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 Supreme Judicial Court Holds State Law Claims Against Manufacturer Of FDA-Approved Medical Device "Parallel" Federal Law Requirements And Hence Are Not Preempted Despite Failure To Identify Requirements Allegedly Violated, But Claims Not Adequately Pled As Allegations Of Inadequate Warning, Adulterated Product and Causation Were Mere "Labels and Conclusions" Without Factual Allegations Making Claims Plausible

In *Dunn v. Genzyme Corporation*, 486 Mass. 713 (2021), a patient sued the manufacturer of a knee injection medical device in Massachusetts Superior Court, alleging that immediately after her injections she suffered pain that led to falls, hospitalization and other injuries. She asserted claims, among others, for negligence, breach of the implied warranty of merchantability (the Massachusetts near-equivalent of strict liability) and unfair and deceptive practices in violation of Mass. Gen. L. ch. 93A because the device was not accompanied by proper warnings, and was "adulterated" and thus defectively manufactured, with no further details other than that this conduct was in violation of the United States Food and Drug Administration ("FDA")'s current good manufacturing practices and labeling regulations.

Because the device had received premarket approval from the FDA as a Class III medical device, and because the Federal Food, Drug, and Cosmetic Act ("FDCA") preempts state law requirements that are "different from, or in addition to" requirements under the FDCA, defendant moved to dismiss plaintiff's claims as preempted and as failing to plead sufficient facts to state a claim under state law. The trial court denied the motion, holding plaintiff's allegations sufficient in light of the disparity in information available to plaintiff and the manufacturer. After defendant appealed to the Massachusetts Appeals Court, the Massachusetts Supreme Judicial Court ("SJC") granted direct appellate review on its own motion.

Regarding preemption, the court first noted that the United States Supreme Court has held the FDCA does not preempt state law claims that merely "parallel" federal requirements, but also noted there was no consensus in either the federal or Massachusetts courts as to how much specificity a plaintiff's allegations needed to avoid preemption. The court then rejected case law that required plaintiff to identify the specific federal requirements defendants allegedly violated as inconsistent with what the court termed "our ordinary, notice-pleading standard" under *Iannacchino v. Ford Mtr. Co.*, 451 Mass. 623 (2008), the leading SJC case governing pleading adequacy.

Because plaintiff's general allegations were "consistent with" state law claims that "can be interpreted as coextensive with" governing federal requirements, she sufficiently alleged "parallel," non-preempted claims.

On the other hand, the court held plaintiff failed to allege sufficient facts to plead a state law claim under *Iannacchino*, which requires "factual allegations plausibly suggesting (not merely consistent with) an entitlement to relief." Here, plaintiff's assertions of "significant dangers" that were not warned of, or an "adulterated" product, were supported by "[no] factual allegations . . . to ground these labels and conclusions," and her allegation of causation was particularly deficient, as it impermissibly relied solely on "the temporal proximity between the injections . . . and [her] injuries." Interestingly, the court did not explain why in this portion of its opinion it characterized *Iannacchino* as establishing a "plausibility standard" under which allegations that were "merely consistent with[] an entitlement to relief" were insufficient, while in its preemption discussion it characterized *Iannacchino* as establishing a "notice-pleading standard" and held that allegations that were merely "consistent with" parallel claims did suffice.

Lastly, the SJC rejected the trial court's reasoning that plaintiff's ostensibly limited access to information about the injections' manufacturing could "somehow justify[]" plaintiff's "bare-bones complaint," agreeing with defendant that "a lack of access to information at the pleading stage does not nullify a plaintiff's pleading obligations."

Members of **Foley Hoag's Product Liability and Complex Tort Practice Group** filed an *amicus curiae* brief on behalf of Washington Legal Foundation ("WLF") in the case, supporting the defendant's position.

## Massachusetts Federal Court Holds No Jurisdiction Over Manufacturer And Distributor Defendants Under Long-Arm Statute For Claims Involving In-State Injury From Out-Of-State Design, Manufacture, Warnings And Sale Where Only Basis For Finding Regular Massachusetts Contacts Was Retailer's Characterization Of Product As "Featured," And Due Process Forbids Jurisdiction Since Claims Did Not Arise Out Of Or Relate To Any In-State Conduct By Defendants

In *Ericson v. Conagra Foods, Inc.*, No. 1:20-cv-11022-ADB, 2020 U.S. Dist. LEXIS 219813 (D. Mass. Nov. 24, 2020), plaintiff sued the designer, manufacturer and distributor of a cooking spray can that allegedly ruptured and sprayed its contents, causing a flash fire that burned plaintiff. Plaintiff had purchased the spray at a Massachusetts store of a national restaurant supply chain and suffered her injuries in Massachusetts, and brought multiple tort claims, including for design, manufacturing and warning defects, as well as for unfair and deceptive trade practices in violation of Massachusetts Gen. L. ch. 93A, in the United States District Court for the District of Massachusetts. As the manufacturer was an Illinois corporation that made the can in Illinois, and the designer and distributor were both Delaware corporations based in Illinois that had sold the can to the restaurant supply chain in New York, defendants moved to dismiss for lack of personal jurisdiction.

