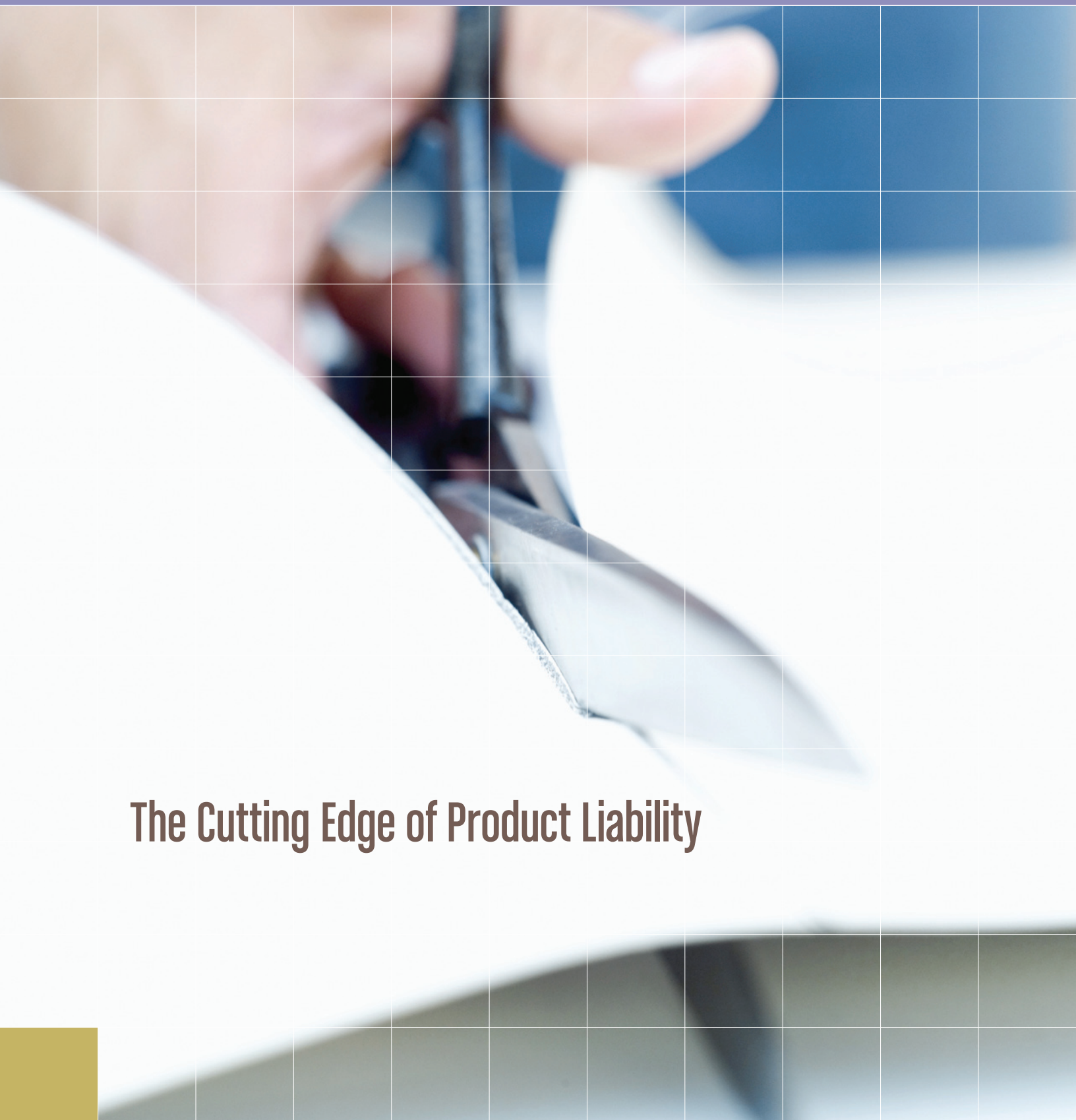
JONES DAY

PRACTICE PERSPECTIVES: PRODUCT LIABILITY & TORT LITIGATION



The Cutting Edge of Product Liability

letter from the practice chair

This is the first issue of Jones Day's Product Liability & Tort Litigation's *Practice Perspectives* in the new year. It is also the first issue during the new administration in Washington. Needless to say, this issue also comes out during a period of economic turmoil unmatched since the Great Depression. So what should a client expect to be new, different, or in flux in the coming year? What should our lawyers be thinking?

As the head of this area of practice for Jones Day—and mindful that, when it comes to making predictions, those who try to get ahead by gazing into a crystal ball usually wind up eating ground glass—let me offer some comments about what to expect.

First, the plaintiffs' contingent-fee bar, still looking for outrageous pay-days similar to what they received in the tobacco settlement and in asbestos litigation, will be more emboldened than ever. They continue to find areas to try to stir up waves of new cases, to aggregate litigation, and to relax standards for causation and injury. Their funding of campaigns at state and federal levels will continue to thwart the kind of meaningful tort reform we should seek so that American companies and interstate commerce can shed the economic drag that such litigation brings. Tort litigation on a grand scale is not going away any time soon.

Unfortunately, American manufacturers and consumers will continue to bear, in one way or the other, the cost and burden that tort litigation brings, at a time when they can least afford to bear them. The media types who characterize runaway verdicts, punitive damages, and mal-practice extortion settlements and claims without injury as "victories for consumers" are economic fools. American companies are less

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Clients want cost-effective solutions; they don't need or want lawyers with big egos who can't find affordable roads to victory.

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TOXIC TRESPASS: LEAD US NOT INTO LITIGATION

by Steven N. Geise and Hollis R. Peterson

Since the chemical revolution began to unfold in the 1950s, people have ingested hundreds of toxic substances—knowingly or not. Our bodies carry chemicals found in the products and processes we use or to which we are exposed. Many toxins take up residence in body fat, where they may remain for decades; others are absorbed into the body and quickly metabolized and excreted. Winds and water currents can carry persistent chemicals thousands of miles until they find a home in our bloodstreams. Just by living in an industrialized society, we all carry a sampling of the chemical cocktail created by our surroundings.

As modern science advances, biomonitoring data is able to detect the presence of specific toxins. But science cannot always inform us about how the chemicals were introduced, how long they have been there, or whether they pose a legitimate health risk. If not for recent developments in detection, we might never know that our bodies harbor such chemicals.

Nevertheless, creative litigants are forcing courts to deal with a new wave of toxic tort claims seeking to make chemicals in a person's bloodstream an actionable offense. This cause of action is known as "toxic trespass." Courts must decide whether the mere presence of chemicals in an individual gives rise to civil liability when the individual has no diagnosed injury and the causal link between the exposure and the potential disease is weak at best. Common sense and legal precedent tell us the answer should be no, but the fight against such suits is just beginning.

LEGISLATIVE EFFORTS TO LEGITIMIZE TOXIC TRESPASS THEORIES

With the advent of sophisticated biomonitoring techniques that permit detection of trivial levels of substances, the public expects that any amount of toxin can be measured. Influenced by modern crime dramas and sensationalized media accounts, the public is often led to believe that even minute levels of toxins are harmful to their health. Not surprisingly, an effort is afoot to turn toxins in the bloodstream into civil and criminal liability.

California was the first state to establish a biomonitoring program. Recognizing that modern life exposes Californians to thousands of chemicals every day, in September 2006, California enacted the California Environmental Contaminant Biomonitoring Program, which requires the California Department of Public Health and the California Environmental Protection Agency to establish a statewide program to monitor the presence and concentration of designated chemicals via surveys of Californians. *See* Cal. Health & Saf. Code §§ 105440–105459 (2008). Under the code, the designated state agencies must make their biomonitoring findings public and notify surveyed individuals if the data suggests exposure to a known health risk. The first report is required by January 1, 2010, and will no doubt stir publicity and litigation against the indicted chemicals.

Recently, special-interest groups have promoted legislation that would make chemical manufacturers strictly liable for the simple detection of chemicals in the body. Strict liability generally applies in situations where the defendant causes injury in the course of an activity characterized as abnormally dangerous or ultrahazardous. When strict liability applies, the plaintiff need not prove that the defendant's conduct was unreasonable. Restatement (Second) of Torts, *supra* n. 104, § 520. The Community Environmental Legal Defense Fund ("CELDF") has proposed a strict-liability model ordinance to local legislators that recognizes "that it is an inviolate, fundamental, and inalienable right of each person… to be free from involuntary invasions of their bodies by corporate chemicals." Corporate Chemical Trespass Ordinance, http://www.celdf.org/Ordinances/CorporateChemicalTrespassOrdinance/tabid/257/Default.aspx (web sites last visited February 6, 2009).

CELDF's "Corporate Chemical Trespass Ordinance" declares the "deposition of toxic chemicals or potentially toxic chemicals within the body" as "a form of trespass." *Id.* It deems corporations (and the people who own or manage them) that manufacture or generate toxic or potentially toxic chemicals detected in a person's body as culpable parties liable for "trespass damages, compensatory damages, punitive damages, and the instatement of permanent injunctive relief." *Id.* Under the ordinance, culpable parties are held strictly liable if one of their toxic or potentially toxic chemicals or compounds is discovered within the body of a resident. *Id.* By putting the duty on the municipality to initiate litigation against culpable parties, the ordinance aims to turn chemical trespasses into quasi-statutory violations. Local governments are following CELDF's lead.

For example, on February 7, 2008, the Halifax, Virginia, Town Council unanimously approved a "Corporate Mining and Chemical and Radioactive Bodily Trespass" ordinance drafted by CELDF. "Halifax 1st in Virginia to adopt 'chemical trespass' defense," *The Gazette-Virginian*, February 20, 2008, *available at* http://www.wpcva.com/articles/2008/02/20/brookneal/news/news02.txt. The action, prompted by concerns over a proposed uranium mine and milling operation, prohibits corporations from interfering with the civil rights of residents and holds the corporation and governing officials permitting the uranium operation liable to the town for chemical trespass. *Id.* According to CELDF project director Ben Price, the ordinance "is a first shot across the bow to let [corporations] know the people have the right to govern." *Id.* It is hardly the first shot—Halifax is the 10th U.S. municipality to adopt such an ordinance.

While these legislative acts do not sanction individual lawsuits, plaintiffs have seized upon violations as grounds for tort claims. Either in add-on claims in putative environmental class actions or in stand-alone individual suits, plaintiffs allege that corporate trespasses violate individual liberties and give rise to civil liability. Even in circumstances where the

exposure is below the "safe" threshold level designated by the U.S. Environmental Protection Agency, lawsuits are springing up, based on simple detection of such substances. As the frequency of legislation like that sponsored by CELDF increases, it is expected that the number of toxic trespass claims based on the detection of chemicals in a person's body will increase as well. Fortunately, old-school litigation strategies can be used to defend against new-school toxic trespass claims.

INTENT AS A HURDLE FOR PLAINTIFFS

Defendants can successfully challenge plaintiffs' ability to establish the intent necessary to commit a battery. "[T]he tort of battery requires intent by the actor 'to bring about a harmful or offensive contact.… [It is] confined to intentional invasions of the interests in freedom from harmful or offensive contact.' " *Janelsins v. Button*, 648 A.2d 1039, 1042 (1994) (quoting Fowler V. Harper, 1 *The Law of Torts* § 3.3, at 272–73, 276 (2d ed. 1986)). Accidental contact does not constitute a battery

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CIVIL BATTERY: A PRIMA FACIE CASE

Plaintiffs base their toxic trespass claims on the allegation that defendants intentionally interfered with their bodies by introducing chemicals into their systems. Tort claims such as these for intentional exposure to hazardous substances are predicated on the theory of battery. A "battery" is a harmful or offensive physical contact to the plaintiff's person through intentional contact by the tortfeasor and without the consent of the victim. Restatement Second, Torts § 13. The harmfulness and offensiveness are judged by a reasonable-person standard, contact can be direct or indirect, and intent exists if the actor intends to cause a harmful or offensive contact with the person or the imminent apprehension of such contact. *Id.* To establish causation, a plaintiff typically must show that a particular defendant's substance more likely than not causes the kind of injury from which the plaintiff suffers and more likely than not caused the plaintiff's injuries.

because "[w]here an accident occurs,… the actor would not have *intended* to invade the other's interest." *Janelsins*, 648 A.2d at fn. 5. The defendant must have done some affirmative act and must have known that an unpermitted contact was substantially certain to follow from that act. Indeed, it is this intent that separates battery from mere negligence.

In *Pechan v. DynaPro, Inc.*, 622 N.E. 2d 108, 111 (Ill. App. 1993), the plaintiff alleged that her former employer was liable for her exposure to secondhand cigarette smoke in the workplace. The appellate court affirmed the dismissal of the plaintiff's battery count, finding that the employer could not, as a matter of law, have had the intent necessary to commit a battery. *Id.* at 118. The *Pechan* court reasoned that "[s]moking is a legal activity and not an act of battery because, generally, smokers do not smoke cigarettes with the intent to touch nonsmokers with secondhand smoke." *Id.*

Thus, to the extent that a defendant is engaged in a legal activity and lacks intent to harm the public, a plaintiff's civil battery claim should fail.

Similarly, in *Shaw v. Brown & Williamson Tobacco Corp*., 973 F. Supp. 539, 548 (D. Md. 1997), the plaintiff argued that the intent requirement of the battery claim was satisfied by Brown & Williamson's intentional manufacture, marketing, and distribution of cigarettes, on the basis that such acts "set[ ] in motion the inevitable series of events leading to [the plaintiff's] injuries." The court disagreed, finding that while Brown & Williamson may have had knowledge that secondhand smoke would reach some nonsmokers, such generalized knowledge was insufficient to satisfy the intent requirement for battery. *Id.* The court stated that a finding that Brown & Williamson had committed a battery by manufacturing cigarettes "would expose the courts to a flood of farfetched and nebulous litigation concerning the tort of battery." *Id.*

As applied to toxic trespass cases, the reasoning in civil battery decisions shows the difficulties plaintiffs will face in proving intent. While a defendant may know that its toxins could reach people in the community, unless the plaintiff can prove that the defendant intended to cause *harmful* contact with those toxins, this requisite element of a battery claim will be lacking. Accidental exposure or contact will not support the intentional tort of battery.

NO PRESENT INJURY—NO LIABILITY?

Even if intent could be established, plaintiffs face other problems. In many instances, a plaintiff bases her cause of action on the fact that biomonitoring revealed a measurable level of chemical even though the plaintiff is asymptomatic and otherwise healthy. This raises the question: Does the mere presence of chemicals in the body or the remote possibility of future harm from such exposure equal an actual injury?

