The John Liner Review

THE QUARTERLY REVIEW OF ADVANCED RISK MANAGEMENT STRATEGIES

VOL. 23 NO. 2 SUMMER 2009

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The U.S. laws regarding strict liability create incentives for manufacturers to conduct appropriate testing of products before putting them on the market.

Private Product-Risk Assessment and the Role of Government

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Most risk assessments in the United States are not performed by government, but by private parties. However, government regulation exerts considerable influence on why and how these risk assessments are done. U.S. law often regulates indirectly by creating incentives for private parties to carry out public mandates. There are a variety of names for this in the legal literature: acting "in the shadow of the law," "general deterrence," "gatekeeper regulation," and "deputizing the private sector." The concept is a simple but fundamental one, and it is deeply embedded in both U.S. law and American political culture: Government lacks the resources and expertise to make all the decisions that may affect the public interest in a complex society; therefore, government often regulates "at the wholesale level" by creating a structure of incentives for private actions. In this way, private actors can be induced, but not ordered, to carry out the public will. It is, however, a misnomer to characterize these private actions in implementing public policies as "voluntary."[1] They reflect the "hidden hand" of government, not the "invisible hand" of an unregulated market.

Product liability law is one clear example of this typically American approach of "hidden-hand" government regulation. Early in the 20th century, U.S. law generally adopted a "strict liability" approach to defective products. The leading example is Justice

Cardozo's opinion in *McPherson v. Buick Motor Co.*,[2] in which the court held that the manufacturer of a defective product could be held liable for civil damages without a showing of fault. The motivating idea was not to increase compensation for victims of product-related injuries, but rather to regulate the safety of products by creating incentives for manufacturers to conduct appropriate testing of their products before putting them on the market. Despite the captivating beauty of this idea, however, there is very little empirical evidence that "internalizing" the costs of product-related injuries actually motivates companies to produce safer products.[3]

The Precautionary Approach

While the "Precautionary Principle,"[4] as such, is not a systemic part of U.S. law in the way that it is officially recognized in the European Union, many aspects of U.S. law and policy do promote "precautionary approaches" by companies that are subject to U.S. law. For example, unlike some countries in Europe that recognize a "state-of-the-art" defense against civil liability, U.S. product liability law in many states does not recognize as a defense against civil liability for damages that relatively little was known about a substance when a manufacturer decided to incorporate that material into its products.[5] On the contrary, at least since the mid-1960s, U.S. law has generally shifted the burden of testing and producing information to the manufacturer of products.[6]

It is not entirely clear whether the private, incentive-based precautionary approach of U.S. law or the Precautionary Principle as lodestar for government regulation in the EU actually results in more precautionary behavior in practice. Empirical attempts to measure the degree of precaution in U.S. and EU law have generally found that there is very little difference.[7] Moreover, a legal system is not necessarily "ahead" merely because it stimulates a greater degree of precautionary behavior by those it regulates. Rather, the proper question is whether a legal system is achieving the degree of precaution that is deemed appropriate under the circumstances.[8] Too much precaution, as well as too little, may have greater cost than benefit, in terms of useful products or innovations that are needlessly withheld from the market.[9] (Substances that are never marketed because the costs of proving them safe are too great are sometimes called "orphan drugs" or "orphan chemicals" in the United States.)

Private Risk Assessments

In this article, we describe two examples of private risk assessments of proposed new products in which we have been involved over the years. Names and some identifying but irrelevant facts have been changed to protect the innocent — and also to maintain our clients' confidentiality. The case studies illustrate how risk analysis has been used by regulated entities to move beyond initial precautionary decisions by providing a more rigorous decision-making framework. At the end of the article, we draw some general conclusions about the adequacy of private risk assessment in the shadow of the law and also make some suggestions about how it can be made more effective.

In our experience, private risk assessments are generally more abbreviated and more focused than those performed by governments. There are three possible interpretations of this phenomenon: government generally requires too much; private enterprise generally does too little; or the differences are attributable to the different purposes of public and private risk assessments. Based on our limited sample, we are reluctant to draw a general conclusion.

