RECORD NO. 21-10306

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

MARILYN WILLIAMS,
Plaintiff–Appellant

v.

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,
BOEHRINGER INGELHEIM USA CORPORATION,
WALGREENS BOOT ALLIANCE, INC.,
Defendants–Appellees

On Appeal from the United States District Court
for the Southern District of Florida

PLAINTIFF-APPELLANT WILLIAMS'S OPENING BRIEF

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March 29, 2021

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Williams v. Boehringer Ingelheim Pharmaceuticals, Inc.
RECORD NO. 21-10306

CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Pursuant to Eleventh Circuit Rule 26.1-1, counsel for Plaintiff-Appellant Marilyn Williams hereby certifies that the following is a complete list of the trial judge(s), all attorneys, persons, associations of persons, firms, partnerships, or corporations that have an interest in the outcome of the particular case on appeal, including subsidiaries, conglomerates, affiliates, and parent corporations, including any publicly held corporation that owns 10% or more of the party's stock, and other identifiable legal entities related to a party:

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Dated: March 29, 2021

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STATEMENT REGARDING ORAL ARGUMENT

Appellant respectfully requests oral argument because this appeal turns on a question of first impression involving the application of fundamental preemption principles to a complex statutory and regulatory regime. Oral argument would assist the Court in clarifying and testing the parties' arguments.

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STATEMENT OF THE ISSUE

In *Mutual Pharmaceutical Co. v. Bartlett,* 570 U.S. 472 (2013), the Supreme Court held that state design-defect claims are preempted when they would require a defendant to stop selling a drug that the FDA has found safe and effective based on the available scientific evidence. But the Court's holding explicitly did "not address state design-defect claims that parallel the federal misbranding statute," which "requires a manufacturer to pull even an FDA-approved drug from the market when it is 'dangerous to health.'" *Id.* at 487, n.4 (quoting 21 U.S.C. § 352(j)). This case squarely presents the question the Supreme Court left open:

Where a plaintiff pleads a design defect in a drug based on post-approval scientific evidence the FDA never considered, is that state-law claim preempted even though both state and federal law required drug sellers to remove the unsafe product from the market?

JURISDICTIONAL STATEMENT

Federal subject matter jurisdiction is proper under 28 U.S.C. § 1332 because there is complete diversity between the parties. This Court has appellate jurisdiction under 28 U.S.C. § 1291 because the district court's order fully disposed of Ms. Williams's claims. Ms. Williams filed a response to Defendants' motion to dismiss for lack of jurisdiction concurrently with this brief, and adopts the arguments presented there by reference.

CONSTITUTIONAL, STATUTORY, AND REGULATORY ADDENDUM

Supremacy Clause of the Constitution

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

U.S. Const. art. VI, cl. 2.

Food, Drug, and Cosmetics Act, Prohibited Acts

The following acts and the causing thereof are prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 344, 350d, 355, or 360bbb-3 of this title.

***

(g) The manufacture within any Territory of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

21 U.S.C. § 331.

Food, Drug, and Cosmetics Act, Penalties

(a) Violation of section 331 of this title; second violation; intent to defraud or mislead

(1) Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both.

(2) Notwithstanding the provisions of paragraph (1) of this section, if any person commits such a violation after a conviction of him under this section has

become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000, or both.

(b) Prescription drug marketing violations

(1) Notwithstanding subsection (a), any person who violates section 331(t) of this title by—

(A) knowingly importing a drug in violation of section 381(d)(1) of this title,

(B) knowingly selling, purchasing, or trading a drug or drug sample or knowingly offering to sell, purchase, or trade a drug or drug sample, in violation of section 353(c)(1) of this title,

(C) knowingly selling, purchasing, or trading a coupon, knowingly offering to sell, purchase, or trade such a coupon, or knowingly counterfeiting such a coupon, in violation of section 353(c)(2) of this title, or

(D) knowingly distributing drugs in violation of section 353(e)(1) of this title,

shall be imprisoned for not more than 10 years or fined not more than $250,000, or both.

***

(c) Exceptions in certain cases of good faith, etc.

No person shall be subject to the penalties of subsection (a)(1) of this section,

(1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the Secretary the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him; or

(2) for having violated section 331(a) or (d) of this title, if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 331(a) of this title, that such article is not adulterated or misbranded, within the meaning of this chapter designating this chapter or to the effect, in case of an alleged violation of section 331(d) of this title, that such article is not an article which may not, under the provisions of section 344 or 355 of this title, be introduced into interstate commerce; or

21 U.S.C. § 333

Food, Drug, and Cosmetics Act, Definition of Misbranding

A drug or device shall be deemed to be misbranded—

(a) False or misleading label

(1) If its labeling is false or misleading in any particular. Health care economic information [is not considered misleading under certain conditions.]

***

(f) Directions for use and warnings on label

Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement. . . .

***

(i) Drug; misleading container; imitation; offer for sale under another name

(1) If it is a drug and its container is so made, formed, or filled as to be misleading; or

(2) if it is an imitation of another drug; or

(3) if it is offered for sale under the name of another drug.

(j) Health-endangering when used as prescribed

If it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

***

(p) Packaging or labeling of drugs in violation of regulations

If it is a drug and its packaging or labeling is in violation of an applicable regulation issued pursuant to section 1472 or 1473 of Title 15.

21 U.S.C. § 352

Food and Drug Administration Regulation on Approved Drugs

Adulteration and misbranding of an approved drug.

All drugs, including those the Food and Drug Administration approves under section 505 of the act and this part, are subject to the adulteration and misbranding provisions in sections 501, 502, and 503 of the Act [codified at 21 U.S.C. §§ 351–353]. FDA is authorized to regulate approved new drugs by regulations issued through informal rulemaking under sections 501, 502, and 503 of the Act.

21 C.F.R. § 314.170

INTRODUCTION

For over five years, Marilyn Williams used Zantac to help treat her mild heartburn. There were other antacids available—but Ms. Williams chose Zantac believing, based on all the information provided to her, that it was safe and effective. Ms. Williams was deceived. She did not know that Zantac—which is generically referred to as ranitidine—degrades over time into huge amounts of a dangerous chemical known as N-Nitrosodimethylamine (NDMA). NDMA was first discovered as a byproduct of rocket fuel combustion. Its only commercial use is to induce tumors in animal experiments. Long recognized by the scientific community as a potent carcinogen, NDMA has no medicinal purpose whatsoever.

In late 2019, after Zantac had been on the market for nearly four decades, the Food and Drug Administration (FDA) finally learned the truth about this dangerous drug. Alerted to Zantac's cancer hazard by a group of independent scientists, FDA required a recall of all Zantac containing unacceptable levels of NDMA. Shortly thereafter, the agency concluded that *no* Zantac was safe and that all of it should be removed from the nation's shelves. Today, thanks to the FDA's decisive actions, Americans are protected from this dangerous drug. Unfortunately, those actions came too late for Ms. Williams, who suffers devastating cancer because of her Zantac use.

Ms. Williams now seeks to hold liable the companies that manufactured and sold the Zantac that caused her cancer. That suit is plainly permitted by the law of Ms. Williams's state, Alabama, which imposes a duty on companies not to sell unreasonably dangerous products. And, contrary to what the district court concluded, it is not preempted by federal law. The reason is simple. Preemption applies when federal and state law *conflict*. In that case, the Supremacy Clause requires state law to yield. But the Constitution does not void the laws of the States where no conflict exists. In that case, the laws of the two sovereigns deserve full respect. Here, far from conflicting, state and federal law are the same. Alabama's design-defect law required Defendants to stop selling their unreasonably dangerous drug. And the federal misbranding statute, 21 U.S.C. § 352(j), required the same thing. Indeed, the FDA compelled Defendants—pursuant to federal law—to cease all Zantac sales, which Defendants went on to do.

