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 OF DEFENDANT-APPELLEE WELLS PHARMA OF HOUSTON L.L.C.

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CERTIFICATE OF INTERESTED PERSONS

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.

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3. 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.

4. 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.

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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

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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 pharmaceutical manufacturers inappropriately using state unfair trade laws to stifle the compounding of certain drugs—an effort, that if successful, will impede patient access to medications. Here, Appellant is attempting to use several state unfair trade practice claims to prohibit compounding of certain drugs by alleging these state laws require Food and Drug Administration ("FDA") approval for compounded drugs. These allegations ignore provisions of the FDCA that allow compounding pharmacies and outsourcing facilities to compound certain drugs. It also ignores the express intent of Congress that the FDA have sole authority in enforcing the FDCA. Amicus has a strong interest in ensuring that the Court has an accurate understanding of the historical context of compounding, the dangers of inconsistent regulations and enforcement, and the protections afforded to the practice of compounding

by the FDCA. Amicus files this brief pursuant to Rule 29(a) 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 affirm the district court's order because it appropriately protects the FDCA's compounding provisions by limiting enforcement of the FDCA to the FDA, as intended by Congress.[1] The regulations governing the ingredients and products of pharmacy compounding are extensive and part of a meticulously devised regulatory framework. As such, Congress enacted a ban on enforcement of these regulations by parties other than the United States. To allow state regulations and private parties to intrude into this framework would upset the carefully crafted regulatory balance set out by Congress and the FDA, and would impede patient access to compounded therapies.

Enforcement of the FDCA is limited, by statute, to the federal government. This Court should not permit an end-run around the ban on extraneous enforcement of the FDCA through state laws. Instead, state regulations should be limited by the states'

[1] APC takes no position regarding Appellee's cross appeal regarding attorneys' fees.

traditional role as regulators of the pharmacy profession. The extensive federal regulations governing compounding do not leave room for meddling by the states and private actors. Accordingly, this Court should deny efforts to inappropriately regulate compounding through state laws.

ARGUMENT

I. Compounding plays a vital role in assuring patient access to essential medications that are unavailable commercially.

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). The science and art of compounding medications can be linked to the origins of pharmacy itself. The first documented chemical processes can be traced as far back as the time of the ancient Egyptians. Ahmed M. Metwaly et al., *Traditional ancient Egyptian medicine: A review*, SAUDI J BIOL SCI. 5823, 5832 (2021). Drug compounding is "typically used to prepare medications that are not commercially available . . . and is taught as part of the standard curriculum at most pharmacy schools." *Thompson*, 535 U.S. at 361. Pharmacy compounding plays an essential role in health and wellbeing of American citizens.

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* Maria

Carvalho & Isabel Almeida, *The Role of Pharmaceutical Compounding in Promoting Medication Adherence.* PHARMACEUTICALS (BASEL), Sep. 15, 2022, at 2. Today, "compounded medicines represent between 1% to 3% of pharmaceutical prescriptions and their use is growing." *Id*.

Many patients' needs can be met with commercial medications approved by the FDA. However, prescribers—in their professional judgment—may find that an FDA-approved commercial drug is inappropriate, or even harmful, for a particular patient. In these situations, pharmacists can compound a customized formulation—using either FDA-approved drugs or active pharmaceutical ingredient—that meets a patient's specific medical treatment needs that no commercially available drug can otherwise provide.

Other common situations in which compounded medications are necessary is when the licensed prescriber is faced with a patient who cannot consume a medication manufactured in its current dosage form. For example, pharmacists can compound a liquid version of a non-chewable tablet or capsule medication that is usually taken by adults or compound a different dosage strength for administration to a child. Additionally, pharmacists can compound medications that have been discontinued by the current manufacturer. Manufacturers sometimes cease production of essential drugs due to factors like lack of profitability, insufficient market demand, or disruptions caused by natural disasters.

The FDA, in agreement with Congress, recognizes the importance of the need for customized, compounded drugs in the above situations:

> 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, Guidance for Industry: Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act at 2 (Jan. 2018), *available at* https://www.fda.gov/files/drugs/published/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.pdf.

Perhaps one of the most important roles compounding pharmacies provide is a role expressly created by Congress that allows a compounding pharmacy or 503B outsourcing facility to compound a mediation when the medication is subject to a national shortage. During the Covid pandemic of 2020, the FDA reported 86 drug shortages including acetaminophen, albuterol, and drugs 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. In response, the FDA issued guidance allowing 503A pharmacies to produce FDA-approved drugs when medical facilities could not otherwise obtain them from traditional sources. *Id*. 503B outsourcing facilities also supported healthcare providers with production of infrequently used drugs and by ensuring steady supplies of medications made scarce by reflexive purchasing. Mike Wascovich, *503B Facilities Help Address Drug Shortages*, Pharmacy Times (Mar. 24, 2022), https://www.pharmacytimes.com/view/503b-facilities-help-address-drug-shortages.

