FOLEY HOAG LLP

Product Liability **Update**

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July 2021

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 Negligence And Breach Of Implied Warranty Of Merchantability Claims Based On Allegedly Defective Design Of Vaginal Mesh Product Legally Deficient For Failure To Plead Existence Of Safer Alternative Design That Would Have Reduced Plaintiffs' Risk Of Harm

In *Ducat v. Ethicon, Inc.*, No. 4:21-cv-10174-TSH, 2021 U.S. Dist. LEXIS 72793 (D. Mass. Apr. 14, 2021), a husband and wife sued a medical device manufacturer in Massachusetts Superior Court for, among other things, negligence and breach of the implied warranty of merchantability (the Massachusetts near-equivalent of strict liability) based on the allegedly defective design of defendant's vaginal mesh product, which allegedly eroded inside the wife and caused a variety of painful injuries. Defendant removed the case to the United States District Court for the District of Massachusetts and moved for judgment on the pleadings.

Defendant argued plaintiffs' defective design claims failed both because their complaint did not allege sufficient facts to make plausible their contention that the mesh's design was unsafe, and because they failed to plead the existence of a safer alternative design. On the first point, the court found plaintiffs had adequately pled a colorable claim that the mesh's design was unsafe because it eroded too easily, as they alleged that multiple physicians had observed that the mesh had moved, was visibly protruding and had caused heavy bleeding that required surgical intervention.

Regarding the second issue, plaintiffs had indeed failed to plead the existence of a safer alternative design. The court noted that Massachusetts law was somewhat ambiguous on the necessity of such an allegation, as the seminal Massachusetts Supreme Judicial Court ("SJC") case of *Back v. Wickes Corp.*, 375 Mass. 633 (Mass. 1978), arguably implied that a safer alternative design was merely one of a number of possibly relevant factors. Nonetheless, the SJC in *Evans v. Lorillard Tobacco Co.*, 465 Mass. 411 (Mass. 2013) (*See July 2013 Product Liabilty Update*), later cited language in section 5 of the Restatement (Third) of Torts: Product Liability, as well as its comments, to the effect that plaintiffs must "prove the availability of a technologically feasible and practical alternative design that would have reduced or prevented the plaintiff's harm," and the United States Court of Appeals for the First Circuit interpreted *Evans* as adopting the Third Restatement's position.

Because *Evans* also established that the same standard applied to both plaintiffs' negligence and implied warranty claims based on design defect, plaintiffs' complaint was legally deficient. The court granted plaintiffs leave to amend to include the necessary allegations, but also held that their failure to do so would result in dismissal.

Massachusetts Federal Court Finds "Clear Evidence" FDA Would Have Rejected Proposed Birth Defects Warning For Prescription Drug, And Hence Plaintiffs' Warning Claims Were Preempted, As Subsequent Owner Of Drug Rights Had Proposed Similar Warnings To FDA But Agency Only Approved Statement That Risk Could Not Be Assessed Due To Inconsistencies and Methodological Limitations In Available Data

In *In re Zofran (Ondansetron) Prods. Liab. Litig.*, No. MDL No. 1:15-md-2657-FDS, 2021 U.S. Dist. LEXIS 102782 (D. Mass. June 1, 2021), 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 there were animal data suggesting adverse fetal effects. Defendant moved for summary judgment, arguing the claims were preempted by the Federal Food, Drug, and Cosmetic Act because the label under which the drugs were sold had been approved by the United States Food and Drug Administration ("FDA").

Decisions by the United States Supreme Court have stated that because the FDA's "changes being effected" regulations permit drug manufacturers to unilaterally strengthen their warning labels, subject to subsequent FDA rejection or approval, when newly acquired information reflects a clinically significant hazard, failure-to-warn claims are not preempted unless there is "clear evidence" the FDA would have rejected the warning argued for by plaintiffs. In *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (2019), the Court held "clear evidence" means "evidence that shows the court that the drug manufacturer fully informed the FDA of the justifications for the warning [alleged to be] required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve [that] change."

While defendant had manufactured the drugs plaintiffs took, it subsequently sold its rights to the drug, and in 2020 the current owner applied to FDA for labeling changes to add a number of warnings related to pregnancy use and the potential for birth defects. The label FDA ultimately approved, however, did not include such warnings but instead stated that inconsistent findings and methodological limitations preclude assessment of the birth defect risk.

