No. 25-

IN THE

Supreme Court of the United States

WELLS PHARMA OF HOUSTON, L.L.C.,

Petitioner,

v.

ZYLA LIFE SCIENCES, L.L.C.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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September 2, 2025

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QUESTION PRESENTED

The Federal Food, Drug, and Cosmetic Act ("FDCA") authorizes manufacturers known as "outsourcing facilities" to market compounded drugs without obtaining premarket approval from the Food and Drug Administration ("FDA") and generally preempts enforcement of the Act's requirements other than by the Federal Government. *See Buckman Co. v. Plaintiff's Legal Committee*, 531 U.S. 341, 352 (2001). In conflict with decisions of the First and Ninth Circuits, the decision below by the Fifth Circuit held that state-law claims by private parties to enforce the Act's premarket-approval requirement against outsourcing facilities for marketing compounded drugs are not preempted. Accordingly, the question presented is:

Whether the FDCA preempts private state-law unfair competition and consumer protection claims premised on the marketing of compounded drugs without premarket approval.

PARTIES TO THE PROCEEDING

Petitioner is Wells Pharma of Houston, L.L.C. It was Defendant in the district court and Appellee/Cross-Appellant in the court of appeals. Respondent is Zyla Life Sciences, L.L.C. Respondent was Plaintiff in the district court and Appellant/Cross-Appellee in the court of appeals.

CORPORATE DISCLOSURE STATEMENT

The sole member of Petitioner Wells Pharma of Houston, L.L.C. is LSE, Inc. The sole stockholder of LSE, Inc. is Gary L. Shapiro, an individual.

STATEMENT OF RELATED PROCEEDINGS

Pursuant to this Court's Rule 14.1(b)(iii), the following proceedings are directly related to this case:

- *Zyla Life Sciences, L.L.C. v. Wells Pharma of Houston, L.L.C.*, No. 23-20533 (5th Cir.) (opinion entered Apr. 10, 2025, revised opinion June 5, 2025);

- *Zyla Life Sciences, LLC v. Wells Pharma of Houston, LLC*, No. 22-cv-4400 (S.D. Tex.) (order entered Sept. 27, 2023).

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PETITION FOR WRIT OF CERTIORARI

Wells Pharma of Houston, L.L.C. respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Fifth Circuit in this case.

OPINIONS BELOW

The revised opinion of the Fifth Circuit is published at 134 F.4th 326 (5th Cir. 2025) and is reproduced in the appendix to this petition at App. 1a–25a. The district court's order on Petitioner's motion to dismiss is unpublished but available at 2023 WL 6301651 and App. 53a–65a.

JURISDICTION

The Fifth Circuit issued its original opinion and judgment on April 10, 2025. The Fifth Circuit denied rehearing *en banc* and issued a revised opinion on June 5, 2025. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

Food, Drug, and Cosmetic Act, 21 U.S.C. § 337(a) provides: "Except as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States."

This provision, and the other pertinent statutory provisions, 21 U.S.C. § 353a and 21 U.S.C. § 353b, are reproduced in the appendix. App. 142a–166a.

INTRODUCTION

This case presents a direct, entrenched, and outcome-determinative conflict among the federal courts of appeals on a single question of national importance in the pharmaceutical industry: Whether the Food, Drug, and Cosmetic Act ("FDCA") impliedly preempts or otherwise bars private state-law unfair competition and consumer protection claims against compounding pharmaceutical companies when those claims are premised on alleged FDCA violations and would "add to" the FDCA's requirements for compounded drugs.

Over the past several years, as compounded drugs have become more ubiquitous, major drug companies have launched a litigation campaign against compounding pharmaceutical companies in federal courts around the country. Here, Respondent Zyla Life Sciences, L.L.C. ("Zyla") sued its competitor Petitioner Wells Pharma of Houston, L.L.C. ("Wells Pharma"), seeking to enjoin the sale of Wells Pharma's compounded indomethacin drug on the theory that it lacked FDA premarket approval. But because the FDCA does not permit private rights of action, Zyla sued under the unfair competition and consumer protection laws of six states, "all of which have [separate] statutes requiring premarket FDA approval." *Zyla Life Scis., LLC v. Wells Pharma of Hou., LLC*, No. 4:22-cv-4400, 2023 WL 6301651, at *2 (S.D. Tex. Sept. 27, 2023). The district court dismissed Zyla's claims as preempted by federal law.

In the decision below, the Fifth Circuit disregarded its own prior precedent and reversed the district court, creating a circuit split with the Ninth and First Circuits.

The Fifth Circuit broadened the issue beyond the FDCA context, holding that state-law claims *never* trigger implied obstacles-and-purposes preemption when state law merely "incorporates federal law," even if those claims intrude on the FDA's exclusive enforcement authority or alter the federal requirements. *Zyla Life Scis., L.L.C. v. Wells Pharma of Hou., L.L.C.*, 134 F.4th 326, 328, 338–39 (5th Cir. 2025). The panel principally relied on *California v. Zook*, 336 U.S. 725 (1949), an inapposite 75-year-old criminal case, to resolve this civil matter. But the issue here is not whether "parallel standards" can exist under both federal and state law. It is whether Zyla's state-law claims—which exist solely by virtue of the federal regulatory scheme and unquestionably add to the FDCA's requirements for compounded drugs—impinge on the Federal Government's exclusive enforcement authority. Because they do, Zyla's claims are preempted and the Fifth Circuit's judgment should be reversed.

As the Ninth Circuit, the First Circuit, and the district court below all recognized, these types of state-law claims fail for two related reasons.

First, Congress gave a clear directive in the FDCA that only the Federal Government may bring "proceedings for the enforcement, or to restrain violations, of [the FDCA]." 21 U.S.C. § 337(a). This Court in *Buckman Co. v. Plaintiff's Legal Committee*, 531 U.S. 341, 349 n.4 (2001), unanimously held that this provision "leaves no doubt" that Congress intended to bar private suits to enforce compliance with the FDCA. As this Court explained, state-law claims are "impliedly preempted" when they "exert an extraneous pull on the scheme established by Congress." *Id.* at 353. Because the state "fraud claims"

in *Buckman* "exist[ed] solely by virtue of the FDCA," they "would exert an extraneous pull on the" FDCA and were thus preempted. *Id.* at 352–53. Without the alleged FDCA violation, the plaintiff in *Buckman* would have had no claim.

In *Nexus Pharmaceuticals, Inc. v. Central Admixture Pharmacy Services, Inc.*, 48 F.4th 1040 (9th Cir. 2022), the Ninth Circuit affirmed dismissal of private state-law claims virtually identical to those asserted by Zyla here. The Ninth Circuit held that "private enforcement of the FDCA statute is barred" and applied *Buckman*'s "implied preemption" doctrine to state-law claims against compounding pharmaceutical companies when those claims "exist[] solely by virtue of the FDCA." *Nexus*, 48 F.4th at 1047–50 (citation modified). Similarly, in a different factual context, the First Circuit held that "state law claims [that] exist solely by virtue of an FDCA infraction . . . are impliedly preempted." *DiCroce v. McNeil Nutritionals, LLC*, 82 F.4th 35, 41 (1st Cir. 2023) (citation modified) (relying on *Buckman*).

Second, Section 503B of the FDCA provides that the premarket approval requirements of Section 505 "shall not apply to a drug compounded by or under the direct supervision of a licensed pharmacist in a facility that elects to register as an outsourcing facility." 21 U.S.C. § 353b(a). In other words, compounded drugs are not subject to premarket approval under federal law. As the district court below correctly held, state-law claims premised on the lack of premarket approval for compounded drugs are also preempted because such claims would "add to" the federal requirements for compounded drugs. *Zyla Life*

Scis., 2023 WL 6301651, at *4–5 & n.4 (citing *Nexus*, 48 F.4th at 1042).

Resolution of this circuit split turns primarily on whether *Buckman* applies. The First and Ninth Circuits applied *Buckman* to conclude that these types of state-law claims premised on FDCA violations are impliedly preempted and barred. *See Nexus*, 48 F.4th at 1046 (applying *Buckman* because the plaintiff "relies on a state statute which itself relies on the federal statute, not traditional state tort law theory"); *DiCroce*, 82 F.4th at 42 (applying *Buckman* because "Congress tasked the FDA with addressing said violations when it enacted § 337(a), not private citizens"). The Fifth Circuit, by contrast, held that *Buckman* does not apply to Zyla's state-law claims because they purportedly "parallel" or "mirror" the FDCA. *Zyla Life Scis.*, 134 F.4th at 338. But the state laws at issue do not mirror federal law at all; they omit the FDCA's compounding exceptions that federal law expressly provides.

The Fifth Circuit's misguided decision creates a circuit split and threatens the Federal Government's exclusive enforcement authority under the FDCA, imposes additional requirements on compounding pharmacies beyond those mandated by federal law, and exposes them to private lawsuits—even when the FDA, after inspection, finds no basis for enforcement. The result is a fragmented regulatory landscape in which the legality of pharmaceutical compounding—a practice permitted by Congress under carefully crafted exemptions—varies by geography and can be challenged by private state-law claims within the Fifth Circuit, but not within the Ninth Circuit or the First Circuit.

If upheld, Zyla's theory would have sweeping consequences in this industry. Though framed as a targeted attack on Wells Pharma, the core of Zyla's lawsuit is that selling any drug not approved by the FDA—including all compounded drugs—is illegal in these six states (and any other states that currently have or may in the future enact similar laws). This would effectively end compounding in multiple jurisdictions around the country, as obtaining FDA approval for every patient-specific modification is impractical. Zyla's claims also jeopardize access to life-saving compounded alternatives to FDA-approved drugs. *See* FDA, Human Drug Compounding Progress Report, *infra*, at 6. Further, allowing such claims to proceed would deter compounding pharmacies from stepping in when there is a shortage of FDA-approved drugs, meaning that major drug companies could continue to restrict supply and inflate prices without the moderating influence of compounded drugs. All of these outcomes would frustrate congressional intent, undermine FDA enforcement discretion, and conflict with the policies of the very states whose laws Zyla invokes—all of which expressly permit compounding. *See* Cal. Code Regs. Tit. 16, § 1735.2; Fla. Stat. § 465.0158; Tenn. Code § 63-10-216; S.C. Code § 40-43-86(CC)(1)–(10); Conn. Gen. Stat. § 20-633b; Colo. Rev. Stat. § 12-280-120.

Only this Court can resolve the conflict between the circuits and restore uniformity to the regulation of pharmaceutical compounding under the federal government's exclusive enforcement authority established by Congress.

STATEMENT OF THE CASE

A. Statutory Background

The compounded pharmaceutical at issue—indomethacin suppositories—contain indomethacin, an anti-inflammatory drug used to treat rheumatoid arthritis and other ailments. *See generally* B. Joseph Elmunzer, et al., *The Skyrocketing Cost of Rectal Indomethacin*, 180 JAMA Internal Med. 631 (2020). Normally, Section 505(a) of the FDCA requires manufacturers to receive premarket approval by the FDA before marketing drugs. 21 U.S.C. § 355(a). But Congress specifically exempted compounded drug mixtures from Section 505(a)'s requirements because pharmacists "have long combined, mixed, and altered ingredients in medicines to tailor them to individual patients." *Nexus*, 48 F.4th at 1042. Congress and the FDA thus exempt compounded drugs from onerous premarket approval requirements given their critical role in addressing individualized patient needs and addressing skyrocketing drug prices and market shortages. *Id.*

Compounding is governed by Sections 503A and 503B of the FDCA, 21 U.S.C. § 353a–b. Congress permits compounding for patients "who cannot be treated with an FDA-approved medication." FDA, Human Drug Compounding Progress Report, at 4 (2017), https://www.fda.gov/media/102493/download. The types of patients who require compounded alternatives include "a patient who has an allergy and needs a medication to be made without a certain dye, or an elderly patient or a child who cannot swallow a tablet or capsule and needs a medicine in a liquid dosage form that is not otherwise available." *Id.* Case-by-case compounding in these situations "serve[s]

an important patient need." *Id.* Additionally, compounding copies of FDA-approved medications is also permitted when the FDA determines that there is a shortage of such medications. 21 U.S.C. § 353b(d)(2)(A).

To ensure safety in the compounding practice, Congress enacted two major amendments to the FDCA in 1997 and 2013. *See Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 362–63 (2002). First, the Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (1997), codified aspects of the FDA's policy permitting compounding without premarket approval. *Id.* at 362. Second, the Drug Quality and Security Act, Pub. L. No. 113-54, 21 U.S.C. § 353b (2013), added Section 503B to the FDCA and reaffirmed the exemption for compounded drugs. Section 503B created a new category of drug maker—"outsourcing facilities"—which remain exempt from premarket approval. 21 U.S.C. § 353b(a).

Wells Pharma is a registered 503B outsourcing facility that compounds drugs under the FDA's comprehensive Section 503B regulations. Outsourcing facilities like Wells Pharma are subject to rigorous FDA oversight. 21 U.S.C. § 353b(b); FDA, *Guidance, Compliance, & Regulatory Information: Human Drug Compounding* (May 15, 2025), https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding; FDA, *Guidance, Compliance, & Regulatory Information: Information for Outsourcing Facilities* (Mar. 29, 2022), https://www.fda.gov/drugs/human-drug-compounding/information-outsourcing-facilities. Approved outsourcing facilities like Wells Pharma must register with the FDA, report the drugs they compound, comply with labeling

and packaging requirements, report adverse events, and submit to FDA inspections. *See* 21 U.S.C. § 353b.

B. Zyla Sued Wells Pharma Under State Law for Violating Federal Law

In 1992, Zyla obtained FDA approval to market Indocin® Suppositories via an Abbreviated New Drug Application. When this action was filed, Zyla was the sole supplier of an FDA-approved indomethacin suppository in the United States. Wells Pharma, an FDA-registered 503B outsourcing facility, compounds its indomethacin suppository product subject to FDA's oversight under section 503B of the FDCA. The dosage of Wells Pharma's compounded drug is different from Zyla's drug, and it contains different excipients and is allergen free to address unique patient needs.

Zyla did not directly challenge Wells Pharma's ability to sell compounded drugs as an outsourcing facility under federal law. Instead, it repackaged its claims under the "consumer protection" and "unfair competition" laws of six states. Specifically, Zyla alleged that Wells Pharma's sale of its compounded indomethacin drug without FDA premarket approval—despite such approval not being required under federal law—violated California, Colorado, Connecticut, Florida, South Carolina, and Tennessee law. Through legislation that was in almost all instances enacted *before* Congress added the compounding exemptions to the FDCA, each state purports to prohibit the sale of drugs that are not preapproved by the FDA:

California: "No person shall sell, deliver, or give away any new drug or new device unless it . . . has been approved for it and that approval has not been withdrawn, terminated, or suspended under Section 505 of the federal act (21 U.S.C. Sec. 355)." Cal. Health & Safety Code § 111550(a) (language last amended in 1995); *see also* Compl. at ¶¶ 31, 34, 55; App. 80a–86a.

Colorado: "No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug not authorized to move in interstate commerce under appropriate federal law." Colo. Rev. Stat. § 12-280-131 (language last amended in 1986); *see also* Compl. at ¶¶ 8, 13, 30, 35, 42, 60; App. 72a–87a.

Florida: "A person may not sell, offer for sale, hold for sale, manufacture, repackage, distribute, or give away any new drug unless an approved application has become effective under s. 505 of the federal act [21 U.S.C. § 355]." Fla. Stat. § 499.023 (last amended in 1982); *see also* Compl. at ¶¶ 9, 13, 30, 36, 42, 70; App. 72a–89a.

Tennessee: "No person shall sell, deliver, offer for sale, hold for sale or give away any new drug unless an application with respect to the drug has become effective under § 505 of the federal act." Tenn. Code Ann. § 53-1-110 (last amended in 1986); *see also* Compl. at ¶¶ 10, 13, 30, 38, 42, 79; App. 72a–91a.

> South Carolina: "No person shall introduce or deliver for introduction into intrastate commerce any new drug unless an application filed pursuant to subsection (b) is effective with respect to such drug, or an application with respect thereto has been approved and such approval has not been withdrawn under Section 505 of the Federal act." S.C. Code Ann. § 39-23-70(a) (last amended in 1976); *see also* Compl. at ¶¶ 11, 13, 30, 39, 42, 85; App. 72a–92a.
>
> Connecticut: "No person shall sell, deliver, offer for sale, hold for sale or give away any new drug unless (1) an application with respect thereto has been approved under Section 355 of the federal act[the premarket approval requirement]." Conn. Gen. Stat. § 21a-110 (last amended in 1963); *see also* Compl. at ¶¶ 12, 13, 30, 40, 42, 93; App. 73a–94a.

Zyla argued that Wells Pharma's compounded indomethacin suppository is illegal under these state laws because it lacks FDA premarket approval. Zyla's state-law consumer protection and unfair trade practice claims thus exist solely because of the FDCA's requirements.

C. The District Court Dismissed Zyla's Claims

The district court rejected Zyla's thinly-veiled attempt to elevate monopolistic pricing over public health. It dismissed Zyla's claims, finding that the six state-law causes of action were entirely dependent on "alleged noncompliance by FDA-regulated compounding facilities," and thus impliedly preempted. *Zyla Life Scis.*, 2023 WL 6301651, at *4-5 (citing *Nexus*, 48 F.4th at 1042).

The district court further held that Zyla's claims "add to" or "impinge" on the FDA's exclusive authority by imposing requirements beyond those in the FDCA. Zyla's claims are preempted because they impose obligations beyond federal requirements—specifically, that drugs be preapproved "regardless of whether they are produced by compounding facilities." *Id.*

D. The Fifth Circuit Reversed the District Court

The Fifth Circuit reversed, holding that state-law claims are not preempted if the state law "incorporates" federal law—even if those claims intrude on the FDA's exclusive enforcement authority or add to federal requirements. *Zyla Life Scis.*, 134 F.4th at 331. The panel reasoned that because the state statutes purportedly mirror federal law, there is "no conflict in terms, and no possibility of such conflict." *Id.* at 328 (quoting *California v. Zook*, 336 U.S. 725, 735 (1949)). According to the Fifth Circuit, implied preemption under *Buckman* did not apply because the state-law claims there "involved a uniquely federal area of regulation, since it alleged only fraud on a federal agency," not "state law mirroring federal requirements." *Id.* at 337 (citation modified).

Despite extensive briefing, the Fifth Circuit did not mention the First Circuit's opposite holding in *DiCroce* and only references once in passing the Ninth Circuit's contrary holding in *Nexus*, without substantively engaging with it. In a footnote, the Fifth Circuit also effectively ignored the district court's additional ruling that Zyla's state-law claims are preempted because they "add to" and contradict the federal regulatory scheme governing compounding pharmacies by dropping the FDCA's

exceptions to premarket approval for compounding pharmacies. *Zyla Life Scis.*, 134 F.4th at 331 n.2.

As it stands, the Fifth Circuit now permits drug companies to sue competitor compounders under state law for failing to obtain FDA approval of specific compounded drugs—approval that federal law does not require. In doing so, it creates a direct conflict with the Ninth Circuit's decision in *Nexus*, which instead applied this Court's decision in *Buckman* to hold that state-law claims against compounding pharmacies for failing to obtain FDA approval are impliedly preempted: "The purported state law violation is of a law that says in substance 'comply with the FDCA,' not a traditional common law tort." *Nexus*, 48 F.4th. at 1050. The First Circuit echoed this in *DiCroce*, also following *Buckman* to hold that "state law claims—for unfair or deceptive trade practices, false advertising, and unjust enrichment . . . are impliedly preempted" because they "exist solely by virtue of an FDCA infraction." *DiCroce*, 82 F.4th at 41 (citation modified).

Thus, in this context, the Fifth Circuit has adopted a position that directly conflicts with the approach taken by the Ninth and First Circuits in applying *Buckman*.

REASONS FOR GRANTING THE PETITION

This petition presents a defined circuit split that implicates the survival of the pharmaceutical compounding industry and Congress's clear intent that only the Federal Government may regulate this industry by enforcing the FDCA. It is difficult to imagine a more compelling issue of national concern for this Court's review.

A. The Decision Below Conflicts with Decisions of the First and Ninth Circuits

This case offers a clean, outcome-determinative, and fully developed vehicle to resolve conflicting decisions from the federal courts of appeals on a question of exceptional national importance in the pharmaceutical industry: whether the FDCA impliedly preempts or otherwise bars private enforcement actions disguised as state unfair competition or consumer protection claims against FDA-registered compounding pharmacies for failing to obtain premarket FDA approval for their compounded drugs.

The Fifth Circuit's decision directly conflicts with the Ninth Circuit's approach on nearly identical facts. This divergence creates a fractured legal landscape in which the legality of pharmaceutical compounding—a practice expressly permitted by Congress under carefully crafted exemptions supervised by the FDA—depends on geography. In the Fifth Circuit, compounding pharmacies face private lawsuits under state law for conduct that is lawful under federal law and explicitly authorized by the FDA. In the Ninth Circuit (and presumably the First Circuit), these same state-law actions are impliedly preempted by the FDCA, shielding compounding pharmacies from private enforcement based on alleged FDCA violations.

As the Ninth Circuit explained in *Nexus*, the FDCA "includes a prohibition on private enforcement: all proceedings to enforce or restrain violations of the FDCA must be 'by and in the name of the United States,' except for certain proceedings by state governments." 48 F.4th at 1044 (quoting 21 U.S.C. § 337(a)). To circumvent this

prohibition, the plaintiff in *Nexus* sued its compounding competitor under state laws, "all of which 'prohibit the sale of drugs not approved by the FDA.'" *Id.* But because the claims "exist only because of the FDCA's requirements," the Ninth Circuit held they "are preempted" by the FDCA's express bar on private enforcement. *Id.* at 1044, 1046.

The Ninth Circuit's analysis was grounded on this Court's decision in *Buckman*, which held that state-law claims are "impliedly pre-empted" when they "exert an extraneous pull on the scheme established by Congress." 531 U.S. at 353. Because "the existence of" the FDCA was "a critical element" in the plaintiff's state-law claims, this Court concluded that such claims—though styled as parallel to federal safety requirements—were preempted. *Id.* ("[A]lthough *Medtronic* can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim.").

The Ninth Circuit applied *Buckman* to the same claims presented here. *Nexus* held that the plaintiff's claims were preempted because they "relie[d] on a state statute which itself relies on the federal statute, not traditional state tort law theory." *Nexus*, 48 F.4th at 1046. Traditional tort claims, by contrast, would not be preempted if they did "not rely on noncompliance with FDA requirements." *Id.* But under *Buckman*, "implied preemption" applies when state law "incorporate[s] federal law," distinguishing it from "traditional tort law." *Id.* at 1047.

This holding cannot be reconciled with the Fifth Circuit's opinion. The Fifth Circuit held that state-law claims are not preempted so long as the state "incorporates federal law," even if those claims intrude on the FDA's exclusive enforcement authority or add to federal requirements. *Zyla Life Scis.*, 134 F.4th at 338–39. The panel reasoned that "there is 'no conflict in terms, and no possibility of such conflict, for the state statute makes federal law its own.'" *Id.* at 328 (quoting *Zook*, 336 U.S. at 735). It further held that *Buckman* did not apply because the claims there "involved a uniquely federal area of regulation, since it alleged only fraud on a federal agency," not "state law mirroring federal requirements." *Id.* at 337 (citation modified). This stands in direct contrast to the Ninth Circuit, which warned that private enforcement against compounding pharmacies under state law "beyond what the FDA has deemed appropriate . . . may indeed 'stand as an obstacle' to FDA's enforcement discretion by enabling what the FDA regards as over-enforcement." *Nexus*, 48 F.4th at 1048.[1]

1. In support of its arguments to the Fifth Circuit, Zyla relied on the Federal Circuit's decision in *Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350, 1355–56 (Fed. Cir. 2013) (holding claims were not impliedly preempted because California law "parallel[s] the FDCA, such that the statutes have consistent goals"). But in *Allergan*, the Federal Circuit was applying Ninth Circuit law, and the Ninth Circuit subsequently made clear that the Federal Circuit had misapplied Ninth Circuit law. *See Nexus*, 48 F.4th at 1049–50 (holding *Allergan* "misinterprets [Ninth Circuit] case law regarding the bar on private enforcement"). Thus, *Allergan* was effectively overruled by *Nexus*. *See In re TS Tech USA Corp.*, 551 F.3d 1315, 1319 (Fed. Cir. 2008) ("[T]his court applies the laws of the regional circuit in which the district court sits[.]").

The First Circuit in *DiCroce* aligned with the Ninth Circuit—albeit on a different fact pattern. The court held that "state law claims—for unfair or deceptive trade practices, false advertising, and unjust enrichment—[that] exist 'solely by virtue' of an FDCA infraction . . . are impliedly preempted" under *Buckman*. *DiCroce*, 82 F.4th at 41 (alteration adopted). The court emphasized that the claims would not exist "if the FDCA did not exist" and were therefore preempted by Congress's grant of exclusive enforcement authority to the FDA. *Id.*

This case presents the preemption question in its purest form, free from factual or procedural complications. The issue has been fully briefed and litigated below. The Fifth, Ninth, and First Circuits have adopted fundamentally different approaches to *Buckman* and implied preemption in substantively similar cases. Further, the question presented is dispositive: if the Fifth Circuit is correct, Zyla's state-law claims may proceed. If the Ninth and First Circuits are correct, each of those claims is impliedly preempted or otherwise barred and must be dismissed. This Court should clarify the proper application of *Buckman* to state-law claims against compounding pharmacies that directly incorporate and are premised on FDCA violations.

B. The Fifth Circuit's Decision Is Wrong

1. The Federal Government's exclusive enforcement authority bars these claims.

The Fifth Circuit's decision is fundamentally incompatible with both the text of the FDCA and this Court's precedent. Section 337(a) provides that "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." As this Court explained in *Buckman*, that provision "amply empowers the FDA" to enforce compliance with the FDCA, reflecting a "delicate balance of statutory objectives" that "can be skewed by allowing . . . claims under state tort law." 531 U.S. at 348. In *Buckman*, the state-law claims "exist[ed] solely by virtue of the FDCA . . . requirements" and "the existence of these federal enactments [was] a critical element in their case." *Id.* at 353. This Court held that such litigation "would exert an extraneous pull on the scheme established by Congress, and it is therefore pre-empted by that scheme." *Id.*

Each of Zyla's state-law claims falls squarely within *Buckman*'s holding because they "exist solely by virtue of" the FDCA. Zyla does not allege that Wells Pharma's compounded drugs are unsafe, defective, or violative of any independent state-law duty. Instead, its claims rest solely on the allegation that Wells Pharma's compounded indomethacin suppositories lack FDA premarket approval—even though such approval is not required under federal law for compounded drugs. The Fifth Circuit's contrary holding—allowing private parties to enforce the FDCA through state-law claims so long as the

state "incorporates" federal law—directly undermines the FDA's exclusive authority. *See Nexus*, 48 F.4th at 1048.

2. Requiring premarket approval of compounded drugs adds to the federal requirements and impermissibly overrules Congress's policy judgment.

Moreover, the Fifth Circuit failed to address how Zyla's claims do not merely "parallel" the FDCA—they "add to" the federal requirements for compounded drugs and overrule Congress's own policy judgment that premarket approval is not required for compounded drugs. State-law claims are preempted if they "would compel [defendant] to comply with requirements different from, or in addition to, those required by the FDA." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 513 (1996) (O'Connor, J., concurring in part and dissenting in part); *see also Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008). As the Court said in *Buckman*, any state-law claim that causes an "extraneous pull on the scheme established by Congress" is preempted. 531 U.S. at 353.

Zyla's claims do exactly that. They demand premarket approval for compounded drugs, even though the FDCA expressly exempts such drugs from that requirement. These claims add to the FDCA's requirements for compounded drugs and threaten to "'stand as an obstacle' to FDA's enforcement discretion by enabling what the FDA regards as over-enforcement." *Nexus*, 48 F.4th at 1048. The Fifth Circuit was therefore wrong when it concluded that Zyla's state-law claims simply "mirror" the FDCA. *Zyla Life Scis.*, 134 F.4th at 330.

