JONES DAY

PRACTICE PERSPECTIVES: PRODUCT LIABILITY & TORT LITIGATION

Bringing Our Best To Every Client Engagement

letter from the

practice chair

BRINGING OUR BEST TO EVERY CLIENT ENGAGEMENT

As I write this for the year-end issue of *Practice Perspectives*, I want to focus on a single honor recently given to Jones Day. On December 1, The BTI Consulting Group released the results of its 2012 client service survey. BTI evaluates individual law-firm performance through the eyes of clients. It obtains feedback from more than 240 corporate counsel and C-level executives on 17 different activities. No law firm influences the results, submits nominations, or provides client names. More than 3,000 client interviews have been conducted in the 11 years during which this survey has been done.

In those 11 years, Jones Day has finished first—the nation's leader in client service—seven times. This year, Jones Day not only won the top spot again, but did so by the widest point margin in the history of the survey. We are honored; we are grateful to the clients who gave BTI their views; and we are humbled in knowing that we cannot rest on these laurels. We must keep our culture of client service and professional excellence.

Jones Day finished with the top score in 10 of the 17 categories. We feel especially proud that we were at the top in three categories that I see as the most important: Legal Skills, Understands the Client's Business, and Innovative Approach. Although each of the 17 categories surveyed is important, those three are at the core of the value proposition we do and must offer our clients. We know there are other fine lawyers and firms competing with us; however, I believe this year's BTI survey shows that we understand better than our competitors that, although we are blessed to be in a learned profession where we are "officers of the court," at the same time, we are in a service business. We believe that our Firm's structure and culture are distinctive and that they create the environment in which we can deliver this value proposition better than others.

We thank those whose input to BTI put us at the top once again, and we restate our commitment to delivering excellence and service as we go forward. We know clients can find cheaper alternatives. So we understand that it is our continuing challenge to show our clients daily that they made the best choice when they entrusted their matters to us, and it is our responsibility to deliver great results, unequaled service, and solutions that are central to the success of their business.

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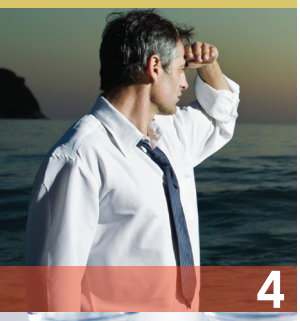

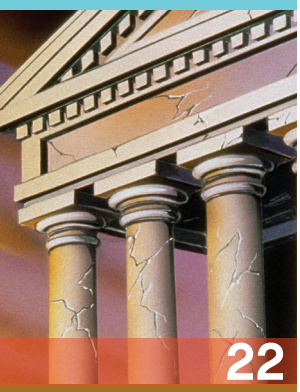

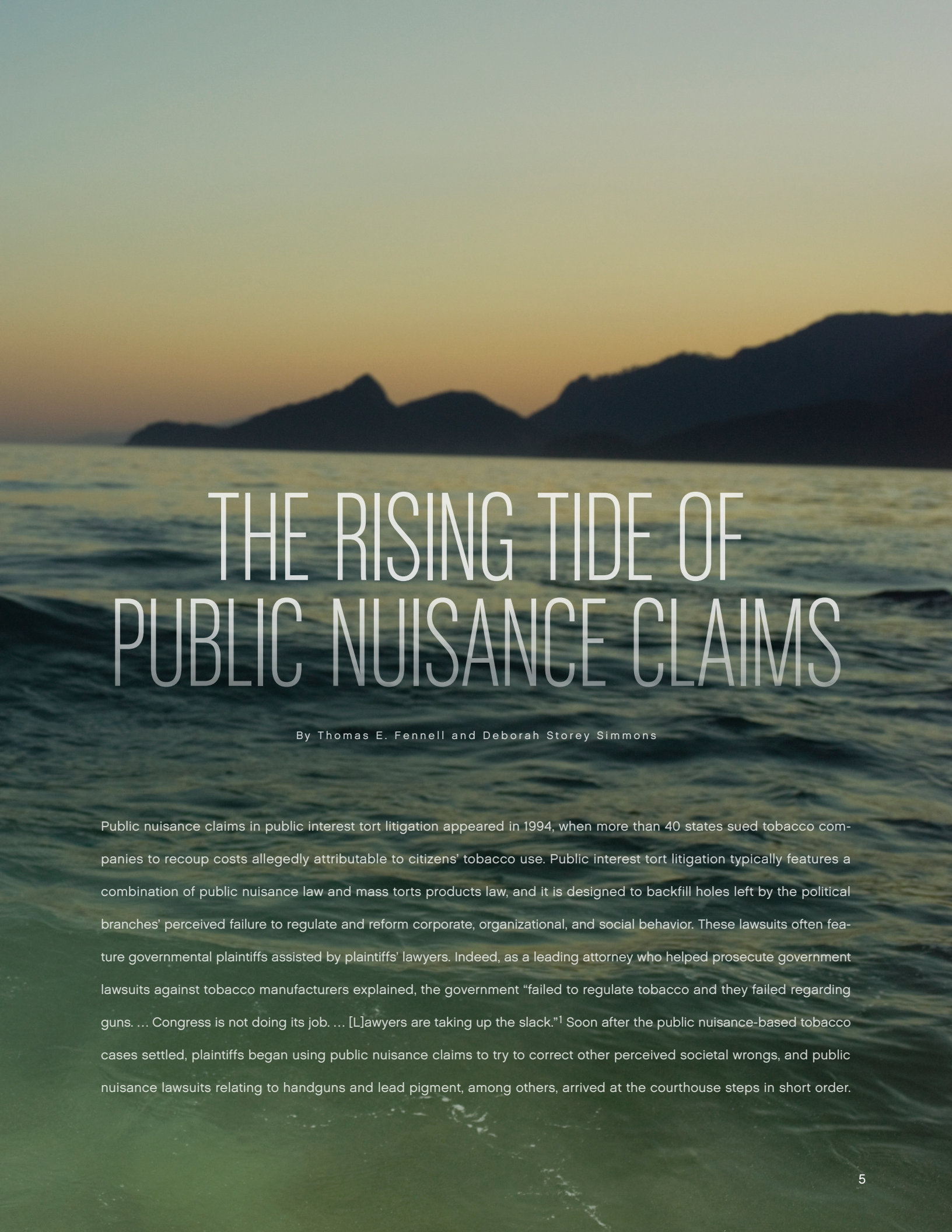

THE RISING TIDE OF PUBLIC NUISANCE CLAIMS

By Thomas E. Fennell and Deborah Storey Simmons

Public nuisance claims in public interest tort litigation appeared in 1994, when more than 40 states sued tobacco companies to recoup costs allegedly attributable to citizens' tobacco use. Public interest tort litigation typically features a combination of public nuisance law and mass torts products law, and it is designed to backfill holes left by the political branches' perceived failure to regulate and reform corporate, organizational, and social behavior. These lawsuits often feature governmental plaintiffs assisted by plaintiffs' lawyers. Indeed, as a leading attorney who helped prosecute government lawsuits against tobacco manufacturers explained, the government "failed to regulate tobacco and they failed regarding guns. … Congress is not doing its job. … [L]awyers are taking up the slack."[1] Soon after the public nuisance-based tobacco cases settled, plaintiffs began using public nuisance claims to try to correct other perceived societal wrongs, and public nuisance lawsuits relating to handguns and lead pigment, among others, arrived at the courthouse steps in short order.

The newest extension of this effort is public nuisance-based climate change litigation, the most prominent example of which is *American Electric Power v. Connecticut*, 131 S. Ct. 1807 (2011). That case began in earnest in July 2004, when two groups of plaintiffs filed separate complaints in the Southern District of New York against five major electric power companies. One plaintiffs' group consisted of eight states and New York City and the other of three nonprofit land trusts. The defendants comprised four private companies and the Tennessee Valley Authority. Alleging that the defendants "are the five largest emitters of carbon dioxide in the United States," the plaintiffs asserted that, by contributing to global warming, the defendants' carbon dioxide emissions created a "substantial and unreasonable interference with public rights," in violation of the federal common law of interstate public nuisance or, in the alternative, of state tort law. The states and New York City claimed that public lands, infrastructure, and health were at risk; the trusts asserted that climate change would destroy animal habitats and rare tree and plant species on trust-owned land. The plaintiffs sought injunctive relief requiring each defendant to cap carbon dioxide emissions at a certain level and reduce that level by a specified percentage each year for at least a decade.

The trial court dismissed the plaintiffs' claims as presenting nonjusticiable political questions, reasoning that no court could resolve the case without initially determining an acceptable global level of greenhouse gas emissions and then assessing which sectors, industries, and individual entities should be held responsible for reducing their emissions—and by what amounts—to achieve that acceptable global level. Those decisions, in the district court's view, involved a number of policy determinations properly reserved for Congress, including the implications of emissions reductions on ongoing negotiations with other nations concerning global climate change, on the United States' energy sufficiency, and thus on national security.

The Second Circuit reversed. It held that a public nuisance cause of action for climate change was implied under federal common law because of the interstate nature of greenhouse gas emissions and climate change. The Second Circuit also opined that the Clean Air Act ("CAA") did not displace a federal public nuisance cause of action for climate change because EPA had not, at the time of the Second Circuit's decision, exercised authority under the CAA to regulate greenhouse gas emissions. Because it held that federal common law governed, the plaintiffs' state-law claims were not addressed by the Second Circuit.

On June 20, 2011, the Supreme Court ruled. Among other rulings, it held that whether the plaintiffs had a federal common-law public nuisance claim for alleged climate change-related harms was an "academic question" because any such claim was displaced by the CAA, which authorizes EPA to regulate carbon dioxide emissions. The Court noted that Congress delegated to EPA the authority to determine whether and how to regulate greenhouse gases and that delegation of authority alone, not the extent to which EPA exercises its authority, was the critical factor in its analysis. Regarding the plaintiffs' state-law public nuisance claims, the Court did not address whether they were preempted, recognizing only that the availability of a state-based public nuisance claim depends, in part, on the preemptive effect of the CAA. The Court remanded the case to the Second Circuit for further consideration of whether the plaintiffs' state public nuisance claims had been preempted. On September 2, 2011, the plaintiffs notified the Second Circuit that they wished to withdraw their complaints and sought remand to the trial court to do so.

The *American Electric* Court's failure to decide whether the CAA preempts state-law public nuisance claims will certainly affect other pending climate change litigation. For example, *Native Village of Kivalina v. ExxonMobil Corp*., 663 F. Supp. 2d 863 (N.D. Cal. 2009), involves a native Alaskan village seeking damages from two dozen defendants and alleging that warmer weather generated by climate change caused injuries related to coastal erosion and flooding. The district court dismissed the case as involving a nonjusticiable political question and for lack of standing. The village appealed to the Ninth Circuit Court of Appeals. While the *American Electric* decision should mandate dismissal for lack of a federal common-law cause of action, the *Kivalina* appellants will be allowed to brief the impact of the Supreme Court's decision.