Although plaintiffs argued the 2020 application withheld certain studies and adverse event data from FDA, the court found that either defendant or the current owner had submitted all such information to FDA over the years through various submissions, and hence FDA was fully informed of plaintiffs' justification for their proposed warning.

Moreover, there was clear evidence FDA would have rejected the warning, as past applications had proposed that type of warning but FDA had instead approved a label noting the available data precluded assessment of the risk. Although the prior submissions had not specifically addressed the label section concerning animal studies, those studies were fully available to the FDA, and preemption did not require that the precise warning sought by plaintiffs have been proposed to the agency. Nor did the facts that the drug's current owner rather than defendant had requested the labeling change that FDA rejected, or that the agency did not communicate its labeling decision to defendant, affect the preemption analysis. As FDA was fully informed and clearly indicated it would reject the warning plaintiffs sought, the court entered summary judgment for defendant.

Massachusetts Appeals Court Holds Statute Of Repose Governing Claims For Defective Design Or Construction Of Improvements To Real Estate Bars Claims For Negligent Installation Of Water Heater That Caused Fatal Burns, As Defendant Plumbing Contractor Did Not Merely Install Specific Water Heater At Issue But Used Professional Judgment To Design And Calibrate Entire System

In *Szulc v. Siciliano Plumbing & Heating, Inc.*, 99 Mass. App. Ct. 729 (2021), decedent suffered a seizure and fell in his bathtub shower, rendering him immobile in several inches of "steaming hot water" that caused second to third-degree burns that eventually led to his death. Decedent's son filed a wrongful death action against a plumbing and heating company in Massachusetts Superior Court, alleging the company's negligent installation of the building's water heaters caused decedent's death. The court granted summary judgment for defendant based on Mass. Gen. L. ch. 260, §2B, a statute of repose that sets a six-year deadline for tort actions "arising out of any deficiency or neglect in the design, planning, construction or general administration of an improvement to real property," generally running from when the improvement was substantially completed and occupancy delivered. Defendant had installed the water heaters and associated piping in 2012, and plaintiff filed suit in 2019.

On plaintiff's appeal, the Massachusetts Appeals Court affirmed the judgment. Plaintiff first argued that defendant's work did not involve the sort of "individual expertise" or "particularized services" that a prior Massachusetts case held was necessary to trigger the statute of repose. The court, however, held that case was inapplicable, as it involved a plumber who "did no structural work, designed nothing, and did no customization work of any kind." In contrast, defendant here had made professional judgments that went beyond mere installation, including analyzing the layout of the new water heaters, designing the flow of the water, and testing and calibrating the faucet water temperature.

Plaintiff also argued that his claims did not arise out of the design of the piping system as a whole, but rather only the installation of the single water heater that caused the harm, and this did not require individual expertise. The court again disagreed, holding that the installation of each water heater and calibration of the temperature in each were all part of the same continuous project, and hence the totality of the project was covered by the statute of repose.

NEW YORK/NEW JERSEY SUPPLEMENT

Second Circuit Holds Claims Against Generic Drug Manufacturer Not Plausibly Pled, As Patients' Non-Receipt Of Medication Guides Did Not Support Inference Defendant Did Not Make Them Available, Claims Of Misleading Third-Party Physicians' References Did Not Identify Specific Misrepresentations Or Defendant's Authority To Correct Them, And Alleged Concealment Of Adverse Events Was Based On Arguable Underreporting Of Such Events Generally And Not Conduct Specific To Defendant

In *Frei v. Taro Pharm. U.S.A., Inc.*, 844 F. App'x 444 (2d Cir. 2021), sixty-seven patients, spouses and estate beneficiaries brought claims, including for failure to warn, against a pharmaceutical manufacturer in the United States District Court for the Southern District of New York. The patients had been prescribed defendant's generic amiodarone, an antiarrhythmic drug, off-label to treat atrial fibrillation and allegedly suffered a variety of injuries, including various pulmonary conditions, as a result.

