
What Does the History of Technology Regulation Teach Us about Nano Oversight?

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"We live in reference to past experience and not to future events, however inevitable."

— H. G. Wells¹

Nanotechnology is the latest in a growing list of emerging technologies that includes nuclear technologies, genetics, reproductive biology, biotechnology, information technology, robotics, communication technologies, surveillance technologies, synthetic biology, and neuroscience. As was the case for many of the technologies that came before, a key question facing nanotechnology is what type of regulatory oversight is appropriate for this emerging technology. As two of us wrote several years ago, the question facing nanotechnology is not whether it will be regulated, but when and how.²

Yet, appropriate regulation of nanotechnology will be challenging. The term "nanotechnology" incorporates a broad, diverse range of materials, technologies, and products, with an even greater spectrum of potential risks and benefits. This technology slashes across the jurisdiction of many existing regulatory statutes and regulatory agencies, and does so across the globe. Nanotechnology is developing at an enormously rapid rate, perhaps surpassing the capability of any potential regulatory framework to keep pace. Finally, the risks of nanotechnology remain largely unknown, both because of the multitude of variations in the technology and because of the limited applicability of traditional toxicological approaches such as structure-activity relationship (SAR) to nanotechnology products.³

In the face of these challenges, legislators, regulators, industry officials, non-governmental organizations (NGOs), and academics are all struggling to find a workable regulatory path for oversight of nanotechnology. In crafting such a strategy, there is much we can learn from previous attempts to regulate other emerging technologies. While there are no doubt numerous possible lessons that can be drawn from the history of

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technology regulation, we suggest that the following five lessons should be given strong consideration in designing oversight frameworks for nanotechnology.

Lesson 1: Central Importance of Public Confidence/Trust

The most obvious and widely accepted lesson from the history of technology regulation is the critical role of public confidence and trust. While scientific risk assessment and economic calculations are part of sound regulatory decision making, they alone cannot assure a viable regulatory scheme in the absence of public trust.

maintaining public trust, providing another rationale for adoption of regulation beyond the substantive need for such provisions.¹⁰

Lesson 2: Level the Playing Field

Perhaps in tension with the first lesson on the need to impose regulatory oversight that will promote public confidence, the second lesson from past efforts is to avoid the temptation to impose discriminatory regulatory burdens on new technologies, even when public sentiment seems to weigh in favor of such restrictions. New technologies and products often have lower risks

At the very time that technology is accelerating, both legislative and regulatory decision-making institutions seem to be bogging down and becoming slower. Congress is handcuffed by the synergistic effect of an impossibly large number of important issues needing attention mixed with partisan gridlock, making prompt action on any but the most urgent or symbolic issues unlikely.

Time after time, we have seen examples in which a single incident gone awry undermined years of careful planning and building of regulatory systems. Examples include the Three Mile Island nuclear accident,⁴ the contamination of the food supply with genetically modified “Starlink” corn that had been approved only for use in animal feed,⁵ and the tragic death of Jesse Gelsinger in a gene therapy clinical trial.⁶ All of these incidents sparked subsequent official investigations and media scrutiny that revealed significant flaws and failures in the regulatory system that severely undermined public trust in both the technology at issue, and the regulatory programs responsible for the oversight of that technology.

False assurances of safety can also undermine trust in regulators and regulatory systems. A classic example of this effect is the British Government’s assurance in the late 1980s and early 1990s that the “mad cow” disease affecting British cattle had no probability of spreading to humans. When British citizens soon began falling ill and dying from the human version of “mad cow” disease (Creutzfeldt-Jakob disease, or CJD), the credibility of British regulators suffered long-term damage.⁷

Public trust is much easier lost than earned, and once lost, it is very difficult to restore.⁸ Surveys indicate that public trust in nanotechnology and its oversight requires an active and formal governmental regulatory role.⁹ Accordingly, it seems that the establishment of a regulatory scheme is a prerequisite for

than the technologies and products they are intended to replace, yet are often subject to stigmatization by the media and advocacy groups resulting in more stringent regulation.¹¹ At the same time, powerful new technologies such as nanotechnology will undoubtedly impose real risks in at least some applications or contexts. In seeking to predict and prevent such risks, regulation must take care not to selectively target products made using a particular process or technology in the absence of evidence showing that the process or technology is any riskier than alternatives.

