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Reinventing oversight in the twenty-first century: the question of capacity

Christopher Bosso · Rob A. DeLeo · W. D. Kay

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Abstract This article addresses a key question emerging from this project based at the University of Minnesota: the fundamental capacity of government to engage in "dynamic oversight" of emergent technologies. This conception of oversight requires additional or new types of capacity for government agencies that must arbitrate conflicts and endow any outcomes with necessary democratic legitimacy. Rethinking oversight thus also requires consideration of the fundamental design and organizational capacity of the regulatory regime in the democratic state.

Keywords Regulation · Oversight · Uncertainty · Risk · Accountability · Governance

Lessons learned

The University of Minnesota-led project on oversight models for nanobiotechnology has generated several important overarching lessons, leading in turn to the development of a historically informed framework for the "dynamic oversight" of emergent technologies. The proposed framework is an appropriate and nuanced reflection on a range of characteristics in the current regulatory system that few defend as optimal for dealing with known risks, much less the range of uncertainties posed by nanotechnology and related emergent technologies (e.g., synthetic genetics) broadly understood.

The ultimate challenge, as the project leaders readily acknowledge, is getting from conceptual framework to a functional, effective, and, perhaps most critical, democratically accountable and legitimate system of risk governance. In a word, the challenge is *feasibility*. In this regard, three lessons from this project strike us as worth deeper exploration:

1. *Need for greater preparedness for novel and/or complex situations*—As the Minnesota investigators write in the consensus recommendations, "Any oversight approach will have to be flexible, with the resources and expertise to anticipate, understand, and respond to change in the science and technology." (Ramachandran et al. 2010, p. 8)
2. *Need for enhanced capacity*—"There has been a serious deficit in the capacity of regulatory systems," the project leaders note, leading to their recommendation that the federal government "invest in development of competent and effective oversight systems." (Ramachandran et al. 2010, p. 8)
3. *Need for coordination mechanisms*—A system of dynamic oversight, as proposed, "provides for strong coordination among various regulatory

C. Bosso (✉) · R. A. DeLeo · W. D. Kay
Department of Political Science, Northeastern University, Boston, MA 02130, USA
e-mail: c.bosso@neu.edu

> agencies, the various stakeholders and the public, and an overall coordinating entity to capture all the dimensions of risk and societal issues posed by active nanobiomaterials as well as provide oversight throughout the life cycle of the technology or product." (Ramachandran et al. 2010, p. 9)

In this article, we explore the challenges that conditions of uncertainty raise for policymakers, the practical murkiness of the concept of "capacity," and the agency cultures and decision-making styles that require attention in devising appropriate and effective coordinating entities. Each of these factors poses considerable difficulty for policy stakeholders, and taken together, they make the task ahead seem daunting. Yet, we are not looking to throw a proverbial wrench into the works. Instead, we seek to illuminate areas for further policy inquiry and, we hope, action. In short, we seek to think out how to get from here to there.

The dilemma of uncertainty

> Regulation after an adverse event has its advantages: The event highlights the need for regulation, crystallizes the policy choices we face, allows us to consider real, not perceived costs of regulating or choosing not to regulate, and the regulations we adopt are more meaningful. (Wilson 2006, p. 707)

Nanotechnology, even narrowly conceptualized, exacerbates existing uncertainty about assessing and managing risk. Even a decade into the federal government's comparatively large research and development expenditures under the umbrella of the National Nanotechnology Initiative (NNI), remarkably little is understood about the basic characteristics of "passive" engineered nanomaterials (e.g., carbon nanotubes) already in the marketplace, much less the "active" nanostructures (e.g., nanoscale drug delivery devices) expected to arrive soon. The qualities of nanomaterials, products, and applications that inspire so much expectation (if not hype) also prompt a range of environmental, health, and safety (EHS) concerns. Some concerns (e.g., occupational exposure) are analogous to generally well-understood risks and probably can be addressed through commonly applied standards and protocols. Others (e.g., dual-use therapeutics and human enhancement technologies) are more novel and perhaps require new ways of thinking.

Conditions of uncertainty frustrate everyone, especially those with a vested economic interest in the successful commercial development of a technology. In its most acute form, uncertainty undermines the ability of those responsible for oversight to set priorities or to make choices. As Marc Eisner notes, "[F]aced with conditions of insufficient data and rapidly evolving scientific theory, regulators may be incapable of identifying underlying causal mechanisms, understanding the health and environmental ramifications of exposure, and designing regulatory responses" (2010, p. 28).

Yet, uncertainty is not an undifferentiated construct, nor do conditions of uncertainty have equal impact on all stakeholders. Political science, for example, lacks a common definition or understanding of the concept of uncertainty on which to base overarching policy design (e.g., "soft" vs. "hard" law approaches) or specific policy tools (e.g., technical standards, rules, incentives) (DeLeo 2010b). Political scientists—and social scientists generally—have long known this. However, what is often ignored, particularly within the context of uncertainty, is the degree to which these diverse conceptualizations prompt notably different policy responses, or even expectations about what is feasible or legitimate.

