FOLEY HOAG LLP

# Product Liability **Update**

## In This Issue:

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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 In Multi-District Litigation Holds Under Six States' Laws That Manufacturer Of Brand-Name Pharmaceutical Is Not Liable For Injuries Caused By Generic Equivalents Whose Manufacturers Were Required To Adopt Branded Manufacturer's Allegedly Inadequate Warnings

In *In re Zofran (Ondansetron) Products Liability Litigation*, 2017 U.S. Dist. LEXIS 130965 (D. Mass. Aug. 4, 2017), a multi-district litigation ("MDL") in the United States District Court for the District of Massachusetts, parents and guardians of children with birth defects sued the manufacturer of a brand-name prescription anti-nausea drug, asserting claims for misrepresentation and negligent undertaking in promoting the drug off-label for pregnancy-related nausea and not adequately disclosing birth defect risks. A number of plaintiffs alleged maternal exposure only to generic equivalents of the brand-name drug, but asserted the branded or innovator manufacturer was liable as it had "created a market" for pregnancy use, should have known generic alternatives would enter that market and knew generic manufacturers were legally required to copy the branded manufacturer's labeling. Defendant moved to dismiss these "innovator liability" claims on the ground that its product had not caused plaintiffs' harm.

The court first noted that none of the highest courts in the six states whose law governed plaintiffs' claims—Georgia, Indiana, Kentucky, Massachusetts, New York and Oklahoma—had directly ruled on the issue. On the other hand, the overwhelming majority of courts, "including all seven federal circuits to have addressed the issue," have held that a brand-name manufacturer cannot be held liable for injuries caused by a generic equivalent. Moreover, the general tort law jurisprudence of the states in question supported adherence to the majority position and hence dismissal of plaintiffs' claims.

Regarding plaintiffs' request at least to certify the question to the highest courts of the states that have a certification procedure (all but New York), the court found certification unnecessary under Georgia law because an intermediate appellate court had directly decided the issue, or under the laws of Indiana, Kentucky and Oklahoma because the Sixth and Tenth Circuits had decided the issue under those states' laws without requesting certification. While there was "some superficial appeal" to certifying the question to the Massachusetts Supreme Judicial Court ("SJC"),

two Massachusetts trial courts had recently followed the "overwhelming and well-reasoned majority view" and hence the MDL court concluded it could make an informed and intelligent prediction that the SJC would do likewise.

The court expressed awareness that its ruling would leave consumers injured by generic drugs without a remedy, because the United States Supreme Court had held claims against generic manufacturers preempted by the federal law requirement that their labeling be identical to that of the brand-name manufacturer. Nonetheless, just because Congress had exempted generic manufacturers from liability, it did not follow that branded manufacturers should bear that liability.

## Massachusetts Federal Court Holds Medical Device Distributor Not Fraudulently Joined As Design Defect and Failure-to-Warn Claims Not Preempted by FDA Regulations That Do Not Prohibit But Merely Require Notification of Design or Labeling Changes, and Distributor May Be Liable On Implied Warranty Claims Even Without Taking Title to Product

In *In re Stryker LFIT V40 Femoral Head Prods. Liab. Litig.*, 2017 U.S. Dist. LEXIS 140808 (D.Mass., Aug. 31, 2017), plaintiffs in three state court actions brought claims against two out-of-state manufacturers and a Massachusetts distributor for breach of the implied warranty of merchantability (the Massachusetts near-equivalent of strict liability) for injuries allegedly caused by a hip replacement device based on design defect and failure-to-warn theories. The manufacturers removed the actions to the United States District Court for the District of Massachusetts, where a related multi-district litigation was pending, asserting diversity jurisdiction and alleging the non-diverse distributor was fraudulently joined. Plaintiffs moved to remand to state court.

In opposing plaintiffs' motion, the manufacturers first argued plaintiffs' claims against the distributor were preempted by 21 C.F.R. §§ 807.81 and 807.20(a)-(c), United States Food and Drug Administration ("FDA") regulations which the manufacturers asserted prohibited a medical device distributor from altering the design or warnings of FDA-regulated devices. The court found, however, that the plain language of the regulations required a distributor to register and submit a premarket notification before repackaging or relabeling a device, but did not prohibit those actions. Accordingly, a distributor's position differs from that of a generic pharmaceutical manufacturer, whose labeling federal law unequivocally requires be identical to that of the corresponding FDA-approved brand-name drug, and plaintiffs' claims against the distributor were not preempted.

