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

First Circuit Holds Putative Class Action Claims Alleging Deceptive Practices In Labeling of Lactase Product As Dietary Supplement Instead Of Drug When Product Claimed To Treat Lactose Intolerance (Allegedly A Disease), And Disclaiming United States Food & Drug Administration (FDA) Approval, Both In Violation Of Federal Food, Drug, And Cosmetic Act (FDCA), Impliedly Preempted, As FDCA Limits Enforcement To FDA And Thus Preempts State Law Claims Predicated Solely On FDCA Violations

In *Dicroce v. McNeil Nutritionals, LLC*, 82 F.4th 35 (1st Cir. 2023), plaintiff brought a putative class action in the United States District Court for the District of Massachusetts alleging a manufacturer mislabeled its dietary supplement consisting of lactase and recommended to manage lactose intolerance in violation of Mass. Gen. L. ch. 93A, the state unfair and deceptive trade practices statute. Plaintiff alleged that lactose intolerance is a "disease" under the Federal Food, Drug, and Cosmetic Act ("FDCA"), and the label's claim to treat that disease rendered the product a drug requiring approval by the United States Food and Drug Administration ("FDA"); accordingly, defendant mislabeled its product both by terming it a dietary supplement and by disclaiming FDA approval, which suggested such approval was not required.

Defendant moved to dismiss the complaint both for failure to state a claim and as preempted by the FDCA. The district court granted the motion on the first ground without reaching the second, finding that "no reasonable consumer could find [defendant's] label deceptive" because it contained a disclaimer stating it was not a drug and was not intended to treat any disease, nor would her purchasing decision be swayed by the alleged fact that the product required FDA regulation as the label expressly disclosed FDA had not approved the product.

On plaintiff's appeal, the United States Court of Appeals for the First Circuit affirmed on preemption grounds. The court noted that the FDCA regulates both dietary supplements and drugs, but the statute expressly limits its enforcement to FDA itself and permits no private right of action. For this reason, the court had previously held, citing the seminal United States Supreme Court decision *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), that the FDCA impliedly preempts any state law claims that exist solely by virtue of an FDCA infraction. Here, plaintiff's claims were premised entirely on her belief that defendant's labeling violated the statute, and she

provided no other grounds for her ch. 93A claim, such as that the product did not perform as promised or that consumers were misled for some reason other than the alleged FDCA violation. Indeed, plaintiff's complaint acknowledged that defendant's disclaimer statements were "literally true." Accordingly, plaintiff's claims were preempted.

First Circuit Holds Due Process Forbids Exercise Of Personal Jurisdiction In New Hampshire Over Claims Against Lettuce Distributor And Restaurant Supplier Based On New Hampshire Plaintiff's Purchase And Consumption Of Contaminated Salad From New Jersey Deli, As Neither Distributor's Distribution Of Lettuce Into New England Nor Supplier's Sale of Lettuce To New Hampshire Restaurants Was Sufficiently Related To Plaintiff's Claims

In *Cappello v. Rest. Depot, LLC*, No. 23-1368, 2023 U.S. App. LEXIS 34444 (1st Cir. Dec. 28, 2023), plaintiff, a New Hampshire resident, purchased a salad from a New Jersey deli which caused a life-threatening E. coli infection necessitating removal of his colon. Plaintiff brought claims for strict liability, negligence and breach of warranty in the United States District Court for the District of New Hampshire against the distributor of the lettuce and the restaurant supplier that sold the lettuce to the deli.

The distributor, which was incorporated and based in California, did not ship any products to New Hampshire, although it did ship to six distribution centers in other New England states that made produce available to New Hampshire businesses. The supplier, a Delaware company based in New York, supplied products, including lettuce, to participating New Hampshire restaurants, much as it did to restaurants in New Jersey such as the deli. Both defendants moved to dismiss for lack of personal jurisdiction, and the District Court granted the motions, finding defendants' contacts with New Hampshire not sufficiently related to plaintiff's claims to permit the exercise of jurisdiction consistent with due process.

On plaintiff's appeal, the United States Court of Appeals for the First Circuit affirmed. As to the supplier, plaintiff argued that although it sold the contaminated lettuce he ate in New Jersey rather than New Hampshire, defendant's New Hampshire conduct was sufficiently related to his claims because it also sold lettuce to restaurants there. Plaintiff relied on the United States Supreme Court's decision in *Ford Motor Co. v. Mont. Eighth Jud. Dist. Ct.*, 141 S. Ct. 1017 (2021) (See April 2021 Product Liability Update), which held that Montana and Minnesota courts could exercise jurisdiction over claims by in-state residents against a non-resident auto manufacturer for in-state accidents allegedly due to vehicle defects even though defendant had sold the vehicles in question in a different state, because the manufacturer "systematically served a market" in the states by extensively advertising, selling and providing for dealers' repair and servicing of the same model vehicle there.

