

Developing Oversight Frameworks for Nanobiotechnology

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Nanotechnology involves the ability to work at the atomic and molecular level to create structures with fundamentally new molecular structures in order to exploit novel properties that do not normally exist at a larger size. The National Nanotechnology Initiative (NNI), made up of twenty-six U.S. federal agencies including the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA), contributed to the development of a description of nanotechnology as involving:

- (1) [r]esearch and technology development at the atomic, molecular or macromolecular levels, in the length scale of approximately 1-100 nanometer range; (2) creating and using structures, devices and systems that have novel properties and functions because of their small and/or intermediate size; and (3) ability to control or manipulate at the atomic scale.¹

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This is a burgeoning field with a large number of potential applications in medicine, drug development, engineering, robotics, electronics, fiber optics, energy, food and agriculture, and environmental science. Nanobiotechnology specifically refers to nanotechnology designed for use in biological systems or in which nanomaterials are derived from biological molecules.² Over 500 products advertised as nanotechnology-based consumer products have already hit the market.³ These include products with biologically active nanostructures (*e.g.*, Spray For Life® Nano-Synergy Vitamin B12 Energy Booster, Abraxane™ anticancer drug, and Canola Active cooking oil fortified with phytosterol nanocapsules).⁴

Oversight systems specific to nanotechnology have not yet been created; stakeholders, government, industry, academia, and the public are debating whether and how to craft such systems and address emerging safety, social, and ethical issues.⁵ The United States has no coordinated policy for oversight of the products and applications of nanotechnology and uncertainty prevails over how existing general regulatory regimes and industry standards apply to emerging nanotechnologies. Empirical assessment of health and environmental risks is still in process. At the same time, public understanding of nanotechnology is rudimentary and

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1. See ENVTL. PROT. AGENCY, NANOTECHNOLOGY: AN EPA RESEARCH PERSPECTIVE: FACTSHEET (2007), available at <http://es.epa.gov/ncer/nano/factsheet/nanofactsheetjune07.pdf>.

2. M.C. Roco, *Nanoscale Science and Engineering: Unifying and Transforming Tools*, 50 AM. INST. CHEMICAL ENGINEERS 890, 895–96 (2004).

3. See The Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, An Inventory of Nanotechnology-Based Consumer Products Currently on the Market, <http://www.nanotechproject.org/inventories/consumer/> (last visited Feb. 20, 2008).

4. *Id.*

5. J. CLARENCE DAVIES, WOODROW WILSON INT'L CTR. FOR SCHOLARS, PROJECT ON EMERGING NANOTECHNOLOGIES, MANAGING THE EFFECTS OF NANOTECHNOLOGY 27–28 (2006), available at http://www.nanotechproject.org/publications/archive/managing_effects_nanotechnology/.

public concern exists.⁶ Nanotechnology, and nanobiotechnology specifically, warrants active discussion of potential oversight mechanisms to assure public confidence in safety and, when health effects are a goal, efficacy. This article focuses on nanobiotechnology, which most directly raises questions of how oversight can address safety and efficacy, outlines the current debate on oversight in the United States, suggests why deliberate development of oversight strategies is important, and recommends how to develop them.

I. THE OVERSIGHT DEBATE

Developing oversight approaches for nanobiotechnology is daunting. Nanobiotechnology encompasses a wide range of fields and products; a single oversight model may be unrealistic. Some argue that nanotechnology is suitably covered by existing regulatory and non-regulatory oversight activities.⁷ Others disagree, arguing that nanoproducts already on the market have failed to receive the oversight they require.⁸ The debate centers on issues including modes of human exposure, toxicity levels, increased reactivity and novel physical properties of nanoparticles, possibility for environmental dispersion, and unique physiological distribution in the body such as the ability to cross the blood-brain barrier. Canvassing oversight options for nanotechnology requires considering government regulatory structures, systems for coordinating multiple agency action, non-governmental standards, and international frameworks.

A. GOVERNMENT AGENCIES

U.S. federal agencies have begun to consider oversight options. The EPA oversees human exposure to chemicals in

6. JANE MACOUBRIE, WOODROW WILSON INT'L CTR. FOR SCHOLARS, PROJECT ON EMERGING NANOTECHNOLOGIES, INFORMED PUBLIC PERCEPTIONS OF NANOTECHNOLOGY AND TRUST IN GOVERNMENT 8–13 (2005), *available at* http://www.nanotechproject.org/publications/archive/informed_public_perceptions/.

7. Ted Agres, *Disagreement About FDA Nanotech Oversight*, SCIENTIST, Oct. 11, 2006, <http://www.the-scientist.com/news/display/25041/>.