For example, public policy literature, and especially work focusing on policy processes, generally presents a reactive conception of government (Jones 1977). That is, policymakers and attentive publics are typically portrayed as reacting to problems that manage to clamber atop the agenda for action (e.g., Cobb and Elder 1972; Kingdon 1984) and usually within the discursive boundaries of some definition of the problem (e.g., Schattschneider 1960; Cobb and Rochefort 1994; Stone 1997). As such, uncertainty is implicitly conveyed as a socially constructed concept that, at least in theory, can be minimized through the strategic definition (and redefinition) of problems by competing interests. In short, uncertainty is a construct, and like any "problem" may even be defined away by dominant interests (Schattschneider 1960; Bachrach and Baratz 1970).

Contrast this view with the work of organization theorists in the field of High-Reliability Organizations

(HROs). Not only do HRO theorists (e.g., La Porte 1996; Weick and Sutcliffe 2007) see uncertainty as an objective fact of life (and certainly not a social construct), they see it as the elemental driver behind all organizational behavior. As a result, organizations designed according to HRO concepts (e.g., nuclear power plants, hospital emergency rooms) incorporate a need to minimize uncertainty by actively seeking out the unexpected. HRO theory thus prescribes a mode of action that identifies objective indicators of potential uncertainty and markers of unexpected events in order to anticipate their occurrence and, by extension, mitigate their implications. In this conception, policy actors are not reactive, responding to whichever problems rise to the top of the agenda for action, but aggressively proactive in shaping their own futures.

Moreover, for HRO theorists, problems rarely appear without foreshadowing. Indeed, Weick and Sutcliffe argue that within HROs small clues reveal themselves over time, indicating that "unexpected things are happening and aren't going away" (2007, p. x). The HRO, they note, has an *acute organizational capacity* to notice and to respond to these clues before they become full-blown problems. Their depiction of the ways in which HROs seek out indicators of potential problems is similar to Thomas Birkland's argument that problems in many policy domains (e.g., an influenza pandemic) reveal themselves through *accumulating indicators* of disaster that can be detected in advance and thus allow for policy change that precedes—and even anticipates—the actual onset of a catastrophic event (2006, p. 7). In each instance there is in place an aggressive process of purposive scanning, planning, and rehearsal. Uncertainty is not acceptable.

These two examples, while obvious abstractions drawn from broad literatures, underscore a dilemma for those seeking to build requisite capacity in oversight systems. Different literatures draw different conclusions about and describe disparate approaches for dealing with uncertainty. Nonetheless, one can tease out some critical features of uncertainty that seem to transcend the various disciplines and may serve as a starting point for any broad discussion about building capacity. In this regard, we look to a framework created by McManus and Hastings (2004). Although it is presented from the point of view of an architect or designer looking to create a specific technical project, their classification of uncertainty is general enough to apply more broadly; as the "project" being designed may be construed as a workable oversight system that can deal with conditions of uncertainty.

McManus and Hastings define uncertainties as "things that are not known, or know only imprecisely" (2004, p. 3). In contrast to social science literature that at least implicitly treats uncertainty in consistently negative terms, McManus and Hastings see uncertainty as a value-neutral concept, neither inherently "bad" nor "good." They then divide uncertainty into two broad classes. The first class refers to uncertainty caused by a *lack of knowledge*, or "facts that are unknown, or are known only imprecisely" (2004, p. 3). These facts may need to be collected or created. Similarly, they may be knowable at some time in the future. The second class refers to uncertainty caused by a *lack of definition*. When they say that something lacks a definition, McManus and Hastings are referring to an aspect of a system that has yet to be explicated. Whether the condition in question is "bad" or "good" will thus hinge on how it is defined. This discussion is equally salient to specification or definition of the solutions adopted in response to a problem. In this regard, McManus and Hastings agree with policy theorists that uncertainty is to some degree a social construct. However, they caution against over-defining aspects of a system too soon. In their view, blithely "defining" a condition as uncertain does not lead to any useful mitigation of its problematic features if the definition is not accurate and representative. For them, as for HRO theorists, uncertainty has empirical features that require careful inventory.

McManus and Hastings go on to distinguish three types of uncertainty that may occur within each of these classes, aligning them along a broad continuum from the least extreme to the most. The least extreme types include "statistically characterized (random) variables/phenomena," or "things that cannot always be known precisely, but which can be statistically characterized, or at least bounded" (McManus and Hastings 2004, p. 4). Weather forecasting is a good example. The trained meteorologist offers probabilistic assessments of certain weather events—even if a local weather celebrity gives it an aura of greater certainty than merited. Governments and other institutions are generally adept at handling this type of uncertainty, particularly given technological advances in statistical computation.

The second type of uncertainty is referred to as *known unknowns*, conditions that may be bounded or that may include entirely unknown values. Known unknowns are the most amorphous type of uncertainty. In such instances, the decision maker may be able to identify a potential source of uncertainty but unable to say anything about its size, scope, or implications. Long-term expenditures trajectories for social programs such as Medicare and future trajectories of new technologies generally fall into this category. For example, while we can forecast with some certainty that a new and transformative technology will have profound social implications, we are harder pressed to know exactly what those implications will be. We know enough to expect a type of impact, just not its shape or specificity.

