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Author: Gregory N. Mandel

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REGULATING EMERGING TECHNOLOGIES

GREGORY N. MANDEL

ABSTRACT

A range of emerging technologies, including biotechnology, nanotechnology, and synthetic biology, are expected to transform society. Handling the development and regulation of these promising technologies is a daunting task as the risks presented will not be understood until the technologies are further developed. This paper proposes a new governance model that seeks manage the dynamic of emerging technology promise versus risk by moving the point of first governance earlier in a technology's development, but enabling the governance structure to evolve after formation. The model aims to turn some of the greatest challenges of managing emerging technologies—scientific uncertainty and the disruption of extant regulatory systems—on their head to create incentives for widespread stakeholder cooperation to produce more proactive, flexible governance.

INTRODUCTION

A wondrous range of emerging technologies are expected to transform society. Biotechnology, nanotechnology, and synthetic biology, to name a few, are anticipated to revolutionize fields as diverse as health care, agriculture, and energy. These innovations may produce wonder drugs that target and destroy cancerous tumors, energy generation that reduces greenhouse gas emissions, and molecular machines that manufacture products cheaply, cleanly, and without waste. On the darker side, these technologies also could produce toxic substances that cause cancer, new organisms that disrupt ecosystems, or self-replicating robots that wreak havoc.

High-potential/high-risk emerging technologies present a social and regulatory quandary. The development and governance of such technologies are inevitably and dynamically intertwined—a technology cannot advance without some freedom in research and development, but too much freedom could lead to a calamity that forecloses any opportunity for the technology. The challenge is how to simultaneously leverage a promising innovation's anticipated benefits while guarding against its potential risks, particularly when the potential risks of the technology cannot be suitably understood until the technology further develops.

This paper proposes a governance system for managing this delicate balance for emerging technologies. Historically, regulation has evolved reactively around relatively mature industries. Most regulation has proven remarkably unyielding to evolution in the face of recognition of its limits and flaws. The new governance¹ model proposed here seeks to move the point of first governance earlier in a technology's development, and enable the governance structure to evolve after its formation. It envisions a more proactive, flexible form of governance; a governance process rather than intractable regulatory rules.

One obstacle to this goal is that new technologies are often met with highly polarized debates over how to manage the development, use, and regulation of the technology (Mandel et al. 2008; Kahan et al. 2007; Abbott et al. 2007; Paddock 2006; Mandel 2005). Proponents of a given technology will argue for promoting rapid technology development, unfettered by unnecessary and costly regulation. Opponents will advocate a stringent regulatory regime to protect against the potential human health and environmental risks of the technology. This polarization usually results in a long period of fractured, at best partially productive, debate. Eventually, after great societal and political resources have been squandered, some form of regulation is instituted. Such regulation then becomes the status quo, tenaciously resistant to change, even as scientific information and the technology advance.

A primary contributor to such polarization and gridlock is the large degree of scientific uncertainty that surrounds any emerging technology, and the regulatory ambiguity that results. Instead of letting the scientific

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¹ "New governance" is a term used to describe more collaborative, flexible, multi-stakeholder regulatory processes and development, often contrasted with conventional top-down, "command and control" regulation.

and regulatory uncertainty to produce stagnation, however, it may be possible to leverage the uncertainty to achieve a more positive outcome. Uncertainty creates problems for all parties involved in a new technology—it creates fear and concern among members of the public and public interest groups, challenges and criticism of regulatory agencies, and limitations on industry plans for investment and development. Rather than being a source of division, it may be possible to harness this common concern. The emergent stage, in particular, with a high degree of uncertainty and a low degree of attachment to a status quo, can present a unique opportunity to bring together diverse stakeholders to produce a collaborative governance product rather than a resource-draining adversarial battle.

1. EMERGING TECHNOLOGY DEVELOPMENT

Though the opportunities for a technology may be literally endless, these opportunities cannot be achieved if a technology is not developed in a secure manner that maintains public confidence. To understand emerging technology development, this analysis draws from various technologies at different stages of technological and commercial maturity, including biotechnology, nanotechnology, and synthetic biology. Examining this range of technological development provides insight for how to manage emerging technologies more generally so as to simultaneously leverage potential benefit and guard against potential risk.

