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

SUPPLEMENTAL BRIEF FOR THE PETITIONER

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SUPPLEMENTAL BRIEF FOR THE PETITIONER

The government's brief underscores the need for this Court's review. That there is a direct, outcome-determinative circuit conflict is undisputed. The Fifth Circuit permits competitor suits that force litigation of Section 503B compliance, while the Ninth Circuit bars those same claims as impliedly preempted. The government acknowledges the conflict but attempts to discount it as "shallow and uncertain," invoking supposed intra-Ninth Circuit "tension" and potential future action by the Food and Drug Administration (FDA) on indomethacin. None of that alters the central point. The split is entrenched and already producing a circuit-based regime in which the same conduct is either immune from suit or subjected to full litigation depending on jurisdiction.

The government embraces the very premise that makes the conflict review-worthy. It repeatedly insists that Petitioner Wells Pharma of Houston, L.L.C. ("Wells Pharma") can defeat Respondent Zyla Life Sciences, LLC's ("Zyla") state-law claims by proving compliance with Section 503B's conditions in court, notwithstanding Congress' decision to exempt qualifying outsourcing facilities from Section 505 premarket approval and to assign Section 503B compliance determinations to an FDA-administered oversight and enforcement framework. Congress did not create a Section 503B "approval" regime; it replaced Section 505's *ex ante* stamp-of-approval model with *ex post* FDA administration through registration, reporting, inspections, and enforcement discretion. That is the point of division between the circuits. The Fifth Circuit forces outsourcing facilities to shoulder

that litigation burden, while the Ninth Circuit holds that private suits requiring litigation of whether a facility qualifies for an exception to FDA approval are barred because that determination is reserved to the FDA. The government's effort to downplay the split only confirms the need for review.

A. The Government's Arguments Confirm the Confusion Created by the Circuit Conflict.

1. The government's brief minimizes the consequences of the Fifth Circuit's decision below, a decision that the government admits conflicts with the Ninth Circuit's decision in *Nexus Pharmaceuticals, Inc. v. Central Admixture Pharmacy Services, Inc.*, 48 F.4th 1040 (9th Cir. 2022). No one disputes that a split exists. That outcome-determinative split turns on a single question: who decides Section 503B compliance in the first instance—FDA or state courts and juries?

The government acknowledges that "the court of appeals' decision conflicts with a Ninth Circuit decision," yet attempts to dismiss the split as "shallow and uncertain." (U.S. Am. Br. 2, 8). It is neither. The Ninth Circuit holds that the same state-law claims at issue here are impliedly preempted because they require "litigating whether the facilities qualified for an exception to FDA approval"—a determination Congress reserved to FDA, not private litigants. *Davidson v. Sprout Foods, Inc.*, 106 F.4th 842, 849 (9th Cir. 2024) (describing the holding in *Nexus*, 48 F.4th at 1050–51).

The Fifth Circuit holds the opposite. It allows these suits to proceed because Wells Pharma cannot establish

at the Rule 12(b)(6) stage that it "satisfies § 353b's many requirements," forcing it to litigate Section 503B compliance through discovery and trial by bearing in court the burden Congress assigned to FDA. *Zyla Life Scis., L.L.C. v. Wells Pharma of Hous., L.L.C.*, 134 F.4th 326, 331 n.2 (5th Cir. 2025). Wells Pharma is thus exposed to competitor suits in the Fifth Circuit for conduct that is categorically shielded from suit in the Ninth Circuit. There is nothing "uncertain" about that conflict.

The government's suggestion of intra-Ninth Circuit "tension" misunderstands *Nexus* and its progeny. *Nexus* applied § 337(a)'s "bar on private enforcement" where a state-law claim operates as a proxy for adjudicating compliance with the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.*, in the first instance. 48 F.4th at 1049. The Ninth Circuit made clear that such claims are preempted because they "would require litigation of the alleged underlying FDCA violation in a circumstance where the FDA has not itself concluded that there was a violation." *Id.* at 1048. These suits "stand as an obstacle" to FDA enforcement because they risk "over-enforcement" beyond what FDA "has deemed appropriate," intruding on the agency's role in administering a complex regulatory scheme. *Id.* Therefore, when regulating outsourcing facilities, 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." *Id.* at 1050.