Courts have taken a variety of approaches to the requirement that a plaintiff must exhibit an actual injury—such as personal physical illness, the presence of disease, or death—to recover on a hazardous substance tort claim, but they tend to answer the question in the negative. In most cases, the injury requirement has been strictly applied. *See Paz v. Brush Engineered Materials, Inc.*, 2007 WL 14891 (Miss. 2007) (rejecting plaintiffs' claims for medical monitoring where plaintiffs claimed to have been exposed to beryllium but did not suffer from any current illness or physical injury); *Lowe v. Philip Morris USA, Inc.*, 207 Or. App. 532 (Or. 2006) (rejecting smoker's claim for medical monitoring where she suffered no actual physical harm); *Wood v. Wyeth-Ayerst Laboratories*, 82 S.W.3d 849, 852 (Ky. 2002) (rejecting medical monitoring on the grounds that "[a] cause of action does not exist until the conduct causes injury that produces loss or damage"). However, in select cases, courts have shown a willingness to overlook the injury requirement, depending on the nature of the particular case. *Sinclair v. Merck & Co., Inc.*, 389 N.J. Super. 493 (N.J. Super. Ct. App. Div. 2007) (ruling that it was premature to dismiss plaintiffs' claims for medical monitoring where they had an increased risk of myocardial infarction due to their use of Vioxx but claimed no present injury).

The judicial trend of rejecting liability where there is no discernible injury should apply to toxic trespass cases. Many courts have concluded that allowing a claim for a mere increase in the possibility of future harm would be inconsistent with the fundamental premise that the plaintiff must have suffered actual, physical harm. *Lowe*, 207 Or. App. at 539. The court in *Lowe*, *supra*, also expressed concern that allowing a claim for increased risk of future harm would create liability that was "virtually limitless" and that there would be "no basis on which to separate spurious or speculative claims from legitimate ones." *Id*. at 553. With so many chemicals and so many ways to detect them, opening the door to toxic trespass cases presents similar concerns.

With new developments in biomonitoring and environmental testing, plaintiffs' counsel may attempt to offer quantitative "proof" of an "injury." Scientific advancements are increasingly able to show that an individual's blood contains chemicals previously unknown or undetectable, such as polychlorinated biphenyls, organophosphates, pesticides, bisphenols, and phthalates. Whether courts will relax the injury requirement to entertain suits where toxins are present at levels above what regulatory agencies have deemed "safe" or, worse yet, where toxins are present in the body at any level, remains to be determined. In any event, defendants will have a strong defense based on the lack of a present injury.

CAUSATION: AN INSURMOUNTABLE BARRIER

In addition to injury and intent, a plaintiff must be able to establish causation to prevail. For a toxic trespass claim, this means proving that the defendant caused the chemical

exposure, that the exposure can cause human disease, and that the exposure caused the plaintiff's disease or risk thereof. The latter two prongs are referred to as "general causation" and "specific causation."

To establish general causation, the plaintiff must prove that human exposure to the toxic agent at issue is capable of causing or exacerbating an identifiable disease from which the plaintiff suffers. This showing generally requires scientific data in the nature of epidemiological studies demonstrating a statistical association between exposure to the substance and an increase in the incidence of the plaintiff's disease. Jeffry D. Cutler, "Implications of Strict Scrutiny of Scientific Evidence: Does *Daubert* Deal a Death Blow to Toxic Tort Plaintiffs?" 10 J. Envtl. L. & Litig. 189, 214 (1995). For cases in which the plaintiff can offer no scientific evidence of an association between exposure to the defendant's agent and a disease of the sort suffered by the plaintiff, the plaintiff would take nothing, no matter how culpable the jury believed the defendant's conduct to be. This should be the outcome for substances in which there is no recognized association between exposure to the defendant's substance and any disease.

To establish specific causation, the plaintiff must prove that her exposure to the toxic material caused her particular injury. This showing typically requires expert testimony regarding the extent to which the plaintiff was exposed to the toxic agent at issue and that the plaintiff's particular affliction was more likely than not caused by the plaintiff's exposure to the substance at issue. If the plaintiff is not able to prove sufficient exposure to the chemical in question, that she suffers from the alleged disease, or that the exposure was sufficient to cause her injury, her claim should be rejected.

Specific causation has frequently proved to be an insuperable barrier in toxic tort cases because of the long latency periods that often exist between the exposure to a toxic substance and the onset of disease. *Cutler*, *supra*, at 199. Given all of the other exposures the plaintiff will have encountered during that time period, the defendant has ample opportunities to suggest alternative explanations for all but the clearest of signature diseases, thereby casting doubt on the plaintiff's expert's testimony on specific causation. Margaret A. Berger, "Eliminating General Causation: Notes Towards a New Theory of Justice and Toxic Torts," 97 Colum. L. Rev. 2117, 2121–22 (1997). Indeed, the plaintiff's own lifestyle or genetic makeup is likely to have contributed to her disease.

Causation is a stumbling block that has precluded compensation for all but the most clearly understood environmentally caused diseases. Jonathan Haar's widely read account of the *Woburn* litigation painted a dramatic, and loosely accurate, picture of the legitimate legal hurdles a plaintiff faces in attempting to recover damages for physical harm allegedly caused by exposure to environmental contaminants. *See* Jonathan Haar, *A Civil Action* (First Vintage Books, 1996). More recently, a Texas judge in the district court in Hidalgo County dismissed a $437 million product liability suit accusing Levi Strauss & Co. and others of exposing workers to toxic dust in garment factories across the Rio Grande Valley, *Nelia G. Alanis et al. v. Allison Manufacturing Co. et al.*, Case No. C-1691-03-H (2008). The defense in that case successfully took the position that plaintiffs had not sufficiently demonstrated that their ailments resulted from their alleged exposure to formaldehyde and other chemicals at the factories. The decision sends the message that legal proofs will not yield to cinematic story lines in even the most liberal jurisdictions.

Even if a plaintiff can prove some direct exposure attributable to the defendant, the defendant can still argue that there are numerous other sources of these chemicals in the environment that could have directly contributed to the level found in the plaintiff's body. For example, what environmental exposures surround the plaintiff's neighborhood? Has he used household products, such as cleaning solvents or cosmetics, containing phthalates and other chemicals? Is his drinking water polluted? What environmental and industrial exposures has he had during his employment? The number of potential sources of contamination is endless—which makes it difficult for a plaintiff to definitively prove a particular source and cause of his injury. For ubiquitous exposures and speculative causal chains, a defendant has multiple options for challenging a plaintiff's ability to demonstrate causation.

THE *DAUBERT* STANDARD

In addition to challenging the elements themselves, a defendant can attack the mouthpiece the plaintiff uses to attempt to satisfy the elements. The admissibility of scientific evidence of causation is governed by the Federal Rules of Evidence and *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579 (1993).

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GLOBAL TRENDS IN CONSUMER PRODUCT SAFETY REFORM

by Peter J. Biersteker and Mark R. Hall

Product recalls, especially of imported products, skyrocketed throughout the developed world in 2007 and 2008. The acting chairman of the U.S. Consumer Product Safety Commission ("CPSC"), for example, dubbed the summer of 2007 the "summer of recalls."[1] The spike in recalls created a perfect political storm—foreign goods posing actual or perceived safety risks to innocent domestic consumers, often children, against a backdrop of increasing skepticism toward free trade and, at least in the United States, the run-up to a presidential election.

For the first time in decades, consumer product safety was high on the political agenda, and governments seized the opportunity to adopt or propose significant legislative reforms. For instance, the United States enacted, on August 14, 2008, the Consumer Product Safety Improvement Act of 2008 ("CPSIA"); Canada is evaluating Bill C-6, the Canada Consumer Product Safety Act, first reading January 29, 2009[2]; and, while the European Union has not yet proposed far-reaching reforms of its General Product Safety Directive ("GPSD"),[3]

it is weighing significant reforms of Directives that cover specific industries, such as its new Toy Safety Directive, adopted on December 18, 2008.[4]

This article explores two broad issues. First, since most consumer products companies have a global reach, it is interesting to compare and contrast different facets of existing and proposed consumer product safety requirements:

1. Harmonization. To what extent do reform proposals serve the goal of increased harmonization of variegated consumer product safety standards?
2. Clarity. From a business perspective, increased clarity as to what is required, with respect to product features and performance as well as the procedures that apply to reporting and recalls, would be desirable. Do the various proposals offer clearer guidance?
3. Partnership. Historically, consumer product safety efforts were a collaboration between business and industry. Do the recent legislative proposals enhance that partnership?
4. Enforcement. Are there trends with respect to enforcement, and if so, what do they augur?

Second, since businesses should at least start planning for how they can most effectively and efficiently comply with the new actual or proposed requirements, what practical suggestions might industry wish to consider?

HARMONIZATION

Increased harmonization of standards would be highly desirable from the perspective of global businesses. It is an explicit goal of the regulators themselves. *See, e.g.*, "Memorandum of Understanding between the Healthy Environments and Consumer Safety Branch of the Department of Health of Canada and the Consumer

Product Safety Commission of the United States of America Regarding Cooperation Related to the Safety of Consumer Products," June 22, 2005, at 1 (declaring as a purpose "to the greatest extent practicable, to make compatible their respective standards-related measures"). Nevertheless, the adopted and proposed reforms generally disserve the goal of increased global harmonization.

The new CPSIA in the United States, for example, adopted *total* lead standards for the surface coatings and substrates of children's products, eschewing the *soluble* lead standards which are favored throughout most of the developed world (EN 71 in the EU; ISO 8124 in most countries) and which are an attempt to limit exposure to safe levels using toxicologically derived health standards.

Likewise, the United States adopted limits on phthalates in children's products, even though risk assessments sponsored by U.S. government agencies had concluded that the substances posed little or no health risk as found in consumer products.[5] And, while the newly adopted quantitative phthalate limits in the U.S. mirror those adopted in the EU and California, the standards apply inconsistently. In the EU, the standards for certain phthalates apply to those portions of toys and child-care articles, such as infant swings, that are capable of being mouthed by children aged three and under. Commission Decision 1999/815/EC (7 Dec. 1999). In the U.S., the new standards arguably apply to all parts of child-care articles, including inaccessible parts that pose no hazard. CPSIA, § 108(a), (b)(1).

CLARITY

From the perspective of business, clear safety standards and procedures would be preferable to ambiguous ones, particularly when violations can give rise to significant penalties.

With respect to safety standards, the CPSIA in the U.S. relies on them to a significantly greater degree, at least for products intended for children aged 12 and under. For example, under the CPSIA, the ASTM F963-07 voluntary standards will become mandatory.[6] The vast majority of consumer products, however, remain subject to the U.S. catchall standard requiring recalls for products possessing a "defect" that creates "a substantial risk of injury to the public" (15 U.S.C. § 2064).

Products covered by specific directives in the EU are also subject to a range of specific, relatively clear standards. The GPSD generally requires all products to be "safe"; a "safe" product is defined as one that, under reasonably foreseeable conditions of use, presents no risk or only minimal risks compatible with the product's use. GPSD, Art. 5(3) and Annex 1(2).

Canada relies heavily on specific, relatively clear rules embodied in Schedules 1 and 2 to its statute. C-6 § 30(1) proposes, however, to adopt a U.S.-style general provision allowing the government to compel recalls where there are "reasonable grounds" to believe that "a consumer product is a danger to human health or safety."

Application of these general criteria to specific circumstances may be ambiguous, particularly in the absence of well-developed case law such as that which informs common-law tort standards. The problem is compounded in two ways.

First, industry reporting obligations are triggered by the actual or constructive receipt of information that reasonably supports the conclusion that there has been a violation of these general, ambiguous standards. 15 U.S.C. § 2064(b), 16 C.F.R. § 1115.12; C-6 § 14(1); GPSD, Art. 5(3) and Annex 1(2). As the acting chairman of the U.S. Consumer Product Safety Commission candidly testified on June 6, 2007, before the U.S. House of Representatives, Committee on Energy and Commerce, Subcommittee on Commerce, Trade, and Consumer Protection, the reporting obligation "is written in very broad and somewhat imprecise terms and requires… judgment calls about its applicability in specific cases."

Second, these "judgment calls" will be examined by government authorities with the benefit of 20/20 hindsight to determine whether significant potential civil and criminal penalties should attach to the failure to timely report to government authorities as well as the marketing of products that violate these general standards. For example, the maximum civil penalty for violations in the U.S. has been increased to $15 million, and the maximum criminal penalty includes up to five years' imprisonment. 15 U.S.C. §§ 2069 and 2070. *See also* C-6 §§ 46–48, 38–45; GPSD, Arts. 7 and 18(3).

PARTNERSHIP

Given scarce resources, government regulators the world over rely heavily on industry to report when products need to be recalled. Canada, for example, currently has no mandatory reporting obligation (unless a recall is required) or power to order recalls of consumer products. Most countries' regulators, moreover, have limited capacity to monitor the millions of consumer products on the market, and they only modestly supplement industry reporting, by collecting data on product-related hospital emergency visits and fielding consumer reports of unsafe products.

This system of industry reporting has worked well. Indeed, of the spate of recent recalls, the overwhelming majority were initiated as a result of industry reporting to authorities—not because of increased government surveillance, not because of inadequate safety standards, not because of manufacturers' exerting "undue influence" on proprietary testing laboratories to color their results, and not because of insufficient enforcement powers. Generalizations are difficult because the facts of individual recalls vary and the precise circumstances giving rise to a recall are often subject to salutary confidentiality protections, but it appears that the increased recall activity generally was due to inadequate design and/or inadequate control of the supply chain, particularly for goods manufactured in China.

A sensible legislative response would be to require technically competent design review and testing of representative samples of finished goods (or their components and raw-material inputs) for compliance with applicable safety standards and adherence to product safety design specifications. Recent legislative proposals generally do not do this. The CPSIA requires third-party testing for and certification of compliance only for "children's products" and only as to mandatory safety standards. CPSIA, § 102(a). The EU's GPSD only generally requires producers to adopt measures for becoming informed of risks their products might pose, including, "where appropriate," sample testing. GPSD, Art. 5(1). And Canada neither has nor proposes a general system of design review or compliance testing and certification as to even mandatory standards, except by order of the Minister of Health in specific circumstances (C-6 § 12) and indirectly by making "due diligence" a defense to potential criminal penalties (C-6 § 38(2)).

Instead of addressing what appear to be the root causes of the recent surge in consumer product recalls, reform proposals focus predominantly on other issues and suggest a disturbing distrust of industry. This trend is reflected through: (1) new mandatory standards (CPSIA, § 106) without any substantial evidence that voluntary standards have been ineffective and sometimes without adequate scientific support; (2) significantly increased civil and criminal penalties, including forfeiture (CPSIA, § 217), that, as the acting chairman of the U.S. CPSC has observed (June 6, 2007, testimony, *supra*), threaten to lead to less cooperation and more litigation between industry and regulators; (3) protections against potential "undue influence" by manufacturers or their third-party testing laboratories (CPSIA, § 102(b)) without evidence that this has been a problem; (4) "whistleblower" protections (CPSIA, § 219) that encourage employees to report perceived violations by their employers without evidence that employers significantly underreport violations; and (5) as discussed in the next section, stepped-up governmental enforcement. *See*, *e.g.*, CPSIA, §§ 216, 217, 218, 222.

