FOLEY HOAG LLP

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

First Circuit Holds Plaintiff Adequately Alleges Deceptive Practices Claim For No-Hazelnut Coffee Labeled "Hazelnut Créme" Despite Ingredient List Excluding Hazelnuts And Mentioning Artificial Flavors, Allegation Of Deception On Purchase Sufficiently Particular As Exact Date And Location Not Needed For Defendant To Respond, And Claim Not Preempted by Food, Drug & Cosmetic Act As Plaintiff Alleged FDCA Violation That Independently Violated State Law

In *Dumont v. Reily Foods Co.*, 2019 U.S. App. LEXIS 23710 (1st Cir. 2019), plaintiff bought a coffee called "Hazelnut Créme" that contained no hazelnuts and sued the manufacturer in the United States District Court for the District of Massachusetts, alleging the label violated Mass. Gen. L. ch. 93A, the state unfair and deceptive practices statute. The district court granted defendant's motion to dismiss, holding the complaint contained insufficient detail regarding the circumstances of plaintiff's purchase and hence violated Fed. R. Civ. P. 9(b)'s requirement that fraud be pled with particularity.

On plaintiff's appeal, the United States Court of Appeals for the First Circuit first noted that plaintiff had assumed Rule 9(b) applied to her 93A claim, so the court would as well. Although the rule requires identifying the "who, what, where, and when" of any alleged misrepresentation, plaintiff had done so: the "who" was defendant, the "what" was "Hazelnut Créme," the "where" was the label and the "when" was at plaintiff's purchase, the date and exact location of which were irrelevant as they were unnecessary for defendant to respond.

The court next rejected defendant's argument that plaintiff failed to state a claim because no reasonable consumer would believe the coffee actually contained hazelnuts, as they were not in the ingredient list, hazelnut créme is not made from hazelnuts and the label said "100% Arabica Coffee." Given that at the pleading stage the court needed to indulge all reasonable inferences in favor of plaintiff, a reasonable consumer might "find the product name sufficient assurance so as to see no need to search the fine print on the back" (particularly since nut-flavored coffees typically note the flavor on the package), and might believe "hazelnut créme" is hazelnut cream and hence akin to hazelnut butter, which *is* made from hazelnuts. Further, "100% Arabica Coffee" is ambiguous, and could simply mean that all the coffee in the package is Arabica. Accordingly, it might be preferable for a jury to determine whether the label was misleading.

Finally, the court rejected defendant's argument that plaintiff's claim was impliedly preempted, as the Federal Food, Drug and Cosmetic Act ("FDCA") in 21 U.S.C. § 343-1 expressly preempts at least certain state food labeling requirements that are "not identical to" specified FDCA requirements, and the United States Supreme Court has held in the medical device context in *Buckman Company v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), that state law requirements are impliedly preempted if they would interfere with the United States Food and Drug Administration's discretion in enforcing the statute. As neither the Supreme Court nor First Circuit has addressed the complexities of food-labeling preemption, the court elected to follow the parties in assuming that to avoid both express and implied preemption plaintiff needed to allege conduct that both violates express FDCA requirements and would also violate ch. 93A even if the FDCA did not exist. Here, defendant conceded it violated 21 C.F.R. § 101.22(i), which among other things requires the manufacturer to include the words "artificial flavor" next to the relevant flavor, and the court had already found plaintiff's allegations sufficiently alleged a 93A violation.

Massachusetts Federal Court Holds Class Certification Of Deceptiveness Issues In Cosmetic Device Marketing Action Not Superior Method For Resolving Controversy As Individual Causation Issues Would Remain, And Varying Representations Made Plaintiffs' Claims Neither Common Nor Typical; Summary Judgment Granted As Plaintiffs' Nationwide Claims Did Not Occur Primarily In Massachusetts, Contracts Disclaimed Merchantability And Unjust Enrichment Cannot Override Express Contract

In *Plastic Surgery Assocs., S.C. v. Cynosure, Inc.*, 2019 U.S. Dist. LEXIS 132152 (D. Mass. Aug. 7, 2019), several plastic surgeons and medical spas brought a putative national class action in the United States District Court for the District of Massachusetts against the Massachusetts manufacturer of a laser device designed to eliminate fat tissue. Plaintiffs alleged defendant's sales personnel variously misrepresented that the device was "one-time," i.e., required only one treatment, "hands-free" and "painless," causing them to purchase the device and suffer reputational harm, and brought claims for violation of Mass. Gen. L. ch. 93A (the state unfair and deceptive practices statute), breach of the implied warranty of merchantability and unjust enrichment. Plaintiffs moved for class certification on four issues included in their ch. 93A claim, namely whether defendant was engaged in a "trade or business" as required by the statute and whether each of the representations at issue was deceptive, and defendant moved for summary judgment on all claims.