The European Union (EU) has violated this principle by regulating food made using genetic engineering much more stringently than equivalent products made using other methods. All foods containing genetically modified (GM) ingredients are per se subject to stringent and burdensome authorization, labeling, and traceability requirements that do not apply to non-GM foods.¹² Scientific authorities around the world have consistently concluded that GM foods as a category are no riskier than any other type of food.¹³ In fact, the EU’s own scientific advisors concluded that “[t]he use of more precise technology and the greater regulatory scrutiny probably make (GM products) even safer than conventional plants and foods.”¹⁴

Notwithstanding this scientific opinion, GM foods are regulated more stringently than other foods in the EU, and to a lesser extent also in the United States. Not only is this discrimination contrary to prevailing scientific opinion, it is also irrational. Consider the

example of herbicide-resistant crops.¹⁵ Some herbicide-resistant crops have been produced using genetic engineering, but some cultivars with the same trait have also been produced using other means, including chemical or nuclear mutagenesis. These latter techniques are much less precise than genetic engineering, and are likely to generate numerous other mutations along the genome in addition to the herbicide-resistance trait of interest.¹⁶ The National Academy of Sciences has noted that “a mutation made by traditional techniques may be accompanied by many unknown mutations, which often have deleterious effects on the organism.”¹⁷ Yet, in “what can only be described as a culture of irrationality,” the regulatory structure penalizes the arguably safer GM crop by regulating it, but not the mutation-laden crop expressing the same trait produced by other methods.¹⁸

Proposals for *sui generis* regulation of nanotechnology products create a similar risk of irrational discrimination. If we have two products with the same functionality — one produced using nanotechnology and the other not — it is not certain or obvious that the nanotechnology version will necessarily be the riskier of the two. They may have the same risks or in some cases the nanotechnology product might even be safer. Automatically treating nanotechnology as more dangerous and thus needing additional regulation will be putting a thumb on the scale against nanotechnology, deterring companies from using nanotechnology except when no other alternative is available.

There is evidence from an incident in Germany in 2006 that the media and some activist organizations are indeed primed to apply a double-standard to nanotechnology. A new bathroom cleaning product called “Magic Nano” was commercially launched, and within a couple days dozens of people started complaining of “inhalation injuries” and several individuals were hospitalized.¹⁹ Front-page newspaper stories around the world promptly focused on the call by some activist groups for an immediate global moratorium on nanotechnology in light of this apparent hazardous response.²⁰ Shortly thereafter, the German government announced that “Magic Nano” was misleadingly named and in fact contained no nanotechnology.²¹ Concern about the incident, and the consumers who had been harmed by the product, quickly faded. It seems that only injuries caused by a nanotechnology product were of significance; the exact same injuries caused by a non-nano product were not of interest, although to the victims it made no difference whether it was a nano or non-nano product that harmed them. Reflecting on this incident suggests a tendency to preferentially stigmatize and discriminate against nano-products. This

incident, and the history of discriminatory regulation and stigmatization of other technology products such as GM foods, indicates the need for a fair and non-discriminatory regulatory approach,²² much like the principle of international trade law against regulating products based on their “process and production methods” (PPMs).²³

Lesson 3: Adaptive Regulatory Approaches

A third lesson from the history of technology regulation is that oversight frameworks need to be adaptable and flexible to keep pace with rapidly evolving technologies. As the rate of development of science and technology has accelerated,²⁴ legislative and regulatory oversight has struggled to keep up-to-date with the technologies they purport to regulate.²⁵ The Office of Technology Assessment (OTA) noted in 1986 that “[o]nce a relatively slow and ponderous process, technological change is now outpacing the legal structure that governs the system, and is creating pressures on Congress to adjust the law to accommodate these changes.”²⁶

At the very time that technology is accelerating, both legislative and regulatory decision-making institutions seem to be bogging down and becoming slower. Congress is handcuffed by the synergistic effect of an impossibly large number of important issues needing attention mixed with partisan gridlock, making prompt action on any but the most urgent or symbolic issues unlikely. For most issues, there is little chance of laws being updated except during infrequent policy “windows” in which circumstances align to bring the issue to a brief moment of congressional attention.²⁷ Once Congress has acted, it may be years or even decades before the issue is revisited by Congress. Similarly, agency rulemaking has been slowed by the myriad of analytical requirements imposed on agencies, the threat of judicial reversal, and the dynamics of interest group politics.²⁸

The combination of this legislative and regulatory inertia has resulted in increasingly obsolete regulatory frameworks where statutes do exist (e.g., many environmental problems, such as the lack of effective regulatory authority over non-point sources under the Clean Water Act).²⁹ Perhaps even worse, for many relatively new technologies, there is no meaningful existing regulatory framework (e.g., embryonic stem cell research, artificial reproductive technologies, pre-implantation genetic screening, direct-to-consumer genetic testing, new surveillance technologies, and internet privacy).³⁰