Congress enacted the FDCA in 1938. In the decades that followed, a handful of States adopted legislation making it illegal under state law to market drugs that were not preapproved by the FDA. But in 2013, Congress made a policy judgment when it specifically carved out Section 503B outsourcing facilities from having to comply with Section 505's premarket approval requirements. *See* 21 U.S.C. § 353b(a). Each state-law claim asserted in this case is premised on the fact that Wells Pharma—a Section 503B facility—did not receive premarket approval for its compounded indomethacin suppositories. Moreover, the state statutes underlying Zyla's claims require FDA approval yet do not incorporate Section 503B's exemption (likely because those statutes were enacted before Congress added the compounding exceptions to the FDCA). Thus, Zyla's state-law claims do not "mirror" the federal scheme, they in fact cause an "extraneous pull on the scheme established by Congress" by requiring more than what is required by either Congress or the FDA. *Buckman*, 531 U.S. at 351, 353 (holding state-law claims were preempted because regulated entities risked being held liable "in state court" for the very conduct already "deemed appropriate by the Administration" under the FDCA).

While the state statutes at issue may have "paralleled" federal law at one time, that ended in 2013. With the addition of Section 503B, Congress took into account each of the policy considerations described above and exempted Wells Pharma from needing premarket approval before marketing its compounded pharmaceuticals. Zyla seeks to utilize outdated state laws to add to the federal requirements and overrule Congress's policy decision.

3. The Fifth Circuit's reliance on Wyeth and Zook is misplaced.

The Fifth Circuit's reliance on *Wyeth v. Levine*, 555 U.S. 555 (2009), and *California v. Zook*, 336 U.S. 725 (1949), is misplaced and ignores critical distinctions.

In *Wyeth*, the plaintiff brought a traditional negligence claim as an injured patient against a drug manufacturer. 555 U.S. at 559. The claims here, by contrast, are expressly premised on violations and incorporation of federal law—not on a traditional tort such as negligence. The Court in *Wyeth* never addressed whether the FDA's exclusive enforcement authority preempted the state-law claim because the plaintiff there did not allege the negligence was premised on a violation of the FDCA. *See Nexus*, 48 F.4th at 1047–48 (distinguishing *Wyeth*). In contrast, every one of Zyla's claims depends on an alleged FDCA violation.

The Fifth Circuit's reliance on *Zook* is equally flawed. *Zook* was a criminal case brought by a State—not a private competitor—under a state law that did not incorporate but simply mirrored federal law with "substantially the same provision." 336 U.S. at 726–27. And there was no indication that Congress had granted exclusive enforcement authority to the Federal Government. Here, by contrast, the state laws at issue do not truly mirror federal law. Rather, they adopt certain premarket approval aspects of the FDCA but omit the compounding exceptions that are integral to the federal scheme. By dropping those exceptions, the state laws add to the FDCA's requirements and directly contradict the federal framework. Moreover, there is an express statutory bar in this case against private enforcement actions.

Neither *Wyeth* nor *Zook* supports the Fifth Circuit's approach. *Wyeth* involved traditional tort claims brought by injured patients—not private enforcement of the FDCA by competitors. *Zook* addressed a different context entirely and did not involve the FDA's exclusive enforcement authority. If left to stand, the Fifth Circuit's decision would "permit [private plaintiffs] to assume enforcement power which the statute does not allow and require the finder of fact to make a decision that the FDA itself did not make." *Nexus*, 48 F.4th at 1049 (citation omitted).

C. The Answer to this Recurring Question is Critically Important to the Pharmaceutical Compounding Industry and to Public Health

If left undisturbed, the Fifth Circuit's decision would have sweeping and potentially devastating consequences—not only for the FDA's regulatory authority, but also for the continued viability of the pharmaceutical compounding industry and the health of millions of patients who rely on compounded medications.

Congress had sound reasons for granting the Federal Government exclusive discretion to enforce the FDCA in 21 U.S.C. § 337(a). And the FDA regularly exercises its enforcement discretion in the compounding space to meet public needs through updated "registration with the FDA, yearly reporting, and regular inspection." *See Nexus*, 48 F.4th at 1043–44 (detailing the FDA's regular enforcement and oversight of 21 U.S.C. § 353b). As this Court recognized in *Buckman*, the FDCA's enforcement provision "leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file

suit for noncompliance with the [FDCA]." 531 U.S. at 349 n.4.[2] The Ninth Circuit echoed this in *Nexus*, explaining that "[t]he statutory prohibition on private enforcement gives the FDA discretion to temper enforcement or not to enforce in circumstances it deems appropriate." 48 F.4th at 1048. State-law claims "may indeed 'stand as an obstacle' to FDA's enforcement discretion" if they seek to "facilitate[] enforcement beyond what the FDA has deemed appropriate." *Id.*

Such over-enforcement would undermine the very purpose of Congress's exemption for compounding pharmacies under Section 503B. The Fifth Circuit's decision invites private competitors to weaponize state-law actions to enforce the FDCA—even where the FDA has inspected an "outsourcing facility" and found no basis for enforcement. As the Ninth Circuit warned, allowing plaintiffs to proceed with claims that the FDA itself declined to pursue "would, in effect, permit [plaintiffs] to assume enforcement power which the statute does not allow and require the finder of fact to make a decision that the FDA itself did not make." *Id.* at 1049 (citation omitted).

The decision below also threatens to impose a de facto ban on compounding by forcing manufacturers to comply with additional requirements—requirements that exceed those imposed by Congress and the FDA. Federal law explicitly authorizes compounding pharmacies to market

2. For example, the Fifth Circuit's decision would allow private litigants (and district courts) to determine compliance with subjective elements of Section 503B of the FDCA, including whether a compounded drug is "essentially a copy of one or more approved drugs," notwithstanding the FDA's exclusive authority to make such determinations. 21 U.S.C. § 353b.

and sell drugs without undergoing the FDA's premarket approval process. *See* 21 U.S.C. § 353b. Yet the Fifth Circuit's ruling nullifies that authorization by "add[ing] to the federal requirements under the FDCA—which does not require compounding facilities to acquire premarket approval." *Zyla Life Scis.*, 2023 WL 6301651, at *4. As *Nexus* emphasized, Congress gave the FDA "exclusive authority to enforce violations of the [FDCA]" precisely to avoid this kind of fragmented enforcement. *Nexus*, 48 F.4th at 1041.

Most troubling, the Fifth Circuit's decision exposes compounding pharmacies—even those that have passed FDA inspections—to harassing private lawsuits by competitors seeking to entrench monopolies by usurping the authority of the Legislative and Executive Branches. *Cf. Dep't of Transp. v. Ass'n of Am. R.R.s*, 575 U.S. 43, 62 (2015) (Alito, J., concurring) ("Private entities are not vested with 'legislative Powers.' Art. I, § 1. Nor are they vested with the 'executive Power,' Art. II, § 1, cl. 1, which belongs to the President."). Zyla did not sue to improve drug safety or protect patients—those are adequately protected by the FDA's enforcement of the FDCA. Rather, Zyla sued to block Wells Pharma from selling a lower-cost alternative to Zyla's indomethacin suppositories—so Zyla could avoid having to "refrain from raising its prices." *See* Compl. at ¶¶ 46–47, App. 83a–84a. Zyla's attack on Wells Pharma for allegedly failing to meet a federal requirement from which it is legally exempt is a transparent attempt to gain monopoly power as the only supplier of indomethacin suppositories. Compl. at ¶¶ 28, 46–47, App. 79a–84a.

This is not a hypothetical concern. As the Sixth Circuit has explained, the FDCA's "public enforcement

mechanism is thwarted if savvy plaintiffs can label as arising under a state law for which there exists a private enforcement mechanism a claim that in substance seeks to enforce the FDCA." *Loreto v. Procter & Gamble Co.*, 515 F. App'x 576, 579 (6th Cir. 2013). So under *Buckman*'s implied preemption doctrine, "private litigants may not bring a state-law claim against a defendant when the state-law claim is in substance (even if not in form) a claim for violating the FDCA." *Id.* (internal quotations and citation omitted). This risk is especially acute for compounding pharmacies, which may be targeted by larger competitors seeking to hijack the FDA's enforcement authority for their own economic gain.

If allowed to stand, the Fifth Circuit's decision threatens the very existence of the compounding industry. Zyla's legal theory—that the sale of any drug not approved by the FDA is illegal under state law—would effectively end compounding in multiple jurisdictions across the country. It is patently impractical for compounders to seek FDA approval every time a drug must be tailored to a patient's unique needs. Congress carved out compounding pharmacies from the FDCA's premarket approval requirements for this very reason. "[C]ompounding has traditionally been seen as an appropriate means of customizing existing drugs to the needs of individual patients." *Nexus*, 48 F.4th at 1042. The FDA permits compounding for patients "who cannot be treated with an FDA-approved medication, such as a patient who has an allergy and needs a medication to be made without a certain dye, or an elderly patient or a child who cannot swallow a tablet or capsule and needs a medicine in a liquid dosage form that is not otherwise available." FDA, Human Drug Compounding Progress Report, *supra*, at

4. And the FDA continues to exercise robust oversight of compounding pharmacies to ensure patient safety. 21 U.S.C. § 353b(b); FDA, *Guidance, Compliance, & Regulatory Information: Human Drug Compounding*, *supra*; FDA, *Guidance, Compliance, & Regulatory Information: Information for Outsourcing Facilities*, *supra*. This is not a case where the Federal Government is absent and the States must fill the void.

This Court's intervention is needed to resolve the entrenched circuit split, reaffirm the FDA's exclusive enforcement authority under the FDCA as granted by Congress, and prevent the destabilizing consequences for the pharmaceutical compounding industry and the millions of patients who depend on it that will result from the Fifth Circuit's misguided ruling.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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September 2, 2025

APPENDIX

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APPENDIX A — REVISED OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT, DATED JUNE 5, 2025

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

No. 23-20533

ZYLA LIFE SCIENCES, L.L.C.,

Plaintiff—Appellant/Cross-Appellee,

versus

WELLS PHARMA OF HOUSTON, L.L.C.,

Defendant—Appellee/Cross-Appellant.

Filed June 5, 2025

Appeal from the United States District Court
for the Southern District of Texas
USDC No. 4:22-CV-4400

Before Ho, Duncan, and Oldham, *Circuit Judges.*

Andrew S. Oldham, *Circuit Judge*:

The question presented is whether a State triggers implied obstacles-and-purposes preemption when it expressly incorporates federal law into state law. The district court held yes. But as the Supreme Court held almost a century ago, "there is no conflict in terms, and

no possibility of such conflict, for the state statute makes federal law its own." *California v. Zook*, 336 U.S. 725, 735, 69 S. Ct. 841, 93 L. Ed. 1005 (1949). Therefore, we reverse.

I

A

1

All preemption has a constitutional source: the Supremacy Clause. *See Philadelphia v. New Jersey*, 430 U.S. 141, 142, 97 S. Ct. 987, 51 L. Ed. 2d 224 (1977) (per curiam). In "our federal system, the States possess sovereignty concurrent with that of the Federal Government, subject only to limitations imposed by the Supremacy Clause." *Tafflin v. Levitt*, 493 U.S. 455, 458, 110 S. Ct. 792, 107 L. Ed. 2d 887 (1990). Under the Supremacy Clause, any state law that contradicts federal law is preempted. *See* U.S. Const. art. VI, cl. 2. But barring any contradiction, the States retain their sovereign prerogatives to regulate.

Supreme Court precedent establishes a preemption taxonomy. The first division is between express and implied preemption. *Kansas v. Garcia*, 589 U.S. 191, 202–03, 140 S. Ct. 791, 206 L. Ed. 2d 146 (2020). Implied preemption is further divided into two types: field preemption and conflict preemption. *Id.* at 208–211. Conflict preemption is then divided into two more types. The first is impossibility preemption. It arises when it is impossible to obey both state and federal requirements. *See Fla. Lime & Avocado*

Growers, Inc. v. Paul, 373 U.S. 132, 142–43, 83 S. Ct. 1210, 10 L. Ed. 2d 248 (1963). The second is obstacles-and-purposes preemption (the only type of preemption at issue here). It arises when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67, 61 S. Ct. 399, 85 L. Ed. 581 (1941). In all these types of preemption, however, "[e]vidence of pre-emptive purpose [must be] sought in the text and structure of the [federal provision] at issue." *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664, 113 S. Ct. 1732, 123 L. Ed. 2d 387 (1993).

2

The federal provisions at issue here come from the Federal Food, Drug, and Cosmetic Act ("FDCA"). On June 25, 1938, President Franklin Delano Roosevelt signed the FDCA into law. *See* Pub. L. No. 75-717, 52 Stat. 1040 (codified as amended at 21 U.S.C. § 301 *et seq.*). The New Dealers who drafted the FDCA did not start from scratch, though. They responded to perceived weaknesses in the Pure Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (repealed 1938), which was signed by Roosevelt's fifth cousin by blood and uncle by law, President Theodore Roosevelt.

The weaknesses with the 1906 Act were brought into the American consciousness by Arthur Kallet and F.J. Schlink's 1933 bestseller, *100,000,000 Guinea Pigs: Dangers in Everyday Foods, Drugs, and Cosmetics. See* David F. Cavers, *The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and Its Substantive*

Provisions, 6 LAW & CONTEMP. PROBS. 2, 5–6 (1939). Kallet and Schlink warned that the American people had been "forced into the role of laboratory guinea pigs" by "the food and drug industries," which had "been making profits by experimenting on [Americans] with poisons, irritants, harmful chemical preservatives, and dangerous drugs." ARTHUR KALLET & F.J. SCHLINK, 100,000,000 GUINEA PIGS: DANGERS IN EVERYDAY FOODS, DRUGS, AND COSMETICS 4 (1933). Kallet and Schlink told the stories of men like "William J. A. Bailey, an ex-auto-swindler," who made his "money by dissolving radium salts in water and selling" the resultant concoction "to rich men to cure their ills." *Id.* at 4–5. To the horror of Kallet and Schlink's readers, "Bailey's radium water" had "sent at least two men to horrible deaths." *Id.* at 5. More horrifying still was Kallet and Schlink's premonition that "a similar fate may be awaiting scores or hundreds of others who drank this deadly fluid." *Ibid.*

The centerpiece of the new FDCA was § 505. *See* Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1761 (1996). Although that provision "was not among the reforms originally sought by the [FDCA's] architects," *ibid.*, it became the focal point of the new FDCA after nearly a hundred Americans died of poisoning from the "Elixir Sulfanilamide" drug sold by the S. E. Massengill Company, *see* Cavers, *supra*, at 20. In response to this tragedy, Congress determined that the Federal Government should act to prevent such incidents from occurring in the first place, rather than merely "respond[] to evidence of harm" after it had occurred. Merrill, *supra*,

at 1761. So Congress decided to forbid manufacturers from marketing drugs "without first notifying [the] FDA and allowing it time to assess their safety." *Id.* at 1762. After further amendments in 1962, Congress converted this "premarket *notification* system" into today's "premarket *approval* system." *Id.* at 1764–65 (emphasis added). Under today's system, no one may sell "any new drug" without prior approval from the FDA. *See* 21 U.S.C. § 355(a).

Ever since the FDCA's enactment in 1938, Congress has given the Federal Government power to enforce its substantive provisions. *See* 52 Stat. at 1046. Today, those enforcement provisions are codified at 21 U.S.C. § 337. Subsection (a) authorizes the United States to bring "all . . . proceedings for the enforcement, or to restrain violations," of the FDCA. And subsection (b) permits States to bring actions to enforce certain provisions of the FDCA.

Originally, the FDCA did not regulate all aspects of drug safety: As relevant here, it left alone the ancient art of compounding. *See Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 362, 122 S. Ct. 1497, 152 L. Ed. 2d 563 (2002); *see also* JUDITH E. THOMPSON, A PRACTICAL GUIDE TO CONTEMPORARY PHARMACY PRACTICE 141 (3d ed. 2009) (discussing compounding's ancient roots). Compounding fell outside the FDCA's premarket approval scheme for new drugs. Compounders, after all, do not make *new* drugs; they merely "combine[], mix[], and alter[]" the "ingredients in" old drugs. *Nexus Pharms., Inc. v. Cent. Admixture Pharmacy Servs.*, 48 F.4th 1040, 1042 (9th Cir. 2022). The goal of compounding is to provide

"medication tailored to the needs of an individual patient." *Thompson*, 535 U.S. at 360–61. For example, some infants and children might need a certain medication, but the commercially available forms of the medication provide too high a dosage. THOMPSON, *supra*, at 142. Other patients might be allergic to some ingredient in the commercially available forms. *Ibid.* That's where compounding comes in. Under the original FDCA, and for roughly a half-century thereafter, compounding regulation was "generally left . . . to the States." *Thompson*, 535 U.S. at 362.

Eventually, though, the Federal Government grew "concerned . . . that some pharmacists were manufacturing and selling drugs under the guise of compounding, thereby avoiding the FDCA's new drug requirements." *Ibid.* Even as the Federal Government began to regulate compounding, Congress maintained a limited exemption from the FDCA's premarket-approval requirement for certain drugs "compounded for an identified individual patient." Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296, 2328 (codified as amended at 21 U.S.C. § 353a). And as relevant in this case, in 2013, Congress also crafted an exemption for certain registered compounding facilities. *See* Drug Quality and Security Act, Pub. L. No. 113-54, 127 Stat. 587, 588 (2013) (codified at 21 U.S.C. § 353b). But under § 353b, registration alone is not enough for a facility to sell compounded drugs without premarket approval. The compounding facility must satisfy a host of additional statutory criteria. *See ibid.*

3

In the face of this ever-expanding federal regulation of drugs, however, the States have not forfeited their traditional prerogative to police drug safety. *Cf. Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485, 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996) (highlighting "the historic primacy of state regulation of matters of health and safety"). As relevant here, six States have decided to mirror federal law by making it illegal to sell any new drug that has not been approved under 21 U.S.C. § 355 (the original § 505 of the FDCA). *See* CAL. HEALTH & SAFETY CODE § 111550(a); COLO. REV. STAT. § 12-280-131(1); CONN. GEN. STAT. § 21a-110; FLA. STAT. § 499.023; TENN. CODE § 53-1-110(a); S.C. CODE § 39-23-70(a). If anyone sells drugs in violation of these state laws, competitors may bring suit under traditional state unfair-competition law.

B

This dispute arises between two such competitors: Zyla Life Sciences, LLC ("Zyla") and Wells Pharma of Houston, LLC ("Wells Pharma").

Zyla sells Indocin Suppositories across the United States.[1] Zyla's suppositories contain indomethacin, a drug used to treat various ailments, such as rheumatoid arthritis. At least until 2023, Zyla's suppositories were

1. Suppositories like Zyla's deliver medication into the body via small, round or cone-shaped objects. People place suppositories into their body—ordinarily in less-than-pleasant places—and once inside, the suppositories dissolve, releasing the medication.

the only ones containing indomethacin that had obtained FDA approval.

Wells Pharma sells compounded indomethacin suppositories. Although the compounded indomethacin suppositories Wells Pharma sells are not FDA-approved, Wells Pharma satisfies at least one of § 353b's many requirements since it is a registered compounding facility under that section.

Zyla wanted to enjoin Wells Pharma from manufacturing and selling its suppositories in California, Colorado, Connecticut, Florida, South Carolina, and Tennessee, so it filed suit under those States' unfair-competition laws. Wells Pharma filed a motion to dismiss under Rule 12(b)(6), arguing the state laws were preempted. The district court granted the motion. Zyla appealed.

The question presented on appeal is whether the state laws somehow conflict with the FDCA by incorporating it.[2]

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2. We address three other theories of preemption briefly in this footnote.

First, field preemption is foreclosed by *Wyeth v. Levine*, 555 U.S. 555, 129 S. Ct. 1187, 173 L. Ed. 2d 51 (2009). *See id.* at 575.

Second, impossibility preemption is irrelevant. It is obviously possible to comply with identical requirements.

The third potential theory, which the district court embraced below, is a bit more complex. The district court concluded that the state laws were preempted because they added to federal requirements. *Zyla Life Scis., LLC v. Wells Pharma of Hous.*,

II

They do not. As we explain, (A) under *Zook*, Wells Pharma's conflict-preemption defense must fail. And (B) Wells Pharma's arguments to the contrary are unpersuasive.

A

Zook controls this case. *Zook* involved a California law that "prohibit[ed] the sale or arrangement of any

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LLC, No. 4:22-CV-04400, 2023 U.S. Dist. LEXIS 173058, 2023 WL 6301651, at *4–5 (S.D. Tex. Sept. 27, 2023). The district court reasoned that the state laws required Wells Pharma to obtain prior approval from the FDA. *Ibid.* But under federal law, Wells Pharma did not need to obtain approval if it satisfied § 353b. *Ibid.*

That's a big if. Because there is no preemption overbreadth doctrine, to establish its preemption defense, Wells Pharma needed to prove that the state laws were preempted "as applied" to it. *Kansas v. Garcia*, 589 U.S. 191, 208, 211, 140 S. Ct. 791, 206 L. Ed. 2d 146 (2020); *see also Moody v. NetChoice, LLC*, 603 U.S. 707, 144 S. Ct. 2383, 2397, 219 L. Ed. 2d 1075 (2024). So to establish this theory of preemption, Wells Pharma needed to prove that the state laws impose additional requirements *as to Wells Pharma*. But the state laws do that only if Wells Pharma satisfies the many requirements of § 353b. Otherwise, the state and federal requirements are the same: To sell drugs, Wells Pharma must obtain FDA approval. But at this stage of the litigation, Wells Pharma cannot have proven that it satisfies § 353b's many requirements. Wells Pharma has only moved to dismiss under 12(b)(6). And given this procedural posture, we cannot draw factual inferences in Wells Pharma's favor concerning its compliance with § 353b.

transportation over public highways of the State if the transporting carrier ha[d] no permit from the Interstate Commerce Commission." 336 U.S. at 726. A federal statute had an identical provision. *Id.* at 726-27. After Berl B. Zook and Wilmer K. Craig violated the state law, California prosecuted them. *Id.* at 727. Zook and Craig argued that the California law was preempted because it mirrored federal law. *See id.* at 732-33.

The Supreme Court held that the California law was not preempted. The mere "fact of identity," the Court explained, did "not mean the automatic invalidity of State measures." *Id.* at 730. On the contrary, there was "no conflict in terms, and no possibility of such conflict, for the state statute ma[de] federal law its own." *Id.* at 735; *see also Garcia*, 589 U.S. at 212 ("[T]here is no basis for inferring that federal . . . statutes preempt state laws whenever they overlap."). Since there was no conflict, the state statute was not preempted.

Zook accords well with preemption first principles. As explained, preemption doctrine comes from the Supremacy Clause. But as the Supreme Court explained over a century ago, when state law mirrors federal law, it "recognizes the supremacy of the national law" by "conform[ing] to it." *Asbell v. Kansas*, 209 U.S. 251, 258, 28 S. Ct. 485, 52 L. Ed. 778 (1908).

Because the States' laws "recognize[] the supremacy of the national law," *ibid.*, it would be anomalous to conclude the Supremacy Clause somehow preempts them. Take the California statute underlying one of Zyla's

claims, for example. It bars selling a "new drug" that has not been approved "under Section 505 of the [FDCA]." CAL. HEALTH & SAFETY CODE § 111550(a). The other state laws are identical in all relevant respects.[3] Those statutes all "make[] federal law [their] own." *Zook*, 336 U.S. at 735. Thus, there can be "no conflict in terms" and no preemption. *Ibid.*

B

Adopting Wells Pharma's contrary position would raise a host of legal problems. It would (1) mark the return of an *ancien* régime of preemption rejected both by Congress and the Supreme Court. (2) The logic of Wells Pharma's position would undermine state sovereignty. Fortunately, (3) that logic has been repudiated in multiple throughlines of preemption and federalism precedent.

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3. *See* FLA. STAT. § 499.023 ("A person may not sell, offer for sale, hold for sale, manufacture, repackage, distribute, or give away any new drug unless an approved application has become effective under s. 505 of the [FDCA]. . . ."); TENN. CODE § 53-1-110(a) ("No person shall sell, deliver, offer for sale, hold for sale or give away any new drug unless an application with respect to the drug has become effective under § 505 of the [FDCA]."); S.C. CODE § 39-23-70(a) ("No person shall introduce or deliver for introduction into intrastate commerce any new drug unless . . . an application with respect thereto has been approved and such approval has not been withdrawn under Section 505 of the [FDCA]."); CONN. GEN. STAT. § 21a-110(a) ("No person shall sell . . . any new drug" that has not "been approved under Section 355 [§ 505 of the FDCA]."); COLO. REV. STAT. § 12-280-131(1) ("No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug not authorized to move in interstate commerce under appropriate federal law.").

1

Adopting Wells Pharma's position would mark a return to the *ancien* régime of *Houston v. Moore*, 18 U.S. (5 Wheat.) 1, 5 L. Ed. 19 (1820). In *Houston*, Pennsylvania sought to punish a militiaman for refusing to respond when called into federal service "in pursuance of a requisition from the President of the United States" during the War of 1812. *Id.* at 3. The Pennsylvania law provided that any militiaman who "neglected or refused to serve when called into actual service, in pursuance of any order or requisition of the President of the United States," would "be liable to the penalties" set out in various "act[s] of the Congress of the United States." *Id.* at 2. In other words, the Pennsylvania law punished the failure to report precisely to the extent federal law did.

Justice Bushrod Washington concluded that the Pennsylvania law was preempted. Washington proclaimed that he could not even fathom how two parallel laws could *not* contradict: As he put it, "I am altogether incapable of comprehending how two distinct wills can, at the same time, be exercised in relation to the same subject, to be effectual, and at the same time compatible with each other." *Id.* at 23. Since the Pennsylvania law sought to act upon "the same subject" as the federal law, it could not be "compatible with" federal law. *Ibid.* Since it was not compatible with federal law, it was preempted.

But "the *Houston* rule was doomed" from the start. J.A.C. Grant, *The Scope and Nature of Concurrent Power*, 34 Colum. L. Rev. 995, 1012 (1934).

First, Washington's opinion "cannot be said to have spoken for the Court." DAVID P. CURRIE, THE CONSTITUTION IN THE SUPREME COURT: THE FIRST HUNDRED YEARS, 1789-1888, at 110 (1992). Although a majority agreed with Washington that the judgment should stand, Washington himself acknowledged that the other justices who formed the majority did "not concur in all respects in the reasons which influence[d] [his] opinion." *Houston*, 18 U.S. (5 Wheat.) at 32. Thus, as Justice Johnson explained in his concurrence, "there [was] no point whatever decided." *Id.* at 47 (Johnson, J., concurring). So Washington's opinion was not precedential.

Second, "the premise upon which" Washington "based" his opinion was "unsound." Grant, *supra*, at 1012. Washington's "assumption that two distinct wills [could] not, in the nature of things, be exercised in relation to the same subject at the same time" was "arid logic." *Ibid.* Washington himself thought that when two laws "correspond in every respect," as is the case when state law mirrors federal law, the state provision is only "idle and inoperative." *Houston*, 18 U.S. (5 Wheat.) at 23. A conflict occurs, thought Washington, only when the laws "differ." *Ibid.* But since an "idle" law is not a conflicting law, there is no reason to think it should be preempted even under Washington's own theory of preemption.

Regardless, a parallel state law would not be "idle." States may have a legitimate interest in punishing or providing redress for wrongs even if federal law already does so. The Federal Government is not the only one with an interest in criminalizing murder or rape. *See Zook*, 336

U.S. at 738 ("[T]he State may punish . . . for the safety and welfare of its inhabitants; the nation may punish for the safety and welfare of interstate commerce. There is no conflict."). Nor is it the only government with an interest in providing remedies for civil wrongs. *Cf. Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 249, 104 S. Ct. 615, 78 L. Ed. 2d 443 (1984). Indeed, the Federal Government often has an interest in allowing parallel state regulation. For that reason, "the Federal Government fully supports [Zyla's] position," *Garcia*, 589 U.S. at 212, as it has shown by filing an amicus brief in a related case not long ago. *See* Brief for the United States as Amicus Curiae, *Athena Cosmetics, Inc. v. Allergan, Inc.*, 576 U.S. 1054, 135 S. Ct. 2886, 192 L. Ed. 2d 923 (2015) (No. 13-1379), 2015 WL 2457643. That should surprise no one. The Federal Government has limited resources. Thus, it often welcomes state aid in enforcing shared legal norms.

