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STATEMENT OF ALLIANCE FOR PHARMACY COMPOUNDING CEO SCOTT BRUNNER ON RESOLUTION OF SEMAGLUTIDE INJECTION SHORTAGE

February 21, 2025

As of this morning, the FDA Drug Shortage List indicates the semaglutide injection shortage is "resolved."

Look, compounding pharmacists have long known that this shortage had a shelf-life. For three years – that's how long this wonder drug has been in shortage – they've been compounding copies of semaglutide injection for patients at a time when Novo Nordisk could not meet the extraordinary demand. They've been serving patients who'd otherwise have no access to this medication. But they've also known that eventually the shortage would be resolved, and they've been prepping patients for months to expect that eventuality.

We can argue about whether this resolution of the shortage is premature or not – indeed, the much more real-world ASHP shortage list continues to show both semaglutide and tirzepatide injection in shortage. And I do question whether in resolving the shortage FDA has taken into account demand for the compounded drug – the number of patients who'll need to be transitioned from compounded version to FDA-approved version. That's likely hundreds of thousands of patients.

What FDA did right this time, something it did not do with its abrupt October 2, 2024, resolution of the tirzepatide injection shortage: The agency is providing an off-ramp, a period of time when their pharmacist and provider can transition patients to the FDA-approved drug if it's available. That period – 60 days for traditional pharmacies, 90 days for outsourcing facilities – can help avoid an interruption of therapy for many patients. We're grateful to the agency for hearing us and granting that off-ramp.

All we can do now is watch what happens as patients hear this news and their providers and pharmacists work to get them a new prescription for the FDA-approved drug. There's likely to be some sticker shock for many, and whether they'll be able to continue to afford the therapy remains to be seen.

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.