Regarding class certification, the court agreed with defendant that the proposed class would not "fairly and efficiently advance the resolution of class members' claims" as required by Fed. R. Civ. P. 23(b)(3), because even if a factfinder resolved all four issues in plaintiffs' favor they would still have to show both factual and proximate cause, which would require individualized proof, and plaintiffs themselves had previously estimated that approximately 300-400 individual trials would be needed. Nor had plaintiffs shown they satisfied Fed. R. Civ. P. 23(a)'s basic class certification prerequisites: the proposed class members' claims were not sufficiently common, as they depended on the specific representations made by the relevant sales representative, nor sufficiently typical, as the circumstances leading each class member to purchase the device varied. For these same reasons, plaintiffs had also not shown they could adequately protect the interests of the class.

Regarding summary judgment, the court first granted it against plaintiff's ch. 93A claims, agreeing defendant had established under § 11 of the statute (applicable to business plaintiffs) that the alleged violations had not occurred "primarily and substantially" within Massachusetts, as the cosmetic devices had been marketed and sold nationwide. Although the device purchase agreements provided they were to be "governed by and construed under" Massachusetts law, this provision did not cover tort claims such as under ch. 93A, nor had plaintiffs shown that any allegedly deceptive marketing materials or emails developed in Massachusetts actually reached them.

The court also granted summary judgment against plaintiffs' implied warranty claims, as the purchase agreements were validly formed and contained a conspicuous disclaimer of merchantability. Lastly, as "Massachusetts law does not allow litigants to override an express contract by arguing unjust enrichment," the court entered summary judgment against this claim as well.

First Circuit Holds Plaintiff In Contract-Based Warranty Of Merchantability Claim Need Not Prove Specific Failure At Issue Foreseeable By Reasonable Testing, Only That Product Not Fit For Reasonably Foreseeable Uses, Notification Of Intent To Change Design At Unspecified Time Not Sufficiently Explicit To Preclude Reasonable Reliance On Later Failure to Change Part Number As Representation Of Unchanged Design And Defendants' Pervasive Control Of Subsidiaries Sufficient To Establish Subsidiaries Were Their Agents

In *AcBel Polytech, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 2019 WL 2536843 (1st Cir. June 20, 2019), a Taiwanese power supply unit ("PSU") manufacturer sued in the United States District Court for the District of Massachusetts the California-based parents of Asian companies that designed, manufactured and sold through an independent Asian distributor voltage regulators ("VRs") that plaintiff incorporated in its PSUs. Plaintiff sold the PSUs to a Massachusetts data storage device manufacturer that incorporated them in its devices sold to customers worldwide. Plaintiff alleged that for a discrete period defendants' subsidiaries changed the VRs to a "shrunk die" design, then reverted to the original design, all without changing their part number as required by industry practice or otherwise notifying plaintiff, and that the "shrunk die" VRs failed at a high rate causing plaintiff and its customer to incur extensive costs replacing defective units in end users' possession. Plaintiff asserted claims for, among other things, breach of the implied warranties of merchantability and fitness for a particular purpose, and intentional and negligent misrepresentations and omissions.

On defendants' summary judgment motion, the district court dismissed all tort claims, ruling as a matter of law on the misrepresentation claims that plaintiff could not reasonably rely on the absence of a changed part number as a representation the VRs' design remained unchanged because plaintiff had previously received notice defendants' subsidiaries intended to change the design. The court also ruled that to prevail on the implied warranty claims, the only claims that remained, plaintiff needed to prove contractual privity with defendants, *i.e.*, that their Asian subsidiaries and independent distributor were all defendants' agents in selling the VRs.

After an ensuing bench trial, the district court found that the shrunk-die VRs did not breach the implied warranty of merchantability because, among other things, they had passed all testing required by established industry standards, their failure could only be replicated when they were subjected sequentially to two non-standard tests that imposed extremely harsh conditions and VRs in plaintiff's PSUs failed at a rate approximately 625 times the failure rate for other users. The court also dismissed plaintiff's warranty of fitness claim, finding no evidence defendants knew of any particular, i.e., non-ordinary, purpose for the VRs.

Plaintiff appealed the district court's rejection of the merchantability and misrepresentation claims, while defendants cross-appealed, among other things, the finding that their Asian subsidiaries were their agents. The United States Court of Appeals for the First Circuit first affirmed the agency finding, holding the district court's unchallenged findings that defendants exercised pervasive control over the subsidiaries supported a conclusion they were authorized to act on defendants' behalf, subject to their control.

