When Less Liability May Mean More Precaution: The Case of Nanotechnology

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I.
INTRODUCTION

Ignorance may be bliss, but it is generally bad policy. This may be especially true with respect to existing and forthcoming products that embody the relatively new, still poorly understood technology called "nanotechnology." Nanotechnology products offer the promise of highly beneficial uses, but also pose uncertain risks of adverse health and environmental effects. For products embodying nanotechnology, there is a powerful normative case for adherence to what I call "the precautionary-study principle." The principle requires that the possible risks from these products be explored before their release to the marketplace. It also would require that possible risks are thereafter continually studied. Continual study after the release of products into the market is important because it allows adverse effects to be isolated and understood using improvements in the background science and real-world observations and reports from consumers and others who have been exposed to the products.

A central question, therefore, is how to shift the nanotechnology status quo toward greater adherence to a precautionary-study principle. To that end, this Article proposes a federal legislative regime of limited protections from tort liability for nanotechnology product manufacturers who engage in pre-market and post-market research and monitoring regarding possible adverse health and environmental effects from their products. The central argument is that less liability may mean more precaution, and, hence, is a good thing.

Nanotechnology is generally defined as technology that incorporates nanomaterials—engineered, extremely small materials that can be as small as 1/80,000th the width of a human hair.[1] Nanomaterials currently used in products employ common organic elements such as gold, silver, titanium, and carbon, but nanomaterials function very differently than larger materials made up of these same elements. Because of their distinctive size-related functional attributes, nanomaterials may be very useful in areas ranging from cancer treatment to smoothing wrinkles. But the size-related attributes of these materials may translate into significant health risks. Notably, the extremely small nature of nanomaterials may allow them to pass various protective barriers in the human body and ultimately lodge in organs—such as the brain or lungs—where they could do damage. There have been relatively few completed studies, and these studies address only a few of the many forms of possible nanomaterials. While not uniform in their results, these studies suggest that some nanomaterials may have significant adverse health and environmental impacts.[2]

There is no consensus as to whether nanotechnology and nanotechnology products should be approached within a precautionary framework. Some commentators—including representa-

1. Precise definitions of nanotechnology vary but all seem to include the idea of extreme small size—including one or more dimensions in size less than 100 nanometers—and the fact that the atomic or molecular material was and is not simply found in its purely natural state but has been the subject of some imaging, measuring, modeling, and/or manipulation at the atomic or molecular scale. *See* J. CLARENCE DAVIES, MANAGING THE EFFECTS OF NANOTECHNOLOGY 7 (2006), http://www.wilsoncenter.org/events/docs/Effectsnanotechfinal.pdf; THE ROYAL SOC'Y & THE ROYAL ACAD. OF ENG'G, NANOSCIENCE AND NANOTECHNOLOGIES: OPPORTUNITIES AND UNCERTAINTIES 5 (2004), *available at* http://www.nanotec.org.uk/report/Nano%20report%202004%20fin.pdf.

2. *See, e.g.*, Ben Harder, *Particles Enter the Nervous System Via The Nose — Conduit to the Brain*, SCI. NEWS, Jan. 24, 2004, at 54. As Dr. Denison of Environmental Defense has testified, the "surprising results" in early studies of nanoparticles include that "[t]hey can cross from the lung, when inhaled, directly into our blood" and these results mean we should not "ignore these behaviors" and should look further. Dr. Denison also stresses that the research to date "has only been short-term in nature" and we "have no chronic toxicity testing . . . ." *Environmental and Safety Impacts of Nanotechnology: What Research is Needed?: Hearing Before the H. Comm. on Science*, 109th Cong. 1 (2005) (statement of Richard A. Denison, PhD, Senior Scientist, Environmental Defense).

tives of industry—have argued that there is an insufficient basis for the regulation of risks from nanotechnology, and have emphasized the great need to secure the potentially vast commercial benefits of nanotechnology.[3] These commentators have argued, in effect, against a precautionary approach to nanotechnology. In sharp contrast, other commentators and non-governmental organizations (NGOs) have called for a moratorium on the release of nanotechnology products until product manufacturers can affirmatively demonstrate the safety of their products.[4] In effect, these commentators have called for the application of a strong form of the precautionary principle to nanotechnology products. This might be called the precautionary-certification principle whereby new technologies may not be deployed in the marketplace unless and until the manufacturer first certifies that they are risk-free or "safe."[5]

These two positions are both too extreme. There are sound theoretical reasons to believe that, absent some commitment to precautionary action, insufficient attention will be paid to the downsides from nanotechnology products. For social welfare as well as pragmatic political reasons, however, the precautionary focus with regard to nanotechnology products should be consistent with a less demanding, more flexible precautionary-study principle. The credible risk posed by most nanotechnology products is not qualitatively great enough—and our scientific abilities to fully evaluate the risks in a reasonable time frame are too limited—to justify a blanket moratorium approach.

Given the marked gaps in research regarding the environmental, health and safety risk posed by nanotechnology products that is detailed in Part II, what is justifiable is greater realization of a

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3. This has been the principal basis for industry arguments against regulation at this time. *See* Gary Marchant et al., *Nanotechnology Regulation: The United States Approach, in* NEW GLOBAL FRONTIERS IN REGULATION: THE AGE OF NANOTECHNOLOGY 189, 201-02 (Graeme Hodge ed., 2007).

4. *See id. See also* NANOACTION, Principles for the Oversight of Nanotechnologies and Nanomaterials (2008), http://nanoaction.org/ nanoaction/doc/nano-02-18-08.pdf; FRIENDS OF THE EARTH, NANOMATERIALS, SUNSCREENS, AND COSMETICS: SMALL INGREDIENTS BIG RISKS (2006), http://www.foeeurope.org/activities/nanotechnology/nanocosmetics.pdf. One very highly-regarded organization, the United Kingdom's Royal Society, has, while not endorsing the general moratorium approach, argued for mandatory regulatory reviews for safety of nanoparticles in products before their release into the marketplace. *See* ROYAL SOC'Y, *supra* note 1, at 84.

5. *See* DAVIES, *supra* note 1, at 19; LINDA BREGGIN ET AL., SECURING THE PROMISE OF NANTECHNOLOGIES: TOWARDS TRANSATLANTIC REGULATORY COOPERATION (2009).

precautionary-study principle with respect to nanotechnology products. There are many obstacles to achieving wider use of the precautionary-study principle. First, current laws and regulations in the United States (as well as other nations) do not provide a clear basis for requiring precautionary study by nanotechnology product manufacturers.[6] Second, there is little public funding for research regarding nanotechnology's health and environmental risks.[7] Third, even if there were a political consensus in support of new mandatory testing requirements and dramatically increased public funding, voluntary testing and monitoring by manufacturers would be an important component of any comprehensive precautionary-study approach. Industry actors have special access to knowledge about emerging technology and product development and products. They can change and adapt quickly to follow a commercial marketplace that may move too fast for legislators and regulators to understand and react to on their own with mandatory testing requirements.

The heart of the Article is an exploration of the possible role of common law tort liability in both encouraging and deterring voluntary, precautionary study of new products generally and nanotechnology products in particular. A key variable in considering liability's role as an incentive or deterrent to testing is the manufacturer's subjective assessment of the probability that any injuries from its product would be detected by the injured parties and successfully attributed to the product absent research by the manufacturer itself on the adverse effects of the product. Another key variable is the legal standard for tort liability and, specifically, how the applicable standard falls on a spectrum from the imposition of liability on manufacturers only for known risks on the one hand to the imposition of liability even for risks the

6. For arguments that current statutory authorities are inadequate for the regulation of nanotechnology by the federal government, *see* DAVIES, *supra* note 1, at 18; MICHAEL R. TAYLOR, REGULATING THE PRODUCTS OF NANOTECHNOLOGY? DOES FDA HAVE THE TOOLS IT NEEDS? 6-7 (2006), http://nanotechproject.org/file_download/files/PEN5_FDA.pdf.

7. *See The National Nanotechnology Initiative Amendments Act of 2008: Hearing on H.R. 5940 Before the H. Comm. on Sci. and Tech.*, 110th Cong. 38 (2008) (statement of Andrew D. Maynard, Chief Science Advisor, Project on Emerging Nanotechnologies, Woodrow Wilson Int'l Ctr. for Scholars) (explaining that only $12.8 million of the research listed in the 2008 NNI nanotechnology risk research strategy for the United States was "highly relevant" risk research); ANDREW D. MAYNARD, NANOTECHNOLOGY; A RESEARCH STRATEGY FOR ADDRESSING RISK 3 (2006), http://www.nanotechproject.org/file_download/files/PEN3_Risk.pdf (explaining that of the $100 billion spent on nanotechnology research only $10 million or .1% has been dedicated to "highly relevant risk research").

manufacturer could not have reasonably foreseen on the other. The lower the perceived probability of detection without manufacturer research and the more the applicable liability standard veers toward requiring actual knowledge of risks on the part of the manufacturer, the more likely it is that the *ex ante* threat of liability will lead a manufacturer to choose not to conduct research into possible adverse effects, either before the product is marketed or once it is on the market. Consideration of these two variables in the nanotechnology context would tend to suggest that liability considerations indeed may be discouraging research into possible adverse effects of nanotechnology products under development and already on the market.

The closest precedent for the regime of limited liability relief that I propose is the regime of federal preemption of state torts that is afforded manufacturers of certain FDA-approved medical devices under federal law. FDA preemption of common law tort claims is controversial, to say the least. In order to avoid the disadvantages and problems of the FDA preemption regime, any regime of liability relief for nanotechnology manufacturers who voluntarily engage in testing needs a number of components that would help ensure political accountability, scientific integrity, transparency, and a reasonable pool of compensation for injured people. The scope of preemption of state tort law claims would have to be specified by federal statute, not agency promulgation or interpretation. Any such preemption should not include claims based on allegations that a manufacturer violated a tort duty by acting or failing to act in response to actual knowledge of adverse health or environmental effects. There must also be vigorous government oversight of both voluntary pre-market and post-market testing and monitoring, and the public must have reasonable access to the key information provided regulators. Finally, in order to prevent drastic denials of compensation while encouraging voluntary study, all companies would be required to maintain liability insurance. Those companies that engaged in pre-market and post-market testing would receive insurance subsidies in one form or another.[8]

8. To my knowledge, this Article is the first exploration of a voluntary regime of testing and monitoring as a *quid pro quo* for liability relief as a respond to the question of inadequate information and research regarding nanotechnology. There has been a call for liability protection for the nanotechnology industry, but that call has focused on the industry's desirability to avoid litigation and bankruptcies and has not outlined additional research and/or disclosure responsibilities that would be imposed on industry in return for liability protection. *See* George J. Mannina, Jr., *Na-*

In voluntary regimes generally, getting initial participation may be difficult due to uncertainties of costs and benefits of participation. As explained below, moreover, there would be strong incentives for some manufacturers to join a voluntary testing regime only once a number of other manufacturers of similar products have joined. Because the recruitment of early participants may be difficult and would be very helpful in ultimately achieving broad participation in a voluntary testing regime, special incentives for early joiners may be warranted.