In the face of those facts, the district court's decision that it was *impossible* for Defendants to comply with both state and federal law makes little sense. It certainly finds no support in preemption precedent, including *Mutual Pharm. Co. v. Bartlett*, 570 U.S. 472 (2013), on which the district court heavily relied. In *Bartlett*, the plaintiff argued that state design-defect law required the defendant to strengthen the warnings for its drug, but federal law forbade those label changes, making it impossible to comply with the laws of both sovereigns. The Court rejected the

argument that the defendant could achieve joint compliance by stopping sales of its drug—which federal law indisputably allowed defendant to keep selling. In doing so, the Court made crystal clear that its holding did not extend to "the rare case where state or federal law actually require[d] a product to be pulled from the market." 570 U.S. at 487, n.3. This is that case.

As Ms. Williams has alleged in her pleadings and will prove at trial, state *and* federal law required Defendants to stop selling Zantac long before FDA learned the truth and forced that result. This consistency between state and federal law means that Defendants cannot hide behind the Supremacy Clause to avoid state-law liability for the harm done by their dangerous drug.

STATEMENT OF THE CASE

I. FACTS[1]

In 2011, Marilyn Williams began taking over-the-counter Zantac, manufactured by Boehringer Ingelheim, to treat the mild heartburn she sometimes experienced. Am. Short-Form Compl., *Williams v. Boehringer Ingelheim Pharmaceuticals, Inc.*, No. 9:20-cv-80512, (S.D. Fla. Jan. 27, 2021) [ASFC], D.E. 12. Ms. Williams purchased that Zantac from Walgreens and used it for more than five years. Never during that time was Ms. Williams told what independent

[1] Plaintiff's claims were rejected by the district court on a motion to dismiss; the facts relevant to this appeal are accordingly the allegations in the pleadings.

scientists and the FDA have finally uncovered: that Zantac, known generically as ranitidine, contains staggering amounts of NDMA, a potent and well-known human carcinogen. Like hundreds of thousands of other Americans, Ms. Williams fell prey to Zantac's cancer danger. In 2016, she was diagnosed with abdominal and ovarian cancer, which she is still afflicted with to this day. In 2019, Ms. Williams brought this suit to hold Defendants liable for her injuries.

A. Zantac Was A Hugely Profitable Drug.

Zantac belongs to a class of drugs, known as H2 blockers, that help to decrease the acidity of the stomach. Master Personal Injury Complaint [MPIC] ¶ 226 (D.E. 887). It was developed in the late 1970s by a predecessor to the pharmaceutical giant GlaxoSmithKline (GSK). Having witnessed the huge success of Tagament, also an H2 blocker, GSK was determined to get a piece of the fast-growing antacid market. MPIC ¶¶ 226–30.

GSK pushed FDA to approve Zantac and in 1983 it was off to the races. MPIC ¶ 231. The company knew that the exclusivity period following FDA-approval, before the generics rush in, is the time to maximize profits. GSK acted aggressively to do so. MPIC ¶ 232. The strategy worked. Zantac delivered huge profits and made pharmaceutical history as the first drug ever to generate $1 billion in annual sales. The success of this "blockbuster" drug sparked a series of corporate mergers

and acquisitions that propelled GSK to the top of the pharmaceutical industry. MPIC ¶¶ 231–35.

In the 1990s, GSK joined with another industry giant, Pfizer, to expand Zantac's market reach even further. MPIC ¶ 233. Together these companies executed a plan to get FDA approval for an OTC version of the drug that patients could take without a prescription or any guidance from a doctor. Eventually, the companies were forced by antitrust issues to transfer the marketing rights for OTC Zantac to Boehringer Ingelheim, the company that made the Zantac Ms. Williams took. MPIC ¶ 236.

For decades, Zantac continued to generate huge dollars in both its branded and generic forms. As recently as 2018, it remained one of the top ten antacid tablets sold in the United States. MPIC ¶ 252. It was just a year later that FDA learned about Zantac's true safety profile and forced the drug companies to pull all ranitidine products from the nation's shelves.

B. The Truth About Zantac Comes Out.

In late 2019 and early 2020, the FDA received two separate Citizen Petitions from groups of concerned, independent scientists. MPIC ¶¶ 285, 299. The first petition alerted the agency that Zantac pills may contain exceedingly high levels of NDMA. MPIC ¶ 285. The second indicated that the NDMA was coming *from the Zantac itself*—providing evidence, that over time and especially when exposed to

heat, ranitidine degrades, throwing off dangerous amounts of the NDMA molecule. MPIC ¶ 299.

These Citizen Petitions got the FDA's immediate attention. And for good reason. Discovered in the early 1900s as a byproduct of rocket fuel, NDMA is a well-known and potent carcinogen. MPIC ¶ 3. EPA and the International Agency for Research on Cancer classify NDMA as a probable human carcinogen. MPIC ¶ 254. The World Health Organization cites "conclusive evidence" that NDMA can cause cancer. MPIC ¶ 259. Both the Department of Health and Human Services and FDA have likewise concluded that exposure to NDMA can cause cancer in humans. MPIC ¶ 255. Today, NDMA has only one recognized use: to induce tumors in animals that are being subject to experimentation. MPIC ¶ 3.

Prompted by the Citizen Petitions, FDA quickly took action to investigate. Its initial testing identified Zantac products containing "unacceptable levels" of NDMA. MPIC ¶ 296. Based on those results, in late 2019 FDA requested that companies recall any Zantac confirmed to contain NDMA above acceptable levels. *Id.* As the FDA explained at the time, the agency issues a recall request where it has determined that a product is in violation of the laws it administers. MPIC ¶ 301, n.47 (citing letter of Janet Woodcock). Generally, the FDA asks companies to perform recalls voluntarily; if they resist the FDA may initiate seizure proceedings. 21 U.S.C. § 334.

In 2020, FDA performed additional testing, which revealed that the NDMA in Zantac increases over time and can rise to dangerous levels as the product approaches its expiration date. MPIC ¶ 302. These results "eroded [the FDA's] confidence" that *any* Zantac product could remain stable and safe through its labeled expiration date. *Id.* That loss of confidence prompted the FDA to call for the immediate withdrawal of *all* Zantac from the market without any delay for NDMA testing. MPIC ¶ 301.

FDA was not alone in taking swift action to protect the public against any further harm from Zantac. By 2020, forty-three other countries and jurisdictions had restricted or outright banned any further sales of the drug. MPIC ¶ 303. Sadly, these actions did nothing to help Ms. Williams. For her and so many others who took Zantac, the drug had already taken its devastating and often deadly toll.

C. Defendants Knew or Should Have Known About Ranitidine's Dangers Decades Sooner.

The tragedy of the Zantac story is that it did not have to happen. From early on, there were glaring red flags pointing to Zantac's cancer hazard. But instead of warning the public, or raising concerns with the FDA, or even further investigating the issue themselves, the drug companies did nothing. They were too intent on protecting their profits from this blockbuster drug.

