Nanotechnology Regulation: A Study in Claims Making

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ABSTRACT There appears to be consensus on the notion that the hazards of nanotechnology are a social problem in need of resolution, but much dispute remains over what that resolution should be. There are a variety of potential policy tools for tackling this challenge, including conventional direct regulation, self-regulation, tort liability, financial guarantees, and more. The literature in this area is replete with proposals embracing one or more of these tools, typically using conventional regulation as a foil in which its inadequacy is presented as justification for a new proposed approach. At its core, the existing literature raises a critical question: What is the most effective role of government as regulator in these circumstances? This article explores that question by focusing upon two policy approaches in particular: conventional regulation and self-regulation, often described as hard law and soft law, respectively. Drawing from the sociology of social problems, the article examines the soft law construction of the nanotechnology problem and the associated solutions, with emphasis on the claims-making strategies used. In particular, it critically examines the rhetoric and underlying grounds for the soft law approach. It also sets out the grounds and framework for an alternative construction and solution—the concept of iterative regulation.

It is generally acknowledged that nanotechnology—the ability to measure and to control matter at the nanoscale level—is "disruptive," meaning it is a radical innovation that fundamentally challenges the existing product/technology market and opens new competitive opportunities.[1,2] While such characterizations focus upon its impact on markets, this new technology is also disruptive in another way; it challenges risk governance in the United States, meaning the legal and institutional decision-making processes used in addressing risks facing society.[3] Nanotechnology raises substantial scientific and policy issues regarding both risk assessment and standard setting, provoking calls for further study and "soft law" approaches relying upon voluntary action by industry rather than mandatory regulation.[4−6] Other commentators, some invoking the precautionary principle, advocate immediate prohibition of or substantial limits on nanotechnology under existing or new law.[7,8]

> Nanotechnology raises substantial scientific and policy issues regarding both risk assessment and standard setting.

Yet even as the debate over whether and how to regulate goes on, rapid nanotechnology deployment in industrial, commercial, and consumer settings continues. The danger of this lag is illustrated by historical examples of potentially hazardous innovations that became entrenched in commerce, ultimately causing substantial adverse health impacts and environmental damage, even as regulators engaged in research, contemplation, and voluntary initiatives. Tetraethyl lead and methyl *tert*-butyl ether (MTBE) are just two classic examples, but there are many others.[9]

The governance challenge with respect to nanomaterials regulation is 2-fold. First, regulatory policy must allow the development and deployment of this rapidly emerging technology while minimizing the negative public health and environmental impacts. Second, the difficulties inherent in balancing market innovation and environmental protection even with well-characterized chemicals and technologies are compounded here because the policy must operate under conditions of great uncertainty.

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TABLE 1. Problem Attributes

problem attribute	consequences	exemplar articles
There is a lack of available methodologies and data regarding uses, hazards, and exposures regarding nanoparticles.	Absent these methodologies and data, conventional direct regulation is not feasible.	6, 22, 32
Government agencies have limited technical capacity, knowledge, and resources.	Governance mechanisms must rely upon the capacity, knowledge, and resources of business firms and third-party organizations.	11, 22, 34
Beneficial but potentially risky development and deployment of nanotechnology is proceeding rapidly.	Balanced implementation of governance mechanisms must occur with comparable speed.	6, 33, 35

in these circumstances? This article explores that question by focusing upon two policy approaches in particular: conventional regulation and self-regulation, often described as hard law and soft law, respectively.

FRAMING THE ISSUES

Conventional direct regulation, or "command and control" regulation as it is typically (and often pejoratively) called, can generally be defined as "the issuance of prescriptive rules intended to directly control the behavior of private actors."[10] As I discuss more fully later, the description of direct regulation found in the literature is often at odds with its actual structure and operation "on the ground."

