2023
YEAR IN REVIEW
Product Liability Litigation

Nutter

Massachusetts federal and state courts issued several important product liability decisions in 2023. 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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Nutter

PREPARED BY

David L. Ferrera
617.439.2247
dferrera@nutter.com

Ritika Bhakhri
617.439.2073
rbhakhri@nutter.com

I. UNITED STATES FIRST CIRCUIT COURT OF APPEALS

In re Zofran (Ondansetron) Prods. Liab. Litig.
57 F.4th 327 (1st Cir. Jan. 9, 2023)

SIGNIFICANT HOLDING: The First Circuit affirmed the district court's holding that plaintiffs' failure to warn claim was preempted by federal law where the animal studies plaintiffs contended warranted a labeling change were not "newly acquired information" and there was "clear evidence" that the U.S. FDA did not approve changing the prescription drug's label.

This appeal is from a **trial court's dismissal of federal multi-district litigation concerning Zofran's off label use to prevent vomiting and nausea during pregnancy.** In 1990, as part of the FDA approval process, the manufacturer submitted a set of U.K. animal studies. After reviewing the studies, the FDA concluded that the drug did not induce a teratogenic effect (meaning that it did not cause birth defects) and assigned it Pregnancy Category B. The manufacturer conducted additional animal studies in Japan but did not submit them to the FDA until 1997. After assessing the Japanese studies, the FDA again concluded that Zofran was not teratogenic. When Novartis acquired Zofran in 2015, it proposed a set of warnings advising against use of Zofran during pregnancy based on human data suggesting an increased risk of birth defects, but the FDA rejected the labeling proposal because it did not find that the published studies had consistent data.

Plaintiffs claim that the manufacturer failed to warn consumers, as required under state law, that the animal studies revealed adverse effects on the fetus. They contended that the manufacturer should have utilized the "Changes Being Effected" procedure to unilaterally change Zofran's label to reflect the "newly acquired information" from the Japanese studies. The District Court had granted summary judgment in favor of the manufacturer, finding that plaintiffs' failure to warn claim was preempted by federal law when there was "clear evidence" that the U.S. The FDA did not approve changing the prescription drug's label to include a warning that the plaintiffs contend was required by state law.

The First Circuit affirmed, holding that the Japanese studies were not "newly acquired information" because (i) due to the similarities of the U.K. and Japanese studies, the FDA was already aware of the risks flagged by the Japanese studies when

it assigned Category B to Zofran and thus, the Japanese studies did not "reveal risks of a different type or greater severity or frequency than previously included in submission to FDA" and (ii) while the Japanese studies mentioned adverse events not mentioned in the U.K. studies, the studies did not find that the birth defects were attributable to Zofran. The First Circuit also found that plaintiffs' expert's testimony that the Japanese studies were "newly acquired information" would likely be inadmissible as this was a question of law.

Even if the Japanese studies were "newly acquired information," the First Circuit found that the FDA had previously rejected Novartis' proposal to change the label. Thus "clear evidence" existed that FDA would have rejected plaintiff's proposed labeling change.

II. UNITED STATES DISTRICT COURT

In re Fresenius GranuFlo/NaturaLyte Dialysate Prods. Liab. Litig.

MDL No. 13-2428 2023 WL 5807340 (D. Mass. Sep. 7, 2023)

SIGNIFICANT HOLDING: Plaintiffs failed to adequately allege failure to warn claims because none of the decedents' medical history supported their general or specific causation theories and they failed to show that physicians would have changed their prescribing decisions based on different warnings.

In this federal multi-district litigation, plaintiffs alleged that manufacturers of dialysate fluids, GranuFlo and NaturaLyte, failed to warn doctors about how to safely use them with their hemodialysis patients and that the acetate in these fluids leads to a "dangerous increase" in serum bicarbonate levels which can trigger a cardiac arrest and sudden cardiac death. Defendants moved for summary judgment on the failure to warn claims of certain opt out plaintiffs.

Acknowledged Levels of Harm

In 2011, defendants' then Chief Medical Officer, Dr. Hakim, authored a memorandum (the "Hakim Memo") discussing the results of a case study that evaluated risk factors in hemodialysis patients who suffered from cardiac arrests. Patients with a pre-dialysis serum bicarbonate level of 28 mEq/L or more were depicted as having the greatest risk for a cardiac arrest. All of plaintiffs' nephrology experts relied on the Hakim Memo as the basis of their opinions and did not conduct any independent studies on the alleged association between serum bicarbonate levels and the risk of cardiac arrest.

