. LAW INST. 2010) (“Tortious conduct must be a factual cause of harm for liability to be imposed. Conduct is a factual cause of harm when the harm would not have occurred absent the conduct.”).

93. See, e.g., *Sindell v. Abbott Labs.*, 607 P.2d 924, 938 (Cal. 1980) (adopting market-share liability).

94. See RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL AND EMOTIONAL HARM § 28 cmt. p (AM. LAW INST. 2010) (“[T]he number of jurisdictions that have addressed and resolved . . . [the question of market-share liability] for DES victims is quite small.”).

95. See *id.* (“Virtually all courts that have considered the question have declined to apply a market-share liability theory to products that are not fungible.”).

96. See *id.* § 3 (“To establish the actor’s negligence, it is not enough that there be a likelihood of harm; the likelihood must be foreseeable to the actor at the time of conduct.”).

97. See generally *id.* § 13 (discussing custom).

98. *Potential Theories of Liability*, 3 TOXIC TORTS LITIGATION GUIDE § 36:14 (2015 supp.).

99. See *Statute of Limitations*, BLACK’S LAW DICTIONARY (10th ed. 2014) (defined as “[a] law that bars claims after a specified period”).

the part of judges, juries, or arbitrators.¹⁰² Moreover, even potentially successful claims would be worthless if the responsible defendant is no longer in business or lacks assets capable of paying a judgment.

Whereas litigation has been successful in generating a “broad-based regulatory change addressing climate change,”¹⁰³ environmental lawsuits seeking compensation for cross-border harm have been much less effective.¹⁰⁴ Thus, even if nanotechnology causes transboundary harm, a plaintiff might fail to recover due to lack of jurisdiction over the defendant, or inability to enforce a judgment. There have been many obstacles in past cases involving science less complex than nanotechnology, and “there is still a pressing need to strengthen tort remedies for transboundary environmental damage.”¹⁰⁵

3. Possible Reforms

It would be possible to improve the chances that a person injured by nanotechnology could recover compensation in tort actions. Claims might be tried before specialized tribunals with environmental expertise,¹⁰⁶ by international tribunals insulated from the pressures of

100. See *Forum Non Conveniens*, BLACK'S LAW DICTIONARY (10th ed. 2014) (defined as “the doctrine that an appropriate forum—even though competent under the law—may divest itself of jurisdiction if, for the convenience of the litigants and the witnesses, it appears that the action should proceed in another forum in which the action might also have been properly brought in the first place”). See generally Chenglin Liu, *Escaping Liability Via Forum Non Conveniens: Conocophillips's Oil Spill in China*, 17 U. PA. J.L. & SOC. CHANGE 137 (2014) (discussing application of the doctrine).

101. See UNIFORM COMPARATIVE FAULT ACT § 1(a), 12 U.L.A. 135–40 (1996) (discussing pure comparative fault).

102. Cf. Shi-Ling Hsu, *The Identifiability Bias in Environmental Law*, 35 FLA. ST. U. L. REV. 433, 504 (2008) (“We . . . do not have sufficient safeguards built in to protect those that most need protecting, those that we cannot identify.”).

103. Jacqueline Peel & Hari M. Osofsky, *Climate Change Litigation's Regulatory Pathways: A Comparative Analysis of the United States and Australia*, 35 L. & POL'Y 150, 175 (2013).

104. See Noah Sachs, *Beyond the Liability Wall: Strengthening Tort Remedies in International Environmental Law*, 55 UCLA L. REV. 837, 838 (2008) (“States have been unwilling to accept treaty language that would impose liability for transboundary pollution on states directly (so-called state liability). In the realm of private international law, . . . states have also rejected most civil liability treaties establishing the tort liability of private actors for transboundary pollution.”).

105. *Id.* at 890.

106. See J. Michael Angstadt, *Securing Access to Justice Through Environmental Courts and Tribunals: A Case in Diversity*, 17 VT. J. ENVTL. L. 345, 347 (2016) (Environmental courts and tribunals “provide a potential mechanism for translating international environmental norms into discrete policy questions at the national or substate level”); Hon. Michael D. Wilson, *The Hawaii Environmental Court: A New Judicial Tool to Enforce Hawaii's Environmental Laws*, HAW. B.J., Aug. 2015, at 4 (discussing a court established to “promote and protect Hawaii's natural environment”) (internal citations omitted).

domestic politics,¹⁰⁷ or via enhanced aggregate litigation procedures.¹⁰⁸ Incentives related to attorney's fees,¹⁰⁹ or punitive or multiple damages,¹¹⁰ might make it easier for plaintiffs to find representation.

Medical monitoring damages¹¹¹ might be awarded in cases where the plaintiff has been seriously exposed to toxic nanoparticles. Even if there is no proof that the exposure has already caused harm, monitoring the possible emergence of a diseased condition and the need for treatment is reasonable and prudent.¹¹²

In products liability litigation, California shifts to a defendant the burden of proving that a product was not defective if the plaintiff introduces evidence that the product's design contributed to the plaintiff's injury.¹¹³ So too, new rules might shift to nanotechnology defendants the burden of proving that nanoparticles did not cause the plaintiff's harm, if the plaintiff shows that the product contained nanotechnology and there is credible scientific evidence that such nanotechnology might be injurious.

However, even this "wish list" of reforms would only increase the chances that nanotechnology defendants would be held liable for harm caused by their products. It would not insure that all costs associated with nanotechnology activities are internalized by potential defendants or that optimal precautions are taken to avoid unnecessary harm. Moreover, because some diseases develop slowly, many judgments might occur so long after the tortious conduct in question as to have little deterrent effect on the conduct of the defendants and others.

107. See Alessandra Lehmen, *The Case for the Creation of an International Environmental Court: Non-State Actors and International Environmental Dispute Resolution*, 26 COLO. NAT. RESOURCES, ENERGY & ENVTL. L. REV. 179, 180 (2015) (discussing "the main characteristics around which such a court would be organized").

108. See, e.g., Vincent R. Johnson, *The Rule of Law and Enforcement of Chinese Tort Law*, 34 T. JEFFERSON L. REV. 43, 87 (2011) ("[In China], there are no provisions for aggregate litigation (e.g., class actions).").

109. See VINCENT R. JOHNSON, *STUDIES IN AMERICAN TORT LAW* 23 (5th ed. 2013) (Noting that under the "American rule" a plaintiff who prevails does not recover attorney's fees).

110. See Vincent R. Johnson, *Punitive Damages, Chinese Tort Law, and the American Experience*, 9 FRONTIERS L. CHINA 321, 326 (2014) (explaining that despite the Chinese Tort Laws' authorization of punitive damages in products liability actions, "punitive damages have never been awarded by a Chinese court").