However, the private system of delegated risk assessments in the United States does stand in marked contrast to the system of government-run risk assessment that seems to be developing in Europe under programs such as REACH (**R**egistration, **E**valuation, **A**uthorisation and **R**estriction of **Ch**emical substances).[10] The new REACH program in Europe requires private parties to submit enormous amounts of data about the safety of chemicals to a new government agency. In our view, one fatal flaw in programs such as REACH is that its drafters appear to imagine that sufficient analytical resources can be marshaled at the governmental level to review all of the risk assessments that need to be conducted in a complex industrial society. We believe that this assumption is incorrect and that the overwhelming majority of the data assembled at great cost by industry in response to the REACH program will remain unread in government files.

The volume of risk-based decisions that are required in a modern society is huge. For example, regulators

who administer the Toxic Substances Control Act (TSCA) new chemicals program at the U.S. Environmental Protection Agency (EPA) report that they are required to make 20 decisions *a day* regarding whether proposed new chemicals are safe enough to go onto the market.[11]

U.S. regulators have developed a variety of techniques to cope with this decision-making load. One is to limit the consequences of an erroneous decision by granting approval only for limited use of a substance.[12] Another is heavy reliance on computer models of structure-activity relationships as a screening technique.[13] Both of these approaches are relatively well known in the literature.

But a third technique, which is less well understood and to which we now turn, is delegating many risk assessment decisions to private parties, either with or without government guidelines for how the risk assessments should be done. We offer two case studies herein, although we are familiar with many situations in which companies conduct private risk assessments before putting a new product on the market. Given this body of experience, we consider the processes described herein to be fairly typical of the risk assessment procedures used by American companies today.

Of Naughty Sayings and Dead Fish

E. Donald Elliott was retained by an apparel company to assess the potential toxicity of its proposed new product line. The new line consisted of a fashion accessory targeted at teenagers that was imprinted with a colorful ink that would change color in response to different temperature conditions. The marketing strategy was to advertise that teenagers could write clever slogans or naughty symbols on their clothing, which would be invisible at home but would show up later when they went to school and the inks were heated by the temperature of the body.

The company had been sensitized to the need for a pre-market risk assessment by a bad experience with a previous product line that had contained a heavy metal. Certain state laws took the precautionary approach of banning the presence of this particular metal in any toys or other items used by children, without regard to whether any potential for exposure was actually present. The company had unknowingly run afoul of these precautionary laws, and under the threat of legal action and a forthcoming exposé on network television, Elliott helped the company to institute a "voluntary" take-back program in which consumers could, at the company's expense, send back the item containing the heavy metal at the end of its useful life for removal and proper recycling or disposal of the heavy metal. (This is a common pattern: Many companies tend to "get religion" about doing risk assessments after a previous brush with the law.)

The risk assessment on the proposed new line with the color-changing ink began by considering any existing legal regulations, but also by retaining an expert medical consultant with a background in toxicology, risk assessment, and occupational and environmental medicine. The expert conducted an extensive literature review of the substances in question. This was made more difficult by the fact that the temperature-sensitive inks were to be supplied by a foreign company, which maintained that their exact composition was a proprietary trade secret. This problem was eventually overcome by identifying the class of chemicals to which they belonged and conducting a literature review for the entire class. A few potentially problematic substances were identified in the class, but the ink company ruled them out by stating that they were not among the substances used in the product.

In addition to the literature review, a conceptual exposure model was constructed for various exposure scenarios, including fate and transport. Dermal exposures and incidental ingestion were evaluated based on reports available in the published literature of the substances' toxicity testing in laboratory animals. In addition, a life-cycle analysis was conducted. The primary disposal route was projected to be through municipal trash and landfills. Possible combustion products resulting from incineration, as well as low-temperature burning by consumers, were considered, and the nature and amounts of hazardous combustion products that might be formed were calculated. Those levels were judged to be well below levels of concern.

