THE SHORTAGE IS OVER. THE RISKS ARE NOT:

How Illegal Mass Compounding Is Undermining Patient Safety—And What Must Happen Next

AMERICANS FOR SAFE & EFFECTIVE MEDICINES

The GLP-1 shortage is over, but the risks associated with mass compounding remain, and they need to be addressed.

Americans are clear about what they value and expect from their GLP-1 medications: U.S. Food and Drug Administration (FDA) approval, expert review, and clinical testing.

Recent survey results revealed a significant difference in expectations and reality:

84% of consumers say FDA approval, expert review, and clinical testing are important when choosing a GLP-1.

9 in 10 current GLP-1 users say those same safeguards are important.

Only 17% of consumers correctly understand that compounded GLP-1s are not FDA approved.

Roughly half of current GLP-1 users mistakenly believe compounded versions have gone through the same approval and testing process as FDA-approved medicines.

82% of general medicine physicians have encountered patients who are unaware that compounded medications are not approved by the FDA.[1]

BACKGROUND

During the FDA-declared shortage of medicines such as Ozempic, Wegovy, Mounjaro, and Zepbound, temporary compounding exemptions expanded patient access. As FDA-approved supply has returned, however, some compounders have continued producing and distributing compounded semaglutide and tirzepatide through telehealth platforms, wellness clinics, and other direct-to-consumer channels.

What began as a temporary access pathway has evolved into a parallel market operating outside key FDA safeguards for safety, quality, and transparency. FDA inspections, recalls, warning letters, and state enforcement actions have identified contamination risks, sterility failures, questionable sourcing practices, and misleading marketing tied to compounded GLP-1 products.[2]

ESCALATING RISKS AND THE PATH FORWARD

UNSAFE COMPOUNDING PRACTICES ARE CREATING PATIENT SAFETY RISKS

Compounded GLP-1 products are not subject to the same standards as FDA-approved medicines, yet many continue to be distributed nationwide at industrial scale. Regulators have documented contamination concerns, sterile-compounding failures, and recalled injectable products. One analysis found adverse events from compounded GLP-1s required hospitalization more than twice as often as those associated with FDA-approved versions.[3] Some compounders continue large-scale production through minor formulation changes or claims of "personalization" after the shortage ended.[4]

RECOMMENDED ACTIONS:

- Strengthen enforcement against unlawful mass compounding;
- Clarify limits on copycat compounding practices;
- Require adverse event reporting for sterile injectable compounders; and
- Require clear labeling identifying compounded GLP-1s as non-FDA-approved medicines.

ILLICIT SUPPLY CHAIN HAS CREATED A PARALLEL MARKET

Many mass compounders rely on sourcing and production channels that would not satisfy standards applied to FDA-approved manufacturers. Government officials have identified concerns involving foreign ingredient suppliers, unverified import channels, and products containing contaminants or excessive impurities.[5] The growth of telehealth platforms, med spas, and wellness clinics has expanded distribution of these products directly to consumers, at times contributing to adverse health events.[6]

RECOMMENDED ACTIONS:

- Strengthen oversight of ingredient sourcing and importation;
- Expand inspection authority for high-volume compounders;
- Apply consistent quality standards to industrial-scale operations; and
- Increase accountability for telehealth distributors and medical spas.

MISLEADING MARKETING IS PREVENTING INFORMED CONSUMER CHOICE

Consumers are frequently led to believe compounded GLP-1s are equivalent to FDA-approved medicines despite not undergoing FDA review for safety or effectiveness. FDA warning letters have cited companies for false or misleading marketing claims, while survey data suggest many consumers incorrectly believe compounded GLP-1s are FDA-approved or subject to the same testing and oversight standards as branded medicines.[1,7]

RECOMMENDED ACTIONS:

- Increase enforcement against misleading GLP-1 marketing claims;
- Strengthen oversight of telehealth advertising and distribution practices; and
- Require standardized disclosures distinguishing compounded products from FDA-approved medicines.

Restoring Accountability to the GLP-1 Market

The GLP-1 shortage is over. The mass-compounding market it enabled should be, too.

Industrial-scale production of knockoff GLP-1s demands stronger enforcement, increased supply chain oversight, and one clear standard for patient safety and accountability.

1 ASEM
2 FDA
3 Expert Opinion on Drug Safety
4 FDA
5 FBI
6 New York City Council
7 FDA

Scan to read the full report.

Americans for Safe and Effective Medicines advocates to preserve quality standards for medicines through research, education, and common-sense policy.

AMERICANS FOR SAFE & EFFECTIVE MEDICINES