1.1. Biotechnology, Nanotechnology, and Synthetic Biology

Biotechnology, and particularly agricultural biotechnology for the purposes of this discussion, involves the purposeful transfer of one or several genes from one species to another in order to provide enhanced traits (National Research Council 2002). For example, agricultural crops can be genetically modified to include genes that make them pest-protected or herbicide-resistant. The biotechnology discipline developed in the 1970s. Field tests of agricultural biotechnology began in the 1980s, and genetically modified crops were first commercialized in the 1990s. Genetically modified plants currently represent a dominant source of soybean, cotton, and corn production in many countries, particularly the United States. Genetically modified livestock are now close to commercial production as well (Royal Society of Canada 2001).

Nanotechnology involves a variety of activities designed to manipulate matter at the atomic scale (Ratner & Ratner 2003). Building matter from the atom up allows for more precise and complex configuration of material, and permits the production of materials with different physical, chemical, and biological properties than previously possible. Certain materials, for example, become stronger, more flexible, change their conductivity, or develop biological and antimicrobial properties at the nanoscale. Such developments have widespread potential application in health care, medicine, energy, environmental sciences, electronics, optics, and other applied materials sciences. Nanotechnology scale manipulation was first achieved in the 1990s, and the first commercial products entered the market in the 2000s. The major advances, as well as areas of potentially greatest risk, however, are yet to come (Health and Consumer Protection Directorate General of the European Commission 2004).

Synthetic biology entails an attempt to bring engineering techniques to biology to permit the purposeful design of new organisms piece by piece (Balmer & Martin 2008). Synthetic biology will permit genes and gene fragments to be added together like building blocks, producing a living entity with any desired combination of traits, much as one can assemble a car by putting together many individual pieces with different functions. The design of an organism through synthetic biology can include both the re-design of existing natural biological systems to have enhanced or novel qualities and the original construction of new biological systems that never existed in nature. While traditional biotechnology involves the transfer of one or a couple of genes from one species to another, synthetic biology will permit the purposeful assembly of an entire organism. Synthetic biology is at the most nascent stage of the technologies discussed: databanks of gene fragments are being developed and several of the steps necessary to engineer new organisms have been achieved, but a fully synthetic organism has not yet been built (Chopra & Kamma, 2006).

These and other emerging technologies will reshape our society in ways which cannot be fully understood. How to harness the power of the technologies while guarding against their risks presents a significant task.

1.2. Regulation versus Governance

Both the type and magnitude of the benefits and risks created by emerging technologies is uncertain. The myriad unknowns presented by rapidly developing technological advance create a considerable challenge for management. The widely varied contexts and characteristics of these technologies mean that traditional one-size-fits-all command-and-control regulation will not suffice. Designing a more flexible governance system that can respond to changing knowledge and information is necessary to optimally handle the benefits and risks of emerging technologies.

“Governance,” as opposed to “regulation,” does not mean that technological risks are not managed carefully. Clearly, the failure to take technological risks seriously can have significant deleterious effects on human health and the environment, not to mention on technological development and society. Addressing potential risks early and transparently is critical to the long-term success of emerging technologies.

The early stages of genetically modified food development in the United States provide an example of how significant public concern over a technology, and the perception that it is not being adequately supervised, can limit technological development. In 1998 Monsanto CEO Robert Shapiro told his shareholders that the commercial introduction of genetically modified seeds was “The most successful launch of any technology ever, including the plow” (Margaronis 1999). Just one year later, a Deutsche Bank report titled “GMOs Are Dead” stated, “The term GMO has become a liability . . . GMOs, once perceived as the driver of the bull case for this sector, will now be perceived as a pariah.” Despite the United States’ current position as a leader in genetically modified food development, public reaction against GMOs has forced several large biotechnology companies to shelve certain plans for further developments, such as research into genetically modified wheat (Brown & Vidal 1999). Public concern about genetically modified food products in many European countries has been even more virulent and has limited their introduction (Durant & Legge 2005, van Calster 2008).

Nanotechnology may face similar challenges as concern about appropriate regulation to protect human health, safety, and the environment in light of potential nanotechnology risks is growing. A number of interest groups and commentators worldwide have called for substantial revisions to federal law in order to manage nanotechnology’s risks; some have gone so far as to call for a nanotechnology moratorium (Wilsdon 2004; ETC Group 2003). Similar pleas were made, and continue to be made, concerning biotechnology. Public concern over nanotechnology (like biotechnology before it) has not been mollified by governmental agencies, whose response to potential nanotechnology risks has been perceived as slow and limited, displaying a degree of complacency not justified by current scientific understanding (like biotechnology before it) (Mandel 2008).

