FOLEY HOAG

Product Liability **Update**

In This Issue:

January 2023

Foley Hoag LLP publishes this quarterly Update primarily concerning developments in product liability and related law from federal and state courts applicable to Massachusetts, but also featuring selected developments for New York and New Jersey.

MASSACHUSETTS

Massachusetts Federal Court Holds State Law Claims Alleging Misleading "Rapid Release" Labeling Of OTC Acetaminophen Tablets Preempted By Federal Food, Drug, And Cosmetic Act, As Tablets' Dissolution Rate Met FDA Regulations and Guidance For "Immediate Release" And "Rapidly Dissolving," Verbatim Language Was Not Required For Preemption And Tablets' Slower Dissolution Than Non-"Rapid Release" Tablets Was Irrelevant

In *Sapienza v. Albertson's Co., Inc.*, No. 22-10968-RGS, 2022 U.S. Dist. LEXIS 217368 (D. Mass. Dec. 2, 2022), plaintiff brought a putative class action in the United States District Court for the District of Massachusetts against the manufacturer and distributors of over-the-counter ("OTC") acetaminophen tablets, asserting among other claims negligent misrepresentation, fraud, breach of the implied warranty of merchantability (the Massachusetts near-equivalent of strict liability) and violation of Mass. Gen. L. ch. 93A (the state unfair and deceptive trade practices statute). Plaintiff alleged the medication's "rapid release" labeling was misleading because the tablets actually dissolved more slowly than defendants' less expensive non-"rapid release" tablets, and this misrepresentation caused her and other consumers to buy the former tablets at a premium. Defendants moved to dismiss, arguing plaintiff's claims were preempted by the National Uniformity for Nonprescription Drugs provision of the Federal Food, Drug, and Cosmetic Act ("FDCA"), which prohibits states from establishing any requirement that is "different from or in addition to, or . . . otherwise not identical with" those imposed by the FDCA.

The United States Food and Drug Administration ("FDA")'s regulations governing the labeling of OTC drugs incorporates the United States Pharmacopeia ("USP")'s dissolution standards for acetaminophen tablets, and the dissolution rate of defendants' tablets met the USP standard for "immediate release" as well as an even more stringent FDA guidance standard for "rapidly dissolving." Plaintiff argued, however, that her claims were not preempted because neither the USP or FDA standards specifically used the term "rapid release."

The court rejected plaintiff's argument, holding that the terms used in defendants' labels did not need to mirror verbatim those of the FDA standards in order for plaintiff's claims to be preempted. Rather, it was sufficient that the FDA regulations clearly addressed the substance of plaintiffs' claims—here, the tablets' dissolution rate—and defendants' tablets met those standards. Requiring verbatim language would impractically force the

FDA to list all possible equivalent phrases in its standards and undermine Congress's intent to give the agency latitude as subject matter experts. Because defendants' tablets met the governing standards, it was irrelevant whether they dissolved more slowly than defendants' non-"rapid release" tablets.

Massachusetts Federal Court Holds: (1) Prescription Drug Failure-To-Warn Claims Preempted By Federal Food, Drug, And Cosmetic Act (FDCA) Because Reported Adverse Events Were Not "Newly Acquired Information" Permitting Manufacturer To Alter Its FDA-Approved Labeling; (2) Claims For Failure to Report Adverse Events To FDA Not Preempted Pending Massachusetts Supreme Judicial Court Ruling Whether State Law Recognizes Such Claims Independent Of FDCA; And (3) Plaintiff Adequately Pled Manufacturer Assumed Duty To Monitor Plaintiff By Assigning Patient Care Advocate And Negligently Failed To Address Plaintiff's Adverse Symptoms

In *Pietrantoni v. Corcept Therapeutics Inc.*, No. 22-10072-WGY, 2022 U.S. Dist. LEXIS 204787 (D. Mass. Nov. 10, 2022), plaintiff sued the manufacturer and distributor of a drug used to treat Cushing's Disease in the United States District Court for the District of Massachusetts, alleging the drug caused ovarian cysts and uterine bleeding that required surgical dilation and curettage and made it unlikely she could carry a pregnancy to term. Plaintiff brought failure-to-warn claims based both on defendants' labeling and reporting of adverse event data to the United States Food and Drug Administration ("FDA"), and also alleged defendants assumed a duty to monitor her health by assigning her a "Patient Care Advocate" and were negligent in performing that duty because the advocate never instructed her to seek medical care or discontinue defendants' drug after she stopped menstruating, her first noticeable symptom. Defendants moved to dismiss all claims as preempted by the Federal Food, Drug, and Cosmetic Act ("FDCA"), arguing the statute forbade defendants to alter its FDA-approved labeling and gave FDA the exclusive power to enforce the statute's reporting requirements.