Subsequent Ninth Circuit cases have confirmed—not undermined—that holding. *Davidson* reaffirmed that claims are preempted if they require courts to determine "whether [outsourcing] facilities qualified for an exception

to FDA approval, i.e., whether an FDCA violation had occurred." 106 F.4th at 849. Just because *Davidson* applied *Nexus* in a different statutory context does not dilute that rule or obscure the core holding that private suits to enforce Section 503B are barred.

Nor does *Bubak v. Golo, LLC*, No. 24-492, 2025 WL 2860044 (9th Cir. Oct. 9, 2025), support the government's position. Both the majority and concurring opinions there reaffirmed *Nexus* and held claims preempted when they "necessarily require[] litigating the alleged underlying FDCA violation" because the "plain text" of 21 U.S.C. § 337(a) assigns that determination to FDA. *Id.* at *1 (citation modified). While distinguishing *Davidson* on its facts and separate statutory scheme, *Bubak* did not retreat from *Nexus*. To the contrary, Judge Callahan wrote separately to criticize any attempt to dilute *Nexus*' broad preemption holding. She emphasized that the claims at issue were "impliedly preempted because they [were] simply a roundabout way to claim violations of the FDCA, which § 337 prohibits." *Id.* at *2 (Callahan, J., concurring).

There is no confusion within the Ninth Circuit, only confirmation of a deepening divide among the circuits. The Fifth and Ninth Circuits have adopted irreconcilable positions on whether competitor suits that require litigation of Section 503B compliance may proceed. That conflict is direct, acknowledged, and outcome-determinative.

2. The government's safe-harbor theory confirms rather than narrows the conflict. The government argues that Zyla's state-law claims may proceed because liability ultimately turns on whether Wells Pharma can establish that its products fall within the States' various safe harbor

provisions in their state laws, and that Wells Pharma can avoid liability by proving Section 503B's exemption applies. (*See*, *e.g.*, U.S. Am. Br. 15–16). Even if the state laws and their safe-harbor provisions "are not ultimately construed to be identical to the FDCA's requirements," the government maintains that Wells Pharma must still establish compliance with Section 503B's requirements in court. (U.S. Am. Br. 15–16). That framing does not resolve the conflict; it defines it.

Under the Fifth Circuit's approach, preemption does not bar these claims at the outset. Instead, it forces an outsourcing facility to litigate and "prove[] that it satisfies § 353b's many requirements." *Zyla*, 134 F.4th at 331 n.2. Put differently, Wells Pharma must bear the burden of establishing federal compliance through discovery, expert testimony, and potentially a jury trial to avoid state-law liability.

The Ninth Circuit, on the other hand, bars precisely the type of claim the government says must proceed—one that requires an outsourcing facility to prove, in the first instance, whether it complied with Section 503B. The Ninth Circuit explained that such suits are barred because they would "require litigation of the alleged underlying FDCA violation in a circumstance where the FDA has not itself concluded that there was a violation." *Nexus*, 48 F.4th at 1048 (citation omitted). And *Davidson* confirmed that claims turning on whether a facility "qualifie[s] for an exception to FDA approval" are preempted because that determination is "a task reserved for the FDA," not private litigants or state tribunals. 106 F.4th at 849.

The government thus endorses the Fifth Circuit's rule that outsourcing facilities must prove compliance with federal law in court to avoid liability under state law. The government's safe-harbor theory places on private litigants, and ultimately state courts and juries, the very compliance determinations Congress assigned to FDA in the first instance.

This is not a "shallow" disagreement. It is a direct conflict over who decides Section 503B compliance and whether outsourcing facilities will be subjected to divergent liability regimes across jurisdictions. The government's position simply aligns itself with one side of the split. Under that rule, identical conduct triggers full-scale litigation of federal compliance in some circuits while being categorically barred in others. That conflict warrants this Court's review.