Though ignoring technological risk can clearly be detrimental, identifying precisely how to respond also usually is not clear. There are often strong calls for enacting entirely new regulatory regimes or substantially overhauling existing laws to respond to new technological risks (Mandel 2008; Mandel 2004). Many such proposals for regulatory reform in light of emerging technologies, however, are neither particularly realistic nor useful. Overhauling health, safety, and environmental laws, for example, is a remarkably expensive task, and one that generally lacks sufficient political support. Even serious consideration of substantial legislative changes would involve a costly, resource-draining, lengthy, and highly uncertain process with no guarantee of an outcome that is more protective or efficient than the existing structure.

On the opposite extreme from regulatory redesign are those who advocate a fully voluntary system, or free market approach, to emerging technology “governance” (Jacobstein 2006). One common variant on this theme is the argument that no regulatory change is necessary in the face of technological advance because emerging technologies and their attendant risks are no different than previous concerns. Such claims were raised in the context of biotechnology when certain proponents maintained that genetically modified plants should not receive specialized regulation because plants have been selectively bred for modification by farmers for generations (National Research Council 2002). Such arguments are also raised in the context of nanotechnology based on the position that non-engineered nanoparticles have been around since the beginning of time (Institute of Medicine 2005). Though careful consideration must always be paid to whether emerging technologies actually present new risks, some concern is legitimate in many cases. Modern biotechnology, for example, presents new risks because it enables a much broader array of genetic

traits, with much greater taxonomic divergence, to be incorporated into a new organism than was ever possible through conventional breeding (National Research Council 2002). Similarly, intentionally engineered nanoparticles have new electrical, chemical, and biological properties that may cause them to have different exposure and risk profiles, and to exist in the environment for longer, than non-engineered nanoparticles (Institute of Medicine 2005).

Though market forces and non-governmental action can provide valuable controls in certain regards, they cannot fully substitute for mandatory requirements. As with regulatory overhaul, there generally is little public support for voluntary or self-regulatory approaches to emerging technologies (Project on Emerging Technologies 2008). An appropriate degree of government oversight is particularly necessary to maintain public confidence in emerging technologies as many people often are largely unaware of them. For example, surveys reveal that over 80% of people have heard nothing or only a little about both nanotechnology and synthetic biology (Mandel et al. 2008; Kahan et al. 2007; Hart 2006; Project on Emerging Nanotechnologies 2008). If people learn that technology risk management is substantially voluntary at the same time they first learn about a technology, public concern would be expected to rapidly increase, as occurred significantly with biotechnology. The combination of low public awareness and polarizing debates present a challenging landscape for the socially-appropriate development of nascent technologies.

In contrast with the “regulatory overhaul,” “moratorium,” “free market,” and “status quo” advocates, this paper recommends a different approach to managing emerging technologies, one that seeks to turn some of the greatest challenges of these technologies—scientific uncertainty and regulatory disruption—on their head to create incentives for diverse stakeholders to work together on a new governance system. This strategy is based on recognizing that scientific and regulatory uncertainty creates problems for most interested parties involved with an emerging technology. Uncertainty creates fear and concern among the public, regulatory challenges for and criticism of regulatory agencies, and produces a problematic environment for investment and technological development for industry.

As discussed, it is critical to industry that the public not lose faith in a technology or its risk-governance system at early stages of technological development. Nanotechnology faces this challenge now, as the first simple nanotechnology products are on the market, and a larger number of more complex next generation advances are soon to be commercialized. Synthetic biology will enter this stage over the next few years as scientists develop the means to engineer novel organisms. Concern about technological risk and uncertainty about how a technology will be governed can lead investors to be unwilling to invest in the technology, and can make it more difficult for firms to know how to proceed with research, development, and commercialization.

Mutual concerns about uncertainty not only provide normally opposed stakeholders incentives to work together, but also could be exploited to produce agreement on a particular governance system. For instance, both those who believe that a particular emerging technology is relatively risk-free and those who are extremely concerned about its risk may be able to agree on a framework that will respond to new scientific information as it develops. Those who believe the technology is relatively risk-free may be satisfied because they believe that no significant risks will be uncovered, and technological development will be able to continue relatively unabated. Those who are more concerned may agree to such a framework because they believe that the technology’s risks will be revealed, and the framework will respond with pre-defined protective measures. This brief example certainly elides many details and challenges, but still provides a potential structure for working towards practical and appropriate emerging technology governance. Efforts in this direction are likely to be more rewarding than a resource-draining adversarial battle over a new command and control regulatory regime (Karkkainen 2006).

