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

Massachusetts Superior Court Holds State Attorney General Unfair And Deceptive Practices Claim Against Opioid Manufacturer Not Preempted Or Statutorily Exempt As FDA Only Approved Defendant's Labeling, Not Marketing Practices, Public Nuisance Claim Adequately Supported By Allegations Of Interference With Public Health, And "Learned Intermediary" Doctrine Based On Adequacy Of Prescriber Labeling Did Not Apply As Defendant's Deceptive Marketing Allegedly Affected Prescribers' Decisions

In *Commonwealth v. Purdue Pharma, L.P.,* 26 Mass. L. Rep. 56 (Mass. Sup. Ct. 2019), the Massachusetts Attorney General sued a pharmaceutical manufacturer in Massachusetts Superior Court alleging defendant's marketing and sale of prescription opioid products violated Mass. Gen. L. ch. 93A, the state unfair and deceptive practices statute, and caused a public nuisance. The complaint alleged defendant's marketing tactics included targeting physicians already suspected of overprescribing and dispensing savings cards encouraging patients to stay on opioids longer, and that these tactics significantly contributed to the "opioid epidemic" that has caused thousands of Massachusetts overdoses and deaths. Defendant moved to dismiss both counts, arguing: (1) the claims were preempted as conflicting with the United States Food and Drug Administration ("FDA")'s approval of the opioids' sale and labeling; (2) the FDA approval mandated a liability exemption under ch. 93A; (3) defendant had not infringed any "public right" as required for a nuisance claim; and (4) the "learned intermediary" doctrine precluded liability for prescriptions written by medical professionals.

The court first noted that preemption would exist if "compliance with both federal and state [law] [was] a physical impossibility." Because the complaint did not challenge defendant's FDA-approved opioid labels by claiming defendant should have given different warnings, but rather alleged defendant's marketing activities were inconsistent with the approved labeling, there was no conflict between state and federal law and the claims were not preempted.

The court next turned to Mass. Gen. L. ch. 93A, § 3, which expressly exempts "transactions or actions otherwise permitted under laws as administered by any regulatory board or officer acting under statutory authority of the commonwealth or of the United States." After noting defendant's "heavy burden" to show the federal regulatory scheme permitted the specific conduct at issue, the court concluded that since the Commonwealth's allegations were based on marketing practices separate from the FDA-approved labeling, there was no exemption under the statute.

Regarding defendant's argument that the Commonwealth's nuisance claim was merely a "poorly disguised, repackaged products liability claim," the court noted that since a public nuisance is conduct that "interferes with the exercise of a public right by directly encroaching on public property or by causing a common injury," the question here was whether defendant's conduct involved "a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience." Citing other Massachusetts cases that allowed public nuisance claims based on dangerous products, the court held the complaint sufficiently alleged conduct that interfered with public health and safety.

Lastly, the court evaluated whether the "learned intermediary" doctrine, which breaks the chain of causation between a prescription drug manufacturer and patient if the manufacturer has adequately warned the prescribing physician, precluded the Commonwealth's claims. The court concluded it did not, as the allegations here were that defendant's deceptive marketing conduct had affected the prescribers' decisions.

Massachusetts Appeals Court Holds Plaintiff's Counsel's Closing Argument Improper In Referring To Himself And Jurors As "Us" And Defendants As "Them," And Asking Jurors To Do "The Right Thing" For "Big Companies" That Refuse To Accept "One Shred Of Responsibility," But Post-Verdict Objection To Argument Must Be Resolved Under New Trial Standard Rather Than Mere Possibility Of Jury Effect

In *Fitzpatrick v. Wendy's Old Fashioned Hamburgers of New York, Inc.*, 96 Mass. App. Ct. 410 (2019), plaintiff sued a fast food chain and its beef supplier in Massachusetts Superior Court for breach of the implied warranty of merchantability and violation of Mass. Gen. L. ch. 93A, the state unfair and deceptive practices statute, after she bit into a small piece of bone in her hamburger, splitting her molar in two and leading to numerous surgeries and dental procedures over the following two years.

At the jury trial of the warranty claim (the 93A claim was reserved for the court), plaintiff noted the meat supplier had not x-rayed the hamburger after its final grind process, while defendants argued the grind was finer than required by industry standards and the finest that would meet a customer's taste expectations. During closing arguments, plaintiff's counsel referred to "[u]s, the average people, not them," suggested "we" don't "go to [the chain's restaurants] and expect to get injured," and argued that defendants, "one of the largest fast food companies and one of the largest beef manufacturers in the world," refused to accept "one shred of responsibility"—"[t]hat's what they do, these big companies." Counsel also asked the jurors to imagine being injured in the future and being able to look back and conclude "we did the right thing."