Lyria Bennett Moses has identified four potential problems that may result from the failure of law to keep pace with technology, including: (1) the failure to

impose appropriate legal restrictions and precautions to control the risks of new technologies; (2) uncertainties in the application of existing legal frameworks to new technologies; (3) the potential for existing rules to either under- or over-regulate new technologies; and (4) the potential for technology to make existing rules obsolete.³¹ For nanotechnology, this “pacing” problem seems particularly acute, given the rapid pace at which the technology is developing: “We have moved into...a ...world dominated by rapid improvements in products, processes, and organizations, all moving at rates that exceed the ability of our traditional governing institutions to adapt or shape outcomes. If you think that any existing regulatory framework can keep pace with this rate of change, think again.”³²

It may therefore be necessary to create innovative, non-traditional regulatory oversight models that will be capable of keeping up-to-date with rapidly developing nanotechnologies.³³ As a senior Intel executive testified to Congress:

What we want to avoid is for the trajectory of nanotechnology to follow that of genetically-modified organisms (GMOs), the most recent ‘magic’ technology. In the case of GMOs, deployment of applications outpaced attention to the environmental, health, and safety implications of the technology. Public concerns that arose because of this have significantly retarded the realization of GMO’s great commercial potential.³⁴

One limited approach to this need to keep regulatory oversight up-to-date with rapidly evolving nanotechnologies would be to incorporate some type of procedural timing mechanism in any statute or regulation specifically directed at nanotechnology, such as a sunset provision or a mandatory independent periodic review requirement that forces revisiting the regulatory approach at regular intervals. A more radical approach would be to consider some alternative form of regulatory oversight mechanism, such as the environmental covenants used in the Netherlands³⁵ or principles-based regulation,³⁶ both of which provide for a more fluid, evolving oversight system.

Lesson 4: Address Social and Moral Concerns

For many emerging technologies, including nanotechnology, public concerns tend to have a strong social or ethical element, in addition to more traditional health, safety, and environmental concerns that regulation has traditionally addressed. These social and ethical issues include the power of corporations to make unilateral decisions about new technologies that can fun-

damentally reshape society; fairness and equity concerns about the distribution of new technologies and their benefits; disruptions to the “natural” purity of food, the human body, or nature; and the ever-present “yuck” factor or repugnance in response to technological developments that cause discomfort or unease, at least on first impression, for many citizens.³⁷

Whatever the substantive merits of these social and ethical concerns, it is imperative that they be given due consideration in a democratic governance system. Unfortunately, existing regulatory frameworks often exclude consideration of social and moral concerns, ruling them outside the bounds of the jurisdiction of regulatory agencies or reviewing courts. An early example of such preclusion was the initial decision to patent living organisms. Unlike its European counterpart (the European Patent Organization), which applies the “*ordre public*” (or public morality) clause to deny patents to morally objectionable technologies,³⁸ the U.S. Patent and Trademark Office is without authority to consider the moral implications of patent applications.³⁹ Moreover, when various religious, environmental, and animal rights groups filed amicus briefs objecting to the patenting of living organisms on ethical grounds, the U.S. Supreme Court refused to consider such arguments on their merits:

[W]e are without competence to entertain these arguments....The choice we are urged to make is a matter of high policy for resolution within the legislative process after the kind of investigation, examination, and study that legislative bodies can provide and courts cannot. That process involves the balancing of competing values and interests, which in our democratic system is the business of elected representatives. Whatever their validity, the contentions now pressed on us should be addressed to the political branches of the Government, the Congress and the Executive, and not to the courts.⁴⁰

A similar exclusion of ethical and social concerns occurs in approval decisions by the Food and Drug Administration (FDA), which has jurisdiction over many medical and related products that raise such issues.⁴¹ For example, thousands of members of the public submitted comments to the FDA raising social and ethical concerns about the FDA’s proposed decision to approve the marketing of milk and meat from cloned animals.⁴² While one could take issue with these claims on their merits, the FDA refused to engage the issues altogether, instead dismissing such claims with a cursory statement that “the agency has not been charged with addressing moral, religious, or ethical

issues associated with animal cloning.”⁴³ Yet, a public opinion poll found that 63 percent of respondents felt (53% felt strongly) that “government regulators should include ethical and moral considerations, in addition to scientific evaluation of risks and benefits, when making regulatory decisions about cloning and genetically modifying animals.”⁴⁴ The FDA’s refusal to consider such concerns is undoubtedly correct in a legal sense, since the agency has only been charged by Congress with ensuring that products are “safe” and “efficacious,” criteria which do not seem to incorporate broader ethical or social concerns. Nonetheless, it is problematic and short-sighted to reject out-of-hand the deeply felt views of many Americans who take the time to comment on a proposed action by their government, simply because their concerns are outside the agency’s constrained mission.

