Disrupting Conventional Policy: The Three Faces of Nanotechnology

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Technological innovation almost always comes at a price in terms of environmental health. In large part, this equation can be traced to one of the fundamental differences between technological innovation and regulatory innovation. The former can often occur swiftly, coming from numerous diffuse sources within the market. The latter, with rare exceptions, moves slowly, flowing from centralized state, national or international sources.[1] Thus, regulatory response typically lags well beyond the introduction of new products and technology. Nanotechnology, defined for these purposes as the use, manipulation or control of materials at the nanometer scale, is yet another case in point. Nanomaterials already are present in hundreds of consumer and industrial applications, yet are subject to minimal regulation in the United States and elsewhere.

Despite the paucity of comprehensive testing of nanomaterials, there is a growing body of evidence that exposure to some types of nanoparticles may pose significant health risks to workers and the general public.[2] The very properties that make engineered nanomaterials valuable—small size, large surface area and highly variable physical and chemical characteristics—both complicate our ability to monitor exposures to nanomaterials and increase the potential that some categories of nanomaterials will prove harmful. Notwithstanding the expected benefits of emerging nanotechnologies and nanomaterials, the hazards associated with them have lead to a cacophony of appeals for various types of regulatory response, ranging from a moratorium to industry self-regulation and virtually everything in between. With this back-

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1. For a discussion of market innovation and regulatory innovation, see Timothy F. Malloy, *Regulating by Incentives: Myths, Models, and Micromarkets*, 80 TEX. L. REV. 531, 540, n.23 (2002).

2. Andre Nel et al., *Toxic Potential of Materials at the Nanolevel*, 311 SCI. 622 (2006).

ground in mind, the UCLA Working Conference on Nanotechnology Regulatory Policy commissioned a series of papers to form the centerpiece of pragmatic discussion regarding the way forward.

Commentators often characterize nanotechnology as "disruptive," meaning it is a form of radical technological innovation that fundamentally challenges the existing product/technology market and leads to new competitive opportunities.[3] Yet this new technology is disruptive in three other significant ways as well. It presents difficult technical issues regarding toxicity testing and hazard assessment so central to conventional regulatory policy. Likewise, it highlights the limits of existing risk governance approaches in use in the United States and abroad, particularly with respect to the role of third parties and the general public in policymaking. Lastly, it strains an already overburdened—and some might say obsolete—regulatory system, raising calls for innovative approaches more suited to managing this strange new technology. The papers that follow deal thoughtfully with these three themes, providing useful background and provocative prescriptions for policymakers, industry and academia alike.

THE NEED FOR A NEW TOXICOLOGY

In *The Scientific Basis for the Regulation of Nanoparticles: Challenging Paracelsus and Pare*, Dr. Bernard Goldstein describes how the unique attributes of nanomaterials can turn commonly accepted laws of toxicology on their head. Consequently, he argues, conventional toxicity testing and assessment are neither protective nor cost-effective. He appeals for substantial investment in new approaches to toxicology, including new toxicological testing modalities, improved exposure assessment, and post-marketing surveillance of nanomaterials in products. Dr. Goldstein's emphasis on developing a new toxicology for nanotechnology is consistent with the growth of predictive toxicol-

3. *See* Steven T. Walsh, *Roadmapping a Disruptive Technology: A Case Study: The Emerging Microsystems and Top-down Nanosystems Industry*, 71 TECHNOLOGICAL FORECASTING AND SOCIAL CHANGE 161, 165-66 (2004); Dana Nicolay, *Challenges and Opportunities for Nanotechnology Policies: An Australian Perspective*, 1 NANOTECH. L. & BUS. 446, 453-454 (2004).

ogy more generally,[4] and with work currently underway at universities and other research centers.[5]

Dr. Goldstein sees a direct link between the new toxicological science and regulatory policy, arguing that better science is required for appropriate risk management. He cautions against embracing the precautionary principle, concerned about the likelihood of incurring unreasonably high social costs. In this regard, he moves beyond purely scientific commentary to address questions of risk governance, a theme taken up more directly by other authors.

