NO. 25-257

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 Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

BRIEF IN OPPOSITION

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QUESTION PRESENTED

Whether the Federal Food, Drug & Cosmetic Act ("FDCA") preempts state laws prohibiting the in-state sale of unapproved drugs whose sale is also prohibited as a matter of federal law by the FDCA.

CORPORATE DISCLOSURE

Respondent Zyla Life Sciences, LLC ("Zyla") is wholly owned by Assertio Holdings, Inc, which is a publicly traded corporation.

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BRIEF IN OPPOSITION

Petitioner Wells Pharma of Houston L.L.C. asks this Court to review a question not presented in this case based on mischaracterizations of the decision below. That Wells Pharma feels the need to fabricate a decision the Fifth Circuit did not make confirms the decision below presents no basis for this Court's review.

In Wells Pharma's telling, the Fifth Circuit held that Zyla may enforce state laws requiring premarket approval against lawfully compounded drugs exempt from the FDCA's premarket-approval requirement. Wells Pharma's question presented thus assumes that its drug is exempt from federal premarket approval because Wells Pharma is an "outsourcing facilit[y]." Pet.i. And the petition repeatedly asserts, based on that premise, that the Fifth Circuit approved Zyla's claims even though they "add to" the FDCA's requirements. *E.g.*, Pet.2, 3, 4.

All of that is fiction. The FDCA exempts a drug made by an outsourcing facility from premarket approval if, and only if, the drug complies with "each" of eleven statutory requirements. 21 U.S.C. § 353b(a)(1)–(11). The Fifth Circuit explained that whether Wells Pharma's drug is exempt from approval is "a big if" because at this early stage of the litigation it "cannot have proven that it satisfies § 353b's many requirements." App.8a–9a n.2. Wells Pharma's petition does not even acknowledge this holding. Instead, the petition repeats ad nauseam the falsehood that Wells Pharma is exempt from the FDCA's premarket approval requirement by virtue of its status as an outsourcing facility. *E.g.*, Pet.8, 13, 14,

18, 19. Moreover, as the Fifth Circuit held and Zyla has made clear at every stage of this case, Zyla seeks to enforce state drug-approval laws only to the extent that Wells Pharma's drug is *not* lawfully compounded and thus *not* exempt from federal premarket approval. In other words, the only way Wells Pharma will be liable on Zyla's state-law claims is if Wells Pharma's drug is illegal under both state *and* federal law.

As the Fifth Circuit recognized, the only "question presented" in this case is "whether a State triggers implied obstacles-and-purposes preemption when it expressly incorporates federal law into state law." App.1a. Under a near-century of this Court's precedent, the clear answer is "no." App.1a–2a (citing *California v. Zook*, 336 U.S. 725, 735 (1949)). No conflict between state and federal law means no conflict preemption.

Wells Pharma's petition also alternates incoherently between contending that Zyla's state-law claims are preempted because they "add to" FDCA requirements and contending that Zyla's claims are preempted under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), because they "are premised on alleged FDCA violations." Pet.2. The first contention is false: for the reasons just discussed, Zyla's claims are parallel to federal law and "add" no requirements. The second contention is meritless: if the very parallelism of Zyla's claims—the absence of any conflict—meant they are preempted, then the FDCA would occupy the field of prescription-drug regulation. But this Court has held the contrary. *Wyeth v. Levine*, 555 U.S. 555 (2009).

Neither version of Wells Pharma's argument warrants this Court's attention. The question whether state-law claims that "add to" federal requirements for compounded drugs are preempted is irrelevant because this case does not involve any such claims. And the question whether state-law claims that do *not* add to federal requirements for compounded drugs are nonetheless preempted does not implicate any review-worthy circuit split. Indeed, this Court has previously denied multiple petitions seeking review of that and closely related questions. *Hope Med. Enters., Inc. v. Fagron Compounding Servs., LLC*, 144 S. Ct. 2560 (2024) (mem.); *Athena Cosmetics, Inc. v. Allergan, Inc.*, 576 U.S. 1054 (2015) (mem.); *Albertson's, Inc. v. Kanter*, 555 U.S. 1097 (2009) (mem.). Nothing in Wells Pharma's petition justifies a different outcome here.

STATEMENT

A. Legal background

1. At the Founding, the power to regulate the in-state sale of drugs not reviewed for safety or approved by any government body belonged exclusively to the States. *Wyeth v. Levine*, 555 U.S. 555, 566 (2009). The federal government first began reviewing drugs before sale in 1938 when Congress passed the FDCA, with its "provision for premarket approval of new drugs." *Id.* The premarket approval requirement provides that "[n]o person" may "introduce or deliver for introduction into interstate commerce any new drug" unless FDA has first "approv[ed]" an "application." 21 U.S.C. § 355(a). The premarket approval requirement "protect[s] the public health" by "assur[ing] the safety, effectiveness, and reliability of drugs." *Wyeth*, 555 U.S. at 567 (cleaned up).

The Court has explained that the FDCA "supplemented" but did not override the "protection for consumers already provided by state regulation." *Id.* at 566. While expanding FDA's authority, Congress still "took care to preserve state law." *Id.* at 567. The original FDCA presumed that States would regulate drug sales alongside the federal government. *See* Pub. L. No. 75-717, ch. 675, § 304(d), 52 Stat. 1040, 1045 (1938) (providing that certain drugs "shall not be sold or disposed of contrary to the provisions of this Act *or the laws of any State* … in which sold" (emphasis added)). Congress has never enacted an express-preemption provision for state laws regulating prescription drugs (unlike for certain other products regulated by FDA). *Wyeth*, 555 U.S. at 574. State and federal drug regulations have thus "coexiste[d]" for the FDCA's entire 87-year history. *Id.* at 581.

