PART I

Introduction

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The Nanotechnology Challenge

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Nanotechnology has moved quickly from the realm of theoretical science and science fiction to the stuff of everyday life for people across the world. Nanotechnology is deployed in hundreds of products and services and will soon be part of many thousands of products and services. Estimates vary, but nanotechnology is a multi-billion dollar enterprise worldwide now and could become a trillion dollar enterprise in the relatively near term. Everything from socks to tennis rackets to food to surgical techniques to state-of-the-art military technology now may include some form of nanotechnology. If petroleum and plastics formed the infrastructure of the chemical/industrial revolution that transformed countries such as the United States in the last 50 to 100 years, nanotechnology and nanotechnology products may well be the tiny – the nano – basis for the next gigantic revolution in how we live.

As Kimberly Gray explains in her contribution to this volume, *nanoparticles* – extremely tiny particles – have always existed and have been known to exist for a very long time. The nanotechnology revolution began when technologies were developed that allowed nanoparticles to be accurately imaged and manipulated to produce materials having surprising properties of value in a wide range of applications. Nanotechnology is not per se the realm of the very, very small, but of the engineered and manipulated very, very small. Indeed, the promise of nanotechnology is that atoms and molecules of common elements such as silver and carbon can be manipulated into so many shapes and with so many different surface modifications that they can perform a vast array of new functions.

Across the world, national governments have invested heavily in promoting the development of nanotechnology, as have individual states within the United States. The benefits – economic, commercial, environmental, humanitarian – of nanotechnology have been widely touted. "Nano" is cutting edge and transformative, promising to cure cancer and solve the energy crisis. For many in policy-making circles and in private industry, the challenge of nanotechnology to date has been to stay in the race or, better yet, to secure a leading position in the development of the

technology. For government officials and investors and business executives, the goal has been to make sure that they and their constituencies share fully in the bounties of this new industrial revolution.

The "nanotechnology challenge" in the title of this volume, however, is not the challenge of how to keep up and win a share of an emerging nanotechnology market. Rather, this volume is addressed to policy makers, citizens, academics, and others who might be interested – and, the essays included here suggest, *should* be interested – in another challenge posed by the nanotechnology revolution. That challenge is simply, how we can we (society) reap nanotechnology's many possible benefits while at the same time avoiding, limiting, or at least being poised to repair damage associated with the human health and environmental risks that this new technology creates.

This nanotechnology challenge is exceedingly difficult – exceedingly challenging, if you will – because the nature of the risks and the magnitudes of the risks from nanotechnology are so poorly understood. Indeed, given the dearth of understanding that we now have, the risks from nanotechnology are likely to remain poorly understood for years to come, even if we do see a significant increase in publically available research in the next few years. The economist Frank Knight used the term *uncertain* to describe risks or possible losses for which too little is known and understood to assign a meaningful numerical probability to the risk of loss.[1] The environmental, health, and safety risks from nanotechnology are without question uncertain risks in the Knightian sense, and so the nanotechnology challenge is not just how to confront risks from a new technology, but also how to confront uncertain risks from a new technology.

Of course, all new technologies pose some conceivable risks to human health and the environment, and, as Laurie Zoloth suggests in her contribution in this volume, genuine scientific uncertainty may be more common than we usually allow ourselves to admit. However, the risks that nanotechnology poses are particularly important ones for us to confront for several reasons, notwithstanding the possibility that, in the end, the risks could turn out to be negligible and to result in very limited, if any, harm, even were they simply ignored. Although we cannot "know" all the possible outcomes associated with nanomaterials and nanotechnology, it is important that decisions regarding nanotechnology development be oriented toward reducing risk.

The remainder of this Introduction sets out, very briefly, the case for why we should confront the challenge of uncertain risks rather than ignoring it. It then explains why current legal institutions are not well-suited for meeting this challenge, and hence why confronting the challenge likely will require new institutions. The Introduction then provides an overview of how the different essays in this volume – written by leading scholars who adopt varied approaches – shed light on the challenge of

[1] *See generally* Frank Knight. Risk, Uncertainty, and Profit. New York: Houghton Mifflin, 1921.

creating legal institutions for the uncertain health, environmental, and safety risks from nanotechnology.

