Slowing the nanoscale revolution? Questions about government regulatory capacity

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ABSTRACT

The National Nanotechnology Initiative has committed substantial funding to nanoscale research and development across a wide array of potential applications. These efforts are expected to bear fruit fairly soon, yet the path from the development to widespread production and use is strewn with a number of potentially considerable legal, regulatory, and societal obstacles. This paper examines several aspects of one of these issues: government capacity.

Keywords: regulation, societal impacts

QUESTIONS ABOUT CAPACITY

Near universal enthusiasm about nanotechnology is tempered by recognition of the potential hurdles that lay ahead. One of these hurdles concerns the *capacity of government*, in the form of appropriate laws, policies, regulations, resources, expertise, and commitment. In an assessment on the applicability of the federal Toxic Substances Control Act (TSCA) to nanoparticles, the Foresight and Governance Project at the Woodrow Wilson Center offered four conclusions with broad relevance to the entire nanotechnology sector:

- The unique properties inherent in nanotechnology will pose new challenges to existing regulatory structures and, in the process, create confusion within both industry and government about the nature and scope of regulation.
- Little attention has been paid to the adequacy of the current regulatory system to protect human health and the environment, or about possible alternatives to existing regulatory regimes.
- The absence of any conclusive understanding about the health risks of nano-based substances makes more urgent the need for attention to and a dialog on regulatory adequacy and needed changes.
- Misguided or poorly designed regulatory approaches could have enormous economic consequences. [1]

In sum, there are expressed concerns about existing federal and state government institutional capacity, including (but not limited to) sufficiency in scientific expertise, legal authority, organizational design, and relevant regulatory frameworks, to address the societal and policy challenges posed by nanoscale substances and innovations.

Although it is not clear yet precisely how nanotechnology will change the regulatory landscape--and in turn be changed by it--there is no doubt these interactions will occur, with profound consequences all around. Anyone interested in nanotechnology therefore has a vested interest in how these as-yet uncertain dynamics play out. Our purpose here is to draw attention to a set of issues that apply beyond the United States to a wide array of nations and, even, transnational organizations and institutions.

Intellectual property rights

Although it does not regulate substances or product uses in the typical understanding of 'regulation,' the role of the U.S. Patent and Trademark Office (USPTO) as intellectual property gatekeeper promises to be an early and major factor in the timely, efficient, and responsible commercialization of nanotechnology. Industry in particular has a huge stake in a technologically informed and smoothly functioning intellectual property process, and therefore in a gatekeeper whose institutional capacity and scientific competence are up to the task. At this time the USPTO faces two significant challenges with relevance to nanotechnology:

Resources: The agency is already sagging under the weight of a deluge of patent applications from sectors ranging widely from software to biotechnology. In 2003 USPTO director James Rogan warned Congress of backlog of over 1 million applications by 2008, with the resulting turnaround time for clearing a patent stretching to an untenable (for industry) four years. [2] Without a significant transfusion of resources, additional patent examiners in particular, the situation is expected to worsen considerably with the projected influx of patent applications for nanoscale innovations.

Scientific Expertise: There are doubts, even within the agency, about the overall scientific capacity of the current roster of patent examiners to assess applications based on nanoscale innovations. The absence of sufficient numbers

of scientifically competent expert examiners will exacerbate the backlog of applications and could lead to instances where patents are granted too easily or approved for similar or identical innovations. Each of these scenarios would be problematic and costly to both applicants and industry at large.

The basic capacity of the intellectual property system will have profound effects on research and development investments, the rate of diffusion of technological information, the innovation process, and, by extension, the pace of commercialization. How the USPTO copes with existing challenges and positions itself for the expected influx of nanoscale innovations, and what actions Congress does or does not take in reforming the USPTO and existing patent law, are of major consequence to the future commercialization of nanotechnology across the board.

Regulatory frameworks

At some point soon those in government will have to confront questions about how to review new products as they move to market, as well as how to respond to possible negative social and environmental effects. Multiple federal, state, and local agencies are expected to be involved in regulating some of the uses of or effects from these technologies, ranging from product or use approval all the way to more prosaic but not inconsequential issues of zoning approvals for manufacturing facilities and permits for waste disposal. The capacity of federal and state regulatory agencies to deal with an expected influx of new nanoscale technologies, uses, and production processes is crucial to the commercialization process.

