Nutter Product Liability: 2016 Year in Review

U.S. First Circuit/Massachusetts

Massachusetts state and federal courts issued a number of important product liability decisions in 2016. The Product Liability and Toxic Tort Litigation 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

Tersigni v. Wyeth, 817 F.3d 364 (1st Cir. Mar. 23, 2016)

Significant Holding: Affirmed First Circuit precedent that a party who preemptively introduces evidence to "remove its sting" waives any later objection to its admissibility. The trial court's admission of other arguably objectionable evidence, if error, was harmless; the jury did not consider it. (Stahl, J.)

Summary: Wyeth manufactured and marketed the weight-loss drug Pondimin from 1989 until 1997. In the last year of the drug's sales, Michael Tersigni received a prescription and took it for about six months. After studies linked Pondimin to heightened risk of primary pulmonary hypertension ("PPH"), as well as valvular heart disease, the FDA ordered Wyeth to pull it from the shelves. Tersigni's doctor told him to stop taking Pondimin in July 1997, shortly before Wyeth withdrew it. After he developed PPH in 2011, Tersigni sued Wyeth under various theories, most notably negligent design and negligent failure to warn.

The District of Massachusetts granted Wyeth's motion for summary judgment on all of Tersigni's claims except for negligent failure to warn. Wyeth prevailed at trial, and Tersigni appealed; he argued that negligent design should have survived summary judgment, and that the admission of certain evidence during the trial was error.

A First Circuit panel that included Justice Souter affirmed; it held that Tersigni failed to prove the existence of a reasonable alternative design, which is required by Massachusetts law to sustain a claim for negligent design. The panel then held that the District Court's admission of evidence of Tersigni's 2008 incarceration for non-payment of child support, and of his decades-prior cocaine use, was not reversible error.

Negligent design claim against a prescription drug: A seller of unavoidably unsafe products—or, those that carry known risks along with their significant benefits—is exempted from strict liability when it provides a proper warning. *Tersigni*, 817 F.3d at 367. This is the spirit of Comment K to the Restatement (Second) of Torts § 402A, and the SJC adopted Comment K in 1982. *Id.* (citing *Payton v. Abbot Labs*, 386 Mass. 540, 573 (1982)). As a result, the District Court decided that Massachusetts courts would not recognize a negligent design claim against a prescription drug, and it allowed Wyeth's summary judgment motion.

The First Circuit was not so sure. Though Wyeth was correct that no Massachusetts court had yet recognized the claim in this context, Tersigni rightly noted that none had ruled it out, either. *Tersigni*, 817 F.3d at 368. Calling the question "quite uncertain," the First Circuit decided the negligent design issue on other grounds; namely, that Massachusetts law definitely requires proof of a reasonable alternative design, and Tersigni offered none. *Id.* at 368-69.

Instead, Tersigni pointed to other means of weight loss as alternatives, but the First Circuit explained that the relevant inquiry "requires the plaintiff to show that the product in question could have been more safely designed, not that a different product was somehow safer." *Id.* at 368.

Evidentiary rulings—harmless error, "removing the sting," and waiver: Before trial on his surviving negligent failure

to warn claim, Tersigni filed motions in limine to exclude evidence of his 2008 incarceration for non-payment of child support and of his cocaine use in the more distant past. Both lines of evidence were purportedly tied to the question of whether Pondimin caused his PPH; the District Court denied Tersigni's motions.

The court allowed incarceration-related testimony with respect to whether his time in jail could have affected Tersigni's blood pressure; it also permitted testimony that he had committed no violent crime. Tersigni argued that the District Court erred in admitting this evidence because it was prejudicial disproportionate to its probative value. *Id.* at 369-70. But the First Circuit explained that any error was harmless; since Tersigni did not establish that Wyeth failed to warn his doctor of Pondimin's risks, the jury never reached causation. *Id.* at 370.

As for the second motion, the District Court wanted to hear and evaluate expert testimony regarding cocaine use and PPH before deciding whether the evidence was admissible. But Tersigni's counsel affirmatively raised the issue during her opening and in the course of two direct examinations. *Id.* With the motion to exclude denied, Tersigni's lawyer wanted to confront and "remove the sting" of tough evidence that would inevitably come in later.