Also, on May 27, 2011, the plaintiffs in *Comer v. Murphy Oil USA*, 607 F.3d 1049 (5th Cir. 2010), refiled their state-based public nuisance lawsuit in the Southern District of Mississippi, claiming that emissions of carbon dioxide, methane, halocarbons, and other substances by more than 80 defendants caused climate change, which allegedly contributed to sea-level rise

and to Hurricane Katrina's strength, resulting in damage to their property. The case had previously been dismissed by the district court; the plaintiffs' appeal was eventually dismissed by an en banc Fifth Circuit Court of Appeals due to loss of a quorum, *Comer v. Murphy Oil USA*; and a petition for writ of mandamus to the Supreme Court also was denied, *In re Comer*, U.S. No. 10-294 (Jan. 10, 2011). However, motion practice in the refiled *Comer* case is now moving forward.

The effect the *American Electric* decision may have on other potential applications of public nuisance law and the future evolution of public interest tort litigation remains to be seen. Since public interest tort lawsuits contort the public nuisance doctrine to remedy claimed collective, widespread harm from legal products, while simultaneously ignoring long-standing principles that govern tort law, it is no surprise that courts have reached largely negative conclusions about their viability. But plaintiffs, undaunted, continue using public nuisance claims as a creative springboard for public interest tort lawsuits. For example, after the tobacco, handguns, and lead-pigment litigation subsided, public nuisance enjoyed a brief moment as the *cause célèbre* in a lawsuit brought by a municipality claiming that banks and financial institutions that made subprime loans were liable for mass home foreclosures, depressed home values, and consequently lower municipal tax collections. Additionally, the plaintiffs in the MTBE litigation have asserted that gasoline refiners and MTBE manufacturers are liable on the basis of a public nuisance theory.

While federal common-law public nuisance lawsuits pertaining to climate change are presently barred by the *American Electric* decision, the viability of state-based claims seeking the same relief has not yet been resolved. It is imperative that attempts to use state public nuisance claims to achieve the same end be defeated, as they should be. The complex issues these types of lawsuits attack are properly left to the political branches of government and appropriate regulatory agencies, not to the courts.

As the *American Electric* decision discusses, courts are poorly equipped to decide climate change issues, the regulation of greenhouse gas emissions requires a careful assessment of competing economic and social interests, and EPA is entrusted with performing this complicated balance. The Court also noted that:

> [f]ederal judges lack the scientific, economic, and technological resources an agency can utilize in coping with issues of this order. … Judges may not commission scientific studies or convene groups of experts for advice, or issue rules under notice-and-comment procedures inviting input by any interested person, or seek the counsel of regulators in the States where the defendants are located.

131 S. Ct. at 2540–41.

This common-sense view is echoed by the fact that at least two states, Texas and Georgia, have enacted laws limiting the use of the public nuisance doctrine to displace traditional tort causes of action. These laws evidence an encouraging limitation to the threatened proliferation of state-based public nuisance/public interest tort litigation, protecting businesses from the specter of liability for lawful conduct. ■

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[1] "Government Sponsored Regulation–What's Next?" in *Regulation By Litigation: The New Wave of Government Sponsored Litigation*, 1 Manhattan Inst. Conf. Series 51, 64 (1999), *available at* http://www.manhattan-institute.org/pdf/mics1.pdf (last visited Dec. 14, 2011).

ESTABLISHING PROOF OF EXPOSURE

By J.C. McElveen, Jr.

The Fall 2010 issue of *Practice Perspectives: Product Liability & Tort Litigation* contained a thought-provoking article entitled "Genes for Justice? Using Gene Expression Analysis to Identify the Molecular Footprints of Environmental Hazards."[1] The authors of that article examined the possibility that in the future, genetic technology might be able to identify a "chemical footprint" in a person's genome, to provide evidence that the individual had exposure to a particular chemical. Though such a "footprint" would not be able to identify the source of the chemical, nor would it be able to prove that whatever disease or illness the individual had was "caused" by the chemical, it could provide evidence that exposure had occurred. Until such technology is available, however, courts are obliged to use a variety of ways to determine the nature and extent of exposure in cases of alleged chemically induced disease and illness. This article will examine how courts currently approach the exposure issue.

Many state courts, and certainly the federal courts, have articulated what is necessary in order for a plaintiff to prove causation in a toxic tort or product liability case alleging chemical exposure. One recent case articulated the requirements this way:

> In determining whether an alleged chemical exposure caused a particular disease or illness, an expert must establish the following criteria: (1) the toxic substance at issue must have been demonstrated to cause in humans the disease or illness suffered by the plaintiff; (2) the individual must have been exposed to a sufficient amount of the substance in question to elicit the health effect in question; (3) the chronological relationship between exposure and effect must be biologically plausible; and (4) the likelihood that the chemical caused the disease or illness in an individual should be considered in the context of other known causes.[2]

Stated another way, the burden is on the plaintiff to prove:

1) That the chemical at issue is capable of causing the disease or illness the plaintiff has (often referred to as "general causation"); and
2) That the chemical at issue did in fact cause the disease or illness this particular plaintiff has (often referred to as "specific causation").

In other words, "[s]cientific knowledge of the harmful level of exposure to a chemical, plus knowledge that the plaintiff was exposed to such quantities, are minimal facts necessary to sustain the plaintiffs' burden in a toxic tort case."[3]

In many toxic tort cases, especially cases involving long-latency-period diseases like cancer, epidemiology is used to try to prove general causation (that a chemical is capable of causing a particular disease). However, numerous cases have held that epidemiology is the study of the occurrence of disease in populations and "does not in and of itself address the cause of an individual's disease."[4]


Caution
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Although defendants in toxic tort litigation routinely devote time and resources to understanding and addressing the epidemiological question—Can the chemical cause the disease?—it is equally important to devote resources to understanding the second question—To what amount of that chemical, if any, was the plaintiff exposed?

The science of individual exposure assessment, at least at the practical level, is one that is not very far advanced. Many courts have recognized this problem in the toxic tort context by saying that it is not necessary to quantify the amount of exposure with precision. However, what is clear, for most courts, is that exposure must be quantified in some way.

The most common ways of measuring potential exposure to a chemical or a physical agent are attempting to quantify it in the air or near a person's breathing zone (industrial hygiene testing) or measuring it in some bodily fluid, like blood or urine, or in tissue, like fat. These tests are almost all done in the work context, either as part of an industrial hygiene program or pursuant to certain requirements under the Occupational Safety and Health Act. (One exception may be periodic blood lead screening, but that is done almost exclusively on the small number of individuals perceived to be at high risk.) Therefore, when an allegation is made that exposure to a particular chemical occurred, objective evidence of the extent of, or even the existence of, exposure is almost never available.

How, then, do plaintiffs go about trying to prove exposure? One way has been by personal testimony. A plaintiff and/or others testify that they smelled something, saw something (like asbestos fibers), or were made sick by something. That type of evidence might suffice in a case in which the disease is a well-recognized entity caused by a particular material, such as asbestosis, caused by asbestos exposure. However, even in that situation, courts have insisted that for a plaintiff to recover against a particular asbestos supplier, there must be evidence that the plaintiff's exposure was on a regular basis over some extended period of time in proximity to where the plaintiff actually worked.[5]

That type of testimony may also be sufficient in a case in which the exposure and the effect are very close in time. For example, one court said, "Under some circumstances … 'if a person were doused with chemical X and immediately thereafter developed symptom Y, the need for published literature showing a correlation between the two may be lessened.'"[6] However, even in acute exposure situations, other courts have excluded testimony that the exposure caused the effect. In *Moore v. Ashland Chemical Inc.*,[7] the court excluded the opinion of a pulmonary specialist that the plaintiff had developed reactive airways dysfunction syndrome ("RADS"), an asthma-like condition, as a result of exposure during a cleanup operation to spilled chemicals that contained, among other things, toluene. The court held that the absence of evidence regarding the dose of chemical the plaintiff actually received, the plaintiff's other risk factors for the type of disorder he had, and the fact that the doctor had never treated another case of RADS based on this type of exposure scenario made the doctor's opinion speculative at best.[8]

In the absence of objective evidence of exposure, many courts do what the New York Court of Appeals recently did in *Parker v. Mobil Oil Corp.*,[9] a case alleging that exposure to benzene in gasoline, in a service-station environment, had caused acute myelogenous leukemia. First, it acknowledged the problem:

> One problem with establishing causation in toxic tort cases is that, often, a plaintiff's exposure to a toxin will be difficult or impossible to quantify by pinpointing an exact numerical value. Here, for example, defendants did not monitor the level of benzene in the air at the service stations. Nor were they required to do so by law or regulation. Further complicating the process of arriving at a specific quantification in this case is that a significant portion of Parker's benzene exposure was through dermal contact—a factor that would not be addressed in the air-based ppm-years standard.[10]

Then, it articulated the rule: "[W]e find it is not always necessary for a plaintiff to quantify exposure levels precisely or use the dose-response relationship, provided that whatever methods an expert uses to establish [specific] causation are generally accepted in the scientific community."[11]

Indeed, in *Parker*, the court pointed out a couple of ways this could be done. It said that:

> exposure can be estimated through the use of mathematical modeling by taking a plaintiff's work history

> into account to estimate the exposure to a toxin. It is also possible that more qualitative means could be used to express a plaintiff's exposure. [For example,] [c]omparison to the exposure levels of subjects of other studies could be helpful, provided that the expert made a specific comparison sufficient to show how the plaintiff's exposure level related to those of the other subjects.[12]

It should be mentioned that all mathematical models, by definition, require inputs that are based on assumptions (about chemical concentrations in the air, the location of the plaintiff, ventilation, and air direction and speed, among others). In addition, the assumptions that go into a model should be as vigorously scrutinized by the court for scientific validity and reliability as the model itself before the expert is permitted to testify to a jury. The problem is that many such models are so technical that once presented to a jury, they run the risk of being overwhelming, and the rule of "garbage in, garbage out" is apt to be overlooked.