The manufacturers next argued the distributor could not be liable for breach of warranty, as it never actually took title to the hip implants but merely acted as a "conduit" in their sale. The court noted that Massachusetts Supreme Judicial Court ("SJC") precedent cited by the manufacturers merely addressed whether a product sale had occurred, and not whether it was necessary for a warranty claim that defendant have held title. Moreover, Mass. Gen. L. ch. 106, § 2-318 eliminates any requirement of privity in breach of warranty actions against a "manufacturer, seller, lessor or supplier of goods," suggesting possession of title was not required. And other SJC rulings had specifically held distributors may be liable for implied warranty product liability claims. As there was a reasonable legal basis for plaintiffs' claims against the distributor, the court granted plaintiffs' motion to remand.

## Massachusetts Federal Court Holds Commercial Breach of Implied Warranty Claims For Purely Economic Loss Require Contractual Privity

In *Organic Mulch & Landscape Supply of New Eng., LLC v. Probec, Inc.*, 2017 U.S. Dist. LEXIS 113716 (D. Mass. July 21, 2017), a corporation asserted a claim for breach of the implied warranties of merchantability and fitness for a particular purpose against the manufacturer of allegedly defective industrial ice-bagging equipment sold to plaintiff by a distributor, whom plaintiff also sued after the distributor

refused to remove the equipment, refund the purchase price and pay consequential damages. The manufacturer moved for judgment on the pleadings based on lack of contractual privity with plaintiff.

Plaintiff argued the motion should be denied because the Massachusetts legislature unambiguously abolished the privity requirement through the enactment of Mass. Gen. Laws ch. 106, § 2-318, which provides that "[l]ack of privity between plaintiff and defendant shall be no defense in any action brought against the manufacturer" of goods for breach of warranty. In the alternative, plaintiff asked the court to certify the question of whether privity was required to the Massachusetts Supreme Judicial Court ("SJC").

The court denied the request for certification and granted the manufacturer's motion. The court first pointed to a line of SJC cases recognizing certain distinctions under section 2-318 between contract-based and tort-based warranty claims, and quoted SJC dicta that "contract-based warranty claims involving commercial transactions may generally call for different treatment than tort-based warranty claims." Then, citing opinions by four different federal district court judges, the court asserted that based on the SJC authority "courts have since uniformly held that a contract-based breach of warranty claim arising in a commercial context requires a showing of privity of contract." In light of this uniformity, there was no need to certify the question.

## First Circuit Rejects Fraud And Unfair And Deceptive Practices Claims Based On Allegedly Inflated "Compare At" Price Tag For Lack of Actual Injury Where No Allegation Product Was Not Worth Price Paid; Unjust Enrichment Claim Fails Due To Existence Of Sales Contract

In *Shaulis v. Nordstrom, Inc.*, 865 F.3d 1 (1st Cir. 2017), plaintiff filed a putative class action in Massachusetts Superior Court against a clothing retailer alleging fraud, breach of contract, unjust enrichment and violations of the Code of Massachusetts Regulations ("CMR"), Federal Trade Commission Act ("FTCA") and Mass. Gen. Laws ch. 93A, the Massachusetts unfair and deceptive practices statute. Plaintiff purchased a sweater from the retailer with a "Compare At" price on its tag that purported to identify a 77% savings, but plaintiff asserted the tag was deceptive as the retailer never sold the sweater at that price and absent the tag she would not have purchased the sweater.

Defendant removed the action to the United States District Court for the District of Massachusetts and moved to dismiss, arguing plaintiff failed to allege a legally cognizable injury under any theory. The district court agreed. Plaintiff did not allege the sweater was worth less than she paid, and her disappointment concerning the bargain she was receiving did not suffice. Further, although the "Compare At" tag violated both the CMR and FTCA, neither regime provided a private right of action.

On plaintiff's appeal as to her Chapter 93A and common law claims, the United States Court of Appeals for the First Circuit affirmed. The court first noted that the Massachusetts Supreme Judicial Court's ("SJC") recent decisions under Chapter 93A held that a plaintiff cannot rely on a "per se" theory of injury but rather must show "real economic damages." Here, plaintiff failed to allege any damages beyond being induced to make a purchase she would not have made, which impermissibly merged the alleged deception with the injury. Plaintiff also lacked any objective claim she expected to receive a higher quality product than she did. Plaintiff's argument that her travel costs to and from the retailer constituted actual injury also failed, as she had not alleged the price tag induced her travel.

Regarding plaintiff's common law claims, her fraud claim failed for the same reasons as her ch. 93A claim. There was no breach of contract claim as plaintiff agreed to pay the stated price. Nor could she recover for unjust enrichment, as under Massachusetts law that equitable remedy cannot override an otherwise valid contract.