The signs started early. In 1983, for example, a group of Italian scientists published a study showing that NDMA is produced when Zantac mixes with nitrites

in the stomach's gastric fluids. MPIC ¶ 310. Nitrites are chemicals contained in certain foods and particularly high in processed meats. MPIC ¶¶ 309, 327. The scientists' study made a simple suggestion: people using Zantac, especially those using it for extended periods, should be advised to eat a diet low in nitrites or avoid taking the medication close in time to meals. MPIC ¶ 310. Discovery has revealed other studies that reached similar conclusions regarding Zantac's cancer danger—studies that were never revealed to the public or the FDA.

Instead of disclosing this mounting science to people like Ms. Williams, the drug companies doubled down on their strategy to maximize profits from Zantac. They spent millions on advertising campaigns showing people taking Zantac to control heartburn caused by foods notoriously *high* in nitrites, like tacos and pizza. MPIC ¶¶ 311, 328. They downplayed the potential hazard flagged by the Italian scientists, telling the FDA the risk was "unrealistic," since most people would use take Zantac for only a short time. MPIC ¶¶ 314–15. As noted above, Ms. Williams purchased and ingested OTC Zantac for more than five years. *See* D.E. 12 at 3. She is not some outlier in the patient population. Scores of Americans used Zantac daily for years or even decades.

In 1987, GSK published a study that further downplayed the risk. The study examined the gastric contents of human patients who had consumed ranitidine and reported finding uniformly safe levels of Nitrosamines. MPIC ¶ 317. But the study,

which GSK conducted itself, failed to employ the widely-accepted gold-standard method for measuring NDMA, relying instead on an inferior technology. Worse, GSK discarded two-thirds of the samples—those with the highest levels of ranitidine—out of concern that those samples would contain supposedly false-positive "high concentrations of N-nitroso compounds," of which NDMA is one. With that manipulation, it is no wonder the study provided exactly the results GSK wanted—a misleading conclusion that ranitidine use did *not* increase nitrosamines. MPIC ¶ 317.

Years later, researchers at Stanford took another independent look at Zantac and NDMA. The Stanford researchers concluded that taking just one dose of ranitidine increased by 400 times NDMA levels in healthy adults. Appearing in the journal *Carcinogenesis*, the Stanford study was widely available for review by the drug manufacturers, distributors, and retailers that had long profited from ranitidine. Still, they did nothing but continue to sell their dangerous drug. MPIC ¶ 321.

D. Selling Pharmaceuticals Is Only Lawful with FDA Approval.

Under the Federal Food, Drug, and Cosmetic Act 21 U.S.C. § 301 *et seq.* (FDCA), it is unlawful to sell any new drug without pre-approval by the FDA. 21 U.S.C. § 355(a). The manufacturer who develops a new drug—referred to as the brand-name drug—must submit a New Drug Application (NDA) to the FDA. The FDA only approves a drug once it determines based on scientific evidence and data

submitted by the NDA applicant that the drug is safe and effective. *Id.* § 355(d); *see also Bartlett*, 570 U.S. at 476 ("for the FDA to consider a drug safe, the drug's 'probable therapeutic benefits must outweigh its risk of harm'" (quoting *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 140 (2000)). After an NDA is approved, the applicant remains obligated to send new and emerging scientific information to the FDA and, where the information warrants it, to update the drug's label without first seeking the FDA's approval. *See* 21 C.F.R. § 314.70.

After FDA-approval, the brand-name manufacturer enjoys a period of exclusivity; but following that period other drug manufacturers can file Abbreviated New Drug Applications (ANDAs) to sell a virtually identical drug called a generic. *See* 21 U.S.C. § 355(j). Generic drugs may differ in some respects from the branded drug (for example, the expiration date), but the warnings and precautions, active ingredient, and dosage must be the same. *Id.* That means ANDA holders are prohibited from changing a generic drug's formulation or warnings unless those changes are necessary to replicate changes made to the branded drug.

The FDCA also applies to retailers such as Defendant Walgreens. They generally comply by selling drugs that are *lawfully* in the stream of commerce (*i.e.,* that have received FDA approval and—based on current science—remain safe and effective).

E. Congress Made Pharmaceutical Manufacturers and Sellers Responsible for Patient Safety.

Receiving FDA approval for a branded or generic drug is necessary to lawfully sell it. But it does not provide blanket license to continue selling the drug no matter what circumstances develop. All participants in the distribution system—from manufacturers to retailers—have a continuing duty under federal law not to sell "misbranded" drugs. A drug is misbranded if it "is dangerous to health when used in the dosage, or manner or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof"; if "its packaging or labeling is in violation of an applicable [FDA] regulation"; or if its "labeling is false or misleading in any particular." 21 U.S.C. § 352(j); (p); (a)(1).

The manufacture, sale, receipt, or delivery of a misbranded drug into interstate commerce triggers civil and criminal penalties (including fines and prison time). *See* 21 U.S.C. §§ 331, 333–334. The FDCA's misbranding provision gives important powers to the FDA, since it can both enforce the statute and create regulations that trigger criminal liability. But the definition of a misbranded drug is unambiguously broader than merely complying with FDA regulations. That is obvious from the text of the statute itself, which refers to FDA regulations in only one of the definitions of misbranding. *See* 21 U.S.C. § 352(p). Other definitions forbid the manufacture or sale of a drug that is dangerous to health when used as labeled or that has a false or misleading label. 21 U.S.C. §§ 352(j), (a)(1). Indeed, "it has remained a central

premise of federal drug regulation that the manufacturer," not the FDA, "bears responsibility for the content of its label at all times" and "is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." *Wyeth v. Levine*, 555 U.S. 555, 570–71 (2009).

The FDA's regulations are just as clear that NDA or ANDA approval in the past offers no dispensation in the present from the misbranding provisions of the FDCA. The agency implemented a separate regulatory section to make just this point, titled "Adulteration and misbranding of an *approved* drug." 21 C.F.R. § 314.170 (emphasis added). This section states: "All drugs, including those the Food and Drug Administration approves under [the NDA and ANDA provisions], are subject to the adulteration and misbranding provisions" of the FDCA. *Id.* At the time this provision was promulgated, "several comments urged that this section be deleted, believing that the only lawful procedure for dealing with adulterated or misbranded approved new drugs is by withdrawal of approval of the application." 50 Fed. Reg. 7452, 7488 (Feb. 22, 1985). The FDA disagreed:

> the new drug provisions do not insulate approved drugs and antibiotics from the general adulteration and misbranding provisions of the act. As FDA has previously noted, the statutory scheme contemplates FDA's application of the adulteration and misbranding standards to all drugs, irrespective of whether those drugs have been subject to the premarket approval requirements of the act.

Id.

Federal misbranding law applies up and down the supply chain. It applies to manufacturers and retailers alike, prohibiting both from manufacturing, receiving, or selling a misbranded drug in interstate commerce. 21 U.S.C. §§ 331, 333–334. Congress was so intent on protecting consumers from misbranded drugs that it created criminal liability with no *mens rea*—a strict liability crime. *See United States v. Dotterweich*, 320 U.S. 277, 281 (1943) (The FDCA "dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing.").

FDA pre-approval and liability for misbranding post-approval are complements in Congress's regulatory scheme. FDA approval speaks authoritatively on the safety and effectiveness of a drug *at the time of approval* based on the information provided. But FDA approval "do[es] not give drug manufacturers an unconditional right to market their federally approved drug *at all times* with the precise label initially approved by the FDA." *Wyeth*, 555 U.S. at 592 (Thomas, J., concurring) (emphasis added). Science develops. New risks come to light. And so, "[t]he misbranding statute requires a manufacturer to pull even an FDA-approved drug from the market when it is 'dangerous to health' even if 'used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.'" *Bartlett*, 570 U.S. at 487, n.4 (quoting 21 U.S.C. § 352(j)).