Institutional capacity? Some potential capacity problems concern agencies responsible for providing "up front" regulatory approval necessary for new technologies to move to commercial production. The U.S. Food and Drug Administration, for example, is expected to confront a wave of new nanomedical devices and treatments, yet the agency already has trouble managing its present workload and is widely criticized for the length and complexity of its clearance process. Recently the agency has been drawing widespread criticism for slowdowns in the pace of pharmaceutical and biotechnological innovation and commercialization.

Adequate regulatory frameworks? At a minimum, policymakers will be faced with the immense task of rewriting large portions of the already vast and complex set of laws, statutes and regulations that deal with manufacturing, health and safety, the environment and other relevant areas. Federal officials at the FDA and EPA, among others, typically claim that existing regulations and standards are adequate for most nanotechnology products, but outside experts are more circumspect about whether adequate regulatory and scientific capacity to fully address nanotechnology needs are in place. [3][4] Whether the FDA and the Environmental Protection Agency in particular will have the basic institutional capacity to handle the expected regulatory challenge generated by nanotechnology is a matter of serious concern for everyone, not least of all the inventors and companies seeking to gain federal approval for their innovations and products.

New responsibilities or a new agency? It is not clear that the current institutional design of the federal regulatory system, one based either on media (e.g., air or water pollution, food pathogens), functional areas (e.g., workplaces), uses (medical versus food consumption), or target populations (e.g., humans versus animals) is adequate or desirable to address a new set of technologies with revolutionary properties. But neither is it clear what is to be done. Will or should nanoscale particles, products, devices, or systems be parts of existing agency jurisdictions, or should there be thought given to the creation of a new federal agency that focuses only on nanoscale products and issues? This latter question is not posed frivolously. The EPA alone is so burdened by existing mandates that one wonders how the agency will handle even more, and more complex, responsibilities. Similar concerns confront the FDA, elements of the USDA, and other front-line federal regulatory agencies.

Policy by analogy or radical rethinking? It also isn't obvious which types of regulatory tools or frameworks will suffice for the challenges posed by the production, use, and disposal of nanoscale products. [5] Will we--must we--end up with a jumble of tools derived analogously from existing rules and regulations, or is there a unified approach that can suit the needs of affected firms and concerned citizens alike? What is the appropriate balance between traditional modes of government enforcement and newer types of performance-based systems? To what extent can the nanotech sector regulate itself, and how?

It may be possible to build adequate regulatory capacity for nanotechnology through incremental changes in existing regulatory agencies and approaches. Policymaking by analogy is not out of the question. However, substantial, even radical, changes also may be required. Just as nanotechology promises to be a revolution in science and industry, it also might require a revolution (perhaps modest, perhaps radical) in our approaches to regulating emerging technologies and their impacts. In short, the moment is opportune for a serious, crosscutting assessment of federal and state regulatory capacity and design.

Crosscutting Challenges? Nanotech broadly understood will challenge existing regulatory designs and, subsequently, compel policymakers to develop technology-relevant and crosscutting interagency and federal-state modes of regulation. With most previous technological

revolutions, governmental regulation and capacity was created only after the need became apparent, often decades after the initial commercial scale introduction of the technology. With respect to nanotechology, by contrast, institutions and knowledge from previous experience do exist, and those in government are aware of both the significance of the technology and the importance of well-designed and competent regulatory institutions. Thus nanotechnology provides an opportunity for historically informed, government supported, anticipatory assessment of the regulatory status quo (including, but not limited to, frameworks, models, resource allocation, divisions of responsibility), and the development of alternatives. Rather than focus on individual laws, rules, or agencies, now is the time to think in systematic terms about how the federal and state governments should address the expected regulatory challenges posed by nanoscale innovations and social and environmental effects.

