FOLEY HOAG LLP

Product Liability **Update**

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Foley Hoag LLP publishes this quarterly Update concerning developments in product liability and related law of interest to product manufacturers and sellers.

Massachusetts Federal Court Dismisses Putative Class Action Because Defendant's Unconditional Checks for Named Plaintiff's Maximum Damages, Even Though Uncashed, Mooted Suit

In *Demmler v. ACH Food Companies*, Civil No. 15-13556-LTS (D. Mass June 9, 2016), plaintiff sued a food product manufacturer individually and on behalf of a putative class of Massachusetts purchasers, alleging defendant's labeling of certain sauces as "all natural" in spite of their containing caramel color violated Mass. Gen. L. ch. 93A, the state's unfair and deceptive practices statute. Defendant moved to dismiss, arguing the case was moot because on two occasions before suit defendant had mailed plaintiff a check (notwithstanding that he had returned it uncashed each time) for his maximum potential damages.

The court granted defendant's motion, holding the checks indeed equaled or exceeded plaintiff's maximum potential damages of $75, representing statutory damages of $25 trebled for willful or knowing misconduct, so that there was no longer a live controversy between plaintiff and defendant. The court rejected plaintiff's argument the tendered check was a mere conditional offer of settlement, which the United States Supreme Court in *Campbell-Ewald Co. v. Gomez*, 136 S. Ct. 663, 669 (2016) **(see Foley Hoag Product Liability Update January 2016)**, held was the legal effect of an offer of judgment pursuant to Fed. R. Civ. P. 68 that went unaccepted by plaintiff and hence lapsed, so that a live controversy remained. Here defendant's check provided funds that were unconditionally plaintiff's and thus made him whole without his having to agree to or accept anything.

The court further held that plaintiff's refusal to deposit the check could not prolong the dispute, again because he had the funds unconditionally. Moreover, as plaintiff had requested no injunctive or declarative relief, he could not rely on the existence of other potential remedies that the check did not provide to avoid dismissal. Nor was plaintiff's interest in receiving an award of attorney's fees, standing alone, sufficient to prevent mootness where there was no live controversy on the underlying claim. The court also rejected plaintiff's argument he had a separate interest in diffusing his litigation expenses across the putative class, noting that unlike in prior cases supporting this ground for avoiding mootness, plaintiff had offered no evidence of his purported expenses.

Finally, the court dismissed plaintiff's putative class claims because, under governing precedent, those claims became moot on dismissing plaintiff's individual claims before a class was certified. Although plaintiff argued defendant's check was an improper "pick off" maneuver so that the class claims were "capable of repetition, yet evading review," and thus within the "inherently transitory" exception to mootness, the court held plaintiff offered no evidence defendant had engaged in any pattern of such conduct so as to merit application of the exception.

First Circuit Holds Consumer Protection Claims Based On Dietary Supplement Label Asserting Vitamin E "Supports Heart Health" Not Preempted by Food, Drug and Cosmetics Act Because Conflicting Studies Cited In Complaint Plausibly Demonstrated Unqualified Label Could Be Misleading

In *Kaufman v. CVS Caremark Corp.*, 2016 U.S. App. LEXIS 16350 (1st Cir., September 6, 2016), plaintiff brought claims in the United States District Court for the District of Rhode Island against a retailer for violating the New York Consumer Protection Act ("NYCPA"), the Rhode Island Deceptive Trade Practices Act, and unjust enrichment, alleging defendant sold a Vitamin E dietary supplement with a label stating the product "supports heart health" that was misleading because it was unsubstantiated by valid scientific studies. Defendant moved to dismiss, arguing the claims were preempted by the federal Food Drug & Cosmetics Act ("FDCA") and not supported by the studies plaintiff cited. The district court granted the motion, finding the label complied with the FDCA's requirements so her claims were preempted, and plaintiff's allegations were "insufficient to state a claim for fraud" because the cited studies did not refute the label statements.