The First Circuit, however, distinguished the facts in *Ford*, as the restaurant supplier did not "cultivate a market" for its products in New Hampshire or "extensively promote" sales or service of lettuce there. Further, unlike durable goods such as automobiles, lettuce is consumed only once, and there is no secondary market for the repair and servicing of used lettuce. Further, automobiles "serve to make their consumers mobile (such as between jurisdictions); lettuce does not." Lastly, with respect to plaintiff's breach of warranty claim, none of defendant's New Hampshire contacts was instrumental to plaintiff's purchase of the salad in New Jersey. Accordingly, plaintiff's claims were not sufficiently related to the supplier's New Hampshire contacts to satisfy due process.

Regarding the lettuce distributor, the connection between plaintiff's claims and any New Hampshire conduct by defendant was even weaker, as plaintiff could only point to defendant's distribution of lettuce to other states in New England with knowledge that some of it could be sold in New Hampshire. As "[n]othing about [defendant's] knowledge its lettuce could end up in a salad in New Hampshire was in any way related to the consumption of a salad in New Jersey," due process forbade the exercise of jurisdiction.

Massachusetts Federal Court Denies Summary Judgment To Manufacturer of Retrievable IVC Filter Against (1) Negligent Design Claim, Holding Factual Dispute Exists Whether Permanent Filters Represent Alternative Design Or Different Product, (2) Strict Liability-Equivalent Design Defect Claim, Refusing To Extend "Comment k" Strict Liability Exemption For Prescription Drugs To Prescription Medical Devices, And (3) Negligent Failure-To-Warn Claims, Holding Expert Testimony Of Warning Inadequacy Sufficient And Presumption Physician Would Have Heeded Adequate Warning And Ambiguity In Physician's Testimony Regarding Effect Of Disclosure Of Comparative Fracture Rates Created Fact Dispute On Causation

In *Knights v. C.R. Bard Inc.*, Civil Action No. 19-11911-FDS, 2023 U.S. Dist. LEXIS 167161 (D. Mass. Sep. 20, 2023), plaintiff sued the manufacturer of a "retrievable" inferior vena cava ("IVC") filter, *i.e.*, one that could either be left in the body permanently or removed if needed, in the United States District Court for the District of Massachusetts after the filter allegedly fractured and perforated her right ventricle, requiring surgical removal of the filter and separated fragment. Defendant moved for summary judgment on all of plaintiff's claims, and plaintiff withdrew all but her claims for negligent design and failure to warn, breach of express warranty that the device was safe and effective, and breach of the implied warranty of merchantability (the Massachusetts near-equivalent of strict liability) based on design defect.

In response to defendant's argument that plaintiff had no evidence of a feasible and safer alternative design as required for a negligent design defect claim, plaintiff pointed to defendant's earlier permanent filters, which had lower rates of fracture. Although defendant cited judicial decisions around the country finding that retrievable and permanent filters were distinct products, such that the latter could not be considered an alternative design for the former, the court concluded there was a material dispute of fact on the issue and denied summary judgment.

Regarding plaintiff's negligent failure-to-warn claim, the court first held plaintiff had sufficient evidence defendant's warning was inadequate for failing to disclose the filter's fracture rate, as two physician experts opined that the warnings were inadequate to warn physicians of the extent of the risk and that this inadequacy prevented plaintiff's physician from making an informed decision whether to use the filter. Defendant then argued plaintiff had no evidence her doctor would not have prescribed the device had he been provided the fracture rates, as he acknowledged he was aware of the risks of IVC filters when he prescribed defendant's device and merely stated that he "would have to study" to decide whether he would have acted differently if given information that defendant's filter was more dangerous than competitors'. The court concluded that once plaintiff met her burden to show an inadequate warning, there was a rebuttable presumption plaintiff's physician would have "heeded" an adequate warning, so this presumption, along with the uncertainty in the physician's testimony and need to draw all inferences in plaintiff's favor, created a factual issue requiring summary judgment denial.

The court did grant summary judgment on plaintiff's express warranty claim, as plaintiff only cited defendant's statement that the filter was "designed to be permanent" (even though it could also be retrieved), but failed to offer any evidence her treating physician relied on that statement in prescribing the filter.