WHY THE UNCERTAIN RISKS WARRANT ATTENTION

Even if there were not yet any studies suggesting that nanoparticles could cause substantial health harms, there are theoretical reasons for suspecting as much. Notably, their incredibly small size may allow them to migrate to and penetrate into places in the human body where they could cause very serious damage. The worst-case scenarios associated with certain types of nanotechnology are very troubling indeed, as the contributions by Gray and Wilson in this volume detail. For example, studies indicate that nanoparticles in certain inhaled or skin products could pass through the protective barriers that usually protect the brain. There is also some evidence that certain forms of carbon nanotubes, because of their small size and shape, may travel into the lungs when inhaled and lodge there in a way not dissimilar to asbestos. History provides a number of examples – including asbestos, lead, and, arguably, endocrine disrupters released from plastics – in which the ignoring of risks led to disease, death, and irreparable environmental damage.

Moreover, nanotechnologies are being deployed in such a range of contexts that many people in many communities and many environments could be at risk. Purchasers of products containing nanotechnology – especially foods and creams and the like – may be at risk. But so too, and perhaps even more so, are workers all over the world who help produce nanotechnology or handle it. The use, deterioration, and disposal of products and other materials containing nanoparticles could result in bioaccumulation of nanoparticles in non-human organisms and ecosystems in ways that could endanger plant and animal populations and adversely affect food webs that sustain human beings.

It bears emphasis that there is currently no effective way for individuals or communities to remove themselves from these nanotechnology risks. Disposal of nanotechnology into the ambient environment is not tracked, and once they enter the ambient environment, nanoparticles are very hard or impossible to detect with current technology. People therefore have no way of knowing what their environmental exposures are to nanoparticles. Even with respect to consumer products, informed choices are not easy because there are no labeling requirements and no practice of voluntary labels indicating the presence and nature of nanoparticle ingredients. For example, the all-"natural" baby product Burts Bees lotion for children reportedly contains nanoparticles, but the product label contains no indication of that fact.[2] Indeed, nanomaterials have been incrementally incorporated into existing products

[2] *See* Project on Emerging Technologies, June 4, 2007, *available at* http://www.nanotechproject.org/inventories/consumer/browse/products/chemical-free_sunscreen_spf_15/.

for so many years and to such an extent that the nanotechnology revolution could be more accurately dubbed the nanotechnology evolution.

The uncertain risks from nanotechnology deserve attention not just because people and non-human systems could be greatly harmed, but also because it is possible – maybe even likely – that the risks could be reduced or minimized without our having to forego many of the possible benefits of nanotechnology. We do not need to choose flatly between confronting uncertainty responsibly and reaping benefits. One reason this is so is that nanotechnology is highly adaptable and configuration-specific. Thus, if (for example) one form of carbon nanotube may perform a useful function but cause lung damage, it is entirely possible that a minor modification in surface features or charge could deliver the same performance without the same harm. The generation of more information is key – as is the quicker generation of information – to steer us toward less risky forms of nanotechnology and away from riskier ones.

It is also important that we confront responsibly uncertain risks from nanotechnology so that a destructive public backlash is avoided. An incident of highly visible human harm from nanotechnology – particularly harm that could have been foreseen with adequate testing – could shape public impressions and create an environment in which *all* nanotechnology products are treated with suspicion. Corporations that responsibly produce nanotechnology products have a stake in how other participants in the industry act because public perceptions can be very broad-brush and very hard to change once they crystallize.