This preliminary screening analysis based on the literature and conceptual disposal scenarios was generally negative except for one possible exposure route. The possibility that some consumers might casually dispose of their used products by throwing them away in nature was identified. The product would biodegrade naturally if disposed on land, but the exposure

scenario of casual disposal in a fresh-water lake was considered potentially problematic because one of the ink ingredients was identified as a powerful aquatic toxicant in screening tests conducted under TSCA. However, the TSCA test was highly precautionary, in that it specified that the material had to be made bioavailable by exposing it to a powerful acid to get it into solution before exposing a particularly sensitive freshwater aquatic species.

The ink company questioned whether the precautionary TSCA screening test was indicative of actual aquatic toxicity exposure potential, because in the actual product, only a small amount of the ink, in dried form, was printed onto the item, and it was covered with a clear, relatively inert outer coating. Therefore, a laboratory experiment was performed to determine the potential of the product to cause aquatic toxicity in a more realistic disposal situation. To simulate casual disposal, samples of the product were physically distressed and placed into a tank containing the same sensitive species used in the EPA-mandated TSCA screening tests for aquatic toxicity in new chemicals. Periodic chemical analysis of the water was conducted, but the chemical constituents of concern could not be detected, and the fish remained healthy and unaffected for a period of 30 days.

A written report was provided summarizing the risk assessment, and the company concluded that the risks, including the risk of aquatic toxicity from casual disposal, were sufficiently low to be acceptable. The company brought the product to market. It was a commercial failure, but for marketing reasons that had nothing to do with its toxicity or environmental acceptability. There were no reports of adverse effects from either human exposure or any known problems in terms of environmental compatibility or disposal related to the marketed product.

Fiber Versus Fiber

Recently, both authors were retained to provide advice to a manufacturer that believed that matching or exceeding the performance of their competitors' products in certain applications would require the use of a particular type of man-made fiber (MF) already in use by those competitors. The primary difference in performance between our client's products and those of its competitors was attributed to the absence of MF from the client's products.

Several years earlier, the manufacturer had made a precautionary-principle-based decision to omit MF from the list of candidate substances to be used in its products. Apparently, no risk assessment or literature review of MF had been performed and MF's potential risks to human health had not been studied at that time. The company, like at least one other industrial firm, had simply decided not to use MF because MF had some superficial similarities to another substance known to cause adverse health effects. Under competitive pressure, our client decided to reevaluate its prior precautionary decision not to use MF and requested an evaluation of risk tradeoffs based on the latest data concerning the relative toxicities of MF and the other refractory ceramic fibers (RCFs) that it had been using instead.

The specific question to be addressed by the risk assessment was how any potential hazards posed by the use of MF were likely to compare to the potential hazards posed by the class of RCFs generally, which are already used widely in both our client's products and those of its competitors. Several possible exposure routes were considered, but we and the client agreed to focus the analysis on the most extensive human exposure to the RCFs used in the client's products.

RCFs are widely used in industry, in some cases as a replacement for asbestos, which is well established as a cause of mesothelioma and lung tumors in humans. Asbestos is classified as a known human carcinogen by both the EPA and the International Agency for Research on Cancer (IARC).[14] RCFs are considered less hazardous than asbestos,[15] although they are classified by EPA as probable human carcinogens based on evidence from laboratory animal studies.[16] IARC has classified RCFs as possibly carcinogenic to humans, also based on laboratory animal studies.[17] The laboratory animal studies include well-designed two-year chronic inhalation bioassays in rats and hamsters. Chronic inhalation of RCFs increased the incidence of mesothelioma in hamsters and of both lung tumors and mesothelioma in rats.[18] There are no epidemiology data from studies of human populations indicating that RCFs are carcinogenic to humans.[19]

The first step of the assessment was to consider whether the use or disposal of MF was restricted by legal regulations in either the United States or the leading countries of Europe. No such regulations affecting MF specifically were identified, although in Germany, some regulations do regulate all man-made

fibers in certain applications. Those regulations were reviewed. Because MF was known to be used by other manufacturers, a wider search was not considered necessary. In addition, searches of case law and the Web sites of law firms specializing in representing plaintiffs were consulted to determine whether MF had been the subject of significant litigation. It had not.