The First Circuit relied on a previous holding that introducing evidence to remove its sting waives any later objection to admissibility. *Id.* (citing *Gill v. Thomas*, 83 F.3d 537, 541 (1st Cir. 1996)). Tersigni argued that the 2000 amendment to Fed. R. Evid. 103—regarding the preservation of claims of evidentiary error—changed the law. But the Advisory Committee Notes were explicit that the amendment was silent as to the waiver-related implications of preemptively "removing the sting" of tough evidence; they even cited *Gill v. Thomas*. *Id.*

Thus, the First Circuit affirmed on all counts.

Milward v. Rust-Oleum Corp., 820 F.3d 469 (1st Cir. April 25, 2016)

Significant Holding: District Court properly excluded expert testimony where the witness conducted a relative risk analysis, but she ignored conflicting studies and failed to explain why. The same expert also ran a differential diagnosis, but she "ruled in" the alleged cause of plaintiff's illness without a reliable basis to do so. Summary judgment affirmed. (Howard, C.J.)

Summary: Plaintiff Brian Milward spent his professional life as a pipefitter and refrigerator technician. In that work, he was exposed to benzene in various products, including Rust-Oleum's paint. Milward contracted Acute Promyelocytic Leukemia ("APL") in 2004. He and his wife filed suit three years later; they claimed that Rust-Oleum and others caused his illness through their negligence.

At the time of this decision, Rust-Oleum was the only defendant left, and it filed contemporaneous motions to exclude the testimony of the Milwards' sole specific causation expert and for summary judgment. The District Court allowed both of Rust-Oleum's motions, and the Milwards appealed. The First Circuit deemed the expert's theories methodologically flawed, so it affirmed the District Court's exclusions and grant of summary judgment.

Rule 702, *Daubert*, and Dr. Butler: The First Circuit explained that qualified experts may offer opinions if their knowledge will assist the trier of fact, if their "testimony is based on sufficient facts or data," if said testimony is the "product of reliable principles and methods," and if the expert "reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702. Expert testimony must "rest[] on a reliable foundation and [be] relevant to the task at hand." *Milward*, 820 F.3d at 473 (quoting *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993)).

The Milwards hired Dr. Sheila Butler, a physician with the Veterans Administration who "specializes in clinical assessments of environmental and occupational exposure in combat-exposed veterans." *Milward*, 820 F.3d at 471. Dr. Butler presented three somewhat interconnected specific causation theories to the District Court, all three were

rejected, and the Milwards pressed two of them on appeal.

No safe exposure level: Although plaintiffs abandoned Dr. Butler's first theory, the First Circuit noted that it was "predominant." *Id*. at 471-72. She claimed that, "there is no safe level of benzene exposure." *Id*. at 471. So Dr. Butler deemed benzene the likely cause of Brian Milward's APL. But the District Court said that this theory was deficient because there was no scientific way to test it "with any known rate of error." *Id*. at 472. Since plaintiffs did not argue this "no safe level" theory above, the First Circuit otherwise left it alone.

Relative risk: Dr. Butler pointed to certain epidemiological studies and explained that they "established that an individual's 'relative risk' of developing APL increases when exposed to specified amounts of benzene." *Id.* Thus, she determined that Milward's exposure above allegedly hazardous levels meant that benzene was the probable culprit of his APL. But Dr. Butler ignored studies that reached different conclusions; namely, that very high benzene exposure caused no increased risk of contracting leukemia. In fact, she testified at her deposition that she was neither willing nor able to assess all of the relevant epidemiological studies; Dr. Butler was unequivocal: "I'm not an epidemiologist if you're going to go there." *Id*. at 474, n.3.

The Milwards argued that no study directly contradicted those that Dr. Butler had selected. But the First Circuit said that "it is not . . . true that the studies must present diametrically opposing conclusions to be in tension with one another." *Id*. at 474. More plainly, if Dr. Butler had selected a different study to form the "baseline" of her opinion, then her testimony would necessarily change. And she was unable to explain why she chose one study over another.

