2022

YEAR IN REVIEW

PRODUCT LIABILITY LITIGATION

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Massachusetts federal and state courts issued several important product liability decisions in 2022. Nutter's Product Liability practice group reviewed these cases and report on their significant holdings as follows: (Click on the case name for a full discussion.)

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I. UNITED STATES FIRST CIRCUIT COURT OF APPEALS

Woodson et al. v. Evenflo Co., Inc.
No. 22-1133 (1st Cir. Nov. 23, 2022)

SIGNIFICANT HOLDING: *First Circuit held hat Article III standing can exist for claims of overpayment without injury.*

Plaintiffs brought a putative class action alleging that Evenflo Company, Inc. ("Evenflo") misled consumers by claiming that their Big Kid car booster seat ("Big Kid") (1) was safe for children as small as 30 pounds and (2) had been side impact tested. Plaintiffs sought monetary relief for overpayment, alleging that had they known about the defective nature of Evenflo's booster seat, they would not have purchased it, would have paid less for it, or would have purchased one of the safer available alternatives. Evenflo moved to dismiss, arguing that plaintiffs lacked standing because they had not been injured by its alleged misconduct. The District Court agreed and granted Evenflo's motion.

On appeal, the First Circuit rejected Evenflo's arguments. First, it reiterated that overpayment is a cognizable form of Article III injury. The First Circuit cited both *Gustavsen v. Alcon Laboratories, Inc.*, 903 F.3d 1 (1st Cir. 2018) – where it held that consumers had plausibly pleaded a concrete injury by alleging that they had overpaid for eyedrops as a result of bottles that dispensed larger than necessary drops – along with various decisions from other circuits in agreement.

Next, it rejected Evenflo's argument that the body of precedent recognizing overpayment injuries contradicts the Supreme Court's decisions in *Spokeo v. Robins*, 578 U.S. 330 (2016) and *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190 (2021). The court viewed those decisions as ruling monetary harms are classified as a real and not abstract injury, thus satisfying the concreteness requirement.

Lastly, the First Circuit reviewed Evenflo's factual arguments that (a) plaintiffs could not forgo buying any car seat because car seats are required by law; (b) plaintiffs did not offer a basis for paying a decreased price; and (c) plaintiffs did not allege that an alternative would have been cheaper, especially given that the Big Kid was $10 cheaper than its chief competitor. The court

concluded that, when read as a whole, the complaint satisfied the plausibility standards because (a) it alleged that booster seats are meant to be used only when children outgrow other models and because Evenflo's marketing suggested that the booster seat could be used sooner than it actually could be, it is reasonable to infer that the parents would have continued using other models rather than buy a new one; (b) the product could have commanded a lower price had it not marketed the Big Kid as safe for children as small as 30 pounds and as side impacted tested; and (c) there was a possibility that cheaper alternatives exist.

The First Circuit, however, rejected injunctive relief because nothing in the complaint suggested any possibility of future harm.

Williams v. Kawasaki Motors Corp. 30 F.4th 22 (1st Cir. Mar. 28, 2022)

SIGNIFICANT HOLDING: *First Circuit held that plaintiff's expert testimony must establish that his injuries were caused by the alleged manufacturing defect.*

Plaintiff suffered second- and third-degree burns after a collision caused his Kawasaki motorcycle's fuel tank to burst into flames. After plaintiff's death, his estate's personal representative, Treslan Williams, filed an amended complaint asserting various product liability causes of action.

Williams disclosed an expert witness who provided a written report and deposition testimony. The expert concluded that plaintiff's injuries were caused by the premature failure of the defective right side frame weld on the motorcycle. In reaching this conclusion, the expert examined the subject motorcycle and compared it to prior model years, noting design and material differences. During his deposition, however, he conceded that he could not opine on whether the forces during the accident would have fractured a proper, non-defective frame weld.