Because under the Federal Food, Drug, and Cosmetic Act ("FDCA") defendant had no control over its generic drug's labeling, as it was required to be the same as that of the reference branded drug, plaintiffs' claims were predicated on theories that defendant: (1) failed to make "Medication Guides" available to patients as required by FDA regulation; (2) failed to ensure the accuracy of information regarding the drug in publications such as the Physicians' Desk Reference; and (3) concealed adverse event information from FDA. The district court dismissed plaintiffs' entire complaint, holding their warning-related claims were preempted by the FDCA and their remaining claims did not plead sufficient facts to plausibly demonstrate an entitlement to relief.

On plaintiffs' appeal to the United States Court of Appeals for the Second Circuit, the court held that none of plaintiffs' claims were plausibly pled under Fed. R. Civ. P. 8 and 9, and therefore did not reach the preemption issue. Regarding plaintiffs' first theory, while the complaint alleged plaintiffs did not receive medication guides at the point of sale, that did not support a plausible inference that defendant was negligent or

otherwise failed to make such guides available; in addition, FDA regulations only required that defendant maintain "the means to produce" medication guides, and the complaint lacked any allegations defendant failed to meet that minimal standard. As for plaintiffs' second theory, the complaint did not state what misleading information was actually included in the publications at issue, nor did it explain why defendant would have had authority to correct such third-party materials.

Lastly, plaintiffs' third theory was based on their argument that the number of adverse events reported to FDA must be low because, given the large number of people diagnosed with atrial fibrillation each year, there would be tens of thousands of adverse events associated with the drug. As the court noted, however, while that allegation might suggest industry-wide underreporting, it did not plausibly demonstrate that defendant had concealed information in its possession, and indeed plaintiffs' counsel had conceded at oral argument that their claim was "based on a broad statistical allegation" and not tied to defendant's specific conduct. Accordingly, the court affirmed the dismissal of plaintiffs' complaint.

New Jersey Superior Court Appellate Division Holds Plaintiffs' Expert Testimony That Non-Asbestiform (Non-Fibrous) Cleavage Fragments in Defendants' Talc Could Cause Mesothelioma Not Shown Reliable, And Hence Inadmissible, Because Experts Could Not Support Opinions With Any Studies

In *Lanzo v. Cyprus Amax Minerals Co.*, Nos. A-5711-17, A-5717-17, 2021 N.J. Super. LEXIS 50 (Super. Ct. App. Div. Apr. 28, 2021), a husband and wife sued the manufacturer of a talc-based baby powder and various talc miners and suppliers in New Jersey Superior Court, alleging the baby powder contained asbestos and caused the husband's mesothelioma. Before and during trial, defendants moved to exclude certain testimony of plaintiffs' expert witnesses, but the trial court denied those motions. After a trial during which the court dismissed some defendants, and the jury rendered verdicts against the remaining ones, the baby powder manufacturer and one of its talc suppliers, the latter appealed to the Appellate Division of the Superior Court.

Defendants argued primarily that the trial court erred in admitting two experts' testimony about non-asbestiform cleavage fragments that may have been contained in defendants' talc. The minerals comprising what is commonly understood as "asbestos" can appear in nature in both asbestiform, *i.e.*, fibrous, and non-asbestiform morphologies. While "asbestos" is typically understood to be only the asbestiform variety of these minerals, cleavage fragments can occur when blocky, non-asbestiform mineral crystals are broken down into smaller shards, and plaintiffs' experts opined that such fragments of dimensions similar to those of asbestiform fibers can cause mesothelioma.

The appellate court first noted that New Jersey's standard for expert testimony follows the federal standard established by the United States Supreme Court in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), which requires the proponent of expert testimony to demonstrate it is reliable in order for it to be admitted. Among relevant factors are whether any scientific theory involved can be or has been tested, whether the theory has been subjected to peer review and publication, whether there is any known or potential error rate for any scientific technique at issue and whether standards exist for the technique's operation, and whether the theory or technique is generally accepted in the scientific community. Thus New Jersey courts can admit new or developing medical causation opinions "provided the proponent of the expert can demonstrate that the expert adheres to scientific norms."

Under this standard, the trial court abused its discretion in admitting plaintiffs' experts' opinions. That court had merely noted that cleavage fragments were a "highly contested" area, but then failed to assess the experts' methodology or underlying data. The experts could not identify any studies demonstrating that non-asbestiform particles cause mesothelioma, and one expert had testified in a prior case that she did not have enough information to determine whether such particles were carcinogenic. While she claimed she had since reviewed additional studies and information, she could not identify any actual studies she was relying upon.

