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Nanotechnology Oversight and Regulation—Just Do It

by Jennifer Kuzma

Editors' Summary: The emergence of nanotechnology in the early part of this century has presented a host of regulatory challenges. Effective governance is complicated by the range of materials and methods implicated in nanotechnology itself, as well as a lack of political will to devise regulatory strategies for this new technology. In this Article, Prof. Jennifer Kuzma explains the particular complications of nanotechnology regulation and suggests that creating new laws and institutions might not be the best solution to nanotechnology regulatory reform. Rather, she argues, nanotechnology regulation must be prioritized, and may be accomplished using legal structures that are already in place.

I. Introduction

When faced with a new situation, society has a choice in its response. The products of new technologies, just beginning to enter the marketplace, pose questions about how to ensure their safety in the face of little experience or information about their use. In this uncertain climate, competing views on product oversight emerge. Some believe that formal oversight (such as government regulation), must precede product entry into the marketplace and be based on comprehensive safety studies that strive to avoid Type II errors (false negatives—or assumptions of no negative effects when there are some).[1] Others take the view that products can enter the market without substantial pre-market oversight, and that safety studies and experience can accumulate while developers bring products to market. Goals in this view are to expedite product use and avoid Type I errors (false positives—or assumptions of negative effects when there are none).[2] Often these views are labeled "precautionary" or "promotional," respectively. Layered upon this contrast are competing notions about systems for oversight. Past experience and ways of regulating can be used or fitted to the new situation, much like individuals draw upon past experiences to respond to new situations. The opposite approach is to wait for new methods, institutions, statutes, or regulations, and in the meantime, allow products to enter the market without tailored approaches for their review. A third possibility is to place a moratorium on product use in the market until new systems are in place.

Nanotechnology entered into this context in the early 21st century. Nanotechnology involves a broad and complex number of technologies, materials, and methods. The breadth of applications adds a third layer of complexity to the oversight of its products. The formal definition of nanotechnology includes the "understanding and control of matter at dimensions of roughly 1 to 100 nanometers (nm or 10^{-9} meters)."[3] It can be used in many settings—basic research, consumer products, food, agriculture, health, environmental remediation, and medicine—just to name a few. Many portray nanotechnology as something new that will revolutionize medicine, manufacturing, and life itself. However, others argue that it is a conglomerate of existing methods and disciplines, such as materials science, biochemistry, and chemical engineering, which has just recently been given a name. In their view, it and its products are the same as previous technologies and products, but at a smaller scale. This argument would suggest that existing laws and regulations could be interpreted to regulate nanotechnology. Yet within the nanotechnology policy community, there is skepticism toward this approach.[4] Currently there is a "wait-and-see" mentality to formal nanotechnology oversight.

Stakeholders adhere to the wait-and-see approach for a variety of reasons. Some are motivated by politics or eco-

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1. National Research Council, Ecological Monitoring for Genetically Modified Crops 18-19 (Joan Esnayra & Robert Pool eds., Nat'l Academy Press 2000).

2. *Id.*

3. National Nanotechnology Initiative, *What Is Nanotechnology?*, http://www.nano.gov/html/facts/whatIsNano.html (last visited Sept. 12, 2006).

4. J. Clarence Davies, *Managing the Effects of Nanotechnology*, http://www.wilsoncenter.org/events/docs/Effectsnanotechfinal.pdf (Project on Emerging Nanotechnologies 2006).

nomics, while others favor voluntary or informal approaches as opportunities to collect data before regulatory standards are set so that "science-based" approaches to regulation prevail. Some experts lament that this laissez-faire approach is the only possible one to oversight right now, as current institutions are not set up to regulate the products of nanotechnology, and existing statutes, such as the Toxic Substances Control Act (TSCA),[5] are not sufficient.[6] Furthermore, little data exist on the products of nanotechnology, which can prevent the formulation of science-based regulatory standards. Many cite the long time it takes to develop and pass new legislation as a deterrent to pursuing it. Although these arguments have merit, the lack of movement by governments is causing concern, and not just among environmental and consumer advocacy groups.[7] Products with nanoparticles are in the marketplace,[8] and others are on the way,[9] yet studies have shown that some of the particles can be harmful to consumers and ecosystems.[10]

This Article will explore the possibility of a coordinated approach to overseeing and regulating the products of nanotechnology in the near term. First, it will argue that coordinated and timely regulation is needed for public safety and confidence, and can also benefit technology development. It will then explore the question of whether new institutions or laws need to be formulated for nanotechnology products. Third, it will briefly describe examples of what could be done with existing statutes and institutions to formally oversee or regulate products. Finally, it will discuss the relationships among law, policy, and ethical principles, to argue for the political will to do what is best for society.

II. To Regulate or Not to Regulate?

Governance can take on many meanings and has been defined in numerous ways, including "the act of governing; exercising authority,"[11] or more broadly, as a complex set of values, norms, processes, and institutions through which society manages its development and resolves conflict formally or informally.[12] Governance includes oversight, which is defined more narrowly as "watchful and responsible care or regulatory supervision."[13] Regulation is a subcategory of oversight and governance and "an authoritative rule dealing with details or procedure or a rule or order issued by an executive authority or regulatory agency of a government and having the force of law."[14] Therefore, regulation can be an important element of governance, but can also be excluded from a governance system. This section argues for the incorporation of formal oversight and regulation into nanotechnology governance.

Recent studies indicate that the general public prefers mandatory oversight systems for nanotechnology products, as these systems engender trust.[15] Public attitudes are important for the ultimate success of technological products.[16] Lack of public trust in institutions governing or regulating technologies can arise from events that have negative consequences; and therefore, there is reason for industry to favor strong regulations designed to prevent unwanted effects and consumer backlash toward products.[17] Trust in laws and institutions are key factors in public perceptions. In two studies, over 60% of participants expressed little or no trust in government or industry to effectively manage the possible risks associated with nanotechnology.[18] However, on the flip side, the public has a positive attitude about technology itself and is generally supportive, depending on the applications and oversight systems in place.[19] For example, in a 2005 study, 76% of study participants thought a ban would be overreacting and 50% were "mostly or quite positive" about the technology.[20] However, the top cited concerns about nanotechnology in these studies were "true unknowns," "regulation," and "human health risks."[21] The majority of participants thought that voluntary standards are insufficient and that more safety testing and information are needed.[22]

Why is the informed public, for example, those individuals who participate in the studies cited above, concerned about oversight for nanotechnology products? Nanoparticles exist naturally. However, scientists point out that human exposure to nanoparticles has significantly increased over the last century due to anthropogenic sources, and they are discovering important safety issues associated with nanoproducts.[23] Nanoparticles and nanomaterials are being used in many products, such as dental ones, fuel cells, tires, optics, electronics, stain-free clothing, wound dressings, sunscreens, and cosmetics. The biological activity of parti-