F. The Proceedings Below.

Like Ms. Williams, thousands of other people filed suit seeking relief for the harm that ranitidine caused them. In 2020, those suits were centralized before Judge Robin Rosenberg in the Southern District of Florida. The district court issued myriad pre-trial orders, one of which required that the MPIC "together with the Short Form Complaint shall be deemed the operative Complaint" for each action. D.E. 876 at 3. The MPIC covered the waterfront, alleging fifteen counts against five groups of defendants.

Ms. Williams's operative short form complaint incorporates only one of those counts and alleges a claim against only Boehringer Ingelheim and Walgreens (including its parent company). Her "sole theory of liability is that the ranitidine [she] consumed was defectively designed under state law, and that these same design defects made ranitidine dangerous to health when used as instructed on the label such that it was misbranded under federal law. The ranitidine Plaintiff consumed was illegal to sell under federal law, and requires compensation under state design defect tort law." D.E. 12 at 4.

The MPIC alleged at length the scientific reasons ranitidine degrades into NDMA, the tests that should have revealed that fact, and the studies that put Defendants on notice of the hazard. Taken as true, the allegations show what the FDA's rapid recall upon learning the risks confirmed: no one with an accurate

understanding of ranitidine's risks would consume or sell it. It is inherently defective. The MPIC alleged that plainly in Count II on design defect: "Defendants' ranitidine-containing products . . . were defective in design and formulation in that, when they left the hands of Defendants, the foreseeable risks exceeded the alleged benefits associated with their design and formulation" and that "Defendants knew or had reason to know that ranitidine-containing products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants." MPIC ¶¶ 479–80.

II. THE RULINGS BELOW

Defendants moved to dismiss on an array of grounds, but only preemption is relevant here. Defendants argued that all design-defect claims were preempted because no Defendant could change the design of ranitidine without pre-approval from the FDA. Plaintiffs responded that state design-defect law requires defendants to stop selling products when the product is unjustifiably dangerous due to its defective design. Plaintiffs explained that that duty is harmonious with federal law when a drug is misbranded, which is to say, when it "is dangerous to health when used in the dosage, or manner or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof," 21 U.S.C. § 352(j), or where the drug's label is "false or misleading in any particular," 21 U.S.C. § 352(a)(1). Because federal law forbids the manufacture, sale, or receipt of misbranded drugs,

21 U.S.C. § 331(a)–(d), and state design defect law requires the same thing, the two regimes do not conflict.

After a two-day hearing, the district court issued five Orders, three of which are relevant in this appeal.

The first Order, D.E. 2512 ("Generic Order"), granted the generic manufacturer defendants' preemption motion. Crucially, the court "assume[d]," for the purposes of its order, "that Plaintiffs have adequately alleged that ranitidine products were misbranded" under the FDCA. D.E. 2512 at 30. Nonetheless, the court held that *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), and *Mutual Pharmaceutical Co., Inc. v. Bartlett*, 570 U.S. 472 (2013), required a finding of preemption. In sum, the court explained,

> *Mensing* and *Bartlett* further instruct that the ability to comply with both federal and state law by withdrawing misbranded ranitidine products from the market does not defeat pre-emption. A claim based on an allegation that a generic drug's labeling renders the drug misbranded is a pre-empted claim because the drug's manufacturer cannot independently and lawfully change FDA-approved labeling.

D.E. 2512 at 27. The district court opined it was "of no matter" that "federal law imposes criminal liability on a drug manufacturer that introduces a misbranded drug into interstate commerce" because only the United States, not a private plaintiff, can enforce it. *Id.* at 28. Similarly, the court deemed Supreme Court cases about parallel claims irrelevant because "*Reigel*, *Bates*, and *Lohr* did not address impossibility

preemption." D.E. 2512 at 36 (referring to *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005); *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), and *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996)).

The court further concluded that preemption applies to factual allegations, not to claims. *Id.* at 29 ("[A]llegations that [generic] ranitidine products were defectively designed because they break down into NDMA and claims based on failure to warn consumers that the products contained NDMA or could break down into NDMA when ingested" are "pre-empted."). Accordingly, the court required "Plaintiffs' counsel" to "identify these allegations and to omit them from the claims against Generic Manufacturer Defendants upon repleading the Master Complaints." *Id.* at 29.

The court's second Order granting the retailers' (including Walgreens's) preemption motion incorporated and relied upon the same reasoning. *See* D.E. 2513 at 30–32 ("Retailer Order"). The court added, however, that the misbranding argument failed because retailers could not stop selling misbranded drugs since "Plaintiffs have not plausibly alleged that the Defendants *knew* that the drugs were misbranded or otherwise could have detected the alleged defects in the ranitidine molecule." *Id.* at 30 (emphasis added). Moreover, the district court concluded design-defect claims "[b]y definition" can "only be brought against a manufacturer—not a retailer or a distributor." *Id.* In this second Order, the court

dismissed all claims (except certain negligence counts) against all retailers "with prejudice" and "without leave to amend as further amendment would be futile." *Id.* at 32.

The court's third Order granting the brand-name manufacturer defendants' preemption motion also incorporated and relied upon the earlier Generic Order. *See* D.E. 2532 ("Brand Order") at 24 ("As with generic drugs, a claim based on an allegation that a brand-name drug's FDA-approved formulation renders the drug misbranded" that is, any claim based on the design of ranitidine, "is a pre-empted claim because the drug's manufacturer cannot independently and lawfully change a drug formulation that the FDA has approved."). The court similarly ordered Plaintiffs to "omit [misbranding] allegations from claims against the [brand-name] Defendants when repleading." *Id.* at 25.

III. STANDARD OF REVIEW

A court of appeals "review[s] *de novo* the district court's grant of a Rule 12(b)(6) motion to dismiss for failure to state a claim, accepting the complaint's allegations as true and construing them in the light most favorable to the plaintiff." *Chaparro v. Carnival Corp.*, 693 F.3d 1333, 1335 (11th Cir. 2012). And it "also review[s] *de novo* . . . whether federal law preempts a state law claim." *Graham v. R.J. Reynolds Tobacco Co.*, 857 F.3d 1169, 1181 (11th Cir. 2017) (en banc).

SUMMARY OF THE ARGUMENT

The FDCA does not impliedly preempt state tort claims that impose the same duties as the FDCA. Preemption flows from the Supremacy Clause, and modern doctrine recognizes different categories of preemption. Congress often preempts certain state duties expressly, for example, by preempting any state requirements that differ from federal law. For statutes with that type of express preemption clause, a line of Supreme Court cases has recognized so-called *parallel* claims. *See Bates*, 544 U.S. at 447. A claim is parallel if the federal and state duties are the same, even if the wording to describe the duty differs. The FDCA has no express preemption clause, but the district court held that Ms. Williams's claim was subject to implied impossibility preemption. Under that doctrine, a state law is preempted only if compliance with both federal and state law is impossible. It follows that a parallel claim, as the Supreme Court has defined it, *always* survives implied impossibility preemption, because it is *always* possible to comply with two duties where those duties are the same.

