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RESEARCH PAPER

Settling into the midstream? Lessons for governance from the decade of nanotechnology

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Abstract This paper analyzes scholarly papers published from 2003 through 2013 on the general theme of nanotechnology and governance. It considers three general points: (1) the "problem" of nanotechnology; (2) general lessons for governance obtained; and (3) prospects for aligning the US regulatory system to the next generation of complex engineered nano-materials. It argues that engineered nano-materials and products are coming to market within an already mature regulatory framework of decade-old statutes, long-standing bureaucratic rules and routines, narrowly directive judicial decisions, and embedded institutional norms. That extant regulatory regime shapes how policymakers perceive, define, and address the relative benefits and risks of both proximate and yet-to-be idealized nano-materials and applications. The paper concludes that fundamental reforms in the extant regime are unlikely short of a perceived crisis.

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The decade of nano

We are over a decade into the "nanotech revolution," if we mark it as starting with the formation of the US National Nanotechnology Initiative in 2001 or, perhaps, with passage of the *21st Century Nanotechnology Research and Development Act* (P.L. 108–153) in 2003. Like synthetic chemical pesticides in the 1940s (Bosso 1987) and recombinant DNA in the 1970s (Krimsky 1983), nanotechnology broadly defined has been hailed as a transformative enabling technology with projected dramatic, even transformative, impacts on human health and material comfort, energy production and storage, computing, and environmental remediation, each with consequential economic and other societal benefits. In contrast with the post-war generation of synthetic pesticides in particular, the development of nanotechnology also has been accompanied by meaningful—and government funded—efforts to incorporate into technology innovation and commercialization research into and consideration of possible environmental, health, and safety (EHS) risks posed by engineered nano-materials (ENMs) and nano-enabled products (NEPs).

Such work has been accompanied by calls for more timely, effective, and *anticipatory* risk governance

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before possibly irreversible adverse effects manifest themselves (Wardak 2003; Wilson 2006; Davies 2006). Ideally, integration of such concerns should occur far earlier—more "upstream"—in the process of innovation and commercialization than had been the case with previous technologies (Guston and Sarewitz 2002). This said, it is useful to note that the societal and policy contexts within which nanotechnology has been emerging are fundamentally different from those in place during the early decades of the pesticides revolution, or even with the emergence of rDNA research. These differences matter in any current discourse and prospects for aligning risk governance—anticipatory ("upstream") or reactive ("downstream")—to any particular challenges posed by emerging or already emergent technologies.

This paper is a first take on that discourse. It is built around a review of nearly 90 scholarly papers published from 2003 through 2013 on a general theme of nanotechnology and governance.[1] Here I consider three main points: (1) the "problem" of nanotechnology; (2) the lessons for governance obtained; and (3) prospects for aligning the US regulatory system for the next generation of complex engineered nano-materials (CENMs). While my primary focus is on environmental and human health governance in the US, insights derived here are relevant to other challenges (e.g., nano-enabled therapeutics) and for other political systems.

Overall, I argue that ENMs and NEPs are coming to market within a US regulatory regime cobbled together 40 years earlier in response to challenges posed by chemicals (Vogel 2003). That *ancien régime*[2] of decade-old statutes, bureaucratic rules, narrowly directive judicial decisions, and institutional norms endures, despite its purported inadequacies (Landy et al. 1990), because attentive and well-organized stakeholders to date have been unable, even unwilling, to agree on needed changes in the absence of an existential crisis of public faith in that system. As a result, the continued embrace of this regulatory *ancien régime* on current policy discourse and action shapes how policymakers perceive, define, and address the relative benefits and risks of proximate and yet-to-be idealized nano-materials and applications. I conclude with thoughts on lessons from the Decade of Nano for anticipatory governance of the next generation of CENMs and other emerging technologies.

The "problem" of nano

In March 2010, the now-defunct *Aol News* published several stories on nanotechnology by investigative reporter Andrew Schneider. The series—*The Nanotech Gamble: Bold Science, Big Money, Growing Risks*—made several broad claims (Schneider 2010):

- Nanoparticles can cause disease and death—and the federal government is doing little to address these concerns.
- "Nano-foods" are coming soon, without adequate government oversight, evoking negative images of genetically modified organisms (GMOs).
- Promoters of nanotechnology emphasize technological innovation and economic growth over concerns about worker safety or consumer health.
- While billions are spent on basic science and technology development, comparatively little goes to environmental, health, and safety research.
- No federal agency is in charge of research on or decisions about nanotechnology EHS risks.
- Producers use their influence in Congress to stall needed reform efforts.
- The rush to commercialize nanotechnology may yet spark a backlash if citizens grow alarmed about the health and safety of nanoparticles.

While the series got little public notice overall, it stirred no small concern among promoters of nanotechnology development and commercialization. An official response came quickly from the National Nanotechnology Coordinating Office (NNCO), the lead unit of the US National Nanotechnology Initiative. Without openly calling the series sensationalistic, NNCO officials stressed that Schneider wrongly presumed that nanoparticles were inherently dangerous and that federal funding for nano-related EHS research had tripled from $34.8 million in fiscal year 2005 to $91.6 million in FY2010—albeit out of a total of $1.7 billion in FY10 dedicated federal R&D spending on nanotechnology (NNI 2010). Most telling, the NNCO made this concluding argument: "*Risk must be balanced against*

[1] A complete list of the articles considered in this analysis is available from the author.