The other method discussed by the New York Court of Appeals—comparison to the exposure levels of subjects in other studies—is also fraught with problems. One of the main problems is that an expert may get on the stand and simply say the exposure of the plaintiff is comparable to the exposures of people in certain studies, without offering any real support for the statement. Indeed, that is what the New York Court of Appeals found had occurred in the *Parker* case. The court held that the "general, subjective and conclusory assertion" of one of the plaintiff's experts, based on the plaintiff's deposition testimony, that the plaintiff "had 'far more exposure to benzene than did the refinery workers in the epidemiological studies' is plainly insufficient to establish causation."[13] The court pointed out that such testimony neither stated the level of the refinery workers' exposure nor specified how the plaintiff's exposure (at service stations) exceeded it.[14] Similarly, the court rejected another expert's "quantification" as insufficient when the expert said that the plaintiff was "frequently" exposed to "excessive" amounts of gasoline and had "extensive exposures … in both liquid and vapor form."[15] The court also criticized that expert for equating the plaintiff's exposure to gasoline to exposure to benzene, which was, at most, a tiny percentage of the gasoline product in the case.[16]

Other cases have taken the same approach. For example, in the Vermont Supreme Court case of *Blanchard v. Goodyear Tire & Rubber Co., et al.*,[17] a plaintiff alleged that his exposure to benzene while playing on a ball field as a teenager in the late 1960s and early 1970s had caused him to develop a rare form of non-Hodgkin lymphoma ("NHL"). The ball field was on a portion of a Goodyear rubber-manufacturing plant that operated from 1936 to 1986. With respect to the exposure issue, the Vermont Supreme Court acknowledged that "in many, if not most, toxic tort cases it is impossible 'to quantify with hard proof—such as the presence of the alleged toxic substance in the plaintiff's blood or tissue—the precise amount of the toxic substance to which an individual plaintiff was exposed.' "[18] However, the court also recognized that "plaintiffs in toxic exposure cases must demonstrate specific causation by submitting evidence concerning 'the amount, duration, intensity, and frequency of exposure.' "[19] Furthermore, the court said that "courts generally preclude experts from testifying 'as to specific causation without having any measurements of a plaintiff's exposure to the allegedly harmful substance.' "[20] In this case, the court rejected three types of "evidence" of exposure and affirmed a lower court's grant of summary judgment for the defense. It rejected the testimony of the plaintiff and his boyhood friends regarding the amount of time the plaintiff had played on the ball field, the odors they had smelled, and the grass discoloration they had observed. It rejected the report and testimony of the project manager of an environmental firm that had been retained to conduct a site investigation, and it rejected the plaintiff's experts' testimony that occupational exposure to benzene is associated with NHL and that this plaintiff's NHL was not caused by any immunodeficiency disorder.

With respect to the lay testimony, the court held that the testimony provided no evidence that benzene was on or in the ball field when the plaintiff was playing there. Perhaps even more significantly, the court held that:

> even if we were to assume that benzene-containing products made their way into the gully and through the field, there is no evidence indicating the amount or concentration of benzene that was present. Nor is there any evidence indicating plaintiff's level of exposure to any benzene that may have been present on the field. Nor is plaintiff able to point to studies indicating a risk of cancer posed by exposure to limited

> amounts of benzene from petroleum products in an outside environment.[21]

The court added, "Putting aside plaintiff's failure to demonstrate the presence of benzene in the field, a jury could only wildly speculate on the level of plaintiff's exposure to any such benzene and on the relationship between any such exposure and plaintiff's disease."[22]

Even cases involving chemical spills, and claims for "medical monitoring" based on no more than "increased risk of adverse outcomes," have been subjected to strict proof regarding exposure. In a case involving a train derailment and fire that resulted in an evacuation, the court held that "[m]ere residence in the impact zone is insufficient evidence of contamination and increased risk because it ignores any individual variables, most notably, at what level the named Plaintiffs were actually exposed [to the chemical]."[23]

Since it appears so difficult to establish exposure, how can it be done? Some courts basically just finesse the issue. One court, for example, disposed of an argument regarding exposure by saying:

> The defendants maintain that [the plaintiff's expert's] dose reconstruction is speculation because it presumes that [the plaintiff] consumed dust. Having considered the briefs, however, the court concludes that the dose reconstruction is specific and reasonable enough to take it beyond the realm of speculation, especially since it is undisputed that everyone consumes a given amount of dust each day.[24]

Another court held that the requirements for proving the requisite amounts of exposure from a Superfund site could be established by the use of a variety of types of indirect evidence. These included information from U.S. EPA and state site remediation reports that discussed soil contamination levels and methods of removal, the fact that the site was open for an extended period of time, evidence that airborne contaminants could travel several miles, reports that people other than the plaintiffs had complained of odors and symptoms, the fact that the plaintiffs spent time in a town park adjacent to the site, and the fact that all the plaintiffs lived within four miles of the site.[25] Finally, the court found that U.S. EPA had written with respect to the site that because "air emissions occurred during the excavation and likely occurred while the excavation was left open for two years, it appears to be likely that some exposure occurred to residents surrounding the Site."[26]

Here, although the court relied on numerous types of evidence, none of it dealt with the dose of chemicals the plaintiffs actually received.

Sometimes, to fill evidentiary gaps, legislatures step in. For example, one court decided a workers' compensation case against a firefighter who claimed he developed non-Hodgkin lymphoma by virtue of smoke inhalation during his work as a firefighter for the City of Burlington, Vermont. The court held, among other things, that the firefighter had not quantified his exposure sufficiently.[27] However, the court noted that the state legislature had recently passed a statute providing that when a firefighter dies from certain cancers, including lymphoma, "the firefighter shall be presumed to have suffered the cancer as a result of conditions in the line of duty."[28] That presumption could be rebutted, but the burden would be on the employer.

Similarly, Congress has periodically stepped in to ease the burden of proving exposure. For example, from the late 1940s until the early 1960s, the United States conducted above-ground tests of atomic weapons. These activities may have exposed to ionizing radiation a considerable number of individuals downwind of the testing ("downwinders"), but radiation-exposure levels were never quantified. In the 1970s and 1980s, members of that group (and others, who mined and milled radioactive materials, such as uranium) alleged that their exposure to radiation caused them to develop cancer more frequently than those who were not so exposed.

Responding to these concerns, Congress enacted the Radiation Exposure Compensation Act ("RECA")[29] in 1990, which recognized that "the lives and health of [individuals] were involuntarily subjected to increased risk of injury and disease to serve the national security interests of the United States."[30] With respect to "downwinders," in the absence of quantifiable exposure levels, Congress established both temporal and geographic requirements for purposes of determining "exposure." Geographically, only residents in a defined "affected area" were eligible for compensation. The "affected area" was defined to include certain counties in

Utah and Nevada; "that portion of Clark County[, Nevada,] that consists of townships 13 through 16 at ranges 63 through 71; and that part of Arizona that is north of the Grand Canyon and west of the Colorado River."[31] Temporally, the claimant must have been present in the "affected area" for at least one year between January 21, 1951, and October 31, 1958, or continuously between June 30, 1962, and July 31, 1962.[32]

Similarly, following 9/11, Congress passed the September 11th Victim Compensation Fund of 2001 (the "9/11 Fund") as part of the Air Transportation Safety and System Stabilization Act.[33] To qualify for compensation under the 9/11 Fund, an individual was required to have been aboard one of the 9/11 flights or to meet the statutory requirements for an "eligible individual." An "eligible individual" (or his or her family) had to prove that: (1) the individual was present at the time of or in the "immediate aftermath" of a crash and that (2) he or she suffered physical harm or death (3) as a result of that crash.[34] As in RECA, Congress specified that "presence" at the crash site had both temporal and geographic requirements. Temporal proximity was straightforward because it turned on physical presence within a discrete time window—the first 96 hours after the crash for rescue workers and the first 12 hours for everyone else.[35]

In contrast, geographical proximity was harder to quantify because the three crash sites differed greatly. Interestingly, Congress left the determination of the geographical boundaries up to a "Special Master" established by the statute. The Special Master concluded that the Pentagon and Shanksville, Pennsylvania, sites were more isolated; thus, no rules were necessary to specify geographical proximity to them. However, the World Trade Center site required detailed specification. Some argued that any person on the island of Manhattan at the time of the attacks should be allowed to file for compensation. The Special Master's Office, however, took a narrower view. In reaching this conclusion, attorneys for the Special Master examined aerial photographs and maps of debris dispersal in New York City and determined that the "Pedestrian No Access Zone" enforced by the New York City Police Department in the days following September 11, 2001, was a fitting area. However, to err on the side of inclusiveness, a street block was added to the perimeter of the zone.[36]

The 9/11 Fund officially closed on June 16, 2004; however, the recent passage of the James Zadroga 9/11 Health and Compensation Act of 2010[37] (the "Act") reopened it. The Act expands the class of eligible individuals in a number of ways. First, the amendments expand the temporal requirement, enlarging the time window from the first 12 or 96 hours after the crash to the period ending May 30, 2002.[38] Second, the amendments expand the geographical boundaries to include not just the World Trade Center, the Pentagon, and the site of the Shanksville, Pennsylvania, crash, but also other buildings or portions of buildings that were destroyed as a result of the terrorist-related aircraft crashes; any area related to or along the routes of debris removal, such as barge routes and the Fresh Kills Landfill; and any contiguous area designated by the Special Master because of a demonstrated risk of physical harm at the site as a result of the crashes or their aftermath.[39]

In addition to the revisions to the 9/11 Fund, the Act creates another funding mechanism for 9/11 victims. This additional approach provides medical benefits and treatment to eligible individuals suffering from a "WTC-related health condition" as listed in the Act.[40] Under the Act, to be eligible for monitoring and treatment benefits, individuals must first qualify as "WTC responders" or "WTC survivors."[41] Those WTC responders and WTC survivors must also satisfy temporal and geographic requirements.[42]

As can be seen, exposure can be difficult to prove in tort litigation, and many courts have taken cases away from juries and ruled for defendants in cases in which plaintiffs have not quantified their exposure by the use of valid and reliable scientific methods. Sometimes, when courts have let cases proceed in the absence of quantifiable exposure data, they have done so on the basis of little more than *post hoc* rationalization. In certain situations, for sound public-policy reasons, legislatures have become involved, either to shift burdens of proof or to establish the prerequisites that are necessary in order to establish exposure. ■

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By John D. Goetz and Dana Baiocco

AVIATION CRISIS MANAGEMENT:

ARE YOU REALLY READY?

Are you prepared to respond to an aviation accident or crisis involving your company? Is your in-house accident team primed and well versed on the issues that will arise in the first few hours following an accident? Do you even *have* an in-house accident team? Have you identified potential litigation issues and pitfalls your company might step into while attempting to do the right things? If not, read on.

While the aviation industry is enjoying its strongest safety record in years, any segment of the industry could be called upon at any moment to deal with a crisis, emergency, or accident situation. Whether in aviation or any other industry, corporate management should work with its various departments, outside counsel, communications specialists, and insurers well in advance to develop a workable emergency plan. The time and preparedness that are required to deal with today's vastly complicated crisis situations should not be underestimated. Indeed, how a company handles a crisis in the first few hours, days, and weeks following a crash or other catastrophe often affects the public's perception of the company and may strike at the bottom line. Even with the best intentions, mishandling a crisis can haunt a company for months and even years.