The final type of uncertainty refers to *unknown unknowns*—or "gotchas" (McManus and Hastings 2004, p. 4). For individuals and agencies alike this type of uncertainty is particularly troubling, and in many cases hopeless to contemplate; for example, the likelihood that an extraterrestrial life form will appear above New York City tomorrow morning is an unknown unknown. Yet, as the authors point out, simply by virtue of the fact that we know that unknown unknowns are out there, we have "motivation for applying conservative mitigation strategies" (2004, p. 4). In this respect they note that many civil engineering projects are based on very high uncertainty probability margins that something *many* years down the road—100 plus—*will* happen.

By and large, most observers would classify the potential health and environmental risks posed by nanomaterials and applications as "known unknowns" (Wilson 2006). There is consensus that nanoparticles could produce harmful health effects; yet, the more we learn about potential or likely health implications the less, it seems, we actually know about specifics. For example, the discovery that nanostructures can transit the blood–brain barrier is met by hope, puzzlement, and alarm, it seems in equal measure. After all, the same nanoscale properties that may enable the precise delivery of therapeutics to parts of the brain may also pose unintended—or even intended—harmful health effects. But nobody yet knows.

Of all the forms of uncertainty, known unknowns constitute the proverbial "perfect storm" for would-be regulators. Technological developments have made us fairly adept at managing statistical uncertainties with at least relative success (save the occasional surprise snow storm, of course). Unknown unknowns, particularly in a governing context marked by severe budget constraints, tend to be seen as too far afield—too intangible—to warrant government attention. Posner writes:

> [B]afflement [is what] most people feel when they try to think about events that have an extremely low probability of occurring even if they will inflict enormous harm if they do occur. We may know that there is chance that a meteor might hit the earth with cataclysmic effects, but there is little we think we can do about it (Hollywood portrayals notwithstanding). The human mind does not handle even simple statistical propositions well, and has particular difficulty grasping things with which human being have no firsthand experience. (2004, p. 9)

Thus, the decision not to consider unknown unknowns is in many regards a natural human response to conditions of extreme uncertainty.[1]

Known unknowns, by contrast, are neither readily quantifiable nor so remote that they can be deemed moot issues (in the short term, at least). They engender a level of uncertainty that demands a policy response. Most studies of risk management and government regulation deal with known unknowns. Wildavsky (1988) argues that governments ultimately deal with uncertainty in one of two ways (or perhaps in some combination). On the one hand, governments can attempt to anticipate future uncertainties. By anticipating what will happen in the future, this logic holds, we can avoid or eliminate pending risks as much as is possible. HRO theorists would recognize themselves in this depiction. On the other hand, there may be instances where we simply cannot anticipate or have enough time to readily prepare for what

[1] Not everyone is willing to wholly disregard the unknown unknown. One could make a fairly persuasive argument that by creating organizational practices designed to mitigate unexpected events, the literature on HROs directly deals with unknown unknowns (see Weick and Sutcliffe 2007). Moreover, in the more than forty years since Alvin Toffler's (1970) *Future Shock*, the futurist movement continues to present works that imagine a society hundred of years in the future.

we've anticipated. In turn, governments must develop resilience or the capacity to respond quickly and effectively to unexpected events once they do occur.

While the work of Wildavsky (1988) and others is useful in framing the overarching context in which uncertainty about nanotechnology's effects emerges, it does not necessarily solve our core dilemma. How do we translate these insights into actual government capacity? Or, as set out in the beginning of the article, how do we actually get from *here* to *there*?

Returning to the work of McManus and Hastings (2004), a first step might be for policymakers to reconsider the definitions applied to the issues they confront. For example, the pervasive assumption that nanotechnology represents a wholly novel set of challenges might bias us against using already tested regulatory tools and create undue pressures to devise entirely new ones. Indeed, the focus on the uniqueness and revolutionary character of nanotechnology in the popular press (aided and abetted by some in the NNI) may well obscure a more prosaic view that much of the purported (or feared) EHS risks posed by nanotechnology are variations on established themes. For example, even without knowing whether any particular nanomaterial holds unique properties, long experience with chemicals should lead us to expect that it will at minimum pose additive environmental and health concerns.

And this isn't about nano *per se*. For example, the Toxic Substances Control Act (TSCA) has explicit procedures for registering new products and new uses for existing ones; yet, the Environmental Protection Agency (EPA) has remarkably little certainty about most of the products registered under the law. Few would argue that TSCA has proven effective in reducing uncertainty about the toxicological risk of the thousands of products already on its list; yet, 35 years after original enactment it is likely to be the federal government's primary frontline tool in regulating nanomaterials. Life under TSCA is already marked by uncertainty. Nano simply exacerbates this condition.

Every regulatory regime requires at least minimum capacity to anticipate problems or identify them before they overwhelm existing oversight systems or governing institutions. In one of their few points of consensus, the disparate literatures on public policy, anticipatory governance, risk management, and organization theory all underscore the importance of strengthening government's capacity to gather "indicators" of potential problems (DeLeo 2010b). Indicators in this context are simply metrics or measurements of a potential problem, the data that allow regulators to make decisions. Kingdon (1984) points out that the gathering and interpreting of indicators are fundamental to governance. Nearly every policy decision rendered, be it in the regulatory or legislative realm, is justified and legitimized by some collection of indicators that point to the need for a given course of action.