Similarly buttressing efforts towards such goals, uncertainty in scientific knowledge and regulatory management at emergent stages often means that interests and organizations often have not yet fully vested around a particular system or become wedded to a status quo. The combination of common concern about uncertainty and lack of a status quo can create a unique window of opportunity for a broadly-developed and widely-supported new governance model. Such a model, due to its wider base of support, could be instituted far earlier in a technology’s development, providing assurance to the public and stability for industry. This window, however, will not remain open indefinitely. As particular regulatory decisions are made or relied upon, and investment is made in particular products and uses, many stakeholders will become less flexible.

New technologies place stress on existing regulation. Regulatory systems are designed to handle the technology in place when the regulatory system was developed. Emerging technologies disrupt these systems. It is not surprising that advances as transformative as biotechnology, nanotechnology, and synthetic biology raise substantial problems for existing, mature (some would say “ossified”) regulatory systems. These disruptions, however, can provide opportunities to illuminate problems with the current system and to rethink how emergent technologies are governed.

2. EMERGING TECHNOLOGY GOVERNANCE

The new governance recommendations presented here are directed at developing a reliable, efficient, adaptive, transparent, and participatory management system. The new governance model for emerging technologies seeks to achieve a number of goals that would likely receive relatively universal support for any technology governance system: protecting human health, safety, and the environment; not unduly hindering the development of a nascent technology; advancing scientific understanding of the technology and its risks; governance that is adaptable as the technology and scientific understanding advance; allowing for widespread participation in management; and maintaining public confidence in the emerging technology and its governance. The proposal seeks these goals through regulatory agency, industry, and public interest group cooperation and management incentives rather than relying primarily on conventional command and control regulation.

Emerging technology governance must traverse a fine line. Insufficient protection could lead to excessive or unknown human health and environmental risks and undercut public confidence. Excessive regulation could limit the development of an extremely promising technology and foreclose potentially great social, health, environmental, and economic benefits. This combination of vast potential benefits and uncertain risks presents unique and difficult challenges. All stakeholders, however, have significant incentives to develop a protective and well-defined governance structure.

Because of the variation and uncertainties in emerging technology development, there are inherent limitations in how precise a universal or *ex ante* governance structure can be developed. These limitations, however, do not prevent the identification of substantial parts of a general governance system, with details that can be worked out for particular technologies and specifications that can be identified as a technology develops and its risks become better understood. A general management structure can provide a kind of best practices for emerging technology governance. Such a structure would provide needed assurance and protection for the public, greater certainty for industry, and resource and time savings for the government.

The new governance proposal developed below includes a variety of recommendations, focused on six areas: (1) improving data gathering and sharing in the face of limited resources; (2) filling newly exposed or created regulatory gaps; (3) incentivizing strong corporate stewardship beyond regulatory requirements; (4) enhancing agency expertise and coordination; (5) providing for regulatory adaptability and flexibility; and, (6) achieving substantial, diverse stakeholder involvement. The result of these proposals would be a system that is more protective of human health and the environment, more efficient for industry and taxpayers, and promotes responsible technology development. The governance recommendations are detailed in the following sections.²

2.1. Data Gathering

One of the greatest challenges facing emerging technology governance is scientific uncertainty concerning the potential human health and environmental impacts of a technology. For example, the United States Environmental Protection Agency has identified the need for greater scientific information on nanotechnology concerning “chemical identification and characterization, environmental fate, environmental detection and analysis, potential releases and human exposures, human health effects and ecological effects.” (Environmental Protection Agency 2007). A primary focus of governance should be on gathering all available data, developing as much new useful information as possible, and providing incentives for data

² Portions of these sections draw from Mandel 2008.

reporting and development. Greater data will provide the government, scientists, and the public with a better understanding of the types and risks presented by a technology.

At a basic level, the public, citizen groups, and industry should place pressure on public sources to increase funding for studies on the human and environmental exposure and risk posed by emerging technology products. Often exposure and risk research is substantially underfunded by the government in relation to the funding available for technology development. Many commentators agree that this has been the case for nanotechnology, although funding for research into nanotechnology hazards has been increased more recently (Mandel 2008). Public agencies also should take a lead role in identifying research needs (Matsuura 2006).