111. See Meyer *ex rel.* Coplin v. Fluor Corp., 220 S.W.3d 712, 714 (Mo. 2007) (allowing recovery of medical monitoring damages without proof of a pre-existing injury).

112. Cf. Johnson, *supra* note 89, at 132–39 (analogizing credit monitoring damages in data breach cases to medical monitoring damages in toxic exposure cases).

113. See *Barker v. Lull Eng'g Co.*, 573 P.2d 443, 455 (Cal. 1978) (discussing how the burden shifts).

There is no assurance that court decisions will identify and address nanotechnology risks in a systematic and timely manner. Nanotechnology has existed in the United States for decades. However, there is still not one reported American case in which tort damages have been awarded to a person injured by nanoparticles.¹¹⁴ This experience is consistent with the track record in other countries.¹¹⁵

IV. REGULATORY OBSTACLES AND REGIMES

Regulation offers the possibility of remedying many of the deficiencies of markets and litigation. If properly employed, regulation can reduce nanotechnology risks. When risks are lower, there is less need for individuals to grapple with the challenges of obtaining and

114. The author conducted a search of the Cases database in Westlaw on May 30, 2016. Of the fifty cases found by searching for the term “nanoparticle,” the great majority were patent infringement actions. None of the tort claims seeking personal injury damages contained a substantial discussion of risks related to nanotechnology. *But see* Rowan v. Sec’y of Health & Human Servs., No. 10-272V, 2014 WL 7465661, at *12 (Fed. Cl. Dec. 8, 2014) (brief mention in unsuccessful action under the National Vaccine Injury Compensation Act; “Dr. Shoenfeld testified that . . . ‘. . . nanoparticles of the aluminum are diffused to the brain to induce . . . [headaches,] but] does not provide any facts from the petitioner’s medical records or any other evidentiary foundation to support his conclusion that petitioner’s headaches were caused by nanoparticles of aluminum in her brain.”); D’Angiolini v. Sec’y of Health & Human Servs., No. 99-578V, 2014 WL 1678145, at *6 (Fed. Cl. Mar. 27, 2014) (brief mention in a case where the plaintiff unsuccessfully sought damages under the National Childhood Vaccine Injury Act; “For the medical theory causally connecting the hepatitis B vaccination to any injury . . . Mr. D’Angiolini asserted: ‘[the] hepatitis B vaccine’s adjuvant . . . diffuses into the brain as nanoparticles . . . causes damage to the brain cells, which leads to cognitive impairment, memory loss and other neurological manifestations.”); *In re* Wright Med. Tech. Inc., Conserve Hip Implant Prods. Liab. Litig., 127 F. Supp. 3d 1306, 1326–27 (N.D. Ga. 2015) (brief mention in products liability case raising issues related to motions relating to expert testimony and summary judgment; “Laposata concluded that the ‘Conserve metal-on-metal hip orthopedic implant generates nanoparticles of cobalt/chromium and chromium phosphate aggregates.’ . . . Laposata explains the unique reactions that occur in the body when nanoparticles of cobalt-chromium are shed from metal-on-metal hip replacements.”); *In re* DePuy Orthopaedics, Inc. Pinnacle Hip Implant Prods. Liab. Litig., No. 3:11-MD-2244-K, 2014 WL 3557345, at *14 (N.D. Tex. July 18, 2014) (refusing to exclude expert testimony about nanoparticles in hip replacements products liability litigation).

115. *See* Hall et al., *supra* note 10, at 776 (“[N]o death or major injury has been attributed to nanotechnology to date [2012].”); Widmer & Meili, *supra* note 10, at 239 (stating in 2010 that “there are no known cases of death that can be conclusively be attributed to nanotechnologies or the use of manufactured nanomaterials”); *see also* Tracy D. Hester, *Quiet So Far: A Muted Response to Allegations of the First Human Fatalities Linked to Nanoparticles*, 40 ENVTL. L. REP. NEWS & ANALYSIS 10007, 10007 n.3 (2010) (“Although the German government issued a recall of MagicNano (a household sealing material) . . . because the product injured over 110 consumers who used it, subsequent reports confirmed that MagicNano did not actually contain any nanoparticles . . .”).

evaluating information about nanotechnology-related products or to sue to recover damages for the harm that they cause.

A. *Balancing Growth and Precautions*

In basic terms, risk regulation is “the exercise of public authority (however broadly construed) with intent to affect the likelihood and/or magnitude of socially undesirable events.”¹¹⁶ Whether regulation is effective is a function of not only whether the regulatory purposes and means are legitimate, but whether, in situations involving technology, the regulatory efforts are properly linked to their target.¹¹⁷

Regulators seeking to manage the largely unidentified health, safety, and environmental risks that may be posed by emerging nanotechnologies face an unenviable task. They must strike a prudent balance between maximizing sustainable economic growth and devoting sufficient resources to precautions.¹¹⁸ Because “risks never affect all segments of the population” alike, the “process of risk identification is therefore simultaneously one of selection, involving controversial normative judgment.”¹¹⁹ Addressing the risks presented by nanoscale materials is especially difficult because in many cases those risks are “too small to be detected by current technology.”¹²⁰

B. *Systemic Challenges to Effective Regulation*

There are systemic obstacles to effective regulation of health, safety, and environmental risks at the national level.¹²¹ These obstacles are likely to be just as great with respect to nanotechnology as in other areas of regulation.

First, regulatory agencies are often underfunded¹²² and lack the resources that are needed to adequately address complex scientific

116. Heyvaert, *supra* note 5, at 819; *see also* Julia Black, *What is Regulatory Innovation?*, in *REGULATORY INNOVATION: A COMPARATIVE ANALYSIS* 11 (Julia Black, Martin Lodge & Mark Thatcher eds., 2005) (defining regulation as “the sustained and focused attempt” to guide the behavior of others).

117. Brownsword, *supra* note 48, at 66.

118. *Introduction*, *supra* note 6, at 3.

119. Heyvaert, *supra* note 5, at 822.

120. Breggin & Pendergrass, *supra* note 25, at 359.

121. *See* Vincent R. Johnson, *Liberating Progress and the Free Market from the Specter of Tort Liability*, 83 NW. U. L. REV. 1026, 1048–53 (1989) (book review) (discussing budgetary limitations, pressures from special interests, and political pressures).

122. *See, e.g.*, Caitlin Troyer Busch, *Ethical Convergence and the Endangered Species Act*, STAN. ENVTL. L.J. BLOG (Apr. 22, 2016, 6:48 PM), <http://journals.law.stanford.edu/stanford-environmental-law-journal-elj/blog/ethical->

issues.¹²³ This is true in part because both governments and their critics often seek to minimize regulatory burdens.¹²⁴ That often means insufficient funds are appropriated for regulatory use.

