FOLEY HOAG

Product Liability **Update**

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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

First Circuit Holds Failure-To-Warn Claims Against Drug Manufacturer Preempted By Federal Food, Drug, And Cosmetic Act Because Animal Studies Cited By Plaintiffs Did Not Demonstrate Risks Beyond Those In Studies Already Submitted To FDA And Hence Were Not "Newly Acquired Information" Permitting Defendant To Change Its FDA-Approved Labeling, And There Was "Clear Evidence" FDA Would Have Rejected Labeling Change Because It Later Rejected Similar Labeling With Awareness Of The Cited Studies

In *Perham v. GlaxoSmithKline LLC (In re Zofran Ondansetron Prods. Liab. Litig.)*, 57 F.4th 327 (1st Cir. 2023), plaintiffs brought failure-to-warn claims against a pharmaceutical manufacturer in a multi-district litigation centralized in the United States District Court for the District of Massachusetts after being prescribed defendant's drug off-label to prevent nausea and vomiting while pregnant. Plaintiffs alleged the drug caused a variety of birth defects, and that it should have had a Pregnancy Category C label warning because there were animal data suggesting adverse fetal effects.

The district court granted defendant's motion for summary judgment, finding the claims preempted by the Federal Food, Drug, and Cosmetic Act because the United States Food and Drug Administration ("FDA") had approved the drug's label and defendant could not lawfully deviate from it (See July 2021 Product Liability Update). The court rejected plaintiffs' argument that defendant could have changed the drug's label under FDA's "changes being effected" regulations, which permit drug manufacturers based on "newly acquired information" to unilaterally strengthen their warning labels, subject to subsequent FDA approval or rejection, because even if the court assumed plaintiffs' cited animal studies constituted "newly acquired information" there was "clear evidence" the FDA would in fact have rejected plaintiffs' suggested warning.

On plaintiffs' appeal, the United States Court of Appeals for the First Circuit affirmed. The court first rejected plaintiffs' argument that the cited animal studies constituted "newly acquired information," as the studies did not reveal "risks of a different type or greater severity or frequency" than animal studies defendant had already submitted to FDA. While the newer studies mentioned multiple adverse conditions arguably not included in the prior studies, the study authors themselves did not find those conditions attributable to the drug. And while plaintiffs' regulatory expert considered the studies "newly acquired information," the issue was one of law, and expert testimony on such

issues is rarely admissible. Moreover, even if that were not so, the specific testimony here was unreliable and hence inadmissible, as the expert had not himself reviewed either defendant's FDA submissions or the cited studies, and his opinion that defendant should have reported all animal studies to the FDA regardless of content was irrelevant to the requirements for employing the CBE process.

Further, even if the cited animal studies met the "newly acquired information" predicate, there was clear evidence FDA would have rejected plaintiffs' proposed labeling change. Here, a subsequent owner of rights to the drug had requested a labeling change to mention the risk of birth defects and recommend against using the drug during pregnancy at a time when FDA was fully informed about the cited animal studies, yet the agency approved a label stating that animal data revealed "no significant effects . . . on the maternal animals or the development of the offspring." Nor was it relevant that FDA had learned of the studies through litigants rather than defendant.

Massachusetts Federal Court Holds Jurisdiction Over Non-Resident Branded Drug Manufacturers Satisfies Long-Arm Statute And Due Process Despite Possibility Plaintiff Took Generic Drug In-State, As Defendants' Out-Of-State Labeling Could Have Harmed Plaintiff In-State Since Generic Labeling Must Follow Branded, And Claims Were "Sufficiently Related" To Defendants' In-State Sales Of Branded Drug; Design Defect Claims Preempted By Federal Food, Drug, and Cosmetic Act Because Defendants Could Not Have Modified Drug's Active Ingredient Without FDA Approval

In *Barnes v. Merck & Co.*, Civil Action No. 22-10496-NMG, 2023 U.S. Dist. LEXIS 872 (D. Mass. Jan. 4, 2023), plaintiff brought claims for design defect, failure to warn, negligence, misrepresentation and breach of express warranty in the United States District Court for the District of Massachusetts against related entities alleged to be the manufacturers and sellers of a brand-name asthma medication that allegedly caused neuropsychiatric events. Plaintiff alleged she was prescribed defendants' drug and her prescriptions were filled with "branded and/or generic" versions. Defendants, residents of New Jersey and Delaware, moved to dismiss for lack of personal jurisdiction, arguing that because they did not make or sell the generic version of the drug and plaintiff could not prove she took the branded version, plaintiff had no evidence of conduct by them that would permit jurisdiction under either Mass. Gen. L. ch. 233A, § 3, the state long-arm statute, or due process. Defendants also moved to dismiss plaintiff's design defect claim as preempted by the Federal Food, Drug, and Cosmetic Act ("FDCA").