Plaintiff's appealed the dismissal of their NYCPA and unjust enrichment claims to the United States Court of Appeals for the First Circuit. The court first noted that, although the district court suggested plaintiff's NYCPA claim of "deception" was subject to Fed. R. Civ. P. 9(b)'s requirement that "fraud" be pled with particularity, the rule does not apply to NYCPA deception claims and in any event the complaint contained the "who, what, where, and when" allegations required by the rule.

Regarding preemption, the FDCA expressly provides in 21 U.S.C. § 343-1(a)(5) that a state may not "establish . . . any requirement respecting any claim of the type described in section 343(r)(1) [concerning a nutrient's relationship "to a disease or health-related condition"] made in the label or labeling of food [which has been interpreted to include dietary supplements used within recommended daily allowance limits] that is not identical to the requirement of section 343(r)." Section 343(r)(6), which specifically governs dietary supplement labels and relates back to § 343(r)(1), adds that a seller may include a label statement regarding "the role of a nutrient or dietary ingredient intended to affect the structure or function in humans"—a "structure/function claim"—only if the seller "has substantiation that such [a] statement is truthful and not misleading." Under the NYCPA, compliance with federal rules and regulations is a complete defense. Accordingly, the "net effect" of these provisions is that neither federal nor state law barred plaintiff's claims if defendant's label violated the FDCA's requirements.

As to whether the complaint pled sufficient facts to plausibly allege an FDCA violation, the court found the "supports heart health" representation was a structure/function claim that required "substantiation" it was truthful and not misleading, which in turn under United States Food and Drug Administration guidance required "competent and reliable scientific evidence." Here, the studies cited in the complaint, unaided at the pleading stage by expert testimony or additional context, did not "render her claim implausible." At least one study indicated Vitamin E in the dose defendant sold could actually damage the heart, so that even if the supplement in some circumstances could also support heart health, a label containing only the latter claim could be found to be misleading.

Lastly, as plaintiff's unjust enrichment claim rested on her allegation that the label was "deceptive," so long as the claim was based solely on conduct that violated the FDCA it was not preempted for the same reasons plaintiff's NYCPA claims were not. The court therefore reversed the dismissal of both of plaintiff's claims.

Massachusetts Appeals Court Vacates Jury Verdict For Pelvic Mesh Manufacturer, Holding Trial Court Improperly Excluded Supplier's Material Safety Data Sheet Caution Against Permanently Implanting Polypropylene Material And FDA Letters Requesting Post-Marketing Surveillance To Address Safety Concerns

In *Albright v. Boston Scientific Corporation*, 90 Mass. App. Ct. 213 (2016), plaintiff brought claims in Massachusetts Superior Court for breach of the implied warranty of merchantability (the Massachusetts near-equivalent of strict liability) and negligence against a surgical mesh manufacturer for injuries suffered after having defendant's device implanted to treat her pelvic organ

prolapse. At trial, plaintiff advanced design defect and failure-to-warn theories, but the jury returned a defense verdict, expressly finding plaintiff had not shown the device was defective.

On appeal to the Massachusetts Appeals Court, plaintiff argued the trial court improperly excluded two pieces of evidence: (1) a medical application caution contained in the material safety data sheet ("MSDS") provided by defendant's polypropylene material supplier; and (2) letters between the United States Food and Drug Administration ("FDA") and defendant concerning FDA's request that defendant conduct post-market surveillance on the device to address safety and efficacy concerns.

Regarding the MSDS caution, the court noted that under Ohio law, which governed because that was the location of plaintiff's injury, defendant's duties were based on the product's known or reasonably foreseeable risks. Under this standard, excluding the MSDS instruction stating "do not use this [polypropylene] material in medical applications involving permanent implantation in the human body" was erroneous. As plaintiff had offered the statement only to show defendant had notice of it, rather than for its truth, the statement was not hearsay, and the statement was relevant to defendant's knowledge of the foreseeable risks.

