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Alliance for Pharmacy Compounding

May 28, 2025

Honorable William Tong
Attorney General
165 Capitol Avenue
Hartford, CT 06106

RE: May 21 Letter on Compounded GLP-1 Medications

Dear Attorney General Tong,

On behalf of the Alliance for Pharmacy Compounding and the compounding pharmacy professionals we represent, I appreciate the opportunity to respond to your May 21 letter to med spas, pharmacies, and others regarding compounded GLP-1 medications.

We share your concern about ensuring that patients receive medications that are legal and appropriately prepared and prescribed. However, your letter unintentionally conflates clearly impermissible activity, such as marketing salt forms of semaglutide or advertising compounded GLP-1s as "generics," with lawful, medically necessary compounding that is permitted under federal law and FDA guidance.

As you note, semaglutide and tirzepatide are no longer on FDA's drug shortage list, meaning traditional 503A pharmacies cannot compound these drugs *as copies* of commercially available products for patients who can be treated using FDA-approved versions. However, compounding is still allowed when a prescriber determines and documents that their patient has a specific clinical need that cannot be met by the FDA-approved GLP-1 drug, in accordance with FDA's "essentially a copy" guidance.

Compounded preparations that are not copies of the FDA-approved drugs but are individualized therapies tailored to unique patient needs – as determined by a legitimate prescriber – are fully authorized under federal law and FDA guidance. Importantly, FDA has explicitly stated that it does not intend to second-guess a prescriber's documented clinical judgment in these scenarios.

We fully support enforcement actions against entities that inappropriately market compounded GLP-1s, particularly those using unapproved salt forms or sourcing APIs from non-compliant suppliers. APC has been vocal in urging compounders to uphold the highest standards and has educated our members on appropriate sourcing, labeling, and marketing of GLP-1 products.

At the same time, we urge your office to avoid discouraging prescribers and pharmacies from providing legitimate, patient-specific compounded therapies that remain fully legal under federal and state law. Compounders play a critical role in ensuring access to care when no commercially available option meets a patient's needs, and we are committed to working with regulators to ensure that role is fulfilled responsibly.

We would welcome the opportunity to meet with your office to provide additional clarity and share the safeguards in place to support appropriate compounding in Connecticut and beyond.

Sincerely,

Scott Brunner, CAE
Chief Executive Officer
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