Regulatory agencies, of course, should take advantage of any existing authority to encourage or require the development and production of scientific information. Agencies also can develop voluntary consultation programs even where they lack authority to mandate reporting. Such policies can provide firms with strong incentives to comply or risk consumer backlash. For example, although consultation with the FDA on the commercialization of most genetically modified food products is voluntary, the FDA believes that it has been consulted prior to the introduction of all new genetically modified products (Mandel 2004).

More innovative approaches to improve data gathering also are available, such as a model proposed for nanotechnology. Nanotechnology substances and uses could be classified as having negligible, low, medium, or high concern (Mandel 2008; Institute of Medicine 2005). The classification would be based on the substance's size, structure, coating, solubility, ease of transport in the body, toxicity characteristics, expected human or environmental exposure, and other relevant factors. For any given nanotechnology product or use, the extent of both pre- and post-commercialization data gathering and reporting requirements could vary according to the level of concern. If a nanomaterial manufacturer believed that certain nanomaterials had been misclassified or demonstrated to be safe, the manufacturer would be able to apply for re-classification. This classification proposal could operate as a default, information-forcing system (Karkkainen 2006; Kysar 2006) that would provide industry the incentive to develop greater data concerning nanotechnology risks, but avoid command and control dictates that prescribe exactly how to act or impose unduly burdensome requirements on low risk activities. Such a system could also provide substantial flexibility to adapt governance to new understandings of risk as greater information develops.

Regulatory agencies also should consider incentives they can provide to industry to promote data gathering and reporting. One option would be to create fast-track review of applications under various statutes where data beyond that required is developed and submitted by the applicant, or where the applicant commits to post-commercialization data gathering and reporting that is not required. Industry would thus be able to get their new technology products to market more rapidly, agencies could conduct the same level of review to achieve adequate protection, and more data on the emerging technology would be developed. Great Britain, for example, has instituted a voluntary reporting system with certain of these characteristics for those involved in developing new engineered nanotechnology materials (Department for Environment, Food and Rural Affairs 2008)

2.2. Filling Regulatory Gaps

Statutes and regulations, almost by definition, are designed to handle regulatory concerns existing at the time of promulgation. It is not surprising that emerging technologies often exacerbate regulatory gaps or introduce new concerns that create new regulatory lacunae.

Biotechnology, for example, permits the production of genetically modified plants and animals that could have significant environmental impacts, yet the existing United States regulatory system often lacks a role for the Environmental Protection Agency (EPA) to review or oversee such products. The EPA lacks authority to regulate genetically modified fish and most other animals, and has no role in the approval or field-testing and widespread planting of genetically modified plants other than those modified to be pest-protected. Perhaps even more troubling, it is unclear whether any United States regulatory agency has authority over transgenic animals not intended for human food or human biologics production (Mandel 2004).

The development of nanotechnology has also produced regulatory gaps. The most significant holes arise from the potential for small volumes or masses of nanotechnology products to pose significant human health

or environmental risks. Most health, safety, and environmental regulations in the United States operate on the basis of volume or mass triggers (Mandel 2008). Examples include the Toxic Substances Control Act's exemption for chemicals made in quantities of less than 10,000 kilograms (40 C.F.R. § 261.5) and the Resource Control and Recovery Act's conditionally exempt small quantity generator status for entities disposing of under 100 kilograms of waste per year (40 C.F.R. § 723.50). The assumption that certain generalized quantities of a hazardous substance are necessary to create health or environmental risks, however, likely does not hold true for nanomaterials. Due to nanoparticles' small size and high surface-area-to-mass ratio, such particles may present unique toxicity concerns in low quantities (Wilson 2006).

New technologies, particularly technology as revolutionary as biotechnology and nanotechnology, disrupt existing regulatory systems. These disruptions can exacerbate problems with existing systems, such as regulatory gaps, but can also provide the opportunity to fix such deficiencies. Regulatory agencies must get beyond the hurdles created by scientific uncertainty and bureaucratic and status quo inertia to respond more proactively to these challenges. Closing regulatory gaps expeditiously can provide certainty for industry and comfort for the public.

2.3. Industry Stewardship

Many of the emerging technology governance goals identified above can be advanced by developing incentives for industry to act in a socially responsible manner. Such incentives can include economic, public relations, social values, and legal mechanisms.

