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PRODUCT LIABILITY
2018 YEAR IN REVIEW

Massachusetts state and federal courts issued a number of important product liability decisions in 2018. The Product Liability practice group at Nutter recently reviewed these cases. Highlighted below are some of the key cases and issues decided in the past year.

UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

Gustavsen v. Alcon Laboratories, Inc.
903 F.3d 1 (1st Cir. 2018)

Significant Holding: District Court properly allowed motion to dismiss, holding that altering the size or shape of an eye drop dispenser would be a "major change" to the container and would require FDA re-approval. [The District Court decision, *Gustavsen v. Alcon Laboratories, Inc.,* 272 F. Supp.3d 241 (D. Mass. 2017), was included in **Nutter's 2017 Year In Review**]. Thus, federal law would preempt plaintiffs' claims that the design of the container violated state consumer protection laws because it dispensed drops larger than the human eye could absorb. (Kayatta, J.)

Summary: Putative class action alleged that manufacturers of prescription eye drops violated state consumer protection laws by deliberately designing their dispensers to emit more liquid than a human eye can absorb. The dispensers wasted liquid that would roll down users' cheeks or drain through their tear ducts. The defendants allegedly designed the droppers this way to cause consumers to buy eye drops more frequently than necessary, which would drive up profits.

The District Court determined that the doctrine of impossibility preemption barred the plaintiffs' claims because the Federal Food, Drug, and Cosmetic Act ("FD&C Act") and FDA regulations prohibited the defendants from changing the dropper design without FDA re-approval. The First circuit affirmed dismissal under this doctrine, but also considered the defendants' argument that the plaintiffs lacked subject matter jurisdiction and held that the plaintiffs had plausibly demonstrated actual injury, and therefore had standing (and subject matter jurisdiction).

Subject-matter jurisdiction: To show "injury in fact" and standing to bring a claim, plaintiffs must establish that the injury arises from a legally protected interest that is both "concrete and particularized" and "actual and imminent." The plaintiffs claimed the purchasers of the prescription eye drops lost money approximating $500–$1,000 per year from the wasted excess liquid. The plaintiffs supported this claim with scientific studies and an admission of a marketing executive for one of the major defendants. The defendants responded that the claimed monetary loss was speculative because future bottles dispensing smaller drops could be priced to obliterate any costs savings because manufacturers had "discretion to base prices on the number of drops or doses provided." *Gustavsen,* 903 F.3d at 8. The court held that the plaintiffs had submitted enough evidence to meet the threshold required to defeat a motion to dismiss.

Impossibility preemption: The court carefully examined the applicable FDA regulations and agreed with the District Court that the plaintiffs' state consumer protection claims were preempted by federal law. 21 C.F.R. § 314.70 governs "the manner in which a manufacturer can make a change to an already-approved product." *Id.* at *10. Changes are divided into three categories: major, moderate, and minor. A "major change" requires FDA preapproval; "moderate" or "minor" changes do not. If changing the design of the droppers to release smaller drops was a "major change," the defendants could not lawfully make that change without prior FDA approval. A major change regulated by the FDA includes "changes in a drug product container closure system that control the drug product delivered to a patient." *Id.* at 11; 21 C.F.R. § 314.70(b)(2)(vi). The court held that the (1) dispensing bottle for the eye solution is a "drug product container closure system," (2) eye solution is "a drug product," and (3) the dispenser, by dictating the size of the drops, "controls" the "drug product delivered" to a patient, making it a major change requiring FDA approval. *Gustavsen,* 903

F.3d at 11.Therefore, the plaintiffs' attempt to use state consumer protection laws to make a change to the eye drop dispenser was preempted.

Informal agency action does not take precedence over official agency guidance: The plaintiffs argued that the FDA does not require preapproval of all container closure systems. The plaintiffs pointed to five occasions where drug manufacturers changed the drop size of their prescription eye medication without first obtaining FDA approval. In some instances, the FDA had considered the change of the drop size a moderate change. The court rejected this argument, explaining that it does not need to defer to an agency's interpretation of its regulations if it does not reflect the agency's "fair and considered judgment." *Id.* at 14. (citations omitted). The court also rejected decisions made by mid-level FDA scientists or a "single reviewer", or due to FDA inaction as dispositive. The court noted that there were other possible inferences, such as the FDA using its discretion not to enforce a rule or letting something slip through the cracks. The evidence the plaintiffs provided was not convincing.