B. Impending FDA Action on Indomethacin Underscores Why Preemption Is Necessary, and Why This Case Is an Ideal Vehicle.

1. The government's "vehicle" argument gets it backwards. Potential FDA action on indomethacin only heightens the need to keep competing state-law adjudications out of the regulatory scheme. The government argues this case is a poor vehicle "because FDA is currently considering whether to take regulatory action" regarding indomethacin and may decide whether to add it to the Section 503B bulks list while this case is pending. (U.S. Am. Br. 2, 21–22). But the possibility that FDA could "materially change the nature of the parties' dispute" is a reason to grant review, not deny it. (U.S. Am. Br. 21).

Congress enacted Section 503B to place oversight of large-scale compounding within FDA's hands, through registration, reporting, inspections, and enforcement. 21 U.S.C. § 353b(a)–(b). The government flips that design by recasting Section 503B from an FDA-administered regulatory framework into an affirmative defense that must be proved in court to avoid competitor-driven state-law liability. Under that approach, the relevant question is no longer what FDA has determined through its oversight regime, but what a state tribunal decides after discovery and trial about compliance with Section 503B's conditions.

That inversion is especially problematic where, as here, FDA is actively exercising its authority. If FDA is evaluating indomethacin under Section 503B's bulks-list process, competitor-driven state litigation invites courts and juries to decide the very compliance issues FDA is contemporaneously assessing. That risks conflicting determinations and the "extraneous pull" underpinning *Buckman*'s implied-preemption holding. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001); *see also Kansas v. Garcia*, 589 U.S. 191, 212 (2020) (recognizing that *Buckman*'s implied-preemption analysis is grounded in the risk of "serious disruption of the sensitive and highly technical process of" FDA's decision-making process). Congress chose to vest the full oversight, inspection, and enforcement framework for Section 503B compliance in FDA. The Ninth Circuit recognized that when it held 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.

The government's approach, adopting the Fifth Circuit's rule, would allow FDCA-proxy state-law suits to proceed precisely because FDA might act. That makes no sense. It would guarantee the collision Congress sought to avoid by forcing regulated entities to "comply[] with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes." *Buckman*, 531 U.S. at 350. It also invites state tribunals to render decisions inconsistent with "FDA's enforcement policy." (U.S. Am. Br. 21). Far from making this case a poor vehicle, the prospect of ongoing FDA action here confirms why this case requires immediate resolution.

2. The government's "wait-and-see" argument would only entrench the circuit conflict further. The government emphasizes that this case remains at the motion-to-dismiss stage and suggests that this Court should simply wait. (U.S. Am. Br. 22). But the conflict is already fully developed. Either § 337(a) and *Buckman* bar these competitor FDCA-proxy suits at the outset, or they do not. That is a purely legal question on which the circuits are already divided.

And a "wait" approach would only deepen the divide on the central preemption point. As long as the split persists, competitors will continue filing suits in circuits that permit them while avoiding those that do not, producing further geographic fragmentation. Regulated entities will face materially different litigation exposure depending solely on where they operate, which is the inconsistency this Court's review and its implied-preemption jurisprudence is designed to prevent. *See Buckman*, 531 U.S. at 350.

C. The Government's Theory Misunderstands Section 503B's Structure and Function.

1. The government's argument also rests on a fundamental misunderstanding of how Section 503B operates. It treats Section 503B as if it functions like Section 505's premarket-approval regime, faulting Wells Pharma for lacking an FDA "approval" for indomethacin that Section 503B does not, and could not, require. (U.S. Am. Br. 14). Congress in fact designed Section 503B to do the opposite. Congress replaced *ex ante* approval with an FDA-administered oversight scheme based on registration, reporting, inspection, and enforcement discretion.

Section 503B expressly provides that Section 505's approval requirements "shall not apply" to qualifying outsourcing facilities. 21 U.S.C. § 353b(a). In place of premarket approval, Congress established an *ex post* system in which FDA evaluates compliance through ongoing supervision, including risk-based inspections and post-market reporting. *Id.* § 353b(b)(2), (b)(4), (b)(5). That structure reflects a deliberate policy choice by Congress to have FDA—not private litigants or courts—determine whether an outsourcing facility complies with Section 503B and whether enforcement is warranted.