The court first analyzed jurisdiction under Massachusetts' long-arm statute, which provides that a court may exercise jurisdiction over a corporation that causes tortious injury in Massachusetts by an act or omission outside it if defendant "regularly does or solicits business or engages in any other persistent course of conduct, or derives substantial revenue from goods used or consumed" in Massachusetts. While plaintiff alleged defendants sold the cooking spray as a "featured brand" in Massachusetts based on the fact that the retailer had so listed it, and asked the court to infer that "sales of a featured brand at the Massachusetts locations of a national retailer are not insubstantial as a matter of law," the court rejected this attempt to satisfy the statute on the ground that it was "based solely on unsupported assertions and inferences."

The court then held that regardless of the long-arm result, the court would lack jurisdiction under the due process

clause, which requires that plaintiff's claims directly arise out of or relate to defendants' in-state activities, defendants have purposefully availed themselves of the privilege of conducting business in the forum and the exercise of jurisdiction be reasonable. Here, plaintiff's claim did not arise out of or relate to defendants' Massachusetts conduct as they had not designed, manufactured or sold the spray can there. And while plaintiff argued defendants purposefully availed themselves of Massachusetts because they presumably knew their spray would be sold there, such a "stream of commerce" theory could not establish purposeful availment without additional "plus factors," such as advertising the product in or designing it for the forum market, which plaintiff had not shown.

Lastly, while plaintiff requested that she at least be permitted jurisdictional discovery, the court held she had not demonstrated that facts supporting jurisdiction would be found if discovery were permitted, hence that would constitute an impermissible "fishing expedition."

### Massachusetts Federal Court Holds "Made From Real Ginger" Label On Ginger Ale Not Fraudulent Or Deceptive Where Product Contained Some Ginger-Derived Flavoring, As Label Was Literally True And No Reasonable Consumer Would Interpret It As Promising Actual Ginger Root Or Its Associated Health Benefits

In *Fitzgerald v. Polar Corp.*, No. 20-10877-RGS, 2020 U.S. Dist. LEXIS 210157 (D. Mass. Nov. 10, 2020), a consumer brought a putative class action in the United States District Court for the District of Massachusetts against a soft drink manufacturer for fraud, breach of express and implied warranties, negligent misrepresentation, unjust enrichment and violation of Mass. Gen. L. ch. 93A, the Massachusetts unfair and deceptive trade practices statute. Plaintiff alleged that defendant falsely labeled, advertised and marketed its ginger ale as "made from real ginger." While conceding that the product contained a "miniscule amount of a ginger flavor extract," she asserted the label was misleading because it led her to believe the soda was made using actual ginger root and was thus a healthy alternative to regular sodas. Defendant moved to dismiss on the ground that its ginger ale was in fact made using some ginger.

The court first dismissed plaintiff's fraud and negligent misrepresentation claims, as both required an actual false representation of material fact. Here, plaintiff conceded the product contained some ginger, and that defendant had made no representation regarding its specific amount. Nor could any reasonable consumer rely on a claim of "real ginger" in a soft drink to mean it contained actual chunks of ginger root, as opposed to ginger-derived flavoring. The court dismissed plaintiff's claims for breach of express and implied warranties and for unjust enrichment based on the same lack of actual falsity.

In support of her ch. 93A claim, plaintiff argued defendant's labeling, even if not technically false, was nonetheless deceptive. The court, however, rejected the notion that consumers would interpret the phrase "made from real ginger" to mean that a soft drink contained ginger root or imparted the health benefits associated with that substance. Rather, any reasonable consumer "would know ginger ale for what it is – a carbonated drink with ginger flavoring and probably containing an unhealthy amount of sugar." The court thus dismissed plaintiff's complaint in its entirety.

## NEW YORK/NEW JERSEY SUPPLEMENT

### Second Circuit Holds Trial Court Properly Excluded Experts' General Causation Opinions For Failing To Reliably Apply Scientific Methodologies—Which Trial Court Noted Included Failing To Consider Known Contrary Evidence And Citing Study For Conclusion Not Reached—And Identify Supporting Studies, And Properly Granted Summary Judgment For Lack Of Proof Of General Causation

In *Coning v. Bayer Pharma AG (In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig.*), 982 F.3d 113 (2d Cir. 2020), a multi-district litigation consolidated for pre-trial proceedings in the United States District Court for the Southern District of New York, plaintiffs alleged an intrauterine device caused their idiopathic intracranial hypertension ("IIH"). Following a hearing on cross-motions under *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993), and Fed. R. Evid. 702 to exclude expert opinions as lacking in scientific reliability, the district court excluded plaintiffs' general causation experts and granted the manufacturer's subsequent summary judgment motion.