8. See Ctr. for Sci., Tech. & Pub. Policy, Univ. of Minn., *The Nanotechnology-Biology Interface: Exploring Models for Oversight: Workshop Report 18–28* (Jennifer Kuzma ed., 2005), *available at* http://www.hhh.umn.edu/img/assets/9685/nanotech_jan06.pdf.

the environment under a number of statutes. One statute that may apply to exposure to nanochemicals is the Toxic Substances Control Act (TSCA), 15 U.S.C. §§ 2601-92, developed 30 years ago.⁹ TSCA regulates “new chemicals” beyond those existing chemicals listed in TSCA Inventory.¹⁰ Since many nanochemicals are variations of chemicals listed in TSCA Inventory, although at much smaller sizes and often with different properties and characteristics, questions remain about whether nanoparticles are “new” chemicals under TSCA, which would be the trigger for pre-market notification. This issue has taken on some urgency as a major carbon nanotube (CNT) manufacturer and supplier has classified its carbon nanotubes as synthetic graphite,¹¹ a relatively innocuous substance listed on the TSCA Inventory, despite the fact that toxicity studies to date show CNTs to have a higher toxicity than traditional graphite.¹² In 2005, the EPA held public meetings and requested comments on the feasibility of a voluntary oversight program involving industry cooperation in creating industry-wide standards for developing and commercializing chemicals at the nanoscale.¹³ The EPA formed the National Pollution Prevention and Toxics Advisory Committee Interim Ad Hoc Work Group on Nanoscale Materials in 2005 in order to design this voluntary nanoscale materials program and to consider potential EPA review of nanoscale materials under TSCA.¹⁴ EPA oversight efforts have been focused on catalyzing private voluntary agreement

9. The Toxic Substances Control Act was originally enacted on October 11, 1976 by Pub. L. 94-469, 90 Stat. 2003 (1976).

10. 15 U.S.C. § 2602(9) (2000).

11. UNIDYM, INC., MATERIAL SAFETY DATA SHEET: UNIDYM CARBON NANOTUBES 1 (2007), *available at* http://www.unidym.com/files/msds_cni_nanotubes.pdf.

12. Chui-wing Lam et al., *A Review of Carbon Nanotube Toxicity and Assessment of Potential Occupational and Environmental Health Risks*, 36 CRITICAL REVIEWS TOXICOLOGY 189, 206 (2006).

13. Notice of Public Meeting on Nanoscale Materials, 70 Fed. Reg. 24574 (May 10, 2005).

14. INTERIM AD HOC WORK GROUP ON NANOSCALE MATERIALS, U.S. ENVTL. PROT. AGENCY, NAT'L POLLUTION PREVENTION AND TOXICS ADVISORY COMM. (NPPTAC), OVERVIEW OF ISSUES FOR PUBLIC DISCUSSION AND CONSIDERATION BY NPPTAC 1 (2005), *available at* <http://www.epa.gov/oppt/npptac/pubs/nanowgoverviewdraft050921finalv2.pdf>.

on standards.¹⁵ In addition, the agency in 2007 proposed a voluntary framework for manufacturers of nanomaterials under TSCA.¹⁶ There have been analyses of EPA's ability to regulate nanomaterials under TSCA which suggest that the law is inadequate or is being interpreted in a manner that does not ensure pre-market testing and safety.¹⁷ In November 2006, the EPA utilized a different approach and announced its intent to regulate consumer items developed with silver nanoparticles marketed as "germ-killing" (including many food storage containers, air fresheners, and washing machines) as pesticides under the Federal Insecticide, Fungicide and Rodenticide Act due to concerns regarding environmental release.¹⁸

The FDA also has authority over certain nanoproducts, especially biologically active nanostructures in human drugs and medical devices.¹⁹ The agency generally regulates on a product-by-product basis, with products often categorized according to the mode of action, and uses intended by the manufacturer. The FDA currently applies its existing regulatory approaches for drugs, medical devices, combination products, foods, and cosmetics to nanotechnology products.²⁰ This approach has been questioned, with some arguing that nanotechnology warrants its own oversight provisions.²¹

15. *Id.*

16. Nanoscale Materials Stewardship Program and Inventory Status of Nanoscale Substances under the Toxic Substances Control Act: Notice of Availability, 72 Fed. Reg. 38083, 38085-86 (July 12, 2007).

17. J. CLARENCE DAVIES, WOODROW WILSON INT'L CTR. FOR SCHOLARS, PROJECT ON EMERGING NANOTECHNOLOGIES, EPA AND NANOTECHNOLOGY: OVERSIGHT FOR THE 21ST CENTURY (2007), available at http://www.nanotechproject.org/publications/archive/epa_nanotechnology_oversight_for_21st/; see also Jennifer Kuzma, *Nanotechnology Oversight: Just Do It*, 36 ENVTL. L. REP. 10913, 10923 (2006).

18. Rick Weiss, *EPA to Regulate Nanoproducts Sold as Germ-Killing*, WASH. POST, Nov. 23, 2006 at A01; Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. § 136 (2000).

19. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 351-60 (2000).

20. U.S. FOOD & DRUG ADMIN., FDA REGULATION OF NANOTECHNOLOGY PRODUCTS, <http://www.fda.gov/nanotechnology/regulation.html> (last visited Feb. 20, 2008).

