No. 25-257

In The
Supreme Court of the United States

WELLS PHARMA OF HOUSTON, LLC,
Petitioner,

v.

ZYLA LIFE SCIENCES, LLC,
Respondent.

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

BRIEF OF *AMICUS CURIAE* AMERICANS FOR ACCESS TO COMPOUNDED MEDICATION IN SUPPORT OF PETITIONER

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INTEREST OF *AMICUS CURIAE*[1]

The Americans for Access to Compounded Medication ("AACM") is a national coalition of pharmacists, physicians, physician assistants, nurse practitioners, patients, businesses, and other medication compounding stakeholders. Compounded medications, prepared under the authority granted by 21 U.S.C. §§ 353a–353b (FDCA §§ 503A–503B), serve as a critical safety net for patients in circumstances where no FDA-approved therapy is available and during periods of drug shortages. Congress has long recognized that individualized compounding is an essential component of pharmacy and physician practice and an integral safeguard for patient care. Unlike mass-manufactured drugs, compounded medications allow prescribers to tailor therapies to meet unique patient needs to avoid allergens, create dosage forms for children or the elderly who otherwise would not be able to consume the medication, or create formulations when commercially available products are unavailable or inadequate.

The legislative history of the FDCA Sections 503A and 503B reflects Congress's intent to preserve and regulate this practice nationally, not to eliminate it or to rely on the states and territories to create 56

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[1] No counsel for any party authored this brief in whole or in Party, and no person or entity other than *amicus curiae,* its members, or its counsel made a monetary contribution intended to fund the preparation or submission of this brief. Additionally, notice of this brief was provided to counsel for the parties on September 22, 2025.

different regulatory schemes to regulate the practice of compounding. When Congress enacted the Food and Drug Administration Modernization Act of 1997 ("FDAMA"), it codified Section 503A specifically to protect traditional pharmacy compounding while providing a framework to prevent its abuse. In response to the 2012 New England Compounding Center tragedy, which revealed dangerous gaps in oversight of large-scale operations masquerading as traditional pharmacies, Congress passed the Drug Quality and Security Act of 2013 ("DQSA"). That law reaffirmed the need for the FDCA's Section 503A for patient-specific compounding and created Section 503B, which established FDA-supervised outsourcing facilities permitted to produce compounded medications in large quantities under current good manufacturing practices (cGMP) for health care providers and 503A pharmacies when needed for large populations of patients, particularly during times of national drug shortages. Together, these provisions struck a deliberate balance: ensuring stronger federal oversight where warranted, while preserving access to the individualized therapies that patients and clinicians depend upon.

This statutory framework demonstrates Congress's clear policy judgment—that compounding is not a loophole or workaround to FDA approval, but a vital, necessary, and authorized practice that complements the commercial drug supply chain. By embedding compounding within the FDCA, Congress acknowledged that the health care system cannot function without a lawful and reliable mechanism to meet patient needs in the management of rare

diseases, drug allergy avoidance, pediatric dosing, palliative care, and emergencies such as national drug shortages. Far from being an afterthought, compounded medications are a congressionally protected component of American pharmacy practice, designed to promote both patient safety and continued access to life-saving care.

While states and territories retain the authority to regulate the practice of pharmacy through licensure and permitting of individuals and businesses within their borders, Congress recognized that compounding services implicate a national interest that cannot be left to a patchwork of inconsistent local regimes. By embedding compounding authority within the FDCA, Congress established a uniform framework that necessarily preempts state efforts to unduly restrict or prohibit compounding services. This reflects a compelling governmental interest: ensuring that patients in every state and territory have reliable access to compounded therapies when commercial drugs are unavailable or unsuitable. Congress understood that barriers at the state level would undermine this federal objective and thus enacted §§ 503A and 503B as a cohesive, nationwide scheme to safeguard patient access while preserving safety through FDA oversight. See U.S. Const. art. VI, cl. 2 (Supremacy Clause); *Wyeth v. Levine*, 555 U.S. 555 (2009) (recognizing federal law may preempt conflicting state requirements under the FDCA); *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472 ,(2013) (holding state law claims preempted where compliance with both federal and state law is impossible); *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011). Recent federal courts have

likewise applied these principles to hold that FDCA enforcement lies exclusively with the federal government, preempting state efforts to regulate matters reserved to FDA jurisdiction.

