Alliance for Pharmacy Compounding

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Statement from the Alliance for Pharmacy Compounding in Response to Recommendations by the American Diabetes Association

January 2025

The Alliance for Pharmacy Compounding questions the validity of claims made by the American Diabetes Association (ADA) in its recent statement on compounded GLP-1 receptor agonists and GIP/GLP-1 receptor agonists. ADA's sweeping assertions about the quality and therapeutic value of compounded medications are simply not accurate. In its statement, ADA overlooks the rigorous regulatory framework – including testing of sterile compounded injectables – in which compounding pharmacies operate.

While FDA-approved drugs are the gold standard in our healthcare system, FDA-approved drugs are not always available. That has been the case for the past 30 months with FDA-approved GLP-1s. Working within FDA guidance, compounding pharmacies have played and continue to play a critical role in providing patients access to life-enhancing GLP-1s during this time when the drugmakers have not been able to meet the demand.

During this prolonged shortage of commercially manufactured semaglutide and tirzepatide injections, compounded alternatives have provided essential access to those therapies for millions of patients managing Type 2 diabetes, obesity, and related conditions. Compounding pharmacies operate under strict state and federal regulation, source active pharmaceutical ingredients (which come with a valid Certificate of Analysis) only from FDA-registered manufacturers, and adhere to the rigorous compounding standards of the U.S. Pharmacopeia. Furthermore, the ADA's apparent misunderstanding of the adverse events data it cites, its conflation of counterfeit substances with legitimate compounded medications prepared in state-licensed pharmacies, and its misrepresentation of dosing and purity concerns is simply wrong. Those inaccurate claims are also strikingly similar to those that have been made by drugmakers, many of which provide funding to ADA.

Following documents further elaborate on the inaccuracy of claims made in ADA's statement:

- APC Letter to FDA in response to Novo Nordisk request to have semaglutide added to the Demonstrably Difficult to Compound List
- APC Letter to FDA in response to Eli Lilly request to have tirzepatide added to the Demonstrably Difficult to Compound List
- APC Statement on Adverse Events and Compounded GLP-1s

The Alliance for Pharmacy Compounding is the voice for pharmacy compounding, representing more than 600 compounding small businesses – including compounding pharmacists and technicians in both 503A and 503B settings – as well as prescribers, educators, researchers, and suppliers.

In traditional compounding, pharmacists create a customized medication, most often from pure ingredients, for an individual patient pursuant to a prescription. Pharmacists' ability to compound medications from pure ingredients is authorized in federal law and for good reason: Manufactured drugs don't come in strengths and dosage forms that are right for everyone, and prescribers need to be able to prescribe customized medications when, in their judgment, a manufactured drug is not the best course of therapy for a human or animal patient.

Every day, APC members play a critical role in patients' lives, preparing essential, custom medications for a range of health conditions, including autism, oncology, dermatology, ophthalmology, pediatrics, women's health, animal health, and others.