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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.

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In *Warner v. Amgen Inc.*, No. 24-cv-10632, 2025 U.S. Dist. LEXIS 26141 (D. Mass. Feb. 13, 2025), a mother brought a failure-to-warn wrongful death claim under Massachusetts law against migraine drug manufacturers in Middlesex Superior Court, alleging that her son's injection a month after the drug's approval by the United States Food and Drug Administration ("FDA") caused a massive seizure that led to his death two years later. Plaintiff alleged that the manufacturers' labeling failed to provide adequate warnings that individuals with a history of seizures and cerebrovascular disease, like her son, were excluded from clinical testing.

After removing the case to the United States District Court for the District of Massachusetts, the manufacturers moved to dismiss, arguing that the Federal Food, Drug, and Cosmetic Act ("FDCA") preempted any state law duty to warn, as the FDA approved the label knowing who was excluded from testing and thus it would have been impossible to comply with FDCA labeling requirements while simultaneously providing a stronger warning label than the FDA approved. Plaintiff opposed the motion, but also moved to amend her complaint, seeking to add that the manufacturers could have modified the drug's label in the month after approval via the FDA's "changes being effectuated" ("CBE") regulation.

Pursuant to the FDCA, before a manufacturer can sell a new drug, it must obtain FDA approval, 21 U.S.C. § 355(a), which requires the manufacturer to submit comprehensive safety information and a proposed label, 21 U.S.C. § 355(b)(1)(A). The FDA must endorse the exact text in the proposed label, which helps ensure the label includes all necessary warnings and does not overwarn, and the manufacturer must then use the FDA-approved label unless the CBE regulation applies. Under that exception, a manufacturer can alter a label unilaterally, subject to later FDA review, to reflect newly acquired information if the modification would "add or strengthen a contraindication, warning, precaution, or adverse reaction" for which there is "evidence of a causal association," 21 C.F.R. § 314.70(c)(6)(iii)(A).

The court granted the motion to dismiss and denied plaintiff's motion to amend. With respect to plaintiff's pre-approval failure-to-warn claim, the court explained that under decisions of the United States Court of Appeals for the First Circuit, the dispositive question was not whether the manufacturers could have proposed a label with a stronger warning in the first place, but whether the FDA considered the safety information that would purportedly give rise to the need for that warning. Plaintiff's claim was thus preempted because the FDA was fully aware of the exclusion criteria used in the drug's clinical trials and considered the attendant risks before it approved the label.

As to plaintiff's post-approval failure-to-warn claim, the court considered nine articles submitted by plaintiff in connection with her motion to amend and held they did not constitute newly acquired information, as they failed to link the drug to any adverse risk and did not contain information about cerebral risks that were unknown to the FDA when it approved the drug. Accordingly, defendants could not have used the CBE regulation to modify the label in the month after approval, plaintiff's proposed post-approval failure-to-warn claim based on such a modification was preempted and the court denied plaintiff's motion to amend as futile.

Massachusetts Federal Court Grants Summary Judgment On Failure-To-Warn Claims Against Medical Device Manufacturer Where Governing Law Did Not Apply "Heeding Presumption" And Plaintiff Failed To Elicit Deposition Testimony From Surgeon Regarding Whether Different Warning Would Have Changed Decision To Use Device

In *In re BioZorb Device Prods. Liab. Litig.*, 2025 U.S. Dist. LEXIS 27055 (D. Mass. Feb. 12, 2025), plaintiff 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. Over eighty plaintiffs in twenty-three cases before the court have alleged injuries resulting from defendant's marker device, used in mastectomies to mark breast tissue surrounding the excised tumor for future radiation targeting. Here, plaintiff 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 pain, mild lymphedema and radiation fibrosis.

Defendant moved for summary judgment on the failure-to-warn claims based on the learned intermediary doctrine, under which a prescription medical product manufacturer's duty is to provide adequate warnings to the physician rather than the patient. The court previously considered a similar summary judgment motion in *Evers v. Hologic, Inc.*, 2024 U.S. Dist. LEXIS 174404 (D. Mass. Sept. 26, 2024), and applied Massachusetts choice-of-law rules to determine that the law of the state where the injury occurred governed (see [October 2024 Foley Hoag Product Liability Update](#)). Based on that ruling, the court applied Colorado law since that was the place of plaintiff's surgery.

