Lilly Update on Mounjaro® and Zepbound® (tirzepatide) Compounding Litigation

May 14, 2024

Following a series of lawsuits Eli Lilly and Company filed in September and October 2023, Lilly has entered into a settlement agreement requiring defendant Totality Medispa to make a monetary payment and prohibiting Totality from engaging in certain conduct. Lilly's settlement will stop Totality Medispa from misleading consumers into believing that this med spa is selling Mounjaro® or Zepbound® approved by the FDA, that its compounded products have been the subject of clinical tests, or that its compounded medicines have been proven safe and effective to achieve certain clinical results.

Patient safety is Lilly's highest priority. Lilly is deeply concerned that products fraudulently claimed by compounding pharmacies or counterfeiters to be FDA-approved tirzepatide, Mounjaro®, or Zepbound® may expose patients to serious health risks. Neither the FDA nor any global regulatory agency has reviewed these products for safety, quality, or efficacy, and unsafe products should not be on the market. Lilly has discovered products claiming to be compounded tirzepatide medicines that contain bacteria, high impurity levels, different chemical structures, and different colors than Mounjaro® or Zepbound®. In at least one instance, the product was nothing more than sugar alcohol.

Lilly is the only lawful supplier of FDA-approved tirzepatide medicines in the United States. Lilly does not sell or provide tirzepatide active pharmaceutical ingredient ("API") to any compounding pharmacies. Patients taking a product referred to only as "tirzepatide" are not taking an FDA-approved product.

The settlement agreement requires Totality Medispa to make a monetary payment and to take several corrective actions. Totality must:

- Only obtain and distribute compounded tirzepatide products that are produced in compliance with U.S. federal law;
- Report to FDA any adverse events that patients experience after using Totality's compounded tirzepatide;
- Display on its website and all advertisements that "Compounded versions of tirzepatide are not FDA-approved, and neither the FDA nor any global regulatory agency has reviewed these products for safety, quality, or efficacy;"
- Not make any statements suggesting its products are genuine, FDA-approved Lilly products; and
- No longer use Lilly branding in the promotion of any of its products.

While this agreement is an important step forward, this is not a problem that Lilly can solve alone. We strongly support state and federal regulators taking action to deter and punish compounding pharmacies, counterfeiters, and others who put patients at risk by selling unsafe products claiming to be tirzepatide.