Second, in many countries, political appointees play an important role in heading regulatory agencies.¹²⁵ Consequently, there is a risk that regulatory decisions will reflect political priorities rather than an even-handed assessment of scientific and economic information about risks and the costs of restrictions.¹²⁶ This is especially true when politicians seek to win the approval of businesses or the public by waging a “war on science,” as has recently been true in the United States.¹²⁷

Third, regulatory agencies are subject to administrative capture¹²⁸ if personnel are recruited from, and move to, the business entities that are regulated. A “revolving door” between public service and the private sector threatens to make regulatory agencies less independent. Official

convergence-and-endangered-species-act (“[T]he Fish and Wildlife Service . . . has been called ‘one of the most severely underfunded natural resource agencies.’”).

123. See Heyvaert, *supra* note 5, at 825 (referring to the European Union as a “cash-strapped” regulator).

124. See *Introduction*, *supra* note 6, at 13 (indicating that some governments “actively seek” to reduce regulatory burdens); *GOP Can Cut Some Regulations Quickly*, DES MOINES REG., Nov. 16, 2016, at B3, 2016 WLNR 35133819 (“Congressional Republicans are poised to act quickly . . . to repeal tens of billions of dollars in environmental regulations and other federal rules”).

125. Cf. Loretta Tuell, *The Obama Administration and Indian Law—A Pledge to Build A True Nation-to-Nation Relationship*, FED. LAW., Apr. 2016, at 44, 45 (“As political appointees typically share the ideology of the president who appoints them, their role is to essentially extend the president’s influence governmentwide.”).

126. See ROBERT BALDWIN ET AL., UNDERSTANDING REGULATION: THEORY, STRATEGY, AND PRACTICE 99 (2d ed. 2011) (quoting Stephen Breyer as stating that a “depoliticized regulatory process might produce better results”).

127. See Joel Achenbach, *Why Do Many Reasonable People Doubt Science?*, NAT’L GEO. (Mar. 2015), <http://ngm.nationalgeographic.com/2015/03/science-doubters/achenbach-text> (“We live in an age when all manner of scientific knowledge—from the safety of fluoride and vaccines to the reality of climate change—faces organized and often furious opposition.”).

128. Johnson, *supra* note 37, at 35 (“Administrative capture” occurs when “an administrative agency is dominated by those it is supposed to regulate and becomes less effective as a result.”). See also Timothy J. Van Hal, *Taming the Golden Goose: Private Companies, Consumer Geolocation Data, and the Need for a Class Action Regime for Privacy Protection*, 15 VAND. J. ENT. & TECH. L. 713, 743 (2013) (“[A]dministrative capture . . . refers to interest groups or market actors exerting a ‘capturing’ influence on the staff or commission members of a regulatory agency, typically leading to the implementation of the preferred policy outcomes of special interest groups.”); Ian Ayres & F. Clayton Miller, *‘I’ll Sell It to You at Cost’: Legal Methods to Promote Retail Markup Disclosure*, 84 NW. U. L. REV. 1047, 1070, 1070 n.87 (1990) (“Regulated agencies . . . can be ‘captured’ by the very firms they are mandated to regulate. Captured agencies have been the source of many inefficient regulations.”).

decision-making may reflect the loyalty of agency employees to their former or potential future employers.¹²⁹

Fourth, regulatory agencies tend toward “inertia.”¹³⁰ They naturally resist change, and tend to apply yesterday’s solutions to tomorrow’s challenges.¹³¹ This is particularly dangerous when the new risks that must be addressed are qualitatively different from earlier problems.

C. *Nanospecific Regulation Versus General Regulation*

There is a fundamental question as to whether the risks related to nanotechnology should be regulated under nanospecific regimes or general regulatory regimes. It can be argued that general regulatory requirements applicable to existing products should be applied to new products containing both nanomaterials and conventional materials. Doing so is a logical starting point for regulation,¹³² for “[i]t is not clear that nanotechnology products as a class are inherently more dangerous than non-nanotechnology products.”¹³³

This is the approach that has been taken by most countries that have addressed issues related to nanotechnology.¹³⁴ The regulation of nanotechnology has “generally been framed by governments as the continuation of scientific developments,” and as merely calling for the application or possible revision of existing regulatory schemes to meet the potential risks posed by nanoapplications.¹³⁵

However, such a general regulatory focus may fail to appreciate what is unique about nanomaterials. Nanoparticles can pass through membranes¹³⁶ and enter the body “through unexpected paths.”¹³⁷ Nanomaterials may also pose special risks because of their tube-like or

129. See Paul Rose & Christopher J. Walker, *Dodd-Frank Regulators, Cost-Benefit Analysis, and Agency Capture*, 66 STAN. L. REV. ONLINE 9, 14 (2013) (“[A]gency capture can occur for many reasons, including the revolving-door phenomenon whereby regulators anticipate taking or returning to jobs in industry and fear alienating the entities they regulate.”).

130. Maynard et al., *supra* note 39, at 577.

131. *Id.* at 577 (“Bureaucracy . . . encourage[s] the shoehorning of new challenges into old regulatory frameworks.”).

132. *Introduction*, *supra* note 6, at 11.

133. *Cf.* Abbott et al., *supra* note 33, at 526.

134. See Falkner et al., *supra* note 20, at 511 (“[G]overnments in leading industrialized countries . . . [began] by relying on existing frameworks for EHS [environment, health, and safety] regulation to deal with nanotechnology risks, making minor adjustments . . .”).

135. Ludlow & Binks, *supra* note 29, at 146.

136. Williams, *supra* note 19, at 119.

137. Widmer & Meili, *supra* note 10, at 238.

wafer shape,¹³⁸ which results in increased surface area in comparison to mass or weight.¹³⁹ “[O]ne of the characteristics that confers special properties to products of nanotechnologies is the large surface-area-to-volume ratio that is encountered at very small dimensions.”¹⁴⁰ That is why nanoparticles are generally more toxic than larger particles when compared on a mass-dose basis.¹⁴¹

Despite the fact that “[t]here does not appear to be any sharp change in either toxicokinetic or toxicodynamic properties of substances at any particular size,”¹⁴² European Union scientists now recognize that “the adverse effects of nanoparticles cannot be predicted (or derived) from the known toxicity of material of macroscopic size, which obey the laws of classical physics.”¹⁴³ Indeed, nanoparticles sometimes display radically different physical or chemical properties than their bulk counterparts. Some materials that are inert in their larger form are reactive when produced at the nanoscale, and may exhibit special optical, electrical, and magnetic behavior.¹⁴⁴

In recent years, a number of key regulatory bodies have moved in the direction of nanospecific regulations.¹⁴⁵ However, in the casualty insurance business, where nanotechnology is one of “the top four emerging risks,”¹⁴⁶ policies continue to cover products and services involving nanotechnology,¹⁴⁷ “without seeing any good reason for nanotechnology-specific changes to liability.”¹⁴⁸ Of course, the judgments of insurers are no substitute for informed decisions by regulators. Insurance companies merely evaluate the financial exposure within which they will provide coverage; regulators have an obligation to protect society from serious avoidable hazards.¹⁴⁹ Providing insurance is merely a decision that “accepting a risk is an attractive proposition.”¹⁵⁰

138. *Introduction, supra* note 6, at 15 (“A further problem is that a conventional application of the risk assessment paradigm that relies on mass concentration as an exposure metric may not be appropriate . . .”).