The decision below threatens uniformity in this carefully balanced framework of centralized governance with federalism by allowing states and private litigants to second-guess FDA authority. Americans for Access to Compounded Medication files to urge review and correction. See Sup. Ct. R. 37.1.

SUMMARY OF ARGUMENTS

The Fifth Circuit permitted state unfair-competition statutes in California, Colorado, Connecticut, Tennessee, South Carolina, and Florida to be used as private enforcement tools against FDA-permitted compounding activities by pharmacists and physicians. *Zyla Life Sciences., L.L.C. v. Wells Pharma of Houston*, L.L.C., No. 23-20533 (5th Cir. Apr. 10, 2025). That holding conflicts with this Court's preemption jurisprudence, particularly *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), and circuit decisions holding that state-law claims are preempted when they intrude into FDA's exclusive domain. The decision threatens immediate disruption to patient care. Compounding pharmacies supply critical medications during shortages, including epinephrine, sterile water for injection, IV solutions after Hurricane Helene, and GLP-1 medications. Allowing private competitors to weaponize state statutes undermines Congress's intent in the Drug Quality and

Security Act of 2013 and fractures national drug policy.

ARGUMENTS

The Fifth Circuit's decision in *Zyla Life Sciences, L.L.C. v. Wells Pharma of Houston, L.L.C.*, No. 23-20533 (5th Cir. Apr. 10, 2025), creates a direct and untenable split with this Court's precedent and the holdings of other circuits. By permitting private competitors to invoke state unfair-competition statutes in California, Colorado, Connecticut, Tennessee, South Carolina, and Florida against pharmacies and physicians engaged in FDA-permitted compounding activities, the Fifth Circuit effectively sanctioned state-law private enforcement of the FDCA. That result cannot be reconciled with *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), which held that claims premised on FDCA violations are impliedly preempted because Congress entrusted the FDA alone with policing compliance. Nor can it be squared with this Court's impossibility-preemption cases, which emphasize that states may not impose requirements "in addition to, or different from" federal law when compliance with both is impossible. See *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011); *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 486–90 (2013).

Other circuits have faithfully applied these principles, holding that state-law claims are preempted where they intrude into the FDA's exclusive regulatory domain. See, e.g., *Patel v. Merck & Co., Inc.*, 485 F. App'x 894 (6th Cir. 2012) (rejecting

private state-law enforcement of FDCA standards); *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919 (9th Cir. 2010) (holding that Lanham Act claims premised on FDCA violations were preempted because the FDA has exclusive enforcement authority). The Fifth Circuit's contrary approach opens the door to a patchwork of state enforcement schemes, where the legality of federally authorized compounding depends not on FDA policy, but on the vagaries of state unfair-competition laws. This Court's intervention is essential to prevent precisely the type of fractured regulatory landscape the Supremacy Clause was designed to avoid. U.S. Const. art. VI, cl. 2.

The consequences are not academic. Compounding pharmacies serve as a vital backstop during drug shortages and emergencies, producing medications such as epinephrine, sterile water for injection, IV solutions after Hurricane Helene, and GLP-1 therapies during ongoing shortages. Allowing private competitors to weaponize state statutes against these federally authorized activities undermines Congress's carefully calibrated scheme in the Drug Quality and Security Act of 2013 ("DQSA"), Pub. L. No. 113-54, 127 Stat. 587, and threatens to fracture national drug policy at the precise moment when coordinated, nationwide access to compounded medicines is most critical. Without this Court's review, the Fifth Circuit's holding will invite further state-law incursions into FDA's exclusive authority, producing immediate disruption to patient care and an inconsistent national framework for access to compounded therapies.

