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Alliance for Pharmacy Compounding

Compounding the Joy of Living®

April 8, 2025

The Honorable James Comer, Chairman
House Committee on Oversight and Reform
2157 Rayburn House Office Building
Washington, DC 20515

Dear Representative Comer:

Thank you for the opportunity to submit written testimony on behalf of the Alliance for Pharmacy Compounding with regard to your April 9 hearing, "Restoring Trust in the FDA: Rooting Out Illicit Products."

APC is the national trade association for pharmacy professionals who prepare individualized medications—known as compounded medications—under state and federal oversight.

Compounding is authorized in the Food, Drug & Cosmetic Act to fill gaps in the drug supply that makers of FDA-approved drugs do not fill. The FD&C Act specifically allows compounding pharmacies to prepare copies of FDA-approved drugs when that drug is in shortage. Further, the Act allows a provider to prescribe a customed formulation – to be created by a compounding pharmacy – when he or she judges there is no commercially available drug in a dosage that is appropriate for a particular patient. Consumers support this ability. In a January 2025 Pharmacy Compounding Foundation consumer survey 84 percent of respondents believe it is important that compounding pharmacies be authorized to prepare copies of an FDA-approved drug when that drug is in shortage.

We represent compounding pharmacies and outsourcing facilities that lawfully and ethically serve patients. Our member pharmacies are state-licensed, pharmacist-operated, and deeply committed to patient care and safety. They have to be. Their licenses – and the lives their work enhances – depend on it.

Strong Support for Enforcement—When Precisely Applied

Let me be unequivocal: **APC strongly supports strong enforcement** against individuals who violate U.S. law—whether by importing active pharmaceutical ingredients (APIs) from unregistered foreign entities, using research-grade peptides or non-sterile substances in products for human use, or manufacturing unapproved drug products without a license.

We applaud the work of U.S. Customs and Border Protection (CBP), the FDA, and law enforcement in intercepting illicit drug shipments and counterfeit medicines, and we support efforts to close regulatory loopholes that bad actors exploit.

But enforcement must be based on evidence, not speculation, undocumented assumptions, or intentional distortion of facts. Unfortunately, in its association of compounded medications with shipments of illicit and counterfeit substances, the testimony of the Partnership for Safe Medicines in this hearing relies on such speculation, assumptions, and distortions to misrepresent an essential therapy in our healthcare system.

Consider the Source

As the Committee considers testimony from organizations such as the Partnership for Safe Medicines, it is important to also consider the source. PSM was established in the first Trump Administration with the explicit aim of opposing drug importation policies that would threaten the market interests of major pharmaceutical manufacturers. According to reporting by *NPR*, PSM has been closely aligned with the pharmaceutical lobby since its inception, and its activities have been largely funded by the brand-name drug industry—in particular, PhRMA and its members.[1]

Today, PSM continues to pursue an agenda that closely mirrors the interests of large pharmaceutical companies. Its most recent campaign targeting compounded GLP-1 medications—relying on exaggerated claims, misleading language, and conflation of lawful compounding with criminal activity—does little to improve patient safety. Instead, it functions as a strategic shield for manufacturers like Novo Nordisk and Eli Lilly, whose market share stands to benefit from efforts to eliminate compounded alternatives.

By eroding public and policymaker trust in state-regulated compounding pharmacies, PSM's actions serve to limit patient access to needed medications during shortages and protect monopolies, all while claiming to act in the name of safety. The reality is that their rhetoric is not about protecting patients—it's about protecting profits.

Policymakers must be vigilant in distinguishing genuine safety concerns from thinly veiled market protectionism. Patients deserve both safety and access, and legitimate compounding pharmacies are part of the solution—not the problem.

What Must Not Be Lost in the Narrative

Recent "reports" – and indeed, its testimony here – by the Partnership for Safe Medicines (PSM) blur the line between counterfeit, illicit drug production, and the lawful practice of pharmacy compounding.