Regarding the long-arm statute, plaintiff relied on one prong of the statute that permitted jurisdiction over a claim that defendant committed an act or omission outside Massachusetts that caused injury within it if defendant regularly did or solicited business, engaged in any other persistent course of conduct, or derived substantial revenue from goods or services used or consumed in the state. The court noted that since federal regulations require a generic drug's labeling to be identical to its branded equivalent, and under Massachusetts law a name-brand manufacturer can be held liable for injuries caused by a generic drug if plaintiff proves the manufacturer was reckless in its labeling, defendants' labeling decisions made outside Massachusetts could have caused plaintiff's in-state injury. Because defendants also derived substantial revenue from selling their branded drug in Massachusetts, plaintiff's claim satisfied the long-arm statute.

For this exercise of jurisdiction to comport with due process, plaintiff's claims were required to be "sufficiently relate[d]" to defendants' actions in Massachusetts. Because defendants extensively marketed and sold the branded drug in Massachusetts with the very labeling that formed the basis of plaintiff's claims, plaintiff satisfied this standard as well.

Although the court denied defendants' jurisdictional motion, it did grant their motion to dismiss plaintiff's design defect claims. While plaintiff alleged that a safer alternative design, a required element of a design defect claim under Massachusetts law, was available by modifying the drug's active ingredient, the FDCA prohibits drug manufacturers from implementing such "major changes" to a drug's chemical formulation without prior approval from the United States Food and Drug Administration. Accordingly, the claim was preempted.

In Putative Class Action For Reduced Vehicle Value Caused By Allegedly Defective Hoods, Massachusetts Federal Court Dismisses Magnuson-Moss Warranty Act Claims Despite Viable Express Warranty Claim, Holding Plaintiff Cannot Use Broader Jurisdictional Provisions Of Class Action Fairness Act To Evade Magnuson-Moss' Jurisdictional Requirement Of At Least One Hundred Named Plaintiffs, Dismisses Fraud By Omission Claims For Failure To Plausibly Allege Hood Condition Was Essential To Purchase, And Dismisses Tort-Based Implied Warranty Claims Because Alleged Damages Were Purely Economic

In *Rezendes v. Mitsubishi Motors N. Am., Inc.*, No. 22-CV-10211-AK, 2023 U.S. Dist. LEXIS 21950 (D. Mass. Feb. 9, 2023), plaintiff brought a putative class action in the United States District Court for the District of Massachusetts alleging the defendant automobile manufacturer sold vehicles with defective hoods that rattled and distracted drivers, diminishing the vehicles' value. Plaintiff asserted, among other claims, fraud by omission, breach of express warranty, violation of the federal Magnuson-Moss Warranty Act ("MMWA"), which requires warrantors to comply with their written warranties, and breach of the implied warranty of merchantability. Defendant moved to dismiss the complaint in its entirety for failure to state a claim.

The court first held plaintiff had not adequately pled fraud by omission, which requires both that defendant has information it knows is necessary to prevent misleading plaintiff and that the information goes to the essence of the transaction. Because plaintiff's complaint did not allege his reasons for choosing defendant's vehicle, any statements relied on in forming his opinion of the vehicle or any discussion involved in its purchase, he had not plausibly pled that the alleged hood defect was essential to the transaction.

Regarding plaintiff's express warranty claim, the court held plaintiff had plausibly pled breach of express warranty, as defendant's New Vehicle Warranty promised the vehicle was "free from defects in materials or workmanship at the time of delivery," and because he had adequately pled an express warranty claim under Massachusetts law he also satisfied the MMWA's substantive elements. The MMWA also imposes jurisdictional requirements for claims brought in federal court, however, including that class actions be brought with at least one hundred named plaintiffs. Plaintiff argued that although the action did not meet the MMWA threshold, the court nonetheless had jurisdiction under the general jurisdictional provisions of the Class Action Fairness Act ("CAFA"), which permits federal courts to exercise jurisdiction over class actions meeting certain requirements if there are at least one hundred putative class members, without regard to how many of them are individually named as plaintiffs. While some federal district courts had accepted this argument, the only federal appellate court to address it—the United States Court of Appeals for the Ninth Circuit—had held CAFA did not allow plaintiffs to evade the MMWA's specific jurisdictional requirements for a claim under that statute, and the court accepted that reasoning and dismissed plaintiff's MMWA claim.

