



Product Liability eNewsletter

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A Word From Our Product Liability Litigation Practice Group Leader

Our practice has been quite busy since the last edition of our newsletter. We secured significant victories for clients in the aviation, chemicals, maritime, and food equipment industries, including a win before an Administrative Law Judge for a tree care company. We appreciate the opportunity to serve our clients and assist them in achieving their legal and business goals.

Congratulations to [Kip Bollin](#) (Cleveland), who will be sworn in as President-Elect of the Federal Bar Association at the organization's annual meeting and convention in September. Members of our Chemical Industry team continue to be active, with [Tim Coughlin](#) (Cleveland) chairing the DRI Toxic Tort and Environmental Law meeting in New Orleans, and [Gary Glass](#) (Cincinnati) and [Bill Hubbard](#) (Cleveland) presenting to the Ohio Chemistry Technology Council (OCTC) and the Society of Chemical Manufacturers and Affiliates (SOCMA), respectively. Tim, Bill, and [Barbara Lum](#) (Cleveland) also attended several chemical industry events.

In this edition we present six articles including one on *Daubert* and failure-to-warn, which [Ryan Winkler](#) (Cleveland) and I authored. [Stacey Greenwell](#) (Cleveland) discusses *trans* fats litigation in California federal courts. [Andrea Daloia](#) (Cleveland) and [Bill Hubbard](#) share their insights on building product litigation defense. [Stacey Greenwell](#) also wrote an article on dealing with the Millennial juror. This edition's guest article comes to us from [David Wilson](#) (Washington, D.C.), who discusses whistleblowers and the SEC. Finally, [Neelam Gill](#) (Washington, D.C.) provides updates on e-cigarettes, food nutrition labels, and food defense plans in our FDA Corner.

We hope you enjoy the latest edition of the Thompson Hine Product Liability eNewsletter, and we welcome any feedback, questions, or suggestions for future editions.

Regards,

[Andrew Cox](#)



Trans Fat Class Action Litigation in California Federal Courts

The Food and Drug Administration's (FDA) June 17, 2015 final determination regarding partially hydrogenated oils (PHOs), the primary source of *trans* fat, has done nothing but fan the flames of the already existing *trans* fat class action litigation in California federal courts. Although in its final determination, the FDA declared that manufacturers may use *trans* fat in food products until June 2018, class attorneys have run amuck with the final determination, claiming it supports their position that *trans* fat is "unsafe" and consumers have been duped into buying "unhealthy" food products containing *trans* fat. On December 18, 2015, Congress fought back, seeking to end the "frivolous" litigation through the Consolidated Appropriations Act for 2016. Class attorneys remain undeterred, and only time will tell whether Congress is successful in ending the costly class action litigation. A full understanding of the evolution of *trans* fat class action litigation, the decisions to date, and the questions yet unanswered is essential to successfully defending plaintiffs' seemingly never-ending quest to formulate a dismissal-proof class action complaint regarding *trans* fat in packaged food products. It also provides valuable insight into how other consumer class actions develop.

In the Beginning ... There Was a Settlement

The *trans* fat class action litigation started as most recurring class actions start: with a large class action settlement. In 2005, McDonald's paid \$8.5 million to settle two class actions alleging it misled consumers about *trans* fat levels in its food. Similar suits followed against KFC Corporation and Wendy's International Inc. in 2006 and 2007. After that, class attorneys started salivating over *trans* fat – the next big prospect for small class payouts and large attorney fee awards – and switched their focus to packaged food. Since 2009, more than 45 class action lawsuits have been filed in California federal district courts against various manufacturers, seeking the eradication of *trans* fat from packaged food products and exorbitant class damages.

The Original Theory: Mislabeling & False Advertising Claims

From 2009 through 2012, the theory was relatively consistent and simple: The plaintiffs alleged that packaged food manufacturers falsely and misleadingly marketed, advertised, or labeled their products as "healthful" even though they contained PHOs, a source of artificial *trans* fat, which allegedly can cause myriad health risks. The lawsuits reused allegations and named plaintiffs and attacked any packaging or marketing statements that even hinted at healthiness, such as "Fruit Flavored," "Naturally Flavored," "Low Fat," "[Number of] Calories," "Good Source of Vitamin C," "Gluten Free," "Made With Real Fruit," "0g *Trans* Fat," "Nutritious," and "All Natural," claiming the representations were false or misleading in light of the products' *trans* fat content.¹ In other words, if a manufacturer's packaged product contained any amount of PHOs and the manufacturer made any statement regarding the product's nutritional value, the product – and the manufacturer – became a target. The lawsuits centered on labeling and advertising, asserting claims for false and deceptive advertising under both federal and California state law.

¹ See, e.g., *Lam v. Gen. Mills, Inc.*, 859 F. Supp. 2d 1097 (N.D. Cal. 2012); *Red v. The Kroger Co.*, No. 2:10-cv-01025-DMG-MAN, 2010 U.S. Dist. LEXIS 115238 (C.D. Cal. Sept. 2, 2010); *Rosen v. Unilever United States*, No. 5:09-cv-02563-JW, 2010 U.S. Dist. LEXIS 43797 (N.D. Cal. May 3, 2010); *Wilson v. Frito-Lay N. Am.*, No. 12-1586 SC, 2013 U.S. Dist. LEXIS 47126 (N.D. Cal. Apr. 1, 2013).



Although the plaintiffs had some success in overcoming the tidal wave of motions to dismiss, they could not fully escape two glaring and prominent defenses: preemption and puffery. With respect to preemption, for example, in *Carrea v. Dreyer's Grand Ice Cream, Inc.*,² the plaintiff brought a putative class action alleging that the defendant misrepresented that its ice cream products contained "0g *Trans* Fat." The court held that the Federal Food, Drug and Cosmetic Act (FDCA), as amended by the Nutrition Labeling and Education Act (NLEA), preempted the plaintiff's claim.³ Specifically, when a product contains less than 0.5 grams of *trans* fat per serving, federal regulations require manufacturers to express the amount of *trans* fat as zero.⁴ Therefore, the plaintiff's claim seeking to impose a requirement not identical to the regulations was expressly preempted.⁵ The court rejected the plaintiff's argument that his claim was not preempted because he was attacking the representation on the product packaging and in marketing materials, not on the nutrition label, reasoning that "the distinction between Nutrition Facts and statements made on product packaging does not remove Plaintiff's claims from the preemptive scope of the federal regulations...."⁶ The Ninth Circuit Court of Appeals affirmed.⁷

Further, to state a misleading or false advertising claim under California law, a plaintiff is required to prove that a "reasonable consumer" likely would be deceived by the packaging, and that he actually relied on the packaging and was deceived.⁸ Several courts determined, as a matter of law, that the advertising statements or product labels the plaintiffs attacked would not likely deceive reasonable consumers into thinking the product was healthy.⁹

The New Theory: "Use" Claims

In January 2013, plaintiffs' attorneys advanced a new theory: the "use" theory. On January 21, 2013, a putative class action was filed against California Pizza Kitchen, Inc. and Nestle USA, Inc., alleging that the sale of packaged frozen pizzas containing *trans* fat is unlawful.¹⁰ The plaintiff did not claim any false or misleading

² No. C 10-01044 JSW, 2011 U.S. Dist. LEXIS 6371 (N.D. Cal. Jan. 10, 2011).

³ *Id.* at *12.

⁴ *Id.* at *8-9.

⁵ *Id.* at *12.

⁶ *Id.*

⁷ *Carrea v. Dreyer's Grand Ice Cream, Inc.*, 475 Fed. Appx. 113 (9th Cir. 2012). See also *Lam v. Gen. Mills, Inc.*, 859 F. Supp. 2d 1097 (N.D. Cal. 2012) (claims relating to "naturally flavored" and "fruit flavored" labels preempted); *Henderson v. Gruma Corp.*, No. CV 10-04173 AHM (AJWx), 2011 U.S. Dist. LEXIS 41077 (C.D. Cal. Apr. 11, 2011) (claims regarding "0 g cholesterol" and "0 g *trans* fat" labels expressly preempted); *Yumul v. Smart Balance, Inc.*, No. CV 10-00927 MMM (AJWx), 2011 U.S. Dist. LEXIS 109952 (C.D. Cal. Mar. 14, 2011) (claims based on "no cholesterol" and "healthy" labels preempted); *Peviani v. Hostess Brands, Inc.*, 750 F. Supp. 2d 1111 (C.D. Cal. 2010) (claims based on "0 Grams of *Trans* Fat" statement preempted); *Red v. Kraft Foods, Inc.*, 754 F. Supp. 2d 1137 (C.D. Cal. 2010) (claims based on "no cholesterol" and specific quantities of "whole grain" per serving preempted); *Chacanaca v. The Quaker Oats Co.*, 752 F. Supp. 2d 1111 (N.D. Cal. 2010) (claims based on "0 grams *trans* fat" label preempted); *Red v. The Kroger Co.*, No. CV 10-01025 DMG (MANx), 2010 U.S. Dist. LEXIS 115238 (C.D. Cal. Sept. 2, 2010) (claims based on "0g *Trans* Fat per serving" statement preempted). But see *Reid v. Johnson & Johnson*, 780 F.3d 952 (9th Cir. 2015 (claim relating to "No *Trans* Fat" statement not preempted); *Wilson v. Frito-Lay N. Am.*, No. 12-1586 SC, 2013 U.S. Dist. LEXIS 47126 (N.D. Cal. Apr. 1, 2013) (claim regarding "0g *Trans* Fat" label not preempted where plaintiff alleged additional disclosures were required because the product contained more than 13 grams of fat).