ENFORCEMENT

Most of the current reform proposals anticipate stepped-up enforcement. Canada, for example, proposes to designate "inspectors" with broad powers to prevent, punish, and remedy perceived violations. C-6 §§ 18–34. In addition to an expanded budget, an increased presence at U.S. ports, and the ability to impose new and stiffer penalties for an expanded array of violations, the CPSIA gives state attorneys general the authority to enjoin certain alleged violations and to retain private counsel to act on their behalf in exchange for statutorily permitted attorneys' fees. 15 U.S.C. § 2073(b).

Unlike the proposed Canadian inspectors, state attorneys general are political officers, they are not under the supervision of national regulators, and their decisions are not subject to review by national regulators.

In short, there is a real risk that product safety issues may become increasingly politicized and that different courts will

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COMPANIES BEWARE

ARMED WITH STRICTER SAFETY STANDARDS AND NEW ENFORCEMENT ARTILLERY, THE CPSC TAKES AIM AT UNSAFE PRODUCTS

The Consumer Product Safety Commission ("CPSC") was recently overhauled to bolster oversight of consumer products, especially imports, with the passage of the Consumer Product Safety Improvement Act of 2008 ("CPSIA"). Armed with new, significantly beefed-up enforcement powers, the CPSC is poised to take aim at companies whose products are not in compliance with all applicable safety standards under the law. U.S. companies must be prepared for these changes or risk facing fines of up to $15 million and/or prison time of up to five years.

BACKGROUND ON THE CPSC

The CPSC was established in 1972 as an independent federal regulatory agency to protect the public from unreasonable risks of injury and death associated with consumer products used in or around the household. Not only does it oversee domestic products, but the CPSC is one of only two government agencies with primary responsibility for overseeing the safety of imported consumer products. (The other is the Food and Drug Administration.)

For many years, the CPSC was underfunded and understaffed, yet American consumers still enjoyed the safest consumer products in the world. Historically, the CPSC relied chiefly on voluntary compliance with all legally required safety standards as well as voluntary reporting by U.S. companies of any product safety issues. When a manufacturer became aware of a "substantial product hazard," it was required to voluntarily report this information to the CPSC.[1] The CPSC would then work with the manufacturer to remedy the "substantial product hazard," occasionally through product recalls. This system of voluntary compliance and reporting was mostly successful for many years. However, the changing landscape of consumer products, both in their complexity and in their countries of origin, recently led to some very

by Carol A. Hogan and Wendy A. Aeschlimann

big, high-profile recalls. These recalls called into question the CPSC's ability to police the safety of U.S. consumer products and prompted Congress to pass the CPSIA.

IMPORTED CONSUMER PRODUCTS SKYROCKET

Every business, from *Fortune* 500 companies to small and mid-sized businesses, has come to depend more and more upon imported products in order to reduce costs and remain competitive. There has been a 101 percent increase in imports over the last decade.[2] According to the Department of Homeland Security, there are 327 official ports of entry in the United States.[3] In 2006, the CPSC valued consumer imports (through an estimated 800,000 separate importers) at $2 trillion.[4] This value is expected to triple to $6 trillion by 2015, according to some figures. For 2007, the CPSC has estimated the value of imports under its jurisdiction alone at $639 billion.[5] The CPSC further estimates that Chinese products comprised approximately 42 percent of that $639 billion.[6] Indeed, the value of Chinese imports nearly *quadrupled* in the 10-year span from 1998 to 2007.[7]

In a draft report issued in July 2008, the CPSC acknowledged not only a vast increase in the number of imports and their manufacturing standards, but also greater product variety, technical complexity, and sophistication.[8] Adding to the CPSC's oversight woes is the fact that imported products are frequently not from one place but contain components from many different countries. These consumer-product realities made the CPSC's ability to police the safety of consumer products a much more challenging task—one that an underfunded and understaffed agency was not equipped to handle.

NEW CONSUMER PRODUCT LEGISLATION PASSED

During the CPSC's fiscal year 2007, it announced 473 recalls.[9] Of those, 82.4 percent were imported products, and of those, 74 percent were from China.[10] The safety of consumer products, primarily imports, and the ability of the CPSC to police them were called into question after what CPSC acting chairman Nancy Nord termed the "summer of recalls" in 2007.

Since then, the public outcry for more oversight has been loud, clear, and consistent. The answer to this cry has come in the form of sweeping legislation, now known as the CPSIA, which was signed into law by President Bush on August 14, 2008.[11] The CPSIA passed the House of Representatives by a sweeping margin of 424 to 1 and the Senate by 89 to 3.

Briefly, the CPSIA:

- Increases the maximum penalty for *each* violation of a safety standard from $8,000 to $100,000.[12]
- Increases the maximum penalty for each series of violations from $1.825 million to $15 million.[13]
- Provides for prison terms of up to five years for individuals who knowingly and willingly manufacture, offer, distribute for sale, or import a noncomplying product.[14]
- Doubles the CPSC's budget to $136 million by 2014.[15]
- Defines "children's products" as those products intended for use by children aged 12 or under.[16]
- Bans all but minute levels of lead in children's products.[17]
- Bans, either permanently or pending further study, six types of phthalates in all children's products.[18]
- Requires children's products to be certified by an independent laboratory for compliance with safety standards.[19]
- Requires tracking labels to be placed on all products.[20]
- Substantially enhances recall authority.[21]
- Allows states to bring enforcement actions on behalf of the CPSC for alleged violations of safety standards. If the state is successful, reasonable costs and attorneys' fees may be recovered from a product manufacturer, distributor, or retailer.[22]
- Issues new safety standards for "durable infant or toddler" products.[23]
- Adopts ASTM International Standard F963-07 as the mandatory consumer product safety standard for children's products and gives the CPSC authority to decide within one year whether stricter standards are warranted for certain toys.[24]
- Provides "whistleblower" protections to employees who report consumer product hazards.[25]
- Requires the CPSC to set up a user-friendly database where consumers, government agencies, child-care providers, and doctors can report incidents of injury, illness, death, or risk related to products. [26]

These sweeping changes, along with the increased power the CPSC now has to enforce its safety standards, make it imperative that U.S. companies know what is coming in the future and how to be ready for it.

The major components of the CPSIA addressed in this article are (1) the general overhaul of the CPSC (its personnel, laboratories, and port presence); (2) the new maximum penalties for violation of safety standards; (3) the CPSC's enhanced recall authority; (4) independent testing and certification

requirements; (5) the ability of states to bring injunctive relief against violators; and (6) the whistleblower protection afforded employees. The article does not summarize each individual section of the 163-page CPSIA, and readers interested in specific details of the new safety standards on lead and phthalates, for example, should consult the CPSIA itself.

OVERHAUL OF THE CPSC—MORE FUNDING AND MORE PERSONNEL

Even before passage of the CPSIA, the CPSC took big steps to bolster its oversight of import safety and make its safety standards more widely understood internationally. One such crucial step by the CPSC was to create a Chinese-language page on the CPSC web site—a necessary tool for assisting Chinese companies that desire more information regarding compliance. In the future, the CPSC web site also will provide links to foreign-language materials for significant supplier nations, such as Vietnam and various Spanish-speaking countries. Furthermore, the CPSC staff has worked with the National Institute of Standards and Technology and the American National Standards Institute to translate U.S. product safety standards into Chinese. [27]

Also in early 2008, the CPSC established an Import Surveillance Division within the Office of Compliance and Field Operations. In the past, the CPSC rarely conducted point-of-entry inspections. The personnel in the new Import Surveillance Division, which works with the Customs and Border Protection ("CBP"), represent the first permanent, full-time presence of CPSC personnel at key ports of entry. These personnel are specifically trained in import surveillance procedures and the rapid identification of defective and noncomplying consumer products.[28] They are charged with identifying possible problem shipments through the use of the CBP's import-tracking system. Products that are identified as suspicious are sampled and then sent to the CPSC's lab in Maryland for testing. In the last year, this laboratory has tested at least three times the number of products it tested in prior years. Those shipments not in compliance are held up at the port of entry.

With the increased funding provided by the CPSIA, port-of-entry activities will be increased. For instance, CPSC personnel have already started using X-ray fluorescence technology to screen for lead and other heavy metals in consumer products, testing more samples of products, and conducting more port-of-entry "blitzes" (periodic large-scale inspections at ports) where appropriate.[29] A permanent inspection office has been set up in Long Beach, California, the nation's second-busiest port, and the CPSC plans to set up permanent inspection offices at other U.S. ports.

Furthermore, the CPSIA requires the CPSC, subject to the availability of appropriations, to increase the number of its full-time employees, currently 420, to at least 500 by 2013, including more port-of-entry facility agents.[30]

Aiding in enforcement, the CPSIA authorizes increased funding levels for the CPSC for six consecutive years, starting at $88.5 million in 2009 and ultimately increasing by approximately 55 percent to $136 million by 2014.[31] What is more, for 2009 and 2010, an additional $40 million is expected to be authorized to upgrade the CPSC's laboratories, and $1 million is authorized to research the safety of nanotechnology in products.

MAXIMUM PENALTIES INCREASED TO $15 MILLION

The net effect of this bolstered enforcement capability is that more fines will be assessed against and collected from companies violating the law. The CPSIA increases civil fines from $8,000 to $100,000 per individual violation and raises the maximum penalty from $1.825 million to $15 million for aggregate violations. It also assesses criminal penalties of up to five years in prison for those who knowingly and willingly violate product safety laws.[32]

According to a recent Congressional Budget Office ("CBO") Budget Report, since 2001, civil penalties *assessed* by the CPSC have averaged $4.9 million annually, while the average penalty actually *collected* during that same time was $470,000, or about 25 percent of the maximum penalties of $1.825 million. Only 20 percent of the historic penalties exceeded $1 million. The CBO estimates that enactment of the CPSIA will increase federal revenues by $43 million over the 2009–2018 period—nearly doubling the average penalties now collected by the CPSC.[33]

The CBO Report states that increasing the cap on penalties would change the dynamics of litigating and settling large cases and that the average penalty would eventually double for larger cases and increase by about 20 percent for smaller ones. The CBO therefore concludes that the CPSIA will not affect direct spending. In other words, any increased funding will be paid for by higher and more frequent fines.

ONE CAN ASSUME THAT THERE WILL BE SOME VERY AGGRESSIVE ACTION TAKEN BY THE CPSC TO SEND THE MESSAGE TO THE OUTSIDE WORLD THAT IT IS NOW VIGILANTLY POLICING THE SAFETY OF CONSUMER PRODUCTS

ENHANCED RECALL POWER

As many product manufacturers know, product recalls are costly and a major business disruption. Now, it will be faster and easier for the CPSC to issue mandatory recalls.

In the past, the CPSC had the power to require a company to recall a product that presented a "substantial product hazard," a term notoriously vague and ill-defined by the CPSC. Historically, the CPSC received direct consumer, governmental, or emergency-room report complaints and then evaluated whether there was a pattern of injury before deciding to investigate further with the manufacturer. Whether a recall, or some action short of a recall, was required was usually a decision made jointly by the manufacturer and the CPSC in a cooperative fashion.

The CPSIA has made material changes to the definition of "hazardous product" and the way that recalls will be handled in the future. First, under the old regime, the CPSC defined "substantial product hazard" as the "failure to comply with an applicable consumer product safety rule which creates a substantial risk of injury to the public."[34] The CPSIA has amended this provision to read that a "substantial product hazard" is the "failure to comply with an applicable safety rule under this Act or a similar rule, regulation, standard or ban under any other Act enforced by the Commission."[35] Thus, the CPSIA broadens the circumstances under which a product may be deemed to be a "substantial product hazard."

Also new under the CPSIA is that the CPSC may recall a consumer product if it determines the product to be "imminently hazardous," not just containing a "substantial product hazard." An "imminently hazardous" consumer product is one that "presents imminent and unreasonable risk of death, serious illness, or severe personal injury."[36]

Next, under the old system, if the CPSC determined, after notice and a hearing, that a product contained a "substantial product hazard," it would send notification of such finding to the public as well as to the manufacturer, distributor, and retailers of the product, and some sort of resolution would be worked out whereby the product would be either repaired, replaced, or refunded. Under the newly revamped CPSIA, the CPSC may order the distribution of the product to cease in its entirety. This power to order a company to cease distribution of a product extends to any product determined by the CPSC to contain an imminent hazard. Perhaps of greatest concern, the CPSIA does not require a hearing to be held prior to the CPSC's ceasing the distribution of a product it has determined may present an imminent hazard.

Finally, under the old law, the manufacturer had the option of offering to refund the purchase price, repair a recalled product, or replace it. The CPSIA now empowers the CPSC to make that election for the manufacturer based on the "public interest."[37]

Many open questions remain about how this new recall authority will play out and how swiftly the CPSC will act in exercising it. Historically, most complaints directed to the CPSC were hearsay and, in many instances, originated from consumers themselves, police departments, or hospital personnel. Due to the anecdotal nature of complaints the CPSC receives, many of which can be unreliable or include misleading or false information, it is unknown whether these complaints will comprise the basis for a swift decision by the newly armed CPSC to recall an "imminent product hazard." It is also unclear how aggressive the CPSC will be in unilaterally instituting orders to cease the distribution of imminently hazardous products or to unilaterally mandate the recall of an imminently hazardous product it determines creates substantial safety hazards. However, in light of the avalanche of negative publicity recently heaped upon the CPSC, one can assume that, at least in the short term, there will be some very aggressive action taken by the CPSC in order to send the message to the outside world that it is now vigilantly policing the safety of consumer products, particularly those for children.

INDEPENDENT TESTING AND CERTIFICATION REQUIRED

The CPSIA now requires all children's products to be submitted to independent third-party testing. Specifically, the CPSIA requires all children's products to be tested by a "third-party conformity assessment body" for compliance with any safety rule applicable to that particular product. The question of who or what is an acceptable "third-party conformity assessment body" is also answered by the CPSIA. In order to meet that definition, the testing facility must be accredited by the CPSC pursuant to requirements established on a statutory timetable that will vary according to the specific safety standard at issue. Under the CPSIA, the CPSC has up to 10 months after enactment to establish requirements for accrediting

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"SO, DO I HAVE TO MAKE ONLY MINIVANS?"

WHAT ARE A MANUFACTURER'S DUTIES WITH REGARD TO SAFER ALTERNATIVE DESIGNS?

by Amanda S. Jacobs

Gas prices are at record levels, and the automobile industry is under pressure to produce more fuel-efficient cars. Let's assume that the market works as it should, and these manufacturers do produce those cars. Can the following scenario be far behind?

A car manufacturer is sued after its "mini"—its compact, two-door, energy-efficient model—collides with a semi. The plaintiff sues for design defect and alleges that a safer, feasible alternative design was available: namely, the larger, heavier, (gas-guzzling) four-door sedan that the manufacturer offers, which ranked higher in crash tests.

What is a "safer, feasible alternative design"? Must this car manufacturer sell only its four-door sedans? Must all of its models be equipped with 18 airbags? Or armored sides? Or high-performance braking and traction systems? In short, to avoid liability, must every vehicle be a minivan or Humvee?

In the vast majority of American courts, proof of an available "safer, feasible alternative design" is an element of a plaintiff's design defect case. The Third Restatement of Torts makes it the sine qua non of a design defect claim. This article analyzes what constitutes a "safer, feasible alternative design," what obligations are imposed upon manufacturers, and what evidence is admissible to prove it (and defend against it).

