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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

Massachusetts Federal Court Grants Summary Judgment On Failure-To-Warn, Negligent Misrepresentation And Deceptive Practices Claims Against Surgical Stapler Manufacturer, As Plaintiffs Offered No Evidence Surgeon Reviewed Stapler Instructions Or Adverse Event Reports Or Relied On Manufacturer Statements, And Manufacturer Has No Duty To Publicly Report Adverse Events

In *Corrigan v. Covidien LP*, No. 22-cv-10220, 2024 U.S. Dist. LEXIS 165161 (D. Mass. Sept. 13, 2024), plaintiff allegedly developed an anastomotic leak after a laparoscopic sigmoidectomy utilizing a surgical stapler, requiring corrective surgery. He sued the stapler manufacturer and related entities in the United States District Court for the District of Massachusetts for negligence and breach of the implied warranty of merchantability (the Massachusetts near-equivalent of strict liability), asserting theories of manufacturing defect, design defect and failure to warn, as well as negligent misrepresentation, loss of consortium and violation of Mass. Gen. L. ch. 93A (the state unfair and deceptive practices statute). At an earlier stage, defendants moved to dismiss all claims, but the court granted the motion only as to breach of warranty and negligence for defective design or manufacture. Following discovery, defendants moved for summary judgment on all remaining claims based on lack of evidence of causation, and the court granted the motion.

In support of his failure-to-warn claims, plaintiff alleged that defendants' decision to report adverse events collectively through the United States Food and Drug Administration's ("FDA") Alternative Summary Reporting ("ASR") process, under which individual adverse event reports were not made available to the public, rather than individually, in which case they would be posted to FDA's publicly available database, deprived his surgeon of sufficient information about the stapler's foreseeable risks. As to those claims, the court held that, whether analyzed under either a traditional or an "underreporting" failure-to-warn theory, plaintiff's claims failed because he offered no evidence sufficient to prove causation.

In assessing plaintiff's claims under a traditional failure-to-warn theory, the court applied the learned intermediary doctrine, pursuant to which the manufacturer's duty to warn runs to the physician rather than the plaintiff, and a "heeding presumption," under which an inadequate warning is presumed to have affected the physician's conduct; if the manufacturer offers evidence to rebut the presumption, however, plaintiff then

has the burden to prove that the inadequate warning caused his injuries. Here, defendants had successfully rebutted the presumption that the surgeon would have heeded an adequate warning, as he had not researched or reviewed any adverse events reported to FDA before using the stapler. Likewise, the court found no affirmative evidence to support a finding of causation, as the surgeon had not reviewed the stapler instructions or any adverse event reports.

Regarding plaintiff's novel underreporting theory, the court agreed with two prior Massachusetts federal court decisions that Massachusetts had not imposed a duty on manufacturers to publicly report adverse events. Additionally, as plaintiff's surgeon did not review any adverse event reports before the surgery, his decision to use the stapler would not have been based on any purported underreporting.

As to plaintiff's negligent misrepresentation claim, plaintiff offered no evidence the surgeon had relied on any manufacturer statements. Plaintiff's chapter 93A claim was based on the same theories as his failure-to-warn claims, and failed for the same reasons. Lastly, as plaintiff's loss of consortium claim was derivative of his other claims, it fell with them.

Massachusetts Federal Court Applies Learned Intermediary Doctrine To Failure-To-Warn Claims Against Medical Device Manufacturer In States With And Without "Heeding Presumption," Holding Presumption In Former State Supplies Inference Adequate Warning Would Have Changed Physician's Conduct And Thus Requires Summary Judgment Denial, But Grants Summary Judgment In State Without Presumption Where Plaintiff Did Not Offer Evidence Adequate Warning Would Have Changed Physician's Conduct

In *Evers v. Hologic, Inc.*, 2024 U.S. Dist. LEXIS 174404 (D. Mass. Sept. 26, 2024), four plaintiffs in consolidated actions sued a medical device manufacturer in the United States District Court for the District of Massachusetts for negligence and breach of the implied warranty of merchantability (the Massachusetts near-equivalent of strict liability), asserting theories of failure to warn and design defect. During partial mastectomies, plaintiffs were implanted with defendant's marker device used to identify breast tissue surrounding excised cancer tissue to help calibrate for radiation targeting. Plaintiffs alleged the device, which was represented to only retain its functional integrity for approximately two months, and to completely re-absorb within one or more years, failed to re-absorb as represented, causing injuries such as palpability, fat necrosis and pain. Defendant moved for summary judgment on the failure-to-warn claims based on the learned intermediary doctrine, under which a prescription medical product manufacturer must provide adequate warnings to the physician rather than the patient.