To be sure, there are reasons why it may be problematic to require regulatory agencies to expressly include moral and social considerations in their decision-making criteria.

Other examples involving emerging technologies likewise suggest a systematic problem of failing to address the moral and social concerns expressed by many citizens. Much of the opposition to GM crops and foods is also based on ethical, social, and religious concerns,⁴⁵ yet both the FDA and reviewing courts have refused to give any weight to such considerations.⁴⁶ The approval of drugs such as human growth hormone that could be used for enhancement as well as therapeutic applications has also proceeded without any significant consideration of the ethical concerns about such enhancement uses.⁴⁷ Even Institutional Review Boards (IRBs), expressly charged with ensuring the ethical conduct of human subject research, are precluded from considering broader social and ethical implications of the proposed research: “The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.”⁴⁸

There is a growing realization that there may be a need to expand the decision-making criteria or create new institutions to expressly consider the moral and social aspects of new technologies. For example, the Department of Health and Human Service Secre-

tary’s Advisory Committee on Genetic Testing recommended in 2000 that:

In the future, tests may be developed that raise major social and ethical concerns. Because FDA’s review will focus on assuring the analytical and clinical validity of a test, the agency’s capacity to assess the ethical and social implications of a test may not be sufficient. The Secretary should consider the development of a mechanism to ensure the identification and appropriate review of tests that raise major social and ethical concerns.⁴⁹

To be sure, there are reasons why it may be problematic to require regulatory agencies to expressly include moral and social considerations in their decision-making criteria. Unlike safety and efficacy, where people can fairly easily reach consensus on what is a good or bad result (e.g., causing tumors is bad), there is more room for disagreement on what is a good or bad moral or social effect (e.g., people may disagree on whether the [hypothetical] impact of genetic engineering in promoting the consolidation of small family farms into larger, more efficient industrial farms is a favorable or unfavorable outcome). In the same vein, social and ethical risks are more intangible, harder to define and quantify, and thus do not lend themselves to the same type of quantitative analyses common for safety or efficacy determinations.

Other problems likewise justify caution in making our regulatory agencies the deciders of moral correctness. The professional staff of regulatory agencies currently consists primarily of scientists, economists, and attorneys. Should these agencies be staffed much more heavily with ethicists and social scientists? The FDA’s reluctance to approve over-the-counter sales of the “Plan B” post-coital contraceptive on what appeared to be moral rather than scientific grounds caused widespread unease and objections.⁵⁰ Would we accept a government agency making such moral and social decisions explicitly, especially when the outcome might shift dramatically with a change in administration? And given that ethical and moral concerns are closely tied to religious beliefs for many people, would this create a risk of violating the First Amendment requirement for separation of church and state?

These concerns suggest that it might be problematic to give regulatory agencies direct and express authority to make ethical or social judgments. On the other hand, it may be even more objectionable to avoid these ethical and social considerations altogether. A possi-

ble, initial compromise would be to set up an ethical and social advisory committee within each regulatory agency to weigh in on the ethical and social dimensions of proposed regulatory actions.⁵¹ A potential precedent for such an approach is the European Group on Ethics in Science and New Technologies (EGE), which provides ethical and social advice to the European Commission and other EU governing bodies relating to the ethical aspects of the sciences and new technologies.⁵²

Lesson 5: International Harmonization

Regulation of new technologies has historically been at a national (or subnational) level, which is a natural focus given existing legal jurisdictions, decision-making structures, and institutions. This nation-by-nation approach has, however, resulted in inefficiencies and conflicts with regard to some past technologies, due to inconsistencies among national approaches. For example, the sharply different regulatory approaches of the United States and EU toward GM foods have resulted in significant global trade disruptions and disputes.⁵³ The inter-national and even intra-national jurisdictional discrepancies in embryonic stem cell policies have likewise resulted in a patchwork of different rules and requirements that disrupts scientific progress, stability, and coordination.⁵⁴ International differences in digital copyright and internet privacy also create problems, given the increasingly international scope of economic and social activity.⁵⁵ These problems — experienced as a result of inconsistent national policies, along with the growth of inherently international issues such as climate change and assigning internet domain names — have created a growing interest and emphasis on mechanisms for international harmonization of technology oversight systems.

