FOLEY HOAG

Product Liability Update

In This Issue:

July 2024

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 Out-Of-State Online Retailer Did Not Purposefully Avail Itself Of Privilege Of Acting In Massachusetts, A Requirement For Personal Jurisdiction Under Due Process, By Employing Session Replay Code That Allowed Defendant To Record And Replay Massachusetts Plaintiff's Website Interactions, As Plaintiff Had No Evidence Code Was Intended To Target Massachusetts Users Or Even Informed Defendant Of Plaintiff's Location

In *Rosenthal v. Bloomingdales.com, LLC*, 101 F.4th 90 (1st Cir. 2024), a Massachusetts resident brought a putative class action in the United States District Court for the District of Massachusetts against an online retailer organized in Ohio and with its principal place of business in New York. Plaintiff alleged defendant violated the Massachusetts anti-wiretapping and invasion-of-privacy statutes, Mass. Gen. Laws ch. 272, § 99 and ch. 214, § 1B, respectively, when it included session replay code ("SRC") in its website, allowing defendant to record and later create a video replay of plaintiff's behavior on the site. Defendant moved to dismiss for lack of personal jurisdiction, and the court granted the motion, finding that plaintiff's claims did not arise out of or sufficiently relate to defendant's in-state conduct and that defendant had not purposefully availed itself of the privilege of acting in Massachusetts, both requirements of due process.

On plaintiff's appeal, the United States Court of Appeals for the First Circuit affirmed, rejecting plaintiff's argument that the district court erred in its purposeful availment analysis because defendant had "cultivated a market in Massachusetts, sought to expand that market through the use of SRC, and benefited from that market." The appellate court first noted that purposeful availment "focuses on the defendant's intentionality and rests on two cornerstones: voluntariness and foreseeability"; the former means that defendant's forum contacts "result proximately from its own actions," while the latter means that defendant's conduct and connection with the forum is "such that he should reasonably anticipate being haled into court there."

Here, plaintiff's evidence failed on both counts. There was no evidence defendant had employed SRCs, which affected website users everywhere in the world, with the intention of specifically targeting Massachusetts customers, so that defendant's Massachusetts contacts resulting from plaintiff's use of its website were not necessarily a proximate result of defendant's own actions. Further, the SRC data did not even inform defendant of plaintiff's location, meaning that any contact with Massachusetts from

plaintiff's website use was not necessarily foreseeable. Because the court affirmed the dismissal under purposeful availment, it did not address the due process "arising out of or relating to" requirement, or whether plaintiff's claims satisfied the state long-arm statute, Mass. Gen. L. ch. 233A, § 3.

Massachusetts Federal Court Grants Summary Judgment On Manufacturing Defect, Failure-To-Warn And Deceptive Practices Claims Against Surgical Stapler Manufacturer After Excluding Some Expert Opinions As Unqualified Or Unhelpful To Jury And Finding No Evidence Plaintiff's Surgeon Relied On Stapler Instructions Or Would Have Relied On Individual Adverse Event Reports If Provided, But Denies Judgment On Design Defect Claim As Plaintiff's Expert Proposed Alternative Designs To Control Force And Rate Of Staple Firing

In *Hunt v. Covidien LP*, No. 22-10697-RGS, 2024 U.S. Dist. LEXIS 94280 (D. Mass. May 28, 2024), 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 manufacturers 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), asserting 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 practices statute). At an earlier stage, defendants moved to dismiss all claims, but the court granted the motion only as to negligent misrepresentation and design defect, with leave to amend the latter claim to include adequate allegations of a feasible alternative design. *See* *Product Liability Update – October 2022*.

Following the close of fact discovery, defendants moved to exclude the testimony of three of plaintiff's expert witnesses and for summary judgment. Regarding plaintiff's expert surgeon's opinion that plaintiff's staple line leak was most likely caused by staple malformation during the stapler's firing, defendant argued the expert's differential diagnosis (actually differential etiology analysis) was inadequate because he failed to rule out the possibility that the leak was idiopathic. The court, however, ruled that the expert had searched for and found no evidence that patient noncompliance with post-surgery instructions caused the leak, and the expert was not required to rule out every possible cause; accordingly, any questions about whether the leak was idiopathic went to the weight of the expert's opinion and not its reliability and hence admissibility.