As the next step, online toxicity and medical databases and government reports were reviewed by an expert in toxicology and risk assessment. As a check on the adequacy of the literature search, EPA's TSCA §8(e) database was consulted to confirm that all relevant literature had been identified. Evaluation of the literature indicated that RCFs can produce both lung tumors and mesotheliomas in rats and hamsters at rates substantially higher than those produced by MF. The potential human carcinogenicity of inhaled MF cannot be ruled out, because it can produce mesotheliomas in hamsters exposed to very high concentrations (10,000 to 100,000 times higher than the recommended workplace exposure limit for RCFs). However, it seems unlikely that MF would be carcinogenic at more realistic exposure concentrations, provided those exposures are less than or in the range of the recommended workplace exposure limit for RCFs, which is 0.2 fibers/cubic centimeter.[20] A report was prepared describing that conclusion and its basis.

Based on that report, we and our client concluded that using MF in its products appears likely to be significantly less hazardous than using the RCFs that are currently widely used by many manufacturers in the marketplace, and the client decided to include MF in certain of its products. The company believes that the improved performance of the products made with MF will probably have beneficial health effects (not related to toxicity) and that adhering to the company's prior precautionary decision not to use MF actually might have been counterproductive. The company's reasoning is qualitative, however, and cannot yet be verified by quantitative analysis.

Reflections on the Case Studies

The case studies raise several issues.

How Much Information Is Enough?

The abbreviated nature of the private risk assessments described above is notable. Both of them were completed in under 90 days. Viewed in the most favorable light, these risk assessments can be said to represent what is sometimes called a "value of information" (VOI) approach to risk assessment.[21] The basic idea is that a rational policymaker wants to minimize the sum of error costs and transaction costs by improving the accuracy of the prediction if possible, but only if the benefits in terms of making and applying policy are not outweighed by the costs of acquiring greater precision. As Adam Finkel puts it: "The cornerstone of VOI analysis is the common-sense notion that one should never spend more money to study a problem than the losses one would incur ... by taking one's best guess and 'letting the chips fall where they may.'"[22]

Unlike corporate executives, governmental decision-makers are less concerned about profit and more concerned about not making a mistake for which they might later be criticized. As a result, governmental decision-makers might be more likely to delay and demand more information before making a decision. Neither of these two possible decision-makers is perfect or "unbiased," however. Both are embedded in a complex set of personal and institutional incentives, reflecting the axiom that "where you stand reflects where you sit."

Paralysis by Analysis?

There is little debate that government risk assessments provide more information than private assessments. The relevant question, however, is whether the additional time and effort devoted to a more thorough development of the facts produce risk management benefits that are worth their costs or, rather, create "paralysis by analysis." Elsewhere, E. Donald Elliott has argued that decisions about risk and precaution become more tractable when viewed diachronically: "the practical question that every regulator must ask is 'shall I act to address this particular problem now, basing my decision on what is currently known (or more accurately, *believed* to be known), or shall I instead defer action until a later date, when more may be known, but at the cost of what occurs in the meantime?'"[23]

Viewed from this practical perspective, neither of the private risk decisions reviewed above seem palpably wrong or likely to have benefited much from a more voluminous and time-consuming risk analysis. Of course, two isolated cases is much too

small a database upon which to make a judgment, but they do raise the question of whether sometimes "the game may not be worth the candle" in the more elaborate risk assessments conducted by government. Of course, the decision to place a particular product on the market is far different both in nature and probable consequences from deciding what level of dioxin or TCE should be permitted in the environment.

Conflicts of Interest

In each of the case studies, the company itself, taking into account its consultants' advice, was the final arbiter of what risks would be deemed acceptable. The idea that the companies conducting the risk assessments decide for themselves how much analysis is enough may be bothersome to some, because the companies are not disinterested parties and wish to commercialize the products in question. Yet it is clear that the incentives of these companies are at least generally aligned with those of consumers and society in general because the companies could suffer liability, as well as reputational and loss-of-market costs, if they put a new product on the market where the benefits do not exceed its ascertainable costs. Although the sample is far too small to draw any reliable conclusions, it is perhaps interesting that in neither of the instances studied did the company involved actually decide not to go forward with the proposed project. In the MF case, the company did institute special precautionary manufacturing controls to minimize employee exposures during the manufacturing process.

