Case No. 23-20533

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

ZYLA LIFE SCIENCES, L.L.C.,

Plaintiff - Appellant/Cross-Appellee
v.
WELLS PHARMA OF HOUSTON, L.L.C.,

Defendant - Appellee/Cross-Appellant

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF TEXAS, CASE NO. 22-CV-4400

UNOPPOSED MOTION FOR LEAVE TO FILE AMICUS BRIEF OF OUTSOURCING FACILITIES ASSOCIATION IN SUPPORT OF REHEARING EN BANC

ANDREW M. GROSSMAN
BAKER & HOSTETLER LLP
Washington Square, Suite 1100
1050 Connecticut Ave., N.W.
Washington, D.C. 20036
(202) 861-1697
agrossman@bakerlaw.com

Attorney for Proposed Amicus
Outsourcing Facilities Association

UNOPPOSED MOTION FOR LEAVE TO FILE AMICUS BRIEF

Pursuant to Federal Rule of Appellate Procedure ("FRAP") 29(b) and Fifth Circuit Rule 29, proposed Amicus Outsourcing Facilities Association ("OFA") moves the Court for leave to file the attached proposed Brief Amicus Curiae of the Outsourcing Facilities Association, in support of Appellee/Cross-Appellant's Petition for Rehearing En Banc. In support of this Motion, OFA states as follows:

1. OFA is a 501(c)(6), non-profit entity organized in the State of Delaware with offices in South Lake, Texas and Washington, DC.

2. OFA is the trade association representing FDA-registered 503B outsourcing facilities who focus on providing patients and healthcare providers with safe and effective compounded medications. OFA members work with patients, healthcare providers, and facilities on a daily basis to ensure the specific needs, of both providers and patients, for compounded medications are satisfied. OFA works with industry, governmental agencies, and healthcare providers to educate and advocate for outsourcing facilities and the critical need to ensure that patients and providers have access to the medications they need.

3. OFA has a fundamental interest in the resolution of this case, and those like it, which are directed at undoing Congress's determination to permit outsourcing facilities compounding under the terms and conditions of applicable federal law.

4. Under FRAP 29(a)(3), applicable here pursuant to FRAP 29(b)(3) (which "governs amicus filings during a court's consideration of whether to grant panel rehearing or rehearing en banc . . . ."), a motion for leave to file an amicus brief may be granted if the movant shows a sufficient interest and that the amicus brief is desirable and relevant. As stated above, the OFA, as the trade association representing FDA-registered 503B outsourcing facilities, has a fundamental interest here as its members are, and have been, subject to similar efforts to interfere or eliminate their ability to market products in a manner consistent with Section 503B of the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 353b, which allows compliant outsourcing facilities to compound and sell drugs *without* first securing new drug approval from the FDA.

5. Consequently, OFA's voice in this matter also is both desirable and relevant. This court has construed these requirements broadly, with reference to the basis of "our adversarial system of justice . . . [in] the same fundamental premise as our First Amendment—a firm belief in the robust and fearless exchange of ideas as the best mechanism for uncovering the truth." *Lefebure v. D'Aquilla*, 15 F.4th 670, 674 (5th Cir. 2021). There, the court granted amici participation to several retired judges, noting that the "court should welcome amicus briefs for one simple reason: '[I]t is for the honour of a court of justice to avoid error in their judgments.'" *Id.* at

675. And, the court also noted that "these principles apply even—indeed, especially—when amici sharply criticize the work of the court." *Id.*

6. Pursuant to FRAP 29(b)(5), this motion is timely, having been filed "no later than 7 days after the petition is filed."

7. Counsel for OFA conferred with Counsel for Plaintiff and Defendant, and they indicated they do not oppose this motion for leave.

For these reasons, proposed Amicus OFA respectfully requests that the Court grant this Motion for Leave to File Amicus Brief and accept the attached brief for filing.