We have gathered some "lessons learned" from various incidents over the years. These points, as outlined here, are intended to serve as a primer for company executives and in-house counsel in advance of a crisis. The discussion is not meant to be exhaustive. And while this article addresses aviation accidents in particular, the concepts we discuss are applicable, in most instances, to any industry or company crisis.[1]

DEVELOP A WRITTEN EMERGENCY PLAN OR MANUAL

One very basic step that companies often overlook is a written emergency plan or manual. A well-written company manual that outlines an emergency action plan can be a very valuable starting point and training tool.

An emergency plan can take several forms. It can be limited to the initial steps the company will follow in the immediate hours and days following an aviation accident, or it can be more comprehensive in scope, expanding well beyond the accident itself. Regardless of scope, however, any emergency plan should be detailed and identify the roles and responsibilities of each department and the department leaders in a crisis. When possible, the manual should include examples of other incidents or recent events from the industry that any user can draw on for direction. A well-written manual is often the cumulative result of lessons learned and constant input from employees at all levels.

To keep your plan up to date, consider scheduling periodic feedback sessions to review and assess the contents of the plan. Revisit and update your plan annually, for example. This is a wise investment of time and will ensure that the company is ready to engage in best industry practices when catastrophe strikes.

ASSEMBLE SPECIAL CRISIS TEAMS

Identifying key individuals with defined roles for accident response is also an important pre-crisis task. A good starting point for crisis management is to assemble a "headquarters" or executive team, who will be charged with high-level decision making.

In addition to the "headquarters team," smaller "ground" or "go" teams should be considered. These teams should comprise individuals charged with traveling to the accident site and addressing the immediate factual investigation, as well as the media and emotional issues at the scene. Specific individuals should be assigned, for example, to interface on site with law enforcement, families, the media, and personnel from the National Transportation Safety Board ("NTSB") and/or the Federal Aviation Administration ("FAA"), particularly in the event that "party status" is allowed. These individuals should be properly trained and experienced with the applicable NTSB rules and regulations, with the design and manufacture of any potentially relevant product, and with any other issue that may arise at the site.

The ground team could also include one or two individuals who are responsible for closely monitoring developments in any accident investigation. For example, a member of the team could be responsible for attending briefings or gathering information from FAA, law-enforcement, or medical personnel at the scene and reporting these developments back to headquarters.

All team members who are dispatched to an accident site should be briefed or trained on how to interact with the personnel they will encounter. Team members should avoid impromptu interviews or expressing opinions or conclusions about the accident or the company's products or position on the crisis. Rather, they should report the facts and identify the people they observe in the field, as well as those authorities on whom they rely for information.

To maximize communication between the team on site and the team at headquarters, there should be a clear reporting structure and instructions on when to inform management

and whether to do so in written or oral form. All members should carry out their individual charges consistently.

Regardless of the specific roles assigned to individual members of a ground or go team, however, all team members should be well versed on policies regarding photographs and videotapes of the events following a catastrophe and on taking notes on what they observe at the scene.

If team members come into possession of wreckage or other evidence following an accident, the wreckage should not be disturbed or moved. There should be a protocol for documenting the wreckage and any inspections that take place. If a team member creates field notes, they should be neutral in content and without opinions or conclusions. Emails should be created carefully and should also be neutral in tone. Assume that all documents created in the wake of an accident will be produced in subsequent litigation.

Document retention and e-discovery issues similarly should not be overlooked. Team members should gather and secure all documents that may be immediately relevant; those documents relating generally to the flight, the aircraft, and any component parts your company might have on the aircraft should be gathered and preserved first. Aircraft maintenance records, operations and maintenance manuals, and training records should also be assembled. Preservation of electronic media should be discussed and coordinated by technical and legal personnel versed in the relevant issues. Longer term, documents relating to the design, manufacture, and sale of component parts should be gathered and analyzed. Involving counsel in this process will be beneficial.

Also, consider holding mock drills for your teams in order to assess the preparedness of assigned personnel and the effectiveness of the plan. Evaluate and reevaluate assigned personnel annually, even if no emergency occurs in the interim. And make sure the roster of assigned personnel is current, to avoid any holes inadvertently created by attrition.

PROMPT AND EFFECTIVE FACT GATHERING AND PUBLIC COMMUNICATIONS

Careful, deliberate, and prompt fact gathering is crucial. Often, facts are acquired in small bites over time, and jumping to conclusions can lead to misinformation. To avoid this pitfall, set up a chain of command for assembling and reporting information from various on-site personnel and first responders. There should be a responsible balance between fact confirmation and disclosure to the public. Conference calls and updates should be held at regular intervals to discuss progress and share information. Protocols for confirming information and releasing facts to the media and the public should also be considered.

Posting messages to the company's web site about the crisis and the steps that are being taken proactively to address the issues can be perilous when fact gathering is incomplete. While toll-free numbers may give customers and family members an opportunity to express needs and concerns that they have, the personnel manning those lines must be knowledgeable and updated constantly and consistently. They, in turn, must pass along that information in a like manner.

In a crisis, the goals of the in-house communications department and any public relations campaign should be consistent. Special care must be used in developing any public message, because factual information in the early stages will be incomplete and may be unintentionally misleading. To avoid this problem, consider retaining a crisis management firm to work with the in-house communications department to develop a communications plan *before* a crisis situation arises.

Another factor to consider is whether to have a designated company spokesperson for emergency situations. If your company values a spokesperson, identify one or two individuals who can consistently put forth an appropriate face and presence on behalf of the company. Whoever is chosen must be able to adequately explain (and defend) the company's position or the status of an investigation.

The spokesperson must also understand the potential legal implications of any interviews that are given. When law-enforcement or other government officials request interviews of company witnesses, outside counsel should help prepare the individuals for their interviews. If possible, counsel should attend the interviews to make sure they proceed fairly. Understand in advance the ground rules for recording and videotaping the interviews. Review any statements closely before electing to have the individuals or spokesperson sign them. Assume that every word articulated by the company spokesperson will be used (and mischaracterized) by

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FRYE'D BY ADMISSIBILITY STANDARDS:

DOES THE STANDARD OF ADMISSIBILITY IN STATE COURT MAKE ANY DIFFERENCE IN PRACTICE?

By Emily C. Baker and Mary E. Desmond

Expert testimony frequently plays a dispositive role in mass tort and complex product liability cases, and the applicable standard used to determine whether such key evidence is admissible in state court can vary across state lines. The two principal standards of admissibility, *Daubert* and *Frye*, have been the subject of innumerable commentaries and articles, with some debating the relative pros and cons, including which standard is stricter;[1] others advocating for particular states to either keep or modify *Frye* or adopt *Daubert*;[2] and still others hypothesizing, as did at least one article previously featured in this publication, that the difference between *Daubert* and *Frye* does indeed make a difference in practice. While providing background on both standards, this article focuses on the primary differences between the two and presents the prevalent views on whether which standard a state applies *really* makes any difference in the way scientific evidence is handled in practice.

BACKGROUND: *FRYE* AND *DAUBERT*

In 1923, the "general acceptance" standard for the admissibility of scientific evidence was set in *Frye v. United States*. *Frye* involved a murder trial where the defendant unsuccessfully sought to introduce expert testimony regarding a lie detector test based on changes in systolic blood pressure. In upholding the exclusion of such evidence, the D.C. Circuit noted that the test had not gained "standing and scientific recognition among physiological and psychological authorities" and thus had not gained "general acceptance in the particular field in which it belongs."[3]

Frye was not often cited until years later—and not regularly until the 1970s—and even then it was applied primarily in criminal cases.[4] It was not applied in a federal civil case until 1984.[5] But as more federal courts and most state courts adopted or applied *Frye*, confusion arose about whether *Frye* was superseded by the enactment of the Federal Rules of Evidence in 1975. Absent from the text of then Rule 702, of course, was any reference to "general acceptance."

The Supreme Court addressed this very issue in 1993 when it decided *Daubert v. Merrell Dow Pharmaceuticals*.[6] In *Daubert*, the Court determined that trial judges must not only ascertain the "general acceptance" of expert testimony, but also ensure that such testimony is "relevant to the task at hand" and "rests on a reliable foundation."[7] The Court further enumerated four nonbinding factors courts could consider in evaluating the admissibility of expert testimony: (1) whether such evidence was generally accepted by the relevant scientific community; (2) whether the methodology was published and subject to peer review; (3) whether the methodology has a known or potential rate of error; and (4) whether the results are testable.[8] *Daubert* was further refined by *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137 (1999) (extending *Daubert*'s general holding to include nonscientific, or technical, expert testimony), and *General Electric Co. v. Joiner*, 522 U.S. 136 (1997) (finding that determinations regarding admissibility of expert testimony were to be reviewed for abuse of discretion). These three cases, referred to as the "*Daubert* trilogy," are the law in federal court.

Today, the majority of states have adopted *Daubert*, if not in name, then in ways that are nearly identical doctrinally. However, within these so-called *Daubert* states, there is some variation. Some states have adopted the entire "trilogy," while some have adopted only certain elements of the "trilogy." And still others, like New Jersey, have adopted *Daubert*, but only in certain types of cases or circumstances. A close look at the *Frye* states shows similar nonuniformity. Kansas, for example, will apply *Frye*, but only to new or developing science;[9] Illinois does not apply *Frye* to expert medical testimony.[10] In addition to Kansas and Illinois, at least 10 other jurisdictions have retained *Frye* (in one form or another).[11]

THE PRINCIPAL DISTINCTIONS BETWEEN *FRYE* AND *DAUBERT*

Beyond the fact that each represents a distinct standard of admissibility, there are two principal distinctions between jurisdictions that apply *Frye* and those that apply *Daubert*—the first concerns which body (the judiciary or the scientific community) makes the call on the science, and the second concerns the evidence to which these standards apply. As to the first, under *Frye*, trial judges are ostensibly charged with assessing whether such testimony is "generally accepted" in the relevant scientific community. In *Daubert* jurisdictions, on the other hand, trial judges in their "gatekeeper" role must assess the reliability of any expert evidence.[12]

As to the second, in those jurisdictions that follow *Kumho* (or some variation thereof), *Daubert* extends to all types of expert testimony, whereas in many *Frye* jurisdictions, challenges to expert testimony are typically limited to scientific testimony only, excluding other types of expert testimony, such as expert medical testimony.[13] Like the states noted above, California also significantly restricts the application of its version of *Frye*—so much so that "there are no reported California cases applying [*Frye*] to cancer causation and the like."[14]

DOES *FRYE* OR *DAUBERT* MAKE ANY DIFFERENCE IN STATE COURT? THREE VIEWS

The distinctions between *Daubert* and *Frye* logically suggest that the adoption of one or the other should make some difference in practice. Recently, however, some commentators have suggested that whether a state applies *Daubert* or *Frye* makes no *real* difference in how those courts assess the admissibility of expert testimony. One of the leading treatises on scientific evidence, for instance, articulates this notion in the following way: "[R]elatively few toxic tort case admissibility rulings actually turn on the difference between *Daubert* and *Frye*. *Daubert*'s shadow now casts itself over state court opinions even in jurisdictions that have not formally adopted the *Daubert* test."[15] Likewise, some recent studies support the proposition that whether a state adopts *Daubert* or *Frye* makes no difference in tort cases. Of course, these are not the only views on this subject, but thoughts about what, if any, difference a state's choice of *Daubert* or *Frye* makes can largely be grouped into the three categories that follow.