While defendants' label warned the drug could cause vaginal bleeding and endometrial changes, it did not mention missed menstrual cycles, dilation and curettage or any potential effects on patients' ability to bear children. Plaintiff argued that adverse events concerning dilation and curettage and hysterectomies constituted "newly acquired information" that permitted defendants to unilaterally change its labeling, subject to eventual FDA approval, under the FDA's "Changes Being Effected" ("CBE") regulation, and defendants could not show FDA would have rejected such changes. The court, however, held the adverse event reports were not newly acquired information because such reports on their own are not evidence of causation and the number of reports between the labellng's approval and plaintiff's use of the drug did not indicate any increased risk. Accordingly, the labeling-based claims were preempted.

Regarding plaintiff's claim that defendants failed to timely report adverse event information to the FDA, United States Supreme Court precedent would hold such a claim preempted if it was based solely on defendants' failure to comply with its obligations under the FDCA, as the FDA alone has authority to enforce the statute, but the claim would survive if it was based on a traditional state tort claim that merely paralleled the federal statute's requirements. Because the Massachusetts Supreme Judicial Court currently has pending a certified question from the United States Court of Appeals for the First Circuit asking whether Massachusetts law recognizes such a claim, the court declined to dismiss it.

Lastly, defendants argued plaintiff's claims for failure to monitor her for adverse events were preempted as "poorly-disguised" failure-to-warn claims. The court disagreed, however, as the claims were predicated on different facts, namely defendants' assignment of a patient care advocate and the advocate's inaction when plaintiff stopped menstruating. While defendants made other arguments addressing the merits of plaintiff's claim, such as that missed menstrual cycles were not an adequate basis for warning a patient, those arguments were not appropriate for resolution at the pleading stage, so the court denied dismissal.

First Circuit Court of Appeals Holds Plaintiffs In Putative Class Action Alleging Misrepresentation Of Child Booster Seat Safe Weight Have Standing To Sue, As Overpayment Constitutes Concrete Economic Injury And Plaintiffs Plausibly Pled They Would Not Have Bought New Seat At All Absent Misrepresentation

In *Xavier v. Evenflo Co. (In re Evenflo Co.)*, 2022 U.S. App. LEXIS 32497 (1st Cir. Nov. 23, 2002), plaintiffs brought a putative class action against a child booster car seat manufacturer in the United States District Court for the District of Massachusetts, alleging defendant misrepresented the seat was safe for children as small as thirty pounds and defendant had "side impact tested" it, and that absent the misrepresentations plaintiffs would not have purchased the booster seat, would have paid less for it or would have purchased a safer alternative. The district court dismissed the action for lack of standing, holding plaintiffs had not sufficiently alleged economic harm because they did not allege the seats failed to perform so that plaintiffs did not receive their expected benefit, and because their claims that they paid more than the seats' true value were not supported by sufficient facts to be plausible, the standard for pleading sufficiency under the Federal Rules of Civil Procedure.

On plaintiffs' appeal, the United States Court of Appeals for the First Circuit reversed. The court first noted that, as recognized by many other federal circuit courts, overpayment was a concrete injury. Although defendant argued plaintiffs had not plausibly pled overpayment, since booster seats are required by law and hence plaintiffs could not have forgone buying any seat, and the complaint itself alleged defendant's seat was cheaper than its chief competitor, the court held it was plausible that plaintiffs could have continued using their existing seats had they known defendant's seat was not actually safe for children weighing only thirty pounds. With respect to the possibility of paying less for a different seat, the court noted that this was only one of the alternative courses of action plaintiffs had pled.

Lastly, the court rejected defendant's argument that plaintiffs' complaint offered no theories regarding how overpayment damages could be calculated, holding that plaintiffs were not required to quantify or offer a formula for quantifying damages at the pleading stage.