Colorado does not apply a "heeding presumption" in failure-to-warn cases under the learned intermediary doctrine; if a manufacturer's warnings are inadequate, such a presumption creates an inference that the warning plaintiff contends defendant should have given would have changed the physician's conduct, shifting to defendant the burden to offer evidence it would not. Absent a presumption, plaintiff must offer affirmative evidence that an adequate warning would have altered the physician's conduct.

Here, plaintiff did not offer such affirmative evidence. In particular, plaintiff's counsel never questioned the surgeon during her deposition as to whether a stronger warning would have changed her decision to use the device. While the surgeon testified she was unaware of certain risks associated with the device, that was not sufficient, as it did not address the critical question of what the surgeon would have done if she *had* known of those risks. Accordingly, the court granted defendant's motion.

New Jersey Appellate Division Holds As Matter Of Law Automobile Not Defectively Designed For Lack Of Lane Departure Warning And Lane Keeping Assist Systems, As Risk Of Departing From Lane Is Inherent And Known To Ordinary User And Vehicle's Steering System Was Reasonably Fit For Maintaining Lane

In *Berkoski v. Honda Motor Co.*, 480 N.J. Super, 379 (2025), an automobile driven by decedent crossed the center line of a two-lane highway and crashed into an oncoming vehicle, killing her. Her husband sued the vehicle manufacturer in New Jersey Superior Court, alleging the vehicle was defectively designed under negligence and strict liability law due to its failure to include lane departure warning (LDW) and lane keeping assist (LKA) systems that allegedly would have prevented the accident, the former by warning decedent and the latter by both warning her and steering the vehicle back into its lane.

Defendant moved for summary judgment, arguing there was no evidence the vehicle's steering system was unfit for maintaining the vehicle's lane and the manufacturer had no duty to include the additional driver assistance systems. Plaintiff opposed dismissal only of his strict liability claim, arguing the defect issue was for the jury, but the trial court granted defendant's motion.

On plaintiff's appeal, the Superior Court Appellate Division affirmed. The court noted that under the strict liability standard of the New Jersey Product Liability Act, plaintiff needed to show that the product was designed in a defective manner and not reasonably fit or safe for its intended use, but there is no liability if the harm is caused by an inherent characteristic of the product that would be recognized by the ordinary user. Here, not only would the ordinary user "recognize[] that a vehicle needs to maintain its lane" to avoid danger, but the owner's manual explicitly noted a driver could not rely on LDW or LKA systems to avoid a collision. In addition, prior case law established that a manufacturer is not required to provide every "known safety device," nor is an automobile manufacturer required to produce "an accident-proof vehicle," and accepting plaintiff's liability theory would "impose on all purchasers and users of passenger vehicles the requirement and cost" of LDW and LKA systems.

Accordingly, defendant's vehicle was "reasonably safe as a matter of law," as "currently it is understood" that safe vehicle operation "is dependent on the driver's diligence," and "[w]hat future technologies may bring [is] not before us." The court added that its conclusion was consistent with the Restatement (Third) of Torts: Products Liability, under which a range of factors are relevant to design defect, including the foreseeability and magnitude of the risks, the nature of consumer expectations, the cost of alternative designs and the range of consumer choice. The court also agreed with an amicus brief filed by the Product Liability Advisory Council that technologies like driver-assistance systems are generally phased in over time, and a requirement of immediate adoption would instead "lead to performance problems."

New York Federal Court Holds Plaintiff's Expert's Testimony That Asbestos Exposure From Defendant's Vessels Caused Plaintiff's Lung Cancer Inadmissible Due To Failure To Quantify Plaintiff's Alleged Exposure

In *Keller v. ExxonMobil Oil Corp.*, Case No. 23-CV-1528-LTS, 2025 U.S. Dist. LEXIS 44043 (S.D.N.Y. Mar. 11, 2025), a former merchant seaman allegedly developed lung cancer as a result of exposure to asbestos during his ten years of employment on defendant's vessels. Invoking the Jones Act (a federal statute allowing seamen to sue their employers for injuries and illnesses sustained during employment), he sued defendant in the United States District Court for the Southern District of New York, alleging defendant was negligent in failing to warn plaintiff about the risks of asbestos and asbestos-containing products and to provide a reasonably safe workplace to mitigate the risks of harmful asbestos exposure. To establish causation, plaintiff proffered a pulmonologist's opinion that, to a reasonable degree of medical probability, plaintiff's lung cancer was caused by his cumulative exposures to asbestos while serving on defendant's vessels.