***Daubert* Is More Liberal Than *Frye*.** Initially, after *Daubert* was decided, many commentators focused on whether it was a more lenient or liberal standard—one, in particular, that would make it more difficult to challenge expert testimony. Even the Court in *Daubert* noted that it was imposing a more liberal standard than *Frye*. In fact, the Court stated that *Frye* was "at odds with the 'liberal thrust' of the Federal Rules and their 'general approach of relaxing the traditional barriers to "opinion testimony." ' "[16] Soon after *Daubert*—as opposed to more recent scholarship—some even speculated that *Daubert* was pro-plaintiff[17] and would ultimately make it easier for plaintiffs to admit expert testimony and therefore avoid potentially dispositive motions practice.[18]

***Daubert* Is Stricter Than *Frye*.** In stark contrast to early reports that *Daubert* could be more liberal than *Frye*, one

survey of post-*Daubert* product liability decisions revealed that two-thirds excluded expert testimony.[19] Other data showed that parties—and especially civil defendants—were hardly shy about filing *Daubert* motions. In the six years post-*Daubert*, the number of federal-court orders issuing rulings in civil cases that addressed the admissibility of expert testimony was 36 times greater than in the previous six-year period,[20] and these motions were successful nearly 70 percent of the time.[21]

Recently, plaintiffs' advocacy groups, apparently accepting the notion that *Daubert* is anything but a more liberal standard and is, instead, far stricter than *Frye*, have advocated against the adoption of *Daubert* in state courts. Scholarship, too, has referred to *Daubert* as "intolerable" for plaintiffs: "Plaintiffs have, in large part, been stymied by their inability to establish that toxic agents, no matter how potentially dangerous, were actually responsible for the harms they have suffered. Their difficulties in this regard have increased exponentially since the Supreme Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*"[22]

The Standard of Admissibility Does Not Matter. Although the adoption of *Daubert* or *Frye* is viewed by many as having *some* impact on the outcome of admissibility determinations, other commentators increasingly question the assumption that the application of one standard over the other may have practical significance. Some suggest that the primary benefit of *Daubert* was not that it was a stricter standard or created a higher hurdle to admissibility, but that it heightened trial courts' awareness of the problem of admitting unreliable science—and thus, whether a *Daubert* or *Frye* jurisdiction, the results are often the same.[23] One survey found that state-court judges considered the "general acceptance" prong to be the most useful of the *Daubert* factors and that, while *Daubert* may have increased judicial scrutiny of the admissibility of expert testimony, these courts were generally applying the same analysis regardless of what standard actually applied in the respective jurisdictions.[24] Other studies have yielded similar results. In one, which involved analyzing hundreds of federal and state criminal appellate decisions, researchers found that *Daubert*—whether in federal or state court—had no statistically significant effect on the rates of admissibility of expert testimony.[25] While this latter study looked only at criminal cases, thereby making it difficult to extrapolate to the civil context, its findings nonetheless contribute to the growing suspicion that the standard of admissibility a state adopts does not matter from a practical standpoint.

CONCLUSION

Expert testimony can ignite or snuff out a mass tort or complex product liability case. And while the commentaries and articles examining the relative merits of the standards of admissibility for such evidence—*Daubert* and *Frye*—are legion, there are varying views on whether the application of one standard over another really makes any difference in practice. For litigants, this means one should not lose hope if stuck in a *Frye* jurisdiction. And, regardless of jurisdiction, both *Daubert* and *Frye*, if rigorously applied, have the potential to be powerful tools in limiting or excluding an opponent's experts. ■

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[1] *See*, *e.g.*, Erica Beecher-Monas, "Blinded by Science: How Judges Avoid the Science in Scientific Evidence," 71 *Temple Law Review* 55, 75–76 (1998).

[2] *See*, *e.g.*, Mary Gaston, "*State v. Gentry:* The Washington Supreme Court Opens the Door for Unreliable Scientific Evidence," 31 *Gonzaga Law Review* 475, 498–99 (1996); Penelope Harley, "Minnesota Decides: *Goeb v. Tharalson* and the Admissibility of Novel Scientific Evidence," 24 *Hamline Law Review* 460, 463 (2001).

[3] *Frye v. United States*, 293 F. 1013, 1014 (D.C. Cir. 1923).

[4] *See* Faigman, Porter & Saks, "Check Your Crystal Ball at the Courthouse Door, Please: Exploring the Past, Understanding the Present, and Worrying about the Future of Scientific Evidence," 15 *Cardozo Law Review* 1799, 1808 n.25 (1994).

[5] *See* Paul C. Giannelli, " 'Junk Science': The Criminal Cases," 84 *Journal of Criminal Law & Criminology* 105, 111 (1993).

[6] 509 U.S. 579 (1993). The *Daubert* Court expressly held that *Frye* was superseded by Federal Rule of Evidence 702. *See id*. at 587.

[7] *Id*. at 584–87.

[8] *Id*. at 594.

[9] *See State v. McHenry*, 136 P.3d 964 (Kan. App. 2006).

[10] *See Warstalski v. JSB Const. & Consulting Co*., 892 N.E.2d 122 (Ill. App. 2008).

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IMPROVING

THE CONSUMER PRODUCT SAFETY IMPROVEMENT ACT?

WHAT THE 2011 AMENDMENTS TO THE CPSIA MEAN FOR RETAILERS AND MANUFACTURERS

In response to the recall of 35 million consumer products in 2007, Congress passed the Consumer Product Safety Improvement Act of 2008 ("CPSIA"), which overhauled the Consumer Product Safety Act and related laws. Congress's remaking of the regulatory landscape overwhelmed both businesses and bureaucrats, and it became a textbook example of unintended consequences. The Consumer Product Safety Commission (the "Commission") struggled to meet its deadlines for issuing a river of new regulations and, for some of the most daunting CPSIA provisions, threw up its hands and successively stayed enforcement. Businesses struggled with new restrictions and requirements for products as varied as books, children's apparel, toys, sporting goods, and electronic products. By one estimate, the CPSIA in its first six months cost the toy industry more than $2 billion. And many small companies abandoned products or went out of business.

Calls for reform of the reform went up immediately, and at last they have been heard—somewhat. On August 16, 2011, the President signed a bill (H.R. 2715) containing several revisions of the CPSIA. Much like the original CPSIA, the bill passed with overwhelming support. This remarkable show of bipartisanship indicates the nature of the changes: the bill is limited to the least controversial "fixes" proposed since 2008. And many of those fixes grant greater discretion to the Commission; manufacturers and retailers will need to wait to see how useful those reforms prove to be in practice, and they will need to remain involved in the regulatory process if they wish to reap the greatest benefit from the changes.

By Peter J. Biersteker, C. Kevin Marshall, and Danielle M. Hohos

The reform that affects all consumer products was the addition of some modest safeguards for manufacturers to the operation of the "SaferProducts.gov" online database of "reports of harm" involving consumer products, which the CPSIA had mandated and which began operating in the spring of 2011 over much protest from businesses. Other reforms focused on children's products—those designed or intended for children 12 years of age or younger—which had suffered most of the CPSIA's wrath. These reforms particularly concerned the CPSIA's new restrictions on lead content and the use of phthalates, its requirement to have product samples tested by third parties, and its requirement to attach tracking labels. Each change is described herein.

TWEAKING THE CONSUMER-PRODUCT DATABASE

The CPSIA required the Commission to establish and maintain a publicly available, searchable, and internet-accessible database on the safety of all consumer products as well as all products or substances regulated by the Commission. Consumers and others may submit "reports of harm," which the Commission posts with minimal review at www.SaferProducts.gov, and manufacturers may have their responses to or comments on the reports included in the database.

The Commission's implementation of the statutory mandate stirred up much opposition and concern from businesses. Among the sources of complaint were the lack of Commission oversight of the accuracy of the reports and the requirement that reports be posted publicly within 15 business days of receipt (and within 10 days of businesses' receiving their copies), which left little time for manufacturers to investigate and respond before the reports were posted. Another concern was the limited amount of detail that the Commission required of reports.

The amendments to the CPSIA included two modest correctives for such concerns. First, the Commission now must stay the publication of a report by an additional five business days if it receives notice, before publication, that information in the report is materially inaccurate. However, this change does not release manufacturers wishing to prevent publication from the obligation to respond to the Commission within 10 days of receiving the report. Thus, it is critical for manufacturers not only to register on the web site's business portal to receive and respond to reports electronically, but also to develop internal controls to swiftly process any report received.

Second, if the Commission does not receive a model or serial number for the product involved in a report of harm, it must ask the submitter for that number (or for a photograph, if the number is not available) and then immediately forward it to the manufacturer. If the Commission seeks such supplementation, it will post the report of harm 15 business days after transmitting it to the manufacturer rather than the baseline 10 days. Although this provision provides the manufacturer more time to respond to the report, as well as the possibility of greater detail to use in a company investigation, it does not prevent posting—even if the submitter does not provide the Commission any additional information.

SOME REPRIEVES FROM GETTING THE LEAD OUT

The immediate catalyst for amending the CPSIA was the looming (on August 14, 2011) reduction of the CPSIA's limit on lead in children's products to 100 parts per million ("ppm") from the prior CPSIA limit of 300 ppm. (Before the CPSIA, only the lead in paint was restricted.) The lower limit, besides involving amounts so miniscule as to be difficult to detect, also was to be retroactive, requiring manufacturers and importers to destroy extensive inventory. The new law addresses this onerous aspect of the CPSIA in several ways.

First, the new limit of 100 ppm is no longer retroactive, which means that goods manufactured on or before August 14, 2011, may continue to be sold if they meet the previous standard of 300 ppm. Any future limits on lead content promulgated by the Commission will also apply only prospectively.

Second, the CPSIA's provisions authorizing the Commission to grant exemptions from the lead limits have been made more workable, primarily by allowing the Commission to consider whether lead in a product presents any real health risk. The Commission now has the authority, on its own initiative or if petitioned, to exempt a product (including a class of product, material, or component part) from the lead standard upon determining that it satisfies three requirements:

- The product requires the inclusion of lead because its manufacture is *not practicable or technologically feasible* if the excess lead is removed or made inaccessible;
- The product is *not likely to be placed in the mouth or ingested*; and
- The product will cause "*no measurable increase in blood lead levels*."

These requirements, however, will remain difficult to meet, particularly the first. And much will depend on how the Commission implements and applies them.

