FOLEY HOAG

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 Federal Court Holds Physician And Marketing Experts Cannot Opine Regarding Pharmaceutical Company's Intent In Allegedly Paying Physicians As Speakers And Consultants Beyond Fair Value In Violation Of Anti-Kickback Statute, Credibility Of Defendant's Witnesses Or Whether Defendant's Conduct Violated Statute, And Cannot Present Narrative Summary Of Factual Events

In *United States v. Biogen Idec, Inc.*, No. 1:12-cv-10601-IT, 2022 U.S. Dist. LEXIS 120549 (D. Mass. July 8, 2022), an individual plaintiff-relator sued a pharmaceutical company in the United States District Court for the District of Massachusetts for allegedly retaining physicians as consultants and speakers as an inducement to prescribe its multiple sclerosis treatments, in violation of the federal Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b. Plaintiff proffered multiple experts including physicians and healthcare marketing executives who opined that the educational purpose and value of defendant's speaker and consultant programs, its compliance processes and its speaker-fee calculations were all inadequate. Defendant filed multiple motions to exclude the experts' testimony, which the court addressed in a single opinion.

The court first allowed multiple motions to preclude six of the experts from opining that defendant's programs were intended to influence physicians' prescribing behavior, holding that while the experts could opine as to defendant's deviations from industry standards, questions of intent were for the jury.

Second, defendant argued that portions of four experts' testimony were improper narrative summaries of documents and witness testimony. The court held that such evidence was properly presented through fact rather than expert witnesses, and the experts also could not characterize the evidence or comment on defendant's witnesses' credibility. The experts could, however, explain why they found specific evidence meaningful for their conclusions.

Third, the court held that although plaintiff's marketing expert could testify about industry standards that were designed to avoid AKS violations and compare defendant's conduct to those standards, she could not opine that particular conduct violated the statute, as that impinged upon the roles of the judge and jury.

Fourth, defendant challenged the opinions of plaintiff's two physician experts on a number of grounds, including that their opinions regarding the value of defendant's medical education were not based on expertise, applied arbitrary value thresholds and were speculative for various reasons. The court held, however, that the physicians' opinions were sufficiently based on their experience as either a medical researcher or academic and defendant's criticisms were best addressed by cross-examination.

Lastly, the court denied defendant's challenge to plaintiff's healthcare marketing expert's opinions regarding whether defendant's consultant and speaker programs served legitimate business needs or purposes, holding the expert could use program-attendance metrics to evaluate the programs even though the metrics were based on her own professional experience rather than any peer-reviewed studies.

Massachusetts Federal Court Holds Plaintiff Adequately Pleaded Manufacturing Defect, Failure To Warn And Deceptive Business Practices Claims Against Surgical Stapler Manufacturer Where Complaint Alleged Stapler Was Subject To Recall For Inadequate Firing At Time Of Plaintiff's Procedure And Defendants Withheld Thousands Of Individual Adverse Event Reports In Favor Of Summary Report On FDA's Public Database, But Dismissed Design Defect And Negligent Misrepresentation Claims Where Plaintiff Failed To Plead Existence Of Reasonable Alternative Design Or Specific Misrepresentations By Defendants

In *Hunt v. Covidien LP*, No. 1:22-cv-10697-RGS, 2022 U.S. Dist. LEXIS 147915 (D. Mass. Aug. 18, 2022), plaintiff allegedly developed an abscess caused by a staple line leak after a gastrectomy, causing among other things severe abdominal pain and sepsis and requiring corrective surgery. She sued the manufacturer of the surgical stapler and stapler reloads used in the procedure along with related entities in the United States District Court for the District of Massachusetts for negligence and breach of the implied warranty of merchantability (the Massachusetts near-equivalent of strict liability) on theories of manufacturing defect, design defect and failure to warn, as well as negligent misrepresentation and violation of Mass. Gen. L. ch. 93A (the state unfair and deceptive business practices statute). Defendants moved to dismiss for failure to state a claim.

