2021
YEAR IN REVIEW
PRODUCT LIABILITY LITIGATION

Nutter
uncommon law

Massachusetts federal and state courts issued several important product liability decisions in 2021. 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):

CONTENTS

Nutter
uncommon law

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

Carrozza v. CVS Pharmacy, Inc.

992 F.3d 44 (1st Cir. Mar. 31, 2021)

Significant Holding: *As a matter of first impression under Massachusetts law, the First Circuit held that a pharmacist's dispensation of prescribed medication was predominantly provision of services, and not sale of goods.*

The plaintiff sued after an allergic reaction to a prescribed drug, Levaquin (the quinolone antibiotic levofloxacin). Neither the plaintiff nor his physician were aware of any allergies to quinolones, but while filling the prescription, the CVS pharmacist received a "hard stop" warning suggesting that the plaintiff was allergic to quinolones. At the same time, CVS's Patient Profile included statements by the plaintiff that he in fact had no quinolone allergy and had received prior prescriptions of Levaquin. Given the conflicting information, the pharmacist exercised his individual judgment and dispensed the Levaquin.

The District Court issued various rulings on the admissibility of testimony by the treating ophthalmologist and the plaintiff's expert, which the First Circuit affirmed. Without an expert opinion on the standard of care and the causation of his injuries, the District Court properly granted summary judgment on the plaintiff's negligence claims. Notably, regarding the plaintiff's strict liability claims resting on breach of implied warranty under the Uniform Commercial Code, the First Circuit agreed that under Massachusetts law a pharmacist's dispensation of prescribed medication is predominately the rendition of services, not sale of goods. Thus, the warranty claim could not survive because the UCC does not apply to agreements for provision of services.

II. UNITED STATES DISTRICT COURT

Ducat v. Ethicon, Inc.

534 F. Supp. 3d 152 (D. Mass. April 14, 2021)

Significant Holding: Under Massachusetts law, the plaintiffs must allege the existence of a safer or reasonable alternative design to state a claim for negligent design and breach of implied warranty of merchantability.

The plaintiffs brought suit for injuries from a pelvic mesh medical implant alleging design defect and breach of implied warranty of merchantability. The defendants moved for judgment on the pleadings, arguing that the plaintiffs' design defect claims should be dismissed for various reasons, including failure to plead the existence of a safer alternative design.

The District Court began by noting ambiguity in Massachusetts law on whether, to prevail on a defective design claim, a plaintiff must follow the "consumer expectations" or "risk-utility" test — which requires proof of the existence of a reasonable alternative design. This ambiguity stems from two decisions of the Massachusetts Supreme Judicial Court that remain in conflict – one involving cigarettes (requiring a technologically feasible and practical alternative design) and the other involving a snowmobile (accepting a consumer's reasonable expectation as proof of design defect when the danger fell within the average juror's knowledge).

Ultimately, relying on the First Circuit's decision in *Tersigni v. Wyeth, 817 F.3d 364 (1st Cir. 2016)*, the District Court found that the plaintiffs here do need to allege the existence of a safer or reasonable alternative design, citing favorably the guidelines set forth in the Restatement (Third) of Torts, §2, and rejecting the reasoning of *Taupier v. Davol, Inc., 490 F. Supp. 3d 430 (D. Mass. 2020)*. The District Court did, however, grant the plaintiffs leave to amend their complaint to comply with this standard.

In re Zofran (Ondansetron) Prods. Liab. Litig.

MDL No. 1:15-md-2657-FDS 2021 WL 2209871 (D. Mass. June 1, 2021)

Significant Holding: *The plaintiffs' failure to warn claims are preempted by federal law when there is "clear evidence" that the U.S. FDA did not approve changing the prescription drug's label to include a warning that the plaintiffs contend was required by state law.*

In this federal multi-district litigation, the plaintiffs who were prescribed the drug Zofran off-label to prevent nausea and vomiting while pregnant brought failure to warn claims, alleging that the product manufacturer failed to disclose material evidence to the U.S. Food and Drug Administration about Zofran's adverse fetal effects. The defendant manufacturer moved for summary judgment, arguing that the plaintiffs' state law claims were preempted by federal law because the FDA approved the product's label and expressly rejected later proposed changes.