[2] A term coined by Alexis de Tocqueville (1856) in describing the French monarchy.

benefits, and the essentially theoretical risk that has so far been identified should be balanced against the benefits in terms of sophisticated products and economic growth and jobs created by this expanding industry" (Teague 2010; see also Maynard 2010).

That argument, reasonable on its face, is familiar to any student of regulation. It was made in 1947 by proponents of synthetic pesticides when Congress enacted the Federal Insecticide, Fungicide, and Rodenticide Act, and again in 1972 when Congress reworked FIFRA in response to two decades of accumulating evidence that these chemicals posed adverse long-term environmental and human health effects (Bosso 1987). It was made about rDNA research prior to the Asilomar Conference of 1976, with chemicals generally when Congress devised the Toxic Substances Control Act (TSCA), also in 1976, and with virtually every environmental and health policy formulated since: we need to balance largely *clear and immediate benefits* against largely *theoretical and possibly far off risks*.

But this argument contains in it a vexing dilemma. As Hodge et al. (2010) observe, the incentives driving innovation and commercialization—billions of dollars in research and development, tantalizing prospects for dramatic technological breakthroughs, the specter of great profits or power for those commercializing those technologies—always outpace incentives for more anticipatory and systematic oversight of a technology's potentially adverse environmental and health impacts. In this regard, they continue (2010, 4), nanotechnology presents a "wicked" problem (Klijn 2008), characterized by "a multitude of stakeholders showing interest, but an inability for stakeholders to agree on either the nature of the 'problem' (to the degree that it exists at all), or on the most desirable solution to be applied…"

The history of DDT and other synthetic pesticides exhibited such asymmetries. Their benefits were evident and immediate—the capacity to grow more food with less labor, eradicate diseases like malaria, provide overall greater material comfort, spur economic growth, generate corporate profits—while any adverse effects on human and non-human species took decades to detect, measure, and acknowledge, usually with great reluctance and no small resistance by those whose economic interests were most affected (Bosso 1987; Wargo 1998). Similar asymmetries emerge with GM crops—the immediate benefits of higher yields and greater resistance to pests and drought versus concerns about genetic, ecological, and economic dislocation—and even more profoundly with global climate change, in which the benefits of burning carbon are immediate and material, and any risks—at least for those in affluent societies—are far off, perhaps beyond our immediate lifetimes (Bord et al. 1997). In general, then, the benefits of any technology or practice *always* seem clear, tangible, and immediate, and any risks they generate are less clear, less tangible, and, often, distant.

So what is the particular "problem" of nanotechnology for risk governance? In some respects, I think, it stemmed early on from a tendency to focus on its *uniqueness* and futurist revolutionary potential. For example, both technophiles like Kurzweil (2005) and technophobes like Michael Crichton (2003) framed the challenges posed by nanotechnology as *ultimate and unfamiliar* (Sandler 2009), whether in merging our biological and technologically augmented consciousness (Kurzweil) or in losing control of self-replicating nanobots (Crichton). In each instance we encounter challenges *we have not encountered before* and can only dimly understand. Such challenges are, in some ways, the stuff of a distant future, and whose form can be utopian or dystopian. Neither citizens nor political systems are well equipped to think about, much less plan for, futures that are far off and may not even occur, a point reinforced in recent work on human decision making and perceptions about risk coming out of behavioral economics (see Thaler and Sunstein 2008; Taleb 2007).

For others, nanotechnology poses challenges that are more *intermediate and vaguely familiar*. Similar challenges have emerged before in the context of other technologies and, as a result, we have *some* experience and resources with which to address their effects. For example, nanoscale genetic therapies may make it possible to alleviate symptoms of, if not cure, a range of neurological diseases and forms of cancer. Such breakthroughs will have dramatic impacts on human health and longevity, enabling many already born to live well beyond 100 years (McKibben 2004). Such longevity in itself will have powerful impacts on "traditional" social relationships (e.g., notions of adulthood, family structures), as well as social policies (e.g., health care, retirement pensions). Yet, in some ways, such concerns are new versions of older technological breakthroughs, whether sanitary sewers, pesticides, or antibiotics (Sandler 2009).

Any such concerns, no matter how distant, improbable, or speculative, merit attention. Yet, insofar as public policy is concerned, the relevant challenges posed by nanotechnology are more *immediate and familiar*. They are challenges that commonly arise in the development and application of any technology, whether the internal combustion engine, synthetic pesticides, petrochemical-based plastics, nuclear power, or therapies derived through biotechnology. Every new technology, by itself or in its modes of production, use, and disposal, generates familiar challenges to human health (e.g., air and water pollution, worker exposure, consumer safety), the natural environment (e.g., loss of species diversity), the economy (e.g., labor market effects, intellectual property), social justice (e.g., differential access, issues of accountability), and individual rights and liberties (e.g., loss of privacy, autonomy).

In this respect, whatever the particular uniqueness of the technological platforms on which nano-enabled products are based, the EHS challenges to be generated by them in our lifetimes are likely to be *variations* on old themes. Kurzweil's eagerness for the Singularity notwithstanding, for most of us the impacts of nanotechnology are likely to mean new and (we hope) better versions of existing materials and applications, ranging from electronics and solar cells to cosmetics and cancer therapeutics. As such, we know which questions we need to ask about challenges to risk governance. We need not wait for evidence of uniqueness.