21. MICHAEL R. TAYLOR, WOODROW WILSON INT'L CTR. FOR SCHOLARS, PROJECT ON EMERGING NANOTECHNOLOGIES, REGULATING THE PRODUCTS OF NANOTECHNOLOGY: DOES FDA HAVE THE TOOLS IT NEEDS? 45-53 (2006), available at http://www.nanotechproject.org/publications/archive/regulating_products_nanotechnology_does/.

Meanwhile, the FDA is reviewing, and in some cases has approved, nanoproducts using established oversight paths under the Federal Food, Drug, and Cosmetic Act (FFDCA).²² Under this statute, new drugs are regulated through a pre-market testing and approval process and have to meet safety, efficacy, and manufacturing standards. Higher risk devices must go through a pre-market application process showing that the device is safe and effective, while a lower risk device can be marketed if shown to be substantially equivalent to an already marketed device. Food and cosmetic products may be marketed without FDA evaluation or review, though for genetically engineered food products, the FDA and industry engage in voluntary consultation prior to market entry. In 2006, the FDA established a Nanotechnology Task Force to investigate “regulatory approaches that encourage the continued development of innovative, safe and effective FDA-regulated products that use nanotechnology materials.”²³ Following a public hearing in October 2006, the Task Force released its findings in mid-2007. This report concluded that the FDA need not develop a new regulatory framework or special regulations for nanotechnology at the current time. Furthermore, the report concluded that no new labeling was necessary to indicate that specific products included nanoparticles or were manufactured using nanotechnology.²⁴ Using its established oversight paths, the FDA has approved nano-drug products such as Abraxane® anticancer drug²⁵ and Estasorb® topical estrogen therapy²⁶ as well as nano-device products such as Vitoss® bone graft substitute²⁷ and EnSeal™

22. Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301–99 (2000).

23. Press Release, U.S. Food & Drug Admin., FDA Forms Internal Nanotechnology Task Force, (Aug. 9, 2006), *available at* <http://www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4241B1-02-33-FDA-Nano%20FDA%20News%20release.pdf>.

24. NANOTECHNOLOGY TASK FORCE, U.S. FOOD & DRUG ADMIN., NANOTECHNOLOGY 34 (2007), *available at* <http://www.fda.gov/nanotechnology/taskforce/report2007.pdf>.

25. See Abraxis Biosciences, Inc. for information on Abraxane. Abraxane Home Page, <http://abraxane.com> (last visited Feb. 18, 2008).

26. See Graceway Pharmaceuticals, LLC for information on Estrasorb. Estrasorb Home Page, <http://www.estrasorb.com> (last visited Feb. 18, 2008).

27. See Orthovita, Inc. for information on Vitoss. Vitoss Home Page, <http://orthovitaportal.com/Vitoss%20Technical%20Information/default.aspx> (last visited Feb. 18, 2008).

tissue sealing and hemostatis system for laparoscopic and open surgery.²⁸ Many cosmetic products have entered the market that contain nanoparticles, such as BINOVA Cosmetics by Barneys New York®, Collagen Fusion™ Botanical Skincare System by AmerElite Solutions®, and Lipoduction™ Body Perfecting Complex by Osmotics.®²⁹

Another U.S. agency with relevant oversight responsibilities is the Occupational Safety and Health Administration (OSHA) pursuant to the Occupational Safety and Health Act (OSHAct).³⁰ Health standards for workplace exposure to toxic substances are established after public notice of proposed standards and eliciting public comments. This approach to overseeing occupational exposure to nanomaterials might be attempted, although OSHA has not yet taken any steps in this direction. Current concerns in the workplace include engineered nanoparticles such as fullerenes and carbon nanotubes.³¹ However, critics have challenged OSHA's oversight methods, questioning the scientific basis of standards, the role of economic factors and cost-benefit analysis in standard setting, how the agency has assessed the feasibility of standards, and the extent to which OSHAct allows nuanced consideration of degrees of risk. Given that OSHA bears the burden of carrying out detailed risk assessments for the thousands of toxic substances on the market and that proposed standards must also be technologically feasible,³² critics have charged that OSHA's oversight approach is inadequate for nanomaterials.

Another relevant regulatory federal agency, the Department of Agriculture (USDA), has yet to act on oversight issues of nanotechnology, although it funds nanotechnology

28. See SurgRX, Inc. for information on EnSeal. EnSeal Home Page, <http://www.surgrx.com/product.html> (last visited Feb. 18, 2008).

29. See The Project on Emerging Nanotechnologies, *supra* note 3.

30. Occupational Safety and Health Act, 29 U.S.C. §§ 651–78 (2000).

31. The University of Minnesota recently held the Second International Symposium on Nanotechnology and Occupational Health on October 3–6, 2005 focusing on issues of implications of nanotechnology in the workplace. UNIV. OF MINN., 2D INTERNATIONAL SYMPOSIUM ON NANOTECHNOLOGY AND OCCUPATIONAL HEALTH (2005), *available at* http://www.envirocorp.com/img/media/CPE1322_NanoTechPrgBkt_2.pdf.