Lack of Evidence of Causation

Because all of the decedents' final pre-dialysis serum bicarbonate levels fell below 28 mEq/L, and plaintiffs' experts acknowledged that these levels fell within an acceptable range, the court found that plaintiffs failed to present competent evidence of general causation. The court also found that plaintiffs failed to establish proximate causation because they did not present any evidence that the treating doctors would have done something different had they been forewarned. According to the plaintiffs' own experts' testimony, a pre-dialysis serum bicarbonate reading of 26 mEq/L and lower did not require prescription changes.

The court also granted defendant's motion for summary judgment on plaintiff's second theory of general causation that dialysates cause alkalosis, which leads to an arrhythmia triggered by an electrolyte shift. Since the Hakim Memo did not mention anything aside from electrolyte-related arrhythmias leading to cardiac arrests, defendants argued that any other "event" causing a cardiac arrest was outside of the scope of this litigation. Because none of the decedents died from electrolyte-related arrhythmias, plaintiff failed to establish general causation.

Plaintiffs failed to show that the decedent's injuries were proximate in time to their last dialysis treatment. Plaintiffs' experts testified that the cardiac arrests were caused by sudden electrolyte shift, however, all the cardiac arrests occurred seven hours after the conclusion of the dialysis.

Similarly, plaintiffs attempted to put forward a general causation theory regarding NaturaLyte, arguing that an excess amount of acetate in NaturaLyte (4 mEq/L) increased the risk of cardiac arrest and death. Several of plaintiffs' experts testified that they did not consider 4 mEq/L of acetate to be excessive, and that they themselves used NaturaLyte or other solutions containing 4 mEq/L of acetate. This testimony combined with the fact that the plaintiffs' expert's reports were conclusory led the court to find in the defendants' favor.

Learned Intermediatory Doctrine

Finally, the court held that the learned intermediatory doctrine barred the remaining plaintiffs' failure to warn claims because they failed to show that physicians would have changed their prescribing decisions based on different warnings. All the clinics in question received several memoranda over the course of the decade urging physicians to observe and monitor the patient's bicarbonate levels. In addition the nephrology experts, including plaintiffs', all testified that nephrology fellows are aware from their training in medical school that acetate metabolizes into bicarbonate in the liver.

Rezendes v. Mitsubishi Motors N. Am., Inc.

No. 22-CV-10211-AK 2023 WL 1864405 (D. Mass. Feb. 9, 2023), reconsideration denied, No. 22-CV-10211-AK 2023 WL 4552030 (D. Mass. July 14, 2023)

SIGNIFICANT HOLDING: The Magnuson-Moss Warranty Act's requirement that a class claim identify at least 100 named plaintiffs was not impliedly repealed by the Class Action Fairness Act.

This case is a putative class action brought against Mitsubishi due to an alleged defect in its 2022 Outlander which causes the vehicles' hoods to flutter and bounce when driving ("the Hood Defect"). Plaintiff purchased his 2022 Outlander in June 2021. His vehicle was accompanied by Mitsubishi's New Vehicle Limited Warranty ("the Limited Warranty").

Within weeks of purchase, plaintiff's vehicle began to exhibit the Hood Defect. When he complained about the defect to the dealership, he was told there was no repair available. A few months later, when he complained again, the dealership attempted repairs in accordance with Mitsubishi's Technical Services Bulletins, however, plaintiff's

vehicle continued to suffer from the Hood Defect. After several complaints to Mitsubishi, plaintiff brought suit alleging breach of express warranty under Massachusetts state law and a violation of the Magnuson-Moss Warranty Act ("MMWA") under federal law. Mitsubishi filed a motion to dismiss.

First, the court found that plaintiff had adequately alleged a plausible breach of express warranty claim because the complaint alleged that plaintiff's vehicle was covered by Mitsubishi's Limited Warranty and that Mitsubishi breached the Limited Warranty by tendering plaintiff a vehicle with the Hood Defect and failing to remedy this defect.

Second, the court found that in addition to the elements of his state law claim, plaintiff also needed to meet the additional requirements imposed by the MMWA, including that a class action needed to name at least 100 plaintiffs. Plaintiff's class claim did not identify at least 100 named plaintiffs, but he argued that pursuant to the Class Action Fairness Act ("CAFA") federal courts could still exercise subject-matter jurisdiction over putative class actions if there are at least 100 class members (who need not be specifically named at the time of filing).

The court noted that there was a split among out-of-circuit authorities on this question and in the absence of First Circuit precedent, adopted the Ninth Circuit's reasoning in Floyd v. American Honda Motor Co., Inc., 966 F.3d 1027 (9th Cir. 2020). In Floyd, the Ninth Circuit, using principles of statutory construction, held that the plain language of the MMWA required a putative class action plaintiff to name at least 100 individuals and that this statutory requirement was not repealed simply through the passage of the CAFA because both statutes could co-exist. As a result, the court granted Mitsubishi's motion to dismiss without prejudice to amend the complaint to comply with the MMWA.