Nanotechnology broadly understood places strains on indicator gathering and assessment. Unlike highway deaths, overdose rates, GDP, and infectious disease incidences, regulators do not yet have quantifiable indicators of nano-related EHS problems. In fact, beyond generalized analogies to previous technologies, regulators don't even know what many of these problems may be. An obvious solution to such uncertainty is to lessen it through more research, to obtain greater precision about the properties of various substances or their risk profiles through more and better information. And, in this regard, the federal government has begun to invest significant funds for basic research in agencies such as the National Institute of Occupational Safety and Health (NIOSH) and university-based initiatives such as the Centers for the Environmental Implications of Nanotechnology at UCLA and Duke University, recipients of a 5-year $25 million joint NSF/EPA grant to generate new scientific knowledge about the toxicity of nanomaterials (NSF 2008). Such research will yield more and better data on everything from exposure levels to workers and other affected populations to the broader environmental impacts of nanomaterials throughout their life cycles.

But, as Kettl reminds us in thinking about the next generation of environmental policy, there is an inherent dilemma about information: "It is everything, and is nothing" (2002, p. 183). Even with more and better information, what should we *do* with it? Despite considerable effort to construct more precise decision models to aid in making choices, information by itself does not—and should not—dictate decisions. To regulate is to *make choices*, and to choose involves values, including the degree to which policy stakeholders—citizens in particular—are willing to embrace a degree of uncertainty about risk in return for other benefits.

Thus arises an inherent tension within the notion of precaution that resides at the core of the anticipatory stance: we cannot eliminate uncertainty. Indeed, there is a fundamental trade-off between being anticipatory and having actionable knowledge. The more anticipatory we want to be, and the longer our time frame, the less information there is to be had, even if it could be collected in a timely way. It is very hard to imagine extending the hierarchy and rigorous attention to detail of the typical HRO to democratic government writ large. And, as history shows, even the typical HRO can get it wrong.

DeLeo's (2010a) case study of avian influenza gets at this dilemma. In contrast to the reactive model of policymaking, which assumes that policy change typically occurs in response to tangible or manifest problems, DeLeo looks at a unique class of policy problems that arguably must be anticipated prior to their occurrence. Such problems are marked by significant uncertainty insofar that policymakers cannot predict if, how, when, or to what extent they will occur. DeLeo notes that although not a single known case of H5N1 avian influenza occurred on American soil, policymakers nonetheless prepared the nation for the threat even as they understood the potential for a non-event—as arguably happened with the swine flu in the 1970s. The uncertainty of the threat—laden with potential for severe impacts on the general population—led policymakers to strategically manipulate the definition of the avian influenza problem in order to limit uncertainty, in this instance using analogies to draw parallels with previous influenza outbreaks. In many ways, this approach to dealing with uncertainty moved away from pure indicator gathering (although indicators, such as case and deaths, were critical in influencing the policy response) and toward a more strategic policy debate over the definition of the problem at hand.

Yet, in key ways the discourse over avian influenza was far more robust than we are yet able to have regarding the potential EHS effects of nanotechnology. Right now regulators find themselves at a comparative informational disadvantage with respect to those industries they are tasked with overseeing (Coglianese 2010). This problem is by no means novel, as regulators in most fields find themselves wanting for more information. Yet, given the overall lack of established scientific knowledge that exists regarding the physical properties of materials at the nanoscale, the gulf between the knowledge base of those working with nanotechnology and those responsible for regulating is heightened.

Does such uncertainty, and the absence of indicators that it engenders, necessitate a leading regulatory role for industry? Perhaps, but proceed with caution, says Coglianese (2010). While a model of industry self-regulation governed by soft-law approaches might make sense in a flexible system of dynamic oversight, "the very reasons that make delegating discretion to industry seem attractive—even necessary—in the context of nanotechnology are reasons to suspect the effectiveness of voluntary or discretionary efforts" (Coglianese 2010, p. 73).

A number of problems are particularly glaring. For example, the absence of a single nanotechnology industry will stifle collective efforts at self-regulation or overarching industry standards. Whereas the nuclear or chemical industries are marked by relative coherence, there is no nano sector *per se*. Instead, nanotechnology is applied to or enables a host of highly independent sectors, including medicine, energy production, electronics, and biomaterials. Similarly, smaller firms may find it difficult to follow the risk management protocols adopted by their larger counterparts like DuPont. Perhaps most importantly, the lack of definitive factual knowledge about nanotechnology's health and environmental implications means that government and third-party regulators will have a very difficult time knowing what they should look for. In this regard, concludes Coglianese, "the same absence of information that makes government a poor central planner or regulator of nanotechnology also inhibits government's ability to act as an effective overseer of firms' own management plans or voluntary actions" (2010, p. 73).

In short, uncertainty, especially within the context of nanotechnology, can leave a regulatory regime chasing its tail. Driven by a desire to anticipate, regulators seek out actionable indicators. The information sought, however, is often imperfect and, worse yet, not relevant, as regulators can only speculate as to the precise problems that might emerge. This dilemma might entice regulators to look inward and focus on developing greater robustness in order to absorb and respond to whatever potential future harms arise; yet, citizens typically expect that government at least appear proactive—that it demonstrate that it is at least thinking about the future, is anticipating potential risks, and, by extension, is being proactive in protecting citizens from serving as guinea pigs in some risk assessment experiment.