Other Observations

In one of the cases described, particular attention was paid to the issue of substitution risks.[27] Companies seem to be particularly sensitive to whether their products are more or less hazardous than other products that are already on the market. This concern with risk vs. risk tradeoffs is particularly interesting, in that product liability law generally does not formally recognize a defense that a product is safer than its competitors, but rather, holds companies to strict liability standard in determining whether products are "defective."[24] At the same time, it is pertinent to note that "safety" or "acceptable risk" is hardly a clear-cut, black-and-white concept or phenomenon, especially when applied to the chemical content of products.

It is also interesting that both of the private risk assessments included attention not only to the scientific literature, but also to whether governments, environmental groups, or plaintiffs' lawyers had raised concerns about the substances in question. This attention reflects the sensible judgment that a pre-market risk assessment is not solely a scientific undertaking, but also includes judgments about how controversial a product is likely to become. (It was clear in both cases that a government ban on the substance at issue, or a limit on its use that would be exceeded by the proposed use, would have immediately led each company to drop consideration of its use.)

Should Product Due Diligence Be More Like Environmental Due Diligence?

It is worth considering whether the public good would be served by additional governmental regulation of private-party pre-market risk assessments of new products, in a manner similar to the government regulation of environmental due diligence. Most corporate or real property transactions in the United States today routinely involve hiring a law firm and/or environmental professionals to conduct "environmental due diligence" on the property to be acquired. The process of performing environmental due diligence is highly, albeit indirectly, regulated by government. Elaborate "checklists" of the items that must be considered have developed in response to incentives created by government.[25] Government influence could take the form of positive incentives in the form of a defense or a partial defense to product liability suits in the event that mandated standards for pre-market risk assessments were followed.[26]

One important difference between the environmental context and the product liability context, however, is that under Superfund, alternative sources of funding are available if a prospective purchaser is immunized from clean-up liability, because both prior owners and generators of the hazardous waste disposed on the property remain liable for the clean-up.[27] In addition, if those sources are not available to fund a clean-up, at least in theory, reimbursement from a government fund is also available, although it provides money to clean up only the highest priority sites.[28]

In the product liability context, however, if the manufacturer is not liable for injuries caused by its products, in general, no alternative sources of com-

pensation would be available. Perhaps, therefore, a product manufacturer should merely be immunized against punitive damages in product liability cases if it conducts a pre-market risk assessment in accordance with government-approved protocols.[29] This change could certainly be accomplished by federal legislation, but legislation might not even be required. Courts uphold jury awards of *punitive* (as opposed to compensatory) damages where they find that a manufacturer's conduct is "culpable" or "unlawful" and deserving of punishment.[30] If a manufacturer followed government-prescribed standards for conducting a private risk assessment prior to placing its product on the market, it is difficult to see how its conduct could legitimately be deemed deserving of punishment thereafter by an appellate court. While less certain, it might even be possible to create a safe harbor to protect manufacturers against liability for punitive damages for new products by promulgating voluntary consensus standards similar to the ASTM standards for environmental due diligence.[31]

Should the Government Regulate Private-Product Due Diligence?

There is suggestive evidence that pre-market screening by government would tend to be somewhat more conservative and risk-averse, and to require somewhat more data, than private-party risk assessments. Approximately 4 percent of premanufacture notifications (PMNs) to market new chemical substances under the Toxic Substances Control Act in the United States are abandoned by private companies while under EPA review.[32] Presumably, the private company had already completed its own internal risk assessment before applying to EPA to manufacture the substance for commercial purposes in the first place, but then later abandoned the application rather than proceed when EPA required more data or when it became apparent that the PMN would not be approved without costly additional studies.

