Government Support of Death & Destruction from Generic Prescription Drugs

Maggie O. Tsavaris*

Gather round, boys and girls. Because Halloween is just around the corner, I’m going to tell you a scary story. I suggest holding hands for this one. It’s even creepier than Stephen King’s *Pet Sematary*. Feel free to scream at any time.

A woman goes to her doctor because she is experiencing shoulder pain. The doctor prescribes a non-steroidal anti-inflammatory drug (NSAID). So far, so good. Recovery should be just around the corner. A few weeks later, however, the woman enters the emergency room with skin blisters, a fever, and eye irritation, among other things. Shortly thereafter, she is diagnosed with Stevens-Johnson syndrome (SJS), which progresses to toxic epidermal necrolysis (TEN), a serious and potentially fatal condition. Well over half of the skin on her body dies off or turns into a gaping, bloody wound, she spends months in the hospital, in a coma for many of those months, undergoes a multitude of eye surgeries, and emerges from the hospital blind, disfigured, and with a ghastly array of disabilities.

In order to recover something—anything—for her loss of sight, the destruction of her life and body as she once knew them, and her medical expenses (which will continue as a result of this injury until she dies), she sues the manufacturer of the drug. Most unfortunately, however, even though her physician prescribed the brand-name drug, her pharmacist dispensed the generic version. Because she ingested solely the generic and not the brand-name drug, the U.S. Supreme Court takes away her $21.06 million jury award and sends the

---

* Associate Professor of Law, Savannah Law School. Many thanks to the members of the Savannah Law Review for allowing me to present this material at their Fall 2015 Colloquium, *The Walking Dead*, on September 19, 2015 (with Halloween just around the corner). This Article grew out of my summer of drafting pre-trial motions and pleadings in my breast cancer case against four large pharmaceutical defendants. I am deeply grateful to my research assistant, Elizabeth Rackley DeSalvo, for her tireless assistance with the breast cancer legal research and fact-finding, and for her happy enthusiasm and thought-provoking comments along the way.


generic manufacturer back onto the streets in search of its next hapless victim.\textsuperscript{3}
As a result of the trial court’s findings of fact, the Court fully understands that, had this manufacturer complied with its duties to monitor the adverse effects of its drug and to review published literature relating to its drug,\textsuperscript{4} it would have known that eighty-nine cases involving the adverse effects of its drug had already been reported to the U.S. Food and Drug Administration (FDA) and published in an international medical journal study showing the direct link between NSAIDs and SJS/TEN.\textsuperscript{5}

What is especially creepy about this story is that, unlike King’s \textit{Pet Sematary}, this is a true story about Karen Bartlett who, in 2004, was prescribed brand-name medication Clinoril for her shoulder pain.\textsuperscript{6} Her pharmacist dispensed to her the generic version of sulindac.\textsuperscript{7} Ms. Bartlett developed an acute case of TEN, in which sixty-five percent of her body “was burned off . . . or turned into an open wound. She spent months in a medically induced coma, underwent 12 eye surgeries, and was tube-fed for a year. She is now severely disfigured . . . and is nearly blind.”\textsuperscript{8}

When she was ingesting generic sulindac, the label warned only about “‘severe skin reactions’ and ‘[f]atalities.’”\textsuperscript{9} SJS and TEN were listed on sulindac’s package insert with the inference that they were remotely possible adverse reactions for those rare patients with unusual hypersensitivity.\textsuperscript{10} After Ms. Bartlett was already suffering, the label was changed in response to a June 2006 letter from the FDA to the manufacturer recommending a more explicit warning about TEN.\textsuperscript{11}

A New Hampshire jury awarded Ms. Bartlett just north of $21 million in damages.\textsuperscript{12} The First Circuit affirmed and concluded that “neither the Federal Food, Drug, and Cosmetic Act (FDCA) nor the FDA’s regulations pre-empted [her] design-defect claims.”\textsuperscript{13} The U.S. Supreme Court, however, reversed and

\textsuperscript{3} Mutual Pharm. Co., Inc. v. Bartlett, 133 S. Ct. 2466, 2479 (2013) (holding that when state law conflicts with federal laws that prohibit a generic manufacturer from unilaterally altering the label or composition of its drug, the state law must yield).
\textsuperscript{5} Bartlett, 731 F. Supp. 2d at 142.
\textsuperscript{6} Bartlett, 133 S. Ct. at 2472.
\textsuperscript{7} Id.
\textsuperscript{8} Id.
\textsuperscript{9} Id. (citing Bartlett, 731 F. Supp. 2d at 146).
\textsuperscript{10} Id. (citing Bartlett v. Mutual Pharm. Co., Inc., 678 F.3d 30, 36 (2012)).
\textsuperscript{11} Id.
\textsuperscript{12} Id.
\textsuperscript{13} Id. at 2472 (citing Bartlett, 678 F.3d at 36-37). The preemption doctrine, born under the Supremacy Clause of the Constitution, provides that the laws of the United States are “the supreme Law of the Land,” and when a state law conflicts with a federal law—such as an FDA regulation requiring a manufacturer to do, or refrain from doing, something—then that state law must give way to the federal law. Id. at 2472-73 (citing U.S. CONST., art. VI, cl. 2). In other words, if a conflict arises between a state law and a federal law, then a plaintiff’s state-law claim is federally preempted. Id.