As to manufacturing defect, the court found plaintiff had plausibly pleaded that due to deviations from its original design the stapler failed to adequately seal off the remaining section of her stomach, which was supported by the fact that at the time of plaintiff's surgery the stapler handle was under active recall for failing to fire or only partially firing.

The court likewise found plaintiff adequately pleaded failure to warn by alleging defendants withheld information regarding thousands of adverse event reports related to the stapler from her surgeons by utilizing the United States Food and Drug Administration's ("FDA") Alternative Summary Reporting program, which allowed certain types of device malfunctions to be reported on the FDA's public adverse event database through a summary of the reports collectively rather than individual reports. That allegation was also sufficient to plead a deceptive practice in violation of ch. 93A, although the court did not address the statute's exemption in § 3 for "actions otherwise permitted under laws as administered by any regulatory board or officer acting under statutory authority of . . . the United States."

Regarding plaintiff's design defect claims, however, the court held that her allegation that defendants' stapler components created a risk that was "far more significant and devastating than the risks posed by other products and procedures available to form a gastric sleeve with a secure staple line" was conclusory and did not adequately plead the existence of a reasonable alternative design, which was necessary for a design defect claim. The court thus dismissed those claims with leave to amend for the limited purpose of pleading such an alternative design.

The court also dismissed plaintiff's claim for negligent misrepresentation, in this instance with prejudice, agreeing with defendants that plaintiff had failed to identify any specific statement or misrepresentation by them on which plaintiff's surgeons had relied in using the stapler.

Massachusetts Supreme Judicial Court Holds Attorneys' Fees For Violation of Unfair And Deceptive Practices Statute Resulting In Bodily Injury Not "Damages Because Of Bodily Injury" Covered By Insurance Policy

In *Vermont Mutual Insurance Company v. Poirier*, 189 N.E.3d 306 (Mass. 2022), a family cleaning business was found liable for damages and attorneys' fees under Mass. Gen. L. ch. 93A (the state unfair or deceptive practices statute) for breaching the implied warranty of merchantability (the Massachusetts near-equivalent of strict liability) by failing to warn its customers to stay out of their basement until the cleaning chemicals the company used had dried, causing one of them to suffer respiratory problems. The company's insurer then sought a declaratory judgment in the Massachusetts Superior Court that it was not required to indemnify the cleaning company for the attorneys' fees, as they did not constitute "damages because of 'bodily injury'" under the policy. After the trial court held the attorneys' fees were such damages because they resulted from the underlying injury-based claim, the insurer appealed to the Massachusetts Appeals Court, from which the Massachusetts Supreme Judicial Court ("SJC") transferred the case on its own initiative.

The SJC reversed. The court first explained that damages caused by bodily injury refers to physical injuries and money required to compensate for them, while attorneys' fees under ch. 93A reflect the costs of bringing suit seeking such compensation. That these two are meaningfully different is shown by the fact that had the customers sued only at common law, they would have recovered damages but not their attorneys' fees, while the fee-shifting aspect of ch. 93A awarded them both damages *and* attorneys' fees. Moreover, the purposes of damages and attorneys' fees differ—the former are meant to compensate for an injury, while the latter are meant to deter misconduct and recognize the public benefit of seeking legal redress for it.

In addition, the SJC agreed with the insurer and trial court that a supplementary insurance provision covering "all costs taxed against the insured in the suit" did not cover attorneys' fees. In the context of a legal proceeding, this provision refers to court fees or other nominal costs such as for deposition transcripts that are recoverable as a matter of course to all prevailing parties under Massachusetts law, not to attorneys' fees that are only recoverable because of a violation of ch. 93A.

NEW YORK/NEW JERSEY SUPPLEMENT

New York Federal Court Grants Summary Judgment Against Asbestos And Silica Personal Injury Claims Based On Lack Of Expert Testimony That Plaintiff Was Exposed To Those Substances In Sufficient Amounts To Cause Her Injury

In *Clark v. New York City Housing Authority*, No. 20 Civ. 251, 2022 U.S. Dist. LEXIS 165555 (S.D.N.Y. Sept. 14, 2022), a former public housing resident sued her housing authority landlord, an abatement services company and an air monitoring company in the United States District Court for the Southern District of New York, alleging she suffered multiple conditions, including chronic obstructive pulmonary disease ("COPD") and lupus, due to asbestos and crystalline silica quartz exposure from asbestos abatement work the contractors performed in her apartment in 2004.