139. Breggin & Pendergrass, *supra* note 25, at 359 (“[P]article count or surface are rather than mass may be more appropriate for measuring the health or environmental effects of nanoscale particles.”)

140. Williams, *supra* note 19, at 112.

141. *See id.* at 120.

142. *Id.* at 110–11.

143. *Id.* at 108.

144. *See* Miles, *supra* note 43, at 94–95.

145. *See* Tassinari et al., *supra* note 45, at 178.

146. Widmer & Meili, *supra* note 10, at 239.

147. *See* Epprecht, *supra* note 26, at 168 (discussing the existing casualty business).

148. *Id.* at 172.

149. *See id.* at 169.

150. *Id.* at 169.

D. *The Precautionary Principle*

Aside from the question of whether regulations should be nanospecific or general, there is a second fundamental choice that greatly influences regulatory design and decision-making. That matter is the priority and weight to be accorded to the “precautionary principle.”¹⁵¹

Virtually everyone agrees that cost-effective measures should be taken to avoid serious risks of unnecessary harm. The question is how to deal with situations where the cost-effectiveness of precautions, or seriousness of risks, is less than clear. The precautionary principle is frequently invoked in efforts to resolve such uncertainties,¹⁵² but how it is articulated often determines the answer it provides. The precautionary principle can be stated in terms that are risk-averse¹⁵³ or risk-tolerant, stringent or lenient, strong or weak. What the principle means depends on how it is phrased.

The precautionary principle can be read to mean that “in those cases in which there is a suspected, but not proven, risk of harm to the public or the environment, the burden of proof is on the producer of the risk to prove the lack of harmfulness.”¹⁵⁴ Such a reading is stronger and more risk-averse than if the principle is construed as meaning that “it may be warranted to undertake regulatory action to protect health or the environment in the absence of conclusive evidence of harm.”¹⁵⁵ Not surprisingly, some scholars argue that the precautionary principle must be given a compelling gloss if a particular innovation threatens to cause potentially irreversible changes or to eradicate mankind.¹⁵⁶

Because the meaning of the precautionary principle is widely debated, it offers few clear answers to questions about how a regulatory system should be structured or administered. As a result, its importance as a policy principle may be “overplayed.”¹⁵⁷ Indeed, despite bearing a moniker that sounds noble and wise, the precautionary principle may

151. See generally Robert W. Hahn & Cass R. Sunstein, *The Precautionary Principle as a Basis for Decision Making*, 2 *ECONOMISTS' VOICE* 1 (2005).

152. See, e.g., Widmer & Meili, *supra* note 10, at 243 (indicating that in Europe “[t]he provisions of REACH explicitly declare that the precautionary principle should be applied when administering the Regulation”).

153. See, e.g., *id.* at 243–44 (stating that in accordance with the precautionary principle, “safety assessment should normally be based on the evidence that gives rise to highest concern (worst-case scenario”).

154. BALDWIN ET AL., *supra* note 126, at 94.

155. Veerle Heyvaert, *Facing the Consequences of the Precautionary Principle in European Community Law*, 31 *EUR. L. REV.* 185, 185 (2006).

156. See generally RICHARD A. POSNER, *CATASTROPHE: RISK AND RESPONSE* (2004) (discussing scientific accidents and events in which even unlikely hypothetical scenarios are not negligible when the outcome would be disastrous).

157. See Heyvaert, *supra* note 155, at 188.

facilitate protectionism¹⁵⁸ or impede the development of new scientific breakthroughs that would enable society to cope with the risks of new technology.¹⁵⁹

Anyone venturing into the thickets of environmental regulation must be prepared to confront many arguments cloaked in the mantle of the very uncertain¹⁶⁰ precautionary principle.¹⁶¹ “[G]overnments increasingly use the precautionary principle when a new technology is to be licensed.”¹⁶² The European Union has been a leader in promoting that view.¹⁶³ However, when a regulatory body invokes the precautionary principle, the most relevant inquiry may be to ask why the body is qualified and authorized to make precautionary decisions.

Cass Sunstein argues that strong versions of the precautionary principle are logically inconsistent and frequently paralyzing, cause serious harm by increasing the use of inferior technologies, and offer no “guidance on *how much* to regulate.”¹⁶⁴ The precautionary principle is no substitute for making the best possible effort to balance the relevant costs and benefits.¹⁶⁵

E. *European Union*

In the European Union, rigorous procedures are in place to balance the public interest in new technologies against competing interests in public health.¹⁶⁶ The Directorate General for Health and Consumer Affairs may seek guidance from the Scientific Committee for Emerging and Newly Identified Health Risks.¹⁶⁷ That committee has considered the risks posed by nanotechnologies on several occasions.¹⁶⁸

The REACH Regulation deals with Registration, Evaluation, and Authorization of Chemicals.¹⁶⁹ One of the most important instruments ever adopted by the European Union, REACH became effective in 2007.

158. See *id.* at 187 (discussing Majone).

159. See *id.* at 187–88 (discussing United States commentators).

160. See *id.* at 189 (“[T]he precautionary principle has been the subject of so many different characterisations and value judgments.”).

161. See, e.g., Aitken et al., *supra* note 8, at 231 (“It is clear that we cannot afford, ethically and financially, to await the human consequences of nanotube exposure before considering the implication of adequate regulations of exposure, use and disposal of nanotubes.”).

162. Altmann, *supra* note 30, at 373.

163. See Hahn & Sunstein, *supra* note 151, at 1.

164. See *id.* at 2–6.

165. See *id.* at 6.

166. See Williams, *supra* note 19, at 107 (describing the European Union regime); *id.* at 119 (“[T]here is an urgent need for toxicokinetic data for nanoparticles.”).

