Statement from Alliance for Pharmacy Compounding CEO Scott Brunner
Regarding FDA's December 19 Declaration on the Tirzepatide Shortage Status

December 19, 2024

FDA's announcement today is not unexpected, but it's also not necessarily the end of the story.

Look, state-licensed compounding pharmacies have long known that their ability to compound copies of tirzepatide injectables had a shelf-life. For two years now, they've been providing access to patients who'd otherwise have to go without this life-enhancing medication. But they've also known that the shortage would eventually end, that the FDA-approved drugs will eventually be widely enough available to meet demand, and that the patients they're serving during this shortage will need to be transitioned to the FDA-approved tirzepatide products or other drugs. They've been preparing their patients for that eventuality.

I'm just not persuaded that the data on which FDA is relying in this doubling-down on its shortage resolution decision is complete enough to say the shortage is really over. We continue to hear from pharmacies that the FDA-approved tirzepatide drugs are not attainable from wholesalers in quantities needed to meet demand by patients transitioning from compounded to commercial versions of the drug. FDA acknowledges in its letter that "many" patients may still be inconvenienced in the short term by the unavailability of the commercial drug. It's nice of them to note that, but it's cold comfort if you're one of those patients.

We do thank FDA for providing the off-ramp we requested for those patients – a period of time during which pharmacists and providers can effect that transition. Hopefully the period FDA is allowing – 60 days for traditional pharmacies, 90 days for outsourcing facilities – will mean most patients will not have to experience an interruption of therapy.

FDA's announcement this morning may not be the end of the story. Though the agency is doubling down on its October 2 shortage resolution, there's still litigation out there. Today's statement from the agency certainly informs that litigation, but it's not a decision by a court. It's a unilateral action by the agency, so don't confuse the two. I suspect what we've heard today from FDA is only one side of arguments the court will have to consider as the OFA/Farmakeio lawsuit proceeds. Which is all to say: Stay tuned.

The Alliance for Pharmacy Compounding is the industry trade association and the voice for pharmacy compounding, representing more than 600 compounding small businesses – including compounding pharmacists and technicians in both 503A and 503B settings, as well as prescribers, educators, researchers, and suppliers. Learn more, at compounding.com or a4pc.org.

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