Applying Massachusetts' choice of law rules, the court held that the law of the state where each injury occurred governed. Three states at issue—California, North Carolina, and Florida—did not recognize a "heeding presumption" under the learned intermediary doctrine, while the fourth—Indiana—did. If a manufacturer's warnings are inadequate, a heeding presumption creates an inference that the warning plaintiff contends defendant should have given would have changed the physician's conduct, shifting to the defendant the burden to offer evidence it would not. In the absence of a presumption, plaintiff must offer affirmative evidence that an adequate warning would have altered the physician's conduct.

Starting with the states that lacked a heeding presumption, the court found that both the California and North Carolina plaintiffs had offered sufficient evidence to support a finding that an adequate warning would have altered their physicians' conduct, and thus denied summary judgment. The California plaintiff testified that her physician told her the device would re-absorb within a certain time frame, which aligned with information in the device instructions, and the physician testified she likely would have reviewed those instructions. Although the North Carolina plaintiff's physician testified that an adequate warning would not have affected her decision to use the device, she in fact had stopped using the device because of its risks.

By contrast, the Florida plaintiff, apparently incorrectly assuming that Massachusetts law and its heeding presumption would apply, failed to offer any evidence that her physician would not have used the device had he received an adequate warning, so the court granted summary judgment.

Finally, the Indiana plaintiff had the benefit of a heeding presumption, and defendant failed to offer evidence that the physician would not have acted differently with an adequate warning, as her testimony was only that she was "not sure" whether she would have. Accordingly, the court denied summary judgment.

Third Circuit Holds Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") Expressly Preempts Failure-To-Warn Claim Against Pesticide Manufacturer Because EPA-Approved Labeling Imposed a "Requirement" Under FIFRA And Pennsylvania's Duty to Warn Would Impose A "Different" Or "Addition[al]" Requirement

In *Schaffner v. Monsanto Corp*., 113 F.4th 364 (3d Cir. 2024), a husband and wife brought a failure-to-warn and other Pennsylvania law claims against a weedkilling pesticide manufacturer in the Court of Common Pleas of Allegheny County, Pennsylvania, alleging the husband's exposure to the product while working as a landscaper caused him to develop non-Hodgkin's lymphoma. The manufacturer removed the case to the United States District Court for the Western District of Pennsylvania and the case was then transferred to the Northern District of California as part of a multi-district litigation ("MDL").

The manufacturer moved for summary judgment on plaintiffs' failure-to-warn claim, arguing the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") expressly preempted any state law duty to warn of the pesticide's carcinogenicity. The MDL court denied the motion, following the reasoning of a decision from the United States Court of Appeals from the Ninth Circuit that had rejected an earlier similar argument in the MDL. The case was subsequently remanded back to the Western District of Pennsylvania, where plaintiffs amended their complaint to limit it to the failure-to-warn claim, the parties stipulated to entry of judgment in plaintiffs' favor, but the manufacturer reserved the right to, and did, appeal from the MDL court's preemption decision.

The United States Court of Appeals for the Third Circuit reversed. The court first rejected plaintiffs' arguments that the Ninth Circuit's ruling on the issue was dispositive. Plaintiffs argued the court should apply the "law-of-the-case doctrine," which generally provides that an appellate panel will not reconsider questions that a panel of another appellate court decided on a prior appeal in the same case. The Third Circuit rejected this argument because cases centralized in an MDL retain their individual identities unless they proceed under a "master complaint," which was not the case here, so the Ninth Circuit's decision was not issued in the same case. Plaintiffs also argued the doctrine of non-mutual offensive issue preclusion prohibited defendants from relitigating the preemption issue, but the court rejected that argument because the doctrine's equitable exceptions, including when the issue is a pure question of law, justified deciding the issue anew.