32. Nicholas A. Ashford & Charles C. Caldart, *Government Regulation, in OCCUPATIONAL AND ENVIRONMENTAL HEALTH: RECOGNIZING AND PREVENTING DISEASE AND INJURY* 39, 43–45 (Barry S. Levy, David H. Wegman, Sherry L. Baron & Rosemary K. Sokas eds., 5th ed. 2006).

research on food and agriculture.³³ Similarly, the National Institute for Occupational Safety and Health (NIOSH) actively funds research into metrics for characterizing worker exposures, new measurement technologies, and for validating technologies for controlling inhalation exposures.³⁴ With respect to nanotechnology specifically, NIOSH has organized workshops on technical issues relating to measurement methods and exposure assessment and has been proactive in terms of research initiatives and education.³⁵ However, it has not yet delved into issues of nanotechnology oversight.³⁶ Thus, it appears that among U.S. federal agencies, the FDA and EPA have begun to consider how to oversee nanotechnology activities and products, while OSHA, USDA, and NIOSH have not yet taken significant steps in considering oversight mechanisms.

B. SYSTEMS TO COORDINATE AGENCIES

Because nanotechnology implicates a number of government agencies, coordination is a significant issue. Systems for coordination must be considered part of the oversight debate. An example of one such system is the U.S. Coordinated Framework for the Regulation of Biotechnology, created by the federal Office of Science and Technology Policy in 1986 to coordinate regulation of products of biotechnology according to their intended use.³⁷ The Framework identifies the EPA, FDA, and USDA as lead agencies to regulate specific products, envisioning that a single product may be regulated by a number of federal agencies.³⁸ The Framework sees the products of biotechnology as the focus of regulation, rather

33. JENNIFER KUZMA & PETER VERHAGE, WOODROW WILSON INTERNATIONAL CENTER FOR SCHOLARS, PROJECT ON EMERGING NANOTECHNOLOGIES, NANOTECHNOLOGY IN AGRICULTURE AND FOOD PRODUCTION: ANTICIPATED APPLICATIONS 16 (2006), *available at* http://www.nanotechproject.org/publications/archive/nanotechnology_in_agriculture_food/.

34. Occupational Safety and Health Act, 29 U.S.C. § 671(22) (2000).

35. *See* National Institute for Occupational Safety and Health, Nanotechnology at NIOSH, <http://www.cdc.gov/niosh/topics/nanotech/> (last visited Nov. 20, 2007).

36. *Id.*

37. Coordinated Framework for the Regulation of Biotechnology, 51 Fed. Reg. 23302 (June 26, 1986).

38. *Id.*

than the field of biotechnology.³⁹ Existing statutes are thus deemed sufficient and the agencies are charged with developing regulatory guidance and policies as needed under those statutes.⁴⁰

This Framework has not been applied to nanotechnology as yet.⁴¹ Applying the Framework or a comparable approach to nanotechnology would create a coordinated framework among the key governmental agencies. As part of such a nanotechnology framework, relevant agencies could develop new regulatory structures, more specific guidance documents, and policy as needed.⁴² However, there is debate over whether this model has worked well for the products of biotechnology and specifically genetically engineered organisms (GEOs). There have been no reports of large-scale adverse effects of GEOs on human or animal health or the environment, but critics have challenged the success of the Coordinated Framework in achieving interagency coordination, the adequacy of existing statutes to handle GEOs, and the success of agencies in performing risk assessment and providing guidance for product developers.⁴³

C. STATE AND LOCAL INITIATIVES

Many states are recognizing and encouraging the development and commercialization of nanotechnology through funding initiatives and other support. These statutes span a variety of commitments to nanotechnology, yet do not provide oversight mechanisms. These provisions include identifying nanotechnology as a priority for the particular state; establishing monetary support and plans to develop and maintain research facilities; encouraging the application of nanotechnologies in particular areas, such as pharmaceuticals and environmental applications; creation of state tax credits or tax exemptions for costs of a facility designing, developing, or producing nanotechnology; issuing grants and advancing educational initiatives; and fostering industry-university

39. *Id.*

40. *Id.* at 23303.

41. Jennifer Kuzma, *Nanotechnology Oversight: Just Do It*, 36 ENVTL. L. REP. 10913, 10920 (2006).

42. *Id.* at 10922–23.

43. NAT'L RESEARCH COUNCIL, GENETICALLY MODIFIED PEST-PROTECTED PLANTS: SCIENCE AND REGULATION 28–37, 144–78 (2000).

collaborations.⁴⁴

The city of Berkeley, California has passed a nanotechnology-specific ordinance regarding mandatory reporting procedures. The disclosure guidelines require “[a]ll facilities that manufacture or use manufactured nanoparticles shall submit a separate written disclosure of the current toxicology, to the extent known, and how the facility will safely handle, monitor, contain, dispose, track inventory, prevent release and mitigate such materials.”⁴⁵ The city of Cambridge, Massachusetts is also considering adopting an ordinance similar to that passed in Berkeley.⁴⁶ A seventeen-member advisory board made up of health and safety experts from Harvard and the Massachusetts Institute of Technology has been appointed to make policy recommendations to the Department of Public Health.⁴⁷ The cities of Boston and Somerville, Massachusetts are also reportedly considering