Defendants next challenged various opinions of plaintiff's mechanical engineering expert based on lack of qualifications. Defendants tested their product by firing staples into foam and determining that this produced either "properly formed" (fully closed) staples, or at least "partially formed" ones (with one curl fully closed), which defendants still deemed acceptable. Plaintiff's expert opined that this testing was deficient because defendant set no limit on the number of staples that could be partially rather than fully formed, the foam did not adequately replicate human tissue and the process lacked repeatability and allowed for operator bias. The court held that the expert, who had researched medical device design and how devices interact with soft tissue, was qualified to render his first two opinions, but not the third, as he had never designed or published about a quality assurance program. The court also agreed the expert was not qualified to opine about specific causation, as he was not a medical doctor, the existence of any manufacturing defect, as he admitted he was not aware of any actual such defect, or the adequacy of defendants' instructions, as he had no experience drafting medical device instructions or reviewing instructions for other surgical staplers.

Third, the court excluded the opinions of plaintiff's regulatory expert as unhelpful in determining any facts at issue. The expert's lengthy report criticizing various aspects of the United States Food and Drug Administration's ("FDA") regulatory regime for medical devices generally lacked "any mooring to the facts of this case." When the expert did opine about defendants' product specifically, such as to say that its testing foam or instructions were inadequate, those opinions were not tied to any FDA requirement and/or were directly contradicted by the warnings defendants included in their instructions.

Turning to summary judgment, the court granted defendants' motion as to plaintiff's claims for manufacturing defect and failure to warn, as the court had excluded plaintiff's experts' opinions supporting those claims. The court also granted the motion as to plaintiff's chapter 93A claim, which was based on alleged safety misrepresentations in the stapler's instructions

and defendant's use of FDA's Alternative Summary Reporting ("ASR") process, under which individual adverse event reports had been not made available to the public. There was no evidence of causation because plaintiff's surgeon had not reviewed the instructions before operating, nor had he reviewed any individual adverse event reports after the ASR program was phased out so as to render it likely he would have done so before plaintiff's surgery if such reports were available.

Lastly, the court largely denied summary judgment as to plaintiff's design defect claims, as plaintiff's mechanical engineering expert identified two sufficient alternative designs, one that would limit the force a surgeon could apply to the staples and the other an automatic firing system, which defendants used in other products, to control the rate at which the surgeon could fire the staples. Because the only ways a surgeon can determine whether a staple has adequately penetrated tissue are visual inspection and tactile feedback, a jury could find these designs would have made it more likely that her surgeon would have noticed malformed staples that caused a leak. On the other hand, since plaintiff could not show how the alleged deficiencies in defendants' testing process affected the stapler's design, no jury could find that such deficiencies amounted to a design defect.

NEW YORK/NEW JERSEY SUPPLEMENT

New Jersey Federal Court Holds Mechanical Engineer With Two Decades Of Experience Designing Lawnmowers And Similar Products Qualified To Opine To Design Defect Based On Inadequate Fuel Tank Roll-Over Protection, And Methodology Reliable Where He Examined Accident Data, Inspected Burnt Lawnmower, And Performed Both Roll-Over Testing On Exemplar Mowers And Engineering Analysis Of Mower Model

In *Visakay v. Sears Roebuck & Co.*, Civil Action No. 2:17-cv-11570, 2024 U.S. Dist. LEXIS 77352 (D.N.J. Apr. 29, 2024), decedent died from burn injuries after his riding lawnmower rolled over, causing fuel to spill and catch fire. Decedent's estate sued the manufacturer in the United States District Court for the District of New Jersey alleging defective design, and defendant eventually moved to exclude the testimony of plaintiff's design expert and for summary judgment. The expert opined that the mower's crossmember, which supported the fuel tank, was inadequate and severely deformed in the roll-over, causing the fuel tank to be crushed and thus to eject fuel and vapors that led to the fire. The court first rejected defendant's argument that the expert was not qualified to opine on lawnmower design, noting that in addition to having a bachelor's degree in mechanical engineering, he had worked for over twenty years designing products that included riding mowers, and had worked with others in the industry to develop a testing standard to validate plastic fuel tank designs.