This said, nanotechnology as an *enabling* technology exacerbates even immediate and familiar challenges for governance because it won't always be clear *what* are we trying to govern. Is it composition—the mere "nano-ness" of a substance? Is it property—how a nanoscale material (e.g., silver) differs from a similar material at bulk scale? Or, is it function? *What your nano is for*? In the end, it may well be the last, in which case talking about "nano" in and of itself may make little conceptual and analytical sense. We will come back to this question later.

Themes in the literature

For this analysis I reviewed nearly 90 scholarly papers published in US and European journals, edited volumes, and reports between 2003 and 2013 that addressed some element of governance as it related to nanotechnology broadly conceived. Most were by experts in the social sciences, law, and business, but with representation from toxicology, engineering, and occupational health, among others. I also made it certain to include papers published in general interest science journals like *Science* and *Nature*, as well as outlets like *Environmental Science and Technology* and, of course, the *Journal of Nanoparticle Research*. I decided not to include in this analysis the rich literature on public perceptions about nanotechnology and risk, which, while relevant to the questions at hand, I saw as already well addressed (e.g., Scheufele and Lewenstein 2005). While most of this literature focused on environmental governance, some extended into other areas of concern, drugs, and devices in particular. Overall, the goal was to use nanotechnology as an analytical lens to tease out general insights about governance.

One notes in the literature the shifts in concerns over time (Table 1). In the earliest years (roughly 2003–2005) scholars typically focused on defining nanotechnology for readers and, in the main, stressed the need to avoid repeating purported errors of past, whether with respect to pesticides, nuclear power, or rDNA. Or, as Krupp and Holliday (2005) famously put it in announcing the joint Environmental Defense Fund/DuPont NanoRisk Framework, "Let's Get Nanotech Right." In many respects, this literature wrestled with the prospect of *uniqueness*: while we long had theoretical understanding of the nanoscale (Feynman 1959), it was not until relatively recently that we had the technical capability to manipulate matter at that level. More to the point, this literature focused on how nanotechnology might converge with other emerging technologies, in new and revolutionary ways. We're not quite sure what to expect, but whatever we do we need to be able to balance innovation with protecting the public health and welfare. As Segal (2004, p. 302) concluded, "substantial societal benefits may be lost if a regulatory structure is either too lax or too strong."

Lurking beneath it all was evident concern that paying insufficient early attention to the potential adverse effects of revolutionary technologies might prompt a public backlash that stifles technological, economic, and social progress. Indeed, one sees in this literature repeated reference to the "GMO analogy," typically framed as a sobering case of an ill-informed

Table 1 Themes in the literature, 2003–2013

Early period (~2003–2005)
Defining nanotechnology; visions of benefits to humanity
Purported lessons from and need to avoid repeating errors with past technologies—the GMO analogy
Need to integrate "other societal issues" inquiry with science and tech to ensure sustainable development—and to prevent techno-skeptics from hijacking discourse
Middle period (~2006–2009)
Need for more EHS research to provide greater clarity about risks and suggest pathways to governance
Need for more ELSI research to enable anticipatory governance
Recognition of deficiencies in current regulatory regime
Late period (~2010–2013)
Recognition of elements of path dependency in regulatory regime
Ideas for new "soft law" approaches
Recommendations for adaptation strategies, trial and error
Focus on resilience and reflexivity in governance

and even technophobic public lashing out at a technology of great promise, thereby stifling its societally beneficial potential. As Bennett (2004, p. 28) observed in reviewing an analysis by Canadian bioethicists on the potential societal impacts on "nanotechnoscience" (NTS): "Chastened by the global backlash against genetically modified organisms, the ethicists are more concerned with safeguarding the blossoming of NTS from similar pitfalls than with any particular legal framework, set of ethical guidelines, or social vision."

Given such a framing, the solution to the perceived problem was predictable: educate the lay public to better understand and, one presumes, accept new technologies. Public acceptance of nanotechnology is vital, Kulinowski (2004, p. 19) warned her fellow technologists, who "ignore public concerns at their own peril. No nanotechnologist wants the field to go the way of GM foods, which are largely viewed as the poster child of misguided public policy." Such concerns get embedded in the *21st Century Nanotechnology Research and Development Act*, which set aside comparatively significant federal funds for research into public perceptions about and deliberation on nanotechnology as well as an array of formal and informal science education resources (e.g., the Nanoscale Informal Science and Education Network, or NISEnet) to ensure that the public has a more "complete" picture of nanotechnology right from the start. While some scholars (Sandler and Kay 2006) thought the GM analogy overdone and misplaced, it stuck, and in some policy circles (notably those in the European Union) the specter of GM foods continues to haunt nano-policy discourse.

Equally important for those promoting more "anticipatory" or "upstream" forms of governance (Guston and Sarewitz, 2002), we see even in the science and engineering literature calls to integrate "other societal issues" inquiry into the research and innovation agenda so as to ensure more sustainable and equitable technological development for the long term. Mills and Fleddermann (2005), for example, argue that nanotechnologists must address ethical issues in a multidisciplinary fashion with all stakeholders involved as technology emerges. Funding research into EHS impacts of nano is essential, but so too is fuller integration of EHS *thinking* into technology development: "Materials engineers and scientists in academic, government, and industrial settings, should be funded to work jointly with medical researchers to assess the health effects of nanomaterials as they are developed" (Mills and Fleddermann 2005, p. 25).