There are many possible objections to the proposed *quid pro quo* voluntary regime. The first concern is how can regulators competently oversee the regime given the informational asymmetries between industry and the regulators regarding developments nanotechnology. In a purely voluntary regime without a *quid pro quo* for industry participation, regulators have little leverage to demand that industry make key information readily available to them; the *quid pro quo* of liability relief would allow regulators to plausibly demand specific industry commitments of active cooperation and disclosure. Making the tests and monitoring procedures and results available to the broader public—including the scientific and public health communities—would provide an important safeguard against the danger of industry participants obtaining relief in return for insufficient effort.

Another objection is why liability relief would or should be limited to nanotechnology, as opposed to any new (or existing but untested) technology or substance that poses unknown risks. The reasoning of this Article might support liability relief for other substances and products for which it is plausible to assume that the fear of generating liability may lead companies to forego testing and monitoring they otherwise would have undertaken. The answer is largely pragmatic: the issue of nanotechnology risks and regulation is now a subject of public discussion and analysis, and nanotechnology products could be a good place to

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notechnology: Don't Delay Liability Risk Assessments and Solutions, 21 WASHINGTON LEGAL FOUNDATION LEGAL BACKROUNDER 37 (2006), *available at* http://www.wlf.org/upload/120806lbmannina.pdf. That the fear of liability or liability avoidance may contribute to an absence of testing or monitoring on the part of companies has been a theme of commentary regarding conventional chemicals, including toxin or possible toxins. *See* Wendy E. Wagner, *Choosing Ignorance in the Manufacture of Toxic Products*, 82 CORNELL L. REV. 773, 820-21 (1997) ("the manufacturing community appears to believe that safety research regarding latent harms invites, rather than wards off, litigation. Defense lawyers tout the effectiveness of long-term product effects as a defense to litigation, and this advice appears to be followed . . . .").

start to explore the merits of regimes of liability relief as a *quid pro quo* for voluntary testing. Were such a regime actually implemented, we could assess how well it worked to advance overall public welfare, and perhaps then move beyond nanotechnology. Indeed, the category of regulation explored here—liability relief as a *quid pro quo* for voluntary pre-market and post-market testing and monitoring—may well end up making even more sense in contexts outside nanotechnology.

II.
Framing The Nanotechnology Problem

What exactly is the nanotechnology "problem" regarding human health and environmental risks? This Part argues that the essence of the problem is what we do not know. Any comprehensive response to the informational deficit regarding nanotechnology should include both mandatory testing and public funding, as well as a voluntary testing and monitoring component.

A. *The Information Deficit*

Relatively little is understood about the health, safety and environmental risks posed by the manufacture, use and disposal of products containing nanotechnology. The lack of adequate research and hence adequate understanding of the risks is a theme of every major report regarding nanotechnology. Academic commentators, NGOs, scientific societies, legislators and major industry players agree that too little research has or is being done —and too little is or likely will soon be known about these risks.[9]

In considering what needs to be known to understand nanotechnology and nanotechnology products better, it is useful to categorize the kinds of information that is not known and must

9. On the general topic of possible risks posed by nanotechnology, and the uncertainties surrounding those risks, see generally Jo Anne Shatkin, Nanotechnology: Health and Environmental Risks (2008); U.S. EPA, Nanotechnology White Paper 1 (2007), *available at* http://www.epa.gov/osa/pdfs/nanotech/epa-nanotechnology-whitepaper-0207.pdf ; Nat'l Research Council, Review of the Federal Strategy for Nanotechnology-Related Environmental, Health, and Safety Research 26 (2008), *available at* http://www.nap.edu/catalog/12559.html.; Royal Soc'y, *supra* note 1; *The National Nanotechnology Initiative Amendments Act of 2008*: *Hearing on H.R. 5940 Before the H. Comm. on Sci. and Tech.*, 110th Cong. 37-38 (2008) (statement of Andrew D. Maynard, Chief Science Advisor, Project on Emerging Nanotechnologies, Woodrow Wilson Int'l Ctr. for Scholars).

be acquired or developed. I suggest three categories : (1) information regarding risk assessment and monitoring metrics, criteria and methods uniquely suited for or tailored to nanotechnology; (2) information regarding the behavior and associated risks of different categories of nanotechnology and the significance of different pathways for the different categories of nanotechnology; and (3) information regarding risks associated with particular products that include nanotechnology.

The first category of information—information regarding nanotechnology risk assessment metrics, techniques and methods—is the kind of information that is needed for assessing the risks associated with different types of nanotechnology and nanotechnology products. Thus, the incompleteness in category one information is a constraint on the acquisition and development of category two and three information. Not surprisingly many scientists have focused on the pressing need for investment in the development of category one information. For example, a group of prominent nanotechnology scientists writing in *Nature* in 2006 set forth a multi-decade agenda as to what methods must be developed for nanotechnology to be responsibly commercialized. This agenda underscores how much critical category one information is not yet in place for assessment of risks, how big the task is for the development of the necessary methods, and how unlikely it is that this task will be substantially completed before hundreds or thousands of new nanotechnology products are introduced into the commercial marketplace. According to the *Nature* agenda, key research goals should be:

- "Develop and validate methods to evaluate the toxicity of engineered nanomaterials, within the next 5–15 years."
- "Develop models for predicting the potential impact of engineered nanomaterials on the environment and human health, within the next 10 years."
- "Develop robust systems for evaluating the health and environmental impact of engineered nanomaterials over their entire life, within the next 5 years."[10]

10. *See* Andrew D. Maynard et al., *Safe Handling of Nanotechnology*, 444 NATURE 267, 269 (2006). *See also* NAT'L RESEARCH COUNCIL, *supra id.*, at 97 (concluding that "[a] robust national strategic plan is needed for nanotechnology-related environmental, health, and safety research that . . . . should focus on research to support risk assessment and management, should include value-of-information considerations, and should identify . . . Specific research needs for the future in such topics as potential exposures to engineered nanomaterials, toxicity, toxicokinetics, environmental fate, and standardization of testing.").

Similar calls have been made by representatives of public interest NGOs as well as entities affiliated with industry. The Environmental Defense Fund has argued:

> Even before the research that will allow hazards and exposures to be quantified, a number of more fundamental needs must be addressed [because w]e currently lack a good understanding of which specific properties will determine or are otherwise relevant to nanomaterials' risk potential. [M]any of the methods, protocols and tools needed to characterize nanomaterials, or to detect and measure their presence in a variety of settings (e.g., workplace environment, human body, environmental media) are still in a very early stage of development.[11]

Lux Consulting, a private sector firm that advises nanotechnology companies, has likewise concluded that there is a great need for "frameworks . . . for evaluating nanotechnology materials" and that greater "understanding [of] the basic science of nanoparticle EHS factors" is needed for "safe nanotech developments."[12]

The second category of information—information about certain categories of nanotechnology and certain pathways into the human body (such as facial skin) or environment for these categories of nanotechnology—has been the subject of sporadic studies and some significant, but still relatively nascent, research programs. For example, a number of studies have been completed on both carbon nanotubes and titanium dioxide.[13] The

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11. *See* Richard Denison, Environmental Defense, A Proposal to increase Federal Funding of Nanotechnology Risk Research By $100 Million (April 2005), http://www.edf.org/documents/4442_100milquestionl.pdf.

> "Even before the research that will allow hazards and exposures to be quantified, a number of more fundamental needs must be addressed. We currently lack a good understanding of which specific properties will determine or are otherwise relevant to nanomaterials' risk potential. Many of the methods, protocols and tools needed to *characterize* nanomaterials, or to detect and measure their presence in a variety of settings (e.g., workplace environment, human body, environmental media) are still in a very early stage of development."

12. Statement of Matthew M. Nordan, Lux Consulting, Nanotech Commercialization Has Advanced, but Government Action to Address Risk Has Not (Sept. 21, 2006), http://science.house.gov/commdocs/hearings/full06/Sept%2021/nordan.pdf.

13. One problem is that the studies have so heavily focused on carbon and ignored "broad classes of other materials already on the market" in products. *See* Robert F. Service, *Priorities Needed for Nano-Risk Research and Development*, SCIENCE, Vol. 314, Oct. 6, 2006, at 45. There has also been a marked inattention to possible effects on the non-human environment, and the possible second-order effects on human beings. *See, e.g.*, LLOYD'S EMERGING RISKS TEAM REPORT, RISKS: NANOTECHNOLOGY RECENT DEVELOPMENTS, RISKS, AN OPPORTUNITIES 3 (2007) (explaining that "[i]t is unclear whether nanoparticles can cause chronic health im-

completed studies so far often suggest inconsistent conclusions regarding the safety of different categories of nanotechnology and, hence, simply underscore the need for more research.[14]

Moreover, even if there were more and better category two information, more research at the level of particular nanotechnology products would be needed. Because there is an incomplete public inventory of nano-components in current products (not to mention products under development), we do not have reliable knowledge regarding the full range of categories of nanotechnology that are or soon will be embodied in commercial processes and products. And even if we had such an inventory, it is certainly possible that the same categories of nanotechnology may behave differently with minor differences in production and formulation. And the distinctive differences in the environment (human and otherwise) in which particular products are used and disposed of may mean that there are significantly different risks from products that contain exactly, or almost exactly, the same nanotechnology.

How much information, then, has been assembled regarding health and environmental risks from particular nanotechnology production processes and products in commercial use? We really do not know, because we do not know how much testing has been completed by private industry. Almost no public information exists regarding product-specific risks from nanotechnology products.

Government regulation in the United States and elsewhere has largely not required pre-market or post-market testing of products containing nanotechnology. There are initiatives on the part of government agencies—notably the EPA—to encourage companies to voluntarily provide regulators with the information they possess regarding their products. But, relatively little of the content of those submissions has been made public; what has been made public suggests a selective response by industry to the call for voluntary disclosure to regulators.

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pacts" and "[t]here is still too little research into the potential negative impacts of this technology on the environment"); ROYAL SOC'Y, *supra* note 1, at 45 (surveying the absence of studies on ecotoxicology of nanoparticles).

14. *See, e.g.*, Nordan, *supra* note 12 (noting inconsistent results regarding nanoparticle toxicity to date, as "[f]or instance, while Günter Oberdörster at Rochester University found that smaller particles of titanium dioxide (TiO2) are more harmful that large ones, David Warheit at DuPont found no relationship between size and toxicity; he also found that nanoparticles of silica (SiO2) and zinc oxide (ZnO) are *less* harmful than larger ones.").

Some companies clearly are doing testing on nanotechnology products. Most notably, DuPont, in conjunction with Environmental Defense, has developed and publicized a testing protocol and reported on the cases of a few nanotechnology products it has considered for development.[15] The DuPont initiative is so notable in part because we have no idea what many major companies, not to mention smaller companies, are or are not doing.

One possible response to the insufficiency of the available information would be a moratorium on the release of new nanotechnology products—or even the continued marketing of those already on the market—pending the development of better assessment methods and actual assessments. In 2007, a broad range of NGOs called for such a moratorium as part of Principles for the Oversight of Nanotechnologies and Nanomaterials. That group endorsed a precautionary principle regime which "would include prohibiting the marketing of untested or unsafe uses of nanomaterials and requiring product manufacturers and distributors to bear the burden of proof." More pithily stated, "simply put, 'no health and safety data, no market.'"[16]

A broad-based moratorium, of course, would deny the public of some nanotechnology products that may have great utility to consumers and to the public at large. The very large economic value of current and projected nanotechnology products suggests that there is a great deal of consumer and other public utility at stake. Some nanotechnology products may have important medical applications. In any case, there appears to be insufficient political support for a general moratorium either in the United States or elsewhere. But the information deficit regarding nanotechnology—in particular the deficit in category one and two information—does or should have implications for one's view of how a non-moratorium approach to nanotechnology products should be conceived. Specifically, these deficits suggest that any conclusions drawn from pre-market testing must be tentative and should be openly acknowledged as such. A substantial emphasis thus must be placed on post-market testing, monitoring and disclosure.