Dated: April 30, 2025

Respectfully submitted,

/s/ Andrew M. Grossman

ANDREW M. GROSSMAN
BAKER & HOSTETLER LLP
Washington Square, Suite 1100
1050 Connecticut Ave., N.W.
Washington, D.C. 20036
(202) 861-1697
agrossman@bakerlaw.com

Attorney for Proposed Amicus Outsourcing Facilities Association

CERTIFICATE OF COMPLIANCE

This motion complies with the type-volume limit of Federal Rule of Appellate Procedure 27(d)(2)(A) as the text consists of 552 words as counted by Word for the Microsoft 365 program used to generate this motion. This motion also complies with the type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) as it was prepared using Word for Microsoft 365 in 14-point Times New Roman font.

Dated: April 30, 2025

/s/ Andrew M. Grossman
Andrew M. Grossman

CERTIFICATE OF SERVICE

I hereby certify that on April 30, 2025, I electronically filed the foregoing motion with the Clerk of the United States Court of Appeals for the Fifth Circuit using the Court's CM/ECF system, which will send a notification of such filing to all counsel of record for all parties.

/s/ Andrew M. Grossman
Andrew M. Grossman

Case No. 23-20533

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

ZYLA LIFE SCIENCES, L.L.C.,

Plaintiff - Appellant/Cross-Appellee
v.
WELLS PHARMA OF HOUSTON, L.L.C.,

Defendant - Appellee/Cross-Appellant

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF TEXAS, CASE NO. 22-CV-4400

BRIEF *AMICUS CURIAE* OF OUTSOURCING FACILITIES ASSOCIATION IN SUPPORT OF REHEARING EN BANC

ANDREW M. GROSSMAN
BAKER & HOSTETLER LLP
Washington Square, Suite 1100
1050 Connecticut Ave., N.W.
Washington, D.C. 20036
(202) 861-1697
agrossman@bakerlaw.com

Attorney for Amicus Curiae
Outsourcing Facilities Association

SUPPLEMENTAL CERTIFICATE OF INTERESTED PERSONS

Zyla Life Sciences, LLC. v. Wells Pharma of Houston, L.L.C., No. 22-cv-4400

Pursuant to Fifth Circuit Rule 29.2 and Fifth Circuit Rule 26.1.1 the undersigned counsel of record certifies that, in addition to the persons and entities listed by the Petitioner/Appellee/Cross-Appellant and Appellant/Cross-Appellees, the following listed persons and entities as described in the fourth sentence of Fifth Circuit Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that the judges of this Court may evaluate possible disqualification or recusal:

Amicus Curiae: The Outsourcing Facilities Association is a non-profit entity with no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

Counsel for Amicus Curiae:

Baker & Hostetler LLP
Andrew M. Grossman
Thomas E. Hogan
Mark N. Wagner
Lee A. Casey
Tanner J. Gattuso
Benjamin D. Janacek

Dated: April 30, 2025

/s/ Andrew M. Grossman
Andrew M. Grossman
Attorney of Record for *Amicus Curiae*

TABLE OF CONTENTS

SUPPLEMENTAL CERTIFICATE OF INTERESTED PERSONS i

TABLE OF CONTENTS ii

TABLE OF AUTHORITIES iii

INTEREST OF *AMICUS CURIAE* 1

INTRODUCTION AND SUMMARY OF ARGUMENT 2

ARGUMENT 3

A. The Statute 3

B. The Drug Manufacturers Strike Back 5

C. This Case Is Not *Wickard v. Filburn* 9

CONCLUSION 12

TABLE OF AUTHORITIES

Cases **Page(s)**

Asbell v. Kansas,
209 U.S. 251 (1908).....8

California v. Zook,
336 U.S. 725 (1949).....7

Nexus Pharms., Inc. v. Cent. Admixture Pharmacy,
48 F.4th 1040 (9th Cir. 2022).....6

Thompson v. W. States Med. Ctr.,
535 U.S. 357 (2002).....3

Wyeth v. Levine,
555 U.S. 555 (2009).....7, 8

Zyla Life Scis., LLC v. Wells Pharma of Houston, *LLC*,
No. 4:22-CV-04400, 2023 WL 6301651 (S.D. Tex. Sept. 27, 2023) 6, 7

