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

REPLY BRIEF FOR THE PETITIONER

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REPLY BRIEF FOR THE PETITIONER

Respondent Zyla Life Sciences, LLC ("Zyla") comes out swinging but ultimately agrees that the courts of appeals are divided on the question presented by Petitioner Wells Pharma of Houston, L.L.C. ("Wells Pharma"): Whether the FDCA preempts private state-law unfair competition and consumer protection claims premised on the marketing of compounded drugs without FDA premarket approval.

Zyla acknowledges that the Ninth Circuit's decision in *Nexus Pharmaceuticals, Inc. v. Central Admixture Pharmacy Services, Inc.*, 48 F.4th 1040 (9th Cir. 2022), squarely conflicts with the Fifth Circuit's decision below. (Opp. 20). Thus, the existence of a direct, outcome-determinative split between the Fifth and Ninth Circuits on the preemption of state-law claims against compounding pharmacies premised on violations of the FDCA is undisputed.

Zyla likewise does not dispute the national importance of resolving this circuit conflict, nor that this case presents the proper vehicle to resolve the conflict. Instead, Zyla argues the *merits* underlying the circuit split. Its arguments are unpersuasive and cannot support a decision to deny certiorari.

I. This Case Implicates the Circuit Conflict That Zyla Acknowledges.

Zyla concedes there is a circuit conflict over the question presented by Wells Pharma's petition, but it contends that the split is not "review-worthy." (Opp. 18, 20). That argument does not warrant denial of certiorari.

The Ninth Circuit's decision in *Nexus* held that state-law claims seeking to enforce FDCA requirements against compounding pharmacies are impliedly preempted because such claims "would require litigating whether the facilities qualified for an exception to FDA approval, i.e., whether an FDCA violation had occurred"—a determination reserved exclusively to the FDA by Congress. *Davidson v. Sprout Foods, Inc.*, 106 F.4th 842, 849 (9th Cir. 2024) (explaining the decision in *Nexus*). The Ninth Circuit reasoned that allowing private litigants to pursue such claims would "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." *Nexus*, 48 F.4th at 1050 (citation omitted).

The Fifth Circuit held the exact opposite. Wells Pharma must continue to litigate whether it "satisfies the many requirements of § [503B]" because, according to the Fifth Circuit, Zyla's state-law claims are not preempted so long as they "incorporate" federal law—even if they require private parties to litigate compliance with the FDCA. *Zyla Life Scis., L.L.C. v. Wells Pharma of Hous., L.L.C.*, 134 F.4th 326, 328, 331 n.2 (5th Cir. 2025). Zyla doubles down on this position before this Court, arguing that "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." (Opp. 23). But as the Ninth Circuit recognized, the decision as to whether a compounding facility qualifies for an FDCA exemption under Section 503B is "a task reserved to the FDA," not private competitors through state-law claims. *Nexus*, 48 F.4th at 1050–51; *see also Davidson*, 106 F.4th at 849.

The core of the circuit split lies in the Fifth Circuit's restrictive interpretation of *Buckman Co. v. Plaintiff's Legal Committee*, 531 U.S. 341 (2001). The decision below confines *Buckman* to only "fraud-on-the-FDA" claims. *Zyla*, 134 F.4th at 337 (suggesting that the claims in *Buckman* were preempted only because they alleged "fraud on a federal agency"). But that cramped reading ignores the broader principle articulated in *Buckman*, as recognized by the Ninth Circuit. *Nexus* held that the state-law claims in *Buckman* were preempted because "the fraud claims existed *solely by virtue of the FDCA* and not on traditional state tort law fraud predating the federal statute." *Nexus*, 48 F.4th at 1046 (cleaned up) (emphasis added). The courts of appeals are therefore now irreconcilably split on whether *Buckman*'s implied-preemption holding applies *whenever* a state-law claim exists solely because of the FDCA, *see id.*, or only when the alleged wrong is done against a federal agency, *see Zyla*, 134 F.4th at 337.[1]

1. It is worth noting that prior to the decision below, the Fifth Circuit had recognized that "[i]mplied preemption precludes state tort claims that 'exist solely by virtue of' the federal regulatory scheme," and that "[s]uch claims . . . cannot be brought under state law because the FDA is the exclusive enforcer of its regulations." *Wildman v. Medtronic, Inc.*, 874 F.3d 862, 868 n.6 (5th Cir. 2017) (citing *Buckman*, 531 U.S. 347–53). But the panel below completely ignored this prior Fifth Circuit decision, despite it being cited by Wells Pharma in the briefing and at oral argument. The author of the opinion below recently spoke on his disdain for the "rule of orderliness," which perhaps explains the panel's decision to not discuss, let alone follow, *Wildman*. *See* Hon. Andrew S. Oldham, *The 2025 Joseph Story Distinguished Lecture*, YouTube (Oct. 22, 2025). Separate and apart from creating an unnecessary circuit split, this disregard of precedent is another troubling aspect of the opinion below.