On the implied warranty claim, the court cited multiple mentions by the district court that the VRs' potential to fail under extreme conditions was not detectable or foreseeable under reasonable—*i.e.*, industry standard—testing, as well as the court's citation of certain case law applicable to tort-based claims for breach of the implied warranty of merchantability, the Massachusetts near-equivalent of strict liability. The circuit held the lower court had improperly conflated the standards for tort and contract-based merchantability breaches, and the latter law was applicable here as the only harm was to the product itself. While under tort law plaintiff must show the specific risk at issue was reasonably foreseeable, under contract law it need only show the product's manner of use was reasonably foreseeable, which could be found here, and that the product was not fit for its ordinary uses. The court therefore remanded for a new trial on the issues of merchantability as well as causation, which the district court had not reached because it found there was no breach, under the proper legal standard.

On misrepresentation, the circuit held the district court erred in ruling against reasonable reliance, as the subsidiaries' notice of a design change did not specify a time for the change, it actually occurred over a year and a half later and any purported conflict between the notice and later

unchanged part number was not so "explicit" as to render reliance unreasonable as a matter of law. Accordingly, the court also remanded the misrepresentation claims for trial.

Members of **Foley Hoag's Product Liability and Complex Tort Practice Group** earlier represented the VRs' independent distributor and obtained its dismissal prior to discovery.

Massachusetts Federal Court Compels Production of Communications Between Plaintiffs and Consulting Expert Who Authored Key Study On Which Plaintiffs' Testifying Experts Relied, Holding Some Communications Outside Consulting Period, And Discovery Needed Based On Expert's Concealment Plaintiffs Funded Study And Litigation Misconduct In Hiring Consulting Expert To Publish Study And Other Experts To Testify Based On It

In *In re Zofran (Ondansetron) Prods. Liab. Litig.*, 392F. Supp. 3d 179 (D. Mass. 2019), a multi-district litigation ("MDL") in the United States District Court for the District of Massachusetts, plaintiffs alleged that defendant's prescription anti-nausea drug caused birth defects. Defendant served interrogatories and requests for production on plaintiffs seeking, in part, communications between their attorneys and a third-party epidemiologist or the consulting company she founded and led; the epidemiologist had co-authored a recent study finding a statistically significant association between the drug and birth defects on which plaintiffs' causation experts relied. In response, plaintiffs' objected the communications were protected under Fed. R. Civ. P. 26(b)(3) as "documents and tangible things . . . prepared in anticipation of litigation or for trial," and under Rule 26(b)(4)(D) as "facts or opinions held by an expert who . . . is not expected to be called as a witness at trial."

Defendant then issued a subpoena for the epidemiologist's deposition, plaintiffs moved for a protective order and the court ruled a deposition could be taken regarding any financial relationship and communications between the epidemiologist and plaintiffs' counsel. After defendant subpoenaed such documents, the epidemiologist herself moved for a protective order, supported by her affidavit that she had "not been retained as an expert witness by any party," had "no direct factual information about the litigation," and monies paid by plaintiffs' counsel were not "to directly fund the study" but were instead "paid to [her] company for unrelated work." The court denied the motion, and the epidemiologist's counsel withdrew from her representation the same day, notifying the court that her affidavit contained inaccurate factual representations.

The epidemiologist served a supplemental affidavit clarifying that there were two separate periods in the previous five years during which plaintiffs' counsel had retained her as a "consulting expert," and her deposition revealed that she, through her company, had received over $200,000 from plaintiffs' counsel to fund the study at issue. Defendant further informed the court that the epidemiologist had given a presentation about the litigation with plaintiffs' counsel at a Las Vegas conference, and moved to compel plaintiffs to fully respond to interrogatories and requests for production relating to the epidemiologist and to compel her to produce responsive documents. Plaintiffs once again moved for a protective order based on Rules 26(b)(3) and 26(b)(4)(D).

The court conducted an *in camera* review of records concerning both the Las Vegas conference and facts known or opinions held by the epidemiologist as a consulting expert. The court ordered production of the conference-related documents, holding they were not "trial preparation materials" as they had been made quasi-public and involved communications made while the epidemiologist was no longer a consulting expert.

As for records concerning the epidemiologist's known facts or opinions, the court first noted that Rule 26(b)(4)(D) protects "facts known or opinions held by" a consulting expert and thus does not appear to apply to document requests, and that many of the records involved communications when the epidemiologist was not consulting. The court ultimately held, however, that the materials sought were covered by exceptions under the rules, as defendant had established both a "substantial need" for the records under Rule 26(b)(3)(A)(ii) and "exceptional circumstances" under Rule 26(b)(4)(D)(ii). Moreover, plaintiff's litigation misconduct waived any protections, as they had attempted to circumvent discovery by paying a consulting expert to publish a study and then separate testifying experts to rely on it. The need "to discover the truth and correct the record" regarding the epidemiologist's initial false affidavit thus outweighed any countervailing policy in favor of confidentiality.