⁸ See *Williams v. Gerber Prods. Co.*, 552 F.3d 934, 938 (9th Cir. 2008).

⁹ See, e.g., *Carrea v. Dreyer's Grand Ice Cream, Inc.*, No. C 10-01044 JSW, 2011 U.S. Dist. LEXIS 6371 (N.D. Cal. Jan. 10, 2011) (statements that ice cream products are "Classic" or "Original" would not mislead a reasonable consumer into thinking the products are wholesome or healthy), *aff'd* 475 Fed. Appx. 113 (9th Cir. 2012); *Henderson v. Gruma Corp.*, No. CV 10-04173 AHM (AJWx), 2011 U.S. Dist. LEXIS 41077 (C.D. Cal. Apr. 11, 2011) (labeling statement "The Authentic Tradition" is non-actionable puffery). But see *Wilson v. Fit-Lay N. Am.*, No. 12-1586 SC, 2013 U.S. Dist. LEXIS 47126 (N.D. Cal. Apr. 1, 2013) (court could not conclude as a matter of law that reasonable consumers would not likely be deceived by representations that chips contained "0 Grams *Trans* Fat" or were "Made with ALL NATURAL Ingredients"); *Lam v. Gen. Mills, Inc.*, 859 F. Supp. 2d 1097 (N.D. Cal. 2012) (court could not conclude as a matter of law that reasonable consumers would not likely be deceived by representation that product was "made with real fruit"); *Yumul v. Smart Balance, Inc.*, 733 F. Supp. 2d 1117 (C.D. Cal. 2010) (court could not conclude as a matter of law that consumers would not likely be deceived by representations that product was "cholesterol free" and "healthy").

¹⁰ *Simpson v. California Pizza Kitchen, Inc.*, 989 F. Supp. 2d 1015 (S.D. Cal. 2013).



advertising or that she relied on such advertising in purchasing the products. Rather, she claimed that just the use of *trans* fat in the products was unlawful. The district court granted the defendants' motion to dismiss, holding that the plaintiff lacked Article III standing because she did not sufficiently plead an increased risk of harm or an economic injury.¹¹ The court further held that the sale of packaged food containing *trans* fat was not unlawful.¹²

Adding Fuel to the Fire: The FDA's Preliminary & Final Determinations Regarding PHOs

By November 2013, more than two dozen class actions relating to *trans* fat had been filed. On November 8, 2013, the FDA added fuel to the fire by issuing a preliminary determination regarding PHOs and a request for comments and scientific data and information. In the preliminary determination, the FDA "tentatively" determined that PHOs, the primary source of *trans* fat, "are not generally recognized as safe (GRAS) for any use in food based on current scientific evidence establishing the health risks associated with the consumption of *trans* fat..."¹³

In line with the new use theory in *Simpson* and now fueled by the FDA's preliminary determination, the plaintiffs shifted focus from claims relating to allegedly false and misleading advertising to a legally inaccurate claim that a determination that a food additive is non-GRAS is equivalent to a determination that the food containing that additive is adulterated and thus illegal to sell. In reality, a determination that an additive is non-GRAS simply means that manufacturers must seek and obtain FDA pre-approval to use the non-GRAS food additive.¹⁴ Packaged-food manufacturers became victims of unfortunate industry phrasing, and the number of lawsuits again spiked. Many of the cases contained a hybrid of both the false advertising and use theories and some asserted only the use theory, as in *Simpson*.

If the FDA's preliminary determination added fuel to the fire, its final determination regarding PHOs caused a raging inferno. On June 17, 2015, in its final determination, the FDA declared that "there is no longer a consensus among qualified experts that" PHOs "are generally recognized as safe (GRAS) for any use in human food."¹⁵ While many commenters requested an immediate compliance date (i.e., the immediate removal of PHOs from products without FDA pre-approval), the FDA set a three-year compliance date of June 18, 2018 to: (1) provide manufacturers sufficient time to submit, and the FDA to review and approve, the use of PHOs; (2) minimize market disruptions by providing sufficient time to identify suitable replacements for PHOs; (3) permit manufacturers to exhaust existing product inventories; and (4) allow time to reformulate and modify labeling of affected products.¹⁶

The FDA's final determination became the focus of new class action complaints and the defendants' motions to dismiss them. The plaintiffs used the FDA's determination that PHOs are non-GRAS as a sword to support their (legally inaccurate) claim that food containing PHOs is adulterated and therefore unlawful. The defendants, on the other hand, used the FDA's final determination and three-year compliance period as a shield, arguing that the plaintiffs' use claims, which seek to make it immediately unlawful to sell food containing *trans* fat: (1) are barred by conflict preemption and California's safe harbor doctrine; (2) are subject to dismissal under the primary jurisdiction doctrine because the determination of the safety of PHOs is best left to the FDA; and (3) fail because

¹¹ *Id.* at 1022-1023.

¹² *Id.* at 1025-1026.

¹³ 78 Fed. Reg. 67169 (Nov. 8, 2013).

¹⁴ 21 C.F.R. § 171.1; see also 78 Fed. Reg. 67169 (Nov. 8, 2013).

¹⁵ 80 Fed. Reg. 34650 (June 17, 2015).

¹⁶ *Id.* at 34668-34669.



the FDA's three-year compliance period allows the sale of food containing *trans* fat until at least June 18, 2018 without FDA pre-approval.

Although the plaintiffs' allegations under the use theory have remained relatively unchanged, being only slightly tweaked when prompted by a court decision on a motion to dismiss, the California district courts have come to inconsistent decisions regarding the viability of the plaintiffs' use claims, and the FDA's final determination has only served to confuse matters further.

Water on the Fire: Congress Seeks to Put an End to the “Frivolous” Litigation

In December 2015, Congress sought to end the *trans* fat litigation, at least insofar as it relates to the plaintiffs' use theory. On December 18, 2015, President Obama signed the Consolidated Appropriations Act for 2016 (H.R. 2029) (“2016 CAA”) into law, explicitly providing that “[n]o [PHOs] ... shall be deemed unsafe.... and no food ... that bears or contains a [PHO] shall be deemed adulterated ... by virtue of bearing or containing a [PHO] until” June 18, 2018.¹⁷ The purpose of this section was to “amend[] an FDA policy relating to the regulatory treatment of [PHOs] **to prevent frivolous lawsuits.**”¹⁸

Only one court has ruled on the preemptive effect of the 2016 CAA. In *Backus v. Nestle USA, Inc.*,¹⁹ the plaintiff brought a putative class action alleging that the defendant's sale of coffee creamer products containing *trans* fat is unlawful. The court granted the defendant's motion to dismiss on the ground that the plaintiff's use claims are preempted by the FDA's final determination and the 2016 CAA, reasoning that the plaintiff's use claims, “which would impose an immediate prohibition on the use of [*trans* fat] in all foods under all circumstances would stand as an obstacle to the fulfillment of the FDA's objectives ... and conflict with Congress's decision not to deem [*trans* fat] unsafe, or the food containing them adulterated.”²⁰ The plaintiff appealed, and the appeal is not yet briefed.

Venturing Further Into the Land of the Unknown: Class Certification

For those actions that have survived motions to dismiss, class certification remains an open question. There are three cases pending before the Ninth Circuit Court of Appeals regarding class certification in food misbranding cases: *Jones v. ConAgra Foods, Inc.*, No. 14-16327 (9th Cir. filed July 14, 2014), *Brazil v. Dole Packaged Foods*, No. 14-17480 (9th Cir. filed Dec. 17, 2014), and *Kosta v. Del Monte Foods*, No. 15-16974 (9th Cir. filed Oct. 2, 2015). In each case, the district court ultimately denied the plaintiffs' request for class certification.²¹ Among the issues before the Ninth Circuit are whether the classes are ascertainable, individual issues predominate over common questions, and a reliable damages model can be formulated. Two of the appeals, *Jones* and *Brazil*, are fully briefed, but oral argument has not yet been scheduled. The *Kosta* appeal is not yet

¹⁷ Consolidated Appropriations Act, 2016, Pub. L. No. 114-113, § 754, 129 Stat. __, __ (2015).

¹⁸ *Legislative Digest*, Dec. 18, 2015, Republican Policy Committee, available at <https://policy.house.gov/legislative/legislative-digest/friday-december-18-2015> (last visited Jan. 19, 2016); see also *FY 2016 Omnibus Summary – Agriculture Appropriations*, House Appropriations Committee, available at http://appropriations.house.gov/uploadedfiles/12.15.15_fy_2016_omnibus_-_agriculture_-_summary.pdf (last visited Jan. 19, 2016).

¹⁹ No. C-15-1963-MMC, 2016 U.S. Dist. LEXIS 29669 (N.D. Cal. Mar. 8, 2016).

²⁰ *Id.* at *13 (internal quotations omitted).

²¹ *Jones v. ConAgra Foods, Inc.*, No. C 12-01633 CRB, 2014 U.S. Dist. LEXIS 81292 (N.D. Cal. June 13, 2014); *Brazil v. Dole Packaged Foods, LLC*, No. 12-CV-01831-LHK, 2014 U.S. Dist. LEXIS 157575 (N.D. Cal. Nov. 6, 2014); *Kosta v. Del Monte Foods, Inc.*, 308 F.R.D. 217 (N.D. Cal. 2015).



fully briefed. A number of district courts have stayed *trans* fat class actions pending the outcome of the appeals in *Jones, Brazil, and Kosta*.²²

So What's Next?