International harmonization can provide additional benefits beyond minimizing disruptions to global trade and scientific coordination. First, many materials cross national boundaries, either as manufactured products sold in commerce or as environmental contaminants in the air or water. A consistent set of safety and environmental standards across jurisdictions may therefore enhance protection of human health and the environment. Second, multinational companies that manufacture or handle materials such as nanotechnology will benefit from the efficiency and consistency of harmonized regulatory requirements in a global marketplace. Third, international harmonization can prevent a “race to the bottom” or “risk havens” in which some nations may refrain from taking appropriate regulatory oversight in order to attract companies to locate in their jurisdiction.

International harmonization can proceed using one of two sequencing options. The first approach would be

to adopt national regulations first, followed by a subsequent phase that seeks to harmonize the pre-existing national regulations. Francis Fukuyama appears to endorse this approach when he writes: “[R]egulation cannot work in a globalized world unless it is global in scope. Nonetheless, national-level regulation must come first. Effective regulation almost never starts at an international level...”⁵⁶ But developing national regulations prior to pursuing international harmonization has two costs. First, it delays international harmonization until after national responses have been adopted and implemented, which could result in substantial delays. Second, and more significantly, international harmonization may be more difficult in the face of entrenched and inconsistent national regulations. This was the case, for instance, with regulations of GM foods, where both the United States and Europe were unwilling to back down from their regulatory approach and be perceived as acceding to the contrary approach of the other.

Of course, international regulation is extremely challenging given the many players and their technological, economic, political, and social differences. Incremental international harmonization, such as development of a framework agreement or other “soft law” approaches, may be the most effective way to begin international harmonization from the “ground up” for an emerging technology such as nanotechnology.⁵⁷

Conclusion

Although nanotechnology is relatively new, attempts to regulate emerging technologies are not, as we have now compiled significant experience and learning about the challenges and opportunities of regulating technology. The five lessons briefly summarized here are examples of such learning, and no doubt there are many more lessons and perspectives that can be gleaned from the growing empirical record on technology regulation. While Edmund Burke warned that “[y]ou can never plan the future by the past,”⁵⁸ it is nevertheless true that by looking backwards in time, we can learn much that can inform and enlighten our look forward at the emerging nanotechnology era and its regulatory oversight.