And Washington's opinion has been thoroughly repudiated. Just a few years after *Houston*, Congress rejected its understanding of congressional intent. Congress passed a statute explaining that federal criminal legislation should not "be construed to deprive the courts of the individual state of jurisdiction," under their *own* parallel laws, "over offenses" that federal law also criminalized. *See* Crimes Act of 1825, ch. 65, § 26, 4 Stat. 115, 122-23; *see also United States v. Coombs*, 37 U.S. 72, 81, 9 L. Ed. 1004 (1838).[4] And of course, *Zook*

4. True, *Houston* and the congressional response to it dealt only with parallel criminal laws. But if parallel criminal laws are not preempted, it follows *a fortiori* that parallel civil laws are not. Parallel criminal laws raise the concern that "enforcement officers

also rejected Washington's opinion. *See supra*, Part II.A (describing *Zook*); *see also Garcia*, 589 U.S. at 212.

2

The logic of Wells Pharma's position would undermine state sovereignty and principles of federalism. Start with Wells Pharma's theory. It contends the conflict comes from the FDCA's allocation of enforcement discretion to the Federal Government. In short, allowing States to enforce their own parallel laws would upset the discretion given to federal officials in enforcing the FDCA.

Now consider some of the state criminal laws Wells Pharma's theory would require us to find preempted. Federal law allocates exclusive enforcement discretion

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are able to circumvent the constitutional guarantees against a second jeopardy for the same offense." Grant, *supra*, at 996–97; *see also* U.S. CONST. amend. V (forbidding anyone from being "twice put in jeopardy of life or limb" "for the same offence"); *Gamble v. United States*, 587 U.S. 678, 681, 139 S. Ct. 1960, 204 L. Ed. 2d 322 (2019) (recognizing the dual-sovereignty doctrine which permits "a State [to] prosecute a defendant under state law even if the Federal Government has prosecuted him for the same conduct under a federal statute"). Because of these background constitutional norms, the arguments for interpreting federal law to preempt parallel criminal laws are much more forceful than they are for parallel civil laws, as Justice Bushrod Washington's opinion in *Houston* recognized. *See* 18 U.S. (5 Wheat.) at 23 (explaining that parallel laws were "particularly" concerning "in a case inflicting pains and penalties"). Constitutional concerns sounding in double jeopardy, of course, do not arise in the context of parallel civil laws.

to the Federal Government over "offenses against the United States." *See* 28 U.S.C. § 547 (imposing enforcement duties upon the U.S. attorneys); 28 U.S.C. § 519 (granting the Attorney General authority to "supervise all" such "litigation"). And "[t]he district courts of the United States" have "exclusive" jurisdiction over such "offenses." 18 U.S.C. § 3231. Still, many state statutes incorporate federal criminal requirements. Such statutes touch on areas ranging from the most mundane,[5] to the constitutionally controversial,[6] to the classic criminal.[7] All those laws, under Wells Pharma's theory, would be preempted because they purportedly undermine U.S. Attorneys' enforcement discretion.

Adopting Wells Pharma's theory would also undermine traditional state tort laws. For instance, violation of a

5. *See, e.g.*, NEV. REV. STAT. § 193.340 ("A provider of Internet service who violates the provisions of 18 U.S.C. § 2703 is guilty of a misdemeanor"); KY. REV. STAT. § 222.429 (barring "solicit[ing] or receiv[ing] any remuneration . . . for referring a resident to a treatment program" unless such conduct is permitted under 18 U.S.C. § 220 and conversely barring any conduct which violates 18 U.S.C. § 220(b)).

6. *See, e.g.*, N.M. STAT. § 30-7-7.1 (providing that a person generally cannot sell firearms "without conducting a federal instant background check" unless they "hold[] a current and valid federal firearms license" under 18 U.S.C. § 923(a)); TENN. CODE § 39-17-1316(a)(1)(A)(iii) (barring selling firearms to anyone "ineligible to receive firearms under 18 U.S.C. § 922").

7. *See, e.g.*, CONN. GEN. STAT. §§ 21a-243(g)-(h), 279 (generally incorporating the Federal Controlled Substances Act); MICH. COMP. LAWS §§ 333.7204, 7403 (similar).

federal statute often constitutes a breach of the duty of care under the negligence *per se* doctrine. *See* Restatement (Third) of Torts § 14 (2010); *see also Wiersgalla v. Garrett*, 486 N.W.2d 290, 292-93 (Iowa 1992) (acknowledging that violation of a federal statute or regulation may constitute negligence *per se*); Barbara Kritchevsky, *Tort Law Is State Law: Why Courts Should Distinguish State and Federal Law in Negligence-Per-Se Litigation*, 60 Am. U. L. Rev. 71, 91 (2010) (explaining that "[m]ost courts . . . find no distinction between state and federal law in applying the doctrine of negligence per se"). Under Wells Pharma's theory, that would be preempted in any case in which the federal statute at issue vests enforcement discretion in the federal government with limited state or private involvement.

Moreover, if the concern is that state law will interfere with federal enforcement discretion, it is not only parallel laws that should be preempted; any state laws that regulate the same primary conduct as federal law should also be preempted. If anything, parallel standards, which ensure that the same primary conduct is regulated *in the same way*, pose reduced risk to federal enforcement priorities as compared to non-parallel standards, which regulate the same primary conduct *in different ways*. So under Wells Pharma's theory, any time a State regulates the same conduct that the Federal Government does, the state regulation should be preempted because it might upset federal enforcement prerogatives.

The implications are staggering. Given the extraordinary reach of federal law in our post-*Wickard*

world, the Federal Government has its hands in nearly every facet of human existence. *See Wickard v. Filburn*, 317 U.S. 111, 63 S. Ct. 82, 87 L. Ed. 122 (1942); *see also Escobedo v. Ace Gathering, Inc.*, No. 23-20494, 2024 U.S. App. LEXIS 24698, 2024 WL 5443121, at *2 (5th Cir. Sept. 30, 2024) (Oldham, J., dissenting from denial of rehearing en banc). Practically any conduct the State wants to regulate is already regulated by the Federal Government. But as the Founders understood, one of the fundamental features of sovereignty is the power to regulate "every thing that passes" within one's own territory. Emer de Vattel, The Law of Nations, § 204 (1797). To preserve the federal system, we do not prevent the States from regulating everything federal law touches.

Fortunately for our federal system, Wells Pharma's logic has been rejected in at least four ways.

First, States may generally regulate the same conduct the Federal Government does. *See* Richard H. Fallon et al., Hart and Wechsler's Federal Courts and the Federal System 680 (7th ed. 2015); *see also Gamble v. United States*, 587 U.S. 678, 690, 139 S. Ct. 1960, 204 L. Ed. 2d 322 (2019). That is especially so when state standards mimic federal ones, as in this case. *See Zook*, 336 U.S. at 735.

Second, the "possibility that federal enforcement priorities might be upset is not enough to provide a basis for preemption." *Garcia*, 589 U.S. at 212.

Third, it is irrelevant that the States have provided remedies under state law that supplement the FDCA's

remedial scheme. Providing redress for a civil wrong under state law does not create a conflict with a distinct "federal remedial scheme." *Silkwood*, 464 U.S. at 257. State law often provides remedies federal law does not. *See California v. ARC Am. Corp.*, 490 U.S. 93, 109 S. Ct. 1661, 104 L. Ed. 2d 86 (1989) (permitting States to offer remedies to certain individuals under state antitrust laws despite federal antitrust law not providing any remedy to those same individuals).

Fourth, under *Wyeth v. Levine*, 555 U.S. 555, 129 S. Ct. 1187, 173 L. Ed. 2d 51 (2009), the FDCA itself permits States to regulate conduct related to drug safety and effectiveness concurrently with the Federal Government. In *Wyeth*, a Vermont court held a drug manufacturer liable under state tort law for failure to provide an adequate warning on its label for the drug Phenergan. *Id.* at 558. But "[t]he warnings on Phenergan's label had been deemed sufficient by the [FDA]." *Ibid.* So not only did the State and Federal Governments regulate the same conduct; they did so in different ways.

Still, the Supreme Court held there was no conflict. *See id.* at 573–81. The Court reasoned as follows:

> If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express preemption provision at some point during the FDCA's 70-year history. But despite its 1976 enactment of an express preemption provision for medical devices, . . . Congress has not enacted such a provision

> for prescription drugs Its silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.

Id. at 574–75 (citations omitted). Simply put, "Congress did not regard state tort litigation as an obstacle to achieving its purposes." *Id.* at 575.

Thus, *Wyeth* foreclosed Wells Pharma's expansive theory of preemption in the specific context of the FDCA. The Court held that States could regulate concurrently with the Federal Government the same primary conduct related to drug safety and effectiveness in different ways without interfering with FDA oversight. If regulating the same primary conduct in different ways does not upset federal enforcement prerogatives, it follows *a fortiori* that regulating it in parallel ways does not either.

III

Wells Pharma's principal response is a single case: *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 121 S. Ct. 1012, 148 L. Ed. 2d 854 (2001). But *Buckman* is not to the contrary.

A

In that case, plaintiffs brought state fraud claims against Buckman after sustaining injuries from FDA-approved

bone screws. *Id.* at 343. They argued Buckman had made fraudulent representations to the FDA and those representations had induced the FDA to approve the bone screws. *Ibid.*

The Supreme Court held that the FDCA preempted these "state-law fraud-on-the-FDA claims." *Id.* at 348. The States had no role, the Supreme Court reasoned, in "[p]olicing fraud against federal agencies." *Id.* at 347. "To the contrary, the relationship between a federal agency and the entity it regulates is inherently federal in character." *Ibid.* And the FDCA gave ample methods to "the FDA to punish and deter fraud against the Administration." *Id.* at 348.

On this front, *Buckman* picked up where prior cases had left off. For instance, in *In re Loney*, 134 U.S. 372, 10 S. Ct. 584, 33 L. Ed. 949 (1890), the Supreme Court held that States had no power to punish perjury committed before a federal tribunal. As the Court explained, "the power of punishing a witness for testifying falsely in a judicial proceeding belongs peculiarly to the government in whose tribunals that proceeding is had." *Id.* at 375. Otherwise, it might deter "witnesses" from feeling "able to testify freely before them" because of "fear of punishment" or other form of liability under "legislation of the state." *Ibid. Buckman* recognized similar concerns. "[F]raud-on-the-FDA claims" under state law, the Court reasoned, would "cause applicants to fear that their disclosures to the FDA" would "later be judged insufficient in state court." *Buckman*, 531 U.S. at 351. As a result, applicants would "'submit a deluge of information that the [agency]

neither wants nor needs, resulting in additional burdens on the [agency's] evaluation of an application,' and harmful delays in the agency process." *Chamber of Com. of U.S. v. Whiting*, 563 U.S. 582, 604, 131 S. Ct. 1968, 179 L. Ed. 2d 1031 (2011) (quoting *Buckman*, 531 U.S. at 351). That would "directly interfere[] with the operation of the federal program." *Ibid.* (discussing *Buckman*).

The problem in *Buckman* had nothing to do with state law mirroring federal requirements; the state law at issue was ordinary, generally applicable fraud. Instead, the problem in *Buckman* was that the claim "involve[d]" a "uniquely federal area[] of regulation," since it alleged only "fraud on a federal agency." *Whiting*, 563 U.S. at 604 (discussing *Buckman*). In other words, the plaintiffs in *Buckman*, just like the States in *Loney*, sought to wield state law to vindicate a wrong committed *against the Federal Government*. The plaintiffs were hurt by that wrongdoing only incidentally.

This case is different. No one here argues that Wells Pharma's wrongdoing was really committed against the Federal Government, like the fraud in *Buckman* or the perjury in *Loney*. Wells Pharma has not unfairly competed against the FDA, leading to some incidental harm to Zyla.

Moreover, Zyla is not policing the uniquely federal relationship between Wells Pharma and the FDA. So there is no reason to think that allowing Zyla's claims to proceed will "*directly interfere[]* with the operation of the federal program." *Whiting*, 563 U.S. at 604 (emphasis added). There is no sense in which any action "deemed

appropriate by the Administration, will later be judged insufficient in state court." *Buckman*, 531 U.S. at 351. And Wells Pharma gives no reason to think allowing Zyla's claims to proceed would somehow "deluge" the FDA in unwanted "information"; result in harmful delays in the FDA's processing of applications; or deter applicants from seeking FDA approval. *Ibid.* In short, there is no reason to think allowing these claims to proceed will in any sense upset any purposes and objectives of Congress whatsoever.

B

Wells Pharma points to certain language in *Buckman* about the preemptive effect of the FDCA's allocation of enforcement discretion to the Federal Government. But the Supreme Court's language, like all language, must be understood in context. And four aspects of that context make us doubt Wells Pharma's interpretation.

First, even *Buckman*'s most sweeping language fully accords with the analysis above when read in context: In context, *Buckman* holds that the FDCA's allocation of enforcement to the Federal Government forecloses non-federal actors from policing *wrongdoing against the Federal Government. See, e.g., id.* at 348 ("The balance sought by the Administration can be skewed by allowing *fraud-on-the-FDA claims* under state tort law." (emphasis added)); *id.* at 349 ("The FDA thus has at its disposal a variety of enforcement options that allow it to make a measured response to suspected *fraud upon the Administration*." (emphasis added; footnote omitted)); *id.*

at 350 ("State-law *fraud-on-the-FDA claims* inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." (emphasis added)).

Second, any broader reading of *Buckman* would conflict with the Court's more recent pronouncements in *Wyeth v. Levine*. *Wyeth* permitted distinct state regulation under the FDCA. If that does not conflict with federal enforcement prerogatives, neither does parallel state regulation. *See supra*, at 14, 16.

Third, many federal statutes grant the Executive Branch extensive enforcement discretion.[8] But as we have explained, those statutes do not preclude parallel or non-parallel state regulation of the same conduct. If they were read to do so, the States' power over criminal and tort law would dissipate. *See supra*, Part II.B.2.

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8. For this reason, 21 U.S.C. § 337(a) is beside the point. Section 337(a) only confers a cause of action upon the Federal Government to enforce the FDCA. That is necessary because otherwise the Federal Government's power to bring non-statutory actions to enforce federal law is unclear. *Cf., e.g.*, 3 Joseph Story, Commentaries on the Constitution of the United States § 1274, at 154 (Boston, Hilliard, Gray & Co. 1833) (noting that the Federal Government has a right to sue only if Congress statutorily authorizes it). Section 337(a) says nothing about the States' authority to provide remedies for violations of state law. *See ARC Am. Corp.*, 490 U.S. at 103 (explaining that offering a state remedy for conduct that violates both state and federal law does not "affect remedies available under federal law" but merely offers a separate remedy under state law for violations of state law).

Fourth and finally, there is no way to maintain Wells Pharma's broad reading of *Buckman* while escaping these problems. *Buckman* cannot be artificially limited to cases where state law incorporates federal standards. *Buckman* itself was not such a case—rather the plaintiffs there sued under generally applicable tort law.

* * *

For the foregoing reasons, the district court's order granting Wells Pharma's motion to dismiss is REVERSED. Wells Pharma's cross-appeal of the denial of its motion for an award of attorney's fees is DISMISSED AS MOOT. The district court's order denying Zyla's motion for leave to amend is VACATED. And the case is REMANDED for further proceedings consistent with this opinion.

APPENDIX B — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT, FILED APRIL 10, 2025

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

No. 23-20533

ZYLA LIFE SCIENCES, L.L.C.,

Plaintiff—Appellant/Cross-Appellee,

versus

WELLS PHARMA OF HOUSTON, L.L.C.,

Defendant—Appellee/Cross-Appellant.

Filed April 10, 2025

Appeal from the United States District Court
for the Southern District of Texas
USDC No. 4:22-CV-4400

Before Ho, Duncan, and Oldham, Circuit Judges.

Andrew S. Oldham, *Circuit Judge*:

The question presented is whether a State triggers implied obstacles-and-purposes preemption when it expressly incorporates federal law into state law. The district court held yes. But as the Supreme Court held almost a century ago, "there is no conflict in terms, and no possibility of such conflict, for the state statute makes federal law its own." *California v. Zook*, 336 U.S. 725, 735, 69 S. Ct. 841, 93 L. Ed. 1005 (1949). Therefore, we reverse.

Appendix B

I

A

1

All preemption has a constitutional source: the Supremacy Clause. *See Philadelphia v. New Jersey*, 430 U.S. 141, 142, 97 S. Ct. 987, 51 L. Ed. 2d 224 (1977) (per curiam). In "our federal system, the States possess sovereignty concurrent with that of the Federal Government, subject only to limitations imposed by the Supremacy Clause." *Tafflin v. Levitt*, 493 U.S. 455, 458, 110 S. Ct. 792, 107 L. Ed. 2d 887 (1990). Under the Supremacy Clause, any state law that contradicts federal law is preempted. *See* U.S. CONST. art. VI, cl. 2. But barring any contradiction, the States retain their sovereign prerogatives to regulate.

Supreme Court precedent establishes a preemption taxonomy. The first division is between express and implied preemption. *Kansas v. Garcia*, 589 U.S. 191, 202–03, 140 S. Ct. 791, 206 L. Ed. 2d 146 (2020). Implied preemption is further divided into two types: field preemption and conflict preemption. *Id.* at 208–211. Conflict preemption is then divided into two more types. The first is impossibility preemption. It arises when it is impossible to obey both state and federal requirements. *See Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43, 83 S. Ct. 1210, 10 L. Ed. 2d 248 (1963). The second is obstacles-and-purposes preemption (the only type of preemption at issue here). It arises when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67, 61 S. Ct. 399, 85 L. Ed. 581 (1941). In all these types of

preemption, however, "[e]vidence of pre-emptive purpose [must be] sought in the text and structure of the [federal provision] at issue." *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664, 113 S. Ct. 1732, 123 L. Ed. 2d 387 (1993).

2

The federal provisions at issue here come from the Federal Food, Drug, and Cosmetic Act ("FDCA"). On June 25, 1938, President Franklin Delano Roosevelt signed the FDCA into law. *See* Pub. L. No. 75-717, 52 Stat. 1040 (codified as amended at 21 U.S.C. § 301 *et seq.*). The New Dealers who drafted the FDCA did not start from scratch, though. They responded to perceived weaknesses in the Pure Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (repealed 1938), which was signed by Roosevelt's fifth cousin by blood and uncle by law, President Theodore Roosevelt.

The weaknesses with the 1906 Act were brought into the American consciousness by Arthur Kallet and F.J. Schlink's 1933 bestseller, *100,000,000 Guinea Pigs: Dangers in Everyday Foods, Drugs, and Cosmetics. See* David F. Cavers, *The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions*, 6 LAW & CONTEMP. PROBS. 2, 5–6 (1939). Kallet and Schlink warned that the American people had been "forced into the role of laboratory guinea pigs" by "the food and drug industries," which had "been making profits by experimenting on [Americans] with poisons, irritants, harmful chemical preservatives, and dangerous drugs." ARTHUR KALLET & F.J. SCHLINK, 100,000,000 GUINEA PIGS: DANGERS IN EVERYDAY FOODS, DRUGS, AND COSMETICS 4 (1933). Kallet and Schlink told the stories of men like "William J. A. Bailey, an ex-auto-swindler," who made his "money by dissolving radium salts in water and selling" the

resultant concoction "to rich men to cure their ills." *Id.* at 4–5. To the horror of Kallet and Schlink's readers, "Bailey's radium water" had "sent at least two men to horrible deaths." *Id.* at 5. More horrifying still was Kallet and Schlink's premonition that "a similar fate may be awaiting scores or hundreds of others who drank this deadly fluid." *Ibid.*

The centerpiece of the new FDCA was § 505. *See* Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1761 (1996). Although that provision "was not among the reforms originally sought by the [FDCA's] architects," *ibid.*, it became the focal point of the new FDCA after nearly a hundred Americans died of poisoning from the "Elixir Sulfanilamide" drug sold by the S. E. Massengill Company, *see* Cavers, *supra*, at 20. In response to this tragedy, Congress determined that the Federal Government should act to prevent such incidents from occurring in the first place, rather than merely "respond[] to evidence of harm" after it had occurred. Merrill, *supra*, at 1761. So Congress decided to forbid manufacturers from marketing drugs "without first notifying [the] FDA and allowing it time to assess their safety." *Id.* at 1762. After further amendments in 1962, Congress converted this "premarket *notification* system" into today's "premarket *approval* system." *Id.* at 1764–65 (emphasis added). Under today's system, no one may sell "any new drug" without prior approval from the FDA. *See* 21 U.S.C. § 355(a).

Ever since the FDCA's enactment in 1938, Congress has given the Federal Government power to enforce its substantive provisions. *See* 52 Stat. at 1046. Today, those enforcement provisions are codified at 21 U.S.C. § 337. Subsection (a) authorizes the United States to bring

"all . . . proceedings for the enforcement, or to restrain violations," of the FDCA. And subsection (b) permits States to bring actions to enforce certain provisions of the FDCA.

Originally, the FDCA did not regulate all aspects of drug safety: As relevant here, it left alone the ancient art of compounding. *See Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 362, 122 S. Ct. 1497, 152 L. Ed. 2d 563 (2002); *see also* JUDITH E. THOMPSON, A PRACTICAL GUIDE TO CONTEMPORARY PHARMACY PRACTICE 141 (3d ed. 2009) (discussing compounding's ancient roots). Compounding fell outside the FDCA's premarket approval scheme for new drugs. Compounders, after all, do not make *new* drugs; they merely "combine[], mix[], and alter[]" the "ingredients in" old drugs. *Nexus Pharms., Inc. v. Cent. Admixture Pharmacy Servs.*, 48 F.4th 1040, 1042 (9th Cir. 2022). The goal of compounding is to provide "medication tailored to the needs of an individual patient." *Thompson*, 535 U.S. at 360–61. For example, some infants and children might need a certain medication, but the commercially available forms of the medication provide too high a dosage. THOMPSON, *supra*, at 142. Other patients might be allergic to some ingredient in the commercially available forms. *Ibid.* That's where compounding comes in. Under the original FDCA, and for roughly a half-century thereafter, compounding regulation was "generally left . . . to the States." *Thompson*, 535 U.S. at 362.

Eventually, though, the Federal Government grew "concerned . . . that some pharmacists were manufacturing and selling drugs under the guise of compounding, thereby avoiding the FDCA's new drug requirements." *Ibid.* Even as the Federal Government began to regulate compounding, Congress maintained a limited exemption from the

FDCA's premarket-approval requirement for certain drugs "compounded for an identified individual patient." Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296, 2328 (codified as amended at 21 U.S.C. § 353a). And as relevant in this case, in 2013, Congress also crafted an exemption for certain registered compounding facilities. *See* Drug Quality and Security Act, Pub. L. No. 113-54, 127 Stat. 587, 588 (2013) (codified at 21 U.S.C. § 353b). But under § 353b, registration alone is not enough for a facility to sell compounded drugs without premarket approval. The compounding facility must satisfy a host of additional statutory criteria. *See ibid.*

3

In the face of this ever-expanding federal regulation of drugs, however, the States have not forfeited their traditional prerogative to police drug safety. *Cf. Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485, 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996) (highlighting "the historic primacy of state regulation of matters of health and safety"). As relevant here, six States have decided to mirror federal law by making it illegal to sell any new drug that has not been approved under 21 U.S.C. § 355 (the original § 505 of the FDCA). *See* CAL. HEALTH & SAFETY CODE § 111550(a); COLO. REV. STAT. § 12-280-131(1); CONN. GEN. STAT. § 21a-110; FLA. STAT. § 499.023; TENN. CODE § 53-1-110(a); S.C. CODE § 39-23-70(a). If anyone sells drugs in violation of these state laws, competitors may bring suit under traditional state unfair-competition law.

B

This dispute arises between two such competitors:

Zyla Life Sciences, LLC ("Zyla") and Wells Pharma of Houston, LLC ("Wells Pharma").

Zyla sells Indocin Suppositories across the United States.[1] Zyla's suppositories contain indomethacin, a drug used to treat various ailments, such as rheumatoid arthritis. At least until 2023, Zyla's suppositories were the only ones containing indomethacin that had obtained FDA approval.

Wells Pharma sells compounded indomethacin suppositories. Although the compounded indomethacin suppositories Wells Pharma sells are not FDA-approved, Wells Pharma satisfies at least one of § 353b's many requirements since it is a registered compounding facility under that section.

Zyla wanted to enjoin Wells Pharma from manufacturing and selling its suppositories in California, Colorado, Connecticut, Florida, South Carolina, and Tennessee, so it filed suit under those States' unfair-competition laws. Wells Pharma filed a motion to dismiss under Rule 12(b)(6), arguing the state laws were preempted. The district court granted the motion. Zyla appealed.

The question presented on appeal is whether the state laws somehow conflict with the FDCA by incorporating it.[2]

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1. Suppositories like Zyla's deliver medication into the body via small, round or cone-shaped objects. People place suppositories into their body—ordinarily in less-than-pleasant places—and once inside, the suppositories dissolve, releasing the medication.

2. We address three other theories of preemption briefly in this footnote.

II

They do not. As we explain, (A) under *Zook*, Wells Pharma's conflict-preemption defense must fail. And (B) Wells Pharma's arguments to the contrary are unpersuasive.

First, field preemption is foreclosed by *Wyeth v. Levine*, 555 U.S. 555, 129 S. Ct. 1187, 173 L. Ed. 2d 51 (2009). *See id.* at 575.

Second, impossibility preemption is irrelevant. It is obviously possible to comply with identical requirements.

The third potential theory, which the district court embraced below, is a bit more complex. The district court concluded that the state laws were preempted because they added to federal requirements. *Zyla Life Scis., LLC v. Wells Pharma of Hous., LLC*, No. 4:22-CV-04400, 2023 U.S. Dist. LEXIS 173058, 2023 WL 6301651, at *4–5 (S.D. Tex. Sept. 27, 2023). The district court reasoned that the state laws required Wells Pharma to obtain prior approval from the FDA. *Ibid.* But under federal law, Wells Pharma did not need to obtain approval if it satisfied § 353b. *Ibid.*

That's a big if. Because there is no preemption overbreadth doctrine, to establish its preemption defense, Wells Pharma needed to prove that the state laws were preempted "as applied" to it. *Kansas v. Garcia*, 589 U.S. 191, 208, 211, 140 S. Ct. 791, 206 L. Ed. 2d 146 (2020); *see also Moody v. NetChoice, LLC*, 603 U.S. 707, 144 S. Ct. 2383, 2397, 219 L. Ed. 2d 1075 (2024). So to establish this theory of preemption, Wells Pharma needed to prove that the state laws impose additional requirements *as to Wells Pharma*. But the state laws do that only if Wells Pharma satisfies the many requirements of § 353b. Otherwise, the state and federal requirements are the same: To sell drugs, Wells Pharma must obtain FDA approval. But at this stage of the litigation, Wells Pharma cannot have proven that it satisfies § 353b's many requirements. Wells Pharma has only moved to dismiss under 12(b)(6). And given this procedural posture, we cannot draw factual inferences in Wells Pharma's favor concerning its compliance with § 353b.

Appendix B

A

Zook controls this case. *Zook* involved a California law that "prohibit[ed] the sale or arrangement of any transportation over public highways of the State if the transporting carrier ha[d] no permit from the Interstate Commerce Commission." 336 U.S. at 726. A federal statute had an identical provision. *Id.* at 726–27. After Berl B. Zook and Wilmer K. Craig violated the state law, California prosecuted them. *Id.* at 727. Zook and Craig argued that the California law was preempted because it mirrored federal law. *See id.* at 732–33.

The Supreme Court held that the California law was not preempted. The mere "fact of identity," the Court explained, did "not mean the automatic invalidity of State measures." *Id.* at 730. On the contrary, there was "no conflict in terms, and no possibility of such conflict, for the state statute ma[de] federal law its own." *Id.* at 735; *see also Garcia*, 589 U.S. at 212 ("[T]here is no basis for inferring that federal . . . statutes preempt state laws whenever they overlap."). Since there was no conflict, the state statute was not preempted.

Zook accords well with preemption first principles. As explained, preemption doctrine comes from the Supremacy Clause. But as the Supreme Court explained over a century ago, when state law mirrors federal law, it "recognizes the supremacy of the national law" by "conform[ing] to it." *Asbell v. Kansas*, 209 U.S. 251, 258, 28 S. Ct. 485, 52 L. Ed. 778 (1908).