208
held that “state-law design-defect claims that turn on the adequacy of a drug’s warnings are pre-empted by federal law under PLIVA [v. Mensing, 131 S. Ct. 2567 (2011)].”¹⁴ This, the Court reasoned, was because the New Hampshire duty of a manufacturer to ensure that a drug is reasonably safe is evaluated by both the drug’s chemical design and the adequacy of its warnings.¹⁵ The generic manufacturer did not have the option of changing the chemical design (because of federal law requiring chemical and bioequivalent “sameness”¹⁶ of a generic drug to that of its brand-name counterpart, and the one-molecule chemistry of this particular drug).¹⁷ The Court thereby mistakenly decided that Ms. Bartlett’s design-defect claim “effectively” required the generic manufacturer to change the label, which federal law prohibited.¹⁸ Accordingly, Ms. Bartlett’s design-defect claim was pre-empted and she was left with a disastrously altered life with neither compensation nor an apology from the drug manufacturer that caused her injuries.¹⁹

After the Court’s gift of blanket immunity to generic drug manufacturers, these companies are dancing on the graves of their victims. In fact, one generic pharmaceutical defendant in a recent pre-trial motion actually alleged that

---

¹⁴ Id. at 2470 (citing PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2572 (2011)). The Supreme Court held in Mensing that “federal drug regulations applicable to generic manufacturers directly conflict with, and thus pre-empt, plaintiff’s failure-to-warn state-law claims.” Mensing, 131 S. Ct. at 2572.

¹⁵ Bartlett, 133 S. Ct. at 2474.

¹⁶ Mensing, 131 S. Ct. at 2575.

¹⁷ Bartlett, 133 S. Ct. at 2471, 2475 (discussing federal sameness requirements as to chemical equivalence and bioequivalence, and citing 21 U.S.C. § 355(j)(2)(A)(ii), (iii), and (iv), and (j)(8)(B) (2012), and examining 21 C.F.R. § 314.70(b)(2)(i) (2012) regarding post-FDA approval prohibitions on changing the formulation of the drug).

¹⁸ Id. at 2476 (citing 21 U.S.C. § 355(j)(2)(A)(v); 21 C.F.R. §§ 314.94(a)(8)(iii), and 314.150(b)(10) (stating that the FDA may withdraw approval for a generic drug if the generic’s label no longer matches its brand-name counterpart’s label)).

¹⁹ Id. at 2473. But, as Justice Sotomayor wrote in her dissent, “New Hampshire’s design-defect law did not require [the generic manufacturer] to do anything other than to compensate consumers who were injured by an unreasonably dangerous drug” and, in this way, “[t]he case is [entirely] unlike Mensing, where it was ‘undisputed’ that applicable state tort law ‘require[d] a drug manufacturer that is or should be aware of its product’s danger’ to strengthen its label[,] a requirement that conflict[s] with federal law preventing the [generic] manufacturer from doing so unilaterally.” Id. at 2489 (Sotomayor, J., dissenting). Here, the state law governing Ms. Bartlett’s design-defect claim did not mandate a label change or any other specific action forbidden by federal law. Id. at 2488. New Hampshire’s law creates an incentive for drug manufacturers to make necessary changes to the product in order to avoid liability for design defects, thereby meeting compensatory and regulatory goals. Id. A manufacturer of an unreasonably dangerous drug in New Hampshire has the choice of changing the drug’s design or label, removing the drug from the market, or compensating injured consumers as a cost of doing business. Id. at 2491. If federal law prohibits re-design, then that does not automatically mean that the manufacturer, under state law, must strengthen the label. And even if the generic manufacturer could or had changed the label, the company could still be liable for defective design. Still, the third choice is open: compensate the injured consumer. Nowhere does federal law pre-empt this. Id. at 2491–92.
“federal law allows it to ‘[keep] quiet its knowledge of the risks of breast cancer associated with its generic version of Activella[.]’”

What then does “EQUAL JUSTICE UNDER LAW” truly mean and to whom does it apply? After the Court’s Mensing and Bartlett decisions, it appears that equal justice can be bought. In other words, big pharmaceutical companies (“Big Pharma,” as they are more commonly, collectively known) that are motivated solely by the goal of raking in financial profits may burglarize our bodies, destroy our health, and dismantle our lives with drugs they know are unreasonably dangerous, and then walk away scot-free because they can buy justice.

In fact, Big Pharma’s top eleven companies took home net profits of nearly three-quarters of a trillion dollars in the decade from 2003–2013. That amount of cold, hard cash enables Big Pharma to conduct some serious lobbying (to the tune of $2.9 billion from 1998–2014) and to make political and speaker contributions that know no bounds.