Arguing against the utility of government-prescribed standards for private risk assessments is the possibility that such prescriptions might include onerous and potentially irrelevant requirements. To economize on its own process costs, government almost never tailors regulation to individual cases. Rather, it typically regulates by imposing uniform requirements on an entire *class* that may be more or less broadly or narrowly defined. But inherent in the concept of *ex ante* determinations by government of "protocols" for doing pre-market risk assessments is an abstract determination that certain procedures are appropriate for an entire class of products, rather than making *ad hoc* judgments on a case-by-case basis as is typical in private risk assessments.

Government mandating a "one-size-fits-all" approach to performing private risk assessments that includes a checklist of requirements (which may or may not actually be relevant to any particular case) could be criticized for many of the same reasons that the Office of Management and Budget's Risk Bulletin was criticized by the National Academy of Sciences review panel.[33] Different products, different goals, and different contexts suggest that attempts to standardize private-product risk assessments might encounter some of the same controversy and resistance as have attempts to standardize government risk assessments. There is unquestionably a cost to imposing a "one-size-fits-all" approach, whether it be in government or the private sector. The difficult question, however, is whether the benefits of imposing the "one-size-fits-all" approach outweigh the costs.

On this key question, the analogy of EPA's "all appropriate inquiries" rule is not comforting to those who would favor a more active role for government in defining criteria for private pre-market risk assessments for new products. While EPA's all appropriate inquiries rule did mandate some changes from the pre-existing ASTM standards, most of them are somewhat bureaucratic in nature and are unlikely to make major improvements in how environmental due diligence is performed. For example, EPA required specific educational credentials for "environmental professionals" who conduct due diligence and mandated a specific time period for updating environmental reports. It is not entirely clear that these specific requirements solved any real problems or substantially improved the process.

An alternative to government standard-setting would be for industry itself to self-regulate the process of pre-market due diligence by developing a code of good practices or voluntary standards. As noted above, the private ASTM standards — not the EPA rule — developed most of the content for generally accepted standards of environmental due diligence. This is similar to a recent Obama-Administration proposal that doctors might be protected from medi-

cal malpractice suits if they follow "evidence-based guidelines."[34]

Conclusion

The private-product risk assessment case studies we have described illustrate one end of the spectrum of possible application of a value-of-information approach to assessing risk. The cases relied on existing published scientific data, which in some cases was voluminous and in others was sparse at best, and were completed within 90 days. At the other end of the spectrum are risk assessments performed for regulatory purposes by government agencies, which require more information than did the private assessments, but do not necessarily protect public health any more effectively.

The incentive for exercising precaution in the private examples is provided by tort liability in the United States; a similar incentive is less apparent in the EU, which remains (as yet) less litigation-prone. The REACH program may help support private risk assessment in the EU by generating extensive toxicity data sets; it remains to be seen how the cost of generating those data will compare to any resulting public health benefits that may accrue.

At the end of the day, we are uncertain whether additional governmental guidance to the private sector about how to perform pre-market risk assessments of new products would be useful or whether the benefits would be outweighed by the costs. We do believe, however, that the topic of private risk assessments is an important one that has received far too little attention to date.