A MANDATORY REQUIREMENT?

States differ on whether evidence of an alternative design is a mandatory element for design defect claims. Some states

require by statute that in order to prevail, a plaintiff must prove a feasible alternative design.[1] In other states, however, the existence of a feasible alternative design is not a mandatory element but is one of the factors to be weighed in a risk-utility balancing test.[2] The Third Restatement of Torts makes the existence of an alternative design *the* test for design defect claims. It provides that a product is defective in design only when "the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller…." Restatement (Third) of Torts § 2(b). The "reasonable alternative design" test set forth in the Third Restatement has been explicitly adopted or applied by courts in Florida and Iowa.[3] While the requirement of an alternative design has been adopted in some form by a majority of states, it still remains a somewhat controversial position, because, as some commentators argue, it places an undue burden of proof on plaintiffs.[4]

"SAFER, FEASIBLE ALTERNATIVE DESIGN"—WHAT IT MEANS

Under the Third Restatement as well as under most states' formulation of the standard, the essential inquiry is whether the design chosen was a reasonable one from among the feasible choices of which the defendant was aware or should have been aware.[5] As the Third Restatement recognizes, this is in essence a negligence standard. Restatement (Third) of Torts, § 2, Comment d ("Assessment of a product design in most instances requires a comparison between an alternative design and the product design that caused the injury, undertaken from the viewpoint of a reasonable person. That approach is also used in administering the traditional reasonableness standard in negligence.").[6]

The phrase "safer, feasible alternative design" can be best understood by an analysis of its parts.

Safer. The term "safer" means that the alternative design would have significantly reduced or prevented the particular plaintiff's injuries. "Safer" does not mean "safest," however. Otherwise, the only cars sold would be ones that traveled 20 mph, and the only guns sold would be ones that shot rubber bullets. "Manufacturers are not required to produce automobiles with the 'strength and crash-damage resistance features of an M-2 Army tank.' " *Curtis v. General Motors Corp*., 649 F.2d 808, 812 (10th Cir. 1981). Indeed, the doctrine of strict tort liability is not intended to be a doctrine of absolute liability.[7] A manufacturer is not an insurer of its product and has no duty to make its product accident-proof or incapable of causing injury under any circumstance.[8] In sum, a manufacturer is not required to design the *safest* product possible, or even a *safer* product than the one sold, as long as the design sold was reasonably safe.[9]

Thus, in response to our car manufacturer's problem—can it offer different car models, even though some models are arguably safer than others?—a manufacturer does not have a duty to manufacture only the safest model available as long as the other models are reasonably safe. For example, in *Curtis v. General Motors Corp.*, 649 F.2d 808 (10th Cir. 1981), defendant General Motors offered several body styles of its 1973 Blazer: a roofless style, one with a canvas top, one with a steel top, and one with a removable fiberglass top. *Id.* at 810. The court noted that even though the evidence (and common sense) showed that the steel top was safer than the fiberglass top—the option the plaintiff chose—a compromise was necessary in order to give consumers choices, and the Blazer was a "special purpose vehicle with off-road capability." *Id.* at 811. "If there be no compromise and only the very safest can be marketed, there obviously would be no choice for the buyer as the less safe options would be eliminated. This exclusion should not be the result…." *Id.* Instead, the court found that "the utility and purpose of the particular type of vehicle will govern in varying degree the standards of safety to be observed in its design." *Id.* (internal citations omitted).

Similarly, in *Dreisonstok v. Volkswagenwerk*, 489 F.2d 1066 (4th Cir. 1974), the court rejected the plaintiffs' argument that defendant Volkswagen's bus, which placed the driver's seat at the very front of the vehicle in order to make more cargo and passenger space, should have been made like a "midsized Ford passenger car." *Id.* at 1075. The court held that the bus had an entirely "different nature and utility" and that "[s]uch a straitjacket on design is not imposed [by the law]." *Id.*

Thus, in our car-manufacturer scenario, the manufacturer should be able to provide consumers with an array of models as long as the compromises made in those models are reasonable. While its "mini" may not be as big and heavy and crash-resistant as its four-door passenger sedan, the "mini" is stylish, maneuverable, and gas-efficient—other qualities that are useful and that consumers demand.

When does a manufacturer have the obligation to adopt certain available safety features or designs? A manufacturer is not required to adopt every possible safety device that may have been invented or to adopt "the ultimate" in technology or design. But a manufacturer does have a duty to adopt those safety devices that are reasonable under the circumstances.[10] In *Nicor Supply Ships v. General Motors*, 1993 U.S. Dist. LEXIS 9342 (E.D. La. July 7, 1993), the court found that even though an independent emergency generator system was "not unheard of" when the plaintiff's ship caught fire, the system did not constitute a reasonable alternative design because it "was not customary in the industry." *Id.* at *8–9. In *Elliott v. Brunswick Corp.*, 903 F.2d 1505 (11th Cir. 1990), the court held that even though an "experimental propeller guard" was available, it was not a reasonable alternative design for the defendant, a boat manufacturer, where "neither industry custom, nor the pertinent regulations" dictated its use. *Id.* at 1508. Thus, our car manufacturer probably does not have the duty to equip all of its models with 18 airbags, "never-flat" tires, and xenon headlights. Those features have not become standard in the industry or been mandated by any regulation, and without those features, its cars are still reasonably safe.

What happens when a manufacturer offers safety devices to the purchaser as product "options"? Courts differ in opinion. Some courts hold that where a safety device is available to the purchaser and the purchaser knowingly declines to buy it, the manufacturer has fulfilled its duty.[11] Courts reason that in such circumstances, the purchaser is the party in the best position to determine the tradeoff between cost and function, and thus the purchaser should bear responsibility for that decision.[12] For example, in *Morrison v. Kubota Tractor Corp.*, 891 S.W.2d 422, 428 (Mo. Ct. App. 1994), the court held that a tractor manufacturer had fulfilled its duty to protect against rollovers when it made the purchaser aware that a rollover-protection system was available for purchase as an option.[13] Similarly, in *Scarangella v. Thomas Built Buses*, 93 N.Y.2d 655, 661–62 (N.Y. 1999), the court held that a bus manufacturer had fulfilled its duty by offering optional "backup alarms" for its school buses when the purchaser, a school district that had experience buying school buses, was a highly knowledgeable consumer; the risk of harm from the absence of a backup alarm was not substantial; and the school district was in the best position to weigh the risk, given the contemplated use of the bus.

Other courts, however, hold that if such safety options are necessary to avoid an unreasonable risk of harm, the fact that the manufacturer offers them to purchasers does not immunize the manufacturer from liability.[14] Thus, manufacturers must consider whether a certain optional feature should be made standard if, without that feature, the product creates an unreasonable risk of harm.

When does a manufacturer have an obligation to retrofit a previously sold product with new technology? Most courts hold that a manufacturer has no duty to retrofit an existing product with subsequently developed safety features if the product was not defective at the time it was sold.[15] Otherwise, "any safety improvement would then charge a manufacturer with a duty to go out and retrofit and update all products which it had ever sold in its past history." *Morrison,* 891 S.W.2d at 430. Thus, our car manufacturer probably has no obligation to retrofit with airbags its 1970 models still in operation.

Feasible. Evidence of a safer alternative design, by itself, is not sufficient to impose liability on a manufacturer; a manufacturer has no duty to adopt an alternative design that is not feasible.[16] "Feasibility" includes not only the determination that the product was technologically feasible at the time of manufacture but also that it was economically feasible, useful, and desirable to consumers.[17] If the proposed alternative design would render the product so expensive as to price it out of the market, the existing design, on balance, may be considered reasonable.[18] In addition, if the proposed alternative design would impose an equal or greater risk of harm, it is not reasonable.[19]

Further, a proposed alternative design cannot destroy the utility of the original product.[20] If a product has a special design due to its unique features or utility, a manufacturer need only consider alternatives compatible with that special design.[21] Thus, in *Delvaux v. Ford Motor Co.*, 764 F.2d 469, 475 (7th Cir. 1985), the court held that a "manufacturer is not negligent for not providing his convertibles with steel roofs, because a convertible is designed as a roofless car." Additionally, in *Felix v. Akzo Nobel Coatings*, 692 N.Y.S.2d 413 (N.Y. App. Div. 1999), the court held that the defendant's flammable lacquer sealer was not defective even though a safer, water-based sealer was available because the two sealers were functionally different: The flammable sealer was quick-drying and resulted in a harder, scratch-resistant surface, while the water-based sealer was

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PROTECTING YOUR DATA PROTECTS THE BOTTOM LINE

by
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and
Jonathan K. Stock

In 2003, the California law requiring the reporting of data security breaches went into effect, and over the next four years, more than 300 million records were lost or stolen; 34 million were expected to be stolen in 2008.[1] Protecting data privacy has evolved into one of the biggest challenges, financial expenditures, and possible sources of legal exposure for companies operating in this new digital world. Companies routinely keep and store data about their customers. Often this information includes sensitive details that customers want and expect the company to safeguard and keep private. Chances are that your credit card information, medical records, Social Security number, and bank account numbers are already in the possession of several hundred companies, government agencies, and nonprofit organizations.

In the right hands, this personal information is a resource that enables efficient and effortless transactions and permits companies and government agencies to provide desired products and services. The same information, however, can spell personal and financial disaster in the wrong hands. Identity theft has claimed an ever-growing list of victims and by one estimate has now struck one in five Americans.[2] The Federal Trade Commission ("FTC") estimates that each year as many as 9 million Americans become identity-theft victims.[3] A survey conducted by the FTC showed that identity-theft losses to businesses and financial institutions totaled nearly $48 billion in a single year.[4] Security breaches at companies that store personal data have contributed to the growth of identity theft.

THEFT AND CONSEQUENCES

Several of these security breaches in recent years have made headlines, perhaps none more so than the massive security breach involving T.J. Maxx. The incident involving T.J. Maxx has been described as the largest data breach in U.S. corporate history.[5] The total cost of the T.J. Maxx security breach has been staggering: The TJX Companies, the parent company of T.J. Maxx, told *The Boston Globe* that "its costs from the largest computer data breach in corporate history, in which thieves stole more than 45 million customer credit and debit card numbers, have ballooned to $256 million."[6] Those costs stem from, among other things, repairing the company's computer system, conducting investigations, and defending the lawsuits and other claims arising from the theft. However, "[s]everal analysts have estimated TJX's costs could run as high as $1 billion, including legal settlements and lost sales."[7]

While it is often difficult to catch the perpetrators of identity theft, the Justice Department recently announced the indictment of 11 individuals in connection with the T.J. Maxx data security breach.[8] According to the indictment, the thieves gained access to the credit and debit card data of millions of customers in part by simply driving around in a car with a laptop computer, looking for accessible wireless networks, and then installing special software that captured the credit and debit card information from the unsecured networks.[9]

A web site that tracks data privacy breaches lists hundreds of data security breaches that have occurred in the United States since 2005.[10] While not every security breach results in identity theft, the exposure of personal information and the risk of identity theft have forced businesses and consumers alike to commit substantial time and resources. Businesses are constantly updating their technology in a race with identity thieves, and they incur substantial costs if personal data in their possession is ever exposed. Consumers have taken time-consuming and burdensome steps to shield their identities and financial resources from identity theft or, even worse, to remedy the harm caused by identity theft.

With the threat of identity theft on the rise, state governments have taken an active role in regulating the steps a company must take after a security breach. At least 44 states, as well as the District of Columbia and Puerto Rico, have enacted legislation requiring notification for security breaches involving personal information.[11] Typically, these laws require a company whose data has been breached to notify the persons whose identity and personal information have been put at risk. While the laws requiring notification give consumers a chance to quickly take steps to re-shield their identity (*i.e.*, cancel credit cards, review credit reports, place a credit hold, etc.), they have done little or nothing to stop the spread of identity theft.[12]

Threats to data privacy have also inspired a response from the federal government. Most notably, the Federal Trade Commission has promulgated rules to govern data privacy in the financial and consumer credit industries.[13] Also, to implement the Fair and Accurate Credit Transactions Act ("FACTA"), the FTC and the federal banking agencies have jointly issued new rules for financial institutions and creditors governing identity theft.[14]

Now the threat of litigation is making data security breaches even more costly and adding extra incentives for businesses to secure their data. Plaintiffs have begun filing suit against companies that suffer data breaches. The T.J. Maxx data breach, for example, spawned at least a half-dozen class actions. As one commentator noted, what makes the T.J. Maxx case so compelling for class actions is that: (1) "unlike the majority of reported security breaches, the TJX intrusion has been demonstratively linked to subsequent fraudulent transactions"; and (2) "early media reports implied that the company was negligent in safeguarding its data," including the suggested absence of a firewall.[15]

Class actions were also filed this year against the Hannaford Bros. supermarket chain for a data breach involving customer credit card numbers. Hannaford had previously notified its customers that a breach of its computer system between December 2007 and March 2008 potentially exposed 4.2 million credit and debit card numbers and resulted in 1,800 fraud cases to date.[16] Only a couple days after the announcement, Hannaford was sued.[17] These suits allege, among other things, that Hannaford was negligent in protecting customer data and failing to promptly disclose the breach of that data to the public.[18]

TD Ameritrade also became the target of a class action after hackers in late 2007 stole the identities of at least 6.3 million TD Ameritrade customers. The parties attempted to settle the suit when they reached agreement for TD Ameritrade to provide spam-blocking software to the class and $1.87 million in fees to the plaintiffs' attorneys,[19] but the judge overseeing the case rejected the proposed settlement as potentially unfair to the class.[20]

Not every data security breach starts with a thief. Unlike the T.J. Maxx and TD Ameritrade cases, where an organized group successfully pirated company data, many data security breaches have more mundane origins. In the summer of 2008, a number of customers with Wagner Resource Group, among them Supreme Court Justice Stephen Breyer, had their personal data exposed, including names, birth dates, and Social Security numbers. The exposure took place when an employee of Wagner Resource Group accessed a file-sharing network called LimeWire.[21] When the employee tried to "trade some music, or maybe a movie," he "inadvertently opened the private files of his firm."[22]

In another example of inadvertent data exposure, two banks recently made news after an unencrypted backup tape full of personal data was lost in transit on February 23, 2008. After the data of approximately 4.5 million people went missing, it did not take long for the first lawsuit to be filed. A group of bank customers filed a civil suit in Bridgeport, Connecticut, seeking class action status and charging those banks with negligence, invasion of privacy, and breach of fiduciary duty.[23] The exposure of personal data, regardless of its source, presents a tempting target for identity thieves and has the potential to embroil a company in litigation.

