Alliance for Pharmacy Compounding

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Issue Summary:

Zyla Life Science v. Wells Pharma

April 17, 2025

This document is informational only and is not to be taken as legal advice.

- Zyla Life Sciences makes a medication used to treat rheumatoid arthritis.
- Wells Pharma (503B) compounds a similar medication.
- In 2023, Zyla sued Wells citing the laws of 6 states – Colorado, California, Florida, South Carolina, Tennessee and Connecticut – which had adopted the 1938 Food, Drug and Cosmetic Act's language saying no drug may be introduced into those states without going through the new drug approval process
    - 503A and 503B compounders are exempt from this requirement under *Federal* laws passed in 1997 and 2013
    - The six states that adopted legislation mirroring the 1938 Act did so long before the 503A and 503B exemptions were added and have not updated their laws to include the exemptions
- Zyla asserted that Wells' introduction of its unapproved compounded product into these six states violated those states' laws and therefore constituted unfair competition (illegal activity is per se unfair competition)
    - In each of those states, pharmacy boards have of course permitted compounding for decades, and have entire bodies of regulations specifically for it – meaning that Zyla is asserting, among other things, that regulations permitting compounding in those states are in violation of state law
- The Federal district court in Texas granted Wells' motion to dismiss on grounds that Federal law (in particular the exemptions for 503A and 503B) preempts state law
- Last week the Federal 5th Circuit (New Orleans) reversed the district court and held that states are free to adopt more or less restrictive versions of Federal law in their own state (think abortion, guns, marijuana, etc.)
    - The effect of the reversal is to send the case back to district court to be litigated on the merits – i.e., did Wells violate state law, how did that

constitute unfair competition, and what are the damages for those violations?

- The Federal 5th Circuit ruling is in direct conflict with a Federal 9th Circuit ruling (*Nexus Pharmaceuticals v. CAPS, et. al* (No. 20-56227 (2022) on a similar FDA preemption issue (involving essential copies of FDA approved drugs compounded at 503B facilities), so there is now a potential split between the circuits – typically resolved via appeal to SCOTUS
- The current makeup of SCOTUS (a majority likely supportive of states' rights as expressed by the Federal 5th Circuit last week) is such that it is very possible the 5th Circuit ruling could be upheld if appealed
- The risk for compounders is that any drug company with a medication for which there is a compounded alternative could try to assert the same claim, in the 5th Circuit.

APC and its partner organizations continue to analyze this case to determine how best to respond to this ruling.