Relying on prior U.S. Supreme Court decisions, including *Merck Sharp & Dohme Corp. v. Albrecht, 139 S. Ct. 1668, 203 L. Ed. 2d 822 (2019)*, the District Court noted that failure to warn claims are not preempted unless there is "clear evidence" that the drug manufacturer fully informed the FDA of the justifications for the warning required by state law, and the FDA, in turn, informed the drug manufacturer that it would not approve the change. Here, the original manufacturer sold its rights to the drug, and the current owner applied to the FDA for labeling changes in 2020. These

changes included warnings related to pregnancy use and birth defects. The plaintiffs argued that the original manufacturer withheld or mischaracterized scientific studies and adverse event data at the time of original approval, but the District Court held that, even if it did, the current owner presented all such information about the drug's safety to the FDA by the time of the requested labeling change in 2020. Based on this information, the FDA rejected the proposed changes, and approved a label that did not include warnings about use during pregnancy.

As a result, "clear evidence" exists that the FDA was fully informed of potential justifications for changing the drug's warning label, and had rejected prior submissions for pregnancy enhanced warnings three separate times (in 2013, 2015, and 2021) after considering the very evidence that the plaintiffs contend required an enhanced warning. Furthermore, the fact that the current owner rather than the manufacturer requested the labeling change did not alter the outcome. Preemption analysis does not depend on whether the original manufacturer requests a label change, or to whom the FDA explicitly communicates its rejection of the proposed change. The District Court therefore granted the manufacturer's motion for summary judgment, and disposed of the entire MDL.

Plourde v. Sorin Grp. USA, Inc., et al.

517 F. Supp. 3d 76 (D. Mass. Feb. 5, 2021)

Significant Holding: *The plaintiffs' state law claims that the defendants had a duty to report or warn the FDA of adverse events about a medical device are preempted by federal law.*

The plaintiffs filed this claim on behalf of their adult daughter who was fatally injured during a heart valve replacement procedure. They alleged that the defendants knew of an increased risk of harm to patients under 30 years old, but failed to notify the FDA. The defendants countered that such claims were preempted by federal law, because the plaintiffs failed to establish that they had a duty to report to the FDA under a Massachusetts law parallel to federal law. The District Court agreed, and also held that a duty to warn doctors under the learned intermediary doctrine does not correspondingly impose a duty to report to the FDA. Furthermore, the plaintiffs' breach of express warranty claim failed because the valve's Instructions For Use contained explicit warnings about the use of the valve in younger individuals. The plaintiffs did not identify any specific statements that the defendant made that could be understood as a guarantee or warranty of the valve's suitability in patients under 30 years old. The District Court therefore granted summary judgment.

NOTE: The plaintiffs appealed, and in early January 2022 the First Circuit Court of Appeals asked the Massachusetts Supreme Judicial Court to answer the certified question of whether "a manufacturer's failure to report adverse events to a regulator—such as one like the FDA—give[s] rise to liability under Massachusetts law."

III. SUPREME JUDICIAL COURT

Dunn v. Genzyme Corp.

486 Mass. 713 (Jan. 29, 2021)

Significant Holding: *The plaintiffs asserting state law claims about medical devices regulated by the FDA are not required to plead specific facts to meet the Commonwealth's notice-pleading standard.*

After experiencing severe side effects, the plaintiff brought personal injury and product liability claims against the defendant manufacturer of Synvisc-One, a Class III medical device subject to premarket approval under the Medical Device Amendments of the U.S. Food, Drug, and Cosmetics Act. The defendant moved to dismiss, asserting that the allegations were preempted by federal regulations and failed to meet the applicable state law pleading standards. The Superior Court denied the motion, and, on transfer from the Appeals Court on interlocutory review, the SJC reversed.

First, the SJC held that the plaintiff's claims under Massachusetts law could be interpreted as coextensive with the comprehensive federal requirements imposed on the defendant rather than adding to them, and therefore satisfied the preemption standard established by the U.S. Supreme Court in *Riegel v. Medtronic, Inc., 552 U.S. 312 (2008)*. Second, the SJC held that the plaintiffs asserting parallel state law claims were not required to plead the precise federal regulations purportedly violated to meet the ordinary notice-pleading standard established by the SJC in *Iannacchino v. Ford Motor Co., 451 Mass. 623 (2008)*. Despite these legal statements, however, the SJC concluded that this plaintiff's complaint provided no factual allegations to establish causality between the defendant's activities and the plaintiff's injuries sufficient to survive a motion to dismiss.