Further, the court found that the expert's methodology was sufficiently reliable to render his opinion admissible. The expert relied on adequate facts and data, including accident scene photos, police reports, medical reports and the mower's operator manual. He also inspected the burned mower, performed simulation tests with exemplar mowers and conducted an "engineering analysis" that included use of a three-dimensional model of the mower. While the expert's exemplar testing did not yield the expected fuel tank damage, his engineering analysis found that the crossmember could crush the fuel tank during impact with the ground. Although defendant disputed that conclusion's validity, that disagreement went to the weight of the expert's opinion, not its admissibility. Similarly, the fact that the expert did not follow specific fire investigation procedures or consider other potential ignition sources also only affected the opinion's weight.

Because the court found the expert's opinion admissible, the court denied defendant's summary judgment motion based on the absence of admissible expert opinion.

New Jersey Federal Court Holds (1) Claims EV Manufacturer Overstated Battery Range Under Its Test Methods In Advertisements Not Preempted By EPA And FTC Regulations, As Those Only Governed EPA-Mandated New Vehicle Sticker And Claims Regarding EPA-Method Range; (2) Plaintiffs Adequately Pled Breach Of Express Warranty, Negligent Misrepresentation And Consumer Protection Claims By Identifying Specific Misrepresentations And Pleading Defendant's Knowledge Of Overstatement; and (3) Breach Of Implied Warranty Of Merchantability Claim Failed As Cars Were Still Fit For Ordinary Purpose Of Providing Transportation

In *Hurst v. BMW of N. Am., LLC*, Civil Action No. 22-03928, 2024 U.S. Dist. LEXIS 104516 (D.N.J. June 11, 2024), plaintiffs purchased electric cars with "range extenders," small gasoline engines that increased the cars' driving range beyond that achieved by battery alone. Before purchasing their cars, plaintiffs allegedly read and relied on statements by the manufacturer that the cars had a range of 80 miles on battery alone and 150 miles with the range extender, but after purchase plaintiffs discovered that the stated electric range was based on ideal conditions, while the winter cold typical in their home states of New Jersey and Colorado yielded far less. Plaintiffs thus brought a putative class action against the manufacturer in the United States District Court for the District of New Jersey, and in their amended complaint asserted claims for breach of express warranties, breach of the implied warranty of merchantability, negligent misrepresentation and unfair and deceptive practices in violation of the New Jersey and Colorado consumer protection statutes. Defendant moved to dismiss for failure to state a claim.

Defendant first argued plaintiffs' claims were preempted by regulatory schemes of both the United States Environmental Protection Agency ("EPA") and Federal Trade Commission ("FTC"). Under the Energy Policy and Conservation Act ("EPCA"), EPA regulates fuel economy and driving range statements in mandatory "Monroney stickers" displayed on the window of for-sale automobiles, and the statute expressly preempts any state law requirements that differ from EPA's. Since plaintiffs' amended complaint did not attack any statements in defendant's Monroney stickers, however, the EPCA did not preempt their claims.

FTC regulations go beyond Monroney stickers and apply to all advertisements about fuel economy and vehicle range. While defendant argued plaintiffs' claims were impliedly preempted because they conflicted with FTC regulations controlling how EPA-estimated vehicle range can be advertised, plaintiffs challenged defendant's range statements that were based on in-house testing rather than the EPA's methodology, so there was no conflict and no preemption.

Regarding the adequacy of plaintiffs' pleading, the court rejected defendant's argument that plaintiffs had not sufficiently identified any express warranty on which they relied, as the amended complaint included numerous references to defendant's representations regarding the cars' range. In addition, because plaintiffs alleged defendant knew its vehicles had a lower-than-advertised range in cold weather, plaintiffs had adequately pled their negligent misrepresentation and consumer protection claims.

