



Lilly Statement on Mounjaro® (tirzepatide) Compounding Litigation

September 19, 2023

Lilly filed this lawsuit to protect patients. Lilly cannot validate the safety or effectiveness of products claiming to contain tirzepatide that are not our own branded product. Because of this, Lilly filed lawsuits to protect patient safety and stop the unlawful marketing and sale of non-FDA approved compounded products fraudulently claiming to be Mounjaro® (tirzepatide) by medical spas, wellness centers and compounding pharmacies. These entities should be stopped from providing drug products in violation of consumer protection laws, particularly where they promise their patients that their drugs offer the same safety profile and clinical benefits as Mounjaro.

Mounjaro, approved for type 2 diabetes, is only available from and manufactured by Lilly and is only commercially available in a pre-filled single-dose pen. Products claiming to contain tirzepatide that are made and/or distributed by compounding pharmacies or distributed by counterfeit sources have not been reviewed by the U.S. FDA or global regulatory agencies for safety, quality, or efficacy; are not FDA-approved like Mounjaro; and may expose patients to potentially serious health risks.

For more information about compounding in the U.S., [please visit the FDA website here](#). If you are concerned that you have received or used compounded or counterfeit tirzepatide – or if you are concerned you may have received Mounjaro from an unauthorized source – please contact your health care provider to discuss options and next steps. In addition, patients and health care providers are encouraged to report counterfeit Mounjaro by calling the Lilly Answers Center (TLAC) at 1-800-LillyRx (1-800-545-5979).