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# MEMORANDUM

**TO: Scott Brunner; Tenille Davis**
**Alliance for Pharmacy Compounding**

**FROM: Randall Nice**

**DATE: April 16, 2025**

**RE: Legal Analysis of *Zyla Life Science v. Wells Pharma***

## ISSUES AND BRIEF ANSWERS

The Fifth Circuit Court of Appeals recently ruled in *Zyla Life Science v. Wells Pharma*, that a pharmaceutical manufacturer may bring a lawsuit against an outsourcing facility for selling a drug not approved by the Food and Drug Administration ("FDA"). The case does not prevent compounding pharmacies and outsourcing facilities from compounding unapproved drugs otherwise in compliance with the Food, Drug and Cosmetic Act ("FDCA"). However, this ruling may provide an additional avenue for pharmaceutical manufacturers to harass compounders with frivolous litigation. There is also a possibility the case may be reviewed by the Supreme Court.

## BACKGROUND

This case stems from a lawsuit initiated by Zyla Life Sciences, LLC ("Zyla") against Wells Pharma of Houston, LLC ("Wells Pharma"). Zyla sells an FDA approved Indocin Suppository. Wells Pharma is a 503b outsourcing facility that compounds Indocin suppositories. Zyla brought a lawsuit alleging that Wells Pharma's compounding violated state unfair-competition ("UFC") laws.

The UFC laws are based upon alleged violations of consumer protection laws in six states. California, Colorado, Connecticut, Florida, and Tennessee all have consumer protection laws making it illegal to sell any new drug that has not been approved under 21 USC § 355.[1] These laws provide that if anyone sells an unapproved new drug, competitors may bring suit under that state's UFC law. Zyla brought its suit against Wells pharma under such a theory.

[1] *See* Cal. Health & Safety Code § 111550(a); Colo. Rev. Stat. § 12-280-131(1); Conn. Gen. Stat. § 21a-110; Fla. Stat. § 499.023; Tenn. Code § 53-1-110(a); S.C. Code § 39-23-70(a).

Zyla filed its lawsuit against Wells Pharma in Texas because that is the location of Wells Pharma's facility. Wells Pharma responded with a motion to dismiss on the grounds that the state laws were preempted by the FDCA. The trial court granted the motion to dismiss.

The trial court reasoned that Zyla's claims were preempted by the FDCA. Fifth Circuit case law holds that "independent state-law duty" claims for violations of the FDCA cannot 1) "add to" federal requirements; or 2) impinge on the FDA's sole authority.[2] The trial court found that the consumer protection laws "added to" the FDCA requirements because the FDCA does not require outsourcing facilities to receive FDA approval for compounded drugs.

The trial court also noted that the 9th Circuit, in *Nexus Pharm., Inc. v. Cent. Admisture Pharmacy Servs.*,[3] previously addressed the preemption issue and found that the FDCA preempts state UFC laws. The 9th Circuit noted that Section 337(a) of the FDCA gives the FDA exclusive authority to enforce the FDCA. The *Nexus* Court reasoned that any enforcement of laws that parallel the FDCA is de facto enforcement of the FDCA and allows private actors to usurp the authority of the FDA.[4]

Zyla appealed the order of dismissal. Zyla and Wells Pharma submitted briefs and the Alliance for Pharmacy Compounding submitted an amicus brief. After hearing oral arguments, the 5th Circuit overturned the trial court's dismissal.

In its decision, the 5th Circuit largely forged its own reasoning for reversing the dismissal and sidestepped the reasoning of both the trial court and other courts. In footnote 2, the decision rejected the trial court's reasoning, holding that the state consumer protection laws did not add to the FDCA and Wells Pharma had to prove at the trial court level that it was in compliance with Section 503b. In footnote 8, the 5th Circuit held that Section 337(a) does not prohibit states from enforcing laws that mirror the FDCA. Ultimately, the 5th Circuit held that states had inherent authority to mirror federal statutes; therefore, Zyla could bring its claim under the consumer protection and UFC laws.

**DISCUSSION**

The 5th Circuits reasoning relied mostly on case law allowing states to pass criminal laws that mirror federal laws. The case at the root of the court's reasoning is a 1949 Supreme Court case called *California v. Zook*[5]. *Zook* involved a California statute that criminalized running an interstate transportation company without a permit from the federal Interstate Commerce Commission. The defendant—essentially a private Uber style ride-sharing company—argued the state statute was preempted by the federal Motor Carrier Act. The Supreme Court found that the state statute had "substantially the same provisions" as its federal counter part and was therefore valid.

From this case, the 5th Circuit largely focused on the ability of states to criminalize conduct that is already criminalized by federal statute. As mentioned above, it relegated its analysis of the

[2] *Spano v. Whole Foods, Inc.*, 65 F.4th 260, 264 (5th Cir. 2023)
[3] 48 F.4th 1040, 1042 (9th Cir. 2022).
[4] *Id* at 1049.
[5] *People of State of Cal. v. Zook*, 336 U.S. 725 (1949).

trial court's reasoning to a single footnote. It also failed to meaningfully mention or address the 9th Circuit precedent in *Nexus*, and other courts, that a state law that mirrors the FDCA is essentially enforcement of the FDCA. The focus on criminal statutes is unusual because none of the statutes at issue are criminal. It is important to note that the UFC laws only allow for civil lawsuits and not criminal enforcement.

The emphasis on the ability of states to parallel federal criminal statutes may be related to ongoing litigation in the 5th Circuit. In *USA v. Texas*, the 5th Circuit is currently considering whether Texas can criminalize unlawful border crossings. As is common with appellate courts, this panel may have been considering the effects of its ruling beyond the immediate facts of this case.

The decision from the 5th Circuit does not prevent compounding pharmacies and outsourcing facilities from compounding drugs. In its footnote addressing the trial court's reasoning, the 5th Circuit noted that Wells Pharma may still be protected under Section 503b if all the requirements of that exception are fulfilled. However, it was too early in the litigation for the appellate court to decide if all the requirements had been met. Thus, the case must proceed to discovery.

This holding is both good and bad news for compounding pharmacies and outsourcing facilities in the relevant states. It is good news because compounders are still protected by the exceptions in Sections 503a and 503b. The bad news is this decision allows manufacturers with deep pockets to force compounders into litigation to prove they are covered under the relevant exceptions. Compounders may be able to offset litigation costs by ensuring their business insurance policies cover these types of actions.

Moving forward, this decision may open the door to review by the Supreme Court. Although the courts in *Zyla* and *Wells* used different logic, they arrived at irreconcilable results: plaintiffs in the 5th Circuit may now sue for violations of the FDCA under state UFC laws while plaintiffs in the 9th Circuit may not. This is referred to as a "circuit split."

Circuit splits are much more likely to be reviewed by the Supreme Court. The Supreme Court receives 7,000 to 8,000 petitions for review each year but usually hears fewer than 100. However, the Court is particularly interested in cases that involve circuit splits, as they help resolve inconsistencies in the federal appellate courts. Accordingly, there is a better than usual chance that the Court will review this case if Wells Pharma appeals.

**SUMMARY AND CONCLUSION**

Compounding pharmacies and outsourcing facilities are still protected by Sections 503a and 503b of the FDCA. However, the *Zyla* decision means compounders may face a heightened risk of a civil lawsuit by a pharmaceutical manufacturer, especially if the lawsuit can be brought in Texas, Louisiana, or Mississippi—the jurisdiction of the 5th Circuit. In such a lawsuit, the compounder will have to prove that it is compliant with the exceptions provided by Sections 503a and 503b.