Third, the new law grants relief for the particular kinds of products that have suffered most under the CPSIA's limits on lead content:

1) Off-highway motorized vehicles, such as ATVs, are exempt.
2) Bicycles and related products (such as jogging strollers and bicycle trailers) are subject to the lead-content limits that the Commission set in its stay of enforcement concerning them only through the end of 2011; thereafter, the limit will be 300 ppm at most. Congress thus bowed to the reality that some lead in the metal-alloy parts of these products (think tire valve stems, spokes, and brakes) is necessary for strength, corrosion resistance, and functionality.
3) Most "used children's products" are exempt from the lead-content standard, the main exceptions being children's metal jewelry and any products subject to a recall. This exemption is a welcome reprieve for Goodwill, the Salvation Army, and garage sales and thrift shops nationwide.

AN OBVIOUS EXCEPTION FROM PHTHALATES LIMITS

The CPSIA effectively banned the use of certain phthalates (chemicals that soften plastic materials) in children's toys and child-care articles. Three phthalates (DEHP, DBP, and BBP) were permanently banned; three others (DINP, DIDP, and DnOP) were banned on an interim basis from children's toys that can be placed in a child's mouth and from any child-care articles.

The new law adds an exception for inaccessible component parts. Borrowing from an exception in the original CPSIA for lead-content limits, the law defines "inaccessible" as "not physically exposed by reason of a sealed covering or casing and that does not become physically exposed through reasonably foreseeable use or abuse of such a product," including aging and children's activities like swallowing, mouthing, and breaking. Congress also directed the Commission to provide further guidance on the scope of this exception within a year.

MITIGATING THE BURDENS OF THIRD-PARTY TESTING

High on the list of banes in the CPSIA for businesses manufacturing children's products was the new requirement to have a "sufficient sample" of their products tested for compliance with the new limits by a Commission-certified "third party conformity assessment body." The cost can be prohibitive, particularly for small manufacturers. The new law offers one general hope for mitigation of this burden, plus two more-targeted efforts at mitigation.

First, Congress directed the Commission to seek comment on opportunities to reduce the cost of third-party testing consistent with ensuring compliance with applicable safety rules. Within a year of the end of the comment period, the Commission must prescribe new or revised third-party testing regulations if it determines that such testing would reduce costs while ensuring compliance. If the Commission determines that statutory constraints preclude it from providing such relief, it is to report that determination to Congress.

Second, Congress directed the Commission to directly take into account the burdens of third-party testing on "small batch manufacturers" and provide alternative testing requirements, or perhaps even exemption from third-party testing, for such manufacturers' "covered products." "Small batch manufacturers" are generally those that have $1 million or less in gross revenue. "Covered products" are those of which the manufacturers made no more than 10,000 units the year before. One option for the Commission is to allow small batch manufacturers to certify products on the basis of compliance with another national or international governmental standard that is the same as or more stringent than the applicable federal standard. However, alternatives and exemptions are not available for lead paint; cribs; small parts; children's metal jewelry; baby bouncers, walkers, and jumpers; and durable infant products.

Third, the CPSIA revisions provide an exemption from third-party testing for ordinary, printed books and other paper-based printed materials, such as magazines, posters, and greeting cards. A book that is really a toy (having "play value"), or a toy packaged with an ordinary book, would not benefit from this exemption. Moreover—as is also the case for small batch manufacturers—the exemption is only from the third-party *testing* requirements, not from compliance with the relevant *content* standards, such as those for lead and phthalates. Manufacturers of children's books will still need

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THE SUPREME COURT RESUMES ITS TREND OF RECOGNIZING THE PREEMPTION OF CLAIMS INVOLVING FDA-REGULATED PRODUCTS

By Jonathan Berman

The manufacture of drugs and medical devices is controlled by pervasive regulation, administered by the Food and Drug Administration ("FDA"). The FDA, on the basis of its independent evaluations of safety and efficacy, issues comprehensive mandates regarding what products may be sold, how they can be manufactured, and what manufacturers can say about them. But should patients using these products become injured, the manufacturers are frequently sued under state-law tort theories. In these cases, preemption is often a key defense.

Since 2001, the Supreme Court has decided five cases analyzing whether state tort claims involving FDA-regulated products are preempted by federal law.[1] Unsurprisingly, given the role of the FDA and its restrictions upon the manufacturers' freedom of action, the Supreme Court has found preemption in all but one of these cases.

The exceptional case, the 2009 *Wyeth* decision, held that consumers can sue the manufacturers of brand-name drugs for failure to provide adequate warnings. The most recent Supreme Court decision, *Pliva, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), presented very similar facts except that the drugs in question were generics. Due to differences in the regulatory scheme governing generic drugs, the Court found that *Wyeth* was distinguishable and that for generics it was impossible to both satisfy the standard allegedly imposed by state law and comply with federal regulations. The Court therefore returned to the prevailing trend of finding tort claims to be preempted.

Pliva is hardly likely to be the last word on preemption. A variety of efforts are already underway by plaintiffs' lawyers and advocacy groups to undercut *Pliva*'s holding. But *Pliva* points the way toward unifying a fragmented area of law and points manufacturers toward a tool that could serve to strengthen preemption defenses.

PREEMPTION LAW

The doctrine of preemption stems from the Supremacy Clause of the United States Constitution (Art. VI, cl. 2). The Supremacy Clause declares that "the Laws of the United States … shall be the Supreme Law of the Land." A state law is thus preempted if it "directly conflict[s]" with federal law or if "it is impossible for a private party to comply with both state and federal requirements." *Pliva*, 131 S. Ct. at 2577. Federal law can preempt state law either expressly or "impliedly." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 & n.2 (2001). State law is preempted if it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 496 (1996). Determining whether state law has been impliedly preempted can require an inquiry into Congress's intent in enacting the relevant statute, or even into what the FDA intended when enacting regulations that are said to conflict with state law. *Hillsborough County, Florida v. Automated Med. Labs., Inc.*, 471 U.S. 707, 716 (1985).

Preemption issues have come before the Supreme Court frequently over the last decade. In *Buckman*, the plaintiff had alleged that the manufacturer of bone screws had procured regulatory approval through fraudulent representations to the FDA. The Court rejected this "fraud on the FDA" theory, holding that it was in conflict with the section of the Food, Drug, and Cosmetic Act (the "Act") that gives the federal government exclusive jurisdiction to enforce the Act.[2] In the 2008 *Riegel* decision,[3] the Court held that the Act preempts tort claims relating to medical devices if the FDA had granted premarket approval. And only a few months before issuing *Pliva*, the Court held that the National Childhood Vaccine Injury Act immunizes the manufacturers of vaccines from design-defect claims.[4]

THE *WYETH* AND *PLIVA* DECISIONS

The *Wyeth* decision stands out from the general trend of recognizing preemption. The plaintiff in *Wyeth* received Phenergan to treat her nausea. Because the drug had been improperly administered, the plaintiff developed gangrene, necessitating amputation of her right forearm. She alleged, and a jury found, that the manufacturer had failed to provide adequate warnings regarding the proper method of administering Phenergan. Wyeth argued that failure-to-warn claims were preempted by federal labeling laws, which subject all prescription-drug labeling, including warnings, to FDA approval. Justice Stevens, writing for a five-judge majority, found that there was no conflict with state tort law obligations and therefore that the state-law claims were not preempted. Although warnings and other labeling cannot be changed without seeking the FDA's approval, once such approval is sought through a "changes being effected" supplemental application, a warning can be strengthened immediately, without awaiting the FDA's decision.[5]

Pliva presented similar facts but came to a different result. In *Pliva*, the plaintiffs' doctors had prescribed the drug Reglan, which is used to treat digestive-tract problems. The plaintiffs' pharmacists filled their prescriptions with the generic version of Reglan, metoclopramide. Both plaintiffs developed a severe neurological disorder known as tardive dyskinesia. In separate suits, the plaintiffs alleged that long-term use of metoclopramide caused their condition and that the generic manufacturers were liable under state tort law for failure to warn of this danger.

The Supreme Court held that generic drugs are required to provide exactly the same warning information on their labels that the FDA had approved for their brand-name counterparts.[6] Thus, the generic manufacturers were precluded from issuing any additional warnings, including the warnings that the plaintiffs alleged would have prevented their injuries. Because it was impossible for the generic manufacturers to

Despite the lop-sided track record, the *Pliva* decision is likely to encourage further litigation, since traditional duty-to-warn claims will not lie against generic companies that faithfully copied the approved labeling.

comply with both federal and state mandates, the state-law tort claims were preempted.

The *Pliva* Court distinguished *Wyeth* on narrow, fact-specific grounds. While brand-name manufacturers can add a warning immediately upon submitting a "changes being effected" supplement to the FDA, that route is not available to generics. It is this difference in the regulatory scheme that makes it possible for brand names, but impossible for generics, to conform to the obligations established by state-law duty-to-warn claims. *See Pliva*, 131 S. Ct. at 2577–78, 2581.

EFFORTS TO UNDERCUT *PLIVA*

Several attempts to minimize *Pliva*'s impact are already afoot. Some plaintiffs, for example, have argued that even if generic-drug manufacturers cannot *change* the approved warnings, they can still be liable for failing to call the approved language to the attention of prescribing doctors. Thus, in recent months, two courts have held that *Pliva* did not preempt a claim asserting that a generic manufacturer should have sent a "Dear Doctor" letter, provided that the letter was "consistent with and not contrary to the drug's approved label."[7] Although this claim was not preempted, it remains unclear whether it was viable under state law. One of the two courts explicitly refrained from finding "whether or not the Defendants in fact had a 'duty' to send a 'Dear Doctor' letter, under any legal theory."[8]

Other plaintiffs who purchased generic drugs will refocus their attacks onto the brand-name manufacturers. Indeed, the very day *Pliva* was published, a group of plaintiffs' attorneys announced its intention to advance claims against brand-name manufacturers for injuries allegedly caused by ingesting generic drugs.[9]

The consumers' argument extends tort law regarding the duty of care. The brand-name manufacturers know that the generic manufacturers must copy onto their own labels, word for word, the safety information from the brand-name manufacturers' labels. Thus, all patients who ingest a drug (whether the drug is brand-name or generic) allegedly will be relying upon the brand-name manufacturer's safety warnings. Therefore, the argument runs, the brand-name manufacturers have a duty of care even to other manufacturers' customers and can be found liable to anyone's customers if the labels are deficient.

This is not a new argument, nor has it been particularly successful. The claims of generic customers against brand-name manufacturers are discussed in dozens of published decisions. While the consumer prevailed in California, consumers have lost almost everywhere else.[10] Generally, courts dismiss such claims upon the ground (among others) that product liability plaintiffs have no claim unless they can prove that they used the defendant's product.

But despite the lopsided track record, the *Pliva* decision is likely to encourage further litigation along these lines, since traditional duty-to-warn claims will not lie against generic companies that faithfully copied the approved labeling. Moreover, none of the existing case law comes from the highest court of any state, and most decisions are from trial courts. It is therefore open to the plaintiffs to try again, and if they fail in one state, they can try again in the others.