Regarding the FDA correspondence issue, the agency had asked defendant to conduct post-marketing surveillance and defendant had replied this was unnecessary because it was discontinuing the device's sale in the United States. At trial, plaintiff offered the letters to rebut testimony of several witnesses who opined, without qualification, that the mesh was safe. The court held plaintiff should have been permitted to cross-examine these witnesses with the FDA letters, and noted the resulting prejudice was compounded by the trial court's having repeatedly allowed defendant to refer to the device as being cleared for sale by FDA as "substantially equivalent" to other marketed devices, which suggested the mesh was "cleared as a safe device." Because the evidentiary rulings left the jury with an incomplete picture of the events at issue, and hence substantially affected plaintiff's rights, the court vacated the jury's verdict and remanded for a new trial.

First Circuit Remands Putative Class Action to State Court Because Defendants' Showing Of Reasonable Probability Amount in Controversy Exceeded $5 Million, As Required For Jurisdiction Under Class Action Fairness Act, Was Based On Speculation About Putative Class Members' Expenses

In *Pazol v. Tough Mudder, Inc.*, 2016 U.S. App. LEXIS 7519 (1st Cir. Apr. 26, 2016), plaintiffs registered for an obstacle course event organized by defendants. Although originally scheduled to take place in Haverhill, Massachusetts, it was relocated twelve miles away to Amesbury two weeks before the event date and a week later relocated again, this time 79 miles from Haverhill to Westbrook, Maine. Plaintiffs, each of whom was unable to attend the relocated event but denied a refund by defendants, filed claims for breach of contract, breach of the covenant of good faith and fair dealing, unjust enrichment and violation of Mass. Gen. Laws ch. 93A (the state's unfair and deceptive practices statute) in Massachusetts Superior Court. Pursuant to Mass. R. Civ. P. 23, plaintiffs sought certification of a class on behalf of: (1) all registrants who did not participate at the changed location; (2) all participants who traveled additional distance to the relocated event and thereby incurred additional expenses; "and/or" (3) "such other class, classes, or sub-classes as certified by the Court."

Defendants removed the action to the United States District Court for the District of Massachusetts under the Class Action Fairness Act of 2005 ("CAFA"), which provides for federal subject matter jurisdiction over class actions alleging state-law claims where there is at least some diversity of citizenship between plaintiffs and defendants, and the amount in controversy exceeds $5,000,000. Defendants further moved to dismiss and compel mediation and arbitration pursuant to the event's Participation Agreement. When plaintiffs moved to remand, arguing defendants had failed to demonstrate jurisdiction, the district court denied the motion, holding defendants demonstrated a "reasonable probability that the amount in controversy . . . exceed[ed] $5 million," and also granted defendants' motion to dismiss and compel mediation and arbitration.

On plaintiff's appeal to the United States Court of Appeals for the First Circuit, the court ordered remand, finding defendants had not shown a reasonable probability that the amount in controversy exceeded the jurisdictional amount.

Defendants' amount-in-controversy estimate was based on (1) the registration fees at issue for *all* registrants, whether or not they attended the relocated event, because plaintiffs' complaint sought "damages in amounts to be determined at trial," and (2) an estimate of the gas, food and lodging expenses incurred by all attendees because of the relocation. The appellate court, however, rejected both components as speculative and therefore unreasonable. Plaintiffs' complaint only sought registration fees for "persons . . . who did not participate," and inclusion of a general prayer for relief did not put fees incurred by persons who did attend at issue. As for the additional expense component, defendants provided no factual support whatsoever for their assumptions about how far attendees needed to travel or their estimated food costs despite defendants' possession of historical data about prior attendees that might have been used to calculate such estimates.

Massachusetts Federal Court Denies Dismissal of Claims Under Limitations Statute Because Unclear When Plaintiff Had Sufficient Notice of Injury And Its Possible Cause, And Prior Class Action Allowed Tolling; Dismisses Post-Sale Failure-to-Warn Claim Because No Facts Pled To Show Defendants Could Have Identified And Effectively Warned Plaintiffs

In *Town of Princeton v. Monsanto*, 2016 U.S. Dist. LEXIS 105618 (D. Mass., August 10, 2016), a municipality sued manufacturers of polychlorinated biphenyls ("PCBs") in the United States District Court for the District of Massachusetts for breach of express warranties, the implied warranty of merchantability (the Massachusetts near-equivalent of strict liability), negligence and violation of Mass. Gen. L. ch. 93A (the Massachusetts unfair or deceptive trade practices statute). Plaintiff alleged defective design and failure to warn in connection with defendants' PCBs, an odorless and colorless alleged human carcinogen plaintiff had discovered in caulking at an elementary school. Defendants moved to dismiss all of plaintiff's claims under the applicable Massachusetts statutes of limitations—three years for the warranty and negligence claims and four years under ch. 93A.