Where, as with nanotechnology, there are theoretical reasons for believing that there may be adverse human or environmental effects from a technology and there is an acknowledged informa-

15. *See* ENVTL. DEF. & DUPONT, NANO RISK FRAMEWORK 11 (2007) *available at* http://www.edf.org/documents/6496_Nano%20Risk%20Framework.pdf.

16. *See* NANOACTION, *supra* note 4.

tional deficit regarding the risk assessment methods for that technology, pre-market testing can reveal only so much. Open acknowledgment of that fact—and open embrace of a relatively undemanding or truly realistic stated goal for pre-market testing—is therefore appropriate. A demanding stated goal as to what pre-market testing must or should show can have two perverse consequences. If adherence to the goal is taken seriously, then testing will be very expensive and prolonged. Even so, the testing may often be deemed inadequate to make the necessary showing for commercial release. An overly demanding pre-market testing standard thus can become the equivalent of adoption of a moratorium. On the other hand, if there is a demanding standard but products are readily deemed to have met the standard notwithstanding the limits in what pre-market testing can reveal, there may be a tendency on the part of regulators, companies, and other stakeholders not to advocate for and/or engage in post-market monitoring and testing. Indeed, under the FDA registration system for new drugs, which purportedly employs a very demanding standard for showings of safety based on pre-market testing, there has been an absence of adequate post-market monitoring, reporting, testing and disclosure, notwithstanding FDA's legal authority to require companies to engage in such post-market measures.

The limits in information regarding risk assessment of the different categories of nanotechnology and different pathways—category one and two information – counsels in favor of post-market measures in two ways. First, to the extent that risk assessment and evaluation methods are improving over time, post-market assessments allow products to be evaluated using better risk assessment methods than were available at the time the product was under development and was released into the marketplace. Second, because pre-market testing is not entirely reliable in detecting adverse effects, the only means to detect such effects and prompt further study of them sometimes may be by means of direct observation of workers, consumers and others who have used or come into contact with nanotechnology products. The same argument has been forcefully made even in the context of conventional (not nanotechnology) drugs that have been subject to the pre-market FDA testing and approval process involving human clinical trials.[17]

17. *See* TAYLOR, *supra* note 6, at 23-24 ("Even the large-scale clinical trials used to assess drug safety and efficacy, which may involve hundreds or even thousands of

Post-market testing is also important for another reason: hundreds of nanotechnology products are currently on the market that, as far as we know, never underwent pre-market testing for potential adverse effects. For this set of products, post-market monitoring and testing may be the only feasible means for assessing their adverse effects to the environment and human health and safety.

A nanotechnology product regime should include substantial, but realistically tentative, pre-market testing coupled with post-market monitoring and testing under conditions of transparency that allow for public accountability. There are three possible components of such a regime: mandatory product testing requirements, public funding for testing, and voluntary commitments on the part of companies to engage in testing and monitoring. These means are in no way exclusive, and all three may be needed in combination.

B. *Three Components of a Precautionary-Study Approach to Nanotechnology*

1. Mandatory Testing and Monitoring Requirements

One approach to achieving pre-market and post-market testing of products, clearly, is mandatory pre-market and post-market release testing. It is at least arguable that current laws in the United States would not support such testing requirements. As Wendy Wagner and others have argued, U.S. laws tend to be very precautionary with respect to a limited range of items (such as certain new drugs) and almost entirely non-precautionary with respect to everything else.[18] As Terry Davies has suggested, a new law may be needed as a framework for mandatory pre-market and post-market testing of nanotechnology products.[19] It re-

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subjects, are not capable of detecting every low-incidence adverse effect that could occur and be of great public heath significance when the drug is administered over long periods to millions of people."); *see also* U.S. GOV'T ACCOUNTING OFFICE, DRUG SAFETY IMPROVEMENT NEEDED IN FDA'S POSTMARKET DECISION-MAKING AND OVERSIGHT PROCESS 13 (2006), *available at* http://www.gao.gov/new.items/d06402.pdf.

18. *See* Wendy E. Wagner, *The Precautionary Principle and Chemical Regulation in the U.S.*, 6 HUMAN AND ECOLOGICAL RISK ASSESSMENT 459, 464 (2000) (characterizing U.S. chemical regulation as "at best, a schizophrenic regulatory program that acts on a certain group of new chemical in a precautionary way, but otherwise proceeds in a way that is essentially unprecautionary: regulator intervention is typically correlated directly, rather than inversely, with the available scientific knowledge regarding product safety.").

19. *See* DAVIES, *supra* note 1, at 18.

mains to be seen whether interest group politics are such that we will see either the use of existing authorities to mandate more testing, or the passage of a new mandatory testing law.[20]

Even if a new law were enacted, there are reasons to suppose that it might be underinclusive or inadequate unless mandatory testing were supplemented by voluntary testing. Nanotechnology is a dynamic arena in which the kinds of nanoparticles and uses for them may be expected to change quickly over time. Mandatory testing rules will have to include definitions of the scope of substances or products to be tested and the substance of the testing. These rules could readily become obsolete as the commercial marketplace evolves in different directions that regulators do not understand well.[21] Moreover, even if regulators can keep apace of changes in technology and commercial interest in emerging technology, it is inherently hard to change mandatory government rules quickly. Such rules can be expected to evoke opposition from at least some industry actors, and that opposition, coupled with the well-known phenomena of legislative and regulatory inertia, may prevent rapid adoption of new rules. Even if new rules are authorized for implementation, implementation takes time.

Mandatory rules, moreover, almost always require voluntary compliance to be truly effective. In particular, regulators are not well-positioned to enforce mandatory post-market reporting and disclosure requirements because they lack direct contact with distributors, vendors, consumers and others who may be the best source of such information. Thus, even in an ostensibly mandatory regulatory regime, voluntary efforts—cooperation and collaboration by industry—are important, and hence so are

20. It is also unclear whether the EU's chemical regulation "REACH" will translate into mandatory testing requirements. *See* Diana Bowman & Geert van Calster, *Reflecting on REACH: Global Implications of the European Union's Chemicals Regulation*, 4 NANOTECHNOLOGY L. & BUS. 375 (2007) (discussing whether a mass condition for testing will exclude nanotechnology products). *See also* John S. Applegate, *Synthesizing TSCA and REACH: Practical Principles for Chemical Regulation Reform*, 35 ECOLOGY L.Q. 721, 765 (2008) ("Having created a demand for information, a regulatory system needs to supply it. As we have seen, REACH—with the advantage of thirty additional years of experience with chemical regulation in Europe and the US—is more urgently focused on information needs than TSCA was.").

21. *See* TAYLOR, *supra* note 6, at 23 ("Companies that are developing new technologies and product applications always know more about them earlier in the process" than federal regulators).

the strength of the incentives for industry to engage in such voluntary efforts.

2. Public Funding

The public could fund pre-market and post-market testing of products containing nanotechnology components that would help reveal their heath, environmental and safety effects. There has been a call for increased federal funding of this kind, at least on behalf of smaller start-ups in the nanotechnology industry.[22] Public funding, however, is unlikely to adequately fill the information deficits discussed above.

First, the competition for federal research funds is intense. Research regarding the environmental, health and safety implications of nanotechnology—research directed at what may be a real health and environmental problem, but is not known to be such—has and likely will continue to have difficulty attracting funding when legislators and regulators must make hard choices as to where to allocate funds. There are simply too many known problems or ailments or crises that could make use of funding. Nanotechnology safety is not an issue that has a singularly motivated and powerful interest group behind it, as (for example) does autism research, and also does not have (yet anyway) a powerful, visceral hook for press coverage and popular mobilization.

Second, public funding, by definition, cannot address many questions of product safety without substantial information from and active cooperation of companies that are developing or have developed products containing nanotechnology. Whether research is funded by companies or by the public, companies must be willing to make disclosures that may be sensitive for trade secrets/business competition reasons and that may lead others to question the safety of the products and whether they have or will create harm. The promise of funding alone may well not be

22. *See Environmental and Safety Impacts of Nanotechnology: What Research is Needed?: Hearing Before the H. Comm. on Science*, 109th Cong. 39 (2005) (statement of Matthew M. Nordan, Vice President of Research, Lux Research, Inc.) (arguing that because "[s]tart-ups . . . have much shorter rime horizons [than large corporations], and thus have financial incentives to bury or disregard EHS issues" and "Start-ups are generally the earliest commercial developers of new nanoparticles and also the parties least likely to be able to afford expensive toxicology studies," then the "only way . . . for nanotech commercialization to proceed rapidly while ensuring that toxicology studies are performed is for governments to supply the funds.").

enough motivation, as the discussion of liability concerns in Part III suggests.

Finally, as a normative matter, it would seem inappropriate for the federal government to fund product-specific safety testing (category three information). Such testing would seem to be rightly regarded as part of the costs of the production of the product. Production costs—like profits from production—presumptively rest with the producer in a market economy. In a standard model of allocative efficiency, product-specific subsidies would result in the overproduction of new nanotechnology products, particularly ones that may entail especially costly testing. Moreover, any proposal to subsidize testing for smaller companies or start-ups who cannot readily afford testing costs is likely to skew the marketplace for nanotechnology product development in favor of such companies. As a historic matter—for example in the FDA drug approval context—product-specific testing has not been publicly funded for either small or large entities. The drug industry has included collaborations between start-ups and larger companies, perhaps partly as a result. The federal government, however, could conduct some of the actual testing with company funding, in which case smaller companies could, collectively, take advantage of economies of scale they otherwise could not achieve.[23]

3. Voluntary Testing

As explained above, mandatory testing requirements and public funding together are unlikely to result in comprehensive product-specific research that keeps pace with developments within the nanotechnology industry. Voluntary testing and monitoring, at a minimum, is needed to fill in important holes in what any mandatory requirements cover in theory or (given highly imperfect information and limited resources on the part of regulators) in practice. More specifically, what is needed is voluntary testing and monitoring, coupled with affirmative cooperation by industry with regulators, including cooperation in public disclosure of testing results. How can voluntary testing with government over-

23. As Lux Research has advocated, there is a clearly a role for public funding of category one—framework and methods—research, as well as a role in supporting basic research that might be considered part of category two. Such research has sufficiently wide applicability to be regarded a public good or quasi-public good, and there is substantial precedent for public funding of public goods or quasi-public goods that have significant benefits for industry.

sight and genuine public disclosure be assured, or at least encouraged?

One conventional answer has been that the threat of common law tort liability will encourage companies to engage in voluntary testing in order to minimize harm to consumers and the environment and hence to minimize their potential tort liability. The threat of liability, it has been supposed, will lead companies to cut off production of dangerous products or recall ones already on the market, and will prompt full disclosure of the risks associated with products brought to or left on the market. The view that liability (or the possibility of liability) will encourage companies to invest in assessing risks from nanotechnology products appears to be shared both by those that oppose mandatory testing requirements as unduly intrusive and those that support tough mandatory testing and certification requirements.