167. See *id.* at 107.

168. See *id.*

169. Commission Regulation 1907/2006, 2006 O.J. (L 396) 1 (EC).

The regulation seeks to ensure both environmental protection and free movement of goods within the European Union.¹⁷⁰ REACH imposes binding obligations on all Member States,¹⁷¹ and thus limits the regulatory options of more environmentally friendly Member States.¹⁷²

Though REACH is the “regulatory framework of greatest relevance to the governance of nanomaterials on the EU level,”¹⁷³ it is not a nanospecific regime. Instead, REACH covers all chemicals,¹⁷⁴ including chemicals in their nanoform. There are no specific provisions related to the size of a material,¹⁷⁵ and thus, “REACH considers nanoparticles in the same category as their bulk form.”¹⁷⁶ However, nanomaterials do not need to be registered until they “pass a threshold of one metric ton or more of annual output or imports.”¹⁷⁷ Higher volumes passing a ten ton per year threshold must submit a chemical safety report containing a chemical risk assessment.¹⁷⁸ Above one hundred tons per year, detailed toxicity testing is required.¹⁷⁹

To obtain authorization for the marketing or use of dangerous chemicals, toxicological data must be disclosed.¹⁸⁰ A company must show that the chemical’s risks are adequately contained or outweighed by the socio-economic benefits of use.¹⁸¹ However, in carrying this

170. See Commission Regulation 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Council Directives 67/548 and 1999/45 and amending Commission Regulation 1907/2006, 2008 O.J. (353) 1 (affirming the dual objectives of a “a high level of protection of health and the environment” and “the free movement of substances”); Widmer & Meili, *supra* note 10, at 245 (the REACH Regulation is based on a principle of “no data, no market” . . . meaning that market introduction can only occur after registration is complete”).

171. See Tassinari et al., *supra* note 45, at 189.

172. See Jean-Philippe Montfort, Giovanni Indirli, Daniela Georgieva & Claire-Marie Carrega, *Nanomaterials Under REACH: Legal Aspects Unless and Until REACH is Adapted to More Specifically Regulate Nanomaterials, Is There Scope for National Measures to Regulate These Materials?*, 1 EUR. J. RISK REG. 51, 62 (2010) (arguing that, under REACH, “national measures which require the reporting or labelling of nanomaterials cannot be justified”).

173. Lawrence G. Cetrulo, *International Regulation—European Union*, in 3 TOXIC TORTS LITIGATION GUIDE § 36:13 (Supp. 2015).

174. See Widmer & Meili, *supra* note 10, at 244.

175. See Montfort et al., *supra* note 172, at 52 (2010).

176. Tassinari et al., *supra* note 45, at 189.

177. *Id.*

178. See Widmer & Meili, *supra* note 10, at 244.

179. See *id.*

180. Cetrulo, *supra* note 173.

181. Widmer & Meili, *supra* note 10, at 244 (“REACH allocates the responsibility to prove that no unreasonable risks will result from the use of a chemical to those who advocate for its use.”).

burden¹⁸² the company enjoys the benefit of the chemical's prior inclusion on the SVHC candidate list.¹⁸³

The obligations imposed by REACH are complemented by harmonized classification, packaging, and labeling requirements. In November 2008, the European Chemical Agency promulgated a regulation "requiring cosmetics containing nanoscale ingredients to disclose that information on their labels."¹⁸⁴

Questions can be raised about the wisdom of the European Union regulatory design.¹⁸⁵ Self-reporting by companies generates a massive amount of information of inconsistent quality and dubious usefulness. The quantity of data is far beyond the verification capacity of regulators. As the Volkswagen emissions scandal¹⁸⁶ has demonstrated, self-reporting is often misleading or outright fraudulent.¹⁸⁷ In addition, the reporting thresholds allow chemicals produced in smaller amounts to "slip through the net of chemical regulations."¹⁸⁸ Moreover, because all relevant information relating to a chemical is reported together, regulators focusing on nanomaterial risks must "make 'informed guesses' on whether a given chemical is used in nanoform or not."¹⁸⁹

REACH imposes post-regulation obligations requiring registrants to update information in relation to changes in the quantities of chemicals manufactured or imported, new uses, or new knowledge about risks to human health or the environment.¹⁹⁰ However, REACH's approach to nanotechnology risk regulation may be fundamentally flawed because it is artificially segmented. It zeros "in on the risk particularities of singular chemicals, but [is] not equipped to generate or even fully

182. See *id.* (describing the responsibility as a "shift" in the burden of proof").

183. But see *Nanoscience and Nanotechnologies: Opportunities and Uncertainties* 71, ROYAL SOC'Y AND ROYAL ACAD. OF ENG'G (July 2004), https://royalsociety.org/~media/Royal_Society_Content/policy/publications/2004/9693.pdf (recommending that nanoparticles or nanotubes be treated as new substances).

184. Cetrulo, *supra* note 173.

185. See Williams, *supra* note 19, at 108.

186. See Peter Whoriskey et al., *11 Million Volkswagens Have Cheating Software*, WASH. POST, Sept. 23, 2015, at A01; Vincent R. Johnson, *Op-Ed: What Did VW's Lawyers Know? The Answer Could Be Career-Ending*, NAT'L L.J. (Nov. 2, 2015), <http://www.nationallawjournal.com/id=1202741218717/OpEd-What-Did-VWs-Lawyers-Know-The-Answer-Could-Be-CareerEnding> (discussing the ethical obligations of the lawyers who represented Volkswagen).

187. Jack Ewing, *Volkswagen Deal on Emission Cheating in U.S. Is Expected*, N.Y. TIMES, Apr. 21, 2016, at B2 ("In Germany, Volkswagen shareholders have sued the company claiming that top executives violated their duty to report information that could affect the share price.").

188. Widmer & Meili, *supra* note 10, at 263.

189. *Id.* at 261.

190. *Id.* at 261.

integrate information on synergistic effects caused by exposure to chemical compounds.”¹⁹¹

The European Union has adopted nanospecific regulations related to cosmetics and biocides. The Cosmetics Regulation mandates that the toxicological risk of all substances contained in cosmetics be evaluated with particular attention to nanomaterials.¹⁹² A report must be made by the manufacturer before the product is placed on the market identifying the nanomaterial at issue, its size and physical and chemical properties, and relevant toxicological and safety data.¹⁹³ The Commission may ban or restrict the use of dangerous substances in cosmetics.¹⁹⁴ The “Biocides Regulation follows the same pattern as the Cosmetics Regulation.”¹⁹⁵

F. *United States*

The United States regulates nanotechnology primarily through the Toxic Substances Control Act.¹⁹⁶ Under the Act, which is general rather than nanospecific, the Environmental Protection Agency (EPA) has authority to control and restrict harmful substances, and to require manufacturers to submit relevant data on health, safety, and environmental impacts.¹⁹⁷ The EPA may require pre-manufacturing notifications of new chemicals, which are then ordinarily subject to special reporting requirements.¹⁹⁸

The EPA may regulate a chemical substance if it demonstrates that there is a reasonable basis for concluding that the chemical “presents, or will present an unreasonable risk of injury to health or environment.”¹⁹⁹ The regulation must be based on conclusive data about the particular chemical, must take into consideration relevant risks, costs, and benefits, and must be the least burdensome alternative.²⁰⁰

These requirements—which are an implicit rejection of the precautionary principle²⁰¹ and a deliberate allocation of the burden of

191. Heyvaert, *supra* note 5, at 825.

192. *See* Bergkamp, *supra* note 74, at 95.

