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SPECIAL FOCUS: GOVERNANCE OF NANOBIOTECHNOLOGY

Does nanobiotechnology oversight present a uniquely complex challenge to interagency cooperation?

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Abstract Numerous regulatory and oversight challenges exist in the field of nanobiotechnology. Although these challenges may appear novel and complex, similar issues have plagued environmental regulation since the 1970 s. This article argues that complexity, uncertainty, and regulatory gaps are common problems in environmental regulation, and that the lessons learned and progress made during more than 40 years of environmental regulation can serve as a guidepost for addressing nanobiotechnology regulation and oversight issues.

Keywords Complexity · Environmental regulation · Nanobiotechnology · Oversight · Uncertainty · Governance

Nanobiotechnology appears to hold almost limitless potential for beneficial applications, and some commentators consider the emergence of this suite of technologies to be the dawning of a "second Industrial Revolution" (Karn and Bergeson 2009). But this tremendous upside comes with a host of governance and oversight challenges (Mandel 2008). Many commentators claim that these regulatory challenges are unique to nanobiotechnology and that the existing apparatus of the regulatory state is inadequate to address the novel problems that are poses (Nelson et al. 2009; Lin 2007).

The rapid emergence of new nanobiotechnology applications does present daunting regulatory and oversight challenges. The statutes that define the current approaches to environmental health and safety protection were written prior to the emergence of nanobiotechnology and must be rewritten, reinterpreted or applied in novel ways to address the new realities posed by the nanobiotechnology revolution (Lin 2007). Yet the problems most centrally associated with the emergence of nanobiotechnology—complexity, uncertainty, and a curious and possibly dysfunctional mix of regulatory gaps and overlapping agency authorities—are pervasive throughout the field of environmental regulation.

Public policy responses to these problems in other areas of environmental regulation have produced, at best, mixed results. Nonetheless, much can be learned from previous efforts to address parallel problems in seemingly unrelated fields, however, successful or unsuccessful those efforts have been in the past. It would therefore be a mistake to view the challenges of nanobiotechnology regulation in isolation, as if they were an entirely novel, unique, and *sui generis*. To a far greater degree than is commonly acknowledged, complexity, uncertainty, and regulatory gaps and overlaps are by now old and familiar problems in

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environmental regulation, however, novel they might appear to be in the nanobiotechnology context (Karkkainen 2008; Ruhl 1996).

At one time, environmental protection may have appeared to be a relatively simple and straightforward task. Congress granted administrative agencies broad powers to impose stringent regulatory standards on the biggest polluters. Bring these large, aberrant actors under control, it was thought, and the problems would largely disappear. As it turned out, however, the task of protecting the environment proved to be far more complex and difficult than originally imagined by those who wrote the foundational environmental statutes in the "environmental decade" of the 1970 s, when most of this regulatory architecture was put into place (Davies 2010).

Beginning with enactment of the National Environmental Protection Act (NEPA) in 1970 and continuing through the Clean Air Act, Clean Water Act, Endangered Species Act, Resource Conservation and Recovery Act (RCRA), and other major federal environmental statutes, Congress incrementally adopted a piecemeal and fragmentary regulatory framework. Each of these statutes was well-intentioned and seemingly sensible. Each statute aimed to address some narrowly defined, often media-specific piece of the environmental protection puzzle, generally focusing on the biggest and most immediate threats and proceeding largely by means of uniform, top-down regulatory requirements. For the most part, however, these centralized rules mitigated only the most visible and egregious environmental stressors, such as large-scale pollution pouring out of the stacks and discharge pipes of large industrial and municipal polluters (Tarlock 2010). Smaller scale and more diffuse environmental threats were largely ignored or relegated to secondary status, even though their cumulative impacts could be severe. Little effort was made to coordinate or rationalize regulatory efforts across these statutory authorities, and cross-media effects, such as water pollution caused by atmospheric deposition of air pollutants, fell through the cracks, "neither fish nor fowl" in the medium-specific regulatory regimes of the Clean Air Act for air pollution and the Clean Water Act for surface water pollution (Karkkainen 2008).