In contrast, self-regulation and soft law generally refer to governance mechanisms that have no or limited legal force.[11,12] There is a great deal of fuzziness regarding what actually counts as self-regulation or soft law,[13,14] particularly in the nanomaterials policy literature. Most commentators would characterize industry codes of conduct such as Responsible Care as within the ambit of self-regulation.[6,11,12] They also include arrangements in which nongovernmental third parties engage with industry in creating voluntary guidelines or decision frameworks as another extended form of self-regulation. The Environmental Defense—DuPont Nano Partnership Nano Risk Framework, essentially a recommended methodology for evaluating and addressing potential risks of nanoscale materials, is an example of this latter form.[6]

Lastly, some commentators also include "enforced self-regulation" within the scope of self-regulation, although here there is some significant ambiguity. As originally conceived by Ayres and Braithwaite in the classic book *Responsive Regulation*, enforced self-regulation was a form of "contractual" regulation in which an individual facility or industry group negotiated plant or industry sector specific, legally enforceable rules with the regulator.[15] Some commentators in nanopolicy appear to take a more expansive view, suggesting that "enforced self-regulation" refers to *voluntary* programs in which industry and government actors jointly participate, such as the Environmental Protection Agency's (EPA) ill-fated Nanoscale Materials Partnership Program.[6,16]

In examining the often competing approaches of hard law and soft law, I focus on how commentators use particular narratives to frame the problem and the potential solutions.[17] The policy debate we see occurring now is not simply a rational, analytic enterprise. Sociologists and political scientists in particular have examined how social problems come to be defined and addressed in policy—be it legislative or administrative. In one leading thread of social problem theory, sociologists characterize policy debate (whether among academics in journals such as this one, in the popular media, or in a legislative or administrative forum) as a "claims-making process." A claims maker develops narratives aimed at persuading their relevant audience (be it peers, the public, or policymakers) to embrace their definition of the problem and their identification and evaluation of the potential solutions.[18,19]

Likewise, political scientists speak of policy entrepreneurs, more intent on advancing a particular policy than on objectively evaluating a range of options. In a complex environment in which streams of problems, policies, and politics swirl about, policy entrepreneurs seek to control the decision agenda and frame the problem definition so as to advance their favorite policy.[20,21] Thus, the problem, its defined attributes, and the nature of the alternatives are constructions rather than objective facts as they are typically presented. They are supported by express and tacit assumptions and claims, both factual and normative. Exploring those assumptions and claims, challenging them, and considering alternative claims, can open up the policy discussion and lead to alternative constructions.

Such an analysis thus begins with problem definition. In the context of nanopolicy, most articles frame the problem definition as which governance approach, if any, is best suited to balance the potential health and environmental dangers of nanotechnology with its actual and potential social benefits. The articles tend to focus on a common set of problem attributes with associated consequences, as described in Table 1.

Detailed analysis and discussion of each of these attributes and their ostensible consequences are beyond the scope of this paper. However, it is important to note that the attributes and related consequences themselves reflect certain underlying, often tacit assumptions about the nature of conventional regulation and the capacities of regulatory agencies. For example, identifying the lack of data about toxicology, metrics, and exposure routes (and the absence of methodologies for obtaining that data in the near term) as an obstacle to direct regulation assumes that such regulation is heavily data-dependent and thus ineffective under conditions of uncertainty. As we shall see, the framing of the problem attributes and consequences also reflects certain assumptions about the incentives and capacities of business firms. The point here is that these attributes, consequences, and supporting assumptions tend to drive the narrative used by commentators to advance soft law approaches.

> The soft law narrative asserts that business firms, with some support from nongovernmental organizations and government, can most effectively balance the twin concerns of protection and innovation.

The soft law narrative responds to the problem attributes by asserting that business firms, with some support from nongovernmental organizations and government, can most effectively balance the twin concerns of protection and innovation, at least in the near-to-medium term. Hard law approaches are cast as impractical, ineffective, and potentially detrimental to beneficial innovation in nanotechnology applications. This soft law narrative appears to be driven by two sets of claims embedded in the problem attributes and consequences. The first is that, even absent direct regulation, business firms have strong incentives and sufficient capacity to adopt safe practices in the use of nanotechnology in products and production processes.[22,23] The second is that direct regulation is substantially hindered by its inherent structure and by the limited capacities of the implementing agencies.[6,22] Careful unpacking of those claims reveals that the foundations for the soft law approach are themselves a bit soft.