In sum, much of this early literature focused on nanotechnology's possible benefits, which almost everyone concluded were significant, even transformative, warned about repeating purported errors of the past, and expressed hopes that early investments in "other societal issues" research and "upstream public engagement" (Willsdon and Willis 2004) would, in the end, help to "get Nano Right."

In the middle period (roughly 2006–2009), the literature begins to exhibit a more evident focus on

uncertainty. That is, we see expressed concerns about possibly unique EHS risks posed by nanoparticles and the need for more research on nanoparticle fate and transport, toxic effects, and proximate and long-term risk challenges. Breggin and Carothers (2006, p. 290) summarize those concerns:

> Even as nanotech products find their way to store shelves, little is known about the risks associated with their manufacture, use, and disposal. There are only minimal data available on the effects of exposure to nano-materials on human health and the environment, and the methods and protocols needed to detect, measure, and characterize nano-materials in many cases are only in the process of being developed. The sheer variety of applications, properties expressed, routes of exposure, and means of disposal make it particularly challenging to identify, estimate, and manage any risks posed by nanotechnologies.

At the same time we see increasing recognition of and more highly specific concerns raised about purported deficiencies in extant regulatory approaches, with particular focus on the perceived shortcoming of the Toxic Substances Control Act (TSCA), the US EPA's primary statutory authority for assessing and managing substances that may pose human health risks. As Lobring (2006, p. 341) observes, each of the environmental regulatory regimes already in place "was developed to address specific threats to health and the environment arising from *either* the chemical reactivity or size of the particles in question. None of the existing regulatory regimes takes *both* into consideration." While most scholars end up advocating for tweaking TSCA to account for such properties, noted risk assessment expert and former EPA official Davies (2009) went so far as to recommend scrapping the existing US risk management regime and integrating its fragmented array of federal environmental and health oversight agencies and activities in a new Department of Environmental and Consumer Protection. Such a step has long been needed, Davies argues (2009, p. 4), but newer technologies make it imperative: "The oversight system is broken now. Revolutionary technologies like nanotechnology and synthetic biology are being commercialized now. The proposed oversight system is just a starting point for thinking about change, but change is urgently needed."

Most recently (2010–2013), we see a range of "middle range" proposals for dealing with the such uncertainties and with the deficiencies in governance identified earlier, led by calls for more flexible combinations of "soft" and "hard" law approaches, including sector-specific "nano codes" (Bowman and Hodge 2009), third party certification (Marchant et al. 2010), voluntary industry standards (Kica and Bowman 2012), and other "self-regulatory" practices (Abbott et al. 2012). Taken as a whole, these works address concerns about system *capacity*. Many of their proposals come out of recognition that the established regulatory regime always was or has become overly rigid and legalistic, and as such lacks a capacity to manage new and more complex ENMs and NEPs. Notably, scholars are also beginning to look at more incremental strategies stressing trial and error, adaptation, reflexivity, and overall system resilience in the face of rapid, cumulative, and convergent technological innovation (Johnson 2011).

Dilemmas for governance

In the main, then, the literatures reviewed posed several dilemmas for governance:

The *dilemma of uniqueness*: Early on much of the analysis focused on whether, or how much, nanotechnology *per se* was unique or in itself posed unique challenges. While one need not be a cynic to admit that framing nanotechnology as unique and transformative was essential to generating government support and R&D funding, for students of governance this line of argument quickly ran into an analytical and practical dead end. If nano *is* unique, we're stuck in place, waiting to see how it all unfolds, a passive stance that isn't helpful for anyone concerned about anticipating and heading off risks before they manifest themselves, perhaps irreversibly. Or, conversely, we don't allow commercialization until we're certain of no adverse effects, a strict reading of the precautionary principle with little support beyond the comparatively small group of activists seeking a moratorium on nanotechnology development until such answers were known. The analytical limits of uniqueness soon led most scholars to focus instead on *similarities*, how nano is like previous technologies (e.g., ag-biotech), even if the analogies themselves were contested (Kuzma and Priest 2010).

The *dilemma of uncertainty*: Beyond uniqueness, a theme in the literature is a concern about uncertainty, in particular the absence of clear and directive data on risks with which to make regulatory decisions. Such concerns generated calls for more funding on EHS research, and in many ways can be credited for the creation of the NSF/EPA-funded Centers for the Environmental Impacts of Nanotechnology at Duke University and the University of California, Los Angeles. Equally important, expressed concerns about uncertainty shed light on the critical issue of asymmetries in information between regulators and the regulated, with particular focus on industry use (and perhaps misuse) of the "confidential business information" (CBI) provision in TSCA to inhibit public scrutiny of risk data. The failure of the EPA's voluntary Nanomaterials Stewardship Program (NMSP) of 2008–2009 to generate much information underscored critics' arguments about the lack of transparency, and changes in CBI provisions are central to their efforts to reform TSCA—so far to no avail.

Beyond actionable data on human health risk, the dilemma of uncertainty also encompasses a lack of clarity or consensus on exactly what is being governed. As noted, it is not at all clear whether nano risk governance should focus on composition, properties, or function. The early literature tended to pay attention to composition and properties, with more recent analysis tending to admit that nano, *qua* nano, may be less the point than what nano is being used for function or the types of claims being made about particular NEPs. As such, the focus gets narrowed down from "governance" in a broad sense to the suitability of particular regulations or agencies when confronted with a new wave of products. If carbon nanotubes are analogous to asbestos fibers, then treat them as such. In this regard, "nano-ness" *per se* is likely to fade as the core focus.