Because the States' laws "recognize[] the supremacy of the national law," *ibid.*, it would be anomalous to

conclude the Supremacy Clause some-how preempts them. Take the California statute underlying one of Zyla's claims, for example. It bars selling a "new drug" that has not been approved "under Section 505 of the [FDCA]." CAL. HEALTH & SAFETY CODE § 111550(a). The other state laws are identical in all relevant respects.[3] Those statutes all "make[] federal law [their] own." *Zook*, 336 U.S. at 735. Thus, there can be "no conflict in terms" and no preemption. *Ibid.*

B

Adopting Wells Pharma's contrary position would raise a host of legal problems. It would (1) mark the return of an *ancien régime* of preemption rejected both by Congress and the Supreme Court. (2) The logic of Wells Pharma's position would undermine state sovereignty. Fortunately, (3) that logic has been repudiated in multiple throughlines of preemption and federalism precedent.

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3. *See* FLA. STAT. § 499.023 ("A person may not sell, offer for sale, hold for sale, manufacture, repackage, distribute, or give away any new drug unless an approved application has become effective under s. 505 of the [FDCA]. . . ."); TENN. CODE § 53-1-110(a) ("No person shall sell, deliver, offer for sale, hold for sale or give away any new drug unless an application with respect to the drug has become effective under § 505 of the [FDCA]."); S.C. CODE § 39-23-70(a) ("No person shall introduce or deliver for introduction into intrastate commerce any new drug unless . . . an application with respect thereto has been approved and such approval has not been withdrawn under Section 505 of the [FDCA]."); CONN. GEN. STAT. § 21a-110(a) ("No person shall sell . . . any new drug" that has not "been approved under Section 355 [§ 505 of the FDCA]."); COLO. REV. STAT. § 12-280-131(1) ("No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug not authorized to move in interstate commerce under appropriate federal law.").

Appendix B

1

Adopting Wells Pharma's position would mark a return to the *ancien régime* of *Houston v. Moore*, 18 U.S. (5 Wheat.) 1, 5 L. Ed. 19 (1820). In *Houston*, Pennsylvania sought to punish a militiaman for refusing to respond when called into federal service "in pursuance of a requisition from the President of the United States" during the War of 1812. *Id.* at 3. The Pennsylvania law provided that any militiaman who "neglected or refused to serve when called into actual service, in pursuance of any order or requisition of the President of the United States," would "be liable to the penalties" set out in various "act[s] of the Congress of the United States." *Id.* at 2. In other words, the Pennsylvania law punished the failure to report precisely to the extent federal law did.

Justice Bushrod Washington concluded that the Pennsylvania law was preempted. Washington proclaimed that he could not even fathom how two parallel laws could *not* contradict: As he put it, "I am altogether incapable of comprehending how two distinct wills can, at the same time, be exercised in relation to the same subject, to be effectual, and at the same time compatible with each other." *Id.* at 23. Since the Pennsylvania law sought to act upon "the same subject" as the federal law, it could not be "compatible with" federal law. *Ibid.* Since it was not compatible with federal law, it was preempted.

But "the *Houston* rule was doomed" from the start. J.A.C. Grant, *The Scope and Nature of Concurrent Power*, 34 COLUM. L. REV. 995, 1012 (1934).

First, Washington's opinion "cannot be said to have

spoken for the Court." DAVID P. CURRIE, THE CONSTITUTION IN THE SUPREME COURT: THE FIRST HUNDRED YEARS, 1789–1888, at 110 (1992). Although a majority agreed with Washington that the judgment should stand, Washington himself acknowledged that the other justices who formed the majority did "not concur in all respects in the reasons which influence[d] [his] opinion." *Houston*, 18 U.S. (5 Wheat.) at 32. Thus, as Justice Johnson explained in his concurrence, "there [was] no point whatever decided." *Id.* at 47 (Johnson, J., concurring). So Washington's opinion was not precedential.

Second, "the premise upon which" Washington "based" his opinion was "unsound." Grant, *supra*, at 1012. Washington's "assumption that two distinct wills [could] not, in the nature of things, be exercised in relation to the same subject at the same time" was "arid logic." *Ibid.* Washington himself thought that when two laws "correspond in every respect," as is the case when state law mirrors federal law, the state provision is only "idle and inoperative." *Houston*, 18 U.S. (5 Wheat.) at 23. A conflict occurs, thought Washington, only when the laws "differ." *Ibid.* But since an "idle" law is not a conflicting law, there is no reason to think it should be preempted even under Washington's own theory of preemption.

Regardless, a parallel state law would not be "idle." States may have a legitimate interest in punishing or providing redress for wrongs even if federal law already does so. The Federal Government is not the only one with an interest in criminalizing murder or rape. *See Zook*, 336 U.S. at 738 ("[T]he State may punish . . . for the safety and

welfare of its inhabitants; the nation may punish for the safety and welfare of interstate commerce. There is no conflict."). Nor is it the only government with an interest in providing remedies for civil wrongs. *Cf. Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 249, 104 S. Ct. 615, 78 L. Ed. 2d 443 (1984). Indeed, the Federal Government often has an interest in allowing parallel state regulation. For that reason, "the Federal Government fully supports [Zyla's] position," *Garcia*, 589 U.S. at 212, as it has shown by filing an amicus brief in a related case not long ago. *See* Brief for the United States as Amicus Curiae, *Athena Cosmetics, Inc. v. Allergan, Inc.*, 576 U.S. 1054, 135 S. Ct. 2886, 192 L. Ed. 2d 923 (2015) (No. 13-1379), 2015 WL 2457643. That should surprise no one. The Federal Government has limited resources. Thus, it often welcomes state aid in enforcing shared legal norms.

And Washington's opinion has been thoroughly repudiated. Just a few years after *Houston*, Congress rejected its understanding of congressional intent. Congress passed a statute explaining that federal criminal legislation should not "be construed to deprive the courts of the individual state of jurisdiction," under their *own* parallel laws, "over offenses" that federal law also criminalized. *See* Crimes Act of 1825, ch. 65, § 26, 4 Stat. 115, 122–23; *see also United States v. Coombs*, 37 U.S. 72, 81, 9 L. Ed. 1004 (1838).[4] And of course, *Zook*

4. True, *Houston* and the congressional response to it dealt only with parallel criminal laws. But if parallel criminal laws are not preempted, it follows *a fortiori* that parallel civil laws are not. Parallel criminal laws raise the concern that "enforcement officers are able to circumvent the constitutional guarantees against a

also rejected Washington's opinion. *See supra*, Part II.A (describing *Zook*); *see also Garcia*, 589 U.S. at 212.

2

The logic of Wells Pharma's position would undermine state sovereignty and principles of federalism. Start with Wells Pharma's theory. It contends the conflict comes from the FDCA's allocation of enforcement discretion to the Federal Government. In short, allowing States to enforce their own parallel laws would upset the discretion given to federal officials in enforcing the FDCA.

Now consider some of the state criminal laws Wells Pharma's theory would require us to find preempted. Federal law allocates exclusive enforcement discretion to the Federal Government over "offenses against the

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second jeopardy for the same offense." Grant, *supra*, at 996–97; *see also* U.S. CONST. amend. V (forbidding anyone from being "twice put in jeopardy of life or limb" "for the same offence"); *Gamble v. United States*, 587 U.S. 678, 681, 139 S. Ct. 1960, 204 L. Ed. 2d 322 (2019) (recognizing the dual-sovereignty doctrine which permits "a State [to] prosecute a defendant under state law even if the Federal Government has prosecuted him for the same conduct under a federal statute"). Because of these background constitutional norms, the arguments for interpreting federal law to preempt parallel criminal laws are much more forceful than they are for parallel civil laws, as Justice Bushrod Washington's opinion in *Houston* recognized. *See* 18 U.S. (5 Wheat.) at 23 (explaining that parallel laws were "particularly" concerning "in a case inflicting pains and penalties"). Constitutional concerns sounding in double jeopardy, of course, do not arise in the context of parallel civil laws.

United States." *See* 28 U.S.C. § 547 (imposing enforcement duties upon the U.S. attorneys); 28 U.S.C. § 519 (granting the Attorney General authority to "supervise all" such "litigation"). And "[t]he district courts of the United States" have "exclusive" jurisdiction over such "offenses." 18 U.S.C. § 3231. Still, many state statutes incorporate federal criminal requirements. Such statutes touch on areas ranging from the most mundane,[5] to the constitutionally controversial,[6] to the classic criminal.[7] All those laws, under Wells Pharma's theory, would be preempted because they purportedly undermine U.S. Attorneys' enforcement discretion.

Adopting Wells Pharma's theory would also undermine traditional state tort laws. For instance, violation of a federal statute often constitutes a breach of the duty of

5. *See, e.g.*, NEV. REV. STAT. § 193.340 ("A provider of Internet service who violates the provisions of 18 U.S.C. § 2703 is guilty of a misdemeanor"); KY. REV. STAT. § 222.429 (barring "solicit[ing] or receiv[ing] any remuneration . . . for referring a resident to a treatment program" unless such conduct is permitted under 18 U.S.C. § 220 and conversely barring any conduct which violates 18 U.S.C. § 220(b)).

6. *See, e.g.*, N.M. STAT. § 30-7-7.1 (providing that a person generally cannot sell firearms "without conducting a federal instant background check" unless they "hold[] a current and valid federal firearms license" under 18 U.S.C. § 923(a)); TENN. CODE § 39-17-1316(a)(1)(A)(iii) (barring selling firearms to anyone "ineligible to receive firearms under 18 U.S.C. § 922").

7. *See, e.g.*, CONN. GEN. STAT. §§ 21a-243(g)–(h), 279 (generally incorporating the Federal Controlled Substances Act); MICH. COMP. LAWS §§ 333.7204, 7403 (similar).

care under the negligence *per se* doctrine. *See* Restatement (Third) of Torts § 14 (2010); *see also Wiersgalla v. Garrett*, 486 N.W.2d 290, 292–93 (Iowa 1992) (acknowledging that violation of a federal statute or regulation may constitute negligence *per se*); Barbara Kritchevsky, *Tort Law Is State Law: Why Courts Should Distinguish State and Federal Law in Negligence-Per-Se Litigation*, 60 Am. U. L. Rev. 71, 91 (2010) (explaining that "[m]ost courts . . . find no distinction between state and federal law in applying the doctrine of negligence per se"). Under Wells Pharma's theory, that would be preempted in any case in which the federal statute at issue vests enforcement discretion in the federal government with limited state or private involvement.

Moreover, if the concern is that state law will interfere with federal enforcement discretion, it is not only parallel laws that should be preempted; any state laws that regulate the same primary conduct as federal law should also be preempted. If anything, parallel standards, which ensure that the same primary conduct is regulated *in the same way*, pose reduced risk to federal enforcement priorities as compared to non-parallel standards, which regulate the same primary conduct *in different ways*. So under Wells Pharma's theory, any time a State regulates the same conduct that the Federal Government does, the state regulation should be preempted because it might upset federal enforcement prerogatives.

The implications are staggering. Given the extraordinary reach of federal law in our post-*Wickard* world, the Federal Government has its hands in nearly

every facet of human existence. *See Wickard v. Filburn*, 317 U.S. 111, 63 S. Ct. 82, 87 L. Ed. 122 (1942); *see also Escobedo v. Ace Gathering, Inc.*, No. 23-20494, 2024 U.S. App. LEXIS 24698, 2024 WL 5443121, at *2 (5th Cir. Sept. 30, 2024) (Oldham, J., dissenting from denial of rehearing en banc). Under our circuit's precedent, for instance, the Federal Government may regulate "subterranean, eyeless arachnids, ranging in size from 1.4mm to 4mm, that are born, reproduce, and die without ever leaving a cave in Texas and have zero connection to economic activity of any kind." Escobedo, 2024 WL 5443121, at *2. So if Wells Pharma's theory is correct, the States would be deprived of just about any power to regulate any conduct at all, simply because of a judicial hunch concerning mysterious congressional purposes allegedly lurking in the bowels of the U.S. Code. Practically any conduct the State wants to regulate is already regulated by the Federal Government. But as the Founders understood, one of the fundamental features of sovereignty is the power to regulate "every thing that passes" within one's own territory. Emer de Vattel, The Law of Nations, § 204 (1797).

So by preventing the States from regulating just about anything federal law touches, we judges would bring to fruition the Anti-Federalists' worst fear: the "entire subversion . . . of the individual states" to an all-powerful federal overlord. Brutus XI, ¶ 2.9.139, *in* 2 The Complete Anti-Federalist 420 (Herbert Storing ed., 1981) ("Storing"); *see also* Centinel II ¶ 2.7.17, *in* 2 Storing 141.

3

Fortunately for our federal system, *Wells Pharma*'s logic has been rejected in at least four ways.

First, States may generally regulate the same conduct the Federal Government does. *See* RICHARD H. FALLON ET AL., HART AND WECHSLER'S FEDERAL COURTS AND THE FEDERAL SYSTEM 680 (7th ed. 2015); *see also Gamble v. United States*, 587 U.S. 678, 690, 139 S. Ct. 1960, 204 L. Ed. 2d 322 (2019). That is especially so when state standards mimic federal ones, as in this case. *See Zook*, 336 U.S. at 735.

Second, the "possibility that federal enforcement priorities might be upset is not enough to provide a basis for preemption." *Garcia*, 589 U.S. at 212.

Third, it is irrelevant that the States have provided remedies under state law that supplement the FDCA's remedial scheme. Providing redress for a civil wrong under state law does not create a conflict with a distinct "federal remedial scheme." *Silkwood*, 464 U.S. at 257. State law often provides remedies federal law does not. *See California v. ARC Am. Corp.*, 490 U.S. 93, 109 S. Ct. 1661, 104 L. Ed. 2d 86 (1989) (permitting States to offer remedies to certain individuals under state antitrust laws despite federal antitrust law not providing any remedy to those same individuals).

Fourth, under *Wyeth v. Levine*, 555 U.S. 555, 129 S. Ct. 1187, 173 L. Ed. 2d 51 (2009), the FDCA itself permits

States to regulate conduct related to drug safety and effectiveness concurrently with the Federal Government. In *Wyeth*, a Vermont court held a drug manufacturer liable under state tort law for failure to provide an adequate warning on its label for the drug Phenergan. *Id.* at 558. But "[t]he warnings on Phenergan's label had been deemed sufficient by the [FDA]." *Ibid.* So not only did the State and Federal Governments regulate the same conduct; they did so in different ways.

Still, the Supreme Court held there was no conflict. *See id.* at 573–81. The Court reasoned as follows:

> If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history. But despite its 1976 enactment of an express pre-emption provision for medical devices, . . . Congress has not enacted such a provision for prescription drugs Its silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.

Id. at 574–75 (citations omitted). Simply put, "Congress did not regard state tort litigation as an obstacle to achieving its purposes." *Id.* at 575.

Thus, *Wyeth* foreclosed Wells Pharma's expansive theory of preemption in the specific context of the FDCA. The Court held that States could regulate concurrently with the Federal Government the same primary conduct related to drug safety and effectiveness in different ways without interfering with FDA oversight. If regulating the same primary conduct in different ways does not upset federal enforcement prerogatives, it follows *a fortiori* that regulating it in parallel ways does not either.

III

Wells Pharma's principal response is a single case: *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 121 S. Ct. 1012, 148 L. Ed. 2d 854 (2001). But *Buckman* is not to the contrary.

A

In that case, plaintiffs brought state fraud claims against Buckman after sustaining injuries from FDA-approved bone screws. *Id.* at 343. They argued Buckman had made fraudulent representations to the FDA and those representations had induced the FDA to approve the bone screws. *Ibid.*

The Supreme Court held that the FDCA preempted these "state-law fraud-on-the-FDA claims." *Id.* at 348. The States had no role, the Supreme Court reasoned, in "[p]olicing fraud against federal agencies." *Id.* at 347.

"To the contrary, the relationship between a federal agency and the entity it regulates is inherently federal in character." *Ibid.* And the FDCA gave ample methods to "the FDA to punish and deter fraud against the Administration." *Id.* at 348.

On this front, *Buckman* picked up where prior cases had left off. For instance, in *In re Loney*, 134 U.S. 372, 10 S. Ct. 584, 33 L. Ed. 949 (1890), the Supreme Court held that States had no power to punish perjury committed before a federal tribunal. As the Court explained, "the power of punishing a witness for testifying falsely in a judicial proceeding belongs peculiarly to the government in whose tribunals that proceeding is had." *Id.* at 375. Otherwise, it might deter "witnesses" from feeling "able to testify freely before them" because of "fear of punishment" or other form of liability under "legislation of the state." *Ibid. Buckman* recognized similar concerns. "[F]raud-on-the-FDA claims" under state law, the Court reasoned, would "cause applicants to fear that their disclosures to the FDA" would "later be judged insufficient in state court." *Buckman*, 531 U.S. at 351. As a result, applicants would "'submit a deluge of information that the [agency] neither wants nor needs, resulting in additional burdens on the [agency's] evaluation of an application,' and harmful delays in the agency process." *Chamber of Com. of U.S. v. Whiting*, 563 U.S. 582, 604, 131 S. Ct. 1968, 179 L. Ed. 2d 1031 (2011) (quoting *Buckman*, 531 U.S. at 351). That would "directly interfere[] with the operation of the federal program." *Ibid.* (discussing *Buckman*).

The problem in *Buckman* had nothing to do with state law mirroring federal requirements; the state law at issue was ordinary, generally applicable fraud. Instead, the problem in *Buckman* was that the claim "involve[d]" a "uniquely federal area[] of regulation," since it alleged only "fraud on a federal agency." *Whiting*, 563 U.S. at 604 (discussing *Buckman*). In other words, the plaintiffs in *Buckman*, just like the States in *Loney*, sought to wield state law to vindicate a wrong committed *against the Federal Government*. The plaintiffs were hurt by that wrongdoing only incidentally.

This case is different. No one here argues that Wells Pharma's wrongdoing was really committed against the Federal Government, like the fraud in *Buckman* or the perjury in *Loney*. Wells Pharma has not unfairly competed against the FDA, leading to some incidental harm to Zyla.

Moreover, Zyla is not policing the uniquely federal relationship between Wells Pharma and the FDA. So there is no reason to think that allowing Zyla's claims to proceed will "*directly interfere[]* with the operation of the federal program." *Whiting*, 563 U.S. at 604 (emphasis added). There is no sense in which any action "deemed appropriate by the Administration, will later be judged insufficient in state court." *Buckman*, 531 U.S. at 351. And Wells Pharma gives no reason to think allowing Zyla's claims to proceed would somehow "deluge" the FDA in unwanted "information"; result in harmful delays in the FDA's processing of applications; or deter applicants from seeking FDA approval. *Ibid.* In short, there is no

reason to think allowing these claims to proceed will in any sense upset any purposes and objectives of Congress whatsoever.

B

Wells Pharma points to certain language in *Buckman* about the preemptive effect of the FDCA's allocation of enforcement discretion to the Federal Government. But the Supreme Court's language, like all language, must be understood in context. And four aspects of that context make us doubt Wells Pharma's interpretation.

First, even *Buckman*'s most sweeping language fully accords with the analysis above when read in context: In context, *Buckman* holds that the FDCA's allocation of enforcement to the Federal Government forecloses non-federal actors from policing *wrongdoing against the Federal Government. See, e.g.*, *id.* at 348 ("The balance sought by the Administration can be skewed by allowing *fraud-on-the-FDA claims* under state tort law." (emphasis added)); *id.* at 349 ("The FDA thus has at its disposal a variety of enforcement options that allow it to make a measured response to suspected *fraud upon the Administration*." (emphasis added; footnote omitted)); *id.* at 350 ("State-law *fraud-on-the-FDA claims* inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." (emphasis added)).

Second, any broader reading of *Buckman* would conflict with the Court's more recent pronouncements

in *Wyeth v. Levine*. *Wyeth* permitted distinct state regulation under the FDCA. If that does not conflict with federal enforcement prerogatives, neither does parallel state regulation. *See supra*, at 14, 16.

Third, many federal statutes grant the Executive Branch extensive enforcement discretion.[8] But as we have explained, those statutes do not preclude parallel or non-parallel state regulation of the same conduct. If they were read to do so, the States' power over criminal and tort law would dissipate. *See supra*, Part II.B.2.

Fourth and finally, there is no way to maintain Wells Pharma's broad reading of *Buckman* while escaping these problems. *Buckman* cannot be artificially limited to cases where state law incorporates federal standards. *Buckman* itself was not such a case—rather the plaintiffs there sued under generally applicable tort law.

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8. For this reason, 21 U.S.C. § 337(a) is beside the point. Section 337(a) only confers a cause of action upon the Federal Government to enforce the FDCA. That is necessary because otherwise the Federal Government's power to bring non-statutory actions to enforce federal law is unclear. *Cf., e.g.*, 3 Joseph Story, Commentaries on the Constitution of the United States § 1274, at 154 (Boston, Hilliard, Gray & Co. 1833) (noting that the Federal Government has a right to sue only if Congress statutorily authorizes it). Section 337(a) says nothing about the States' authority to provide remedies for violations of state law. *See ARC Am. Corp.*, 490 U.S. at 103 (explaining that offering a state remedy for conduct that violates both state and federal law does not "affect remedies available under federal law" but merely offers a separate remedy under state law for violations of state law).

Appendix B

* * *

For the foregoing reasons, the district court's order granting Wells Pharma's motion to dismiss is REVERSED. Wells Pharma's cross-appeal of the denial of its motion for an award of attorney's fees is DISMISSED AS MOOT. The district court's order denying Zyla's motion for leave to amend is VACATED. And the case is REMANDED for further proceedings consistent with this opinion.

APPENDIX C — JUDGMENT OF THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT, FILED APRIL 10, 2025

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

No. 23-20533

ZYLA LIFE SCIENCES, L.L.C.,

Plaintiff—Appellant/Cross-Appellee,

versus

WELLS PHARMA OF HOUSTON, L.L.C.,

Defendant—Appellee/Cross-Appellant.

Appeal from the United States District Court
for the Southern District of Texas
USDC No. 4:22-CV-4400

Before Ho, DUNCAN, and OLDHAM, *Circuit Judges*.

JUDGMENT

This cause was considered on the record on appeal and was argued by counsel.

IT IS ORDERED and ADJUDGED that the District Court's order granting Wells Pharma's Motion is REVERSED and Wells Pharma's cross- appeal of

the denial of its motion for an award of attorney's fees is DISMISSED AS MOOT. The District Court's order denying Zyla's motion for leave to amend is VACATED and the case is REMANDED for further proceedings consistent with the opinion.

The judgment or mandate of this court shall issue 7 days after the time to file a petition for rehearing expires, or 7 days after entry of an order denying a timely petition for panel rehearing, petition for rehearing en banc, or motion for stay of mandate, whichever is later. See Fed. R. App. P. 41(b). The court may shorten or extend the time by order. See 5th Cir. R. 41 I.O.P.

APPENDIX D — OPINION OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF TEXAS, HOUSTON DIVISION, FILED SEPTEMER 27, 2023

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

CIVIL ACTION NO. 4:22-CV-04400

ZYLA LIFE SCIENCES, LLC,

Plaintiff,

VS.

WELLS PHARMA OF HOUSTON, LLC,

Defendant.

ORDER

Before the Court are Plaintiff Zyla Life Sciences, LLC's First Amended Complaint (Doc. #9), Defendant Wells Pharma of Houston, LLC's Motion to Dismiss Plaintiff's First Amended Complaint and for Attorneys' Fees (the "Motion") (Doc. #20), Plaintiff's Response (Doc. #22), and Defendant's Reply (Doc. #25). Having considered the parties' arguments, submissions, and the applicable legal standards, the Court grants the Motion in part.

Appendix D

I. Background

Plaintiff Zyla Life Sciences, LLC is a Delaware corporation that markets and sells Indocin Suppositories, which contain the active pharmaceutical ingredient indomethacin. Doc. #9 ¶ 19. Plaintiff's Indocin Suppositories are the only Food and Drug Administration ("FDA") approved suppository products on the market that contain the active pharmaceutical ingredient indomethacin. *Id.* Indocin Suppositories serve to treat moderate to severe rheumatoid arthritis, osteoarthritis, and ankylosing spondylitis, among other ailments. *Id.* ¶ 21. Plaintiff sells its product across the United States, including in California, Colorado, Florida, South Carolina, Tennessee, and Connecticut (collectively, the "Six States"). *Id.* ¶ 20.

Defendant Wells Pharma of Houston, LLC is a Texas limited liability company and registered compounding outsourcing facility under Section 503B of the Federal Food, Drug, and Cosmetic Act (the "FDCA").[1] Doc. #20 at

1. While Plaintiff insinuates in its First Amended Complaint that Defendant is in the business of compounding, it fails to mention that Defendant is a registered compounding facility under the FDCA. *See* Doc. #9 ¶¶ 29, 93. However, in evaluating a Federal Rule of Civil Procedure 12(b)(6) motion to dismiss, the Court may take judicial notice of some facts, including "matters of public record" such as "publicly available documents and transcripts produced by the FDA." *Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011); *Lovelace v. Software Spectrum, Inc.*, 78 F.3d 1015, 1017-18 (5th Cir. 1996). "Wells Pharma of Houston, LLC" is listed by the FDA as a registered compounding outsourcing facility under Section 503B of the FDCA. U.S. FOOD AND DRUG ADMINISTRATION,

2; Doc. #9 ¶ 93; *see* 21 U.S.C. § 353b. "Drug compounding is the process by which a pharmacist combines or alters drug ingredients according to a doctor's prescription to create a medication to meet the unique needs of an individual . . . patient." *Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383, 387 (5th Cir. 2008). Defendant sells compounded indomethacin suppositories and ships its product to numerous states, including the Six States. Doc. #20 at 1; Doc. #9 ¶ 23. Defendant's indomethacin suppositories are not approved by the FDA. Doc. #9 ¶ 23.

On January 1, 2023, Plaintiff filed its First Amended Complaint against Defendant in this Court. Doc. #9. Plaintiff seeks to enjoin Defendant from manufacturing and selling its indomethacin suppositories in the Six States. *Id.* ¶ 1. Plaintiff does not allege any violation of Texas law. Rather, Plaintiff asserts that Defendant is in violation of: (1) California's Unfair Competition Law, CAL. BUS. & PROF. CODE § 17200, *et seq.*; (2) the Colorado Consumer Protection Act, COLO. REV. STAT. § 6-1-105(1)(z), and Colorado Common Law of Unfair Competition; (3) Florida's Deceptive and Unfair Trade Practices Act, FLA. STAT. ANN. § 501.201, *et seq.*; (4) the Tennessee Consumer Protection Act, TENN. CODE ANN. 47-18-104(b)(43)(C);

Registered Outsourcing Facilities (last updated Aug. 25, 2023), https://www.fda.gov/drugs/human-drug-compounding/registered-outsourcing-facilities. Thus, the Court takes judicial notice of this fact. However, this does not mean, as Plaintiff suggests, that the Court also takes notice that Defendant complies, or does not comply, with the FDCA's requirements for compounding facilities—the Court merely takes note that Defendant is indeed a registered compounding facility. *See* Doc. #22 at 6-7.

(5) the South Carolina Unfair Trade Practices Act, S.C. CODE ANN. § 39-5-20; and (6) the Connecticut Unfair Trade Practices Act, CONN. GEN. STAT. § 42-110b. *Id.* ¶¶ 49-95. The basis of Plaintiff's claims is that Defendant sells "unapproved" pharmaceutical drugs in the Six States, all of which have statutes requiring premarket FDA approval. Four of the states that Plaintiff brings its claims under—Colorado, Florida, Tennessee, and Connecticut—require premarket approval of pharmaceutical drugs by the FDA in order to be sold in the state.[2] The other two states—California and South Carolina—require drugs to be approved either under federal law or by their respective state health departments.[3]

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2. In Colorado, it is unlawful to sell pharmaceutical drugs that are "not authorized to move in interstate commerce *under appropriate federal law*." COLO. REV. STAT. § 12-280-131 (emphasis added). Florida prohibits the selling and marketing of new drugs unless "an approved application has become effective *under s. 505 of the federal act* or unless otherwise permitted by the Secretary of the United States Department of Health and Human Services." FLA. STAT. ANN. § 499.023 (emphasis added). Tennessee prohibits the sale of new drugs "unless an application with respect to the drug has *become effective under § 505 of the federal act*." TENN. CODE ANN. § 53-1-110 (emphasis added). And Connecticut prohibits selling new drugs unless "an application with respect thereto has been approved *under Section 355 of the federal act*." CONN. GEN. STAT. § 21a-110 (emphasis added).