Most States have enacted laws that prohibit the in-state sale of a drug that has not received premarket approval from FDA or an appropriate state agency.[1]

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[1] Alaska Stat. § 17.20.110(a)(1); Ariz. Rev. Stat. § 32-1962; Ark. Code §§ 20-56-202(1)(E), 20-56-215(1); Cal. Health & Safety Code § 111550; Colo. Rev. Stat. § 12-280-131(1); Conn. Gen. Stat. § 21a-110; Fla. Stat. § 499.023; Ga. Code Ann. § 26-3-10; Haw. Rev. Stat. § 328-17; Idaho Code § 37-128; 410 Ill. Comp. Stat. 620/17; Ind. Code § 16-42-3-7; Iowa Code § 126.12; Kan. Stat. § 65-669a; Ky. Rev. Stat. Ann. § 217.075; Md. Code Ann., Health-Gen. § 21-223; Mich. Comp. Laws § 333.7402(1); Mo. Rev. Stat. § 196.105; Mont. Code Ann. § 50-31-311; Nev. Rev. Stat. § 585.490; N.J. Stat. Ann. § 24:6A-1; N.M. Stat. Ann. § 26-1-14; N.Y. Educ. Law § 6817(1)(a); N.C. Gen. Stat. § 106-135; N.D. Cent. Code § 19-02.1-16; Ohio Rev. Code Ann. § 3715.65; Or. Rev. Stat. § 689.135(13); 35 Pa. Cons. Stat. § 780-113(36); R.I. Gen. Laws § 21-31-16; S.C. Code Ann. § 39-23-70; Tenn. Code Ann.

And several States have "act[ed] within [their] historic[al] purview to regulate health and safety" by "authorizing private suits to enjoin the intrastate distribution, sale, and marketing of an unapproved drug." U.S. Br. as Amicus Curiae 16–17, *Athena*, 576 U.S. 1054 (No. 13-1379), 2015 WL 2457643 ("U.S. *Athena* Br.").

This case involves the drug-approval laws of six States: California, Connecticut, Colorado, Florida, South Carolina, and Tennessee. Cal. Health & Safety Code § 111550(a)–(b); Colo. Rev. Stat. § 12-280-131; Conn. Gen. Stat. § 21a-110; Fla. Stat. § 499.023; S.C. Code Ann. § 39-23-70(a); Tenn. Code Ann. § 53-1-110. As part of the "long history of state common-law and statutory remedies against … unfair business practices," *California v. ARC Am. Corp.*, 490 U.S. 93, 101 (1989), these States have also enacted unfair-trade-practice laws that allow private litigants to sue based on violations of other state laws. Cal. Bus. & Prof. Code § 17200; Colo. Rev. Stat. § 6-1-105(z); Conn. Gen. Stat. § 42-110b; Fla. Stat. §§ 501.203, 501.204, 501.211; S.C. Code Ann. §§ 39-5-20, 39-23-70; Tenn. Code Ann. § 47-18-104.

2. The FDCA contains an exception to its premarket approval requirement for lawfully "compounded" drugs. 21 U.S.C. §§ 353a, 353b. Traditionally, "compounding" referred to a pharmacist's "combin[ing], mix[ing], or alter[ing]

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§ 53-1-110; Tex. Health & Safety Code Ann. § 431.114; Vt. Stat. Ann. tit. 18, § 4065; Va. Code § 54.1-3421; Wash. Rev. Code § 69.04.570; Wyo. Stat. Ann. § 35-7-118; *see also* 10 Guam Code Ann. § 40117; P.R. Laws Ann. tit. 24, § 726.

ingredients to create a medication tailored to the needs of an individual patient." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 360–61 (2002). This case has nothing to do with such traditional patient-specific compounding. Instead, the case illustrates the danger that "compounding," if not appropriately confined, can become large-scale manufacturing of unapproved drugs.

The practice of pharmacy, like other professions, was traditionally the province of state, not federal, regulation, and until the early 1990s "FDA generally left regulation of compounding to the States." *Id.* at 361–62. But "FDA eventually became concerned" that "pharmacists were manufacturing and selling drugs under the guise of compounding, thereby avoiding the FDCA's new drug requirements." *Id.* And in 2012, a mass outbreak of deadly meningitis caused by contaminated compounded drugs led Congress to amend and add to the FDCA provisions relating to compounding. ROA.45.[2]

Those provisions—§ 503A and § 503B—impose requirements for different kinds of compounding that, *when satisfied*, exempt a drug from premarket approval. 21 U.S.C. §§ 353a, 353b. Section 503A applies to traditional compounders, such as individual licensed pharmacists and physicians working within a licensed pharmacy. It is not at issue in this case. Section 503B applies to "outsourcing facilities," a new

[2] "ROA" citations refer to the district court record distinctly paginated for the appeal. Unless otherwise noted, all record citations are compiled in the Record Excerpts in the Fifth Circuit. *See* COA.Dkt.33.

category of drug producer that, unlike traditional compounders, may produce large quantities of standardized drugs under strictly limited circumstances. *Id.* § 353b. Merely being registered as an outsourcing facility is not enough "to qualify for the exemptions under section 503B." FDA, *Questions and Answers: Outsourcing Facility Registration* (July 2, 2019), http://tinyurl.com/4aec78m3; App.6a. Rather, to be exempt from premarket approval, a drug made at an outsourcing facility must satisfy "each" of eleven distinct conditions. 21 U.S.C. § 353b(a)(1)–(11).