Ultimately, relying on an opinion from the Seventh Circuit, the Milwards claimed that Dr. Butler based her testimony on reliable evidence, and that was good enough. But the First Circuit distinguished that case (the expert there had explained why other studies were unreliable) and noted that "the district court is on firm ground in requiring . . . an explanation" when an expert chooses certain studies in favor of others. *Id*. at 474-75 (discussing *Schulz v. Akzo Nobel Paints, LLC*, 721 F.3d 426 (7th Cir. 2013)).

As a result, the First Circuit held that the District Court properly excluded Dr. Butler's relative risk analysis.

Differential diagnosis: Dr. Butler also used "essentially a process of elimination" to conclude that benzene exposure caused Milward's APL. She ruled out certain other potential causes (e.g., obesity and smoking), and the District Court took little issue with those. *Milward*, 820 F.3d at 475. More problematically, she ruled out idiopathic (i.e., cause-unknown) APL simply because she "ruled in" benzene exposure as the cause. *Id*. Since the record suggested that 70%-80% of APL cases are idiopathic, Dr. Butler's determination was suspect. The District Court called her thinking "circular" and excluded this line of testimony. *Id*. at 475-76.

The First Circuit found no abuse of discretion because an expert conducting a differential diagnosis must use reliable methods to rule potential causes in or out, and Dr. Butler "appears to have 'ruled in' benzene exposure solely by relying on her two other theories." *Id*. at 476. In light of the aforementioned problems with those theories, neither could form the basis of Dr. Butler's conclusion. And she offered no independently sound reason to rule out idiopathic APL. *Id*.

With Dr. Butler's differential diagnosis also excluded, the Milwards had no medical expert testimony on specific causation left. Without it, they could not establish medical causation, so the First Circuit affirmed summary judgment in Rust-Oleum's favor.

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

Fertik v. Stevenson, 186 F. Supp. 3d 98 (D. Mass. May 13, 2016)

Significant Holding: *Res ipsa loquitur* barred cardiac guide wire manufacturer's motion for summary judgment as to plaintiff's manufacturing defect claim. No evidence suggested that the wire was mishandled between its manufacturer and the operating theater, so the wire was still in defendant's "control" when it broke during surgery. And while the operating surgeon's use was off-label, it was foreseeable. Since such breaks are rare, a jury could find that a defect caused this one. (Saris, C.J.)

Summary: During his cardiac ablation surgery, a guide wire broke and a fragment remained inside plaintiff William Fertik. His surgeons did not notice the break, and Fertik showed symptoms of a stroke a few days later; he needed another surgery to remove the wire. Fertik and his wife sued Abbott Vascular, Inc.—the wire's manufacturer—for manufacturing defect. Abbott moved for summary judgment, claiming that Fertik failed to prove its negligence. Fertik argued that *res ipsa loquitur* foreclosed the possibility of summary judgment.

The District Court denied Abbott's motion. Chief Judge Saris held that the wire remained in Abbott's exclusive control because there was no allegation that it was mishandled after its shipment to the surgeon. And though the surgeon's use was technically off-label, it was nonetheless foreseeable, and *res ipsa* could apply.

Res ipsa loquitur: The District Court first offered a primer on *res ipsa*, noting that the doctrine allows:

> an inference of negligence in the absence of a finding of a specific cause of the occurrence when an accident is of the kind that does not ordinarily happen unless the defendant was negligent in some respect and other responsible causes including conduct of the plaintiff are sufficiently eliminated by the evidence.

Fertik, 186 F. Supp. 3d at 102 (quoting *Enrich v. Windmere Corp.*, 416 Mass. 83, 88 (1993)). Or, when a rare accident happens without a clear cause, a factfinder may infer negligence if the evidence rules out other potential causes.

A jury is permitted to apply *res ipsa* if two threshold requirements are met by a preponderance of the evidence: 1) the device that caused the injury was in the defendant's sole control, and 2) the accident would not normally happen unless the defendant was negligent. *Fertik*, 186 F. Supp. 3d at 102 (citing *Wilson v. Honeywell, Inc.* 409 Mass. 803, 805 (1991)).

Control: The District Court first noted that there was no evidence that the wire was mishandled in transit between Abbott and the hospital, that it appeared undamaged to the surgeons who removed and used it, and that those surgeons testified that they did not mishandle it themselves. *Id.* at 103. The District Court explained that—in a case involving a broken epidural catheter—it had held that the device was in the manufacturer's exclusive control since it was, "'out of the box and new' prior to surgery." *Id.* (quoting *Laspesa v. Arrow Int'l, Inc.*, No. CIV. 07CV12370-NG, 2009 WL 5217030, at *1 (D. Mass. Dec. 23, 2009)). Since that was also true here, *res ipsa's* exclusive control requirement was met.