193. *See id.* at 96.

194. *See id.*

195. *See id.* at 97.

196. Toxic Substances Control Act of 1976, 15 U.S.C. §§ 2601–2697 (2012).

197. Widmer & Meili, *supra* note 10, at 247.

198. *Id.* at 247–48 (citing Toxic Substances Control Act, Pub. L. No. 94-469, § 6, 90 Stat. 2003, 2017 (1976) (amended 2016)).

199. *Id.* at 250 (citing Toxic Substances Control Act, Pub. L. No. 94-469, § 6, 90 Stat. 2003, 2017 (1976) (amended 2016)).

200. *Id.*

201. *Id.* at 256.

proof to the regulator, rather than manufacturers²⁰²—create substantial obstacles to the imposition of regulatory restrictions for purposes of mitigating nanotechnology risks.²⁰³ However, since 2008, the EPA has held that carbon nanotubes are different from graphite and other forms of carbon.²⁰⁴ The EPA now requires separate registration and inspection of carbon nanotubes.²⁰⁵ In 2012, the EPA promulgated rules related to infused carbon nanostructures and fullerenes²⁰⁶ that are intended to protect workers and bystanders from the inhalation of these particles.²⁰⁷ In contrast to the European Union’s REACH regime,²⁰⁸ the EPA has little ability to require manufacturers to test chemicals or to develop or update safety data.²⁰⁹ The EPA maintains a Nanomaterial Research website that provides extensive details about EPA research into nanomaterials and related issues.²¹⁰

Beyond the EPA, more than twenty federal departments or agencies have expressed interest in nanomaterials.²¹¹ However, despite “attempts to develop a coordinated approach to regulating nanomaterials,” no coordinated federal approach exists.²¹²

V. BROADENING THE REGULATORY ENTERPRISE

A. *Beyond Command-and-Control*

The recent trend in scholarship is to view regulation broadly. From this perspective the available tools include not merely hard law instruments, such as statutes and regulations enforced by the

202. *Id.* at 258.

203. *See, e.g., id.* at 253 (“[S]ince Congress passed the TSCA over 30 years ago, the EPA issued regulations under the act to ban, limit, or restrict the production or use of only five existing chemicals or chemical classes.”).

204. *See* Tassinari et al., *supra* note 45, at 184 (describing EPA actions).

205. *See id.* at 187.

206. *See* John Miller et al., *Derivatized Fullerenes: A New Class of Therapeutics and Imaging Agents*, 4 NANOTECHNOLOGY L. & BUS. 423, 423 (2007) (explaining that “[f]ullerenes, formally known as buckminsterfullerene, were discovered by Richard Smalley in 1985. [They] are molecules usually comprised of 60 carbon atoms and have the symmetry of soccer balls.”).

207. Lawrence G. Cetrulo, *Regulation—United States*, in 3 TOXIC TORTS LITIGATION GUIDE § 36:9 (Supp. 2015) (citing 40 C.F.R. § 721.170(b)(3)(ii)).

208. *See generally* John C. Monica, *Nanotechnology Regulation in Washington and Brussels: TSCA vs. REACH*, in NANOTECHNOLOGY LAW § 12:26 (Supp. 2015) (comparing the United States and European Union regimes).

209. Widmer & Meili, *supra* note 10, at 253.

210. U.S. ENVTL. PROT. AGENCY, RESEARCH ON NANOMATERIALS, <https://www.epa.gov/chemical-research/research-nanomaterials> (last updated Oct. 18, 2016).

211. *See* Roger Hanshaw, *Regulation of Nanomaterials: What Are They? How Are They Regulated? Who Decides?*, 29 NAT. RESOURCES & ENV’T 44–45 (Spring 2015).

212. *Id.* at 45.

government, but soft law instruments, such as industry²¹³ and governmental codes of conduct (such as the European Commission Code of Conduct for Responsible Nanosciences and Nano Technologies Research),²¹⁴ aspirational guidelines and statements of best practices,²¹⁵ voluntary reporting programs,²¹⁶ nonbinding standards,²¹⁷ voluntary risk management systems,²¹⁸ and licensing, accreditation, or certification²¹⁹ schemes.²²⁰

These options, many of which are located outside of the public sector²²¹ and are cross-disciplinary,²²² offer opportunities for raising the

213. Weidl et al., *supra* note 80, at 466 (“In the majority of cases, codes of conduct are not very restrictive or detailed.”); *id.* at 466–67 (setting forth two nanotechnology-related codes of conduct).

214. See EUROPEAN COMM’N, COMMISSION RECOMMENDATION ON A CODE OF CONDUCT FOR RESPONSIBLE NANOSCIENCES AND NANOTECHNOLOGIES RESEARCH & COUNCIL CONCLUSIONS ON RESPONSIBLE NANOSCIENCES AND NANOTECHNOLOGIES RESEARCH 13 (2009) (articulating principles of good governance, due respect for precaution, and monitoring).

215. See Tassinari et al., *supra* note 45, at 195–97 (recommending that suppliers should share material data; producers should engage with NGOs; manufacturers should join industry consortia; and producers should work hand-in-hand with regulators); Anna Gergely, Qasim Chaudhry & Diane Bowman, *Regulatory Perspectives on Nanotechnologies in Food and Food Contact Materials*, in HANDBOOK, *supra* note 6, at 321, 329 (recommending that the food industry regulate the use of nanotechnologies through best practices and voluntary initiatives).

216. See Cetrulo, *supra* note 207, at § 36:9 (discussing the EPA’s now-defunct Nanoscale Materials Stewardship Program); Christoph Meili & Markus Widmer, *Voluntary Measures in Nanotechnology Risk Governance*, in HANDBOOK, *supra* note 6, at 446, 448–49 (discussing the UK Department for Environment, Food and Rural Affairs (Defra) Voluntary Reporting Scheme).

217. See Weidl et al., *supra* note 80, at 467–72 (discussing the nanospecific standards developed joint by Environmental Defense and Dupont, and by TUV SUD).

218. Meili & Widmer, *supra* note 216, at 451–54 (discussing programs).

219. See Weidl et al., *supra* note 80, at 463 (“[C]ertification’ refers to a procedure that verifies systems, process, or products and a company’s implementation to comply with certain standards”); *id.* at 465 (noting that certification is a form of “voluntary self-regulation.”). To be effective, a “certification body must monitor public discussion as well as new scientific findings and technological innovations and observe and track regulatory trends and developments.” *Id.* at 475.

220. *Introduction*, *supra* note 6, at 10 (listing options); Brownsword, *supra* note 48, at 78 (“[W]e need interventions that offer the right support and incentives for beneficial nanotechnology development.”); Chaudhry et al., *supra* note 50, at 140 (“On the regulatory side, it is prudent to promote voluntary schemes for industry to establish codes of best practice in relation to production, emission, application and disposal of [engineered nanomaterials], and support risk communication and consumer awareness programmes.”).