For example, an outsourcing facility may not "compound using bulk drug substances" unless either: (1) the bulk drug substance "appears on a list established by [FDA] identifying bulk drug substances for which there is a clinical need" under § 503B; or (2) the "drug compounded from such bulk drug substance appears on [FDA's] drug shortage list." 21 U.S.C. § 353b(a)(2); *see Azurity Pharms., Inc. v. Edge Pharma, LLC*, 45 F.4th 479, 501 (1st Cir. 2022). In this way, outsourcing facilities may fill gaps but do not displace FDA-approved drugs. *See* FDA, Guidance for Industry: Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act 4–6 (Mar. 2019), *available at* https://tinyurl.com/ynpaap64.

Sections 503A and 503B did not abrogate the States' historical authority to regulate compounding. The FDCA itself contemplates cooperation between FDA and States in the regulation of compounding. *See* 21 U.S.C. § 353a(b)(3)(B). And Wells Pharma concedes that States, including the six States at issue in this

case, continue to regulate compounding. Pet.6; *see* Pew Charitable Trs., State Oversight of Drug Compounding (Feb. 2018), *available at* http://tinyurl.com/2nvus45j.

3. The FDCA does not provide a private right of action. *Wyeth*, 555 U.S. at 574. The lack of a private FDCA right of action is spelled out in the statute's standing provision, which states that "proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." 21 U.S.C. § 337(a).

Notwithstanding § 337(a), the FDCA contains no preemption provision for state laws regulating prescription drugs. *Wyeth*, 555 U.S. at 574. Thus, although private plaintiffs may not bring a private right of action directly under the FDCA, *see Buckman*, 531 U.S. at 349 n.4, section 337(a) neither prohibits States from enacting laws that incorporate or parallel the FDCA's requirements nor bars private claims brought under such state laws.

Courts have long held that the FDCA does not preempt state laws like those at issue here. *E.g.*, *Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350, 1354–56 (Fed. Cir. 2013), *cert. denied*, 576 U.S. 1054; *Farm Raised Salmon Cases*, 175 P.3d 1170, 1181–84 (Cal. 2008), *cert. denied sub nom. Albertson's*, 555 U.S. 1097. The United States agrees that such parallel state laws are not preempted, as the Solicitor General explained in briefs filed in both of those cases in response to this Court's invitation. U.S. *Athena* Br. 8–17; U.S. Br. as Amicus Curiae 8–20, *Albertson's*, 555 U.S. 1097 (No. 07-1327), 2008 WL 5151069 (U.S. *Albertson's* Br.).

B. This litigation

1. Zyla and Wells Pharma sell competing indomethacin suppositories to treat rheumatoid arthritis. ROA.46. Zyla's Indocin® Suppositories were approved by FDA in 1992. ROA.47. Wells Pharma's drug, in contrast, has never been reviewed or approved as safe and effective by FDA or any relevant state agency. ROA.49–50.

Zyla's complaint alleges that Wells Pharma violates six States' unfair-competition laws by selling its unapproved drug in those States in violation of those States' drug-approval statutes. ROA.51–58. All six States prohibit the sale of drugs that have not been approved or otherwise authorized for sale by FDA and permit violations of those drug-approval requirements to be enforced through the States' unfair-competition laws. ROA.47–51. By selling its unapproved drug in the six States, therefore, Wells Pharma unlawfully competes with Zyla. ROA.50–51.

Wells Pharma contends that its unapproved drug is exempt from FDA premarket approval because it is "compounded" from the bulk drug substance indomethacin under § 503B. D.Ct.Dkt.20 at ROA.76. Zyla understands Wells Pharma's claim that § 503B exempts its drug from premarket approval to be an affirmative defense. ROA.103. For that reason, Zyla was not required to proactively allege Wells Pharma's noncompliance with § 503B. *See Perry v. Merit Sys. Prot. Bd.*, 582 U.S. 420, 435 n.9 (2017) (plaintiffs need not "anticipate and negate" affirmative defenses). However, Zyla has consistently made clear that it was prepared to allege, based on evidence in its possession, that Wells Pharma's drug does *not* comply with

§ 503B. ROA.104–105, 116. Most obviously, it is undisputed that Wells Pharma uses the "bulk drug substance" indomethacin, but indomethacin has never appeared on FDA's 503B "clinical need" list and Zyla's FDA-approved drug has never appeared on FDA's drug shortage list. ROA.47, 105.[3] Wells Pharma, far from being a legitimate compounder, uses a claim of "compounding" as a smokescreen for the illegal mass production of unapproved and potentially unsafe drugs.

2. Wells Pharma moved to dismiss Zyla's claims as impliedly preempted by the FDCA, arguing that Zyla seeks to impose state premarket approval requirements on drugs that are exempt from premarket approval under § 503B. Wells Pharma argued that its registration as a 503B outsourcing facility exempted its unapproved drug from premarket approval. D.Ct.Dkt.20 at ROA.75–76.

In response, Zyla explained that Wells Pharma's mere registration under § 503B does not exempt its drugs from premarket approval. ROA.103–104. Section 503B's exemption, rather, turns on whether Wells Pharma's drugs comply with all of § 503B's requirements—a factual question that cannot be

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[3] *See* FDA, *503B Bulk Drug Substances List* (May 16, 2024), https://www.fda.gov/drugs/human-drug-compounding/503b-bulk-drug-substances-list; FDA, *Drug Shortages List*, https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm. In August 2023, FDA (at Wells Pharma's request) placed indomethacin on its "category 1" list of bulk drug substances it is considering for the 503B clinical need list. But that cannot help Wells Pharma, which unlawfully used bulk indomethacin long before August 2023. D.Ct.Dkt.50 at ROA.437–440.

resolved in Wells Pharma's favor on a motion to dismiss. Zyla, moreover, made clear that it seeks to enforce state drug-approval requirements only to the extent they are identical to the FDCA's requirements. ROA.105. As a result, while Zyla is confident that Wells Pharma's § 503B-compliance defense will fail as a factual matter, Zyla has conceded that Wells Pharma faces no risk of state-law liability if its drug is exempt from premarket approval under § 503B. ROA.103–105.