Another battle over the import of *Pliva* will be fought before the FDA. Public Citizen, a lobbying organization that purports to "defend[] democracy" by "resisting corporate power," has filed a lengthy citizen petition.[11] This petition asks the FDA to change its labeling regulations to permit generic manufacturers to supplement their safety warnings without prior approval. The petition points out that *Pliva*, in finding preemption, distinguished *Wyeth* on the grounds that the FDA regulation permitting immediate label changes applies only to brand-name manufacturers. Public Citizen seeks to render the regulation applicable to all manufacturers, with the explicit goal of eliminating generics' preemption defense.

One cannot know how the FDA will respond to this petition, but it is noteworthy that the Obama administration had filed an amicus brief in *Pliva* arguing against preemption. The FDA's deadline for responding to Public Citizen's petition is March 12, 2012. Interested parties can submit comments for the FDA's consideration.[12]

PLIVA AND THE PATH TOWARD STRENGTHENING PREEMPTION DEFENSES

The many recent Supreme Court cases on preemption in the FDA context reflect the fractured nature of this area of law. There is no single statute governing preemption issues for all FDA-regulated products, or even for all medical products. While different code sections directly address some preemption questions,[13] no one section applies across the preemption case law. Furthermore, due to the complexity of the underlying regulatory scheme, similar fact patterns can lead to disparate results. *Compare Pliva* with *Wyeth*. A further example of this phenomenon can be seen in the cases discussing medical devices. The manufacturer of a device that received "premarket approval"[14] can assert preemption defenses that are unavailable to the manufacturer of a device that received approval through the "510(k)" process.[15] *Compare Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), *with Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).

The *Pliva* decision indicates that a more unified approach may be forthcoming. A plurality of the Court[16] opined that the Supremacy Clause contains a "*non obstante*" provision, meaning that courts should not strain to find a way to uphold both federal and state laws; state laws must give way if so indicated by the ordinary meaning of the federal law. Furthermore, an emphasis of the *Pliva* majority was that courts should not speculate as to what the FDA *might* do if asked to decide an issue pertinent to a claim. If the status of FDA regulations and approvals prevented a defendant from satisfying a standard imposed by state law, courts will not entertain conjecture as to what approvals or rule changes the defendant might have been able to obtain.

Lastly, *Pliva* and *Wyeth* point toward a way in which manufacturers can obtain more certainty regarding their liability exposures: where the proper course of conduct is unclear, one can always ask the FDA. In both *Wyeth* and *Pliva*, the defendants had not asked the FDA whether the drug warnings in question should be enhanced. Had the FDA provided a ruling, both cases would have been simple—no tort claim will lie for failing to provide a warning that the FDA expressly deemed to be inappropriate.[17]

Indeed, for another reason, the *Pliva* decision will likely encourage generics to ask the FDA to implement labeling changes. The majority noted the FDA's position that generic manufacturers are "required to propose[] stronger warning labels … if they believe[] such warnings [are] needed." *Pliva*, 131 S. Ct. at 2576–77.[18] Whether or not the FDA's view is correct, the industry is now on notice that the FDA may consider failure to request a labeling change to be a violation of applicable regulations. One can expect the generics to take this asserted obligation seriously, which may lead to more

dialogue between the FDA and all affected manufacturers regarding what warning should accompany drugs.

There may, of course, be good reason not to ask the FDA to look into a potential labeling change. For example, one should not discourage the use of a drug—through excessively dire warnings or otherwise—in circumstances where the drug's benefits are real and the potential harm is conjectural. But where a manufacturer faces a close call, getting the bad news out earlier may be better than waiting to see if a potential risk results in injured patients and punishing lawsuits.

CONCLUSION

The law of preemption remains difficult to apply to the complex regulatory schemes governing drugs and devices. In recognizing this reality, the *Pliva* court gave opponents of preemption a sound bite that they have already used extensively. The Court wrote: "We recognize that from the perspective of [plaintiffs], finding pre-emption here but not in *Wyeth* makes little sense." *Pliva*, 131 S. Ct. at 2581. Critics of the *Pliva* decision—judges (starting with the dissenting justices), plaintiffs' lawyers, and newspaper editorialists—have repeatedly quoted the "makes little sense" language in arguing that preemption is misguided.

The point the Court was trying to make, perhaps awkwardly, is that neutrally applying preemption principles to the existing regulatory scheme can yield disparate results. While that point may have been lost, the "makes little sense" language does serve to underscore that the law of preemption is still in flux. Until this area of law is better settled—until the case holdings become intuitive—we should expect the battles to shape preemption law to intensify. ■

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[1] *Pliva, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) (generic drugs); *Bruesewitz v. Wyeth LLC*, 131 U.S. 1068 (2011) (vaccines); *Wyeth v. Levine*, 555 U.S. 555 (2009) (brand-name drugs); *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008) (medical devices); *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001) (medical devices).

[2] FD&C Act, § 310(a).

[3] *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), applying FD&C Act § 521(a).

[4] *Bruesewitz v. Wyeth LLC*, 131 U.S. 1068 (2011), applying 42 U.S.C. § 300aa-22(b)(1).

[5] 21 C.F.R. § 314.70(c)(6)(iii)(A).

[6] FD&C Act, §§ 505(j)(2)(A)(v), 505(j)(4)(G).

[7] *Keck v. Endoscopy Center of Southern Nevada, LLC*, Case No. 08A575837 (Dist. Ct., Clark County, Nev. Aug. 19, 2011); *Brasley-Thrash v. Teva Pharmaceuticals USA, Inc.*, 2011 WL 4025734 (S.D. Ala. Sept. 12, 2011).

[8] *Keck v. Endoscopy Center of Southern Nevada, LLC*, Case No. 08A575837 (Dist. Ct., Clark County, Nev. Aug. 19, 2011).

[9] Conte Foundation: Supreme Court Focuses Reglan Liability Back on Brand-Name Company, *PR Newsweb* (June 23, 2011). http://www.prweb.com/releases/2011/6/prweb8597519.htm. A similar intention was posted on a blog maintained by plaintiffs' lawyers Rheingold, Valet, Rheingold, McCartney & Giuffra, LLP. http://www.rheingoldlaw.com/blog/2011/07/pliva-v-mensing-supreme-court-decision-huh.shtml (all web sites herein last visited Dec. 14, 2011).

[10] The leading case rejecting such claims is *Foster v. American Home Products Corp.*, 29 F.3d 165 (4th Cir. 1994). The claims succeeded in only two published cases: *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299 (Cal. Ct. App. 2008), and *Kellogg v. Wyeth*, 762 F. Supp. 2d 694 (D. Vt. 2010).

The "Drug and Device Law" blog attempted to compile a comprehensive list of all cases addressing "whether a name brand … drug manufacturer can be liable in a suit where the plaintiff only took a generic version." The list indicates that such claims failed at least 50 times, succeeding only in the *Conte* and *Kellogg* cases and in an unpublished state trial-court opinion. Two other courts dismissed product liability claims but permitted misrepresentation or fraud claims to proceed. http://druganddevicelaw.blogspot.com/2009/11/scorecard-non-manufacturer-name-brand.html.

[11] Public Citizen's petition is docketed as FDA-2011-P-0675-0001/CP and is also available at http://www.citizen.org/documents/Citizen-Petition-8-26.pdf.

[12] 21 C.F.R. § 10.30(d), (e)(2).

[13] *See* FD&C Act § 310(a) (federal government generally has exclusive jurisdiction to enforce the Act), FD&C Act § 521(a) (preemption regarding devices), 42 U.S.C. § 300aa-22(b)(1) (preemption regarding vaccines).

[14] The premarket-approval process is commonly required of "Class III" devices, which involve the highest risk of danger to the patient. *See* FD&C Act §§ 513(a)(1)(C), 515(a). The applicant must prove the safety and efficacy of the device. *See* FD&C Act § 515(d)(2)(A), (B). Doing so generally requires the submission of a detailed application, supported by appropriate data. *See generally* 21 C.F.R. Part 814.

[15] Under the "510(k)" process (which is named after section 510(k) of the Food, Drug, and Cosmetic Act), a manufacturer must establish that a new device is substantially equivalent to devices currently in commercial distribution. Approval does not require further proof of the device's safety or efficacy. *See generally* 21 C.F.R. Part 807 Subpart E. In general, the 510(k) process is available only after the FDA has ruled that a particular class of devices does not require more exacting scrutiny.

[16] Although five justices joined the bulk of the primary opinion in *Pliva*, only four joined the portion discussing *non obstante* clauses. The four dissenters are in express disagreement on this point, and the remaining justice, Justice Kennedy, expressed no views either way.

[17] *See Wyeth*, 555 U.S. 555 ("absent clear evidence that the FDA would not have approved a change to [the drug's] label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements").

[18] The FDA's assertion of an obligation to petition for label changes comes as something of a surprise. To be sure, all drug manufacturers must report adverse drug experiences and must report with some urgency adverse events that are both serious and outside the scope of known dangers. 21 C.F.R. §§ 314.80(c), 314.98. But no regulation directly spells out that *generics* have an obligation to ask for a labeling change. The *Pliva* record contains "no evidence of any generic drug manufacturer ever acting pursuant to any such duty." *Pliva*, 131 S. Ct. at 2577. Independent research confirms that petitions by generics to alter safety labeling are indeed rare, although not entirely unprecedented. The Supreme Court was careful neither to endorse nor to overrule the FDA's position on this point.

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[1] *Jones Day Practice Perspectives: Product Liability & Tort Litigation*, Fall 2010, pp. 8–11, 42.

[2] *Henricksen v. ConocoPhillips Co.*, 605 F. Supp. 2d 1142, 1156 (E.D. Wash. 2009), citing Eaton, D.L., "Scientific Judgment and Toxic Torts—A Primer in Toxicology for Judges and Lawyers," 13 *Journal of Law and Policy* 5, pp. 38–40 (2003).

[3] *Allen v. Pennsylvania Engineering Corp.*, 102 F.3d 194, 199 (5th Cir. 1996).

[4] *Beck v. Koppers, Inc.*, 2006 WL 270260 (N.D. Miss. 2006).

[5] *See Thacker v. UNR Industries, Inc.*, 603 N.E.2d 449, 457 (Ill. 1992), and *Lohrmann v. Pittsburgh Corning Corp.*, 782 F.2d 1156, 1162–63 (4th Cir. 1986).

[6] *Bonner v. ISP Technologies, Inc.*, 259 F.3d 924, 931 (8th Cir. 2001), quoting *Heller v. Shaw Industries, Inc.*, 167 F.3d 146, 154 (3d Cir. 1999).

[7] 151 F.3d 269 (5th Cir. 1998).

[8] *Id.* at 278–79.

[9] 857 N.E.2d 1114 (N.Y. 2006).