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

Plourde v. Sorin Group USA, Inc.
--- F.Supp.3d---, 2018 WL 1542361 (D. Mass. March 29, 2018)

Significant Holding: In a case of first impression, District Court denied motion to dismiss on a failure to warn claim. Referencing decisions from other circuits, the court held that a state law claim for failure to report new information to the FDA was not preempted by federal law. As importantly, the court held that the plaintiffs would need to prove that such a state law claim exists under Massachusetts law. (Burroughs, J.)

Summary: Allison Plourde suffered from heart defects and underwent an aortic heart valve replacement surgery at Boston Children's Hospital ("BCH"), where her physicians implanted the Sorin Mitroflow Aortic Pericardial Heart Valve (the "Valve") in her heart. BCH physicians later notified patients, including Ms. Plourde, that some cases necessitated a second surgery. After some testing, the physicians determined that Ms. Plourde's Valve had severely deteriorated and required immediate removal. Ultimately, Ms. Plourde died due to hemorrhaging and chest wall bleeding. BCH physicians subsequently published a study where they concluded that younger patients with a Valve were at a heightened risk for certain issues. Ms. Plourde was one of the patients referenced in the study.

The plaintiffs, the parents of Ms. Plourde, sued the manufacturers of the Valve, alleging breach of warranty, negligence, failure to warn, and a violation of the consumer protection statute under Massachusetts state law. In terms of the failure to warn claim, the plaintiffs alleged that the defendant manufacturers knew, or should have known, of studies conducted in other countries that discussed similar issues with the Valve. The defendants should have updated the FDA with this information and, in turn, the FDA could have issued a more particularized warning concerning certain risks for certain types of patients, like Ms. Plourde, thus preventing her death.

Preemption: The defendants argued that the plaintiffs' claims were preempted by the Medical Device Amendments ("MDA") to the FD&C Act. The MDA establishes various levels of oversight for medical devices depending on their risks. After approving a device, the MDA forbids a manufacturer from making any changes that would affect the safety or effectiveness of the device without further FDA approval. The MDA also contains an express preemption provision that preempts applying any state laws that are different from, or in addition to, the federal rules.

The court explained that when reading together *Buckman v. Plaintiffs' Legal Committee,* 531 U.S. 341, 348 (2001) and *Riegel v. Medtronic, Inc.,* 552 U.S. 312 (2008), key Supreme Court decisions on preemption, there exists a narrow gap where states may impose parallel requirements to ones imposed by federal law. Those state law claims would not be expressly or impliedly preempted by the MDA.

The plaintiffs conceded that all of its claims were preempted by the MDA except for the failure to report new information to the FDA. They alleged that Massachusetts state law imposed a duty on device manufacturers "to report new scientific studies and incidents in which the device contributed to a serious injury or death to the FDA" that was a parallel claim fitting within this narrow gap. *Plourde,* 2018 WL 1542361, at *4. Without deciding whether there was such a state law claim

in Massachusetts, and rejecting a contrary Superior Court decision, the court agreed that if the claim existed under state law it would not be preempted.

There are no directly applicable First circuit cases on point, but several federal courts have considered whether reporting new information to the FDA would be preempted by the MDA.

Stearns v. Metropolitan Life Ins. Co.

308 F. Supp. 3d 471 (D. Mass. March 30, 2018)

Significant Holding: District Court declined to apply the Massachusetts Statute of Repose to a contractor's asbestos-related conduct during the construction of two power plants distinguishing the Massachusetts Supreme Judicial Court's seminal decision in *Klein v. Catalano,* 386 Mass. 701 (1982). Although the legal issue before the court met the requirements for certification, the court exercised its discretion not to certify. (Zobel, J.)

Summary: The plaintiffs brought a wrongful death action against several defendants, including General Electric Company ("GE"), which designed, manufactured, and sold steam turbine generators for installation at two nuclear power plants. GE's engineers also supervised the installations and, for one of the plants, continued regular maintenance, inspections, and refueling after completing installation. GE specified using asbestos-containing insulation materials with its generators and rejected using non-asbestos alternatives.

In the 1970s, the decedent, an employee of the architect-engineer with responsibility for the construction at the plants, was exposed to asbestos. He was diagnosed with malignant mesothelioma in 2015 and died in 2016.

GE moved for summary judgment based on the Massachusetts Statute of Repose, G.L. c. 260, §2B, which sets a six-year limit on bringing a tort action based on any deficiency or neglect in the design, planning, construction, or general administration of an "improvement to real property." GE maintained that the plaintiffs' claims were time-barred. The plaintiffs argued the statute did not apply because the asbestos-containing insulation was not an improvement to real property within the meaning of the statute. In the alternative, the plaintiffs argued that the court should not apply the statute to asbestos-related conduct.