That conflict is directly presented here. Each of Zyla's claims depends on proving an FDCA violation. The split is real, acknowledged, and outcome-determinative. Identical conduct triggers litigation in the Fifth Circuit yet is shielded from suit by preemption in the Ninth Circuit. The Fifth Circuit's decision entrenches a fractured legal landscape where the legality of pharmaceutical compounding—and the risk of private enforcement by competitors—depends on geography.

II. The Circuit Conflict Will Not Resolve Itself.

Zyla contends that this Court should deny certiorari based on wishful thinking that the split is "likely to be resolved" or that "the Ninth Circuit [will] abandon *Nexus*." (Opp. 20, 23). This argument is both implausible and insufficient to warrant denying certiorari. Zyla cannot dispute that having even one circuit in conflict with another on this important issue warrants review.

The Fifth and Ninth Circuits are irreconcilably divided on whether attempts to litigate compliance for compounding pharmacies are barred by the FDCA. Yet Zyla argues that this Court should not settle the dispute because the Ninth Circuit's opinion was "poorly reasoned" and the split is "likely to be resolved as additional courts reject the Ninth Circuit's approach." (Opp. 20). That speculative assertion ignores the actual trajectory of the caselaw.

To the contrary, the Ninth Circuit has reaffirmed its position in *Nexus* in six subsequent cases. *See Davidson*, 106 F.4th 842; *Bubak v. Golo, LLC*, 2025 WL 2860044 (9th Cir. Oct. 9, 2025); *Hope Med. Enters., Inc. v. Fagron*

Compounding Servs., LLC, 2023 WL 4758454 (9th Cir. July 26, 2023); *Grand River Enters. Six Nations, Ltd. v. Knudsen*, 2024 WL 2992503 (9th Cir. June 14, 2024); *Nexus Pharmas., Inc. v. QuVa Pharma, Inc.*, 2022 WL 4181714 (9th Cir. Sept. 13, 2022); *Nexus Pharmas., Inc. v. Leiters, Inc.*, 2022 WL 4181716 (9th Cir. Sept. 13, 2022). The Ninth Circuit has not retreated from *Nexus*; it has strengthened its commitment.

Majority opinions, concurrences, and dissents in the Ninth Circuit's *Davidson* and *Bubak* decisions separately emphasized the soundness of the reasoning in *Nexus*. *Davidson* explained that in *Nexus*, the state-law claims against compounding pharmacies would require litigation on "whether the facilities qualified for an exception to FDA approval, i.e., whether an FDCA violation had occurred. Because this was a task reserved for the FDA," *Nexus* "held that the claim was impliedly preempted under § 337 . . . as an attempt to privately enforce the FDCA's requirements for compounding facilities." 106 F.4th at 849 (citation omitted); *see also id.* at 862 (Collins, J., concurring in part and dissenting in part) ("Here, as in *Nexus*, the California statute at issue merely incorporates FDCA requirements and says in substance 'comply with the FDCA.'" (cleaned up)). *Bubak* explained that the claims in *Nexus* were preempted because they would "require litigating questions that are reserved for the FDA." *Bubak*, 2025 WL 2860044, at *2 (cleaned up); *see also id.* (Callahan, J., concurring) ("The court in *Nexus* held these allegations impliedly preempted because they are simply a roundabout way to claim violations of the FDCA, which § 337 prohibits.").

As evident from these decisions, Zyla has no basis to suggest that the Ninth Circuit may "abandon *Nexus*" or that the circuit conflict is "likely to be resolved." (Opp. 20, 23). Moreover, Zyla cites no intervening decisions outside of the decision below (because there are none) that suggest the Ninth Circuit even *should* abandon *Nexus*. The Fifth Circuit, for its part, did not substantively engage in any way with the contrary reasoning in *Nexus*.

Zyla's arguments regarding denial of certiorari are flawed. The split is not likely to disappear, and only this Court can resolve the entrenched, outcome-determinative conflict that Zyla itself acknowledges.