The idea that the threat of liability will encourage voluntary testing and disclosure, however, presupposes two things that are almost certainly not true in the context of nanotechnology products. First, this argument assumes a robust standard for liability whereby alleged tortfeasors are held liable even when they did not actually have knowledge of a potential hazard or could have gained such knowledge only with great difficulty, if at all. Second, this argument assumes that the harms that would form the basis of the tort claims would be apparent to the victims and that the connections between those harms and their causes could be readily drawn by the victims and accepted by courts. But, as discussed below, the American tort system largely employs a standard of liability in which the absence of actual knowledge of a risk or hazard or adverse effect is extremely helpful in avoiding liability. Plaintiffs must show that the defendant either knew or reasonably should have known of the risk or effect. Moreover, with respect to many kinds of products, the harms may not become apparent for many years and may not even occur to victims as related to particular products, and indeed may be very hard for even the most determined plaintiffs to establish as having been caused by particular products.

Nanotechnology products, if they do have harmful effects, likely would fall in the category of products for which adverse effects are hard to isolate and connect to the production, use or disposal of the products. Consider, for example, the possibility that nanoparticles in skin creams may have adverse effects. Because most consumers do not even know which creams contain nanoparticles and which do not, almost no one would ever retain records as to which nanotechnology-containing cosmetics he or she used over time. Indeed, almost no one would retain records of the cosmetics he or she used at all. Moreover, if nanoparticles in skin creams can permeate skin barriers and affect internal systems in the body, there might be any number of adverse effects from them. Many of these adverse effects might relate to conditions or ailments that might have a range of other causes, from genetics to diet to smoking.[24] And these ailments or conditions might surface decades after the use of the product ended. Asbestos-based liability has dominated the American tort system in large part because asbestos exposure creates an easily identifiable, signature disease, asbestosis, but there is no *a priori* reason to suppose that nanoparticles in products would similarly result in signature diseases or conditions.

Moreover, the very defining attribute of nanoparticles—their incredibly small size—may mean that it will continue to be very hard to detect their presence in the environment.[25] As a result, it is and may well continue to be extremely hard to isolate nanoparticle pathways in the environment and prove that nanoparticles via these pathways caused human health effects or other harms that might be the basis for liability. The closest analogy would be endocrine disrupting chemicals, which may have some toxic effects but are pervasive in small quantities in the environment. Although much has been made of the possibility of tort liability related to endocrine disrupters, that liability in fact has not been imposed. This is likely due to the difficulty of establishing particular concentrations and particular pathways into the human body (or given the particularity of private tort, the particular human bodies of plaintiffs).[26] The possibility of environ-

24. *See* Margaret A. Berger, *Eliminating General Causation: Notes towards a New Theory of Justice and Toxic Torts*, 97 COLUM. L. REV. 2117, 2121-22 (1997) (arguing that in toxic torts generally "in most instances, the adverse health effects for which plaintiffs seek compensation are also found in others who have not been exposed to the substance or product in question. Because this 'background' rate exists, it is impossible to tell whether any individual plaintiff's injury is attributable to the product . . . .").

25. *See* Gregory Mandel, *Nanotechnology Governance*, 59 ALA. L. REV. 1323, 1345 (2008) (overviewing the risks from nanotechnology and noting that "[e]xacerbating the challenge of nanotechnology risks is that there currently is very limited capability to detect or measure nanoparticles . . . .").

26. For a review of the current state of the litigation and the defense bar's positions, see generally Bruce J. Berger & Michael L. Junk, *Endocrine Disrupters: The Potential Cloud of Manufacturer Toxic Tort Liability*, 74 DEF. COUNSEL J., 106 (2007). On the difficulties of prevailing in environmental tort actions, see generally

mental tort liability based on nanoparticle exposure may be even more uncertain, given nanoparticles' small size and elusive nature, even assuming *arguendo* that nanoparticles in fact can cause human health harms.

III.
MODELLING MANUFACTURER DECISIONMAKING

This Part develops a model that illustrates how the threat of liability may lead nanotechnology producers not to test products, and how limits on liability might produce more testing.

One way to think about the decisions of nanotechnology companies under the current tort system is to imagine how a particular nanotechnology product manufacturer (the company) might evaluate the decision whether to invest in researching any adverse health effects of a product while it is under development and after its introduction to the market. Imagine that the product is a cosmetic, such as wrinkle cream, that contains a form of nanotechnology for which there is almost no existing research, and the nanotechnology is not, to the company's knowledge, a known component of any other product under development or on the market.

A. *Assumptions*

This model assumes that any assessment of the product's possible adverse effects would take significant time, and that any reasonably reliable conclusions regarding what can be gleaned about adverse effects cannot be made until the assessment is complete. The model also assumes that the company believes it has some reasonably reliable sense as to how long the product, absent safety issues, would have a "run" on the market before it likely will be considered stale or obsolete and the company would introduce a new, differently-composed product to take its place.

In addition, the company believes it has some reasonably reliable sense of how well the product will sell at different times during this run. That a company would have such beliefs would seem essential for the company to even consider making an investment in product development and marketing at all.[27]

Troyen A. Brennan, *Environmental Torts*, 46 VAND. L. REV. 1 (1993); *see also* Berger, *supra* note 24, at 2138.

27. Somewhat unrealistically, in the interest of simplicity, the model will assume that the company does not update or change its projections of how long the product

The model contains three distinct time periods, which contain two distinct decision points for the company. At T0, the product is under development. T0 is the company's first decision point, because any pre-market testing for the product would have to begin then, so as to produce results by the time the product is scheduled for market release (T1). Period One is the time between T0 to T1.

At T1, the time of the product's release into the marketplace, the company has its second decision point. At that time, the company must decide whether to undertake post-market testing of the product, the results of which would not be available until T2. By T2, the product would have been on the market some time but still would have a significant amount of time left in its anticipated market run. Period Two is the time between T1 and T2.

After T2, the company has no further decision points. Unless pulled from the market at T2, the product will remain on the market until it has finished its anticipated market run and is obsolete. T3 is the time at which the product has had its full anticipated market run: the company will introduce a next generation product to take its place at that time. Period Three is the time between T2 and T3.

B. *Variables*

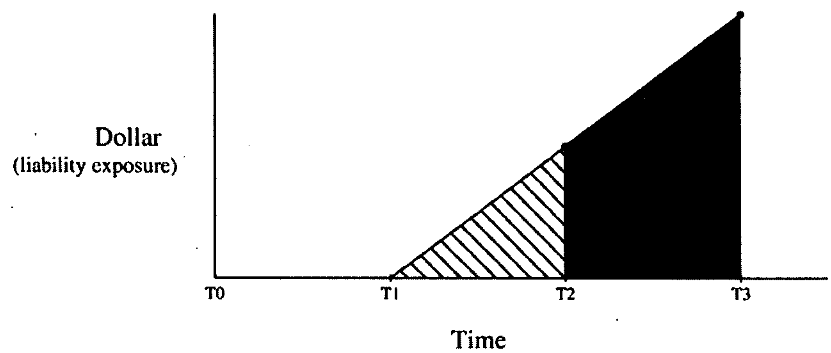
1. Damages (D) and Standard of Liability (S)

The company realizes that, if the product causes adverse health effects and those health effects are linked to the product, the company might incur substantial liability based on sales of the products during Periods Two and Three. As a baseline for estimating its liability exposure, the company might estimate the damages (in monetary terms) consumers would incur as a result of the product, assuming very adverse effects for a significant fraction of consumers of the product. They might also include an estimate of environment damages as a result of the manufacture and disposal of the product during those two periods. D is the damages attributable to the product.

Figure One depicts the company's damages estimates. Time is the variable on the x axis below. The variable on the y axis are total damages incurred up until time T. D_{T2} represents total

will have a run in the market and how well it will sell once the product enters the marketplace.

damages incurred during Period Two. D_{T3} represents total damages incurred during both Periods Two and Three. The upward slope of the line on the figure reflects the fact that as time passes, more people purchase and use the product, and as more people purchase and use the product, the number of potentially harmed people increases. As that number increases, total damages increase. For products with rapid growth in sales over time, we would expect a sharper upward slope than for products that maintain more or less even sales over time.



Actual damages—even damages clearly attributable to a product—do not necessarily translate into a liability to pay damages under tort law. There are several different liability standards for manufacturer liability, ranging from liability only for sale and distribution of products known to be harmful to negligence to strict liability. Depending on the applicable standard, a manufacturer might always, sometimes, or virtually never be held liable for damages attributable to its product. S will signify the applicable standard for liability.

The two relevant causes of action in tort law for producers of a nanotechnology cosmetic would be defective product design and failure to warn of risks associated with the product. With respect to both such causes of action, three key points in time according, to both the case law and commentary, are (1) the time the product first enters the market, (2) the time the product is sold to the particular plaintiff, and (3) the time at trial. A central debate in tort law has concerned the question of when, if ever, should a manufacturer be held liable for product risks that the manufacturer did not know about, and perhaps could not have known about, at the time of the sale of the product to the plaintiff(s). Arguments rooted in efficiency and fairness have been invoked to support and defend against manufacturer liability for failing to warn of, or otherwise address, unknown risks.

One position that some courts and commentators have sometimes articulated is that a manufacturer is or should be liable for harms that at trial can be shown to have been caused by the product even if the manufacturer did not know or could not have reasonably foreseen that the product would cause such harm when the product was first manufactured, released or sold. This approach is sometimes described as hindsight liability or genuine strict liability. It effectively removes any defense based on the absence of, or limit in, scientific evidence regarding causation prior to the time of trial.[28]

At the other side of the spectrum from genuine strict liability is liability that requires a showing of actual knowledge on the part of the manufacturer of the harmful effects of the product at the time the product was sold to the particular plaintiff. Although actual knowledge has been alleged in many of the best known mass products liability cases, it is not clear that any court has completely embraced an actual knowledge requirement in products liability cases. The state tort statutes in some states establish a strong form of the so-called "state of the art" defense; such statutes could be read to mean that scientific information or evidence developed after a product is introduced into the market cannot be used against the manufacturer in establishing liability. However, these statutes presumably were drafted with mechanical devices in mind (e.g., lawnmowers that turn out to malfunction) and have not been construed to mean that a manufacturer has absolutely no obligation to ignore developments in scientific evidence regarding drugs, chemicals or similar products after the product first enters the market. This is likely true even if the product was tested to the highest industry standards prior to it being first introduced into the market.