Lastly, defendant argued plaintiff's implied warranty claim—again, in Massachusetts the near-equivalent of strict liability—failed as a matter of law because the filter was "unavoidably unsafe" within the meaning of comment k to Section 402A of the Restatement (Second) of Torts. The comment provides that certain products, often drugs, are incapable of being made safe for their intended use but nonetheless provide substantial medical benefits, so that such products are neither defective nor unreasonably dangerous. Although the Massachusetts Supreme Judicial Court ("SJC") has adopted the comment with respect to prescription drugs, neither the SJC nor the United States Court of Appeals for the First Circuit has addressed whether the comment applies to prescription medical devices, so the court declined to so extend the doctrine and denied summary judgment on plaintiff's implied warranty claim.

Massachusetts Federal Court Holds Swiss Manufacturer Of Allegedly Defective Bicycle Part Did Not Transact Business In-State Under Long-Arm Statute Where Manufacturer Only Advertised Globally And Sold Only To Distributors Outside State; Due Process Did Not Prohibit Jurisdiction Over British Online Seller Of Part As Seller Sent Plaintiff Direct Advertisements In Massachusetts For Product And Created Account Through Which He Bought And Returned Multiple Products, Hence Claim Arose Out Of Seller's Purposeful Availment Of Massachusetts Law And Jurisdiction Was Reasonable, But Jurisdictional Discovery Needed To Determine Whether Claims Satisfied Long-Arm Statute

In *Sheldon v. DT Swiss AG*, Civil Action No. 1:22-cv-11198-IT, 2023 U.S. Dist. LEXIS 169108 (D. Mass. Sep. 22, 2023), plaintiff, a Massachusetts resident, purchased a ratchet wheel-mounting system ("RWS") for his bicycle from the website of a United Kingdom seller with a single brick-and-mortar store located in England. Plaintiff alleged the RWS broke and caused a bicycle accident resulting in serious injuries, and he and his wife brought claims for manufacturing and design defect against the seller and the RWS manufacturer, a Swiss company, in the United States District Court for the District of Massachusetts. Both defendants moved to dismiss for lack of personal jurisdiction.

As to the manufacturer, the court held that Mass. Gen. L. ch. 223A, § 3, the state's long-arm statute providing for jurisdiction over claims "arising from" certain Massachusetts conduct, did not support jurisdiction. Plaintiffs argued their claims arose from the manufacturer's "transacting any business" in the state under § 3(a) of the statute because the manufacturer advertised there, and both sold products and provided repair and warranty services through Massachusetts dealers. The court held, however, that the advertising did not amount to transacting business in the state because it was global in nature and there was no evidence defendant specifically targeted Massachusetts. Moreover, the Massachusetts dealers had no relationship with the manufacturer itself, but rather only with non-Massachusetts third-party distributors over which the manufacturer had no control, and the manufacturer's only service center was in Colorado. And even if the manufacturer had transacted business in Massachusetts, plaintiffs' claims did not arise out of that business because the RWS was purchased from the British seller.

As to the seller, plaintiffs argued that §§ 3(a) and (b) of the long-arm conferred jurisdiction because the seller both transacted business and "contract[ed] to supply services or things" in Massachusetts by selling products to residents through "directed marketing" and providing educational, advisory and return services to such residents. Under Massachusetts Supreme Judicial Court precedent, merely shipping goods to the state through an independent carrier does not qualify as contracting to supply goods "in the Commonwealth." Whether a defendant's Massachusetts contacts are sufficient to constitute transacting business in the state turns on whether the contacts were "deliberate, as distinguished from fortuitous," and while a contract with an in-state party, without more, is viewed as "ancillary activity" that does not trigger jurisdiction, courts can perform a "holistic review" of the parties' relationship and give plaintiff the opportunity to prove their communications with defendant were "beyond the typical" such that the relationship qualifies as transacting business. Because the court found that, depending on the results of further discovery, jurisdiction "may" have been appropriate under § 3(a), it turned to the due process issue.

