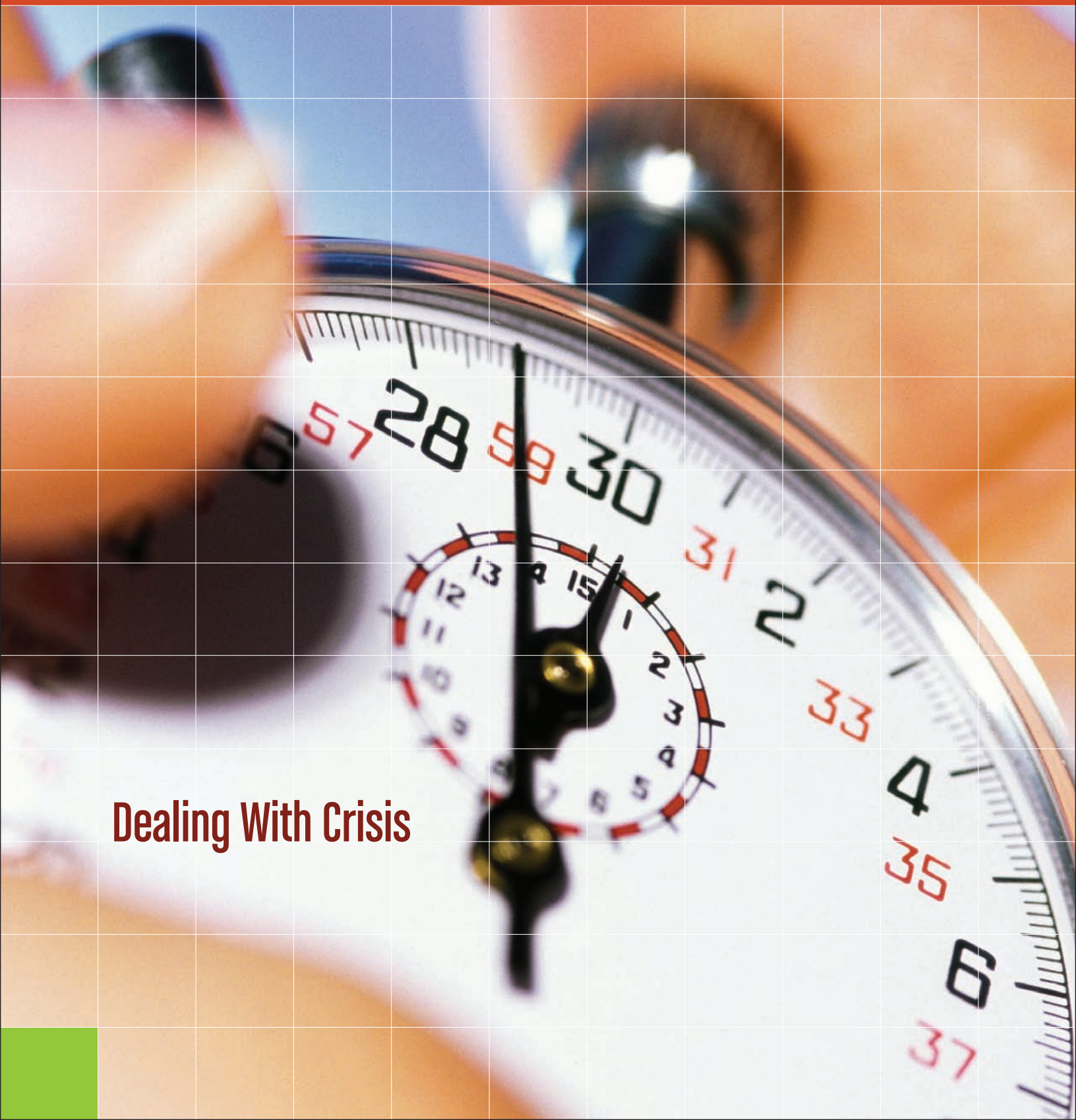
JONES DAY

PRACTICE PERSPECTIVES: PRODUCT LIABILITY & TORT LITIGATION



Dealing With Crisis

letter from the practice chair

This issue of *Practice Perspectives: Product Liability & Tort Litigation* focuses on our experience in dealing with unforeseen and unexpected business crises involving products. Viewed against the backdrop of international trade, electronically stored information, government regulations, and media hype, what used to be basic consumer product issues now have the potential to engulf a company in a multifaceted, and global, legal crisis.

The articles in this edition address a variety of potential crises, whether the cause is an accident involving a product, a change in the law, a marketing decision that unwittingly runs afoul of federal regulations, or a verdict awarding economic or punitive damages. When crisis strikes, we recognize that our role is much broader than crafting winning legal points that eventually may become part of some dusty legal reporter or dry legal treatise. Oftentimes, our most significant role is to assist clients in quickly and efficiently framing their response to the crisis, so as to minimize damage to their reputation while keeping an eye on long-range strategic business issues. In these articles, we strive to provide you with a balanced approach—identifying legal issues you may encounter, without losing sight of your need for practical solutions that business realities demand. The common thread is coordinated management of the crisis, regardless of what legal issues may arise.

As we learn daily, the Information Age threatens to engulf us. The internet distributes news and perpetuates urban legends, frequently before the subject of the news or legend is aware that its actions were "newsworthy." A well-meaning email chain among friends warning of tainted consumer goods can undo in one day the consumer perceptions that took years and millions of marketing dollars to create. Questions abound as to how to confirm or deny the accuracy of the information, how to publicize correct

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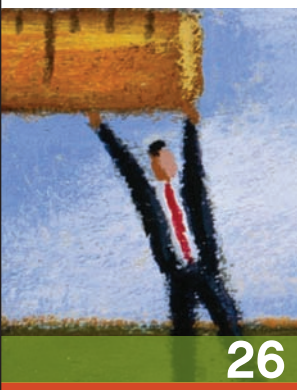

THE PRODUCT CRISIS: STAYING AHEAD BY PLANNING AHEAD

by Sean P. Costello and Kathryn A. Furfari

Product "crises" have gotten bigger, more expensive, and more complex with each passing year. They are the subject of media attention, regulatory scrutiny, political grandstanding, and, of course, lawsuits by class-action plaintiffs' lawyers.

A product crisis can take many forms, from product recalls necessitated by real or claimed defects in the product design or manufacturing process to hoaxes and rumors concocted by criminals and miscreants. The fact that the internet has now become a staple of modern life means that claims—both true and untrue—about a company's products spread rapidly. Every company, therefore, must contemplate the risk that it will one day face a product crisis, no matter how fastidious its design and manufacturing processes. And every company must have a plan for dealing with the crisis should that risk materialize. Having a plan in place *before* the crisis strikes is key to a company's ability to emerge from the crisis successfully.

PRODUCT CRISES TAKE MANY FORMS

Recently, product recalls, many relating to food, have been the subject of intense media, regulatory, and legal scrutiny. Westland/Hallmark recently undertook the largest meat recall in history—143 million pounds of beef—because the company's employees purportedly violated federal rules by butchering sick cattle. Last year, Menu Foods recalled 60 million cans of pet food after wheat gluten in its products was linked to pet deaths across the nation, resulting in a public relations and legal nightmare. That recall reportedly cost $56 million. Food-related recalls shared the spotlight with consumer product recalls, particularly those for children's toys that were made in China or contained parts made in China. A visit to the Consumer Product Safety Commission's web site (http://www.cpsc.gov) reveals numerous product recalls, from infant cribs to snowmobiles. As sure as night follows day, civil litigation followed (or, in some cases, may have preceded) the announcement of many of these recalls.

Product recalls due to alleged defects in design or manufacturing processes have not been the exclusive source of product crises. Over the past several decades, many well-respected companies have fallen victim to phantom crises, urban legends, hoaxes, and even criminal product tampering whose apparent purpose was to damage a company or its brands. The textbook example is the Tylenol tampering scare in 1982, when criminals injected Tylenol capsules with cyanide, which resulted in the deaths of several people. At the time, Tylenol, made by Johnson & Johnson, was one of the most respected brands in the world, and the over-the-counter pain-killer was a major contributor to Johnson & Johnson's profits, responsible for nearly 20 percent of the company's profits in 1981. Ian Mitroff, *Managing Crises Before They Happen* 13–14 (2001). Johnson & Johnson's reaction to this tragedy and crisis is offered as a case study in how a company *should* react in crisis situations. The company got out in front of the issue. Johnson & Johnson made clear that its sole concern was public safety, not protecting short-term profits. It immediately began working with the Food and Drug Administration ("FDA") to recall the lots from which the poisoned capsules had come. It engaged in a public relations campaign to both inform and reassure the public, and its CEO was front and center during that campaign. *Id.* at 16. Remarkably, the company even ignored the advice of the FDA and recalled *all* of its Tylenol bottles worldwide—about 31 million bottles—at a cost of $100 million. *Id.* The FDA, along with the FBI, had urged a more limited recall to protect against copycats. *Id.* Ultimately, changes were made to the way off-the-shelf medications are packaged to prevent such tampering. Johnson & Johnson suffered short-term damage, but it emerged triumphant, having regained public trust and, ultimately,

Having a plan in place before the crisis strikes is key to a company's ability to emerge from the crisis successfully.

its dominant market position. Today, Tylenol has the largest market share of any over-the-counter pain reliever. *Id.* at 17.

Another famous example of a product crisis caused by external forces is the Diet Pepsi "syringe in the can" urban legend in 1993, in which some individuals falsely claimed to have found syringes in their cans of Diet Pepsi. There, Pepsi took an approach that differed from Johnson & Johnson's a decade before. The company thoroughly investigated the matter and embarked on an aggressive public relations campaign aimed at demonstrating that there was no truth to the rumor. Its aggressive approach, executed to perfection, worked. The company publicly exposed the rumors as fiction and protected one of its leading brands from permanent damage.

The Diet Pepsi incident happened before the internet had become the real-time rumor mill it is today. Today, the World Wide Web allows for even greater mischief and more immediate threats to product manufacturers of all stripes. In 2005, for instance, a Nevada woman claimed that she had found a severed finger in a bowl of Wendy's chili, which attracted nationwide media attention and threatened consumer confidence in the popular restaurant chain. This "urban legend" spread like wildfire, thanks largely to the internet, where bloggers, chatters, and online rumormongers exploited and bolstered the claim, giving the impression that it was true simply because it was ubiquitous. As with the Diet Pepsi episode a decade before, the claim was demonstrably false, but it was not exposed as a falsehood before doing economic harm to Wendy's. According to media reports, Wendy's lost $2.5 million as a result of the claim, the copycat claims that followed, and the attendant bad publicity. The woman who made the claim recently was sentenced to 12 years in prison for attempted grand larceny and other charges, based on her false claim.

THE VIRAL PRODUCT CRISIS

The internet—and the speed with which it allows information and misinformation to make their way across states, countries, and continents—means that a potential product crisis can become a real crisis in almost no time. More than 70 percent of U.S. adults use the internet at least occasionally. It is not surprising that a recent Harris poll found that 80 percent of U.S. adults were aware of recent recalls and that 50 percent of those surveyed said that they would switch brands—at least temporarily—in response to a recall. "Consumer Concern Over Product Recalls High," Harris Poll #53 (June 12, 2007).

Moreover, most companies sell not just in the U.S. but abroad as well. With internet usage numbers comparable in Europe and other industrialized countries, any company that sells products outside the U.S. may face a crisis that is not just domestic but international in scope, within hours of the first internet- or other media-generated rumor. In today's cyber-parlance, the rumors "go viral"—that is, they spread ferociously, at a speed that would not even have been contemplated a generation ago. Once that happens, the company is on the fast track to a product crisis.

Before the next potential product crisis "goes viral," becomes the subject of the blogosphere, winds up on CNN, and spawns class-action litigation, every company should have a product crisis plan in place. Scrambling to piece together a plan after a crisis starts makes no more sense than conducting business without a budget.

PLANNING FOR PRODUCT CRISES: ONE SIZE DOES NOT FIT ALL

Product crises are obviously a risk factor for every company doing business, and the threat of a viral product crisis must be taken seriously. Even the most careful and fastidious company cannot completely control the risk that it will one day be the subject of an online hoax or the victim of criminal actions designed to harm it and its most important brands. While preventing crises may be next to impossible—they are bound to happen, whether due to external or internal causes—having an effective plan will help a company recover faster and minimize damage to its reputation and bottom line.

There is no one-size-fits-all plan for dealing with product crises. Every company is uniquely situated, and every company must tailor its plan to its particular situation. A company that sells products around the world will not have the same plan as a company that sells its products only in the United States or a region of the United States. A company that makes products composed of parts from foreign suppliers will not have the same plan as a company that makes all of the component parts itself. Offered here are guidelines and considerations, not prescriptions.

THE THREE Cs: CAUTION, COMMUNICATION, AND COORDINATION

Every successful plan should be premised on the three Cs: caution, communication, and coordination. A company's plan must include measures and processes for exercising caution, communicating effectively, and coordinating both internally and with the third parties engaged in guiding the company through the crisis.

Caution. Exercising caution means avoiding rash or hasty decisions, to the extent circumstances permit. Once a course of action for dealing with a product crisis is undertaken, it is difficult to change. Caution, therefore, dictates that the company carefully consider the appropriate response to the crisis before it starts communicating with the various stakeholders, who may include regulators, politicians, consumers, and lawyers. Has the company investigated the problem thoroughly? Is the problem due to internal or external causes? Is there a chance that the company is responsible, or did third parties create or invent the problem? Is the company going to take an aggressive approach and try to show that the claims about its product are false, as in the Diet Pepsi and Wendy's examples? Or is the company going to engage in public contrition and do all it can to ensure that its customers are protected and that the problem is eliminated, as in the Tylenol example?

In other words, before the company starts talking about the crisis, it must have a firm grasp on what kind of crisis it is dealing with and, based on that, what course of action it will take. Time is of the essence. There will be no time for months-long investigations before the company has to start talking to the public, regulators, politicians, and opposing lawyers.

Ultimately, caution is not so much a stand-alone consideration as an important part of effective communication and coordination.