If you are following the *trans* fat class action litigation, there are several things to watch out for in 2016 and 2017:

- The outcome of the appeal in *Backus v. Nestle USA, Inc.*,²³ which held that the plaintiff's use claims are preempted by the FDA's final determination and the 2016 CAA.
- The outcome of the appeal in *Hawkins v. The Kroger Co.*²⁴ *Hawkins* is a hybrid case in which the plaintiff asserted both false advertising and use claims relating to the defendant's sale of bread crumbs that allegedly contain *trans* fat. The district court granted the defendant's motion to dismiss, holding that the plaintiff's false advertising claims relating to the "0g *Trans* Fat" label were expressly preempted. Further, the court held that the plaintiff's use claims could not survive dismissal because the plaintiff failed to plausibly allege an economic injury as required by California statutory law. The plaintiff appealed, and the appeal is not yet briefed.
- The outcome of the appeals in *Jones v. ConAgra Foods, Inc.*, *Brazil v. Dole Packaged Foods*, and *Kosta v. Del Monte Foods*. These cases likely will set the stage for class certification in any *trans* fat class action that survives dismissal.
- The outcome of pending motions to dismiss. Several motions to dismiss are fully briefed and awaiting decisions. Particularly of interest will be whether the courts follow the lead of the court in *Backus v. Nestle USA* and hold that Congress' declaration has – once and for all – put an end to the *trans* fat class action lawsuits, at least to the extent they are based on a use theory.

Conclusion

Only time will tell whether the courts finally put an end to the *trans* fat class actions. What is known is that the plaintiffs' attorneys will not be deterred. Despite the Ninth Circuit's ruling in *Carrea v. Dreyer's Grand Ice Cream, Inc.*,²⁵ at least eight more lawsuits asserting claims based on "0g *Trans* Fat" representations nonetheless have been filed. And at least two more lawsuits asserting claims under the use theory have been filed since Congress declared that no PHOs "shall be deemed unsafe" and no food "that bears or contains a [PHO] shall be deemed adulterated" until the June 18, 2018 compliance date set forth in the FDA's final determination. Therefore, unfortunately for packaged-food manufacturers, there is no end in sight.

²² *Samet v. Kellogg Co.*, No. 5:12-cv-01891-PSG, 2016 U.S. Dist. LEXIS 45516 (N.D. Cal. Apr. 4, 2016); *Thomas v. Costco Wholesale Corp.*, No. 12-cv-02908-BLF, 2015 U.S. Dist. LEXIS 149060 (N.D. Cal. Nov. 2, 2015); *Wilson v. Frito-Lay N. Am., Inc.*, No. 12-CV-1586 SC, 2015 U.S. Dist. LEXIS 94179 (N.D. Cal. July 20, 2015); *Pardini v. Unilever United States, Inc.*, No. 13-cv-01675-SC, 2015 U.S. Dist. LEXIS 49752 (N.D. Cal. Apr. 15, 2015). *But see Martinelli v. Johnson & Johnson*, No. 2:15-cv-01733-MCE-EFB, 2016 U.S. Dist. LEXIS 16481 (E.D. Cal. Feb. 10, 2016) (denying motion to stay).

²³ No. C-15-1963-MMC, 2016 U.S. Dist. LEXIS 29669 (N.D. Cal. Mar. 8, 2016).

²⁴ No. 3:15-cv-02320-JM-BLM, 2016 U.S. Dist. LEXIS 53632 (S.D. Cal. Mar. 17, 2016).

²⁵ 475 Fed. Appx. 113 (9th Cir. 2012), holding that the plaintiff's claim based on the "0g *Trans* Fat" representation was expressly preempted.



Using *Daubert* to Close the Gate on Failure-to-Warn Claims

Defending against a failure-to-warn claim always presents unique challenges. Plaintiffs' attorneys often file design-defect claims, tacking on a failure-to-warn count as an afterthought. It is common for plaintiffs' attorneys to focus almost exclusively on developing their cases for defective design, which in turn puts the manufacturer in the position of focusing their defense on that particular claim. If manufacturers are not careful, those pesky warnings claims may still be there by the time trial rolls around. Thus, it is critical that manufacturers and their counsel are prepared to remind courts of their gatekeeping function under *Daubert*, and to close the gate on unreliable warnings opinions. This article takes a look at some successful attempts to exclude "warnings experts."

Lack of Qualifications

While not always the most successful avenue for excluding a proposed expert, the first area to consider attacking is the expert's qualifications. The focus should be on whether the expert is qualified to render an opinion about the particular product or warning method. For instance, in *Calisi v. Abbott Labs.*, No. 11-1010671, 2013 U.S. Dist. LEXIS 139257 (D. Mass. Sept. 27, 2013), the plaintiff sued drug manufacturer Abbott Laboratories for failure to warn about the alleged risks of developing lymphoma from taking the drug Humira, a drug designed to treat rheumatoid arthritis. The plaintiff proffered their warnings expert as an expert in FDA regulations "with a specialization in drug labeling," who was to testify regarding the adequacy of Humira's label while the plaintiff was taking the drug.

At first blush, the proposed expert appeared qualified; he was a biochemist with a Ph.D. in pharmacology, had completed a postdoctoral fellowship in cancer research, and had even worked for the FDA as a pharmacologist reviewer and served as chief of regulatory affairs at the National Institutes of Health. But the court found that, under *Daubert* and Federal Rule of Evidence 702, he was not qualified to render an opinion about the adequacy of the warning. First, he was not a medical doctor, so he lacked "qualifications to opine on what is clinically appropriate in terms of treating patients." Second, he was neither an expert nor had he received specialized training in psychology, cognitive decision making, or behavioral science. Thus, he could not show "how the label's relevant target audience would interpret the Humira labels." The court granted the manufacturer's motion to exclude the warnings expert, and, as a result, awarded the manufacturer summary judgment.

Similarly, in *Robertson v. Norton Co.*, 148 F.3d 905 (8th Cir. 1998), the plaintiff was injured when a power sander's ceramic grinding wheel exploded. The plaintiff sued the manufacturer, claiming that the warnings were inadequate. The grinding wheel warned that "[i]mproper use may cause grinding wheel breakage and serious injury." At trial, the plaintiff offered a ceramics expert who opined that the ceramic wheel's warning label did not explain "improper use," and its cross-reference to an ANSI publication was ineffective. The manufacturer's attempt to exclude the expert failed at trial.



The circuit court reversed on appeal and provided the following reasoning:

Whether or not a given warning is adequate depends upon the language used and the impression that it is calculated to make upon the mind of an average user of the product. Questions of display, syntax, and emphasis are involved in evaluating a warning, or set of directions, and upon those matters [many experts in other areas] are not necessarily qualified to speak.

Thus, while the ceramics expert was qualified to testify about a manufacturing defect in the exploding ceramic grinding wheel, that did not qualify him as a warnings expert. His ceramics knowledge did not provide the necessary expertise on “questions of display, syntax, and emphasis” to assist the jury.

Lack of Reliable Methodology Due to Insufficient Testing of Causation Theory

Under *Daubert*, the first factor for determining the reliability of expert testimony is whether the expert’s theory can be and has been tested. Product manufacturers should focus on this factor, because it often helps smoke out the *ipse dixit*, or “because I said so,” opinions. In *Parker v. Brush Wellman, Inc.*, Nos. 1:04-CV-606, 1:08-CV-2725, 2010 U.S. LEXIS 97702 (N.D. Ga. Sept. 17, 2010), the plaintiffs were employees of Lockheed Martin Corp., where they used beryllium-containing alloys to manufacture component parts for Lockheed. The plaintiffs allegedly developed beryllium-related sicknesses and sued the manufacturer of the alloys for failure to provide Lockheed with adequate warnings pertaining to the health risks associated with beryllium.

It is generally recognized that beryllium is the cause of the sickness alleged by the plaintiffs. Therefore, the manufacturer focused its *Daubert* attack on whether the plaintiffs’ expert had established specific causation as to the particular plaintiffs – i.e., could the expert show that the plaintiffs’ actual exposure level at Lockheed was sufficient to cause the sickness? The court agreed with the manufacturer, and found that the proposed expert could not establish causation stemming from the plaintiffs’ exposure at Lockheed, and thus, could not establish causation resulting from the manufacturer’s alleged failure to warn Lockheed. Specifically, the expert did not sufficiently test his theory, stating that “only industrial hygiene sampling for a period of time can document the actual exposure.” Since Lockheed had since implemented controls that were not in place at the time of the alleged beryllium exposures, and the sampling did not occur until after those exposures, those samples were not an appropriate test. Furthermore, the plaintiffs’ proposed expert could have placed the products in an environmental chamber and reenacted the relevant machining procedures that the plaintiffs performed, but failed to do so. Because the expert did not perform sufficient testing to establish causation due to elevated beryllium exposure at Lockheed, his theory that the failure to warn Lockheed of beryllium’s health risks caused the plaintiffs’ illnesses was deemed unreliable and excluded.

Failure to Establish Known Error Rate

Akin to the lack-of-testing factor is *Daubert*’s consideration of whether an expert’s theory has a known error rate. Manufacturers should be quick to point out that if a plaintiff’s warnings expert has not established an error rate for his theory, his opinions are unreliable. For instance, in *Shepherd v. Michelin Tire Corp.*, 6 F. Supp. 2d 1307 (N.D. Ala. 1997), a laborer was fatally injured when he attempted to place a 16-inch tire on a 16.5-inch rim, causing the tire to explode. Even though the existing warning on the tire warned against placing smaller tires on larger rims, the estate brought a warning claim. The plaintiff’s expert was eminently qualified, having written several scholarly articles on the subject of warnings, and having studied and testified regarding the theory of



human factors related to warnings. In this case, he opined that the tire lacked adequate warnings and that if the tire contained his proposed alternative, or “candidate” warning, the injury would not have occurred.