Cambridge Mutual Fire Ins. Co. v. Rust-Oleum Corp., et al.

No. 22-1211-NMG (D. Mass. Nov. 14, 2023)

SIGNIFICANT HOLDING: An insurance company's state law failure to warn claim seeking to impose labeling requirement for spontaneous combustion was preempted by federal law because it exceeded the labeling requirements under the Federal Hazardous Substances Act.

This lawsuit is a result of a kitchen fire caused by a spontaneous combustion of rags containing Varathane manufactured by defendant Rust-Oleum. Cambridge Mutual's insured filed claims to recover its losses and Cambridge Mutual in turn brought the instant subrogation action against defendants for breach of the warranty of merchantability and negligence based on a failure to warn theory. Both parties agree that Varathane is a "hazardous substance" under the Federal Hazardous Substances Act ("FHSA").

Defendants filed a motion for partial summary judgment on plaintiff's failure to warn claim arguing (1) that FHSA preempts state law failure to warn claims that exceed the requirements of the FHSA and (2) that there was no duty to warn about spontaneous combustion because it is not a "principal hazard" under the FHSA. The court agreed.

Regarding the preemption claim, the court found that courts have uniformly held that FHSA preempts all warnings-based claims seeking to impose labeling requirements different from those imposed by the FHSA. The court noted that even plaintiff conceded this point. Regarding classification of spontaneous combustion as a "principal hazard" under FHSA, the court found that the FHSA and related regulations do not describe the specific risk of spontaneous combustion as a "principal hazard." Four other federal court cases have held that spontaneous combustion is not a "principal hazard" under FHSA.

III. MASSACHUSETTS SUPREME JUDICIAL COURT

Doucet v. FCA US LLC

492 Mass. 204 (June 8, 2023)

SIGNIFICANT HOLDING: In a long-standing litigation, the Supreme Judicial Court reversed a Superior Court decision and reinstated the ruling of a United States District Court to dismiss a litigation for lack of personal jurisdiction.

In 2020, a United States District Court exercised personal jurisdiction over FCA, an out-of-state manufacturer who expressly assumed predecessor's liabilities. **The federal district court found personal jurisdiction existed because the defendant sold vehicles in Massachusetts; the claims arose out of and were related to the car's sale in Massachusetts; and because exercising jurisdiction in Massachusetts would not impose an unusual burden on the defendant.** The federal district court then remanded the case to the Massachusetts Superior Court for lack of subject matter jurisdiction because the inclusion of another defendant, a Massachusetts corporation, prevented complete diversity.

On remand, the Superior Court disagreed with the federal district court and granted FCA's motion to dismiss for lack of personal jurisdiction. In a long-standing litigation, the Supreme Judicial Court reversed a Superior Court decision and reinstated the ruling of a United States District Court to exercise personal jurisdiction over an out-of-state manufacturer.

Fabiano v. Philip Morris, et al. and Fuller v. R.J. Reynolds Tobacco Company, et al.

492 Mass. 361 (July 6, 2023)

SIGNIFICANT HOLDING: Personal representatives of smokers were barred from bringing wrongful death claims where the statute of limitations for smoking related injuries had passed before the smokers' death.

The Supreme Judicial Court consolidated two unrelated cases on appeal. In both cases, the personal representatives brought wrongful death claims under G.L.c. 229, § 2, alleging breach of warranty, negligence, and conspiracy. Also, in both cases, the decedents could not have brought direct claims at the times of their death due to the expiration of the three-year statute of limitations. The lower court in both cases found that the wrongful death claims were barred because the statute of limitations on the underlying claims had lapsed at the time of the decedent's death. Plaintiffs filed for appeal and argued that the language in Sec-

tion 2, that an action shall be commenced within three years from the date of death, unambiguously demonstrated the legislative intent to permit a personal representative to bring a wrongful death action within three years after the decedent's death regardless of the date of injury. The SJC disagreed.

The SJC first referenced their ruling in *GGNSC Admin. Servs., LLC v. Schrader, 484 Mass. 181* (2020), where they concluded that wrongful death claims are derivative claims based on an amendment of G.L.c. 229, § 2, which permits compensation only "under such circumstances that the deceased could have recovered damages for personal injuries if his death has not resulted." In *GGNSC*, the court held that the "under such circumstances" clause in the statute demonstrated the legislature's intent to tether a wrongful death claim to the tortious conduct that caused the decedent's personal injury.

The court next examined the statute of limitations for wrongful death claims and noted that while it does set a time period to bring wrongful death claims, it does not confer an independent right to bring one. The court explained that because the decedents had no right on the date of their death to bring suit for their personal injuries, a cause of action for wrongful death was never vested in the personal representatives. Because the wrongful death cause of action never came into existence, the three-year statute of limitations was never triggered.