In fact, Big Pharma has been able to

---

20 Plaintiff’s Memorandum of Law in Opposition to Defendant Breckenridge Pharm., Inc.’s Motion for Judgment on the Pleadings at 10, Tsavaris v. Pfizer, Inc., No. 1:15-cv-21826-KMM (S.D. Fla. Aug. 24, 2015), ECF No. 65 (citing Defendant Breckenridge Pharm., Inc.’s Motion for Judgment on the Pleadings and Incorporated Memorandum of Law at 8-9, Tsavaris v. Pfizer, Inc., No. 1:15-cv-21826-KMM (S.D. Fla. Aug. 10, 2015), ECF No. 63) [hereinafter Breckenridge Motion for Judgment on the Pleadings] (alteration in original) (distinguishing Mensing from Plaintiff’s instant case, stating that Mensing’s ruling “was confined solely to failure-to-warn claims brought against a generic manufacturer because the FDA requires sameness after FDA approval”).

21 “These words, written above the main entrance to the Supreme Court Building, express the ultimate responsibility of the Supreme Court of the United States. . . . As the final arbiter of the law, the Court is charged with ensuring the American people the promise of equal justice under law and, thereby, also functions as guardian and interpreter of the Constitution.” The Court and Constitutional Interpretation, SUP. CT. U.S. (Oct. 5, 2015), http://www.supremecourt.gov/about/constitutional.aspx (last visited May 31, 2016).

22 Big Pharma, DrugWatch, http://www.drugwatch.com/manufacturer/ (last visited May 31, 2016). Pharmaceutical sales exceeded $1 trillion in 2014, and the world’s ten largest drug manufacturers raked in $429.4 billion of that revenue. Id. So, how does Big Pharma spend its profits? It contributes heavily to the annual budget of the FDA, the very agency that makes the rules governing Big Pharma’s drug products and medical devices. Id. From 1998–2014, Big Pharma spent close to $2.9 billion on its lobbying efforts, which is more than any other industry spends on lobbying. Id. Big Pharma also spent more than $15 million for campaign contributions from 2013–2014, and it spends billions each year on direct-to-consumer advertising. Id.


24 See DRUGWATCH, supra note 22.

25 Hagopian, supra note 23; Doctors and Hospitals Raking in Billions from Big Pharma, Huge Data Trove Reveals, HUFFINGTON POST (Sep. 30, 2014), http://www.huffingtonpost.com/2014/09/30/doctors-big-pharma_n_5908350.html (“U.S. doctors and teaching hospitals received $3.5 billion from pharmaceutical companies and medical device makers in the last five months of 2013 . . . . The payments . . . . include consulting and speaking fees, travel, meals, entertainment, and research grants.”).
convince Congress to pass legislation that severely undermines the mission of the FDA and further endangers the lives and well-being of patients.

The reason most of us take a prescription drug is because we want to get better, not worse, yet prescription drugs are the fourth leading cause of death after stroke, heart disease, and cancer. These drugs kill approximately 128,000 hospitalized people in the United States and an estimated 200,000 people in Europe each year. If a drug does not kill, it often causes injuries much worse than the original symptom for which the patient began taking the drug. And often, the manufacturer will downplay or do its best to conceal from the public the published scientific studies that reveal the dangers of the drug so that its sales will not suffer. Crime pays.

26 The “FDA is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation’s food supply, cosmetics, and products that emit radiation.” About FDA, U.S. Food & Drug Admin. (Aug. 5, 2014), http://www.fda.gov/AboutFDA/WhatWeDo/.


29 Light, Lexchin & Darrow, supra note 27 (noting that “[d]eaths and serious reactions outside of hospitals would significantly increase the total[]”); Interview with Gøtzsche, supra note 28.

30 The risks of many pharmaceutical drugs far outweigh their benefits. For example, the hormone replacement therapy (HRT) drugs Prempro (manufactured by Wyeth, which was acquired by Pfizer in 2008) and Activella (manufactured by Novo Nordisk A/S, a Danish pharmaceutical corporation with headquarters in Copenhagen) are approved by the FDA for relief of menopausal symptoms, such as hot flashes and night sweats. These drugs, however, contain dangerous active ingredients that have been proven to significantly increase a woman’s risk of breast cancer. See First Amended Complaint & Demand for Jury Trial at 15–16, 28–30, Tsavaris v. Pfizer, Inc., No. 1:15-cv-21826-KMM (S.D. Fla. June 15, 2015), ECF No. 30 [hereinafter Tsavaris Amended Complaint] (citing numerous scientific studies establishing the link between the use of HRT drugs and breast cancer); Breckenridge Motion for Judgment on the Pleadings, supra note 20, at 8–9 (asserting that federal law preempts any state law duty to warn generic drug users of health risks known by the manufacturer).

31 Tsavaris Amended Complaint, supra note 30, at 22–26 (discussing Wyeth’s techniques for downplaying women’s fears of breast cancer and distracting the medical community from the results of the Women’s Health Initiative (WHI) study that had to be prematurely halted because Wyeth’s HRT drug, Prempro, produced a twenty-six percent
Big Pharma drowns physicians in more drugs—each one with 20 or 30 or 40 harmful or potentially fatal side effects—than they could ever fully comprehend. As such, the physicians rely on the pharmaceutical sales representatives, who are carefully trained by the companies to convince and incentivize physicians to prescribe their drugs, and who leave free samples the physicians can gift to their patients. In this manner, Big Pharma has effectively and drastically reduced “the role of the FDA as the protector of public health.”

