October 7, 2024

Robert Califf, MD
Commissioner

Valerie Jensen
Director, Drug Shortage Staff

Gail Bormel, JD
Director, Office of Compounding Quality and Compliance
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf, Ms. Jensen, and Dr. Bormel:

FDA's recent determination that the tirzepatide injection shortage is resolved has created extraordinary uncertainty and challenges:

- for patients taking compounded copies of the drug;
- for prescribers who must now transition the patients to the FDA-approved versions;
- for pharmacists trying to source still-scarce Mounjaro and Zepbound from their wholesaler(s).

That uncertainty extends to practical concerns that are not answered in FDA's "essentially a copy" guidance, but which are germane to this situation. We seek the Agency's response in providing clarity that will guide pharmacies in complying with FDA guidance.

Our primary concern is continuity of care. Patients who have been receiving compounded tirzepatide cannot immediately transition to the FDA-approved product due to a variety of practical "speedbumps," including getting a new prescription from their provider, navigating insurance coverage (including possible delays due to insurance prior authorizations), and a very real and continuing shortage of the products. This is creating a disruption of treatment, potentially leaving many patients without timely access to their medication.

An informal scan of social media sites over the past few days suggests that many increasingly desperate patients, as a result of the abrupt end of the shortage, are turning to illicit online entities to source resource-grade tirzepatide and other substances purporting to be tirzepatide. It's an unintentional and dangerous phenomenon exacerbated by the abrupt end to the declared shortage without a transition period.

We reiterate our request that the FDA issue an emergency amendment to 503A copies guidance to allow for at least a 60-day transition period that allows for compounded copies to be dispensed. During this transition period, prescriptions can be authorized for the FDA-

approved products, coverage determinations made by insurance companies, and the FDA-approved products can be obtained by pharmacies to fill the prescriptions. All of this can be done while patients maintain access to their medication.

As we look ahead to when the semaglutide injection shortage will be resolved – an event that will affect considerably more patients than the tirzepatide injection shortage resolution has – we urge the Agency to implement a framework that ensures a smoother transition for those patients.

Such a framework should be portable and applicable to other drugs coming out of shortage as well, to allow for better patient care. As you know, there is a developing issue around IV fluids due to the September 2024 flooding at the Baxter plant in North Carolina. 503A pharmacies and 503B outsourcing facilities may both be needed to help mitigate the loss of production of those products – including, perhaps, the sort of temporary guidance FDA provided for 13 COVID drugs during the Public Health Emergency.

A more formal, practical transition plan from compounded shortage drugs to FDA-approved drugs will benefit patients and provide essential clarity.

Questions: 503B distributing to 503A
For outsourcing facilities, the Agency's 503B copies guidance allows a 60-day window during which the 503B can continue to compound, dispense, and/or distribute a copy of the drug that was on the FDA drug shortage list. We are getting questions from pharmacies about how long 503A pharmacies can dispense 503B drugs after the resolution of a shortage. Please assist by clarifying the following:

- How long after the resolution of a shortage are 503A pharmacies permitted to dispense 503B copies of the drug that was in shortage?
    a. Can 503A pharmacies continue to dispense the 503B drug during the 60-day period that 503Bs can distribute their products?
    b. Can 503A pharmacies obtain the 503B compounded drug during the 60-day period provided to 503Bs and dispense the drug through the remaining beyond-use date of the 503B drug?

In closing, patients need a transition period between the resolution of a drug shortage and when they lose access to the compounded copies of those drugs. We urge the Agency to immediately implement this policy.

Thank you for your attention to this urgent issue and for your answers to our questions. We look forward to your response.

Sincerely,

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