The trial court held a *Daubert* hearing and excluded the testimony. The expert’s proposed warning system was, in part, to include posters and pamphlets describing the potential dangers of inflating tires on mismatched rims. However, he did not sufficiently test his theory, and thus, the court was concerned that he could not provide an error rate for his methodology. As a result, the plaintiff’s expert “[could] not say that the degree of effectiveness of his warning scheme would exceed 50% in cases such as this one.” The court further reasoned that “[s]imply concluding, as is reasonable, that a more prominent warning would decrease the danger, although plausible, does not make such a conclusion ‘relevant’” in a case where the plaintiff bears the burden to prove causation.

Lack of “Fit” With the Facts of the Case

The *Daubert* factors are not exhaustive, and courts must customize their inquiries to the facts of each particular case. Indeed, so must the proposed warnings expert. In *Jaurequi v. Carter Mfg. Co.*, 173 F.3d 1076 (8th Cir. 1999), the plaintiff brought design and warning claims against the manufacturer of a corn harvesting tool after an accident in which his legs were amputated by one of the tool’s components. In support of his warning claims, the plaintiff offered a human factors engineer with a doctorate in experimental psychology to opine that the tool was defective because the original warning signs were “too small, too far from the point of danger, and oriented at an angle which made them difficult to read.” He testified that the warnings should have been accompanied by stripes and chevrons to draw the user’s attention.

But the Eighth Circuit affirmed the district court’s decision to exclude the proposed warnings expert. According to the court, there was a lack of “fit” between the testimony and the facts of the case. First, the proposed expert failed to take into account that the warnings that originally accompanied the tool had been painted over prior to the plaintiff’s use. When pressed on this issue, the proposed expert could not say whether his suggested warnings would have also been painted over. As a result, the plaintiff could not establish that the allegedly defective warnings proximately caused the accident.

Conclusion

Even if plaintiffs focus almost exclusively on developing their design-defect claims, manufacturers should not be caught off guard when plaintiffs offer a warnings expert prior to trial. While this article focused on a select number of *Daubert* factors, be prepared to vigorously apply each of the *Daubert* reliability criteria to the proposed expert’s opinions. By doing so, courts will be more inclined to slam the gate on unreliable warnings opinions.



Know the Industry: Defending Building Product Defect Claims

Successfully defending against a claim that a building product is defective requires an understanding of the construction industry, especially the documents, project delivery methods, and insurance used in a particular project. These cases usually involve many different parties and such project information is vital in developing the proper litigation strategy and anticipating which parties will fall into the various camps that may share in expert witnesses, coordinate on motion drafting, align on theories of liability, and take a similar settlement posture.

A typical case involves a claim by the building owner or building owner's insurer that there is something wrong with the building – e.g., leaking roof, failing windows, buckling floors, inadequate ventilation, mold growth, collapsed wall, or burst pipe, to name just a few. The owner/insurer usually asserts some combination of claims of breach of contract, breach of express and implied warranties, negligence, professional negligence, or strict product liability against the architect, engineer, contractor, subcontractors, sub-design consultants, building product manufacturer, product supplier, or anyone else who could have had any conceivable connection to the failure. The general theories of liability come down to:

- **Architect liability.** The manufacturer properly designed and manufactured the product and the contractor properly installed the product in accordance with the construction drawings, but the architect chose (specified) the wrong product for the application or improperly designed how it was to be installed.
- **Contractor liability.** The manufacturer properly designed and manufactured the product and the architect properly specified the product and properly designed its installation, but the contractor improperly installed the product.
- **Manufacturer liability.** The architect properly specified the product and properly designed its installation and the contractor properly installed the product in accordance with the construction drawings, but the manufacturer defectively designed or manufactured the product.

As a result, after filing a complaint, the owner often sits back and watches the finger-pointing. A working knowledge of the construction industry allows you to anticipate who will point at whom and to build your litigation strategy accordingly.

Documents

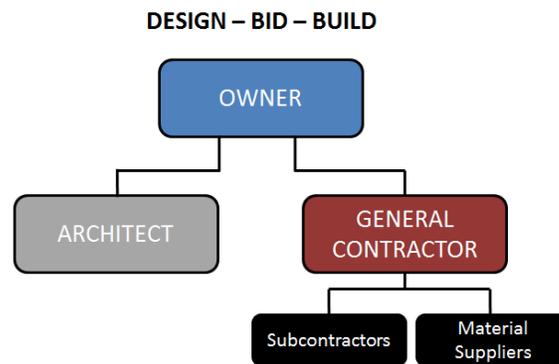
First, there are several different types of documents that you will want to request during the discovery phase of a construction defect case that will prove pertinent. They fall into a few main categories:

- **Contract documents:** requests for proposal, bids, owner/architect agreements, owner/contractor agreements, sub-consultant agreements, subcontracts, general and supplemental conditions, specifications, drawings, and change orders.
- **Project records:** meeting minutes, daily reports, logs, diaries, inspection reports, requests for information and responses, architect bulletins, construction change directives, correspondence, project schedules, applications for payment, accounting records, as-built drawings, photo-documentation reports, and email correspondence.
- **Product documents:** product literature, submittals, installation instructions, warranties, warnings, purchase orders, bills of lading, invoices, specifications, pricing, and quotations.

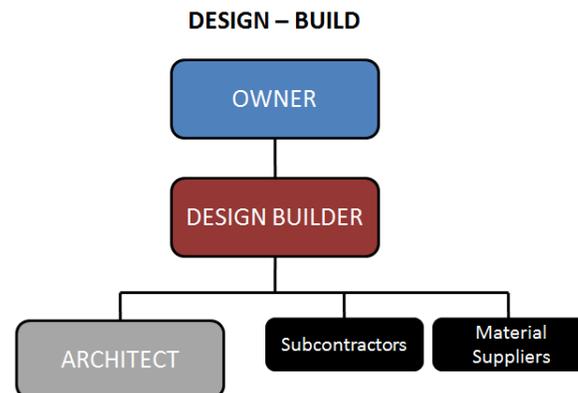
These documents will tell how the construction was intended to proceed, how it actually did proceed, and whether any issues arose during construction and how those issues were dealt with and by whom.

Project Delivery Methods

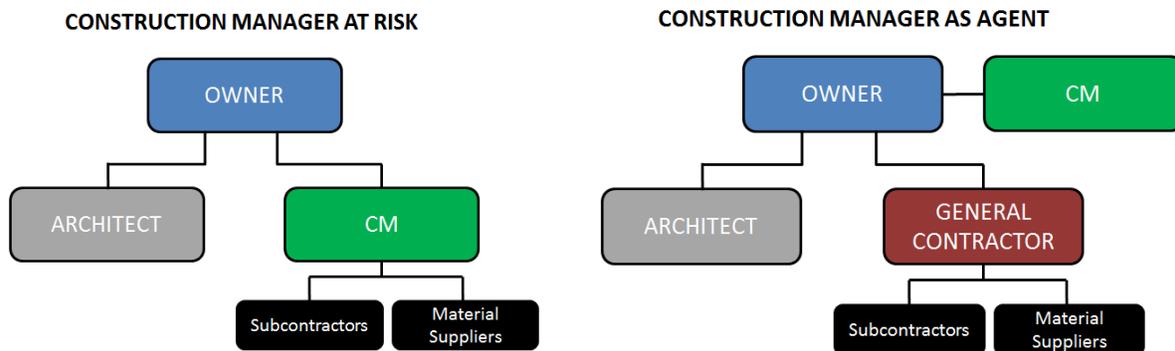
Next, a general understanding of the various construction (or project) delivery methods is necessary to understand the primary responsibilities of the key project participants. A project delivery method is the process used to execute a construction project for the purpose of assigning responsibilities and risk to the project team. There are dozens of variations of project delivery methods, but the most common, basic methods are Design-Bid-Build, Design-Build, Construction Manager as Agent, and Construction Manager at Risk.



Design-Bid-Build, also known as the general contracting project delivery method, is probably the most familiar. The process is linear, where one phase is completed before another begins. The architect is selected based on a negotiated professional fee and works with the owner to design the building under a separate contract with the owner. The architect drafts a complete set of construction drawings and project specifications. The owner then, often with the architect's assistance, seeks bids from qualified contractors who base their bids on their estimated cost to construct the project in accordance with the drawings and specifications. The contractor is usually selected based on the lowest responsive bid, and there are often many subcontractors under its contract/direction. The contractor and owner then enter into a separate contract, and the contractor is responsible for supplying all building products in accordance with the specifications.



Under the Design-Build project delivery method, a single entity is solely responsible to the owner for both design and construction of the building. With the assistance of a program architect, the owner determines the basic program for the building (e.g., square footage, number of floors, basic functionality, performance specifications) and provides that information to the design-builder, who sets about designing and building the project in accordance with owner's program. This process does not require a full set of construction drawings to be completed before construction starts and therefore often results in a faster construction process. It can also result in cost savings because the design-builder is involved early in the design process and can suggest to the owner design and construction options that may reduce the construction costs. It also provides a single point of responsibility for the owner and fosters better communication by reducing adversarial roles between design and construction. Here, the design-builder is also responsible for supplying all building products.