And just in case the physicians are not convinced, Big Pharma reaches out directly to the patients by spending more on advertising than any other industry in the United States, to the tune of nearly $3.5 billion in 2012 alone. This is nearly double what it spends on researching safer, more effective drugs. Advertisements for every type of pill—whether for pleasure, love, sleep, relief of anxiety or pain, or for better and longer-lasting sex—along with “marching orders to request specific drugs from their doctors,” now saturate every media communication conceivable. And Big Pharma has convinced physicians, consumers, and the Court that because these drugs are approved by the FDA, they are safe.

Granted, before 1962, drugs were subject to frighteningly minimal testing before being allowed to enter the marketplace. One infamous drug, thalidomide, was marketed as a mild sleeping pill that was safe even for pregnant women. By 1960, however, physicians became concerned about the drug’s possible side effects and, in 1962, they realized that the drug was the cause of malformed limbs in thousands of babies around the world. As a result, the FDA...
made significant changes to the Federal Food, Drug, and Cosmetic Act (FDCA), which had originally been passed in 1938.\footnote{44 Legislation, U.S. Food & Drug Admin. (July 2, 2015), http://www.fda.gov/RegulatoryInformation/Legislation/} With the new regulations, companies had to prove that a drug was safe and effective before it could be approved by the FDA and enter the marketplace.\footnote{45 Chris Woolston, History of Generic Drugs, HealthDay (Mar. 11, 2015), http://consumer.healthday.com/encyclopedia/drug-center-16/misc-drugs-news-218/history-of-generic-drugs-646390.html.} All new drugs were required to complete a long and expensive process that included clinical (human) trials.\footnote{46 Id.} Generic companies had to wait for the brand-name patent to expire before they could even begin the required testing.\footnote{47 Id.} And because the stringent, new regulations applied to both brand-name and generic drugs, the generic companies, for the most part, did not bother to enter the market and, by 1983, only thirty-five percent of top-selling brand-name drugs had generic competitors, even after the brand-name patents expired.\footnote{48 Id.}

In order to get cheaper, generic versions of brand-name drugs to market, the Drug Price Competition and Patent Restoration Act of 1984 (known as the Hatch-Waxman Act) was passed.\footnote{49 Id.} Now, with this simplified approval process, the generic manufacturer was required only to show that its product was bioequivalent to the brand-name drug, which it easily accomplished by submitting an Abbreviated New Drug Application (ANDA).\footnote{50 21 U.S.C. § 355(j)(2)(A) (2015); Abbreviated New Drug Application (ANDA): Generics, U.S. Food & Drug Admin. (July 14, 2015), http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/default.htm [hereinafter ANDA].} In this way, the generic manufacturer could bypass costly development of preclinical (animal) and clinical (human) data required by the FDA of a brand-name manufacturer to establish safety and effectiveness.\footnote{51 ANDA, supra, note 50.} In addition to demonstrating bioequivalence of the active ingredients in its drug, the generic manufacturer simply had to show that its labeling was identical to that of the innovator drug.\footnote{52 21 U.S.C. § 355(j)(2)(A)(v).}

To further encourage the presence of cheaper, generic drugs in the marketplace, all fifty states in America now have some form of generic substitution laws.\footnote{53 State Regulations on Generic Substitution, Pharmacist’s Letter (Apr. 2009), http://pharmacistsletter.therapeuticresearch.com/pl/ArticleDD.aspx?nidchk=1&cs=&s=PL&pt=2&segment=1186&dd=220901.} Some states require pharmacists to substitute a therapeutically equivalent generic version for a brand-name drug when neither the prescriber nor the patient specify brand only.\footnote{54 Id.} Other states allow, but do not
require, pharmacists to substitute the generic for the brand-name drug. Pharmacists generally encourage their pharmacists to substitute the generic whenever permissible by law because the pharmacy can recognize greater profits with generic sales. Many physicians write the brand-name on the prescription without specifying brand only and, accordingly, the pharmacist, in compliance with his state law substitution duties, dispenses the generic.

The trouble is that, most of the time, the patient has no knowledge that she is receiving the generic version of what her physician prescribed and, even if she does realize this, she does not know that she may have no recourse if she sustains injuries caused by the generic drug, as was the case with Karen Bartlett.

A huge number of people are in the same boat as Ms. Bartlett because seven out of ten Americans are taking at least one prescription drug, and more than half are taking at least two. And approximately eighty percent of all of those prescription drugs dispensed are generic. This number likely will increase for at least the next few years as some popular brand-name drugs come off patent through 2015.

If, on the other hand, the injured or deceased patient happened to receive the brand-name drug and can establish causation, then she has a far better likelihood of being awarded compensation by the courts. In April 2000, Diana Levine received an injection of brand-name manufacturer Wyeth’s anti-nausea drug, Phenergan. When the physician assistant injected her with the drug by the IV-push method, the solution came in contact with arterial blood, Ms. Levine developed gangrene, and doctors amputated her right forearm. Ms. Levine incurred medical expenses, pain and suffering, and the loss of her livelihood as a professional musician.