The *dilemma of capacity*: Some—but by no means many—of the papers reviewed acknowledge limits on the *institutional capacity* of the extant regulatory regime in terms of agency legal authority, jurisdictional flexibility, scientific expertise, and, overall, the resources needed to act flexibly and more holistically with respect to technologies of high complexity and uncertain risk profiles. Such concerns get little traction in a political atmosphere of fiscal austerity and antipathy to regulation generally, leaving scholars of governance to seek solutions that don't actually require government.

The *dilemma of delegation*: In a similar vein, one sees over time a consensus on the limits of "traditional" command-and-control approaches to risk governance and consequent proposals for various "soft" law approaches, including industry codes of behavior, voluntary information sharing, and other carefully prescribed modes of self-regulation. Such schemes also reflect the aforementioned recognition of the uncertainty about risks inherent in emerging technologies, as well the information asymmetries between regulators and regulated, within a context of rapid technological change. This said, even proponents of "soft" law approaches recognize their limitations, in particular their varied efficacy and problems of democratic accountability.

The *dilemma of path dependence*: Most of the papers reviewed acknowledge one way or another that the established regulatory regime imposes severe limits on the ability of government to act with flexibility and effectiveness. Many focus on flaws in extant statutes, and a relative few on overlapping, fragmented, or overly constrained agency jurisdictions. As we will explore in greater detail in the next section, policies put in place enacted decades ago shape thought and action today. While not narrowly deterministic—change is possible—such embedded elements make adapting to new challenges that much more difficult.

The *dilemma of accountability*: Finally, a few papers explicitly or implicitly pose the classic question: Who governs? Who decides which risks are or are not acceptable, and for whom? While these questions are matters for a different paper, they are worth pondering, particularly if widespread use of some nano-enabled product (a cosmetic, perhaps) leads to unexpected adverse health effects that, in turn, generates an existential crisis about "nano" similar to public concerns about GMOs. Current public demands for mandatory labeling on food products containing GM variants, regardless of expert views about the relevance or efficacy of such laws, are suggestive about this dilemma.

For those concerned about governance of next generation nanotechnologies, perhaps the best news from the literature addresses the purported dilemma of uniqueness. If early assessments worried about the fundamental uniqueness of ENMs as a barrier to action, this concern has faded. That is, even taking into account any unique properties at the nanoscale, the

consensus seems to be that it is not "too early" to consider modes of effective governance, nor is there a need to wait for scientific certainty to anticipate and act on potential adverse effects. That is, we have enough lessons from previous technologies and their impacts to know what questions to ask and which types of governance approaches have worked best. For example, we do not need to know whether ENMs hold unique properties to know that we *should* be concerned about their possible health effects. We have sufficient experience with other types of particles (e.g., asbestos, silica) to take appropriate measures to reduce uncontrolled exposure, whether in the workplace, through everyday use, or when released into the environment. Equally important, we already have in place some technical, management, and legal resources to address such challenges. We may debate whether the measures actually taken are sufficient, but at least we have something to work with. Should targeted EHS research show engineered nanoparticles to be *uniquely* toxic or as presenting *uniquely* chronic risks, we would look for appropriately new ways to address such effects. Until then, however, we *are not* confronted by, or held prisoner to, uniqueness. We do not need to wait for definitive "proof" of a nano-material's environmental and health risks to anticipate its first-order effects, and to prepare accordingly.

However, even if not "revolutionary," the sheer range, diversity, and impacts of new and new types of nano-enabled materials and products already emerging in so many different sectors of the market *does* pose considerable additive challenges to existing risk governance regimes. If nothing else, nanotechnology—even in its most elemental and "passive" forms—exacerbates the complexity of even the most immediate and familiar challenges, such as protecting workers from exposure, which in turn generates new stresses for businesses and governments alike. If this is the case, we need to focus attention on whether the current risk governance regime adequately addresses known, even somewhat prosaic risks.

Upstream, midstream, downstream

Saying we need to focus greater attention on risk governance is easy enough. But *where* in the "stream" of innovation, commercialization, and use of products do we focus? And, having so affixed our gaze, what types of tools or approaches to risk governance do we try?

In Table 2, I lay out some of the concepts, approaches, and tools suggested by a range of scholars of governance at various phases or action points in the innovation stream, as well as thoughts on the trade-offs involved.

Not surprisingly, the challenges of upstream approaches like anticipatory governance speak to their transformative potential, and in many respects are long-term efforts directed at a paradigmatic reordering of core processes of discovery, innovation, and production. But they are long term. At the other end, as noted, scholars in the works examined here have largely set aside calls to reform "downstream" elements. They instead look increasingly to "mid-stream" elements of stakeholder engagement and "soft law" as means to instill greater co-production and reflexivity in governance under conditions of information uncertainty. This trend seems to reflect widespread recognition of and, perhaps, resignation about, the dim prospects for reforming the regulatory *ancien régime* absent of some existential crisis.

Path dependence in US environmental policy

Recognition that nanotechnology, in itself and in other so-called NBIC (nanotechnology, biotechnology, information technology, cognitive science) technologies will pose a range of challenges to risk governance has generated among experts and policymakers a consensus on the need for systematic approaches that combine principles of precaution, life-cycle thinking, sustainability, transparency, and meaningful public engagement (Paddock 2006). The question is to what degree any of these principles are embodied in current law and practice. In the European Union, one can argue that they infuse both the 2006 REACH framework on chemicals and newly enacted regulations on product labeling (Selin 2007). How key elements in the REACH framework—in particular the emphasis on data completeness and transparency, and placing greater responsibility on industry to manage risks—will fare in the implementation is less certain. Even so, the fact that these principles *are* embedded into law has implications for how EU nations at least think about and act on any risks posed by nano-materials.