The Restatement (Third) of Torts articulates what is probably the standard that most courts in the United States now endorse. Under this reasonable foreseeability or "should have known" standard, manufacturers can be held liable if they should have known of the harm the product could create when they sold it to

28. *See* Beshada v. Johns-Manville Products Corp., 447 A.2d 539, 548 (N.J. 1982) (apparently embracing hindsight liability in the asbestos context); *see also* Omri Ben Shahar, *Should Products Liability Be based on Hindsight?*, 14 J. L. ECON. ORG. 325 (1998) (reviewing the state of the law and then modeling corporate research incentives under hindsight liability).

the plaintiff without an appropriate warning. Lack of actual knowledge is not a defense, but neither can the plaintiff simply hold the manufacturers liable for risks and harms that the manufacturer could not have known when the products were sold to the plaintiffs.[29] The Restatement approach is very similar to that followed in European and Japanese law.[30]

The reasonable foreseeability/should have known standard is, of course, a kind of negligence standard. Indeed, citing the Restatement and similar authorities, some commentators have concluded that American products liability torts, although still sometimes labeled a strict liability domain, is squarely within the domain of negligence.[31] And like all negligence standards, the reasonable foreseeability/should have known standard used for products is flexible and imprecise, and the standard is subject to more or less defendant-friendly interpretations and applications. Indeed, there probably are few cases in which one could not plausibly argue opposite positions under this standard—that a manufacturer reasonably could not have foreseen an unknown product risk, or that a manufacturer reasonably should have foreseen the risk and engaged in more testing and product re-design or warned consumers of the risk. Everything depends on the conception of "reasonableness" one employs.

For the company facing potential liability, it might be logical for them to think of the standard of liability as a spectrum varia-

29. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2(c) (1998). Under this standard, lack of actual knowledge is not a defense, but neither can the plaintiff simply hold the manufacturers liable for risks and harms that the manufacturer could not have known when the products were sold to the plaintiffs. With respect to product testing, the Restatement provides that "a seller bears responsibility to perform reasonable testing reasonable testing prior to marketing a product and to discover risk and risk avoidance measures such testing would reveal. A seller is charged with knowledge of what reasonable testing would reveal." RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmt. m (1998). As Mark Geistfeld has explained, because proving what a reasonable research program would reveal is an "extraordinarily demanding" standard, the Restatement (Third) standard "effectively immunizes" the manufacturer even from liability for many knowable risks. MARK A. GEISTFELD, PRINCIPLES OF PRODUCTS LIABILITY 152-53 (2006).

30. The Restatement approach is very similar to that followed in European and Japanese law. *See* JANE STAPLETON, PRODUCT LIABILITY 50-51 (1994). The central legal development limiting liability in Europe was the EEC Directive (1985/374/EEC). *See id* at 49.

31. *See* GEISTFELD, *supra* note 29, at 248 ("Despite the 'strict liability' rhetoric... this has overwhelmingly remained the majority view: the liability of manufacturers for design conditions . . . is . . . fault-based."); Gary T. Schwartz, *The Beginning and the Possible End of the Rise of Modern American Tort Law*, 26 GA. L. REV. 601, 625-27 (1992).

ble, with proof of actual knowledge required on one end, a range of possible formulations of "should have known" in the middle, and genuine strict liability at the other end. S will have a value of 1 at the hindsight liability end of the spectrum, which means that the company will be legally responsible for 100 percent of the damages its products cause. At the "actual knowledge required" end of the spectrum, S will have a value of 0, which means that the company will not be legally responsible for any damages its products cause, assuming the company will not market or continue to market the product without warning once it has actual knowledge of harm. The magnitude of S increases from left to right as "should have known" is applied as imposing an increasingly demanding duty on the manufacturer to find out about possible risks and mitigate, avoid and/or warn of them. In the middle of the spectrum, where S = .5, there is a 50 percent possibility that the court would conclude the manufacturer should have known, which in expected value terms, means that, *ex ante*, the manufacturer's expected costs would be 50 percent of the damages its products actually cause.

For the company, there could be two relevant S values. S_{T2} is the standard of liability applicable to Period Two consumers who sue after the company finishes its post-market testing and pulls the product at T2. S_{T3} is the standard of liability applied to Period Two and Three consumers at T3, after independent research shows that the product, which by then will have finished its market run, is harmful. Under current tort law, the applicable standard of liability is formally the same whether the manufacturer removes the product voluntarily based on its own testing and monitoring before the end of the product's anticipated market run or whether the products completes its market run and then independent non-company research ties the product to injuries of consumers and others (at or after T3).

L_{T2}, the total liability for the company at Time T2, would thus be $(D_{T2})(S_{T2})$, again assuming the company finds adverse effects and pulls the product from the market. L_{T3}, the total liability for the company at T3 or after, would be (D_{T3}) (S_{T3}), assuming that non-company research at T3 or later has shown that the product caused adverse effects during Periods Two and Three. One might generally assume that L_{T3} will be greater than L_{T2} because more consumers are exposed as of T3 than as of T2. If neither the company nor entities outside the company detect and establish the link between the product and injuries to consumers and others, there will be no liability whatsoever for the company at either T2 or T3 or after.

2. Probability of Detection/Attribution (P) and Research Costs (R)

The model assumes that the company believes that, absent its own independent research into the possible links between the product and adverse effects, there is no possibility that the product will be linked to adverse effects prior to the end of Period Three. For products whose potential adverse effects, if any, likely would not be obvious for years and would even then not be obviously linked to the product but instead could well be attributed to other causes, this would be a reasonable belief.

The company believes that there is some probability that, absent any research or monitoring for adverse effects on its part, the product could be linked to adverse effects by Time T3 or at some time thereafter. We will call that probability P_{T3}. The company's estimate of the magnitude of P_{T3} (and the actual P_{T3}) would depend on a number of factors. One of these would be ingredient or component disclosure and labeling requirements, if any, for the product: the weaker those requirements are, the less likely it is that a link between adverse effects and product use could be drawn.

A second, and crucial, factor is the extent of non-company investment in research that could shed light on the effects of nanotechnology generally, nanotechnology in cosmetics, and nanotechnology of similar or the same composition as that found in the company's products. Public and academic research investments might have the biggest influence on the estimate, because the products of such research investments would be most likely to be widely disseminated and could be used as a basis for ultimately assessing—or at least raising the question of—the effects of the company's product. Because nanotechnology research anywhere in the world might affect P_{T3}, public and academic investments levels throughout the world would be relevant. The relevance of other companies' research would depend in substantial part on how likely it is that it would be shared with the public.

The legal standard for proof for admission of scientific evidence regarding causation of harm would also be relevant. The more demanding the standard for the admissibility of such evidence is, the more difficult it would be for plaintiffs at T3 or later to locate and/or generate evidence that would allow them to survive summary judgment in a tort lawsuit against the company. If, for example, the courts limit their vision of admissible evidence of causation of human harm to peer-reviewed, human-subject clinical or epidemiological studies, then the company's estimate of P_{T3} may be quite low, even if there is or is likely to be significant public investment in animal studies and other laboratory explorations of the possible toxic dimensions of nanotechnology. The overall attitude of the United States courts at the state and federal level in the last few decades has veered toward restrictiveness as to what kinds of causation evidence is sufficiently reliable to warrant admission, so one relevant question for the company would be the likelihood that that trend will continue.

As noted, there are two possible research efforts the company could undertake—one during pre-market Period One, culminating at T1, and one during post-market Period Two, culminating at T2. We will call the direct cost of the Period One research efforts R1, and the direct costs of the Period Two research efforts R2.[32]

The company recognizes there is some probability that the pre-market, Period One research effort would detect adverse health effects, in which case the company would cancel the planned release of the product into the marketplace. We will call that probability P_{T1}. The company also realizes that there is some probability that the post-market research efforts would detect adverse health effects, in which case the product would be pulled from the marketplace at T2. We will call that probability P_{T2}.

One question is whether the company would assume that P_{T2} is greater when pre-market testing has been done and adverse effects are not found than when no pre-market testing has been done. On the one hand, one might suppose that the finding of no adverse effects in pre-market research would give rise to a greater confidence level that the product is not harmful and hence a greater confidence that post-market research will not identify harmful effects. On the other hand, one might suppose that the more familiarity the company has with the behavior of

32. Specific pre-market testing could include a range of laboratory toxicity testing, and post-market testing could include follow-up surveys of distributors and consumers as well as longer-term toxicity testing, such as longer-term study of use or exposure of the product on an animal test group. For the purpose of the analysis here, the same reasoning would apply whether the company was choosing whether to adopt a given single pre- or post-market effort or whether they were making the marginal to decision whether to undertake one more or one additional pre- or post-market effort.

the nanotechnology component of the product, the more effective it could be in structuring a post-market testing program that could find any adverse effects from the product. For example, if pre-market testing showed that certain nanoparticles tend to follow certain pathways, that would help the company know where to look, in the post-market period, for potentially problematic accumulations in consumers and the environment. These two effects—one tending to suggest a lower P_{T2}, the other suggesting a higher P_{T2}, as a result of pre-market testing having been done—might well cancel out.[33]

C. *Comparing the Expected Costs of the Four Options*

The first question for the company, presumably, would be what are the expected liability costs if the company does nothing—that is, invests in neither the pre-market, Period One research effort or the post-market, Period Two research effort? If the company does nothing, it faces a possible liability of L_{T3}, but it will be burdened with L_{T3} only if independent, non-company research identifies adverse effects and links them to the company's product. Thus, the expected liability costs if the company does nothing are $(P_{T3})(L_{T3})$. For the company, therefore, the relevant questions boil down to:

Would conducting the pre-market research effort in Period One result in lower expected costs than $(P_{T3})(L_{T3})$?

Would conducting the post-market research effort in Period Two result in lower expected costs than $(P_{T3})(L_{T3})$?

Would conducting both research efforts result in lower expected costs than $(P_{T3})(L_{T3})$?

If doing nothing (foregoing both research efforts) is not the expected-cost-minimizing choice, which choice is: conducting only the pre-market research effort in Period One, conducting only the post-market research effort in Period Two, or conducting both?

33. The model also assumes that the company's estimate of PT2 and PT3 are unconnected or independent variables. In the absence of a public disclosure requirement on the part of the company, that may be a reasonable assumption. However, if the company were required to disclose the research it conducted in Period One or Two, then, even if the company's conclusion were that the product is safe, the release of the research would increase the information available about the product and in that way might guide independent research and result in a higher PT3.

1. Period One, Pre-Market Investment

If the company invests in research during Period One, and finds that the product is harmful, the product will not be marketed and total liability will be zero, but the company will bear the direct research cost of R1. However, there presumably will be a relatively low expected probability of finding that the product is harmful by the end of the pre-marketing research: P_{T1} is presumably well below .5. If no harm is found, then the company could bear liability if independent research links the product to harmful effects by T3 or later. Thus, the expected costs of doing the pre-market research project is $R1 + (1-P_{T1})(P_{T3})(L_{T3})$. Undertaking the pre-market research is worthwhile if $R1 + (1-P_{T1})(P_{T3})(L_{T3}) < (P_{T3})(L_{T3})$.

2. Period Two, Post-Market Investment

Now assume that the company chooses to skip the pre-market research investment. If the product does go to market, then the research during Period Two could detect harm and result in the product being removed from the market at the end of Period Two, that is, at T2. The potential benefit for the company under this scenario is avoidance of the additional liability that otherwise might be imposed as a result of exposures that would take place during Period Three. If the Period Two research detects harmful effects, and the company pulls the product, the company will be liable only for L_{T2}. If the research is conducted but does not detect harmful effects and subsequent independent research links the product to adverse effects after the product has run its market course, then the company will be liable for $L_{T3.}$ Hence, the company's total expected costs if it conducts only the Period Two, post-market research are: $R2 + (P_{T2})(L_{T2}) + (1-P_{T2})(P_{T3})(L_{T3})$. It would make sense for the company to proceed with the Period Two research if $R2 + (P_{T2})(L_{T2}) + (1-P_{T2})(P_{T3})(L_{T3}) < (P_{T3})(L_{T3})$.