The cases filed against companies that suffered data security breaches have yielded mixed results, with a number of companies reaching settlements and others successfully defending. TJX, whose data security breach made major headlines, reportedly settled a number of the lawsuits filed against it, including one for an amount in excess of $40 million.[24]

However, not every data security breach leads to liability. Instead, case law has held that identity exposure alone, absent evidence of actual identity theft caused by that exposure, is insufficient to support a claim for damages. Such cases include, for example, *Pisciotta v. Old National Bancorp*; *Kahle v. Litton Loan Serv. LP*; *Randolph v. ING Life Ins. and Annuity Co.*; *Giordano v. Wachovia Sec., LLC*; *Forbes v. Wells Fargo Bank, N.A.*; *Guin v. Brazos Higher Educ. Serv. Corp.*; *Hendricks v. DSW Shoe Warehouse*; and *Stollenwerk v. Tri-West Healthcare Alliance*.[25] While most cases frame the absence of damages as a failure to prove all the elements of a claim, in some instances, the cases hold that the federal courts lack jurisdiction because plaintiffs whose data has been compromised but not yet misused have not suffered an injury-in-fact necessary for Article III standing.[26] Several common factual threads unite these cases. In almost every instance, the typical plaintiff has not suffered from identity theft. Instead, the plaintiff is alleged to have incurred costs from the increased risk of identity theft. Those costs include the time and expense necessary to purchase credit card monitoring and protection services. Almost invariably, the cases are centered around a claim for common-law negligence and rely upon the argument that the defendant failed to meet its duty of care to safeguard and protect the plaintiff's data.

The courts in the above cases have rejected these negligence-based claims and have not held the companies liable for the mere exposure of data. The central fault of these causes of action is that the plaintiff, who has not suffered from identity theft, cannot prove actual damages.[27]

The courts, in addition to noting the absence of actual damages, have often found support for rejecting liability from diverse sources. First, some courts have looked to the analogous field of toxic tort litigation to explain why the speculative injury of a future identity theft is not compensable.[28] Some courts also point to the absence of any private right of action for a data breach in state law to support the noncompensable nature of the claim.[29]

Finally, in *Guin*,[30] the court noted in exculpatory fashion that the defendant, despite the data breach, had demonstrated good data protection practices, commenting that the defendant "had policies in place to protect the personal information, trained [its employee] concerning those policies, and transmitted and used data in accordance with those policies."

Several broad lessons can be gleaned from the divergent outcomes of cases where some companies have been forced into settlement while others have defended successfully. First, the exposure of data alone does not necessarily lead to liability. The cases demonstrate that the occurrence of identity theft poses a much greater risk to companies than the mere exposure of data. The degree of that risk can be mitigated by a company that adopts and diligently follows the best policies and practices to safeguard its data. It is no coincidence that companies like T.J. Maxx have paid significant sums to settle cases that have alleged lax data protection practices resulting in identity theft. In the event of a data security breach, time is of the essence. By promptly seeking counsel and complying with all applicable laws (including the many state notification statutes), a company can reduce its risks and limit the likelihood that any data breach can be successfully exploited.

PRACTICAL STEPS AND SOLUTIONS

The Federal Trade Commission has put together a list of five steps that businesses can take to minimize their exposure to data theft.[31] These are relatively simple steps that may seem intuitive but are all too often overlooked.

First, every business that stores personal data should take stock of what data exists and where it is kept. Businesses should: (1) take inventory of all computers, laptops, flash drives, and other storage equipment to find out where data is kept throughout the company; (2) track the personal information used and relied upon by each department; and (3) pay special attention to the types of personal information commonly sought by identity thieves, such as Social Security numbers and credit card information.

Second, keeping personal data on file carries a risk. Businesses should therefore scale down their storage of any information that does not support legitimate business needs.

Third, businesses must safeguard the information they keep. Personal data should not be something that is open to everyone in the company. Employee access should be a matter of business necessity, and any unauthorized access from within

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WHAT'S BEHIND THE CURTAIN?

JUDICIAL SCRUTINY OF "DIFFERENTIAL DIAGNOSIS" UNDER *FRYE* AND *DAUBERT*

by Sean P. Costello and Brooke Werner McEckron

The past several years have witnessed significant legal reforms at both the state and federal levels, many aimed at curbing the excesses of mass tort and class action litigation. The Class Action Fairness Act, or "CAFA," is easily the most famous among the latest legal reforms. Enacted in 2005, it promised to open the federal courthouse doors to more mass torts and class actions, and by all reliable measures, it has delivered.[1]

This has been good news for corporate defendants. Given a choice, most would prefer federal court, particularly in mass tort and class action litigation. The usual litany of reasons for this is familiar to most—federal judges are not dependent upon plaintiff–lawyer contributions to win elections, Federal Rule of Civil Procedure 23 is more demanding than many state analogues and allows the chance to appeal a class-certification decision, and so on. But one reason that often escapes mention is that along with federal court come *Daubert* and the Federal Rules of Evidence. Mass tort and exposure-based class actions that survive to the merits stage often turn on expert testimony about the plaintiffs' alleged injuries (or diseases) and their causes. Surveys show that expert testimony to establish injury and causation is the most frequent type of expert testimony among *all* cases.[2]

Through an analysis of recent decisions, this article seeks to explain why the distinction between *Daubert* and *Frye*—and thus between federal and some state courts—can make a difference. We focus on expert testimony based on "differential diagnosis" to establish cause and effect. In one *Frye* jurisdiction, the state's *highest court* recently was hypnotized by an expert's incantation of the phrase "differential diagnosis" to the point that it deemed expert testimony claiming a cause-and-effect relationship admissible despite the fact that dozens of courts in jurisdictions around the country had

rejected virtually identical testimony. Courts that countenance this form of sophistry transform a clinical diagnostic tool designed to identify one disease among several into a dangerous litigation weapon that serves no higher good than supporting a lawyer's pet theory of causation.

FRYE AND *DAUBERT*: A REVIEW

Frye became the prevailing test in federal and state courts for many decades by virtue of a federal appellate court's decision in *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923). In *Frye*, the defendant in a murder trial passed a polygraph test—back when this was a relatively new technology—and sought to have the results admitted. The court of appeals held that the test results and expert testimony about them were not admissible because polygraphs were too experimental. In so doing, the court set forth what has come to be called the "*Frye* test" in this famous passage (*id.* at 1014): "[T]he thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs." Most states subsequently adopted *Frye*'s "general acceptance" test.

Seventy years later, interpreting then Rule 702 of the Federal Rules of Evidence, the United States Supreme Court decided *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). In *Daubert*, a woman sued Merrell Dow Pharmaceuticals, alleging that the drug she took during pregnancy (Bendectin) was responsible for her child's birth defects. Experts for the plaintiff testified at trial that animal studies had shown that Bendectin had negative effects on early development, and they also recalculated data from previous epidemiological studies showing that Bendectin was a human teratogen (a substance that causes development problems in infants).

The Supreme Court held that the testimony of the plaintiff's expert should not have been allowed. In so doing, the Court established the following four-part test of nonexclusive and nondispositive factors that courts are to consider when deciding whether expert testimony should be admitted: (1) whether the testimony was based on generally acceptable means of predicting effects on humans (incorporating this aspect of *Frye*); (2) whether the methodology used was published; (3) whether the methodology had been subjected to peer review; and (4) whether the results are testable. *Id.* at 594.

According to *Daubert*'s four-part test, refined in subsequent decisions like *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137 (1999), and *General Electric Co. v. Joiner*, 522 U.S. 136, 146 (1997), the expert's chosen tool must be demonstrably the right tool for the job *and* the expert must use it properly. The fundamental difference between *Frye* and *Daubert* is thus reduced to this: *Frye* tests "the thing from which the deduction is made"; *Daubert* tests both the deduction and its premise.[3] As Professor Julia Luyster explains, "[W]hen a party proffers expert testimony on causation, *Frye* requires the trial judge to examine whether the scientific community recognizes the underlying principle, while *Daubert* requires the judge to examine the merit of the underlying scientific research."[4]

Based as it was on Federal Rule of Evidence 702,[5] *Daubert* became the governing standard for expert testimony in federal court. Several states soon jumped on the *Daubert* bandwagon.[6] But not all. Sixteen years after *Daubert,* 12 jurisdictions continue to follow *Frye* or a variation thereof.[7] And in a few of these jurisdictions, mischief is being made that would not be possible under *Daubert*.

ETIOLOGY VERSUS "DIFFERENTIAL DIAGNOSIS": DIFFERENT TOOLS FOR DISTINCT JOBS

Empirical evidence confirms what common wisdom assumes: the test that is applied to scrutinize expert testimony strongly affects whether that testimony is allowed. A Federal Judicial Center survey showed that federal judges excluded some or all of a proposed expert's testimony in 25 percent of the cases in 1991; in 1998, five years after *Daubert*, judges reported that they excluded some or all of a proposed expert's testimony in 41 percent of the cases.[8]

Reliable subsequent data is not available, but Judge Janis Jack's headline-grabbing decision in the silica MDL litigation is strong anecdotal evidence that federal court and *Daubert* have a potentially case-killing impact on gargantuan mass tort litigation. Indeed, Judge Jack's decision excluding expert testimony has been identified as one of the causes of the mass tort's reported death.[9] Excluding the plaintiffs' proposed expert testimony and sanctioning the plaintiffs' lawyers in the process, Judge Jack wrote that "[i]n a majority of cases, [the plaintiffs' experts'] diagnoses were more the creation of lawyers than of doctors." *In re Silica Prods. Liab. Litig.*, 398 F. Supp. 2d 563, 635 (S.D. Tex. 2005). In a scathing indictment of the practice among mass tort lawyers, she rejected outright

the attempted use of mass diagnoses: "[I]t is apparent that truth and justice had very little to do with these diagnoses—otherwise more effort would have been devoted to ensuring they were accurate. Instead, these diagnoses were driven neither by health nor justice; they were manufactured for money." *Id*. So much for assembly-line litigation.

The differences between *Daubert* and *Frye* are starkest when it comes to causation evidence in the tort context. This is no small matter, since causation is a central issue—perhaps *the* central issue—in nearly all tort or product liability litigation. And if the tort or product liability case is a mass tort or class action, the significance is exponentially larger.

Experts often claim to base their causation opinions on a so-called "differential diagnosis," but courts often confuse "differential diagnosis" with "differential etiology." The distinction can make a difference. "Differential diagnosis" is a "term used by physicians to refer to the process of determining which of two or more diseases with similar symptoms and signs the patient is suffering from, by means of comparing the various competing diagnostic hypotheses with the clinical findings."[10] A "differential diagnosis" is *not* a tool for determining the *external* cause of a disease or illness. Therefore, it cannot *establish* external cause.

"Differential etiology" is the proper tool for identifying external cause. Put differently, etiology is the tool an expert should be using when he or she is attempting to show general causation (*i.e.*, "rule in" potential causes) and specific causation ("rule out" candidate causes in order to arrive at a single cause). Differential diagnosis and differential etiology thus address "fundamentally different questions: the nature of the illness as opposed to the cause of the illness."[11]

While a differential diagnosis may counsel a specific treatment, it does not dictate a disease's specific cause, with some exceptions where the disease and the cause are clearly and inextricably linked. But exceptions prove the rule; they do not make it. As a general matter, physicians are "inexperienced and uncomfortable" when it comes to performing a differential etiology because, while the process of elimination is common to both procedures, the skills, knowledge, and relevant literature differ for each.[12] Indeed, a court put it even more bluntly: "The ability to diagnose medical conditions is not remotely the same… as the ability to deduce, delineate, and describe, in a scientifically reliable manner, the causes of those medical conditions." *Wynacht v. Beckman Instruments, Inc.*, 113 F. Supp. 2d 1205, 1209 (E.D. Tenn. 2000). Because diagnosis and etiology are different tools with distinct purposes, the Federal Judicial Center's *Reference Manual on Scientific Evidence* advises that "an expert's opinion on diagnosis and his or her opinion on external causation should generally be assessed separately, since the bases for such opinions are often quite different."[13]

Nonetheless, courts routinely say "differential diagnosis" when they mean to say "etiology," and *Daubert* courts are as guilty of this as *Frye* courts. In *Daubert* jurisdictions, the gaffe amounts to semantics. But in *Frye* jurisdictions, the error is more serious. Under *Frye,* at least as applied in some jurisdictions, an expert's claimed use of "differential diagnosis" may preclude the court from even treating the analysis as expert analysis at all, thereby avoiding judicial scrutiny altogether. We will start with the good news.

LOOKING BEHIND THE CURTAIN: DIFFERENTIAL DIAGNOSIS UNDER *DAUBERT*

In *Daubert* jurisdictions, it does not matter what the court calls the analysis used to determine a cause-and-effect relationship, because the court is duty-bound to scrutinize whether the methodology used was (a) suited for the job, and (b) properly employed to reach the claimed conclusion. Some examples make the point.

The Fifth Circuit's analysis in *Black v. Food Lion, Inc.*, 171 F.3d 308 (5th Cir. 1999), is a good starting point. In *Black,* the Fifth Circuit held that expert testimony purporting to link fibromyalgia to a plaintiff's car accident was inadmissible under *Daubert.* The court explained that neither the plaintiff's doctor nor medical science generally "knows the exact process that results in fibromyalgia or the factors that trigger the process." *Id.* at 314. Thus, the physician's "use of a general methodology [like differential diagnosis] cannot vindicate a conclusion for which there is no underlying medical support." *Id.* The court acknowledged that "[n]o one doubts… the process by which doctors rule out some known causes of disease in order to finalize a diagnosis. But such general rules must, under *Daubert* [and] *Kumho Tire*… be applied fact-specifically in each case." *Id.* Only with that fact-specific application of a generally accepted methodology is it "possible to fasten legal liability for a person's disease or injury." *Id*.

The Third Circuit's 2008 decision in *Feit v. Great-West Life and Annuity Ins. Co.*, No. 07-1481, 2008 WL 847930 (3rd Cir. Mar. 31, 2008), provides a more recent example. There, the plaintiff's expert purported to rely on a "differential diagnosis" in concluding that the plaintiff's husband died from head and neck injuries; the expert also rejected myocardial infarction as a cause of death. The Third Circuit got the name of the analysis wrong but reached the right result. After acknowledging that "differential diagnosis" is a "generally recognize[d]" methodology, the court went on to caution that it nonetheless must be properly performed. *Id.* The physician's claimed differential diagnosis failed that test, because it neglected to "rule in" all potential causes (to establish general causation), as well as "rule out" causes in order to arrive at the most likely candidate (to establish specific causation). *Id.* As the court explained, the conclusion should "reliably flow from the data and methodology." *Id.* at *8. In *Feit*, that was not the case.

Most recently, the Eighth Circuit confronted the attempted use of differential diagnosis to arrive at a causation opinion in *Bland v. Verizon Wireless, L.L.C.*, ___ F.3d ___, No. 07-3010, 2008 WL 3474178 (8th Cir. Aug. 14, 2008). The Eighth Circuit began, like the Third Circuit in *Feit*, with the proposition that "a medical opinion about causation, based upon a proper differential diagnosis, is sufficiently reliable to satisfy *Daubert*." *Id.* at *4 (citation omitted). The court, predictably, confused "diagnosis" and "etiology," describing the former as "a technique that identifies the cause of a medical condition by eliminating the likely causes until the most probable cause is isolated." *Id.* (citation omitted). But that was of no consequence, because the court applied *Daubert* to determine whether the methodology had been properly employed.