Under the Construction Manager (CM) method of project delivery, the owner holds separate contracts with the architect and the contractor, who is engaged before the drawings and specifications are complete to provide pre-construction services, such as cost estimating, constructability review of the documents, and project scheduling. Because the construction drawings and specifications have not been completed, CM selection is not based on price, but on qualifications (e.g., experience, history of successful performance, financial strength). Under one of the more popular variations of the CM method, the contractor's fee is negotiated based on the ultimate project costs and the owner has open-book access to all project costs. The owner participates in the bidding and selection of trade subcontractors and vendors, the most costly component of development, to a much greater degree than in other project delivery methods. Many owners select the CM method knowing that the lowest initial price derived through the design-bid-build bidding process does not always ultimately turn out to be the lowest price nor the best value by the end of construction due to change orders and other variations in project scope and costs. The CM method provides the advantage of involving a construction company early in the design process to advise the owner on cost and constructability issues during the crucial early planning phase.

Within the overall label of construction management there are two different project delivery systems, with variances related primarily to pricing and contractual obligations. In CM at Risk, the CM holds the trades and vendor contracts, taking on the financial risk of construction by providing the owner with a guaranteed maximum price for construction and a set date for completion, along with a negotiated professional fee (typically a percentage of the cost of construction) for the CM services. Under the second type, CM as Agent, the owner holds all trades and vendor contracts and the CM serves as an extension of its staff, managing all the contracts, but holding no financial or performance risk. The risk is contracted with each trade contractor. Thus, under a CM at risk scenario, the CM purchases the building products either directly or through its trade subcontractors,

whereas under a CM as agent scenario, the owner purchases the building products either directly or through its trade contractors.

Thus, depending on the delivery method used to build the project, different entities in the project have differing roles, responsibilities, and relationships with one another, which affects the way that each of the parties approaches liability. For example, in a design-bid-build project, the design team, contractor, and manufacturer are each interested in establishing that the failure is not a result of their role. In a design-build project, however, because the design and construction are both the responsibility of a single design-builder, its likely strategy is to prove that the failure is the result of a defect in the manufactured product, and the manufacturer is alone in establishing that the failure is a result of improper building design or product installation.

For a specific example, consider a case where the initial investigation suggests that a leaking window is the result of improper installation. In a design-bid-build or CM at Risk project, the architect and window manufacturer will likely align in looking to the contractor or CM as the responsible entity. Alternatively, in a design-build project, the window manufacturer will likely be on its own looking to the design-builder as the responsible entity. In a CM as Agent project, the architect, manufacturer, and construction manager would be aligned against the contractor.

Thus, different groups of allies are created depending on the project delivery system used. This is important in predicting litigation costs and exposure to liability. The aligned parties will often be willing to share in deposition and other discovery costs, including jointly retained expert witnesses, and they will likely cooperate on litigation strategy and possibly share in motion drafting. They are also likely to take similar positions when it comes to settlement posture and the amount they would be willing to contribute to a global settlement.

Insurance

Another important aspect to consider in building a successful defense strategy is the type of insurance applicable to the construction project. There are myriad insurance products and policies that may provide coverage for the loss, and they each have individual and unique coverage issues, all of which vary from state to state. But coverage issues should be considered because understanding the different sources of coverage will assist in anticipating how the parties might contribute toward settlement.

Faced with a construction defect claim, a contractor will look to its commercial general liability (CGL) policy for coverage. The standard CGL policy covers “property damage” that is caused by an “occurrence.” Whether CGL insurance covers property damage that arises from construction defects depends on the interpretation of occurrence. That analysis differs from state to state and is a contested issue in many. Moreover, even where a construction defect is found to be an occurrence, there are policy exclusions (such as the “your work” exclusion) that must be analyzed. As a result, a specific state-by-state analysis is required to parse out potential pockets of coverage amongst the defendants.

The use of “wrap-up” insurance programs adds an additional level of complexity. Traditionally, each participant (i.e., owner, contractor, subcontractor) in a construction project obtains insurance individually to protect against the risk of financial loss. More recently, wrap-up insurance programs have developed on large-scale projects as an alternative to the traditional method of risk management and a way to reduce insurance costs for the entire project. In a wrap-up program, one entity (either the project owner, general contractor, or design-builder) purchases an insurance policy that will cover all the key construction participants such as the owner, design-

builder, construction manager, general contractor, and subcontractors. Typical wrap-up policies provide coverage for workers' compensation, general liability, and excess liability for the length of a construction project for all or a majority of the parties involved, rather than requiring each participant to be responsible for procuring their own insurance. Wrap-ups are used on large individual projects or on a "rolling" basis by aggregating smaller projects that are started and completed over a defined time period.

The most common types of wrap-up programs are Owner Controlled Insurance Programs (OCIPs) and Contractor Controlled Insurance Programs (CCIPs). The type of Controlled Insurance Program (CIP) is determined by the party that sponsors the wrap-up. The *owner* of a construction project sponsors an OCIP, while a *general contractor or design-builder* sponsors a CCIP. The sponsor is in charge of securing insurance coverage and paying for and administering the insurance program.

Wrap-up insurance eliminates duplications in coverage that occur when each contractor and subcontractor purchases independent liability insurance, often with different limits of liability, deductibles, and insurers. This duplication also can result in litigation between the respective insurance companies over responsibility for a claim. In theory, with a CIP, there should be less litigation among contract participants since the same policy insures all of them. What does all this mean for a building product manufacturer involved in a complex construction litigation action? If a CIP is involved, all of the covered entities will be represented by the same counsel with a single litigation strategy and there will be fewer insurers willing to contribute toward settlement.

Coverage for an architect is typically available under the architect's professional liability insurance policy. An architect has responsibility to perform design services, including preparation of plans and specifications, in accordance with the applicable standard of care and the terms of its contract with the owner. Unlike a CGL policy, the standard professional liability policy does not limit coverage to a specific type of injury, such as "bodily injury" or "property damage," but covers all amounts that the insured is legally liable to pay as damages because of its professional negligence. As a result, in a construction defect claim, while a contractor may not be covered under its CGL policy, the architect is typically covered under its professional liability policy.

Finally, builder's risk (or inland marine) property insurance will often come into play where there is damage to other portions of the building during construction as a result of a defective building product. It is not unusual for project documents (especially the General Conditions) to contain a broad waiver of claims/subrogation in favor of all construction participants, including suppliers, that essentially waives the subrogation rights of the builder's risk insurer for insured claims.

Conclusion

These are just some of the things that are unique to the construction industry. Having a basic understanding of the relevant documents, project delivery methods, and insurance issues can help in developing an efficient and effective litigation strategy when defending a manufacturer against a claim that its building product is defective. In these cases, the risk of exposure is always greater for the manufacturer. If an architect is found liable for its faulty design or specification, or the contractor is found liable for its improper installation, that liability generally is confined to the project. But if a manufacturer's product is found to be defective, that finding can have repercussions far beyond a single project and may require the recall of the product or expose the manufacturer to liability across the country – potentially involving every project where the product has been installed. In light of this, developing a successful defense based on a complete understanding of the construction industry is vital.



Meet the Millennial Juror: Effectively Communicating With “The Narcissistic Generation” at Trial

Let’s face it: Millennials are fascinating. For those of us who grew up passing notes in high school instead of trading texts, sharing our innermost thoughts with only our close friends instead of posting them on the internet for the world to see, and only getting a trophy if we actually won, understanding Millennials is difficult. But you better get to know them because Millennials have surpassed Baby Boomers as the nation’s largest living generation and already comprise over one-third of the jurors who show up for jury duty. Therefore, learning how to effectively communicate with Millennials is becoming increasingly important.

Who Are the Millennials?

Generally, Millennials are those born from the early 1980s to around 2000 (current ages 16-36). They are the first generation to come of age in the new millennium. Millennials are the children of Baby Boomers and are generally characterized by one term: narcissistic. They are on track to become the most educated generation and have a strong sense of self-entitlement, imparted by their overprotective and over-involved “helicopter parents.” Millennials are team-oriented, confident, impatient, and effective multitaskers. They are accustomed to having a large amount of information at their fingertips and sifting through it quickly to find answers.

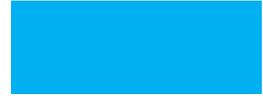
The Pew Research Center published two comprehensive reports¹ on Millennials’ behaviors, values, and opinions, which reveal the following insights that are of particular importance to trial lawyers:

- Millennials are more ethnically and racially diverse than previous generations.
- Millennials are the least overtly religious of all previous generations.
- Millennials are more highly educated than previous generations.
- Millennials are less likely to be married or have children than previous generations were at comparable ages. They are more likely to be living with other family members, such as their parents, than were those in the two previous generations at the same age. They are more tolerant and supportive of nontraditional behaviors regarding marriage and children.
- The Millennial Generation is the first “always connected” generation, and Millennials highlight technology use as the defining characteristic of their generation. They treat their cell phones as appendages, with 83 percent sleeping with their cell phone at their bedside every night. Seventy-five percent of Millennials have profiles on at least one social networking site, 62 percent connect to the internet wirelessly when away from home, 20 percent have posted videos of themselves online, and the typical Millennial sends or receives 20 texts per day. These statistics far surpass prior generations’ technology usage.
- Millennials are underemployed but remain optimistic about their future. They are more likely to switch jobs and careers than previous generations.
- Millennials are significantly more politically and socially liberal than members of other generations.
- Millennials are skeptical of people, with two-thirds saying “you can’t be too careful” when dealing with people.

¹ See “Millennials in Adulthood: Detached from Institutions, Networked with Friends,” The Pew Res. Center (2014), http://www.pewsocialtrends.org/files/2014/03/2014-03-07_generations-report-version-for-web.pdf; “Millennials: Confident. Connected. Open to Change,” The Pew Res. Center (2010), <http://www.pewsocialtrends.org/files/2010/10/millennials-confident-connected-open-to-change.pdf>.