3. Combining Pre-Market and Post-Market Research

Another option for the company is to commit to undertake both pre-market, Period One and (assuming the product goes to market after pre-market testing) post-market, Period Two research. The cost of pre-market research itself—R1—remains the same whether or not post-market research is to be undertaken. If harm is detected and the product is never released to market, there will be no post-market costs. If no harm is detected during the pre-market research and the product is released to the market, there is the possibility that post-market research will detect harm and the product then will be pulled from the market. There is also the possibility that, if post-market testing does not detect harm and the product remains on the market, independent research will later detect harm. Either way, the company bears R2, the direct cost of post-market testing. Thus, the expected costs of the pre-market and post-market research option are R1 + $(1-P_{T1})$ [R2 + $(P_{T2})(L_{T2})$ + $(1-P_{T2})(P_{T3})(L_{T3})$].

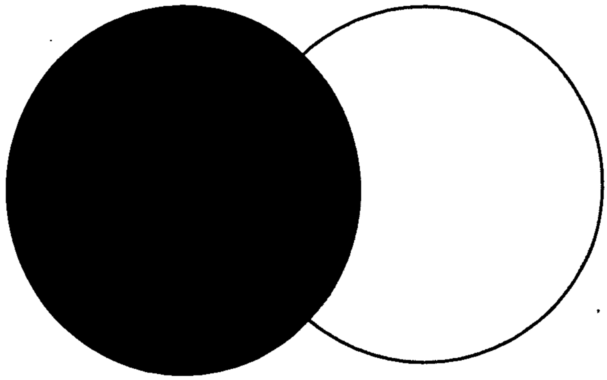
4. Comparing the Research Options

We now have cost estimates for the three research options and the do nothing option. These are:

- Committing to pre-market and post-market research ("the pre & post research option"): R1 + $(1-P_{T1})$ [R2 + $(P_{T2})(L_{T2})$ + $(1-P_{T2})(P_{T3})(L_{T3})$]
- Committing to pre-market research only ("the pre-market-only option"): R1 + $(1-P_{T1})(P_{T3})(L_{T3})$
- Committing to post-market research only ("the post-market-only option"): R2 + $(P_{T2})(L_{T2})$ + $(1-P_{T2})(P_{T3})(L_{T3})$
- Doing nothing: $(P_{T3})(L_{T3})$.

For the company, absent the possibility of incurring LT2 liability as a result of its own testing and monitoring and the adverse effects they reveal, it would always be worthwhile to engage in post-market testing and monitoring if R2 + $(1-P_{T2})(P_{T3})(L_{T3}) < (P_{T3})(L_{T3})$. That universe of cases is represented by the left side of the diagram below. There is a universe of cases for which the avoidance of possible LT2 liability makes it worthwhile to avoid post-market testing and instead do nothing, which meet the condition that R2 + $(P_{T2})(L_{T2})$ + $(1-P_{T2})(P_{T3})(L_{T3}) > (P_{T3})(L_{T3})$. The right side of the diagram represents those cases. There is an intersection area in the middle of the diagram consisting of cases that meet the two previous conditions and for which it is also true that $(P_{T2})(L_{T2}) > (P_{T3})(L_{T3})$ - (R2 + $(1-P_{T2})(P_{T3})(L_{T3})$). This is the universe of cases for which liability avoidance will lead a company to avoid post-market testing and monitoring that they otherwise would have undertaken.

FIGURE TWO



How big is this intersection area? The answer, of course, depends on the values we assign to the relevant variables. We can deduce that less testing or no testing may be a liability-minimizing option in some cases when—on a social welfare basis—such testing would be beneficial. Testing would be most attractive from a social perspective in those cases in which the testing would be highly effective at detecting any adverse effects from the product. Such testing would be inexpensive, and the damages ultimately suffered by consumers and others would be huge if such testing does not occur and the product remains on the market without proper warnings. As described below, the company might well choose not to engage in testing in a subset of these cases—those in which the company perceives a very low probability of detection of the product's adverse effects on the basis of independent, non-company research.

The easiest way to see how liability-minimization can deter testing is to imagine an extreme case in which post-market testing would be extremely effective at detecting any adverse effects and would be extremely cheap to do. In such a case, there might be a 99 percent probability that adverse effects (if there are any) would be detected by the company in post-market testing and such testing would cost almost nothing, perhaps a few thousand dollars. It would be reasonable in such a case to round P_{T2} up to 1 and round R2 down to 0. In terms of the intersection condition described above $[(P_{T2})(L_{T2}) > (P_{T3})(L_{T3}) - (R2 + (1-P_{T2})(P_{T3})(L_{T3}))]$, that would mean that $(P_{T2})(L_{T2})$ now equals

(L_{T2}) and that (1-P_{T2})(P_{T3})(L_{T3}) becomes 0. The company therefore will prefer doing nothing to engaging in highly effective, cheap post-market testing if the liability the company would expect to incur as a result of post-market testing (L2) would be more than the liability the company would expect to bear if it does not test and keeps the product on the market without a warning ((P_{T3})(L_{T3})). The relevant question, then, is when would L_{T2} ever be greater than (P_{T3})(L_{T3})?

One answer (but not necessarily the only one) is where the damages that will be incurred by consumers and others in Period Three are just enormous relative to the damages incurred in Period Two but the independent probability of detection at T3 (P_{T3}) verges on 0. Where P_{T3} is of a similar magnitude to P_{T2}, the possibility of a huge L_{T3} should make the company decide to engage in post-market testing. But it might be a liability-minimizing strategy for the company to avoid post-market testing even when confronted with a relatively huge L_{T3} if P_{T3} is very small. For example, imagine that L_{T2} is 3 million, L_{T3} is 400 million, and P_{T3} is just .007. Recall that P_{T2} is effectively 1 and R2 is effectively 0. The expected costs for the company of doing nothing and not engaging in post-market testing would be (400,000,000)(.07) or \$2.8 million, which is \$200,000 less than L_{T2}. In other words, doing nothing would save the company \$200,000 in expected liability in a case where post-market testing could yield great social benefits for minimal social costs.

D. *Decreasing the Likelihood of Liability-Driven Avoidance of Post-Market Testing*

Let us assume that the scenario just described is likely enough to warrant attention. The question then, is how can any of the relevant variables be manipulated to make it less likely that companies will avoid post-market testing that they otherwise might have undertaken were it not for the threat of liability resulting from post-market testing? In the language of the previous discussion, that question boils down to how can we make it more likely that (L_{T3})(P_{T3}) will be greater than (L_{T2})? There are essentially three possible manipulations of the relevant variables—increasing P_{T3}, increasing L_{T3}, and decreasing L_{T2}. The discussion that follows focuses on decreasing L_{T2}, which is the most realistic policy option.

P_{T3}—the independent detection variable—is a key variable in terms of creating an incentive for the company to engage in post-market testing. Any increase in P_{T3} translates into an increase in the cost of doing nothing—$(P_{T3})(L_{T3})$—and makes it more likely that post-market testing will be a cheaper option than doing nothing. Any given increase in P_{T3}, moreover, also makes the pre-market and-post-testing option less expensive relative to all the other options. Increasing PT3, therefore, might result in shifts not just from the do nothing option to post-market testing, but also shifts from just-pre-market testing or just-post-market testing to both pre-market and-post market testing.[34] That may be a good thing, at least from the vantage of the precautionary-study principle, which would seem to call for both pre-market and post- market testing.

It is not obvious, however, that increasing P_{T3} is feasible. The best means of increasing P_{T3} probably would be an increased expenditure in public research. As already discussed, there has not been political support for substantial public funding to date. It is also not clear how much of an expenditure in such research would be needed to lead to significant changes in estimates of P_{T3}. Moreover, as already discussed, there are probably inherent limitations in public funding as a means to fill the product-specific or category three information deficit, and hence inherent limitations in the extent to which increases in public funding can boost P_{T3}.

One possible way to increase L_{T3} and the cost of doing nothing would be to alter the standard for liability applicable at Time T3 and later. For example, if the standard of liability at T2 and T3 initially were a middle-of-the road "should have known" standard (e.g. S=.5), then a change to a genuine strict liability/hindsight standard at T3 and after would increase the magnitude of L_{T3} relative to L_{T2} by 100 percent. That change, in turn, could be enough to make post-market testing a liability-minimizing strategy when, before, doing nothing was the liability-minimizing strategy.

There is no tradition, however, of states and states' common law imposing different standards of liability depending on whether adverse effects were detected by company research or

34. Assuming non-zero probabilities of detection of adverse effects for both pre- and post-market testing (that is, a non-zero P_{T1} and a non-zero P_{T2}), the pre-and-post approach is the strategy that minimizes the possibility of the company ultimately bearing the cost represented by (P_{T3}) (L_{T3}). Any increase in P_{T3} and hence $(P_{T3})(L_{T3})$, therefore, increases the expected costs of the pre-and-post option the least, and thus makes that option relatively less expensive than it previous was with respect to the other options.

were, instead, detected by independent, non-company research. One could imagine a federal law that purports to force the states to adopt a stricter standard of liability (genuine strict liability) when the adverse effects were detected by independent, non-company research after the product had been on the market a long time and completed its market run (T3). But there would be deep federalism, fairness, and chilling-investment concerns about, and strong political opposition to, any federal law that would require states to shift from a negligence standard to a genuine strict liability standard.

As discussed below, there are plausible federal law changes that could result in the reduction or elimination of L_{T2}. A reduction or elimination in L_{T2} would reduce the attractiveness of the do-nothing option relative to the post-market testing options. It thereby would alleviate the problem of liability-avoidance leading companies to forego post-market testing.

However, reducing or eliminating L_{T2} could have perverse effects. L_{T2} liability is a component of the post-market testing option but not a component of the pre-market-only research option, so reducing L_{T2} will decrease the cost of the post-market testing option relative to the pre-market testing option. Moreover, L_{T2} is a more heavily discounted component of the pre-market and-post market research option than it is of the post-market only testing option.[35] As a result, any given reduction in L_{T2} translates into a bigger cost reduction for the post-market testing than it does for the pre-research and post-research option, and hence decreases the cost of the post-market only testing option relative to the pre-research and post-research options.[36]

Table One summarizes the possible effects of the elimination of L_{T2} liability. As the center column reflects, the elimination of L_{T2} liability may result in no change—the lowest cost option before may be the same after. It is also possible that liability elimination would reduce the costs of the post-market only option and thus shift companies from doing nothing to post-market only testing. However, it is also the case that the reduction in the cost of the post-market only option may cause shifts from the

35. L_{T2} is discounted by PT2 in the formula for the post-market-only option. L_{T2} is discounted by (1-PT1)(P2) in the formula for the pre-and-post research option.

36. For a similar argument developed in the context of proposals to immunize companies from penalties from compliance violations discovered during internal audits, see David A. Dana, *The Perverse Incentives of Audit Immunity*, 81 IOWA L. REV. 969, 982-88 (1996).

pre-market only option or the pre and post option to the post-market only research option.