The district court granted Wells Pharma's motion on the basis of implied conflict preemption. App.60a. Specifically, the court found that Zyla's claims would improperly "add[]" premarket approval requirements that do not exist under the FDCA. App.62a–63a. To make that finding, the court concluded that a facility registered under § 503B is exempt from premarket approval for all of its drugs simply by virtue of its registration. App.54a–55a, 62a–64a. The court thus did not address whether Wells Pharma's drug actually complies with § 503B's requirements. App.54a–55a, 62a–63a. Instead, the court held that all state drug-approval laws are preempted because they "require compounding facilities to obtain premarket approval," which the court categorically concluded "is not a requirement under the FDCA." App.65a.

The district court also denied leave to amend as futile. App.64a–65a. The court held that § 337(a) would preempt Zyla's claims "[e]ven if" Wells Pharma does not "compl[y] with the FDCA's compounding requirements." App.64a.

3. The Fifth Circuit reversed in a unanimous opinion authored by Judge Oldham.

The Fifth Circuit began by succinctly stating the "question presented": "whether a State triggers implied obstacles-and-purposes preemption when it expressly incorporates federal law into state law." App.1a. The Fifth Circuit corrected the district court's error in concluding, based on an assumption that Wells Pharma complies with § 503B, that Zyla's claims would "add[] to federal requirements." App.8a–9a n.2. As the Fifth Circuit recognized, "registration alone is not enough for a facility to sell compounded drugs without premarket approval." App.6a. Instead, the facility "must satisfy a host of additional statutory criteria." App.6a. The state drug-approval laws under which Zyla sues would "impose additional requirements as to Wells Pharma … only if Wells Pharma satisfies the many requirements of [§ 503B]," a factual question that cannot be resolved in Wells Pharma's favor on a motion to dismiss. App.8a–9a n.2. (emphasis omitted).

The only question before the Fifth Circuit, therefore, was whether the FDCA conflicts with state drug-approval laws that impose the same drug-approval requirement as the FDCA. App.8a–9a. The Fifth Circuit answered that question through a scholarly overview of preemption law, focusing on this Court's decision in *Zook*. App.9a–20a. In *Zook*, the Court rejected an implied-preemption challenge to a state licensing law that incorporated the requirements of an "identical" federal statute. App.9a–10a (citing *Zook*, 336 U.S. at 726–27). The Court held there was "no conflict in terms, and no possibility of such conflict, for the state statute ma[de] federal law its own." *Zook*, 336 U.S. at 735.

The Fifth Circuit concluded that "*Zook* controls this case." App.9a. As in *Zook*, the state drug-approval laws at issue "all 'make federal law their own'" by prohibiting the in-state sale of drugs that do not satisfy the FDCA's drug-approval requirement. App.11a (alterations omitted) (quoting *Zook*, 336 U.S. at 735). Because those state laws, as enforced in this case, impose the same drug-approval requirement as the FDCA, "there can be 'no conflict in terms' and no preemption." App.11a (quoting *Zook*, 336 U.S. at 735).

The Fifth Circuit found further support for its conclusion in this Court's more recent preemption cases. For example, this Court held in *Wyeth* that "the FDCA itself permits States to regulate conduct related to drug safety and effectiveness concurrently with the Federal Government" because Congress did not "th[ink] state-law suits posed an obstacle to [the FDCA's] objectives." App.19a–20a (quoting *Wyeth*, 555 U.S. at 574–75). Similarly, the Court held in *Kansas v. Garcia*, 589 U.S. 191, 212 (2020), that "the 'possibility that federal enforcement priorities might be upset is not enough to provide a basis for preemption.'" App.18a.

Based on these holdings, the Fifth Circuit rejected Wells Pharma's arguments for preemption. Wells Pharma relied heavily on *Buckman* and § 337(a), but the court explained why that reliance was misplaced. App.20a–25a. *Buckman* held that § 337(a) preempted a claim intruding on "a 'uniquely federal area[] of regulation,' since it alleged only 'fraud on a federal agency.'" App.22a (quoting *Chamber of Com. v. Whiting*, 563 U.S. 582, 604 (2011)). Zyla's claims, in contrast, do not seek "to wield state law to vindicate a

wrong committed *against the Federal Government*" or to "polic[e] the uniquely federal relationship between Wells Pharma and the FDA." App.22a. And the Fifth Circuit explained that § 337(a) "confers a cause of action upon the Federal Government" but "says nothing about the States' authority to provide remedies for violations of state law." App.24a n.8.

4. Wells Pharma filed a petition for rehearing en banc, which the Fifth Circuit denied without dissent. COA.Dkt.113-1.

REASONS FOR DENYING THE PETITION

I. The Fifth Circuit did not decide Wells Pharma's question presented.

The only question the Fifth Circuit answered is "whether the state laws [under which Zyla sues] somehow conflict with the FDCA by incorporating it." App.8a. Wells Pharma, however, asks this Court to address a different question that the Fifth Circuit did *not* decide: "Whether the [FDCA] … 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*." Pet.2 (emphasis added). Even if *that* question were worthy of this Court's review (and it is not), this case presents no opportunity to answer it. The Court should deny Wells Pharma's petition for that reason alone.

Wells Pharma's framing of the question depends on a false premise and a fictitious description of the case. Wells Pharma presumes that it is selling a lawfully "compounded drug[]" exempt from the

FDCA's premarket approval requirement. Pet.i. But, as the Fifth Circuit correctly held, whether Wells Pharma's drug satisfies all of § 503B's requirements cannot be resolved or assumed in Wells Pharma's favor on a motion to dismiss. App.8a–9a n.2. As the case proceeds below, Zyla will introduce evidence proving that Wells Pharma's drug does *not* comply.