Lastly, the court dismissed plaintiff's claim for breach of the implied warranty of merchantability, asserting that under Massachusetts law it is a tort-based theory that requires injury beyond purely economic loss. Because plaintiff's only plausible injury was the cost to repair his vehicle's hood, his implied warranty claim failed. In so noting, the court appeared not to recognize that while in actions for personal injury or property damage a breach of the implied warranty of merchantability claim is the near-equivalent of strict liability under Massachusetts law, in actions for purely economic loss the claim is a contract-based one under the Uniform Commercial Code.

Massachusetts Federal Court Holds Plaintiff Failed To Prove Personal Jurisdiction Over Surgical Mesh Manufacturer's Parent Or Distributor, As Plaintiff Could Not Prove Manufacturer Was So Dominated By Parent As To Be Its Alter Ego And Hence Impute Its In-State Conduct To The Parent, And Affidavit Established Distributor Did Not Sell Mesh Product In Massachusetts Until After Plaintiff's Surgery; Plaintiff Pleads Adequate Design Defect Claim By Identifying Other Mesh Products As Feasible Alternative Design, But Not Manufacturing Defect Claim For Failing To Identify Any Departure From Product's Intended Design

In *Paye v. Atrium Med. Corp.*, No. 22-100005-FDS, 2023 U.S. Dist. LEXIS 9935 (D. Mass. Jan. 19, 2023), plaintiff

brought claims for defective design, manufacturing defect, failure to warn, breach of express warranty and negligent misrepresentation against a surgical mesh manufacturer, its parent and distributor in the United States District Court for the District of Massachusetts. Plaintiff alleged that years after its implantation in his hernia surgery, the mesh migrated away from the hernia site and became surrounded by scar tissue, causing permanent injuries and pain. The Sweden-based parent company and New Jersey-based distributor moved to dismiss for lack of personal jurisdiction, and the manufacturer moved to dismiss for failure to state a claim.

Regarding jurisdiction, plaintiff argued the manufacturer's sale of the mesh in Massachusetts should be imputed to its parent because the manufacturer was merely an alter ego of the parent. The court rejected the argument, however, as plaintiff had no evidence the manufacturer was "a sham entity designed to defraud investors and creditors" or that the parent exercised "exclusive domination and control" over the manufacturer, as would be required to pierce the corporate veil under the law of Delaware, the manufacturer's state of incorporation. As to the distributor, plaintiff had not proved it had engaged in activities in Massachusetts that were sufficiently related to his claims, which due process would require to support jurisdiction, as an affidavit from the manufacturer's president attested that the distributor did not begin promoting and selling the manufacturer's mesh until after plaintiff's surgery, and plaintiff provided no evidence to the contrary.

As to the adequacy of plaintiff's claims against the manufacturer, the court granted in part and denied in part its motion to dismiss. Because plaintiff's complaint described other types of surgical mesh, plaintiff had adequately pled the existence of a feasible alternative design as required by Massachusetts law and thus a claim for design defect. Because the alleged defects at issue were all inherent in the mesh's design, however, plaintiff had not sufficiently alleged his injury was caused by any deviation from the product's design and thus his manufacturing defect claim failed.

With respect to failure to warn, even though plaintiff had not specifically alleged what warnings the manufacturer gave his physician, his allegations that those warnings were inadequate in a number of specific safety-related respects were sufficient. Similarly, the complaint's references to package inserts and other written materials representing the mesh was safe were sufficient to sustain plaintiff's express warranty claim to the extent it relied on such labeling, but not to the extent the claim relied on oral communications, as plaintiff had failed to describe them with any specificity. Likewise, plaintiff's negligent misrepresentation claim failed, as he had not identified any specific communications by which either he or his physicians were misled.

