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. 4:22-CV-4400

BRIEF OF THE ALLIANCE FOR PHARMACY COMPOUNDING AS *AMICUS CURIAE* IN SUPPORT OFAPPELLEE/CROSS-APPELLANT WELLS PHARMA OF HOUSTON, L.L.C.'S PETITION FOR REHEARING EN BANC

Mark Boesen
Randall Nice
BOESEN & SNOW, LLC
8501 E. Princess Dr., Suite 220
Scottsdale, AZ 8525
602-900-8562
Attorneys for the Alliance for Pharmacy Compounding-Amicus

CERTIFICATE OF INTERESTED PERSONS

No. 23-10422, *Zyla Life Sciences, L.L.C. v. Wells Pharma of Houston, L.L.C.*

USDC No. 4:22-cv-4400

The undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of 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.

1. **Plaintiff-Appellant / Cross-Appellee:**

Zyla Life Sciences, L.L.C.

Counsel for Plaintiff-Appellant/Cross-Appellee:

Jeffrey S. Bucholtz,
Counsel of Record
King & Spalding LLP
1700 Pennsylvania Avenue NW
Washington, D.C. 20006
(202) 737-0500
jbucholtz@kslaw.com

Joseph N. Akrotirianakis
Aaron B. Craig
King & Spalding LLP
633 West Fifth Street, Suite 1600
(213) 443-4355
jakro@kslaw.com
acraig@kslaw.com

Nicole Bronnimann
King & Spalding LLP
1100 Louisiana Street, Suite 4100
Houston, TX 77002
(713) 751-3200
nbronnimann@kslaw.com

Matthew V.H. Noller
King & Spalding LLP
50 California Street, Suite 3300
San Franciso, CA 94111
(415) 318-1200
mnoller@kslaw.com

Erich J. Almonte
King & Spalding LLP
1100 Louisiana Street, Suite 4100
Houston, TX 77002
(713) 751-3200
ealmonte@kslaw.com

2. **Defendant-Appellee / Cross-Appellant:**

   Wells Pharma of Houston, LLC

   Counsel for Defendant-Appellee:
   David L. Patrón
   Jeremy T. Grabill
   R. Harrison "Harris" Golden
   Phelps Dunbar LLP
   365 Canal Street, Suite 2000
   New Orleans, LA 70130
   (504) 566-1311
   david.patron@phelps.com
   jeremy.grabill@phelps.com
   harris.golden@phelps.com

3. **Amicus Curiae:**

   The Alliance for Pharmacy Compounding. The Alliance for Pharmacy Compounding is a Texas Non-Stock Corporation. As such, there is no parent corporation nor any publicly held corporation that owns 10% or more of its stock.

   Counsel for Amicus Curiae:
   Mark Boesen
   Randall Nice
   BOESEN & SNOW, LLC
   8501 E. Princess Dr., Suite 220
   Scottsdale, AZ 85255
   mboesen@bslawusa.com
   rnice@bslawusa.com

4. **Entities with a Financial Interest:**

   Zyla Life Sciences, LLC and its sole member, Assertio Holdings, Inc., which is a publicly traded corporation.

   Wells Pharma of Houston, LLC and its sole member, LSE, Inc. The sole stockholder of LSE, Inc. is Gary L. Shapiro.

s/ Randall Nice
Mark Boesen
Randall Nice
BOESEN & SNOW, LLC
8501 E. Princess Dr., Suite 220
Scottsdale, AZ 85255
602-900-8562

Attorneys for the Alliance for Pharmacy Compounding-Amicus

DISCLOSURE STATEMENT

The Alliance for Pharmacy Compounding is a non-profit, Texas Non-Stock Corporation. As such, there is no parent corporation nor any publicly held corporation that owns 10% or more of its stock

/s/ Randall Nice

Randall Nice

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

STATEMENT OF IDENTIFICATION

Amicus curiae Alliance for Pharmacy Compounding ("APC") is a Texas Non-Profit Corporation. APC is a non-profit trade association representing compounding pharmacists and technicians in both state-licensed pharmacies acting under authority of Section 503A of the Food, Drug & Cosmetic Act of 1938 ("FDCA") and outsourcing facilities acting under the authority of Section 503B of the FDCA. The APC also represents compounding pharmacy stakeholders including prescribers, educators, patients, and pharmacy suppliers. Including APC partner organizations, APC represents approximately 150,000 patients, compounding professionals, prescribers, and others.