Communication. Once the company understands, first, what sort of potential crisis it is facing (internal or external; real or hoax) and, second, how it intends to approach the crisis, it must communicate its message to the various stakeholders. As one public relations consultant has explained, "Crisis management is storytelling." Eric Dezenhall, *Damage Control: Why Everything You Know About Crisis Management Is Wrong* 4 (2007). A good story cannot be told unless it is communicated effectively. And effective communication has many components.

First and foremost, the company employees who will have some role in dealing with the product crisis must know what message they are to communicate. Second, the company must communicate that precise message, and must do so consistently. To that end, the company should generally have one of its senior officers serve as the face and voice of the company. Usually, that should be the CEO, or at least the executive in charge of the business unit that makes the product in question and who has the authority to make decisions about the course of the company's reaction, including whether to recall and to what extent (tempered, obviously, by obligations imposed by the regulatory agency with authority over the recall). *See id.* at 4. In the Tylenol tampering case, Johnson & Johnson's CEO, James Burke, was the "face" of the company.

In addition, if the company must communicate with audiences in different countries, it should take care to tailor its communications to account for language and cultural differences, not to mention differences in the governing regulatory and legal regimes. Effective communication in the United States may not be effective communication in another country. This issue requires careful thought well before a crisis looms.

A public relations consultant should be used to help guide the company's response, fine-tune the message it wants to communicate, and evaluate the best media for communicating its message. But the company should not cede control over its message or where and how the message is delivered to the consultant. The consultant's advice must be taken with a grain of salt. There is a tendency among public relations consultants to want to talk to the media, no matter what. Sometimes, however, it is better to say less and to say it less often. As one public relations consultant put it, "The advice crisis consultants give is often designed to benefit the consultant, not the client." Dezenhall, *Damage Control,* at 2.

Coordination. There are a lot of moving parts in any potential product crisis. The company must deal with its customers and investors, interact with lawyers filing or threatening claims, respond to media inquiries, and deal with a host of other stakeholders and interested parties. The company must coordinate its interactions with these stakeholders, constituents, and interested parties. You do not want the company's lawyers filing pleadings and briefs in court that are

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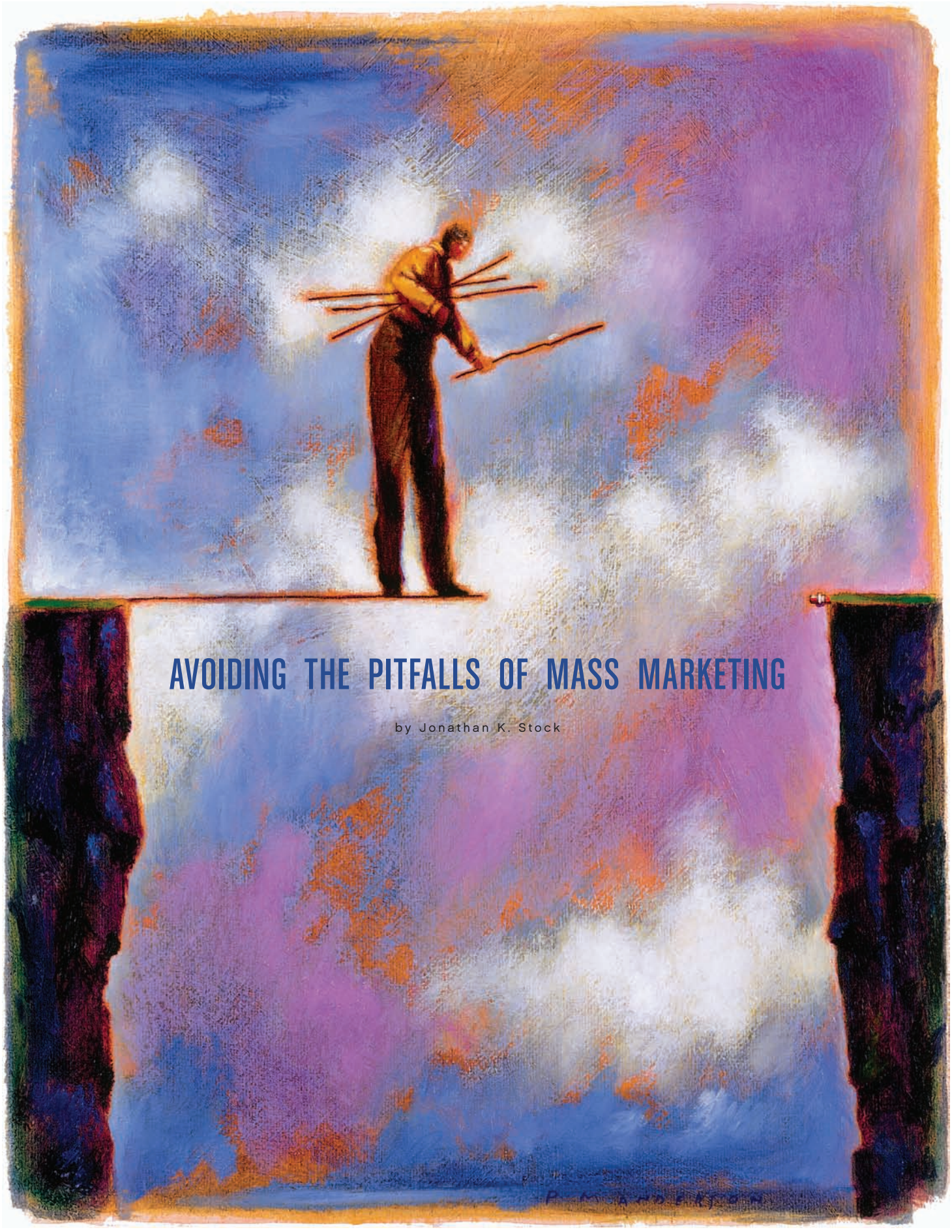

AVOIDING THE PITFALLS OF MASS MARKETING

by Jonathan K. Stock

o matter how great a company's product or service, promoting that product or service to customers can be essential. Many businesses depend upon mass marketing to achieve this objective. Often, unbeknownst to those businesses, the mass-marketing campaigns performed on their behalf ignore federal laws and regulations.

While it may be tempting to leave advertising decisions to an advertising agency or in-house marketing department, the pitfalls from a mistake in mass marketing have become increasingly apparent. An advertising campaign that violates one of the myriad laws and regulations governing mass marketing can turn a single bad decision into literally thousands of statutory violations. Those violations can threaten crippling liability when harnessed to a class action seeking statutory damages or subjected to an enforcement action by a federal agency. To avoid those mistakes, it is critical for businesses to understand and seek guidance on the laws governing mass marketing before they simply sign off on the next advertising campaign.

Over the past several decades, mass marketing has undergone a revolution driven by technology. The old methods of mass marketing (*i.e.*, mail, newspaper advertisements, signage, and in-person solicitation, etc.) are still available but have been increasingly pushed aside. Newer methods (*i.e.*, email, faxing, and telemarketing) have gained in prominence. These newer methods are often more attractive to businesses because they reach more customers at a reduced cost.

Congress has tried to keep pace with these changes in technology by imposing limits on mass marketing. Federal laws now govern commercial advertisements sent via email, fax, and telephone. The CAN-SPAM Act (Controlling the Assault of Non-Solicited Pornography and Marketing Act, 15 U.S.C. § 7701 *et seq.*) regulates the transmission of commercial email. The TCPA (Telephone Consumer Protection Act, 47 U.S.C. § 227) does the same for commercial fax advertising and telemarketing. For telemarketing, the Federal Trade Commission ("FTC") has also played an important role, by adopting the TSR (Telemarketing Sales Rule, 16 C.F.R. § 310), which is the regulation that enforces the Do Not Call Registry. Complying with these federal laws and regulations is essential for any mass marketer.

COMPLYING WITH THE TCPA FOR FAXING

Faxing is a common method of business-to-business communication that initially had some appeal for mass marketing. That appeal, however, waned considerably when plaintiffs began enforcing the TCPA. The TCPA makes it unlawful for any person "to use any telephone facsimile machine, computer, or other device to send, to a telephone facsimile machine, an unsolicited advertisement." 47 U.S.C. § 227(b)(1)(C). An important exception to this rule occurs if the sender has "an established business relationship with the recipient," obtained the recipient's fax number in an appropriate and voluntary fashion, and provided the recipient with the opt-out notice required by the Act. *Id*. at §§ 227(b)(1)(C) and (b)(2)(D).

For faxes that do not qualify for the exception, the TCPA imposes a broad ban on unsolicited advertisements. An unsolicited advertisement includes "any material advertising the commercial availability or quality of any property, goods, or services which is transmitted to any person without that person's prior express invitation or permission, in writing or otherwise." *Id*. at § 227(a)(5). Thus, the burden is on the fax sender to have the recipient's "prior express invitation or permission" before sending a fax.

What it means to have the recipient's "prior express invitation or permission" to send a fax has long been the subject of considerable debate. Written permission, though not required, provides a clear and well-documented expression of consent, but it is often impractical for businesses to obtain it. The Federal Communications Commission ("FCC") has offered further guidance on how to obtain a customer's prior express invitation or permission:

> In the absence of an EBR [established business relationship], the sender must obtain the prior express invitation or permission from the consumer before sending the facsimile advertisement. Prior express invitation or permission may be given by oral or written means, including electronic methods. We expect that written permission will take many forms, including e-mail, facsimile, and internet form. Whether given orally or in writing, prior express invitation or permission must be express, must be given prior to the sending of any facsimile advertisements, and must include the facsimile number to which such advertisements may be sent. It cannot be in the form of a "negative option" [*i.e.*, a fax asking the recipient to call and request not to receive any further faxes]. However, a company that requests a fax number on an application form could include a clear statement indicating that, by providing such fax number, the individual or business agrees to receive facsimile advertisements from that company or organization.

See Rules and Regulations Implementing the Telephone Consumer Protection Act of 1991, Junk Fax Prevention Act of 2005, CG Docket Nos. 02-278 and 05-338, FCC 06-42 (released Apr. 5, 2006) (Report and Order) at ¶ 45. Because any form of permission obtained by a fax sender may later be challenged in court, the sender should document the express permission that it received and follow policies and practices for fax advertising that are consistent with the customer's consent.

As noted above, the established business relationship is a critical exception to the statute's requirement for fax senders to have the recipient's express invitation or permission to send faxes. The importance of the exception is reflected in the TCPA's history of enforcement. For mass marketing conducted prior to the 2005 amendment, businesses were sometimes being sued for sending faxes to their own customers. To put a stop to this abusive practice, Congress amended the TCPA in 2005 to confirm that the TCPA permits fax senders to send faxes to recipients with whom they have an established business relationship. The FCC defines "established business relationship" as "a prior or existing relationship formed by a voluntary two-way communication between a person or entity and a business or residential subscriber with or without an exchange of consideration, on the basis of an inquiry, application, purchase or transaction" regarding the advertiser's products or services as long as the "relationship has not been previously terminated by either party." *Id.* at ¶ 18. This is ultimately good news for mass marketers because "a sender that has an EBR with a customer may send a facsimile advertisement to that customer without obtaining separate permission from him." *Id.* at ¶ 45.

The enforcement of the TCPA has both a public and private component. Actions can be brought by the FCC, state attorneys general, or private individuals. Enforcement actions by private individuals can seek injunctive relief and an award of $500 per unsolicited fax (or up to $1,500 if the defendant "willfully or knowingly" violated the Act). 47 U.S.C. § 227(b)(3). Actions by state attorneys general can seek the same relief on behalf of the state's residents. *Id.* at § 227(f)(1). The FCC may also assess a forfeiture of up to $11,000 for each violation of the TCPA.

The FCC remains an active enforcer of the TCPA, and a list of its recent enforcement actions appears on its web site. In a Forfeiture Order issued last March, the FCC fined The Hot Lead Company $2,591,500 for "willful or repeated violations" of the TCPA "by delivering at least 417 unsolicited advertisements to the telephone facsimile machines of at least 149 consumers." *See In re The Hot Lead LLC d/b/a The Hot Lead Company*, File No. EB 06-TC-120 (Forfeiture Order, adopted Mar. 14, 2008).

Individual fax recipients have also filed class actions seeking millions of dollars in damages for fax advertising campaigns that have supposedly gone awry. A list identifying several hundred of those TCPA class actions can be found at http://www.tcpalaw.com/free/cases.htm.[1] While very few TCPA class actions have gone to trial, a number have resulted in significant settlements. Two examples of those settlements over the past year are *Mey v. Herbalife International, Inc. et al.*, Case No. 01-C-263 (Cir. Court of Ohio Cty., W. Va.), a TCPA class action settled for $7 million, and *Derose Corp. v. Goyke Health Center, P.C.*, Case No. 06 CH 6681 (Circuit Court of Cook Cty., Ill.), an Illinois TCPA case styled as a class action settled from insurance proceeds for $4 million.

What is particularly ironic about the wave of TCPA class actions is that the TCPA's statutory-damage award was originally intended to permit individual plaintiffs to recover

damages without being represented by counsel. As former Senator Fritz Hollings (D-SC), the TCPA's sponsor, explained, "Small claims court or a similar court would allow the consumer to appear before the court without an attorney. The amount of damages in this legislation [$500 per violation] is set to be fair to both the consumer and the telemarketer." 137 Cong. Rec. S16205 (Nov. 7, 1991); *see also* 41 U.S.C. § 227(b)(3)(B). Those individual cases now play a relatively small role in private enforcement.

The trend toward filing TCPA class actions began with the decision issued in *Nicholson v. Hooters of Augusta*, Case No. 95-RCCV-616 (Ga. Sup. Ct. Apr. 25, 2001), which awarded just under $12 million in damages to 1,321 class members who each received six unsolicited fax advertisements. Since then, a small cottage industry has developed that has been supported by TCPA plaintiffs who have filed class actions against some of America's best-known companies, including Wal-Mart and the Dallas Cowboys.