The court did, however, dismiss plaintiff's implied warranty of merchantability claim. Under the Uniform Commercial Code as adopted by New Jersey (the court did not address Colorado, but presumably its law was the same), the sale of goods by a commercial seller includes an implied warranty that they are "fit for the ordinary purposes for which such goods are used." While plaintiffs argued the cars' diminished range made them unfit for daily commuting, case law held that vehicles were unfit only where they could not provide transportation at all, which was not the case under plaintiffs' allegations.

New York Appellate Division Holds Expert Testimony Regarding Disease Causation By Mold Exposure Inadmissible, As Proffered Scientific Literature And Expert Testimony Did Not Show General Causation Opinion Had Gained General Acceptance In Scientific Community, And Expert Failed To Quantify Plaintiff's Exposure And Therefore Could Not Establish Specific Causation

In *Buist v. Bromley Co., LLC*, 209 N.Y.S. 3d 98 (2d Dep't 2024), plaintiff sued her building developer and management company in the New York Supreme Court for Kings County, alleging she suffered toxic encephalopathy, mycotoxicosis, nasal osteochondritis, dermatitis, and rhinosinusitis from mold in her apartment. Defendants moved for summary judgment or, alternatively, to preclude plaintiff's expert's medical causation testimony. After an evidentiary hearing, the trial court concluded the expert's testimony satisfied New York's "general acceptance" standard in accordance with the seminal case of *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), and denied defendants' motion.

On defendants' appeal, the Supreme Court Appellate Division, Second Department, reversed. The court first determined that it had appellate jurisdiction. While pretrial evidentiary rulings ordinarily are not reviewable by interlocutory appeal in New York, here the trial court's order denying exclusion of plaintiff's causation expert "clearly involved the merits of the case and affected a substantial right of the parties," rendering it appealable.

Regarding the merits, the court held that plaintiff's expert's opinions on general and specific causation—two essential elements of every toxic tort case—each did not satisfy *Frye*, which requires the party offering the testimony to show through "texts and scholarly articles on the subject, expert testimony, or court opinions" that the testimony has "gained general acceptance in the relevant scientific field"; a showing that the expert's opinion has only "some support" does not suffice. Whereas defendants' expert relied on a 2006 position paper of the American Academy of Allergy, Asthma and Immunology that controverted plaintiff's expert's opinion that the diseases from which plaintiff allegedly suffered could be caused by mold exposure, plaintiff's expert cited no scientific literature or testimony in support of her opinion.
As to specific causation, the New York Court of Appeals' decisions in *Parker v. Mobil Oil Corp*., 7 N.Y.3d 434 (2006), and *Nemeth v. Brenntag N. Am.*, 38 N.Y.3d 336 (2022), hold that a toxic tort plaintiff cannot prove such causation by expert testimony that exposure to a toxin was "excessive" or "far more" than background, or that "merely links a toxin to a disease or works backwards from reported symptoms to divine an otherwise unknown concentration of a toxin"; rather, plaintiff must offer evidence that she was exposed to levels of the allegedly toxic substance that are known to cause the kind of harm that she suffered. In this case, because plaintiff's expert only used the technique of differential diagnosis (here, strictly speaking, differential etiology) to conclude that mold caused plaintiff's injuries, and "failed to quantify the plaintiff's exposure to mold," the testimony was insufficient to prove specific causation.

New York Federal Court Rejects Second Plaintiffs' Attempt In MDL To Introduce Expert Testimony That Prenatal Exposure To Acetaminophen Is Capable Of Causing ADHD Because Expert Failed Adequately To Account For Possible Confounding By Genetic Causation, And Analysis Of Bradford-Hill Causation Criteria Such As Temporality And Dose-Response Relationship Ignored Critical Information And Thus Displayed Results-Oriented Reasoning