Endnotes

1. *See, generally*, Elliott, E. Donald, "Environmental TQM: A Pollution Control Program that Works!" *Michigan Law Review* 92 (1994): 1840 for the argument that it is a misnomer to consider actions "voluntary" when they are a response to general incentives created by law.
2. *McPherson v. Buick Motor Co.*, 217 N.Y. 382 (1916).
3. *See* Elliott, E. Donald, "Re-Inventing Defenses/Enforcing Standards: The Next Stage of the Tort Revolution?" *Rutgers Law Review* 23 (1991): 1069.
4. There are many different formulations of the Precautionary Principle and no generally accepted definition. A good approximation is the following: "a moral and political principle which states that if an action or policy might cause severe or irreversible harm to the public or to the environment, in the absence of a scientific consensus that harm would not ensue, the burden of proof falls on those who would advocate taking the action." *See* http://en.wikipedia.org/wiki/Precautionary_principle.
5. Although the "state of the art" defense is not widely recognized in the United States, evidence regarding the state of technology and scientific knowledge is typically admissible, but not dispositive, for the trier of fact's inquiry into whether a product is reasonably safe or the manufacturer should have adopted an alternative design. *See* American Law Institute, *Restatement (Third) of the Law of Torts: Products Liability* § 2 cmt. d (1997).
6. *See* American Law Institute, *Restatement (Second) of the Law of Torts* §402A (1964). *See, e.g., Adams v. G.D. Searle & Co., Inc.*, 576 So. 2d 728, 730-31 (Fla. Dist. Ct. App. 1991) ("The duty to test ... is a subpart of a manufacturer's duty to design a product with reasonable care, and thus is subsumed in the plaintiffs' claims for defective design and failure to warn."); *Wood v. Phillips Petroleum Co.*, 119 S.W.3d 870 (Tex. App. 2003) ("[A] manufacturer is held to the knowledge and skill of an expert ... This means that it must not only keep abreast of scientific knowledge, discoveries, and advances, but, more importantly, test and inspect its product."); *Kociemba v. G.D. Searle & Co., Inc.*, 707 F. Supp. 1517 (D. Minn. 1989).
7. Hammitt, James K., Jonathan B. Wiener, Brendon Swedlow, Denise Kall, and Zheng Zho, "Precautionary Regulation in Europe and the United States: A Quantitative Comparison," *Risk Analysis* 25, no. 5 (2005): 1215–1228.
8. *See, generally*, Renn, Ortwin, and E. Donald Elliott, "Precautionary Regulation of Chemicals in the US and EU," *Precautionary Risk Appraisal and Management: An Orientation for Meeting the Precautionary Principle in the European Union*, eds. Ortwin Renn, Pia-Johanna Schweizer, Ulrich Müller-Herold, Andrew Stirling (Bremen, Germany: Europaeischer Hochschulverlag, to be published in 2009).
9. Sunstein, Cass R; *Laws of Fear: Beyond the Precautionary Principle* (Cambridge: Cambridge University Press, 2005).
10. Europa, "REACH: What Is REACH?," available at http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm.
11. National Academy of Sciences/National Research Council, *Models in Environmental Regulatory Decision-Making* (Washington, D.C.: National Academies Press, 2005).
12. For a description, see Renn, Ortwin, and E. Donald Elliott, id. at note 8.
13. National Academy of Sciences/National Research Council, id.