APC is concerned about the panel opinion's departure from controlling case law which has created significant uncertainty within the compounding industry. Amicus has a strong interest in ensuring that this Court has an accurate understanding of compounding, the dangers of inconsistent regulation enforcement, and the protections afforded to the practice of compounding by the FDCA. Amicus files this brief pursuant to Rule 29(b) of the Federal Rules of Appellate Procedure and all parties to the appeal have consented to the filing of this brief.

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 APC and its counsel contributed financial support intended to fund the preparation or submission of this brief.

SUMMARY OF ARGUMENT

This Court should grant Appellee's petition for rehearing en banc because the panel decision undermines the FDCA's intent to allow drugs to be compounded for individual needs and during national shortages. Broadly, the FDCA—under Sections 503A and 503B[1]—permits compounding in two scenarios: 1) to create a custom medication for a patient's specific needs pursuant to a physician's prescription; and 2) to create an exact copy of a commercial medication when the Food and Drug Administration ("FDA") has declared a shortage of that drug. Section 337(a) of the FDCA prohibits private enforcement of the FDCA in order to protect the ability of compounders to engage in these activities.

The panel's decision permits pharmaceutical manufacturers to sue compounders who can now only raise Sections 503A and 503B as an affirmative defense. As such, each time a compounder provides a patient with a customized or in-shortage medication, it risks having to litigate against a pharmaceutical manufacturer. The likely result is pharmacies and outsourcing facilities scaling back, if not outright ceasing, their compounding activities. Thus, public health will be threatened as patients face difficulty in finding specialized or in-shortage medications. Accordingly, this Court should grant an rehearing en banc.

[1] 21 U.S.C. §§ 353a, 353b

ARGUMENT

I. THE PANEL DECISION DIRECTLY THREATENS THE AVAILABILITY OF PERSONALIZED MEDICATIONS AND DRUGS THAT ARE IN SHORTAGE.

There are considerable public health risks if the panel decision is not revisited en banc and reversed. The compounding of medications is an integral part of the public health care system and protected by the FDCA. However, the panel decision effectively permits a new cause of action that allows private enforcement of the FDCA through state laws. Now, crucial compounding services are at risk from aggressive litigants.

A. Compounding Plays a Crucial Role in Public Health.

Compounding is a traditional component of the practice of pharmacy involving "a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication tailored to an individual patient's needs." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 361 (2002). Drug compounding—the creation of medicines for patients whose clinical needs cannot be met by FDA-approved products or when an FDA-approved product is subject to a national shortage—has long been a part of modern pharmacy practice. *See* Carvalho M, Almeida IF. *The Role of Pharmaceutical Compounding in Promoting Medication Adherence.* PHARMACEUTICALS (BASEL), Sep. 15, 2022, at 2. The FDA recognizes the importance of the need for customized, compounded drugs:

> Compounded drug products serve an important role for patients whose clinical needs cannot be met by an FDA-approved drug product, such as a patient who has an allergy and needs a medication to be made without a certain dye, an elderly patient who cannot swallow a pill and needs a medicine in a liquid form that is not otherwise available, or a child who needs a drug in a strength that is lower than that of the commercially available product.

FDA, *Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry* 2 (2018).