3. In California, "new drugs" may not be sold unless an "application has been approved for it . . . *under Section 505 of the federal act* (21 U.S.C. Sec. 355)" or "the [State Department of Health Services] has approved" it. CAL. HEALTH & SAFETY CODE § 111550(a)—(b) (emphasis added). In South Carolina, it is unlawful to sell a new drug "unless an application filed [with the Director of the South Carolina Department of Health and Environmental Control]

Because the Six States require premarket approval, Plaintiff claims that Defendant is in violation of each state's respective unfair competition laws. Plaintiff further asserts that Defendant's unlawful selling of indomethacin suppositories in these states has (1) jeopardized public health and (2) harmed Plaintiff because "[s]ales made by Defendant in each of these states would have been made by Plaintiff, but for Defendant's unlawful and unfair competition." *Id.* ¶ 47. In short, Plaintiff believes it was harmed because it is the only supplier of FDA-approved indomethacin suppositories, and Defendant is the only "known" seller of the non-approved version of the drug. *Id.* ¶ 46.

Defendant now moves to dismiss all of Plaintiff's claims and seeks attorneys' fees. Doc. #20. Defendant's chief argument is that all of Plaintiff's state law claims are preempted by federal law. Doc. #20 at 7-13. Pursuant to Section 505 of the FDCA, most prescription drugs require premarket approval by the FDA in order to be sold. 21 U.S.C. § 355(a) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug."). However, the FDCA creates an exception to this premarket approval requirement for qualifying compounding outsourcing facilities. *See* 21 U.S.C. § 353b ("[Section 355(a)] shall not apply to a drug compounded by or under the direct supervision of a licensed pharmacist in

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is effective with respect to such drug, or an application with respect thereto has been approved . . . *under § 505 of the Federal act*." S.C. CODE ANN. § 39-23-70(a) (emphasis added).

a facility that elects to register as an outsourcing facility."). In addition, 21 U.S.C. 337(a) bars private enforcement of the FDCA. As such, Defendant argues that because the FDCA explicitly authorizes the sale of compounded drugs without premarket approval, Plaintiff's claims that the laws of the Six States require Defendant —a compounding facility—to seek FDA approval are preempted and must be dismissed. Doc. #20 at 7-8. Defendant further asserts that Plaintiff's state law claims are a "thinly veiled attempt to usurp the exclusive enforcement power of the FDA." *Id.* at 1. In the event of dismissal, Plaintiff seeks leave to amend its First Amended Complaint. Doc. #22 at 18.

II. Legal Standard

To survive a Rule 12(b)(6) motion to dismiss under the Federal Rules of Civil Procedure, a complaint "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007)). This plausibility standard is satisfied "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* In its analysis of a Rule 12(b)(6) motion to dismiss, a court may consider the complaint, any documents attached to the complaint, and matters of which it takes judicial notice. *Lovelace v. Software Spectrum,*

Inc., 78 F.3d 1015, 1017-18 (5th Cir. 1996). In evaluating the complaint, the court takes "the well-pleaded factual allegations in the complaint as true" but does "not credit conclusory allegations or allegations that merely restate the legal elements of a claim." *Chhim v. Univ. of Tex. at Austin*, 836 F.3d 467, 469 (5th Cir. 2016).

III. Analysis

a. Federal Preemption at the Rule 12(b)(6) Motion to Dismiss Stage

As a threshold matter, Plaintiff argues that Defendant prematurely raises a federal preemption defense at the motion to dismiss stage. Doc. #22 at 5-6. "Federal preemption is an affirmative defense that a defendant must plead and prove." *Fisher v. Halliburton*, 667 F.3d 602, 609 (5th Cir. 2012). However, when "the complaint itself establishes the applicability of a federal-preemption defense[,] . . . the issue may properly be the subject of a Rule 12(b)(6) motion." *Id.* Thus, a Rule 12(b)(6) dismissal may be warranted "when a successful affirmative defense appears on the face of the pleadings." *Kansa Reinsurance Co. v. Cong. Mortg. Corp. of Tex.*, 20 F.3d 1362, 1366 (5th Cir. 1994). Indeed, this Court has granted 12(b)(6) motions based on federal preemption stemming from the FDCA. *See, e.g., Schouest v. Medtronic, Inc.*, 13 F. Supp. 3d 692, 710-11 (S.D. Tex. 2014) (dismissing state laws claims brought by the plaintiff against a medical device manufacturer based on federal preemption). Here, the Court finds that Defendant's federal preemption defense is not premature because Plaintiff's First Amended

Complaint "establishes the applicability of a federal-preemption defense." *See Fisher*, 667 F.3d at 609.

b. Federal Preemption of Plaintiff's State Law Claims

Defendant moves to dismiss Plaintiff's First Amended Complaint in its entirety, arguing that each claim is preempted by federal law. Doc. #20 at 7. Preemption doctrine arises under the Constitution's Supremacy Clause, which "invalidates state laws that 'interfere with, or are contrary to,' federal law." *Hillsborough Cnty., Fla. v. Automated Med. Lab'ys, Inc.*, 471 U.S. 707, 712, 105 S. Ct. 2371, 85 L. Ed. 2d 714 (1985) (quoting *Gibbons v. Ogden*, 22 U.S. 1, 9 Wheat. 1, 211, 6 L. Ed. 23 (1824)). Federal law may expressly or impliedly preempt state law. Express preemption occurs when Congress includes "explicit preemptive language" in the statute. *Pacific Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm 'n*, 461 U.S. 190, 203-04, 103 S. Ct. 1713, 75 L. Ed. 2d 752 (1983). Implied preemption exists in "instances where the challenged state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Arizona v. United States*, 567 U.S. 387, 399, 132 S. Ct. 2492, 183 L. Ed. 2d 351 (2012) (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67, 61 S. Ct. 399, 85 L. Ed. 581 (1941)).

Here, Defendant relies on implied preemption. In analyzing whether a state law claim is preempted under the FDCA, "an independent state-law duty may form the basis of a tort claim for which violations of the FDCA may

be presented as evidence of breach, assuming that the state-law claims do not (a) 'add to' federal requirements or (b) impinge on the FDA's sole authority" over enforcement. *Spano as next friend of C.S. v. Whole Foods, Inc.*, 65 F.4th 260, 264 (5th Cir. 2023). In other words, the FDCA does not preempt state-law claims that "parallel" the federal requirements, so long as the state laws do not threaten or interfere with the federal requirements. *Gomez v. St. Jude Med. Daig Div. Inc.*, 442 F.3d 919, 932 (5th Cir. 2006).

Plaintiff claims that Defendant, an FDA-registered compounding facility, is violating the Six States' unfair competition laws because it failed to obtain premarket approval prior to selling pharmaceutical drugs. The Fifth Circuit has not directly addressed whether the FDCA preempts state law claims based on alleged noncompliance by FDA-regulated compounding facilities.[4] However, in *Spano*, the Fifth Circuit analyzed implied preemption in the context of the FDCA's food-labeling requirements.

4. The Ninth Circuit, however, has addressed this issue in a case with facts similar to those presented here. *See Nexus Pharm., Inc. v. Cent. Admixture Pharmacy Servs., Inc.*, 48 F.4th 1040, 1042 (9th Cir. 2022). In *Nexus*, the Ninth Circuit affirmed a Rule 12(b)(6) dismissal of state law unfair competition claims against an outsourcing facility. *Id.* at 1041. There, as here, the plaintiff drug manufacturer sold an FDA-approved drug and sought to enjoin the defendant compound phamiacy from selling a non-approved compounded variation of that drug. *Id.* 1042-43. Based on the FDCA's exclusive enforcement provision, 21 U.S.C. § 337(a), the Ninth Circuit held that the plaintiff's state-law claims were preempted. The court reasoned that allowing an action alleging FDA violations to proceed when the FDA has not made such a determination would essentially permit the plaintiff to assume enforcement power that the FDCA does not allow. *Id.* at 1049.

Spano, 65 F.4th at 262-63. The Fifth Circuit noted that the FDCA contains no private right of action. *Id.* at 262 (citing 21 U.S.C. § 337(a)). Yet, the court held that "an independent state-law duty may form the basis of a tort claim for which violations of the FDCA may be presented as evidence" as long as the "state-law claims do not (a) 'add to' federal requirements or (b) impinge on the FDA's sole authority over food-labeling requirements." *Id.* at 264.

The Fifth Circuit in *Spano* found that the plaintiffs' claims were not preempted. First, the court reasoned that the plaintiffs did not seek to enforce the FDA's food-labeling requirements through its state law claims because the state claims did not impose requirements "*beyond* those imposed by the FDA." *Id.* (emphasis added). Second, the plaintiffs' claims did not appear to impinge on the FDA's authority over food labeling because their claims did not "depend on speculation that the FDA would have taken any particular regulatory action in response to violation of the regulations at issue." *Id.* (quoting *Hughes v. Bos. Sci. Corp.*, 631 F.3d 762, 775 (5th Cir. 2011)). The Fifth Circuit therefore reversed the district court's 12(b)(6) dismissal and held the plaintiffs' claims were not preempted. *Id.* at 265.

Plaintiff alleges that Defendant's sale of non-approved indomethacin suppositories violates the Six States' unfair competition laws. While most prescription drugs require premarket approval, the FDCA excepts qualifying compounding outsourcing facilities from this requirement. *See* 21 U.S.C. § 353b. As such, Plaintiff's assertion that Defendant must obtain premarket approval under the

laws of the Six States adds to the federal requirements under the FDCA which does not require compounding facilities to acquire premarket approval. *See Spano*, 65 F.4th at 264. Plaintiff thus seeks to enforce premarket approval requirements for registered compounding facilities "beyond" those imposed by the FDA. *See id.* Further, Plaintiff's state law claims "impinge on the FDA's sole authority" over enforcement of the FDCA's drug approval requirements. *See id.* Plaintiff's claims "depend on speculation" that the FDA would have taken regulatory action in response to Defendant's sale of compounded indomethacin suppositories, as Plaintiff does not allege that Defendant violated the FDCA but asserts state law claims that hinge on FDCA compliance. *See id.* Indeed, Plaintiff fails to plead any facts to support the assertion that Defendant is noncompliant with the compounding provisions of the FDCA, while relying on state laws that require compliance with the FDCA.

Plaintiff cites various Fifth Circuit cases in which the court found that certain state law claims that paralleled federal requirements were not preempted by the FDCA. *See* Doc. #22 at 10 (citing *Gomez*, 442 F.3d 919; *Hughes*, 631 F.3d 762; *Bass v. Stryker Corp.*, 669 F.3d 501 (5th Cir. 2012)). All of these cases are distinguishable. Each case emphasizes that the state law at issue did not create a requirement that was "'different from or in addition to' a federal requirement." *Hughes*, 631 F.3d at 768; *Gomez*, 442 F.3d at 929; *Bass*, 669 F.3d at 507. As discussed, the state law claims raised by Plaintiff seek to create a requirement "in addition to" the FDCA's requirements—that premarket approval is required for drugs regardless

of whether they are produced by compounding facilities. *Supra* pp. 7-8. Because federal law does not require such approval, Plaintiffs claims are preempted, and Defendant's Motion is granted.

c. Defendant's Request for Attorneys' Fees

Defendant also moves for attorneys' fees. Doc. #20 at 18. However, Defendant solely relies on Florida law and Eleventh Circuit cases to support its request, neither of which are binding upon this Court. As such, Defendant's request for attorneys' fees is denied.

d. Plaintiff's Request for Leave to Amend its Complaint

Plaintiff requests leave to amend its First Amended Complaint to allege that Defendant does not comply with the various compounding provisions of the FDCA. Doc. #22 at 6, 19. Federal Rule of Civil Procedure 15(a) states that "leave shall be freely given when justice so requires." However, "[a] district court acts within its discretion when dismissing a motion to amend that is frivolous or futile." *Martin's Herend Imports, Inc. v. Diamond & Gem Trading U.S. of Am. Co.*, 195 F.3d 765, 771 (5th Cir. 1999); *see also Ayers v. Johnson*, 247 F. App'x 534, 535 (5th Cir. 2007). Here, the Court finds that amendment would be futile. Even if Plaintiff amended its complaint to address Defendant's compliance with the FDCA's compounding requirements, Plaintiffs state law claims would still be preempted by the FDCA's exclusive enforcement provision. *Nexus Pharm., Inc. v. Central Admixture*

Pharmacy Services, Inc., 48 F.4th 1040, 1042 (9th Cir. 2022) (holding the plaintiffs state law unfair competition claims were preempted where the basis of the claims was the defendant outsourcing facility's alleged noncompliance with the FDCA compounding requirements); 12 U.S.C. § 337(a). Thus, Plaintiffs claims are preempted and its request for leave to amend is denied.

IV. Conclusion

In conclusion, the Court finds that all of Plaintiffs claims are preempted by federal law. Each of Plaintiffs claims are premised on the theory that the Six States' laws require compounding facilities to obtain premarket approval, which is not a requirement under the FDCA. Thus, the Six States' laws "add to" the federal requirements and are therefore preempted. As such, Defendant's Motion to Dismiss (Doc. #20) is GRANTED IN PART. In addition, Defendant's request for attorneys' fees is DENIED because Defendant relies on nonbinding law. Plaintiffs request for leave to amend its First Amended Complaint is DENIED because amendment would be futile.

It is so ORDERED.

SEP 27 2023
Date

/s/ Alfred H. Bennett
The Honorable Alfred H. Bennett
United States District Judge

APPENDIX E — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT, DATED JUNE 5, 2025

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

No. 23-20533
USDC No. 4:22-CV-4400

ZYLA LIFE SCIENCES, L.L.C.,

Plaintiff—Appellant/Cross-Appellee,

v.

WELLS PHARMA OF HOUSTON, L.L.C.,

Defendant—Appellee/Cross-Appellant.

Appeal from the United States District Court for the Southern District of Texas

ON PETITION FOR REHEARING EN BANC

Before Ho, Duncan, and Oldham, *Circuit Judges.*

Per Curiam:

Treating the petition for rehearing en banc as a petition for panel rehearing (5th Cir. R.40 I.O.P.), the petition for panel rehearing is DENIED. Because no member of the panel or judge in regular active service requested that the court be polled on rehearing en banc

Appendix E

(FED. R. APP. P.40 and 5TH CIR. R.40), the petition for rehearing en banc is DENIED.

UNITED STATES COURT OF APPEALS
FIFTH CIRCUIT
OFFICE OF THE CLERK

LYLE W. CAYCE
CLERK

TEL. 504-310-7700
600 S. MAESTRI PLACE,
SUITE 115
NEW ORLEANS, LA 70130

June 05, 2025

MEMORANDUM TO COUNSEL OR PARTIES
LISTED BELOW:

No. 23-20533

Zyla Life Sciences v. Wells Pharma.

USDC No. 4:22-CV-4400

Enclosed is an order entered in this case.

Sincerely,

LYLE W. CAYCE, Clerk

By: /s
Christy M. Combel, Deputy Clerk
504-310-7651

Appendix E

Ms. Nicole Bronnimann
Mr. Jeffrey S. Bucholtz
Mr. Aaron B. Craig
Mr. Robert Harrison Golden
Mr. Jeremy Thomas Grabill
Mr. Andrew Michael Grossman
Ms. Margaret Manning
Mr. Randall Nice
Mr. Nathan Ochsner
Mr. David Lee Patron

APPENDIX F — FIRST AMENDED COMPLAINT IN THE UNITED STATES DISTRICT COURT, SOUTHERN DISTRICT OF TEXAS, HOUSTON DIVISION, DATED JANUARY 3, 2023

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

CIVIL CASE NO. 4:22-CV-04400

ZYLA LIFE SCIENCES, LLC,

Plaintiff,

v.

WELLS PHARMA OF HOUSTON, LLC,

Defendant.

PLAINTIFF'S FIRST AMENDED COMPLAINT

Plaintiff Zyla Life Sciences, LLC ("Plaintiff" or "Zyla"), brings this action against Defendant Wells Pharma of Houston, LLC ("Defendant" or "Wells") and alleges the following:

I. NATURE OF THE ACTION

1. Zyla brings this action to stop Defendant from unlawfully manufacturing and selling unapproved new drugs. Various state laws require drug manufacturers to demonstrate their

drugs are safe and effective in order to obtain regulatory approval to market them. Defendant violates these laws by marketing and selling unapproved new drugs throughout the United States, including into states where such sales are unlawful.

A. State Laws Against Unlawful and Unfair Business and Trade Practices

2. California's Unfair Competition Law ("CUCL") exists to stop unscrupulous practices by "prohibiting unfair, dishonest, deceptive, destructive, fraudulent and discriminatory practices by which fair and honest competition is destroyed or prevented." Cal. Bus. & Prof. Code §§ 17001, 17200.

3. Colorado's Consumer Protection Act ("CCPA") prohibits refusing or failing to "obtain all governmental licenses or permits required to . . . sell the goods . . . as agreed to or contracted for." Colo. Rev. Stat. § 6-1-105(z). It also prohibits failing to disclose material information concerning goods which information was known at the time of sale if such failure to disclose such information was intended to induce the purchaser to enter into a transaction. Colo. Rev. Stat. § 6-1-105(u). Colorado common law also proscribes unfair competition.

4. Florida's Deceptive and Unfair Trade Practices

Act ("FDUTPA") "protect[s] the consuming public and legitimate business enterprises from those who engage in unfair methods of competition, or unconscionable, deceptive, or unfair acts or practices in the conduct of any trade or commerce." Fla. Stat. § 501.202(2). FDUTPA further forbids Defendants from violating "[a]ny law, statute, rule, regulation, or ordinance which proscribes unfair methods of competition, or unfair, deceptive, or unconscionable acts or practices." Fla. Stat. Ann. § 501.203(3)(c).

5. Tennessee's Consumer Protection Act ("TCPA") likewise prohibits "advertising, promoting, selling or offering for sale any good or service that is illegal or unlawful to sell in the state." Tenn. Code Ann. § 47-18-104(b)(43)(C).

6. South Carolina's Unfair Trade Practices Act ("SCUTPA") and Connecticut's Unfair Trade Practices Act ("CUTPA") both prohibit "unfair methods of competition" and "unfair [ ] acts or practices in the conduct of any trade or commerce." S.C. Code Ann. § 39-5-20; Conn. Gen. Stat. § 42-110b.

B. State Laws Prohibiting the Sale of Unapproved Drugs

7. California regulates the manufacture and sale of prescription drugs under the Sherman Food, Drug, and Cosmetic Law (the "Sherman Law").

As relevant here, the Sherman Law specifies that "[n]o person shall sell, deliver, or give away any new drug" that has not been approved by the California Department of Health Services or the United States Food and Drug Administration ("FDA"). Cal. Health & Safety Code § 111550(a)–(b). The Sherman Law's drug- approval provision is designed to ensure that when Californians are treated with prescription drugs, they can rest assured that the products are safe and effective for their intended uses.

8. Colorado law prohibits the sale of "any new drug not authorized to move in interstate commerce under appropriate federal law." Colo. Rev. Stat. § 12-280-131-).[1]

9. Florida also regulates the manufacture and sale of prescription drugs under the state's Drug and Cosmetic Act. As relevant here, the Florida Drug and Cosmetic Act specifies that no person may "sell, offer for sale, hold for sale, manufacture, repackage, distribute, or give away any new drug" that has not been approved by FDA. Fla. Stat. Ann. § 499.023. Florida's drug-approval provision is designed to ensure that when Floridians are treated with prescription drugs, they can rest assured that the products are safe and effective for their intended uses.

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1. Federal law prohibits delivering any drug for introduction into interstate commerce unless an approval of an application is effective with respect to such drug. 21 U.S.C. § 355(a).

10. The Tennessee Food, Drug and Cosmetic Act specifies that "no person shall sell, deliver, offer for sale, hold for sale or give away any new drug unless an application with respect to the drug has become effective under § 505 of the federal act." Tenn. Code Ann. § 53-1-110.

11. As relevant here, South Carolina law provides that: "No person shall introduce or deliver for introduction into intrastate commerce any new drug unless an application filed [with the Director of the South Carolina Department of Health and Environmental Control] is effective with respect to such drug, or an application with respect thereto has been approved and such approval has not been withdrawn under § 505 of the Federal act." S.C. Code Ann. § 39-23-70(a).

12. The Connecticut Uniform Food, Drug and Cosmetic Act, Conn. Gen. Stat. § 21a- 110, states: "No person shall sell, deliver, offer for sale, hold for sale or give away any new drug unless (1) an application with respect thereto has been approved under section 355 of the federal act [the premarket approval requirement....] "

13. Defendant disregards these and other state laws respecting the distribution of unapproved drugs. Rather than invest the time and resources necessary to research, develop, and test their products in order to ensure that they are safe and effective and to obtain regulatory approval

to market them, Defendant is simply creating, marketing, selling, and distributing unapproved new drugs for unapproved uses throughout the United States, including California, Colorado, Florida, Tennessee, South Carolina, and Connecticut.[2]

C. The Importance of Drug Approval and the Purpose of this Action

14. Defendant's business model is unlawful. Defendant is engaged in unlawful and unfair business and trade practices because Defendant manufactures and dispenses drugs in violation of the Sherman Law, the Florida Drug & Cosmetic Act, the Tennessee Food, Drug & Cosmetic Act, Colorado Revised Statutes, the Code of Laws of South Carolina, and the Connecticut Uniform Food, Drug and Cosmetic Act. These laws prohibit the sale of drugs not approved by FDA.

15. Testing new drugs and obtaining the legally required regulatory approval to sell them is time-consuming and very costly. Ignoring drug-approval requirements provides Defendant an unfair competitive advantage over law-abiding pharmaceutical manufacturers like Zyla. Worse, it puts patients at risk by exposing them to drugs that have not been shown to be safe or effective.

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2. Defendant states on its website, *see, e.g.*, https://www.wellspharmatx.com/shipping/, that it ships its unapproved drugs to 47 of the 50 United States, excluding only Alabama, New York, and Wyoming.

16. Federal and state law require approval for new drugs for good reason. Drug approval is evidence-based, and it is essential to ensure the quality, safety, and effectiveness of new drugs. When companies circumvent the drug-approval process, safety and efficacy are, at best, unknown. The danger is not merely theoretical, as manufacturing and distribution of unapproved new drugs of unknown quality has endangered or adversely impacted public health. For example, in 2012, nearly 800 patients in 20 states were diagnosed with a fungal infection after receiving injections of an unapproved preservative-free methylprednisolone acetate drug manufactured in Massachusetts. Of those 753 patients, the U.S. Centers for Disease Control and Prevention reported that 64 patients in nine states died, though other sources report the death toll as exceeding 100 victims. Other adverse events related to the sale of unapproved and unsafe drugs have occurred in the years following 2012, including in the State of Texas. For example, in 2018, it was widely reported that at least 68 cataract surgery patients in the Dallas area were permanently blinded, fully or partially, after receiving an injectable unapproved drug.

17. Zyla brings this action under the CUCL, CCPA, FDUTPA, TCPA, SCUTPA and CUTPA to stop Defendants from unlawfully manufacturing, marketing, selling, and distributing unapproved new drugs. Zyla seeks a declaration that

Defendants' business practices violate the CUCL, CCPA, FDUTPA, TCPA, SCUTPA and CUTPA by manufacturing, distributing, and selling unapproved new drugs and an injunction prohibiting Defendants from committing such violations. See Cal. Bus. & Prof. Code § 17200; Cal. Health & Safety Code § 111550(a)–(b); Colo. Rev. Stat. §§ 6-1-105, 12-42.5-128; Fla. Stat. Ann. §§ 499.005, 499.023, 501.203(3)(c); Tenn. Code Ann. § 47-18-104(b)(43)(C); Tenn. Code Ann. § 53-1-110; S.C. Code Ann. § 39-23-70(a), Conn. Gen. Stat. § 21a-110, 42-110b.

II. THE PARTIES

18. Zyla is a limited liability company organized and existing under the laws of the State of Delaware. Zyla's sole member is a corporation organized and existing under the laws of the state of Delaware, with a principal place of business in Illinois. (At the time this action was filed, and at all relevant times prior to December 31, 2022, Zyla was itself a Delaware corporation with a principal place of business in Illinois.)

19. Zyla markets and sells Indocin® Suppositories containing the active pharmaceutical ingredient indomethacin. Indocin® Suppositories are the only FDA-approved suppository product containing indomethacin as the active pharmaceutical ingredient.

20. Plaintiff sells Indocin® Suppositories to medical facilities and customers across the United States, including in California, Colorado, Florida, South Carolina, Tennessee, and Connecticut.

21. Plaintiff (and its predecessors-in-interest) has invested significant time and resources to research, develop, manufacture, and test Indocin® Suppositories, in order to obtain regulatory approval from FDA to market Indocin® Suppositories as a treatment for moderate to severe rheumatoid arthritis, osteoarthritis, and ankylosing spondylitis, as well as acute painful shoulder and acute gouty arthritis.

22. Defendant is a limited liability company organized and existing under the laws of Texas, with its principal place of business at 9265 Kirby Dr., Houston, Texas 77054. On information and belief, Defendant's sole member is a Nevada corporation with its principal place of business in Nevada.

23. Defendant markets itself as shipping products to 47 states, including California, Colorado, Florida, Tennessee, South Carolina, and Connecticut. Defendant manufactures its unapproved drug products in this judicial District and sells them throughout the United States, including in this judicial District and in California, Colorado, Florida, Tennessee, South Carolina, Connecticut and nationwide (except Alabama, New York,

and Wyoming). The unapproved drug products Defendant manufactures in this judicial District and offers for sale and ships to 47 states include unapproved indomethacin suppositories which, upon information and belief, contain bulk indomethacin.

III. JURISDICTION AND VENUE

24. This Court has subject matter jurisdiction under 28 U.S.C. § 1332. The parties are citizens of different States (¶¶ 18-23, supra), and the matter in controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

25. This Court has personal jurisdiction over Defendant. Defendant's principal place of business is located in this District and Defendant manufactures its unapproved drugs in this District and ships them across the United States from this District. Plaintiff's claims arise out of or relate to Defendant's activities in this District.

26. Venue in this District is proper under 28 U.S.C. § 1391(b).

Appendix F

IV. FACTUAL ALLEGATIONS

A. Plaintiff Sells the only Indomethacin Suppository Approved by FDA for Sale in the United States

27. Plaintiff sells Indocin® Suppositories pursuant to Abbreviated New Drug Application (ANDA) #A073314, which FDA approved August 31, 1992, as a treatment for moderate to severe rheumatoid arthritis, osteoarthritis, and ankylosing spondylitis, as well as acute painful shoulder and acute gouty arthritis.

28. Plaintiff is the only supplier of an FDA-approved indomethacin suppository drug in the United States.

B. Defendant's Activities Violate State Laws Against Selling Unapproved Drugs

1. California, Colorado, Florida, Tennessee, South Carolina and Connecticut law require FDA Drug Approval (or State-Specific Drug Approval)

29. Defendants' manufacturing, marketing, sale, and distribution of unapproved new drugs, under the guise of compounding, is unlawful.

30. Under the laws of California, Colorado, Florida, Tennessee, South Carolina, and Connecticut, a

new drug may not be introduced or delivered for introduction into interstate commerce (California, Colorado, Florida, Tennessee, Connecticut) or for introduction into intrastate commerce (South Carolina) unless an application approved by FDA under section 505 of the FDCA is in effect for the drug. See Cal. Health & Safety Code § 111550(a); Colo. Rev. Stat. § 12-42.5-128(1).; Fla. Stat. § 499.023; Tenn. Code Ann. § 53-1-110; SC-ST § 39-23-70; Conn. Gen. Stat. 21a-110.

31. California's Sherman Law provides that "[n]o person shall sell, deliver, or give away any new drug" that has not been approved by FDA or by the State of California. Cal. Health & Safety Code § 111550(a)–(b).

32. The Sherman Law incorporates "[a]ll regulations relating to . . . new drug applications . . . adopted pursuant to Section 505" of the FDCA. Id. § 110110(a).

33. California's Sherman Law and the FDCA's definitions of "drug" and "new drug" are the same. See id. § 109925(c) (drug), § 109980 (new drug); 21 U.S.C. § 321(g)(1), (p).