TABLE ONE
POSSIBLE SHIFTS WITH LIABILITY PROTECTION

Lowest-Cost Option Before Liability Protection	Possible Lowest-Cost Options after Liability Protection	Possible Lowest- Cost Options After Liability Protection Conditional upon pre-market and post-market testing
Do Nothing (No Testing)	Do Nothing (No testing) Post-Market Only Pre & Post Market	Do Nothing (no testing) Pre & Post Market
Pre-Market Only	Pre Post Pre & post	Pre Pre & post
Post-Market Only	Post-Market Only	Post-Market Only
Pre & Post Market	Pre & Post Market Post-Market Only	Pre & Post Market

From a public policy perspective, these two possible shifts—the shift from pre-market only research to post-market only research and the shift from pre-market and-post market research to post-market only research—are problematic. It is not always true that pre-market testing is preferable to post-market testing, but pre-market testing is essential because such testing, if it does indeed detect harmful effects, can avoid putting any consumers or other human populations at risk. By definition, post-market testing entails putting human beings at risk. And (as already suggested) one certainly might not want to encourage shifts from a clearly higher-research-investment, greater precaution option (pre-and-post testing) to a clearly lesser-research-investment, lesser precaution option (post-market only research).

These problematic shifts could be avoided by making L_{T2} liability relief contingent on the company completing both pre-market and post-market research. The right-hand column on Table One shows the possible effects of such conditional liability relief. Conditioning liability relief on pre-market as well as post-market testing raises the cost of obtaining the relief for companies, and thus presents a difficult tradeoff from a policymaking perspective. On the one hand, conditioning liability relief in this way avoids the creation of an incentive for companies to abandon pre-market research they otherwise would have undertaken. On the other hand, the conditioning of liability relief on both pre-market and post-market testing may mean that some companies that would have shifted away from a do-nothing approach as a result of liability relief for will instead continue to follow that approach.

1. Which Products Will Be the Subject of Voluntary Testing

So far, we have spoken of a single nanotechnology product. However, a company may have many products that contain nanotechnology and that might be candidates for a regime of voluntary testing in return for liability relief. All else being equal, we might expect a company to choose those products with the greatest possible liability exposure—those it expects to sell the most or that it suspects may have some dangerous aspect—for enrollment in the regime of voluntary testing. In this way, the voluntary regime may focus attention to the products that pose the greatest perceived risks to public health. Mandatory testing requirements could also focus on such products, but in the context of the possible or planned imposition of mandatory testing requirements, the company would not necessarily have an incentive to share with regulators or the public its views (and the information behind its views) as to which products pose the greatest possible risks to the public and hence most warrant testing and monitoring.

2. Products Containing Identical or Substantially Identical Materials or Technology

The previous discussion assumed that there is simply one company making a decision regarding whether and how to invest in research into possible adverse effects. For that reason, it was assumed that the only research that can produce L_{T2} liability is the Period Two research of that single company. But there may be many settings where several companies are producing substantially identical products, or more specifically, products that contain substantially identical materials or technology that may pose risks. For example, imagine two companies—company A and company B—that produce sunscreens containing the same or virtually the same kind of nanomaterials in the same configuration. Pre-market or post-market testing by company A could have an effect on company B whether or not company B chooses to engage in its own research. If company A detects harm as a result of its post-market research and recalls the product (or adds a warning), regulatory, market, and liability pressure may force company B to take parallel action with respect to its product.

Let us first consider the case where there is no liability (L_{T2}) relief for a company that voluntarily tests its product and pulls the product if harm is detected. In that sort of regime, company B has a free-riding-related incentive not to engage in post-market research regarding its product. If company A finds that the product is harmful in post-market testing and both company A and company B therefore must pull their products from the market, company B is (all else being equal) better off than if it had undertaken the safety research. Both company A and B will bear costs in terms of lost sales and perhaps liability awards, but at least company B will have avoided R2, the direct costs of research.

Now consider the case where liability relief is available for any company that conducts post-market testing (Period Two testing) and finds harmful effects and removes the product from the marketplace. Any incentive company B might have had to free ride on company A's research now would be countered—and perhaps more than offset—by its incentive to obtain liability relief by engaging in testing. It might well be economically rational, therefore, for company B to agree to participate in a research-for-liability-relief program if company A has already agreed to participate and thus increased the likelihood of detection of harmful effects, but refuse to participate if company A has already refused to participate. Another possible incentive for company B to agree to participate in a program after Company A has already agreed is that there might be savings from pooling research funds or merging research efforts with Company A. Table Two summarizes Company A and B's choices under the current and under a new liability relief regime.

TABLE TWO

Current Regime: Company A Tests Compamy A and B both Liable	Current Regime: Company A Doesn't Test Neither Liable
New Regime: Company A Tests Only Compamy B Liable	New Regime: Company A Doesn't Test Neither Liable

One implication of this analysis is that securing the initial participants in any research-for-liability-relief program is particularly important, but may be particularly challenging, for any such program. The first participant does not have as strong an incentive to join, all else being equal, as the second or third participant. In order to give all potential participants equally strong incentives to participate, the extent of liability arguably should be tiered, with greater relief going to early-to-agree companies and lesser relief to the later-to-agree companies.

3. Producers of Products Containing the Same General Category of Potentially Risky Materials or Technology

Large clusters of products may contain similar materials or technologies, and research regarding one or more of these products thus might help inform and focus research regarding the other products in the cluster. For example, drug A may alter mood disorders through the same theorized chemistry as drug B but may have different active ingredients. The discovery of a correlation between use of Drug A and heart attacks would not prove that such a correlation exists between use of Drug B and heart attacks, but the discovery almost certainly would provide an impetus to study heart health within the pool of people using Drug B. In the nanotechnology context, we believe that the same basic type of nanotechnology may behave differently in different product formulations. But research regarding any nanotechnology product may shed some light on nanotechnology generally and hence all nanotechnology products, and certainly research on any nanotechnology product containing a particular element (such as silver or carbon) may shed some light on the range of nanotechnology products containing that element.

In terms of the model above, one way to understand the effect of some company's research on others is in terms of the variable P_{T3}, the probability that a product will be established as having harmful effects as a result of non-company research once the product has finished its market run (T3). Imagine company A and company B produce the same general category of nanotechnology. The research completed by company A, if made public, would add to the body of scientific evidence and understanding and, in that sense, would be equivalent to additional academic or public research. That additional contribution to public knowledge would presumably increase (if minimally) the likelihood that any adverse effects from company B's product will be identified by the time that product has finished its market run at T3. Company A's additional contribution to public knowledge, in other words, would boost company B's estimate of P_{T3} and hence boost the expected cost of the doing nothing option. If we imagine not just one company engaging in research but one hundred companies engaging in research, we can imagine that the research would significantly boost company #101's estimate of P_{T3} used in choosing whether to continue to do nothing or instead commence research and follow the lead of companies #1-100.

One possible implication of this analysis, like the analysis regarding substantially identical products, is that broad voluntary engagement in research efforts within an industry could itself result in more, even broader engagement in research in the industry—at least if the results of all the research were accessible to the public. If the goal is to significantly increase voluntary research regarding products that contain a general category of technology that is poorly understood and potentially risky, an important hurdle is to secure a research commitment from a good number of the companies in the industry. Special incentives for early committers can produce the dividend of voluntary engagement in research by companies that will then follow suit in part because of their perception that the research that will be produced by the early committers, on net, will increase the likelihood that adverse effects could one day be tied to their products.

IV.
FDA PREEMPTION AS A MODEL FOR FASHIONING A VOLUNTARY-TESTING-FOR-LIABILITY-RELIEF REGIME FOR NANOTECHNOLOGY

Liability relief as a *quid pro quo* for voluntary testing is a policy or legal reform that could, in theory, be adopted at the state, federal or international level. Because at least initial state or international adoption seems less likely than federal adoption, this Part focuses upon how such a federal regime could, and should, be structured. But first, it is worth explaining the difficulties with a state-based or international approach.

The basic political economy of state legislatures and courts would work against the adoption of any liability relief reform in the context of nanotechnology products. State courts, applying existing state common law, perhaps could reduce liability for companies that engage in voluntary pre-market and post-market testing of products. More readily, state legislatures could adopt such liability relief by statute. But states are unlikely to adopt such measures and, even if they did, are not well equipped to ensure that the appropriate kind of testing and monitoring actually was undertaken. For an individual state, a reduction in liability means (presumably) a reduction in resources available to its injured citizens. Liability relief is thus an in-state cost. The manufacturers (and perhaps even distributors) of nanotechnology products sold or consumed within a state in many cases would be based outside the state and indeed might be based outside the United States altogether. And there is likely to be skepticism that liability relief in any particular state would lead to significantly more testing of the products developed and manufactured in that state, given that those products presumably would be marketed throughout the country and perhaps the world.

Even if states were open to adopting liability relief, they would not be well positioned to implement it. States do not have the staff and other resources to oversee pre-market and post-market voluntary testing and monitoring (let alone to undertake such testing with company funds). There are no state drug agencies akin to the FDA; there is no state institute of health comparable to the National Institute of Health. The building blocks for meaningful oversight and administration are found at the federal, not state, level. Knowing that, even state officials and politicians who see the case for liability relief are likely to look to the federal government for any liability reforms tied to oversight of testing.

At the international level, any proposed legal reform confronts the deep difficulty of bridging national differences and sovereignty concerns to form binding and enforceable accords. Tort liability, in particular, has long been regarded as a national prerogative, and is not the subject of even significant "soft" international law. There are also no international oversight agencies as such akin to the FDA. One might imagine international coordination once the U.S., Japan and EU adopted some kind of liability program, but action at the nation state level almost certainly would have to come first.[37]

It would thus seem that any liability relief-for-testing regime would have to be a federal regime established by federal statute. Tort liability is, of course, a traditional domain of the states. Congress has interfered with state prerogatives *vis-à-vis* tort law, despite federalism concerns, in two situations. The first is where some good or activity deemed essential to national welfare is arguably not being produced or might not be produced because of liability threats (such as nuclear power or certain types of aircraft). The second is where a regime of mandatory federal testing administered by the FDA has (arguably) ensured that a product reflects a considered federal judgment as to the balance of benefits and costs. An implicit rationale for FDA preemption may be that if companies are to be willing to take on the costs and the burdens of a thorough approval process, including testing, they need to, or at least should be, able to set aside concerns about state tort liability that might require even more testing, even more limits on releases of product, and even more product warnings. Liability relief from state tort law for voluntary testing of nanotechnology products under federal oversight would be similar to liability relief from state tort law for mandatory testing

37. Another consideration of institutional design is how a regime of voluntary testing for U.S. liability relief would dovetail with international law. Under the WTO's evolving jurisprudence, a U.S. statute providing liability relief in return for testing probably would pass muster as long as the stated purpose of encouraging testing would be the protection of U.S. consumers and others from effects realized in the United States from the use and disposal of imported products, as opposed to protection of foreign workers and others from adverse effects from the manufacture of the products outside the United States. There might, therefore, be some limits on the testing that could be asked of foreign companies *vis-à-vis* worker exposures and safety.

and approval by the FDA: in both cases, testing with oversight would translate into some reduction in liability.

FDA preemption of common law tort law, however, remains extremely controversial. A regime of liability relief for voluntary testing of nanotechnology products, depending on the design of the regime, could be subject to the same kinds of objections. To be tenable and succeed, therefore, a liability relief for voluntary testing and monitoring regime should have the component discussed in the following sub-Parts.