Recognizing the importance of compounded medications, Congress permits compounding under certain circumstances. Under Section 503A of the FDCA, a compounding pharmacy may compound patient-specific medications pursuant to a provider-issued prescription that states the compounded, customized drug is medically necessary. 21 U.S.C. § 353a(a). The FDCA places a number of requirements on 503A compounding to ensure patient safety. *See* § 353a(b). Outsourcing facilities registered and monitored by the FDA may compound drugs without a patient specific prescription. 21 U.S.C. § 353b. Outsourcing facilities must also follow safety requirements and cannot wholesale the drugs they compound. *Id*. Both compounding pharmacies and outsourcing facilities may compound drugs that the FDA have declared to be "in shortage." FDA, *Compounded Drug Products* 5 (2018).

Today, "compounded medicines represent between 1% to 3% of pharmaceutical prescriptions and their use is growing." Carvalho & Almeida, at 2. With billions of prescriptions written every year in the United States, compounded medications impact a significant number of Americans. *See* SignleCare, *Prescription Drug Statistics 2025*, (February 4, 2025) https://www.singlecare.com/blog/news/prescription-drug-statistics/ ("There were 6.7 billion total prescriptions across the U.S. in 2022, up from 6.1 billion in 2018").

Additionally, compounders play an important public health role in mitigating drug shortages. In November of 2022, the FDA announced an "acute shortage" of amoxicillin and "an urgent need to increase the supply" of the medicine. FDA, *Compounding Certain Beta-Lactam Products in Shortage Under Section 503A of the Federal Food, Drug, and Cosmetic Act* 1 (2022). Compounding pharmacies responded to help alleviate the shortage of this life-saving medication. *See* Christine Blank, *Compounding Pharmacies to Help Alleviate Amoxicillin Shortage*, Managed Healthcare Executive (Nov. 21, 2022) https://www.managedhealthcareexecutive.com/view/compounding-pharmacies-to-help-alleviate-amoxicillin-shortage. Likewise, during the Covid pandemic of 2020, the FDA reported 86 drug shortages, including those related to ventilator use. James Broughel, *Allowing Compounding Pharmacies to Address Drug Shortages*, Mercatus Center at George Mason University (Nov. 1, 2021) https://www.mercatus.org/research/policy-briefs/allowing-compounding-pharmacies-

address-drug-shortages. Compounders were able to provide crucial stop gaps when the public health system was strained by these shortages. *Id*.

Compounding plays a critical role in the U.S. health care system by ensuring patients have access to customized medications that may not be otherwise available. The panel's opinion, however, fails to consider the broader consequences of its ruling on patient care and the healthcare system. In particular, the decision needlessly risks subjecting compounders to litigation and potentially disrupting access to essential compounded medications

B. The Panel Opinion Permits Private Parties to Threaten Patients' Access to Important Medications.

The panel opinion gives pharmaceutical manufacturers the power to drag compounding pharmacies and outsourcing facilities into court just to prove they follow the FDCA. In reversing the district court's ruling, the panel opinion suggested that Appellee could obtain dismissal only after it proved compliance with § 353b through discovery. (*see* Panel Op., p. 7 n.2). Taken to its logical conclusion, Appellant's unfair trade practice theory would allow a pharmaceutical manufacturer to sue any pharmacy or outsourcing facility that compounds a drug. This is because all compounded drugs lack FDA approval by their very nature. The pharmacy or outsourcing facility will then have to proceed with litigation to show that its operations comply with the FDCA.

The panel opinion is therefore likely to become a potent weapon for pharmaceutical manufacturers who can now wield enforcement action previously reserved to the FDA. Courts recognize the burden litigation can place on defendants in civil actions. *C.f., Trevino v. Iden*, 79 F.4th 524, 530 (5th Cir. 2023). "Civil litigation in the federal courts is often an expensive affair, and each party, win or lose, generally bears many of its own litigation expenses, including attorney's fees that are subject to the so-called American Rule." *City of San Antonio, Texas v. Hotels.com, L. P.*, 593 U.S. 330, 332 (2021). These burdens are particularly troublesome for compounding pharmacies which are usually small businesses. *See* Donald R. Mattison et al., eds., *The Clinical Utility of Compounded Bioidentical Hormone Therapy: A Review of Safety, Effectiveness, and Use* 30 (The National Academies Press 2020) ("Compounding, particularly in smaller, independent community pharmacies, remains an important component of pharmacy practice").