34. California's Sherman Law incorporates the FDCA's requirement that pharmaceutical manufacturers must obtain approval before selling a new drug. See Cal. Health & Safety Code § 110105; 21 U.S.C § 355.

35. Under Colorado law, "No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug not authorized to move in interstate commerce under appropriate federal law." Colo. Rev. Stat. § 12-280-131.

36. Florida's Drug and Cosmetic Act provides that no person may "sell, offer for sale, hold for sale, manufacture, repackage, distribute, or give away any new drug" that has not been approved by FDA. Fla. Stat. Ann. § 499.023.

37. Florida's Drug and Cosmetic Act's and the FDCA's definitions of "drug" and "new drug" are the same. Fla. Stat. Ann. § 499.003(17) (drug), § 499.003(32) (new drug); 21 U.S.C. § 321(g)(1), (p).

38. The Tennessee Food, Drug and Cosmetic Act provides that "no person shall sell, deliver, offer for sale, hold for sale or give away any new drug unless an application with respect to the drug has become effective under § 505 of the federal act." Tenn. Code Ann. § 53-1-110.

39. Under South Carolina law, a new drug may not be introduced or delivered for introduction into intrastate commerce unless an application under South Carolina Statute § 39-23- 70(b) or section 505 of the FDCA is in effect for the drug. S.C. Code Ann. § 39-23-70.

40. The Connecticut Uniform Food, Drug and Cosmetic Act states that "no person shall sell, deliver, offer for sale, hold for sale or give away any new drug unless an application with respect thereto has been approved under Section 355 of the federal act [the premarket approval requirement]." Conn. Gen. Stat. § 21a-110.

41. Defendant does not have an approved New Drug Application or Abbreviated New Drug Application for any indomethacin suppository drug product.

42. Defendant is violating California's Sherman Law, Colorado Revised Statutes § 12- 42.5-128; Florida's Drug and Cosmetic Act, the Tennessee Food, Drug and Cosmetic Act, South Carolina Statutes § 39-23-70 and the Connecticut Uniform Food, Drug and Cosmetic Act because (i) it is selling its unapproved indomethacin suppositories nationwide, including, on information and belief, in California, Colorado, Florida, South Carolina, Tennessee and Connecticut; and (ii) it has not obtained the approval of FDA (or any other relevant regulatory authority) to introduce into any state, or into interstate commerce generally, the unapproved indomethacin suppository drug that it manufactures, markets, sells, and distributes.

C. Defendant's business and trade practices jeopardize public health

43. Defendant's unfair competition jeopardizes public health. FDA has stated that compounded drugs pose a higher risk to patients than FDA-approved drugs because they have not undergone FDA premarket review for safety, effectiveness, and quality. FDA's Guidance for Industry, Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act at 4 (December 2016). To avoid potentially devastating clinical harm from underdosing or overdosing, critically ill patients should be treated with high-quality, FDA-approved medications whenever available.

44. Defendant manufactures its drugs under dangerous conditions, failing to follow the procedures necessary to prevent their drugs from being contaminated. Within the past eighteen months, FDA cited Defendant because "procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written and followed."

D. Plaintiff has been Injured by Defendants' Unlawful and Unfair Competition

45. Defendant's actions are also harming the public by unfairly competing with Plaintiff.

46. Plaintiff is the only supplier in the United States of FDA-approved indomethacin suppositories.

Defendant is the only known supplier in the United States of unapproved indomethacin suppositories.

47. On information and belief, Defendant sells its unapproved indomethacin suppositories to customers in California, Colorado, Florida, South Carolina, Tennessee, and Connecticut. Sales made by Defendant in each of these states would have been made by Plaintiff, but for Defendant's unlawful and unfair competition. Plaintiff has lost customers and market share for its Indocin® Suppositories as a direct result of Defendant's unlawful and unfair competition. Plaintiff has also refrained from raising its prices and in certain instances has reduced its prices in an effort to dissuade its customers from switching to Defendants' unlawful indomethacin suppositories.

48. As a result of Defendant's unlawful and unfair competition, Plaintiff has been deprived of money or property and has suffered injury in the form of price erosion, as well as the lost sales, lost customers and lost market share that have been diverted from Plaintiff to Defendant.

V. CAUSES OF ACTION

COUNT ONE

Violation of California's Unfair Competition Law ("CUCL") (Cal. Bus. & Prof. Code § 17200, *et. seq.*)

49. Plaintiff realleges and incorporates by reference each and every allegation set forth in paragraphs 1-48, above, as if fully stated herein.

50. Defendant's practices, as described in this Complaint, constitute unlawful and/or unfair business practices in violation of the CUCL, Cal. Bus. & Prof. Code, § 17200, *et seq.*

51. Defendant's products are "drugs" under California and federal law, namely California Health & Safety Code sections 109925(b)-(c), 110110, and 21 U.S.C. § 321(g)(1) and 21 C.F.R. § 310.527(a), because they are intended to cure, mitigate, treat, or prevent disease and/or affect the structure and/or function of the human body and are promoted by Defendants for those purposes and used by healthcare professionals and consumers in California for those purposes.

52. Defendant's products are "new drugs" under California law, namely California Health & Safety Code section 109980, and 21 U.S.C. § 321(p)(1) and 21 C.F.R. § 310.527(a), as incorporated by California Health & Safety Code section 110110, because they are not generally recognized by qualified experts as safe and effective for their intended uses.

53. Defendant's products, including its indomethacin suppository, have not been approved by FDA or by the California Department of Health Services as required by California Health & Safety Code

sections 111550(a)–(b).

54. Defendant has violated the CUCL by engaging in the unlawful business practice of marketing, selling, and distributing its products, including its indomethacin suppository drug, in California in violation of the California Sherman Law.

55. Defendant's practices as alleged in this Complaint constitute unfair business practices in violation of the CUCL because they are substantially injurious to consumers and any utility of such practices is outweighed by the harm to consumers. Defendant's practices violate California's legislative policy of protecting patients and consumers by prohibiting the marketing, sale, and distribution of new drugs that have not been approved by FDA or the California Department of Health Services. Defendant's practices have caused and are causing substantial injuries to Plaintiff and to the public. Those injuries are not outweighed by any benefits.

56. Plaintiff has lost money or property because of Defendant's unlawful and unfair business practices in California.

57. Plaintiff seeks declaratory and injunctive relief requiring Defendant to cease the unlawful actions alleged herein.

58. In addition, Plaintiff is entitled to an award of its attorney's fees under California Code of Civil Procedure section 1021.5.

COUNT TWO

(Violation of Colorado Consumer Protection Act and Colorado Common Law of Unfair Competition)

59. Plaintiff realleges and incorporates by reference each and every allegation set forth in paragraphs 1-58, above, as if fully stated herein.

60. Defendant has engaged in an unfair trade practice by selling unapproved drugs in Colorado, including its indomethacin suppository drug, in violation of Colorado law, Colo. Rev. Stat. § 12-280-131. Defendant has failed to obtain all governmental licenses or permits required to sell its drugs, and therefore violates the CCPA, Colo. Rev. Stat. § 6-1-105(z). Defendant has also failed to disclose material information concerning its indomethacin suppositories—namely, that their sale is unlawful because they are unapproved—which information was known to Defendant at the time of sale and Defendant's failure to disclose that information was intended to induce its customers to purchase its unapproved indomethacin suppositories. This also violates the CCPA, Colo. Rev. Stat. § 6-1-105(u). Defendant's sale of an unlawful product also constitutes common law unfair competition.

61. Defendant's unfair trade practice occurred in the course of Defendant's business of selling drugs.

62. Defendant's unfair trade practice significantly impacts the public as actual or potential consumers of the Defendant's drugs.

63. Plaintiff has suffered an injury in fact to a legally protected interest by price erosion and by losing sales, customers and market share.

64. Plaintiff's injury was caused by Defendant's illegal sale of unapproved drugs.

65. Plaintiff is entitled to declaratory and injunctive relief as well as its reasonable attorney's fees and costs pursuant to Colo. Rev. Stat. § 6-1-113(2)(b).

COUNT THREE

Violation of Florida's Deceptive and Unfair Trade Practices Act ("FDUTPA") (Fla. Stat. Ann. § 501.201, *et seq.*)

66. Plaintiff realleges and incorporates by reference each and every allegation set forth in paragraphs 1-65 above, as if fully stated herein.

67. FDUTPA makes "unlawful" "unfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce." Fla. Stat. Ann. § 501.204.

68. FDUTPA also creates a cause of action for "anyone aggrieved" by a violation of FDUTPA to bring an action against "a person who has violated, is violating, or is otherwise likely to violate" the Act. Fla. Stat. Ann. § 501.211.

69. Plaintiff is "aggrieved" under FDUTPA.

70. Defendant is a "person" who has violated and is violating FDUTPA.

71. Defendant engages in unfair, unconscionable, and deceptive conduct in "trade" and "commerce" in violation of FDUTPA when it unlawfully manufactures and sells unapproved drugs in Florida, including its indomethacin suppository drug.

72. Given that Defendant's drugs are unapproved (and therefore potentially dangerous to consumers), Defendant's manufacture and sale of its drugs is a practice that is immoral, unethical, oppressive, unscrupulous, and/or substantially injurious to physicians, medical facilities and patients alike.

73. The practices described herein also offend established public policy regarding the protection of consumers against companies, like Defendant, that engage in unfair methods of competition. Defendant's conduct has caused substantial injury to Plaintiff in the form of price erosion, lost sales, lost revenues, lost market share and loss of customers, that is not outweighed by

countervailing benefits to any consumers or competition.

74. Defendant's business acts and practices are also unfair because they have caused harm and injury-in-fact to Plaintiff for which Defendant has no justification other than to increase, beyond what Defendant would have otherwise realized, its market share and revenue from the sale of unapproved drugs.

75. Defendant has further violated FDUTPA by violating a "statute . . . which proscribes unfair methods of competition, or unfair, deceptive, or unconscionable acts or practices." Fla. Stat. 501.203(3)(c). Here, Defendant violated the FDCA and Florida's Drug and Cosmetic Act which proscribes unfair methods of competition and unfair, deceptive, and unconscionable acts and practices.

76. Plaintiff is entitled to declaratory and injunctive relief as well as reasonable attorney's fees and costs pursuant to Fla. Stat. § 501.201, *et seq.*

COUNT FOUR

(Violation of Tennessee Consumer Protection Act, Tenn. Code Ann. 47-18-104(b)(43)(C))

77. Plaintiff realleges and incorporates by reference each and every allegation set forth in paragraphs 1-76, above, as if fully stated herein.

78. The TCPA prohibits "unfair or deceptive acts or practices affecting the conduct of any trade or commerce." Tenn. Code Ann. § 47-18-104(a). The TCPA explicitly defines "advertising, promoting, selling or offering for sale any good or service that is illegal or unlawful to sell in the state" to be an unfair or deceptive act or practice that is declared to be unlawful. Tenn. Code Ann. § 47-18-104(b)(43)(C).

79. Defendant has engaged in unfair or deceptive acts or practices declared unlawful by the TCPA by advertising, promoting, selling and offering for sale in Tennessee its unapproved indomethacin suppositories in violation of the Tennessee Food, Drug & Cosmetic Act and the FDCA.

80. Defendant's conduct has caused Plaintiff to suffer an ascertainable loss of money or property in the form of price erosion, lost sales, lost revenues, lost market share and lost customers.

81. Over and above the fact that Defendant's sale of its unapproved indomethacin suppositories explicitly falls within the scope of Tenn. Code Ann. § 47-18-104(b)(43)(C), Defendant also violates the prohibition against "unfair" acts and practices in that its sale of unapproved indomethacin suppositories in Tennessee is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and is not outweighed by countervailing benefits to consumers or to competition.

82. Plaintiff is entitled to declaratory and injunctive relief as well as reasonable attorney's fees and costs pursuant to Tenn. Code Ann. § 47-18-109.

COUNT FIVE

(Violation of South Carolina Unfair Trade Practices Act, S.C. Code Ann. § 39-5-20)

83. Plaintiff realleges and incorporates by reference each and every allegation set forth in paragraphs 1-82, above, as if fully stated herein.

84. SCUTPA prohibits "unfair methods of competition or unfair [ ] acts or practices in the conduct of any trade or commerce." S.C. Code Ann. § 39-5-20(a). Under South Carolina law, an act is "unfair" when it is offensive to public policy or when it is immoral, unethical or oppressive.

85. Defendant has engaged in unfair methods of competition and unfair trade acts and practices in violation of SCUTPA by unlawfully delivering for introduction into intrastate commerce drugs that have not been approved under South Carolina or federal law, in violation of S.C. Code Ann. § 39-23-70, including Defendant's indomethacin suppository drug. Defendant's delivering such drugs for introduction into intrastate commerce is offensive to public policy, immoral, unethical and oppressive, as it is unlawful under South Carolina law.

86. Plaintiff has suffered actual, ascertainable damages and injury as a result of Defendants' unlawful trade practices and unfair methods of competition and unfair acts, including price erosion, lost sales, lost revenues, lost market share and lost customers.

87. Defendant's unlawful trade practices have had an adverse impact on the public interest in the manner set forth above.

88. Plaintiff is entitled to declaratory and injunctive relief as well as reasonable attorney's fees and costs pursuant to S.C. Code Ann. § 39-5-140.

COUNT SIX

(Violation of Connecticut Unfair Trade Practices Act, Conn. Gen. Stat. § 42-110b)

89. Plaintiff realleges and incorporates by reference each and every allegation set forth in paragraphs 1-88, above, as if fully stated herein.

90. CUTPA prohibits "unfair methods of competition or unfair [ ] acts or practices in the conduct of any trade or commerce." Conn. Gen. St. § 42-110b. Under Connecticut law, an act is "unfair" when it offends public policy as it has been established by statutes, the common law, or otherwise, or when it is immoral, unethical, oppressive, or unscrupulous.

91. Defendant's practices described above are both offensive to public policy, and are immoral, unethical, oppressive, and unscrupulous.

92. Plaintiff is a competitor of Defendant in that both Plaintiff and Defendant sell indomethacin suppositories throughout the United States, including in Connecticut.

93. Defendant's conduct was in the course of its primary trade or commerce—the selling of compounded drugs.

94. Defendant's unlawful practices described herein have caused substantial injuries to Plaintiff and to consumers: the injuries caused by Defendant have been substantial; they are not outweighed by any countervailing benefits to consumers or competitors that the practice produces; and the injuries are ones that Plaintiff and consumers could not reasonably have avoided.

95. Within three years of the commencement of this action, Plaintiff has suffered an actual, ascertainable loss of money or property as a result of Defendant's unlawful trade practices and unfair methods of competition and unfair acts, including price erosion, lost sales, lost revenues, lost market share and lost customers. Defendant's sales of its indomethacin suppositories are the proximate cause of Plaintiff's losses. Plaintiff is therefore entitled to declaratory and injunctive

relief under CUTPA, including its attorney's fees. Conn. Gen. St. § 42-110g.

VI. CONCLUSION AND PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in its favor:

1. A preliminary and permanent injunction enjoining Defendant from continuing the unlawful and unfair business practices alleged in this complaint, which injunction has a value to Plaintiff in excess of $75,000;

2. A judgment that Defendant violated the CUCL;

3. A judgment that Defendant violated the CCPA;

4. A judgment that Defendant violated the FDUTPA;

5. A judgment that Defendant violated the TCPA;

6. A judgment that Defendant violated the SCUTPA;

7. A judgment that Defendant violated the CUTPA;

8. Declaratory relief;

9. Attorney's fees and costs incurred in this action; and

10. Any further relief the Court may deem just and proper.

Dated: January 3, 2023

Respectfully submitted,
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Appendix F

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the above and foregoing pleading has been electronically filed on this 3rd day of January 2023, with the Clerk of the Court using CM/ECF and will be served on the Defendant pursuant to the Federal Rules of Civil Procedure.

/s/ Erich Almonte
Erich Almonte

APPENDIX G — PETITION IN THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT, FILED APRIL 23, 2025

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

Case No. 23-20533

ZYLA LIFE SCIENCES, L.L.C.,

Plaintiff – Appellant/Cross-Appellee,

v.

WELLS PHARMA OF HOUSTON, L.L.C.,

Defendant – Appellee/Cross-Appellant.

ON APPEAL FROM THE UNITED STATES
DISTRICT COURT FOR THE SOUTHERN
DISTRICT OF TEXAS

PETITION FOR REHEARING EN BANC BY APPELLEE/CROSS-APPELLANT WELLS PHARMA OF HOUSTON, L.L.C., CASE NO. 22-CV-4400

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CERTIFICATE OF INTERESTED PERSONS

Pursuant to Fifth Circuit Rule 28.2.1, the undersigned counsel of record certifies that the following listed persons and entities have an interest in the outcome of this case. These representations are made in order that the judges of this Court may evaluate possible disqualification or recusal.

1. Plaintiff – Appellant/Cross-Appellee:

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3. Entities with Financial Interest:

Zyla Life Sciences, LLC and its sole member Assertio Holdings, Inc., which is a publicly traded corporation

Wells Pharma of Houston, L.L.C. and its sole member, LSE, Inc. The sole stockholder of LSE, Inc. is Gary L. Shapiro.

SO CERTIFIED, this 23rd day of April, 2025.

/s/ Jeremy T. Grabill
Jeremy T. Grabill

Counsel for Appellee/Cross-Appellant Wells Pharma of Houston, L.L.C.

Appendix G

RULE 35 STATEMENT OF REASONS FOR REHEARING EN BANC

En banc consideration is necessary in this case for two fundamental reasons.

First, and most troublingly, in blatant violation of this Court's rule of orderliness, Judge Oldham's opinion for the panel completely ignores and implicitly overrules binding Fifth Circuit precedent that directly controls the outcome of this pharmaceutical case. *See Garcia-Gonzalez v. Garland*, 76 F.4th 455, 466 n.16 (5th Cir. 2023) ("Under our rule of orderliness, one panel of our court may not overturn another panel's decision, absent an intervening change in the law, such as by a statutory amendment, or the Supreme Court, or our *en banc* court.") (cleaned up).

The plaintiff here, Zyla Life Sciences, L.L.C. ("Zyla"), sued compounding pharmacy Wells Pharma of Houston, L.L.C. ("Wells Pharma") under various state laws to enjoin Wells Pharma from selling its compounded indomethacin drug on the theory that Wells Pharma's compounded drug did not go through the FDA premarket approval process (a dubious theory given that compounded drugs are not subject to premarket approval under federal law). As the district court correctly held, this type of state-law claim is clearly preempted and barred under this Court's precedents. *See Spano ex rel. C.S. v. Whole Foods, Inc.*, 65 F.4th 260, 264 (5th Cir. 2023) (holding that state-law claims are preempted and barred if they "add to" federal requirements or "impinge on the FDA's sole authority"); *Morris v. PLIVA, Inc.*, 713 F.3d 774, 777 (5th Cir. 2013)

(holding that state-law claim that the defendant "breached a federal labeling obligation sounds exclusively in federal (not state) law, and is preempted") (citing 21 U.S.C. § 337(a) and *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001)); *Wildman v. Medtronic Corp.*, 874 F.3d 862, 868 n.6 (5th Cir. 2017) ("Implied preemption precludes state tort claims that 'exist solely by virtue of' the federal regulatory scheme. Such claims . . . cannot be brought under state law because the FDA is the exclusive enforcer of its regulations.") (citing *Buckman*). These binding cases—*Spano*, *Morris*, and *Wildman*—were cited by Wells Pharma in its brief and discussed at oral argument, but the panel opinion does not mention any of them even once and, in fact, implicitly overrules all of them in violation of the rule of orderliness.

Inexplicably, the panel opinion relegates the actual basis for the district court's decision to a footnote (see Panel Op., p. 7 n.2), and unilaterally broadens the actual issue presented far beyond the narrow FDCA context in order to proclaim that a State never triggers implied obstacles-and-purposes preemption, in any context, when it expressly incorporates federal law into state law. This is judicial activism at its worst. The panel opinion holds that *California v. Zook*, 336 U.S. 725 (1949), a 75-year-old criminal case, controls the outcome of this civil matter, and Judge Oldham cites his own dissent from this Court's denial of rehearing en banc in *Escobedo v. Ace Gathering, Inc.* last year to reach this curious result. *See* Panel Op., p. 14 (citing No. 23-20494, 2024 WL 5443121, at *2 (5th Cir. Sept. 30, 2024)).

But *Zook* does not control this case, and obviously neither does the dissent from the denial of rehearing in *Escobedo*. Contrary to the panel's characterization, the issue is not whether "parallel standards" can generally be established under both federal and state law in certain contexts. Rather, under this Court's precedents in FDCA cases, the issue is whether Zyla's state-law claims exist solely by virtue of the federal regulatory scheme, otherwise add to the federal requirements, or impinge on the FDA's exclusive enforcement authority. If any of those things is true (and all three are true here), then the claims are preempted/barred. En banc consideration is necessary to ensure that this Court's prior FDCA decisions are faithfully applied and not brusquely cast aside by the panel.

Second, the panel opinion's disregard of this Court's prior rulings will create an unnecessary circuit split on this important issue of federal law that, if not corrected, is likely to attract the Supreme Court's attention. *See In re Dale*, 582 F.3d 568, 575 n.8 (5th Cir. 2009) ("Our conclusion is bolstered by general prudential concerns with creating unnecessary circuit splits.").

Both the Ninth and First Circuits have held—consistent with *Spano, Morris,* and *Wildman*, and the district court in this matter—that state-law claims like those asserted by Zyla are preempted and barred under *Buckman* and 21 U.S.C. § 337(a) (which gives the FDA exclusive authority to enforce the FDCA). *See Nexus Pharm., Inc. v. Cent. Admixture Pharm. Servs., Inc.*, 48 F.4th 1040, 1049-50 (9th Cir. 2022) (Kleinfeld, Nelson,

VanDyke, JJ.) (affirming dismissal of an identical claim against a compounding pharmacy as preempted because "private enforcement of the FDCA statute . . . [is] barred" and because the state-law claim "exists solely by virtue of the FDCA"); *DiCroce v. McNeil Nutritionals, LLC*, 82 F.4th 35, 41 (1st Cir. 2023) (holding that plaintiff's claims were "impliedly preempted under *Buckman*" given that plaintiff was "suing because the conduct violates the FDCA").

Again, these two cases were briefed extensively by both parties but the panel opinion doesn't mention *DiCroce* and only references Nexus once in passing when describing what compounding is, without engaging in any meaningful discussion of the Ninth Circuit's contrary preemption holding. En banc consideration is thus also necessary here to avoid creating an unjustified and insupportable circuit spilt.

[TABLES INTENTIONALLY OMITTED]

STATEMENT OF THE ISSUE FOR EN BANC CONSIDERATION

Contrary to the panel opinion's broad characterization, the actual issue presented in this case is whether, under this Court's existing precedents, Zyla's state- law claims seeking to enjoin Wells Pharma from selling its compounded indomethacin are impliedly preempted or barred given that (i) the claims exist solely by virtue of the FDCA, (ii) the FDCA includes exemptions to the premarket approval process for compounded drugs that

the state laws at issue do not incorporate, and (iii) the FDCA provides (at 21 U.S.C. § 337(a)) that the FDA has exclusive enforcement authority and discretion regarding such issues.

COURSE OF PROCEEDINGS AND DISPOSITION OF THE CASE

In 1992, Zyla obtained FDA approval to sell its Indocin® Suppositories pursuant to an Abbreviated New Drug Application.[1] Wells Pharma, an FDA- registered 503B outsourcing facility, compounds its indomethacin suppository product subject to FDA's oversight under section 503B of the FDCA.[2] The dosage of Wells Pharma's compounded drug is different from Zyla's drug, and it contains different excipients and is allergen free.

Zyla filed suit in the Southern District of Texas attempting to circumvent the FDCA's private enforcement prohibition by cloaking its lawsuit in state-law "consumer protection" and "unfair competition" claims. In its operative complaint, Zyla alleged only that Wells Pharma's sale of its compounded indomethacin without FDA premarket approval violates various laws in six

1. *See* ROA.47 [Compl. at ¶ 27].

2. *See* ROA.48, ROA.50, ROA.58 [Compl. at ¶¶ 29, 43, 93]; s*ee also* U.S. Food and Drug Administration, *Registered Outsourcing Facilities*, available online at https://www.fda.gov/drugs/human-drug-compounding/registered-outsourcing-facilities (listing Wells Pharma as an approved "compounding outsourcing facility" under Section 503B of the FDCA).

states (California, Colorado, Connecticut, Florida, South Carolina, and Tennessee) that make it illegal to sell drugs that do not obtain FDA premarket approval.[3]

The district court granted Wells Pharma's Rule 12(b)(6) motion to dismiss, holding that Zyla's claims were impliedly preempted and barred because they sought to "add to" the federal requirements for compounding outsourcing facilities under the FDCA and impinged upon "the FDA's sole authority" under 21 U.S.C. § 337(a) regarding enforcement of the FDCA.[4] As the district court explained:

> Plaintiff's assertion that Defendant must obtain premarket approval under the laws of the Six States adds to the federal requirements under the FDCA—which does not require compounding facilities to acquire premarket approval. Plaintiff thus seeks to enforce premarket approval requirements for registered compounding facilities "beyond" those imposed by the FDA. Further Plaintiff's state law claims "impinge on the FDA's sole authority" over enforcement of the FDCA's drug approval requirements.[5]

3. *See* ROA.51-58 [Compl. at ¶¶ 49-95].

4. *See* ROA.471-473.

5. ROA.471 (internal citations omitted).

The district court also correctly denied Zyla's request at the end of its opposition brief for leave to further amend its claims. Acting within its discretion, the district court ruled: "Here, the Court finds that amendment would be futile. Even if Plaintiff amended its complaint to address Defendant's compliance with the FDCA's compounding requirements, Plaintiff's state law claims would still be preempted by the FDCA's exclusive enforcement provision."[6]

Zyla appealed the district court's decision, and on April 10, 2025 a panel of this Court reversed the district court's dismissal of Zyla's claims. Relying on inapposite cases, the panel opinion ignores and implicitly overrules this Court's FDCA precedents by broadly holding that there can be no implied preemption in any context where a "state statute makes federal law its own." Panel Op., p. 1 (quoting *California v. Zook*, 336 U.S. 725, 735 (1949)). And in doing so, the panel creates a needless split with the Ninth and First Circuits.

Wells Pharma now petitions for rehearing en banc to ensure that this Court's prior FDCA decisions are faithfully applied and to give the Court an opportunity to avoid creating an unjustified and insupportable circuit split on this important question of federal law.

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6. ROA.472 (citing *Nexus Pharm., Inc. v. Cent. Admixture Pharm. Servs., Inc.*, 48 F. 4th 1040, 1042 (9th Cir. 2022)).

Appendix G

ARGUMENTS AND AUTHORITIES

I. The Panel Opinion Ignores and Implicitly Overrules Prior Fifth Circuit Decisions that Control this Case.

In announcing a new and misguided general rule that state-law claims can never be preempted or barred so long as the underlying state law makes some aspect of federal law its own, the panel disregards several prior Fifth Circuit decisions that directly control this pharmaceutical dispute and implicitly overrules those decisions in violation of this Court's rule of orderliness. *See Garcia-Gonzalez v. Garland*, 76 F.4th 455, 466 n.16 (5th Cir. 2023) ("Under our rule of orderliness, one panel of our court may not overturn another panel's decision, absent an intervening change in the law, such as by a statutory amendment, or the Supreme Court, or our *en banc* court.") (cleaned up).

The panel opinion suggests that the outcome in this case is not governed by the Supreme Court's decision in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), but rather flows from the Supreme Court's later decision in *Wyeth v. Levine*, 555 U.S. 555 (2009). *See* Panel Op, pp. 16-19. But the *Wyeth* decision was issued before this Court's subsequent decisions in *Spano, Morris,* and *Wildman*, and those decisions make clear that under Buckman, when evaluating state-law claims in the pharmaceutical context, not all claims survive, and a more nuanced analysis is required. Specifically, while traditional state-law tort claims may proceed where an alleged FDCA violation is merely evidence of breach of

a traditional state-law duty that would exist without the FDCA, other state-law claims are preempted or barred where they (a) add to the federal requirements or (b) impinge on the FDA's sole enforcement authority. *See Spano ex rel. C.S. v. Whole Foods, Inc.*, 65 F.4th 260, 264 (5th Cir. 2023). Indeed, in multiple cases, this Court has grappled with whether state-law claims can survive or are instead preempted/barred under this analysis, and the framework for adjudicating this issue under the FDCA is well- established in this Circuit. *See Wildman v. Medtronic Corp.*, 874 F.3d 862, 868 n.6 (5th Cir. 2017) ("Implied preemption precludes state tort claims that 'exist solely by virtue of' the federal regulatory scheme. Such claims . . . cannot be brought under state law because the FDA is the exclusive enforcer of its regulations.") (citing *Buckman*); *see also Morris v. PLIVA, Inc.*, 713 F.3d 774, 777 (5th Cir. 2013) (holding that a claim that "sounds exclusively in federal (not state) law . . . is preempted") (citing 21 U.S.C. § 337(a) and *Buckman*).