44. See, e.g., S.C. CONST. art. III, § 17; ARK. CODE ANN. §§ 14-144-204(a)(15), (b)(2)(J), 15-4-2102(f)(2), 15-4-2103(a) (2007); CAL. EDUC. CODE § 88500(e) (Deering 2007); COLO. REV. STAT. §§ 24-48.5-108(3)(a), (c)(I)(B), 39-26-722(1) (2007); CONN. GEN. STAT. §§ 4-124hh(a)(5), (b)(4)(A)-(C), (c)(3) (2007); IND. CODE ANN. § 5-28-10(4)(2)(E) (LexisNexis 2007); KAN. STAT. ANN. § 74-99b83, 74-99b04 (2006); MASS. GEN. LAWS ch. 23I, §§ (1)(7), (2), (4)-(5) (2007); MICH. COMP. LAWS SERV. § 125.2088a(a)(ii) (2007); N.J. STAT. ANN. § 52:9X-12(II) (West 2007); N.Y. EXEC. LAW § 209(7) (Consol. 2007); N.Y. PUB. AUTH. LAW § 3154(10(a) (Consol. 2007); N.C. GEN. STAT. § 143B-437.44(4) (2007); OKL. ST. ANN. tit. 74 § 5060.1(a) (West 2007); OKL. ST. ANN. tit. 75 § 5060.4(14), 5060.43 (West 2007); OR. REV. STAT. ANN. §§ 284.740, 351.350(11)(4)(b), 351.509 (West 2007); 24 PA. STAT. ANN. § 6250.902(c) (West 2007); P.R. LAWS ANN. tit. 23, § 695(a)(1)(K) (2004); S.C. CODE ANN. § 2-75-90(A), (B) (2005); TEX. GOV'T CODE ANN. §§ 481.0296(a)(5), 489.213(b), 489.213(e), 489.213(h) (Vernon 2006); TEX. GOV'T CODE ANN. § 490.003(b)(7) (Vernon 2007); UTAH CODE ANN. § 63-38g-303(1)(c) (2007); VA. CODE ANN. § 2.2-255(9) (2007); WIS. STAT. ANN. § 13.48(25r) (West 2006).

45. BERKELEY, CAL., MUNICIPAL CODE ch. 15.12.040(I) (2007); see also CAL. HEALTH & SAFETY CODE § 25500 (2007) (“[I]t is not the intent of the Legislature to preempt . . . local ordinances containing the same or greater standards and protections” regarding the release or threatened release of hazardous materials.); TOXICS MGMT. DIV., CITY OF BERKELEY PLANNING & DEV. DEP'T, INTRODUCTION TO MANUFACTURED NANOSCALE MATERIAL HEALTH & SAFETY DISCLOSURE FOR THE REPORTING PERIOD OF JUNE 1, 2007 - JUNE 2, 2008 (2007), available at <http://www.ci.berkeley.ca.us/toxics/Manufactured%20Nanoparticle%20Reporting%20Final.pdf>.

46. Hiawatha Bray, *Cambridge Considers Nanotech Curbs*, BOSTON GLOBE, Jan. 26, 2007, at C1.

47. Catherine Williams, *Big Talks Over Small Tech*, MASS HIGH TECH, June 15, 2007, at 1, available at <http://www.bizjournals.com/masshightech/stories/2007/06/18/story1.html>.

similar ordinances.⁴⁸ These initiatives, while not oversight of nanotechnology per se, are an initial attempt by cities to require some local level of reporting and accountability for use of nanoparticles.

D. NON-GOVENMENTAL STANDARDS

Oversight can be performed not just by government, but also by private companies and industry groups coordinating to articulate standards and create safeguards. The Foresight Nanotech Institute, a nonprofit institute, has published voluntary “Guidelines for Responsible Nanotechnology Development” recommended for industry adoption.⁴⁹ The nonprofit Institute for Molecular Manufacturing has also proposed industry guidelines specific to molecular nanotechnology with the assistance of the Foresight Nanotech Institute.⁵⁰ DuPont has partnered with the non-profit Environmental Defense to develop a corporate framework to assess nanotechnology risk.⁵¹ The framework was published in Summer 2007 and focuses on steps for risk assessment within organizations that manufacture nanomaterials.⁵² Several non-governmental consumer and environmental organizations have been critical of the framework as it is premised on voluntary oversight and industry self-regulation.⁵³

E. INTERNATIONAL OVERSIGHT

Other countries are also beginning to take action on nanotechnology oversight. The British government, for example, commissioned the Royal Society and the Royal Academy of Engineering, two premiere independent science

48. Bray, *supra* note 46.

49. Neil Jacobstein, *Foresight Guidelines for Responsible Nanotechnology Development*, FORESIGHT NANOTECH INST., April 2006, <http://www.foresight.org/guidelines/current.html> (draft version 6).