Ms. Levine filed claims grounded on common-law negligence as well as strict liability theories for defective labeling and for a drug that is not reasonably safe for intravenous administration because of the foreseeable risks of gangrene and loss of limb that outweighed any therapeutic benefits. Wyeth tried to convince the court that Ms. Levine’s state law failure-to-warn claims were pre-
empted by federal law because the FDA had approved its label and it could not change the label without FDA approval.\footnote{Id. at 559–61 (“Although [the label] warned of the danger of gangrene and amputation following inadvertent intra-arterial injection, Levine alleged that the labeling was defective because it failed to instruct clinicians to use the IV-drip method of intravenous administration instead of the higher risk IV-push method.”). Further, in regards to Wyeth’s contention that a preemption conflict existed “between a specific FDA order, and Levine’s failure-to-warn action, the [trial] court [had] reviewed the sparse correspondence between Wyeth and the FDA about Phenergan’s labeling and found no evidence that Wyeth had ‘earnestly attempted’ to strengthen the intra-arterial injection warning or that the FDA had ‘specifically disallowed’ stronger language” and, as such, the record “lack[ed] any evidence that the FDA had set a ceiling on this matter,” Id. (citations omitted). In addition, Wyeth’s attempt to argue that FDA approval of its label excused it from further responsibility falls flat because the FDA places responsibility on the manufacturer for the content of its label at all times. Id. at 567–68; 21 C.F.R. § 201.809(e), 314.80(b) (2015).}

A Vermont jury determined that Wyeth could have prevented Ms. Levine’s injury if Phenergan’s label had contained a specific warning about the risks of the IV-push method of injection that Wyeth already knew could cause the corrosive solution to inadvertently enter an artery and lead to gangrene and loss of limb.\footnote{Levine, 555 U.S. at 562–63.}

The Vermont Supreme Court affirmed because no conflict existed between FDA regulations and Wyeth’s state-law duties where Wyeth could have used the CBE\footnote{The CBE (changes-being-effected) process provides that if a brand-name manufacturer is updating a label to add or strengthen a warning, precaution, or instruction about “administration that is intended to increase the safe use of the drug product,” it may make the labeling change upon filing its supplemental application with the FDA [and] need not wait for FDA approval.” Id. at 568 (citing 21 C.F.R. §§ 314.70(c)(6)(iii)(A), (C)). As such, “Wyeth had a duty to provide a warning that adequately described [the risk of gangrene from IV-push administration when that risk became apparent], and the CBE regulation permitted it to provide such a warning before receiving the FDA’s approval.” Id. at 571.} process to update its label to warn against IV-push administration.\footnote{Id. at 571. Id. at 581. When Congress amended the FDCA in 1962, it “shifted the burden of proof from the FDA to the manufacturer.” Id. at 567. When it expanded the rules by which the FDA would “protect the public health” and “assure the safety, effectiveness, and reliability of drugs,” it “took care to preserve state law.” Id. Congress added a saving clause to the 1962 amendments, which provided that any state law provisions would be invalidated only if the manufacturer could establish the existence of a “direct and positive conflict” with the FDCA. Id. Additionally, Congress could have enacted an express preemption provision for prescription drugs as it did for medical devices in 1976, but it declined to do so. Id. (citing 21 U.S.C. § 360k(a) (2008)).} The court noted that at least twenty amputations similar to Ms. Levine’s had been reported since the 1960s, and “federal labeling requirements create a floor, not a ceiling, for state regulation.”\footnote{Id. at 562–63.} The U.S. Supreme Court affirmed and concluded that Ms. Levine’s claims were not federally preempted because it was “not impossible for Wyeth to comply with its state and federal law obligations,” and Ms. Levine’s common-law claims presented no obstacle to the congressional objectives of the FDCA.\footnote{Id. at 581.}
Shortly after the Levine decision in 2009, the Northern District of Florida held a generic manufacturer liable for the death of a generic prescription drug consumer.\textsuperscript{72} In 2003, Kristina Flatt’s physician diagnosed her with attention deficit hyperactivity disorder and prescribed her the brand-name Adderall.\textsuperscript{73} The pharmacist dispensed the generic version manufactured by Barr Laboratories, Inc.\textsuperscript{74} Two years after Ms. Flatt began taking the drug, she “felt ill, sat down in a chair, and lost consciousness.”\textsuperscript{75} Less than an hour later, she was dead from “[a]cute fatal cardiac dysrhythmia without pulse, [d]ue to toxic effects of [generic Adderall] and two other drugs.”\textsuperscript{76}

Ms. Flatt’s mother, Jane Munroe, brought suit in which she alleged negligent failure-to-warn and strict liability failure-to-warn under Florida law (and other claims later abandoned).\textsuperscript{77} Barr moved to dismiss on federal preemption grounds and also for summary judgment on the basis that Ms. Flatt’s physician was an adequately warned, learned intermediary.\textsuperscript{78}