I. The Decision Below Deepens a Circuit Split

Section 337(a) of the FDCA bars private enforcement. This Court confirmed in *Buckman* that claims existing solely by virtue of the FDCA are preempted. *Buckman* 531 U.S. at 353. Yet the Fifth Circuit allowed mirror statutes to survive preemption. By contrast, the Ninth Circuit has held that such claims are preempted when they intrude into FDA's exclusive enforcement. The Court of Appeals held that FDCA's prohibition on private enforcement barred action by a manufacturer of Food and Drug Administration (FDA) approved ready-to-use ephedrine sulfate product when it brought action against operator of network of compounding pharmacies alleging that their sale of ephedrine sulfate preloaded into ready-to-use syringes violated state laws prohibiting sale of drugs not approved by FDA, which is the precise question in this case. *Nexus Pharmaceuticals, Inc. v. Central Admixture Pharmacy Services, Inc.*, 48 F.4th 1040, 1041 (9th Cir. 2022). See also, e.g. *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919 (9th Cir. 2010); *Perez v. Nidek Co.*, 711 F.3d 1109 (9th Cir. 2013).

II. The Decision Is Inconsistent with a Comprehensive Federal Framework to Govern Compounding

Congress has long recognized the indispensable role of pharmacy compounding in patient care, but it also understood that compounding implicates national interests too important to leave to a patchwork of state regulation. In the Food and Drug Administration Modernization Act of 1997 ("FDAMA"), Congress codified Section 503A of the FDCA to preserve

traditional, patient-specific compounding as part of pharmacy and physician practice. 21 U.S.C. § 353a. Section 503A struck a deliberate balance: it exempted compounded medications from certain federal approval and labeling requirements while making clear that the practice remained subject to FDA oversight.

Congress reaffirmed and strengthened this judgment in the wake of the 2012 New England Compounding Center tragedy. The DQSA was a direct response to the dangers of large-scale operations operating outside any clear regulatory structure. In it, Congress reaffirmed the authority of Section 503A and created Section 503B, establishing FDA-supervised outsourcing facilities permitted to manufacture compounded drugs in bulk under current good manufacturing practices ("cGMP"). 21 U.S.C. § 353b. By doing so, Congress addressed the need for scalable compounded medications during shortages, while ensuring such operations were firmly subject to national oversight. The DQSA reflects Congress's clear intent to prevent inconsistent state-by-state rules that would undermine patient access and fracture national drug policy.

This framework leaves no doubt that Congress entrusted the FDA—not private litigants or state courts—with the exclusive responsibility of enforcing the FDCA's requirements for compounded drugs. See *Buckman*, 531 U.S. at 348. While states retain the traditional authority to license pharmacists and pharmacies, that authority does not extend to second-guessing FDA determinations about permissible compounding. To allow otherwise is to substitute fifty

different regulatory schemes for the uniform system Congress carefully designed.

III. The Fifth Circuit's Decision in Zyla Creates a Direct Conflict With This Court's Preemption Jurisprudence

The Fifth Circuit's ruling authorizes precisely what Congress sought to prevent: the use of state law as a vehicle for private enforcement of the FDCA. By permitting plaintiffs to invoke state unfair-competition statutes in jurisdictions such as California, Colorado, Connecticut, Tennessee, South Carolina, and Florida, the decision transforms local business-tort statutes into tools to challenge compounding practices the FDA has authorized under Sections 503A and 503B. This result undermines the federal framework and invites litigation designed to chill lawful compounding activity rather than protect public health.

That outcome cannot be squared with this Court's precedent. In *Buckman*, the Court held that claims premised on FDCA violations are impliedly preempted because Congress entrusted enforcement exclusively to the FDA. Likewise, in its impossibility-preemption cases, the Court has made clear that states may not impose obligations "in addition to, or different from" federal requirements where compliance with both is impossible. See *Mensing*, 564 U.S. at 617-18; *Bartlett*, 570 U.S. at 486–90. The Fifth Circuit departs sharply from these principles by allowing private litigants to leverage state law to dictate whether pharmacies may engage in compounding practices federal law expressly permits.