Without a doubt, this blunt-edged approach produced substantial improvements in overall environmental conditions (Ruhl 2005). Factory stacks no longer spew uncontrolled air pollution, and municipalities are prohibited from dumping raw sewage into waterways. Air quality in most major cities has improved dramatically, as regulatory standards for the most ubiquitous air pollutants have been ratcheted down over time, and tens of thousands of point-source water polluters have been sued under relatively stringent regulatory standards through the Clean Water Act's permitting system. Viewed from a broader perspective, however, environmental regulation to date has picked mainly the low-hanging fruit (Karkkainen 2001). The most obvious and most easily controllable problems were successfully brought under control, but smaller and more diffuse pollution sources remain largely unregulated or only lightly regulated. Cumulative and synergistic impacts of multiple environmental stressors on ecosystems are by and large ignored. The authors have yet to see the emergence of an overarching and integrated regulatory approach that accounts for complex biological reactions and interactions among co-dependent species, as the effects of these environmental stressors reverberate through dynamic, causally interdependent ecological systems (Karkkainen 2002).

In no other field of environmental law is this problem more prevalent than in the regulation of toxic substances. Relatively few toxic pollutants are regulated. Indeed, relatively few substances have been thoroughly tested for potentially toxic effects on humans or other species. (National Research Council (NRC) 1984) sampled the commercial chemicals produced across the nation and found that toxicity tests were unavailable for more than 80% of all potentially toxic substances in commerce, and that only 22% of high production volume chemicals had even a minimum data set available (Steering Commission 1984).

The situation has changed little since 1984 (Applegate 2008). Although the Toxic Substances Control Act (TSCA) authorizes the Environmental Protection Agency (EPA) to require chemical manufacturers to undertake a battery of toxicity tests, this power is rarely exercised (Karkkainen 2001). For new chemicals, TSCA adopts a relatively toothless premanufacture-notice (PMN) procedure that requires manufacturers to notify the EPA of new chemical production and to report any toxicity data they have available. However, manufacturers are not required to submit an enumerated "base dataset" under PMN.

Consequently, fewer than half the PMNs submitted to the EPA include toxicological data (Lin 2010).

TSCA's data-gathering framework is equally insufficient for existing chemicals. The EPA can require manufacturers to submit a variety of existing environmental and health-based review under a "substantial evidence" standard (Guth 2008). This skeptical and searching review requires the EPA, ironically, to generate large amounts of data before it can even request a manufacturer to provide data.

Even more data—indeed, mountains of it—must be generated before EPA or other regulatory agencies can promulgate regulatory standards. Throughout this process, both the burden of information production and the burden of persuasion lie squarely with the regulatory agency (Kimbrell 2009). Manufacturers and emitters of potentially toxic chemicals have little incentive to investigate the effects of the substances they are introducing into the environment, lest that information serve as the basis for regulatory standards (Lyndon 1989). Once the regulatory standard-setting machinery is set in motion, however, industry's incentives may shift toward the production of countervailing or confounding research and obfuscatory information, so as to complicate and delay the standard-setting process and to lay the foundation for legal challenges on judicial review. For their part, regulatory agencies must react cautiously and defensively, responding to and parrying every industry, dataset, study, and expert or risk having months or years of regulatory effort overturned by the courts (McGarity 1997). Under these conditions, relatively few regulatory standards for toxic chemicals are adopted.

An extreme illustration of this problem came in the *Corrosion Proof Fittings* case, in which the Fifth Circuit Court of Appeals held that the EPA's ten-year study of the effects of asbestos was insufficient to support the restrictions promulgated by the agency (Applegate 2008). Since that case, EPA has largely abandoned efforts to regulate toxic chemicals under TSCA.

In part, the difficulty of regulating under TSCA, as illustrated in the *Corrosion Proof Fittings* case, may be traced to defects in the statutory scheme. Courts have interpreted some environmental statutes, notably the Clean Air Act, to employ a "precautionary approach," allowing the agency to resolve doubts and uncertainties in the direction of precautionary regulation (Sunstein 2006). In contrast, TSCA's framework has been interpreted to place a higher information burden on the regulatory agency. The presumption is that no regulation should occur unless the agency demonstrates an "unreasonable risk," understood to require a showing that a substance not only poses a significant risk to human and environmental health, but that the risk outweighs the benefits of the uses of the substance (Sachs 2009). Furthermore, the agency must show that it has selected the "least burdensome" restriction, which, in turn, requires a detailed comparative cost-benefit analysis of numerous, if not all, potential regulatory options, with the most stringent restrictions requiring the strongest justification (Kannan 2007). Consequently, TSCA requires the regulatory agency to present a comprehensive medical, scientific, technological, and economic case to justify any proposed regulation in light of any and all alternatives, including the "no action" alternative. As a result of this heavy information demand, EPA has promulgated only five chemical regulations under TSCA since 1976 (Kimbrell 2009). Overall, the result is a regulatory framework that addresses only the most straightforward and easy cases, as residual uncertainties operate as a barrier to regulation.