There are zero exceptions to that observation as a matter of basic logic. For that very reason, it should come as no surprise that no implied impossibility precedent has ever barred parallel claims. The Supreme Court cases the district court relied on are in accord with Ms. Williams's position. They applied impossibility preemption to state law claims that required generic manufacturers to change their

drug label; but federal law prohibited such a change. *Mensing*, 564 U.S. 604, and *Bartlett*, 570 U.S. 472. Comparing the duties showed they were both different and incompatible. *Bartlett*, 570 U.S. at 487, n.4 ("We do not address state design-defect claims that parallel the federal misbranding statute. . . . [T]he misbranding provision is not applicable here."). The question *Bartlett* did not address is squarely posed here. And it is simple to resolve. Where state and federal law impose the same duty, it is not impossible to obey both sovereigns.

The original public meaning of the Supremacy Clause supports that reasoning. The framers wrote the Supremacy Clause so that courts would apply federal law as the law of the state, but of higher priority, much like a later-in-time law. On that conception, as originalist scholarship and contemporary cases show, a state law is *preempted* by a federal law if, imagining it as a later-in-time state enactment, it would repeal state law by implication. This amounts to a rule that state laws are preempted when they logically contradict federal law.

Both state design-defect law and the FDCA's misbranding provision require Defendants to pull a dangerous drug from the market. This theory is consistent with *Bartlett*, which involved a drug that the Supreme Court expressly noted was not recalled or misbranded. Under those facts, there was a clear conflict between federal law (that allowed selling the drug with a certain label) and state law (that forbade it). Here, federal law and state law command the same thing. The preemption test from

the original public meaning of the Supremacy Clause also rejects preemption here, since no one would think a later-in-time law impliedly repeals an earlier law that requires the same conduct. It is axiomatic that the *same* duty cannot contradict itself.

The district court evaded this outcome by misapplying basic preemption doctrine in myriad ways. Its erroneous judgment must be reversed.

ARGUMENT

IV. THE FDCA DOES NOT IMPLIEDLY PREEMPT STATE TORT CLAIMS THAT IMPOSE THE SAME DUTIES AS THE FDCA.

The FDCA does not preempt state law that imposes the same requirements. This rule is consistent with basic preemption principles: state laws are not preempted unless they conflict with federal law, and laws that are the same do not conflict. It is consistent with established precedent applying the FDCA: no case has *ever* held that the FDCA preempts independent state law duties that require the same thing as the FDCA. It is consistent with common sense: federal policy is not undermined in any way by a state law that requires the same thing as federal law. And it is consistent with the original public meaning of the Supremacy Clause: the framers drafted the Supremacy Clause to create preemption only where federal law could be read as an implied repeal of state law, and a later-in-time statute would never be read to repeal an earlier law that imposed the same requirements.

A. Federal Law Does Not Preempt Parallel State Law Duties.

Preemption flows from the Supremacy Clause, which provides:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

U.S. Const. Art. VI, cl. 2. Any "thing" in state law that "interferes with or is contrary to federal law, must yield." *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 108 (1992) (internal quotation marks omitted). Occasionally, Congress decides to occupy an entire field of law, such that *any* state regulation in the same domain will necessarily conflict with federal law. *Arizona v. United States*, 567 U.S. 387, 401 (2012) ("Where Congress occupies an entire field, as it has in the field of alien registration, even complementary state regulation is impermissible. Field preemption reflects a congressional decision to foreclose any state regulation in the area, *even if it is parallel to federal* standards." (emphasis added)). But where Congress decides not to occupy the field, the resulting statute, by definition, allows state laws to regulate the same conduct to the extent they impose parallel duties.

This principle applies even where Congress manifests an *express* intent to preempt state laws. For example, in *Bates*, the Supreme Court held that the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which expressly preempts all state pesticide requirements "in addition to or different from" federal law, did not preempt state requirements that were parallel to the federal requirements. 544 U.S. at 447 (quoting 7 U.S.C. § 136v(b)). The Court started with the simplest case: "state

regulation requiring the word 'poison' to appear in red letters, for instance, would not be pre-empted if an EPA regulation imposed the same requirement." *Id.* at 444. The Court then held that state common-law duties are also not preempted if they are "equivalent to, and fully consistent with" the federal law. *Id.* at 447. Borrowing its analysis from the Medical Device Amendments to the FDCA, the Court dubbed such requirements "parallel." *Id.* ("The 'parallel requirements' reading . . . finds strong support in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).").

The Court further explained that "[t]o survive pre-emption, the state-law requirement need not be phrased in the *identical* language as its corresponding [federal] requirement." *Bates*, 544 U.S. at 454. Thus, if federal law required a label to say "Poison" in red letters, and the state-law duty required a reasonable warning, then a plaintiff could prevail by showing that the label lacked a reasonable warning *because* it did not say "Poison" in red letters. The failure to comply with federal law put the defendant out of compliance with state law too, making the duties parallel. Ample case law in this circuit and elsewhere apply these familiar principles to parallel claims. *See, e.g.*, *Mink v. Smith & Nephew Inc.*, 860 F.3d 1319, 1329 (11th Cir. 2017); *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1234 (9th Cir. 2013) (en banc); *Hughes v. Bos. Sci. Corp.*, 631 F.3d 762, 769 (5th Cir. 2011); *Bausch v. Stryker Corp.*, 630 F.3d 546, 558 (7th Cir. 2010).

If state common-law duties that "parallel" federal requirements survive preemption under an *express* preemption clause like that at issue in *Bates*, it follows *a fortiori* that such duties cannot fall to implied conflict preemption. That is because implied conflict preemption is a far tougher row for defendants to hoe. The mere "possibility of impossibility" is not enough. *Merck*, 139 S. Ct. at 1678 (quotation omitted). A defendant must show that it is actually "*impossible* for a private party to comply with both state and federal requirements." *English v. General Elec. Co.*, 496 U.S. 72, 79 (1990) (emphasis added). Where state law parallels federal law in the duty it imposes, it is not impossible to comply with "both state and federal requirements." Just as a parallel state law would survive express preemption, it per force survives impossibility preemption as well.

B. FDCA Precedent Does Not Support Preemption of Parallel Duties.

It is a defendant's burden to establish impossibility preemption and it is a "demanding defense." *Wyeth*, 555 U.S. at 573. Yet Defendants can point to no impossibility preemption case that has *ever* applied the FDCA to preempt parallel state-law duties. Indeed, Defendants cannot identify any case in *any context* finding implied impossibility preemption where state law requires the same thing as federal law.

The Supreme Court's opinions in *Mensing*, 564 U.S. 604, and *Bartlett*, 570 U.S. 472, certainly do not check that box. Instead, both cases recognize

straightforward instances of impossibility preemption. The plaintiffs alleged and sought to prove that state law required the defendants, generic drug manufacturers, to add stronger warnings to their labels. *Mensing*, 564 U.S. at 609; *Bartlett*, 570 U.S. at 475. But that state-law requirement conflicted directly with federal law, which *prohibits* generic drug companies from unilaterally changing their labels. *See* 21 U.S.C. §§ 355(j)(2)(A)(v); 355(j)(4)(G). It was impossible for the defendants to satisfy their state-law duty to strengthen their drug warnings without violating the federal law that prohibited them from doing so. *Mensing*, 564 U.S. at 618; *Bartlett*, 570 U.S. at 480. The impossibility meant that the Supremacy Clause required state law to yield. Nothing in *Mensing* or *Bartlett* suggests that state law must yield where it requires the same thing federal law does. And that is not surprising, because such a result would defy common sense.

