

Alliance for Pharmacy Compounding Statement in Response to FDA Commissioner Califf's Misstatement Conflating Compounded Drugs and Counterfeit Substances

Alexandria, VA, February 29, 2024 – Yesterday, in public comments expressing concern about the sale of counterfeit and unverified substances purporting to be GLP-1 drugs, FDA Commissioner Robert Califf erroneously referred to them as compounded substances multiple times. We presume that the Commissioner's conflation of legitimate compounded drugs with illicit substances sold direct-to-consumer was inadvertent. Regardless, it requires a correction.

Legitimate compounded drugs are prescribed by a physician or other prescriber for a specific patient. They are prepared and dispensed by state-licensed compounding pharmacies using documented pure active pharmaceutical ingredients that come from FDA-registered facilities. Compounding pharmacies are authorized by federal law and follow FDA Guidance for Industry to prepare copies of FDA-approved drugs when that drug is listed as "currently in shortage" on FDA's Drug Shortage list – as semaglutide and tirzepatide (the active pharmaceutical ingredient in Ozempic and Wegovy and in Mounjaro, respectively) currently are. FDA guidance is unequivocal in its approval of pharmacy compounding in this situation.

"The selling of substances – counterfeit, research-grade, or otherwise – purporting to be FDA-approved drugs direct-to-consumer without a prescription is illegal," said Alliance for Pharmacy Compounding (APC) CEO Scott Brunner, CAE. "Those aren't compounded substances. It's not even pharmacy. Commissioner Califf's misstatement requires correction because it could lead patients to question the compounded drugs they've been prescribed that, in the judgment of their physician, they need to live more normal lives. Compounded medications are a critical link in the healthcare system, providing patients with life-saving drugs they could not otherwise get."

Brunner continued, "We presume the Commissioner knows this and simply misspoke. APC strongly supports FDA's efforts to end the sale of illicit substances, which put consumers at risk. At the same time, we urge the agency to take care in enunciating the difference between actual counterfeit products and legitimate compounded drugs."

Learn more about compounded drugs – including GLP-1 compounding – [on APC's home page](#).