Other circuits have rejected this approach. The Ninth Circuit in *PhotoMedex*, 601 F.3d at 924–28, and the Sixth Circuit in *Patel*, 485 F. App'x at 898–99, recognized that courts cannot entertain claims requiring them to determine whether conduct violates the FDCA, because that determination belongs solely to the FDA. The Fifth Circuit's ruling thus places it in direct conflict not only with this Court's preemption jurisprudence but also with its sister circuits' recognition of the FDA's exclusive enforcement authority.

IV. The Circuit Split Will Produce a Patchwork of Regulatory Outcomes

The Fifth Circuit's ruling threatens to create precisely the fractured regulatory environment Congress and this Court have long sought to prevent. By allowing private parties to invoke state unfair-competition statutes, the court invited state-law enforcement of federal standards in areas Congress reserved exclusively to the FDA. Pharmacies now face litigation not because the FDA has found them noncompliant, but because private competitors seek to weaponize local statutes as proxy enforcement mechanisms.

This outcome stands in stark contrast to the approach taken in other circuits. Both the Ninth Circuit (*PhotoMedex*) and the Sixth Circuit (*Patel*) rejected attempts to recast FDCA violations as state-law claims, recognizing that if state law may serve as a vehicle for FDCA enforcement, the result will be conflicting judgments and obligations—exactly what Congress avoided in enacting the DQSA.

The Supremacy Clause makes clear that federal law prevails over conflicting state regimes. U.S. Const. art. VI, cl. 2. Allowing states to impose additional or inconsistent obligations on compounding providers would erode FDA's authority and frustrate Congress's express intent to ensure reliable access nationwide. Without this Court's intervention, pharmacies in one state may be free to engage in FDA-authorized compounding, while those in a neighboring state may be barred under state-law theories—an intolerable disparity in a field where uniform national standards are indispensable.

V. The Decision Threatens Immediate and Severe Disruption to Patient Care

The stakes of the Fifth Circuit's ruling extend far beyond statutory interpretation—they reach directly into hospitals, clinics, and pharmacies where patients rely on compounded medicines. Compounding pharmacies supply critical therapies when FDA-approved options are unavailable, unsuitable, or in short supply. For example, compounded epinephrine has served as an indispensable emergency therapy when commercial products were scarce. After Hurricane Helene, when supply chains for sterile injectables collapsed, compounding pharmacies produced sterile water and IV solutions to sustain patient care. More recently, national shortages of GLP-1 medications have forced prescribers to rely on compounded formulations to manage diabetes and weight-related conditions for patients who would otherwise be left without treatment.

Permitting private competitors to weaponize state unfair-competition statutes undermines the reliability of this safety net. Instead of focusing on FDA oversight, providers may now be forced to defend against duplicative state-law claims. This litigation risk will chill lawful compounding, discourage providers from stepping in during emergencies, and ultimately reduce the availability of life-saving medications when patients need them most.

The inevitable result is unequal access. Patients in states where unfair-competition statutes may be invoked will face diminished access to compounded therapies, while those in other jurisdictions will continue to benefit from the uniform federal system Congress designed. Such disparities are untenable in practice and contrary to Congress's express intent.

VI. This Court's Review Is Necessary to Prevent Fractured National Drug Policy

The Supremacy Clause requires that federal law govern where Congress has enacted a comprehensive framework to address a matter of national importance. Through the FDCA and specifically Sections 503A and 503B, Congress created such a framework for compounding, assigning exclusive enforcement authority to the FDA. The Fifth Circuit's decision disregards that mandate by allowing private litigants to use state unfair-competition statutes as de facto enforcement tools. This invites states to intrude into the FDA's domain, producing precisely the

regulatory disarray Congress sought to prevent when it enacted the DQSA.

If left unreviewed, the decision will fracture national drug policy along state lines. Pharmacies and prescribers will face different legal standards depending not on federal law, but on local statutes and lawsuits. Patients in one jurisdiction may lose access to compounded therapies available across state borders, creating the very patchwork Congress deliberately avoided. Only this Court can restore the uniformity the Supremacy Clause demands and prevent further disruption to patient care.