Ultimately, a successful, accountable, and legitimate regulatory regime provides government and citizens alike with the capacity to recognize these opposing tensions—anticipation *and* resilience, certainty *and* uncertainty—and to consider how to balance them in daily life. A decade has passed since the inauguration of the NNI, and so far little clarity has emerged regarding what such a balance would actually look like.

The conundrum of capacity

In the consensus recommendations, the Minnesota investigators argue:

> [O]versight authorities need more capacity and resources. Until there is a commitment on the part of the federal government to support oversight, providing more resources to agencies and coordination bodies, it will be difficult to improve oversight. Fixing this will require political will and funding (Kuzma 2006). Increasing oversight capacity will require increased investment and there is growing recognition of this within the government (e.g., NNI, 2010) (Ramachandran et al. 2010).

Nobody can argue that "more" or "better" or "enhanced" agency capacity isn't needed. The problem is that we aren't entirely sure what we mean by "capacity" in the first place. Indeed, *capacity* is a concept widely employed in many literatures but, surprisingly, seldom examined closely. For decades, scholars in fields ranging from political development to regulation, not to mention the life sciences and engineering, have identified capacity building in one form or another as an absolute prerequisite for achieving stated ends or missions. There is also a large body of literature, particularly in public policy studies, portraying the dire consequences of its *absence*: lacking capacity, or having insufficient capacity, is frequently cited as a cause of failure at all levels of government, and, upon occasion, of government itself (e.g., Goldstein 1992; Frederickson and Frederickson 2006).

Lack of capacity ought to be cause for great concern, and not only for stakeholders in the nanotechnology community. For a variety of political and economic reasons, the opening decade of the twenty-first century witnessed a substantial erosion of government capacity at all levels. Today, every news cycle seems to bring yet another story about some public agency lacking the means to meet its mandated obligations: county officials in North Dakota, unable to maintain some remote rural roads, are turning asphalt back into gravel (Etter 2010); employees at the Securities and Exchange Commission complain of severe overwork and low morale during the economic meltdown (O'Keefe and Rein 2010); the Food and Drug Administration blames lack of personnel for outbreaks of salmonella poisoning in eggs during the Summer of 2010 (Martin 2010). Government in general, it seems, is facing a "capacity crisis."

But what *is* capacity, exactly? What do we really mean in bandying this term about, often casually, in thinking about the purpose of government? Most frequently, it is taken simply to refer to the *means* by which a desired goal is attained. Unfortunately, given the wide usage referred to above, this could mean almost anything. Thus, it is hardly surprising that the literature on capacity and capacity building, such as it is, is highly fragmented. For some authors, capacity refers narrowly to resources; to others, it is a function of management; still others see it as an organizational or institutional feature.

There is good reason to believe that a more generalized and overarching notion of capacity—and of capacity building—is needed. Every so often—and such occasions are sure to be more frequent and more challenging in the years ahead—governments need to "re-tool." Sometimes this is a relatively straightforward process, as when public officials respond to local population growth by increasing the number of police units or firefighters—a matter of simple addition. Most often these decisions are guided by tested formulae or by analogies to similar organizations or government units. Other cases, unfortunately for decision-makers, are trickier. For example, developing nuclear power both as a weapon and a source of energy required government organizations—initially the U.S. Army and later the Atomic Energy Commission—to take on a task that no government had never performed before.

As the nuclear power example suggests, emerging technologies, including and not limited to nanotechnology, pose challenges to government capacity. These developments will (and, in some areas, already do) place considerable strain on a range of federal agencies, from the U.S. Patent and Trade Office and National Institute of Standards and Testing to the Environmental Protection Agency and Food and Drug Administration, to name only a few. Most, if not all, of these agencies are already overburdened by present workloads, and by legacies of long-established statutory mandates that may have less relevance to newer challenges. As a result, expectations that government deal with waves of completely new and often not fully understood technologies should raise major concerns for those who worry about the ability of democratic government to foster technological innovation while also protecting the public health and welfare against the inevitable side effects of any new technology.

However, technical change is only part (albeit a large part) of the problem. Increasing globalization, with consequently rapid expansion in the diversity of markets and of service populations, will inevitably lead to new and unique demands upon public institutions. So too, will the ever-shifting requirements of national and homeland security. In short, it is no longer sufficient to regard government capacity building in an *ad hoc*, as-needed fashion. Public organizations, in the near future, will be called upon to develop new skills and capabilities—in effect, to "upgrade"—on a sustained basis.

By "unpacking" the concept of capacity, we hope to learn how to build it more readily, and to avoid the "reinventing the wheel" syndrome that characterized earlier efforts. In this regard, much writing vastly oversimplifies the concepts of capacity and capacity building, at least implicitly. There is a marked tendency, for example, to regard capacity as an attribute of single entities, such as (depending upon the immediate policy or administrative needs of the authors) management or a budget. Accordingly, capacity building often comes to be understood as a process of extending the capabilities of, or increasing the size of, the entity in question. Bigger, it seems, is better, although for what end is rarely clear.