Upon examination of the U.S. Supreme Court’s decision in Levine and other district court decisions applying Levine to generic drugs, the Barr court noted that the decisions by courts holding that state-law claims were not federally preempted had the better arguments.\textsuperscript{79} It also found that no impossibility existed for a generic manufacturer to comply with both the federal law requiring an FDA-approved label and any state law requiring a stronger warning.\textsuperscript{80} In fact, the court pointed out that both generic and brand-name manufacturers may strengthen their labels while seeking FDA approval of the change and, as such, Levine is fully applicable to generic manufacturers.\textsuperscript{81}

The court also noted that no law requires a manufacturer to sell a generic drug at all.\textsuperscript{82} As a generic manufacturer, Barr chose to sell the drug and did so without incurring the cost of developing it and obtaining the initial approval.\textsuperscript{83}

\textsuperscript{72} Munroe v. Barr Laboratories, Inc., 670 F. Supp. 2d 1299, 1306 (N.D. Fla. 2009).
\textsuperscript{73} Id. at 1301.
\textsuperscript{74} Id.
\textsuperscript{75} Id.
\textsuperscript{76} Id.
\textsuperscript{77} Id.
\textsuperscript{78} Id. at 1302; see generally John A. Camp & Gary M. Pappas, The Learned Intermediary Doctrine in Florida: Courts Wrestle with Claimed Exceptions to the Doctrine in Drug and Device Litigation, 82 Fla. B. J. 9 (2008) (discussing the learned intermediary doctrine in Florida). Most states, Florida included, recognize the learned intermediary doctrine, which provides a defense for pharmaceutical manufacturer defendants. Id. at 9. Under this doctrine, the manufacturer has a duty to warn only the learned intermediary, who usually is the patient’s prescribing physician, of the dangers associated with its drug. Id.
\textsuperscript{79} Munroe, 670 F. Supp. 2d at 1302.
\textsuperscript{80} Id.
\textsuperscript{81} Id. at 1302–03. Even though generic manufacturers must include the same labeling information as their innovator (brand-name) cohorts, generic manufacturers may “add or strengthen warnings and delete misleading statements on labels, even without prior FDA approval.” Id. at 1303 (citing 21 C.F.R. § 314.70 (2008)).
\textsuperscript{82} Munroe, 670 F. Supp. 2d at 1303.
\textsuperscript{83} Id.
Where “the generic manufacturer rides the brand manufacturer’s coattails” and thereby gains the right to sell the drug, but fails to properly design the drug and copies the brand’s label without change, then the generic manufacturer cannot possibly expect to be exempt from the same liability faced by the brand manufacturer for a defectively designed drug or one with an inadequate warning. As such, no other application of Levine makes any sense.

As to Barr’s argument that the learned intermediary doctrine entitled it to summary judgment, Florida law requires a drug manufacturer to provide an adequate warning to the learned intermediary, who, most often, is the physician prescribing the drug. If a warning has misrepresented or omitted material information that could have made a difference in a physician’s decision to prescribe the drug at all, or in the physician’s advice or instructions to the patient, then the adequacy of the warning becomes a question of fact for a jury to decide. These types of disputes do not entitle the pharmaceutical defendant to summary judgment because they “are the [very] stuff of which jury trials are made.”

The soundly reasoned Levine and Barr decisions did not allow the drug manufacturers—one brand-name and one generic—to escape liability for their wrongdoing, because no impossibility preemption existed where the manufacturers could comply with both federal regulations and state law requirements. A few years later, however, the U.S. Supreme Court inexplicably decided that the sound rationale and holding of Levine should apply only to brand-name manufacturers, and that generic manufacturers should be shielded from liability for the injuries caused by their defective drugs.

In 2011, the Court decided that the failure-to-warn claims brought by two plaintiffs, Gladys Mensing and Julie Demahy, were federally preempted, because impossibility existed when the manufacturers—generic, this time—could not independently do under federal law what state law required of them. In order to arrive at its decision, the Court embarked on a bizarre and convoluted path.

In 2001 and 2002, Ms. Mensing and Ms. Demahy, were prescribed the brand-name medication, Reglan, for their digestive troubles. But their pharmacists, acting in accord with their state substitution laws, dispensed the generic version, metoclopramide. After ingesting the drug as prescribed for several years, both women developed tardive dyskinesia, a severe, often

84 Id.
85 Id.
86 Id. at 1305 (citing Felix v. Hoffman-LaRoche, Inc., 540 So. 2d 102, 104–05 (Fla. 1989)); Plaintiff’s Memorandum of Law in Opposition to Defendant Novo Nordisk Inc.’s Motion to Dismiss the Complaint at 7, Tsavaris v. Pfizer, Inc., No. 1:15-cv-21826-KMM (S.D. Fla. Jul. 13, 2015), ECF No. 48 (citing Buckner v. Allergan Pharm., Inc., 400 So. 2d 820, 822 (Fla. 5th DCA 1981)).
87 Munroe, 670 F. Supp. 2d at 1305–06; Felix, 540 So. 2d at 105.
88 Munroe, 670 F. Supp. 2d at 1306.
90 Id.
91 Id. at 2573.
92 Id.
irreversible neurological disorder, characterized by uncontrollable facial grimacing and tongue thrusting. The women claimed that the generic manufacturers were liable under state tort law for failure to provide adequate warnings.