Apart from the particular problems of the TSCA statutory scheme, however, the difficulty of regulating toxic or potentially toxic substances has proven to be pervasive across the span of U.S. environmental law. The Clean Air Act and Clean Water Act, for example, have long included provisions addressing toxic pollutants. Originally these statutes employed a health-based approach, instructing EPA to set regulatory standards strictly on the basis of health effects. But the information demands of this approach proved insurmountable, as the agency was able to assemble sufficiently detailed and comprehensive health effects information for only a small handful of toxic pollutants. In frustration, Congress abandoned the health-based approach and ordered EPA to adopt technology-based regulations for toxic pollutants, something the agency had proven more adept at doing (Farber 2000). While some have criticized what they perceive to be agency foot-dragging, the more fundamental problem is that toxicological science is often incomplete and frustratingly slow to develop, leaving huge uncertainties. The authors may be reasonably confident that a pollutant is toxic at

some level of exposure, but the detailed data required to establish and defend a regulatory standard at any particular level may take substantial investments of time and money to produce (Lyndon 1989). In short, uncertainties and data gaps abound, and regulatory agencies are quickly overwhelmed by the information production burden they face.

These problems are compounded by the fragmented nature of the present regulatory system. The Occupational Health and Safety Administration (OSHA) bears primary responsibility for regulating toxic substances in the workplace; the Food and Drug Administration (FDA) regulates potentially toxic food additives, drugs, and cosmetic products; the Consumer Product Safety Commission (CPSC) regulates toxic substances in most other consumer products; and the EPA regulates toxic air and water pollutants, hazardous waste disposal and clean-up, toxic spills, pesticides, and toxic contaminants of public water supplies. Even within EPA, however, separate offices administer the various statutes addressing particular aspects of toxic substances, each office applying a unique set of statutory standards and definitions. There is generally little coordination among these various programs within EPA, and almost no coordination across the span of federal agencies responsible for parts of the toxic substances puzzle. Research compiled for purposes of setting discharge standards for a toxic water pollutant, for example, will probably have little or no relevance for purposes of setting workplace exposure limits or product safety rules. The statutes use different definitions and require agencies to consider different factors and to regulate, if at all, under different circumstances and in different ways. Thus, the difficulty that any particular agency or program office faces in setting regulatory standards for toxic substances is compounded by a vast redundancy of effort across the federal bureaucracy. Under these arrangements, relatively few toxic substances get regulated, but those that do may be regulated six or eight times under six or eight unique regulatory programs, each designed with a narrow purpose in mind, with no thought given to how the pieces interact so as to form a coherent whole.

The regulatory system described here is characterized by uncertainty, complexity, regulatory gaps, multiple regulatory authorities, and lack of interagency and inter-program coordination. If those features sound strikingly similar to the situation described by commentators on nanobiotechnology governance and oversight, it is no accident. Indeed, a case can be made that the problems of nano-bio governance and oversight are simply the problems of toxic regulation writ small, but on a "nano" scale. Scale does add some unique features. Nanoparticles are more difficult to detect, and releases of and exposures to nanoparticles are likely to be in extremely small volumes. Those complications aside, however, the fundamental characteristics of uncertainty, complexity, regulatory gaps, and lack of interagency and inter-program coordination apply with equal force to nano-scale as they do to larger-scale toxic substances.

If the thesis of this article—that regulation of nanobiotechnology is essentially just the problem of regulating potentially toxic substances on a smaller scale—is correct, then we should be able to apply some useful lessons from the last several decades of toxics regulation to nanobiotechnology regulation. Unfortunately, however, the system of toxics regulation has been only modestly and sporadically successful. It is beyond the scope of this article to offer a comprehensive assessment, but three important developments are worth noting briefly.