One need not look very far to find the shortcomings of this idea. Take, for example, the view that equates capacity building with budget growth. There are many cases in which the simple appropriation of additional funds produced little or nothing in the way of desired policy outcomes. For example, full implementation of President Bush's multi-billion dollar effort to combat AIDS in sub-Saharan Africa, generally adjudged to have made real progress, was hampered in part because many recipient countries lacked the organizations and/or infrastructure to utilize—or in some instances, even to receive—critical funds (GAO 2008a).

Or, to return to the nuclear fission example, consider the exchange, in early 1943, between a very worried Secretary of War Stimson and President Roosevelt. Stimson conveyed to the President his "deep concern" that the Allies could be as much as eighteen months behind Nazi Germany in nuclear weapons research. Roosevelt immediately offered to provide more money. The Manhattan Project, however, was already fully funded (its total cost would exceed $2 billion and it would employ as many people as the entire U.S. auto industry). What the program needed at that stage—tangible research results—could not be bought. The critical element in this case was *time* (Hewlett and Anderson 1962).

In a similar—and more recent—vein, scrutiny of the EPA raises doubts as to whether a better-resourced agency will be able to fulfill its multiple, often conflicting, and inextricably path-dependent missions. More resources may help counteract the agency's institutional erosion following years (decades?) of underfunding, but they won't get at the EPA's core problem—its fundamental "incapacity" to deal with risk. We will address this matter below.

It is better, we think, to conceptualize budgetary and similar resources as one among a number of capacity *elements*, that is specific items or components that agencies require to fulfill their missions. Other examples, such as personnel and raw materials, seem rather obvious. There are, however, a great many important capacity elements that do not have physical form at all, including organization structure, knowledge and expertise, legal authority, political reputation, and time.

Elements, in turn, are best thought of as one of several capacity *dimensions*. Officials who are seeking additional organizational capacity must choose not only the set of elements desired, but also where it is to be located (e.g., management or line personnel), what function(s) to be served (manufacturing, service delivery, regulatory, etc.), whether it is for everyday or reserve use, and so on.

Seen in this way, equating capacity with budgetary resources is to some extent understandable. One approach to capacity building, which we have termed *capacity conversion*, involves transforming or trading one capacity element for another. Obviously, money is more easily converted or traded than most other commodities. Nevertheless, it is important to keep in mind that, as the saying goes (and the above examples make clear), money cannot buy everything.

However, there is a more practical reason why it is a mistake to focus narrowly on budgets. Traditionally, when adequacy of resources becomes an important issue—and the Minnesota project recommendations suggest that such will be the case here—the dominant strategy is to turn outside, to the legislators and responsible executive branch officials who control the budget. Given the circumstances—increased workloads, expanded responsibilities, and new and unfamiliar technologies– calling for significant budget increases for agencies with oversight responsibilities for nanotechnology is to be expected.

The reality, of course, is that this capacity crisis is occurring against a backdrop of a severely constrained fiscal environment. Thus, while some modest funding increases related to the oversight of nanotechnology can be expected (and some has already occurred), these are almost certain to be far below what is needed, and it would be a mistake to depend upon traditional external sources, such as Congress, for much capacity-building assistance.

Given this reality, for the foreseeable future success will come to those agencies able to develop internal and/or novel external sources of capacity building. Regulatory agencies in particular must develop considerable capacity to deal with rapidly changing information. They must be able to *scan*, to gather and process new information from the outside (what organization theorists know as "boundary spanning"); to *assimilate and integrate* those inputs; and to *adapt* (presumably successfully) in response to environmental changes.

In short, regulatory agencies must be able to and be given the opportunity to *learn*, to acquire and integrate new knowledge and skills, to accommodate new structures and procedures—even to reorganize—in response to rapid and unexpected environmental turbulence, and to be resilient in responding within the context rapid technological change. Such traits will be essential to an effective system of dynamic oversight. The key question, of course, is whether our current regulatory agencies are equipped for this task.

Redirecting agency "path dependency"

In May 2010, the Government Accountability Office (GAO), responding to a request by Senator Barbara Boxer (D–CA) in her role as chair of the Committee on Environment and Public Works, examined the capacity of the EPA to assess and address the potential environmental, health, and safety risks posed by the broad range of new nanoscale materials entering the general marketplace. The report, "Nanomaterials Are Widely Used in Commerce, but EPA Faces Challenges in Regulating Risk," was the latest in a string of GAO reports going back to at least 2005 on the potential regulatory implications posed by nanotechnology (e.g., GAO 2008b). This report, echoing earlier ones, concluded that although the agency was taking steps to understand and mitigate known and suspected risks:

> products may be entering the market without EPA review of all available information on their potential risk. Moreover, EPA faces challenges in effectively regulating nanomaterials that may be released in air, water, and waste because it lacks the technology to monitor and characterize these materials or the statutes include volume based regulatory thresholds that may be too high for effectively regulating the production and disposal of nanomaterials." (GAO 2010, p.i)

The GAO then made a series of recommendations for EPA action:

- Make greater use of the current statutory authority (e.g., the Toxics Substances Control Act, Clean Water Act) to gather information on nanomaterials;
- Revise TSCA rules on "significant new use" for nanomaterials and revise its chemicals inventory rules better capture information on the production and use of nanomaterials
- Modify Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) pesticide registration guidelines to require applicants to identify nanomaterial ingredients in pesticides, which EPA will consider to be new products under the statute. (2010, p. 50)

The EPA, for its part, responded affirmatively to these suggestions (GAO 2010, pp. 56–67), which to critical observers such as Richard Denison, Senior Scientist at the Environmental Defense Fund, seemed like low-hanging fruit to begin with (Denison 2009a). Progress of sorts has been claimed, and perhaps even achieved if compared to the agency's comparative immobility under the George W. Bush administration. Yet, nowhere in the report, or in the agency's response, was there mention of any need for the GAO's parent institution, the U.S. Congress, to address the array of statutes that collectively dictate what the EPA does or how the agency operates. Nor did the GAO mention the possibility that nanotechnology and related emergent technologies might offer the federal government an opportunity to reframe its fundamental approach to assessing and managing risk, a regulatory regime embedded (some say entombed) in statutory authority that is largely unchanged from the 1970s.

The EPA has generally insisted that it can regulate nanomaterials at any point in the product life cycle under existing statutory authority, albeit with some adjustments in TSCA and FIFRA in particular (GAO 2010, p. 40). Such assertions are greeted with some skepticism. Denison (2009b), for one, argues that TSCA is already "badly broken" and requires significant structural reforms to handle existing chemicals, much less new kinds of substances. J. Clarence Davies (2009a, p. 12), a leading expert on U.S. chemicals policy, calls TSCA "a deeply flawed act that needs major overhauling, not just for nano, but for any type of chemical." As Marc Eisner concludes in considering past EPA difficulties in dealing with toxic substances under TSCA, "[O]ne can only hope that the eventual regulation of nanotechnology will not be grafted onto existing regulatory capacity" (2010, p. 43).

Davies, an architect of the 1970 reorganization plan that led to the creation of the EPA, goes even further, arguing that the potential EHS risks posed by nanotechnology and related technologies should prompt a fundamental organizational overhaul of the federal regulatory regime. In particular, Davies calls for.

> the creation of a new Department of Environmental and Consumer Protection, which would incorporate six existing agencies: EPA, CPSC, OSHA, the National Oceanic and Atmospheric Agency (NOAA), U.S. Geological Survey (USGS), and National Institute for Occupational Safety and Health (NIOSH). This new meta-agency would focus on science and monitoring, although it would have a strong oversight component. It would foster more integrated approaches, requiring new legislation. (Davies 2009a, p. 13).

Yet, nowhere in the GAO report do we find any mention of organizational reform. To be fair, Senator Boxer never asked the GAO to ponder such fundamental questions, and GAO was not about to suggest them without being prompted to do so.

All of this ferment on TSCA and the EPA underscores the reality that the future of any proposed oversight model for nanotechnology and related technologies is inextricably tied to the future of the Environmental Protection Agency—and vice versa. The agency is commonly observed to be at a crossroads 40 years after being stitched together by President Nixon out of disparate and often contradictory parts of other federal units. For one thing, a great many of its professional staff, first hired in the expansionary period of the agency's founding, are at retirement age. Who will replace them, and with what skills and orientations? What would a twenty-first century EPA look like?

Marc Landy, for one, thinks that the EPA as currently situated cannot take up the risk challenge, regardless of budget and related resources (Landy 2010). This condition is not new, Landy argues, because the agency from its origins has been *institutionally* incapable of asking the right questions about risk. Such questions

> focus agency and public attention on the choices that are available and the ethical issues those choices raise…. They must reveal the moral and scientific presuppositions that underlie designations such as 'carcinogen' and 'hazardous substance.' They must acknowledge that nature's inherent unpredictability renders outcomes uncertain. And, they must confront the limitations that the available scientific information places upon the ability to take effective action (Landy et al. 1990, pp. 320–321).

According to Landy's line of argument, the EPA lacks the institutional capacity to lead such a deliberative approach because of the path-dependent nature of its multiple missions, its basic organization, the legal constraints under which it operates, and its organizational culture. Such contextual features are rooted in the distinctive political and institutional contexts of the agency's birth and early years, and they become ever harder to change "because the political and bureaucratic interests that they favor mobilize politically to protect them from change" (Landy 2010, p. 92). If few think that EPA is institutionally suited for its array of current responsibilities, fewer still would trade an imperfect present for much less certain future.

Even under the best of circumstances, the agency's legacy leaves it hamstrung (see Kettl 2002). EPA efforts to innovate through experiments in voluntary collaboration with industry such as the now-canceled National Environmental Performance Track or the short-lived and ultimately failed Nanoscale Materials Stewardship Program, "operate at the margins of the agency's activities. In critical areas of environmental regulation, the fundamentals of the old regime, rooted in statutes enacted in the 1970s, remain in place" (Landy 2010, p. 97).