50. Neil Jacobstein, *Foresight Guidelines for Responsible Nanotechnology Development*, INST. MOLECULAR MANUFACTURING, April, 2006, <http://www.imm.org/guidelines/> (draft version 6).

51. Virginia Gewin, *Nanotech's Big Issue*, 443 NATURE 137, 137 (2006).

52. ENVTL. DEFENSE-DUPONT NANO PARTNERSHIP, NANO: RISK FRAMEWORK, 7 (2007), available at http://www.environmentaldefense.org/documents/6496_Nano%20Risk%20Framework.pdf.

53. *Activist Groups Reject DuPont-ED Nanotechnology Risk Framework*, NANOWERK, Apr. 12, 2007, <http://www.nanowerk.com/news/newsid=1766.php>.

academies, to study developments in the field and to identify the potential pros and cons of nanotechnologies for society.⁵⁴ In a joint 2004 report, the academies proposed a ban on some uses of nanotechnology, stating that “the use of free (that is, not fixed in a matrix) manufactured nanoparticles in environmental applications such as remediation [should] be prohibited until appropriate research has been undertaken and it can be demonstrated that the potential benefits outweigh the potential risks.”⁵⁵

In France, the Ethics Committee of the French National Centre for Scientific Research (COMETS) published an October 2006 opinion, listing eight ethics recommendations for nanotechnology, including the creation of ethics guidelines for researchers.⁵⁶ COMETS has advocated adoption of these recommendations by the French Ministry of Health and the French National Assembly’s parliamentary office on scientific and technological policy.⁵⁷

At the European Union level, the European Economic and Social Committee of the European Parliament published an opinion in 2005 recommending that the European Commission introduce methods to identify nanotechnology risks and propose European guidelines by 2008.⁵⁸

II. SIGNIFICANCE OF THE OVERSIGHT DEBATE

This review of early oversight efforts by U.S. governmental agencies and non-governmental actors as well as international oversight efforts demonstrates the need for more work. No one agreed-upon approach or ideal model has

54. THE ROYAL SOC’Y & THE ROYAL ACAD. OF ENG’G, NANOSCIENCE AND NANOTECHNOLOGIES: OPPORTUNITIES AND UNCERTAINTIES (2004), *available at* <http://www.nanotec.org.uk/finalReport.htm>.

55. *Id.* at 85 (follow link titled “Chapter 10-Recommendations”).

56. Press Release, Centre National de la Recherche Scientifique, The CNRS Ethics Committee Publishes Its Recommendations on Nanotechnology (Oct. 16, 2006), *available at* <http://www2.cnrs.fr/en/727.htm>.

57. *Id.*

58. EUROPEAN ECON. & SOC. COMM., OPINION ON THE COMMUNICATION FROM THE COMMISSION TO THE COUNCIL, THE EUROPEAN PARLIAMENT AND THE ECONOMIC AND SOCIAL COMMITTEE—NANOSCIENCES AND NANOTECHNOLOGIES: AN ACTION PLAN FOR EUROPE 2005–2009 ¶ 3.5.7 (2006), *available at* http://eescopinions.eesc.europa.eu/viewdoc.aspx?doc=%5C%5Cesppub1%5Cesp_public%5Cces%5Cint%5Cint277%5Cen%5Cces582-2006_ac_en.doc.

yet emerged. A variety of reports have recently issued from academics, professional organizations, scholarly organizations, and government bodies assessing existing regulatory frameworks, measuring public perceptions and understanding, and suggesting oversight options.⁵⁹

This debate on nanotechnology oversight is important. Progress in the field depends on societal interest, available funding, and ultimately public confidence. Without appropriate and effective oversight to minimize harms, maximize benefits, and assure standards, public confidence and funding may be at risk. Mishaps can retard development of even the most promising of technologies. One recent study shows that while consumers are excited about nanotechnology and its potential benefits, there is already concern about who is developing and promoting this technology, who will assess and manage the potential risks, and who will be responsible for monitoring products after they hit the marketplace.⁶⁰