Doull et al. v. Foster et al.

487 Mass. 1 (Feb. 26, 2021)

Significant Holding: *Redefining the Massachusetts standard for factual causation in negligence cases involving multiple alleged causes of harm, the SJC adopts a "but-for" standard and abandons the "substantial contributing factor" test.*

After a patient developed a pulmonary embolism and chronic thromboembolic pulmonary hypertension ("CTEPH") which caused her death, the patient's estate brought a medical malpractice action against her nurse practitioner and physician employer, alleging that the nurse practitioner failed to obtain informed consent as to the potential risks of pulmonary embolism associated with use of a progesterone cream for perimenopause-related symptoms, and that she failed to diagnose the patient's pulmonary embolism. The defendants' experts testified there was no evidence that the cream increased the risk of clotting, or that the patient's CTEPH would have been preventable had she been diagnosed with it earlier. The jury returned a verdict for the defendants, finding no failure to obtain informed consent, and that, even though the nurse practitioner was negligent in failing to diagnose the pulmonary embolism and her employer was negligent in supervising her, neither defendant was the "sole/but-for" cause of the harms suffered by the patient.

On appeal, the plaintiffs argued that the trial judge had to instruct on a "substantial contributing factor" standard because there were several possible causes and multiple tortfeasors involved in the patient's injuries and death. The SJC disagreed and affirmed, holding that in a majority of negligence cases, the jury should be

instructed using the but-for standard. Causation is an essential element of any negligence claim and involves two components – factual and legal cause. Generally, a defendant is a factual cause of a harm if the harm would not have occurred "but for" the defendant's negligent conduct. The SJC explained that in some cases – for example, toxic tort and asbestos cases involving multiple causes – the but-for standard can cause unjust results, and alternative causation standards like the substantial factor test could be more appropriate. The SJC distinguished the current malpractice action from a toxic tort or asbestos case in which it would be impossible for a plaintiff to determine which exposures were necessary to bring about the harm and which were not. Here, the SJC believed the jury could separate the conduct that did not affect the harm from the conduct that caused the harm.

Notably, the SJC supported the approach proposed by the Restatement (Third) of Torts, § 27, to supplement rather than abandon the but-for standard in cases involving multiple causes to avoid confusing terminology and eliminate the risk of a trial judge instructing the jury on the wrong standard. Furthermore, in a long footnote, the SJC stated that it would reconsider use of the substantial factor test in Massachusetts if an appropriate toxic tort case came before it in the future.

Laramie v. Philip Morris USA Inc.

488 Mass. 399 (Sept. 15, 2021)

Significant Holding: *The doctrine of claim preclusion did not apply when a prior action by the Attorney General did not adequately represent the plaintiff's personal interest in punitive damages.*

The plaintiff, a widow of a cigarette smoker, sued pursuant to Massachusetts' wrongful death statute, G.L. c. 229 § 2, claiming that the defendant caused her husband's death by selling him defective and unreasonably dangerous cigarettes. The jury awarded her $11 million in compensatory damages and $10 million in punitive damages. The defendant appealed, arguing that the punitive damages were precluded by a 1998 master settlement agreement with the Massachusetts Attorney General. The agreement covered claims against the defendant alleging conspiracy to mislead the Commonwealth and its citizens about the health risks of smoking, and recovered the Commonwealth's costs for providing smoking-related medical assistance to Massachusetts residents.

On appeal, the SJC affirmed, rejecting the defendants' argument of claim preclusion. The master settlement agreement released the defendant from liability for punitive damages to persons acting as private attorney general seeking relief on behalf of the general public, but preserved claims for individual relief for separate and distinct injuries. The SJC held that this language explicitly stated the parties' intention to preserve personal rights, including actions under the Commonwealth's wrongful death act. As a result, the master settlement agreement did not preclude the plaintiff's punitive damages claim because (1) the plaintiff's personal interest in punitive damages was not adequately represented by the AG because the prior action did not seek damages for personal injuries, but sought damages for the Commonwealth's increased medical expenditures; and (2) the two causes of action were distinguishable because the "wrong" that the plaintiff sought to remedy was the loss sustained due to her husband's death, while the "wrong" the Attorney General sought to remedy was the Commonwealth's increased medical expenditures.