BUSINESS INCENTIVES AND CAPACITIES

With respect to the business narrative, I turn first to the incentives that shape business firm behavior. The literature generally relies upon three behavioral influences to support the notion that industry will effectively regulate itself: fear of tort liability, fear of technology stigma, and operation of the "good neighbor" norm.[23,24]

Take, for example, the fear of tort liability that a company may face when considering whether and how to incorporate a nanomaterial into a consumer product such as a toy, a tie, or a tire. Broadly speaking, should the consumer suffer harm as a result of exposure to that nanomaterial, the company may be liable for personal injuries and other damages under either a negligence standard or a strict liability standard. Negligence occurs where the company failed to act with "due care"; that is, the company did not meet the level of care one would expect from a reasonable person under the circumstances. Strict liability, on the other hand, does not directly depend upon the level of care exhibited by the manufacturer. Instead, it applies where a manufacturer sells a product that is unreasonably dangerous due either to a design or manufacturing defect or to inadequate warning of dangers associated with the product.[25,26] These forms of tort liability serve a compensatory function; they attempt to make the injured party whole. In theory, they also serve a deterrent function; the threat of liability drives companies to adopt reasonable measures to reduce risks to consumers.[27,28]

Fear of technology stigma focuses upon the public reaction to revealed hazards rather than technical legal liabilities. The story here is straightforward; if an accident or other incident involving nanomaterials in a consumer product or industrial process causes or even threatens substantial injury or damage, the resulting backlash could devastate not only the involved business, but the industry sector and perhaps even nanotechnology as a field. Salient examples include the impact of the Three Mile Island incident on the nuclear power industry and of the Starlink incident on genetically modified foods.[29,30] In some instances, the reaction will be rejection of the technology by the consumers or public more broadly; in other cases, the result may be onerous regulation.

Both fear of tort liability and fear of technology stigma relate primarily to the business firm's profit-making motive. The third behavioral influence—the "good neighbor" norms—relates to social values internalized by the firm as an institution, and by its managers and employees as individuals. By good neighbor norms I mean a number of social norms and personal values that may push members of business firms and the firms themselves to engage in "other-regarding" behavior. At the corporate level, this is reflected in the concept of corporate social responsibility, the notion that firms should—and in many cases actually do—engage in socially responsible behavior. In other words, firms attempt to "do the right thing." While some researchers link such behavior to instrumental motives (*i.e.*, good behavior leads to higher profits), others attribute socially responsible behavior to ethical or normative drives embedded in firm culture.[31] At the individual level, other-regarding behavior such as altruism has been documented by sociologists, psychologists, anthropologists, and others, and can be observed in everyday interactions.[36] Most commentators attribute this behavior to the operation of social norms, although there is continued debate over whether such norms are externally enforced through nonlegal social sanctions, self-enforced through feeling of guilt or shame, or rather fully internalized and thus essentially self-executing.[37,38]

At the outset, we should recognize that these three incentives—liability, stigma, and norms—do appear to have some role in business firm decision making. No doubt firms spend money and other resources attempting to avoid product liability lawsuits and to avert public and government perceptions that a product or production process is harmful. With that said, however, there is ample evidence that these factors are only part of the story, and in many circumstances are more than overcome by other individual and organizational drives and limitations. In particular, these incentives can lose behavioral traction in three ways, through what I call rational slippage, routine slippage, and cognitive slippage.

Rational slippage occurs when the firm engages in a calculation of the economic risks and benefits of selling a potentially dangerous product, or using an unreasonably hazardous process. It can significantly weaken the impact of those incentives, such as fear of liability and fear of technology stigma, that play upon a firm's self-interested profit motive. When the incentives are not properly aligned or structured, the profits from that activity may exceed the firm's perceived risk of loss.[28] For example, in practice, substantial tort actions based upon environmental harms and emerging technologies are difficult to win.[27,39]

One formidable hurdle is that the injured party in a tort lawsuit must establish causation, a particularly complicated and multifaceted element of the case. Typically, proving causation would require demonstrating both that a particular nanomaterial is capable of causing the disease in question (known as general causation) and that exposure to that material actually caused the injured party's disease in this case (specific causation). This is a difficult enough standard to meet in any situation; it can be insurmountable where there is a long lag between exposure and onset of disease, a likely scenario with nanomaterial exposures. This difficulty is also compounded by the relative paucity of data regarding nanomaterial uses, toxicity, and exposure pathways.[27,40] It is further complicated by the so-called *Daubert* standard for the admissibility of scientific evidence regarding causation in tort cases, a high bar generally requiring that the proffered theory or technique have achieved general acceptance within the relevant scientific community.[27,40,41]