Table 2 Where and how in the innovation stream

Upstream
Transforming processes of innovation and commercialization
Anticipatory governance/"real time technology assessment", embedded humanists (Guston and Sarewitz 2002)
"Upstream" public engagement in framing research questions/decision forums; scenario testing/problem framing/definition/use of analogies
Responsible Research and Innovation (RRI)—recent EU/US focus
"Sustainable" production (Life-Cycle Assessment, Green Chemistry)
Information needs—moderate to high depending on goal; role for stories and scenarios to aid in discourse
Relationships based on trust, capacity to think broadly about possible impacts
Role for public—central (in theory), structured through citizen forums, other mediated settings
Hardest to transform: must account for embedded structures of power, ways of thinking; a long-term strategy
Role of government—R&D support, remove barriers to innovation, change, remove policy supports for unsustainable methods
Midstream
Engaging stakeholders in co-production of knowledge, action
Soft law approaches
Self-interest, cooperation to avoid hard forms of regulation
Codes of conduct, statements of principles, partnership programs, voluntary programs and standards, certification programs, and private industry initiatives
Emerging tech coordinating committees (Marchant and Wallach 2015)
Information needs: Moderate; enough info to establish standards, codes, etc., but not so much as to measure and respond to risks.
Role for public—modest, mediated through NGOs
Easiest path? But problem of free riders, defectors
Government role is supportive, facilitative, but with threat of regulation
Downstream
Addressing externalities; Hard law, regulation—punishing rule breakers, etc.
Government role is central—sword and shield
Information needs: High; need sufficient, and sufficiently strong, information/data on which to make decisions; withstand counter-arguments, legal challenges
Role for public—relatively passive, central role for NGOs, lawyers
Path dependency issues, but change is possible under certain conditions

In the US, by contrast, one is struck by the reality that the foundational laws that continue to frame what Klyza and Sousa (2008) call the American "green state" were enacted from 1969 to 1976, the "golden age" of environmental lawmaking. The seismic changes in US environmental policy during this remarkable period were generated in large part by intense competition between Republican presidents and a Congress dominated by Democrats, each side determined to win the hearts of voters newly concerned about environmental and health issues (Jones 1974; Guber 2003). In this regard, one is reminded that the EPA was created by Richard Nixon, not Congress, to foster greater administrative efficiency by consolidating functions spread over 44 agencies (Shenkman 2011). This wave of assertive environmental policy innovation ebbed by the late 1970s, dissipated by the stresses of successive Middle East oil shocks and economic recession, and accompanied by the dominance of conservative elements in the Republican Party skeptical of regulation. The decades to follow saw a marked downturn in policy innovation, reflecting the deeper ideological and partisan stalemate that has come to characterize US politics. As a result, few new major environmental laws have been enacted since, and few of the laws created in the 1970s have been updated (Guber and Bosso 2012).

More important for the governance of next generation technologies, this stasis has essentially locked in the conceptual forms of the regulatory *ancien régime* insofar that the laws enacted in the 1970s have been judged by experts to be particularly pivotal in defining US environmental policy (Rejeski 2011). In part, these laws marked a "starting from zero" period of innovation in environmental policy, particularly in terms of more assertive and adversarial approaches to regulating risks. These laws remain disproportionately important because in most instances there has been little success in amending them to reflect new scientific knowledge about risk, adjustments based on experience, or new thinking about effective risk governance. Indeed, any changes over time in how these policies work largely have come from narrowly directive court decisions, the daily routines of rulemaking, and a legacy of resource constraints—not the purposive actions of democratically elected representatives.

In social science terms, the contours of the contemporary US environmental regulatory regime have been highly *path dependent*, operating within and shaped by formal-legal contexts set decades ago (Pierson 2000). Path dependence does not imply a narrow determinism: policy change is possible, and does occur. However, as became clear in cobbling together the Food Safety Modernization Act of 2010, it suggests that the decisions or actions of the past leave essential marks on the boundaries of discourse and action decades later. More important, as Levi (1997, p. 27) notes, "once a country or region has started down a track, the costs of reversal are very high. There will be other choice points, but *the entrenchments of certain institutional arrangements obstruct an easy reversal of the initial choice*."

Why does this matter for governance of next generation CENMs? For one thing, the foundational laws of the US "green state" were put into place long before current scholarly and policy discourses of precaution, risk management, and life-cycle analysis, so such comparatively holistic thinking is nowhere embodied into US statutory authority beyond, perhaps, requirements in the National Environmental Policy Act of 1969 mandating completion of environmental impact statements before facilities like dams or nuclear power plants can be constructed. Such statutory silences make it difficult for regulatory agencies (even the Food and Drug Administration on therapeutics to some extent) to break out of the kinds of narrowly construed and highly legalistic notions of adverse impact and risk that marked 1970s-era lawmaking, and which endure to this day (Landy 2010). Kamieniecki and Kraft (2008, ix) summarize the conundrum:

> A central concern in contemporary environmental policy debates is the political difficulty of modernizing the core statutes from the 1970s … to improve their coherence, effectiveness, and efficiency. Countless recommendations for sensible reforms from scholars and policymakers notwithstanding, those statutes remain largely unchanged. As a result, they cannot assist sufficiently in promoting the kind of environmental governance needed for the twenty-first century.