Plaintiff filed suit on July 1, 2015. The court observed that tort claims typically accrue, and the statute of limitations begins to run, when a plaintiff is injured. The parties agreed, however, that PCB contamination was an "inherently unknowable danger" when the school was built in 1962, thus the "discovery rule" applied here. Under that rule, a plaintiff's claims accrue when she has (1) actual knowledge of both her injury and its likely cause, or (2) sufficient facts from which she reasonably should have discovered the causal relationship between her injury and a defendant's conduct. Once a plaintiff has sufficient notice of a potential injury, she has a "duty to inquire" into it and its possible cause.

Defendants argued plaintiff's claims accrued on September 25, 2009, when the United States Environmental Protection Agency ("EPA") issued a press release detailing steps schools should take to reduce exposure to PCBs from caulk in buildings constructed between 1950 and 1978, while plaintiff argued it had no notice of injury until April 2011, when it first received test results reporting PCBs at the school. The court concluded that a single, broadly addressed press release, on its own, would be insufficient to trigger plaintiff's duty to investigate. As the pleadings contained no evidence about how the press release was disseminated, the detectability of PCBs or whether they had received any other publicity at the time, the court could not conclude without a fuller record, such as on summary judgment, that the warranty and negligence claims were barred as a matter of law.

The court next considered whether the statute of limitations was tolled during an earlier putative class action against defendants that asserted plaintiff's claims until class certification was denied. That action, *Town of Lexington v. Pharmacia* **(see Foley Hoag Product Liability Update October 2015)**, was brought on September 4, 2012 on behalf of a putative class of all Massachusetts school districts owning buildings with airborne PCBs exceeding EPA's limit, and class certification was denied on March 25, 2015. Defendants conceded plaintiff's warranty and 93A claims were identical to those asserted in *Lexington* and thus there was tolling as to them, but argued against tolling for negligence claims as *Lexington* included no such claim. The court, however, held that tolling was available if plaintiff's claims were sufficiently similar to those asserted by the failed class so that defendants were effectively on notice of them, which was the case here as plaintiff's negligence claim involved essentially the same evidence of defendants' actual or imputed knowledge of PCBs' dangers, and failure to warn of them, as the *Lexington* warranty claim.

Lastly, the court separately addressed plaintiff's ch. 93A claim, which alleged defendants' failure to warn was an unfair and deceptive trade practice. The court observed that unless

defendants had a continuing *post-sale* duty to warn, their alleged wrongful conduct occurred before ch. 93A's November 13, 1969 effective date and thus would not be actionable. Moreover, the essential elements of a post-sale warning claim included, among other things, that defendants could both have identified, and effectively communicated a warning to, direct purchasers. Here, plaintiff failed to allege any facts supporting either element, and indeed it was not even clear from the pleadings whether defendants sold the PCBs to plaintiff directly or to an intermediary. Nor could plaintiff's assertion it would present evidence defendants gave post-sale warnings to some customers in 1970, but omitted the dangers of PCBs, cure its insufficient pleading. The court thus granted defendants' motion to dismiss the 93A claims, but did so without prejudice because amending the complaint would not necessarily be futile.

Massachusetts Federal Court Refuses to Exclude Engineer's Testimony Salt Spreader Was Defectively Designed Due To Unguarded Hopper Because Expert Had Safeguarding Expertise And Examined Spreader And Documents Produced, And Was Not Required to Assess Design in Context of Overall Spreader Industry

In *Linhares v. Buyers Prods. Co.*, Civ. Action No. 15-11881-LTS, 2016 U.S. Dist. LEXIS 119128 (D. Mass 2016), plaintiff sued the manufacturer of a truck-installed salt spreader in the United States District Court for the District of Massachusetts for defective design and failure to warn after his foot became stuck in the device's hopper, causing him to fall and injure himself. Following the close of fact discovery and pursuant to a scheduling order, the parties filed expert reports with the court. Plaintiff's expert engineer opined that the unit's design was dangerous and a prudent manufacturer would have added a lid to enclose the hopper's open top, and defendant moved to exclude the expert's testimony.