Negligence: Fertik and Abbott offered conflicting evidence as to whether a guide wire break could ordinarily occur with no manufacturer negligence. Fertik presented multiple surgeons' testimony that they had performed thousands of similar procedures with a comparatively infinitesimal number of breaks. But Abbott countered that the FDA's website identified breakage as the number one adverse event reported for guide wires like these, "most commonly because of handling use error." *Id.*

However, the District Court noted that, in this case, "all parties agree there was no negligence by the doctors or other third parties handling the guide wire." *Id.* So Abbott also argued that the wire's delicacy made it a breakage risk even with no negligence. The District Court held that—in the summary judgment context—a jury could find a defect in light of all of the proffered evidence.

Off-label use: Abbott also argued that its guide wire was used in an "off-label" manner; that is, one not expressly approved by the FDA. The District Court reminded its readers that "'[o]ff-label' usage of medical devices is an 'accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine.'" *Id.* at 104 (quoting *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001)). So while manufacturers are obligated to consider off-label uses in the course of designing their devices, they are "not liable for the consequences of the unforeseeable misuse of a product." *Id.* (quoting *Back v. Wickes Corp.*, 375 Mass. 633, 640 (1978)).

The off-label debate was nuanced. Fertik said this surgery was not actually off-label, though the procedure was absent from the guide wire's label. He relied on the approved product classification, which stated more broadly that Abbott's guide wire was "intended to facilitate the placement of equipment such as atherectomy and compatible stent devices during other diagnostic and therapeutic procedures." *Id.* at 105. Fertik contended that this included his cardiac ablation.

Abbott cited the surgeon's affidavit, in which he said that this use was off-label. Further, Abbott's director of regulatory

affairs testified that only four uses were approved; cardiac ablation was not among them. So the District Court assumed that the use was off-label but deemed it entirely foreseeable in light of evidence that this guide wire had been used thousands of times in procedures like Fertik's. *Id*.

Thus, Abbott's final obstacle was to establish that it could not be held liable for manufacturing defect when its devices were used off-label. It relied upon cases that dealt with surgical screws, opening the door for this gem: "[Abbott] unsuccessfully attempts to turn the screws on the plaintiff relying on cases largely involving surgical screws." *Id*. But those cases simply held that manufacturers are not liable for surgeons' off-label use absent a defect, and the District Court explained that "there is no controlling authority that immunizes Abbott from a product defect claim based on a foreseeable 'off-label' use." *Id*. at 105-06.

The District Court denied Abbott's motion.

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Fertik and Abbott agreed to settlement terms a few months after this decision; on November 7, 2016, they filed a stipulation of dismissal with prejudice.

MASSACHUSETTS APPEALS COURT

Albright v. Boston Scientific Corp., 90 Mass. App. Ct. 213 (2016)

Significant Holding: Massachusetts Appeals Court reversed a defense verdict in favor of a transvaginal mesh manufacturer and remanded the case. The Appeals Court held that it was prejudicial error to exclude from evidence a caution from the supplier of an ingredient in the mesh and two letters from the FDA to the manufacturer of the mesh. (Katzmann, J.)

Summary: In 2014, a Massachusetts Superior Court jury returned a defense verdict for Boston Scientific, the manufacturer of transvaginal mesh used to treat pelvic floor conditions. The plaintiff brought design defect and failure to warn claims under Ohio law—the plaintiff lives in Ohio, and the pelvic mesh was implanted at an Ohio hospital—related to severe pain she experienced after the implantation of Boston Scientific's transvaginal mesh to treat pelvic organ prolapse.

On appeal, the plaintiff challenged the trial court's exclusion of 1) a medical application caution provided to Boston Scientific by the supplier of the polypropylene material used in the mesh, and 2) two letters from the FDA to Boston Scientific related to the transvaginal mesh. The Appeals Court held that the exclusion of the polypropylene supplier's caution and the FDA letters was prejudicial error requiring reversal.