The government's theory transforms that scheme into something Congress rejected. By requiring outsourcing facilities to prove compliance with Section 503B in litigation, it effectively converts the statutory framework into a jury-adjudicated "permit" requirement. That inversion is incompatible with Section 503B's text and structure. As the Ninth Circuit explained, the FDCA

disclaimed a pre-approval or permitting process for outsourcing facilities and instead turned to FDA to balance "risks and concerns *in its enforcement process*." *Nexus*, 48 F.4th at 1050 (emphasis added).

The text and structure of Section 503B in contrast to Section 505 demonstrate how Congress intended both to operate. As discussed above, FDA actively administers the outsourcing-facility regime, including through its bulk-substances evaluation process. In exercising that authority, FDA has placed indomethacin on its Category-1 list under the interim bulks-policy framework and has determined, after reviewing the drug, that it does not intend to take enforcement action against qualifying outsourcing facilities compounding Category-1 substances under specified conditions. That ongoing regulatory judgment underscores that Congress authorized FDA, not juries, to be "attentive to the difficult issues of interpreting and enforcing" Section 503B. *Id.*

As Justice Alito reasoned in *Wyeth v. Levine*, 555 U.S. 555, 605 (2009) (Alito, J., dissenting), the "real issue" presented by this case is "who—the FDA or a jury[]—has the authority and responsibility" to make the relevant determinations under Section 503B. This Court's preemption jurisprudence reflects the correct allocation of authority, recognizing that courts must avoid disrupting the "balance" struck by FDA in administering a complex regulatory scheme. *Id.* at 621. "By their very nature, juries are ill equipped to perform the FDA's cost-benefit-balancing function." *Id.* at 626. By recasting Section 503B as if it imposed a judicially enforceable approval requirement, the government's approach invites exactly

the type of jury-driven second-guessing that displaces FDA's role.

2. The government's reliance on medical-device "parallel claim" concepts is misplaced. It attempts to analogize this case to the Court's medical-device precedents, asserting that the decision below "accords with the FDCA's medical-device provisions" because States may impose "parallel" requirements. (U.S. Am. Br. 2, 11). But that analogy confuses two fundamentally different statutory frameworks. In the medical-device context, Congress expressly addressed federal-state overlap through an express preemption clause that permits state requirements only if they are not "different from, or in addition to, any [federal] requirement." 21 U.S.C. § 360k(a)(1); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996). That framework also requires a "rigorous" premarket approval process against which parallel state duties may be meaningfully assessed. *Lohr*, 518 U.S. at 477.

Section 503B reflects no such design. Congress created an FDA-administered category of outsourcing facilities and deliberately carved qualifying compounded drugs out of Section 505's premarket-approval regime. 21 U.S.C. § 353b(a). In place of approval, Congress imposed ongoing FDA oversight through registration, reporting, inspections, and enforcement. 21 U.S.C. § 353b(b)(1)–(2), (b)(4)–(5). And unlike the device statute, Section 503B contains no express preemption clause, no "identical" or "parallel" requirement provision, and no indication that private plaintiffs may use state law to litigate compliance with its conditions in the first instance.

Against that backdrop, Zyla's claims are not "parallel" in any meaningful sense. The state statutes it invokes do not incorporate the carve-outs Congress enacted in Section 503B. Instead, they impose liability based on the absence of FDA premarket approval—even though Section 503B provides that Section 505 "shall not apply." 21 U.S.C. § 353b(a). Those claims therefore do not mirror federal law; they override it by reintroducing, through state law, the very approval requirement Congress displaced. That is not "parallel enforcement." It is the imposition of additional requirements, producing the same "extraneous pull" on the federal regulatory scheme that *Buckman* forbids. 531 U.S. at 353.

This case presents a conceded, outcome-determinative circuit split on a single question: who decides Section 503B compliance in the first instance, FDA or courts and juries applying state law? In the Fifth Circuit, Wells Pharma must litigate Section 503B compliance through discovery and trial, bearing the burden of proving federal compliance in court to avoid state-law liability. In the Ninth Circuit, those same claims are barred at the outset because claims requiring private parties to litigate FDCA compliance are preempted. The conflict is immediate and irreconcilable. It turns on Congress' judgment to assign the "delicate balance" of administering Section 503B to FDA, not to private competitors or state tribunals.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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