The largest companies generally have strong incentives to maintain robust public confidence in their technological field across the board. These companies have the largest economic stake in a particular technology industry, and will be harmed the most by any perceived adverse event, whether traced to their company or another in the same industry. Confirming this, the director of regulatory affairs at one of the largest companies engaged in nanotechnology reported that the company was very aware of making sure that consumer reaction to nanotechnology did not follow the path of consumer concerns about biotechnology. And, the American Chemistry Council, which represents a number of larger nanotechnology companies, has been relatively sympathetic to some nanotechnology regulation (Davies 2007).

Larger technology companies thus have incentives to develop—in concert with government, scientists, and public interest groups—guidelines for best management practices. The larger companies also have incentives to exert industry pressure on smaller start-ups to comply with these best management practices (Lin 2007). As noted, any perceived technology concern would be expected to ripple through the entire industry.

In one substantial confirmatory example, DuPont teamed with Environmental Defense to develop a risk management framework for nanomaterials (Environmental Defense—DuPont Nano Partnership 2007). This framework was designed to “establish a process for ensuring the responsible development of nanoscale materials, which can then be widely used by companies and other organizations” (*Id.*). Similarly, the Royal Society of the United Kingdom worked with nanotechnology investors and companies to produce a voluntary “Code of Conduct for Responsible Nanotechnology” (Responsible NanoCode 2008). There have also been non-regulatory efforts to create and implement nanotechnology best practices at the international level, such as the joint effort of a number of private and government-funded groups to develop a “Code for Responsible Nanotechnology” (Woodrow Wilson International Center for Scholars 2007).

That being said, the Environmental Defense—DuPont framework has been criticized by some environmental and labor groups as an attempt by “industry and its allies” to usurp government oversight and public participation in the regulatory process (Davies 2007). Also of concern is the potential for larger companies to promote overly expensive or complex management practices in an effort to create barriers to entry for smaller competitors. On the other hand, there also are concerns that smaller nanotechnology companies may be willing to take greater risks than are generally socially acceptable. There is no question that any industry-produced best management practices must be appropriately scrutinized, but such efforts should also be encouraged for their potential to produce efficient and rapid governance. Once best management practices are developed, all companies will be heavily incentivized to implement them due to industry peer pressure, public perception, and the threat of tort liability if established practices are not observed and an adverse event occurs.

In addition to the public relations and fast-track opportunities identified in this and the preceding sections, emerging technology industry can be encouraged to engage in activities beyond those mandated through other incentives, such as potential penalty avoidance. A firm that agrees to conduct regular auditing and self-reporting of regulatory agency-determined practices, for example, could be exempted from certain regulatory fines for minor violations that are not intentional or the result of gross negligence (American Bar Association 2006). Firms thus can be incentivized to go beyond what is legally required to address unregulated matters, adopt preventive measures, and help regulatory agencies gather greater data (*Id.*).

Under this model, regulatory rules are not intended to set the ideal standard for behavior, but serve as a mandatory back-stop that applies only if firms do not achieve alternative arrangements that provide greater protection. In this manner, greater protection than mandated can be accomplished, at a lower cost to both taxpayers and industry, by offering industry flexibility to achieve more efficient protection and by highlighting the importance of public confidence in emerging technology development.

A broad system of industry stewardship, as outlined here, could also have substantial long-run returns. Such a system could help develop more of an industry ethic of responsibility and a goal of teamwork between the government, industry, and consumer organizations. This teamwork can also help build commitment among various stakeholders to the governance structure and to cooperation itself, instead of each entity constantly challenging the program and each other over every perceived deficiency.

2.4. Agency Expertise and Coordination

Emerging technologies often exacerbate enduring problems with regulatory agency staffing, funding, lack of scientific expertise, and coordination. For example, in the United States, the EPA, Food and Drug Administration (FDA), United States Department of Agriculture (USDA), and Office of Safety and Health Administration (OSHA) each have been identified as understaffed, underfunded, and lacking personnel properly trained to handle pertinent emerging technologies (Davies 2007; Pederson 2007; Davies 2006; Weiss 2006; Kuzma 2005; Mandel 2004). Similar concerns exist for European regulatory agency oversight of emerging technologies as well (Health and Consumer Protection Directorate General of the European Commission 2004; van Calster 2008).

The problems of agency inexperience will be great for most emerging technologies due to the technological complexity and forefront-of-science issues involved, but it may be particularly severe for nanotechnology. Nanotechnology represents a strikingly interdisciplinary field. Depending on the particular technology or product in question, advanced understanding in materials science, chemistry, physics, and biology all may be required to analyze risks. There are few scientists with sufficient training in the multiple necessary areas, let alone those who work for government agencies (Davies 2007; Miller et al. 2004). This problem is exacerbated by the disparity between the remuneration such scientists could receive in the private nanotechnology sector versus their opportunities at government agencies.