Kawasaki moved for summary judgment, arguing that the expert's opinions were inadmissible. The District Court granted the motion and held that there was a large analytical leap between the data examined and the opinion offered. The First Circuit affirmed, holding that the expert's opinion missed the relevant causation question – whether the alleged manufacturing defect to the right-side frame weld caused plaintiff's injuries.

II. UNITED STATES DISTRICT COURT

Corrigan v. Covidien LP, et al.
No. 22-cv-10220 (D. Mass. Nov. 21, 2022)

SIGNIFICANT HOLDING: *District Court held that alleged misuse of an FDA adverse event reporting program is a viable claim.*

Plaintiff alleged that an EEA31 surgical stapler failed to completely seal the tissue causing bowel contents to leak into his lower abdomen and contaminating his internal sterile spaces. Plaintiff brought various product liability, loss of consortium, and M.G.L.c. 93A claims. Defendants moved to dismiss for failure to state a claim.

The District Court dismissed plaintiffs' manufacturing defect claim because plaintiffs identified no improper manufacturing processes or how the device deviated from the intended design. Similarly, the court dismissed plaintiffs' design defect and negligent design claim for failure to allege the existence of a feasible alternative design.

The District Court, however, allowed the failure to warn claim to go forward based on alleged misuse of the FDA's Alternative Summary Reporting Program ("ASR Program"). The ASR Program allowed manufacturers of certain devices to submit quarterly reports of certain "well-known" events rather than file individual device failure reports to the publicly available MAUDE database. Plaintiffs alleged that because defendants reported adverse events through the ASR Program when they should have been submitted to the MAUDE database, they hid malfunctions and injuries associated with the EEA31 stapler and created a knowledge gap where surgeons were unaware that the surgical stapler malfunction rate was higher than expected.

The District Court also found that plaintiffs met the heightened pleading standard for their fraud allegations as they provided data asserting that defendants submitted EEA31 stapler adverse event reports through the ASR Program so that the surgeons only had access to diluted public reports.

Lastly, the District Court allowed plaintiff's Chapter 93A claims to continue on the grounds that defendants have their principal place of business in Massachusetts and the alleged misuse of the ASR Program happened in their regular course of business in Massachusetts.

Sundaramurthy v. Abbott Vascular, Inc.
594 F. Supp. 3d 117 (D. Mass. March 18, 2022

SIGNIFICANT HOLDING: *District Court relied upon other federal circuits in holding that plaintiff can survive a motion to dismiss on preemption grounds by stating a parallel claim alleging a violation of a general FDA regulation.*

Plaintiff brought this lawsuit in Massachusetts state court alleging that he was injured after the balloon part of defendant's Graftmaster stent system failed to retract inside plaintiff's artery. Defendant removed the case to federal court and

moved to dismiss for failure to state a claim.

The court held that plaintiff's original claims of negligent design and manufacture and failure to warn were preempted because they imposed requirements that were different from, or in addition to, federal requirements. In his amended complaint, plaintiff alleged violation of federal regulations applicable to the stent system, specifically, the Current Good Manufacturing Practices ("CGMP"). The court noted that while the First Circuit has not addressed the issue, the Fifth, Sixth, Seventh, and Eleventh Circuits have held that a plaintiff can state a parallel claim by alleging a violation of a general FDA regulation such as the CGMP. The District Court agreed with the approach of the other circuits in favor of the plaintiff.

As to the manufacturing defect claim, the court found that plaintiff had plausibly alleged that defendant exposed the balloons to excess heat; their manufacturing process failed to address this error despite repeated reports of injuries; this failure violated the CGMP as it relates to quality insurance; and this failure ultimately caused him injury. As to the failure to warn claim, however, the court found that plaintiff did not identify a regulation requiring defendant to provide any warnings that are different from, or in addition to, the requirements of the CGMP.