State government capacity? What should states be doing? B.G. Rabe has observed, in the context of studying state level action on climate change, that policymaking at the state level is often more informal, with fewer entrenched interests and a less densely populated administrative sector. "Consequently," Rabe notes, "many state capitals may offer particularly promising entrepreneurship opportunities, particularly for relatively 'new' issues for which an infrastructure of established policies and interest group positions has not been created." [6]

State governments are more likely to openly balance regulation against economic development, and are therefore less likely to look at environmental regulation, for example, through a zero-sum lens. A useful question, then, is to what degree any emerging nanotechnology regulatory regime should be based on uniform federal rules or allow for state flexibility.

Bringing the public in? We need a better understanding of the extent to which the expressed and latent needs of the broader public should be considered in institutional and policy design, as well as whether existing institution and policy designs, or incremental changes from them, are sufficiently responsive to and protective of these values in the context of the challenges posed by the nanotech revolution. In particular,

- What role should the public be afforded in regulatory and policy decisions regarding nanotech at different levels and on different issues, particularly given the complexity of the scientific information that may be relevant to those decisions?
- How can responsiveness on the part of regulatory institutions be encouraged, without inappropriately ceding regulatory authority to the public, but while maintaining appropriate standards of public access to process and participatory justice?
- How can distributive justice be effectively encouraged in the context of what is expected to be a dynamic labor market and economic landscape?
- How are communal values, aesthetic values, and the good of animals and ecosystems, for example, to be afforded consideration?
- To what degree does scientific complexity feed into public uncertainty of and potential opposition to the commercialization of some products or applications?
- How should we proceed under conditions of complexity and uncertainty--with what levels of precaution and assurance, at what pace, in which directions, and with what safeguards?

The history of previous technological revolutions shows that economic values and human health are not the only goods at stake with emerging technologies. It is crucial to consider, particularly in the context of a systematic and integrative assessment of U.S. regulatory approaches, whether, to what extent, and how these other values should inform our regulatory institutions and policy designs as we build the requisite capacity for nanotechnology.

Why it matters

It is vitally important to those industries and innovators concerned about the future of nanotechnology to pay attention to issues of government capacity and societal impacts. Three major reasons for this stand out:

1. Promoting innovation and expediting commercialization. Ensuring sufficient governmental capacity is crucial to promoting innovation and expediting commercial production. It is not difficult to imagine a scenario in which a nanoscale-based product, one representing a substantial investment in time and resources, is either forced to make expensive modifications or rejected altogether because of unforeseen obstacles or changes in the regulatory landscape.

2. Protecting the public interest. Whatever their broader views about the "proper" role of government, citizens generally expect it to protect them from the potentially harmful effects of technology and its applications. Moreover, citizens expect that government will be open and responsive to their concerns and wants. [7] The lessons of the past for nanotechnology are that governmental agencies must be anticipatory and proactive if they are to protect the public interest from possible risks of emerging technologies. The great hope for nanotechnology, as articulated in the NNI, is that it will promote the welfare of U.S. citizens in a just and sustainable way. Governmental capacity (state, federal, and local) to protect human and environmental health and to encourage participatory democracy and distributive justice is crucial to realizing this vision.

3. Promoting public confidence. Systematic failure by government to respond to public concerns and protect the public with respect to emerging technologies (for reasons of resources, capability, or commitment) eventually undermines public confidence in government. [8] Such a lack of confidence can have spillover that result in opposition to those technologies, which, in turn, hamper technological and economic development. While a latent faith in the adequacy in the regulatory system may not assure total public acceptance of novel technologies, its absence will most certainly throw up another obstacle to timely and effective commercialization.

Reframing the role of regulation

Rather than acting as impediments to technological innovation, appropriately configured and effective regulatory institutions can serve to promote the advancement of research and development, promote smooth and timely commercialization of products containing nanoscale technologies, protect the public from possible negative effects of these technologies and their use, and, along the way, be responsive to public concerns regarding those effects. For their part, firms seeking to profit from their current research and development efforts have an obvious vested interest in effective regulatory institutions, even if they do not always publicly admit as much. Those who care about the future of nanotechnology should also care about the capacity of government to do its job, and no less to the satisfaction of the attentive public. Abstract and often arid ideological debates over the proper "size" of government miss the central point: size will not matter, but competence and transparency most assuredly will.

Sources

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