FOLEY HOAG LLP

Product Liability **Update**

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Foley Hoag LLP publishes this quarterly Update concerning developments in product liability and related law of interest to product manufacturers and sellers.

First Circuit Affirms Judgment Against Generic Drug Manufacturer on Plaintiff's Design Defect Claim, Holding: (i) Product May Be Found "Defective" on Proof It Is "Unreasonably Dangerous"; (ii) Design Defect Claim Not Preempted by Federal Food, Drug, and Cosmetic Act; and (iii) Expert Testimony Based on Adverse Event Reports to FDA Admissible

In *Bartlett v. Mutual Pharmaceutical Company, Inc.*, 678 F.3d 30 (1st Cir. May 2, 2012), plaintiff suffered toxic epidermal necrolysis ("TEN") after taking sulindac, a generic version of the non-steroidal anti-inflammatory drug Clinoril®. Plaintiff sued the drug's manufacturer in New Hampshire state court for breach of warranty, negligence and fraud based on the drug's allegedly defective manufacture and design and the manufacturer's alleged failure to warn of the drug's dangers. After defendant removed the case to the United States District Court for the District of New Hampshire, the federal district court dismissed all but the design defect claim, which proceeded to trial. At trial, plaintiff argued that sulindac's risks outweighed its benefits, thus making it unreasonably dangerous to consumers, notwithstanding the United States Food and Drug Administration ("FDA")'s having approved the brand-name drug to which sulindac was identical as "safe and effective" and never having withdrawn that approval. The jury found for plaintiff, awarding over $21 million, and the district court denied defendant's motion for judgment as a matter of law.

On appeal to the United States Court of Appeals for the First Circuit, defendant contended that plaintiff's claim failed as a matter of law because plaintiff was required to prove a specific "defect" in addition to the drug's unreasonable dangerousness, and no proof of any identifiable defect in sulindac was shown. Defendant also argued the claim was preempted by the federal Food, Drug, and Cosmetic Act ("FDCA") because sulindac's design was required by the act to be the "same" as the branded drug's, and that the testimony of plaintiff's experts based on "adverse event reports" ("AERs") to the FDA should have been excluded under *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993), which requires the proponent of expert testimony to demonstrate that it is reliable based on such factors as objective testing, peer-reviewed publication and the like.

With respect to the requirements for a design defect claim, the First Circuit characterized defendant as arguing that New Hampshire law required proof of a feasible alternative design to establish such a claim, and held that New Hampshire precedent had already rejected that argument. Defendant's actual argument, however, had been that New Hampshire law, which follows the Restatement (Second) of Torts § 402A (1965), requires that a design defect plaintiff prove that the product was in a "defective condition" as well as being "unreasonably dangerous." Ignoring these conjunctive requirements, the First

Circuit held that the district court properly allowed plaintiff to show that sulindac was in a "defective condition" solely by virtue of its being "unreasonably dangerous" due to its propensity to cause TEN.

On preemption, the court recognized that the Hatch-Waxman amendments to the FDCA--which permit the marketing of generic drugs that are chemically identical to a previously approved branded drug and carry the same labeling--were intended to make safe and effective drugs available more cheaply and thus lower health care costs. The court also recognized the Supreme Court's holding in *PLIVA v. Mensing*, 131 S. Ct. 2567 (2011) (see **July 2011 Foley Hoag Product Liability Update**), that a failure-to-warn claim against a generic manufacturer was impliedly preempted because the generic manufacturer was not free under the FDCA to change the warnings to vary from those of the branded manufacturer, as plaintiff's claim would require. Nonetheless, the court held that a design defect claim was not preempted because, even though the generic manufacturer could not change the drug's design to vary from that of the branded manufacturer, the manufacturer *could* decide not to sell the drug at all. The court did not ponder how that squared with the Hatch-Waxman amendments' cost-lowering purposes which the court had recognized, or how it was logical that a jury could not require a generic drug manufacturer to tweak its labeling but could require the manufacturer to discontinue sale of the drug altogether. The court did note that the preemption question was one of "exceptional importance that the Supreme Court has yet to decide," and that "[g]iven the widespread use of generic drugs and the developing split in the lower courts, . . . this issue needs a decisive answer from the only court that can supply it."

Finally, defendant argued that plaintiff's experts' opinions were inadmissible, primarily because they relied on unreliable AERs as evidence of sulindac's causation of TEN and/or the incidence rate of that adverse effect. While the court acknowledged that many courts do not permit the use of AERs for such purposes, the court noted that both defendant's own expert and the FDA itself had written reports that made some use of AER data. Thus the existence of a significant number of AERs was admissible as "part of the calculus" for an expert who was opining on the risk-benefit ratio of a drug.

Following its decision, the First Circuit issued a stay of its mandate, at defendant's request, to permit defendant to seek review of the decision by the United States Supreme Court.