Massachusetts Superior Court Excludes Interventional Radiologist's Design Defect And Failure-To-Warn Opinions Regarding IVC Filter As Expert Was Not Engineer, Had No Medical Device Design Or Labeling Experience And Did Not Explain How Warning Was Inadequate; Plaintiff Also Lacked Actual Injury As Alleged IVC Perforation Caused No Symptoms Or Additional Medical Treatment

In *Fuss v. Boston Scientific Corp.,* No. 2019-02348, 2022 Mass. Super. LEXIS 251 (Mass. Super. Ct. Oct. 20, 2022), plaintiff sued the manufacturer of an inferior vena cava ("IVC") filter in Massachusetts Superior Court, alleging the filter perforated his IVC wall and bringing claims for design defect, failure to warn, and failure to conform to representations under the Ohio Product Liability Act, and for unfair or deceptive acts under the Ohio Consumer Sales Practices Act. Ten years after plaintiff's filter implantation, he saw a lawyer advertisement stating that IVC filters are prone to fracture and migration, so he thereafter obtained a CT scan.

Although his treating surgeon did not observe any injuries or problems with the filter, plaintiff retained an interventional radiology expert who opined that plaintiff had sustained a perforation, was at risk for future injury and would need his filter replaced; the expert also opined, among other things, that the filter design was defective and defendant had failed adequately to warn of the perforation risk. Defendant moved to exclude the expert's opinions as unsupported by adequate qualifications or a reliable foundation.

Regarding design defect, the expert opined that defendant's filter caused outward pressure to be concentrated on a limited number of hook contact points, creating "significant problems related to perforation of the hooks beyond the vena cava wall," while a different filter model dispersed that outward pressure "over a large surface area" and was thus a safer alternative design. The court held that the expert was not qualified to offer these opinions because, although he had implanted hundreds of IVC filters, he was not an engineer and had never worked for a medical device company or designed a marketed medical device. The expert's opinion regarding the purported safer alternative design was also inadmissible because he had not analyzed the actual risks associated with that design.

The court further excluded the expert's opinion that the filter's label failed to adequately warn of the potential for perforation, because the expert admitted he was not a warning or labeling expert and did not explain how the label—which did warn of a perforation risk—was inadequate. Nor could the expert opine that a change in the labeling would have altered the implanting surgeon's behavior and prevented plaintiff's alleged injury, as he had never read the surgeon's deposition or spoken with him.

The court also excluded the expert's opinion that plaintiff was injured and at risk of further injury, as industry guidelines defined perforation as filter struts extending more than three millimeters into the IVC wall, but plaintiff's expert had not measured the alleged protrusions. And the expert's opinion that defendant misrepresented that the filters were "permanent" was "nonsensical," as it was flatly contradicted by the expert's admission that the United States Food and Drug Administration had cleared the device as a permanent one.

Because plaintiff's claims required expert testimony, the court granted defendant's summary judgment motion. In further support of that ruling, the court noted that plaintiff could not demonstrate any actual physical injury, as the alleged perforation had not caused him any pain, required any treatment or caused any change to his life.

NEW YORK/NEW JERSEY SUPPLEMENT

New York Appellate Division Holds Third-Party Claims Against Car And Tire Manufacturers "Aris[e] From" New York Marketing And Sales Activities Under Long-Arm Statute Based On "Substantial Relationship" To Claims Even Though Design, Manufacturing And (As To Car Manufacturer) Sale Of Particular Products At Issue Occurred Out-Of-State, And Applies New York Court Of Appeals Rather Than United States Supreme Court Precedent In Finding Jurisdiction Satisfies Due Process

In *Aybar v. US Tires & Wheels of Queens LLC*, 178 N.Y.S.3d 73 (2d Dep't 2022), New York resident plaintiffs sued an auto servicing shop in the New York Supreme Court for Queens County, alleging defendant negligently inspected and installed tires on plaintiffs' car in New York, which contributed to their auto accident in Virginia, and defendant then asserted third-party indemnification and contribution claims under product liability theories against the tire and car manufacturers. Both manufacturers were incorporated and headquartered outside of New York, neither had designed or manufactured the specific products at issue in-state and the car manufacturer had not sold its product in-state (the tire manufacturer apparently did). In addition to plaintiffs' having purchased both the car (from another New York resident who originally bought it in Ohio) and tires in New York, the manufacturers conducted marketing, promotion, advertising, sales and servicing activities for their products, including the product styles at issue, there.