The impact of past negative experiences with other new

59. See, e.g., COMM. TO REVIEW THE NAT'L NANOTECHNOLOGY INITIATIVE, NAT'L RESEARCH COUNCIL, A MATTER OF SIZE: TRIENNIAL REVIEW OF THE NATIONAL NANOTECHNOLOGY INITIATIVE (2006), available at http://www.nap.edu/catalog.php?record_id=11752; NANOSCALE SCI., ENG'G, & TECH. SUBCOMM., NAT'L SCI. & TECH. COUNCIL, ENVIRONMENTAL HEALTH, AND SAFETY RESEARCH NEEDS FOR ENGINEERED NANOSCALE MATERIALS (2006), available at http://www.nano.gov/NNI_EHS_research_needs.pdf; NANOTECHNOLOGY WORKGROUP, U.S. EPA, NANOTECHNOLOGY WHITE PAPER (2007), available at <http://es.epa.gov/ncer/nano/publications/whitepaper12022005.pdf>; SECTION OF ENV'T, ENERGY, AND RES., AM. BAR ASS'N, EMS/INNOVATIVE REGULATORY APPROACHES (2006), available at <http://www.abanet.org/environ/nanotech/>; SECTION OF ENV'T, ENERGY, AND RES., AM. BAR ASS'N, RCRA REGULATION OF WASTES FROM THE PRODUCTION, USE, AND DISPOSAL OF NANOMATERIALS (2006), available at <http://www.abanet.org/environ/nanotech/>; SECTION OF ENV'T, ENERGY, AND RES., AM. BAR ASS'N, REGULATION OF NANOSCALE MATERIALS UNDER THE TOXIC SUBSTANCES CONTROL ACT (2006), available at <http://www.abanet.org/environ/nanotech/>; SECTION OF ENV'T, ENERGY, AND RES., AM. BAR ASS'N, THE ADEQUACY OF FIFRA TO REGULATE NANOTECHNOLOGY-BASED PESTICIDES (2006), available at <http://www.abanet.org/environ/nanotech/>; DAVIES, *supra* note 5; PETER D. HART RESEARCH ASSOCS., INC., REPORT FINDINGS: BASED ON A NATIONAL SURVEY OF ADULTS (2006), available at http://www.nanotechproject.org/file_download/98; ANDREW D. MAYNARD, WOODROW WILSON INT'L CTR. FOR SCHOLARS, PROJECT ON EMERGING NANOTECHNOLOGIES, NANOTECHNOLOGY: A RESEARCH STRATEGY FOR ADDRESSING RISK (2006), available at http://www.nanotechproject.org/publications/archive/nanotechnology_research_strategy_for/; CTR. FOR SCI., TECH., & PUB. POLICY, *supra* note 8.

60. MACOUBRIE, *supra* note 6.

technologies shows the need to consider appropriate oversight models for nanotechnology and then to develop whatever new or modified oversight mechanisms, if any, are required. For instance, the field of gene transfer research in human beings (often called “gene therapy”) was jolted by the 1999 death of 18-year-old Jesse Gelsinger, a gene transfer research subject, and subsequent revelations of other adverse events that had not been successfully communicated between the key oversight bodies: the FDA and the Recombinant DNA Advisory Committee (RAC).⁶¹

Examples outside the domain of biomedicine include the 1999-2000 failure to segregate a genetically modified food source approved only for animal feed. StarLink was a genetically modified yellow corn variety containing an insecticidal protein.⁶² The EPA approved it for use only in animal feed due to concern that the genetically modified protein, Cry9C, did not break down easily in the human digestive system and might provoke human allergies.⁶³ However, StarLink became commingled with corn-based products in the human food supply in an evident failure of enforcement by post-market oversight systems.⁶⁴ The backlash and negative effect on public confidence were considerable.⁶⁵

If nanotechnology is to avoid similar negative events and ensuing setbacks, it is important to consider how to proactively create and implement an effective oversight system.

III. DEVELOPING OVERSIGHT OPTIONS FOR NANOTECHNOLOGY

There are a number of oversight options for nanotechnology, including creating new laws and regulations for applications of nanotechnology, revising existing laws and

61. Doris Teicher Zallen, *US Gene Therapy in Crisis*, 16 TRENDS GENETICS 272, 274 (2000).

62. MICHAEL R. TAYLOR & JODY S. TICK, THE STARLINK CASE: ISSUES FOR THE FUTURE 3 (2001), available at http://www.pewtrusts.org/our_work_ektid33384.aspx?category=442.

63. *Id.*

64. *Id.*

65. *Id.*

regulations, interpreting existing laws and regulations to cover nanoproducts, designing new non-regulatory governance approaches (e.g., voluntary standards), and revising existing non-regulatory approaches.

Oversight frameworks and regulatory approaches are diverse, and this oversight is conducted by a range of institutions with various capabilities, cultures, and motives.⁶⁶ Regulations can articulate general guidelines or specific standards. They can regulate the result or mandate the processes by which the results are achieved. They can operate by motivating industry to share information, innovate, or change to meet articulated targets, or they can manage industry more directly through what is often called “command and control.”⁶⁷ Regulatory and oversight tools include performance standards, tradable allowances, consultation between government and industry, and pre-market safety and efficacy reviews. The choice of approach can profoundly affect technological development, individual interests, and collective interests.⁶⁸ It is important to achieve an appropriate balance so that oversight does not stifle innovation or impose unnecessary costs or burdens.

Nanotechnology may pose significant oversight challenges. The diversity of nanoproducts may preclude a single approach or framework and instead require different oversight regimes for different product types. In addition, risk assessment for nanomaterials may be difficult. There is little information to date on the effects of nanotechnology, including what types of human exposure to anticipate, dose-response relationships, kinetics and cellular interactions, fate and transport in the environment, and correlations of properties of materials to their toxicity. A number of commentators believe that any risk assessment should consider the special properties and effects of nanoparticles and that new toxicology strategies are needed.⁶⁹ Disappointed with current movement

66. See John Abraham, *Regulatory Science as Culture: Contested Two-Dimensional Values at the US FDA*, 11 *SCI. AS CULTURE* 309, 309–14, 329–31 (2002).