Massachusetts Appeals Court Affirms Directed Verdict for Paint Stripper Manufacturer on Failure-to-Warn Claim Where Product's Labels Complied with Regulations Under Federal Hazardous Substances Act

In *Namundi v. Rocky's Ace Hardware, LLC*, 81 Mass. App. Ct. 665 (Apr. 30, 2012), plaintiffs were severely burned in a flash fire that erupted when vapors from a can of paint stripper were ignited by the hot water heater in plaintiffs' basement. The label had a warning printed on the bottom that had the words "DANGER!" and "POISON!" in large capital letters, illustrated with a skull and crossbones. Following those words, the label stated in still-capitalized, but somewhat smaller, letters, "EXTREMELY FLAMMABLE. MAY BE FATAL OR CAUSE BLINDNESS IF SWALLOWED. VAPOR HARMFUL. SKIN AND EYE IRRITANT. Read other cautions and HEALTH HAZARD INFORMATION on back panel."

Plaintiffs sued the retailer and manufacturer of the paint stripper in Massachusetts Superior Court alleging the stripper was improperly labeled, defectively designed and unreasonably dangerous. The trial court directed a verdict for defendant on the failure-to-warn claim, ruling that the labeling complied with the Federal Hazardous Substances Act ("FHSA"), 15 U.S.C. §§ 1261 et. seq. (2006), and the jury found defendants not liable on the design defect claim. After denial of their motion for a new trial, plaintiffs appealed, arguing that the label did not comply with the FHSA and its regulations. Plaintiffs asserted that: (1) by capitalizing the word "poison" and making it larger than the word "flammable," defendant improperly used "poison" as a "signal word" causing plaintiffs to discount the balance of the warning as simply an explanation of the product's poisonous qualities; and (2) a specific warning about the flammability of the vapor, as distinguished from the stripper itself, should have been placed on the label in the principal display panel.

Making extensive reference to specific regulations under the FHSA, the Massachusetts Appeals Court rejected both of plaintiffs' arguments. First, the court held that although the regulations are unclear as to whether "poison" may be used as a signal word, it was undisputed that the regulations required the word to appear on the label in capital letters and there was no prohibition against capitalizing the word, whether classified as a signal word or not. The court also rejected plaintiffs' argument that, pursuant to a regulation requiring all label statements of principal hazard to appear in the same size and

style, the word "poison" should have been the same size as "flammable" so that neither hazard would be emphasized to the detriment of the other. The court found the regulation cited by plaintiffs inapplicable because "poison" was not a "principal hazard" under the regulatory scheme; rather, it fell under the separate category of "other cautionary material," which includes all labeling statements other than "signal words" or "statements of principal hazard(s)."

Turning to plaintiffs' second argument, the court held the FHSA did not require specific warnings concerning vapor flammability to appear on the primary display panel, citing and following a decision of the United States Court of Appeals for the First Circuit in a similar case. In that case, the court held that a flammable cleaning agent's labeling was sufficient where the container's label stated that the cleaner was "EXTREMELY FLAMMABLE," and provided additional warnings concerning the build-up of vapors on a different display panel. Here, the label explicitly stated in capital letters in the principal display panel that the stripper was "EXTREMELY FLAMMABLE" and further directed the reader to the back panel where vapor flammability was exhaustively explained. The fact that the stripper was flammable in different material states, or that some states are more flammable than others, did not render each physical state a distinct "principal hazard" that must be warned against in the principal display panel. Such a requirement is not found in the current regulatory scheme, and to the extent the Consumer Product Safety Commission determines that amplified or more specific warnings should be required, the FHSA provides the Commission with authority to so require.

Massachusetts Appeals Court Affirms Summary Judgment for Gun Manufacturer, Finding Claims Barred by Federal Protection of Lawful Commerce in Arms Act Because They Arose out of Criminal or Unlawful Use of Firearms

In *Ryan v. Hughes-Ortiz*, 81 Mass. App. Ct. 90 (Jan. 6, 2012), the decedent, a convicted felon, was killed by an accidental, self-inflicted gunshot wound he sustained while trying to return a gun he had stolen to its owner's previous hiding place. Plaintiff, the administratrix of decedent's estate, sued the gun owner and its manufacturer in Massachusetts Superior Court asserting claims of negligence and wrongful death against both the owner and manufacturer, as well as breach of the implied warranty of merchantability (the Massachusetts near-equivalent of strict liability) and violation of Mass. Gen. L. ch. 93A (the Massachusetts unfair and deceptive practices statute) against the manufacturer alone. Plaintiff's claims against the manufacturer alleged that the gun and gun case were defectively designed because the case caused the loaded gun to discharge through the case and the gun itself was likely to discharge unintentionally. The trial court granted summary judgment for both defendants, and plaintiff appealed to the Massachusetts Appeals Court.