More critically, these statutes—encrusted by decades of judicial opinions, regulatory rules, bureaucratic norms, and the hardened positions of competing societal stakeholders—may actually *preclude* policymakers from acting with the flexibility arguably needed to address contemporary challenges. For example, while the EPA advocates greater "cradle to cradle" life-cycle thinking in product manufacturing, use, and reuse or disposal, current language in the Toxic Substances Control Act (TSCA) does not make it easy for the agency to even obtain the information on which to develop essential life-cycle inventories, much less incorporate life-cycle analysis into regulatory decision making (EPA 2006, p. 24). Indeed, as noted earlier, provisions in TSCA—enacted in 1976 and still the nation's primary statute for regulating chemicals—*exempt* producers from making public any data deemed as confidential business information (CBI). Critics argued that such CBI exemptions, which are defined by companies in registering their products, have left major holes in the knowledge base of front line public health regulators and first responders, and have undermined the ability of other stakeholders (e.g., environmental advocacy organizations) to judge the validity or utility of the information submitted by registrants (Vogel and Roberts 2011). The EPA, meanwhile, is burdened with deciding CBI claims on a case-by-case basis, a task the overstretched agency takes on largely depending on the broader regulatory goals of the occupant of the White House. In addition, many if not most solids (e.g., silica) were among the 62,000 "existing chemicals" grandfathered in when

TSCA was enacted, a deal cut with industry to gain passage of the law in the first place, and thus remain on the market without ever having gone through systematic testing.

Equally telling was the agency's inability to plug its informational gaps by other means. Of particular note here was the fate of the EPA's Nanoscale Materials Stewardship Program (NMSP), a voluntary effort late in the George W. Bush administration that in critics eyes failed to generate useful information about which companies are working with what types of nano-materials. To outside observers, such shortcomings underscored the EPA's comparative weakness *vis* producers and highlighted its structural/legal incapacity to incorporate integrated and more flexible modes of thinking into its decision making (GAO 2010). Some observers go so far as to argue that the political and statutory origins of the EPA *itself*, overlayered by limits on agency discretion imposed by Congress and the courts, has over time locked the agency into path dependent processes and behaviors that leave little room for a nuanced balancing of benefits and risks. In fact, the agency has not attempted to use the law to get a substance off the market since 1991, when a federal court severely narrowed its options for dealing with asbestos (Landy 2010). If, as argued, the problems of nanotechnology are immediate and familiar, the continued persistence of this regulatory *ancien régime* spells trouble for those hoping to promote norms of anticipation and precaution in environmental governance.

In December 2011 the EPA's Office of Inspector General issued a report on the agency's capacity to manage the risks posed by nano-enabled products. While the agency's IG argued that the EPA can find sufficient statutory authority over nano-materials in existing laws, TSCA in particular, the agency "does not currently have sufficient information or processes to effectively manage the human health and environmental risks of nano-materials" (EPA 2011). The report called on the EPA to improve both its internal and external information collection and distribution efforts, yet was silent about the agency's legal or institutional capacity to gather the information necessary to make nuanced decisions on environmental and health risks.

Prospects for updating the law were problematic. In 2009–2010, Democrats in Congress, working with the Obama administration, exerted considerable effort to bring TSCA up to date in large part out of concern about the law's relevance to new generations of ENMs (Vogel and Roberts 2011). Those efforts had some support from global chemical firms like DuPont and Monsanto, which already must comply with provisions in REACH (Layton 2008). However, changes designed to enable EPA to gather more information and shift the burden of proof to registrants were opposed by congressional Republicans, backed by smaller chemical firms and by ideological conservatives skeptical about regulation. The drive to update TSCA lost momentum, and collapsed after Republicans took control of the House of Representatives after the 2010 election.

No movement occurred until June 2015, when the Republican-led House passed a TSCA reform bill that gave EPA some added flexibility in evaluating and regulating chemicals. However, environmental and health advocates argued that the House bill was too favorable to industry and failed to address toxicity concerns about substances already on the market, much less enable the agency to deal proactively with novel materials. These groups favored a somewhat more comprehensive chemicals risk management measure that in December 2015 gained approval in the also Republican-led Senate. Observers were skeptical of compromise between the two bills. However, so many diverse interests, from chemical firms to their critics in the environmental community, had come to see TSCA reform as essential, in part because of the already apparent wave of new nano-materials. In May 2016 a House-Senate conference committee managed to devise a compromise that gained surprisingly easy passage in both chambers. At this writing the bill has gone to President Obama, who pledged to sign it into law (Davenport 2016).

Critics argue that the TSCA Modernization Act of 2015 makes only modest improvements in risk governance and favors industry by preempting the rights of state governments to devise more effective approaches. Supporters see it is an improvement over the old law because it mandates safety reviews for substances in commerce, broadens the capacity of the EPA to rank and address risks, and narrows the range of confidential business information claims by registrants (Denison 2016). Whether "new TSCA" really is an improvement won't be known for years, but that it happened at all said volumes about a consensus that this element of the regulatory ancien régime could not address contemporary risk governance challenges.