Zyla Life Scis., LLC v. Wells Pharma of Houston, LLC,
No. 23-20533, 2025 WL 1076889 (5th Cir. Apr. 10, 2025) 7, 8, 9, 10

Other Authorities

21 U.S.C. § 337.....5

21 U.S.C. § 353a.....4

21 U.S.C. § 353b.....*passim*

21 U.S.C. § 379j-62 11

159 Cong. Rec. S8072 (2013).....4

159 Cong. Rec. S8074 (2013).....5

EMMERICH DE VATTEL, THE LAW OF NATIONS (Luke White ed. 1792).....9

Pub. L. No. 105-115, 111 Stat. 2328 (1997).....3

Pub. L. No. 113-54, 127 Stat. 587 (2013).....4

INTEREST OF *AMICUS CURIAE*

Outsourcing Facilities Association ("OFA") is the trade association representing FDA-registered Section 503B outsourcing facilities who focus on providing patients and healthcare providers with safe and effective compounded medications. OFA members work with patients, healthcare providers, and facilities on a daily basis to ensure the specific needs, of both providers and patients, for compounded medications are satisfied. OFA works with industry, governmental agencies, and healthcare providers to educate and advocate for outsourcing facilities and the critical need to ensure that patients and providers have access to the medications they need.

OFA has a fundamental interest in the resolution of this case, and those like it, which are directed at undoing Congress's decision to allow operation of outsourcing facilities compounding under the terms and conditions of applicable federal law.

No party's counsel authored this brief in whole or in part. No party or its counsel contributed financial support intended to fund the preparation or submission of this brief. No individual or organization other than OFA and its counsel contributed financial support intended to fund the preparation or submission of this brief.

INTRODUCTION AND SUMMARY OF ARGUMENT

The panel set out to strike a blow for federalism but lost the plot. This is not a case of congressional overreach, interfering in matters reserved to the States, but an instance of state law being employed to revise a federal program to the liking of one set of market participants against another.

In a legitimate exercise of its constitutional authority to regulate interstate commerce, Congress established a program to permit a special class of drug compounders to compete with drug manufacturers. Its purpose was to ensure the availability of medications needed by the public. Accordingly, Congress added Section 503B to the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 353b, allowing outsourcing facilities to compound and sell drugs *without* first securing the FDA approval ordinarily required before new pharmaceuticals can be offered to the public. When compounded drugs are marketed under the terms and conditions of Section 503B, they compete with major pharmaceutical manufacturers' products.

The plaintiff in this case, like other pharmaceutical manufacturers in other cases, seeks to thwart this program by using state law to drive its competitors from the market because the FDA will not do it for them. And, despite the panel's efforts to wrap the plaintiff's case in federalism's flag, neither Congress's enactment of Section 503B, nor the FDA's enforcement of that statute, threaten the original

constitutional balance between the Federal Government and the States. Roscoe Filburn's ghost may rest in peace as there is no home-grown wheat at issue here.

The panel decision was incorrect. As explained in the petition for rehearing *en banc*, it is inconsistent with Fifth Circuit precedent and creates a circuit split where none should exist. The petition should be granted and the District Court's ruling affirmed.

ARGUMENT

A. The Statute.

Before 1992, "the FDA generally left regulation of [pharmaceutical] compounding to the States." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 362 (2002). Pharmacists compounded drugs without FDA approval. *Id.* In that year, the agency decided to deem compounded drugs produced and sold in large quantities as subject to the FDCA, excluding from the statute's new-drug approval requirements only drugs compounded on a small scale for individual patients, among other limitations. Its goal was to confine compounding to "the bounds of traditional pharmacy practice." *Id.* at 363 (citation omitted).