Millennials



Communicating With Millennials at Trial

To effectively communicate with Millennials, trial lawyers must keep in mind several key traits that distinguish them from previous generations. First, Millennials define themselves by technology, and thus, trial lawyers must embrace technology. They have grown up in a time when, within hours of an event, news stations have animations, visuals, and graphically created depictions of the event. Millennials expect to see the same in the courtroom. And many of them can create (or at least believe they can create) such visuals themselves through any number of computer programs or iPhone applications in an instant. Gone are the days where there was a concern that impressive graphics and animations might look too “expensive” or “fancy” and will turn off jurors. Instead, we have come full circle to a place where impressive graphics and animations are expected and necessary for effective juror communication.

Second, Millennials are impatient and have short attention spans. They are used to learning through short bursts of information accompanied by graphical depictions that communicate directly and get to the point quickly. They do not want lengthy, detailed, and unnecessary information. Keep in mind that they grew up in the world of television courtroom dramas such as *Law & Order*, where a trial commenced about halfway through the show and concluded within 30 minutes. While *Law & Order* obviously is unrealistic, the point is that Millennials simply will not tolerate mass amounts of irrelevant information. This is the complete opposite of Baby Boomers who – while still expecting top-notch work in the courtroom – will put the work into sorting through information.

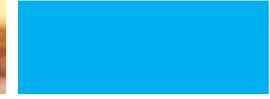
Third, Millennials are narcissistic and highly educated. They do not view lawyers or expert witnesses as experts or voices of authority. *They* are the authorities and want to be the experts. They want to be educated and led to the conclusion, not told the conclusion. While experts still play a critical role at trial, their importance to Millennials is as teachers rather than authority figures. While Baby Boomers tend to trust the word of an expert with the best academic credentials and real-world experience who worked hard to advance just like they did, these attributes are less important to Millennials, who will not “take an expert’s word for it” just because of the expert’s lengthy résumé. Rather, the expert must teach them in a way they will understand, keeping their attention and leading them to the answer, rather than telling them the answer.

Fourth, like Generation Xers, Millennials are visual learners who are used to oral messages being accompanied by and reinforced with visuals. This is how they process and retain information. Therefore, having clean, simple, polished, and professional visuals to accompany messages at trial is critical to reaching Millennials. Further, having multiple visual aids will keep Millennials’ attention and is a way to emphasize messages without unwelcome repetition.

Finally, Millennials are skeptical of people, and lawyers are no exception. Therefore, similar to Generation Xers, the title of “lawyer” does not earn you any amount of respect or trust from Millennials. Again, they do not view anyone but themselves as authorities. Trial lawyers must work hard to earn their respect and trust. This means being yourself, being honest, and not “playing games” with the other side during trial. Many trial lawyers make the mistake of believing that the theatrics that once defined a great trial lawyer will appeal to Millennials because they are entertaining, but don’t underestimate Millennials’ intelligence. While they may find the theatrics entertaining, they are likely to see them for what they are and will only become more skeptical of the lawyer.



Millennials



Conclusion

Based on their stereotypes as narcissistic, lazy, and self-entitled, lawyers tend to count Millennials out as influential jurors. But don't. More and more, Millennial jurors are volunteering for the foreperson role. Due to their highly structured childhoods, they tend to be structural leaders rather than opinion leaders, making sure that all jurors have an opportunity to speak and that they follow the law. From the plaintiffs' perspective, Millennials tend to award significantly higher damages, having grown up hearing dollar figures that seemed outrageous to previous generations. From the defense perspective, Millennials' skepticism of people can serve a critical role. For instance, they are more likely to question a plaintiff about what conduct or failure to act by that plaintiff may have played a role in the event leading to an injury or lawsuit.

Technology, visual communication, and getting to the point *quickly* are the keys to effectively communicating with Millennials. Consider this: When was the last time you were on an elevator with a Millennial who wasn't looking at his or her smartphone even while talking to someone else? Millennials lose focus fast when something does not keep their attention and interest them. To keep them from spending their time in the jury box panicking from the temporary loss of their most important accessory, trial lawyers must have an entertaining, visual presentation that keeps Millennials' attention. They have neither the patience nor the inclination to watch a story unfold on a chalkboard or flip chart.

Millennials are game-changers who require trial lawyers to rethink how they communicate with jurors. A failure to adjust and adapt and take Millennial jurors into consideration when preparing for trial undoubtedly will result in adverse outcomes as the Millennial juror population continues to rapidly grow.



Thompson Hine was named one of the top 22 law firms nationally in *BTI State of Alternative Fee Arrangements 2016*, an analysis of firms' efforts to help clients control costs based on more than 300 in-depth telephone interviews with leading legal decision makers. The report notes that corporate counsel named these law firms, in an unprompted manner, as best at developing and delivering AFAs and bringing improved client focus, budget predictability, a more streamlined approach to work, and double-digit savings.



GUEST ARTICLE

Whistleblowers Are Flooding the SEC: What Should You Do?

by [David Wilson](#), Partner, Business Litigation Practice Group

The Securities and Exchange Commission's (SEC) March 8 announcement that it had paid almost \$2 million to three whistleblowers underscores the burgeoning number of tips the agency is receiving, its whistleblower program's importance to enforcement efforts, and the increased risk for SEC-regulated companies. The largest of those three awards – approximately \$1.8 million – went to an unnamed informant who the SEC said voluntarily provided information that led to the agency opening an investigation. The SEC does not identify whistleblowers by name and does not disclose information that might reveal their identities.

This award announcement was the first for 2016, but it comes on the heels of the agency's report to Congress on its fiscal year 2015 Dodd-Frank Whistleblower Program. The report shows that the SEC received nearly 4,000 tips and paid out more than \$37 million in awards in the prior year, a 30 percent increase from 2012, the first full year of the program, in which the SEC received 3,001 tips. In the March 8 announcement, Sean McKessy, Chief of the SEC's Office of the Whistleblower, attributes the surge in tips to "increased public awareness of our program and the tens of millions of dollars we've paid to whistleblowers for information that helped us bring successful enforcement actions." The program provides a bounty of up to 30 percent of the amount the SEC collects in a resulting enforcement case.

To be sure, only a small fraction of these tips lead to significant enforcement actions, and the SEC's Office of the Whistleblower faces substantial challenges in sorting through the complaints to determine which of them warrant follow-up. But considering the volume of complaints, the breadth of subject areas they address, and the consequences a company may face if a complaint leads to an SEC inquiry, companies that ignore the risk do so at their peril.

Topics raised in whistleblower tips have remained fairly consistent over the three full years of the program's existence. In the 2015 fiscal year, 687 of 3,923 total complaints involved corporate disclosures and financial issues, comprising the largest share of complaints (18 percent), followed by offering fraud (16 percent), and market manipulation (12 percent). Perhaps resulting from this breakdown and the agency's creation of its Financial Reporting and Audit Task Force in 2013, the SEC has brought more cases alleging financial reporting and audit violations recently – 134 in 2015, compared with 98 such cases in 2014 and 68 in 2013.

One obvious message for companies in this high-stakes whistleblower environment: Get your internal controls and financial reporting right. Having an effective compliance program and procedures to prevent securities law violations may not eliminate the possibility of an employee becoming a whistleblower, but will make dealing with an SEC inquiry that results from a tip more manageable.



But more than that, a critical consideration for companies is whether they have the appropriate compliance culture. The best way to avoid whistleblower complaints to the SEC about your company is to prevent them from happening. SEC officials have reported that the vast majority of tips they pursue come from employees who first raised their concerns internally, but who felt their concerns were either ignored or not taken seriously. Therefore, companies need to have procedures in place to maximize the possibility that they can learn about and investigate complaints of wrongdoing before an employee becomes an SEC whistleblower. Companies must provide employees with clear avenues for internal reporting (including doing so anonymously) and describe what the company will do to handle reports. Once a complaint is received, the company must take prompt action to not only understand whether there is merit to the complaint, but also to demonstrate to the whistleblower that his or her concerns have been taken seriously. Moreover, in the event that the whistleblower ultimately provides a tip to the SEC (or any other regulator), as part of its assessment of the company's commitment to compliance, the agency will question what steps the company took to address the complaint. The company's ability to demonstrate such a commitment is important to achieving the best possible result from an agency inquiry or investigation.

Of course, the company also must make clear that it has no tolerance whatsoever for retaliation of any kind. A company's response to an internal complaint must focus on the substance of the complaint rather than on an attempt to learn the identity of an employee who reports concerns anonymously. This admonition holds true whether the company is conducting an internal investigation only or has received an inquiry from the SEC that may be the result of a whistleblower complaint. Dodd-Frank explicitly prohibits retaliation against those who report misconduct to the SEC, and the SEC has made clear that it considers Sarbanes-Oxley anti-retaliation protections to apply equally to whistleblowers who only report internally. Should SEC staff make an inquiry about what may be a whistleblower complaint, the company should recognize that the staff likely believes there may be some merit to the complaint. Any effort by the company to impugn the whistleblower's integrity or motivations will be, at a minimum, counterproductive. Similarly, employee evaluations of a known or suspected whistleblower should be drafted with great care to ensure that no claim can be made that a negative comment is retaliatory.

The SEC has gone a step further by addressing what it contends are actions by companies that might chill the willingness of employees to make whistleblower complaints to the SEC. Last year it brought an enforcement action alleging that KBR, Inc.'s use of a confidentiality agreement prohibiting witnesses in an internal investigation from discussing the subject matter of their interviews was a violation of Rule 21F-17(a), which forbids taking actions that would impede an individual from communicating directly with the SEC about a possible securities law violation. The agency brought this proceeding even in the absence of any evidence that KBR intended the confidentiality provision to apply to whistleblower complaints, or that any whistleblower was actually deterred from making a report. Companies need to be mindful of this issue in their use of severance agreements and other employee contracts that contain confidentiality provisions.