First, the EPA's Toxics Release Inventory (TRI) is a useful example of the power of transparency to alter private incentives. TRI requires businesses that emit enumerated toxic substances exceeding specified volumetric thresholds to report their emissions annually to EPA, which enters the data into a publicly accessible database. Environmental groups, community organizations, regulatory agencies, local governments, directors and investors, and others can use this information to compare toxic emissions at facility-, firm-, or community-wide scales, and to track trends over time. Emissions have fallen sharply since TRI's inception, in part because many leading emitters, publicly embarrassed by their emissions levels, undertook voluntary reduction programs, and in part because the increased transparency unleashed community, regulatory, and investor pressures to which some firms responded. Industry responses varied, but, in general, transparency has been an invaluable quasi-regulatory tool, producing significant reductions in toxic emissions, even in the absence of enforceable regulatory standards (Karkkainen 2001).

A second promising approach is demonstrated by California's Proposition 65, enacted by voter initiative in 1987. Like the TRI, Proposition 65 mandates industry disclosure, but through a different approach. Businesses exposing anyone to an enumerated set of carcinogenic or reproductive toxins are required to give all exposed persons "fair and adequate warning" of the exposure. Proposition 65 warning labels led consumers to avoid certain products, putting market pressure on manufacturers to reformulate their products so as to avoid the need for warning labels. Environmental exposures are treated somewhat differently. They require the emitter of the toxic pollutant to warn all persons who may be exposed, or face stringent civil penalties enforceable by citizen suit. This exposes toxic polluters to an open-ended threat of litigation and civil liability. However, a state regulatory agency is authorized (but not required) to set "safe harbor" pollution thresholds below which warnings are not required. Enactment of Proposition 65 shifted industry's incentives so that it was suddenly in their interest to produce and disclose toxicity data to assist state regulators in establishing "safe harbor" thresholds. This allows industries to avoid the threat of Proposition 65 liability by meeting the regulatory thresholds. As a consequence, the state of California was able to promulgate hundreds of regulatory standards for toxic substances in record time and with industry's full cooperation. This suggests that at least some of the residual uncertainty as to the toxic effects of chemicals is an artifact of industry's perverse incentives to remain willfully blind under standard approaches to regulation.

A third promising approach is demonstrated by the European Union's new REACH directive on chemical regulation. REACH tackles the data and information gap in chemical toxicity assessments directly by requiring manufacturers and producers of chemicals to submit data and information on the "safe use" of their chemical products. If the European Chemicals Agency is not satisfied with the information presented or has doubts as to a chemical's safety, it may demand additional testing and data submissions by the manufacturer or importer, and it may deny or suspend the registration of a chemical product until those conditions are met. REACH is by no means a panacea, in part because the triggering volumetric thresholds for the scheme are set rather high, and in part because the scheme threatens to inundate the European Chemicals Agency with information that it may be ill equipped to process effectively. But REACH does signal the European Union's intention to place the onus of demonstrating a chemical's safety squarely on the manufacturer and importer, the party presumably in the best position to make the initial determination. REACH also, arguably, sets up a healthier dialog between the chemical industry and regulatory agencies, with the potential to substantially increase the flow of information on chemical toxicity and chemical safety over time.

Toxic substances regulation is not the only area in which uncertainty, complexity, regulatory gaps, overlaps, and lack of interagency coordination have plagued environmental regulation. From the outset of modern efforts to regulate the environment, some in the scientific community, such as the ecologist C. S. "Buzz" Holling (1978), argued that the piecemeal and fragmented approach to environmental protection reflected in the major environmental statutes would be ineffective. Holling (1978) first raised the issue in the context of environmental impact assessment, pointing out that he and other scientists were being asked to make complex ecological judgments regarding the environmental impacts of proposed actions under conditions in which such predictions were highly unreliable. Essentially, Holling believed that too many gaps existed in baseline data, in the underlying science behind environmental protection, and in the understanding of the complex dynamics of ecological systems.

Holling argued there was often too little understanding of the complex interactions among the biological, physical, and chemical components of ecosystems to make sound predictions concerning environmental impacts, and that this factor was compounded by anthropogenic and natural stressors on those systems—all of which interacted in complex, dynamic, and sometimes highly uncertain ways (Stewart 2001; Flournoy 2000). Worse, the highly uncertain environmental predictions that went into environmental impact assessments were not reexamined to verify whether the initial predictions were correct. Regulators simply assumed clairvoyance at the front end and then crossed their fingers and hoped for the best, without ever checking to verify the initial predictions or to reexamine their predictive models using actual outcomes (Noble 2000).