What makes these suits dangerous is the toxic combination of statutory damages (assessing $500 per violation, or up to $1,500 if the violation is willful) and the large numbers of fax advertisements typically sent in a mass-marketing campaign. Highlighting this point, one suit filed against a fax broadcaster sought an eye-opening $2.2 trillion in damages. *Kirsch v. Fax.com, Inc.*, Case No. CV810516 (Santa Clara Cty. Cal. Super.) (filed Aug. 22, 2002). While Congress in 2005 stepped in to amend the TCPA and make clear that businesses are allowed to send faxes to customers with whom they have an established business relationship, plaintiffs have continued to file TCPA class actions, and businesses engaged in mass marketing should remain wary.

COMPLYING WITH THE TCPA AND TSR FOR TELEMARKETING

The principal restrictions on telemarketing come from the TCPA and the Telemarketing Sales Rule, or TSR. The TCPA prohibits certain telemarketing practices, including:

(1) The use of an automatic dialing system or prerecorded voice to make sales calls to emergency phone lines, medical offices, hospital rooms, homes for the elderly, paging services, or cellular phones. 47 U.S.C. § 227(b)(1)(A)(i)–(iii);

(2) The use of artificial or prerecorded voice telemarketing, except where there is an emergency or the call recipient gives prior consent. 47 U.S.C. § 227(b)(1)(B); and

(3) The use of an automatic dialing system that occupies two or more telephone lines of a single business simultaneously. 47 U.S.C. § 227(b)(1)(D).

In addition, the FCC requires a person or entity placing telemarketing calls to keep a record of residential phone numbers for all persons who have asked not to receive further telemarketing calls from that person or entity. That record must be maintained for at least five years.

The TCPA provides the same menu of enforcement options for telemarketing violations as for unsolicited fax advertising. It creates a private right of action for individuals to seek injunctive relief or damages in court of up to $500 per violation, or $1,500 if the telemarketer "knowingly" or "willfully" violated the Act. 47 U.S.C. § 227(b)(3). Enforcement actions seeking the same relief can also be brought by state attorneys general. *See* 47 U.S.C. § 227(f)(1). Likewise, the FCC may assess penalties of up to $11,000 per violation against parties that violate the TCPA.

The TSR is best known as the regulation enforcing the Do Not Call ("DNC") Registry. It was promulgated by the FTC under the Telemarketing and Consumer Fraud and Abuse Prevention Act (15 U.S.C. §§ 6101–6108). 16 C.F.R. § 310.4(b)(iii)(B). The DNC Registry is a list of telephone numbers to which unsolicited telemarketing calls are generally prohibited. *Id.* The DNC Registry has grown from its inception to include more than 145 million telephone numbers. *See* "Notice of Proposed Rulemaking" by FCC at 3 (released Dec. 4, 2007).

There are a few important exceptions that permit calls to numbers on the DNC Registry. The DNC Registry does not prohibit calls to persons with whom the seller has an established business relationship. 16 C.F.R. § 310.4(b)(iii)(B)(ii). In addition, telemarketing calls are permitted to persons who register their telephone numbers with the DNC Registry but have nonetheless provided the seller with their express written consent to be contacted. 16 C.F.R. § 310.4(b)(iii)(B)(i). In most instances, calls to businesses are also exempt from the TSR's regulations. 16 C.F.R. § 310.6(b)(7). There is also a safe harbor if a call is inadvertently made to a number on the DNC

Registry, as long as the telemarketer can show that it otherwise routinely complies with the TSR.[2]

In addition to the Registry, the TSR includes other noteworthy restrictions. Telemarketers must disclose upfront the name of the seller and the fact that the call is being made for sales purposes. For a transaction, telemarketers must disclose the total amount of the sale, any restrictions on the sale, and whether there is a refund policy. Additional disclosures are required for sweepstakes telemarketing, including the fact that no purchase is necessary in order to participate, the odds of winning, and any cost associated with participation. Telemarketing should not be conducted before 8 a.m. or after 9 p.m. in the recipient's time zone. Telemarketers must obtain "express verifiable authorization" before engaging in certain transactions, such as taking a draft directly from a bank account. Telemarketers must also maintain certain records related to their activities.

The consequences of violating the TSR are significant. A violator can be subject to fines of up to $11,000 per telemarketing call in violation of the rule and can be enjoined from committing further violations.[3] In addition to regulatory actions, the TSR authorizes enforcement actions by state attorneys general and private individuals.[4]

Businesses that engage in telemarketing should keep in mind that telemarketing restrictions are not uniform. Many states have independent state laws regulating telemarketing or maintain their own do-not-call lists. The TSR makes clear that those state laws are not preempted.[5] Likewise, the TCPA does not generally preempt state laws, but instead expressly permits state laws that "impose[] more restrictive intrastate requirements." 47 U.S.C. § 227(e)(1). As a result, state laws can and do impose additional and overlapping restrictions on telemarketing and fax advertising.

COMPLYING WITH THE CAN-SPAM ACT FOR EMAIL

Before the CAN-SPAM Act, the rapid expansion of email marketing resulted in a host of overlapping and conflicting state-law restrictions. State governments passed laws in an effort to stem the tide of billions of spam emails that cost recipients in time, productivity, resources, and equipment. Every year, businesses and consumers spend considerable resources on anti-spam software alone. According to recent estimates,

An advertising campaign that violates one of the myriad laws and regulations governing mass marketing can turn a single bad decision into literally thousands of statutory violations.

more than 180 billion emails are sent every day, and spam email now accounts for up to 95 percent of all email transmitted. *See* "Email and webmail statistics," by Mark Brownlow (Apr. 2008) (http://www.email-marketing-reports.com/metrics/email-statistics.htm) (a study by The Radicati Group from October 2006 estimated the number of emails sent per day in 2006 to be around 183 billion); "Study: 95 percent of all e-mail sent in 2007 was spam," by Matt Asay (Dec. 12, 2007) (http://www.cnet.com/8301-13505_1-9831556-16.html). Against this backdrop, the CAN-SPAM Act has established a uniform standard for commercial email.

The CAN-SPAM Act, which became effective in 2004, preempted a patchwork of preexisting state laws, replacing those laws with a national standard governing commercial email. State laws still play an important role governing false

and deceptive advertising, but the CAN-SPAM Act covers the rest of the spectrum for commercial email. The CAN-SPAM Act regulates the transmission of commercial emails but does not prohibit them. An email qualifies as a commercial email subject to the Act if its "primary purpose" is a commercial advertisement.

The CAN-SPAM Act prohibits a sender of commercial email from using false information and deceptive subject lines. In each email, senders must include a "from" line that accurately identifies the sender of the email, along with a valid physical postal address. Moreover, they may not use another person's email or computer account to send commercial email. Senders must also clearly and conspicuously identify unsolicited commercial email as advertisements or solicitations, and they must include a warning label on unsolicited commercial email containing sexually oriented material. Each commercial email must also contain a clear and conspicuous notice to recipients of their opportunity to unsubscribe from future mailings, using a method that will remain operational for 30 days after the email is sent. The sender must stop sending emails to recipients within 10 business days of receiving the opt-out request. Finally, senders are prohibited from using automated means to harvest email addresses from web sites or online service providers that have policies of not sharing email addresses, and they cannot use automated means to register for multiple email accounts to be used to send spam.

Enforcement of the CAN-SPAM Act includes both a public and a private component. The Act permits enforcement actions by the FTC, state attorneys general, and providers of internet access services, commonly called "ISPs." As with the TCPA, the FTC can levy fines for violations of the CAN-SPAM Act of up to $11,000 per violation.[6] A state attorney general may sue on behalf of the state's residents, seeking an injunction or statutory damages for the actual loss suffered by the state's residents or up to $250 per violation, whichever amount is greater. Damages generally may not exceed $2 million, although that amount may be trebled for a knowing and willful violation. The damages available to ISPs suing under the Act are slightly different. ISPs can sue both the sender of the email and the business advertising its wares (if different from the sender) for up to $25 per violation or, if the header information on the email is false or misleading, up to $100 per violation. Damages are generally capped at $1 million, although a court can treble that amount if the sender knowingly or willfully violated the CAN-SPAM Act. For enforcement actions by either state attorneys general or ISPs, the damage caps are lifted if the header information on the email is false or misleading.

The CAN-SPAM Act's broad definition of "ISP" has left the door open for many businesses, including non-internet-based businesses, to consider enforcement actions. An ISP eligible to sue includes providers of "Internet access services adversely affected by a violation."[7] (An "Internet access service" is "a service that enables users to access content, information, electronic mail, or other services offered over the Internet.") While this definition would certainly include well-known ISPs such as AOL and EarthLink, it could also include businesses that provide internet service to their employees. As one staff attorney for the FTC remarked, businesses providing internet services to employees may qualify as ISPs under the CAN-SPAM Act and therefore have the right to sue email advertisers impinging upon those internet services.[8] If businesses begin to take a more active role in enforcement, the impact could be significant. A single email sent to each employee of a 10,000-employee company could trigger a $1 million violation of the CAN-SPAM Act.

To date, relatively few private lawsuits have been filed under the CAN-SPAM Act. One recent case filed by social networking giant MySpace made headlines when the company obtained a $230 million judgment against "Spam King" Sanford Wallace and his partner, Walter Rines. *See* "MySpace Wins $230 Million From 'Spam King' Wallace," by Stefanie Hoffman, *ChannelWeb* (May 14, 2008) (http://www.crn.com/security/207800154). Yet enforcement actions like the one brought by MySpace are infrequent. This result can be attributed, at least in part, to the CAN-SPAM Act's relatively narrow private right of action. While ISPs have the right to sue, individual email recipients do not. Moreover, the willingness of ISPs to undertake such enforcement is tempered by the difficulty some ISPs have had in collecting judgments. *See* "AOL gives up treasure hunt," by Jay Fitzgerald, *Boston Herald* (July 24, 2007) (discussing the disappearance of a spammer who owed AOL for a $12.8 million judgment). Private enforcement of the CAN-SPAM Act could improve if more businesses realize that they are eligible to sue as ISPs and act to stem the tide of commercial emails violating the Act.

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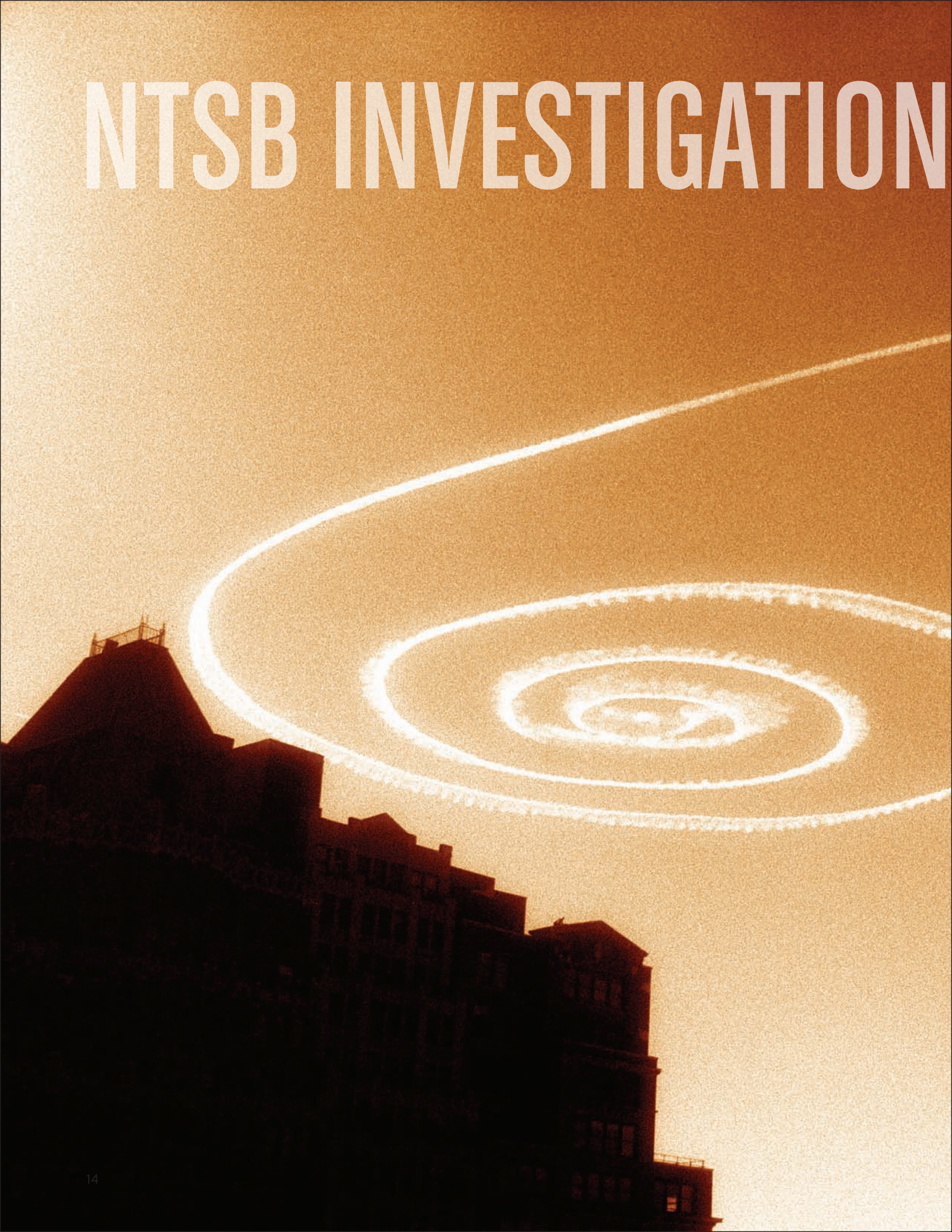
NTSB INVESTIGATION



S: THE INS AND OUTS

by John D. Goetz

Early one Sunday morning, the president of ABC Manufacturing Company is awakened by a frantic call from the vice president of engineering. Hours earlier, an airliner containing the company's newly designed computer avionics equipment crashed in a remote area in bad weather. Initial media stories have blamed the accident on a failure of the plane's electronic systems. Local law enforcement officials, in a press conference, have demanded accountability and a full investigation.