Defendant first argued the expert was not qualified to offer an opinion about the salt spreader, and cited cases in which the courts had excluded engineers' product design testimony relating to products such as a skid-steer loader or crane as beyond the experts' expertise. The court, however, found plaintiff's expert qualified here, because, although he had no experience with salt spreaders in particular, his general expertise in "safeguarding devices to prevent operator injury" and "machinery safeguarding and fall protection" could be properly applied to the hopper opening, which— rather than the more complicated mechanics of the hopper itself—was the subject of the suit.

Second, defendant argued the expert's opinions were not based on sufficient facts or data because he relied on a "'data set' of [plaintiff's] single tripping incident," and had not significantly investigated other incidents or the design of other salt spreaders. The court also rejected this argument, holding the expert's "inspection of the salt spreader at issue, the owner's manual, assembly drawings, and various discovery materials" was sufficient basis for his opinion, and there did not need to be numerous accidents for an expert to opine about a design defect.

Finally, defendant argued the expert did not reliably apply his methodology to the facts of the case, as required by Federal Rule of Evidence 702(d), because he did not examine the spreader opening in the context of the "larger material aggregate spreader industry." Again the device's simplicity persuaded the court, which found the expert could not possibly have failed to understand the device or consistently apply his expertise to it, and that no assessment of the broader industry was required. The court therefore denied defendant's motion to exclude in full.

Massachusetts Federal Court Holds Foreign Defendant Subject to Personal Jurisdiction Because It Installed, Maintained and Provided Training in Massachusetts for 3D Printer That Caused Plaintiff's Injury

In *Ferguson v. Concept Laser, GmbH*, No. 14-cv-12835-ADB, 2016 U.S. Dist. LEXIS 54833 (D. Mass. April 25, 2016), plaintiff was severely burned in Massachusetts when his employer's 3D printer exploded. Plaintiff sued the printer's manufacturers and distributors together with the company and individual that provided installation, maintenance and training for the printer,

all in Massachusetts, in the United States District Court for the District of Massachusetts asserting numerous claims, including breach of warranty (the Massachusetts near-equivalent of strict liability) and negligence based on design defect and failure to warn. The Italian installer defendant, headquartered in Modena, Italy, moved to dismiss for lack of personal jurisdiction alleging it had no meaningful connection to Massachusetts and never engaged in substantial, continuous and systematic activity there.

The court first analyzed whether defendant's conduct fell within the Massachusetts long-arm statute, Mass. Gen. L. ch. 223A, § 3, which among other provisions permits jurisdiction where (1) plaintiff's claims arise from defendant's transaction of business in Massachusetts, or (2) defendant caused tortious injury by acts or omissions there. Accepting plaintiff's allegations as true, the court found that because defendant installed, maintained and trained plaintiff to use the printer in Massachusetts, plaintiff's claim "arose" from defendant's transaction of business and negligent acts in Massachusetts.

The court next considered the three-part test for determining whether exercise of specific jurisdiction over a foreign defendant was proper under the Due Process Clause: (1) the litigation must result from alleged injuries with a "demonstrable nexus" to defendant's forum-based activities ("relatedness"); (2) defendant must have deliberately targeted its behavior toward the forum, thus invoking the benefits and protections of its laws ("purposeful availment"); and (3) it must be reasonable to require defendant to defend a suit there. The court found all elements satisfied here. By installing and maintaining the machine and training plaintiff, defendant "voluntarily and purposefully generated contacts with Massachusetts" from which plaintiff's claim arose. Nor did defendant demonstrate why exercising specific jurisdiction would be unreasonable or unfair, and any burden on defendant in adjudicating the dispute in Massachusetts was outweighed by plaintiff's and the state's interests because the events and injury had occurred there. The court therefore denied defendant's motion to dismiss.

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