It is therefore stunning that Wells Pharma told this Court that the Fifth Circuit rejected preemption for state-law claims that "alter the federal requirements," Pet.3, or that "the core of Zyla's lawsuit is that selling any drug not approved by the FDA—*including all compounded drugs*—is illegal," Pet.6 (emphasis added). Rather, the Fifth Circuit held that, "given th[e] procedural posture" of this case, it had to treat "the state and federal requirements [as] the same." App. 8a–9a n.2. The Fifth Circuit did not consider whether the FDCA would preempt state laws that "alter the federal requirements," Pet.3, because Zyla's state-law claims do no such thing.[4]

Zyla could not have made it clearer that it does *not* contend that selling lawfully compounded drugs

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[4] Wells Pharma fills its petition with similar misstatements in an effort to make this case look worthy of review. *E.g.*, Pet.14 ("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."); Pet.16 ("The Fifth Circuit held that state-law claims are not preempted … even if those claims … add to federal requirements."); Pet.19 ("[T]he Fifth Circuit failed to address how Zyla's claims … 'add to' the federal requirements for compounded drugs"); Pet.24 ("Zyla[] attack[s] Wells Pharma for allegedly failing to meet a federal requirement from which it is legally exempt").

violates the state laws at issue. Zyla has consistently explained that it seeks to hold Wells Pharma liable under state law only if Wells Pharma's sale of its unapproved drug *also* violates federal law. ROA.105; Opening Br. 19 (COA.Dkt.32). Pleading burdens aside, the simple reality is that Wells Pharma was violating § 503B by using bulk indomethacin, as Zyla believed when it brought this action and now knows. Zyla's pursuit of only state-law claims that do *not* "add to" FDCA requirements is consistent with if not dictated by the state laws at issue. For example, Florida's unfair-competition statute contains a "safe harbor" stating that the statute "does not apply to … [a]n act or practice required or specifically permitted by federal or state law." Fla. Stat. § 501.212(1).[5] As a result, if Wells Pharma's drug complied with § 503B, its sale would not violate state law. This safe harbor is a built-in protection against conflict between state and federal law.

Zyla's express concession that it does not seek to hold Wells Pharma liable if its drug complies with § 503B guarantees that, as applied in this case, the relevant state-law requirements are identical to the FDCA's requirements. Thus, Wells Pharma is wrong to complain that the state drug-approval statutes "omit the FDCA's compounding exceptions." Pet.5.

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[5] The other States whose unfair-competition laws Zyla invoked have similar defenses for conduct that complies with applicable law. Colo. Rev. Stat. § 6-1-106; *Am. Television & Commc'ns Corp. v. Manning*, 651 P.2d 440, 445 (Colo. App. 1982); Conn. Gen. Stat. § 42-110c(a)(1); S.C. Code Ann. § 39-5-40; Tenn. Code Ann. § 47-18-111; *Cel-Tech Commc'ns, Inc. v. L.A. Cellular Tel. Co.*, 20 Cal. 4th 163, 182 (1999).

That is irrelevant: as the Fifth Circuit correctly held, there is "no preemption overbreadth doctrine," so Wells Pharma could mount a preemption defense only if state law added to federal requirements "'as applied'" *in this case*. App.8a–9a n.2 (quoting *Garcia*, 589 U.S. at 208, 211).

Wells Pharma suggests (at 4) that 503B facilities, merely by virtue of registering with FDA, enjoy a status-based exemption from premarket approval, but the Fifth Circuit refuted that argument: "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." App.6a; *see also* App.8a–9a n.2. Wells Pharma never acknowledges the Fifth Circuit's holding, and its argument is irreconcilable with § 503B's plain text. Section 503B provides that the premarket approval requirement does "not apply to a drug compounded by … a facility that elects to register as an outsourcing facility *if each of the following conditions is met*," followed by a list of eleven strict requirements. 21 U.S.C. § 353b(a) (emphasis added). Remarkably, Wells Pharma abridges this provision by inserting a period after "elects to register as an outsourcing facility," falsely suggesting that registration alone confers the exemption. Pet.4.[6]

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[6] Wells Pharma's selective quotation is no mere oversight. Its petition is littered with misleading assertions that the FDCA flatly and categorically exempts "compounded drugs"—by which Wells Pharma apparently means all drugs produced by a registered 503B facility—from the FDCA premarket approval requirement. *E.g.,* Pet.13 ("[T]he Fifth Circuit now permits drug companies to sue competitor compounders under state law for

For all these reasons, the Fifth Circuit's decision does not present the question whether the FDCA preempts state drug-approval laws that "add to" federal law by requiring premarket approval for drugs that qualify for § 503B's exemption. Pet.2. Because that question is central to Wells Pharma's petition, the Court should deny the petition.

II. This case presents no review-worthy circuit split.

As just explained, the Fifth Circuit held only that the FDCA does not preempt claims under state drug-approval laws that parallel federal drug-approval requirements. Wells Pharma contends this Court should review that decision to resolve a supposed conflict with the First Circuit's decision in *DiCroce v. McNeil Nutritionals, LLC*, 82 F.4th 35 (1st Cir. 2023), and the Ninth Circuit's decision in *Nexus Pharmaceuticals, Inc. v. Central Admixture Pharmacy Services, Inc.*, 48 F.4th 1040 (9th Cir. 2022). The decision below does not conflict with *DiCroce*, and any conflict with *Nexus* does not justify this Court's review.