Personal jurisdiction does not violate due process if a defendant purposefully avails itself of the protections of the forum's laws, plaintiff's claims arise out of or relate to defendant's in-state activities and the exercise of jurisdiction is reasonable. Here, the seller had purposefully availed itself of Massachusetts law by sending bi-weekly newsletters and advertisements to plaintiff, including for the RWS itself, and creating an account for plaintiff through which he made two prior purchases and returns, so that defendant was on notice its products were sold in Massachusetts and it could be subject to claims there. Plaintiffs' claims arose from these Massachusetts contacts because the seller sent advertisements for the RWS directly to plaintiff there and later shipped there. And exercising jurisdiction was reasonable, as the burden imposed on the seller was outweighed by the state's interest in obtaining jurisdiction over a defendant who allegedly caused tortious injury there and plaintiffs' interest in obtaining convenient relief. Accordingly, the court denied the seller's motion to dismiss without prejudice and granted plaintiffs' request for discovery to resolve whether the long-arm statute authorized jurisdiction.

New York Federal Court Rejects Arguments Of Social Media Companies Sued For Video Content Encouraging Plaintiffs' Son's Suicide That New York Municipal And Transit Entities Sued For Failure To Maintain Fencing Were Improperly Joined To Defeat Federal Court Jurisdiction, As All Claims Arose From Same Occurrence, And That Jurisdictional Issue Should Be Transferred For Determination By Court In Multi-District Litigation Where Plaintiffs Originally Sued Before Voluntarily Dismissing

In *Nasca v. Bytedance Ltd.,* No. 23-cv-2786 (NGG) (JMW), 2023 U.S. Dist. LEXIS 193392 (E.D.N.Y. Oct. 27, 2023, the New York parents of a teenager who committed suicide brought a product liability claim in the New York Supreme Court against three related non-resident social media companies, as well as negligence claims against two New York public transit authorities and a New York township, alleging the social media companies promoted videos that persuaded their child to step in front of an oncoming train and the transit authorities and township failed to maintain fences leading to the railroad tracks. The parents had initially sued the social media companies in a California federal court, but the suit was transferred for pretrial management to a federal multidistrict litigation ("MDL") in the state involving approximately 200 similar claims against the companies, and plaintiffs voluntarily dismissed that suit without prejudice before refiling it in the New York court.

The social media companies removed the case to the United States District Court for the Eastern District of New York, claiming jurisdiction under 28 U.S.C. § 1332(a)(1) on grounds of diversity of the parties' citizenship, and plaintiffs moved to remand to state court, arguing among other things that the transit authorities' and township's New York citizenship precluded removal under 28 U.S.C. § 1441(b)(2), which prohibits removal if "any of the parties in interest properly joined and served" is a forum state citizen. The social media companies responded that plaintiffs had improperly joined the New York entities to circumvent federal jurisdiction, and under binding precedent of the United States Court of Appeals for the Second Circuit the case should be transferred to the MDL judge to resolve the jurisdictional issue.

A federal magistrate judge recommended rejecting both of the social media companies' arguments, and the federal district judge adopted the recommendation in full and remanded. The court first held that both the plain text of the removal statute, 28 U.S.C. § 1441(a), addressing removal of "any civil action brought in a State court," as well as interests of comity and federalism require federal courts to determine whether a party is "properly joined" by reference to state law. New York's CPLR § 1002(b), in turn, permits joinder of all defendants "against whom there is asserted any right to relief jointly, severally, or in the alternative, arising out of the same transaction, occurrence, or series of transactions or occurrences," which courts have interpreted as requiring (1) a single event (or related series of events) involving all parties and (2) "at least one question of law or fact that links the claims among all the parties." Because plaintiffs' claims against the social media companies, transit authorities, and township were all "based on the single occurrence of their [child's] premature death," and because those various claims would present at least one common question of law or fact—the Court noted that "both defendants will likely introduce experts discussing suicide in teens," along with other overlapping proximate causation issues—joinder was proper.

The court also rejected the social media companies' argument that under *In re Ivy*, 901 F.2d 7 (2d Cir. 1990), the case was required to be transferred back to the California MDL and the jurisdictional arguments determined by the MDL judge. *Ivy* did not establish a bright-line rule requiring transfer to the MDL court of all related cases for jurisdictional assessments, but rather only when such a transfer would promote judicial efficiency. Because the improper joinder arguments made by the social media companies here turned on issues of state law, and the MDL court currently only faced one similar question in a case involving New Mexico law, transfer would not promote judicial efficiency.