Specifically, at the time the women were taking metoclopramide, the label on the brand-name drug (and perforce on the generic versions) had been modified (in 1985) and provided that “tardive dyskinesia . . . may develop in patients treated with metoclopramide,” and the drug’s package insert added that “[t]herapy longer than 12 weeks has not been evaluated and cannot be recommended.” In 2004, the brand-name manufacturer for Reglan requested, and the FDA approved, a label addition warning that “[t]herapy should not exceed 12 weeks in duration.” In 2009, a black box warning—the FDA’s very strongest warning—provided that “[t]reatment with metoclopramide can cause tardive dyskinesia,” and “[t]reatment with metoclopramide for longer than 12 weeks should be avoided in all but rare cases.”

Although the Court did touch upon the fact that all manufacturers—brand-name and generic alike—are responsible for the content of their labels at all times, the Court still managed to arrive at the conclusion that impossibility preemption existed where it was not lawful under federal law for the generic manufacturers to independently change their labels to satisfy their state law duty to exercise reasonable care by providing an adequate warning. The FDA regulations, however, required the generic manufacturers to propose—independently or otherwise—stronger warning labels to the FDA if they believed such warnings were needed, and then the FDA would work with the brand-name manufacturer to create a new label for all of them to place on their drugs.

Precisely like the brand-name manufacturer, a generic manufacturer of an FDA-approved drug has federally mandated post-marketing duties of pharmacovigilance wherein it must review and report to the FDA adverse drug events and materially significant data from scientific studies pertaining to its drug. Where the brand-name manufacturers have available the CBE process for updating their labels, the generic manufacturers must take a slightly different route to comply with both their state law duty to exercise reasonable

---

94 Mensing, 131 S. Ct. at 2573.
95 Id. at 2572 (quoting Physicians’ Desk Reference 1635–36 (41st ed. 1987)).
96 Id.
97 Id. at 2573 (quoting Physicians’ Desk Reference 2902 (65th ed. 2011)).
98 Id. at 2576 (citing Wyeth v. Levine, 555 U.S. 555, 570–71 (2009)).
99 Id. at 2579 (“The question for ‘impossibility’ is whether the private party could independently do under federal law what state law requires of it.”).
100 Id. at 2577.
care and their federal duties “to seek to revise their labeling and provide FDA with supporting information about risks” when necessary.\footnote{103 \textit{Mensing}, 555 U.S. at 2585 (Sotomayor, J., dissenting) (citing 21 C.F.R. § 201.57(e) (2006) (currently codified at 21 C.F.R. § 201.80(e) (2010)); \textit{Levine}, 555 U.S. at 570–71).}

No matter the route taken, and no matter whether the label belongs to a brand-name drug or to its generic version, the FDA still retains the ultimate authority to approve or disapprove of any label changes—and the FDA could have rejected or approved those changes made by the brand-name manufacturer, Wyeth, pursuant to the CBE regulation.\footnote{Id. at 2588 (citing 21 C.F.R. § 314.70(c)(6)).} If the FDA had disapproved of the label change, then the brand-name manufacturer, Wyeth, could have established, 	extit{at that point and not before}, the impossibility of complying with both its state law duty to exercise reasonable care and the federal regulations governing it.\footnote{See id. at 2587-88.} As a result, the \textit{Levine} Court correctly decided that Wyeth was unable to show impossibility because it could not establish that the FDA would have prohibited the label change.\footnote{\textit{Levine}, 555 U.S. at 573, 577 (noting that Congress has never authorized the FDA to pre-empt state law directly, and the FDA has never suggested that “state tort law stood as an obstacle to its statutory mission”).}

Where the generic manufacturers in \textit{Mensing} could not use the CBE process reserved for their brand-name counterparts, they had available the process of reporting to the FDA information pertaining to their drug that could then allow the FDA to decide whether the drug was no longer safe as labeled.\footnote{\textit{Levine}, 555 U.S. at 570–71 (noting that Congress has never authorized the FDA to pre-empt state law directly, and the FDA has never suggested that “state tort law stood as an obstacle to its statutory mission”).} Just as the FDA might have approved of brand-name manufacturer Wyeth’s label change, the FDA, upon review of any relevant and critical scientific studies or adverse reports from the \textit{Mensing} generic manufacturers, might have approved—or mandated—a label change for the brand-name drug, and perforce the generic versions.\footnote{\textit{Mensing}, 555 U.S. at 2591 (Sotomayor, J., dissenting).} As such, the \textit{Mensing} Court’s finding of impossibility preemption where none existed is quite mind-boggling.


Notably, the events in \textit{Mensing} took place before the 2007 FDA amendments, under which generic manufacturers can now propose stronger labeling and the FDA can \textit{unilaterally} (without working with the brand-name

\textit{”).\footnote{\textit{Trahan}, 2015 WL 2365502, at *6 n.5 (citing \textit{Levine}, 555 U.S. at 579).}
manufacturer) order it for everyone. Unfortunately, an enormous number of courts today are blindly honoring and applying the Mensing decision, along with the Bartlett decision that is so firmly grounded on the Mensing case.