221. See Reut Snir, *Trends in Global Nanotechnology Regulation: The Public-Private Interplay*, 17 VAND. J. ENT. & TECH. L. 107, 111 (2014) (“The continual interplay between public and private regulation is what shapes the current landscape and drives regulatory innovation.”).

222. Brownsword, *supra* note 48, at 63 (“[T]he coding that makes up the regulatory environment will come from many sources, governmental and non-governmental, public

awareness of key actors to potential health, safety, and environmental issues and for building consensus about how to address those problems.²²³ Since 2006, such non-binding mechanisms have increasingly been used in the United States, and to a lesser extent in the European Union, to address issues related to nanomaterials.²²⁴

What is notable about the current discussion of nanotechnology regulation is that it is taking place while nanotechnology and related developments are at an early stage.²²⁵ In contrast, earlier regulatory efforts—dealing, for example, with automobile safety—took place long after industry practices had become well-established.²²⁶ Thus, it is now possible to act to minimize nanotechnology risks before industry practices become deeply engrained.²²⁷

To an important degree, the strategy of regulators should be to engage “the practical reason of regulatees”²²⁸ because law is only “[t]he most formal contribution to the regulatory environment.”²²⁹ Viewed broadly, the “regulatory environment” includes not only governmental laws and regulations, but nongovernmental norms.²³⁰ This array of options may aid “early detection of emerging risks and control of known risks to ensure maximum safety in nanotechnology.”²³¹

1. Public Participation

Some groups see nanotechnology risks as raising issues of transparency and of having a voice in regulation.²³² To the extent that the regulatory process allows opportunities for public participation in deliberative processes, it addresses these concerns and enables regulatory practices to be viewed as more legitimate.²³³ In Europe, there is a “trend” of voter and consumer involvement in influencing risk-related policy issues, such as those concerned with genetically modified food.²³⁴

and private, secular and non-secular, ‘official’ and ‘unofficial’, and it will be more or less formal.”).

223. Cf. Weidl et al., *supra* note 80, at 477 (arguing that the point of certification programs is to bridge the knowledge gap).

224. Meili & Widmer, *supra* note 216, at 447.

225. Maynard et al., *supra* note 39, at 579.

226. *Id.*

227. See Abbott et al., *supra* note 33, at 525 (noting the “unprecedented opportunity to craft new regulatory or oversight approaches on a clean slate”).

228. Brownsword, *supra* note 48, at 62.

229. *Id.* at 64.

230. *Id.* at 65.

231. Weidl et al., *supra* note 80, at 481–82.

232. Ludlow & Binks, *supra* note 29, at 148 (discussing transparency and public participation).

233. *Introduction*, *supra* note 6, at 16.

234. Maynard et al., *supra* note 39, at 582.

The scientific value of such public participation, which is often self-interested,²³⁵ is open to question.²³⁶ In the United States, a majority of the citizenry is convinced that the benefits of nanotechnology outweigh the risks “although they know little about the technology.”²³⁷ However, the moral point is clear: it is ethically “questionable to deny citizens the opportunity to be part of the process of technology regulation” if it potentially impacts their lives in important ways.²³⁸

The Rio Declaration clearly states that “[e]nvironmental issues are best handled with participation of all concerned citizens.”²³⁹ Citizen participation can inject into a highly technical regulatory process, where there are few clear answers, both a measure of common sense and a valuable indication of what measures are politically sustainable. Citizen perceptions of risk reflect a range of factors other than the probability and magnitude of harm.²⁴⁰ Public participation in regulatory processes can counter the perception that “governments have a conflict of interest as key nanotechnology proponents, major funders, risk assessors, regulators and public ‘educators’”²⁴¹

Viewed broadly, regulation offers a “much richer mix of possibilities” than tightly constrained “command and control” models.²⁴² Nevertheless, that mix includes some hard law options, such as applying existing environmental laws governing clean air, pure water, and waste disposal, to the problems associated with nanotechnology processes and products.²⁴³

Of course, there are disadvantages to the use of soft law approaches to resolving serious environmental issues. Certification programs that

235. Cf. MARK SAGOFF, PRICE, PRINCIPLE, AND THE ENVIRONMENT 2 (2004) (“[T]here is an important difference between saying that something is *good for me* and saying something is . . . *good from the point of view of the world in general*”) (italics in original).

236. See BALDWIN ET AL., *supra* note 126, at 96–98 (discussing the advantages and dangers of public participation).

237. Ludlow & Binks, *supra* note 29, at 151.

238. Maynard et al., *supra* note 39, at 580.

239. U.N. Conference on Environment and Development, *Rio Declaration on Environment and Development*, U.N. Doc. A/CONF.151/26/Rev. 1 (Vol. I), annex I, principle 10 (Aug. 12, 1992).

240. BALDWIN ET AL., *supra* note 126, at 93

241. Georgia Miller & Gyorgy Scrinis, *The Role of NGOs in Governing Nanotechnologies: Challenging the “Benefits Versus Risks” Framing of Nanotech Innovation*, in HANDBOOK, *supra* note 6, at 409, 429.

242. *Introduction*, *supra* note 6, at 19; see also Abbott et al., *supra* note 33, at 532; Brownsword, *supra* note 48, at 61 (“[S]ome environments are regulated in a top-down fashion (with regulators clearly distinguishable from regulatees), others are more bottom-up (in the sense that they are self-regulatory).”).

243. Breggin & Pendergrass, *supra* note 25, at 367–68 (Noting that nanotechnology “regulators and stakeholders should be encouraged to focus on removing existing barriers to the use of current laws.”).

are intended to enhance understanding of complex issues and promote best practices are the type of voluntary measure that is likely to be cut by a business facing financial pressures.²⁴⁴

B. *Internationalizing Regulation*

Efforts to regulate the risks related to nanotechnology have been concentrated at the national or regional (i.e., European Union) level. However, the issues can easily be seen as international because those risks and related practices routinely cross borders and pose issues worldwide.²⁴⁵ “Internationally consistent standards would also protect against a ‘race to the bottom,’” in which countries sacrifice health, safety, and environmental interests in an effort to attract nanotechnology enterprises.²⁴⁶

To date, “international coordination of technology regulation has been limited to a relatively small set of treaties and subject matter,” and “even in the product-specific sector of pharmaceutical regulation, there is so far nothing to match the more internationally harmonized regulation of trade or intellectual property.”²⁴⁷ That record, and the difficulties of achieving an international consensus on how to address even well documented problems, such as climate change,²⁴⁸ make the enactment of any convention imposing detailed regulatory requirements most unlikely.²⁴⁹ This is particularly true because the multidisciplinary scientific foundations of nanotechnology make it unlikely that a single regime can be crafted to address the full range of risks. However, a soft law approach to regulation might succeed even though a hard law approach would fail.