[10] *Id.* at 1120.

[11] *Id.* at 1121.

[12] *Id.* In the recent case of *Nonnon v. City of New York*, 2011 WL 4089536 (N.Y.A.D. 1 Dept.), an appellate division of the New York Court of Appeals held that "the strength of the epidemiological data alone permits an inference of (specific) causation." That would seem to be insufficient, under the ruling in *Parker*, to prove individual causation, because epidemiology is generally acknowledged to be a study of populations, not of individuals, and epidemiology alone cannot prove causation in an individual case.

[13] *Id.*

[14] *Id.* at 1121–22.

[15] *Id.* at 1122.

[16] *Id.*

[17] – A.3d –, 2011 WL 3505236 (Vt. 2011).

[18] *Id.* ¶ 7, quoting *Plourde v. Gladstone*, 190 F. Supp. 2d 708, 721 (D. Vt. 2002).

[19] *Id.* ¶ 6, quoting *White v. Dow Chem. Co.*, 321 F. App'x 266, 273 (4th Cir. 2009).

[20] *Id.* ¶ 7, quoting *Henricksen v. ConocoPhillips Co.*, 605 F. Supp. 2d 1142, 1157 (E.D. Wash. 2009).

[21] *Id.* ¶ 11.

[22] *Id.*

[23] *Mann v. CSX Transportation, Inc.*, 2009 WL 3766056 (N.D. Ohio 2009).

[24] *Beck v. Koppers, Inc.*, 2006 WL 270260 (N.D. Miss. 2006).

[25] *Donaldson v. Central Illinois Public Service Co.*, 767 N.E.2d 314, 332–33 (Ill. 2002).

[26] *Id.* at 333, quoting CIPS's *Air Monitoring Report*.

[27] *Estate of George v. Vermont League of Cities and Towns*, 993 A.2d 367 (Vt. 2010).

[28] *Id.* Reiber, C.J., dissenting, p. 385, n.16.

[29] Pub. L. No. 101-426, 104 Stat. 920 (1990).

[30] *Id.* at § 2(a)(5).

[31] *Id.* at § 4(b)(1).

[32] *Id.* § 4(a)(1). Other temporal requirements also apply. *See* § 4(a)(1), 4(a)(1)(A), 4(a)(2), 4(b)(2).

[33] Pub. L. No. 107-42, 115 Stat. 230 (2001).

[34] *Id.* at § 405(c).

[35] 28 C.F.R. Part 104.2(b).

[36] Feinberg, K.R., *Final Report of the Special Master for the September 11th Victim Compensation Fund* (2004), vol. 1, p. 19, and n.58, *available at* http://www.justice.gov/final_report.pdf (last visited Dec. 14, 2011).

[37] Pub. L. No. 111-347, 124 Stat. 3623 (2011).

[38] *Id.* at § 201.

[39] *Id.*

[40] *Id.* §§ 3312(a) and 3322.

[41] *Id.* §§ 3311–3323.

[42] *Id.* § 3311(a)(2), § 3311(a)(1)(B), § 3306(7).

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a "general conformity certification," based on a "reasonable testing program," that they meet the content requirements.

MORE PRACTICAL TRACKING LABELS

In the name of enabling better identification of children's products subject to corrective action such as a voluntary recall, the CPSIA requires manufacturers of children's products to mark them with information making it possible to trace the products to their original batches or runs or to provide them with other tracking identification. The CPSIA vaguely provided that such labels should be placed on the product "to the extent practicable" and did not expressly authorize the Commission to exempt any product or class of product.

The amendments grant such exemption authority, which the Commission may use upon finding it not practicable for a given product or class of product to bear the marks required for tracking. In such cases, the Commission may establish alternative requirements.

CONCLUSION

These correctives to the CPSIA offer some relief from that law's worst excesses. But much will depend on the Commission, and thus much depends on the involvement of businesses in providing comments to the Commission and, where appropriate, raising their particular concerns to the Commission through petitions. The CPSIA is not going away, but it may become a bit more workable. ■

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Our product liability lawyers have had some major successes since the last issue of this periodical (*see*, *e.g.*, *Gaines v. Sherwin-Williams*, *McTaggart v. Yamaha*, and the results of our Florida R.J. Reynolds cases). But nothing says more about the strength of Jones Day's lawyers across the nation and around the world than what clients have told BTI. I thank my partners and colleagues for this achievement.

Best wishes to all for success and prosperity in 2012. ■

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an adversary in open court as a purported admission by the company in subsequent litigation.

The role of the company spokesperson should not be assigned lightly or assumed without appropriate guidance, consultation, and training. In the rare circumstance where a lawyer is chosen as the spokesperson, make sure privilege-waiver issues are analyzed and any potential consequences understood.

NOTIFY INSURANCE BROKERS AND INSURERS

Insurance-related issues are a critical part of crisis management. Insurance issues should be identified early and quickly. All applicable insurance policies should be gathered and made easily accessible to the headquarters team for review. Contact information for the appropriate brokers should be available.

It is critical to understand policy terms that provide coverage for all or part of expenses, potential liability, and costs of defense. Assign a particular individual or department head to review and analyze relevant policies for applicable notice requirements. Discuss these and other relevant insurance issues with outside counsel and underwriters (if appropriate) early on to help protect the company from inadvertently waiving its rights, and be sure to identify the steps and missteps that could jeopardize coverage.

One particular issue that should be addressed well in advance of an accident is whether the company has control over the selection of outside counsel. Retaining outside counsel during the initial stages of an emergency has many benefits. For example, having outside counsel in place can free up the in-house legal team to address sensitive and immediate business, public disclosure, media, and family-related issues. Outside counsel can also assist with document and information gathering, research and analysis of legal issues, and conducting witness interviews.

Companies can, and should, have preferred outside counsel for different situations. Particularly when facing a catastrophe, executives and company officers often have preferred or go-to counsel whom they trust and rely upon to identify relevant issues, provide guidance, and assess risks in bet-the-company incidents.

In addition, many routine aviation accidents are now being "criminalized" by local law-enforcement officials. These officials are quick to open investigations, demand production of files, and subpoena interviews of company personnel located "on the ground" where an accident occurs—a trend that is becoming increasingly prevalent in European and Asian countries. Having control over the choice of even local counsel can be critical, especially when you need effective representation for corporate officials who may be faced with varied and immediate requests from local law-enforcement officers following an accident. Uncertainty as to whether you have control over the choice of outside counsel at such a crucial time will increase cost and cause delay. Negotiate this benefit into your policy well before an accident strikes. It will be a wise investment.

COMMUNICATIONS WITH SUPPLIERS AND BUSINESS PARTNERS

Insurers are not the only parties to whom notice might be necessary. In-house counsel should also review, earlier rather than later, relevant supply or business contracts to determine whether notice should be given of any intent to seek indemnification for loss due to or during the crisis. In addition, it is good business practice to communicate with and provide updates to suppliers and other relevant business partners who might have a stake in the accident. This will enable such business partners to engage in adequate response plans and strategies on behalf of their own companies. When appropriate, product audits should be scheduled.

SEC AND DISCLOSURE ISSUES

In addition to the litigation and regulatory issues associated with a crisis, publicly traded companies are likely to have to address disclosure and other securities-law issues in a compressed time frame. When a crisis strikes, it is important to engage internal investor-relations leaders to begin appropriate steps for disclosure. Outside securities counsel should similarly be engaged and notified at an early stage to determine whether special disclosures are required or prudent.

CONCLUSION

The importance of advance and thorough preparation for addressing an aviation crisis cannot be overstated, as it will help a company deal with adversity if and when the real event occurs. Corporate executives and their in-house teams should not face such an extraordinarily stressful event alone or unprepared; there are many resources available to help put together an effective crisis management plan. Thought and deliberate action must be taken in implementing it, however, since good intentions alone will not suffice. Don't be caught unprepared. ■

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[1] Jones Day's multidisciplinary Product Recall & Accident Response team assists clients who have questions, concerns, or problems related to product recalls, as well as governmental civil and criminal investigations into product safety, both in the United States and around the globe. For more information, *see* http://www.jonesday.com/product__recall__accident__response, or contact Dana Baiocco at dbaiocco@jonesday.com.

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[11] *See generally*, *e.g.*, Clifton T. Hutchinson, "*Daubert* in State Courts," 9 *Kansas Journal of Law & Public Policy* 15 (1999).

[12] *Daubert*, 509 U.S. at 592–93.

[13] *See* Samuel J. McNaughton, "What is Good Science?" 13 *Natural Resources & Environment* 513, 518 (1999).

[14] Kennedy & Martin, *California Expert Witness Guide* § 4.15, at 56 (2d ed. 1999).

[15] David Faigman *et al*., *Modern Scientific Evidence* § 35-1.3, at 150–51 (2d ed. 2002).

[16] *Daubert*, 509 U.S. at 588.

[17] Paul M. Barrett, "Justices Rule Against Business in Evidence Case—Restrictive Standard for Use of Scientific Testimony in Trials Is Struck Down," *Wall Street Journal*, June 29, 1993, at A3.

[18] *See* C. Robert Showalter, "Distinguishing Science From Pseudo-Science in Psychiatry: Expert Testimony in the Post-*Daubert* Era," 2 *Virginia Journal of Social Policy & the Law* 211, 219 (1995) ("Legal commentators generally view … *Daubert* as a 'plaintiff's victory' "); *see also generally Joiner*, 522 U.S. at 142 ("[T]he Federal Rules of Evidence allow district courts to admit a somewhat broader range of scientific testimony than would have been admissible under *Frye*.").

[19] *See* Jonathan Hoffman, "A Briefcase and an Opinion: Post-*Daubert* Expert Testimony—A Major Shift," *Product Safety & Liability Reporter* 379 (Apr. 8, 1994).

[20] *See* D. Michael Risinger, "Navigating Expert Reliability: Are Criminal Standards of Certainty Being Left on the Dock?" 64 *Albany Law Review* 99, 104 (2000).

[21] *See id*. at 108.

[22] Berger & Twerski, "Uncertainty and Informed Choice: Unmasking *Daubert*," 104 *Michigan Law Review* 257, 258, 288 (2005).

[23] *See also* Paul C. Giannelli, "Admissibility of Scientific Evidence," 28 *Oklahoma City University Law Review* 1, 11 (2003) (finding that *Daubert* has "crept into the *Frye* lexicon").

[24] *See* Sophia I. Gatowski *et al*., "Asking the Gatekeepers: A National Survey of Judges on Judging Expert Evidence in a Post-*Daubert* World," 25 *Law and Human Behavior* 433, 444–48, 452–53 (2001).

[25] *See* Jennifer L. Groscup *et al*., "The Effects of *Daubert* on the Admissibility of Expert Testimony in State and Federal Criminal Cases," 8 *Psychology, Public Policy, and Law* 339, 342, 344 (2002).

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