The SEC's encouragement of whistleblowing is here to stay. Companies that develop and adhere to robust compliance practices, properly handle internal complaints, and promote a healthy, non-retaliatory culture can avert costly and damaging SEC investigations.



FDA Corner

E-Cigarette Deeming Rule

On May 5 the FDA finalized its Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act rule, making e-cigarettes and other tobacco products subject to extensive FDA regulation. We expect the final rule to have a substantial impact on small and medium-sized market participants, with the potential overall effect of allocating greater market share to large traditional tobacco companies. In short, the final rule imposes significant costs on the e-cigarette industry, along with premarket authorization requirements for “new” tobacco products that are not substantially equivalent to a valid predicate product, or are not exempt from substantial equivalence (SE). Given the rapidly evolving technology and innovation germane to the e-cigarette industry, it is unlikely that a valid predicate product will be available for many of today’s e-cigarette models.

This means that e-cigarettes are now subject to various market entry requirements, including the submission of a Premarket Tobacco Product Application (PMTA). Among other things, a PMTA requires manufacturers to provide detailed information on product ingredients and additives, health risks, product use (including expected use with other products), labeling, and manufacturing. In addition, new nonclinical and clinical studies may also be required for market authorization if few or no scientific studies have been performed assessing the product’s potential public health impact. Although larger industry members may be well positioned to expend such resources, these requirements may hinder market entry for smaller businesses, especially given that each PMTA can take 5,000 hours and cost approximately \$300,000, based on FDA estimates.

For non-flavored and tobacco-flavored newly deemed products that are on the market as of August 8, 2016, the final rule’s effective date, but were not on the market as of February 15, 2007, FDA is providing the following staggered compliance policy:

- 12-month initial compliance period for manufacturers to submit an SE exemption request
- 18-month initial compliance period for manufacturers to submit SE reports
- 24-month initial compliance period for manufacturers to submit a PMTA

After the end of the compliance period, e-cigarettes may be subject to FDA enforcement action unless the products are grandfathered or the subject of a marketing authorization order. This staggered compliance policy is designed to allow applicants more time to submit robust premarket submissions and allow FDA to efficiently manage incoming applications, all while balancing public health concerns.

FDA Makes Major Changes to Nutrition Facts Label

The FDA recently issued two final regulations that present overhaul changes to the Nutrition Facts and Supplement Facts labels and update serving sizes. The labels are being revised for the first time in decades to reflect updated scientific information regarding public health, diet, and chronic diseases. Serving sizes have been adjusted to be more representative of the amount of food that is actually consumed today.



Some updates consist of formatting changes designed to direct the consumer's attention to calories and serving sizes. For instance, the word "Calories" is presented in larger typeface than other items on the Nutrition Facts label to highlight the importance of calories as an element consumers consider when making healthier food choices and to address the American obesity epidemic. The listing of mandatory nutrients has also changed. Vitamin D and potassium are now required to be listed, given that a deficiency of these nutrients has been associated with higher risks for chronic disease. Vitamins A and C, on the other hand, are no longer required on the Nutrition Facts label since deficiencies of these vitamins are now rare. Another major and controversial change to the Nutrition Facts label is the requirement for food companies to now declare "added sugars," a new category intended to assist consumers in distinguishing between sugars added during processing and those that are naturally present in certain foods (such as fresh fruits). This change is consistent with expert recommendations advising consumers to reduce intake of added sugars based on the belief that they deliver empty calories to the diet without providing additional nutritional benefits.

Other changes to the Nutrition Facts label include the definition for dietary fiber being revised to consist of naturally occurring fibers and fibers added to foods for a physiological health benefit, and updates to serving sizes to be more realistic representations of what consumers actually consume at one time. Further, despite FDA's final determination on *trans* fat, it will remain on the Nutrition Facts label because certain foods may contain naturally occurring *trans* fat. In addition, the explanation of Percent Daily Values at the bottom of the Nutrition Facts label has been simplified; however, it is still based on a 2,000 calorie diet.

The FDA also made some changes to the Supplement Facts label found on dietary supplements to make it consistent with the Nutrition Facts label.

These changes mean additional documentation responsibilities for manufacturers, which now will be required to keep records to verify the mandatory declaration of certain food constituents for which analytical methods are not available, such as added sugars, certain dietary fibers, vitamin E, folic acid, and folate. Industry has two years to comply with these requirements, with the exception of companies with less than \$10 million in annual sales, which will have an additional year to comply. The new requirements will affect nearly all conventional foods and may lead to major reformulations of certain products. For instance, the mandatory declaration of added sugars may lead manufacturers to reformulate sodas and processed foods. FDA estimates that while implementing the changes may cost the food and beverage industry approximately \$500 million annually, the changes should result in roughly \$2 billion annually in reduced health care costs over the next two decades.

FDA Requires Industry to Implement Food Defense Plans

The FDA's recently issued final rule, Mitigation Strategies to Protect Food Against Intentional Adulteration, requires food companies to implement plans to protect their products from acts of intentional adulteration. The rule requires covered domestic and foreign food facilities to consider their production processes and facilities and develop proactive strategies to ensure product safety and security and mitigate any widespread harm to public health. According to FDA, the requirements are intended to further bolster the safety and security of an increasingly global and complex food supply system.

Under the rule, certain covered facilities must prepare and implement written food defense plans that identify "vulnerabilities," or areas that may present risk in the manufacturing process. To identify vulnerabilities, food facilities should assess, among other factors, the degree of physical access to the product, the speed by which the product moves through production and the distribution system, the ability of an attacker to successfully



contaminate the product, and any potential agents that may be used by attackers. Based on this assessment, food facilities are required to implement mitigation strategies addressing the vulnerabilities and procedures for food defense monitoring. Where issues are identified, facilities must assign appropriate corrective actions and implement procedures to routinely verify that the food defense monitoring system is working. The rule also presents additional training and recordkeeping requirements – facilities must ensure that personnel (particularly those working in vulnerable areas) are properly trained, and companies must maintain records of food defense monitoring, corrective actions, and verification activities. While the requirements incorporate concepts similar to the Hazard Analysis Critical Control Point (HACCP) system (an approach for the identification, evaluation, and control of food safety hazards), a food defense plan is not the same as a food safety plan, given that the former is designed to address intentional contamination, and the latter focuses on unintentional health and safety risks inherently associated with food processing and storage. Accordingly, a food defense plan must take into account other considerations not seen in a typical HACCP system, such as the possibility of an inside attacker or physical barriers to access.

FDA has provided staggered compliance periods based on the size and operations of a covered food facility. Very Small Businesses (businesses averaging less than \$10,000,000 in sales per year, as defined under the regulations), while exempt, still have to comply with the modified requirements (i.e., documentation retention requirements supporting exemption) within five years. Small Businesses (those that employ fewer than 500 persons) must comply four years after the publication of the final rule. Covered food facilities that do not meet the foregoing requirements have to comply three years after the publication of the final rule.



Wins

Tim Coughlin successfully represented a chemical company in state court in Kentucky against a claim that TCE caused the plaintiff's birth defects. The court granted summary judgment when the plaintiff failed to rebut evidence that the facility where her parents worked and were allegedly exposed stopped using TCE more than 10 years prior to her conception.

Andrew Cox obtained dismissals of two separate actions filed against a commercial kitchen equipment manufacturer in California and Illinois state courts.

In March 2016, the Sixth Circuit affirmed a District Court's decision to dismiss Jones Act negligence and unseaworthiness claims against a shipowner defendant in a case where the plaintiff claimed his asthma and chronic obstructive pulmonary disease were aggravated due to purported exposure to coal dust on the defendant's vessel. **Robert Burger** and **Eric Daniel** moved to dismiss both causes of action in the U.S. District Court for the Eastern District of Michigan based on a theory that the plaintiff had improperly failed to file the lawsuit within three years of discovering that he had developed the medical conditions at issue. The District Court rejected the plaintiff's argument that equitable estoppel precluded the shipowner defendant from asserting a statute of limitations defense. As a result, the District Court dismissed the Jones Act negligence and unseaworthiness claims against the defendant. The District Court also denied the plaintiff's subsequent motion for reconsideration. The Sixth Circuit affirmed the District Court's dismissal of the Jones Act negligence and unseaworthiness claims and specifically rejected the plaintiff's equitable estoppel argument.

In May 2016, **Elizabeth Wright**, **John Mitchell**, and **Stacey Greenwell** obtained a decision and order from an administrative law judge (ALJ) vacating citations the Occupational Safety and Health Commission issued to a tree care company under the logging standard. The tree care company contested the citations, arguing, among other things, that the plain language of the logging standard did not apply to the company's tree care operation and even if it did, the company did not violate the standards. The ALJ presided over a three-day trial in Boise, Idaho, after which the parties submitted post-hearing briefs to the court. The ALJ vacated the citations under the logging standard, finding that it was inapplicable to the tree care operation. The ALJ also found that the evidence presented at the hearing established that the company did not violate the cited standards.