In *Buckman*, the Supreme Court held that state-law claims were "impliedly preempted" where they would "exert an extraneous pull on the scheme established by Congress." *Buckman*, 531 U.S. at 353. *Buckman* distinguished itself from a previous case, *Medtronic v. Lohr*, 518 U.S. 470 (1996), because in *Buckman* "the fraud claims exist[ed] solely by virtue of" the FDCA and were not premised upon the breach of a traditional state-law tort duty. *Id.* at 352-53. In other words, without the purported violation of the FDCA, the plaintiff in *Buckman* would have no claim. The same is true of Zyla here. And most importantly, this interpretation of Buckman is settled law

in this Circuit under *Spano, Morris,* and *Wildman*. The panel was not free to reject these decisions and to adopt its own narrower reading of *Buckman*.

Ultimately, the panel stretched far beyond these binding cases in order to announce a new expansive rule that "barring any contradiction" between federal and state law, "the States retain their sovereign prerogatives to regulate." Panel Op., p. 2. The panel's reliance on *California v. Zook*, 336 U.S. 725 (1949), is particularly problematic because *Zook* was a criminal case where a State—not a private competitor—brought an action under a state law that actually mirrored federal law. And there was no indication from Congress that any federal agency had exclusive enforcement authority of that federal law. Here, by contrast, the state laws at issue do not mirror federal law. Rather, they adopt certain premarket approval aspects of the FDCA but fail to incorporate related compounding exceptions that exist under that same federal law. By dropping the exceptions, the state laws clearly "add to" the federal requirements regarding compounding and contradict the federal scheme. And regarding enforcement, this is far from a situation requiring a "judicial hunch concerning mysterious congressional purposes allegedly lurking in the bowels of the U.S. Code." Panel Op., p. 14. Congress left absolutely no doubt about its intent in this context by barring private enforcement and giving the FDA sole enforcement authority under the FDCA in 21 U.S.C. § 337(a). Again, the panel improperly disregards and overrules *Spano, Morris,* and *Wildman* by holding that "21 U.S.C. § 337(a) is beside the point." Panel Op., p. 20 n.8.

This Cout should grant this petition, faithfully apply *Spano, Morris,* and *Wildman*, and affirm the district court's dismissal of Zyla's state-law claims.

II. The Panel Opinion Will Create an Unnecessary and Unjustified Circuit Split.

En banc consideration is also warranted here because the panel opinion's disregard of this Court's prior FDCA rulings will create an unnecessary circuit split on this important issue of federal law that, if not corrected, is likely to attract the Supreme Court's attention. Both the Ninth and First Circuits have held—consistent with *Spano, Morris,* and *Wildman,* and the district court in this matter—that state-law claims like those asserted by Zyla are preempted and barred under *Buckman* and 21 U.S.C. § 337(a).

The leading decision is a unanimous ruling by Judges Kleinfeld, Nelson, and VanDyke in the Ninth Circuit. *See Nexus Pharm., Inc. v. Cent. Admixture Pharm. Servs.*, Inc., 48 F.4th 1040, 1049-50 (9th Cir. 2022). In Nexus, the Ninth Circuit affirmed the Rule 12(b)(6) dismissal of essentially identical state-law claims that sought to enjoin the defendant from selling a compounded variation of plaintiff's FDA-approved drug on the theory that the compounded drug was not approved by the FDA. The Ninth Circuit recognized that the purported state-law violation was "of a law that says in substance 'comply with the FDCA.'" *Id.* at 1050. The court then correctly held that not only is "private enforcement of the FDCA statute . . . barred," but the plaintiff's state-law claim "exists solely by

virtue of the FDCA," and thus is preempted. *Id.* at 1049. The court drew attention to a fundamental problem that the panel opinion here disregards: "[T]o permit Nexus to proceed with a claim that Defendants violated this law when the FDA did not so determine would, in effect, permit [Nexus] to assume enforcement power which the [FDCA] does not allow and require the finder of fact to make a decision that the FDA itself did not make." *Id.* (citation omitted).

In *DiCroce v. McNeil Nutritionals, LLC*, 82 F.4th 35, 41 (1st Cir. 2023), the First Circuit similarly held that a plaintiff's state-law claims of false advertising, unfair and deceptive trade practices, and unjust enrichment that "exist[ed] 'solely by virtue' of an FDCA infraction" were impliedly preempted. Consistent with this Court's statement of the law in *Spano, Morris, and Wildman*, the First Circuit held that, in order to avoid preemption, "[t]he plaintiff must be suing for conduct that violates the FDCA . . . but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)." *Id.* This is because "§ 337(a) preempts any state-law claim that exists solely by virtue of an FDCA infraction." *Id.* at 40. The First Circuit ultimately held that the plaintiff's claims were implied preempted because they were premised upon an alleged FDCA violation. *Id.* at 42.

The panel opinion doesn't mention *DiCroce* at all and only references Nexus once in passing when describing what compounding is, without engaging in any meaningful discussion of the Ninth Circuit's contrary preemption

holding. En banc consideration is thus also necessary here to avoid creating an unjustified and insupportable circuit spilt. *See In re Dale*, 582 F.3d 568, 575 n.8 (5th Cir. 2009) ("Our conclusion is bolstered by general prudential concerns with creating unnecessary circuit splits."); *Alfaro v. Comm'r of Internal Revenue*, 349 F.3d 225, 229 (5th Cir. 2003) (noting that circuit splits are disfavored).

III. The Posture of this Case Further Undermines the Panel's Opinion.

Lastly, it is important to note that the posture of this case also undermines the panel's opinion. Zyla's operative complaint only alleged that Wells Pharma was in violation of various state statutes that make it illegal to sell drugs that are not pre-approved by the FDA. In response to Wells Pharma's Rule 12(b)(6) motion to dismiss, Zyla's counsel suggested in Zyla's opposition brief that Zyla could amend its complaint to also allege that Wells Pharma was not in compliance with the FDCA's compounding exceptions. But critically, Zyla did not file a separate motion for leave to amend nor did it submit a proposed further amended complaint. Moreover, while the state statutes at issue incorporate the FDCA's premarket approval rule, they do not incorporate the FDCA's compounding exceptions. Thus, the panel opinion's reasoning about state statutes that "make federal law their own" would have no applicability to the proposed amended claim by Zyla that Wells Pharma is violating the FDCA compounding rules. This is yet another reason why the panel opinion is misguided and should be corrected by the Court en banc.

Appendix G

CONCLUSION

For the foregoing reasons, this Petition should be granted and the full Court should correct the panel opinion's errors and ensure that this Court's FDCA precedents are faithfully applied. Ultimately, this Court should affirm the district court's dismissal of Zyla's state-law claims as preempted and barred by the FDCA and affirm the district court's denial of Zyla's informal request for leave to amend.

Respectfully submitted,

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Appendix G

APPENDIX

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

No. 23-20533

ZYLA LIFE SCIENCES, L.L.C.,

Plaintiff—Appellant/Cross-Appellee,

versus

WELLS PHARMA OF HOUSTON, L.L.C.,

Defendant—Appellee/Cross-Appellant.

Appeal from the United States District Court
for the Southern District of Texas
USDC No. 4:22-CV-4400

Before Ho, Duncan, and Oldham, *Circuit Judges.*

Andrew S. Oldham, *Circuit Judge*:

The question presented is whether a State triggers implied obstacles- and-purposes preemption when it expressly incorporates federal law into state law. The district court held yes. But as the Supreme Court held almost a century ago, "there is no conflict in terms, and no possibility of such conflict, for the state statute makes federal law its own." *California v. Zook*, 336 U.S. 725, 735 (1949). Therefore, we reverse.

Appendix G

I

A

1

All preemption has a constitutional source: the Supremacy Clause. *See Philadelphia v. New Jersey*, 430 U.S. 141, 142 (1977) (per curiam). In "our federal system, the States possess sovereignty concurrent with that of the Federal Government, subject only to limitations imposed by the Supremacy Clause." *Tafflin v. Levitt*, 493 U.S. 455, 458 (1990). Under the Supremacy Clause, any state law that contradicts federal law is preempted. *See* U.S. CONST. art. VI, cl. 2. But barring any contradiction, the States retain their sovereign prerogatives to regulate.

Supreme Court precedent establishes a preemption taxonomy. The first division is between express and implied preemption. *Kansas v. Garcia*, 589 U.S. 191, 202–03 (2020). Implied preemption is further divided into two types: field preemption and conflict preemption. *Id.* at 208–211. Conflict preemption is then divided into two more types. The first is impossibility preemption. It arises when it is impossible to obey both state and federal requirements. *See Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43 (1963). The second is obstacles-and-purposes preemption (the only type of preemption at issue here). It arises when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). In all these types of preemption, however,

"[e]vidence of pre-emptive purpose [must be] sought in the text and structure of the [federal provision] at issue." *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993).

2

The federal provisions at issue here come from the Federal Food, Drug, and Cosmetic Act ("FDCA"). On June 25, 1938, President Franklin Delano Roosevelt signed the FDCA into law. *See* Pub. L. No. 75-717, 52 Stat. 1040 (codified as amended at 21 U.S.C. § 301 *et seq.*). The New Dealers who drafted the FDCA did not start from scratch, though. They responded to perceived weaknesses in the Pure Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (repealed 1938), which was signed by Roosevelt's fifth cousin by blood and uncle by law, President Theodore Roosevelt.

The weaknesses with the 1906 Act were brought into the American consciousness by Arthur Kallet and F.J. Schlink's 1933 bestseller, *100,000,000 Guinea Pigs: Dangers in Everyday Foods, Drugs, and Cosmetics*. *See* David F. Cavers, *The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions*, 6 LAW & CONTEMP. PROBS. 2, 5–6 (1939). Kallet and Schlink warned that the American people had been "forced into the role of laboratory guinea pigs" by "the food and drug industries," which had "been making profits by experimenting on [Americans] with poisons, irritants, harmful chemical preservatives, and dangerous drugs." ARTHUR KALLET & F.J. SCHLINK, 100,000,000 GUINEA PIGS: DANGERS IN EVERYDAY FOODS, DRUGS, AND COSMETICS

4 (1933). Kallet and Schlink told the stories of men like "William J. A. Bailey, an ex-auto-swindler," who made his "money by dissolving radium salts in water and selling" the resultant concoction "to rich men to cure their ills." *Id.* at 4–5. To the horror of Kallet and Schlink's readers, "Bailey's radium water" had "sent at least two men to horrible deaths." *Id.* at 5. More horrifying still was Kallet and Schlink's premonition that "a similar fate may be awaiting scores or hundreds of others who drank this deadly fluid." *Ibid.*

The centerpiece of the new FDCA was § 505. *See* Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 Va. L. Rev. 1753, 1761 (1996). Although that provision "was not among the reforms originally sought by the [FDCA's] architects," *ibid.*, it became the focal point of the new FDCA after nearly a hundred Americans died of poisoning from the "Elixir Sulfanilamide" drug sold by the S. E. Massengill Company, *see* Cavers, *supra*, at 20. In response to this tragedy, Congress determined that the Federal Government should act to prevent such incidents from occurring in the first place, rather than merely "respond[] to evidence of harm" after it had occurred. Merrill, *supra*, at 1761. So Congress decided to forbid manufacturers from marketing drugs "without first notifying [the] FDA and allowing it time to assess their safety." *Id.* at 1762. After further amendments in 1962, Congress converted this "premarket notification system" into today's "premarket approval system." *Id.* at 1764–65 (emphasis added). Under today's system, no one may sell "any new drug" without prior approval from the FDA. *See* 21 U.S.C. § 355(a).

Appendix G

Ever since the FDCA's enactment in 1938, Congress has given the Federal Government power to enforce its substantive provisions. *See* 52 Stat. at 1046. Today, those enforcement provisions are codified at 21 U.S.C. § 337. Subsection (a) authorizes the United States to bring "all . . . proceedings for the enforcement, or to restrain violations," of the FDCA. And subsection (b) permits States to bring actions to enforce certain provisions of the FDCA.

Originally, the FDCA did not regulate all aspects of drug safety: As relevant here, it left alone the ancient art of compounding. *See Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 362 (2002); *see also* JUDITH E. THOMPSON, A PRACTICAL GUIDE TO CONTEMPORARY PHARMACY PRACTICE 141 (3d ed. 2009) (discussing compounding's ancient roots). Compounding fell outside the FDCA's premarket approval scheme for new drugs. Compounders, after all, do not make new drugs; they merely "combine[], mix[], and alter[]" the "ingredients in" old drugs. *Nexus Pharms., Inc. v. Cent. Admixture Pharmacy Servs.*, 48 F.4th 1040, 1042 (9th Cir. 2022). The goal of compounding is to provide "medication tailored to the needs of an individual patient." *Thompson*, 535 U.S. at 360–61. For example, some infants and children might need a certain medication, but the commercially available forms of the medication provide too high a dosage. THOMPSON, *supra*, at 142. Other patients might be allergic to some ingredient in the commercially available forms. *Ibid.* That's where compounding comes in. Under the original FDCA, and for roughly a half-century thereafter, compounding regulation was "generally left . . . to the States." *Thompson*, 535 U.S. at 362.

Eventually, though, the Federal Government grew "concerned . . . that some pharmacists were manufacturing and selling drugs under the guise of compounding, thereby avoiding the FDCA's new drug requirements." *Ibid.* Even as the Federal Government began to regulate compounding, Congress maintained a limited exemption from the FDCA's premarket-approval requirement for certain drugs "compounded for an identified individual patient." Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296, 2328 (codified as amended at 21 U.S.C. § 353a). And as relevant in this case, in 2013, Congress also crafted an exemption for certain registered compounding facilities. *See* Drug Quality and Security Act, Pub. L. No. 113-54, 127 Stat. 587, 588 (2013) (codified at 21 U.S.C. § 353b). But under § 353b, registration alone is not enough for a facility to sell compounded drugs without premarket approval. The compounding facility must satisfy a host of additional statutory criteria. *See ibid.*

3

In the face of this ever-expanding federal regulation of drugs, however, the States have not forfeited their traditional prerogative to police drug safety. *Cf. Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (highlighting "the historic primacy of state regulation of matters of health and safety"). As relevant here, six States have decided to mirror federal law by making it illegal to sell any new drug that has not been approved under 21 U.S.C. § 355 (the original § 505 of the FDCA). *See* Cal. Health & Safety Code § 111550(a); Colo. Rev. Stat. § 12-280-131(1); Conn.

GEN. STAT. § 21a-110; FLA. STAT. § 499.023; TENN. CODE § 53-1-110(a); S.C. CODE § 39-23-70(a). If anyone sells drugs in violation of these state laws, competitors may bring suit under traditional state unfair-competition law.

B

This dispute arises between two such competitors: Zyla Life Sciences, LLC ("Zyla") and Wells Pharma of Houston, LLC ("Wells Pharma").

Zyla sells Indocin Suppositories across the United States.[1] Zyla's suppositories contain indomethacin, a drug used to treat various ailments, such as rheumatoid arthritis. At least until 2023, Zyla's suppositories were the only ones containing indomethacin that had obtained FDA approval.

Wells Pharma sells compounded indomethacin suppositories. Although the compounded indomethacin suppositories Wells Pharma sells are not FDA-approved, Wells Pharma satisfies at least one of § 353b's many requirements since it is a registered compounding facility under that section.

Zyla wanted to enjoin Wells Pharma from manufacturing and selling its suppositories in California, Colorado, Connecticut, Florida, South Carolina, and

1. Suppositories like Zyla's deliver medication into the body via small, round or cone-shaped objects. People place suppositories into their body—ordinarily in less-than-pleasant places—and once inside, the suppositories dissolve, releasing the medication.

Tennessee, so it filed suit under those States' unfair-competition laws. Wells Pharma filed a motion to dismiss under Rule 12(b)(6), arguing the state laws were preempted. The district court granted the motion. Zyla appealed.

The question presented on appeal is whether the state laws somehow conflict with the FDCA by incorporating it.[2]

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2. We address three other theories of preemption briefly in this footnote.

First, field preemption is foreclosed by *Wyeth v. Levine*, 555 U.S. 555 (2009). *See id.* at 575.

Second, impossibility preemption is irrelevant. It is obviously possible to comply with identical requirements.

The third potential theory, which the district court embraced below, is a bit more complex. The district court concluded that the state laws were preempted because they added to federal requirements. *Zyla Life Scis., LLC v. Wells Pharma of Hous., LLC*, No. 4:22-CV-04400, 2023 WL 6301651, at *4–5 (S.D. Tex. Sept. 27, 2023). The district court reasoned that the state laws required Wells Pharma to obtain prior approval from the FDA. *Ibid.* But under federal law, Wells Pharma did not need to obtain approval if it satisfied § 353b. *Ibid.*

That's a big if. Because there is no preemption overbreadth doctrine, to establish its preemption defense, Wells Pharma needed to prove that the state laws were preempted "as applied" to it. *Kansas v. Garcia*, 589 U.S. 191, 208, 211 (2020); see also *Moody v. NetChoice, LLC*, 144 S. Ct. 2383, 2397 (2024). So to establish this theory of preemption, Wells Pharma needed to prove that the state laws impose additional requirements *as to Wells Pharma*. But the state laws do that only if Wells Pharma satisfies the many requirements of § 353b. Otherwise, the state and

II

They do not. As we explain, (A) under *Zook*, Wells Pharma's conflict-preemption defense must fail. And (B) Wells Pharma's arguments to the contrary are unpersuasive.

A

Zook controls this case. *Zook* involved a California law that "prohibit[ed] the sale or arrangement of any transportation over public highways of the State if the transporting carrier ha[d] no permit from the Interstate Commerce Commission." 336 U.S. at 726. A federal statute had an identical provision. *Id.* at 726–27. After Berl B. Zook and Wilmer K. Craig violated the state law, California prosecuted them. *Id.* at 727. Zook and Craig argued that the California law was preempted because it mirrored federal law. *See id.* at 732–33.

The Supreme Court held that the California law was not preempted. The mere "fact of identity," the Court explained, did "not mean the automatic invalidity of State measures." *Id.* at 730. On the contrary, there was "no conflict in terms, and no possibility of such conflict, for

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federal requirements are the same: To sell drugs, Wells Pharma must obtain FDA approval. But at this stage of the litigation, Wells Pharma cannot have proven that it satisfies § 353b's many requirements. Wells Pharma has only moved to dismiss under 12(b)(6). And given this procedural posture, we cannot draw factual inferences in Wells Pharma's favor concerning its compliance with § 353b.

the state statute ma[de] federal law its own." *Id.* at 735; *see also Garcia*, 589 U.S. at 212 ("[T]here is no basis for inferring that federal . . . statutes preempt state laws whenever they overlap."). Since there was no conflict, the state statute was not preempted.

Zook accords well with preemption first principles. As explained, preemption doctrine comes from the Supremacy Clause. But as the Supreme Court explained over a century ago, when state law mirrors federal law, it "recognizes the supremacy of the national law" by "conform[ing] to it." *Asbell v. Kansas*, 209 U.S. 251, 258 (1908).

Because the States' laws "recognize[] the supremacy of the national law," *ibid.*, it would be anomalous to conclude the Supremacy Clause somehow preempts them. Take the California statute underlying one of Zyla's claims, for example. It bars selling a "new drug" that has not been approved "under Section 505 of the [FDCA]." CAL. HEALTH & SAFETY CODE § 111550(a). The other state laws are identical in all relevant respects.[3] Those

3. *See* FLA. STAT. § 499.023 ("A person may not sell, offer for sale, hold for sale, manufacture, repackage, distribute, or give away any new drug unless an approved application has become effective under s. 505 of the [FDCA] "); TENN. CODE § 53-1-110(a) ("No person shall sell, deliver, offer for sale, hold for sale or give away any new drug unless an application with respect to the drug has become effective under § 505 of the [FDCA]."); S.C. CODE § 39-23-70(a) ("No person shall introduce or deliver for introduction into intrastate commerce any new drug unless an application with respect thereto has been approved and such approval has not

statutes all "make[] federal law [their] own." *Zook*, 336 U.S. at 735. Thus, there can be "no conflict in terms" and no preemption. *Ibid.*

B

Adopting Wells Pharma's contrary position would raise a host of legal problems. It would (1) mark the return of an *ancien régime* of preemption rejected both by Congress and the Supreme Court. (2) The logic of Wells Pharma's position would undermine state sovereignty. Fortunately, (3) that logic has been repudiated in multiple throughlines of preemption and federalism precedent.

1

Adopting Wells Pharma's position would mark a return to the *ancien régime* of *Houston v. Moore*, 18 U.S. (5 Wheat.) 1 (1820). In *Houston*, Pennsylvania sought to punish a militiaman for refusing to respond when called into federal service "in pursuance of a requisition from the President of the United States" during the War of 1812. *Id.* at 3. The Pennsylvania law provided that any militiaman who "neglected or refused to serve when called into actual service, in pursuance of any order or requisition of the President of the United States," would "be liable to the

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been withdrawn under Section 505 of the [FDCA]."); CONN. GEN. STAT. § 21a-110(a) ("No person shall sell any new drug" that has not "been approved under Section 355 [§ 505 of the FDCA]."); COLO. REV. STAT. § 12-280-131(1) ("No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug not authorized to move in interstate commerce under appropriate federal law.").

penalties" set out in various "act[s] of the Congress of the United States." *Id.* at 2. In other words, the Pennsylvania law punished the failure to report precisely to the extent federal law did.

Justice Bushrod Washington concluded that the Pennsylvania law was preempted. Washington proclaimed that he could not even fathom how two parallel laws could *not* contradict: As he put it, "I am altogether incapable of comprehending how two distinct wills can, at the same time, be exercised in relation to the same subject, to be effectual, and at the same time compatible with each other." *Id.* at 23. Since the Pennsylvania law sought to act upon "the same subject" as the federal law, it could not be "compatible with" federal law. *Ibid.* Since it was not compatible with federal law, it was preempted.

But "the *Houston* rule was doomed" from the start. J.A.C. Grant, *The Scope and Nature of Concurrent Power*, 34 Colum. L. Rev. 995, 1012 (1934).

First, Washington's opinion "cannot be said to have spoken for the Court." David P. Currie, The Constitution in the Supreme Court: The First Hundred Years, 1789–1888, at 110 (1992). Although a majority agreed with Washington that the judgment should stand, Washington himself acknowledged that the other justices who formed the majority did "not concur in all respects in the reasons which influence[d] [his] opinion." *Houston*, 18 U.S. (5 Wheat.) at 32. Thus, as Justice Johnson explained in his concurrence, "there [was] no point whatever decided." *Id.* at 47 (Johnson, J., concurring). So Washington's opinion was not precedential.

Second, "the premise upon which" Washington "based" his opinion was "unsound." Grant, *supra*, at 1012. Washington's "assumption that two distinct wills [could] not, in the nature of things, be exercised in relation to the same subject at the same time" was "arid logic." *Ibid*. Washington himself thought that when two laws "correspond in every respect," as is the case when state law mirrors federal law, the state provision is only "idle and inoperative." *Houston*, 18 U.S. (5 Wheat.) at 23. A conflict occurs, thought Washington, only when the laws "differ." *Ibid*. But since an "idle" law is not a conflicting law, there is no reason to think it should be preempted even under Washington's own theory of preemption.

Regardless, a parallel state law would not be "idle." States may have a legitimate interest in punishing or providing redress for wrongs even if federal law already does so. The Federal Government is not the only one with an interest in criminalizing murder or rape. *See Zook*, 336 U.S. at 738 ("[T]he State may punish . . . for the safety and welfare of its inhabitants; the nation may punish for the safety and welfare of interstate commerce. There is no conflict."). Nor is it the only government with an interest in providing remedies for civil wrongs. *Cf. Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 249 (1984). Indeed, the Federal Government often has an interest in allowing parallel state regulation. For that reason, "the Federal Government fully supports [Zyla's] position," *Garcia*, 589 U.S. at 212, as it has shown by filing an amicus brief in a related case not long ago. *See* Brief for the United States as Amicus Curiae, *Athena Cosmetics, Inc. v. Allergan, Inc.*, 576 U.S. 1054 (2015) (No. 13-1379), 2015 WL 2457643. That should surprise no one. The Federal Government

has limited resources. Thus, it often welcomes state aid in enforcing shared legal norms.

And Washington's opinion has been thoroughly repudiated. Just a few years after *Houston*, Congress rejected its understanding of congressional intent. Congress passed a statute explaining that federal criminal legislation should not "be construed to deprive the courts of the individual state of jurisdiction," under their *own* parallel laws, "over offenses" that federal law also criminalized. *See* Crimes Act of 1825, ch. 65, § 26, 4 Stat. 115, 122–23; *see also United States v. Coombs*, 37 U.S. 72, 81 (1838).[4] And of course, *Zook* also rejected Washington's opinion. *See supra,* Part II.A (describing *Zook*); see also *Garcia*, 589 U.S. at 212.

4. True, *Houston* and the congressional response to it dealt only with parallel criminal laws. But if parallel criminal laws are not preempted, it follows *a fortiori* that parallel civil laws are not. Parallel criminal laws raise the concern that "enforcement officers are able to circumvent the constitutional guarantees against a second jeopardy for the same offense." Grant, *supra*, at 996–97; see also U.S. Const. amend. V (forbidding anyone from being "twice put in jeopardy of life or limb" "for the same offence"); *Gamble v. United States*, 587 U.S. 678, 681 (2019) (recognizing the dual-sovereignty doctrine which permits "a State [to] prosecute a defendant under state law even if the Federal Government has prosecuted him for the same conduct under a federal statute"). Because of these background constitutional norms, the arguments for interpreting federal law to preempt parallel criminal laws are much more forceful than they are for parallel civil laws, as Justice Bushrod Washington's opinion in *Houston* recognized. *See* 18 U.S. (5 Wheat.) at 23 (explaining that parallel laws were "particularly" concerning "in a case inflicting pains and penalties"). Constitutional concerns sounding in double jeopardy, of course, do not arise in the context of parallel civil laws.

The logic of Wells Pharma's position would undermine state sovereignty and principles of federalism. Start with Wells Pharma's theory. It contends the conflict comes from the FDCA's allocation of enforcement discretion to the Federal Government. In short, allowing States to enforce their own parallel laws would upset the discretion given to federal officials in enforcing the FDCA.

Now consider some of the state criminal laws Wells Pharma's theory would require us to find preempted. Federal law allocates exclusive enforcement discretion to the Federal Government over "offenses against the United States." *See* 28 U.S.C. § 547 (imposing enforcement duties upon the U.S. attorneys); 28 U.S.C. § 519 (granting the Attorney General authority to "supervise all" such "litigation"). And "[t]he district courts of the United States" have "exclusive" jurisdiction over such "offenses." 18 U.S.C. § 3231. Still, many state statutes incorporate federal criminal requirements. Such statutes touch on areas ranging from the most mundane,[5] to the constitutionally controversial,[6] to the classic

5. *See, e.g.*, Nev. Rev. Stat. § 193.340 ("A provider of Internet service who violates the provisions of 18 U.S.C. § 2703 is guilty of a misdemeanor"); Ky. Rev. Stat.§ 222.429 (barring "solicit[ing] or receiv[ing] any remuneration . . . for referring a resident to a treatment program" unless such conduct is permitted under 18 U.S.C. § 220 and conversely barring any conduct which violates 18 U.S.C. § 220(b)).

6. *See, e.g.*, N.M. Stat. § 30-7-7.1 (providing that a person generally cannot sell firearms "without conducting a federal instant background check" unless they "hold[] a current and

criminal.[7] All those laws, under Wells Pharma's theory, would be preempted because they purportedly undermine U.S. Attorneys' enforcement discretion.