PSM's most recent report—accompanied by public testimony—makes sweeping claims about shipments of semaglutide and tirzepatide API from unregistered sources and leaps to the conclusion that these were "likely used in knockoff products sold to unsuspecting Americans." Not a shred of evidence is presented to show that **any** state-licensed pharmacy used these substances or that any

[1] Kopp, E. (2017, April 18). Nonprofit working to block drug imports has ties to pharma lobby. *NPR*. https://www.npr.org/sections/health-shots/2017/04/18/524363014/nonprofit-working-to-block-drug-imports-has-ties-to-pharma-lobby

such pharmacy was involved in their importation or distribution. PSM's assertion reflects a misunderstanding of how most compounding pharmacies source API – not directly from a manufacturer, but from a wholesaler. Those wholesalers must be properly registered with FDA and in the states in which they operate, and they must provide the pharmacy with a certificate of analysis (COA) for any API they sell. The wholesaler has the responsibility for ensuring the COA is valid and the testing was performed by the manufacturer or a valid third-party testing entity. Additionally, APC recommends that its members send a sample of any API obtained from a new or unfamiliar wholesaler to a third-party analytical laboratory for potency and purity testing before using in compounded drug products.

PSM asserts without proof that shipments of illicit substances marked "for use in pharmacy compounding" must indeed have been ordered by and bound for legitimate state-licensed pharmacies, as if the labeling was a statement of fact and not a clever ruse by a trafficker. In insinuating complicity of legitimate pharmacies in importation of illicit substances, the PSM report's language is rhetorical and speculative, not evidentiary. It refers to "unauthorized semaglutide and tirzepatide" and implies that "compounders" are routinely and irresponsibly using such substances—without acknowledging that the FDA's actual warnings have been far narrower, specifically cautioning against *semaglutide salts* and emphasizing the requirement that APIs must come from FDA-registered sources.

Worse still, the report conflates state-licensed pharmacies with telehealth companies and med spas, the overwhelming majority of which are not pharmacies at all and fall outside the traditional and state-regulated practice of pharmacy compounding.

The result of this clever conflation by PSM is an erosion of public trust in a legitimate profession that serves a vital public health need.

Compounded Drugs Are Not "Knockoffs"

Let us be clear: **Compounded medications are prescription drugs**, tailored to meet individual patient needs when no FDA-approved product is suitable. They are dispensed only pursuant to a valid prescription, and their preparation is governed by both state pharmacy boards and applicable federal law.

The idea that these personalized therapies are "knockoffs"—as PSM alleges—is both misleading and offensive. These are not counterfeit drugs. They are not illegally manufactured. And, importantly, there is no evidence in the report that legitimate compounding pharmacies are importing or using unregistered substances.

In fact, compounding pharmacies source APIs from FDA-registered distributors – to source directly from an FDA-registered manufacturer may occasionally occur, but it is the rare exception, not the rule – and rely on certificates of analysis and other verification protocols to ensure product integrity. Unlike the rogue actors PSM calls out, licensed compounding pharmacies operate transparently and under oversight.

Enforcement That Worked

Pharmacies that have come under investigation for concerning practices related to the marketing and preparation of compounded GLP-1 drugs have faced legal action—and rightly so.

But let us be clear: **This is the system working as intended**. When needed, a state board of pharmacy and federal authorities investigate, identify noncompliance, and take action. These few cases are the exception, not the rule—and they affirm that regulators have the tools and authority to hold bad actors accountable without smearing an entire profession in the process.

Enforcement Must Be Specific and Smart

We urge this Committee to hear and read PSM's testimony with a critical ear and eye. We share PSM's concern about the scourge of illicit substances. We bemoan PSM's self-serving misrepresentation of pharmacy compounding.

Please recognize that as illicit substances go, legitimate, state-licensed compounding pharmacies are not the problem. They are not importing illicit APIs. They are not producing "knockoff" drugs. And they are not circumventing federal law.

What they *are* doing is stepping up to serve patients—especially during unprecedented drug shortages—by providing customized medications that are often the only available treatment. We agree that policymakers and regulators should act against those who break the law. But enforcement must be targeted, not sweeping. It must protect patients from harm—but also protect their access to the safe, legal, and essential care that compounding pharmacies provide.

Thank you for your attention to this issue. I would welcome the opportunity to speak further or appear before the Committee if invited.

Thank you,

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