Moreover. the trial court's failure to perform its gatekeeping duty was not harmless because plaintiffs' testing expert admitted the methodology he used to identify asbestos in

defendants' talc could not distinguish particles as being asbestiform or not. Since the jury heard the inadmissible expert opinion that cleavage fragments cause mesothelioma, they could have believed the testing expert's inability to differentiate the mineral forms was immaterial. Accordingly, the appellate court reversed the verdict against defendants and remanded the case.

In addition to ruling on plaintiffs' experts' testimony, the court also held that the trial court did not err by giving an adverse inference instruction against one remaining talc supplier as a sanction for destroying certain talc samples. The court also held, however, that the trial court should have granted the other remaining defendant's motion for a severance, as that defendant had utilized the sanctioned supplier's talc in its products, making it near impossible for the jury not to apply the adverse inference to it as well despite its having committed no spoliation.

New York Federal Court Holds Design And Manufacturing Defect And Failure To Warn and Negligent Misrepresentation Claims Against Hernia Mesh Manufacturer Inadequately Pled For Failure To Allege Economically Feasible And Safer Alternative Design, Defective Materials Or Workmanship In Plaintiff's Specific Mesh Or Specific Inadequacies Or Misrepresentations In Labeling And How They Were Relied Upon

In *Cosh v. Atrium Med. Corp.,* No. 1:18-cv-08335 (ALC), 2021 U.S. Dist. LEXIS 59649 (S.D.N.Y. Mar. 29, 2021), a husband and wife sued a medical device manufacturer in the United States District Court for the Southern District of New York after defendant's hernia mesh had to be removed due to infection and a non-healing wound one month after being implanted in the wife. Plaintiffs alleged defendant defectively designed and manufactured the mesh, and failed to warn and made negligent misrepresentations about its risks. In a prior decision, the court had dismissed plaintiffs' claims without prejudice as being inadequately pled, and after plaintiffs filed an amended complaint defendant again moved to dismiss for failure to state a claim.

In its prior decision, the court held plaintiffs had failed to adequately plead a design defect claim because they failed to plead the existence of a feasible alternative design as required by New York law. In their amended complaint, plaintiffs alleged defendant could have made its mesh using a different material and/or constructed it differently, such as with different pore sizes, but they still failed to allege necessary facts showing any such changes would be technically and economically feasible or result in a safer design.

The court had previously dismissed plaintiffs' manufacturing defect claims because they did not identify a specific component of the mesh that was defective, or any deviations from the intended manufacturing process or improper workmanship. Plaintiffs' amended complaint added allegations regarding the United States Food and Drug Administration ("FDA")'s documentation of safety regulation violations at defendant's factory, including hair being present in sterile medical devices. These additions remained insufficient, however, as they did not allege that the particular mesh implanted in plaintiff had any such defect, or explain how the cited FDA violations could have led to plaintiffs' injuries.

Regarding failure to warn, plaintiffs' prior pleadings were insufficient because they did not include any facts about how defendant's warnings were inaccurate or misrepresented anything. Their amended complaint added that defendant represented its mesh was safe and effective and failed to disclose that it was not made of "medical grade" materials and was "adulterated." But these additions failed to make the claim any more viable, as the "safe and effective" allegation still did not identify any specific misleading statements, and assertions about the mesh's material quality and adulteration merely reframed plaintiffs' legally inadequate design and manufacturing defect claims as warning claims.

Lastly, concerning negligent misrepresentation, the court had previously found plaintiffs' allegations that defendant misrepresented the safety of its mesh and omitted information regarding its risks failed to identify how defendant's statements were fraudulent or what misrepresentations plaintiff or her physician actually relied upon. While plaintiffs had amended their complaint to add allegations that defendant failed to adequately investigate adverse events reported to FDA, none of those additions addressed the reasons the court had previously dismissed the claim.

Because plaintiffs' amended complaint did not cure any of the deficiencies noted in the court's prior dismissal order, the court again dismissed plaintiffs' entire complaint, this time with prejudice.

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