Polypropylene supplier's MSDS: A material safety data sheet ("MSDS") the polypropylene supplier provided to Boston Scientific contained the following warning: "Do not use this material in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues." The trial court excluded the caution because the plaintiff did not establish its scientific basis, and the record was inconclusive with respect to why the supplier included the caution in the MSDS.

Applying Massachusetts evidence law, the Appeals Court held that the caution should have been admitted for notice purposes—i.e., to show the effect it had, or should have had, on Boston Scientific. The caution was material—and its exclusion was prejudicial—because Boston Scientific's knowledge of the foreseeable risks of the pelvic mesh was the crux of the case. The caution would round out the information presented to the jury related to the mesh's safety about which Boston Scientific knew or should have known.

The caution is admissible for the limited purpose of showing notice to Boston Scientific and should not be offered to establish causation. Thus, on retrial, limiting instructions and, "if necessary, . . . a tailored statement in the jury charge," can address any concerns about the jury misusing the caution for causation purposes. 90 Mass. App. Ct. at 223.

Despite concluding that the caution is admissible, the court acknowledged that the caution was included in the MSDS for arguably legal—not scientific—reasons. 90 Mass. App. Ct. at 225 (Boston Scientific challenged the admissibility of the caution on the ground "that it was added [to the MSDS] at the insistence of legal counsel in response to liability concerns."). That court responded that this challenge goes to the weight, not the admissibility, of the caution.

FDA's letters: The FDA sent two letters to Boston Scientific.

The first ordered Boston Scientific to conduct a postmarket surveillance study to examine the safety and efficacy of the transvaginal mesh in treating pelvic organ prolapse. The second letter granted Boston Scientific's request to suspend that study because Boston Scientific planned to stop manufacturing and marketing the transvaginal mesh in the United States.

The Appeals Court concluded that these letters should have been admitted for the limited purpose of cross-examining Boston Scientific's witnesses who had testified that the transvaginal mesh was safe at the time of trial. The exclusion of the FDA's letters was particularly prejudicial because Boston Scientific was permitted to introduce evidence that the mesh was cleared through the FDA's § 510(k) process. Thus, the plaintiff should have been allowed to use the FDA's letters to rebut Boston Scientific's claim that the mesh was "cleared" as a safe device. The court also noted, in dicta, that evidence of the mesh's § 510(k) could have been excluded altogether. 90 Mass. App. Ct. at 223 ("We add that the judge would have been well within her discretion to exclude all reference to the § 510(k) clearance . . . because of its potential to mislead the jury and confuse the issues."). Quoting decisions from transvaginal mesh MDL cases, the court reasoned: "'That a device has been given clearance through the FDA's [§] 510(k) process is not relevant to state tort law. . . . The prejudicial value of evidence regarding the [§] 510(k) process far outweighs its probative value.'" *Id.* (citations omitted).

Niedner v. Ortho-McNeil Pharm., Inc., 90 Mass. App. Ct. 306 (2016)*

Significant Holding: The exception under Massachusetts law to the learned intermediary doctrine for oral contraceptives applies to hormonal birth control products, such as the birth control patch. The manufacturer of the Ortho Evra patch adequately warned the patient of the patch's risks and was not liable for defective design because the plaintiff did not show that the patch has a safer alternative design. (Blake, J.)

Summary: At a doctor's appointment at which her mother (the plaintiff) was present, Arianna Duffy asked her doctor about the Ortho Evra birth control patch, manufactured by Johnson & Johnson, because it was "an easy and simple" option. The doctor warned Duffy and her mother about the risks of the patch, including blood clots, and then prescribed Duffy the patch. The patch's packaging contained an insert from Johnson & Johnson and a leaflet from the pharmacy, both of which warned about the risks of the patch, including stroke, heart attack, and blood clots. Several months later, Duffy died of a pulmonary embolism. Her mother, as the administrator of her estate, brought several claims against Johnson & Johnson, including failure to warn (of the comparative risk of suffering blood clots between the patch and oral contraceptives) and design defect claims. The Appeals Court affirmed summary judgment in Johnson & Johnson's favor.