In Putative Class Action Alleging Diminished Value Of Pet Food Based On Levels Of Heavy Metals And BPA, Massachusetts Federal Court Dismisses Plaintiffs' Fraud-Related Claims For Lack Of Plausible Allegation Of Objective Injury Where Product Complied With FDA Standards, Express Warranty Claim For Lack Of Allegation Of Promise Made Part Of Basis Of Bargain And Implied Warranty And Unjust Enrichment Claims Where Dogs Ate Food Without Harm So Plaintiff Received Full Benefit Of Bargain

In *Slawsby v. Champion Petfoods USA, Inc.*, No. 18-10701-GAO, 2023 U.S. Dist. LEXIS 51309 (D. Mass. Mar. 27, 2023), plaintiff filed a putative class action against a pet food manufacturer and its parent in the United States District Court for the District of Massachusetts asserting various fraud-related claims, including under Mass. Gen. L. ch. 93A, the Massachusetts unfair and deceptive practices statute, as well as claims for breach of express and implied warranties and for unjust enrichment. Plaintiff alleged that defendants sold premium pet foods that they advertised as safe, fresh and natural without disclosing that they contained some amounts of certain heavy metals and Bisphenol A ("BPA"), and that she would not have paid a premium price for the products had she known they contained these substances. Defendants moved to dismiss the complaint in its entirety, a motion that the court granted.

As to plaintiff's Chapter 93A and other fraud-related claims, the court found that plaintiff failed to allege any actual injury distinct from the alleged deception itself. Plaintiff failed to identify an objective basis for her claim that the products' heavy metal and BPA levels, which were within United States Food and Drug Administration standards according to a white paper referenced in plaintiff's complaint, were harmful, and her subjective belief that they reduced the products' value did not establish

cognizable harm. Moreover, plaintiff had received the benefit of her bargain, in that "[s]he purchased the food, she fed her dog, the food is gone, and the dog is apparently okay (and fed)."

Regarding her breach of express warranty claim, plaintiff failed to allege any particular affirmation of fact or promise, such as about the absence of heavy metals or BPA in the products, that became part of the basis of the bargain, which is required for such a claim. Her claim for breach of the implied warranty of merchantability was similarly deficient, as she did not plausibly allege the pet food was not fit for its ordinary purpose or that such unfitness caused her dog harm. And, as with her express warranty claim, plaintiff did not plausibly allege the food failed to conform to its labels. Finally, plaintiff's unjust enrichment claim was inadequate, as she failed to allege facts showing she did not receive what she paid for or that defendants had retained an inequitable benefit.

NEW YORK/NEW JERSEY SUPPLEMENT

In Case of First Impression, New York Federal Court Holds Claims Involving Class II Medical Device Undergoing FDA "De Novo" Review Because Not Substantially Equivalent To Marketed Devices And Hence Subjected To FDA Special Controls Not Expressly Preempted By Food, Drug, And Cosmetic Act Because Controls Did Not Impose Specific Requirements On Device; Plaintiff's Claim For Failure To Warn Physicians About Adverse Events Properly Includes Claim Based On Failure To Report Events To FDA As Required By Act

In *Desch v. Merz N. Am., Inc.*, No. 22-CV-02688 (HG), 2023 U.S. Dist. LEXIS 57618 (E.D.N.Y. Mar. 31, 2023), a woman sued the manufacturers of a medical device that uses ultrasound to provide a non-invasive alternative to face lifts in the Supreme Court of New York, alleging that although the device had been cleared by the United States Food and Drug Administration ("FDA") only to lift skin on the neck and under the chin, and to reduce lines and wrinkles on the chest, her physician used the device on her whole face, an indication for which the FDA had specifically denied clearance. Plaintiff alleged she suffered permanent facial, eye and nerve damage, and asserted claims for breaches of express and implied warranties, negligence, misrepresentation by omission, and strict products liability for both manufacturing defects and failure to warn.

After defendants removed the case to the United States District Court for the Eastern District of New York, they moved to dismiss, arguing the claims were preempted by 21 U.S.C. § 360k(a), part of the Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act ("FDCA"), which prohibits any state law "requirement" that is "different from, or in addition to" any "requirement" imposed by the FDCA and that relates to the device's safety or effectiveness. The court noted that the United States Supreme Court had held in *Lohr v Medtronic, Inc.*, 518 U.S. 470 (1996), that the statute did not preempt claims regarding Class II medical devices cleared for marketing by the FDA as "substantially equivalent" to devices already on the market as of the MDA's effective date, because such clearance "does not impose specific requirements on those devices," but had also held in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), that claims against Class III devices that had received FDA "pre-market approval" were preempted, as that approval did impose specific requirements on the devices.

Although FDA had classified the device at issue here as a Class II device, the agency had also concluded the device was not substantially equivalent to other marketed devices and therefore subjected it to a "de novo" review, which resulted in the agency's promulgating a "special controls" document applicable to the device and any future substantial equivalents. Defendants argued the special controls imposed sufficiently specific requirements on the device to trigger express preemption.