Congress enacted portions of this policy into law as part of the Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2328, which added Section 503A to the FDCA. Section 503A codified portions of FDA's

compounding policy, layering federal regulatory requirements atop state law regulating compounding by state-licensed pharmacies. *See* 21 U.S.C. § 353a.

In 2013, Congress added Section 503B to the FDCA as part of the Drug Quality and Security Act, Pub. L. No. 113-54, 127 Stat. 587. It thereby created a detailed and comprehensive federal regulatory scheme for drug compounding by a new category of "outsourcing facilities," defined as facilities with "one geographic location or address" that engage "in the compounding of sterile drugs," have "elected to register" with the FDA, and comply with numerous other requirements imposed by that section. 21 U.S.C. § 353b(d)(4)(A). Under this provision, outsourcing facilities are regulated like drug manufacturers, including stringent manufacturing standards that must be met. Unlike the compounding pharmacies subject to Section 503A, outsourcing facilities need not be state-licensed pharmacies. *Id*. § 353b(d)(4)(B).

Congress's purpose was clear. Before Section 503B's enactment, the FDA sought to confine drug compounding to traditional pharmacies, generally preparing prescriptions for specific individuals or small groups of patients. Congress adopted Section 503B to "create a whole new alternative for safe sources of sterile compounded drugs that are held to a nationwide quality standard." 159 Cong. Rec. S8072 (daily ed. Nov. 18, 2013) (statement of co-sponsor Sen. Alexander); *see also*

id. at S8074 (statement of co-sponsor Sen Warner) (The Act "ensures that patients and providers have access to safe compounded drugs.").

Accordingly, Section 503B exempts from the FDA's normal approval process compounded drugs manufactured in compliance with its requirements. Outside of annual registration, bi-annual reporting, and inspection requirements, *see* 21 U.S.C. § 353b(b)(1), (2), & (4), Section 503B is "self-executing." That is, a compounder can rely on Section 503B's exemption from otherwise applicable FDA drug approval requirements without seeking and securing FDA's agreement that it is, indeed, in compliance with that section's provisions. In addition, unless the FDA-approved drug is in shortage, the 503B exempted drug cannot be "essentially a copy of one or more approved drugs." *Id.* at § 353b(a)(5).

Significantly, the FDCA—of which Section 503B is a part—prohibits private enforcement actions, requiring that "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a). There are limited exemptions for certain state civil enforcement actions, but only after the Secretary of Health and Human Services fails to bring such an action. No provision is made for private enforcement.

B. The Drug Manufacturers Strike Back.

Because FDA, bowing to Congress's purpose and intent in enacting Section 503B, will not use its enforcement authority to eliminate compounded drugs from

the marketplace, plaintiffs in this case and other pharmaceutical manufacturers have sued compounders under state laws that supposedly "adopt" federal requirements. Plaintiffs' claims, as the Ninth Circuit explained in *Nexus Pharmaceuticals, Inc. v. Central Admixture Pharmacy*, 48 F.4th 1040, 1044 (9th Cir. 2022) (a case squarely on point that the panel all but ignores), involve four propositions: (1) their products are the only "FDA approved" ones on the market; (2) the compounder's products do not have "FDA approval" and do not fall within Section 503B's exception because they are "essentially a copy" of plaintiffs' products; (3) state law forbids sale of drugs not approved by the FDA; and (4) the compounders have violated those laws by selling products not so approved.

Number (2) is the key. This step requires a determination not simply that a product is not "FDA approved," but that it is "essentially a copy of an approved drug" and so excluded from Section 503B's exception to the approval requirement. *See* 21 U.S.C. § 353b(d)(2). But the FDCA vests this determination in the FDA, by limiting enforcement actions to that agency. As a result, the panel's decision allowing state law private enforcement actions either (1) substitutes a judicial determination, whether state or federal, that a compounder's product is "essentially a copy" for FDA's; or (2) requires the compounder to seek and obtain FDA's "pre-approval" of its compliance with these federal statutory requirements. In this case, the District Court correctly concluded that such a pre-approval requirement was inconsistent

with the FDCA and preempted. *See Zyla Life Scis., LLC v. Wells Pharma of Houston*, LLC, No. 4:22-CV-04400, 2023 WL 6301651, at *5 (N.D. Tex. Sept. 27, 2023).[1]