5. 15 U.S.C. §§2601-2692, ELR Stat. TSCA §§2-412.
6. Davies, *supra* note 4.
7. Royal Society and the Royal Academy of Engineering, Nanoscience and Nanotechnologies: Opportunities and Uncertainties 1 (Royal Soc'y Press 2004).
8. Project on Emerging Nanotechnologies, *A Nanotechnology Consumer Products Inventory*, http://www.nanotechproject.org/44/consumer-nanotechnology (last visited Sept. 12, 2006).
9. Jennifer Kuzma & Peter S. VerHage, *Nanotechnology in Agriculture and Food Production: Anticipated Applications*, http://www.nanotechproject.org/50 (Project on Emerging Nanotechnologies 2006).
10. Andrew S. Maynard, *Nanotechnology: A Research Strategy for Addressing Risk* (Project on Emerging Nanotechnologies 2006).
11. Webster's Dictionary, *Governance*, http://www.websters-online-dictionary.org/definition/governance (last visited Sept. 14, 2006).
12. Lamont C. Hempel, Environmental Governance: The Global Challenge (Island Press 1996).
13. Merriam-Webster Dictionary, *Oversight*, http://www.m-w.com/cgi-bin/dictionary?va=oversight (last visited Sept. 14, 2006).
14. Merriam-Webster Dictionary, *Regulation*, http://www.m-w.com/dictionary/regulation (last visited Sept. 14, 2006).
15. Jane Macoubrie, *Informed Public Perceptions of Nanotechnology and Trust in Government* (Project on Emerging Nanotechnologies 2005).
16. Isaac Rabino, *How European and U.S. Genetic Engineering Scientists View the Impact of Public Attention on Their Field: A Comparison*, 19 Sci., Tech. & Hum. Values 23-46 (1994).
17. M. Seigrist, *The Influence of Trust and Perceptions of Risks and Benefits on the Acceptance of Gene Technology*, 20 Risk Analysis 195-204 (2000).
18. Jane Macoubrie, *Nanotechnology: Public Concerns, Reasoning, and Trust in Government*, 15 Pub. Understanding Sci. 221-41 (2006). Michael D. Cobb & Jane Macoubrie, *Public Perceptions About Nanotechnology: Risks Benefits and Trust*, 6 J. Nanoparticle Res. 395-405 (2004).
19. Macoubrie, *supra* note 15. Bernhard Zechendorf, *What the Public Thinks About Biotechnology: A Survey of Opinion Polls*, 12 Bio/Tech. 870-75 (1994).
20. Macoubrie, *supra* note 15.
21. *Id.*
22. Macoubrie, *supra* note 18.
23. Gunter Oberdorster et al., *Nanotoxicology: An Emerging Discipline Evolving From Studies of Ultrafine Particles*, 113 Envtl. Health Persp. 823-39 (2005).

cles generally increases as particle size decreases, and there is a growing literature on nanoparticle and ultrafine-particle toxicity.[24] Materials at the nanoscale react differently than bulk materials, and increases in surface area and penetration increase the potential for biological interaction.[25] For example, gold elicits a biological response at the nanoscale, but does not in bulk.[26] Yet, few nanotechnology products other than drugs or devices require pre-market testing (see below and Parts III and IV).

Environmental health and safety research on products in the marketplace is lacking.[27] In the words of experts in toxicology, "it would be prudent to examine and address environmental and human health concerns before the widespread adoption of nanotechnology."[28] However, there is evidence that inhaled nanoparticles more readily migrate into lung tissues after inhalation—causing chronic breathing problems—and from the lungs to the bloodstream than their larger counterparts.[29] In one study, nanosized polytetrafluoroethylene particles caused death in rats only 30 minutes after exposure to an amount that, if the particles were larger, would be considered safe.[30] Silver nanoparticles, currently used in products as antimicrobial agents, are causing concern about harm to microbes and higher organisms in the environment.[31]

Nanoparticles can enter cells and cause damage, raising many questions about gastrointestinal (GI) and dermal exposure.[32] Titanium dioxide nanoparticles, used in commercial sunscreens, and silver particles, used as antimicrobials, impair cell function in experiments with cultured cells.[33] There is a lack of toxicological and risk studies on these exposure routes, although there is enough information to suggest that nanoparticles would likely travel to the lymph nodes and blood after dermal or GI exposure.[34] Carbon nanotubes (CNTs), used in many industrial applications, cause inflammation, fibrosis, and toxicological changes in the lung. When they are applied to skin cells, biochemicals that indicate cellular damage increase.[35] Single-walled CNTs have been shown to be more toxic than quartz, which is a serious health hazard.[36] So despite the view that nanotechnology does not require new formal regulation, there is general consensus among experts that nanomaterials and nanoparticles have unique characteristics and pose special safety issues that warrant attention.

Cosmetics, food additives, and chemicals in consumer products or the environment are just a few of the kinds of products of nanotechnology that can enter the market without prior regulatory review and approval.[37] These products often have different risk-benefit distributions than medical applications of nanotechnology, as the party that benefits will not necessarily bear the risk, or benefits to consumers are not life-saving. For example, if a patient has cancer, he or she might choose to accept a larger risk with a more effective nanomedicine than a consumer using a skin cream with nanoparticles to improve appearance or eating a food that has nanoparticles to improve texture or flavor. This section and the following ones will focus largely on nonmedical types of applications, which pose different risk perception, social, policy, and ethical issues.

The U.S. Environmental Protection Agency (EPA) may choose not to regulate nanochemicals under TSCA if they have molecular formulas of chemicals already on the market (see Part III). The Food and Drug Administration (FDA) only investigates cosmetics if safety questions emerge after a product is on the market, and there is no pre-marketing approval process for cosmetics. The agency has no specific regulations for nanoparticles, and manufacturers are not required to tell the FDA if they are using nanotechnology in cosmetics. However, there is interest on the part of the agency in nanotechnology safety issues. The FDA is currently supporting studies on whether the zinc oxide nanoparticles already in sunscreens can penetrate skin.[38] Additionally, in the fall of 2006, the FDA hosted a public meeting to "gather information about current developments in uses of nanotechnology materials in FDA-regulated products."[39] The FDA meeting is expected to focus on, among other things, nanotechnology that would be used in foods, dietary supplements, and animal feeds.

Not only is regulation important for public attitudes about technological products, but there is evidence that it is good for business. Porter hypothesized that stringent regulations promote innovation, which can lead to better economic performance and new market opportunities.[40] A weaker version of his hypothesis is that regulation places constraints on profits of firms that were not there before; therefore, firms need to behave differently than they would have to meet constraints at lower cost, and this new behavior benefits the firms. Other studies have supported this claim, noting a pos-

24. Gunter Oberdorster et al., *Principles for Characterizing the Potential Human Health Effects From Exposure to Nanomaterials: Elements of a Screening Strategy*, 2 Particle & Fibre Toxicology 8-43 (2005).