WHY NEW LEGAL INSTITUTIONS ARE NEEDED TO ADDRESS THE UNCERTAIN RISKS OF NANOTECHNOLOGY

Both in the United States and Europe, the debate over the regulation of emerging technologies has been dominated by two models – a strong precautionary model, in which regulatory approval requires an affirmative showing of safety, and what might be called reactive regulation, in which safety or other studies or regulatory restrictions are mandated only on evidence of the substantiality of a health or environmental risk or actual harm. Neither the precautionary model nor the reactive will work well for nanotechnology, as the contributions by Kysar and Dana in this volume suggest. A new, "Third Way" model of regulation – a more flexible, adaptive, fluid model – is needed for the uncertain risks from nanotechnology. Precautionary regulation would be too slow and cumbersome given the current informational gaps regarding nanotechnology risk and risk assessment and the rapid speed of technological development of new generations of nanotechnology. Nor does there appear to be a strong enough political constituency for strongly precautionary regulation, and certainly not in the United States. Reactive regulation would only come into play too late (perhaps decades too late), when concrete harm may finally be identified and understood. However, by that time, almost nothing could be done to avoid future

harms from exposures that had already occurred, and it might be impossible even to assure funding for compensation and repair of already damaged environments.

New legal institutions are required for regulating nanotechnology risks not only because of the limits of the prevailing precautionary/reactive models, but also because nanotechnology cuts across the conventional, organizing lines for regulation of environmental, health, and safety risks. Much regulation is organized around settings (e.g., workplaces) or product or substance types (e.g., new drugs), but nanotechnology involves many, many different settings and a wide range of different substances and products that traverse the usual jurisdictional lines that dictate the agendas of different domestic regulatory agencies.

Moreover, nanotechnology is an international phenomenon: it is produced and used throughout the world, with China emerging as a dominant producer. Because that is so, a cross-national or international regulatory approach – or at least degree of coordination – ultimately will be needed, but there are limited successful precedents for such an approach. At a minimum, we need to think hard about approaches that can work not just in the United States or just in the European Union (EU), but rather that make nanotechnology safer on a global scale.

In sum, the nanotech challenge – the challenge of uncertain risks – is well worth confronting, and it must be confronted with regulatory creativity and innovation. Regulatory solutions cannot be constricted by traditional categories or ways of thinking.

OUTLINE OF THIS VOLUME

This volume begins with the fundamental question – what is nanotechnology and what do we know and not know about risks from nanotechnology? In her contribution, Kimberly Gray argues against five propositions that have been invoked in support of the proposition that our current approach to nanotechnology development involves only negligible risk. She argues against the claims – or as she calls them, myths – that nanoparticles are safe because they are made out of common elements and that they will be unstable and hence ultimately innocuous in ambient environmental conditions. She also argues against another assumption in the public policy debate – that testing for safety will necessarily be very costly and time-consuming.

Addressing the risks of nanotechnology – however that is to be accomplished – will require understanding, trust, and the avoidance of unjustified fear on the part of the general public. Part II of this volume addresses the role of public perceptions. As the Druckman/Bolsen and Diermeier contributions underscore, public perceptions of new technology are often driven by the personal characteristics of the members of the public as much or more than by what is objectively understood or not understood about the technology. Read together, the essays by Druckman/Bolsen and Diermeier suggest that any solutions to the nanotechnology challenge may be constrained if they are delayed until after the public and activist groups develop hostility toward

the uncertain risks associated with nanotechnology. Both essays suggest that once a public mindset and attitudes are established, the introduction of new factual information does not readily affect opinion regarding safety or lack of safety. The essays also suggest that any response to the nanotechnology challenge that relies heavily on public disclosure of risks and product labeling must pay careful attention to how lay people process – and sometimes incorrectly process – information regarding an unfamiliar technology such as nanotechnology.

The third and longest section of this volume is devoted to exploring a range of Third Way regulatory solutions to the problem of regulating nanotechnology despite the massive lack of information and hence uncertainties regarding what may and may not be the most problematic forms of nanotechnology and how best to address the most problematic types. The focus of all the essays, in one way or another, is on how we can change the current regulatory regime and incentive structure to encourage the production of more information regarding possible risks from nanotechnology. The essays reflect an awareness that regulatory solutions need to be broad-based, rather than targeted at particular products using nanotechnology, and that there needs to be mechanisms whereby accumulating information can be fed back into and used to improve the regulatory framework.