Rational slippage increases when one considers what economists call the "agency problem." A business firm is a useful fiction but, in reality, individual executives and managers are the actual decision makers, acting as agents for the firm. In theory, they should be making decisions that are in the best interests of the firm. In practice, their own immediate interest in maximizing salary, bonuses, and status often leads to decisions that enhance short-term performance of the business, while undermining the long-term success or even survival of the firm.[42] This phenomenon is particularly acute where the action in question gives rise to immediate corporate profit coupled with potentially devastating but long-delayed consequences, as in tort claims involving diseases with long latency periods.

All of this is not to say that potential tort liability has no influence upon business behavior. Clearly, it has some influence; one need only observe the prevalence of insurance markets and the existence of risk-management departments and professionals within business firms to recognize that firms respond to the tort regime in structuring their organizations and operations. But the central questions are how strong an influence tort liability is, and what behavior it spawns. For example, concern over tort liability could drive an organization to make safer products, just as proponents of soft regulation contend. Alternatively, the specter of liability may also lead to strategic defensive responses, such as the underproduction of information regarding hazards or the conscious squelching of safer but more costly alternatives so as to undermine the viability of potential future tort claims.[28,43] When one takes into account the substantial legal and evidentiary hurdles facing the injured party, adds the high transactions costs associated with such lawsuits, and layers on top the likelihood of strategic behavior, "nano-tort" liability is not a particularly strong incentive for safe behavior.

Routine slippage focuses upon how the structural and organizational features of a business firm itself can undermine the effectiveness of incentives. Except for the very smallest of businesses, a company is a network of participants, with each performing assigned tasks in a coordinated effort to produce a product or service effectively and efficiently. Within that organizational network, resources such as funding and authority are allocated through a variety of internal rules, procedures, and practices. Likewise, the network participants are supplied with the information needed to perform their tasks through a variety of formal and informal communication channels.[44]

Whether a company is driven by profit maximization or social responsibility or both, the capacity of managers and staff to act in accordance with those goals is dependent upon their access to the necessary information, authority, and funding. For example, a product designer with a sincere desire to protect the consumer will not avoid a potentially hazardous component unless he is aware of that hazard and has the authority to alter the product specifications. Likewise, a trustworthy, economically rational executive will likely choose investment in an ostensibly cheaper, established production process over funding an apparently more expensive, safer alternative where the potential tort liability costs of the former have not been incorporated into the financial estimates. For a variety of reasons described in extensive literatures in law, sociology, economics, and business management, the flow of authority, funding, and information in many companies prevents optimal protection of public health and the environment.[44] This can be so even in those firms that, whether based on economic rationality or on other-regarding norms, are sincerely committed to reducing the impacts of their operations.

Cognitive slippage acknowledges humans' remarkable facility to "work around" even strongly held normative beliefs when it suits their self-interest. One such cognitive strategy is norm neutralization, in which the individual uses cognitive scripts to justify wayward behavior—a handy list of excuses for situations in which the relevant norm has been activated.[45] An example is the "metaphor of the ledger" script, in which the individual justifies an imminent norm violation by balancing it against a prior history of compliant behavior, characterizing him or herself as an essentially "good" person doing their best.[46] Defensive denial is another common cognitive strategy that works not by justifying an acknowledged norm violation, but rather by recharacterizing the situation so as to deny that the relevant norm is even applicable.[47,48] For example, one empirical study demonstrated that when conserving energy would impose high personal costs on individuals, they avoided the conservation norms by adjusting their perceptions of the seriousness of energy shortages or the harms flowing from current levels of energy use.[47]