According to the court, the issue was one of first impression, as the only other court confronted with the question—the United States District Court for the Northern District of Georgia—had held it lacked sufficient information to decide the issue at the motion to dismiss stage. Reviewing the special controls document at issue here, however, the court held it did not impose any specific requirements on the device, instead only requiring defendants and manufacturers of equivalent devices to comply with FDA's general device labeling regulations and describing the types of tests other

manufacturers should perform when seeking to market equivalent devices. Accordingly, express preemption was not triggered.

Nonetheless, the court dismissed most of plaintiff's claims on other grounds. Her manufacturing defect claims under strict liability, negligence and implied warranty failed because her conclusory allegations did not identify any specific manufacturing defect. Because the device was a prescription medical device for use only by learned intermediary physicians, plaintiff's claims that defendants misrepresented their device as "approved"—the FDA's term for devices that pass Class III review—rather than "cleared"—the FDA's term for devices that pass Class II review—failed because she did not allege that her physician, rather than she, reasonably relied on the alleged misrepresentation, and because any reasonable physician would have understood the FDA's review of Class II devices does not culminate in "approval." And plaintiff's claims based on defendants' alleged marketing of the device for off-label use, here for the full face, was impliedly preempted by the FDCA because by the statute's own terms only the FDA, and not private plaintiffs, were permitted to enforce any prohibitions on off-label promotion grounded in the statute, and New York tort law did not prohibit off-label promotion.

The court, however, denied defendants' motion to dismiss plaintiff's failure-to-warn claims based on defendants' alleged failure to report to the FDA, and to warn the medical community about, adverse events related to the use of the device, such as "permanent nerve injuries," holding that the duty to warn the medical community was well established in New York law and that that duty embraced an obligation to report adverse events to FDA to the extent required by the FDCA.

New York First Department Holds Plaintiff Injured By Store Display Fitness Band Failed Adequately To Plead Claims For Breach Of Express Warranty Where He Did Not Allege He Saw Representations On Packaging From Which Product Had Been Removed, Implied Warranty Of Fitness For Particular Purpose Where He Did Not Allege Any Purpose For Product Other Than Its Ordinary One Or Implied Warranty Of Merchantability Where He Did Not Allege Any Deficiency In Product Itself But Rather That It Was Compromised By Repeated Customer Use

In *Fiuzzi v. Paragon Sporting Goods Co. LLC*, 212 A.D.3d 431 (1st Dep't 2023), plaintiff sued the manufacturer of, and a sporting goods store that displayed, an elastic exercise band that injured plaintiff in the Supreme Court of New York, asserting claims for breach of express warranties as well as the implied warranties of merchantability and fitness for a particular purpose. Plaintiff alleged the store's employee encouraged plaintiff to test a display model of the product that had been removed from its packaging, so that plaintiff did not see its written warnings, and that while he was testing the band its end slipped from under his foot and projected into his right eye. On defendants' motions to dismiss, the court dismissed plaintiff's express warranty claim because he failed to allege he was even aware of any warranties contained on the product's packaging, but concluded plaintiff had alleged viable breach of implied warranty claims against both defendants.

The parties cross-appealed and the Appellate Division, First Department, affirmed dismissal of the express warranty claims, agreeing the absence of any allegation that either defendant made any promises that plaintiff relied upon was fatal to the claims. The court, however, reversed the trial court's ruling that plaintiff had pled viable implied warranty claims, ruling that those claims, too—and thus plaintiff's entire complaint—should have been dismissed.

As to the implied warranty of fitness for a particular purpose, the court noted such a warranty would arise only if defendants "had reason to know any particular purpose for which the goods are used" and that plaintiff relied on defendants' "skill or judgment to select or furnish those suitable goods." Because plaintiff's complaint did not allege any purpose that

he intended for the exercise band other than its ordinary purpose for exercise, that defendants knew or should have known of any such purpose, or that plaintiff relied on defendants' skill or judgment in selecting the product for that purpose, plaintiff's claim failed.

Regarding the implied warranty of merchantability, such a claim required that (i) the product was defective such that it was not fit for its ordinary purpose, (ii) the defect was a substantial factor in causing plaintiff's injury, and (iii) the alleged defect existed at the time the product left the defendant's possession. Because plaintiff alleged only that that the exercise bands became compromised as a "result of repeated use by the public," rather than due to any inherent defect rendering the product not reasonably fit for its ordinary purpose, plaintiff failed to allege a prima facie claim.

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