Adopting Wells Pharma's theory would also undermine traditional state tort laws. For instance, violation of a federal statute often constitutes a breach of the duty of care under the negligence *per se* doctrine. *See* Restatement (Third) of Torts § 14 (2010); *see also Wiersgalla v. Garrett,* 486 N.W.2d 290, 292–93 (Iowa 1992) (acknowledging that violation of a federal statute or regulation may constitute negligence *per se*); Barbara Kritchevsky, *Tort Law Is State Law: Why Courts Should Distinguish State and Federal Law in Negligence-Per-Se Litigation*, 60 Am. U. L. Rev. 71, 91 (2010) (explaining that "[m]ost courts . . . find no distinction between state and federal law in applying the doctrine of negligence per se"). Under Wells Pharma's theory, that would be preempted in any case in which the federal statute at issue vests enforcement discretion in the federal government with limited state or private involvement.

Moreover, if the concern is that state law will interfere with federal enforcement discretion, it is not only parallel laws that should be preempted; any state laws that

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valid federal firearms license" under 18 U.S.C. § 923(a)); Tenn. Code § 39-17-1316(a)(1)(A)(iii) (barring selling firearms to anyone "ineligible to receive firearms under 18 U.S.C. § 922").

7. *See, e.g.*, Conn. Gen. Stat. §§ 21a-243(g)–(h), 279 (generally incorporating the Federal Controlled Substances Act); Mich. Comp. Laws §§ 333.7204, 7403 (similar).

regulate the same primary conduct as federal law should also be preempted. If anything, parallel standards, which ensure that the same primary conduct is regulated *in the same way*, pose reduced risk to federal enforcement priorities as compared to non-parallel standards, which regulate the same primary conduct *in different ways*. So under Wells Pharma's theory, any time a State regulates the same conduct that the Federal Government does, the state regulation should be preempted because it might upset federal enforcement prerogatives.

The implications are staggering. Given the extraordinary reach of federal law in our post-*Wickard* world, the Federal Government has its hands in nearly every facet of human existence. *See Wickard v. Filburn*, 317 U.S. 111 (1942); *see also Escobedo v. Ace Gathering*, Inc., No. 23-20494, 2024 WL 5443121, at *2 (5th Cir. Sept. 30, 2024) (Oldham, J., dissenting from denial of rehearing en banc). Under our circuit's precedent, for instance, the Federal Government may regulate "subterranean, eyeless arachnids, ranging in size from 1.4mm to 4mm, that are born, reproduce, and die without ever leaving a cave in Texas and have zero connection to economic activity of any kind." *Escobedo*, 2024 WL 5443121, at *2. So if Wells Pharma's theory is correct, the States would be deprived of just about any power to regulate any conduct at all, simply because of a judicial hunch concerning mysterious congressional purposes allegedly lurking in the bowels of the U.S. Code. Practically any conduct the State wants to regulate is already regulated by the Federal Government. So state regulation would be preempted. But as the Founders understood, one of the fundamental features

of sovereignty is the power to regulate "every thing that passes" within one's own territory. Emer de Vattel, The Law of Nations, § 204 (1797). So by preventing the States from regulating just about anything federal law touches, we judges would bring to fruition the Anti-Federalists' worst fear: the "entire subversion . . . of the individual states" to an all-powerful federal overlord. Brutus XI, ¶ 2.9.139, *in* 2 The Complete Anti-Federalist 420 (Herbert Storing ed., 1981) ("Storing"); *see also* Centinel II ¶ 2.7.17, *in* 2 Storing 141.

3

Fortunately for our federal system, Wells Pharma's logic has been rejected in at least four ways.

First, States may generally regulate the same conduct the Federal Government does. *See* Richard H. Fallon et al., Hart and Wechsler's Federal Courts and the Federal System 680 (7th ed. 2015); *see also Gamble v. United States*, 587 U.S. 678, 690 (2019). That is especially so when state standards mimic federal ones, as in this case. See *Zook*, 336 U.S. at 735.

Second, the "possibility that federal enforcement priorities might be upset is not enough to provide a basis for preemption." *Garcia*, 589 U.S. at 212.

Third, it is irrelevant that the States have provided remedies under state law that supplement the FDCA's remedial scheme. Providing redress for a civil wrong

under state law does not create a conflict with a distinct "federal remedial scheme." *Silkwood*, 464 U.S. at 257. State law often provides remedies federal law does not. *See California v. ARC Am. Corp.*, 490 U.S. 93 (1989) (permitting States to offer remedies to certain individuals under state antitrust laws despite federal antitrust law not providing any remedy to those same individuals).

Fourth, under *Wyeth v. Levine*, 555 U.S. 555 (2009), the FDCA itself permits States to regulate conduct related to drug safety and effectiveness concurrently with the Federal Government. In *Wyeth*, a Vermont court held a drug manufacturer liable under state tort law for failure to provide an adequate warning on its label for the drug Phenergan. *Id.* at 558. But "[t]he warnings on Phenergan's label had been deemed sufficient by the [FDA]." *Ibid.* So not only did the State and Federal Governments regulate the same con- duct; they did so in different ways.

Still, the Supreme Court held there was no conflict. *See id.* at 573–81. The Court reasoned as follows:

> If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express preemption provision at some point during the FDCA's 70-year history. But despite its 1976 enactment of an express preemption provision for medical devices, . . . Congress has not enacted such a provision for prescription drugs. Its silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful

> evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.

Id. at 574–75 (citations omitted). Simply put, "Congress did not regard state tort litigation as an obstacle to achieving its purposes." *Id.* at 575.

Thus, *Wyeth* foreclosed Wells Pharma's expansive theory of preemption in the specific context of the FDCA. The Court held that States could regulate concurrently with the Federal Government the same primary conduct related to drug safety and effectiveness in different ways without interfering with FDA oversight. If regulating the same primary conduct in different ways does not upset federal enforcement prerogatives, it follows *a fortiori* that regulating it in parallel ways does not either.

III

Wells Pharma's principal response is a single case: *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). But *Buckman* is not to the contrary.

A

In that case, plaintiffs brought state fraud claims against Buckman after sustaining injuries from FDA-approved bone screws. *Id.* at 343. They argued Buckman had made fraudulent representations to the FDA and those representations had induced the FDA to approve the bone screws. *Ibid.*

The Supreme Court held that the FDCA preempted these "state-law fraud-on-the-FDA claims." *Id.* at 348. The States had no role, the Supreme Court reasoned, in "[p]olicing fraud against federal agencies." *Id.* at 347. "To the contrary, the relationship between a federal agency and the entity it regulates is inherently federal in character." *Ibid.* And the FDCA gave ample methods to "the FDA to punish and deter fraud against the Administration." *Id.* at 348.

On this front, *Buckman* picked up where prior cases had left off. For instance, in *In re Loney*, 134 U.S. 372 (1890), the Supreme Court held that States had no power to punish perjury committed before a federal tribunal. As the Court explained, "the power of punishing a witness for testifying falsely in a judicial proceeding belongs peculiarly to the government in whose tribunals that proceeding is had." *Id.* at 375. Otherwise, it might deter "witnesses" from feeling "able to testify freely before them" because of "fear of punishment" or other form of liability under "legislation of the state." *Ibid.* Buckman recognized similar concerns. "[F]raud-on-the-FDA claims" under state law, the Court reasoned, would "cause applicants to fear that their disclosures to the FDA" would "later be judged insufficient in state court." *Buckman*, 531 U.S. at 351. As a result, applicants would "'submit a deluge of information that the [agency] neither wants nor needs, resulting in additional burdens on the [agency's] evaluation of an application,' and harmful delays in the agency process." *Chamber of Com. of U.S. v. Whiting*, 563 U.S. 582, 604 (2011) (quoting *Buckman*, 531 U.S. at 351). That would "directly interfere[] with the operation of the federal program." *Ibid.* (discussing *Buckman*).

The problem in *Buckman* had nothing to do with state law mirroring federal requirements; the state law at issue was ordinary, generally applicable fraud. Instead, the problem in Buckman was that the claim "involve[d]" a "uniquely federal area[] of regulation," since it alleged only "fraud on a federal agency." *Whiting*, 563 U.S. at 604 (discussing Buckman). In other words, the plaintiffs in *Buckman*, just like the States in *Loney*, sought to wield state law to vindicate a wrong committed a*gainst the Federal Government*. The plaintiffs were hurt by that wrongdoing only incidentally.

This case is different. No one here argues that Wells Pharma's wrong-doing was really committed against the Federal Government, like the fraud in Buckman or the perjury in *Loney*. Wells Pharma has not unfairly competed against the FDA, leading to some incidental harm to Zyla.

Moreover, Zyla is not policing the uniquely federal relationship between Wells Pharma and the FDA. So there is no reason to think that allowing Zyla's claims to proceed will "*directly interfere[]* with the operation of the federal program." *Whiting*, 563 U.S. at 604 (emphasis added). There is no sense in which any action "deemed appropriate by the Administration, will later be judged insufficient in state court." *Buckman*, 531 U.S. at 351. And Wells Pharma gives no reason to think allowing Zyla's claims to proceed would somehow "deluge" the FDA in unwanted "information"; result in harmful delays in the FDA's processing of applications; or deter applicants from seeking FDA approval. *Ibid*. In short, there is no reason to think allowing these claims to proceed will in

any sense upset any purposes and objectives of Congress whatsoever.

B

Wells Pharma points to certain language in *Buckman* about the preemptive effect of the FDCA's allocation of enforcement discretion to the Federal Government. But the Supreme Court's language, like all language, must be understood in context. And four aspects of that context make us doubt Wells Pharma's interpretation.

First, even *Buckman*'s most sweeping language fully accords with the analysis above when read in context: In context, *Buckman* holds that the FDCA's allocation of enforcement to the Federal Government forecloses non-federal actors from policing wrongdoing *against the Federal Government*. *See, e.g.*, *id.* at 348 ("The balance sought by the Administration can be skewed by allowing *fraud-on-the-FDA claims* under state tort law." (emphasis added)); *id.* at 349 ("The FDA thus has at its disposal a variety of enforcement options that allow it to make a measured response to suspected *fraud upon the Administration*." (emphasis added; footnote omitted)); *id.* at 350 ("State-law *fraud-on-the-FDA claims* inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." (emphasis added)).

Second, any broader reading of *Buckman* would conflict with the Court's more recent pronouncements in *Wyeth v. Levine*. Wyeth permitted distinct state

regulation under the FDCA. If that does not conflict with federal enforcement prerogatives, neither does parallel state regulation. *See supra*, at 14, 16.

Third, many federal statutes grant the Executive Branch extensive enforcement discretion.[8] But as we have explained, those statutes do not preclude parallel or non-parallel state regulation of the same conduct. If they were read to do so, the States' power over criminal and tort law would dissipate. *See supra*, Part II.B.2.

Fourth and finally, there is no way to maintain Wells Pharma's broad reading of *Buckman* while escaping these problems. *Buckman* cannot be artificially limited to cases where state law incorporates federal standards. *Buckman* itself was not such a case—rather the plaintiffs there sued under generally applicable tort law.

* * *

8. For this reason, 21 U.S.C. § 337(a) is beside the point. Section 337(a) only confers a cause of action upon the Federal Government to enforce the FDCA. That is necessary because otherwise the Federal Government's power to bring non-statutory actions to enforce federal law is unclear. *Cf., e.g.*, 3 Joseph Story, Commentaries on the Constitution of the United States § 1274, at 154 (Boston, Hilliard, Gray & Co. 1833) (noting that the Federal Government has a right to sue only if Congress statutorily authorizes it). Section 337(a) says nothing about the States' authority to provide remedies for violations of state law. *See ARC Am. Corp.*, 490 U.S. at 103 (explaining that offering a state remedy for conduct that violates both state and federal law does not "affect remedies available under federal law" but merely offers a separate remedy under state law for violations of state law).

For the foregoing reasons, the district court's order granting Wells Pharma's motion to dismiss is REVERSED. Wells Pharma's cross-appeal of the denial of its motion for an award of attorney's fees is DISMISSED AS MOOT. The district court's order denying Zyla's motion for leave to amend is VACATED. And the case is REMANDED for further proceedings consistent with this opinion.

APPENDIX H — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT, FILED MAY 2, 2025

UNITED STATES COURT OF APPEALS
FIFTH CIRCUIT

No. 23-20533

ZYLA LIFE SCIENCES, L.L.C.,

Plaintiff -Appellant/Cross-Appellee,

versus

WELLS PHARMA OF HOUSTON, L.L.C.,

Defendant-Appellee/Cross-Appellant.

Filed May 2, 2025

ORDER

Appeal from the United States District Court
for the Southern District of Texas
USDC No. 4:22-CV-4400

A judge of this Court withholds issuance of the mandate in this appeal.

/s/_____
Lyle W. Cayce, Clerk
United States Court of Appeals
for the Fifth Circuit

APPENDIX I — STATUTORY PROVISIONS INVOLVED

21 U.S.C.A. § 337

§ 337. Proceedings in name of United States; provision as to subpoenas

(a) Except as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States. Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any proceeding under this section.

(b)(1) A State may bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of section 341, 343(b), 343(c), 343(d), 343(e), 343(f), 343(g), 343(h), 343(i), 343(k), 343(q), or 343(r) of this title if the food that is the subject of the proceedings is located in the State.

(2) No proceeding may be commenced by a State under paragraph (1)—

(A) before 30 days after the State has given notice to the Secretary that the State intends to bring such proceeding,

(B) before 90 days after the State has given notice to the Secretary of such intent if the Secretary has, within such 30 days, commenced an informal or formal

enforcement action pertaining to the food which would be the subject of such proceeding, or

(C) if the Secretary is diligently prosecuting a proceeding in court pertaining to such food, has settled such proceeding, or has settled the informal or formal enforcement action pertaining to such food.

In any court proceeding described in subparagraph (C), a State may intervene as a matter of right.

Appendix I

21 U.S.C.A. § 353a

§ 353a. Pharmacy compounding

(a) In general

Sections 351(a)(2)(B), 352(f)(1), and 355 of this title shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient, if the drug product meets the requirements of this section, and if the compounding—

(1) is by—

(A) a licensed pharmacist in a State licensed pharmacy or a Federal facility, or

(B) a licensed physician,

on the prescription order for such individual patient made by a licensed physician or other licensed practitioner authorized by State law to prescribe drugs; or

(2)(A) is by a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient; and

(B) is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders

for the compounding of the drug product, which orders have been generated solely within an established relationship between—

(i) the licensed pharmacist or licensed physician; and

(ii)(I) such individual patient for whom the prescription order will be provided; or

(II) the physician or other licensed practitioner who will write such prescription order.

(b) Compounded drug

(1) Licensed pharmacist and licensed physician

A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician—

(A) compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations—

(i) that—

(I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

(II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or

(III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (c);

(ii) that are manufactured by an establishment that is registered under section 360 of this title (including a foreign establishment that is registered under section 360(i) of this title); and

(iii) that are accompanied by valid certificates of analysis for each bulk drug substance;

(B) compounds the drug product using ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

(C) does not compound a drug product that appears on a list published by the Secretary in the Federal Register of drug products that have been withdrawn or removed from the market because such drug products or components of such drug

products have been found to be unsafe or not effective; and

(D) does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product.

(2) Definition

For purposes of paragraph (1)(D), the term "essentially a copy of a commercially available drug product" does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product.

(3) Drug product

A drug product may be compounded under subsection (a) only if—

(A) such drug product is not a drug product identified by the Secretary by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product; and

(B) such drug product is compounded in a State—

(i) that has entered into a memorandum of understanding with the Secretary which addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State; or

(ii) that has not entered into the memorandum of understanding described in clause (i) and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician.

The Secretary shall, in consultation with the National Association of Boards of Pharmacy, develop a standard memorandum of understanding for use by the States in complying with subparagraph (B)(i).

(c) Regulations

(1) In general

The Secretary shall issue regulations to implement this section. Before issuing regulations to implement subsections (b)(1) (A)(i)(III), (b)(1)(C), or (b)(3)(A),

the Secretary shall convene and consult an advisory committee on compounding unless the Secretary determines that the issuance of such regulations before consultation is necessary to protect the public health. The advisory committee shall include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopoeia, pharmacy, physician, and consumer organizations, and other experts selected by the Secretary.

(2) Limiting compounding

The Secretary, in consultation with the United States Pharmacopoeia Convention, Incorporated, shall promulgate regulations identifying drug substances that may be used in compounding under subsection (b)(1)(A)(i)(III) for which a monograph does not exist or which are not components of drug products approved by the Secretary. The Secretary shall include in the regulation the criteria for such substances, which shall include historical use, reports in peer reviewed medical literature, or other criteria the Secretary may identify.

(d) Application

This section shall not apply to—

(1) compounded positron emission tomography drugs as defined in section 321 (ii) of this title; or

(2) radiopharmaceuticals.

(e) "Compounding" defined

As used in this section, the term "compounding" does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.

(f) Redesignated (e)

Appendix I

21 U.S.C.A. § 353b

§ 353b. Outsourcing facilities

(a) In general

Sections 352(f)(1), 355, and 360eee-1 of this title shall not apply to a drug compounded by or under the direct supervision of a licensed pharmacist in a facility that elects to register as an outsourcing facility if each of the following conditions is met:

(1) Registration and reporting

The drug is compounded in an outsourcing facility that is in compliance with the requirements of subsection (b).

(2) Bulk drug substances

The drug is compounded in an outsourcing facility that does not compound using bulk drug substances (as defined in section 207.3(a)(4) of title 21, Code of Federal Regulations (or any successor regulation)), unless—

(A)(i) the bulk drug substance appears on a list established by the Secretary identifying bulk drug substances for which there is a clinical need, by—

(I) publishing a notice in the Federal Register proposing bulk drug substances to be included on the list, including the rationale for such proposal;

(II) providing a period of not less than 60 calendar days for comment on the notice; and

(III) publishing a notice in the Federal Register designating bulk drug substances for inclusion on the list; or

(ii) the drug compounded from such bulk drug substance appears on the drug shortage list in effect under section 356e of this title at the time of compounding, distribution, and dispensing;

(B) if an applicable monograph exists under the United States Pharmacopeia, the National Formulary, or another compendium or pharmacopeia recognized by the Secretary for purposes of this paragraph, the bulk drug substances each comply with the monograph;

(C) the bulk drug substances are each manufactured by an establishment that is registered under section 360 of this title (including a foreign establishment that is registered under section 360(i) of this title); and

(D) the bulk drug substances are each accompanied by a valid certificate of analysis.

(3) Ingredients (other than bulk drug substances)

If any ingredients (other than bulk drug substances) are used in compounding the drug, such ingredients comply

with the standards of the applicable United States Pharmacopeia or National Formulary monograph, if such monograph exists, or of another compendium or pharmacopeia recognized by the Secretary for purposes of this paragraph if any.

(4) Drugs withdrawn or removed because unsafe or not effective

The drug does not appear on a list published by the Secretary of drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective.

(5) Essentially a copy of an approved drug

The drug is not essentially a copy of one or more approved drugs.

(6) Drugs presenting demonstrable difficulties for compounding

The drug—

> (A) is not identified (directly or as part of a category of drugs) on a list published by the Secretary, through the process described in subsection (c), of drugs or categories of drugs that present demonstrable difficulties for compounding that are reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug or category of

drugs, taking into account the risks and benefits to patients; or

(B) is compounded in accordance with all applicable conditions identified on the list described in subparagraph (A) as conditions that are necessary to prevent the drug or category of drugs from presenting the demonstrable difficulties described in subparagraph (A).

(7) Elements to assure safe use

In the case of a drug that is compounded from a drug that is the subject of a risk evaluation and mitigation strategy approved with elements to assure safe use pursuant to section 355-1 of this title, or from a bulk drug substance that is a component of such drug, the outsourcing facility demonstrates to the Secretary prior to beginning compounding that such facility will utilize controls comparable to the controls applicable under the relevant risk evaluation and mitigation strategy.

(8) **Prohibition on wholesaling**

The drug will not be sold or transferred by an entity other than the outsourcing facility that compounded such drug. This paragraph does not prohibit administration of a drug in a health care setting or dispensing a drug pursuant to a prescription executed in accordance with section 353(b)(1) of this title.

(9) Fees

The drug is compounded in an outsourcing facility that has paid all fees owed by such facility pursuant to section 379j-62 of this title.

(10) Labeling of drugs

(A) Label

The label of the drug includes—

(i) the statement "This is a compounded drug." or a reasonable comparable alternative statement (as specified by the Secretary) that prominently identifies the drug as a compounded drug;

(ii) the name, address, and phone number of the applicable outsourcing facility; and

(iii) with respect to the drug—

(I) the lot or batch number;

(II) the established name of the drug;

(III) the dosage form and strength;

(IV) the statement of quantity or volume, as appropriate;

(V) the date that the drug was compounded;

(VI) the expiration date;

(VII) storage and handling instructions;

(VIII) the National Drug Code number, if available;

(IX) the statement "Not for resale", and, if the drug is dispensed or distributed other than pursuant to a prescription for an individual identified patient, the statement "Office Use Only"; and

(X) subject to subparagraph (B)(i), a list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient.

(B) Container

The container from which the individual units of the drug are removed for dispensing or for administration (such as a plastic bag containing individual product syringes) shall include—

(i) the information described under subparagraph (A)(iii)(X), if there is not space on the label for such information;

(ii) the following information to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088 (or any successor Internet Web site or phone number); and

(iii) directions for use, including, as appropriate, dosage and administration.

(C) Additional information

The label and labeling of the drug shall include any other information as determined necessary and specified in regulations promulgated by the Secretary.

(11) Outsourcing facility requirement

The drug is compounded in an outsourcing facility in which the compounding of drugs occurs only in accordance with this section.

(b) Registration of outsourcing facilities and reporting of drugs

(1) Registration of outsourcing facilities

(A) Annual registration

Upon electing and in order to become an outsourcing facility, and during the period beginning on October 1 and ending on December 31 of each year thereafter, a facility—

(i) shall register with the Secretary its name, place of business, and unique facility identifier (which shall conform to the requirements for the unique facility identifier established under

section 360 of this title), and a point of contact email address; and

(ii) shall indicate whether the outsourcing facility intends to compound a drug that appears on the list in effect under section 356e of this title during the subsequent calendar year.

(B) Availability of registration for inspection; list

(i) Registrations

The Secretary shall make available for inspection, to any person so requesting, any registration filed pursuant to this paragraph.

(ii) List

The Secretary shall make available on the public Internet Web site of the Food and Drug Administration a list of the name of each facility registered under this subsection as an outsourcing facility, the State in which each such facility is located, whether the facility compounds from bulk drug substances, and whether any such compounding from bulk drug substances is for sterile or nonsterile drugs.

(2) Drug reporting by outsourcing facilities

(A) In general

Upon initially registering as an outsourcing facility, once during the month of June of each year, and once during the month of December of each year, each outsourcing facility that registers with the Secretary under paragraph (1) shall submit to the Secretary a report—

(i) identifying the drugs compounded by such outsourcing facility during the previous 6-month period; and

(ii) with respect to each drug identified under clause (i), providing the active ingredient, the source of such active ingredient, the National Drug Code number of the source drug or bulk active ingredient, if available, the strength of the active ingredient per unit, the dosage form and route of administration, the package description, the number of individual units produced, and the National Drug Code number of the final product, if assigned.

(B) Form

Each report under subparagraph (A) shall be prepared in such form and manner as the Secretary may prescribe by regulation or guidance.

(C) Confidentiality

Reports submitted under this paragraph shall be exempt from inspection under paragraph (1)(B)(i), unless the Secretary finds that such an exemption would be inconsistent with the protection of the public health.

(3) Electronic registration and reporting

Registrations and drug reporting under this subsection (including the submission of updated information) shall be submitted to the Secretary by electronic means unless the Secretary grants a request for waiver of such requirement because use of electronic means is not reasonable for the person requesting waiver.

(4) Risk-based inspection frequency

(A) In general

Outsourcing facilities—

(i) shall be subject to inspection pursuant to section 374 of this title; and

(ii) shall not be eligible for the exemption under section 374(a)(2)(A) of this title.

(B) Risk-based schedule

The Secretary, acting through one or more officers or employees duly designated by the Secretary,

shall inspect outsourcing facilities in accordance with a risk-based schedule established by the Secretary.

(C) Risk factors

In establishing the risk-based schedule, the Secretary shall inspect outsourcing facilities according to the known safety risks of such outsourcing facilities, which shall be based on the following factors:

(i) The compliance history of the outsourcing facility.

(ii) The record, history, and nature of recalls linked to the outsourcing facility.

(iii) The inherent risk of the drugs compounded at the outsourcing facility.

(iv) The inspection frequency and history of the outsourcing facility, including whether the outsourcing facility has been inspected pursuant to section 374 of this title within the last 4 years.

(v) Whether the outsourcing facility has registered under this paragraph as an entity that intends to compound a drug that appears on the list in effect under section 356e of this title.

(vi) Any other criteria deemed necessary and appropriate by the Secretary for purposes of allocating inspection resources.

(5) Adverse event reporting

Outsourcing facilities shall submit adverse event reports to the Secretary in accordance with the content and format requirements established through guidance or regulation under section 310.305 of title 21, Code of Federal Regulations (or any successor regulations).

(c) Regulations

(1) In general

The Secretary shall implement the list described in subsection (a)(6) through regulations.

(2) Advisory committee on compounding

Before issuing regulations to implement subsection (a)(6), the Secretary shall convene and consult an advisory committee on compounding. The advisory committee shall include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopeia, pharmacists with current experience and expertise in compounding, physicians with background and knowledge in compounding, and patient and public health advocacy organizations.

(3) Interim list

(A) In general

Before the effective date of the regulations finalized to implement subsection (a)(6), the Secretary may designate drugs, categories of drugs, or conditions as described such[1] subsection by—

(i) publishing a notice of such substances, drugs, categories of drugs, or conditions proposed for designation, including the rationale for such designation, in the Federal Register;

(ii) providing a period of not less than 60 calendar days for comment on the notice; and

(iii) publishing a notice in the Federal Register designating such drugs, categories of drugs, or conditions.

(B) Sunset of notice

Any notice provided under subparagraph (A) shall not be effective after the earlier of—

(i) the date that is 5 years after November 27, 2013; or

(ii) the effective date of the final regulations issued to implement subsection (a)(6).

1. So in original.

(4) Updates

The Secretary shall review, and update as necessary, the regulations containing the lists of drugs, categories of drugs, or conditions described in subsection (a)(6) regularly, but not less than once every 4 years. Nothing in the previous sentence prohibits submissions to the Secretary, before or during any 4-year period described in such sentence, requesting updates to such lists.

(d)[2] **Definitions**

In this section:

(1) The term "compounding" includes the combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering of a drug or bulk drug substance to create a drug.

(2) The term "essentially a copy of an approved drug" means—

(A) a drug that is identical or nearly identical to an approved drug, or a marketed drug not subject to section 353(b) of this title and not subject to approval in an application submitted under section 355 of this title, unless, in the case of an approved drug, the drug appears on the drug shortage list in effect under section 356e of this title at the time of compounding, distribution, and dispensing; or

(B) a drug, a component of which is a bulk drug substance that is a component of an approved drug or a marketed drug that is not subject to section 353(b) of this title and not subject to approval in an application submitted under section 355 of this title, unless there is a change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug.

(3) The term "approved drug" means a drug that is approved under section 355 of this title and does not appear on the list described in subsection (a)(4) of drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective.

(4)(A) The term "outsourcing facility" means a facility at one geographic location or address that—

(i) is engaged in the compounding of sterile drugs;

(ii) has elected to register as an outsourcing facility; and

(iii) complies with all of the requirements of this section.

(B) An outsourcing facility is not required to be a licensed pharmacy.

(C) An outsourcing facility may or may not obtain prescriptions for identified individual patients.

(5) The term "sterile drug" means a drug that is intended for parenteral administration, an ophthalmic or oral inhalation drug in aqueous format, or a drug that is required to be sterile under Federal or State law.

(d)[2] Obligation to pay fees

Payment of the fee under section 379j-62 of this title, as described in subsection (a)(9), shall not relieve an outsourcing facility that is licensed as a pharmacy in any State that requires pharmacy licensing fees of its obligation to pay such State fees.

2. So in original. Two subsecs. (d) have been enacted.