The company has been contacted by the National Transportation Safety Board (the "NTSB" or "Board") for technical assistance immediately at the scene. The vice president asks several questions: Should the company agree to participate? Will it help or hurt the company to assist the NTSB? Will it make litigation more likely? What should the company be prepared to face, and can it protect itself?

THE NTSB INVESTIGATION PROCESS

The NTSB conducts independent investigations of all civil aviation accidents in the United States and also major accidents involving rail, highway, and marine transportation and pipelines. When the Board is first notified of a major accident, it quickly assembles and dispatches a "Go Team" to the accident site.[1] While the Go Team may vary in size, depending on the severity of the accident and the complexity of the issues, the NTSB has two goals: to begin the investigation as quickly as possible and to assemble a broad spectrum of technical expertise to determine exactly what happened.

The Go Team is coordinated by an investigator-in-charge, a career NTSB employee with years of investigation experience. As many as 14 specialties may be

represented, in areas such as aircraft operations, airframe structures, aircraft systems, power plants, human performance factors, piloting, fire and explosion, meteorology, radar data, event recorders, air traffic control, and witness statements. Each specialist on the Go Team manages a group of individuals from government agencies and experts invited from private industry, in order to collect the facts and determine the circumstances surrounding the accident. These smaller teams are called "working groups."

The NTSB conducts investigations of major accidents according to procedures set forth in its *Investigation Manual*.[2] During the on-scene phase, one member of the Board conducts daily media briefings on the latest, confirmed factual information that has been developed. The working groups work on site, gathering facts, analyzing pieces of wreckage, reviewing records and data, taking measurements, and talking with witnesses. They work continuously and diligently, remaining at the accident scene as long as necessary to complete their designated areas of work. This can vary from several weeks to months. Some working-group members also travel to manufacturers' plants or to the NTSB's testing laboratories to complete tear-downs of key systems or parts or to conduct sophisticated analyses of the recorder tapes.

Each working group eventually prepares a factual report containing the information it has developed. Each member of the group must verify the report's accuracy. The Board also may hold public hearings to gather sworn testimony from witnesses, both voluntary and subpoenaed, and to allow the public to observe the investigation's progress.

After an investigation is completed, the NTSB staff prepares a draft final report. The report analyzes the investigative record in detail and identifies the probable cause(s) of the accident. Parties that have been invited to participate in the investigation, along with family members, can also submit proposed findings of cause to the Board for consideration. The Board then deliberates over the draft report and other submissions in closed session. A final report is completed and presented to the full Board for adoption at a public meeting. When the report is approved, an abstract containing the Board's conclusions, probable-cause determinations, and safety recommendation is placed on the Board's web site. The full report is posted shortly afterward.

THE PARTY-REPRESENTATIVES PROCESS

The NTSB is quick to recognize that product manufacturers have the most, and best, technical knowledge of the components on an aircraft. The Board, in its discretion, will therefore invite companies to be "parties" to accident investigations. When the Board designates a manufacturer to be a party representative, the company agrees to provide technical and specialized expertise regarding its system or component parts on the plane. The manufacturer essentially agrees to work for the Board during the investigation.

Each party representative must sign a "Statement of Party Representatives" form, pledging to work with the Board in a neutral, objective manner. Family members, insurance representatives, and attorneys are not permitted to be involved in an investigation. It is important to note that the company must also pledge that while information obtained may ultimately be used in litigation, the company's participation is not for the purpose of preparing for litigation.[3] The company also must agree not to assert any privilege in subsequent litigation with respect to information or documents that are obtained during the course of, and as a result of participation in, the NTSB investigation. This agreement, however, does *not* prevent a company or its employees who become party representatives from participating in subsequent litigation arising out of the accident. Nor does it require disclosure of a company's communications with counsel at any stage.

TIPS FOR PRODUCT MANUFACTURERS: BEING PART OF THE PROCESS

A company should quickly accept an invitation from the NTSB to be a party representative to an accident investigation. There is little downside, because being part of the process is far better than standing outside it. If a manufacturer becomes a party representative, it will learn relevant facts and information in "real time," as it is being developed. The company will have the opportunity to propose and review field notes created by its assigned working group[4] and to make comments on draft reports before they are finalized and become part of the public record. The company will see the process firsthand and won't have to wait months before learning the results of the Board's fact investigation. This can be extremely valuable later on, if plaintiffs' counsel in subsequent litigation give in to the temptation to mischaracterize the facts or contents of the accident report.

The benefits of participating in an NTSB investigation are so great that a company should be *proactive* in contacting the Board to offer assistance. A wise manufacturer will make its presence known to the Board and identify the products that it manufactured. Otherwise, it may be left out of the process and stuck with a lot of disagreements after reading the Board's final report—months or years after the incident.

After becoming party representatives, a company and its employees will want to pay close attention to how the investigation is being conducted. Who was involved in the recovery efforts? What measures were taken to preserve and document the physical evidence? What happened during each day or event, and what follow-up analysis was (or should have been) conducted? The company's team will want to have its eyes and ears open, to learn as much information as possible under the Board's direction and without interfering with the Board's essential and overriding function.

EARLY EXAMINATION OF COMPONENT PARTS

Companies also will want to examine their products at the earliest stage possible. Investigations may take years to resolve: recovery, handling, movement, shipping, and storage of wreckage can and do change the condition of sensitive component parts. Debris may be jarred or altered, parts and fragments may be lost, settings may change, data may be corrupted, and damage to parts may occur during human efforts to recover and analyze evidence. This may create the potential for plaintiffs' counsel to skew the record unfavorably in subsequent litigation, by making claims about the condition of products that were not true at the time of the accident.

A company should videotape any disassembly of its components, without audio. It should bring the very best cameras possible to photo-document its parts or any analysis or movement that occurs. Close-up photos should be taken to obtain fine detail. More photos and videotape should be taken than the company believes it will ever need, because wreckage and components may never be seen in the same condition again. It is critically important to preserve the moment carefully—and completely.

A company should ensure that measurements are taken of all critical areas and are memorialized in field notes. Draft notes should be meticulously reviewed before they are signed. Any comments that a company provides on draft field notes and reports should be purely factual in content. Opinions or speculation should not be offered. An ongoing investigation is simply the wrong time to offer conjecture or opinions beyond the narrow factual subject matter at hand.

A company's role in an NTSB investigation is thus to assist the NTSB fully and within the parameters of the party-representatives process. The manufacturer should also carefully document and photograph its products and participate fully in the process, to put itself in the best position to defend litigation if and when it comes.

ACCIDENTS OUTSIDE THE U.S.

International accidents present unique issues. The NTSB sends Go Teams to accidents that occur on U.S. territory or in international waters, but for accidents occurring outside the U.S., the lead investigator is the government in whose territory the crash occurred. The NTSB is generally invited to assist in these investigations abroad, especially if a U.S. carrier or U.S.-manufactured plane is involved. The NTSB will always choose to do so, and it will invite companies to participate as well. Obviously, however, the Board is a guest in another land, and it is not the lead.

International accident investigations require close, professional cooperation between representatives of different states.[5] Annex 13 of the International Civil Aviation Organization ("ICAO") outlines procedures and standards for accident investigations, and the *ICAO Manual of Aircraft Accident Investigation* contains technical information and examples of objective investigative techniques. In reality, however, language barriers and cultural differences can present major obstacles to a complete, objective investigation. Politics and a variety of local pressures, seen and unseen, can also threaten to impede or even influence the results of an investigation. Local media and authorities can create a highly charged atmosphere by rushing to judgment and loudly calling for criminal investigations and prosecutions.[6]

In addition, some countries lack experienced, professional investigators to recover and analyze evidence and to lead complicated investigations. Investigation teams may wind up working in isolation, and evidence and findings developed

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by John Q. Lewis, Pearson N. Bownas, and Matthew P. Silversten

THE REVERSE "READ AND HEED" CAUSATION PRESUMPTION: A PRESUMPTION THAT SHOULD BE GIVEN LITTLE HEED

Failure-to-warn claims in pharmaceutical and medical device litigation are under attack. Medical device manufacturers applauded the Supreme Court's landmark ruling in *Riegel v. Medtronic, Inc.*,[1] which held that state-law failure-to-warn claims involving medical devices approved through the FDA's premarket approval process are preempted. Next term, the Supreme Court will decide *Wyeth v. Levine* and pass on the viability of a similar failure-to-warn preemption defense for pharmaceutical manufacturers in cases involving FDA-approved prescription drugs. Combined, these two cases potentially affect, and may ultimately eliminate, a significant number of product liability failure-to-warn claims.

But a double victory will not end failure-to-warn claims altogether. *Riegel*, for instance, has no impact on the Supreme Court's decision in *Medtronic, Inc. v. Lohr*,[2] which found that certain failure-to-warn claims against medical devices approved through the FDA's "less rigorous" 510k approval process are not preempted. And some pundits expect that a favorable decision in *Levine* nonetheless will leave open the possibility for failure-to-warn claims in specifically defined cases involving pharmaceuticals.

For leftover failure-to-warn claims, the battleground is causation, *i.e.*, whether the alleged failure to warn proximately caused the plaintiff's injuries. Proving this element poses significant problems for plaintiffs. To survive summary judgment, they must offer evidence that, had the manufacturer given the "proper" warning, the plaintiff's injury would have been avoided. Because a failure-to-warn claim necessarily

involves a warning that was *not* given, plaintiffs must operate in a hypothetical Never-Never Land, in which their causation "evidence" often constitutes after-the-fact speculation that is properly disregarded.

Plaintiffs' difficulties are compounded by application of the learned intermediary doctrine, which has been adopted in most jurisdictions. That doctrine holds that manufacturers of prescription medical devices and pharmaceuticals have a duty to warn the physician, and not the patient, of any risks associated with use of the product. The doctrine is based, in part, on the longstanding principle that for decisions about prescription products, the physician is in the best position to counsel the patient. In failure-to-warn cases, application of this rule also means that plaintiff patients are not in control of their causation "evidence." Rather, the plaintiff must seek out testimony from the physician and hope that the testimony is not inconsistent with the plaintiff's causation theory.

To help plaintiffs' uphill causation battle, some courts hold that plaintiffs should be given a presumption of causation that essentially shifts the burden to defendants to disprove causation. But courts can reach such a result only by applying unreasonable and doctrinally inconsistent logic. Drug and device makers and their lawyers facing state-law failure-to-warn claims must be well armed to point out these flaws, make the proper arguments, and ultimately convince courts not to apply a causation presumption in a prescription product failure-to-warn case.

THE REVERSE "READ AND HEED" CAUSATION PRESUMPTION

This plaintiff-friendly causation presumption is rooted in a rule that is designed to benefit defendants. Section 402A of the Restatement (Second) of Torts imposes strict liability on manufacturers who sell "defective and unreasonably dangerous" products, including products that lack adequate warnings of dangers associated with their use. Comment j to that section states that when an adequate warning is given, the manufacturer "may reasonably assume that it will be read and heeded; and a product bearing such a warning, which is safe for use if it is followed, is not in defective condition, nor is it unreasonably dangerous." Some courts construe Comment j as creating a presumption, called the "read and heed" presumption. Thus, under Section 402A, defendants avoid liability entirely by showing that a warning is adequate. Defendants do not need to prove that the consumer actually read the adequate warning, as the rule presumes that an adequate warning will be read.

In failure-to-warn cases, plaintiffs routinely allege that defendants failed to provide an adequate warning to their physicians. To avoid actually proving causation, which, as shown, can be difficult, plaintiffs often argue for a *reverse* "read and heed" presumption. Plaintiffs say that since defendants get the benefit of a presumption that warnings they give will be read and followed, plaintiffs too should get a presumption—that an omitted warning would have been read and heeded *and* would have changed the decision to prescribe the drug or device. In other words, plaintiffs say they do not have to prove causation; it should be presumed.

COURTS SPLIT ON APPLICATION OF THE REVERSE "READ AND HEED" CAUSATION PRESUMPTION

Some courts have indulged a plaintiff's reverse "read and heed" causation presumption in prescription drug and medical device cases. In *Woulfe v. Eli Lilly & Co.*,[3] for example, a patient taking an antidepressant committed suicide. The patient's son sued the drug manufacturer, Eli Lilly, claiming that the antidepressant caused the suicide and that Eli Lilly failed to warn of that risk. Eli Lilly moved for summary judgment based on the son's inability to prove that the alleged failure-to-warn proximately caused the suicide. The son countered by asserting the reverse "read and heed" causation presumption. The court sided with the son.

The court recognized a rebuttable presumption in favor of the son that an adequate warning would have been read and heeded. The court also found, without analysis, that the presumption should apply even in context of the "learned intermediary" doctrine—under which a prescription drug or medical device maker's duty to warn runs not to the patient but to the prescribing physician. The court concluded that because of the presumption, the son "need not present any direct evidence that [the prescribing doctor] would have acted differently had a proper warning been given" to make his *prima facie* failure-to-warn case.[4]

Other courts, by contrast, have rejected the "read and heed" causation presumption in prescription drug and device cases.[5] In *Thomas v. Hoffman-LaRoche, Inc*., for example, the United

States Court of Appeals for the Fifth Circuit rejected the presumption as contrary to how a reasonable person would act under the circumstances. The court noted two types of risks—preventable and unavoidable. If a manufacturer warns of preventable risks and the consumer heeds those warnings, then the product can be used safely. With preventable risks, therefore, the consumer's choice is between heeding warnings to use the product safely and ignoring warnings against using the product unsafely.

The court reasoned that unavoidable risks are different. Unavoidable risks are, naturally, those that a consumer cannot avoid if he or she uses the product. With unavoidable risks, the choice is whether to use the product at all. Thus, with unavoidable risks, the appropriate question is whether the product's potential benefits outweigh its potential risks.