The issue in *Bland* concerned the plaintiff's claim that his ingesting of Freon in a water bottle (a practical joke that went wrong and hit the wrong target) caused his asthma. The Eighth Circuit concluded that the plaintiff's expert could not make such a claim to the jury. It held that the attempted use of differential diagnosis to establish the cause and effect failed *Daubert*, because the scientific literature shows that the cause of asthma in most cases is unknown. Where the cause is unknown, a physician cannot claim to have employed a *proper* differential diagnosis to identify a single cause as the "most probable" cause of the illness. *Id.* at *4. In other words, the expert could not "rule in" all other causes of the asthma to establish general causation. *Id.* The court also concluded that the expert "failed to eliminate scientifically other possible causes as part of her differential diagnosis," thus neglecting to "rule out" other causes sufficient to establish specific causation. *Id.* Instead, what the expert did was to conclude that there was a cause-and-effect relationship between ingestion and asthma based on the "temporal link" alone. *Id.* That was speculation, not science. *Id.*

PERPETUATING THE MYTH OF THE WIZARD: DIFFERENTIAL DIAGNOSIS UNDER *FRYE*

The above decisions—and many others like them—stand in sharp contrast to the way *Frye* jurisdictions approach similar claims. In some *Frye* jurisdictions, the courts are unwilling to pull aside the curtain and expose an expert's "differential diagnosis" as speculation.

Our first example is from New York. In *Friedman v. Madison 40 Assoc. LP*, No. 29065-01, 2008 N.Y. Misc. LEXIS 3532, at *15, 239 N.Y.L.J. 111 (N.Y. Sup. Ct. June 10, 2008), the court denied the defendants' motion to preclude the causation testimony of plaintiffs' experts in a toxic-mold case. The plaintiffs' treating physician intended to testify that, based on a "differential diagnosis," he had concluded that exposure to mold in the defendants' premises caused one plaintiff to suffer from hypersensitivity pneumonitis and the other plaintiff to suffer mucous membrane irritation, skin irritation, and chronic rhinitis/sinusitis. *Id.* at *6–8. Deeming the testimony admissible, the court explained that "[t]he issues related to specific causation" were issues that a jury could resolve at trial. *Id.* at *15.

Florida has taken *Frye* to the extreme. Though Florida's evidentiary rule on expert testimony is virtually indistinguishable from Federal Rule 702 at the time *Daubert* was decided,[14] Florida applies *Frye,* sort of. The "sort of" is that Florida courts apply *Frye only* to "new or novel scientific techniques." *United States Sugar Corp. v. Henson*, 823 So.2d 104, 109 (Fla. 2002). This means that the *Frye* test is not applied to what Florida courts call "pure opinion testimony." *Flanagan v. State*, 625 So.2d 827, 828 (Fla. 1993). "Pure opinion testimony" is testimony that is based on an "expert's personal experience and training." *Id.* In Florida, differential diagnosis is generally regarded as "pure opinion." That is troubling.

The troubling consequences of Florida's uncritical *Frye* analysis are on full display in the Florida Supreme Court's recent decision in *Marsh v. Valyou*, 977 So.2d 543 (Fla. 2007), *reh'g denied*.

In *Marsh,* a woman claimed that the trauma of a car accident caused her to suffer from fibromyalgia, a soft-tissue disorder causing chronic pain. Her treating physician intended to so testify, even though there was no general consensus that trauma causes fibromyalgia and virtually every court in the country that had considered the issue—under *either Frye* or *Daubert*—had rejected such a theory of causation.

In the trial court, the defendants succeeded in getting the expert testimony excluded on the ground that the opinion that trauma can cause fibromyalgia had not been "generally accepted" in the scientific community. Because the plaintiff was unable to establish causation without expert testimony, the court then granted the defendants' motion for summary judgment. The plaintiff appealed; the court of appeals affirmed. So far, so good. Even under *Frye*, the court had reached the right result. But then the issue wound its way up to the Florida Supreme Court. In a splintered 4–3 decision, the Florida Supreme Court in *Marsh* reversed.

The court held that the testimony should have been admitted for two principal reasons. First, because the treating physician's testimony that a plaintiff's fibromyalgia was caused by trauma (a car accident) was premised on a differential diagnosis, it was based on "personal experience and training," not a "new or novel scientific test[] or procedure[]." *Id.* at 549. Therefore, it was "pure opinion testimony" and as such was not even subject to *Frye*. *Id.* In the court's view, "Experts routinely form medical causation opinions based on their experience and training." *Id.* at 548. Second, the court held that, even assuming that "differential diagnosis" is subject to *Frye*, it was a "generally accepted method for determining specific causation." *Id.* at 549 (citations omitted). Moreover, said the court, "[n]umerous published articles and studies recognize an association between trauma and fibromyalgia." *Id.* at 550. The court acknowledged a "lack of studies conclusively demonstrating a causal link between trauma and fibromyalgia" and that other studies had "call[ed] for further research," but it concluded that this did not preclude the testimony. *Id.* The Florida Supreme Court harrumphed that "*Frye* does not require unanimity." *Id.* It was thus up to the jury to decide whether to accept the testimony.

For people accustomed to thinking in *Daubert* terms, the result is hard to swallow. The dissenting justices could barely believe it themselves. Justice Cantero authored the dissent, in which Justices Bell and Wells joined. (Justices Cantero and Bell resigned from the Florida Supreme Court last fall.) The dissent demonstrated the fundamental flaws with the majority's analysis and conclusion.

The dissent properly took issue with the majority's conclusion that the testimony was "pure opinion." Testimony is "pure opinion" "only when it is based s*olely* on experience and training, and does not rely [in any manner] on a novel scientific principle, test, or methodology." *Id.* at 560 (Cantero, J., dissenting). Consequently, if an expert purports to base an opinion on his own personal experience and training (while examining a patient) *and* his examination of external studies, outside analyses, or other matters, his opinion is not "pure opinion" at all. *Id.* If an expert (in the form of a treating physician) is correctly performing a differential etiology—though calling it a "diagnosis"—then he or she *must* refer to outside materials to identify potential causes; such information simply cannot be found merely by examining the patient. Thus, a proper differential *etiology* can never be "pure opinion." As the dissent explained, by "holding that an opinion about specific causation need not pass the *Frye* test, even where the underlying theory of general causation is not accepted," the majority had effectively rendered "specific causation testimony always admissible as the 'pure opinion' of the expert." *Id.* at 562. And the dissent cited to numerous cases in which expert-opinion testimony claiming that a car accident or other trauma caused fibromyalgia had been excluded. *Id.* The dissent made its point with strong words: "Differential diagnosis is not a wild card that can be used to introduce novel scientific theories into the courtroom. Any other logic would revert us to the science of the Salem Witch Trials." *Id.* at 565.

The dissent's fundamental point was that there is no reason simply to take an expert's word that he or she performed a proper "differential diagnosis" and then based his or her conclusion on it. The court should look to see what is behind the curtain, for that is the only way to expose the expert as a sophist or his wizardry as a sham. The majority's approach in *Marsh* invites fraud. Its legacy will be forcing corporations to spend enormous sums to defend against scientifically baseless claims.

The dissent had the better of the argument, but that is cold comfort. With two of the dissenters leaving the court and rehearing having been denied, *Marsh* is and will remain the

law in Florida, unless the legislature sees fit to change things. Thus, we can only hope that Florida's hands-off approach to differential diagnosis in the context of causation determinations does not spread to other *Frye* jurisdictions.

MORE REFORM IS NEEDED, AND EXISTING REFORMS SHOULD BE PROTECTED

A lazy application of *Frye* may deserve more of the blame for results like *Marsh* than the *Frye* test itself. Arguably, a more vigorous application might have led to a proper result; in fact, other courts applying *Frye* had excluded testimony purporting to link trauma and fibromyalgia based on "differential diagnoses." But not even the most otiose application of *Daubert* would result in a decision like *Marsh*, because *Daubert* forces courts to look behind the curtain. More troubling still is the fact that *Marsh* was not the decision of a trial court or even an intermediate appellate court. The decision belonged to the state's highest court.

What is science in one state is what Professor David Bernstein would call "quackspertise" in another.[15] That imbalance should be fixed. Until then, however, corporate defendants at risk for mass tort and class action claims should be thankful for CAFA, and they should make sure that its reforms are not washed away with changing political tides. ■

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[1] *See* Emery G. Lee III and Thomas E. Willging, Federal Judicial Center, *The Impact of the Class Action Fairness Act of 2005 on the Federal Courts: Fourth Interim Report to the Judicial Conference Advisory Committee on Civil Rules* 12 (April 2008).

[2] Carol Krafka et al., Federal Judicial Center, *Judge and Attorney Experiences, Practices, and Concerns Regarding Expert Testimony in Federal Civil Trials* at 10–11, 13 (2002).

[3] *See, e.g.*, Julia Luyster, "*Frye* and *Daubert* Challenges: Unreliable Options vs. Unreliable Science," 26 *Trial Advocacy Q.* 29, 30, 31 (Spring 2007).

[4] *Id.* at 30.

[5] Rule 702 of the Federal Rules of Evidence was subsequently amended and now incorporates *Daubert*'s principles: "If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case."

[6] Alaska, Arkansas, Colorado, Connecticut, Delaware, Idaho, Indiana, Iowa, Kentucky, Louisiana, Maine, Michigan, Mississippi, Montana, Nebraska, New Hampshire, New Mexico, North Carolina, Ohio, Oklahoma, Oregon, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Vermont, West Virginia, and Wyoming. *See* 90 A.L.R. 5th 453, §§ 3–27.

[7] Arizona, California, the District of Columbia, Florida, Illinois, Kansas, Maryland, Minnesota, New York, North Dakota, Pennsylvania, and Washington. *See id.* at §§ 28–43. Although Alabama, Hawaii, Massachusetts, Missouri, Nevada, and New Jersey have not rejected *Frye*, they have evaluated the reliability of expert testimony using *Daubert* factors. *See id.* at §§ 44–49. Georgia, Utah, Virginia, and Wisconsin have developed their own peculiar tests for the admissibility of scientific and expert testimony, which may include some elements of *Daubert* and some of *Frye*. *Id.* at §§ 50–53.

[8] *See* Krafka et al., *supra*, at 15.

[9] *See* Allison Frankel, "Who Killed the Mass Torts Bonanza?" (Dec. 12, 2006) (available at http://www.law.com; last visited Feb. 6, 2009).

[10] Federal Judicial Center, *Reference Manual on Scientific Evidence* 481 (2d ed. 2000).

[11] Edward J. Imwinkelried, "The Admissibility and Legal Sufficiency of Testimony about Differential Diagnosis (Etiology): Of Under- and Over-Estimations," 26 *Baylor L. Rev.* 391, 405 (2004); *see also McClain v. Metabolife International, Inc.*, 401 F.3d 1233, 1252 (11th Cir. 2005) (noting that differential diagnosis "leads to the diagnosis of the patient's condition, not necessarily the cause of that condition").

[12] Imwinkelried, *supra*, at 405.

[13] Federal Judicial Center, *Reference Manual on Scientific Evidence* 472 (2d ed. 2000).

[14] Fla. Stat. Ann. 90.702 provides: "If scientific, technical, or other specialized knowledge will assist the trier of fact in understanding the evidence or in determining a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify about it in the form of an opinion; however, the opinion is admissible only if it can be applied to evidence at trial."

[15] David Bernstein, "Quackspertise," *AEI-Brookings Joint Center Policy Matters* 06-23 (Oct. 2006).

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Under *Daubert*, a court must rule on the admissibility of expert scientific testimony by conducting a two-part inquiry. First, the court must determine whether an expert's testimony reflects "scientific knowledge," whether the findings are "derived by the scientific method," and whether the work product is "good science." *Daubert*, 509 U.S. at 590, 593. Second, the court must determine whether the expert's testimony is "relevant to the task at hand." *Id.* at 597. This gatekeeping function is important, because "due to the difficulty of evaluating their testimony, expert witnesses have the potential to be both powerful and quite misleading." *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) (quoting *Daubert*, 509 U.S. at 595) (internal quotation marks omitted). Nowhere is gatekeeping more important than in monitoring novel causes of action like toxic trespass.

Federal Rule of Evidence 702 ("FRE 702") provides that:

> if scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

In *Daubert* and related cases, the U.S. Supreme Court has elucidated a number of factors for courts to consider when determining whether to admit expert testimony under FRE 702.

For example, the U.S. Supreme Court stated in *Daubert* that courts may consider the following: whether the theory or technique employed by the expert is generally accepted in the scientific community; whether it has been subjected to peer review and publication; whether it can be and has been tested; whether the known or potential rate of error is acceptable; and the existence and maintenance of standards and controls. *Id*. at 593–95. These factors are neither exclusive nor dispositive. Since *Daubert*, the U.S. Supreme Court and lower courts have identified additional factors that may be considered, such as whether an expert has unjustifiably extrapolated an unfounded conclusion from an accepted premise, *see GE v. Joiner*, 522 U.S. 136, 146 (1997); whether an expert has adequately accounted for obvious alternative explanations, *see Claar v. Burlington N. R.R.*, 29 F.3d 499, 502 (9th Cir. 1994); or whether experts are proposing to testify about matters "growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying." *Daubert v. Merrell Dow Pharms.*, 43 F.3d 1311, 1317 (9th Cir. 1995) (*Daubert II*).

Always a trusty arrow in defense counsel's quiver, *Daubert* remains an important consideration in attacking toxic trespass claims. With barely detectable exposures and unproven causal relationships, opinions offered by experts in support of plaintiffs' theories of causation may not meet the requirements for admissibility under FRE 702 and *Daubert.* At such low or arbitrary levels of exposure, defendants can argue that the causative risks are not recognized by traditional, reliable scientists, effectively excluding the plaintiffs' causation evidence.

CONCLUSION

The ever-advancing tide of science has fostered a new wave of toxic tort claims. Spurred by legislative initiatives such as California's biomonitoring program, efforts are on the rise to create new sources of liability based on detectable levels of chemicals in the body. While the plaintiffs' bar attempts to broaden traditional tort law to include new theories such as toxic trespass, defendants must master and understand the new scientific developments and use traditional defense strategies to expose the flaws of plaintiffs' theories. ■

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third-party conformity assessment bodies for all safety standards applicable to children's products.

The CPSIA also addresses proprietary or "firewalled" conformity assessment bodies, which would be those testing bodies affiliated or associated with a manufacturer due to the need to protect proprietary and confidential information relating to the product. The CPSIA continues to allow these proprietary or firewalled testing facilities to qualify as conformity assessment bodies. However, to be accredited by the CPSC, a proprietary conformity assessment body must meet additional criteria, showing that it provides equal or greater consumer safety protection than an independent third-party conformity assessment body and has a variety of procedures to protect against "undue influence" by interested parties.[38]

STATES PERMITTED TO ENFORCE CPSC SAFETY STANDARDS

The CPSIA provides for an additional assault on unsafe products by permitting state attorneys general to take steps to obtain injunctive relief when they believe that a company is violating any consumer product safety rule, standard, regulation, certification, or labeling requirement. The only impediment that the states apparently have prior to instituting such injunctive relief is to provide 30 days' notice to the CPSC and allow the CPSC to intervene. If the injunctive relief involves a "substantial product hazard," the state may file a civil action immediately after notifying the CPSC of its intent to do so.