DiCroce v. McNeil Nutritionals, LLC 21-11660-PBS 2022 WL 16847696 (D. Mass. Nov. 10, 2022)

SIGNIFICANT HOLDING: *District Court ruled that a reasonable consumer could not find a product label deceptive where it states the product is not a drug nor intended to treat any disease.*

Plaintiff alleged that despite advertising Lactaid as a dietary supplement and not a drug, defendants made labeling statements suggesting effectiveness to treat a disease in violation of U.S. FDA law and regulations. In her Amended Complaint, plaintiff brought three causes of action: violation of M.G.L.c. 93A, unjust enrichment, and false advertising.

Plaintiff argued that the misleading statements caused her an injury-in-fact because but for those statements, she would not have purchased Lactaid and may have purchased a cheaper alternative. She also claimed to have paid at least $0.11 per pill more for Lactaid than she would have paid for another brand because Lactaid allegedly made claims to treat a disease.

The court found that plaintiff had satisfied the concreteness and particularization elements of an injury-in-fact claim by alleging that she paid a premium for Lactaid because plaintiff has a legally protected interest in her money. The court, however, allowed defendant's motion to dismiss, finding that no reasonable consumer could find Lactaid's product labels deceptive due to its conspicuously located disclaimers that it is not a drug but instead a dietary supplement.

III. APPEALS COURT OF MASSACHUSETTS

Main v. R.J. Reynolds Tobacco Co., et al.
100 Mass. App. Ct. 827 (April 8, 2022)

SIGNIFICANT HOLDING: *Under Evans, the appropriate jury instruction for determining whether cigarettes were designed defectively is whether a reasonable alternative design was, or reasonably could have been, available at the time of sale or distribution — not at the time before a smoker became addicted.*

Richard Main's estate brought an action against cigarette manufacturers alleging breach of implied warranty and wrongful death. After the jury found for the manufacturers, the estate appealed. At issue was whether the judge correctly instructed the jury on plaintiff's burden of proof for his breach of warranty claim based on a theory of design defect.

Under Massachusetts law, a "product is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design and the omission of the alternative design renders the product not reasonably safe." *Evans v. Lorillard Tobacco Co.*, 465 Mass. 411 (2013). The instruction at issue here told the jury that the plaintiff has to prove that a reasonable alternative design was available before Main became addicted to cigarettes.

In assessing the appeal, the court first outlined that when reviewing jury instructions to which there has been an objection, a two-part test is conducted: whether the instructions were legally erroneous and, if so, whether the error was prejudicial.

First, the Appeals Court held that the jury instructions were legally erroneous. Under *Evans*, the jury should have been instructed that plaintiff bore the burden to prove that a reasonable alternative design was, or reasonably could have been, available at the time of sale or distribution. The court further added that the purpose of anchoring the liability to the time of sale and distribution is to incentivize creation of safer products. Attaching liability only up until the time a smoker becomes addicted would severely diminish the incentive.

Second, the court concluded that plaintiff made a plausible showing that the jury might have reached a different result absent the erroneous instruction that essentially told the jury to disregard the abundant evidence from which they could have concluded that technologically feasible alternative designs existed during the time Main smoked. Even though defendants challenged this evidence at trial, the court found that evidence of alternative designs was of sufficient strength that a reasonable jury could have concluded that defendants sold or distributed defective products to Main during the time he smoked, and that available alternative designs would have reduced or prevented his risk

of developing lung cancer. For these reasons, the Appeals Court vacated the judgment as to the breach of warranty claims and remanded for a new trial.

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For decades, product liability defense has been one of the cornerstones of Nutter's highly successful litigation practice. Leading multinational companies have turned to Nutter to defend cases in courts throughout the United States and around the world involving allegedly defective medical devices, pharmaceuticals, consumer health care products, industrial materials, and automotive and heavy equipment products. We are dedicated to our client's objectives and aggressively prepare cases for trial. That approach has led to major defense verdicts, but it has also led to many more pre-trial dismissals and favorable settlements without the negative publicity that often encourage further lawsuits.