Dana's contribution on regulatory definitions addresses the question of how a regulatory definition of nanotechnology can take account of gaps in our understanding of risks and how it can keep pace with the extraordinary variety and rapid development of nanotechnology. In a separate chapter, Dana discusses the promise of liability relief as a means to encourage voluntary testing by producers of nanotechnology. Also focusing on creating incentives for private investment in and disclosure regarding safety research, Kysar advocates the use of mandatory environmental bonds for nanotechnology producers. Both Kysar and Wilson emphasize the need for regulation that ensures the creation of a pool of funds for compensation of people and communities that may be harmed from nanotechnology, assuming some harms cannot and will not be prevented.

Explicitly addressing the cross-national and international aspects of the nanotech challenge, Marchant et al. and Adler both argue that "softer," more purely voluntary measures that can form the basis for international coordination may be the best approach to the uncertain risks posed by nanotechnology. Marchant et al. emphasize how soft law approaches may lend themselves to effective international coordination of nanotechnology risks. Adler emphasizes standardized labeling practices that may be voluntarily adopted at first before later becoming mandatory. Both Marchant et al. and Adler acknowledge the limits of voluntary approaches, but both are also wary of heavy-handed regulatory mandates, which they view as likely to chill investment without necessarily increasing social welfare.

The essays by McGinnis and Lin consider very different approaches. McGinnis explores the use of prediction markets (where investors bet on the safety or non-safety

of particular technologies) as a way of aggregating available information and guiding regulators facing uncertainty. McGinnis also emphasizes the need not to ignore uncertain *benefits* from nanotechnology as we seek to address uncertain risks from nanotechnology and the need to reconfigure the regulatory state to allow it to act with a speed that matches changes in technology. Lin's essay, unlike the others (with the possible exception of Dana's), does not focus so much on statutory, regulatory, and industry organizational-based reforms, but rather on the potential of courts using common law to address difficult problems when legal institutions cannot do so or require the common law's prompting.

The essays by Wilson and Zoloth take very different approaches to the question of new institutions for nanotechnology. Focusing intensely on one industry (cosmetics), Wilson documents the need for regulation and offers a vision of what that regulation should entail. Zoloth, by contrast, takes a broad view, placing nanotechnology in the context of the deep problem of scientific uncertainty generally and offers general principles that should guide our discussion of new legal institutions.

The last part of the volume brings us back to earth, as it were, analyzing in more detail than the previous chapters where we currently are in terms of the legal treatment of nanotechnology risks under U.S. and European law. O'Brian's chapter is important in offering the perspectives of a leading practitioner who actually counsels companies facing regulatory risks (O'Brian). Porter et al. survey the relevant laws and regulations in both the United States and EU, drawing on a massive research project. Both the O'Brian and Porter et al. chapters suggest that legal reforms on both sides of the Atlantic may be needed to effectively regulate risks from nanotechnology.

It bears note that none of the mechanisms or tools explored in these very different essays are mutually exclusive in any way. There is nothing inconsistent about mandatory testing, liability relief, bond requirements, prediction markets, and/or labeling requirements. They all offer possible advantages, as well as certain possible costs. In the end, the best regime for nanotechnology may blend many of these ideas. Voluntary labeling can exist alongside testing as a quid pro quo for liability relief, just as voluntary or mandatory labeling requirements can be accompanied by environmental bond or insurance requirements. The goals of all these approaches are fundamentally the same – the production of more and better information regarding risk, the use of more testing and monitoring, and the reasoned engagement of the public, all alongside the reaping of nanotechnology's many possible benefits.

As almost all the essays in this volume suggest, the nanotechnology challenge raises issues of relevance beyond the context of nanotechnology. Just as the problems addressed in this volume are not really altogether new and instead reflect the larger tension between protecting ourselves against the dangers of new technology and securing its benefits, the Third Way solutions suggested in this volume could be generalized to address the many risks from existing and new technologies

other than nanotechnology where information also appears to be inadequately produced. Uncertain risks are characteristic of the nanotechnology challenge, but they are a reality beyond nanotechnology. Addressing nanotechnology responsibly may help us learn how to address the broad array of risks to human and environmental health and safety on our fast-changing planet.