PROTECTION FOR WHISTLEBLOWERS

The CPSIA prohibits manufacturers and others in the chain of distribution from taking any discriminatory or adverse personnel action against (1) any employee because the employee or person acting pursuant to the employee's request provides information about the employer to a federal or state agency "about any act or omission that the employee 'reasonably believe[d]' was a violation of an order, rule, regulation, or other provision" under any Act enforced by the CPSC; or (2) any employee who testifies about such a violation, or who planned, assisted with, or participated in any proceeding involving such a violation, or who objected to or refused to participate in any action that he or she reasonably believed was such a violation.[39] After an investigation by the Secretary of Labor, if the employee's claim is found to be meritorious, the relief available includes (1) affirmative action to abate the violation; (2) reinstatement with back pay and restoration of seniority and other terms and conditions of employment; and (3) compensatory damages. What's more, should the employee prevail, the CPSIA makes it mandatory that the employee be reimbursed for all costs and expenses, including reasonable attorneys' fees and expert fees.[40]

CONCLUSION

It is critical that all U.S. companies that sell or distribute any consumer products that fall under the CPSC's jurisdiction immediately get a handle on the details of the CPSIA. Equally important is a clear appreciation for the real weapons now available to the CPSC to recall unsafe products, to step up enforcement, and to assess and collect big-ticket penalties from companies that violate any safety standards applicable to their products. ■

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[1] The term "substantial product hazard" is defined by statute to mean "(1) a failure to comply with an applicable consumer product safety rule which creates a substantial risk of injury to the public, or (2) a product defect which (because of the pattern of the defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise) creates a substantial risk of injury to the public." 15 U.S.C. § 2064 (a).

[2] *See* U.S. Consumer Product Safety Comm'n draft report, *Import Safety Strategy* (July 2008), at 2.

[3] *See* Customs & Border Protection web site: http://www.cbp.gov/xp/cgov/toolbox/contacts/ports/ (last visited Feb. 6, 2009).

[4] *See* U.S. Consumer Product Safety Comm'n draft report, *Import Safety Strategy* (July 2008), at 5.

[5] *Id.* at 2.

[6] *Id.*

[7] *Id.*

[8] *Id.*

9 *Id.* at 3.

10 *Id.*

11 Enacted as Public Law 110-314, commonly known as (and cited herein as) "H.R. 4040."

12 H.R. 4040, Sec. 217 (a)(1)(A).

13 H.R. 4040, Sec. 217 (a)(1)(B).

14 H.R. 4040, Sec. 217 (c)(1).

15 H.R. 4040, Sec. 201 (a).

16 H.R. 4040, Sec. 235 (a).

17 H.R. 4040, Sec. 101.

18 H.R. 4040, Sec. 108.

19 H.R. 4040, Sec. 102 (a)(1)(A).

20 H.R. 4040, Sec. 103 (a).

21 H.R. 4040, Sec. 214.

22 H.R. 4040, Sec. 218.

23 "Durable infant or toddler product" is defined as "durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years." (*See* H.R. 4040, Sec. 104.)

24 H.R. 4040, Sec. 106.

25 H.R. 4040, Sec. 219.

26 H.R. 4040, Sec. 212.

27 *See* U.S. Consumer Product Safety Comm'n draft report, *Import Safety Strategy* (July 2008), at 7.

28 *Id.* at 9.

29 *Id.*

30 H.R. 4040, Sec. 202 (c)(1).

31 The funding authorized is approximately $118 M for FY 2010, $115.6 M for FY 2011, $124 M for FY 2012, $132 M for FY 2013, and $136 M for FY 2014. (*See* H.R. 4040, Sec. 201 (a).)

32 H.R. 4040, Sec. 217 (a)(1)(A)–(B) & (c)(1).

33 *See* Congressional Budget Office Cost Estimate, H.R. 4040 (Aug. 8, 2008).

34 *See* 15 U.S.C. § 2064 (a)(1).

35 H.R. 4040, Sec. 214 (a)(1).

36 H.R. 4040, Sec. 214 (a)(3)(B).

37 H.R. 4040, Sec. 214 (b)(3).

38 H.R. 4040, Sec. 102 (b).

39 H.R. 4040, Sec. 219 (a).

40 H.R. 4040, Sec. 219 (a).

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slow-drying and resulted in a softer finish. Further, there was a "vast difference in price between the two products." *Id.* at 414.

In *Rose v. Brown & Williamson Tobacco Corp.* (N.Y. Supreme Court), the plaintiffs argued that the defendant cigarette manufacturers negligently designed their higher-tar "regular" cigarettes and should have sold only their allegedly safer, "ultra light" cigarettes. Jones Day partner Steve Kaczynski argued that in the plaintiffs' proposed world of alternative designs, consumers would be forced to sacrifice cheeseburgers, sports cars, and doughnuts for veggie burgers, minivans, and bran muffins. Such is "not the real world" and not the law, he pointed out. The New York appellate division agreed.[22] It held that the plaintiffs had not proved their design defect claim because their proposed alternative design—light cigarettes—did not have the same "functionality" or "utility" as regular cigarettes and there was no evidence that consumers would have accepted them.[23]

WHAT EVIDENCE IS ADMISSIBLE TO PROVE ALTERNATIVE DESIGN?

Evidence of a safer, feasible alternative design is generally elicited through the testimony of expert witnesses. Evidence of the custom in the manufacturer's industry, the technological state of the art of the particular product, consumer acceptability, and compliance with government regulations may all be considered in determining whether a proposed alternative design should have been adopted. While a prototype of an alternative design is not necessary, an expert who testifies that a product could have been designed differently but who has never made or seen the proposed alternative design—and therefore has no idea of its feasibility, utility, or cost—does not make out a prima facie case that a safer, feasible alternative design was available.[24]

Plaintiffs often attempt to use evidence of a defendant's subsequent repairs or design changes as proof that an alternative design was available. Under Federal Rule of Evidence 407, however, evidence of changes made to a product after an injury occurs is excluded if that evidence is used to prove a defendant's negligence or to prove a "defect" in a product or in the "product's design." For example, in *Padillas v. Stork-Gamco, Inc.*, 2000 U.S. Dist. LEXIS 14373 (E.D. Pa. Oct. 2, 2000), the plaintiff was injured while cleaning a chicken-processing machine. Following the injury, the plaintiff's employer modified the machine by installing additional metal guarding on the rotating blade, which the plaintiff argued was admissible to prove a safer alternative design. The court, however, excluded the evidence under Rule 407, finding that "there is essentially no difference between admitting evidence of subsequent remedial measures for the purpose of proving a defect in design and for proving the existence of an alternative design." *Id.* at *9.

Prior to a 1997 amendment to Rule 407, there was a conflict of authority as to whether Rule 407 applied in product liability actions. The amendment clarified that the exclusion of evidence of subsequent remedial measures applied equally to strict product liability actions and, specifically, to design defect claims.[25] The Rule applies to any kind of post-accident change, repair, or precaution, including changing policies and procedures,[26] putting new warnings on products,[27] conducting disciplinary hearings,[28] making design changes,[29] or modifying manuals or regulations.[30] A defendant's remedial measures taken *prior* to the injury do not fall within the scope of excluded evidence.

Evidence of subsequent remedial measures is not excluded absolutely under Rule 407, however. It is admissible if offered for another purpose, such as "proving ownership, control, or feasibility of precautionary measures, if controverted, or impeachment."[31] Thus, the exceptions to Rule 407 have the potential to swallow the rule. A defendant may consider whether to stipulate that an alternative design was "feasible" in order to gain the benefit of Rule 407. For example, in *Gauthier v. AMF, Inc.*, 788 F.2d 634, 638 (9th Cir. 1986), the defendant argued that evidence of subsequent remedial measures should have been excluded because it conceded that certain safety devices were technologically and economically feasible but contended that the safety risk was nonetheless too small to warrant the tradeoff of consumer frustration, increased complexity of the product, and risk of consumer efforts to disconnect the safety device. The Ninth Circuit agreed and held that the trial court's admission of subsequent design changes was prejudicial error that warranted a new trial. Moreover, where evidence of subsequent remedial measures is admitted solely to impeach the

testimony of the manufacturer's expert as to the availability of an alternative design, the defendant should request the trial court to give an appropriate limiting instruction.[32]

In sum, manufacturers don't have to make injury-proof products, and our car maker doesn't have to produce only Humvees. The pre-sale design choices they make, however, should be reasonable. Further, manufacturers should understand how post-sale design repairs may affect them in litigation. ■

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[1] *See*, *e.g.*, N.J. Stat. Ann. § 2A:58C-3(a)(1); Ohio Rev. Code Ann. § 2307.75(F); Mich. Comp. Laws § 600.2946(2).

[2] *See*, *e.g.*, *Carmical v. Bell Helicopter Textron*, 117 F.3d 490, 495 (11th Cir. 1997) (applying Georgia law).

[3] *Scheman-Gonzalez v. Saber Mfg. Co.*, 816 So. 2d 1133 (Fla. Dist. Ct. App. 2002); *Wright v. Brooke Group Ltd.*, 652 N.W.2d 159, 162 (Iowa 2002).

[4] *See* Note, "Just What You'd Expect: Professor Henderson's Redesign of Products Liability," 111 Harv. L. Rev. 2366-2372-74 (1998) (discussing criticisms of the Third Restatement's reasonable alternative design requirement).

[5] *Lancaster Silo & Block Co. v. Northern Propane Gas Co.*, 427 N.Y.S.2d 1009, 1016 (N.Y. App. Div. 1980); *Carmical*, 117 F.3d at 495.

[6] *See also Voss v. Black & Decker Mfg. Co.*, 59 N.Y.2d 102, 108 (N.Y. 1983) (test for design defect in New York is whether "a reasonable person would conclude that the utility of the product did not outweigh the risk").

[7] *See*, *e.g.*, *Nesselrode v. Executive Beechcraft, Inc.*, 707 S.W.2d 371, 375 (Mo. 1986).

[8] *See*, *e.g.*, *Townsend v. General Motors*, 642 So. 2d 411, 415 (Ala. 1994).

[9] *Kern v. General Motors Corp.*, 724 P.2d 1365, 1367 (Colo. Ct. App. 1986).

[10] *Morrison v. Kubota Tractor Corp.*, 891 S.W.2d 422, 426 (Mo. Ct. App. 1994); *Westinghouse Elec. Corp. v. Nutt*, 407 A.2d 606, 609 (D.C. 1979).

[11] *Biss v. Tenneco, Inc.*, 409 N.Y.S.2d 874, 876 (N.Y. App. Div. 1978); *Anderson v. P.A. Radocy & Sons, Inc.*, 865 F. Supp. 522, 531 (N.D. In. 1994) ("a party cannot be liable for failing to equip its products with an optional device that the employer of the plaintiff knowingly rejected").

[12] *Wagner v. Int'l Harvester Co.*, 611 F.2d 224, 231 (8th Cir. 1979) ("the purchaser may be in the best position to make the cost-benefit analysis implicit in the principles of general negligence"); *Morrison*, 891 S.W.2d at 428.

[13] *Accord*, *Biss*, 409 N.Y.S.2d at 876; *Wagner*, 611 F.2d at 231; *Butler v. Navistar Int'l Transp. Corp.*, 809 F. Supp. 1202, 1209 (W.D. Va. 1991).

[14] *Turney v. Ford Motor Co.*, 94 Ill. App. 3d 678, 683 (Ill. App. Ct. 1981) (noting that it is not a defense for the manufacturer that plaintiff's employer chose not to purchase safety features as options; manufacturer cannot delegate its duty to produce a reasonably safe product).

[15] *Habecker v. Copperloy Corp.*, 893 F.2d 49, 54 (3d Cir. 1990) (applying Pennsylvania law); *Ostendorf v. Clark Equipment Co.*, 122 S.W.3d 530, 534 (Ky. 2003); *Morrison*, 891 S.W.2d at 429–30.

[16] *Westinghouse Elec. Corp.*, 407 A.2d at 611.

[17] *Loitz v. Remington Arms Co. Inc.*, 177 Ill. App. 3d 1034, 1046 (Ill. App. Ct. 1988).

[18] *Micallef v. Miehle Co.*, 39 N.Y.2d 376, 386 (N.Y. 1976).

[19] *Uniroyal Goodrich Tire Co. v. Martinez*, 977 S.W.2d 328, 337 (Tex. 1998).

[20] *Id.*

[21] *Curtis v. General Motors Corp.*, 649 F.2d 808, 811–12 (10th Cir. 1981) (applying Colorado law); *Delvaux v. Ford Motor Co.*, 764 F.2d 469, 474 (7th Cir. 1985) (applying Wisconsin law).

[22] *See Rose v. Brown & Williamson Tobacco Corp.*, 855 N.Y.S.2d 119 (N.Y. App. Div. 2008). The jury, however, only partially agreed, rendering a verdict for R.J. Reynolds but against Philip Morris and Brown & Williamson.

[23] *Id.* at 122–26. *See also Clinton v. Brown & Williamson Holdings, Inc.*, 498 F. Supp. 2d 639, 648–49 (S.D.N.Y. 2007) (holding that plaintiff's proposed alternative designs—cigarettes with no tar or nicotine—were "simply not functional equivalents" to the cigarettes plaintiff smoked).

[24] *Peck v. Bridgeport Machines, Inc.*, 237 F.3d 614, 618 (6th Cir. 2001) (applying Michigan law).

[25] *See* Fed. R. Evid. 407 advisory committee's note. Prior to the 1997 amendments, Rule 407 only explicitly excluded evidence of subsequent remedial measures as "proof of negligence or culpable conduct."

[26] *See*, *e.g.*, *Wilkinson v. Carnival Cruise Lines, Inc.*, 920 F.2d 1560, 1568–69 (11th Cir. 1991).

[27] *See*, *e.g.*, *In re Joint E. Dist. & S. Dist. Asbestos Litig. v. Armstrong World Indus., Inc.*, 995 F.2d 343, 346 (2d Cir. 1993).

[28] *See*, *e.g.*, *Maddox v. City of Los Angeles*, 792 F.2d 1408, 1417 (9th Cir. 1986).

[29] *See*, *e.g.*, *Alexander v. Conveyors & Dumpers, Inc.*, 731 F.2d 1221, 1229–30 (5th Cir. 1984).

[30] *See*, *e.g.*, *Mills v. Beech Aircraft Corp.*, 886 F.2d 758, 763–64 (5th Cir. 1989).

[31] Fed. R. Evid. 407.

[32] *See Hopkins v. Duo-Fast Corp.*, 123 Idaho 205 (Id. 1993).

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or outside the company should be blocked. For physical documents, this can be a matter of keeping them under lock and key. For electronic data, businesses have a number of important tools that they should put to good use: firewalls, password protection, and up-to-date anti-virus and anti-spyware programs are a must. Businesses that transmit personal data over a wireless network or store data on a computer with internet access should recognize the threat posed by hackers and take steps to secure their networks.

