Lilly Warns Patients About Counterfeit and Compounded Medicines Releases Open Letter and Takes Further Legal Action Against Counterfeit, Fake, Unsafe, and Untested Products

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Eli Lilly and Company is committed to meeting the needs of people living with diabetes and obesity with treatment options that change the way healthcare providers can treat these diseases. Today, we are publishing an open letter to ensure that people living with diabetes and obesity, their families, and their healthcare providers are informed about potentially serious risks posed by the proliferation of counterfeit, fake, compounded, and other unsafe or untested versions of our FDA-approved tirzepatide medications (Mounjaro® and Zepbound®) and about appropriate use of our authentic medicines.

As part of this effort, Lilly is filing several legal actions against med-spas, wellness centers, and other entities selling unapproved compounded products containing what they claim is tirzepatide. In these actions, Lilly alleges that the defendants: (1) misleadingly refer to their products as Mounjaro®/Zepbound® or the same as Mounjaro®/Zepbound® (2) misleadingly refer to the results of Lilly's clinical trials in their advertising, deceiving consumers to believe the defendants' compounded drugs were part of Lilly's clinical trials; and (3) misleadingly refer to the FDA approvals for Mounjaro®/Zepbound® as if defendants' compounded drugs were themselves FDA-approved. Lilly also identifies significant dangers to patient safety associated with the defendants' products and their deceptive conduct.

Lilly's open letter addresses appropriate uses of its medications and explains that counterfeit products and unsafe or untested compounded tirzepatide put people at risk.

Important takeaways from the open letter include:

- Lilly is concerned by the proliferation of fake or counterfeit products that are advertised or designed to look like Lilly's genuine FDA-approved Mounjaro® and Zepbound® medications. These products are often advertised and sold online, through social media, or at certain med-spas. They may contain no medicine, the wrong medicine, incorrect dosages, or multiple medicines mixed together, which could result in serious harm. They are never safe to use. The National Association of Boards of Pharmacy has explained that "illegal actors are taking advantage of high demand and short supply [of incretin medications] in order to sell substandard and falsified versions of these products to patients around the world." Their "unlawful actions put patients at risk."
- Compounded products may be legal in limited circumstances to address specific patient needs, but they are not FDA-approved and lack the same safety, quality, and efficacy protections as FDA-approved medicines. FDA has explained: "compounded drugs pose a higher risk to patients than FDA-approved drugs," and that the "unnecessary use of compounded drugs exposes patients to potentially serious health risks."
- Lilly has discovered compounded drugs advertised as tirzepatide with safety, sterility, and efficacy problems. Some have contained bacteria, high impurity levels, different colors (pink, instead of colorless), or a completely different chemical structure than Lilly's FDA-approved medicines. In at least one instance, the product was nothing more than sugar alcohol.
- Certain online pharmacies are now advertising compounded pill or other oral versions of "tirzepatide." FDA has only approved administration of tirzepatide via under-the-skin injection. No regulator has evaluated the safety or effectiveness of pill or oral versions of "tirzepatide."
- Lilly also reiterates that Mounjaro® and Zepbound® are approved only for use by adults to treat serious diseases—they are not intended for cosmetic weight loss or use by people under 18.

Today's lawsuits follow a series of cases Lilly filed in September and October 2023 as part of its commitment to ensure patient safety.

In May 2024, Lilly entered into a settlement agreement with Totality Medispa that required Totality to make a monetary payment and prohibited it from engaging in certain conduct that misled consumers into believing that it sells Lilly's Mounjaro® or Zepbound® or an FDA-approved alternative. It has entered into similar settlements with other med-spas and wellness centers who previously had infringed Lilly's trademarks and falsely advertised the med-spas' products.

The complete open letter can be found here.

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