The Fifth Circuit concluded that prescription drugs pose unavoidable risks, and unless the plaintiff can establish that using the drug is riskier than not using it, then presuming that an additional warning would have caused the doctor not to prescribe the drug is inappropriate. In fact, assuming that the potential benefits outweigh the potential risks and that people act reasonably to minimize risk, the Fifth Circuit concluded that a reasonable person would not change his or her decision to use the drug even if warned of the unavoidable risk. In the learned intermediary context, the court did recognize a presumption that the prescribing doctor would have "read and heeded" an adequate warning. "But 'heed' in this context means only that the learned intermediary would have incorporated the 'additional' risk into his decisional calculus." The court still required the plaintiff to present evidence showing that the "additional non-disclosed risk was sufficiently high that it would have *changed the treating physician's decision to prescribe the product to the plaintiff*" (emphasis supplied).

THE REVERSE "READ AND HEED" CAUSATION PRESUMPTION SHOULD BE REJECTED

The Fifth Circuit got it right in *Thomas*, and the *Woulfe* court got it wrong. When plaintiffs in drug and device failure-to-warn cases rely on *Woulfe* and similarly decided cases to claim a causation presumption, drug and device makers and their lawyers must resist, and they have several grounds on which to do so.

Comment j Provides No Basis for a Causation Presumption. The *Woulfe* court based its causation presumption on Comment j to Section 402A. Because that comment provides a "read and heed" presumption that favors defendants when a proper warning is given, the court reasoned, it is fair to apply a similar presumption that favors the plaintiff when a proper warning is allegedly not given. But the two presumptions are hardly similar, and the result hardly makes sense.

The "presumption" in Comment j is only marginally beneficial in most cases to manufacturers who give adequate warnings. Those manufacturers are shielded from failure-to-warn liability because they actually provided adequate warnings; any "presumption" about what consumers did with those warnings is largely beside the point. Comment j does not change the elements of proof or increase the plaintiff's evidentiary burdens.

The reverse "read and heed" causation presumption, in sharp contrast, is a windfall to plaintiffs. It eliminates a required—and difficult—element of a plaintiff's *prima facie* case and requires the defendant to rebut the presumption by disproving causation. This is hardly the other side of the same presumption coin.

The Plaintiffs' Presumption Does Not Reflect Reality. The reverse "read and heed" causation presumption ignores the dynamics of the medical decision-making process. The presumption holds that if the manufacturer had given an adequate warning, the doctor would not have prescribed the drug or device for the patient, and the patient's injury therefore would have been avoided. But virtually every prescription drug and device comes with page after page of warnings. Yet doctors still prescribe them. That is because doctors find that the potential benefits of the drug or device outweigh the potential risks of leaving the patient's condition untreated. To simply presume that any one particular additional warning would have tipped the balance against prescribing the drug or device—in every case—is unrealistic.

Consider, for example, that the supposed risk of suicidal thoughts and/or behavior that some plaintiffs have (mostly unsuccessfully) alleged is associated with certain antidepressants. Even these plaintiffs allege that this risk exists for only a "small vulnerable subpopulation" of patients. Untreated depression itself is the leading cause of suicide.

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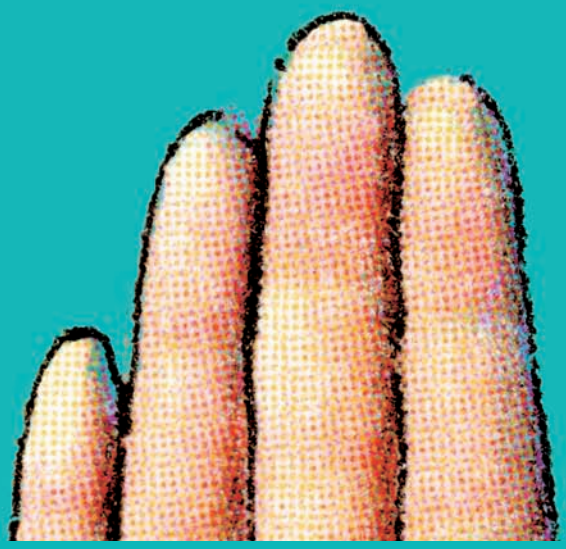
TORT REFORM

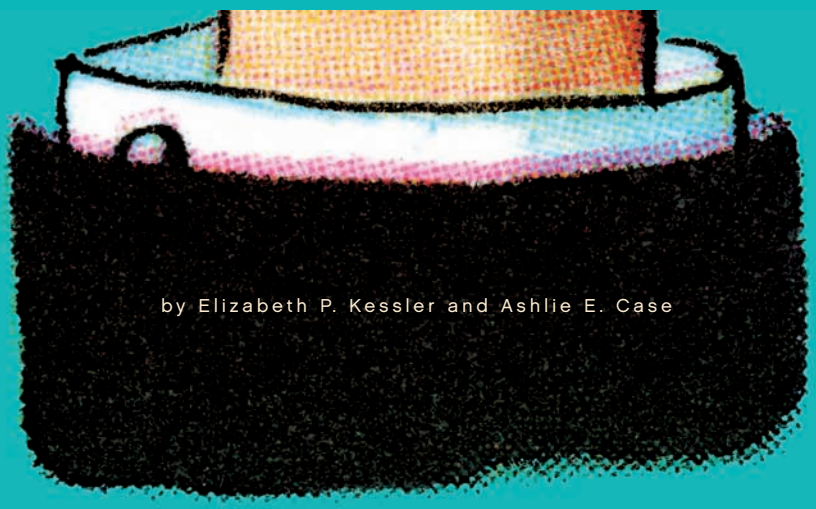
OFTEN LIES IN THE HANDS OF STATE SUPREME COURTS



Efforts by states to reform their tort laws are nearly universal. One of the incarnations of such efforts is to set limits on the amount of compensatory damages that plaintiffs can recover. Those damages are either economic or noneconomic. Economic damages awards compensate plaintiffs for actual expenses, such as medical bills and lost wages, incurred as a result of the defendant's wrongful conduct. Measuring economic damages often is fairly straightforward—reviewing hospital billing records, calculating time off work and hourly wages, etc. On the other hand, noneconomic damages awards serve to compensate plaintiffs for intangible losses, such as the capacity for enjoyment of life or mental anguish. These damages are not so easy to calculate because they are inherently subjective and there is no reliable standard by which to measure them.

Because of the unpredictable nature of noneconomic damages awards, legislatures across the country have enacted laws limiting recovery for intangible losses, often as part of their more wide-ranging tort reforms. Plaintiffs challenge the constitutionality of these damages caps on a variety of grounds, such as the right to trial by jury, the right to a remedy, the guarantee of "open courts," due process, equal protection, and separation of powers. The constitutionality of tort reforms generally and damages caps specifically is hardly settled law. Because these analyses rest almost exclusively on state constitutional grounds, which vary from state to state and, as shown by a recent decision from the Ohio Supreme Court, can change over time, the fate of these tort-reform efforts lies in the hands of state supreme courts.

By way of background, the first major tort-reform legislation in Ohio was enacted in 1975 and capped damages in medical-malpractice cases at $200,000. It was struck down on due process grounds—the Ohio Supreme Court found that it was arbitrary and irrational to impose the cost of combating a perceived medical-malpractice crisis on the people most severely injured by medical malpractice.[1] Subsequent legislative tort reforms were also struck down by the court on a variety of constitutional grounds: the right to trial by jury, the right to a remedy, the guarantee of an open court, due process, equal protection, and separation of powers.[2] So when the Ohio Supreme Court upheld a noneconomic damages cap in *Arbino v. Johnson & Johnson* against attacks on all those constitutional grounds, it signified a change from the court's past approach.[3]



by Elizabeth P. Kessler and Ashlie E. Case

The *Arbino* decision provides a useful framework for evaluating and comparing the varying treatment by state supreme courts on the constitutionality of states' tort-reform measures. Melisa Arbino sued the makers of the Ortho Evra® birth control patch after she suffered blood clots and other side effects from its use.[4] Under Ohio law, noneconomic damages for a plaintiff like Arbino (who had suffered no permanent physical deformity, loss of limb or organ system, or other injury that left her unable to care for herself) were limited to $250,000, or three times economic damages up to $350,000, or $500,000 per occurrence.[5]

RIGHT TO TRIAL BY JURY USED TO ATTACK DAMAGES CAPS

One avenue plaintiffs like Arbino use to attack the constitutionality of damages caps is whether juries must decide the amount of plaintiffs' damages. The problem is that there is no uniform analysis for evaluating the right-to-a-trial-by-jury argument. The Seventh Amendment right to a jury in civil trials does not preclude imposing caps on damages (and in any event is not incorporated to the states through the due process clause of the Fourteenth Amendment), so each state is free to interpret its own trial-by-jury guarantees as more expansive than the federal protection.[6]

The *Arbino* court found that the cap on noneconomic damages for noncatastrophically injured plaintiffs did not violate the right to a jury trial found in the Ohio Constitution.[7] The court reasoned that the cap did not prevent the jury from fulfilling its traditional role: deciding all issues of fact.[8] But once a jury has fulfilled this role, awards may be altered as a matter of law.[9] For example, courts can treble damages awards under antitrust and consumer-protection statutes.[10] If damages can increase by operation of law, they can decrease as well.[11] Other states have concluded the same.[12] And like Ohio, other states have permitted noneconomic damages caps after previous rulings that they were unconstitutional.[13]

In contrast, the Washington Supreme Court in *Sofie v. Fibreboard Corp.* struck down a state statute limiting noneconomic damages in personal-injury and wrongful-death actions because the limits interfered with the jury's traditional role to determine damages.[14] The court stated that the "measure of damages is a question within the jury's province" and that "[i]t would defeat the intention of our constitution's framers to interpret an essential right so that it slowly withers away."[15] But as the dissent noted, "The majority errs by equating historical fact with constitutional necessity."[16] In other words, just because juries traditionally have determined the amount of noneconomic damages does not mean they are required to do so. Thus, there is no independent constitutional right to have noneconomic damages determined by a jury.[17] The jury's fact-finding function does not extend to the remedy phase; remedy is a matter of law, not fact.[18] Indeed, Washington abolished punitive damages without transgressing its trial-by-jury guarantee.

The *Arbino* ruling and the *Sofie* dissent get it right. It is foolish to say that a legislature can abolish a cause of action or a category of damages but cannot limit damages recoverable for that cause of action. Legislatures should be free to divine the contours of a cause of action and limit the recovery available (*e.g.*, comparative negligence takes what was the plaintiff's recovery and subtracts a portion based on the plaintiff's culpability). Capping the total damages is no different. The lesser power to limit recovery is included in the greater power to abolish causes of action.

STATE CONSTITUTIONAL PROVISIONS TO OPEN COURTS AND THE RIGHT TO A REMEDY CAN ALSO AFFECT TORT-REFORM EFFORTS

Another avenue by which plaintiffs attack the constitutionality of damages caps is under state constitutional provisions that guarantee open courts and/or the right to a remedy. These rights are often found in the same constitutional provision, but some states have only one or the other. In any event, the purpose is the same: to guarantee that people will be able to access the courts to redress their injuries. There is no analog to these provisions in the federal Constitution (because there is no federal common law), so like the trial-by-jury analysis, the results vary by state.

The *Arbino* court held that Ohio's cap did not violate the plaintiff's right to a remedy or Ohio's open-courts provision.[19] The court had interpreted those provisions as prohibiting laws that effectively prevent individuals from obtaining redress for an injury in a meaningful time and manner.[20] Considering Arbino's options, the court concluded that the cap did not foreclose her from relief or obliterate an entire jury award, since recovery of $250,000 to $500,000 in noneconomic damages for noncatastrophic injuries is a meaningful remedy. [21]

The Florida Supreme Court reached a different conclusion in *Smith v. Department of Insurance*, where it held that Florida's $450,000 cap on noneconomic damages violated its "open courts" and right-to-a-remedy provisions.[22] It is noteworthy that this cap is the only portion of the tort-reform scheme that was struck down. The court applied its holding from an earlier case that required the legislature to meet one of two conditions to restrict the right of redress from what existed at the time the Florida Constitution was adopted. The legislature had to either (1) provide a reasonable alternative benefit (like the workers' compensation program) or (2) show overwhelming public necessity and no alternative method of meeting that need (a standard not unlike strict scrutiny under a due process or equal-protection analysis, which is discussed below).[23]

The Oregon Supreme Court recently reached the same result in *Clarke v. Oregon Health Sciences University*, where it struck Oregon's cap on remedy-clause grounds (Oregon has no "open courts" language in its constitution).[24] The Oregon Constitution guarantees a "remedy by due course of law for injury done."[25] The challenged statute eliminated any cause of action for medical malpractice against individual tortfeasors—doctors, nurses, etc.—employed by a public entity and capped economic and noneconomic damages at $100,000 each in a suit against the public entity. The court found that when Oregon adopted its remedy guarantee, the plaintiff would have been entitled to seek and recover both economic and noneconomic damages from the tortfeasors without limitation as to the amount.[26] The legislature could not deny the plaintiff those damages in a tort action without providing an adequate substitute for the preexisting right to recovery.[27] The court reasoned that although the legislature has the right to modify common-law remedies to some extent, what it provided in this instance was an "emasculated version of the remedy that was available at common law."[28]

Analysis of the remedy issue will depend on the extent to which the cap curtails the availability of noneconomic damages. A cap of $15 million would not interfere with the right to a remedy, because it is a rare case where noneconomic damages are awarded in such a large amount. But the lower the limit, the more likely a court is to construe the cap as a roadblock on the avenue of redress, thus making the cap more susceptible to a finding of unconstitutionality.

STATE SUPREME COURTS' DUE PROCESS AND EQUAL-PROTECTION ANALYSES OF NONECONOMIC DAMAGES CONSTITUTIONALITY ARE LESS STATE-SPECIFIC

In contrast to the trial-by-jury and remedy/open-courts arguments, due process and equal-protection analyses by state courts almost always follow the federal standards for these protections. In the due process context, state courts usually apply the rational-basis test (because there is no fundamental right implicated), asking whether the cap bears a rational relation to public health, safety, morals, or welfare and is not arbitrary or unreasonable.[29] In the equal-protection context, the court looks for a rational relation to a legitimate government purpose.

The *Arbino* court found that Ohio's General Assembly acted in the public's interest in enacting the cap, which is all that is required by the first prong of the due process analysis.[30] The legislature made the finding that the state of civil litigation was deleterious to the economy; noneconomic damages are difficult to calculate and lack precise monetary value, so they are susceptible to inflation based on irrelevant factors. That cost is then passed on to the general public.[31] Enacting the cap, therefore, serves the public interest of making damages awards more predictable.