Failure to warn: Ordinarily under Massachusetts law, the learned intermediary doctrine insulates a drug manufacturer from liability for failure to warn a patient of risks associated with a prescription drug product. The duty to warn lies with the physician, rather than the manufacturer, because the physician is generally in the best position to evaluate the risks and benefits of a drug with respect to a given patient. In *MacDonald v. Ortho Pharmaceutical Corp.*, 394 Mass. 131, 138 (1985), the Supreme Judicial Court created a narrow exception to the learned intermediary doctrine under which the manufacturer of an oral contraceptive has a duty to directly warn the consumer of the risks of the contraceptive.

In *Niedner*, the Appeals Court held that the *MacDonald* exception applies to the patch because the patch is "a hormonal birth control product, like the birth control pills at issue in *MacDonald*." 90 Mass. App. Ct. at 309. Johnson & Johnson, though, satisfied its duty to warn the patient and her mother. Specifically, the patch's packaging contained an insert with instructions for use and warnings of the patch's risks. The risk of blood clots in the lungs—which Duffy developed—was "expressly set forth in the insert" in at least four places. *Id.* at 311. The insert described that the patch has a greater dose of estrogen than oral contraceptives "and the corresponding increased risk of adverse events, such as blood clots." *Id.* In particular, the insert referred to the results of a study showing a doubling of the risk of blood clots associated with the patch in comparison to oral contraceptives. *Id.* at 311-12. The insert also cautioned that despite its warnings, patients should carefully discuss the patch with a healthcare professional when the patient first

uses the patch and at subsequent visits. *Id*. The court found that the terms of the insert were "understandable to a lay person" and adequately warned Duffy and her mother of the increased risk of developing fatal blood clots as compared to the risks of oral contraceptives. *Id*. at 312.

Design defect: To succeed on a design defect claim, the plaintiff must show the existence of a safer alternative design for the product. In *Niedner*, the plaintiff argued that oral contraceptives, which are taken daily, are a feasible, safer alternative to the patch, which is applied weekly for three weeks and removed for a patch-free fourth week. The court rejected this argument: "While both products [(the pill and the patch)] are hormonal contraceptives that prevent pregnancy, the difference in the drug delivery method, each of which has its own advantages and disadvantages, makes the pill fundamentally different from the patch. As such, one cannot serve as a safer alternative for the other." 90 Mass. App. Ct. at 313 (internal citations omitted).

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As of the time of publication, plaintiff's application for further appellate review was pending before the Supreme Judicial Court.

***Disclosure:** Nutter is local counsel for Defendants/Appellees Ortho-McNeil Pharmaceutical, Inc., Johnson & Johnson, and Johnson & Johnson Pharmaceutical.

MASSACHUSETTS SUPERIOR COURT

Rafferty v. Merck & Co., No. 2013-04459, 2016 WL 3064255, 2016 Mass. Super. LEXIS 48 (Mass. Super. Ct. May 23, 2016)

Significant Holding: A Massachusetts trial court rejected the theory of innovator liability in dismissing a plaintiff's claims against a brand-name drug manufacturer related to injuries the plaintiff allegedly sustained after ingesting a generic version of the drug. (Fishman, J.)

Summary: The plaintiff ingested a generic version of a brand name drug Merck manufactures to treat an enlarged prostate. The prescribing physician did not warn the plaintiff about any of the generic drug's side effects. After ingesting the generic drug, the plaintiff experienced side effects including sexual dysfunction. He stopped taking the generic drug, and the side effects temporarily waned. Those symptoms and new symptoms returned, and specialists diagnosed the plaintiff with hypergonadism and androgen deficiency that were induced by the generic drug. His treatment for those conditions will continue indefinitely.

When a brand-name drug manufacturer, such as Merck, develops a new drug, it must submit a new drug application ("NDA") to the FDA. The NDA must include certain data relating to the drug's safety and efficacy, a proposed label, and a discussion of why the drug's benefits exceed its risks when used in the conditions specified in the label. This process is "onerous and lengthy." *Rafferty*, 2016 WL 3064255 at *2 (internal quotation marks and citation omitted).

A generic drug manufacturer, on the other hand, can obtain FDA approval by showing that the generic drug is equivalent to an approved brand name drug in certain respects, including the labeling. FDA regulations prohibit generic manufacturers from making any unilateral changes to a drug's label. Thus, a brand-name manufacturer must ensure that a drug's label is accurate and adequate while a generic manufacturer must ensure only that the generic drug's label is the same as the brand name drug's.