At her deposition, plaintiff testified that the abatement work was performed improperly, causing her to be exposed to asbestos and silica. Plaintiff rested her conclusion on her subsequent COPD and lupus diagnoses, which she asserted were caused by such exposures. While plaintiff offered no expert testimony buttressing these conclusions, defendants' occupational and environmental medicine physician opined in a report that there was no evidence plaintiff was exposed to either asbestos or silica in her apartment, and that in the "remote scenario" that any asbestos or silica was present the levels would have been below the Occupational Safety and Health Administration's permissible exposure limits and not capable of causing disease. Defendants therefore moved for summary judgment, arguing that on the record evidence no reasonable jury could find that asbestos or silica caused plaintiff's injuries.

The court granted defendants' motion, applying the seminal holding of *Parker v. Mobil Oil Corp.*, 7 N.Y.3d 434 (2006), under which a plaintiff in a toxic tort claim must prove both "'general causation'—that the toxin at issue is capable of causing the symptoms or illness of which the plaintiff complains," and "'specific causation'—that the plaintiff was exposed to sufficient levels of the toxin to cause the symptoms or illness of which the plaintiff complains." Moreover, under *Parker* and its progeny, proof of these elements requires expert testimony. Although under

these cases "it is not always necessary for a plaintiff to quantify exposure levels precisely or use the dose-response relationship, a plaintiff must, through *scientific expression*, establish sufficient exposure to a substance to cause the claimed adverse health effect." Accordingly, plaintiff's lack of expert testimony doomed her claim.

Notably, the court's decision comes on the heels of a series of state court appellate decisions from both the Court of Appeals, in *Nemeth v. Brenntag N. Am.*, 38 N.Y.3d 336 (2022), and the First Department of the Superior Court's Appellate Division, each of which confirms that *Parker*'s holding is just as applicable to claims involving asbestos as it is to claims involving benzene (the substance at issue in Parker) or any other alleged toxin.

New York Federal Court Holds Foreign Corporation's Manufacture Of Saws Exclusively For United States-Based Distributor To Be Distributed Throughout North America Does Not By Itself Establish Sufficient Minimum Contacts With New York To Support Personal Jurisdiction Consistent With Due Process

In *Piotrowicz v. Techtronic Indus. N. Am., Inc.*, 2022 U.S. Dist. LEXIS 129938 (S.D.N.Y. 2022), a New York resident who suffered serious injuries in New York while using a miter saw that he purchased from a New York retail store sued the saw's China-based manufacturer in the United States District Court for the Southern District of New York. The manufacturer moved to dismiss, arguing plaintiff failed to meet his burden to establish personal jurisdiction under New York's long-arm statute and due process.

According to the complaint and declarations filed by the parties, defendant was not authorized to conduct business outside of China and did not itself sell products, solicit business, maintain an office or bank account, or otherwise engage in transactions in New York. Defendant manufactured the saw in China pursuant to an agreement between its Bermuda-based parent company and a United States-based distributor, which required defendant to manufacture saws exclusively for the distributor, specified that the saws were for North America and to be made in compliance with standards applicable to the United States, and required that the distributor order enough saws for defendant to operate near full capacity. The distributor in turn sold the saws to United States retailers, including national chain retailers with stores in New York such as the one from which plaintiff purchased.

The court first held defendant was subject to jurisdiction under CPLR § 302(a)(3)(ii), part of New York's long-arm statute, which provides that non-resident corporations are subject to jurisdiction in New York if they engage in tortious conduct outside the state that causes injury within it, and if defendant should "reasonably expect the act to have consequences in" New York and "derives substantial revenue from interstate or international commerce." Based on precedent from the United States Court of Appeals for the Second Circuit, defendant could reasonably foresee that its saw manufacturing in China would have consequences in New York because the saws would be sold exclusively through a United Stated-based distributor that served the New York market.