67. Jonathan B. Wiener, *The Regulation of Technology, and the Technology of Regulation*, 26 *TECH. SOC'Y* 483, 489 (2004).

68. See generally *id.* (tracing the development and effects of various types of regulatory instruments).

69. See, e.g., Günter Oberdörster et al., *Nanotoxicology: An Emerging Discipline Evolving from Studies of Ultrafine Particles*, 113 *ENVTL. HEALTH*

towards voluntary and industry-driven schemes, a coalition of civil society, public interest, environmental, and labor organizations have signed a statement articulating general principles for nanotechnology oversight.⁷⁰ These include the creation of a precautionary foundation, developing mandatory nano-specific regulations along with provisions for manufacturer liability, assuring the health and safety of the public and workers, protecting the environment, and facilitating transparency and public participation in the process.⁷¹

Because nanotechnology raises significant oversight challenges, it is important to consider now what kind of oversight structures and processes would work well. This calls for evaluating both emerging approaches to nanotechnology oversight as well as oversight strategies used in the past for closely related technologies. We can learn from case studies of oversight for past technologies and products which approaches have worked well and which have not.⁷²

There are some methods already in use for evaluating oversight approaches, though they may require refinement. These methods are grounded in different disciplines and literatures, including public policy analysis, economic impact assessment, and ethical evaluation. Whatever the disciplinary origin, evaluation of oversight models to date has typically used just a few criteria for analysis. For example, regulatory impact assessment (RIA) by the U.S. federal government has focused on the benefits and economic costs of proposed rules.⁷³ Executive Order 12,866 on *Regulatory Planning and Review* suggests broader criteria, requiring for every new regulation

PERSP. 823, 835 (2005).

70. See ACCIÓN ECOLÓGICA ET AL., PRINCIPLES FOR THE OVERSIGHT OF NANOTECHNOLOGIES AND NANOMATERIALS 1 (2008), available at http://www.icta.org/pubs/publications.cfm?page_id=15§ion_title=Nanotechnology.

71. *Id.* at 2.

72. This is the focus of our current National Science Foundation grant, SES-0608791 (Principal Investigator Susan M. Wolf; Co-Principal Investigators Efrosini Kokkoli, Jennifer Kuzma, Jordan Paradise and Gurusurthy Ramachandran). Co-author Ralph Hall serves as a Working Group member on this project. An abstract is available at <http://nsf.gov/awardsearch/showAward.do?AwardNumber=0608791>.

73. See U.S. EPA, GUIDELINES FOR PERFORMING REGULATORY IMPACT ANALYSIS, at M2 (1983), available at <http://yosemite.epa.gov/ee/epa/erm.nsf/vwRepNumLookup/EE-0228A?OpenDocument>.

not only a cost-benefit test, but also evaluation of adverse effects of regulations on health and the environment, qualitative assessment of distributional impacts, and assurances of transparency.⁷⁴

Some groups of scholars are making progress in systematically integrating multiple criteria for analyzing oversight frameworks. For example, one team designed the Fast Environmental Regulatory Tool (FERET) as a computerized template to “structure the basic integration of impacts and valuation; provide a core survey of the literature; incorporate uncertainty through simulation methods; and deliver a bottom line benefit-cost analysis that reports quantitative impacts, economics values, and qualitative elements.”⁷⁵ A more qualitative oversight evaluation method grounded in bioethics is reported in a 2004 article from the Consortium to Examine Clinical Research Ethics.⁷⁶ This diverse expert group designed fifteen oversight problems in research involving human participants and evaluated whether proposed reforms would address those challenges.⁷⁷

Oversight evaluation methods thus range from quantitative models to qualitative expert group consensus approaches. Whichever method we use to develop nanotechnology oversight options, a preliminary inquiry should focus on the goals oversight should serve. Likely goals in developing oversight mechanisms for nanotechnology are transparency in development, opportunities for public input, accountability to diverse stakeholders, ability to safeguard human and environmental health, and ability to foster innovation. The mechanisms should also be able to cope with novel materials that will undoubtedly be developed over time.

Debate over the need for and ultimate scope of nanotechnology oversight is becoming increasingly urgent. Development of sound oversight mechanisms responsive to public concerns and values as well as nanoscience innovation

74. Wiener, *supra* note 67, at 493.

75. R. Scott Farrow et al., *Facilitating Regulatory Design and Stakeholder Participation: The FERET Template with an Application to the Clean Air Act*, in *IMPROVING REGULATION: CASES IN ENVIRONMENT, HEALTH AND SAFETY* 429, 430 (Paul Fischbeck & R. Scott Farrow eds., 2001).

76. See Ezekiel J. Emanuel et al., *Oversight of Human Participants Research: Identifying Problems to Evaluate Reform Proposals*, 141 *ANNALS INTERNAL MED.* 282, 282 (2004).

77. *Id.*

will be critical to the evolution of this field. Creating oversight systems can and should be deliberate, schooled by analyses of different oversight regimes and historical consideration of which oversight approaches have worked well for related technologies in the past.