CONFRONTING QUESTIONS OF RISK GOVERNANCE

Risk governance refers to the social, legal and institutional decision-making processes used in identifying and responding to risks facing society.[6] Historically, governance of public health and environmental hazards embraced a technocratic risk management approach, using quantitative risk assessment to identify legitimate concerns and relying upon experts to select the appropriate response.[7] Typically the conventional risk management approach minimized the role of the public in the problem-framing and decision-making process, and eschewed a precautionary approach as lacking a legitimate scientific basis. In his article,

4. *See* COMMITTEE ON TOXICITY TESTING AND ASSESSMENT OF ENVTL. AGENTS, NAT'L RES. COUNCIL, TOXICITY TESTING IN THE 21ST CENTURY: A VISION AND A STRATEGY 35-55 (2007); Francis S. Collins et al., *Transforming Environmental Health Protection*, 319 SCI. 906-907 (2008).

5. *See* Huan Meng et al., *A Predictive Toxicological Paradigm for the Safety Assessment of Nanomaterials*, 3 ACS NANO 1620, 1625 (2009) (describing predictive toxicology work on nanomaterials at UCLA's Center for the Environmental Implications of Nanotechnology).

6. Regarding "governance" as a concept, see, e.g., ALAN HUNT & GARY WICKHAM, FOUCAULT AND LAW: TOWARDS A SOCIOLOGY OF LAS AS GOVERNANCE (1994); Nan D. Hunter, *"Public-Private" Health Law: New Directions in Public Health*, 10 J. HEALTH CARE L. & POL'Y 89 (2007); Orly Lobel, *The Renew Deal: The Fall of Regulation and the Rise of Governance in Contemporary Legal Thought*, 89 MINN. L. REV. 342 (2004). For risk governance more particularly, see, e.g., ORTWIN RENN, RISK GOVERNANCE: COPING WITH UNCERTAINTY IN A COMPLEX WORLD (2008); PRESIDENTIAL/CONG. COMMISSION ON RISK ASSESSMENT AND RISK MANAGEMENT (PCCRARM), FRAMEWORK FOR ENVIRONMENTAL HEALTH RISK MANAGEMENT (1997); INT'L RISK GOVERNANCE COUNCIL, WHITE PAPER ON RISK GOVERNANCE (2007).

7. Susana Borrás, *Legitimate Governance of Risk at the EU Level? The Case of Genetically Modified Organisms*, 73 TECHNOLOGICAL FORECASTING & SOCIAL CHANGE 61, 63-64 (2006); Daniel J. Fiorino, *Citizen Participation and Environmental Risk: A Survey of Institutional Mechanisms*, 15 SCIENCE, TECHNOLOGY, & HUMAN VALUES 226, 226-27 (1990).

Precautionary Governance and the Limits of Scientific Knowledge: a Democratic Framework for Regulating Nano-Technology, Professor Oren Perez challenges those two aspects of risk management, arguing that in the case of nanotechnology the legitimate scope and application of the precautionary principle should be determined through democratic processes. He seeks to "re-politicize" the precautionary principle by providing for meaningful public participation in identifying and resolving questions regarding potentially substantial hazards involving conditions of scientific uncertainty.

Newly emerging conceptions of risk governance recognize that actors beyond government can serve important and even primary roles in governance, either as stakeholders or as primary decision-makers.[8] In *The Private Dimension in the Regulation of Nanotechnologies: Developments in the Industrial Chemicals Sector*, Dr. Diana Bowman and Dr. George Gilligan examine the role that private businesses can play in developing and implementing systems of self-regulation. They note that non-governmental regulatory initiatives in industries affected by nanotechnology have been on the rise, reflecting broader adoption of such approaches more generally in industry. Using the industrial chemical sector's varied experiences with self-regulation of nanomaterials as a case study; they ask under what circumstances the public and governments can rely upon businesses to regulate their own behaviour effectively. The answer is decidedly contingent, depending heavily upon the extent to which such initiatives incorporate principles of transparency, effective monitoring, enforcement mechanisms and sanctions, and independent or third party oversight functions. In particular, they observe that the very scientific uncertainties identified by Dr. Goldstein prevent businesses from establishing scientifically validated standards and exposure levels, potentially undermining the public's assessment of the legitimacy of the self-regulatory initiative.