The court found that insulated turbine-generators were an improvement to real property, but declined to apply the six-year limit, holding that while the statute facially covers designers, engineers, and contractors like GE, its protection is determined in the context of the underlying facts.

Improvement to real property: The Statute of Repose does not define "improvement to real property," but the Massachusetts Supreme Judicial Court has read this to mean "a permanent addition to or betterment of real property that enhances its capital value and that involves the expenditure of labor or money and is designed to make the property more useful or valuable as distinguished from ordinary repairs." *Milligan v. Tibbetts Engineering Corp.,* 391 Mass. 364 (1984) (citation omitted). The plaintiffs argued that the asbestos-containing insulation materials on the generators were not finished products and therefore not an improvement to real property. The court dismissed that argument, holding that Statute of Repose protected activities such as design, planning, and construction that were a "process of improvement" as well as finished products. Therefore asbestos-containing materials, which were essential to the turbine generators, were part of the overall improvement and covered by the statute.

Asbestos-related conduct: The public policies underlying the Statute of Repose are analyzed thoroughly in *Klein.* In an oft-quoted line, *Klein* explains that "there comes a time when a defendant ought to be secure in his reasonable expectation that the slate has been wiped clean of ancient obligations." *Stearns,* 308 F. Supp. 3d at 479 (quoting *Klein* at 520). Moreover, *Klein* explained that a defendant "ought not to be called on to resist a claim when evidence has been lost, memories have faded, and witnesses have disappeared . . . ." *Id.* at 480 (quoting *Klein* at 520).

The *Stearns* court did not find either of these policies persuasive in the context of asbestos claims generally or specifically to this case. *Klein,* the court explained, involved an architect that had no reason to believe the design of a plate-glass door would hurt anyone. On the other hand, dangers of asbestos were well known by the 1970s and allegedly known by the defendants. Second, the realities of asbestos exposure are different. The vast majority of personal injury claims are discovered within six years; asbestos exposure illnesses will rarely appear within that time frame and often have an extended latency period of 20

to 40 years. For example, the plaintiff was diagnosed after more than 30 years. Likewise "staleness of evidence" was not as important a factor because the burden of proof is somewhat relaxed in the asbestos context. In this case, the plaintiffs had strong evidence of both product identification and exposure. Lastly, it would not be unfair to extend liability to actors like GE. The *Klein* architect's work was completed nine years before the plaintiff's injury; whereas GE had control during construction and continued regular on-site maintenance and inspections for at least two decades post-construction.

SUPREME JUDICIAL COURT OF MASSACHUSETTS

Rafferty v. Merck & Co.

479 Mass. 141 (March 16, 2018)

Significant Holding: Innovator, brand-name drug manufacturer may be liable to a generic drug user for a reckless failure to warn of an unreasonable risk of death or grave bodily injury. Brand-name drug manufacturer not liable for negligent failure to warn consumers or under state consumer protection laws. (Gants, J.)

Summary: The plaintiff, Brian Rafferty, ingested a generic version of a drug to treat an enlarged prostate. Merck & Co. ("Merck") manufactured the brand-name version (Proscar) of the generic drug prescribed to the plaintiff (finasteride). The plaintiff began experiencing side effects related to sexual dysfunction and immediately stopped taking the drug. Despite stopping the medicine, the side effects continued and even worsened. The product label for finasteride warned that there was a potential for such side effects, but stated that these side effects would end if drug use stopped.

Federal law requires the generic drug manufacturer of finasteride to provide its users the same warning label that the brand-name counterpart Proscar provides to its users. Accordingly, the finasteride label was identical to the Proscar label.

When the plaintiff was using this generic drug, several studies emerged suggesting that side effects from these drugs could persist after discontinuing drug use. In certain foreign markets, Merck had already changed the label for Proscar to include such a revised warning, but had not done so in the U.S. Therefore, the generic drug manufacturer had not revised its label to warn of continuing side effects.

The plaintiff sued Merck in the Massachusetts Superior Court for negligence, failure to warn, and a violation of G.L. c. 93A. [The Superior Court decision, *Rafferty v. Merck & Co.,* No. 2013-04459, 2016 WL 3064255 (Mass. Super. Ct. May 23, 2016) was included in **Nutter's 2016 Year in Review**]. The Superior Court granted Merck's motion to dismiss. The Massachusetts Supreme Judicial Court granted direct review.