OUR COMMITMENT TO BUILDING A CULTURE AND ATMOSPHERE OF LEGAL EXCELLENCE HAS LED TO TOP INDUSTRY ACCOLADES, INCLUDING:

- Nutter earned a Tier 1 ranking for Product Liability Litigation—Defendants in Boston in the *U.S. News & World Report/Best Lawyers 2023* "Best Law Firms" survey.
- Nutter has been named a "Go-To" law firm in Torts Litigation by Johnson & Johnson.
- *Chambers USA 2022* recognized Nutter in the Litigation: General Commercial category.

In the *U.S. News & World Report / Best Lawyers* survey of "Best Law Firms," clients described the group as follows*:

- "Nutter is absolutely a top notch firm."
- "Dedicated and excellent strategic thinkers. They align the defense strategy with the business objectives."
- "Nutter McClennen & Fish attorneys are excellent litigators and also excellent trial lawyers.
- They are very strong at strategy. They are more business savvy than many other litigators. They are results oriented with a practical approach. I also very much enjoy the Nutter lawyers I work with. They are smart and have a good sense of humor."

REPRESENTATIVE EXPERIENCE

Nutter's Product Liability Defense practice group has a proven track record of successfully resolving complex cases. We have:

- Defended life sciences mass torts in a variety of contexts such as: medical devices, including artificial knees, hips, and spinal discs, cardiac devices, surgical instruments, bone cement, surgical sutures, spinal fusion plates, tissue morcellators, and latex gloves; pharmaceuticals, including antibiotics, anti-inflammatory drugs, and birth control patches; and consumer products, including baby powder, contact lenses, and facial cleansers.
- Defended claims arising from alleged exposures to asbestos-containing products; vinyl chloride; toxic dust from commercial printing facilities; and a wide variety of industrial solvents and chemicals.
- Successfully tried, arbitrated, and mediated cases involving allegedly defective automotive and industrial vehicle products, and various industrial and commercial materials used in all kinds of products and manufacturing processes.
- Represented clients in various roles, including as trial counsel, national counsel, leading expert teams, and local counsel.

INDUSTRY EXPERTISE

Nutter lawyers are frequently sought after by the media for their insights on cutting-edge developments in the products liability sector, including medical devices, pharmaceuticals, asbestos, automotive liability, 3D printing and artificial intelligence, cybersecurity, food and beverage litigation, and other topics.

Nutter's products liability lawyers have been featured in *Bloomberg, Corporate Counsel, IADC's Drug, Device and Biotechnology Committee Newsletter, Risk Management Magazine, Medical Design & Outsourcing, DRI's The Voice, Inside Counsel, Medical Device and Diagnostic Industry (MD+DI), Additive Manufacturing Today, Massachusetts Lawyers Weekly, MCLE's Massachusetts Courtroom Advocacy, Medical Design & Outsourcing and the Products Liability Litigation Newsletter.*

A member of the group also co-authored the "Product Liability" chapter in the Massachusetts Superior Court Civil Practice Jury Instructions and currently serves as chair of the Massachusetts Supreme Judicial Court's Standing Advisory Committee on the Rules of Civil and Appellate Procedure.

A LEADER IN PROFESSIONAL ORGANIZATIONS

Nutter is highly active in numerous organizations, strengthening its industry knowledge and cultivating relationships with key members of the business community. Highlights include:

- Presented at ACI's Drug and Medical Device Litigation Conference, DRI's Drug and Medical Device Seminar, International Association of Defense Counsel's (IADC) Annual Meeting, the American Bar Association, and the Boston Bar Association.
- Selected as Fellows of the American College of Trial Lawyers, the Litigation Counsel of America, and 2019 Benchmark Litigation Star.
- Participated in conferences addressing motor vehicle product liability litigation, pharmaceutical, medical device, biotech, and asbestos litigation, and the food and beverage sector.

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