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The demonstrated effects of calculated, routine, and cognitive slippage thus undermine the soft law narrative's reliance on tort liability, technology stigma, and other-regarding norms as incentives for effective self-regulation. Yet even when such incentives do play a strong part in business decision making, there is good reason to question the capacity of businesses to engage in effective self-regulation. Recall that as part of problem definition, the soft law literature tends to characterize businesses as agile innovators, responding efficiently to dynamic conditions. While that may be true for certain firms, business management researchers have identified the opposite effect in a variety of studies, concluding that many otherwise successful business organizations exhibit the inability to translate valuable new knowledge into effective action. This effect—called the performance paradox—is one manifestation of the wider phenomenon of organizational inertia, defined as the strong persistence of existing form and function.[44,49] No doubt the strength of inertial forces will vary across individual firms and industry sectors, but as a general matter, many organizations resist changing their internal processes and core functions.[44,50] While this inertia assures stability and reliable performance over shifting conditions, in some cases, conditions change in ways that render the firm's standard behavior inefficient or socially detrimental.[51]

Even assuming that a particular firm is operationally nimble, that trait alone is not sufficient to conclude that the firm is best left to its own devices in responding to the challenges of nanotechnology management. The firm will also need the requisite information regarding the hazards of that technology and the technical skills to select and to implement an effective response. Here, the heroic image of the environmentally conscious firm acting swiftly on the basis of its deep knowledge of its own operations breaks down. For example, while companies obviously understand their processes and the needs of the market, they often lack sufficient information regarding the chemicals and (sometimes ill-defined) materials they use in those processes to adequately protect their own employees. Likewise, extensive experience in a particular industrial process does not ensure knowledge about the nature or proper management of emissions or wastes from that process.[19,52]

Recent surveys of companies producing and using nanomaterials provide troubling evidence that such knowledge gaps are an impediment to effective management of nanomaterials.[53−55] Third parties such as trade associations can help to mitigate the problem by coordinating the collection and dissemination of information across the relevant industry sector. But dynamics in the business environment raise meaningful concerns about the completeness and accuracy of the information developed by trade associations. They are not simply neutral coordinators, but instead are strategic actors who may have incentives to withhold information, or to skew it so as to reduce costs to the industry or to benefit players within the industry having disproportionate influence over the association.[19]

RECASTING REGULATION AND THE REGULATORS

Turning now to the regulatory side of the story, we see that the soft law's narrative here is likewise flawed, both with respect to the nature of direct regulation and the capacity of regulatory agencies. Conventional direct regulation is typically depicted as a rigid, top down, one-size-fits-all approach. In particular, soft law advocates tell a story of regulation in which agencies establish prescriptive exposure limits based upon extensive toxicological and exposure data. According to the soft law narrative, it is this data-intensive approach that prevents the effective application of direct regulation in the data-poor environment of nanotechnology policy. This narrative mischaracterizes conventional regulation in two important ways.

First, while it is true that some regulatory programs rely heavily upon toxicological and exposure data to trigger regulatory action or set acceptable exposure levels, it is also true that many do not. In the United States, health standards under the Occupational Health and Safety Act (OSHA) are an example of the former, whereas emission standards under the Clean Air Act (CAA) and management standards in the federal hazardous waste programs are examples of the latter. Indeed, several CAA programs eschew risk assessment altogether and instead develop emissions limits on the basis of the best practices used within the relevant industry sector. The limits are almost uniformly written as performance standards, meaning that individual facilities are free to select the means of attaining the standard. Moreover, standard setting takes into account differences among firms within the relevant sector by breaking the sector down into categories and subcategories based upon company size, type of process, and other relevant factors, and—to the extent appropriate—setting different emission limits for the categories and subcategories.[19]

Second, although conventional regulation often does involve standard setting (whether technology-based or risk-based), it is substantially broader than the narrow soft law narrative suggests. Two other types of direct regulation commonly used in existing programs are information-based regulation and management-based regulation. Information-based regulation is intended to address situations in which the regulated firm has information regarding its operations not otherwise available to the government or some relevant third party. Thus, under the hazardous waste regulations, generators of hazardous waste must report data regarding waste generation and disposal to the government. Likewise under OSHA, manufacturers of hazardous chemicals must provide specified information to downstream commercial users. Management-based regulation requires companies to develop and to implement facility plans and procedures for evaluating and addressing various hazards.[56] For example, as part of the Risk Management Program established under the CAA, the EPA requires certain firms to prepare and to implement risk-management plans, including a specific obligation to develop appropriate management systems.[57,58] As discussed below, each of these types of direct regulation can play an important, immediate role in nanotechnology regulation.