Hard as they may try, Defendants cannot show that it would be impossible to comply with both state and federal law where both state and federal law require the same thing. One might as well endeavor to square the circle or show where two parallel lines cross. Thus, unless Defendants' response brief adopts the remarkable position that Congress intended the FDCA to displace the entire field of pharmaceutical safety, Defendants' preemption argument must fail.

C. The Original Public Meaning of the Supremacy Clause Confirms That the FDCA Does Not Preempt Parallel Duties.

Applying federal law to preempt parallel state duties would violate not only law and logic—but also the original public meaning of the Supremacy Clause.

The Supremacy Clause reflects a federalism balance struck by the framers after they discarded the Articles of Confederation. To better protect the people's cherished liberties, it was necessary to "split the atom of sovereignty"—with a *truly* sovereign federal government created from the fission. *Gamble v. United States*, 139 S. Ct. 1960, 1968 (2021) (internal quotations and citation omitted). But the framers feared that state courts might treat federal law as American courts routinely treated the laws of foreign sovereigns such as England or France: helpful authority that may be followed or ignored based on principles of comity and sound considerations of domestic policy. *E.g.*, *Bank of Augusta v. Earle*, 38 U.S. 519, 520 (1839).

To address that concern, the Supremacy Clause makes clear that federal law is "supreme"—the "Law of the Land" that states must treat as if it were enacted by the state itself, "rather than as the law of another sovereign." Caleb Nelson, *Preemption*, 86 Va. L. Rev. 225, 249 (2000). The phrase "supreme" also gave federal law a "rule of priority," requiring states to treat that law as not only enacted by the state's legislature, but also as later-in-time, allowing federal law to expressly repeal state law. *Id.* at 250. But even absent express preemption language, federal

law—like any later-in-time law—repeals any state law that is *inconsistent* with that federal law. *Id.* at 253–54. Chief Justice Marshall employed this understanding in *McCulloch v. Maryland*, opining that "[a] law, absolutely repugnant to another, [] entirely repeals that other *as if express terms of repeal were used*." 17 U.S. 316, 425–26 (1819) (emphasis added). Thus, if a prior-in-time law is "absolutely repugnant" to a later-in-time law, courts presumed in 1789 (and still presume today) that the legislature intended to repeal the earlier statute, even without express words of repeal in the later-enacted legislation.[2]

In short, the Supremacy Clause mandates that when state and federal law are alleged to conflict, courts must: (i) act as if both were enacted by the same sovereign; (ii) treat federal law *as if* it were enacted later in time, even if it is was not; and (iii)

[2] Professor Nelson and Justice Thomas have further argued for treating the "notwithstanding" language of the Supremacy Clause as a *non obstante* provision. Under English law received at the time of the framing, courts applied a strong "general presumption against implied repeals." Nelson, Preemption, 86 Va. L. Rev. at 241–42. That strong presumption authorized courts to avoid a plain-text reading of later-enacted statutes to harmonize them with preexisting law. "In the words of Matthew Bacon's New Abridgment of the Law, '[a]lthough two Acts of Parliament are seemingly repugnant, yet if there be no Clause of *non Obstante* in the latter, they shall if possible have such Construction, that the latter may not be a Repeal of the former by Implication.'" Nelson, Preemption, 86 Va. L. Rev. at 242 (quoting 4 Matthew Bacon, A New Abridgment of the Law at 631 (London, W. Strahan 4th ed. 1778) (emphasis added). The "notwithstanding" language in the Supremacy Clause provides a *non obstante* clause, preventing courts from deploying strained interpretations of Congress's intent to avoid an implied repeal. Because Ms. Williams's argument relies on a plain reading of the FDCA, it is wholly consistent with Justice Thomas's reading of the Supremacy Clause.

determine if federal law impliedly repeals some or all of the state law at issue. Justice Thomas's opinion in *Mensing* adopted this originalist reading, explaining that the Supremacy Clause "plainly contemplates conflict pre-emption by describing federal law as effectively repealing contrary state law." *Mensing*, 564 U.S. at 621 (plurality) (citing Nelson); *see also Wyeth*, 555 U.S. at 590 (Thomas, J., concurring) (citing Nelson).

The original understanding of the Supremacy Clause confirms what modern doctrine requires. The FDCA, viewed as a later-enacted statute, leaves intact any state law not repugnant to the FDCA's provisions. It certainly does not impliedly repeal a state law (whether statute or common law) that imposes duties parallel to those contained in the FDCA.

V. MS. WILLIAMS'S TORT CLAIMS ARE NOT IMPLIEDLY PREEMPTED BECAUSE THEY IMPOSE THE SAME DUTIES ON DEFENDANTS AS THE FDCA.

The FDCA does not preempt Ms. Williams's state-law claim. As Ms. Williams has alleged, and will prove at trial, both state *and* federal law required Defendants to stop selling Zantac. That result was required by the state-law duty not to sell unreasonably dangerous products. And it was required by the FDCA's prohibition on manufacturing, receiving, selling, or marketing misbranded drugs. It cannot be impossible to perform state duties that match requirements imposed by the

FDCA. *Bates*, 544 U.S. at 447. Whatever the FDCA states by implication, it does not state an affront to basic logic.

A. Ranitidine Is Misbranded.

Start with the facts supporting the federal duty not to sell ranitidine. The pleadings allege that NDMA is a potent carcinogen, and cite the broad scientific consensus that it "has caused cancer in nearly every laboratory animal tested so far." MPIC ¶ 253; ¶¶ 254–84. The pleadings allege—and all agree—that no ranitidine product listed NDMA as an ingredient, MPIC ¶ 421, warned of its cancer risk, MPIC ¶ 382, or in any other way mitigated its dangers. No manufacturer, prior to the recent citizen petitions, ever told the FDA about the dangers of NDMA in ranitidine. MPIC ¶ 382. The pleadings allege that ranitidine degrades into NDMA in the human stomach, through an enzymatic reaction, and over time under normal storage conditions. MPIC ¶ 308. Considering just degradation in the stomach, "[u]nder biologically relevant conditions" just "one dose of 150 mg [of] ranitidine" breaks down into NDMA levels "ranging between 245 and 3,100 times above the FDA-allowable limit. One would need to smoke over 500 cigarettes to achieve the same levels of NDMA found in one dose of 150 mg ranitidine . . . ." MPIC ¶ 330. When this information became public, the FDA and comparable regulators from *43 different countries* restricted or banned ranitidine. MPIC ¶ 303.

Taking the allegations as true, the pleadings make plain as day that ranitidine is "dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 352(j). A risk of cancer is the quintessence of a "danger[] to health." And ranitidine's label did not provide any suggestions or recommendations that removed or reduced the risk of cancer. Moreover, this risk is *completely* unjustified, since "[t]here are multiple alternatives to ranitidine that do not cause cancer." MPIC ¶ 365.

The FDA, of course, concluded ranitidine was not dangerous to health when it approved the drug *in 1983*. And, if the jury were to simply second-guess that determination based on the *same evidence* presented to the FDA *then*, that may present a preemption concern. *See Bartlett*, 570 U.S. at 487 ("Because the jury was not asked to find whether new evidence concerning sulindac that had not been made available to the FDA rendered sulindac so dangerous as to be misbranded under the federal misbranding statute, the misbranding provision is not applicable here."). But here, the FDA ordered a recall and told consumers to dispose of any ranitidine they had in their homes. MPIC ¶ 566. Surely the FDA's recent actions "allows the court to draw the reasonable inference" that it encountered new, and scientifically significant information. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). With the benefit of discovery, Plaintiffs will be able to show precisely what information the

FDA considered in 1983, and which pieces of information that led it to withdraw ranitidine were new and scientifically significant. The district court "assume[d], without finding, that Plaintiffs have adequately alleged that ranitidine products were misbranded." D.E. 2512 at 30.