Regarding the merits of the preemption issue, FIFRA's express preemption clause, at 7 U.S.C. § 136v(b), provides that no state shall "impose or continue to effect any requirements for labeling or packaging in addition to or different from those required under [FIFRA]." Pursuant to the statute, the United States Environmental Protection Agency ("EPA") has promulgated regulations regarding a labeling preapproval process ("Preapproval Regulations"), including (1) a requirement that health warnings on a pesticide's label conform to the labeling approved by EPA during its extensive product registration and review process (the "Preapproved Label"), and (2) a prohibition, subject to limited exceptions, against modifying health warnings on a Preapproved Label unless the manufacturer obtains approval of an amended registration containing the modification.

Based on these provisions, the court held that plaintiffs' failure-to-warn claims were preempted. None of the exceptions to the Preapproval Regulation was applicable. The EPA's Preapproval Regulations constituted a "requirement[] for labeling and packaging" under FIFRA, and the pesticide's Preapproved Label did not include a cancer warning. Accordingly, any state-law requirement that the manufacturer include such a warning would impose a requirement that was "in addition to or different from" FIFRA requirements, and was preempted.

Finally, the court rejected two arguments by plaintiffs that would have compelled a different conclusion. Plaintiffs first argued that defendant's label was "misleading" in its omission of a cancer warning, rendering the product "misbranded" as defined by 7 U.S.C. § 136(q)(1), so that plaintiffs' state law claim merely sought to impose the same requirements as FIFRA's misbranding provision; further, under 7 U.S.C. § 136a(f)(2) the mere fact of a pesticide's registration could not be "construed as a defense for the commission of any [misbranding violation]." The court, however, held that EPA's approval of defendant's label "g[a]ve content to FIFRA's misbranding standards," so that plaintiffs' state law claim would indeed be imposing additional requirements

beyond those standards. Plaintiffs also argued that under a United States Supreme Court decision only agency actions carrying the "force of law" can have preemptive effect, but that decision involved an implied preemption analysis, whereas FIFRA contains an express preemption provision the language of which governed.

New York Federal Court, After Twice Excluding As Unreliable Plaintiffs' Expert Testimony That Prenatal Acetaminophen Exposure Can Cause Autism Spectrum Disorder And ADHD In Humans, Holds *Defense* Expert's Deposition, Literature And LinkedIn Statements Also Insufficient To Support General Causation Finding

In *In re Acetaminophen–ASD–ADHD Products Liability Litigation*, No. 22md3043 (DLC), 2024 U.S. Dist. LEXIS 148550 (S.D.N.Y. Aug. 20, 2024), plaintiff children (or their parents or guardians) in a multi-district litigation ("MDL") pending in the United States District Court for the Southern District of New York sued manufacturers and retailers of store-branded acetaminophen products, alleging the children suffered autism spectrum disorder ("ASD") and attention deficit hyperactivity disorder ("ADHD") from pre-natal exposure to the products, and the product labeling was deficient under various states' laws. In one earlier ruling, the court excluded the general causation opinions of five experts proffered by plaintiffs on the ground, among others, that the experts failed adequately to consider the potential confounding role of genetics in causing the children's conditions. *See* Product Liability Update – January 2024. In a subsequent opinion, the court concluded that another epidemiologist proffered by plaintiffs failed to grapple adequately with studies showing that an observed increased incidence of ADHD could be the result of genetic confounding, and otherwise engaged in "result-oriented reasoning." *See* Product Liability Update – July 2024.

Defendants moved for summary judgment, arguing that in light of the court's prior rulings plaintiffs lacked any admissible evidence on the essential element of general causation. In response, plaintiffs argued that statements by one of *defendants'* experts in deposition testimony, peer-reviewed scientific literature or other formal documents, and elsewhere, including on the website LinkedIn, could support a finding of causation.