The Fifth Circuit's reasoning turns entirely on whether mirror statutes escape preemption. The issue is clean, outcome-determinative, and nationally significant. Review is warranted.

VII. This Case Is an Ideal Vehicle

This case presents the Court with a clean, outcome-determinative question of national significance: whether state statutes that mirror or overlap with the FDCA can be used as private enforcement mechanisms without violating federal preemption principles. The Fifth Circuit held that they can. That reasoning conflicts directly with this Court's precedents, including *Buckman*, and with other circuits that have barred such claims.

No threshold issues obscure the path to review. The question presented was squarely addressed below, the record is fully developed, and the decision's

consequences are immediate and sweeping—placing access to critical compounded medications at risk nationwide. This Court's intervention is therefore imperative to restore uniformity in federal drug policy, protect Congress's carefully crafted scheme, and ensure that patients across the country continue to receive the therapies they need.

The Fifth Circuit's reasoning turns entirely on whether mirror statutes escape preemption. The issue is clean, outcome-determinative, and nationally significant. Review is warranted.

Because the decision below squarely conflicts with this Court's precedent and threatens to fracture national drug policy, review is essential. And this case provides the ideal vehicle for resolving the conflict once and for all.

Finally, there is a further concern that counsels strongly in favor of review. The decision below arises from an unremarkable dispute over a very old medication technology that was invented more than 55 years ago. That product, indomethacin, especially in its suppository dosage form, is unlikely to garner national media attention or prompt robust public scrutiny. The *amicus curiae* does not see any one of the Sunday morning television Supreme Court analysts putting together a segment on the nuanced legal analysis regarding how something as innocuous as a holding regarding states' rights regarding compounded indomethacin suppositories out of the Fifth Circuit now affects more profound issues such as Americans' rights to bear arms, reproductive healthcare, or a

state's role in the enforcement of immigration policies. This amicus makes no judgement on the importance of these issues or the profound role the states can and should play in their implementation and enforcement. A case this low-salience and lightly scrutinized should not be the occasion for precedent based on questionable reasoning that will harden into doctrine and drive substantial constitutional outcomes in future, higher-stakes disputes.

In the end, if left undisturbed, *Zyla* becomes a one-way ratchet: litigants can cite it to justify broad state-law incursions into FDA-reserved terrain well beyond indomethacin or even traditional compounded products. The immediate effect will be felt by pharmacies and prescribers chilled from providing FDA-permitted compounded therapies; the longer-term effect will be a patchwork of state-law "mirror" regimes that displace the very national uniformity Congress enacted in the FDCA and DQSA. This Court has cautioned against precisely this sort of end-run around federal allocation of authority: doctrines forged in easy cases that silently reshape the law for hard ones.

Review is warranted to prevent that hydraulic pressure from building around a weak vehicle. There will be future cases that squarely present the alleged state interests, the federal interests, and a full record on actual risk and patient impact. This is not one of them. The Court should grant review to ensure that any doctrinal shift with nationwide consequences occurs—if at all—in a case that places those consequences in clear view and within the proper federal framework.

CONCLUSION

The decision below deepens a square circuit conflict, departs from this Court's preemption jurisprudence, and invites state-by-state private enforcement of the FDCA in an area Congress reserved to FDA. Left in place, it will fracture national drug policy, chill FDA-permitted compounding precisely when patients most need it and undermine the uniform framework Congress enacted in FDAMA and the DQSA.

This is an ideal vehicle to resolve the question presented: whether "mirror" state statutes may be used as de facto private FDCA enforcement. The issue is clean, outcome-determinative, and nationally significant. It should not be allowed to harden into precedent through a low-salience dispute over indomethacin suppositories—an unremarkable context that masks the decision's far-reaching structural consequences.

For these reasons, the Court should grant the petition for a writ of certiorari. If the Court grants review, it should reverse the judgment of the Fifth Circuit (or, at minimum, vacate and remand) and reaffirm that the FDCA and DQSA preempt private efforts to police FDCA compliance through state unfair-competition law, thereby restoring the uniform federal scheme and protecting patient access to compounded medicines nationwide.

Respectfully submitted,

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