ISSUE BRIEF:

Compounding MOU: Federal judges says FDA violated the law

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A federal district court judge has issued a summary judgment in favor of a group of compounding pharmacies, ruling that FDA's MOU on interstate shipments of compounded drugs violated the law, and the agency cannot enforce it.

The MOU will be remanded back to FDA, and the agency must "either certify that it will not have a significant economic effect on small businesses or prepare a regulatory flexibility analysis."

While obviously not the end of issue, the ruling will allow APC and its coalition partners more time to work with FDA and boards of pharmacy to craft an MOU that's less onerous for states to implement and which doesn't expand FDA oversight beyond what the statute mandates.

The ruling was in response to a suit brought by a group of seven compounding pharmacies, alleging several significant issues with the process FDA used to develop the MOU.

The court found that, because FDA made arbitrary decisions that have "significant binding legal consequences for plaintiffs and pharmacies across the country, and [...] signals a substantive change in the current legal regime governing interstate compounding," the MOU becomes a legislative rule. "As a result," wrote United States District Judge Christopher Cooper, "FDA was required to comply with the Regulatory Flexibility Act before issuing it. It did not."

BACKGROUND

When Congress added section 503A to the Food, Drug & Cosmetic Act in 1997, it directed the FDA to come to an agreement with the states — a memorandum of understanding — to help FDA "address … the distribution of inordinate amounts of compounded drug products interstate."

The legislation offered the states a choice: They could sign the MOU and report to FDA on inordinate amounts of compounded medications shipped by in-state compounding pharmacies to patients in other states. Or don't sign it, and pharmacies in that state would be limited to shipping out-of-state no more than five percent of all prescription orders, even those that are patient-specific.

Congress' expectation, communicated in committee testimony and in Appropriations Committee reports to FDA, was that FDA would structure the MOU in such a way that states would be motivated to sign it. That motivation was to be an administrative regime that was workable for state boards of pharmacy, the agencies that in most states are charged with regulating pharmacy compounding and whose funding comes not from the federal government but from the state legislature. In return, states would collect and report data on in-state pharmacies that shipped more than 50 percent of their compounded drugs out of state.

If the MOU was to be the carrot, the cap on out-of-state shipments was the stick. Impeding patients' access to compounded meds was not Congress' goal. The goal was to incentivize states to help FDA gather data on large shippers of compounded drugs – so that it could properly inspect and document patient safety in those pharmacies.

For patients served by compounding pharmacies based in states that don't sign the MOU (many of whose lives are sustained by the compounded medications that are shipped to them) the loss of access to those drugs – because of that five percent cap on shipments – would be significant. There will also be an economic cost to states, as compounding pharmacies limited by the five percent cap close or relocate to a state that did sign the MOU.

FDA had 23 years to create that MOU and get buy-in from the states. Unfortunately, the "final" MOU, released by FDA in May 2020, failed to address earlier concerns raised by states and pharmacy groups. As a result, seven compounding pharmacies sued FDA, saying FDA had violated the Regulatory Flexibility Act in promulgating the

MOU. With several states hinting that they couldn't or wouldn't sign the MOU, FDA this past summer extended the signing deadline to October 2022. **Then, in September, the federal court ruled, remanding the MOU back to FDA.**

WHAT NOW? It's wait-and-see. The federal judge has given FDA 60 days to determine how it will respond to the court's directive. When and in what form the MOU may be implemented depends in large part on how FDA responds to the court.

A QUICK MOU TUTORIAL

Following is a very brief tutorial on the effects of signing or not signing the MOU – and how patient access to compounded medications could be restricted:

1. For states that DO sign:
    a. The MOU has serious flaws. It conflates definitions of 'distribute' and 'dispense' in a way Congress never anticipated. As a result, in states that sign the MOU, FDA will gain oversight of certain aspects of traditional dispensing, which has long been the purview of state boards of pharmacy, NOT a federal agency.
    b. FDA seriously underestimated the administrative burden on states that sign the MOU – the costs of staffing, reporting, etc., required of states in order to comply. The MOU creates, in effect, an unfunded mandate on states that sign.

2. For states that DON'T sign:
    a. If your state does not sign the MOU, compounding pharmacies in your state will be limited to shipping NO MORE THAN 5% of their compounded preparations out of state – even to areas just across the state line.
    b. For many, many compounders, that 5% cap could seriously hurt their business, and impede countless patients from getting their medications. It may even put some compounders out of business and create a loss of jobs (and tax revenue) in the state. (This 2020 op-ed by Virginia Congressman Morgan Griffith (VA-9) makes that point well.)

3. Clearly, there are negative implications for both signing and not signing. *But the implications for patient access to their medications are what matter most to us, and, we know, to the state board of pharmacy. That five percent cap, if implemented, will deprive patients of medication and your state of tax revenue and, potentially, jobs.*

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