Plaintiff's appeal raised an issue of first impression in Massachusetts--application of the Protection of Lawful Commerce in Arms Act ("PLCAA"), 15 U.S.C. §§ 7901-7903 (2006), which provides immunity to firearms manufacturers and dealers from any civil action brought by any person for damages or other relief resulting from the criminal or unlawful misuse of a firearm by the person or a third party. Before analyzing whether plaintiff's claim was barred by the PLCAA, the court first noted that it would not consider plaintiff's argument, raised for the first time on appeal, that summary judgment should not have been granted against that portion of her claim targeting the design of the gun case because the PLCAA applies only to firearms, ammunition and their components.

Expressing no opinion as to whether the PLCAA would preclude a future plaintiff from bringing claims involving the interaction between products covered by the statute and others not covered, the court held that plaintiff's claims against the manufacturer were barred by the act. The court found that five of the six requirements for applicability of the statute were easily met--plaintiff's suit was (1) a civil action, (2) brought by a person, (3) against a manufacturer, (4) of firearms, and (5) for damages. The only remaining issue was whether the suit

"resulted from the criminal or unlawful misuse of [a firearm] by the person or a third party." The statute defines "unlawful misuse" to mean "conduct that violates a statute, ordinance or regulation as it relates to the use of [a firearm]." Here, although no criminal charges were brought against decedent in connection with the incident, his possession of a firearm and ammunition after having been convicted of a felony was in violation of 18 U.S.C. § 922(g)(1), thus constituting "criminal or unlawful misuse" under the PLCAA. For the same reason, the "design defect exception" to the statute did not apply. That exception provides that the PLCAA will not foreclose claims where the harm results directly from a defect in design or manufacture of the product when used as intended or in a reasonably foreseeable manner, except in cases where the discharge of the firearm was caused by a volitional act that constitutes a criminal offense.

Massachusetts Appeals Court Affirms Judgment for Failure to Warn of Dangerous Conditions From Cleaning Products; Expert Testimony Regarding Asthma Risk and Causation Based on Plaintiff's Exposure and Peer-Reviewed Scientific Literature Concerning Effects of Product Ingredients Held Admissible

In *Maston v. Poirier*, 81 Mass. App. Ct. 1131 (Apr. 24, 2012), plaintiff allegedly developed chronic asthma from exposure to a disinfecting product used by defendants' cleaning business which plaintiff hired to clean her basement after a city sewer backup. Plaintiff and her husband brought suit in Massachusetts Superior Court asserting, among other claims, breach of the implied warranty of merchantability (the Massachusetts near-equivalent of strict liability) and violation of Mass. Gen. L. ch. 93A (the Massachusetts unfair and deceptive practices statute) based on defendants' failure to warn of the dangerous conditions resulting from their use of the cleaning product. Because plaintiff had not been advised of the need to properly ventilate the area and stay away from it until dry, she entered the basement to perform additional cleaning as soon as defendants left, and continued to work in the basement over several days. Following a bench trial, at which plaintiffs' expert testified that chemical compounds in the product have the ability to cause asthma and respiratory sensitization and that plaintiff's exposure caused her injuries, the court entered judgment for plaintiffs. Defendants appealed to the Massachusetts Appeals Court, arguing that (i) plaintiff's claims failed as a matter of law because her exposure to the cleaning product came about as a result of defendants' provision of services and not the sale of goods, (ii) the expert's causation testimony was scientifically unreliable, and therefore inadmissible, and (iii) without expert testimony, there was insufficient evidence to support the judge's finding of a duty to warn.

First, the appellate court refused to consider defendants' argument, raised for the first time on appeal, that there could be no breach of the warranty of merchantability, and hence no liability under ch. 93A, because plaintiff's alleged injury was caused by defendants' provision of services and not the sale of goods. Although the court did not resolve the goods/services argument, it did take note of plaintiffs' response that, in addition to providing clean-up services, defendants had supplied the cleaning product and thus the transaction was "predominantly" a sale of goods.

Turing to the merits, the court held that the evidence was sufficient to permit the trial judge to find that defendants were required to warn or instruct plaintiffs about hazards associated with the cleaning product and necessary precautions after its use. In particular, it was within the trial judge's discretion to rely upon the testimony of plaintiffs' expert concerning general and specific causation and to deny defendants' motion to strike that testimony. The appeals court found the expert sufficiently qualified by his education, experience and research in the fields of toxicology, medicine and environmental health. Moreover, the court found the expert's causation opinion met the reliability standards of *Commonwealth v. Lanigan*, 419 Mass. 15 (1994) (accepting the basic reasoning of *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993), which requires the proponent of expert testimony to demonstrate both its reliability, and its relevance or "fit" to the legal issues), as it was based upon (i) the existence of quaternary ammonium compounds ("QUATS") in the product, (ii) peer-reviewed, scientific literature linking QUATS to the development of asthma and respiratory sensitization, (iii) the history of plaintiff's exposure, (iv) her symptoms and (v) the results of a methacholine challenge test, which confirmed a diagnosis of hyperactive airways. Neither the lapse of time between plaintiff's exposure and her asthma diagnosis nor the absence of quantitative analysis of exposure rendered the expert's opinion inadmissible; rather, these were issues to be explored on cross-examination and through the testimony of defendants' expert.

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