B. Ranitidine Is Illegal to Sell Under State Law.

Next, consider the state duty. The district court denied Defendants' state law motions to dismiss as moot, and has not ruled on the scope of any state-law issue (much less engaged in choice-of-law briefing). D.E. 2513 at 45. But it seems unlikely there are many states that would not deem ranitidine defective and illegal to sell. Ranitidine appears to meet the very highest tort standard, comment k of the Second Restatement:

> In determining whether placing a commodity on the market is "unreasonably dangerous per se," the reasonable man standard of the Restatement becomes the fulcrum for a balancing process in which the utility of the product properly used is weighed against whatever dangers of harm inhere in its introduction into commerce. Obviously, use of an unavoidably unsafe product always presents at least a minimal danger of harm, but only if the potential harmful effects of the product—both qualitative and quantitative—out-weigh the legitimate public interest in its availability will it be declared unreasonably dangerous per se and the person placing it on the market held liable.

Reyes v. Wyeth Labs., 498 F.2d 1264, 1274 (5th Cir. 1974). If ranitidine is dangerous enough—with no countervailing benefits—to meet *that* standard, then it would easily trigger liability in the states that would *not* apply Comment k here. *See*

Restatement (Second) of Torts § 402A (Am. Law Inst. 1965). And it would satisfy hybrid states, such as Florida (where the district court sits), which "use[s] both the consumer expectations test and risk utility test as alternative definitions of design defect." *Aubin v. Union Carbide Corp.*, 177 So. 3d 489, 512 (Fla. 2015).

The Supreme Court proposed a practical option in *Bates*, suggesting that "[i]f a defendant so requests, a court should instruct the jury on the relevant [] misbranding standards, as well as any regulations that add content to those standards" to ensure the federal and state standards are genuinely equivalent. 544 U.S. at 454. The district court here could do the same for the FDCA misbranding standard to guarantee the jury finds liability only when *both* the federal and state standards are met.

C. Finding a Parallel Claim Here Is Consistent with *Bartlett*.

Bartlett involved an FDA-approved medication, sulindac, that remained FDA approved at the time of the plaintiff's lawsuit. Unlike ranitidine, sulindac was never subject to any recall or withdrawal, even after FDA "completed a comprehensive review of [sulindac's] risks and benefits." Nor did the *Bartlett* plaintiffs allege or ask the jury to find that "new evidence concerning sulindac that had not been made available to the FDA rendered sulindac so dangerous" as to violate the federal misbranding statute. 570 U.S. at 487, n.4. Unlike here, there was no allegation that

federal law had, at any time, imposed on the defendant a requirement to stop selling sulindac.

To be sure, in *Bartlett*, the Court considered the argument that it was not "literally impossible" for the defendant to remain in compliance with both sovereigns' laws because the defendant could have chosen "not to make sulindac at all." *Bartlett*, 570 U.S. at 488. After all, federal law does not *require* drug companies to keep selling their FDA-approved drugs. *Bartlett* rejected this argument, reasoning that if a defendant's *option* to stop-selling was enough to overcome impossibility preemption, the doctrine would be a dead letter. *Id.* Where there was no dispute that a drug manufacturer was providing FDA-approved medication in full *compliance* with federal law, the Court refused to reach a result that would require the manufacturer "to cease acting altogether in order to avoid [state law] liability." *Id.*

The distinction between *Bartlett* and this case is obvious and dispositive. In *Bartlett* the plaintiffs were suggesting that state tort law required a drug manufacturer to either (a) alter its warning label in direct violation of federal law or (b) *because the label violated state (but not federal) law,* pull the drug from the market. Here, by contrast, Ms. Williams has alleged, and will show at trial, that the FDCA *prohibited* Defendants from selling ranitidine *and* that state law also imposed a duty not to sell this unreasonably dangerous drug.

To the extent there were any doubt that this distinction is material, the Supreme Court removed it in *Bartlett* itself. The Court expressly noted that its decision was *not* addressing "the rare case in which state or federal law actually requires a product to be pulled from the market." 570 U.S. at 487, n.3. When the Supreme Court says it is not deciding a question, it necessarily believes that the question held open is not controlled by its holding. Any argument by Defendants that the distinction is irrelevant ignores the express views of the Supreme Court.

It also ignores what the original public meaning of the Supremacy Clause teaches. Ms. Williams' claims assert that state tort law imposed on Defendants a duty not to sell their unreasonably dangerous product. Her complaint further alleges that the FDCA imposed the same obligation. If the FDCA is viewed as a later-in-time law and Ms. Williams' state tort claim is treated as an earlier-enacted statute, there is no plausible argument that the latter impliedly repeals the former. A later statute saying "stop selling ranitidine" cannot impliedly repeal an earlier statute saying "stop selling ranitidine."

Where state law and federal law require the same thing, there is no conflict between sovereigns, no impossibility of compliance for defendants, and thus no preemption. That conclusion accords with long-standing Supreme Court precedent on parallel claims, common sense, and the original public meaning of the Supremacy

Clause. Defendants, who bear a heavy burden to establish implied impossibility preemption, have identified nothing to the contrary.

VI. THE DISTRICT COURT'S REASONING IS FLAWED

A. The Parallelism of State and Federal Law Is Not "Irrelevant" to Implied Preemption Analysis.

The district court dismissed as categorically "irrelevant" the fact that the state-law duty Ms. Williams invokes is parallel to requirements the FDCA imposes, noting that the Supreme Court cases finding no preemption for parallel claims—"*Reigel*, *Bates*, and *Lohr*"—were express preemption cases and "did not address impossibility preemption." D.E. 2512 at 36 (referring to *Bates*, 544 U.S. 431; *Riegel* 552 U.S. 312, and *Lohr*, 518 U.S. 470). But the basic logic of those cases—where the state and federal duties are identical, there is no preemption—is not confined to express preemption cases. If anything, that logic applies *more* strongly where a defendant invokes implied possibility preemption, which imposes a much higher bar. *Bates*, *Riegel*, and *Lohr* each involved statutory clauses that invalidated state-law requirements that differed *in any way* from federal requirements. *See* 7 U.S.C. § 136v(b) (pesticides, "in addition to or different from"); 21 U.S.C. § 360k(a)(1) (medical devices, "different from, or in addition to"). In other words, if state and federal law were not exactly the same, state law was preempted. If a state claim

would survive preemption under those stringent express preemption clauses, then it cannot be preempted by implied impossibility preemption.[3]

The district court further justified its decision by reasoning that Plaintiffs' theory would "render pre-emption caselaw meaningless," because: "If Plaintiffs' position were accepted, a plaintiff could avoid pre-emption simply by asserting, for example, that a drug's labeling was 'false or misleading in any particular' or that the drug was 'dangerous to health when used' as prescribed. D.E. 2512 at 28 (quoting 21 U.S.C. § 352(a)(1), (j)). The district court is mistaken. First, it is not enough merely to "assert" that the FDCA's definition of misbranding is satisfied. That legal conclusion must be plausibly supported by factual content. *See Iqbal*, 556 U.S. at 678. That conclusion is more than plausible on the facts Ms. Williams alleges, including that the FDA—in reliance on terrifying science not previously known to the agency—took quick action to make sure no American would ever be exposed to Zantac's dangers again.