The manufacturers moved to dismiss, arguing they were not subject to personal jurisdiction either under New York's long arm statute, CPLR 302(a)(1)—which requires that (1) a defendant have "transact[ed] any business" in New York and (2) the claims "aris[e] from" that business—or under due process. The trial court rejected the manufacturers' motion on both grounds.

On the manufacturers' appeals, the Appellate Division, Second Department, affirmed. Citing New York Court of Appeals precedent, the court held that CPLR 302(a)(1)'s "arise from" prong requires only an "articulable nexus" or "substantial relationship" between the claims and defendant's business transactions in New York; "causation" is not needed. Here, the third-party indemnity and contribution claims "could not exist but for [the auto shop's] alleged negligence, which occurred in New York," and the manufacturers "purposefully availed themselves of the New York market to sell motor vehicles and tires" and thus "undoubtedly benefit from the sale of replacement parts and services from third-party companies" like the auto shop. Accordingly, the auto shop's third-party claims were sufficiently "tethered" to the manufacturers' New York business activities.

The court also agreed that subjecting the manufacturers to personal jurisdiction in New York did not violate due process. The manufacturers conceded they had sufficient "minimum contacts" with the state, one of two elements identified in Court of Appeals due process precedent, leaving only the second element of whether exercising personal jurisdiction would be "unreasonable." The court concluded the manufacturers had presented no "compelling reason as to why the exercise of jurisdiction is unreasonable," and

rejected their argument based on United States Supreme Court precedent that the third-party claims did not "arise out of or relate to their contacts in this state," reasoning that the argument "completely ignor[ed]" the Court of Appeals standard. In addition, while there was "no discernible difference" for the manufacturers whether they were sued in New York or in Virginia as the accident locale, New York had an interest in adjudicating the dispute, as it was the residence of both plaintiffs and the auto shop, as well as the location of the latter's alleged negligence.

damages are reserved for "singularly rare cases such as cases involving an improper state of mind or malice or cases involving wrongdoing to the public." This was not such a case, as the record lacked any evidence of a "concerted effort to suppress information about the dangers of asbestos." To the contrary, defendant's product came with multiple warnings that it could not be safely worked with using dry saws or the like, and while there was evidence that those warnings were not on every pipe, this was at most evidence of negligence and not the "malice" required for imposing punitive damages.

New York Appellate Division Holds Evidence Distributor Affixed Warning Labels To Some But Not All Asbestos-Containing Pipes At Most Constituted Negligence, But Not Malice Sufficient To Justify Punitive Damages

In *Maffei v. A.O. Smith Water Prods. Co.*, 210 A.D.3d 537 (1st Dep't 2022), a commercial contractor sued a former distributor of asbestos cement pipe in the New York Supreme Court for New York County, alleging he was exposed to asbestos and suffered lung cancer as a result of working with pipes sold by defendant. Plaintiff asserted that defendant concealed the hazardous nature of its pipes by failing to affix labels to each of them, and this warranted punitive damages. Defendant moved for summary judgment on the punitive damages claim, arguing plaintiff's evidence could not support a finding of conduct that was "wanton or malicious, bordering on criminal, or reckless," which is required to justify punitive damages.

The trial court denied defendant's motion, holding defendant's failure to place a warning on each pipe created a factual issue as to whether punitive damages were warranted, unlike under a prior decision where summary judgment was granted because defendant had placed a warning on every product.

On defendant's appeal, the Appellate Division, First Department, reversed. The court noted that punitive

This Update was prepared by Foley Hoag's Product Liability and Complex Tort Practice Group, which includes the following members:

David R. Geiger
Practice Group Chair and Update Editor

Neil Austin

Matthew C. Baltay

Kristyn Bunce DeFilipp

Jonathan M. Ettinger

Matthew E. Miller

Creighton K. Page

Madeleine Rodriguez

Peter A. Sullivan

Shrutih V. Tewarie

Colin J. Zick

Peter G. Ellis
Associate Editor

James M. Gross,
Associate Editor

Adam Aguirre

Susanna Chi

Rachel Davidson

Christian A. Garcia

Stephen Garvey

Caroline Holliday

Aaron Lang

Joanna McDonough

Christopher Modlish

Leah Rizkallah

Ethan Severance

FOLEY HOAG