25. Oberdorster et al., *supra* note 23.

26. Catherine M. Goodman et al., *Toxicity of Gold Nanoparticles Functionalized With Cationic and Anionic Side Chains*, 15 Bioconjugate Chemistry 897-900 (2004).

27. Maynard, *supra* note 10.

28. Oberdorster et al., *supra* note 23.

29. Juraj Ferin & Gunter Oberdorster, *Deposition Clearance and Effects in the Lung*, 5(3) J. Aerosol Med. 179-87 (1992). Oberdorster et al., *supra* note 23.

30. Gunter Oberdorster et al., *Association of Particulate Air Pollution and Acute Mortality: Involvement of Ultrafine Particles?*, 7 Inhalation Toxicology 111-24 (1995).

31. Maynard, *supra* note 10.

32. Oberdorster et al., *supra* note 23.

33. Saber M. Hussain et al., *In Vitro Toxicity of Nanoparticles in BRL 3A Rat Liver Cells*, 19 Toxicology In Vitro 975-83 (2005).

34. Oberdorster et al., *supra* note 23. Ning Li et al., *Ultrafine Particulate Pollutants Induce Oxidative Stress and Mitochrondrial Damage*, 111 Envtl. Health Persp. 455-60 (2003).

35. Chiu-Wing Lam et al., *A Review of Carbon Nanotube Toxicity and Assessment of Potential Occupational and Environmental Health Risks*, 36 Critical Rev. Toxicology 189-217 (2006).

36. *Id.*

37. Jennifer Kuzma, *Moving Forward Responsibly: Oversight for the Nanotechnology-Biology Interface*, J. Nanoparticle Res. (in press 2006). Davies, *supra* note 4.

38. Neil Cohen, *Morning Edition* (National Public Radio broadcast Mar. 13, 2006).

39. U.S. FDA, *FDA Announces Plans for Nanotechnology Public Meeting* (Apr. 13, 2006), http://www.fda.gov/bbs/topics/NEWS/2006/NEW01356.html, (last visited Sept. 12 2006).

40. Michael E. Porter & Claas van der Linde, *Toward a New Conception of the Environment-Competitiveness Relationship*, 9 J. Econ. Persp. 97-118 (1995). Michael E. Porter, *America's Green Strategy*, 264 Sci. Am. 168 (1991). Adam B. Jaffe & Karen Palmer, *Environmental Regulation and Innovation: A Panel Data Study*, 79 Rev. Econ. & Stat. 610-19 (1997).

itive effect on research and development expenditure with increasing environmental compliance expenditures and concluding that regulatory compliance will stimulate certain types of innovation.[41] For example, innovation to comply with regulations can improve product performance or quality. Raytheon was required by the Montreal Protocol and the Clean Air Act (CAA)[42] to eliminate chlorofluorocarbons (CFCs). At first, the company resisted, stating that it was impossible. However, in the end, it adopted a new cleaning agent that could be reused and produced at lower costs.[43] A new report suggests that CNTs can be made less toxic by modification with nitrogen.[44] This new nanotube is an innovation designed to address safety issues, but could also have special advantages in the market.

In addition to public mistrust of voluntary standards, there are more fundamental problems with such standards. A standard is usually imposed at an early stage in the production of a product. There must be a high level of confidence that upstream standards can meet downstream safety goals, and their upstream nature can inhibit innovation by preventing companies from developing cheaper means of meeting targets during downstream steps.[45] Furthermore, specific standards can become obsolete very rapidly, and it takes a long time to develop new ones through international and national standard-setting bodies.[46] Upstream standards for nanotechnology have also been cited as currently impossible to set given the lack of risk information.

In one study, the voluntary, or self-regulatory, program for chemicals called Responsible Care was evaluated.[47] The program contains 10 guiding principles and six codes of management practices centered on safety and environmental objectives. The codes that set standards for inputs are specified, but the outputs or the desired levels of pollution are not. Company membership is revoked if operations are inconsistent with the program. The study evaluated whether or not "opportunism" (profitability) would prevail over other forces, such as normative (value) and coercive (penalty) ones. After assessing the performances of participants and nonparticipants, the researchers concluded that behaviors of the participants are dominated by opportunism and company members do not make safety improvements any faster than non-members.[48] The study's broader conclusions are that self-regulation will not achieve objectives without sanctions for noncompliance and that enforcers should be outsiders to ensure unbiased and appropriate penalties. Recommendations such as these are addressed through government regulation, and there are several studies that demonstrate the relative success of command-and-control type government regulation compared to other approaches.[49]

Decentralized oversight mechanisms, driven by local as opposed to federal governments, can also pose problems. They require that citizens and producers be better informed about standards in various locations. Transboundary impacts are difficult to handle, and local governments might be pressured into relaxing standards or procedures by local industries that have personal relationships with them.[50] Inconsistency from place to place can create inequities in the marketplace and cause confusion. Centralized regulation can help reduce ambiguity, and ultimately help industry navigate the system.

However, centralized international regulation would not account for social preferences of local cultures and citizens.[51] On a national level, centralized regulation might be the best approach, yet on the international level, decentralized oversight with access to good information about varying systems around the world and some mechanism to detect and enforce safety violations might be the best option. United Nations (U.N.) bodies like the World Health Organization, World Trade Organization, or U.N. Educational, Scientific, and Cultural Organization (UNESCO), or multilateral treaties like the Convention on Biological Diversity or Kyoto Protocol, deserve exploration for blending national, centralized systems into decentralized, yet coordinated and monitored international ones. However, due to space limitations, this Article will focus on U.S. domestic oversight possibilities.

III. The Question of New Laws or Institutions

Why is there no central and formal coordinated mechanism for nanotechnology product oversight in the United States, even though many products are on the market and likely warrant special safety review? At the Environmental Law Institute's meeting on "Nanotechnology Governance: Environmental Management From a Global Perspective" in May 2006, many experts agreed that the formulation of new laws or mechanisms for oversight is nearly impossible at this time. Others argued that current statutes that could be used are insufficient, lacking specificity for nanotechnology, and some argued that the products of nanotechnology span too many different areas for a coordinated approach to make sense. Industry groups believe that without clear data and standards for nanotechnology products, science-based regulation is impractical, and even that "[t]he current state of knowledge is insufficient to set new regulations."[52]

41. Adam B. Jaffe & Karen Palmer, *Environmental Regulation and Innovation: A Panel Data Study*, 79(4) Rev. Econ. & Stat. 610-19 (1997).

42. 42 U.S.C. §§7401-7671q, ELR Stat. CAA §§101-618.

43. Raytheon, Inc., *Alternate Cleaning Technology*, January-October Technical Report Phase II (1991).

44. J.C. Carrero-Sanchez et al., *Biocompatibility and Toxicological Studies of Carbon Nanotubes Doped With Nitrogen*, 6 Nano Lett 1609-16 (2006).

