

A Statement on Needed Reforms to Protect Patient Safety from Fred H. Mills Jr., PharmD – ASEM Chief Policy Officer:

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"As a compounding pharmacist for nearly 50 years, I know the importance of legitimate, patient-specific compounding. I also know that there is a fundamental difference between the compounding that ensures a cancer patient has the right treatment dosage versus the mass compounding of GLP-1s today – unvetted additives, no batch consistency, telehealth distribution by faux-pharmacists, and very little meaningful accountability when patients are harmed.

Following yesterday's announcement that ASEM has launched to protect patients and hold bad actors accountable, the Alliance for Pharmacy Compounding (APC) issued a statement outlining the reforms it views as protecting the practice of "legitimate, state-licensed pharmacy compounding." As a former state regulator and policymaker, I know that these reforms do not go far enough to address the practices that enable the inappropriate mass compounding of GLP-1s to continue.

Both ASEM and APC are in agreement that we need better guardrails and stronger enforcement against bad actors.

The difference is that ASEM's policy roadmap actually achieves that, by requiring strict oversight of imported ingredients infiltrating the U.S. supply chain, shutting down unlawful mass compounding, and ensuring consumers are made aware of the difference between FDA-approved and compounded medicines.

At the end of the day, we need policymaking and regulatory enforcement at the state and the federal levels that go the distance when it comes to protecting patients.

That's what ASEM is here to fight for."