Contrast this with the inquiry required in *California v. Zook*, 336 U.S. 725 (1949), an elderly case the panel (incorrectly) found controlling. *See* 2025 WL 1076889, at *4. *Zook* involved a state permitting requirement that (like federal law) required an Interstate Commerce Commission ("ICC") permit to lawfully sell certain transportation services in California. The defendants sold such services without that permit and argued that the state statute was invalid because it contained the very same prohibition—selling transportation services without an ICC permit—as federal law. The Court rejected their claim, reasoning that "the fact of identity does not mean the automatic invalidity of State measures" and noting that such a rule would require the Court to set "aside great numbers of state statutes to satisfy a congressional purpose which would be only the product of this Court's imagination." 336 U.S. at 730–33.[2] But no such rule is at issue here.

---

[1] The panel relegated its discussion of this analysis to a footnote, incorrectly dismissing it as in the nature of a "preemption overbreadth doctrine." 2025 WL 1076889, at *3 n.2. But Section 503B neither requires nor contemplates obtaining the FDA's approval of an exemption claim. As a result, the state laws at issue either have added a requirement to federal law as a prerequisite to legally selling compounded products in their State, or they have usurped that determination to the courts, one or the other. Both are constitutionally impermissible.

[2] *Wyeth v. Levine*, 555 U.S. 555 (2009), on which the panel also relies, is similarly inapposite. That case involved a traditional state tort action where the defendant sought to use the fact of FDA approval of its inferior labelling as a defense, asserting

The panel claims its application of "*Zook* accords well with preemption first principles" in that "when state law mirrors federal law, it 'recognizes the supremacy of the national law' by 'conform[ing] to it.'" 2025 WL 1076889, *4 (quoting *Asbell,* 209 U.S. at 258). But this says too little. The FDCA is far more complex than the provisions at issue in *Zook*, and the state statutes here do not "mirror" its requirements. The States adopted, or at least the plaintiffs assert, only the bits they considered useful—notably excluding Section 503B and Congress's clear rejection of private action enforcement. Consequently, contrary to the panel's claim, Wells Pharma's logic is *correct*, and it does not "undermine state sovereignty and principles of federalism." 2025 WL 1076889, at *6. The principle is straightforward. When a state cause depends upon the application of federal law as an element, the courts cannot simply substitute their application of the relevant statute for that of the regulatory agency to which it is committed, or eliminate the problem by adding a pre-approval requirement.

---

this approval was preemptive. In this case, however, the States have linked liability to a federal finding that only FDA can make.

The same is true of *Asbell v. Kansas*, 209 U.S. 251 (1908), also cited by the panel, which involved the same type of permitting requirement at issue in *Zook*. Where the permit requirement is the only basis for complying with federal law, then a state law also requiring a federal permit does not trench on the Commerce Clause as it adds nothing to the federal requirement. Where it is possible, as in this case, to comply with federal law through qualifying for an exemption, a State cannot require the permit regardless and still be said to "mirror" federal law.

C. This Case Is Not *Wickard v. Filburn*.

In its zeal to defend state sovereignty, the panel misstates the very nature of that sovereignty, quoting Vattel for the proposition that "as the Founders understood, one of the fundamental features of sovereignty is the power to regulate 'everything that passes' within one's own territory." 2025 WL 1076889, at *7. Like Blackstone, Vattel was a Framer favorite, in their libraries if not on their nightstands, but as inspiration not architect. More to the point, Vattel was not speaking of a *federal republic* in the above quoted passage.