Massachusetts Federal Court Precludes Opinion Of Allergist and Immunologist Regarding Pharmacist's Standard Of Care For Dispensing Antibiotic And Causation of Stevens-Johnson Syndrome Where Expert Admitted He Had No Knowledge Of Standard Of Care, His Only Knowledge Of Syndrome Came From One Seminar And His Opinion Plaintiff Had Syndrome Was Based Solely on Inadmissible Affidavit Of Precluded Expert

In *Carrozza v. CVS Pharm., Inc.*, 391 F. Supp. 3d 136 (2019), plaintiff took a prescription antibiotic, one of the quinolone class of antibiotics, and developed the serious dermatologic condition known as Steven-Johnson Syndrome ("SJS"). He sued the dispensing pharmacy in the United States District Court for the District of Massachusetts, alleging the pharmacy's computer system contained a "hardstop" warning that plaintiff was allergic to quinolones and asserting claims for negligence, breach of the implied warranty of merchantability (the Massachusetts near-equivalent of strict liability) and violation of Mass. Gen. L. ch. 93A (the state unfair and deceptive business practices statute). The pharmacy, which argued its pharmacist filled the prescription based on notes stating plaintiff filled three prior quinolone prescriptions without adverse effects, ultimately moved to preclude plaintiff's expert testimony and for summary judgment.

Plaintiff's sole expert, an allergist and immunologist, opined that filling plaintiff's prescription notwithstanding the hardstop warning was a breach of the pharmacy's duty of care, and the drug was the likely cause of plaintiff's SJS. In an affidavit, the expert explained that SJS can occur rapidly, as it had in plaintiff, in patients who ingest quinolones after they have previously experienced reactions to the antibiotic. At deposition, however, the expert admitted he did not know the standard of care applicable to a pharmacist under the circumstances. In addition, the doctor "had a limited understanding of the facts of the case and SJS generally," as he had not reviewed any medical records, was unaware of the diagnostic criteria for SJS and derived his entire knowledge of the condition from a single medical seminar. Indeed, his opinion that plaintiff even had SJS was based entirely on the affidavit of another expert whom plaintiff had failed to properly disclose and whose opinion the court had therefore already precluded.

Based on this record, the court granted defendant's motion to preclude the expert's testimony. Here, contrary to the requirements of Fed. R. Evid. 702, the expert was not sufficiently "qualified" to opine on either the standard of care or causation. In response to plaintiff's argument that the expert could rely on the previously precluded expert's affidavit even though it was itself inadmissible, the court noted that under Fed. R. Evid. 703 experts may rely on inadmissible evidence only if it is "of a type reasonably relied upon by experts in the particular field." Because the allergist/immunologist had no relevant expertise or even familiarity with SJS, he could not "simply parrot the conclusions of an expert who does." As plaintiff therefore lacked admissible expert testimony regarding either the standard of care or causation, the court entered summary judgment against all claims.

NEW YORK/NEW JERSEY SUPPLEMENT

New York Supreme Court Holds Asbestos in Some Of Defendant's Talc Products And In Supplying Mines Sufficient To Support Inference Plaintiff's Specific Products Had Asbestos, And Fiber Release Studies Plus Medical Expert's "No-Safe Level" Opinion Sufficient To Support Finding Asbestos Caused Plaintiff's Mesothelioma

In *Moldow v. A.I. Friedman, L.P.*, 2019 NY Slip Op 32060(U) (N.Y. Sup. Ct., N.Y. Cty.), plaintiff brought suit in the New York Supreme Court for New York County alleging that asbestos in defendant's cosmetic talc product caused her mesothelioma. Plaintiff alleged she used the product daily from 1977 to 1983 and periodically from 1983 to 1987, each time using three or four handfuls that created dust. Defendant moved for summary judgment, arguing plaintiff's experts failed to establish causation.

According to the court, defendants seeking summary judgment in asbestos cases must unequivocally establish either that plaintiff was not exposed to asbestos from their products or that any exposure levels were not sufficient to contribute to development of plaintiff's disease. Defendant first argued that its expert geologist found no asbestos in the

over seventy product samples that he tested, so that even though plaintiff's geology and microscopy experts found asbestos contamination in historical samples of defendant's product, she had no evidence the specific containers she used contained asbestos. The court held, however, that this was not dispositive, as plaintiff did not have to show "the precise cause of her damages" but only "facts and conditions from which the defendant's liability may be reasonably inferred." Here, plaintiff's experts' product testing and opinions regarding asbestos contamination in the mines that provided talc for the product were sufficient to raise issues of credibility and fact for trial.