14. U.S. Environmental Protection Agency, Integrated Risk Information System, "Asbestos," available at http://www.epa.gov/iris/subst/0371.htm; World Health Organization, International Agency for Research on Cancer, "Monographs on the Evaluation of Carcinogenic Risks to Humans. Overall Evaluations of Carcinogenicity: An Updating of IARC Monographs Volumes 1 to 42, Supplement 7" (1998), available at monographs.iarc.fr/ENG/Monographs/suppl7/suppl7.pdf.
15. Agency for Toxic Substances and Disease Registry, "Toxicological Profile for Synthetic Vitreous Fibers" (2004), available at http://www.atsdr.cdc.gov/toxprofiles/tp161.html.
16. U.S. Environmental Protection Agency, Integrated Risk Information System, "Refractory ceramic fibers" (1992), available at http://www.epa.gov/iris/subst/0647.htm.
17. World Health Organization, International Agency for Research on Cancer, "IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 81: Man-made Vitreous Fibres" (2002) summary available at http://monographs.iarc.fr/ENG/Monographs/vol81/volume81.pdf.
18. Mast, R.W., E.E. McConnell, R. Anderson, J. Chevalier, P. Kotin, D.M. Bernstein, P. Thevenaz, L.R. Glass, W.C. Miller, and T.W. Hesterberg, "Studies on the chronic toxicity (inhalation) of four types of refractory ceramic fiber in male Fischer 344 rats," *Inhalation Toxicology* 7 (1995): 425–467; McConnell, E.E., R.W. Mast, T.W. Hesterberg, J. Chevalier, P. Kotin, D.M. Bernstein, P. Thevenaz, L.R. Glass, and R. Anderson, "Chronic inhalation toxicity of a kaolin-based refractory ceramic fiber in Syrian golden hamsters," *Inhalation Toxicology* 7 (1995): 503–532.
19. Mast, R.W., L.D. Maxim, M.J. Utell, and A.M. Walker, "Refractory ceramic fiber: toxicology, epidemiology, and risk analyses — a review," *Inhalation Toxicology* 12 (2000): 359–399.
20. *Threshold Limit Values for Chemical Substances and Physical Agents* (Cincinnati, OH: American Conference of Governmental Industrial Hygienists, 2006).
21. *See* Finkel, Adam, *Confronting Uncertainty in Risk Management: A Guide for Decision-Makers* (RFF Press, 1991): 63; Finkel, A.M., and J.S. Evans, "Evaluating the Benefits of Uncertainty Reduction in Environmental Health Risk Management," *Journal of the Air Pollution Control Association* 37 (1987): 1164–1171.
22. Finkel, id. at 63.
23. Renn and Elliott, id. at note 8.
24. See note 6 for examples from case law in several jurisdictions.
25. All Appropriate Inquiries Rule, 40 CFR §312 (2005).
26. *See, generally*, Elliott, id. at note 1 (suggesting a possible defense to product liability claims if a manufacturer complies with government-mandated standards).
27. *See* Superfund §107(a)(2) and (3), 42 U.S.C. 9607(a)(2) and (3).
28. Superfund §111(a)(2), 42 U.S.C. §9611(a)(2).
29. For a general discussion of the role of punitive damages in product liability cases, *see BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996).
30. *See, e.g., BMW v. Gore*, ibid., 517 U.S. at 568 "[p]unitive damages may properly be imposed to further a State's legitimate interests in punishing unlawful conduct and deterring its repetition" (emphasis supplied). A more recent U.S. Supreme Court decision holds that the Due Process Clause of the U.S. Constitution forbids a state from using punitive damages to punish a defendant for injuries inflicted on other persons who are not parties to the litigation. *Philip Morris USA v. Estate of Williams*, No. 05–1256 (February 20, 2007).
31. Some commentators have suggested that in certain jurisdictions, such as New York, "[c]ompliance with standards promulgated by industry groups such as ANSI (American National Standards Institute), ASME (American Society of Mechanical Engineers), ASTM (American Society for Testing Materials) or SAE (Society of Automotive Engineers) may also provide strong evidence that the product was not defective." *See also* Wilensky, Saul, and Carl Schaerf, "Defending the Design Defect Case: Strategic Considerations," *Products Liability in New York*, ed. Neil A. Goldberg (New York: New York State Bar Association, 1997): 273; *American Law Institute, Restatement (Third) of the Law of Torts: Products Liability* § 2 cmt. d (1997) ("The defendant is thus allowed to introduce evidence with regard to industry practice that bears on whether an alternative design was practicable."). Others have argued, however, that "[t]he 'standard of the industry' defense has been discredited by most courts, beginning with the opinion of *The T.J. Hooper* such that "... a manufacturer may show compliance with industry standards to indicate reasonableness, but the industry standard is always open to the question of reasonableness."); Schaden, Richard F., and Victoria C. Heldman, *Product Design Liability* (Practising Law Institute 1982): 127; *see The T. J. Hooper*, 60 F.2d. 737, 740 (2d Cir. 1932) (compliance with prevailing custom in the industry is not a defense in a tort case; "a whole calling may have unduly lagged in the adoption of new and available devices."). However, *The T. J. Hooper* involved compensatory, not punitive, damages.
32. *See* Renn and Elliott, id.
33. Remarks by President Barack Obama to the Ameri-

can Medical Association (June 15, 2009), available at http://www.ama-assn.org/ama/pub/about-ama/our-people/house-delegates/2009-annual-meeting/speeches/president-obama-speech.shtml.

34. National Academy of Sciences/National Research Council, Scientific Review of the Proposed Risk Assessment Bulletin from the Office of Management and Budget/ (Washington, D.C.: National Academies Press, 2007).

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