The trial court denied defendants' motion for a mistrial but reminded the jury, among other things, not to be swayed by prejudice, that lawyers' arguments were not evidence and the jury's job was to determine whether plaintiff had proved her case, not "deter any conduct or to punish any party" or decide based on "whether a party is a big company or a small company." After the jury awarded plaintiff more than $150,000, however, the court granted a mistrial, ruling counsel's argument improperly created an "us versus them dichotomy," suggested the jury act as "the voice of the community," asked jurors to place themselves in plaintiff's shoes, interjected counsel's own personal beliefs, and resorted to the "so-called reptile approach" whereby a lawyer appeals to the "primitive and survival-based" part of the brain to "trigger a juror's fear of danger to the community as a result of a defendant's conduct." After a retrial resulted in only a $10,000 award, plaintiff appealed.

The Massachusetts Appeals Court held the trial court erred in failing to consider whether lesser measures would have sufficed to remedy counsel's conduct. In addition, because the motion the lower court ultimately granted came after the jury's verdict, it should have been considered under the standard for a new trial motion, *i.e.*, whether the verdict was so "markedly against the weight of the evidence" as to suggest the jurors were "misled, were swept away by bias or prejudice, or for a combination of reasons, including misunderstanding of the applicable law, failed to come to a reasonable conclusion." Instead, the judge had applied the factors for prejudicial error, including whether the improper argument "possibly" affected the jury's conclusion, and also did not explain why her curative instructions were inadequate since jurors are presumed to follow instructions.

Regarding the propriety of plaintiff's counsel's closing, the appellate court agreed it was improper for the same reasons cited by the trial court. Due to that court's application of the

wrong legal standard, however, the appellate court remanded so defendants' post-verdict motion from the first trial could be resolved under the appropriate standard.

Massachusetts Federal Court Refuses To Consider Adequacy Of Plaintiffs' Specific Causation Evidence On Motions Designed To Address General Causation, And Holds Neither Counsel's Statements Nor Experts' Deposition Testimony Conceded Plaintiffs Lacked General Causation Evidence Where Statements Were Not Unambiguous Concessions Or Were Accompanied By Explanations Showing They Were Not Concessions

In *In re Zofran Ondansetron Prods. Liab. Litig.*, 2019 U.S. Dist. LEXIS 183884 (D. Mass. Oct. 23, 2019), a multi-district litigation ("MDL") in the United States District Court for the District of Massachusetts, numerous plaintiffs alleged that defendant's prescription anti-nausea drug, when taken by pregnant women, crossed the placental barrier and caused various birth defects. Defendant moved for summary judgment against a subset of plaintiffs based on lack of general-causation evidence that the drug could cause injuries other than cardiac defects and isolated cleft palate (*i.e.*, cleft palate in the absence of other orofacial defects). Two plaintiffs opposed the motion individually, and 48 filed an omnibus opposition.

The two individual plaintiffs had children who suffered additional defects alongside either cardiac defects or cleft palate, respectively. Defendant argued there was no evidence the drug could cause heart defects in a patient with the first child's particular "constellation of defects," or cleft palate along with the second child's other defects given that they were independently associated with cleft palate. The court held, however, that defendant's arguments went to specific causation, *i.e.*, whether the children's cardiac and palate defects were actually caused by the drug in light of their other conditions. As general causation was the only issue being considered by the court at this stage, and there was a genuine factual dispute regarding the drug's ability to cause cardiac and cleft palate defects, the court denied summary judgment against the two plaintiffs.

The other 48 plaintiffs alleged their children suffered cleft lip with or without cleft palate. Defendant first argued plaintiffs' counsel had made a judicial admission that there was no general causation evidence for orofacial defects other than isolated cleft palate. In response to a question from the court, plaintiffs' counsel had said, "If there are defects outside of heart and palate . . . I don't believe the scientific evidence has caught up to proving these, if they are simply existing on an independent basis outside of a heart or a palate." Generally, judicial admissions arise only from deliberate waivers that expressly concede the truth of an alleged fact for the purposes of trial. Here counsel's statement was in response to a question about defects "that are not either cardiac or orofacial" and therefore was not an admission because the context was not specific to palate injuries as differentiated from other orofacial injuries.