Further, as already noted, *Mensing* and *Bartlett* did *not* include any suggestion that federal law required defendants to stop selling the drugs in question. By

[3] Even taken on its own terms, the district court's reasoning fails because the Supreme Court has looked to *Reigel*, *Bates*, and *Lohr* time and again in its impossibility preemption cases on pharmaceuticals. *See, e.g.*, *Bartlett*, 570 U.S. at 482, 487 & n.4, 492–93 (citing *Riegel* once, *Lohr* once, and *Bates* six times, including when discussing "parallel claims" in footnote 4); *Wyeth*, 555 U.S. at 565, 567, 574, 577, 579, 582, 587 (citing *Riegel* twice, *Lohr* three times in the majority and twice in a concurrence, and *Bates* in the majority and both concurrences).

contrast, Ms. Williams has alleged precisely that, a distinction that *Bartlett* expressly noted was material. Ms. Williams's position on preemption in no way suggests that *Mensing*, *Bartlett*, and the Court's other impossibility preemption cases are wrongly decided. It hardly renders those precedents "meaningless" to allow an alternative theory—uniquely supported by the facts of this case—that *Bartlett* expressly left untouched.

B. Parallel Claims Are Not Enforcement of the FDCA.

The district court took no issue with Ms. Williams's definition of misbranding under the FDCA; and it assumed that she pleaded facts sufficient to show that Zantac was "misbranded." D.E. 2512 at 30. Nonetheless, the court ruled that the federal misbranding statute was "of no matter" because only the United States, not a private plaintiff, can enforce it. D.E. 2512 at 28; *see also* D.E. 2513 at 31 (same reasoning). That is a truthful irrelevancy. Ms. Williams *agrees* that she cannot enforce the FDCA. And she has never tried to do so. Her complaint contains no claim, in substance or in form, titled "private right of action under the Food, Drug, and Cosmetic Act." She does not even bring a state-law claim—such as negligence *per se*—with an element that incorporates the FDCA. She instead is pursuing a common-law design-defect claim and nothing more. Her cause of action would exist even if the FDCA did not.

The simple reason Ms. Williams *referenced* the FDCA in her pleading was to show that its requirements parallel state law. Demonstrating that state and federal duties are the same—and that it is not impossible to comply with both—does not alter the source of law that creates the cause of action. *Cf. Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 352–53 (2001). Under the district court's reasoning, plaintiffs could never reference federal law, even for background or to show consistency, without somehow seeking to enforce it. That is not, and never has been, the law.

C. Misbranding and Design Defect Law Apply to Retailers.

With respect to Ms. Williams's claim against Walgreens, the lower court decided that claim was preempted because she did not plausibly allege "Defendants knew that the drugs were misbranded." D.E. 2513 at 30. In the first place, if such an allegation were somehow necessary for Ms. Williams to avoid preemption, she should have been given an opportunity to replead it. Beyond that, its premise is simply mistaken. Misbranding under the FDCA has no knowledge requirement. Federal law bars the "introduction or delivery for introduction into interstate commerce of any [] drug . . . that is adulterated or misbranded" as well as the "misbranding" of a drug and the "receipt in interstate commerce of any" "drug . . . that is adulterated or misbranded." 21 U.S.C. § 331(a)–(d). The term "knowing" appears six times in section 331 in other subsections (for example, subsection

331(w), prohibiting "the making of a knowingly false statement" in an importation certification), but does not appear in the misbranding provisions. The penalties provision for misbranding likewise requires knowledge for certain penalties—namely, anything above one year in prison—but not for others. *See* 21 U.S.C. § 333(a).

The Supreme Court has held that no knowledge is required. *See Dotterweich*, 320 U.S. at 284–85.[4] As Justice Frankfurter explained:

> Hardship there doubtless may be under a statute which thus penalizes the transaction though consciousness of wrongdoing be totally wanting. Balancing relative hardships, Congress has preferred to place it upon those who have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless.

Id. at 284–85.

Finally, because the seizure provision is keyed to misbranding, if a drug were not misbranded unless the retailer knew it was, then the FDA would lack authority

[4] Walgreens argued below that the good faith defense in section 331(c) means federal law is not parallel to state law unless state law has a similar good faith defense. Because the district court did not reach this argument, *see* D.E. 2513 at 31, n.11, it cannot explain the court's erroneous ruling on knowledge. In any event, the argument is wrong, since a defense applicable to some *criminal*—but not civil—penalties does not modify the scope of the substantive requirement. And even if it were correct, some states *do* have comparable good faith defenses, so this provision furnishes no reason to dismiss claims in every state without analyzing any state's law.

to seize a retailer's dangerous drugs whenever the retailer lacked knowledge that the drugs were dangerous. *See* 21 U.S.C. § 334(a)(1).

The district court also noted that design defect claims "[b]y definition" can "only be brought against a manufacturer." D.E. 2513 at 30. This could not be more wrong.[5] Design defect claims are commonplace against retailers. *E.g.*, *Vandermark v. Ford Motor Co.*, 391 P.2d 168, 171–72 (Cal. 1964) ("[T]he retailer may be the only member of that enterprise reasonably available to the injured plaintiff. . . . Strict liability on the manufacturer and retailer alike affords maximum protection to the injured plaintiff and works no injustice to the defendants, for they can adjust the costs of such protection between them . . . ."). The widely accepted Second Restatement strict-liability provision draws no distinction among defendants because the theory of strict liability is liability without fault. *See generally* Restatement (Second) of Torts § 402A (Am. Law Inst. 1965). Some states have enacted statutes that provide immunity for "innocent sellers," but the district court could not have been relying on such state-law grounds, since it denied as moot the motions to dismiss dedicated to these statutes. D.E. 2513 at 45. In any event, the existence of an affirmative defense would not show design defects are unavailable "by definition," and would require a defendant to demonstrate each element of the

[5] Even if it were right, the "definition" of design defects would be a matter of each state's law, not a reason to *preempt* claims in every state.

defense—including, in many states, showing who the manufacturer was, that the court has jurisdiction over it, and that it is solvent.[6]

* * *

It is virtually automatic in today's litigation. A plaintiff injured by a dangerous drug seeks a remedy under the duly recognized laws of his or her State. The drug companies try to avoid any potential liability by claiming preemption. Those preemption arguments can sometimes be difficult to resolve. But not so here. Modern doctrine, originalist meaning, and common sense all say the same thing: where state and federal law do not conflict, there is no preemption, and the laws of the States deserve full respect. Here, far from conflicting, state and federal law required the same thing: for Defendants to stop selling their unreasonably dangerous drug. The Supremacy Clause is no barrier to Ms. Williams's effort to hold Defendants accountable for the cancer their Zantac caused her.

CONCLUSION

For the foregoing reasons, the district court's dismissal below should be reversed, and the case remanded for further proceedings.

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[6] Each of these prongs matters. It may be easy for a plaintiff to prove purchases from Walgreens, but hard to show which manufacturer made the pills without records Walgreens provides. Foreign entities in the MDL have already disputed personal jurisdiction. And, as the plaintiffs from the Round-Up or opioids MDLs could attest, insolvency is a risk for even the largest manufacturers.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 10,181 words, excluding the parts exempted by Fed. R. App. P. 32(f).

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Dated: March 29, 2021

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CERTIFICATE OF SERVICE

On March 29, 2021, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Eleventh Circuit by using the CM/ECF system. All participants in this case are registered CM/ECF users, and service will be accomplished by the CM/ECF system.

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