The court granted defendants' motion, concluding that even if the defendants' expert's statements were admissible, they were insufficient to create a triable issue on general causation. For one thing, many of the statements did not refer to acetaminophen at all, but rather spoke only generically of "environmental risk factors" that can contribute to ADHD. Moreover, while the expert in multiple statements acknowledged studies that documented an "association" between prenatal acetaminophen exposure and ADHD, statistical association is not equivalent to causation, which plaintiffs were required to prove in order to prevail. Finally, while the expert's statements referred to prenatal acetaminophen exposure as a "risk factor" for ADHD, he repeatedly clarified in his deposition that that term was synonymous with "correlate," which again is "not the same as cause." Accordingly, no jury could reasonably find general causation from any of these statements.

New York Appellate Division Holds Plaintiff's Failure-To-Warn And Design Defect Claims Against Seller Of Compressed Gas Tank Preempted By Federal Hazardous Materials Transportation Act Of 1975 ("HMTA"), As Claims Were "About" The "Designing And Manufacturing" Of A "Package, Container, Or Packaging Component"—Specifically, A Valve Assembly On The Tank—That Was "Qualified For Use In Transporting Hazardous Material In Commerce"

In *Malerba v. New York City Transit Authority*, 2024 N.Y. App. Div. LEXIS 4528 (Aug. 29, 2024), a plaintiff suffered severe injuries when a compressed gas tank "suddenly actuated and struck him." Plaintiff asserted claims for negligence, breach of express and implied warranties, strict liability and loss of consortium against the tank manufacturer, among other defendants, alleging the valve assembly on the tank cylinder should have included a warning about accidental actuation and been designed differently. The manufacturer moved for summary judgment, arguing plaintiffs' claims were preempted under the federal Hazardous Materials Transportation Act of 1975 ("HMTA"). The New York Supreme Court for New York County summarily denied the motion on the grounds that there "are significant questions of fact that can only be resolved by the trier thereof, including (but not limited to) the HMTA's applicability to the tank at issue, the

extent of [the manufacturer's] duty to warn, and whether [the manufacturer's] design of the tank/valve was defective."

On the manufacturer's appeal, the Supreme Court Appellate Division, First Department, reversed. Noting that the issue of federal preemption is one of law, the court observed that the HMTA, at 49 U.S.C. § 5125(b), expressly preempts any state law that is (1) "about" the "design, manufacturing, fabricating, inspecting, marking, maintaining, reconditioning, repairing, or testing" of any "package, container, or packaging component that is represented, marked, certified, or sold as qualified for use in transporting hazardous materials in commerce" and (2) not "substantively the same" as a provision of the HMTA or regulations under it. The court further noted that the United States Court of Appeals for the Second Circuit had recently held in *Buono v. Tyco Fire Products, LP*, 78 F.4th 490 (2d. Cir. 2023), that the HMTA preempted state law claims stemming from an injury suffered from the rupturing of a compressed gas cylinder. *See* Product Liability Update – September 2023.

The court then held that the HMTA preempted plaintiff's claims. As to plaintiff's argument that the HMTA applies only when the product is in transit and therefore does not reach "end users" like himself, the court agreed with *Buono* that nothing in the statute suggests preemption turns on whether a container is in transport or contains hazardous material at a particular time. Moreover, plaintiff's claims fell squarely within the text of the HMTA's preemption provision, as the claims (1) centered on an item or component (a valve) meant to contain compressed gas and thus involved a "package, container, or packaging component," (2) were "about" the "designing and manufacturing" of the valve, (3) involved "markings" because, as *Buono* recognized, that term encompasses instructions and warnings about the potential dangers of a container, and (4) the valve assembly was "represented, marked, certified, or sold as qualified for use in transporting hazardous material."

As to that fourth element, plaintiff argued that a container or component would be represented to be "qualified" for hazardous material transport only if it was represented to be "appropriately authorized" for that use, and here the United States Department of Transportation ("DOT") did not specifically evaluate, let alone authorize, the valve but rather only the cylinder as a whole. The court, however, held that "qualified" for use only meant capable of, not affirmatively authorized for, that use, and representing the cylinder as capable of hazardous material transport necessarily represented its component valve as so capable. Moreover, since the statutory phrase in question mirrored the scope of DOT's authority, plaintiff's proposed interpretation would mean that a manufacturer could escape DOT purview by representing its product to be suitable for hazardous material transport but remaining silent about DOT authorization, an interpretation that was at odds with the HMTA's purpose of protecting against risks in hazardous material transport and hence "implausible."

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