Defendant also argued that deposition testimony by plaintiffs' expert embryologist and epidemiologist conceded there was no evidence the drug caused cleft lip, either with or without cleft palate. Both experts had agreed the phenotypes for isolated cleft palate and cleft lip with or without cleft palate were pathogenetically and etiologically distinct, and the epidemiologist agreed "the epidemiological evidence currently only supports an association with isolated cleft palate." The court noted, however, that the embryologist had also explained that distinct phenotypes could mean that a substance could cause only one of the defects, or that it could cause both by a common mechanism, and the epidemiologist had explained that evidence from other fields could establish general causation without violating epidemiological principles. Accordingly, neither expert had conceded a lack of general causation, and since at least two of plaintiffs' other experts had opined the drug could cause cleft lip with or without cleft palate, the court denied summary judgment against the 48 plaintiffs.

Massachusetts Federal Court Holds FDA Expert's Opinions About Effect On Labeling Of Animal And Adverse Event Data Allegedly Not Fully Disclosed To Agency Admissible Where Based On Regulatory Record Even Without Independent Analysis Of Underlying Data, Opposing Expert's Opinions Based On FDA Guidance And Practices But Not Drug-Specific Agency Statements Also Admissible, But Expert's Opinions About Defendant's Marketing Practices Inadmissible As Not Involving Regulatory Expertise

In *In re Zofran (Ondansetron) Prods. Liab. Litig.*, 2019 U.S. Dist. LEXIS 190372 (D. Mass Nov. 1, 2019), plaintiffs in a multi-district litigation ("MDL") in the United States District Court for the District of Massachusetts alleged their children suffered a variety of birth defects caused by defendant's prescription anti-nausea drug. Among other things, plaintiffs claimed defendant failed to disclose a series of Japanese animal studies to the United States Food and Drug Administration ("FDA") and to accurately inform the agency about certain adverse event reports. Plaintiffs alleged that with proper disclosure FDA would not have approved the drug under pregnancy "Category B," meaning that animal studies had failed to demonstrate a birth defect risk and there were no adequate and well-controlled studies in humans, as opposed to "Category C" or "Category D," which would have warned of a risk based on either animal studies or adverse event data. Plaintiffs also claimed that, following FDA approval, defendant should have updated its labeling to reflect the studies and adverse event reports.

Each side offered a regulatory expert to support its positions and moved to preclude the opposing expert's opinions. Plaintiffs argued the defense expert was unqualified, and employed an unreliable methodology, to opine that the Japanese animal studies would not have changed the drug's Category B labeling, as the expert was a clinician rather than toxicologist and had failed to even consider one of the studies. The court, however, noted the expert did not claim to independently interpret any of the studies but rather only to determine that on the full regulatory record, including the studies and defendant's scientists' interpretation of them, the pregnancy categorization was appropriate. Based on her thirteen years of regulatory experience, which included work on FDA's Pregnancy Labeling Task Force, the expert was qualified to give these opinions, and analyzing the regulatory record and applicable standards was a sufficiently reliable method.

Plaintiffs also sought to preclude the expert's opinions that defendant had adequately disclosed the human adverse event reports, arguing the opinions were unreliable because the expert had not analyzed the raw data underlying the reports. Once again, the court concluded the expert's review of the reports and comparison of them to the entirety of FDA's safety database matched what the agency itself would have done and was therefore sufficiently grounded in the regulatory record and standards. And on both the animal and human data, questions about the rigor of the expert's analysis went to the weight rather than admissibility of her opinions.

As to plaintiffs' regulatory expert, defendant argued his opinion that FDA would not have approved a Category B pregnancy labeling if they had disclosed the Japanese animal studies was speculative and without reliable basis, as it was not based on any actual FDA statements or actions. The court, however, concluded the expert's reliance on FDA guidance documents as well as his own eleven years of FDA experience rendered his methodology sufficiently reliable. For similar reasons, the court rejected defendant's argument that the expert's opinion that defendant should have reported the human adverse events differently was unreliable as not based on any specific FDA regulations, concluding such deficiencies went only to the testimony's weight.

Finally, the court granted defendant's motion to preclude plaintiffs' expert's opinions that defendant's off-label marketing for use in pregnancy-related nausea and vomiting created a false sense of the drug's pregnancy safety and failed to inform prescribers and patients about the drug's true risks. The expert's testimony in this regard was essentially only "a narrative summary of [defendant's] internal documents," and drew "on little, if any, of his regulatory expertise."