On the second prong of the due process analysis, whether the law is unreasonable or arbitrary, this cap alleviated concern from prior cases striking reforms by exempting from the cap those most severely injured.[32] The earlier caps on recovery applied to all plaintiffs, even those with devastating injuries. But this time, the legislature limited the application of the cap to those without catastrophic injuries. The court found this statute was "tailored to maximize benefits to the public while limiting damages to litigants"[33] and that "[a]t some point, the General Assembly must be able to make a policy decision to achieve a public good."[34]

As to equal protection, *Arbino* found the cap rationally related to the legitimate state interest of reforming the civil justice system to make it more fair and predictable, thereby improving the state economy.[35] The Western District of Virginia, in analyzing such a cap, concluded that the legislature may, consistent with due process, "make rules concerning the type of damages that are recoverable and the way in which damages are paid."[36] States have usually reached this conclusion.[37]

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PUNITIVE DAMAGES UPDATE: ASSESSING THE IMPACT OF *PHILIP MORRIS USA V. WILLIAMS* ONE YEAR LATER

by Paul D. Koethe

A little over a year ago, the U.S. Supreme Court added to its punitive damages jurisprudence by issuing an opinion in *Philip Morris USA v. Williams*, 127 S. Ct. 1057 (2007). We discussed the *Williams* decision in a previous Jones Day *Practice Perspectives* article.[1] At the time, the decision was generally viewed in the press as a "victory" for corporate defendants whose behavior or products are alleged to have caused widespread injury or harm.[2] The Court in *Williams* ruled that due process bars states from assessing punitive damages awards "to punish a defendant for injury that it inflicts upon nonparties … *i.e.*, injury that it inflicts upon those who are, essentially, strangers to the litigation."[3] The Court went on to say that state judicial systems have a constitutional obligation to provide "some form of protection" to avoid an "unreasonable and unnecessary risk" that a jury would calculate punitive damages based on harm or injury to those not before the court.[4] The Court remanded the case to the Oregon Supreme Court for further consideration.

As we pointed out in our earlier analysis, the Supreme Court refused to impose a blanket prohibition on the admission of evidence of harm to nonparties. While such evidence may not be used by the jury for purposes of punishing the defendant, it may properly be considered in assessing the "reprehensibility" of the defendant's conduct.[5] This distinction remains elusive. An analysis of recent cases in the aftermath of *Williams* reveals that courts have not consistently applied its holding concerning the jury's consideration of evidence of harm to third parties. Thus, while *Williams* provides additional ammunition to counsel in crafting an effective punitive damages defense strategy, it has not proved to be a cure-all, and counsel must continue to give careful consideration to protecting due process rights in the context of punitive damages.

Several courts applying *Williams* have been willing to strike down punitive damages awards where it appears that adequate safeguards were not in place to prevent the jury from awarding the damages based on harm to others. For example, in *Merrick v. Paul Revere Life Ins. Co.*, 500 F.3d 1007 (9th Cir. 2007), the court found that when fundamental due process is at issue, the trial court has

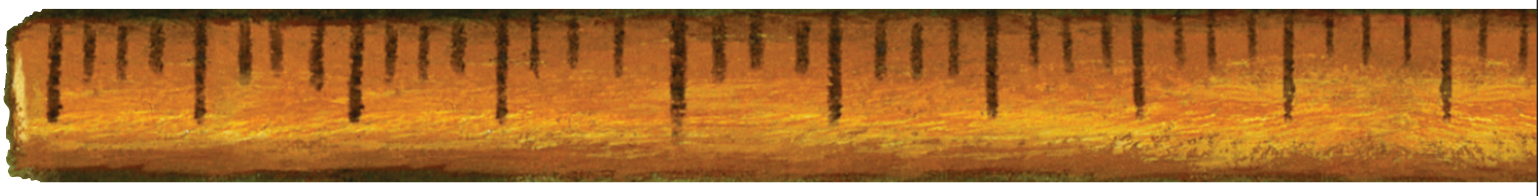
an obligation to fashion an appropriate jury instruction on the topic and is not relieved of that obligation simply because the defendant proposes an instruction that is deficient in some way. *Merrick* involved a claim for breach of good faith and fair dealing. At trial, the plaintiff presented evidence through expert witness testimony and company documents that the defendant had engaged in a decade-long scheme of alleged improper and unethical behavior that caused harm to many victims other than the plaintiff. During closing argument, the plaintiff's counsel repeatedly referenced this pattern of alleged improper behavior, including practices not alleged to have occurred in the plaintiff's case. The defendant offered an instruction on punitive damages, but the trial court refused to give it. The jury ruled in favor of the plaintiff and awarded $1.65 million in compensatory damages and $10 million in punitive damages.

Applying *Williams*, the appellate court found that the plaintiff's evidence created a "significant risk" that the jury would assess punitive damages to punish the defendant's pattern of improper behavior *rather than* the conduct that affected the plaintiff specifically. *Merrick*, 500 F.3d at 1016. Likewise, the jury instructions were found to be inadequate because they did not "provide the jury with clear direction regarding the proper and improper uses of [plaintiff's] 'bad company' evidence." *Id.* at 1017.[6] The court further found that even though the defendant's proposed instruction on punitive damages was misleading in certain respects, this fact "does not alone permit the district judge to summarily refuse to give any instruction on the topic." *Id.* The trial court should have given a nonmisleading instruction that captured the substance of the proposed instruction. Accordingly, the court vacated the punitive damages award and remanded for a new trial on punitive damages.

Similarly, in *White v. Ford Motor Co.*, 500 F.3d 963 (9th Cir. 2007), the district court's refusal to give the defendant's "harm to nonparties" jury instruction was found to violate due process. *White* involved a pickup-truck "rollaway" that resulted in the death of the plaintiffs' child. The plaintiffs' counsel presented evidence and argument at trial that Ford knew about 54 other people who had been injured by rollaways and that Ford "decided to do everything possible to avoid telling the truth" about the rollaway problem and the people injured by rollaways because it "[doesn't] ever want to have to be accountable for that conduct." *Id.* at 972. The jury awarded $2.3 million in compensatory damages and $52 million in punitive damages against Ford.

At trial, Ford requested a specific instruction that would have informed the jury that it could not punish Ford for harm to other persons. The trial court refused to give the instruction. Instead, it gave an "extraterritoriality" instruction restricting jurors from imposing damages to protect people or punish harm to people outside the State of Nevada. The appellate court found this instruction to be inadequate because it may have been interpreted as allowing punitive damages to be imposed for harm to nonparties residing *inside* Nevada. The court ordered a new trial on punitive damages and held that on remand, the district court "must explain to the jury that although evidence of harm to nonparties may bear on Ford's reprehensibility, any award of punitive damages cannot be used 'to punish Ford directly for harms to nonparties.' " *Id.* at 973 (quoting *Williams*, 127 S. Ct. at 1064).[7]

Other courts have been less willing to vacate large punitive damages awards even though they may have been influenced by improper jury considerations. For example, in *Buell-Wilson v. Ford Motor Co.*, 160 Cal. App. 4th 1107 (2008), *petition for review pending*, the plaintiff suffered serious injury in a vehicle-rollover accident. During trial, the plaintiff's counsel made reference to the impact of Ford's actions on third parties within California, stating that "thousands of these vehicles were manufactured and sold in their defective condition and they are on our highways in California," and that Ford "marketed to, specifically, the soccer moms, the women with babies, the toddler seats, the families." *Id.* at 1166. The jury returned a verdict of $122 million in compensatory damages and $246 million in punitive damages.



While *Williams* provides additional ammunition to counsel in crafting an effective punitive damages defense strategy, it has not proved to be a cure-all, and counsel must continue to give careful consideration to protecting due process rights in the context of punitive damages.

Although the U.S. Supreme Court later vacated and remanded the case for reconsideration in light of *Williams*, and although the California courts ultimately reduced the jury award to $27 million in compensatory damages and $55 million in punitive damages, the appellate court refused to vacate the punitive damages award on the grounds that it may have been influenced by improper evidence and arguments concerning third-party harm. In a lengthy discussion, the court found that Ford had forfeited its right to assert this argument because, among other things, Ford (1) submitted incorrect and misleading jury instructions on third-party harm, (2) did not timely object to the plaintiff's closing argument, (3) did not request a limiting instruction during trial, and (4) did not raise instructional error on its original appeal. *Id.* at 1161–87.

Grefer v. Alpha Tech., 965 So. 2d 511 (La. App. 2007), *cert. denied*, *Exxon Mobil Corp. v. Grefer*, 2008 LEXIS 3513 (U.S. Apr. 21, 2008), involved a $56 million compensatory damages award and $1 billion punitive damages award against Exxon Mobil arising out of a land-contamination claim. Although the plaintiffs claimed only property damage and no physical harm, the trial court allowed the plaintiffs to argue and present substantial evidence (over Exxon's objection) of the potential or alleged actual harm to other persons who were not parties to the suit and whose claims were not before the court. This evidence included a video depicting elementary-school children getting off a bus and questions to witnesses about the potential harm of radiation to children and the unborn. At trial, Exxon did not request, and the court did not give, a specific instruction precluding the jury from awarding damages based on harm to nonparties. After the Louisiana appellate court reduced the punitive damages award to $112 million, the U.S. Supreme Court vacated and remanded for further consideration in light of *Williams*. *Exxon Mobil Corp. v. Grefer*, 127 S. Ct. 1371 (2007).

On remand, the Louisiana appellate court reaffirmed the $112 million punitive damages award. Although it acknowledged that the trial court's instructions may have permitted

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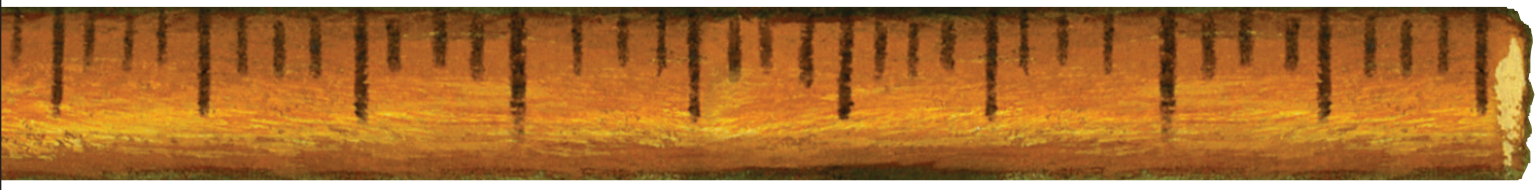

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fundamentally at odds with what the company is telling consumers and the media. Mixed messages will cause the company to lose credibility, and where the company's reputation already is being questioned because of claimed product failures (whether real or imagined), the company cannot risk losing whatever credibility it may have left. It will need that credibility, along with some political capital, to fashion solutions to regulatory and legal challenges.

Moreover, the company must have a plan in place for executing its reaction to the potential crisis. If the matter involves a product recall, it must ensure that the employees responsible for dealing with the mechanics and logistics of the recall know what they are supposed to do and are confident in carrying out the instructions given to them. Distributors and retailers must also be instructed in the mechanics of the recall—*i.e.*, whether the retail outlets are to take the products and what they are supposed to provide the customers (vouchers, coupons, cash, or claim forms), how they are to respond to customer and media inquiries, the length and scope of the recall, and myriad other issues.

Mock-recall exercises may be something to consider, and some have suggested them. As a practical matter, however, mock-recall exercises present significant cost and other obstacles, not the least of which is that a mock recall may be mistaken as an actual recall, become a "viral" product crisis, and create the very crisis the company was planning for—and hoping to avoid.

Effective coordination and exercising caution work together. One area in particular concerns the interaction of the legal and public relations teams. There is often tension between the public relations and legal teams in what, when, how, and where to communicate about a product crisis or some aspect of it. Public relations consultants will often push corporate representatives to make a statement as early as possible to ease the fears of consumers, while the lawyers may insist that such a statement could open up the corporation to future legal liability. Clearly, legal strategy cannot trump business considerations completely, and business considerations cannot entirely trump legal strategy. Indeed, in bet-the-company litigation, the continued viability of the company itself may turn on the outcome of litigation. But if the company wins the litigation while losing its entire customer base forever, the victory will be of little significance. A balance must be struck. There is no quick fix for resolving this inherent tension, but it must be acknowledged, and steps should be put in place for resolving these conflicts.

Another area where coordination and caution dovetail, and which also concerns the interaction of public relations consultants and attorneys, is the extent to which the attorney-client privilege applies to discussions about public relations strategy and planning. This is a potential minefield for those who do not think through the consequences in advance. Case law is divided over whether the company or its law firm should retain the public relations firm in order to protect the privilege. Similarly, case law is all over the map with respect to whether discussions with public relations consultants are protected from disclosure by the attorney-client privilege or attorney work-product doctrine. Careful evaluation of the laws of the relevant jurisdiction (or jurisdictions) should be undertaken. As a practical matter, the decision may already have been made, as most companies already have longstanding relationships with public relations firms, unless the company decides that a separate firm should be retained (by it or the law firm) for purposes of the product crisis it is currently facing.

Companies also should bear in mind that communications to the public may be used in regulatory and civil litigation proceedings. Anything a company says to the public may find its way into the litigation, and vice versa. And the impact of a company's public statements on investors must be taken into account as well. Anything the company does, including when it undertakes certain actions, may figure into the litigation or lead to litigation. Consequently, those communicating with customers must coordinate with the regulatory and legal teams.

Of course, as a practical matter, every member of every team in a product crisis cannot communicate with every member of every other team. At the very least, that would not be a very efficient system of communication. A point person should be identified for each of the responsible groups (manufacturing, customer relations, etc.). Care should be taken to ensure that you do not create a paralyzing bureaucratic structure of

committees, meetings, and endless discussions. A potential crisis requires a company to remain nimble, to be able to deal with a fluid situation. A formal committee structure is not a nimble one.