## Massachusetts Federal Court Holds No Duty to Warn of Fall Hazard From Grooves In Concrete Around Gas Pumps As Any Danger Was Open and Obvious; Court Also Questions Admissibility Of Expert Opinion Of Duty Based on Safety Standard For Gaps In Sewer Grates

In *Potvin v. Speedway LLC*, 2017 U.S. Dist. LEXIS 145707 (D. Mass. Sep. 8, 2017), plaintiff filed an action claiming a gas station operator negligently failed to warn about a fall hazard posed by concrete grooves known as positive limiting barriers ("PLBs") encircling gas pumps which are designed to contain spilled gasoline. Plaintiff alleged she fell and injured her hip while pumping gas and that, although she did not see what caused her fall, she believed her shoe's heel wedged itself into one of the PLBs. Operator moved for summary judgment, arguing (1) PLBs do not pose a sufficient hazard to require a warning, (2) even if they did, there was no duty to warn as any danger was open and obvious, and (3) plaintiff failed to establish any breach of duty as her expert's opinion, which was based on an industry safety standard for the spacing of gaps in sewer grates, was scientifically unreliable and hence inadmissible.

As to any duty to warn, the court first noted that the PLBs consisted of five concentric concrete grooves clearly visible to any customer paying attention to his or her whereabouts. Accordingly, any danger posed was so obvious that no warning was necessary. The court rejected plaintiffs' argument that defendant knew PLBs posed a fall hazard as two other customers had purportedly tripped on PLB grooves at two of defendant's other gas stations in the two previous years. Even assuming these falls were comparable, they would be insignificant given the number of people who visit a gas station every day.

Although the court ultimately did not reach the admissibility of plaintiff's expert testimony, the court nevertheless noted its considerable weaknesses. Plaintiff's expert, a civil engineer, lacked experience with PLBs, and Massachusetts had not adopted the standards on which he relied. Moreover, the only commonality between sewer grates and PLBs was that they are both present in places where people walk. The court concluded it would have been hard pressed to find the reliability required by Federal Rule of Evidence 702 to admit this testimony, but granted defendant's summary judgment motion for lack of any legal duty.

## NEW YORK/NEW JERSEY SUPPLEMENT

## New Jersey Appellate Division Holds Trial Court Erroneously Excluded Experts' Causation Opinions Based On Non-Epidemiologic Evidence And Single Small Epidemiologic Study, While Discounting Study Adjustment And Multiple Larger Studies, As Experts' Detailed Methodological Challenges To Latter Rendered Testimony Sufficiently Reliable To Be Admitted

In *In re Accutane Litig.*, 165 A.3d 832 (N.J. Super. Ct. App. Div. 2017), a multi-county litigation ("MCL") in New Jersey Superior Court, thousands of plaintiffs sued multiple manufacturers of a prescription acne drug alleging it caused them to develop Crohn's disease. Plaintiffs' experts relied for their causation opinions upon non-epidemiologic evidence such as animal studies, case reports and side effects reported from the use of analogous drugs, as well as the initial results of a small epidemiologic study that showed a statistically significant increase in the risk of Crohn's disease after use of the drug. The experts challenged the study authors' subsequent adjustment rendering the results no longer statistically significant, and opined that several larger epidemiologic studies relied on by defendants' experts as not finding increased risk were also flawed.

During the first six years of the MCL, when no relevant epidemiologic studies existed, the previous MCL judge had allowed plaintiffs' experts to opine about causation based on the non-epidemiologic evidence. Once such studies became available, however, defendants argued the experts could no longer rely on the non-epidemiologic evidence, and moved to preclude their causation opinions. The current presiding judge allowed the motion, and subsequently dismissed 2,076 actions premised on those opinions. The judge ruled the experts "cherry-pick[ed]" the evidence by ignoring the multiple larger epidemiologic studies in favor of less reliable evidence, and their reasoning and methodology were "slanted . . . in the direction of advocacy," "conclusion-driven" and scientifically inferior to that of defendants' experts.

On plaintiffs' appeal, the Appellate Division of the Superior Court reversed, concluding that regardless of whether "the trial judge found [plaintiffs'] experts[']  opinions persuasive in substance, the experts relied on methodologies and data of

the type reasonably relied upon by comparable experts." The court acknowledged the evolution of the relevant science over the course of the MCL, and stated it was "a close question concerning the survival of plaintiffs' cause of action in the face of [the] new scientific information." Nonetheless, "legal decision making in toxic tort and similar cases may vary from scientific decision making."

On the existing record, the multiple negative epidemiologic studies were "not a conclusive bar to plaintiffs' case." While epidemiologic studies are "high on the tier of evidence bearing on the question of causation," they, like any other form of scientific evidence, are subject to challenges to their methodology. Here, plaintiffs' experts had not simply ignored the key epidemiologic studies, as the trial court had suggested, but rather had challenged their methodology "in extensive and detailed testimony." The judge's gatekeeping function in assessing the admissibility of expert evidence is to "weed out 'junk science,'" but not to "shield jurors from hearing expert testimony that is statistically-based but unpersuasive to the trial judge." As the trial judge had impermissibility weighed the credibility of the experts' testimony, a role reserved to the jury, his exclusion of the testimony was an abuse of discretion.


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