In *A New Soft Law Approach to Nanotechnology Oversight: A Voluntary Product Certification Scheme*, Professor Gary Marchant and his co-authors likewise focus upon the importance of public perception and acceptance, albeit in a different context. Their contribution offers a different form of risk governance—shared governance. After outlining the limits of conventional

8. INT'L RISK GOVERNANCE COUNCIL, WHITE PAPER ON RISK GOVERNANCE 22-23 (2007); PCCRARM, *supra* note 4, at 14-15.

regulation in dealing with nanotechnology (most prominently inability to characterize nanomaterial hazards and exposure), Professor Marchant calls for a voluntary, government-supervised safety-testing certification program. Under this "soft law" program, the government would certify those products manufactured in accordance with government-specified safety testing, data disclosure and risk management requirements. The government imprimatur signals to consumers that the manufacturer produced the good in a reasonably responsible manner, and seeks engender the public trust. While acknowledging that the same scientific uncertainties and limitations that bedevil conventional regulation would likewise present challenges in the development of the required testing and risk management standards, Professor Marchant suggests that the certification scheme can make use of existing protocols while the science advances.

Deploying New Regulatory Tools

Professors David Dana and Douglas Kysar broaden the focus of nanotechnology regulatory policy to include both deterrent and compensatory goals. In doing so, they rely upon well-developed areas of law, applying them in insightful and nuanced ways in the context of nanotechnology.

Professor Dana seeks to leverage incentives associated with tort liability to increase precaution on the part of manufacturers, but with a twist. In *When Less Liability May Mean More Precaution: The Case of Nanotechnology,* Professor Dana builds regulatory policy around the "precautionary-study principle." The principle requires that the potential risks from products incorporating nanotechnology be reasonably explored both before and after their introduction into commerce. Like other commentators, Professor Dana is skeptical of the ability of mandatory regulation to prescribe and enforce pre- and post- market testing, yet has serious doubts regarding the efficacy of voluntary approaches. Fearing as well that conventional tort liability for harms caused by nanomaterials could act as a disincentive to testing, he proposes a new tort-based approach in which manufacturers can secure liability relief as a *quid pro quo* for voluntary pre- and post-market testing and monitoring.

Professor Kysar takes a different tack in *Ecologic: Nanotechnology, Environmental Assurance Bonding, and Symmetric Humility.* He identifies and evaluates deficiencies in two well-tread approaches to policy: purportedly rational, objective meth-

ods grounded in a cost-benefit analysis perspective and morality-tinged approaches reflecting the precautionary principle. As an alternative incorporating desirable aspects of each, Professor Kysar offers a market-based policy instrument—the environmental assurance bond. Regulated firms would be required to post a bond equal to the current best estimate of the worst case damages to persons and the environment. Thus, the burden of scientific uncertainty would rest with the manufacturers of the nanomaterials, causing the required bond amount to increase. The bonding mechanism addresses compensation concerns by providing recompense for injury. In addition, because bonding costs would presumably decrease as the worst case estimate drops, it provides incentives for safety testing and precaution intended to shrink that estimate.

Lastly, Professor Paddock provides a holistic approach to regulatory design in his article *An Integrated Approach to Nanotechnology Governance,* tying together a set of regulatory proposals not unlike those presented by the other Conference papers. For Professor Paddock, the speed and dynamic nature of nanotechnology development, the limits of existing regulatory systems, the global competitiveness in the nanotechnology marketplace, and the unique nature of nanomaterials and their complex risks combine to necessitate a multi-faceted regulatory approach. His article sets out a suite of measures, including an expanded information generation and disclosure, enhanced public engagement mechanisms, voluntary programs as transitional tools, incentivizing corporate social responsibility policies and voluntary codes of conduct, and retention of civil liability.

These articles then offer multiple perspectives on science, risk governance and specific policy tools as they relate to nanotechnology. These three areas are not independent of one another, and consequently each of the articles are in one or more ways linked with others presented in this edition of the Journal. No proposal is without pitfalls, ambiguities or unanswered questions, yet each attempts to clear away some of the brush surrounding nanotechnology policy and suggests a pragmatic way forward for regulators, businesses and the public.