PLANNING FOR THE PRODUCT CRISIS: WHAT YOU CAN DO NOW

Planning ahead is critical, but planning for every contingency is impossible. There is no such thing as a "crisis textbook" to guide you through every conceivable crisis a company might face. But there are steps every cautious company can take to deal with potential crises, and one planning tool every product manufacturer may wish to consider is a "crisis handbook." The contents of such a handbook would vary, depending on the industry involved, the regulatory environment in which it operates, the geographic scope of product distribution, and a host of other factors. Below are a few suggestions that may help product manufacturers evaluate whether such a handbook would be a useful tool and what it might contain.

First, the handbook may include a short, general description of the protocol for dealing with different types of crises, including the chain of command for bringing a potential crisis to the attention of company officials before it becomes an actual crisis. It would also include instructions to employees on handling media and public inquiries and on logging and recording such inquiries. In addition, this section of the handbook might include synopses or summaries of the regulations and rules governing the conduct and timing of a product recall. Thus, the handbook of a toy manufacturer would contain rules and regulations of a recall under the Consumer Product Safety Commission ("CPSC") but not the National Highway Traffic Safety Administration ("NHTSA").

Second, the handbook may contain a "contact" list, which would include the key individuals in the company responsible for coordinating the company's crisis response (more than one, in the event someone is not available when the crisis hits); contacts at the potentially responsible government agencies (CPSC, NHTSA, etc.); contacts at the company's public relations and law firms; and other relevant information.

Third, the handbook could include an "FAQ" section, identifying questions that are likely to arise, including, for instance, to whom questions from the media should be referred, and dos and don'ts when dealing with a boiling crisis.

Fourth, if the company has dealt with recalls before, the handbook may be a good place to include template, or exemplar, documents, such as "litigation holds," notices, and instructions to employees. Having such materials in a single, readily accessible source may be a tremendous help as the crisis develops.

JONES DAY'S PRODUCT RESPONSE TEAM

Jones Day is particularly well suited to counseling product manufacturers about planning and preparing for product-related crises and assisting manufacturers facing the prospect of product recalls or similar challenges. The Firm has created an interdisciplinary Product Response team, consisting of experienced lawyers who can be quickly assembled and dispatched to counsel a product manufacturer facing a crisis and help it navigate through the regulatory and legal issues confronting it. Jones Day's Product Response team lawyers can assist at every stage, from counseling to representing the company before regulatory agencies and Congress to defending the company against individual and class-action litigation across multiple jurisdictions. ■

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Even in this difficult enforcement environment, the FTC has played an important role in pursuing violators of the CAN-SPAM Act and assessing significant fines. In March of this year, for example, online advertiser ValueClick, Inc., agreed to pay a fine of $2.9 million, in part for alleged violations of the CAN-SPAM Act. *See* "ValueClick to Pay $2.9 Million to Settle FTC Charges" (press release dated Mar. 17, 2008) (http://www.ftc.gov/opa/2008/03/vc.shtm). In February, the FTC won an award of $2.6 million in an Illinois federal-court decision against marketer Sili Neutraceuticals for violating the Act. *See FTC v. Sili Neutraceuticals, LLC*, Case No. 07 C 4541 (N.D. Ill.). The number of enforcement actions by the FTC, however, has not kept pace with the nearly unstinting growth of spam email.

If private or public enforcement of the CAN-SPAM Act were stepped up, many businesses that rely upon email advertising would be in for a surprise. Surveys suggest that the majority of businesses that rely on email advertisements are not aware of the CAN-SPAM Act and do not comply with it. *See* "Majority of Email Marketers Not Aware of CAN-Spam Regulations" (June 29, 2007) (http://www.prleap.com/printer/83322).

CONCLUSION

If your business relies upon mass marketing, be prepared before you hire a mass marketer or launch your next advertising campaign. Have the mass marketer inform you of its marketing plan, including the type of media involved, and ask the right questions to ensure that the mass marketer complies with the applicable laws and regulations. Also, review the policies and procedures of in-house marketing departments to make sure they are compliant. Finally, take steps to protect your business. Insurance contracts typically provide coverage for advertising and property damage. In a number of cases, insurance contracts have either indemnified or paid for the defense of mass marketers who have been sued. Thus, it is important to review your insurance policies with an eye toward mass marketing. Although none of these recommendations can make a business immune to the risk of litigation, adopting the best advertising practices can help your business better avoid litigation and limit liability. ■

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This article was prepared with assistance from Kasey T. Ingram, an associate in the Firm's Columbus Office.

[1] All web sites herein were last visited on June 25, 2008.

[2] 16 C.F.R. § 310.4(b)(3) (requiring for safe harbor written procedures, trained personnel, a list of telephone numbers not to contact, an updated version of the DNC Registry not more than 31 days old, and the monitoring and enforcement of compliance).

[3] *See* Federal Trade Commission, "Complying with the Telemarketing Sales Rule" (Jan. 2004) (http://www.ftc.gov/bcp/edu/pubs/business/telemarketing/bus27.shtm); 15 U.S.C. § 6105(b) (authorizing the FTC to enforce violations of the Telemarketing Sales Rule as though they were violations of Section 5 of the FTC Act); *FTC v. Consumer Alliance, Inc.*, 2003 U.S. Dist. LEXIS 17423 (N.D. Ill. 2003) (imposing officer liability for violations of the FTC Act and the TSR Rule).

[4] 16 C.F.R. § 310.07(a).

[5] 16 C.F.R. § 310.07(b).

[6] The CAN-SPAM Act also provides for criminal penalties with respect to certain fraud-related violations. *See* 15 U.S.C. § 7703.

[7] *See* 15 U.S.C. § 7706(g) (authorizing suits by providers of internet access services); 15 U.S.C. § 7702(11) (adopting the definition of "Internet access service" from 47 U.S.C. § 231(e)(4)).

[8] *See* BNA, Inc., "Definition of 'ISP' Under CAN-SPAM Could Permit Legal Actions by Employers," 72 *The United States Law Week* 2696 (May 18, 2004).

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during investigations may not be taken into account in the final report. In short, investigative practices and cultures differ. Final reports can contain unexpected "points of view" and conclusions that did not come to light earlier.

It is especially critical for a manufacturer to take advantage of any opportunity to participate in an accident investigation abroad. The company should assemble the most talented, complete team possible and send it quickly to the site. Steps like documenting evidence, observing daily developments in the investigation, providing technical expertise and commentary, and appropriately memorializing any shortcomings in the process become even more important in an investigation outside the U.S.

A company should immediately retain experienced legal counsel to advise on the parameters and the local subtleties of the investigation process abroad. An experienced accident investigator, who has been through the process in that country, also should be retained as a consultant. If possible, the manufacturer should retain a former investigator for the agency that will be charged with the proceeding. Finding out about the dos and don'ts of participating in the investigation, and learning about the personalities and backgrounds of those who are in charge, is well worth the investment and will prove invaluable.

When it participates in an investigation outside the U.S., the NTSB usually has the opportunity to submit a proposed report with findings for the lead investigating authority to consider. The NTSB also may choose to file an addendum, or a dissenting report, to a country's final accident report if the Board disagrees with it. In these situations, a careful manufacturer will be well rewarded for learning about the ins and outs of the process *in advance* and for carefully documenting the evidence as the investigation unfolds.

CONCLUSION

A prudent product manufacturer will seek out the opportunity to participate in an NTSB investigation. It is also well advised to learn about the procedures in advance. A few ounces of preparation and attention to detail will be worth a pound of cure when and if litigation arises. ■

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[1] See http://www.ntsb.gov/abt__ntsb/invest.htm (last visited June 25, 2008).

[2] The *National Transportation Safety Board Aviation Investigation Manual, Major Team Investigations*, can be downloaded from its web site.

[3] This is consistent with the overarching purpose of the NTSB: to investigate accidents in a neutral manner and to render probable-cause determinations objectively and free from outside influences, in order to enhance future public safety.

[4] The NTSB investigation procedures specify that only one set of official field notes may be developed and that every working-group member must sign it. *NTSB Aviation Investigation Manual, Major Team Investigations*, Sec. 3.6.1.

[5] The International Society of Air Safety Investigators is an example of an entity that promotes close, professional cooperation between accident-investigation professionals from different countries.

[6] There are various recent examples of government attempts to "criminalize" aviation accidents and prosecute basic human error. This is a grave mistake, because these efforts interfere with the objective investigation of an accident and shift the focus to exacting punishment. Investigations should focus instead on what happened and why and make recommendations to prevent recurrence of the accident.

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One commentator has compared the relatively higher risk of suicide associated with untreated depression with the relatively lower risk of suicide allegedly associated with antidepressants and explained that any reasonable person would eagerly trade the higher risk for the lower one: "Every person who takes [an antidepressant] trades in some large risk of suicide and other depressive behavior" from his untreated depression "in exchange for a small risk of suicide and a far better life style and prognosis to boot" from taking an antidepressant. "That deal is attractive from the ex ante perspective to any sane person even in the absence of any tort remedy. . . . The rational person would assume the risk; only persons with serious cognitive limitations would balk at so attractive a deal."[6] Presumptions should not rest on unlikely and unreasonable behavior.

The Causation Presumption Undermines the Learned Intermediary Doctrine. The reverse "read and heed" causation presumption in drug and device cases is inconsistent with the learned intermediary doctrine. The learned intermediary doctrine recognizes that physicians play a crucial role in assessing the risks and benefits of a patient's treatment. The doctor is charged with applying his or her specialized learning to the patient's particular condition, analyzing the risks and benefits of different treatments, and recommending a patient-specific course of action. A doctor may have two patients with the same condition and prescribe a different treatment to each, based on myriad factors, including the patients' history, age, and sex. The one-size-fits-all "read and heed" causation presumption undermines the foundation of the learned intermediary doctrine by presuming, across the board, that no physician would prescribe the subject drug or device to any patient if the allegedly omitted warning had been provided.

Some courts have recognized this and expressly declined to apply the causation presumption in learned intermediary situations. Recently, in *Ackermann v. Wyeth Pharmaceuticals*,[7] the United States Court of Appeals for the Fifth Circuit refused to recognize the reverse "read and heed" presumption in a prescription drug case. There, the plaintiff alleged that Wyeth failed to adequately warn of the risk of suicide associated with its antidepressant drug. Lacking any evidence of causation, the plaintiff attempted to invoke the reverse "read and heed" presumption to satisfy this element of her claim. The Fifth Circuit, applying Texas law, recognized that "[i]n general" a rebuttable presumption arises that shifts the burden of proving causation to the defendant. But the court refused to apply that presumption to a "pharmaceutical case[ ] involving [a] learned intermediar[y]." While in some cases a warning about an ordinary consumer product might reasonably be presumed to cause the consumer to change his or her behavior to avoid the risk entirely, that presumption should not apply to a doctor, who must balance risks of various treatments with the benefits of those treatments and the risks of leaving a condition untreated or using a lesser treatment. Thus, the court in *Ackermann* followed the cases holding that "to 'read and heed,' in the context of a learned intermediary, means only that the physician would have incorporated the additional risk into his decisional calculus."

The Causation Presumption Is Contrary to Principles of Presumption Law. The "read and heed" causation presumption also flies in the face of law governing presumptions generally. A presumption works such that, if a party establishes a certain fact, the trier of fact must also accept additional facts as being true (the presumed facts) unless the other side disproves the truth of the presumed facts. The justification for presumptions is the "substantial likelihood" that if the predicate fact is true, the presumed facts must also be true. Presumptions are also used to offset a party's lack of availability to evidence. Neither reason for recognizing a presumption works here.[8]

It may be reasonable to presume that if a manufacturer had provided a warning, the prescribing doctor would have read the warning. But it does not necessarily—or even probably—follow that upon reading the warning, the doctor would have stopped prescribing that product for all patients. As discussed above, the learned intermediary doctrine presumes that doctors will weigh a drug's benefits and risks for a particular patient before making prescription decisions. Manufacturers warn of many potentially adverse reactions, and doctors still prescribe these drugs and devices every day.

The reverse "read and heed" causation presumption also is not needed to balance an access-to-evidence disparity. The source of causation evidence is the prescribing doctor. The plaintiff has at least as much access to his or her own doctor as the defendant does and has even more access than the defendant in those jurisdictions that prohibit defendants from interviewing treating physicians *ex parte*. At bottom, there simply is no basis in the law of presumptions for the reverse "read and heed" presumption of causation.

CONCLUSION

Plaintiffs should not be permitted to avoid their burden to prove causation in prescription product failure-to-warn cases, and the reverse "read and heed" causation presumption does just that. Those courts that have adopted the plaintiff-friendly presumption have not meaningfully analyzed whether the presumption makes sense—logically or realistically—or whether the presumption is grounded in sound principles of law. But that is not always the court's fault. Defense counsel representing drug and device manufacturers in failure-to-warn cases must fully understand the legal and factual issues surrounding the presumption and be prepared to properly educate the court through briefing and arguments before, or at, the summary-judgment stage. Well-developed arguments encompassing the issues outlined above should result in rejection of the reverse "read and heed" causation presumption. ■

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[1] 128 S. Ct. 999, 169 L. Ed. 2d 892, 76 U.S.L.W. 4087, No. 06-179, 2008 U.S. LEXIS 2013 (Feb. 20, 2008).

[2] 518 U.S. 470 (1996).

[3] 965 F. Supp. 1478 (E.D. Okla. 1997).

[4] Eli Lilly was ultimately able to rebut the presumption with testimony from the prescribing physician that he still would have prescribed the anti-depressant if Lilly had provided an "adequate" warning of suicide risk. *Id.* at 1485.

[5] *See, e.g.*, *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 813–14 (5th Cir. 1992); *Odom v. G.D. Searle & Co.*, 979 F.2d 1001, 1003 (4th Cir. 1992); *Motus v. Pfizer Inc.*, 196 F. Supp. 2d 984, 991–95 (C.D. Cal. 2001).

[6] Richard A. Epstein, "Why the FDA Must Preempt Tort Litigation: A Critique of Chevron Deference and a Response to Richard Nagareda," 1 J. Tort L., Iss. 1, Art. 5, at 25 (2006).