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References

1. H. G. Wells, *Mind at the End of Its Tether*, quoted in E. Ehrlich and M. de Bruhl, *The International Thesaurus of Quotations*, 2nd revised ed. (New York: Collins, 1996): at 493.
2. G. E. Marchant and D. Sylvester, "Transnational Models for Regulation of Nanotechnology," *Journal of Law, Medicine & Ethics* 34, no. 4 (2006): 714-725, at 714.
3. G. Oberdörster et al., "Principles for Characterizing the Potential Human Health Effects from Exposure to Nanomaterials: Elements of a Screening Strategy," *Particle & Fibre Toxicology* 2, no. 8 (2005): 1-35, at 19.
4. J. V. Rees, *Hostages of Each Other: the Transformation of Nuclear Safety Since Three Mile Island* (Chicago, IL: University of Chicago Press, 1994); R. E. Kasperon et al., "The Social Amplification of Risk: A Conceptual Framework," *Risk Analysis* 8, no. 2 (2006): 177-187.
5. D. L. Uchtmann, "StarLink – A Case Study of Agricultural Biotechnology Regulation," *Drake Journal of Agricultural Law* 7, no. 1 (2002): 159-211.
6. R. Weiss and D. Nelson, "Gene Therapy's Troubling Crossroads: A Death Raises Questions of Ethics, Profit, Science," *Washington Post*, December 31, 1999, at A3.
7. See K. K. Jensen, "BSE in the UK: Why the Risk Communication Strategy Failed," *Journal of Agricultural & Environmental Ethics* 17, nos. 4-5 (2004): 405-423.
8. P. Slovic, "Perceived Risk, Trust, and Democracy," *Risk Analysis* 13, no.6 (2006): 675-682; D. M. Bowman and G. A. Hodge, "'Governing' Nanotechnology without Government?" *Science & Public Policy* 35, no. 7 (2008): 475-487, at 483.
9. J. Macoubrie, *Informed Public Perceptions of Nanotechnology and Trust in Government* (Washington, D.C.: Project on Emerging Nanotechnologies, 2005): at 19.
10. D. J. Sylvester, K. W. Abbott, and G. E. Marchant, "Not Again! Public Perception, Regulation, and Nanotechnology," *Regulation and Governance* (in press, 2009); R. Bratspies, "Some Thoughts on the American Approach to Regulating Genetically Modified Organisms," *Kansas Journal of Law & Public Policy* 16, no. 3 (2007): 393-423, at 395-397.
11. G. R. Heaton and R. D. Banks, "Toward a New Generation of Environmental Technology: The Need for Legislative Reform," *Journal of Industrial Ecology* 1, no. 2 (1997): 23-32, at 23; P. Huber, "The Old-New Division in Risk Regulation," *Virginia Law Review* 69, no. 6 (1983): 1025-1106; R. Gregory, J. Flynn, and P. Slovic, "Technological Stigma," *American Scientist* 83, no. 3 (1995): 220-223, at 220-221.
12. European Union, Council Regulation No. 1830/2003, Concerning the Traceability and Labeling of Genetically Modified Organisms and the Traceability of Food and Feed Products Produced from Genetically Modified Organisms, 2003 O.J. (L 268) 24, 24.
13. See, e.g., National Research Council, *Genetically Modified Pest-Protected Plants: Science and Regulation* (Washington, D.C.: National Academies Press, 2000): at 43 ("There is no strict dichotomy between, or new categories of, the health and environmental risks that might be posed by transgenic and conventional pest-protected plants."); National Research Council, *Environmental Effects of Transgenic Plants* (Washington, D.C.: National Academies Press, 2002): at 49 (reaffirming the finding that "the transgenic process presents no new categories of risk compared to conventional methods of crop improvement"); National Research Council, *Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects* (Washington, D.C.: National Academies Press, 2004) ("Genetic engineering...poses no unique health risks that cannot also arise from conventional breeding and other genetic alteration methods.");
14. European Commission, *A Review of Results: EC-Sponsored Research on Safety of Genetically Modified Organisms*, C. Kessler and I. Economidis, eds. (Luxembourg: Office for Official Publications of the European Communities L-2985, 2001) available at <<http://europa.eu.int/comm.research/quality-of-life/gmo>> (last visited March 25, 2009).