III. This Case Presents The Proper Vehicle To Resolve The Circuit Conflict On an Issue of National Importance.

Zyla provides no argument against this case being the proper vehicle to resolve the circuit conflict. As Wells Pharma's petition explains, the central issue is whether 21 U.S.C. § 337's exclusive-enforcement regime and *Buckman*'s preemption doctrine bar private state-law claims that require adjudicating a compounder's compliance with the FDCA. If preemption applies, then Zyla's claims must be dismissed; if not, Wells Pharma must defend prolonged private litigation over its FDCA compliance. The question thus determines the result. The Fifth Circuit's approach compels continued litigation into whether Wells Pharma "satisfies the many requirements of § [503B]," treating that as a factual matter for private suits initiated by competitors. *Zyla*, 134 F.4th at 331 n.2. But the Ninth Circuit holds that such litigation is preempted because only the FDA can police compliance with the FDCA.

The case presents a clean, purely legal issue suitable for certiorari: Do § 337(a) and *Buckman* preempt or bar state-law claims against compounding pharmacies that "exist solely by virtue of" Section 505(a) premarket approval requirements and Section 503B's requirements? *See Buckman*, 531 U.S. at 353. The courts of appeals disagree on whether this is an inquiry Congress reserved solely for the FDA. This legal question touches on the scope of federal preemption and congressionally delegated agency authority, not a fact-bound dispute about Wells Pharma's operations. In the Fifth Circuit, this question cannot be resolved on a motion "to dismiss under 12(b)(6)." *Zyla*, 134 F.4th at 331 n.2. The Ninth Circuit, however, resolved the same issue on a Rule 12(b)(6) motion to dismiss, holding the "plain text of the FDCA leaves that determination in the first instance to the FDA's balancing of risks and concerns in its enforcement process." *Nexus*, 48 F.4th at 1050.

This type of litigation against compounders causes persistent uncertainty for pharmacies, providers, and patients across jurisdictions. That instability invites forum-shopping, chills lawful compounding, and yields uneven access to medications—access that Congress expressly carved out from premarket approval requirements through Section 503B. This case tees up the preemption rule that will govern those suits nationwide. Amicus briefs supporting this petition have been filed by the Outsourcing Facilities Association and Americans for Access to Compounded Medication, reflecting the need for industry-wide uniformity to address patient access that has been thrust into uncertainty by the decision below. Amici further emphasize Congress' decision to grant the FDA exclusive enforcement authority to

"enforce[] or to restrain violations" of Section 503B. *See* Br. of *Amicus* Outsourcing Facilities Ass'n, at 11–21. Amici's participation confirms the national importance of resolving the circuit conflict now.

Congress, in its considered judgment, vested FDCA enforcement in the FDA. Zyla admits the following:

(i) The "FDCA contains an exception to its premarket approval requirement for lawfully 'compounded' drugs." (Opp. 5).

(ii) The FDCA furnishes no "private right of action" and commits enforcement "by and in the name of the United States" to the FDA. (Opp. 8).

(iii) Zyla's state-law claims rise and fall with whether Wells Pharma's product is "approved or otherwise authorized for sale by FDA." (Opp. 9).

Those concessions crystallize the principal issue here. Zyla seeks to use state-law causes of action to litigate whether Wells Pharma complies with the FDCA, thereby overriding Congress' assignment of that task exclusively to the FDA. Yet under the Fifth Circuit's approach, Wells Pharma "cannot have proven that it satisfies § [503B]'s many requirements" at the pleadings stage. *Zyla*, 134 F.4th at 331 n.2. The Ninth and Fifth Circuits squarely conflict on whether these suits may proceed in the first instance. The result is geography-dependent exposure to private suits. *Contra Buckman*, 531 U.S. at 350 ("[C]omplying with the FDA's detailed regulatory regime in

the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants—burdens not contemplated by Congress in enacting the FDCA."). In the Ninth Circuit, compounders are shielded from state-law FDCA-proxy claims; in the Fifth Circuit, they are not. Only this Court can restore uniformity.

This case is the right vehicle to resolve the conflict and reaffirm the FDA's exclusive enforcement role. The record squarely presents the legal question; Zyla has not identified any procedural obstacles; and the conflict is entrenched and acknowledged by Zyla itself. Certiorari here would harmonize the competing approaches, prevent the back-door displacement of Congress' enforcement scheme, and avoid the practical harms already flowing from the Fifth Circuit's decision. This Court should thus grant review to resolve the split and reaffirm that § 337(a) and *Buckman* preempt and/or bar private competitors from using state law to litigate Section 503B compliance, a determination Congress reserved to be made by the FDA.