Negligence: A defendant owes a duty of care to all persons foreseeably endangered by his or her conduct unless the duty "is deemed either inadvisable or unworkable." *Id.* at 1214 (citing *Jupin v. Kask,* 447 Mass. 141, 150-151 (2006). The court held that Merck did not owe a duty of care to generic drug users because holding otherwise would disfavor the development of new and more effective drugs. Brand-name manufacturers were in the best position to prevent injury from inaccurate or inadequate warnings, but were not in the best position to absorb the costs resulting from failure to warn claims. The court explained that the costs "would not be incurred until after the brand-name manufacturer's patent monopoly expires and generic competitors enter the market, at which point the brand-name manufacturer will have suffered a precipitous decline in sales of the product." *Id.* at 1216. Also, prices drop with generic competition, so "the sales of generic drugs may exceed the sales generated during the patent monopoly period, and may continue indefinitely," long after the brand-name manufacturer had moved on to other products. *Id.* Generic competitors could better absorb significant costs of litigating or settling claims, but federal preemption laws barred these types of claims against the generic manufacturers, leaving only the brand-name manufacturer with this burden. This would be a chilling effect on drug innovation.

Recklessness: The court did not want to leave generic drug consumers without a remedy. So, the court concluded that brand-name manufacturers owe a duty not to act in reckless disregard of an unreasonable risk of death or grave bodily injury. Reckless conduct must be intended and involve a substantially greater risk than is required for ordinary negligence. The court reasoned that this was consistent with longstanding public policy not to tolerate reckless disregard for the safety of

others. For example, if a brand-name manufacturer learns that its drug is repeatedly causing death or serious injury or causes birth defects to pregnant mothers, and fails to warn, it could be liable to generic drug consumers.

With this decision, the Massachusetts Supreme Judicial Court joins a minority of courts that have decided that an innovator, brand-name drug manufacturer has any duty to generic drug users. According to the court, it is the only court to limit the scope of liability arising under this duty to reckless disregard of the risk of death or grave bodily injury. The court remanded the case to give the plaintiff an opportunity to amend his complaint, if warranted.

Chapter 93A claim: A party may be liable under Chapter 93A for unfair or deceptive "advertising, the offering for sale,… or distribution of any services and any property, tangible, or intangible. . . " in the conduct of trade or commerce. G.L. c. 93A, § 1(b). The court held that "it would stretch the limits of 93A" to hold that Merck's alleged failure to warn occurred in the conduct of any trade or commerce when it never advertised, offered to sell, or sold the generic drug. *Id.* at 1223.

MASSACHUSETTS APPEALS COURT

Dubuque v. Cumberland Farms Inc.

93 Mass. App. Ct. 332 (June 6, 2018)

Significant Holding: Massachusetts Appeals Court held that an internal report of 485 prior car strikes at various Cumberland Farms convenience stores was admissible in a case involving a car strike at the Cumberland Farms store in Chicopee, MA. The reported incidents only needed to be substantially similar, not identical, to the car strike at issue, and were relevant to breach of duty and foreseeability. (Sullivan, J.)

Summary: Kimmy Dubuque died instantly when hit by a speeding car while walking into a Cumberland Farms convenience store in Chicopee. The store did not have bollards or other protective barriers along its walkway to protect pedestrians from motor vehicles, although it was aware that one of its entrances allowed drivers to enter the store parking lot at a high rate of speed.

There were no prior accidents at that store, but between 1990 and 2010 there had been reports of vehicle strikes at other locations and, in some cases, litigation. One company representative estimated accidents at a rate of approximately once a week. The company had installed bollards at other stores (primarily to protect its property) and some bollards at the Chicopee store (to protect its sign). Over the objections of the defendant, a Superior Court judge admitted an internal company report documenting 485 prior car strikes at other stores.

A jury found that the defendant acted negligently and awarded $32,369,024.30 in compensatory damages (later reduced by the trial judge to $20 million). The defendant sought a new trial, arguing that the trial judge improperly admitted an internal report that included accidents that were not substantially similar to the accident at the Chicopee store.

Admission of evidence of prior accidents: Courts will not admit prior accident evidence unless the circumstances of the other accidents are substantially similar to the accident at issue. The court explained that the test is one of relevance. The defendant contended that the trial judge should only admit evidence of other accidents that involved the same factors as at the Chicopee store. For example, only accidents that involved a vehicle traveling at a high speed in a low speed zone or with the same individual driver behavior. The court rejected this as an exceedingly rigorous test. Instead, the relevant risk "was uncontrolled vehicles hitting at or near a Cumberland Farms store entrance and endangering pedestrians due to a lack of adequate protective barriers." *Dubuque,* 93 Mass. App. Ct. at 329. Using this as its guidepost, the court held that the other accidents were substantially similar.

