March 20, 2025

Sara Brenner, M.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Acting Commissioner Brenner,

We, the undersigned organizations, write to acknowledge the U.S. Food and Drug Administration's (FDA) recent declaration that the shortages of Novo Nordisk's Wegovy and Ozempic have been resolved.

This announcement follows the agency's December 11th announcement that Eli Lilly's tirzepatide, marketed as Zepbound for weight loss, was no longer in shortage and it would give compounders 60 to 90 days before putting a stop to their production of the GLP-1s. Both developments serve as significant milestones in ensuring that patients have reliable access to these essential medications.

As you are aware, U.S. regulations permit some compounding pharmacies to produce versions of brand-name medications under limited circumstances, including when they are in short supply or where necessary to meet the individualized needs of a specific patient.

During the recent shortages, these regulations allowed for the compounding of GLP-1s to meet patient needs. However, with the FDA's confirmation that the supply of these drugs now meets current and projected demand, the conditions that justified shortage-driven compounding no longer exist.

We recognize that the FDA has provided a 60- to 90-day grace period for compounders to cease production of these medications. While we understand the need for a transition period, we emphasize the importance of upholding the regulations that govern pharmaceutical compounding. These regulations are in place to ensure patient safety and to maintain the integrity of our pharmaceutical supply chain.

The availability of compounded medications during times of shortage serves as a critical stopgap measure. However, continued mass-production compounding of GLP-1s in the absence of a shortage undermines the regulatory framework designed to protect patients from potential risks associated with unapproved and unregulated drug formulations.

We urge the FDA to:

1. **Enforce Existing Regulations**: Ensure that compounding pharmacies adhere to federal regulations by discontinuing the production of GLP-1 medications now that the shortage has been resolved.
2. **Monitor Compliance**: Implement measures to monitor and enforce compliance during and after the grace period to prevent unauthorized compounding of these medications.
3. **Educate Stakeholders**: Provide clear guidance to healthcare providers, pharmacists, and patients about the transition back to FDA-approved medications and the importance of obtaining treatments through appropriate channels.
4. **Enforce Existing Rules Against Misleading Information:** Ensure that companies promoting misleading information about compounded GLP-1s are held accountable under existing regulatory authority of the FDA**.**

With the GLP-1 shortage now resolved, we urge the FDA to reaffirm its commitment to patient safety and enforce regulations that safeguard public health and to enforce the existing regulatory framework related to compounding. We appreciate your attention to this important issue.

Sincerely,

Aimed Alliance
Alliance for Women's Health & Prevention
Association of Black Cardiologists
Bone Health & Osteoporosis Foundation
Chronic Care Policy Alliance
Color of Gastrointestinal Illnesses
Diabetes Patient Advocacy Coalition
Global Liver Institute
HealthyWomen
Mended Hearts
Minority Health Institute
National Alliance for Caregiving

National Black Nurses Association
National Consumers League
National Hispanic Health Foundation
National Hispanic Medical Association
Obesity Action Coalition
The Obesity Society
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