On that subject, he said that when "several sovereign and independent states . . . unite themselves together by a perpetual confederacy," together forming "a federal republic: the deliberations in common will offer no violence to the sovereignty of each member, though they may, in certain respects, put some constraint on the exercise of it, in virtue of voluntary engagements." EMMERICH DE VATTEL, THE LAW OF NATIONS § 10 (Luke White ed. 1792). Vattel cautioned further that, "[a] person does not cease to be free and independent, when he is obliged to fulfil the engagements into which he has very willingly entered." *Id.*

The Constitution is that engagement for us, and it was designed to accommodate *two* sovereignties on a single territory. The question here is the extent to which, in creating a federal regulatory system for drug manufacture and safety, in particular those provisions applicable to outsourcing facilities, Congress left the

States free to reorder the legal requirements for compounders selling their products in that State by (1) eliminating the self-executing exemption of Section 503B and (2) permitting private action enforcement when Congress has plainly rejected it. The answer to both questions is no, and that answer does not affect the balance of power between the Federal Government and the States.

Nor is *Wickard v. Filburn*'s inconsistency with the Constitution's original meaning and structure at issue here. The panel reasoned that, because the *Wickard* Court brought nearly every aspect of life within reach of the Commerce Clause, the "implications" of Wells Pharma's argument "are staggering." *See* 2025 WL 1076889, at *7. But *Wickard* involved federal regulation of a farmer growing wheat for his own use. Filburn's impact on the federal regulatory program, let alone interstate commerce, by growing and eating his own wheat was tangential at best.

Regulation of the sort of large-scale pharmaceutical compounding undertaken by outsourcing facilities is at the core of Congress's power to regulate interstate commerce. And neither plaintiff nor the States can evade Congress's determination to exclude private suit enforcement of its compounding statute by bringing suit under state statutes referencing some, but not all, federal requirements and thereby transferring enforcement authority to competing drug companies and the plaintiffs' bar.

Under normal and applicable preemption rules, federal law does not deprive the States of their ability to regulate anything not constitutionally reserved to federal authority, unless that is what Congress provided for in exercising its own legitimate constitutional power. A ruling that States cannot, under the guise of adopting "parallel" laws or making federal law "their own," impose different requirements on those acting lawfully under a federal statute, is entirely consistent with Congress's constitutional power and certainly will not destroy State sovereignty any more than any other pre-emption ruling does.[3]

[3] Indeed, with respect to congressional intent in this regard, it is noteworthy that Section 503B(d)[2] specifically states that any outsourcing facility that is also "licensed as a pharmacy in any State that requires pharmacy licensing fees," is not relieved "of its obligation to pay such State fees" because it has paid the federal annual establishment and reinspection fees required by Section 503B(a)(9), 21 U.S.C. § 353b(a)(9); 21 U.S.C. § 379j-62. This strongly suggests that Congress expected Section 503B to displace inconsistent state requirements, but did not want to deprive a licensing State of the fees to which it would otherwise be entitled to on account of the state pharmacy licensing process.

CONCLUSION

The Court should grant the petition for rehearing *en banc* and affirm the District Court's dismissal of this case.

Dated: April 30, 2025

Respectfully submitted,

/s/ Andrew M. Grossman

ANDREW M. GROSSMAN
BAKER & HOSTETLER LLP
Washington Square, Suite 1100
1050 Connecticut Ave., N.W.
Washington, D.C. 20036
(202) 861-1697
agrossman@bakerlaw.com

Attorney for Amicus Curiae
Outsourcing Facilities Association

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 29(b)(4) as the text consists of 2,583 words as counted by Word for the Microsoft 365 program used to generate this brief. This brief also complies with the type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) as it was prepared using Word for Microsoft 365 in 14-point Times New Roman font.

Dated: April 30, 2025

/s/ Andrew M. Grossman
Andrew M. Grossman

CERTIFICATE OF SERVICE

I hereby certify that on April 30, 2025, I electronically filed the foregoing brief with the Clerk of the United States Court of Appeals for the Fifth Circuit using the Court's CM/ECF system, which will send a notification of such filing to all counsel of record for all parties.

/s/ Andrew M. Grossman
Andrew M. Grossman