Conor McLaughlin won an appeal before an en banc panel of the Pennsylvania Commonwealth Court, with the court ruling 6-1 to overturn an administrative agency decision finding that a company using GPS to provide asset management and location consulting services committed the unlicensed practice of land surveying. For years a potential turf war has been building between licensed land surveyors throughout the country and companies that provide asset identification, management, and location services to utility companies and other businesses using GPS and other related tools. In 2011, the Pennsylvania Board of Professional Engineers, Land Surveyors, and Geologists issued a complaint against a company that provided a field inventory for a Pennsylvania utility, which included collecting the GPS coordinates of all of the utility's field assets, such as telephone poles and meters, and then providing those coordinates in a format to be converted into a geographic information system that operates like Google Maps. The Thompson Hine team conducted a three-day administrative trial that resulted in an adverse decision by the board. Undeterred, the team appealed to the Pennsylvania Commonwealth Court, which ultimately heard the appeal en banc. The Commonwealth Court agreed that the work performed by the consulting service did not meet the statutory definition of the practice of land surveying or any other defined practice that required a license, and took the unusual step of reversing an administrative board.



Hal Henderson led a team that secured summary judgment in three maritime asbestos wrongful death lawsuits in the U.S. District Court for the Eastern District of Pennsylvania, resulting in dismissals of eight of our clients. Each lawsuit had been filed in the name of a person who was deceased at the time the actions were filed. In a reported decision, the federal multidistrict litigation transferee judge agreed with our position that a lawsuit brought in the name of a deceased person is a legal nullity, void from its inception, and that the fatal flaw cannot be rectified by amending the complaint or substituting an administrator as the party plaintiff.

Hal Henderson also led a team that secured summary judgment in December 2015 on behalf of a client in the lead case among 44 maritime wrongful death cases involving essentially identical issues in the New York City Asbestos Litigation. In 2013-2014, we obtained dismissals in the Ohio federal asbestos litigation of more than 11,000 claims against our clients for lack of personal jurisdiction. Thereafter, the plaintiffs' counsel refiled more than 150 of the cases in five state courts around the country, including New York City. Our motion in the lead New York case argued that the New York action was barred by the statute of limitations, and since the plaintiff had no reasonable basis for believing our client would have been subject to personal jurisdiction in Ohio, the previous Ohio action did not equitably toll the statute of limitations. The New York court agreed there was no basis for equitable tolling and that the current claims were barred by the statute of limitations. As a result of that ruling and similar rulings obtained in Seattle and San Francisco, the plaintiffs' counsel voluntarily dismissed the remaining 43 refiled cases in the New York City Asbestos Litigation, 34 cases refiled in San Francisco, 15 cases refiled in Charleston, South Carolina, and six appeals of similar dismissals then pending in the Washington Court of Appeals.

In a unanimous opinion, Ohio's Second District Court of Appeals affirmed a defense verdict for a component part manufacturer represented by **Elizabeth Wright**, **Andrew Cox**, and **Stacey Greenwell** in an aviation product liability action. The plaintiffs represented the estates of a pilot and two passengers who died in a 2005 accident involving a 1974 Grumman AA-5 Traveler. The plaintiffs alleged the aircraft's muffler system, manufactured by a predecessor of our client, was defectively designed, resulting in its internal components blocking the engine's exhaust and causing a loss of engine power. After the jury returned a defense verdict on all five claims submitted, the plaintiffs appealed, asserting five assignments of error relating primarily to evidentiary rulings at trial. In a 134-paragraph opinion, the Second District analyzed and overruled each assignment of error, concluding its opinion by stating, "From our review of the record, the litigation of this case has been in the hands of excellent attorneys, who have represented their clients zealously and professionally. The trial court also made considerable efforts to ensure each side a fair trial of the issues, and we cannot find that any of the alleged errors raised on appeal fell outside of the trial court's reasonable discretion. Simply stated, the parties had a full and fair opportunity to present their cases to the jury, and the jury rendered a verdict. We find no prejudicial error to justify a retrial."



What's Happening

Barbara Lum moderated the panel “A Seat at the Table: Witness Prep, Trial Examinations and Other Essential Trial Skills for Young Lawyers” at the National Asian Pacific American Bar Association 2016 Convention in New Orleans in November 2015.

Ileana Martinez, **Seth Litman**, **Elizabeth Wright** and **Brian Troyer** attended ACI’s 20th Drug & Medical Device Litigation conference in New York City in December 2015. Brian also moderated the panel “Recent Developments and Strategies for Strengthening Your Class Action Defense.”

Gary Glass presented “Multi-Employer Worksites: What Are the Risks and How Does a Company Reduce Them?” at the PSARA Technologies Annual EHS Seminar in Cincinnati in December 2015 and at the OCTC Annual Conference in Columbus in May 2016.

Tim Coughlin attended the SOCMA Annual Dinner in New York City in December 2015.

Bill Hubbard attended the 30th Construction Super Conference in San Diego in December 2015.

Kip Bollin attended the Federal Bar Association (FBA) Quarterly Board Meeting in Miami in January 2016.

Barbara Lum was appointed to the Boys & Girls Clubs of Cleveland board of directors in January 2016.

Tim Coughlin attended the InformEx: The Home of Chemistry Innovation Seminar/Tradeshow in New Orleans in February 2016.

Tim Coughlin, **Andrew Cox**, **William Hubbard**, **Barbara Lum**, and **Kip Bollin** attended the Defense Research Institute’s (DRI) Product Liability Committee Conference in New Orleans in February 2016. Barbara was also a panelist presenter for “Best Practices for Reducing Warranty and Product Liability.”

Neelam Gill attended the Women Grow Leadership Summit in Denver in February 2016.

Barbara Lum and **Nancy Niu** attended the DRI Women in the Law Seminar in Scottsdale, Arizona in February 2016.

Tim Coughlin attended the IADC mid-year meeting in Pebble Beach, California in February 2016.

Barbara Lum attended DRI Young Lawyers Fly-In Meeting in Chicago in March 2016.

Gary Glass presented “What’s on the Horizon: Possible Changes to OSHA’s PSM and EPA’s RMP Requirements” at the OCTC Safety Committee Meeting in Columbus in March 2016.

Bill Hubbard and **Barbara Lum** attended and **Tim Coughlin** chaired the DRI Toxic Tort and Environmental Law meeting in New Orleans in March 2016.

Barbara Lum was featured in the *Crain’s Cleveland Business* “Source Lunch with ...” column in March 2016.

Elizabeth Wright, **Andrew Cox**, and **Stacey Greenwell** attended Southern Methodist University’s 50th Annual Air Law Symposium in Dallas in March 2016.



Kip Bollin attended the FBA Mid-Year Meeting in Washington, D.C. in March 2016.

Tim Coughlin attended SOCMA's Fly-In, an annual event focused on meetings with lawmakers and their staff, in April 2016.

Tim Coughlin attended the United States Law Firm Group (USLFG) mid-year meeting in May 2016.

Conor McLaughlin and **Ryan Winkler's** article "Beware of Opposing Counsel's Attempt to Create a New Record on Appeal" appears in the May 2016 issue of *For The Defense*, published by DRI.

Barbara Lum was honored as a Woman of Professional Excellence at the YWCA Greater Cleveland 2016 Women of Achievement Awards Luncheon & Conference in May 2016.

Tim Coughlin attended the OCTC Annual Conference in May 2016.

Conor McLaughlin presented to the United States District Court, Northern District of Ohio Advisory Committee on proposed changes to the Northern District of Ohio Local Civil Rules in May 2016.

Mike Hardy served as a panelist for "Managing Scientific and Expert Information," a webinar in May 2016 sponsored by the American College of Environmental Lawyers for the Environmental Council of the States, the "trade" association of the environmental agencies for the 50 states and various territories. Mike's topic was "The Need To Quickly Synthesize Technical Information Especially for Lay Boards and Commissions in Adjudicatory Hearings and Rulemakings."

Bill Hubbard presented "In the Crosshairs: Targeting of Building Products by California's Green Chemistry Initiative ... and Other Regulations Focusing on Environmental Exposure to Toxins," a SOCMA webinar in June 2016.

Barbara Lum and **Ryan Winkler** attended the DRI Young Lawyers conference in Las Vegas in June 2016.

Tim Coughlin served as the lead planner for the annual DRI Toxic Torts and Environmental Law Committee Fly-In Meeting in June 2016.



About the Group

Our Product Liability lawyers have handled tens of thousands of cases throughout the United States and abroad involving all facets of product liability law. We have litigated product liability and major tort matters in a wide range of industries, including admiralty and maritime, aerospace, automotive, chemicals, commercial and consumer products, electrical, food equipment, mechanical, medical devices, nanotechnology, pharmaceuticals, and plastics.

Our trial lawyers actively are involved in national product liability organizations and have lectured and written extensively on product liability matters. We act as national and regional product liability counsel for Fortune 500 companies, protecting their interests throughout the United States and abroad. Our practice covers all aspects of product liability matters, from preventive counseling and alternative dispute resolution through trial and appeals.

For more information about our practice group and its services, contact:

Andrew H. Cox • Practice Group Leader, Product Liability Litigation,
Andrew.Cox@ThompsonHine.com, 216.566.5747.

About Thompson Hine. Thompson Hine LLP, a full-service business law firm with approximately 400 lawyers in 7 offices, is ranked number 1 in the category “Most innovative North American law firms: New working models” by *The Financial Times*. For 4 straight years, Thompson Hine has distinguished itself in all areas of Service Delivery Innovation and is one of only 7 firms noted in the *BTI Brand Elite* for “making changes to improve the client experience.” The firm’s commitment to innovation is embodied in Thompson

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What Our Clients Can Expect From Us . . .

- 1 We will know your business.
- 2 We will plan our engagements with you.
- 3 We will manage your work as if we were the client.
- 4 We will be available when you need us.
- 5 We will communicate often.
- 6 We will provide the highest-quality counsel.

What Our Clients Can Do To Help . . .

- 1 We ask you to share your goals.
- 2 We want to know your preferences for working with us.
- 3 We need your feedback.