A. *Genuine Statutory (Rather Than Agency) Preemption*

One of the most controversial aspects of FDA preemption of state tort actions is that federal statutes, in plain language, do not clearly call for such preemption of tort actions. As a result, commentators—as well as some of the U.S. Supreme Court Justices—have criticized FDA preemption of common law suits as a joint creation of the courts and federal bureaucrats, instead of Congress.[38]

The preemption doctrine makes congressional intent the touchstone of when state law, including common law, is preempted. This is appropriate because, in a federal system where state prerogatives necessitate respect, preemption should be regarded as an exceptional and hence one that has courts should recognize only with clear direction from the only federal branch of government explicitly authorized to make federal law, Congress. Thus, to be fully legitimate, any regime of voluntary testing for liability must be built on specific language in federal statutes providing when and to what extent state common law claims are preempted.

B. *Preemption Limited to Torts Based on Failures to Test or Monitor*

Another source of controversy regarding FDA preemption of state tort cases has been that it has been extended (or industry has sought to extend it as in *Wyeth v Levine*) to risk or dangers of which the manufacturer/defendant allegedly had clear knowledge. Defendants have argued, with some success, that they were not required to warn of risks they comprehended as long as

38. For example, Justice Ginsburg criticized the Court's finding of preemption of state common law suits under the Medical Device Act (MDA) as "not mandated by Congress" and "at odds with the MDA's central purpose: to protect consumer safety."

the warning they did issue had been approved by the FDA. Critics of preemption in this context argue that federal regulators sometimes do not understand or receive the necessary data or are unduly pressured to accept incomplete warning. To the extent this occurs, federal preemption rewards companies for sitting on "bad" information and knowingly endangering the public without warning.

These same concerns counsel in favor of circumscribing tort preemption as a *quid pro quo* for voluntary testing and monitoring to state tort claims predicated on allegations that the manufacturer failed to conduct adequate testing or monitoring and hence did not apprehend the risk from its products and make decisions based on knowledge of those risks. Companies that sat on "bad information," failed to disclose it as required, or misled the relevant agencies or public in the disclosure that was made would not be rewarded with liability relief. (If relief took the form of insurance premium subsidies, *see infra*, those subsidies could be recovered by the government if company misconduct later came to light.) Moreover, because a voluntary regime would not mandate any particular labels or warning labels for products, companies could not argue that they had every reason to think they need not have or should not have included any warning based on "bad information" in addition to those required by federal regulators.

C. *Government Oversight and Transparency*

In the FDA drug and device approval context, there have been strong claims made that there has been too little vigorous agency oversight of private research and too little transparency; this has produced too little oversight by the general public of failures of regulators.[39] The litany of charges includes that large companies pressure scientists to reach favorable results; scientists fail to disclose all conflicts or private funding sources; there is inadequate accounting by regulators and lack of public information regarding studies that are abandoned, suspended or left open indefinitely because preliminary results would not be helpful to the sponsoring company; and the public lacks access to the data in studies submitted to regulators. Critics also point to inadequate

39. Two powerful indictments of regulatory oversights are David Michaels, Doubt Is Their Product: How Industry's Assault on Science Threatens Your Health (2008); and Marcia Angell, The Truth About the Companies: How They Deceive Us and What To Do About It (2004).

funding of the FDA and other oversight bodies. Along with the criticisms have come many proposals: more government research with public funding, a public registry for all initiated studies with updates, public access to the data supporting or underlying private study results relied upon by regulators, and thorough disclosure of conflicts requirements for scientists.[40]

All of the concerns about oversight and public access and all the possible reforms that have been invoked *vis-à-vis* the FDA mandatory approval process would have relevance to a voluntary regime of testing and monitoring as a *quid pro quo* for liability relief. These oversight and transparency concerns would need to be addressed for a voluntary regime to gain widespread legitimacy. One particularly thorny issue concerns confidential business information. Nanotechnology product developers and producers have and probably will continue to insist that such information is embedded in much of their testing data and reports, and that such data and reports therefore cannot be disclosed to the public. Specific guidelines and review mechanisms, however, must be used to ensure that confidential business information is not invoked expansively to curtail all meaningful public access. Even with respect to core confidential business information, there must be creative means to ensure the substance of public accountability, such as release of detailed summaries by regulators and review of data by designated NGOs (or other designated third-party inspectors).

D. *Subsidized Insurance as an Alternative Liability-Relief Mechanism*

FDA preemption—or any tort preemption—is also controversial because it can leave injured persons without any compensation. One of the essential roles of the tort law is compensation, after all. The same concern would apply to injured persons whose suits would be preempted or partially preempted by any nanotechnology liability relief regime based on voluntary testing. One can argue that a regime of liability relief does not necessarily result in anyone being denied compensation because, in the absence of liability relief, companies might not have tested their products and the information regarding adverse effects would

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40. Two excellent sources regarding criticisms of the current regime and reform proposals are THOMAS O. MCGARITY & WENDY WAGNER, BENDING SCIENCE (2008) (especially chs 10-12); and RESCUING SCIENCE FROM POLITICS (Wendy Wagner & Rena Steinzor eds., 2006) (especially pp. 281-298).

not have come to light. However, in any particular case, it will be impossible to know whether the information regarding adverse effects and their causes would have come to light even in the absence of the promise of liability relief. Moreover, from the *ex post* perspective of an injured person and his family, what truly matters is not *ex ante* incentives and considerations of institutional design but just the current moment and whether compensation is available for very real injuries.

From the perspective of honoring the compensation mission of the tort system, the best way to provide liability relief would not be limits on liability per se but rather subsidies for liability insurance. The federal government already provides or subsidizes insurance directly or re-insurance guarantees in some contexts,[41] and could also subsidize part of the cost of private insurance premiums for companies that opt into a pre-market and post-market testing regime for nanotechnology products. Insurance subsidies could be as powerful an incentive for companies as direct liability relief, while avoiding the problem of the uncompensated injured. Insurance subsidies could be combined with partial tort preemption in a blended regime that would mean reduced, but not eliminated, compensation for injured persons.

There are, however, several problems with an insurance subsidy approach. First, there is a significant history of (in the view of many) industry capture of government insurance or insurance subsidy programs. Second, government insurance subsidies are, like direct funding of research, a government expenditure that must compete with a great many other possible claims on government resources. It is true, however, that the magnitude of insurance subsidies may be hard to calculate and they are partly to be paid, if at all, in the future, so they are not particularly visible in the budgeting process. But that opaqueness, while making them more politically viable, also makes insurance subsidies more susceptible to interest group manipulation.

The value of insurance subsidies as a means to incentivize participation in a testing regime would be enhanced if the subsidies were tied to a requirement that all producers of nanotechnology

41. *See* Terrorism Risk Insurance Act of 2002, Pub. L. No. 107-297, 106 Stat. 2322 (requiring insurers not to exclude terrorism-related claims and providing for the government to act as an excess insurer of terrorism-related claims); Price-Anderson Act, 42 U.S.C. § 2210 (2006), *amended by* the Energy Policy Act of 2005, Pub. L. No. 109-58, 119 Stat. 594 (requiring nuclear power provider to carry an insurance and providing for federal payment of insurance claims in excess of the private insurance mandated by the statute).

products carry adequate liability insurance that does not exclude nanotechnology-related claims.[42] With a mandatory insurance requirement, small start-up companies that might be insensitive to long-term liability risks would have an incentive to test generally to keep private insurance premiums down (to the extent insurers would give them credit for testing) and an incentive to test products so as to qualify for government insurance subsidies.[43] Indeed, the availability of subsidies might help counter arguments by such companies that they lack the cash for testing and insurance and therefore will be driven out of business if additional costs are foisted upon them.

It is true, nonetheless, that the liability relief regime outlined here might be of greater advantage to larger, more-liability-sensitive and better-funded companies than small start-ups with potentially limited lives as legal entities. It is also true that the adoption of mandatory insurance requirements with liability relief or subsidies for voluntary testing might change the patterns of organization among producers of nanotechnology products. We might observe fewer stand-alone start-ups and more and earlier collaborations between start-ups and larger companies. But such a shift in industries that produce nanotechnology products might be a good thing, reflecting the fact that the production and marketing of potentially very risky products (as with FDA approved prescription drugs) may require the extensive participation, if not dominance, of relatively large corporate entities.

E. *Features Unique to a Voluntary Regime*

As the discussion in Part III suggests, the goal of obtaining significant participation by industry makes it essential that there be some early participants who can in effect draw in later partici-

42. *See* Robin Wilson, *Nanotechnology: The Challenge of Regulating Known Unknowns*, 34 J. L., MED. AND ETHICS 704, 711 (2006) (advocating that nanotechnology developers who receive federal funds be required to carry commercial liability insurance); Maksim Rakhlin, *Regulating Nanotechnology: A Private-Public Insurance Solution*, DUKE L. & TECH. REV. (2008) (iBrief), *available at* http://www.law.duke.edu/journals/dltr/articles/pdf/2008DLTR0002.pdf (advocating mandatory insurance coverage for nanotechnology producers with government guarantees of liabilities over coverage caps, modeled after the insurance regime for nuclear power producers under the Price-Anderson Act and the Energy Policy Act of 2005).

43. *Compare* DAVIES, *supra* note 1, at 22 ("A major disadvantage of voluntary programs is that they may leave out the people who most need to be included. In the case of NT, small firms making risky products and large firms with small consciences are not likely to volunteer to do health testing or to give EPA information that might indicate significant risk.").

pants. Greater liability relief could be offered to early participants as an inducement, perhaps in the form of greater insurance subsidies than those that would be made available to later participants. Another inducement for early participants might be their ability to advertise to consumers and others that they have opted into and met the guidelines of a safety regime, whereas (if that were true) their competitors had not yet done so. As Wagner has suggested (although not in the nanotechnology context), legal authorization and protection for companies to make such claims might offer enough of a competitive advantage to encourage testing that they otherwise might have been foregone.[44] Whether companies would regard the ability to make such claims as advantageous is unknown, but if they do, that ability, coupled with special liability relief incentives based on early entry into the voluntary testing regime, might be enough to energize an initial round of participation that could set the ground for broad industry participation.

V.
CONCLUSION: NANOTECHNOLOGY AND BEYOND

This Article offers a model of why nanotechnology companies might forego safety testing and monitoring in order to avoid liability and suggests a regime of liability relief as a *quid pro quo* for voluntary pre-market and post-market testing and monitoring. Nanotechnology products fit the conceptual space where such a voluntary regime might be helpful—a space in which the company developing the product rationally may foresee some liability risk in the absence of company research into environmental, health and safety effects but also rationally may perceive that such research itself could create liability that the company otherwise would have avoided.

44. See Wendy E. Wagner, *Using Competition-Based Regulation to Bridge the Toxics Data Gap*, 83 IND. L.J. 629, 631 (2008). In the realm of the nanotechnology product market, making such a claim could have offer substantial competitive advantage as a practical matter if it were accompanied by an effective labeling regime that required all products containing nanotechnology to contain some kind of statement of that fact. However, if that were done, Wagner's point might be even more applicable in the nanotechnology context than in the context of industrial chemicals that are the focus of TSCA, because the primary consumers of such chemicals are businesses rather than retail, individual consumers.