Defendant next argued that, to the extent its talc did contain asbestos, it was not at levels sufficient to cause plaintiff's mesothelioma. Defendant's epidemiologist noted the lack of any study showing an increased risk of mesothelioma from cosmetic talc, and its industrial hygienist gave a "worst case" estimate of plaintiff's lifetime exposure from defendant's product that was below ambient lifetime exposures and thus insufficient to cause disease. But the court found plaintiff's occupational medicine expert's opinions that there is "no safe level" of asbestos exposure, and that based on the sample testing and asbestos releasability simulations conducted by plaintiff's geology and microscopy experts plaintiff's exposure to defendant's talc was sufficient to cause her mesothelioma, also to created a triable issue.

Finally, the court denied summary judgment on plaintiff's punitive damages claim, which required wanton, reckless or malicious acts by defendant. Although defendant argued it had conducted product testing under the proper standards during the period plaintiff used its product, plaintiff's evidence of defendant's testing from the 1970s that found asbestos in its talc, later representation of its talc as uncontaminated and advocacy for the industry's use of screening methods plaintiff alleged were unable to detect asbestos were sufficient to create an issue for the jury.

New York Federal Court Precludes Engineering Expert's Opinion Lawnmower Design Was Defective For Lack Of Shutoff Upon One-Handed Operation As Unsupported By Reliable Methodology Or Others' Adoption Of Such Feature, And Opinion English-Only Warnings Were Defective Where Expert Failed To Account For Employer's Ignoring Defendant's Warnings And Offer Of Spanish Warnings

In *Fuentes v. Scag Power Equpment Division of Metalcraft of Mayville, Inc.,* 2019 LEXIS 136802 (E.D.N.Y. Aug. 13, 2019), a non-English speaking landscaper injured by a lawn mower sued his employer and the mower manufacturer in the United States District Court for the Eastern District of New York. The mower originally had a discharge chute cover, which the employer removed to allow use with an after-market grass catcher, and plaintiff was operating the mower with neither in place when tree roots caused him to take one hand off the mower and lose control; the mower then swung around and plaintiff's foot went into the open chute, resulting in serious injury. While the operator's manual included both English and Spanish warnings against operation with an unguarded chute, the only such warning on the mower itself was in English, although it was partially rubbed off by the after-market grass catcher, and a separate Spanish decal advised that all warnings were also available in Spanish.

Plaintiff brought negligence, strict liability and breach of implied warranty claims against the manufacturer for both design defect and failure to warn. Defendant moved to preclude plaintiff's expert's opinions as inadmissible under Fed. R. Evid. 702 both for lack of qualifications and as unreliable, and for summary judgment on all claims.

On plaintiff's design defect claim, the court agreed that his expert was qualified because, although he had never worked with lawnmowers, he was an engineering professor with degrees in mechanical engineering and mechanics and held automotive engineering certifications. On the other hand, his opinions were not reliable, as he provided no data or reliable methods to support them. For example, the expert opined the mower was defective for failing to shut off after plaintiff removed one hand from the handlebar, but he provided no methodology for his conclusion, pointed to no other similar mower with this

feature and failed to specify how a design change would have avoided plaintiff's injury.

As for the expert's opinion that the mower should have had both English and Spanish decals about operating without a chute cover, the expert provided no citations, statistics or explanations as to why the manufacturer should have had knowledge of its end users' demographics, or why it was its responsibility to provide Spanish decals as opposed to the employer's to acquire them for its non-English speaking workers. The expert also failed to address the decal about the availability of Spanish warnings.

In analyzing plaintiff's claims, the court noted that negligence and strict liability are functionally synonymous, and implied warranty is essentially the same as strict liability. As design defect claims require expert testimony regarding an alternative design, the court granted summary judgment against those claims. There was also no evidence the warning decals were insufficient, or that defendant was responsible for the employer's failure to acquire Spanish warning decals (or otherwise convey the warnings to plaintiff) or specific direction that he operate the mower without a chute cover. In addition, plaintiff failed to show that lack of a Spanish warning was a substantial factor in causing his injuries, as any such decal would have been rubbed off by the after-market grass catcher. Accordingly, the court granted summary judgment on the warning claims as well.

This Update was prepared by Foley Hoag's Product Liability and Complex Tort Practice Group, which includes the following members:

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