1. Wells Pharma concedes that *DiCroce* presents "a different fact pattern" than this case, Pet.17, which

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failing to obtain FDA approval of specific compounded drugs—approval that federal law does not require."); Pet.18 ("[Zyla's] 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."); Pet.19 ("Zyla's claims ... demand premarket approval for compounded drugs, even though the FDCA expressly exempts such drugs from that requirement.').

significantly understates matters. *DiCroce* did not even present the same legal question. The plaintiff in *DiCroce* alleged that statements on a dietary supplement's label were false, but the theory of falsity was "premised entirely on [the plaintiff's] belief that said label violates the FDCA," without any theory for why the label was actually misleading as required by state law. 82 F.4th at 41 (emphasis omitted). The First Circuit thus found that the plaintiff did not assert an independent state-law claim parallel to the FDCA. *Id.* at 41 n.7.

That is not the case here, where Zyla sues under *state* unfair-trade-practice statutes for violations of *state* drug-approval statutes. Those state-law requirements incorporate and parallel the FDCA's requirements, but they remain *state-law* requirements. *DiCroce* did not address any such parallel state law, much less hold that the FDCA preempted it.

Indeed, there is good reason to think the First Circuit would *not* find preemption in a case like this one. *See Azurity*, 45 F.4th at 500–05. In *Azurity*, the First Circuit held that that the FDCA did not preclude a Lanham Act claim premised on allegations that the defendant falsely represented that its drug satisfied § 503B. The defendant argued that § 337(a) precluded that claim because it required adjudicating whether the defendant complied with § 503B, but the First Circuit disagreed. *Id.* at 505. It held that the plaintiff sought "to enforce the Lanham Act, not the FDCA or its regulations." *Id.* at 500 (quoting *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 117, 120 (2014)). That reasoning applies with full force to Zyla's claims here. By suing under state unfair-competition and

state drug-approval statutes, Zyla seeks to enforce those state statutes, not the FDCA. And because those state statutes, as applied, parallel the FDCA's requirements, there is no conflict with federal law.

2. Although the decision below does conflict with the Ninth Circuit's opinion in *Nexus*, that conflict does not support this Court's review.

Nexus stands alone as the only decision from any appellate court, state or federal, ever to hold that the FDCA preempts state laws that impose the same drug-approval requirements as the FDCA. No other circuit follows *Nexus*, which is poorly reasoned, conflicts with this Court's precedent, and is inconsistent with the United States' own views on FDCA preemption. So any circuit split involving *Nexus* is shallow, undeveloped, and likely to be resolved as additional courts reject the Ninth Circuit's approach. Such a split does not support certiorari. *See Hope*, 144 S. Ct. 2560 (denying petition seeking review of *Nexus* rule).

In *Nexus*, the plaintiff sued the defendant under the consumer-protection statutes of California and other States, alleging that the defendant violated those States' drug-approval laws by selling a drug that had not been approved by FDA. 48 F.4th at 1044. Although the defendant claimed its drugs were exempt from premarket approval under the FDCA's compounding provisions, the plaintiff alleged that the defendant did not lawfully compound its drugs, such that their sale was equally prohibited under state and federal law. *Id.*

The Ninth Circuit held that § 337(a) preempted the plaintiff's state-law claims, finding—in direct

conflict with *Zook*—that § 337(a) impliedly preempts "state statute[s] which [themselves] rel[y] on the [FDCA]." *Id.* at 1046. The Ninth Circuit also held that FDA's "enforcement discretion" preempts state laws that impose the same drug-approval requirements as the FDCA. *Id.* at 1048. But this Court held in *Garcia* that the "possibility that federal enforcement priorities might be upset" by the enforcement of "overlap[ping]" state law does not "provide a basis for preemption." 589 U.S. at 211–12; *see also Wyeth*, 555 U.S. at 575 ("Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.").

Nexus was the first decision in which any appellate court held that the FDCA preempts state drug laws that impose the same requirements as the FDCA. Indeed, *Nexus* itself acknowledged that it departed from the Federal Circuit's earlier decision in *Athena*. *Nexus*, 48 F.4th at 1049–50. Like Zyla, the plaintiff in *Athena* sued the defendant for violating California's unfair-competition and drug-approval laws by selling an unapproved drug. 738 F.3d at 1353. Like Wells Pharma, the defendant argued that § 337(a) preempted California's drug-approval statute because it "incorporate[d] FDCA provisions" and private enforcement of that parallel state law "interfere[d] with the FDA's discretionary authority." *Id.* at 1355. The Federal Circuit disagreed. "The fact that the [California statute] parallels certain FDCA provisions," the court held, "does not mean that it does

not implicate an historic state power that may be vindicated" by state law. *Id.*[7]

The United States endorsed the Federal Circuit's decision in a brief to this Court opposing the defendant's petition for certiorari. The Government explained that States may "authoriz[e] private suits to enjoin the intrastate distribution, sale, and marketing of an unapproved drug." U.S. *Athena* Br. 17. The Government took the same position in an earlier case holding that the FDCA does not preempt the California statute's food-labeling provisions. *See* U.S. *Albertson's* Br. 12–13 ("Actions to enforce state laws that impose requirements identical to those under the FDCA are not actions to enforce the FDCA itself. … [E]ven when state-law claims are predicated on violations of the FDCA, they remain state-law claims."); *Farm Raised Salmon*, 175 P.3d at 1181 (California's imposition of "obligations identical to those imposed by the FDCA" did "not substantively transform plaintiffs' action into one seeking to enforce federal law").

Since *Nexus*, the Fifth Circuit is the only circuit to have considered whether the FDCA preempts state drug-approval statutes that parallel the FDCA's requirements. And given the Federal Circuit's and United States' earlier disagreement with the Ninth Circuit's approach, there is every reason to think that further percolation in the courts of appeals will

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[7] Wells Pharma contends that because *Athena* originated within the Ninth Circuit, it was overruled by *Nexus*. Pet.16 n.1. That is hardly obvious, but if it were true it would only confirm that there is not currently any deep or review-worthy circuit split.

confirm *Nexus*'s status as an unpersuasive outlier. That could well lead the Ninth Circuit to abandon *Nexus*. In all events, any split between the Ninth and Fifth Circuits is too shallow and undeveloped to justify review at this time.