45. Anthony Ogus, *Regulatory Institutions and Structures*, 73 Annals Pub. & Cooperative Econ. 627-48 (2002).

46. Peter Hatto, *Technology Assessment and Management*, *in* The Risk Governance of Nanotechnology: Recommendations for Managing a Global Issue, Zurich, http://www.irgc.org/irgc/knowledge_centre/irgceventmaterial/ (last visited Sept. 14, 2006).

47. Andrew King & Michael Lenox, *Prospects for Industry Self-Regulation Without Sanctions: A Study of Responsible Care in the Chemical Industry*, 43 Acad. of Mgmt. J. 698-716 (2000).

48. *Id.*

49. David L. Greene, *CAFÉ or Price? An Analysis of the Effects of Federal Fuel Economy Regulations and Gasoline Price on New Car MPG, 1978-1989*, 11 The Energy J. 37-58 (1990). Daniel H. Cole & Peter Z. Grossman, *When Is Command and Control Efficient? Institutions, Technology, and the Comparative Efficiency of Alternative Regulatory Regimes for Environmental Protection*, 5 Wis. L. Rev. 887 (1999).

50. Ogus, *supra* note 46.

51. *Id.*

52. International Risk Governance Council, *Survey on Nanotechnology Governance: Volume B. The Role of Industry* 92, http://www.Irgc.org/irgc/_b/contentFiles/IRGC_white_paper_2_PDF_final_version.pdf.

Yet, there is always incomplete knowledge and a degree of uncertainty about systems; this dilemma can never be fully solved. Uncertainty has not prevented us from regulating in the past, nor should it. In fact, the opposite approach—making sure regulatory systems are in place when there is incomplete knowledge of effects—is more likely to promote safety and public trust. In past experiences with new technologies, less than perfect existing statutes and institutions were used or laws and institutions were quickly formulated to adapt to new situations. This section and subsequent ones in this Article will explore oversight and regulatory possibilities for nanotechnology, taking a "can and must do" attitude. With this attitude, much can be done now.

Some believe that we need new laws and institutions to properly regulate nanoproducts. An argument for a new law for nanoproducts was promoted by J. Clarence Davies,[53] who pointed out the limitations of TSCA, the Occupational Safety and Health Act (OSHA),[54] and the Federal Food, Drug, and Cosmetic Act (FFDCA).[55] His reasons for this view are that TSCA does not explicitly cover nanoparticles, and OSHA is understaffed and not well-funded. Furthermore, the FDA does not have a mandatory pre-market review for foods or cosmetics under the FFDCA. These arguments are predicated, however, on specific interpretations of existing laws. There seems to be room for interpreting TSCA in different ways if desired. TSCA is a broad statute, in that it covers all stages of production and release and is designed to cover "chemical substances and mixtures" defined as "any organic or inorganic substance of a particular molecular identity."[56] Nanomaterials could be considered new chemicals under this definition (with loose interpretation of new molecular identity). Even if they are not, in cases of large quantities of chemicals or significant new environmental or human exposure, EPA can act under the significant new use rule (SNUR) provision. The EPA Administrator has the ability to declare that an existing chemical be regulated as if it were a new chemical if it is put to uses that might change its effects.[57] Nanoscale chemicals seem to fit this criterion quite well, as effects and characteristics change at the nanoscale. Thus Premarket Manufacturing Notices (PMNs) and their review by EPA would be required for nanoparticles and nanomaterials if the definition of new chemicals or novel uses was interpreted to cover them. What seems to be missing is the will—political and otherwise—to do so. In fact, a recent series of reports by the American Bar Association concludes that TSCA, CAA, the Clean Water Act (CWA),[58] the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),[59] the Resource Conservation and Recovery Act (RCRA),[60] and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)[61] provide EPA with sufficient legal authority to regulate nanochemicals and deal with the risks and benefits of using nanotechnology.[62]

Similar arguments for OSHA regulation can be made. Occupational exposures are perhaps the most urgent ones to address, given the current manufacturing of toxic nanomaterials, like CNTs, with little information about worker health or protection.[63] The language of OSHA is broad enough to cover nanotechnology materials and chemicals. Section 3(8) of the Act indicates that a standard can be set "which requires conditions, or the adoption of use of one or more practices, means, methods, operations or processes reasonably necessary or appropriate to provide safe or healthful employment and places of employment."[64] Davies argues that OSHA is weak because of meager resources and inadequate detection methods to set and monitor standards.[65] However, flaws with detection and toxicity testing exist for most chemicals, not just nanochemicals, and additional resources could be directed toward OSHA if there was the will to do so. Therefore, the statute does not appear to be limiting, but the scientific information and political climate are.

In the case of cosmetics, the FDA does have authority to classify a cosmetic product containing nanoparticles as "adulterated" if it "bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under conditions of use as are customary and usual."[66] Davies rightly argues that the FDA has no authority to recall the products or take direct action against the manufacturer.[67] However, the agency can act through the U.S. Department of Justice to remove adulterated and misbranded cosmetics from the market. For example, the FDA may request a federal district court to issue a restraining order against the manufacturer of the cosmetic. The cosmetic may be subject to seizure. It is possible, and probably wise, for the FDA to develop a recommended consultation policy for cosmetics, like the one for bioengineered foods, *Statement of Policy: Foods Derived From New Plant Varieties 1992* (also discussed in Part IV).[68] Perhaps this consultation policy for cosmetics could eventually be mandatory through a premarket notification process in order to better ensure public confidence in the system.[69] This type of mandatory notifica-

53. Davies, *supra* note 4.

54. 29 U.S.C. §§651-678.

55. 21 U.S.C. §§301-399.

56. 15 U.S.C. §2602(2)(a).

57. Davies, *supra* note 4.

58. 33 U.S.C. §§1251-1387, ELR STAT. FWPCA §§101-607.

59. 7 U.S.C. §§136-136y, ELR STAT. FIFRA §§2-34.

60. 42 U.S.C. §§6901-6992k, ELR STAT. RCRA §§1001-11011.

61. 42 U.S.C. §§9601-9675, ELR STAT. CERCLA §§101-405.

62. ABA Section of Environment, Energy and Resources, *CAA Nanotechnology Briefing Paper, CERCLA Nanotechnology Issues, CWA Nanotechnology Briefing Paper, EMS/Innovative Regulatory Approaches, The Adequacy of FIFRA to Regulate Nanotechnology-Based Pesticides, RCRA Regulation of Wastes From the Production, Use, and Disposal of Nanomaterials, Regulation of Nanoscale Materials Under the Toxic Substances Control Act* (2006), *available at* http://www.abanet.org/environ/nanotech/.

63. University of Minnesota, *2nd International Symposium on Nanotechnology and Occupational Health, Proceedings and Final Program* (October 3-6, 2005), http://www.cce.umn.edu/pdfs/cpe/conferences/nanotech_abstracts.pdf (last visited Sept. 14, 2006).

64. 29 U.S.C. §652.

65. Davies, *supra* note 4.

66. FDA—Center for Food Safety and Nutrition, Office of Cosmetics and Colors, *FDA Authority Over Cosmetics* (Mar. 3, 2005), http://www.cfsan.fda.gov/~dms/cos-206.html (last visited Sept. 14, 2006).