Nemirovsky v. Daikin North Am., LLC, et al.

177 N.E.3d 901 (Dec. 16, 2021)

Significant Holding: *The component parts doctrine applies to non-defective components even if they cannot function separate and apart from the integrated product or were produced specifically for use in the integrated product.*

The consumer of an HVAC system sued various defendants, including the distributor of evaporator coils used to replace leaking coils in the system. After the jury found the coil distributor liable for breach of implied warranty and other claims, it filed a motion for judgment notwithstanding the verdict, contending that the component parts doctrine precluded liability. Under this doctrine, the manufacturer of a non-defective component placed in an integrated product generally is not liable for damage caused by a defect in the integrated product. The trial court denied the defendant's motion, holding that (1) the doctrine only applies to "stand-alone components," i.e., components that function separate and apart from the system in which they are integrated; and (2) the coils here were not stand-alone, because the manufacturer produced and distributed them specifically for use in the subject HVAC system.

On appeal, the SJC reversed, accepting the Restatement (Third) of Torts, §5, analysis that the doctrine also applies to specialized components that have no functional capabilities unless integrated into other products. Unless the coils themselves were found to be defective, the component parts doctrine applied, and liability should not flow to the coil distributor for harm caused by the defective HVAC system. The SJC also clarified that this doctrine applies to both tort and warranty claims, as it arises in the context of product liability which involves the intersection of both legal schemes.

IV. SUPERIOR COURT

Noorchasm et al. v. Muto et al.

1584-CV-03245 2021 WL 3612425 (Suffolk Cnty. Sup. Ct. July 8, 2021)

Significant Holding: *Under some factual circumstances, a medical device manufacturer's duty to warn a learned intermediary runs not only to the treating surgeon, but also to the purchasing hospital.*

This claim stems from the use of a power morcellator which led to the dissemination of cancerous tissue within a patient's body and caused her death. The plaintiffs brought a negligent failure to warn claim, among others. The manufacturer defendant moved for summary judgment on multiple grounds, arguing in part that because the surgeon did not read the instruction manual, any harm could not have been caused by a deficiency in the product warnings. The manufacturer relied on the learned intermediary doctrine to support its argument that the treating surgeon has superior knowledge of her patient's medical history, and the manufacturer need only warn the surgeon who in turn owes a duty to advise her patient of the risks associated with the use of the product.

The plaintiffs responded that when a surgeon relies on her hospital to apprise her of the relevant risks, a manufacturer's duty to warn runs not only to the treating surgeon, but also the purchasing hospital. Here, evidence existed that the hospital's unit chief received notifications about product safety, forwarded them to physicians in his department, and would have shared allegedly missing information with his department surgeons and required them to comply with it. Under these factual circumstances, the court held that the learned intermediary doctrine does not require that a manufacturer defendant's duty runs only to the surgeon using the product, and therefore denied summary judgment.

PRODUCT LIABILITY LITIGATION

2021 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 *U.S. News & World Report/Best Lawyers 2022* "Best Law Firms" survey.
- Nutter has been named a "Go-To" law firm in Torts Litigation by Johnson & Johnson.
- *Chambers USA 2021* 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.

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
Michael J. Leard	617.439.2159	mleard@nutter.com
Brian K. Lee	617.439.2490	blee@nutter.com

Associates

Ritika Bhakhri	617.439.2073	rbhakhri@nutter.com
Natalie M. Cappellazzo	617.439.2390	ncappellazzo@nutter.com
Maya H. Ginga	617.439.2035	mginga@nutter.com
Sara Lonks Wong	617.439.2139	slonkswong@nutter.com
Ashley M. Paquin	617.439.2147	apaquin@nutter.com
Mariel T. Smith	617.439.2183	msmith@nutter.com
Melanie V. Woodward	617.439.2130	mwoodward@nutter.com

Nurse Paralegal

Amanda Lessard, LNCC	617.439.2174	alessard@nutter.com

Paralegals

Erin Matheson	617.439.2835	ematheson@nutter.com

e-Discovery Specialists

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

**This comment was collected as part of the U.S. News—Best Lawyers® "Best Law Firms" research process.*