The panel opinion therefore risks letting pharmaceutical manufacturers use litigation—or the threat of litigation—to force pharmacies to stop compounding. This represents a serious threat to public safety considering the important role compounding plays in our healthcare system. Accordingly, this matter should be reheard en banc.

II. THE PANEL OPINION UNDERMINES THE INTENT OF CONGRESS TO PROHIBIT PRIVATE ENFORCEMENT OF THE FDCA.

The panel opinion breaks from well-established case law recognizing the importance of federal control over FDCA enforcement. The FDCA only permits its enforcement through the federal government. 21 U.S.C. § 337(a). The FDA uses this authority to "achieve a somewhat delicate balance of statutory objectives" and priorities. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001). Courts have consistently limited FDCA enforcement to the federal government. *See DiCroce v. McNeil Nutritionals, LLC,* 82 F.4th 35, 41 (1st Cir. 2023); *Nexus Pharm., Inc. v. Cent. Admixture Pharm. Servs., Inc.*, 48 F.4th 1040, 1049-50 (9th Cir. 2022); *Loreto v. Procter & Gamble Co.*, 515 Fed.Appx. 576, 579 (6th Cir. 2013); *PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105, 1113 (2nd Cir. 1997). To deliver services to patients, compounders—like many other types of health care providers—rely upon the FDA's consistent guidance and enforcement positions regarding the FDCA.

Permitting enforcement of the FDCA by private plaintiffs wielding identical state laws risks disastrous results for the millions of patients who rely upon compounded medications. As discussed above, private plaintiffs could potentially shut down large portions of the compounding industry just when they are needed most. Such authority should remain where it has always been: in the hands of the FDA. Accordingly, this Court should grant Appellee's Motion for Rehearing En Banc.

CONCLUSION

For the foregoing reasons, this Court should grant Appellee's petition for an rehearing en banc and affirm the district court's dismissal of Appellant's state-law claims.

Dated: April 30, 2025

_s/ Randall Nice_____
Mark Boesen
Randall Nice
BOESEN & SNOW, LLC
Attorneys for the Alliance for Pharmacy Compounding
8501 E. Princess Drive, Suite 220
Scottsdale, Arizona 85255
602-900-8562
mboesen@bslawusa.com
rnice@bslawusa.com

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rules of Appellate Procedure 29(b)(4) because the brief contains 1723 words, excluding the parts of the brief exempt by Federal Rule of Appellate Procedure 32(f).

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared in a proportionally spaced typeface using Word in 14-point Times New Roman font.

Dated: April 30, 2025

s/ Randall Nice

Mark Boesen
Randall Nice
BOESEN & SNOW, LLC
Attorneys for the Alliance for Pharmacy Compounding
8501 E. Princess Drive, Suite 220
Scottsdale, Arizona 85255
602-900-8562
mboesen@bslawusa.com
rnice@bslawusa.com

CERTIFICATE OF SERVICE

This is to certify that a copy of the foregoing was e-filed with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit by using the appellate CM/ECF system on April 30, 2025, which will send a notice of electronic filing to all participating counsel of record.

Dated: April 30, 2025

_s/ Randall Nice_____
Mark Boesen
Randall Nice
BOESEN & SNOW, LLC
Attorneys for the Alliance for Pharmacy Compounding
8501 E. Princess Drive, Suite 220
Scottsdale, Arizona 85255
602-900-8562
mboesen@bslawusa.com
rnice@bslawusa.com