Pessimism about the capacity of government as a regulator dissipates when the role of the government is clarified. Clearly, there are substantial troubling questions regarding the capacity of government to "micromanage" individual facility operations, particularly under the conditions of uncertainty surrounding nanotechnology. However, regulators are particularly well suited to engage in the actual type of regulatory activity typically taken: the nuanced codification of best practices and the implementation of information-based and management-based programs. For example, using broad information-collection authority arising from the CAA, the EPA gained extensive experience in collecting and disseminating data regarding best practices in terms of engineering and management. In doing so, it leverages the capacities of the trade associations as participants in the design and implementation of those collection activities. Unlike informal efforts of trade associations and research institutions, this formal authority reaches all members of the relevant industry and provides sanctions for recalcitrant or deceitful facilities.[19]

Governmental regulators are particularly well suited to engage in the actual type of regulatory activity typically taken: the nuanced codification of best practices and the implementation of information-based and management-based programs.

Where adequately funded, a government agency can also serve as a relatively neutral referee, providing coordination and direction when management practices across an industry sector conflict. Through its standard-setting process in the CAA, EPA served this role in the context of a mandatory rulemaking process. (The National Institute for Occupational Safety and Health's nanotechnology activities through the Nanotechnology Research Center is a particularly salient example of this coordination and guidance role in the nanotechnology context, albeit as part of a nonregulatory voluntary program.[59]) The public nature of the CAA rulemaking process, which invites participation from a broad range of interested parties, coupled with the right of judicial review, provides a level of accountability, legitimacy, and transparency not evident in voluntary soft law approaches.[19] These features are enhanced by the regulatory agency's capacity to ensure quality control through compliance assistance and enforcement, assuming the agency is provided sufficient resources.

CONCLUSIONS AND PROSPECTS

The above discussion challenged the soft law narrative regarding businesses incentives and capabilities, and concerning the structure of direct regulation and the capacities of the regulatory agencies. It offers a different story, one which is skeptical of the role that normative and economic incentives play in securing safe business behavior, and more optimistic about the ability of government to regulate successfully. But what would be the nature and scope of a nanotechnology regulatory regime that embraces that alternative story? While extensive discussion is beyond the scope of this article, it is useful to sketch out the potential framework for an alternative *iterative* approach to regulation.

Iterative regulation is based on two organizing principles. First, where reasonable concerns are raised about a nanomaterial in the scientific literature, regulators should make reasonable efforts to minimize potential hazards in the near term.[60] Although existing information gaps largely preclude the setting of quantitative technology-based or health-based exposure limits, a variety of qualitative best practices for managing nanotechnology do exist. Examples of such practices range from the streamlined approaches to risk evaluation such as control banding, to guidelines for the selection and use of specific engineering controls and work practices.[59,61] It is unlikely that those best practices will diffuse broadly and consistently throughout the relevant industry sectors absent government intervention in the form of direct regulation. Thus, regulators should deploy the full suite of direct policy tools in promoting the diffusion and effective implementation of best practices, including information disclosure and management-based regulation. Thus, agencies would use existing or newly granted information-based regulation to identify a range of best practices, and mandate that individual firms evaluate, select, and implement best practices most suitable to their operations.

Second, the nature, scope, and rigor of the regulatory action should adjust over time to reflect improvements and developments in data availability and scientific methodologies. So, for example, as toxicity testing and risk-evaluation methods progress, regulators may move from qualitative best practices to quantitative exposure limits. Alternatively, efforts are currently underway to develop methods for systematically identifying and evaluating safer alternative materials and processes. The National Institute for Occupational Safety and Health's Prevention through Design (PtD) initiative is one example of this approach, which seeks to anticipate and to "design-out" potential hazards in products and processes.[62] Other researchers are developing formal decision-analysis tools such as multicriteria decision analysis methods to assist in comparing alternatives.[16] Such methodologies may eventually enable regulators to shift from a conventional risk-management approach focused on setting acceptable levels to a comparative approach seeking the safest viable alternative. The promise of such future regulatory developments, however, need not and should not hinder the use of currently available conventional approaches in the interim.

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