New York Federal Court Holds Plaintiff's Ignoring Warning Not To Move Deep Fryer Without Draining Reduces But Does Not Bar Failure-To-Warn Claim Where Not Sole Cause Of Accident, Surveillance Video Not Needed To Prove Causation Nor Does Third-Party Spoliation Of Same Bar Recovery, And Expert's Design Defect Opinions Admissible Despite Lack Of Testing And Calculations Where Based On Examination Of Product And Detailed Schematics

In *Hernandez v. Pitco Frialator, Inc.,* 2019 U.S. Dist. LEXIS 187690 (W.D.N.Y. October 28, 2019), plaintiff sued the manufacturer of a wheel-mounted deep fryer in the United States District Court for the Western District of New York, alleging he suffered second- and third-degree burns when the fryer tipped over while he was moving it, spilling oil onto him. The fryer bore a label warning against moving it unless hot liquids were completely drained, and the manual added that "splashing hot liquids can cause severe burns." Plaintiff asserted, among others, negligence and strict liability claims for failure to warn that the fryer was top-heavy and for design defect in failing to incorporate either bottom weighting to lower the fryer's center of gravity, a separate handle to increase its stability during movement or a securable cover to prevent spills on tipping over. Defendant moved for summary judgment on all claims.

The court first rejected defendant's argument that plaintiff's contributory negligence in failing to follow the fryer's warnings barred his claims, since under New York law a plaintiff's negligence does not bar, but only proportionately reduces, recovery under both negligence and strict liability. As for defendant's argument that plaintiff's "glaring misuse" of the fryer at least barred his strict liability claims, while that would be true if the misuse were the sole proximate cause of the accident, here the jury could find the fryer's top-heaviness also contributed.

With respect to design defect, the court rejected defendant's argument that plaintiff could not prove causation because the restaurant had not preserved surveillance video of the incident, noting there was no precedent for requiring video evidence to prove causation and in any event a defendant could not escape liability based on a third party's alleged spoliation of evidence. The court also rejected defendant's argument that as a matter of law the fryer was not unreasonably dangerous because its risks were obvious and avoidable with ordinary care, noting that while the risk hot oil could splash was readily foreseeable, the risk of a tip-over due to top-heaviness was not. The court similarly rejected defendant's argument its warning against moving the fryer with hot oil was adequate as a matter of law, and not even necessary because the risk was obvious, noting again that the tip-over risk was not obvious.

Lastly, the court rejected defendant's challenges to the admissibility of plaintiff's expert's design defect opinions. Although the expert was not a professional engineer and had never operated or designed a fryer, his multiple engineering degrees, including a Ph.D. in mechanical engineering, and thirty years' experience in product design rendered him adequately qualified. Defendant also argued the expert's opinions that the fryer should have incorporated an additional handle or weighted bottom were unreliable because they were not supported by any testing, calculations or specific designs, or assessment of the risk or cost. The court, however, found the expert's methodology, which included his personal inspection of the fryer and review of "detailed schematics," was sufficient, and that issues such as the cost of alternative designs could be addressed through cross-examination. The court thus denied defendant's summary judgment motion in its entirety.

New York Federal Court Holds Operator Of Online Marketplace Not Liable In Tort Or Warranty For Damage Caused By Defective Product Sold By Third Party Through Marketplace Because Defendant Never Took Title To Product And Thus Was Not Part of Distribution Chain

In *Phila. Indem. Ins. Co. v. Amazon.com, Inc.*, 2019 U.S. Dist. LEXIS 209144 (E.D.N.Y. December 4, 2019), an insurer brought claims for strict liability, negligence and breach of warranty in the United States District Court for the Eastern District of New York against the operator of an online

marketplace, alleging that a defective blender sold by a third party through the marketplace had caused property damage to the insured's policyholder. Under its written agreement with the third party, in exchange for approximately 15% of the sales price, defendant had listed the blender for sale on its website, processed payment, warehoused and shipped the blender and agreed to provide customer service. The agreement also provided, however, that defendant never took title to the blender.

Defendant moved for summary judgment, arguing it could not be held liable on any of the insurer's claims because it did not manufacture, distribute or sell the blender. The court agreed, noting that under New York law, strict liability, negligence and breach of warranty all extend only to entities within the distribution chain such as manufacturers, wholesalers, retailers or distributors. Defendant would only qualify as part of that chain if it had taken title to the blender, which it had not. Accordingly, it was entitled to summary judgment.

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

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