On plaintiffs' appeal, the United States Court of Appeals for the Second Circuit first held the trial court had not abused its discretion in excluding plaintiffs' experts. Plaintiffs' argument that the court had improperly taken a "hard look" at the experts' methodology failed because courts are required to conduct a "rigorous examination" of expert evidence to ensure reliability. While plaintiffs argued the court had improperly focused on the experts' ultimate conclusions rather than methodologies, its opinion had in fact repeatedly identified flaws in the experts' methodologies and how they applied them. For example, the court noted one expert's "serious methodological deficiencies" that included "an unweighted and unmoored application of the nine Bradford Hill factors [for assessing general causation], a failure to consider known contrary evidence, a contravention of principles [the expert] has acknowledged should guide an epidemiologist's inquiry, a selective use of case report data, a lack of qualification to opine on biological mechanisms by which [the device] might cause IIH, and the citation of [a study] for propositions that it did not find."

Further, regarding plaintiffs' complaint that the trial court had improperly required the experts to identify studies that "definitively" supported their conclusions, there was no abuse of discretion. While the absence of supporting studies typically goes to weight rather than admissibility, such absence could serve as a basis for excluding opinions where, as here, the court found the expert did not reliably use scientific methods. In addition, the absence of supporting studies could show the experts' conclusions were not generally accepted by the scientific community, a factor courts may consider under *Daubert* in deciding whether to admit expert testimony.

The court then affirmed the entry of summary judgment in light of plaintiffs' lack of evidence of general causation, *i.e.*, whether the product at issue is capable of causing the plaintiff's condition. Plaintiffs failed to identify any jurisdiction where general causation evidence is not required on complex product liability or medical issues. That some states allow specific causation evidence, *i.e.*, whether the product actually caused the specific plaintiff's condition, before or contemporaneously with general causation evidence does not alter the fact that general causation evidence is universally required.

Further, plaintiffs' argument that the trial court improperly excluded all, rather than only portions, of the experts' opinions did not overcome their lack of general causation evidence because plaintiffs neither identified what portions of the opinions should have been admitted nor explained how they would have established general causation. And plaintiffs' complaint that the trial court improperly excluded "differential diagnosis" evidence likewise did not overcome the lack of general causation evidence. Differential diagnosis, as the term is used in product liability cases, typically involves reaching a conclusion of specific causation by attempting to identify through a process of elimination which among the known causes of a disease caused it in the particular plaintiff (hence this Update prefers the term "differential etiology" or "differential causation"). While no bright line rule prohibits the use of differential diagnosis to prove general causation, the trial court did not abuse its discretion in excluding the evidence where plaintiffs failed to explain "how the rigor of the differential diagnosis performed, the expert's training and experience, the type of illness or injury at issue, or some other case-specific circumstance militates in favor of admitting that evidence to establish general causation."

Finally, while plaintiffs argued they were denied general causation discovery needed to oppose summary judgment—including discovery related to defendants' other contraceptive devices that used the same active ingredient—the trial court did not abuse its discretion in managing discovery. Rather, it had properly evaluated both relevance and proportionality in resolving numerous discovery disputes, and ordered defendants to produce millions of documents from over 50 custodians, including eleven not originally identified.

## New York Federal Court Holds Allegation Of "Natural" Label Despite Synthetic Ingredients Adequately Pleads State Deceptive Practices And False Advertising Claims, Express Warranty Claim Fails For Conclusory Pleading Of Notice Of Breach Within Reasonable Time And "Natural" Was Not Promise Of Freedom From Defect Or Specific Performance Level So As To Constitute Warranty Under Magnuson-Moss Warranty Act

In *Grossman v. Simply Nourish Pet Food Co.*, No. 20-CV-1603, 2021 U.S. Dist. LEXIS 15864 (E.D.N.Y. Jan. 27, 2021), plaintiff filed a putative class action in the United States District Court for the Eastern District of New York

against a pet food manufacturer and a retailer, alleging they falsely and deceptively represented that 99 of their pet food varieties were made from "natural" ingredients even though they contained synthetic ones. Plaintiff asserted claims for deceptive consumer practices under New York General Business Law ("GBL") § 349, false advertising under GBL § 350, breach of express warranty under state law, breach of warranty in violation of the Magnuson-Moss Warranty Act ("MMWA"), 15 U.S.C. § 2301, and unjust enrichment. She sought a class-wide injunction that defendants correct their practices, and damages for alleged overpayment for the products. Defendants moved to dismiss for lack of standing and failure to state a claim.