The United States Supreme Court has twice held that under federal law, generic manufacturers cannot change generics' labels or composition. *See PLIVA, Inc. v. Mensing,* 564 U.S. 604, 608-09, 618 (2011) (federal drug regulations prohibit generic manufacturers from changing drug labels and, thus, preempt state-law claims that generic manufacturers did not provide adequate warnings); *Mut. Pharm. Co. v. Bartlett,* 133 S. Ct. 2466, 2470, 2475, 2477 (2013) (federal statutes requiring generic drugs to have same active ingredients, administration, dosage, strength, and labeling as their brand-name equivalents preempt state-law design-defect claims based on the adequacy of a generic's warnings). These cases foreclose plaintiffs "from bringing failure to warn claims against [a] generic manufacturer," so the plaintiff in *Rafferty* sued Merck, alleging it "had a duty to maintain the accuracy of the labels for those individuals who would rely on [the brand name drug's] labels," including consumers of a generic equivalent. *Rafferty*, 2016 WL 3064255 at *4.

No Massachusetts appellate court has addressed whether a plaintiff who was allegedly injured by a generic drug can hold the brand-name manufacturer liable for an inaccurate label.

The *Rafferty* court, though, relied on three well-established legal principles in refusing to recognize this theory of relief, which is known as innovator liability.

First, a plaintiff generally must prove that the item that allegedly caused the plaintiff's injury can be traced to the specific manufacturer the plaintiff sued. It is not enough for a manufacturer to issue instructions for using the *kind* of product that caused the injury.

Second, Massachusetts courts have never extended liability to a manufacturer for failing to warn of the risks of (mis)using a product made by another manufacturer.

Third, public policy considerations underlying general negligence principles counsel against holding brand-name drug manufacturers liable for injuries caused by generic equivalents. Specifically, brand-name manufacturers shoulder the costs of developing pioneer drugs. In comparison, it is much less costly for generic manufacturers to duplicate successful drugs. It would be "especially unfair" to burden brand-name manufacturers with a duty to warn consumers who take generic drugs. *Rafferty*, 2016 WL 3064255 at *5 (internal quotation marks and citation omitted). Further, in tort law, liability usually follows control. But brand-name manufacturers have no control over the manufacturing and distribution of generics. Finally, the FDA—not the courts—should govern the relationship between brand-name and generic manufacturers. In 2013, the FDA proposed amendments to its regulations to create a framework under which generic manufacturers can be held liable for the inadequacy of generics' labels. The final rule is scheduled to be published in the spring of 2017.

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As of the time of publication, plaintiff's appeal was pending before the Appeals Court.

Nutter's Product Liability: 2016 Year in Review is a publication of the Product Liability and Toxic Tort Litigation Group of Nutter McClennen & Fish LLP in Boston. The bulletin was prepared by Andrew R. McArdell and Alison T. Holdway. For further information or if we can be of assistance, please contact your Nutter product liability lawyer or the chairperson of the Product Liability and Toxic Tort Litigation Group:

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Industry Expertise

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

In 2016, Nutter's products liability lawyers were featured in *Bloomberg BNA*, *Corporate Counsel*, *DRI's The Voice*, *Huffington Post*, *Inside Counsel*, *Medical Device and Diagnostic Industry (MD+DI)*, *The Gourmet Retailer*, *Additive Manufacturing Today*, *Food Manufacturing Magazine*, and the ABA's *Products Liability Litigation Newsletter*.

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. In 2016, attorneys in the group:

- Presented at ACI's 21st Drug and Medical Device Litigation Conference and the Boston Bar Association
- Served as chair of the Massachusetts Supreme Judicial Court's Standing Advisory Committee on the Rules of Civil and Appellate Procedure
- Presented at a program on U.S. litigation in Zurich, Switzerland
- Sponsored DRI's Drug and Medical Device Conference, ACI's 21st Drug and Medical Device Litigation Conference, and the Advanced Medical Technology Association (AdvaMed) Conference
- Participated in conferences addressing motor vehicle product liability litigation, the food and beverage sector, and current issues in pharmaceutical, medical device, and biotech litigation

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