67. Davies, *supra* note 4.

68. 57 Fed. Reg. 22984 (May 29, 1992).

69. Pew Initiative on Food and Biotechnology, *How Consumers Process Information at Heart of Debate Over Labeling of Genetically Modified Foods*, http://www.connectlive.com/events/pewagbiotech

tion was developed for bioengineered foods and published by the FDA for comment in 2001,[70] although ultimately the agency decided not to promulgate it. Even some proponents of agricultural biotechnology are disappointed in the agency's decision to ignore the public consensus (obtained through several FDA-hosted public meetings in 1999) for mandatory pre-market review of bioengineered foods.[71]

Nanoparticles are being used in a few food products on the market, and many more are being developed to better deliver nutrients or improve quality.[72] Section 402(a)(1) of FFDCA[73] does not require premarket approval for new food products; however, the FDA is authorized to seize adulterated (injurious to health) foods and prosecute those responsible for their distribution.[74] The agency has pre-market authority for food additives, which includes data and information that show reasonable certainty that the additive will be safe for its intended use.[75] Petitions for food additives are subject to public notice and comment. Food additives are defined by the FDA as substances with the intended use of "becoming a component of food" and "which is not generally recognized as safe (GRAS)."[76] It seems as if the FDA could choose to develop a policy that would classify certain, or most, nanoparticles in food as "food additives" instead of GRAS. In this case, the additives would have to undergo pre-market testing and approval. At the minimum, the FDA could develop a policy for consultation, like the agency did for bioengineered foods (discussed above in the context of cosmetics). In summary, the FDA seems to have the ability to cover cosmetics and foods using nanoparticles through an existing statute, if desired.

Consumer products, with the exception of those covered by other agencies, are covered by the Consumer Product Safety Act (CPSA).[77] For example, nanomaterials in electronics, clothes, and golf balls would come under this Act. The CPSA established the Consumer Products Safety Commission (CPSC), defines its basic authority, and "provides that when the CPSC finds an unreasonable risk of injury associated with a consumer product it can develop a standard to reduce or eliminate the risk."[78] The CPSA also provides the CPSC with the authority to ban products without feasible standards and pursue recalls for products that present a substantial hazard. Nanoproducts that have been shown or suspected to be hazardous could be banned or recalled under this Act. Davies, however, argues that the CPSA is mainly an Act of encouragement, and that the CPSC is severely understaffed to carry out this authority.[79] Again, his arguments for a new law are based not on shortcomings of the language of the statute, but the political decision to deprive the CPSC of resources.

In the end, Davies argues that a new law would be easier "politically and substantively, to draft and enact" than to remedy weaknesses in current regulatory practices.[80] However, this point raises the question that if there is not the political will to adequately staff existing agencies to interpret laws in favor of regulation for nanoproducts, why would the political drive for a new law designed for nanotechnology products exist? Most laws require years of groundwork for enactment, and more years to execute them through proposed notices in the *Federal Register* (*FR*), comment periods, and final rulemaking. Exceptions to this lag period seem to occur when there is intense and urgent political ambition for new laws. This certainly was the case after the terrorist attacks of September 11, 2001. The U.S. Patriot Act was passed just two months later.[81] However, in the absence of urgent and intense political situations, it seems more plausible to broadly interpret existing statutes and adjust current systems to fit new technologies.

There are organizational theory and business arguments for adapting current systems instead of creating new ones. Terry Moe points out that structural choice for institutions is a never-ending process, and that in principle at least, "all of the choices that have been made in the formative round of decisionmaking can be reversed or modified later."[82] Furthermore, he states that "the bureaucracy arises out of politics, and its design reflects the interests, strategies, and compromises of those who exercise political power."[83] These principles apply to regulatory agencies and governance of new technologies—oversight of new products is highly dependent on the interpretation of existing laws and the resources provided to governing institutions. These, in turn, are highly dependent on political climate. Moe uses cases of the formation and evolution of the CPSC, OSHA, and EPA to illustrate how the agencies were designed, molded, and adapted over time based on the politics of various Administrations, and how their level of attentiveness to social regulation and environmental and health protection fluctuated accordingly.[84] In his view, it is the "political institutions, not the bureaucracy, that must be reformed if solutions are ever to be found. . . . The bureaucracy itself is not the problem."[85]

In most cases, it will not make sense to create new systems, as they will still be subject to the political climate of the time. Furthermore, institutions are constantly evolving and should continue to evolve to fit new situations. They provide the place in which "democratically arrived at policy is translated into feasible and legitimate policy outputs."[86] Organizational theory suggests that learning in complex environments is a prerequisite for developing collaborative

062702/PEW-062702-transcript-html.html (last visited Oct. 20, 2006).

70. 66 Fed. Reg. 4706 (Jan. 18, 2001).

71. Pew Initiative on Food and Biotechnology, *Ag Biotech Buzz, Volume 4, Issue 3*, http://pewagbiotech.org/buzz/display.php3?StoryID=125 (last visited Sept. 14, 2006).

72. Jennifer Kuzma & Peter VerHage, Analysis of Early Stage Research and Development of Agrifood Nanotechnology (Project on Emerging Nanotechnologies 2006), *available at* http://www.hhh.umn.edu/img/assets/21307/Agrifood%20Handout.pdf.

73. 21 U.S.C. §§301-399.

74. *Id.* §§332-334.

75. *Id.* §409.

76. *Id.* §321(s).

77. 15 U.S.C. §§2051-2084.

78. U.S. CPSC, *Purpose of the CPSA*, http://www.cpsc.gov/businfo/cpsa.html (last visited Sept. 14, 2006).

79. Davies, *supra* note 4.

80. *Id.*

81. Pub. L. No. 107-56, 115 Stat. 272-402 (2001).

82. Terry Moe, *The Politics of Bureaucratic Structure*, *in* Can the Government Govern? 267, 285 (Chubb et al. eds., Brookings Institution 1989).

83. *Id.* at 267.

84. *Id.*

85. *Id.* at 329.

86. Ronald A. Boin & Tom Christensen, *Reconsidering Leadership and Institutions in the Public Sector: A Question of Design?*, European Group of Public Administration Annual Conference Ljubljana, Slovenia (Sept. 1-4, 2004).

capacity and successful policy implementation.[87] In fact, by creating permanent, new fixed structures, the government "runs the risk of not only achieving a suboptimal organization, but also of prematurely shutting off organizational learning and adaptation of organizational activities to address emerging threats and consequences."[88] Executive Order coordination and statutory coordination are alternatives to new Departmental organizations.[89] Such approaches will be considered in the context of nanotechnology products in Part IV.