In response, Holling (1978) proposed an alternative he referred to as "adaptive environmental assessment and management." This practice involved making environmental predictions based on the best judgments of interdisciplinary teams of scientists and then verifying these predictions through follow-up monitoring. The process goal was to treat the management intervention as a hypothesis that could be tested against real-world experience and subsequently adjusted as necessary in light of new learning, additional data, or changed conditions (Holling 1978). The theory was driven more by the research needs of science than by the goal of improving management predictions (Karkkainen 2003). But, nonetheless, from Holling's work two management principles—adaptive management and ecosystem management—have emerged.

Adaptive management focuses on how to structure the decision-making process. It examines how best to build in feedback loops, structure management interventions as testable and revisable hypotheses, and construct a regulatory approach that aims to be an ongoing learning exercise that is never perfect, but always capable of improvement (Holling 1978). Applying this approach results in a decision-making process that both maximizes learning and adjusts management interventions in light of that learning (Camacho 2010).

Taking the principles of adaptive management and placing them in an ecological context is the basis behind ecosystem management. The central thesis of ecosystem management is that place matters (Walters 1986). Ecosystem management recognizes that nationally uniform pollution standards are likely to be ineffective because what is an optimal pollution level in one ecological context may be disastrous in another. In other words, optimal pollution levels depend on ecological context, including what species are affected, what the species' particular sensitivities are, and whether synergistic stressors on the system exist. Implicit in the theory of ecosystem management is the idea that command-and-control, fixed-rule approaches are insensitive to local variations. Thus, at the root of any effective management plan is a need for local and regional decision-making that rejects the fragmentary and piecemeal, but simultaneously uniform and top-down approach that characterizes major federal environmental statutes.

"Place-based" ecosystem management promises to be more effective because it embraces the synergistic effects and complex interdependencies of natural ecosystems. For example, in the Chesapeake Bay, oyster populations are profoundly affected by water quality and the availability of suitable habitat, but these variables fall outside the jurisdiction of state fisheries agencies that can only manage oyster abundance by regulating the size of the harvest (Karkkainen 2003). By the same token, filter-feeding oysters play a critical role in regulating the Chesapeake Bay's estuarine water quality, but state and federal water pollution agencies attempt to manage water quality solely by regulating pollution inputs.

In response, the Chesapeake Bay Program was created to link the efforts of the six states and the District of Colombia that make up the Chesapeake basin. In addition to restoring oyster populations that have fallen to less than 1% of historic levels, the interagency initiative has targeted urban sprawl in the basin, since urbanization is a major contributor to non-point source pollution. It has also attempted to restore riparian wetlands and forest buffers in order to trap and filter out polluted run-off before it enters the network of tributaries that feed the Bay.

Since a suite of interconnected environmental stressors affect the Chesapeake Bay, continuing down a fragmented and piecemeal management system that addresses one environmental stressor at a time was thought to be infeasible and ineffective. A central premise of the ecosystem management plan in the Chesapeake Bay is management at the appropriate scale, tailored to the ecological context. Doing so required the implementation of a permanent committee comprising representatives from 27 federal and regional agencies (Karkkainen 2004). The program embraces the complex interconnectedness of the ecological system and restructures institutional arrangements from a top-down approach to one of coordination across different tiers of federal, state, and local governments.

Mandated information disclosure programs (such as TRI and REACH), efforts to alter industry's incentives to produce information and to cooperate in the regulatory enterprise (such as Proposition 65), and regulatory programs that adopt a dynamic, continuous learning process and interagency and intergovernmental integration (such as the Chesapeake Bay Program and other adaptive management

and ecosystem management efforts) are changing the face of environmental regulation. Each of these approaches emerged in response to problems of uncertainty, complexity, regulatory gaps, and lacks of interagency and inter-program coordination, very much like those problems faced by nanobiotechnology governance and oversight. The authors have a long way to go to craft a truly effective approach to managing the environmental health and safety risks of nano-bio without unnecessarily impeding its progress. It is critically important going forward, however, to recognize that nano-bio does not exist in a vacuum. The very real challenges the authors face in nanobiotechnology have direct parallels, if not perfect counterparts, in other areas of environmental regulation. Both the successes and failures of regulatory efforts in those areas may be instructive as it was design nano-bio governance and oversight regime for the future.

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