Alliance for Pharmacy Compounding

Compounding the Joy of Living®

October 12, 2024

Dr. Robert M. Califf
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf:

As we raised with you last week, the Alliance for Pharmacy Compounding has serious concerns about FDA's decision to abruptly remove tirzepatide from the agency's drug shortage list. A transitionary period is needed as patients taking compounded tirzepatide return to their prescriber for a new prescription and work with their pharmacies to access Mounjaro and Zepbound. Over the last ten days, pharmacies have been unable to source anywhere near the volume of Mounjaro and Zepbound needed to meet demand, and patient continuity of care has been jeopardized.

We took interest in the recent lawsuit filed by the Outsourcing Facilities Association against FDA for removing tirzepatide from the drug shortage list, as well as FDA's unopposed motion requesting a stay to the court proceeding and a remand back to the agency so that FDA can reconsider its decision. We were pleased that the court ordered the stay and remanded the case back to FDA.

Because the court order references FDA's intention not to take action against the case's plaintiffs while the reconsideration of the action is undertaken, there is confusion about how the order will be enforced. Can *all* outsourcing facilities and state-licensed pharmacies — not just the named plaintiffs of the lawsuit — resume compounding of tirzepatide pursuant to all relevant existing laws, regulations and agency guidance? 503As and 503Bs both are needed to meet the current demand and ensure patient continuity of care.

We respectfully request prompt action by FDA to reverse the decision to remove tirzepatide from the drug shortage list so that patient continuity of care is not disrupted further. We also ask that FDA provide written clarification that the agency will not take enforcement action against *any* outsourcing facility or state-licensed pharmacy otherwise lawfully compounding tirzepatide while FDA reconsiders its decision to remove the drug from the shortage list.

It is our hope that going forward, FDA will work more closely with hospitals, prescribers, pharmacies, and outsourcing facilities to better determine which drugs should be placed on or removed from the FDA Drug Shortage List. APC also hopes that FDA will consider providing guidance for industry establishing a transitionary period of enforcement discretion as high-demand drugs come off the shortage list to allow patients time to revisit their prescribers and source the FDA-approved versions of the drugs.

Thank you in advance for your prompt attention to this request. We are available to discuss this letter and the broader issue of maintaining patient access to drugs as they transition off the FDA Drug Shortage List.

Sincerely,

Scott Brunner, CAE
Chief Executive Officer