IV. The Decision Below Is Wrong.

Zyla devotes most of its brief to arguing that review is unwarranted because the Fifth Circuit's decision was correct. That would not justify denying certiorari even if true, given the acknowledged circuit conflict and the undisputed importance of the question presented. And crucially, it is not true. The Fifth Circuit's reasoning misapplies the text of the FDCA and Congress' deliberate choice to vest enforcement authority exclusively in the FDA.

Wells Pharma did not "fabricate" a question or misstate the law. (Opp. 1). The state statutes at issue prohibit the sale of drugs not approved by the FDA, but they do not incorporate Sections 503A and 503B's compounding exceptions. (Pet. 9–11; Opp. 9). By that omission, these statutes necessarily "add to" federal requirements by imposing liability without recognizing the carve-outs Congress enacted. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 513 (1996) (O'Connor, J., concurring in part and dissenting in part) (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"). By forcing Wells Pharma to affirmatively prove compliance with all statutory conditions in Section 503B to avoid state-law liability when the FDA "has not taken enforcement action against it to date," (Opp. 29) the decision below permits the very burden Congress sought to prevent. The FDA alone decides whether a compounder meets those requirements. *See* 21 U.S.C. § 337(a) (stating "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. § 353b (stating Section 505(a) premarket approval "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").

Zyla's "concessions" cannot cure this defect. Zyla repeatedly asserts that Wells Pharma "can be liable under state law only if selling its unapproved drug also violates federal law." (*See*, *e.g.*, Opp. 23 n.8). But that framing ignores the core preemption problem. Congress gave FDA, not private competitors, discretion to determine

whether a compounding pharmacy violates the FDCA and whether enforcement is warranted. Allowing private suits to litigate FDCA compliance under state law undermines that express federal scheme and imposes burdens "not contemplated by Congress in enacting the FDCA." *Buckman*, 531 U.S. at 350. As *Buckman* explained, "complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants." *Id.* Those concerns apply with full force here, where the Fifth Circuit invites competitors to second guess the FDA's enforcement discretion through state-law claims.

Zyla's reliance on *Kansas v. Garcia*, 589 U.S. 191 (2020) (Alito, J.), cuts against its argument. *Garcia* reaffirmed a broad reading of *Buckman*'s implied preemption holding, and it did not narrow *Buckman* as the Fifth Circuit below did to just fraud-on-the-FDA claims. *Garcia* distinguished the state criminal prosecutions at issue from the state-law claims in *Buckman* because state criminal prosecutions posed "no comparable risk" to the federal criminal scheme. *Id.* at 212. By contrast, the unfair competition and consumer-protection claims here, like the fraud-on-the-FDA claim in *Buckman*, are predicated on compliance with a federal statute, and thus "threaten[] serious disruption of the sensitive and highly technical process of" approving pharmaceuticals for marketing that Congress entrusted to FDA. *Id.* (citing *Buckman*, 531 U.S. at 347–53). Zyla repeatedly emphasizes that its claims turn on whether Wells Pharma meets Section 503B's requirements. The Fifth Circuit's decision thus permits exactly the "extraneous pull" on the FDA's regulatory balance that *Buckman* forbids. *See Buckman*, 531 U.S. at 353; *see also Garcia*, 589 U.S. at 212.

Finally, the practical consequences confirm the error. Under the Fifth Circuit's approach, compounders face divergent litigation risks across the country: shielded in the Ninth Circuit, exposed in the Fifth Circuit. That fragmentation undermines uniformity, impedes FDA oversight, and destabilizes access to compounded medications—an area Congress addressed precisely because of patient-safety concerns and drug shortages. To avoid that inconsistency, Congress specifically "delegated authority" to the FDA to enforce compliance with Section 503B. *Cf. New York v. FERC*, 535 U.S. 1, 18 (2002) (citation omitted); 21 U.S.C. § 337(a). The decision below effectively overrides Congress' policy judgment, substituting the FDA's enforcement discretion with private enforcement.

For these reasons, the Fifth Circuit's decision is wrong, and it is vital that this Court grant review to resolve the circuit conflict and reaffirm the FDA's exclusive authority to enforce the FDCA.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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