MASSACHUSETTS SUPERIOR COURT

Bennett v. R.J. Reynolds Tobacco Co.

34 Mass. L. Rptr. 547 (Mass. Super. Ct. Jan. 8, 2018)

Significant Holding: In a case of first impression, the Massachusetts Superior Court held that a personal representative of an estate with limited authority under G.L. c. 190B, § 3-108(4) of the Uniform Probate Code ("UPC") did not have standing to bring a wrongful death action under G.L. c. 229, § 2 or conspiracy claims. (Kaplan, J.)

Summary: Tina Bennett, the personal representative of David Bennett's estate, brought an action against the defendants related to

smoking cigarettes manufactured or sold by the defendants. The plaintiff filed suit three years later and petitioned to be appointed as the personal representative of the estate pursuant to G.L. c. 190B, § 3-108(4). Under this statute, the personal representative's authority is limited to "confirming title to estate assets in the successors and paying expenses of administration, if any." *Bennett,* at *2 (referencing the MUPC Estate Administration Procedural Guide, Second Edition). The defendants moved to dismiss because the plaintiff's appointment status does not give her authority to bring these claims. The court agreed.

Tort claims: A G.L. c. 190B, § 3-108(4) appointment is limited in scope. It is referred to as a "Late and Limited Appointment." A personal representative appointed this way does not possess a cause of action, such as one for conscious pain and suffering experienced by the deceased prior to his or her death. Although such a tort claim is the property of the estate, the nature of the appointment bars the representative from asserting such claims. Accordingly, the plaintiff could not assert conspiracy claims that may have belonged to Mr. Bennett before his death.

Wrongful death: Generally, wrongful death claims are not the property of the estate and any recovered damages belong to the statutory beneficiaries of the wrongful death claim. G.L. c. 229, § 2 provides that "damages shall be recovered in action of tort by the executor or administrator of the deceased." The UPC, enacted in 2012, discontinued the use of terms such as "executor" and "administrator" in favor of "personal representative," complicating how to apply existing case law and statutory schemes to UPC terms. The Massachusetts Supreme Judicial Court in a pre-UPC case decided that a voluntary administratix did not have standing to prosecute wrongful death claims pursuant to G.L. c. 229, § 2. *Marco v. Green,* 415 Mass. 732 (1993). The court analogized a personal representative appointed under § 3-108(4) to a voluntary administratix, holding the plaintiff did not have standing.

Of note, G.L. c. 190B, § 3-709 gives personal representatives plenary rights to possession or control of the decedent's property. The plaintiff appears to have missed the deadline to be appointed as a personal representative under this provision. Under this provision, she likely had the rights to pursue the above causes of action.

This is a case of first impression in Massachusetts and other states that have adopted the Uniform Probate Code.

THIS ADVISORY WAS PREPARED BY DAVID FERRERA, SA'ADIYAH MASOUD, AND RITIKA BHAKHRI OF NUTTER'S LITIGATION DEPARTMENT. FOR MORE INFORMATION, PLEASE CONTACT YOUR NUTTER ATTORNEY AT 617.439.2000.

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PRODUCT LIABILITY DEFENSE

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, drugs, industrial materials, and automotive 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 or materially adverse settlements 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* 2019 "Best Law Firms" survey.
- Nutter has been named a "Go-To" law firm in Torts Litigation by Johnson & Johnson.
- *Chambers USA 2018* recognized Nutter in the Litigation: General Commercial category.

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 spinal discs, artificial metal-on-metal hips, artificial knees, 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 contact lenses, facial cleansers and baby powder.
- 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.

PRODUCT LIABILITY DEFENSE

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, 3D printing, food and beverage litigation, automotive liability, and other topics.

Nutter's products liability lawyers have been featured in *Bloomberg BNA, Corporate Counsel,* IADC's *Drug, Device and Biotechnology Committee Newsletter, Risk Management Magazine, Medical Design & Outsourcing,* DRI's *The Voice, Huffington Post, Inside Counsel, Medical Device and Diagnostic Industry (MD+DI), The Gourmet Retailer, Additive Manufacturing Today, Food Manufacturing Magazine, 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" 2018 chapter supplement 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. Recent highlights include:

- Presented at ACI's Drug and Medical Device Litigation Conference, DRI's Drug and Medical Device Seminar, the American Bar Association, and the Boston Bar Association.
- Selected as Fellows of the American College of Trial Lawyers and the Litigation Counsel of America.
- 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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