Soft law—which generally refers to “non-binding international agreements or norms”²⁵⁰—embraces the idea that “resolutions and

244. See Weidl et al., *supra* note 80, at 478.

245. Ludlow & Binks, *supra* note 29, at 151 (discussing how nanotechnology issues can be framed as an international concern); Abbott et al., *supra* note 33, at 528 (“[C]ommerce generally, and nanotechnology development specifically, are increasingly global in nature, and so must be addressed at a global level.”).

246. Abbott et al., *supra* note 33, at 528.

247. Ludlow & Binks, *supra* note 29, at 152–53.

248. See *The 2015 Paris Agreement on Climate Change: Significance and Implications for the Future*, 46 ENVTL. L. REP. NEWS & ANALYSIS 10,267, 10,268–69 (2016) (discussing the difficult, more than twenty-year-long process that finally led to a major agreement on climate change”).

249. Ludlow & Binks, *supra* note 29, at 153 (“[W]hile there are serious problems with national public health laws, it will be difficult to get international consensus on such international regulation of nanotechnology.”); Abbott et al., *supra* note 33, at 526 (noting that “very little has occurred”).

250. Jeffrey M. Pollock & Jonathan S. Jemison, *The Emerging of International Environmental Law*, N.J. LAW. 25, 28 (1999).

recommendations of international organizations can ‘gradually acquire some legal value.’”²⁵¹ The basic role of soft law is to create expectations which, once widely subscribed to, can be translated into binding legal obligations, *i.e.*, hard law.

Ideally, soft lawmaking is a fluid process because binding obligations and enforcement mechanisms are not in issue. This fluidity may enable international parties to reach a consensus more quickly, and thereby respond more promptly to scientific and technological changes.

Soft law could be used to firmly place nanotechnology risks on the international agenda, create a basis for reporting and sharing relevant information,²⁵² and lay the groundwork for a framework treaty to be enacted.²⁵³ That framework treaty might be patterned on the Vienna Convention for the Protection of the Ozone Layer,²⁵⁴ a treaty which imposed no binding substantive obligations, but set the stage for adopting ozone reduction mandates under the Montreal Protocol on Substances that Deplete the Ozone Layer.²⁵⁵ Soft law can be particularly useful in situations where there are scientific uncertainties, but common interests, for it allows binding obligations to emerge as the facts become clearer.²⁵⁶

Soft law instruments, such as United Nations resolutions and recommendations, could be coupled with increased efforts to build international governance capacity through institutions such as the United Nations Environment Programme and the World Health Organization,²⁵⁷ and to promote regulatory convergence of the disparate legal frameworks, institutions, and practices found throughout the world.²⁵⁸ The World Bank sometimes adopts soft law principles and might place environmental requirements derived from nanotechnology soft law into their lending policies and conditions, and thereby give international actors additional reason to comply with those standards.²⁵⁹

251. *Id.*

252. *Cf.* Falkner et al., *supra* note 20, at 509 (“Ongoing international efforts to create scientific building blocks for risk assessment of nanomaterials needs to be stepped up.”).

253. *See* Andrew T. Guzman & Timothy L. Meyer, *International Soft Law*, 2 J. LEGAL ANALYSIS 171, 188 (2010) (explaining that soft law can serve as a coordinating device).

254. Vienna Convention for the Protection of the Ozone Layer, Mar. 22, 1985, 1531 U.N.T.S. 324.

255. *See* Montreal Protocol, *supra* note 1.

256. *See* Timothy Meyer, *Shifting Sands: Power, Uncertainty and the Form of International Legal Cooperation*, 27 EUR. J. INT’L L. 161, 162 (2016).

257. *Cf.* Falkner et al., *supra* note 20, at 510.

258. *See id.* at 514 (discussing the need to promote international regulatory convergence).

259. *See* Pollock & Jemison, *supra* note 250, at 28 (discussing the World Bank); *but see* Ida Koivisto, *The IMF and the “Transparency Turn,”* 25 MINN. J. INT’L L. 381, 403

An argument in favor of using soft law to address the health, safety, and environmental issues related to nanotechnology stands on firm ground. There is a well-established principle of international environmental law, “affirmed in virtually all international environmental agreements of bilateral and regional application,”²⁶⁰ as well as in global instruments,²⁶¹ that there is a duty to cooperate in matters concerning the protection of the environment.

VI. CONCLUSION

General regulatory regimes, such as those dealing with chemical and toxic substances in the European Union and the United States, may prove to be inadequate to deal with the scientifically complex challenges of nanotechnology. At the same time, nanospecific regulations are likely to be difficult to enact,²⁶² and even if established at the national level may produce an inconsistent patchwork of obligations²⁶³ incapable of grappling effectively with what is in fact an international problem.²⁶⁴

Minimizing the health, safety, and environmental risks related to nanotechnology requires raising the visibility of the issue, collecting reliable data, establishing prudent practices, building an international consensus, and eventually enacting and enforcing binding obligations that reflect a prudent balance between economic progress and hazard precautions in each of the many areas of life that will be affected by emerging nanotechnologies. These goals can best be advanced by viewing risk regulation broadly and using soft law instruments to lay the groundwork for the adoption of binding nanospecific provisions once scientific developments permit a clear assessment of relevant risk data and the advantages and costs of regulation.

(2016) (“Some developing countries have expressed concern over these covertly and asymmetrically imposed soft law obligations.”).

260. PHILIPPE SANDS, JACQUELINE PEEL, ADRIANA FABRA & RUTH MACKENZIE, *PRINCIPLES OF INTERNATIONAL ENVIRONMENTAL LAW* 204 (3d ed. 2012).

261. See Vienna Convention for the Protection of the Ozone Layer, *supra* note 254, at art. 2(2); Convention on Biological Diversity art. 5, June 5, 1992, 31 I.L.M. 818 (entered into force Dec. 29, 1993).

262. See Cetrulo, *supra* note 173, at § 36:10 (“[G]overnments worldwide have done very little to slow the expansion of nanotechnology in the consumer market.”).

263. Cf. Bergkamp, *supra* note 74, at 94 (“[EU] Member States have enacted nanotech-specific requirements, such as mandatory reporting with national nanotech registries . . . [which] prevents an effective coordination between EU and national initiatives and thereby carries a risk of fragmenting the internal market.”).

264. Cf. Taylor L. Kraus, *Caring About Personal Care Products: Regulation in the United States, the European Union, and China in the Age of Global Consumption*, 33 WIS. INT’L L.J. 167, 169 (2015) (“[A]bsent effective, consistent, and overlapping legislation between foreign nations, consumers in the global market place are inadequately protected.”).