15. S. H. Morris, "EU Biotech Crop Regulations and Environmental Risk: A Case of the Emperor's New Clothes?" *Trends in Biotechnology* 25, no. 1 (2007): 2-6.
16. A. McHughen, *Pandora's Picnic Basket: The Potential and Hazards of Genetically Modified Foods* (New York: Oxford University Press, 2000): at 62-72.
17. National Academy of Sciences, *Introduction of Recombinant DNA-Engineered Organisms into the Environment: Key Issues* (Washington, D.C.: National Academy Press, 1987): at 11.
18. See Morris, *supra* note 15, at 5.
19. R. F. Wilson, "Nanotechnology: The Challenge of Regulating Known Unknowns," *Journal of Law, Medicine & Ethics* 34, no. 4 (2006): 704-713; see Bowman and Hodge, *supra* note 8, at 481.
20. C. Pillar, "Science's Tiny, Big Unknown," *Los Angeles Times*, June 9, 2006, at 1; R. Weiss, "Nanotech Product Recalled in Germany," *Washington Post*, April 6, 2006, at A2.
21. See Editorial, "Safeguard on Nanotechnology," *Christian Science Monitor*, May 20, 2008, at 8.
22. G. E. Marchant, "Lessons for New Technologies," Mercatus Center Working Paper 08-26, August 2008, available at <http://my.mercatus.org/uploadedFiles/Mercatus/Publications/WP0826_RSP_Lessons%20for%20New%20Technologies.pdf> (last visited June 3, 2009) (calling for enshrinement of the principle of non-discrimination in regulatory regimes).
23. R. Read, "Like Products, Health and Environmental Exceptions: The Interpretation of PPMs in Recent WTO Trade Dispute Cases," *Estey Centre Journal of International Law & Trade Policy* 5, no. (2004): 123-146.
24. See generally R. Kurzweil, *The Singularity Is Near: When Humans Transcend Biology* (New York: Viking Press, 2005).
25. L. B. Moses, "Recurring Dilemmas: The Law's Race to Keep Up with Technological Change," *University of Illinois Law, Technology & Policy* 2007, no. 2 (2007): 239-285.
26. Office of Technology Assessment, *Intellectual Property Rights in an Age of Electronics and Information* (Washington, D.C.: Government Printing Office, 1986): at 3.
27. J. W. Kingdon, *Agendas, Alternatives, and Public Policies*, 2nd ed. (Upper Saddle River, NJ: Pearson Education Press, 1995).
28. T. O. McGarity, "Some Thoughts on Deossifying the Rulemaking Process," *Duke Law Journal* 41, no. 6 (1992): 1385-1462.
29. See, e.g., J. M. McElfish Jr. et al., "Inventing Nonpoint Controls: Methods, Metrics and Results," *Villanova Environmental Law Journal* 17, no. 1 (2006): 87-216.
30. See, e.g., President's Council on Bioethics, *Reproduction and Responsibility: The Regulation of New Biotechnologies*, Washington, D.C., 2004, at xvii ("[R]egulatory institutions have not kept pace with our rapid technological advance. Indeed, there is today no public authority responsible for monitoring or overseeing how these [reproductive] technologies make their way from the experimental to the clinical stage, from novel approach to widespread practice. There is no authority, public or private, that monitors how or to what extent these new technologies are being or will be used, or that is responsible for attending to the ways they affect the health and well-being of the participants or the character of human reproduction more generally"); D. J. Solove, "Reconstructing Electronic Surveillance Law," *George Washington Law Review* 72, no. 6 (2004): 1264-1305, at 1266 ("[E]lectronic surveillance law... has failed to keep pace in adapting to new technologies, and... provides for insufficient judicial and legislative oversight."); G. H. Javitt, E. Stanley, and K. Hudson, "Direct-to-Consumer Genetic Tests, Government Oversight, and the First Amendment: What the Government Can (and Can't) Do to Protect the Public's Health," *Oklahoma Law Review* 57, no. 2 (2004): 251-302, at 301 ("Many critics lament both the lack of federal oversight of genetic tests and the increasing efforts by some companies to promote and sell them directly to consumers.");
31. See Moses, *supra* note 25, at 248.