Fourth, when a business no longer needs the personal data that it keeps on file, that data should be destroyed consistent with the company's document-retention policy. Old credit card numbers and outdated customer records pose an attractive target to identity thieves. Oftentimes this older data is not as well secured by the company keeping it. Paper or other physical records can be shredded, burned, or pulverized. Electronic records can be overwritten or wiped clean through available software solutions.

Fifth, any business that stores personal data must have a plan to respond to data security threats. That plan should include steps for stopping, investigating, and reporting any attempted or successful data security breach. Once a breach has occurred, the business should promptly seek counsel and take steps to remedy the breach. Those steps can include: (1) curing the source of the data breach; (2) identifying what, if any, data was compromised; and (3) complying with all applicable customer-notification laws. A fast response to a data breach makes it more difficult for identity thieves to successfully use any information they might obtain.

While this may seem like easy advice to follow, far too many businesses have no plan in place or refuse to seek advice following a data breach. In a survey of business executives and IT security officers in U.S. companies conducted by the Ponemon Institute, only 43 percent of respondents said their companies had incident response plans in place for data security breaches, and 82 percent failed to consult with legal counsel before responding to an incident.[32]

In many ways, companies that store personal data are in a never-ending race with identity thieves. As companies come up with better ways to safeguard information, identity thieves find more clever ways to obtain it. A company that follows the best practices to safeguard its data is ultimately safeguarding its bottom line. In 2007, the estimated cost of a data security breach amounted to $197 per compromised record and $6.3 million per incident.[33] By taking steps now to safeguard personal data, a company can also safeguard its financial future. ■

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[1] http://www.etiolated.org/statistics (web sites last visited Feb. 6, 2009).

[2] "Survey: One in Five Americans Have Been Victims of Identity Fraud," *Insurance Journal*, July 8, 2005, http://www.insurancejournal.com/news/national/2005/07/08/57054.htm.

[3] http://www.ftc.gov/bcp/edu/microsites/idtheft/consumers/about-identity-theft.html.

[4] "FTC Releases Survey of Identity Theft in U.S. 27.3 Million Victims in Past 5 Years, Billions in Losses for Businesses and Consumers," Sept. 3, 2003, http://www.ftc.gov/opa/2003/09/idtheft.shtm.

[5] "TJX consumer data theft largest in history," Jacqui Cheng, Ars Technica, Mar. 30, 2007, http://arstechnica.com/news.ars/post/20070330-tjx-consumer-data-theft-largest-in-history.html.

[6] "Cost of data breach at TJX soars to $256m," Ross Kerber, *The Boston Globe*, Aug. 15, 2007, http://www.boston.com/business/globe/articles/2007/08/15/cost__of__data__breach__at__tjx__soars__to__256m/?page=2.

[7] *Id.*

[8] "11 charged in largest I.D. theft in U.S. history," Andrea Chang and Joseph Menn, *Los Angeles Times*, Aug. 6, 2008.

[9] *Id.*

[10] http://www.privacyrights.org/ar/ChronDataBreaches.htm#CP.

[11] List compiled by the National Conference of State Legislatures as of Sept. 16, 2008; http://www.ncsl.org/programs/lis/cip/priv/breachlaws.htm.

[12] "Do Data Breach Disclosure Laws Reduce Identity Theft?" Sasha Romanosky, Rahul Telang, and Alessandro Acquisti from Carnegie Mellon University (June 2008) ("We find no statistically significant effect that laws reduce identity theft, even after considering income, urbanization, strictness of law and interstate commerce."), http://weis2008.econinfosec.org/papers/Romanosky.pdf.

[13] *See*, *e.g.*, 16 CFR Parts 313 and 314 (establishing privacy and security rules for financial institutions adopted under the Gramm-Leach-Bliley Act, which require financial institutions to: (i) give consumers notice of their data privacy policies; (ii) limit their use of consumer data; and (iii) adopt security plans to protect data confidentiality); 16 CFR Part 682 (requiring the proper disposal of consumer data from financial statements and credit reports).

[14] 15 U.S.C. §1581m(e).

[15] "TJX Being Sued Over ID Thefts," PatriotLedger.com, Feb. 17, 2007, http://identitytheft911.org/alerts/alert.ext?sp=870.

[16] "Grocer Hannaford hit by computer breach," Ross Kerber, *The Boston Globe*, Mar. 18, 2008, http://www.boston.com/business/articles/2008/03/18/grocer__hannaford__hit__by__computer__breach/.

[17] "Hannaford hit by class-action lawsuits in wake of data-breach disclosure," Jaikumar Vijayan, *Computerworld*, Mar. 20, 2008, http://www.computerworld.com/action/article.do?command=viewArticleBasic&articleId=9070281.

[18] *Id.*

[19] *See Elvey v. TD Ameritrade*, Case No. C 07 2852 VRW (U.S.D.C. for the N.D. Cal.), Class Action Settlement Agreement, filed May 30, 2008, http://blog.wired.com/27bstroke6/files/ameritrade.pdf.

[20] *See* "Judge Scuttles Ameritrade Hacking Settlement," David Kravets, *Wired*, June 13, 2008, http://blog.wired.com/27bstroke6/2008/06/judge-scuttles.html.

[21] "Justice Breyer Is Among Victims in Data Breach Caused by File Sharing," Brian Krebs, WashingtonPost.com, July 9, 2008, http://washingtonpost.com/wp-dyn/content/article/2008/07/08/AR2008070802997__pf.html.

[22] *Id.*

[23] "The Data Breach," HartfordBusiness.com, June 9, 2008, http://www.hartfordbusiness.com/news5711.html.

[24] *See* "TJX, Visa reach $40.9M settlement for data breach," Mark Jewell, *USA Today*, Nov. 30, 2007, http://www.usatoday.com/money/industries/retail/2007-11-30-tjx-visa-breach-settlement__N.htm.

[25] *Pisciotta v. Old National Bancorp*, 499 F.3d 629, 639–640 (7th Cir. 2007) (cost of credit card monitoring not recoverable as compensable damages); *Kahle v. Litton Loan Serv. LP*, 486 F. Supp. 2d 705, 712 (S.D. Ohio 2007); *Randolph v. ING Life Ins. and Annuity Co.*, 486 F. Supp. 2d 1 (D.D.C. 2007); *Giordano v. Wachovia Sec., LLC*, 2006 U.S. Dist. LEXIS 52266, at *12 (D.N.J. July 31, 2006); *Forbes v. Wells Fargo Bank, N.A.*, 420 F. Supp. 2d 1018, 1021 (D. Minn. 2006); *Guin v. Brazos Higher Educ. Serv. Corp.*, 2006 U.S. Dist. LEXIS 4846, at *15 (D. Minn. Feb. 7, 2006); *Hendricks v. DSW Shoe Warehouse*, 444 F. Supp. 2d 775, 783 (W.D. Mich. 2006); *Stollenwerk v. Tri-West Healthcare Alliance*, 2005 U.S. Dist. LEXIS 41054, at *10 (D. Ariz. Sept. 8, 2005).

[26] *See Randolph*, 486 F. Supp. 2d at 7–8; *Giordano*, 2006 U.S. Dist. LEXIS 52266 at *12.

[27] *Pisciotta*, 499 F.3d at 639 ("Without more than allegations of increased risk of future identity theft, the plaintiffs have not suffered a harm that the law is prepared to remedy."); *Forbes*, 420 F. Supp. 2d at 1021 (noting plaintiffs' "expenditure of time and money was not the result of any present injury, but rather the anticipation of future injury that has not materialized").

[28] *Pisciotta*, 499 F.3d at 638–639 (noting that the recovery of damages for toxic tort liability "requires more than an exposure to a future potential harm"); *Stollenwerk*, 2005 U.S. Dist. LEXIS 41054, at **10–11.

[29] *Pisciotta*, 499 F.3d at 637 (upholding trial court's award of summary judgment, while noting that "[h]ad the Indiana legislature intended that a cause of action should be available against a database owner for failing to protect adequately personal information, we believe that it would have made some more definite statement of that intent"); *Hendricks*, 444 F. Supp. 2d at 783 (noting in favor of dismissal that "[t]here is no existing Michigan statutory or case law authority to support plaintiff's position that the purchase of credit card monitoring constitutes either actual damages or a cognizable loss").

[30] 2006 U.S. Dist. LEXIS 4846, at *15 (D. Minn. Feb. 7, 2006).

[31] *See* "Protecting Personal Information: A Guide for Business," Federal Trade Commission, http://www.ftc.gov/infosecurity/.

[32] *See* "Survey: Companies disregard data security breach risks," Robert Westervelt, SearchSecurity.com, May 17, 2007, http://searchfinancialsecurity.techtarget.com/news/article/0,289142,sid185__gci1294452,00.html#.

[33] *See* "Press Release: Ponemon Study Shows Data Breach Costs Continue to Rise," PGP, Nov. 28, 2007, http://www.pgp.com/newsroom/mediareleases/ponemon-us.html.

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adopt different or even conflicting interpretations of what the law requires.

PREPAREDNESS

In light of the enacted and proposed reforms, are there steps that industry might take to minimize risk?

First, the adage that an ounce of prevention is worth a pound of cure seems apt. There are principally two areas on which industry might wish to focus: product design and manufacturing.

As to design, global consumer products companies should design their products to meet the most stringent mandatory safety standards that apply wherever their products are sold. To the extent that there are safety issues that are not addressed by mandatory standards, designs should be subjected to a safety review to avoid or minimize foreseeable risks.

As to manufacturing, manufacturers, particularly those that rely on third-party vendors in the developing world, should consider implementing quality assurance systems. The systems should test for conformity to all product safety requirements, not just mandatory standards, with adequate recordkeeping. To the extent that manufacturers rely on their vendors to perform the testing, they may wish to conduct process audits to ensure that the testing is performed.

Second, companies should attempt to minimize the threat, discussed earlier, of substantial penalties for a failure to timely report under "imprecise" standards that require "judgment calls" subject to Monday-morning quarterbacking by regulators. Companies should consider collecting and consolidating data from consumer reports and implementing periodic review for emerging safety issues by appropriately senior personnel. They might also want to consider whether it would be advisable to adopt or adapt the U.S. CPSC's Retailer Reporting Model, whereby retailers are deemed to comply with their reporting obligations by automatically sending certain consumer report data to government regulators once thresholds, which are defined by the frequency and severity of the risk or injuries, are met. *See*, *e.g.*, http://www.cpsc.gov/BUSINFO/Retailreport3805.pdf (last visited Feb. 2, 2009).

Third, companies should institute internal procedures that quickly elevate safety-related issues within the company to management for action.

Finally, companies should participate in the political and regulatory processes. Once established, government regulation of the kind evidenced in the current wave of reform proposals typically progresses incrementally over the long haul. In short, the recent reforms are unlikely to be the last and, once adopted, often will require administrative regulations to effect their implementation. It is important that industry members communicate to legislators and regulators their perspective on product safety issues and how problems can be most effectively and efficiently avoided or minimized. ■

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[1] Kevin Drawbaugh, "Toy Recalls Fuel Momentum Toward U.S. Safety Reforms," Reuters, October 4, 2007.

[2] C-6 is available at: http://www2.parl.gc.ca/HousePublications/Publication.aspx?Docid=3633883&&File=14.

[3] Directive 2001/95/EC (15 Jan. 2002).

[4] Directive 88/378/EEC (3 May 1988); new Directive, P6__TC1-COD(2008)0018 (18 Dec. 2008) at http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P6-TA-2008-0626.

[5] These include a number of risk assessments conducted under the U.S. National Toxicology Program, an interagency program involving the National Institutes of Health, the Centers for Disease Control, and the Food and Drug Administration, as well as a 2002 safety assessment by the Consumer Product Safety Commission. Based upon that assessment, the CPSC declined to take action on a petition to ban phthalates in children's toys.

[6] Some of these new standards may require further refinement through the regulatory process—*e.g.*, what parts of children's products are "inaccessible" and therefore exempt from the new lead standard for substrates?

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competitive and Americans pay more for their products than they should because of these distortions in our legal system.

So, expect no significant falloff in tort cases.

What is more difficult to predict is how juries will react amidst the current economic collapse. One school of thought is that juries will become stingy and verdicts will be lower than in recent years, because almost everyone is waking up to the lessons of these tough economic times. The competing view is that jurors will be mad at corporate America and may be tougher on corporate defendants than ever before. Recognizing that many jurors and voters are not economically sophisticated (and also recognizing that investment bankers and financial wizards have been shown to have been highly paid havoc makers), I do not expect to see any measurable changes in verdicts in the near term.

Where there will be a longer and more discernible sea change will be in the judiciary. With unions and the contingent-fee bar expecting enhanced clout in Washington, it seems reasonable that judicial appointees will be more likely to be plaintiff-friendly in product liability or tort cases. Lifetime appointments for a crop of plaintiff-friendly judges could mean fewer summary judgments and an expansion of cognizable claims and remedies. That said, it will continue to be true that most plaintiffs' lawyers will still try to keep their cases in state courts.

You can also expect increased litigation relating to the environment, global warming, product stewardship, fears of toxic exposure, mining residue and runoff, consumer products, and actions emanating from the Consumer Product Safety Commission. Tort litigation relating to investments and foreclosures will also be hotbeds for the cultivation of new theories. Fraud and misrepresentation will be the new darlings of that arena.

As for the harsh realities of the practice of law, law firms that irresponsibly leveraged growth with debt and excessive partner draws will find themselves in financial trouble. Some big names have already had major layoffs, and a few will blow apart. Expect a lot of lateral moves in the profession this year.

Corporate clients, under intense economic pressure, will in turn put intense pressure on rates, and they can and should expect their lawyers to work with them to become more efficient and provide better service. Jones Day understands that.

The year 2008 was a good year for Jones Day's litigators. Major victories in lead paint and pigment litigation, tobacco litigation, pharmaceutical cases, and medical devices gave our lawyers recognition and our clients results that each can be proud of. Perhaps most important to us, however, was the report of The BTI Consulting Group that we again were voted the No. 1 firm in client service. Our culture of service, combined with the experience, depth, and training of our lawyers (and, in my view, the talent of our young litigators), is what will enable us to continue to prosper in these difficult times.

Our clients have heard me say repeatedly that we expect our lawyers to understand the client's business, business strategies, and economic circumstances so we can best handle litigation with an eye on the big picture. Clients want cost-effective solutions; they don't need or want lawyers with big egos who can't find affordable roads to victory.

We were especially proud of the work our lawyers have done for Mattel in handling global issues relating to allegations of impermissible levels of lead in toys. The recent settlement with more than 40 state attorneys general reflected a lot of hard work and good judgment by the Jones Day team and the fine people at Mattel. Special thanks to that team and to Mattel for entrusting that matter to us.

We hope you will enjoy and benefit from the scholarly and practical articles on cutting-edge topics that are contained in this issue. As always, we thank our clients for the opportunities you give us, and we invite your comments on our publications. ■

Paul M. Pohl


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