There is also recent evidence that new institutions do not necessarily solve problems with novel issues and challenges. Several stakeholders and experts are disappointed with the U.S. Department of Homeland Security's (DHS) ability to enhance coordination and communication of agencies and experts in the national security community.[90] Stated more strongly, it has even been responsible for "creating new stovepipes and reinforcing existing organizational and institutional barriers."[91] Only 60% of the homeland security budget goes to the DHS, and there still are remaining issues about getting security data in one place.[92] Also, with the consolidation of disparate agencies into the DHS, focal points of some agencies have changed, with negative consequences. For example, some believe that the Federal Emergency Management Agency is now too heavily focused on terrorism recovery and response and less equipped to deal with environmental or natural disasters.[93]

Other arguments for using existing systems include effects on industry. Gerardo Rivera Ungson, Christopher James, and Barry H. Spicer note that large changes in regulatory systems place a greater burden on industry, particularly small or emerging companies, who do not have the staff or resources to learn new systems.[94] Therefore, regulatory reform that uses familiar systems with which companies have dealt in the past can ease the transition in overseeing new kinds of products.

IV. What Can Be Done?

If new institutions or laws pose difficulties and are not the best choices for initial oversight and regulation of new products, what should we do now to adequately regulate the products of nanotechnology? Regulatory reform for nanotechnology could focus on improving coordination among agencies to cover all products and safety angles and minimize inefficiencies without altering the basic form or intent of the relevant statutes and regulations. There is historical precedence for this type of approach. The Coordinated Framework for the Regulation of Biotechnology (CFRB) was published by the Office of Science and Technology in 1986 and instructed the federal agencies to use TSCA, FIFRA, the FFDCA, and the Federal Plant Pest Act (FPPA)[95] to regulate the products of biotechnology, and in particular genetically engineered (GE) organisms, which were just emerging at the time.[96] The political will to adopt this framework stemmed from controversies, court cases, and congressional hearings about the proposed release of a GE organism, the "ice minus" bacterium, into the environment.[97]

In the CFRB, the boundaries of various statutes were significantly stretched to promulgate agency regulations for diverse products. Twenty years later, this framework is still operational. GE plants are regulated as "plant pests" under the FPPA, because they often contained engineered sequences from viruses and bacteria that cause plant disease and can be considered plant pests in themselves.[98] GE plants created with pesticide-like proteins or molecules are regulated under FIFRA and the FFDCA as pesticides (a.k.a. plant-incorporated protectants) by EPA.[99] GE microorganisms are regulated as toxic chemicals under TSCA.[100] GE or bioengineered foods are reviewed under the FFDCA by the FDA through a voluntary consultation mechanism (previously discussed in Part III). GE animals are likely to come under consideration by the FDA as "investigational new animal drugs,"[101] although no formal policy or regulation has been issued.[102] Interpretations of old statutes seem to be loose in the case of biotechnology products, and the question arises as to why the same could not be done for the products of nanotechnology. For some products it is occur-

87. Charles R. Wise, *Organizing for Homeland Security*, 62 Pub. Admin. Rev. 131-44 (2002).

88. *Id.*

89. *Id.*

90. *Testimony Before the Subcomm. on National Security, Emerging Threats and International Relations and the Subcomm. on Energy Policy, Natural Resources and Regulatory Affairs* (2004) (statement of James Lee Witt, Director of the Federal Emergency Management Agency).

91. Kathleen Tierney, *Recent Developments in U.S. Homeland Security Policies and Their Implications for the Management of Extreme Events*, *in* First International Conference on Urban Disaster Reduction, Kobe, Japan (2005).

92. Siobhan Gorman, *On Guard, But How Well?*, Nat'l J. (Mar. 5, 2004).

93. James K. Mitchell, *The Fox and the Hedgehog: Myopia About Homeland Security in U.S. Policies on Terrorism. Terrorism and Disaster: New Threats, New Ideas*, 11 Res. Soc. Probs. & Pub. Pol'y 53-72 (2003).

94. Gerardo Rivera Ungson et al., *The Effects of Regulatory Agencies on Organizations in Wood Products and High Technology Electronics Industries*, 28 Acad. Mgmt. J. 426-45 (1985).

95. 7 U.S.C. §150aa-jj, as amended (1957).

96. 51 Fed. Reg. 23302 (1986).

97. *Environmental Implications of Genetic Engineering: Hearings Before the Subcomm. on Investigations and Oversight and the Subcomm. on Science, Research, and Technology, Comm. on Science and Technology*, 98th Cong. (1983).

98. 7 C.F.R. §340; *Genetically Engineered Organisms and Products; Notification Procedures for the Introduction of Certain Regulated Articles; and Petition for Nonregulated Status*, 58 Fed. Reg. 17044 (Mar. 31, 1993).

99. *Regulations Under FIFRA for Plant-Incorporated Protectant*, 66 Fed. Reg. 37771 (July 19, 2001); National Research Council, Genetically Engineered Pest Protected Plants: Science and Regulation 263 (Nat'l Academy Press 2000).

100. 15 U.S.C. §2604(h)(4); 40 C.F.R. pt. 725; *Microbial Products of Biotechnology; Final Regulations Under the Toxic Substances Control Act*, 62 Fed. Reg. 17910 (Apr. 11, 1997).

101. 21 C.F.R. §511.1(b); Pew Initiative on Food and Biotechnology, Issues in the Regulation of Genetically Engineered Plants and Animals (2004), *available at* http://pewagbiotech.org/research/regulation/RegulationExecSum.pdf. FDA—Center for Veterinary Medicine, *CVM and Bioengineered Animals and Drugs*, http://www.fda.gov/cvm/1666.htm (last visited Oct. 20, 2006).

102. Pew Initiative on Food and Biotechnology, Issues in the Regulation of Genetically Engineered Plants and Animals (2004), *available at* http://pewagbiotech.org/research/regulation/RegulationExecSum.pdf. FDA—Center for Veterinary Medicine, *CVM and Bioengineered Animals and Drugs*, http://www.fda.gov/cvm/1666.htm (last visited Oct. 20, 2006).

ring,[103] but there is no published policy on a "coordinated framework for the regulation of nanotechnology products," comparable to the CFRB, and other products are falling through the cracks.

It seems as if the concept of public and environmental health protection behind several federal statutes is most important for nanotechnology, and that the lack of particular conceptions or experiences should not be a limiting factor.[104] Underlying concepts of TSCA, FIFRA, the FFPA, the FFDCA, and other statutes seem suitable for nanotechnology. As discussed above, nanoparticles in the environment could be reviewed under TSCA; nanoparticles in food and cosmetics could be reviewed under the FFDCA. For agricultural products, the U.S. Department of Agriculture (USDA) could use the Federal Meat Inspection Act to review nanoparticles applied in slaughterhouses and the FPPA to review plants altered by nanoparticles, e.g., gene delivery through nanotechnology. EPA, with the will to do so, could use TSCA in the workplace, and FIFRA for nanoparticles used as pesticides or household cleaning products. OSHA and CPSC resources could be strengthened to act under their authorities. There are many possibilities. Examples of what could be done to cover the products of nanotechnology under existing authorities are presented in Table I.