In an attempt to provide the generic manufacturers with the same control over their labels as the brand-name manufacturers and to fill the gap in safety left by the Mensing and Bartlett decisions, the FDA has proposed a rule that would require generic manufacturers to unilaterally update their labels, which would then allow injured consumers to recover from generic manufacturers for their failure to warn. As expected, the generic manufacturers are not too pleased with this idea and have even threatened lawsuits against the FDA, with the result that a very long time, perhaps even an eternity, could pass before the rule sees daylight.

Accordingly, for now, the consumer injured by a generic drug in the vast majority of states that have not declined to extend Mensing and Bartlett must carefully and precisely argue under a theory of negligence that the generic manufacturer “could have taken actions in line with its federal obligations that would also have allowed it to discharge its duty to exercise reasonable care.” By venturing along this rocky path, the plaintiff might be able to recover under a theory of negligence as long as she does not set forth allegations sounding even remotely in design-defect or failure-to-warn.

As to claims based on a theory of innovator liability, most states do not allow recovery against the brand-name manufacturer by an injured plaintiff who ingested solely the generic version. But innovator liability in the pharmaceutical drug setting, given the facts, regulations, and laws governing the industry, makes complete sense. The brand-name manufacturer, as the sole party in control of the product design and label, “is well aware of the expiration

---

114 Id.
116 Guarino v. Wyeth, Inc., 719 F.3d 1245, 1251 (11th Cir. 2013) (“Every court in Florida to consider the question has concluded that the brand manufacturer of a prescription drug cannot be held liable for injuries suffered by consumers who ingested only the generic form of a drug.”). At least 93 decisions applying the laws of 24 states have expressly rejected a theory of innovator liability. See, e.g., id. at 1253; Smith v. Wyeth, Inc., 657 F.3d 420, 424 (6th Cir. 2011), pet. for reh’g en banc denied (Nov. 22, 2011), cert. denied, 132 S. Ct. 2013 (2012).
of its patent and well aware that a generic version of the drug will be made when that patent expires.”

It also knows “that generic substitutions are allowed [or mandated] in all 50 states.” As such, it “could reasonably foresee that a physician prescribing a brand-name drug (or a generic drug) to a patient would rely on the warning drafted by the brand-name manufacturer even if the patient ultimately consumed the generic version of the drug.”

A brand-name defendant who has proximately caused injuries, at least in very large part, by its negligent or intentional dissemination of inaccurate information (as when the brand-name manufacturer’s label—and perfore the generic counterpart’s label—contains an inadequate warning), should be made to shoulder its share of responsibility. “The fact that [the brand-name manufacturer] did not manufacture or sell the [generic version that the injured plaintiff] ingested does not relieve [the brand-name manufacturer] from its general duty to use due care in disseminating product information to those it knows or should know are likely to be harmed as a result of their physician’s reliance on that information.” Indeed, the brand-name defendant “should reasonably perceive that there could be injurious reliance on its product information by a patient taking [the generic version].” Hence, the foreseeability of a plaintiff’s injury as a result of the brand-name manufacturer’s breach of its duty of reasonable care with respect to its product’s design and warning label should not be controversial.

Whether we have made any progress at all since the thalidomide disaster of 1962 is entirely debatable because hundreds of FDA-approved prescription drugs are recalled every year, but not before they maim or kill hundreds of people.

The Court, in finding preemption in a context where Congress never intended it, is inexplicably and suddenly stripping away this country’s longstanding availability of state-law remedies for consumers who are injured or killed by illegal conduct. When Congress enacted an express preemption provision for medical devices in 1976, it declined to do so for prescription drugs, thereby

117 Wyeth, Inc. v. Weeks, 159 So. 3d 649, 670 (Ala. 2014). Sadly, on May 1, 2015, Alabama Governor Robert Bentley signed SB80, which expressly bars liability claims against manufacturers that did not design or make the product that a plaintiff actually ingested or used, available at http://openstates.org/la/bills/2015rs/SB80/. The legislation was introduced and passed in reaction to the Weeks case.

118 Id.

119 Id.


121 Id. at 318.

122 Id. at 313.


124 Hagopian, supra note 25.


evidencing its intent that “[s]tate tort suits[, which] uncover unknown drugs hazards and provide incentives for drug manufacturers to disclose safety risks promptly,” would provide appropriate relief for the injured consumer of a generic drug.

As such, one cannot help but wonder whether the Court might decide differently on a case in which one of its family members watched more than half of her body become an open wound, spent months in a medically induced coma, underwent twelve eye surgeries, was tube-fed for a year, and is now severely disfigured and nearly blind, as a result of ingesting a dangerously defective prescription drug that happened to be generic.

Sounds more disturbing than any Stephen King novel I’ve ever read. You can scream now, boys and girls.

End.

---

128 Levine, 555 U.S. at 579.
129 See Bartlett, 133 S. Ct. at 2472.