Defendant moved to preclude the pulmonologist's opinion, arguing it "does not rely on established facts and data pertaining to [p]laintiff's alleged asbestos exposure aboard [defendant's vessels]." Defendant also moved for summary judgement, arguing that without the pulmonologist's opinion

plaintiff could not meet his burden to prove causation.

The court granted both motions. The court first found that the pulmonologist's opinion was not based "on any specific testing or any other objective measurement of the actual dose of asbestos" to which plaintiff was allegedly exposed. Rejecting plaintiff's argument that a "quantitative estimate" of a patient's asbestos exposure is unnecessary, the court held that without "computations of [p]laintiff's 'cumulative exposure' to asbestos in fiber years for any period of [p]laintiff's career," the expert's opinion fell "well short of [Federal Rule of Evidence] 702's mandate that expert testimony be 'based on sufficient facts or data.'" Merely testifying "in general terms that [p]laintiff 'clearly was repeatedly exposed to asbestos'"—without quantifying that exposure—was insufficient. Moreover, the expert failed to consider alternative causes of lung cancer such as radon exposure. As plaintiff had no admissible expert testimony to establish a causal link between his alleged asbestos exposure and lung cancer, the court also granted defendant's motion for summary judgment.

New York Federal Court Dismisses Design And Manufacturing Defect Claims Against Surgical Stapler Manufacturer For Failure To Identify Specific Defect, Reasonable Alternative Design Suitable For Decedent's Surgery And Connection Of Staple Line Leak To Decedent's Death Months Later, But Holds Failure-To-Warn Claim Adequately Pled Based On Failure To Instruct Surgeons About Higher Failure Rate Of Longer Staple Line Lengths And Need For Additional Precautions, And Withholding Of Adverse Event Information By Submitting Only Summary Report For FDA's Public Database

In *Kane v. Covidien LP*, No. 2:23-cv-9207, 2025 U.S. Dist. LEXIS 25718 (E.D.N.Y. Feb. 12, 2025), after undergoing three abdominal surgeries to treat a recurrent incisional hernia, decedent allegedly developed a staple line leak and other complications, and died three months later. His wife sued the surgical stapler manufacturer and related entities in the United States District Court for the Eastern District of New York for design defect, manufacturing defect, failure to warn,

breach of the implied warranty of merchantability, loss of consortium and wrongful death. Defendants moved to dismiss for failure to state a claim.

The court first dismissed both the design and manufacturing defect claims. As to the former, plaintiff failed to identify any specific defect that posed a substantial likelihood of harm, instead relying on reported malfunctions and injuries related to surgical staplers generally. She also failed to establish that a stapler model that placed a shorter staple line length offered a reasonable alternative design, as she did not plead facts showing such models would have been suitable for decedent's surgery. In addition, she failed to plead any facts concerning the cause of the staple line failure or how that failure caused her husband's death three months later. And regarding manufacturing defect, plaintiff similarly failed to identify any specific such defect, offering only the surgeon's conclusion that a staple line failure caused the leak but no allegations that all non-manufacturing defect causes of that failure had been excluded or, again, how the staple failure was connected to decedent's eventual death.

By contrast, plaintiff adequately pled failure to warn by alleging defendants should have informed surgeons which staple line lengths were appropriate for certain procedures, and that since the longer staple line model used in her husband's surgery had a higher failure rate, surgeons using that model should either add reinforcements or closely inspect the surgical site for leaks. Also, plaintiff alleged defendants withheld from surgeons information regarding adverse events related to the stapler by utilizing the United States Food and Drug Administration ("FDA")'s Alternative Summary Reporting program, which allowed certain types of device malfunctions to be reported on the FDA's public adverse event database through a summary of the reports collectively rather than individual reports. Further, plaintiff plausibly pled causation by alleging that her husband's surgeon would not have used the stapler at issue had he been adequately informed of the risks. Accordingly, the court denied dismissal of plaintiff's failure-to-warn claim and its derivative loss-of-consortium and wrongful death claims.

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