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New York Federal Court Holds All Of Plaintiffs' Expert Testimony That Prenatal Exposure To Acetaminophen Caused Autism Spectrum Disorders and ADHD Unreliable And Hence Inadmissible; As Example, One Expert Applied Bradford Hill Causation Criteria To Neurodevelopmental Disorders, Including Autism And ADHD, Collectively Rather Than Separately, That Disorders In Studies Were Diagnosed Following Maternal Acetaminophen Use Did Not Address Whether They Only Developed After That Use And Expert Did Not Sufficiently Consider Evidence Regarding Potential Confounding Role Of Genetic Causation

In *In re Acetaminophen – ASD – ADHD Products Liability Litigation*, No. 22-md-3043 (DLC), 2023 U.S. Dist. LEXIS 224899 (S.D.N.Y. Dec. 18, 2023), a consolidated multi-district litigation ("MDL") in the United States District Court for the Southern District of New York consisting of more than 600 cases, numerous children and their parents and guardians sued a manufacturer and retailers of acetaminophen products that plaintiffs alleged caused the children to develop autism spectrum disorder ("ASD") and/or attention-deficit/hyperactivity disorder ("ADHD"). Plaintiffs asserted multiple state law claims, including strict liability for failure to warn and design, negligence, negligent misrepresentation and breach of implied warranty. In support of those claims, plaintiffs offered testimony from five expert witnesses, each of whom sought to opine that there is a causal link between prenatal exposure to acetaminophen and ASD and/or ADHD. Following expert reports and depositions, defendants moved to preclude the testimony of all five experts as lacking in reliability and hence inadmissible under Federal Rule of Evidence 702.

In a 150-page, detailed and highly fact-specific opinion, the court granted defendants' motions in full, holding that while each expert was "eminently qualified," each of their causation opinions lacked support in the existing scientific literature, was not the product of a methodology generally accepted by the scientific community, and otherwise only "obscured instead of informing the inquiry on causation." After excluding the experts' testimony, the plaintiffs were left without any "admissible evidence to demonstrate that prenatal exposure to acetaminophen causes either ASD or ADHD in offspring," suggesting that summary judgment would be appropriate on plaintiff's claims.

The court's treatment of the proposed testimony of one of plaintiffs' experts, a physician holding a Ph.D. in toxicology and occupational health and M.S. in epidemiology in addition to his medical degree, is illustrative of the court's approach. The expert testified that, among another methodology, he weighed the so-called Bradford Hill factors—a non-exhaustive nine-factor test that epidemiologists use to distinguish an actual causal connection from a mere association, which includes the criteria "strength of association," "consistency," "dose-response," "biological plausibility," "temporality," "coherence," "specificity," "analogy," and "experimental evidence"—and concluded that eight of the factors (all but specificity) were satisfied when analyzed with respect to whether prenatal acetaminophen exposure causes neurodevelopmental disorders "as a group," which would include ADHD, ASD, and/or symptoms consistent with those disorders in children, thereby demonstrating a "causal association" between acetaminophen and ASD and/or ADHD. Defendants argued that the expert's Bradford Hill analysis was unreliable, including because he cherry-picked and misrepresented study results, failed to consider sufficiently the role of genetics in the etiology of ASD and ADHD and otherwise elided meaningful differences between the two disorders.

In excluding the expert, the court generally agreed with defendants. The court began by noting that because a Bradford Hill analysis is intended to analyze causation with respect to "*an* association," rather than multiple associations, the expert's attempt to apply a Bradford Hill analysis to multiple associations at once— neurodevelopmental disorders including ASD and ADHD—lacked reliability, as the conjoined analysis obscured limitations in the scientific data pertaining to any individual association.

As for the expert's treatment of the Bradford Hill factors, the expert's conclusions as to all eight he deemed satisfied were unsupported by the studies he cited. For instance, the expert concluded that "temporality" was satisfied because prenatal use of acetaminophen has already occurred by the time a child is diagnosed with ADHD or ASD. The court, however, concluded that this factor required "a more rigorous

analysis," as the relevant question was not whether the exposure precedes the diagnosis of a disorder, but rather whether it precedes the disorder's development. Given that some of the studies the expert relied upon collected data about acetaminophen use at various stages of pregnancy, a reliable assessment temporality "would engage with the fact that it is not currently known when either ASD or ADHD develop in the fetal brain, and with the possibility that some studies measured acetaminophen use before or after the development window."

Finally, the expert's Bradford Hill analysis was unreliable because the expert failed "to assess with sufficient rigor the relevant evidence of confounding by genetics." Because that evidence could partially explain the observed associations and thus undercut the expert's opinion, he appeared to have departed "from settled and rigorous methodology" and instead engaged in "motivated, result-driven reasoning," which was an independent basis for excluding his opinion. Overall, the expert's testimony "[did] not reflect a reliable application of scientific methods" and was thus inadmissible under Rule 702.

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