Emerging technologies also often raise particular challenges for interagency coordination. The regulation of genetically modified plants and animals in the United States, for example, implicates as many as twelve different statutes and five different agencies and services (Mandel 2004). The multiplicity of statutes and agencies has created confusion among regulated industry and the public, reduced clarity regarding scientific standards and requirements, and retarded the efficiency of biotechnology development and regulation. There have even been instances inconsistencies in regulation between the FDA, EPA, and USDA (Mandel 2004). Regulatory agency coordination for nanotechnology has been identified as a critical need as well (Mandel 2008).

Regulatory coordination and consistency for emerging technologies is important on a number of fronts. First, coordination can offer significant cost savings. In a system where agencies are understaffed and underfunded, coordination allows a pooling of personnel, data, and other resources, rather than wasteful duplication. Second, because scientific uncertainty rates as one of the most significant problems facing emerging technology regulation, coordinating research concerning human health and environmental risks can allow scarce agency research resources to be stretched further. Finally, a coordinated approach to regulation and requirements can provide efficiency benefits for both government and industry. New governance systems for emerging technologies should include a focus on promoting both intra- and inter- agency coordination.

2.5. Governance Adaptability

Emerging technologies develop rapidly. It is often impossible to predict what products and risks will need to be governed even a short time into the future. For example, the United States' Coordinated Framework for Regulation of Biotechnology was adopted in 1986, yet did not cover the regulation of transgenic pest-protected plants, despite the fact that such products began field testing only one year later and are now one of the dominant biotechnology products (Mandel 2004). It is necessary that any emerging technology governance system be flexible enough to be able to adapt, as best as possible, to technological change and advances in scientific understanding of the technology.

Problematically, most regulatory requirements become stringently fixed once put into place, and resist attempts at evolution, even in the face of strong evidence that there are significant problems with the existing standards. Despite problems that have been identified for many years, the USDA only recently proposed changes to their program governing the import, movement, and environmental release of genetically modified organisms (Animal and Plant Health Inspection Service 2008). These changes represent the first comprehensive review and revision of the regulations since they were first promulgated in 1987, at the time of the first field trials of genetically modified plants. As noted above, such plants now represent dominant sources of soybeans, cotton, and corn in the United States. One purpose of the proposed changes was to bring the USDA regulations into line with the Plant Protection Act, a statute enacted almost a decade ago.

One method for achieving adaptability and flexibility is for emerging technology governance to include mechanisms that allow for incremental changes in governance as the need arises. Such an approach simultaneously provides flexibility in governance and limits the likelihood of quickly upsetting settled expectations for industry. Emerging technology governance should be an iterative process at early stages of technological development and commercialization. A particular system of governance should be developed, followed by data gathering, followed by result evaluation, followed by modifications to the system as warranted, in a continuing cycle until industry and scientific understanding has matured.

There can be institutional and legal hurdles to establishing such an iterative process. In the United States, for example, the Administrative Procedure Act mandates that final rules cannot simply be revised once promulgated (5 U.S.C. §§ 551–59). One solution to this type of problem could be to build options into final rules. In addition, instituting a somewhat standardized process for modification allows such change to become part of the expected governance system, and should allow future change to occur faster and at lower cost. As more scientific evidence becomes available, this will allow the system to adapt more rapidly (Abbott et al. 2006).

Governmental agencies also should work with firms to permit flexibility in how regulatory requirements are satisfied to the extent practicable while still protecting human health and the environment. Flexibility will allow industry to experiment with economic or technical feasibility and various control approaches, while still ensuring adequate protection. Such experimentation also may help develop additional information on technology risks and the relative advantages of various governance approaches.

2.6. Stakeholder Involvement

Critical to this proposal for emerging technology governance is wide and diverse stakeholder involvement. This involvement will require regular communication with and workshops among a variety of stakeholders, including regulatory agencies, industry representatives, research scientists, environmental organizations, public interest groups, academics, and others. Broad stakeholder outreach and dialogue can bring credibility, new ideas, current information, continual feedback, and public trust to a governance system.

The communication should include information on the known and unknown risks and benefits of an emerging technology (provided in a form accessible to a broad cross-section of lay individuals), disclosure of new scientific information concerning the technology as it arises, and further encouragement of public involvement. Such communication is particularly important at the early stages of a technology's development because of the public's limited knowledge and awareness of the technology. A well-informed public, in turn, can allow consumers to "vote with their dollars" to try to affect industry decisions. Of course, there also must be a high level of transparency in regulatory decision-making and activity.