In *In re Acetaminophen–ASD–ADHD Products Liability Litigation*, No. 22md3043 (DLC), 2024 U.S. Dist. LEXIS 121259 (S.D.N.Y. July 10, 2024), plaintiff children (or their parents or guardians) in a multi-district litigation ("MDL") pending in the United States District Court for the Southern District of New York sued manufacturers and retailers of store-branded acetaminophen products, alleging the children suffered autism spectrum disorder ("ASD") and attention deficit hyperactivity disorder ("ADHD") from pre-natal exposure to the products and the product labeling was deficient under various state laws. In an earlier ruling, the court excluded the causation opinions of five experts proffered by plaintiffs on the grounds that the experts, among other things, failed adequately to consider the potential confounding role of genetics in causing the children's conditions. *See Product Liability Update – January 2024*. Subsequent MDL plaintiffs then offered general causation testimony from a different expert—an M.D./M.P.H. whom the court characterized as an "esteemed epidemiologist" with expertise

in “women’s health and epidemiology”—that prenatal acetaminophen exposure is capable of causing ADHD, and defendants moved to exclude that expert’s testimony under Federal Rule of Evidence 702 as unreliable.

The court granted defendants’ motion, noting initially that, as recently reemphasized in the December 1, 2023 amendments to Rule 702, judicial gatekeeping with respect to expert testimony is essential, as jurors’ lack of specialized knowledge may prevent them from evaluating “meaningfully the reliability of scientific and other methods underlying expert opinion.” The amendments also clarified that in its gatekeeper role the court must ensure that the proponent of expert testimony demonstrates by a preponderance of the evidence that the testimony is admissible. Here, the proffered testimony was unreliable, and thus inadmissible, for two independent reasons.

First, the expert failed to grapple adequately with studies showing that ADHD can result from genetic confounding as opposed to prenatal acetaminophen exposure. While she acknowledged that genetic confounding might “partially inflate” the observed association between prenatal exposure and ADHD, she opined based on three studies that there was no data showing genetics was the “most likely” explanation. In a detailed discussion, however, the court found her analysis of each study flawed. For example, she relied on one study’s finding of an increased ADHD risk with maternal acetaminophen use compared to no such use, but ignored the same study’s finding that a father’s pre-conception acetaminophen use was as strongly associated with ADHD as a mother’s use in any trimester or any two trimesters combined, which raised a question of genetic rather than acetaminophen causation. The expert also ignored a recent and large-scale NIH-funded study finding there was no association between acetaminophen and ADHD when genetic confounding was accounted for by analyzing 31,000 siblings.

Second, the expert’s Bradford Hill analysis—a nine-factor analysis used by epidemiologists to discern actual causation from mere statistical association—was deficient under Rule 702, as her treatment of the three factors she testified were most important—consistency (across multiple studies), temporality (the suspected cause precedes the observed effects) and dose-response (greater exposures demonstrate greater risk)—displayed “result-oriented reasoning.” For example, the expert claimed a temporal relationship existed because multiple studies showed an association between ADHD and acetaminophen use in the third trimester, when the prefrontal cortex—the brain region most important for ADHD—is most sensitive to disruption. In so claiming, however, the expert cited a finding in one study of a high risk ratio between a child’s use of ADHD medication and third trimester exposure, but ignored another finding in the same study that the risk ratio for an actual diagnosis of hyperkinetic disorder (“HKD”), the World Health Organization disease classification term for ADHD, was not statistically significantly elevated for third trimester exposure and was actually higher for the first trimester. And as to any dose-response, the expert relied most heavily on studies that failed to address the impact of genetic confounding.

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

David R. Geiger
Practice Group Chair and Update Editor

Matthew C. Baltay

Kristyn Bunce DeFilipp

Jonathan M. Ettinger

Christopher E. Hart

Matthew E. Miller

Creighton K. Page

Madeleine Rodriguez

Peter A. Sullivan

Shrutih V. Tewarie

Colin J. Zick

James M. Gross
Associate Editor

Fernando Berdion-Del Valle

Jasmine Brown

Monica Frascona

Christian A. Garcia

Caroline Holliday

Marilyn Icsman

Rachel Kerner

Aaron Lang

Leah Rizkallah

Nicole Smith

FOLEY HOAG