Regarding standing, the court agreed plaintiff lacked standing to seek an injunction due to her lack of imminent risk of injury, as she now knew the products included synthetic ingredients. She did have standing to seek classwide damages for the 97 pet food varieties she did not purchase, however, because her complaint alleged sufficient similarity between those products and their labeling to the ones she did purchase, and any differences could be addressed at the class certification stage.

Regarding the motion to dismiss, the court denied it as to plaintiffs' deceptive practices and false advertising claims, both of which require proof of misleading conduct. Plaintiff plausibly alleged a reasonable consumer might be misled by "natural" to believe the products contained no synthetic ingredients, and the words "added vitamins and minerals" in close proximity did not alter the result because the consumer could reasonably believe those ingredients were also natural (and at least some of the products did not even include that language). Nor could the court conclude as a matter of law that the packaging's ingredient list would render unreasonable a belief that no synthetic substances were present. And while guidelines of a regulatory officials' association cited by defendants as discussing 'natural' claims might be relevant at trial, they were not at the pleading stage where the only question was reasonable consumer belief.

The court then dismissed all of plaintiff's remaining claims. On the state law warranty claim, while "natural" was a factual representation that would create an express warranty, plaintiff's conclusory assertion that "within a reasonable time" after she knew or should have known of the breach she "placed Defendants on notice of [it]" did not provide sufficient details to demonstrate compliance with New York Uniform Commercial Code § 2-607(3)'s requirement of such notice. The court did give plaintiff leave to amend her complaint to add such details.

For different reasons, the "natural" representation did not support a warranty claim under the MMWA. That statute defines a written warranty as a promise that "material or workmanship is defect free or will meet a specified level of performance over a specified period of time," which "natural" did not do. The court acknowledged its approach diverged from that of some courts that have declined to separately assess MMWA claims where a state law express warranty claim is adequately pled on the theory that those two claims either "stand or fall together."

Finally, plaintiff's unjust enrichment claim failed as it arose out of the same alleged facts as her other state law claims, and plaintiff failed to show how it differed from them. An unjust enrichment claim is not available where the alleged conduct is governed by tort or contract law, even if the tort or contract claim is ultimately dismissed.

### New York Federal Court Permits Defendants' Partially Destructive Testing Of Allegedly Defectively Manufactured Cooking Spray Can, As Its Thickness Was Directly Relevant To Defense That Can Was Within Specifications And Plaintiff Did Not Show Prejudice Or Propose Viable Alternative To Obtain Desired Evidence

In *Bozick v. Conagra Foods, Inc.*, No. 19-cv-4045, 2020 U.S. Dist. LEXIS 223770 (S.D.N.Y. Nov. 20, 2020), plaintiff brought a manufacturing defect claim in the United States District Court for the Southern District of New York against the designer and manufacturer of a cooking spray can that allegedly exploded in plaintiff's kitchen and caused serious injuries. While the can warned against placing it near a heat source, plaintiff claimed the can was away from heat when it exploded and that its bottom buckled and vented at ordinary room temperatures because it was manufactured grossly out of specification.

In discovery, defendants moved to have an independent laboratory inspect the can, which plaintiff had retained.

Measuring the bottom's thickness would require cutting into it, and plaintiff objected to such destructive testing. The court then applied a four-part test that other federal courts have used to decide whether to permit destructive testing: whether the proposed testing is reasonable, necessary and relevant to proving the movant's case, whether it would hinder the opposing party's ability to present evidence at trial or otherwise cause prejudice, whether there are less prejudicial alternatives to obtain the evidence sought and whether there are adequate safeguards to minimize any prejudice to the opposing party.

Here, the proposed testing was directly relevant and necessary to support defendants' theory that the can was not out of specification, and thus that any explosion was indeed caused by high temperatures. While plaintiff's experts opined that the testing would not detect the kind of flaws she claimed had caused the explosion, plaintiff was "not entitled to make this determination for her opponents," and "[d]efendants need not prove their case for the opportunity to prove their case."

In addition, plaintiff failed to identify any specific prejudice from the testing, as she could not explain how the ability to inspect the can exactly as it was after the explosion was relevant to her case or why any evidentiary value that did exist could not also be introduced through photographs and witnesses who had inspected the can. Lastly, plaintiff had not proposed any viable alternatives for obtaining the evidence defendants sought, and had not objected to any specific elements of their testing protocol. The court therefore granted defendants' motion.


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