It won't be about nano much longer anyway

To restate: the *problem* of nano is not uniqueness or uncertainty. Instead, it is in some ways identical to the conceptual dilemma posed by pesticides in the 1960s, rDNA research in the 1970s, or GM variants in the 2000s: How do we balance evident, proximate, and usually material benefits with unclear, less proximate, and often intangible risks? If we look back through the history, we find that the incentive structure almost always favors those promoting technological innovation and commercialization: greater efficiency and convenience, more material comfort, better physical health, longer life, and so on. By contrast, those seeking to avoid or reduce risks confront more difficult tasks, starting with the contested notion of which risks are "acceptable" and exacerbated by the reality that risks may take years, if not longer, to show themselves.

The Age of Nanotechnology, whatever else it produces, has focused our attention on the challenges of balancing benefits and risks. In the US, the promise of nanotechnology forces even its promoters to worry that laws enacted decades ago no longer address the multiplicity and complexity of risks generated by technological development—if they ever did. If "command and control" approaches typical of 1970s-era regulation became seen over time as rigid, legalistic, and adversarial, calls for "self-regulation" and voluntary industry codes are criticized as being overly lenient and for failing to fulfill even modest goals (Coglianese and Nash 2001; Coglianese 2010). The challenge, as stated by the Intergovernmental Risk Governance Council (IRGC 2005 p. 119), "is really how to move beyond simplistic notions, such as self-regulation, to building systems of accountability and governance that are conducive to appropriate expansion of both science and democracy." Yet such exhortations neglect a reality that a regulatory regime based in the age of chemicals still imposes its shape, even with the most recent TSCA reform.

What are prospects for fundamental change? Until the recent passage of the "new TSCA", the long stalemate at the federal level had generated growing activism at the grassroots for more effective and accountable approaches to risk governance, demands borne out of mounting citizen concerns that they are being subject to harms over which they have little real understanding or personal control (Denison 2011). However, citizen concern and activism are necessary but not sufficient conditions for major policy reform (Baumgartner and Jones 1993). If history is a guide, fundamental change—more than relatively modest adjustments in TSCA—may require an existential crisis of faith in science and technology that dislodges the old order. *Silent Spring* catalyzed a major (if imperfect) rethinking of US pesticides policy, Three Mile Island fundamentally altered attitudes toward nuclear power (which even worse disasters at Chernobyl and Fukushima did little to dispel), outbreaks of "mad cow" disease (BSE) in the 1990s forced EU nations to overhaul their food safety systems (Baggott 1998), and similar perceived failures in chemicals management led to passage of REACH. Promoters of nanotechnology, minds firmly fixed on "lessons" of GMOs (Kulinowski 2004), worry about such crisis of faith just as the promised generation of nano-enabled products and applications are emerging from research and development. They should.

This being the case, an important lesson from the Decade of Nano is the importance of having in place a vibrant "advocacy coalition" (Sabatier 1988) clustered around various ethical, legal, and social issues (ELSI), and not just the soft educational and workforce concerns reflected in the *21st Century Nanotechnology Research and Development Act* (Sandler and Bosso 2007). In this regard, the role of the National Science Foundation in creating a cross-program nanotechnology program that funded ELSI research early on cannot be overstated. Where would our discourse on nanotechnology be today without NSF investments in the two Centers for Nanotechnology and Society, various Nanotechnology Interdisciplinary Research Teams, the societal implications thrusts in Nanoscale Engineering Research Centers, and the Nanoscale Informal Science Education Network? Whatever criticisms have been leveled at such efforts, without them one is hard pressed to imagine the existence of a broad and diverse network of experts not tied to industry or government who pay close attention to the broader societal dimensions of nanotechnology. Such "real time" assessment may not be as systematic or integrated at Guston and Sarewitz (2002) prescribed or desire, but it exists, and has informed the discourse on the benefits and risks of emerging technologies broadly understood.

What will become of all of this now that federal funding for nano-specific ELSI work has largely ended? In some ways those concerned about risks

posed by nanotechnology face greater challenges than those who focus their attention on pesticides, nuclear power, and GMOs. After all, nanotechnology enables other technologies. It has never been about nano, *per se*, but *what the nano is for*. Once we get beyond the laboratory or, even, the production space, the core issues will be functionality and intended use. Is it meant to have anti-microbial properties? Then it's a pesticide under current law, and will be of interest to existing environmental and public health advocacy groups focusing on that class of substances. Is it to deliver therapeutics to the brain? Then "nano" is a drug, and will be of interest to advocates concerned about the ethical research into, FDA approval for, and unintended side effects of *any* therapeutic. And so on.

The point here is that we aren't likely to see the institutionalization of a "nano" advocacy coalition because, barring some Crichton-esque existential crisis coming out of manipulating matter at the nanoscale, we won't be talking about nano that much longer. Once NEPs hit the market we will be talking, once again, about pesticides, therapeutics, materials, energy devices, electronics, and dual use technologies. No advocacy group will be dedicated solely to nanotechnology since looking at governance through a nano frame won't make sense.

What *will* remain is a loose network of principal investigators, researchers, and their intellectual progeny funded over the Decade of Nano, many of them now embedded in university positions and conveying lessons obtained to new generations of students and researchers. While this loose network is no substitute for the long-dead (and unlikely to be resuscitated) Office of Technology Assessment, a science court, or some other institution with a clear mandate and dedicated funding (see Marchant and Wallach 2015), it may well be effective over the long term as embedded memory and perspective, expertise that can anticipate, and that can still speak some truth to power. That's no trivial legacy.

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