Davies argues that such a framework would not be feasible for nanotechnology, given the breadth of products and the uncertainty about what products of nanotechnology would be developed in the future.[105] There is significance to his arguments. Yet, the CFRB has been effectively used for biotechnology products, imperfections and all, and biotechnology also can be applied to a wide range of products. Davies is correct in asserting that a coordinated framework approach has significant difficulties, and it will need improvement for both biotechnology and nanotechnology products. For example, there is concern that the CFRB leads to over- and under-coverage and certain risk issues.[106] In addition, the CFRB was not transparent throughout the 1990s, nor was it truly coordinated in operation.[107] Furthermore, there is still much uncertainty about how emerging biotechnology products, like GE insects and animals, will be covered by it, as they were not explicitly addressed by the CFRB at the time of its publication in 1986.[108] However, with the lessons learned from biotechnology, a better coordinated framework for nanotechnology could be developed—the tools and institutions seem to be in place to gather or review existing data or support the generation of new data.

103. Norris Alderson, *Overview of FDA's Activities at the Nano-Bio Interface*, The Nanotechnology-Biology Interface: Exploring Models for Oversight, Workshop Presentation (Sept. 15, 2005), *available at* http://www.hhh.umn.edu/img/assets/18323/Norris%20Alderson.pdf.

104. Ronald Dworkin, *Taking Rights Seriously: Constitutional Cases*, *in* American Constitutional Interpretation 249 (Murphy et al. eds., The Foundation Press 1995).

105. Davies, *supra* note 4.

106. National Research Council, *supra* note 100.

107. *Id.*

108. Pew Initiative on Food and Biotechnology, Exploring the Regulatory and Commercialization Issues Related to Genetically Engineered Animals: Summary of Two Multi-Stakeholder Workshops (2005), *available at* http://pewagbiotech.org/events/0321/proceedings.pdf; Pew Initiative on Food and Biotechnology, Bugs in the System? Issues in the Science and Regulation of Genetically Modified Insects (2004), *available at* http://pewagbiotech.org/research/bugs/bugs.pdf.

Table 1. Example of U.S. Coordinated Framework Approach for Nanotechnology Products*

Product	Agency or Agencies	Statutes	Action Needed
General	Office of Science and Technology Policy, White House	Several	Develop Executive Order and *FR* policy asking agencies to interpret statutes broadly and develop *FR* notices and/or regulations indicating so.
Agricultural in meat processing	USDA	Federal Meat Inspection Act	Develop *FR* policy and support data gathering for regulatory standards.
Agricultural in plant growth	USDA	FPPA	Develop *FR* policy and support data gathering for regulatory standards.
Agricultural pesticides	FDA, EPA	FIFRA and FFDCA	Develop *FR* policy and support data gathering for regulatory standards.
Chemicals	EPA, OSHA	TSCA, CERCLA, RCRA, CAA, CWA, OSHA, etc.	Develop *FR* notices to interpret existing laws broadly; consider nanoparticles as new chemicals or SNURs under TSCA; Congress to provide increased resources to OSHA and EPA to help gather data on safety and review applications. Ban CNT from workplaces until safety standards and equipment become available.
Consumer Products	CPSC	CPSA	Exercise existing authority; Congress to provide more resources to the CPSC for review of safety.
Cosmetics	FDA	FFDCA; Fair Packaging and Labeling Act	Develop policy to encourage voluntary labeling of cosmetics containing nanoparticles and consult with the FDA prior to market entry; consider products adulterated if significant safety information is not available.
Dietary Supplements	FDA	Dietary Supplement Health and Education Act	Consider nanoparticles or materials in dietary supplements as new dietary ingredients; develop policy on pre-market notification; require inclusion of nanoparticle contents on labels; Congress to provide the FDA with more resources for data and review.
Drugs and Devices	FDA	FFDCA	Continue rigorous pre-market safety review; support data gathering for products with nanomaterials or nanoparticles and develop specific guidelines for them.
Food packaging	FDA	FFDCA; FDA Modernization Act	Use intended discretion to consider nanoparticles in food packaging through petition process initially; when data accumulates, return to notification.
Particles in food	FDA	FFDCA	Develop policy under the FFDCA for consultation before nanoparticles are used in food; exercise authority to consider nanoparticles as food additives initially unless there is strong evidence for being GRAS.

* Table 1 is not meant to be complete and is not necessarily comprehensive.

V. Law, Policy and Ethics in Oversight

What should underpin a regulatory or oversight system? Does everyone, regardless of race, culture, economic status, and location, have the right to benefit from nanotechnology products? Do people have a right to know what they are consuming or using, as well as have access to the safety studies on products? Do they have a right to refrain from using or being exposed to something that may put them or their children at risk? Are people and their health a means to an end (like product quality or global competitiveness), or should they be treated as ends in themselves? These questions are fundamentally ethical ones. In the absence of a well-developed field of "nanoethics," principles of bioethics can be applied. Autonomy (importance of individual freedom and choice), beneficence (welfare of consumers or patients, or abstaining from harm), and justice (treatment according to what is fair, due, or owed) relate to choices that we, as a society, make about oversight and governance, even regulation.[109] There is a need to interpret these and other ethical principles in the context of nanotechnology.

Many ethicists argue that law should be based on policy, which is in turn based on ethical principles.[110] Likewise, many legal scholars subscribe to the view that the concepts (principles) of the law matter, not necessarily the particular conceptions or cases.[111] For example, Ronald Dworkin argues for a marriage between law and moral theory, and rebukes legal positivism, or the idea that legal validity has little essential connection with morality or justice.[112] This view dates back to the writings of St. Thomas Aquinas, in which eternal law reflected God's grand design, divine law was that set of principles manifested in scripture, and natural law was eternal law applied to human conduct.[113] Man-made law was constructed by human beings to fit natural law to the various societal contexts in time and space. According to Aquinas, the fundamental precepts of natural law were understandable by all human beings and self-evident.[114] *Riggs v. Palmer*[115] is a classic case in which common principles trumped the language of law. The case held that a murderer cannot inherit his victim's property, despite the facts that the victim's will stated unambiguously that the murderer was the heir and the statute of wills said the will was valid and should be carried out. Put another way, law is a collection of community principles and its interpretation should be based on principles as well.[116] In light of this premise, one could argue that there are a number of laws, with concepts of ensuring public health and safety while promoting the economic and social well-being of societies (ethical principles which are self-evident), which are already in place for the products of nanotechnology. There seems to be an urgent moral imperative to adapt and execute the laws to do what is right.