It seems clear, if observers such as Denison, Davies, and Landy are indicative of any general consensus, that EPA as currently constituted is institutionally incapable of addressing already known risks, much less uncertain ones that may result from emergent technologies. Even if the "fault" lay in the agency's origins and the rigidity of the statutes it must administer, the fact remains that it is hardly likely to be able to play the needed coordinating role in any effective system of dynamic oversight of nanobiotechnology and related technologies. The result, barring fundamental institutional reordering along the lines argued by Davies (2009a, b), or major reform of TSCA, is continued muddling through, continued federal government stasis on critical questions of benefits and risks, and continued frustration among the wide array of interests with a stake in nanotechnology's future.

On the other hand, as Landy argues, nanotechnology throws all environmental regulatory stakeholders off their "accustomed games;" environmental and health advocates admit to nanotechnology's great potential benefits and industry interests admit to nanotechnology's potential environmental and health risks. In short, all stakeholders approach nanotechnology with ambivalence borne of experience with other technologies (e.g., genetically modified organisms).

> These ambivalences could set the stage for a grand political bargain: environmentalists support government validation of nanotechnologies in exchange for industry willingness to take on a far greater amount of preproduction environmental testing and data-sharing. Both sides thus obtain what they need the most. Industry obtains a government seal of approval for specific products and processes and may improve its overall public image in the process. Environmentalists gain the possibility of improved forms of environmental mitigation and escape the political trap of being branded as anti-technological Luddites. Both sides also make sacrifices. Industry must endure public probing into matters it would greatly prefer to keep proprietary. Environmentalists give up the ability to reflexively stir up fear about the risks of an emerging technology as a tool for mobilizing political support and financial contributions. (Landy 2010, p. 100).

Such a "grand bargain" ultimately requires leadership by the president and in Congress. Given current political circumstances, one is hard-pressed to see anything beyond an incremental adjustment in TSCA anytime soon, and even that may be beyond the current capacity of Congress to pull off absent crystallized public concern about some contaminant. Yet, even outrage about the unprecedented oil spill caused by the Deepwater Horizon disaster and unease about the potential health effects of cumulative exposure to bisphenol-A seems not to have translated into clarion calls for fundamental reform in the nation's regulatory regime.

Nor is Congress likely to grant coordinating authority to the NNI itself. There are, one suspects, far too many embedded interests in existing regulatory bodies to let that happen. Moreover, the NNI's primary role as nanotechnology promoter within the federal establishment probably disqualifies it from having any potential oversight role, if the history of other federal agencies with dual promotion and regulatory duties (e.g., the Atomic Energy Commission, the U.S. Department of Agriculture) offers lessons (see Denison 2007). We think, reluctantly, that the creation of a coordinating body sufficient to foster an effective system of dynamic oversight may need to await a crisis of confidence in the technology, or in environmental governance more generally, sufficient to cut through decades of encrustation.

Conclusion—fostering citizen engagement

This article has considered three of the Minnesota project's recommendations for instituting a system of dynamic oversight of nanobiotechnology and other emergent technologies. As noted, we think the project gets it right. However, as we suggest here, the path to implementation is an arduous one. First, there is no overarching conception of uncertainty on which to base an oversight system able to accommodate novel and/or complex situations. Second, a more nuanced understanding of the dimensions of agency capacity is essential before we can or should go about enhancing "it." Finally, and perhaps most critical, chances are remote that the nation's political leaders will be willing or able to create the type of coordinating mechanism deemed essential to such a system of oversight anytime soon. Landy's "grand bargain" about risk is nowhere on the horizon, unfortunately.

Yet, there are glimmers of hope for progress in the broader societal discourse about benefits and risk, a necessary precursor to movement on these other fronts. If nothing else, the "nanotechnology revolution" has forced hard thinking about long-settled views about risk, out of recognition that nanotechnology, broadly framed, exacerbates the regulatory regime's existing pathologies. Even if not entirely "unique" or "revolutionary," the sheer volume of nanoscale materials and products to hit the marketplace will certainly strain an already creaky oversight system, hence the first serious effort in Congress in decades to revisit the Toxic Substances Control Act (Davies 2009c). Even if Congress fails to enact TSCA reforms in 2010, its effort to consider them will have advanced needed discourse on U.S. chemicals policy.

This discussion is also taking place within a broader political context characterized by corroded citizen trust in government and business alike (Pew Center for People and the Press 2010). Citizens are more empowered than ever by their unparalleled ability to share access and information, prompting regulatory agencies to take more seriously the values of transparency and responsiveness (Bosso and Kay 2010). And, given the apparent stalemate on statutory or organizational change, an overt focus on transparency may be a good place to start. Greater transparency will not solve immediate problems with a particular regulatory framework or policy tool, but in the longer term transparency can bolster agency credibility as it engages the public in more honest conversations about risk and reward. Such credibility, ultimately, is the coin of the realm for those responsible for making the hard decisions on products entering the marketplace (Carpenter 2010).

The near-term challenge is for policymakers to realize that nanotechnology, combined with powerful transformations in information access and exchange, challenges longstanding approaches to oversight and regulation. An effective and legitimate twenty-first century oversight regime will be one that enlists many possible actors in a transparent public discourse designed to reap the benefits of technology development without sacrificing public health or other societal goals. One cannot hope to have a dynamic oversight system without first cultivating dynamic citizens. The insights obtained by this project provide a useful roadmap for doing so.

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