III. The decision below is correct.

For the reasons above, this Court should deny review whether or not it agrees with the decision below. But that decision is unimpeachably correct, and Wells Pharma's contrary arguments lack merit.

1. The Fifth Circuit correctly rejected Wells Pharma's argument that Zyla's claims would "add[] to" the FDCA's requirements. App.8a–9a n.2.[8] As explained above, the state drug-approval requirements that Zyla seeks to enforce parallel—rather than conflict with or add to—the FDCA's requirements. *Supra* pp.14–18. Wells Pharma will be liable on Zyla's state-law claims *only* if Wells Pharma's drug does not qualify for § 503B's compounding exemption. In that case, "the state and federal requirements [will be] the same." App.8a–9a n.2. Zyla

[8] It is not clear whether "adding to" federal requirements would make a state-law claim regarding compounded drugs conflict-preempted. Some express-preemption provisions bar "additional" state-law requirements, but no such provision applies to prescription drugs. *Wyeth*, 555 U.S. at 574; *see* Pet.19 (mistakenly relying on *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), which involved the express-preemption provision for certain medical devices). But Zyla's concession that Wells Pharma can be liable under state law only if selling its unapproved drug also violates federal law makes this question academic.

is challenging only the sale of unapproved drugs that do *not* qualify for § 503B's compounding exemption.[9]

That fact, which Wells Pharma cannot honestly deny, deflates Wells Pharma's and its amici's claims that the sky is falling. Zyla's claims would not "effectively end compounding," Pet.25, or "forc[e] manufacturers to comply with additional requirements … that exceed those imposed by Congress and the FDA," Pet.23, because Zyla is explicitly not challenging lawful compounding that complies with § 503B.

2. The Fifth Circuit also correctly held that the relevant state drug-approval statutes, as applied in this case, do not conflict with the FDCA. Because the FDCA has no express-preemption provision for prescription drugs and this Court has held that the FDCA does not occupy the field of prescription-drug regulation, the FDCA can preempt state drug-approval statutes only if those statutes *conflict* with the FDCA. *Wyeth*, 555 U.S. at 574–75; App.8a–9a n.2. But Wells Pharma cannot identify any actual conflict between the FDCA's requirements and the state-law

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[9] This case also has nothing to do with compounding to address "a shortage of FDA-approved drugs." Pet.6; *see also* OFA Amicus Br. 2, 12–17 & nn.8, 12; AACM Amicus Br. 6, 11. There has never been a shortage of Zyla's FDA-approved Indocin® Suppositories, and nothing in the Fifth Circuit's decision would preclude lawful compounding in the event of a shortage. Nor does this case have anything to do with traditional compounding—making "drugs tailored to the needs of individuals or small patient communities," OFA Amicus Br. 3, 5–9. Such traditional compounding is addressed by § 503A; 503B outsourcing facilities like Wells Pharma manufacture standardized drugs in large quantities.

requirements Zyla seeks to enforce. As applied in this case, those state-law requirements are identical to the FDCA's requirements.

As the Fifth Circuit recognized, this Court has long held that state statutes may borrow or incorporate federal requirements without triggering preemption. App.9a–20a. In *Zook*, for example, the Court upheld a California statute prohibiting motor carriers from selling transportation without a federal or California permit. The Court held that when a "state statute makes federal law its own" in this way, there is "no possibility of [a] conflict" between state and federal law, and thus no preemption. 336 U.S. at 735; *accord Gilbert v. Minnesota*, 254 U.S. 325, 331 (1920); *Asbell v. Kansas*, 209 U.S. 251, 256–58 (1908). In the years since *Zook* was decided, this Court has reaffirmed its holding on multiple occasions. *E.g.*, *Garcia*, 589 U.S. at 211–12 (holding federal law did not preempt state law criminalizing conduct prohibited by federal law); *cf. Arizona v. United States*, 567 U.S. 387, 402 (2012) ("a State may make violation of federal law a crime," unless federal law occupies the field).

Zook similarly "controls this case." App.9a. Wells Pharma tries to distinguish *Zook* because it involved a criminal prosecution rather than a civil suit, but Wells Pharma cannot explain why that should make any difference. Pet.21. State drug-approval statutes can be criminally enforced,[10] and this Court has never

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[10] *E.g.*, Cal. Health & Safety Code § 111825; Conn. Gen. Stat. § 21a-97; Fla. Stat. § 499.066(1); S.C. Code Ann. § 39-23-80; Tenn. Code Ann. § 53-1-103.

suggested that preemption applies differently in criminal and civil cases. *Cf.* App.14a–15a n.4 (suggesting that if there were a difference, it would cut against Wells Pharma's argument).

There is no basis to depart from *Zook* and adopt a contrary rule for the FDCA. This Court held in *Wyeth* that the FDCA reflects an intent to preserve rather than preempt state drug laws. 555 U.S. at 572–81. That was true, the Court held, even though state-law claims could require or induce a drug manufacturer to put a "stronger warning" on its label than the FDA-approved label. *Id.* at 573–74. The long history of coexistence between the FDCA and state drug regulation convinced the Court that "Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Id.* at 575.

That holding forecloses Wells Pharma's argument that Zyla's claims conflict with FDA's enforcement authority. Even more recently, this Court rejected Wells Pharma's argument that the "possibility that federal enforcement priorities might be upset" by the enforcement of "overlap[ping]" state laws can "provide a basis for preemption." *Garcia*, 589 U.S. at 211–12; App.18a. That is because "[t]he Supremacy Clause gives priority to 'the Laws of the United States,' not the criminal law enforcement priorities or preferences of federal officers." *Garcia*, 589 U.S. at 211–12 (quoting U.S. Const. art. VI, cl. 2). Therefore, as the United States has explained, "[n]o conflict with a supposed FDA position … can be inferred from the absence of FDA enforcement or other regulatory action." U.S. *Athena* Br. 10.