[7] *E.g.*, *Ackermann v. Wyeth Pharms.*, No. 06-41774, slip op. at 15 (5th Cir. Apr. 24, 2008). Jones Day represented Wyeth in the *Ackermann* case.

[8] 29 Am. Jur. 2d *Evidence* §§ 181, 185 (1994).

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On the other hand, the Texas Supreme Court in *Lucas v. United States* (on certified questions from the Fifth Circuit) held that the $500,000 limitation on compensatory damages was an unreasonable and arbitrary way to ensure a rational relationship between actual and awarded damages.[38] The court specifically construed federal due process protections as the floor, and not the ceiling, of the protections that a state may offer its citizens and ruled that Texas provides a higher ceiling than the federal standard.[39] The severity of the cap explains this decision to some extent.

Striking a cap on equal-protection grounds, North Dakota's highest court held that in the absence of a crisis, a $300,000 cap on all damages did not provide adequate compensation to patients with meritorious claims and did nothing to eliminate nonmeritorious claims.[40] This extremely stringent cap led to a finding that the law did not pass rational-basis muster. Caps of this nature are the exception, not the norm, particularly in more recent times as legislatures have learned to enact provisions that take the prior pronouncements of courts into account on these issues.

For the most part, as long as the court applies a rational-basis analysis to both due process and equal-protection claims, reasonable limits such as those in Ohio should withstand scrutiny. It is when the limits are more drastic or when courts apply a heightened scrutiny (either strict or intermediate) that such reforms are more likely to fail.[41]

SEPARATION-OF-POWERS ANALYSES VARY BY STATE AS WELL

A final method of attack common to many challenges to noneconomic damages caps (and tort reforms generally) is the claim that in enacting such reforms, the legislature infringes on the exclusive province of the judiciary. For example, the *Arbino* plaintiff argued that the statute enacting the cap impermissibly infringed on the judicial power to decide damages for personal injuries and represented a reenactment of legislation previously found unconstitutional.[42] But the court found that the newer reforms did not infringe on judicial power—the legislature can change amounts available in certain circumstances, *e.g.*, trebling damages by statute.[43] It found the enactment sufficiently different from previous legislation struck down.[44]

The Supreme Court of Washington in *Sofie*, however, suggested that a cap on damages might violate the separation of powers as a legislative remittitur.[45] But it did not decide the case on that basis. The lesson here is that, like the trial-by-jury and remedy/open-courts issues, the separation-of-powers analysis is likely to differ by state, particularly because of the circumstances underlying the enactment and previous tort-reform efforts within the state.

CONCLUSION

The attacks on efforts to limit damages in tort litigation will continue as long as state legislatures make tort reform a priority. Damages caps generally and noneconomic damages caps specifically have become more insulated from those assaults as legislatures have learned from the lessons of precedent and designed subsequent reforms to harmonize with court rulings on these state constitutional issues. But plaintiffs will always fight to cushion the impact of any damages caps, no matter how eminently reasonable. And state supreme courts will remain the final arbiters of these issues under the respective state constitutions. ■

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[1] *Morris v. Savoy*, 61 Ohio St. 3d 684, 686–87, 691 (1991) (citation omitted).

[2] *Sorrell v. Thevenir*, 69 Ohio St. 3d 415 (1994); *Galayda v. Lake Hosp. Sys.*, 71 Ohio St. 3d 421 (1994); *Zoppo v. Homestead Ins. Co.*, 71 Ohio St. 3d 552 (1994); *State ex rel. Ohio Academy of Trial Lawyers v. Sheward*, 86 Ohio St. 3d 451 (1999).

[3] *Arbino v. Johnson & Johnson*, 116 Ohio St. 3d 468 (2007).

[4] *Id.* at ¶ 1.

[5] *Id.* at ¶ 28.

[6] *Minneapolis & St. L. R.R. v. Bombolis*, 241 U.S. 211 (1916); *Walker v. Sauvinet*, 92 U.S. 90 (1876); *Arbino*, 116 Ohio St. 3d at ¶ 41 (citation omitted).

[7] *Id.* at ¶ 42.

[8] *Id.* at ¶ 35.

[9] *Id.* at ¶ 37.

[10] *Id.* at ¶ 39.

[11] *Id.*

[12] *Johnson v. St. Vincent Hosp.*, 273 Ind. 374 (1980) (upholding $500,000 limit on noneconomic damages because legislatures can restrict causes of action through statutes of limitation and procedural rules without transgressing the right to a jury trial); *Franklin v. Mazda Motor Corp.*, 704 F. Supp. 1325 (D. Md. 1989) (upholding Maryland's $350,000 cap on noneconomic losses to a right-to-jury challenge) ("a legislature adopting a prospective rule of law that limits all claims for pain and suffering in all cases is not acting as a fact finder in a legal controversy. It is acting permissibly within its legislative powers that entitle it to create and repeal causes of action.").

[13] *See*, *e.g.*, *Kansas Malpractice Victims Coalition v. Bell*, 243 Kan. 333 (1988) (striking noneconomic damages cap) *overruled in Bair v. Peck*, 248 Kan. 824 (1991) ("constitutional right to trial by jury does not guarantee that every jury damage award will be collectible or guarantee any source for payment of such an award. The duty of the jury is to determine liability and determine the amount of damages suffered. It has nothing to do with the collection of the damages.").

[14] *Sofie v. Fibreboard Corp.*, 771 P.2d 711 (Wash. 1989).

[15] *Id.* at 717.

[16] *Id.* at 729–30 (Callow, C.J., dissenting).

[17] *Id.*

[18] *Id.* at 732. *See Tull v. U.S.*, 481 U.S. 412, 425, 426 n.9 (1987) ("Nothing in the [7th] Amendment's language suggests that the right to a jury trial extends to the remedy phase of a civil trial.").

[19] *Arbino*, 116 Ohio St. 3d at ¶¶ 43–47.

[20] *Id.* at ¶ 44.

[21] *Id.* at ¶¶ 45, 47.

[22] 507 So. 2d 1080 (Fla. 1987).

[23] *Id.* at 1087–88 (citing *Kluger v. White*, 281 So. 2d 1 (Fla. 1973)).

[24] 175 P.3d 418 (Or. 2007).

[25] Oregon Const., Art. I, § 10.

[26] 175 P.3d at 433.

[27] *Id.* at 434.

[28] *Id.*

[29] *Arbino,* 116 Ohio St. 3d at ¶¶ 48–62.

[30] *Id.* at ¶ 56.

[31] *Id.* at ¶ 53; *id.* at ¶ 54.

[32] *Id.* at ¶¶ 59–61.

[33] *Id.* at ¶ 61.

[34] *Id.*

[35] *Id.* at ¶ 69.

[36] *Boyd v. Bulala*, 647 F. Supp. 781, 789–90 (W.D. Va. 1986) (but striking the enactment based on the right to trial by jury).

[37] *See*, *e.g.*, *Fein v. Permanente Medical Group*, 38 Cal. 3d 137 (1985) (upholding $250,000 limitation on noneconomic damages in medical-malpractice cases as rationally related to legitimate government objection); *C.J. v. State*, 151 P.3d 373 (Alas. 2006) (upholding $400,000 noneconomic damages cap to due process challenge under the Alaska Constitution).

[38] 757 S.W.2d 687 (Tex. 1988).

[39] *Id.* at 692.

[40] *Arneson v. Olson*, 270 N.W.2d 125 (N.D. 1978).

[41] *See*, *e.g.*, *Carson v. Maurer*, 120 N.H. 925 (1980) (striking down $250,000 cap on equal-protection grounds) *overruled by Cmty. Res. for Justice, Inc. v. City of Manchester*, 154 N.H. 748 (2007) (holding that the intermediate-scrutiny test adopted and applied in *Carson* was incorrect).

[42] *Arbino*, 116 Ohio St. 3d at ¶ 73.

[43] *Id.* at ¶ 74.

[44] *Id.* at ¶ 76.

[45] *Sofie*, 771 P.2d at 721.

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the jury to consider harm to nonparties, the court stated that such consideration is permissible in assessing the reprehensibility of the defendant's conduct. *Grefer*, 965 So. 2d at 517. Similarly, while the court acknowledged that the punitive verdict may have been influenced by the improper argument and evidence concerning nonparties, it nonetheless refused to vacate the award. According to the court, in reviewing the award *de novo*, it "noted" and "essentially sustained" Exxon's objections to this evidence. The court further claimed that it "disregarded" this evidence and considered only the harm done to the plaintiffs when it reduced the jury's original award from $1 billion to $112 million. *Id.* at 526.

Finally, in the *Williams* case itself, the U.S. Supreme Court instructed the Oregon Supreme Court to apply the correct constitutional standard to the defendant's appeal and to determine whether appropriate procedures had been used at trial to prevent the jury from punishing the defendant for harm to others. 127 S. Ct. 1057 (2007). On remand, the Oregon court chose instead to uphold the $79.5 million punitive damages award on an entirely separate and independent state law basis, without considering the constitutional issue raised by the U.S. Supreme Court's decision. *Williams v. Philip Morris Inc.*, 176 P.3d 1255 (Or. 2008). The Oregon Supreme Court held that the trial court did not err in refusing to give the defendant's instruction—advising the jury that it could not punish the defendant for harm to third parties—because the proposed instruction misstated Oregon law in two respects unrelated to third-party harm. The court found that a jury instruction need not be given unless it is "clear and correct in all respects, both in form and in substance, and … altogether free from error." *Id.* at 1261. It is not enough to offer a proposed instruction that is "correct in part and erroneous in part, leaving the trial court to solve the problem for itself." *Id.* The court reached its decision even though the plaintiff raised objections to the proposed instruction on remand that had not been previously raised in the trial court. *Id.* at 1261–62. On June 9, 2008, the U.S. Supreme Court granted the defendant's renewed petition for *certiorari* and will consider whether the Oregon Supreme Court acted properly in upholding the punitive damages award on separate state law grounds.

Each of these decisions in the wake of *Williams* indicates that counsel must continue to give careful attention to punitive damages jury instructions, motion practice to exclude or limit evidence concerning harm to nonparties, and timely objections to evidence and argument that may be used at trial for improper purposes. ■

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Jones Day law clerk (and fall 2008 associate) Jamie Cole assisted in the preparation of this article.

[1] "Punitive Damages in Light of the Recent United States Supreme Court Decision in *Philip Morris USA v. Williams*," *Jones Day Practice Perspectives: Product Liability & Tort Litigation*, p. 24 (Summer 2007).

[2] "Justices Overturn $79.5 Million Tobacco Ruling," *The New York Times*, Feb. 21, 2007.

[3] *Practice Perspectives* at 27 (citing 127 S. Ct. at 1063).

[4] 127 S. Ct. at 1064–65.

[5] *Practice Perspectives* at 27 (citing 127 S. Ct. at 1064–65).

[6] The trial court simply instructed the jury that "[y]ou may in your discretion award such damages, if, but only if, you find by a clear [and] convincing evidence that said defendant was guilty of oppression, fraud or malice in the conduct upon which you base your finding of liability." The verdict form further asked whether the insurer acted "with oppression, fraud, or malice, express or implied, in its dealings with plaintiff such to justify an award of punitive damages." *Id*. at 1017.

[7] *See also Bullock v. Philip Morris USA*, 159 Cal. App. 4th 655 (2008), *petition for review denied*, 2008 Cal. LEXIS 4848 (Cal. Apr. 30, 2008). In *Bullock*, the plaintiff presented evidence at trial concerning the defendant's alleged campaign to mislead the public about the dangers of smoking and argued that for each lawsuit filed against the defendant, 28,000 Californians had died from smoking-related illnesses in the past 40 years. The jury awarded $850,000 in compensatory damages and $28 billion in punitive damages (equivalent to $1 million for each of the purported deaths). The trial court subsequently reduced the punitive damages award to $28 million. On appeal, the court vacated the punitive damages award in light of *Williams*, finding that the trial court had erred in refusing the defendant's proposed instruction to the jury that "[y]ou are not to impose punishment for harms suffered by persons other than the plaintiff before you."

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information to dispel the myth making the rounds, and when and how to respond to regulatory or legal inquiries concerning the alleged "tainted" product, should they arise. This example illustrates that businesses must promptly manage the "news" before consumer perceptions of a product, whether based on half-truths, misinformation, or pure urban legend, become reality in the marketplace. Of course, mastery of the legal issues confronting product manufacturers is essential to crafting any response to a crisis, particularly given the ever-changing landscape of product liability and the novel product theories being advanced to hold manufacturers as perpetual insurers of their products. But businesses also need lawyers who understand the practical issues created by a product crisis—consumer perceptions, business reputation, investor relations—that in the long term are more meaningful to financial success than the crafting of novel legal arguments for long-drawn-out proceedings.

Jones Day's Product Liability & Tort Litigation lawyers possess the experience and judgment to guide our clients through such a crisis. With more than 2,300 lawyers resident in 30 offices worldwide, Jones Day is positioned to provide prompt and efficient advice toward effective business solutions. Our lawyers are at the forefront of legal issues affecting product manufacturers, and we bring experienced and educated judgment to bear in addressing the legal issues surrounding a crisis. More important, we bring that same depth of knowledge to understanding a client's business and jointly developing a plan to minimize a crisis's impact on business operations.

Experience has shown that promptly mobilizing a multidisciplinary team of professionals from Jones Day and our client permits a coordinated and well-reasoned response to crisis on both the legal and business fronts. As earlier editions have noted, Jones Day's Product Response team undertakes such an approach in order to provide quick responses to clients who may have a product recall or related issues thrust upon them. We regularly draw on that experience to provide comprehensive and coordinated solutions to business problems.

Our goal in every engagement is to provide clients with cost-effective and practical legal advice. We know that there are many smart lawyers vying for your business. We recognize that we must work in tandem with your business team to find effective solutions. We also recognize that we must continually strive to enhance the services available from our team. As always, we appreciate your continued trust in our services and hope that you provide us with your comments on this edition so that we can better serve you.

Our best wishes for a crisis-free summer, filled with sun and easy shots into the green. ■

Paul M. Pohl

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