32. D. Rejeski, "The Next Small Thing," *The Environmental Forum* (March/April 2004): 42-49, at 42, 45.
33. G. E. Marchant, D. S. Sylvester, and K. W. Abbott, "Risk Management Principles for Nanotechnology," *NanoEthics* 2, no. 1 (2008): 43-60, at 50-53; see Bowman and Hodge, *supra* note 8, at 477.
34. Testimony of Stephen Harper, Director of EHS Policy, Intel Corp., *Prepared Testimony to the Senate European Affairs Subcommittee of the Foreign Relations Committee 9-10*, May 11, 2005, available at <<http://foreign.senate.gov/testimony/2005/HarperTestimony050511.pdf>> (last visited June 3, 2009).
35. D. J. Fiorino, *The New Environmental Regulation* (Cambridge: MIT Press, 2006): at 179-186. Under the Dutch covenants program, the government sets broad environmental goals, and then each company negotiates a "covenant" with various regulators and non-governmental organizations that sets forth its environmental obligations. *Id.*, at 181-182. These covenants can be revised and updated more quickly than traditional regulation. *Id.*, at 183.
36. J. Black, "Forms and Paradoxes of Principles Based Regulation," *Capital Markets Law Journal* 3, no. 4 (2008): 425-457. Principle-based regulation is a more decentralized, flexible, and adaptive form of regulation, in which the government promulgates broad principles rather than detailed rules that it requires regulated parties to comply with, and then the regulated entities are responsible for developing their own framework for implementing the governing principles. *Id.*, at 431-432.
37. L. R. Kass, Editorial, "Defending Human Dignity," *American Enterprise Institute Newsletter*, December 2007, at 53; Editorial, "Beyond the Yuck Factor," *New Scientist* 186, no. 2505 (2005): 5; K. Kulinowski, "Nanotechnology: From 'Wow' to 'Yuck?'" *Bulletin of Science, Technology & Society* 24, no. 1 (2004): 13-20.
38. European Patent Office, European Patent Convention, pt. II, ch. I, art. 53, available at <[http://documents.epo.org/projects/babylon/eponet.nsf/0/E4F8409B2A99862FC125736B00374CEC/\\$File/EPC_13th_edition.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/E4F8409B2A99862FC125736B00374CEC/$File/EPC_13th_edition.pdf)> (last visited June 3, 2009). See J. Chambers, "Patent Eligibility of Biotechnological Inventions in the United States, Europe, and Japan: How Much Patent Policy Is Public Policy?" *George Washington International Law Review* 34, no. 1 (2002): 223-246, at 233.
39. M. A. Bagley, "Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law," *William and Mary Law Review* 45, no. 2 (2003): 469-547, at 502.
40. *Diamond v. Chakrabarty*, 447 U.S. 303, 317 (1980).
41. D. Fox, "Safety, Efficacy, and Authenticity: The Gap between Ethics and Law in FDA Decisionmaking," *Michigan State Law Review* 2005, no. 4 (2005): 1135-1197, at 1159-1160.
42. Z. Meghani and I. de Melo-Martin, "The U.S. Food and Drug Administration's Evaluation of the Safety of Animal Clones," *Bulletin of Science, Technology & Society* 29, no. 1 (2009): 9-17, at 9; R. Weiss, "FDA Is Set to Approve Milk, Meat from Clones," *Washington Post*, October 17, 2006, at A1.
43. Food and Drug Administration, *FDA's Response to Public Comment on the Animal Cloning Risk Assessment, Risk Management Plan, and Guidance for Industry* (Docket No. 2003N-0573), January 15, 2009, available at <http://www.fda.gov/cvm/CloningRA_FDAResponse.htm> (last visited March 25, 2009).
44. Mellman Group, *Memorandum to the Pew Initiative on Food and Biotechnology, Recent Findings*, November 7, 2005, at 7, available at <http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/News/Press_Releases/Food_and_Biotechnology/PIFB_Public_Sentiment_GM_Foods2005.pdf> (last visited September 3, 2009).
45. L. Frewer et al., "Societal Aspects of Genetically Modified Foods," *Food & Chemical Toxicology* 42, no. 7 (2004): 1181-1193, at 1183; I. de Melo-Martin and Z. Meghani, "Beyond Risk," *EMBO Report* 9, no. 4 (2008): 302-306, at 302.
46. *Id.* (de Melo-Martin and Meghani), at 302.
47. See Fox, *supra* note 41, at 1179-1189.
48. 45 C.F.R. § 46.111(a)(2) (2007).
49. Secretary's Advisory Committee on Genetic Testing, *Enhancing the Oversight of Genetic Tests: Recommendations of the SACGT*, July 2000, at xi, available at <http://oba.od.nih.gov/oba/sacgt/reports/oversight_report.pdf> (last visited September 3, 2009).
50. S. Kokjohn, "The Imposition of an Age Restriction on Over-the-Counter Access to Plan B Emergency Contraception: Violating Constitutional Rights to Privacy and Exceeding Statutory Authority," *Minnesota Journal of Law, Science & Technology* 9, no. 1 (2008): 369-398.
51. These advisory committees would differ from the more generic, government-wide advisory committee such as the President's Council on Bioethics, in that they would focus on ethical concerns about specific regulatory actions by one agency, rather than the broader issues usually not directly tied to a specific regulatory proposal addressed by the Council on Bioethics.
52. See H. Busby, T. Hervey, and A. Mohr, "Ethical EU Law? The Influence of the European Group on Ethics in Science and New Technologies," *European Law Review* 33, no. 6 (2008): 803-842.
53. See S. A. Blaustein, "Splitting Genes: the Future of Genetically Modified Organisms in the Wake of the WTO/Cartagena Standoff," *Pennsylvania State Environmental Law Review* 16, no. 2 (2008): 367-401.
54. See R. M. Isasi et al., "Legal and Ethical Approaches to Stem Cell and Cloning Research: A Comparative Analysis of Policies in Latin America, Asia, and Africa," *Journal of Law, Medicine & Ethics* 32, no. 4 (2004): 626-640; M. Mariani, "Stem Cell Legislation: An International and Comparative Discussion," *Journal of Legislation* 28, no. 2 (2002): 379-411; P. Lesko and K. Buckley, "Attack of the Clones...and the Issues of Clones," *Columbia Science & Technology Law Review* 3, no. 1 (2002): 1-45.
55. S. Kim, "The Reinforcement of International Copyright for the Digital Age," *Intellectual Property Journal* 16, no. 1 (2002): 93-122; B. Dalling, "Protecting Against International Infringements in the Digital Age Using United States Copyright Law: A Critical Analysis of the Current State of the Law," *Brigham Young University Law Journal* 2001, no. 3 (2001): 1279-1311; C. Bulford, "Between East and West: The APEC Privacy Framework and the Balance of International Data Flows," *I/S: A Journal of Law and Policy for the Information Society* 3, no. 3 (2007-08): 705-722.
56. F. Fukuyama, "Gene Regime," *Foreign Policy* (March/April 2002): 57-63, at 57, 59.
57. See Marchant et al., *supra* note 33, at 58; K. W. Abbott, G. E. Marchant, and D. J. Sylvester, "A Framework Convention for Nanotechnology?" *Environmental Law Reporter* 38, no. 8 (2008): 10507-10514.
58. E. Burke, *Letter to a Member of the National Assembly*, 3rd ed. (Paris, 1791).