Contrary to Wells Pharma's argument, § 337(a) does not alter this conclusion. Section 337(a) "confers a cause of action upon the Federal Government" to enforce the FDCA, App.24a n.8, and bars private enforcement *of the FDCA*, *Buckman*, 531 U.S. at 352. But it does not deprive States of their historic authority to regulate the in-state sale of unapproved drugs, particularly when there is no conflict between state and federal requirements.

That is because a *state-law* claim under a duly enacted *state* statute does not become an FDCA claim merely because the state-law claim incorporates or parallels FDCA requirements. This Court has recognized that a claim under a statute other than the FDCA does not constitute private enforcement of the FDCA just because the claim would require litigating the defendant's FDCA compliance. *See POM Wonderful*, 573 U.S. at 117 (§ 337(a) does not preclude a Lanham Act claim premised on FDCA violations because a suit "to enforce the Lanham Act" is not a suit to enforce "the FDCA or its regulations" even if it requires litigating FDCA compliance); *Merrell Dow Pharms. Inc. v. Thompson*, 478 U.S. 804, 814 (1986) (a state-law claim premised on "a claimed violation of the [FDCA]" is not an FDCA claim supporting federal-question jurisdiction).

Wells Pharma is simply wrong to say that Zyla's claims "exist solely by virtue of the FDCA." Pet.18 (cleaned up). Zyla seeks to enforce *state* statutes that *States* have enacted in areas of traditional state authority. To say that Zyla's claims are somehow really just disguised FDCA claims is to pretend that those state statutes don't exist, which the Fifth Circuit

correctly found would "undermine state sovereignty and principles of federalism." App.15a. Nothing in § 337(a) denies States their traditional authority to regulate drug safety and fair competition in ways that do not conflict with federal law. *See* App.7a, 24a n.8.

This Court did not hold otherwise in *Buckman*. The claim this Court found preempted in *Buckman* was a "fraud-on-the-FDA" claim premised entirely on allegations that a medical-device manufacturer lied to FDA to obtain premarket approval. 531 U.S. at 347–48. The Court held that claim preempted because "[p]olicing fraud against federal agencies is hardly a field which the States have traditionally occupied." *Id.* at 347 (cleaned up). And because the plaintiff challenged the manufacturer's interactions with FDA during the premarket approval process, the plaintiff's claim would have "threatened serious disruption of the sensitive and highly technical process of approving medical devices." *Garcia*, 589 U.S. at 212 (discussing *Buckman*).

As this Court held in *Wyeth*, *Buckman* is limited to circumstances where a plaintiff seeks to use state law to intrude on an area of exclusively federal interest, such as "fraud-on-the-agency claims." 555 U.S. at 565 n.3. *Buckman* does not extend beyond that context to broadly preempt all parallel "state regulation of health and safety." *Id.*

Buckman thus does not apply to claims like Zyla's, which have nothing to do with a manufacturer's interactions with FDA. Unlike the plaintiff in *Buckman*, Zyla does not seek "to vindicate a wrong committed *against the Federal Government*" or to "polic[e] the uniquely federal relationship between

Wells Pharma and the FDA." App.22a. Zyla's claim is not that Wells Pharma obtained FDA approval through fraud—it's that Wells Pharma did *not* obtain FDA approval *at all*, in violation of state laws that parallel the FDCA's requirements.

"[T]here is no reason to think allowing these claims to proceed will in any sense upset any purposes and objectives of Congress whatsoever." App.23a. Contrary to Wells Pharma's misleading insinuations, Pet.23–24, FDA has never decided that Wells Pharma's unapproved drug is exempt from premarket approval. Wells Pharma references inspections in which FDA reviewed its facility for safety and cleanliness—and found numerous violations.[11] But FDA has never made any findings about Wells Pharma's compliance with § 503B. So the most Wells Pharma could say is that FDA, for whatever reason, has not taken enforcement action against it to date. And this Court's precedent confirms that "[n]o conflict with a supposed FDA position … can be inferred from the absence of FDA enforcement or other regulatory action." U.S. *Athena* Br. 10; *see Garcia*, 589 U.S. at 211–12; *Wyeth*, 555 U.S. at 575.

If Wells Pharma's contrary argument were correct, the FDCA would preempt the entire field of prescription-drug regulation. States could not pass laws that differ from the FDCA—because such laws would "add to" the FDCA's requirements—and also

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[11] *See* FDA, *Compounding: Inspections, Recalls, and Other Actions* (Sep. 18, 2025), https://www.fda.gov/drugs/human-drug-compounding/compounding-inspections-recalls-and-other-actions#W.

could not pass laws that do *not* differ from the FDCA—because claims under such laws would be nothing more than "disguised" FDCA claims barred by § 337(a). Pet.14. Wells Pharma's amicus makes this explicit, pressing the astonishing claim that the FDCA entirely excludes States from the field of compounding. *See* AACM Amicus Br. 3–4, 12–13, 16; *see also* Pet.6 (asserting that "pharmaceutical compounding" is regulated "under the federal government's exclusive enforcement authority"). But this Court rejected field preemption in *Wyeth*. 555 U.S. at 575. Perhaps for that reason, Wells Pharma avoids expressly arguing for field preemption. Instead, it offers the incoherent argument that Zyla's claims simultaneously "alter the federal requirements" while also being disguised FDCA claims because they "merely 'incorporate[] federal law.'" Pet.3; *see also* Pet.2, 12, 16. That argument contradicts itself.

CONCLUSION

The Court should deny the petition for certiorari.

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