Compounding is an important and integral part of keeping Americans healthy. It provides an important flexibility to our healthcare system, allowing the delivery of important medications to consumers in unique situations.

A. Congress enacted a complex set of regulations to facilitate the compounding of drugs.

The FDCA regulates drug manufacturing, marketing, and distribution. *See* 21 U.S.C. § 301 *et seq*. As part of this regulatory process, Congress invested the FDA with sole power to enforce the FDCA. *See* 21 U.S.C. § 337(a); *Thompson*, 535 U.S. at 361. The FDCA does not require compounded drugs to go through the same processes required of new, commercially manufactured drugs. *See generally*, 21 U.S.C. §§ 353a, 353b; 21 CFR § 216.23 (d). Instead, Congress and the FDA have created a comprehensive regulatory framework informed by decades of experience and knowledge.

When first enacted in 1938, the FDCA did not address drug compounding, only commercial manufacturing. However, after fifty years, the FDA became concerned that pharmacists were using the compounding exception to manufacture and sell new drugs. *Thompson*, 535 U.S. at 362. In response, the FDA issued Compliance Policy Guide 7132.16 stating that the FDA would permit pharmacists to compound drugs in limited quantities. However, the FDA stated it would take enforcement action when a pharmacy's compounding raised concerns normally associated with manufacturing. *Thompson*, 535 U.S. at 362-63. The Guidance included a list of activities the FDA would consider when determining if a pharmacy was engaged in compounding. *Id*. These activities included: 1) advertising; 2) compounding large amounts of commercially available drugs; 3) using commercial manufacturing or testing equipment; 4) selling compounded drugs at wholesale; 5) distributing large amounts of compounded drugs; and 6) dispensing compounded drugs to third parties for resale. *Id*. at 363.

In 1997, Congress passed the Food and Drug Administration Modernization Act (FDAMA), converting some of the Guidance policies into law. 64 Fed. Reg. 1207 (Jan. 8, 1999) (Rescinding the Policy Guide). The FDAMA amended the FDCA by adding 21 U.S.C. § 353a, an exemption to the FDCA's new drug approval process known as "Section 503A." 64 Fed. Reg. 1208. Section 503A exempts compounded drugs from the FDCA's new drug requirements provided certain conditions are met. § 353a.

These conditions include the requirement that the drug must be compounded pursuant to a prescription and in limited quantity by a licensed pharmacist in a state licensed pharmacy.[2] § 353a(a). Importantly, the drug must be compounded with bulk drug substances that "comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph."[3] § 353a(b)(1)(A). If a monograph does not exist, the drug components must be components of drugs approved by the FDA. *Id*.

Congress deliberately created exceptions to the FDCA under which the compounding of drugs may occur. Indeed, from the initial drafting of the FDCA in 1938, legislative intent always contemplated that the critical role state-licensed physicians practicing medicine and pharmacists practicing pharmacy play when compounding medications would be separate from that of drug manufacturers. In the Congressional Record, Washington State's Representative John M. Coffee quoted then Agriculture Secretary Henry Wallace's report on contaminated drugs from manufacturers:

> In the interest of safety, society had required that physicians be licensed to practice the healing art. Pharmacists are licensed to

[2] Physicians are also permitted to compound under Section 503A. *Id*.

[3] A monograph is a written document that contains the attributes of FDA approved medicines, such as identity, strength, purity, and performance. United States Pharmacopoeia Convention, *An Overview of USP Monographs*, https://www.usp.org/about/public-policy/overview-of-monographs, (last visited Feb. 6, 2024).

> compound and dispense drugs. Electricians, plumbers, and steam engineers pursue their respective trades under license. But there is no such control to prevent incompetent drug manufacturers from marketing any kind of lethal poison.

Med. Ctr. Pharm. v. Mukasey, 536 F.3d 383, 397 (5th Cir. 2008); Letter from Secretary of Agriculture in Response to Senate Resolution no. 194, a Report on Elixir Sufanilamide-Massengil (Nov. 26, 1937), *available at* https://archive.org/stream/CAT10509199/CAT10509199_djvu.txt. Thus, the FDCA's regulations were targeted at the unlicensed drug manufacturing industry, not compounding pharmacist. Requiring compounding pharmacies and outsourcing facilities to seek FDA approval for compounded drugs would inappropriately expand the FDCA beyond the scope intended by Congress.