The communication efforts must include specialized outreach to smaller technology companies. Current health and environmental regulatory programs generally evolved around existing, mature industries, at times when there were relatively fewer and larger companies. Larger companies are generally more aware of and able to respond to regulatory requirements. Emerging technology governance, on the other hand, will evolve with an industry itself. In order to be effective, start-up and small companies, including many that are not familiar or sophisticated with respect to existing health and environmental regulations, will need to be made aware of, and in some cases receive assistance with, regulatory requirements. Training and technical assistance on compliance for start-ups and small companies should be provided.

As noted, public trust in an emerging technology and its governance is critical to the success of the technology (Institute of Medicine 2005; Kuzma 2005; Elliott 2005). The failure to provide for adequate stakeholder involvement and public communication, in particular, has been identified by some as one reason for some of the public backlash against biotechnology (American Bar Association 2006; Institute of Medicine 2005). The potential for a public reaction against emerging technologies is elevated by the complex science involved, the high level of uncertainty concerning risk, and the potential for interest group polarization (Mandel et al. 2008; Abbott et al. 2007; Kahan et al. 2007; Paddock 2006). Perhaps recognizing this concern, there are growing efforts to more proactively incorporate discussion of ethical, legal, and social implications of synthetic biology into its research and development in Europe and the United States (Calvert & Martin 2009).

Communication will not resolve all concern or potential for conflict, but can go a long way towards establishing broad public trust. Implementing these measures in concert with those above can produce a framework for emerging technology governance that could simultaneously better protect against health and environmental risks, develop greater information about a technology, permit the technology industry to continue to rapidly advance, and maintain public confidence in the governance system.

This proposal is undoubtedly optimistic. Governing emerging technologies present many complex social, political, cultural, and technological issues, some of which have only been barely noted here. Implementing these recommendations would be neither simple nor frictionless. These proposals are meant, however, to provide a road map, in the form of a best case argument, for what could be achieved.

CONCLUSION

Studies of public perception of various emergent technologies, including synthetic biology, nanotechnology, and genetically modified foods, have found that individual perceptions of the technologies tend to polarize along traditional cultural and social lines (Mandel et al. 2008; Kahan et al. 2007). The groups that polarize are not the same for each technology, but each technology faces significant risk of producing concerning schisms. This polarization implicates not only the perceived scientific benefits and risks of the technology in question, but also perceptions of the potential economic, cultural, and social effects of a given technology.

These public opinion studies highlight that the development of any emerging technology and the system for governing it are inevitably and dynamically intertwined. Each will continually affect the other. The new governance proposals developed here aim to institute a collaborative, transparent, adaptable system at an early stage of technological development to ameliorate the potential for social division over a technology and to set the tone for a long-term governance model.

Given the uncertainty surrounding an emerging technology's development and risks, there will be inherent limitations concerning how specific a framework can be developed at early stages. The proposal outlined above is not intended to be exhaustive by any means, but to develop a core structure that will provide greater certainty for the public and industry, and allow details to be developed as knowledge evolves.

Though the early stages of a technology's development, when there are still many unknowns, is a challenging time to develop a governance framework, it also can be an opportune time to take advantage of the flexibility of a new approach. At the early stages, fewer interests have vested around particular governance regimes, there are not as significant sunk costs to overcome, and industry and the public are less wed to a status quo. The early stages of an emerging technology's development present a unique opportunity to shape its future. But, it is an opportunity that does not remain open forever. Interests, investment, and opinion can quickly begin to vest around certain regulatory and governance expectations. It is important to put an appropriate governance system in place early in a technology's developmental stages, and before the commitment to the status quo becomes too great.

For the first time in history, there is the opportunity for governance systems to develop simultaneously with emerging technologies, permitting proactive rather than reactive management structures. The opportunity to reap the potentially spectacular health, environmental, industrial, and economic benefits of emerging technologies is great, but these opportunities will be severely hampered if the technologies are not managed properly. The opportunities will be hampered because society will face inefficient costs and delays in technological development and unnecessary technological risks, but also because distrust of the governance system or high-profile problems caused by inadequate regulation could result in a public backlash against the technology. The emerging technology governance system proposed here offers a model to navigate these many hazards in order to promote responsible and valuable technology development.

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