IV. MASSACHUSETTS APPEALS COURT

Coyne v. R.J. Reynolds Tobacco Company
102 Mass.App.Ct. 1122 (May 30, 2023)

SIGNIFICANT HOLDING: In a summary decision pursuant to M.A.C. Rule 23.0, the Appeals Court vacated a jury's award of punitive damages and remanded for a new trial where plaintiff provided insufficient evidence for his claim that negligent marketing by cigarette manufacturer caused decedent to start smoking at an early age.

Decedent's personal representative brought this lawsuit, after she became addicted to smoking cigarettes at a young age and died of lung cancer. The lawsuit alleged negligent marketing, conspiracy, breach of warranty, and violation of G.L.c. 93A. Following trial, the jury found in the plaintiff's favor on all claims and awarded compensatory and punitive damages. The judge also found in plaintiff's favor on the Chapter 93A claim. Defendant appealed.

In a summary disposition pursuant to Rule 23.0, the Appeals Court agreed that there was insufficient evidence to support plaintiff's negligent marketing claim, vacating the award of punitive damages and remanding that claim for a new trial, but affirming in all other respects.

Regarding the negligent marketing claim, although the manufacturer conceded that it had a duty to "avoid marketing cigarettes in a manner calculated to induce purchases by minors," it argued that there was insufficient evidence to support the conclusion that any negligence on its part caused decedent to start smoking. Testimonies

from decedent's sister and childhood friend were unable to link any of the manufacturer's actions to decedent's decision to start smoking. The Appeals Court noted that while direct evidence regarding why the decedent began smoking was not required, a reasonable inference "must be based on probabilities rather than possibilities and cannot be the result of mere speculation and conjecture." The court also noted that other courts have concluded that a tobacco company's advertising in and of itself is insufficient to establish that the marketing campaign influenced someone's decision to smoke. For these reasons, the court held that a directed verdict should have been entered in the manufacturer's favor for the negligent marketing claim.

Regarding the conspiracy and Chapter 93A claims, the court found there was sufficient evidence to support the verdict because plaintiff's expert provided testimony that the cigarette industry created the concept of "light" cigarettes based on research showing that smokers would switch to "lights' thinking they were healthier when in fact the cigarette industry knew that "lights" were just as harmful. Furthermore, decedent's daughter testified that decedent switched to the "lights" because she believed it would make it easier to quit smoking when in reality her smoking did not decrease. Also, decedent's oncologist testified that decedent's decision to smoke "lights" instead of quitting contributed to her lung cancer.

Finally, the court found sufficient evidence to support plaintiff's breach of warranty claim because the plaintiff offered several alternative designs. In particular, plaintiff's expert testified that the technology to make low nicotine cigarettes which are not addictive existed long before decedent began smoking. The manufacturer argued that low nicotine cigarettes could also cause lung cancer; however, the court noted that it was the non-addictive quality of low nicotine cigarettes that made them a reasonable alternative, opining the decedent would have stopped smoking were it not for her addiction.

2023 YEAR IN REVIEW

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 2024 "Best Law Firms" survey by *Best Lawyers.*
- Nutter has been named a "Go-To" law firm in Torts Litigation by Johnson & Johnson.
- *Chambers USA 2023* recognized Nutter in the Litigation: General Commercial category.

In the *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 ORGANIZATION

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.

MEET OUR TEAM

Partners

Nelson G. Apjohn	617.439.2246	napjohn@nutter.com
Stephen J. Brake	617.439.2223	sbrake@nutter.com
Dawn M. Curry	617.439.2286	dcurry@nutter.com
David L. Ferrera	617.439.2247	dferrera@nutter.com
Sarah P. Kelly	617.439.2461	skelly@nutter.com
Sara Lonks Wong	617.439.2139	slonkswong@nutter.com
Michael J. Leard	617.439.2159	mleard@nutter.com
Brian K. Lee	617.439.2490	blee@nutter.com
Melanie V. Woodward	617.439.2130	mwoodward@nutter.com

Associates

Ritika Bhakhri	617.439.2073	rbhakhri@nutter.com
Natalie M. Cappellazzo	617.439.2390	ncappellazzo@nutter.com
Ashley M. Paquin	617.439.2147	apaquin@nutter.com
Natalia Peña	617.439.2250	Npena@nutter.com
Maya Ritchie	617.439.2035	mginga@nutter.com
Mariel T. Smith	617.439.2183	msmith@nutter.com

e-Discovery Specialists

Kate Jansons Johns	617.439.2658	kjohns@nutter.com
Paige Smith	617.439.2253	psmith@nutter.com

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