As to due process, however, defendant lacked sufficient minimum contacts with the state to support jurisdiction. The fact that the distribution agreement provided that defendant's saws should be made to United States standards evidenced that defendant knew its distributor would sell the saws in the United States, but not necessarily in New York. Likewise, the fact that the national retailer chain periodically inspected defendant's factories in China only demonstrated knowledge of United States, but not specifically New York, sales. Nor did defendant engage in any additional contact to target New York markets, such as by shipping saws directly to the state (defendant only delivered its saws to third parties inside China), and the record did not reveal the number of saws actually sold in New York or that there was any "particularly large or unique" customer base for the saws there. Accordingly, "despite [defendant's] sustained contacts with the United States as a whole," plaintiff had not "mustered any direct evidence of [defendant's] purposeful contact with New York."

New Jersey Appellate Division Holds Slip And Fall Claims Against Paint Manufacturer Not Barred By Statute Of Limitations Where Plaintiff Timely Filed Complaint Naming Fictitious Manufacturer, Could Not Reasonably Have Known Manufacturer's Identity Then And Thereafter Acted With Reasonable Diligence To Discover Manufacturer's Identity And Amend Complaint To Name It

In *Radzewick v. Mhm Winsdor*, No. A-2842-20, 2022 N.J. Super. Unpub. LEXIS 1386 (Super. Ct. App. Div. Aug. 1, 2022), an auto dealer employee sued, among others, an independent painting contractor in New Jersey Superior Court after she slipped and fell on a newly painted floor in the dealership's service department on June 2, 2015. Plaintiff filed her complaint on June 1, 2017, just before the expiration of New Jersey's two-year statute of limitations, N.J.S.A. 2A:14-2(a), and included defective product claims against fictitious parties involved in manufacturing the paint, whose identities she did not then know.

In response both to plaintiff's pre-suit requests and initial interrogatories, the painting contractor did not identify the paint manufacturer, but at his July 12, 2019 deposition he produced documents that identified it. On May 28, 2020, plaintiff's expert issued a report opining that the paint made the floor unduly slippery because it was designed for use with an anti-slip additive that the contractor was unaware of and thus failed to use. On August 17, 2020, plaintiff filed what was by then a second amended complaint naming the manufacturer for the first time, and shortly thereafter she filed a third amended complaint adding claims against it for negligent product recommendation and failure to warn. After the manufacturer moved to dismiss the complaint under the statute of limitations, the trial court denied the motion, concluding that plaintiff's claims were tolled under the discovery rule and related back to her original complaint under the fictitious party rule. The manufacturer then appealed to the Appellate Division of the Superior Court.

The court first noted that the trial court had incorrectly held that under New Jersey's discovery rule—under which a claim does not accrue until plaintiff "discovers, or by an exercise of reasonable diligence and intelligence should have discovered that [she] may have a basis for an actionable claim"—the running of the statute of limitations on plaintiff's claims was tolled until she could have discovered the manufacturer's actual identity. Rather, her claims accrued no later than the date of her original complaint, as she was at that point aware her injuries might have been caused, at least in part, by the paint manufacturer even if she did not then know its identity. The trial court also erred to the extent it found separate, and later, accrual dates for plaintiff's negligent recommendation and failure-to-warn claims, as they were merely alternative causes of action under the product liability umbrella that plaintiff initially pled.

The appellate court held, however, that the trial court had correctly applied the fictitious party or pleading rule. That rule allows plaintiffs to initially name a fictitious party within the statute of limitations and later have an amended complaint naming the party relate back the original complaint where the party's identity "cannot be ascertained by the exercise of due diligence prior to filing the complaint." Here plaintiff had attempted unsuccessfully to identify the paint manufacturer through pre-suit requests and interrogatories, and thus had no reasonable opportunity to learn its name before the contractor's deposition. Nor did plaintiff fail to act diligently to sue the manufacturer after the deposition, as it was reasonable to first consult an expert to affirm that there was a valid claim, and plaintiff's second amended complaint naming the manufacturer followed within a reasonable time after the expert's report.

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