It is misleading to describe the process of compounding drugs as "unapproved." Rather, drug compounding occurs under a meticulously crafted regulatory framework. Accordingly, there is no need to require compounding to occur under regulations that Congress expressly exempted from that process.

B. Congress continues to monitor and refine the regulations regarding compounding when necessary.

Congress has maintained a vigilant presence over compounding procedures and their governing laws. In 2012, Congress recognized the need for regulations related to large scale compounding operations and passed the Drug Quality and Security Act of 2013 (DQSA). *See Nexus Pharms., Inc. v. Cent. Admixture Pharmacy Servs., Inc.*, 48

F.4th 1040, 1043 (9th Cir. 2022). The DQSA created a regulatory framework for "outsourcing facilities," 21 U.S.C. § 353b(a), also known as "503B facilities." 503B facilities register with the FDA and can compound large quantities of drugs without a patient-specific prescription. *See generally, id*.

The compounding of drugs by 503B outsourcing facilities is governed by an extensive framework of laws, regulations, and standards. These requirements include limiting the use of bulk drug substances to those on the FDA drug shortage list or the FDA's list of bulk drug substances for which there is a clinical need. *Id*. Additionally, other ingredients must comply with the standards of any United States Pharmacopeia (USP) or National Formulary monograph and cannot appear on the FDA's list of drugs that have been withdrawn. § 353b(a)(2)(B). 503B facilities must comply with current good manufacturing practices (CGMP), which are extensive guidelines and standards to ensure the quality, safety, and efficiency of pharmaceuticals. *See* 21 U.S.C. § 351. The FDA continues to regulate the ingredients and bulk substances used in compounding facilities. *See e.g.*, FDA, FDA-2018-D-1067, Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act (2019).

Congress, in collaboration with the FDA, has established a multifaceted regulatory framework to oversee pharmacy compounding. This intricate system encompasses a

range of regulations aimed at ensuring the FDA's role when enforcing the FDCA versus the state's role in regulating the practice of medicine and pharmacy as it relates to compounding medications. Through legislative initiatives and FDA guidelines, such as DQSA, FDAMA, and the Pharmacy Compounding Compliance Policy Guide, Congress and the FDA work in tandem to address the unique challenges posed by pharmacy and outsourcing facility compounding. By implementing stringent and consistent standards for facilities, ingredients, labeling, and more, this regulatory framework aims to uphold the integrity of compounded medications while protecting public health.

II. This Court must safeguard federal compounding regulations from state and private interference to maintain Congress and the FDA's carefully balanced regulatory framework.

State laws can regulate the profession of pharmacy, but they cannot intrude on the federal regulations governing the ingredients and products of compounding. The Supreme Court has acknowledged that states have "a compelling interest in the practice of professions within their boundaries, and ... as part of their power to protect the public health, safety, and other valid interests they have broad power to establish standards for licensing practitioners and regulating the practice of professions." *Fla. Bar v. Went For It, Inc.*, 515 U.S. 618, 625 (1995) (quoting *Goldfarb v. Va. State Bar*, 421 U.S. 773, 792 (1975)). However, under the Constitution's Supremacy Clause, state laws that interfere with or are contrary to federal law are preempted, even if the state law is firmly within a

state's acknowledged power. *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 108 (1992).

Preemption can occur "where the scheme of federal regulation is sufficiently comprehensive to make reasonable inference that Congress left no room for supplementary state regulation." *Hillsborough Cnty., Fla. v. Automated Med. Lab'ys, Inc.*, 471 U.S. 707, 713 (1985) (internal quotation marks omitted). This preemption is "inferred when the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject." *Id* (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 236 (1947)). Courts will not permit state laws that "exert an extraneous pull on [a regulatory] scheme established by Congress." *Buckman Co. v. Plaintiff's Legal Committee*, 531 U.S. 341, 353 (2001).

Preemption can also occur when a state law conflicts with federal law. *Id*. State law conflicts with federal law compliance when compliance with both laws is an impossibility or where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Gade*, 505 U.S. at 98 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)). State laws cannot contravene a federal law's objective and policies. *Id*.

This Court should not allow states to exceed the distinct role Congress designated for them in the complex system that regulates the compounding of drugs. Congress

protected states' compelling interest in regulating the practice of professions when it required 503A compounding to occur in state licensed pharmacies by state licensed pharmacists. Accordingly, any further effort by state laws to regulate other aspects of compounding should be viewed with suspicion.