So how then can we integrate ethical principles into oversight? Ethical issues in oversight transcend scientific risk assessment and regulatory standards. They include accountability in a system—for example, financial accountability, whereby regulators minimize administrative costs (maximize economic well-being of citizens or beneficence to developers); procedural accountability, where there is an appropriate framework for decisions which serve the public interest and resist the inappropriate influence of private interests (fairness, autonomy to choose, and beneficence); and substantive, which seeks to ensure that the decisions are justifiable in terms of the public interest goals of the regulatory system (beneficence and autonomy).[117] In the context of procedural accountability, the World Bank states that good governance is "among other things participatory, transparent and accountable. It is also effective and equitable."[118] It is "epitomized by predictable, open and enlightened policy making; a bureaucracy imbued with a professional ethos; an executive arm of government accountable for its actions; and a strong civil society participating in public affairs; and all behaving under the rule of law."[119] Thus, we see that "good governance" is founded on ethical principles, yet carried out through laws and policies. This particular expression of a government view of good governance supports the writings of legal and moral philosophers.[120] It seems that if there is a will, there is a way to do what is best for society and that laws should not take on a life of their own in new and important situations, nor should they be limiting factors.

Ideas of good governance transcend national boundaries. In a recent European Union (EU) white paper, five principles underpinning good governance are identified: openness, participation, accountability, effectiveness, and coherence.[121] Each principle is important for establishing democratic governance, and according to the paper, they apply to all levels of government—global, European, national, regional, and local.[122] According to Anthony Ogus, the main characteristics of a good regulatory system include legal instruments that are appropriate in light of economic and social justifications and procedures that have legitimacy within the community.[123] He states that "certain process values must be recognized, including those of expertise, transparency, and accountability."[124] In the EU, a series of scandals relating to science, technology, and health, such as dioxin in chicken feed and government denial of a causative link between bovine spongiform encephalopathy (known as BSE or mad cow disease) and new variant Creuzfeldt-Jakob Disease (known as nvCJD), have undermined the legiti-

109. Tom L. Beauchamp & LeRoy Walters, *Ethical Theory and Bioethics*, *in* Contemporary Issues in Bioethics 1 (Wadsworth Publ'g Co. 1999).

110. *Id.* at 25-27.

111. Dworkin, *supra* note 105.

112. *Id.*

113. Thomas Aquinas, *Question 94 of the Prima Secundae*, Summa Theologiae (1265-1274).

114. *Id.*

115. 115 N.Y. 506 (1889).

116. Ronald Dworkin, Law's Empire 488 (Harvard Univ. Press 1988).

117. Ogus, *supra* note 46.

118. The World Bank, *What Is Governance? Good Governance*, http://web.Worldbank.org/WBSITE/EXTERNAL/COUNTRIES/MENAEXT/EXTMNAREGTOPGOVERNANCE/0,,contentMDK:20513159~pagePK:34004173~piPK:34003707~theSitePK:497024,00.html (last visited Sept. 14, 2006).

119. *Id.*

120. Beauchamp & Walters, *supra* note 110; Dworkin, *supra* note 117.

121. Commission of the European Communities, European Governance: A White Paper (2001), *available at* http://eur-lex.europa.eu/LexUriServ/site/en/com/2001/com2001_0428en01.pdf.

122. *Id.*

123. Ogus, *supra* note 46.

124. *Id.*

macy of EU government organizations.[125] These events are hypothesized to have caused consumer backlash to GE organisms in agriculture and food, and ultimately, have led to an emphasis in the EU on precaution and social concerns in regulatory decisionmaking.[126]

How do we translate previous experiences with legitimacy, social and ethical concerns, and precaution v. promotion with emerging technologies (such as genetic engineering) to fit the current situation with nanotechnology? A recent UNESCO report on nanotechnology describes attitudes toward risk on a scale ranging from precautionary, or placing the burden on industry to prove no significant risk, to less precautionary, or putting the burden on government to demonstrate significant risk.[127] The choice of these two approaches is not a scientific issue, but a social judgment. Statutes that could be or are applied to nanotechnology contain a mixture of approaches. Sometimes opposite approaches exist within the same statute. For example, TSCA has been argued as putting the burden of proof on regulators and "implicitly assumes that no knowledge about a chemical means that there is no risk."[128] Davies argues that in light of this, a new law is needed which puts the burden of proof on industry.[129] However, §5(e) of TSCA states that if EPA does not have enough information "to permit a reasoned evaluation of the health and environmental effects of a chemical," it can delay or prohibit its manufacturing if it can show that the chemical "may present an unreasonable risk."[130] This appears to be a dilemma, but a regulatory climate that favors qualitative evidence for "unreasonable risk" and attempts to avoid Type II errors (false negatives, see Part I) would be sufficient to move the burden of proof to industry. The policy intent of TSCA, in which "adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures," could guide the process.[131] Not only would this help ensure health and environmental safety, but also, if the burden of proof were on industry, it would be more engaged in the regulatory process, and innovation might be encouraged (see Part II).

VI. Conclusions

In this Article, I have argued that political will and climate are the main drivers of approaches to governance, oversight, and the regulation of technological products. Politicians and civil servants need to balance an ever-growing list of social priorities such as terrorism and war, global health, energy security, and education. There are, indeed, limited resources to handle all of the challenges that nations face. However, if the success of new technologies is a priority for our nation and the world, we will need to better ensure the safety of their products and take government action to do so, in order to foster public trust and innovation. Nanotechnology holds great promise for the future—clean water, anti-cancer drugs, sensors for chemicals in the environment, and more rapid disease diagnostics, just to name a few.[132] However, it will not succeed in the long run without the optimism and will to properly oversee it. Using independent sources for safety testing, making that information available in the public domain, communicating about social and ethical issues in open forums and with multiple stakeholders, and fostering political climates that favor and support both industry innovation and consumer safety will all be necessary for good governance and oversight.[133] We should no longer make excuses for delaying the development of a coordinated federal and international system for oversight of nanotechnology products. We should not make excuses for delaying the development of domestic regulatory systems. Existing tools can be interpreted, adapted, and bolstered to ensure safety, while new laws or institutions are considered to improve the system. It all starts with the willingness to do so.

125. Ragnar E. Lofstedt & David Vogel, *The Changing Character of Regulation: A Comparison of Europe and the United States*, 21 Risk Analysis 399-405 (2001).

126. Sheila Jasanoff, Designs on Nature: Science and Democracy in Europe and the United States 94-135 (Princeton Univ. Press 2005).

127. UNESCO, The Ethics and Politics of Nanotechnology 16 (2006), *available at* http://unesdoc.unesco.org/images/0014/001459/145951e.pdf.

128. Davies, *supra* note 4.

129. *Id.*

130. 15 U.S.C. §2604(e).

131. *Id.* §2601(b).

132. Mihail C. Roco & William S. Bainbridge, *Societal Implications of Nanoscience and Nanotechnology: Maximizing Human Benefit*, 7 J. Nanoparticle Res. 1-13 (2005).

133. University of Minnesota Hubert H. Humphrey Institute of Public Affairs, The Nanotechnology-Biology Interface: Exploring Models for Oversight, Workshop Report 1-48 (Jennifer Kuzma ed., 2005), *available at* http://www.hhh.umn.edu/img/assets/9685/nanotech_jan06.pdf.