Inconsistent regulations and varying standards would cause chaos for patients who rely upon compounded medications to live normal lives. Permitting states and private actors to impose their own regulations on compounding will result in the inconsistent oversight of the compounding process. *C.f.* NAT'L ACAD. OF SCI., ENG'G, AND MED., THE CLINICAL UTILITY OF COMPOUNDED BIOIDENTICAL HORMONE THERAPY: A REVIEW OF SAFETY, EFFECTIVENESS, AND USE 65-66 (Donald R. Mattison et al., 2020). This is concerning because the pharmacy compounding the drug may be sending the final product to a patient in another state. Conflicting regulations could make it difficult for prescribers who rely on consistency across compounding pharmacies when writing prescriptions. Access to medications will be impeded when compounding entities in one state are prohibited from sending medications to another state because of conflicting regulations regarding that medication. Importantly, such a patchwork of regulations could hamper the response to a future pandemic or public health emergency.

Ultimately, the essential role and credibility of compounded therapies in the American healthcare system will be undermined by the inconsistent standards of multiple

jurisdictions across the United States. These inconsistencies and their potential side effects are cause for concern. *See id*.

As discussed above, Congress and the FDA created an expansive set of regulations and rules related to the ingredients and final products involved in compounding. This arrangement acknowledges the traditional role states have played in the regulations of professions within their state while ensuring protection of the interstate drug supply chain.

The FDCA, FDAMA, DQSA and other precise and expansive regulations leave no room for enforcement of state regulations on the ingredients and products of compounding. Instead, state regulations on compounding must be limited to their traditional roles as regulators of pharmacists as a profession. Accordingly, the use of state unfair trade practices to regulate compounding products is preempted by the FDCA.

III. Allowing plaintiffs to sue for violations of the FDCA under state laws contravenes the express intent of Congress to limit FDCA enforcement to the FDA.

The desire of Congress to preempt state involvement in the FDCA is evidenced by the restriction on the Act's enforcement. *See* 21 U.S.C. § 337(a). Section 337(a) provides that "[a]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United Staes." The FDA is able "to achieve a somewhat delicate balance of statutory objectives" by limiting the enforcement authority of the FDCA. *See Buckman*, 531 U.S. at 348. This Court should recognize that "the

balance sought by the [FDA] can be skewed by allowing" state level enforcement. *See id*.

Courts have protected this important balance by holding that state statutes which mirror or depend on the FDCA, such as the one at issue here, are preempted. In *Buckman*, the Court held that a state tort law relying on a fraud claim which "exist[ed] solely by virtue of the FDCA disclosure requirements" was preempted. 531 U.S. at 353. The Second Circuit has also acknowledged state law claims are invalid when they attempt to "privately enforce alleged violations of the FDCA." *PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105, 1113 (2nd Cir. 1997). In that case, the plaintiffs alleged the defendants could not sell products without FDA approval because of advertising that falsely represented the products were FDA approved. *Id*. at 1107. The Sixth Circuit recognized that the desire of Congress to limit enforcement of the FDCA "is thwarted if savvy plaintiffs can label as arising under a state law for which there exists a private enforcement mechanism a claim that in substance seeks to enforce the FDCA." *Loreto v. Procter & Gamble Co.*, 515 Fed.Appx. 576, 579 (6th Cir 2013). Including Section 337(a) in the FDCA would be meaningless if plaintiffs can use state law claims to enforce the FDCA.

Here, Appellant is attempting an end run around Section 337(a) by enforcing the FDCA through state law claims. Appellant has not alleged a violation based upon any

independent state law regulating drugs. Instead, like the plaintiff in *PDK Labs*, Appellant is alleging FDA approval is required for these compounded drugs. This ignores the compounding provisions of Section 503A & 503B. But, important to the matter at hand, it also means Appellant's claims "exist solely by virtue of the FDCA," like the claims in *Buckman*. Permitting these state law claims would introduce an obstacle into the FDCA's statutory objectives related to compounding.

CONCLUSION

Congress has enacted a complex regulatory structure to balance the important need for compounded drugs while ensuring the safety of the public. As part of that balance, Congress limited enforcement of the FDCA through Section 337(a). The attempt to circumvent Section 337(a) by bringing claims for violations of the FDCA under state law claims troubles Amicus and its members. Accordingly, the APC joins Appellees in urging the Court to affirm the district court's decision.

Respectfully submitted,

/s/ *Randall Nice*

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rules of Appellate Procedure 29(a)(5) and 32(a)(7) because the brief contains 3,524 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.

/s/ *Randall Nice*

Randall Nice

CERTIFICATE OF SERVICE

I hereby certify that I e-filed the foregoing 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 February 20, 2024.

Participants in the case who are registered CM/ECF users will be served by the appellate CM/ECF system.

s/ *Randall Nice*
Randall Nice