The Partnership for SAFEMEDICINES®

November 4, 2025

The Honorable Brett Guthrie
2161 Rayburn House Office Building
United States House of Representatives
Washington, D.C. 20515

The Honorable Frank Pallone
2107 Rayburn House Office Building
United States House of Representatives
Washington, D.C. 20515

RE: Opposition to H.R. 5316, The Drug Shortage Compounding Patient Access Act

Dear Chairman Guthrie, Ranking Member Pallone, and Members of the House Energy & Commerce Committee:

On behalf of The Partnership for Safe Medicines (PSM), we write to express our strong opposition to H.R. 5316, the *Drug Shortage Compounding Patient Access Act*. While we recognize the importance of addressing drug shortages and ensuring patient access to necessary medications, this legislation undermines critical patient safety protections established by Congress in the wake of tragedies caused by poorly regulated compounded medicine.[1]

PSM is a public health group committed to the safety of prescription drugs and protecting consumers against counterfeit, substandard or otherwise unsafe medicines. Our membership of non-profit organizations is dedicated to protecting the safety of American consumers by curbing the manufacturing and sale of dangerous counterfeit and substandard drugs.[2]

Compounded medicine serves an important role in our healthcare system, but the Food and Drug Administration (FDA) does not verify the safety, effectiveness, or quality of compounded drugs, nor are compounded drugs subject to the same rigorous safety reporting requirements that apply to FDA-approved drugs or as carefully monitored as approved drug manufacturers inspected by the FDA. Some compounders[3] have used unapproved ingredients when producing medicines, and incidents of patient harm must not be overlooked.

Heightened risk for patients is particularly concerning as the demand for and popularity of diabetes and obesity drugs skyrockets. The FDA has issued several public warnings about poorly compounded and counterfeit versions of these sterile injectables.[4] Their concerns follow a long trend of FDA investigations into compounding pharmacies that have revealed:

- Medicine contaminated with dangerous bacteria in non-sterile working conditions;
- Cheap ingredients that don't meet purity standards for human pharmaceuticals; and
- Unapproved ingredients not safety-tested for human use. [5]

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[1] "Have Patients Been Harmed by Unsafe Drug Compounding?" PSM, www.safemedicines.org/2024/07/compounding-patient-harm.html.
[2] A list of PSM's members list may be found here: www.safemedicines.org/about-us/members.
[3] "Compounding and the FDA: Questions and Answers," FDA, September 16, 2025, www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers.
[4] "FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss," September 25, 2025: www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss and "FDA Warns Consumers Not to Use Counterfeit Ozempic (semaglutide) Found in U.S. Drug Supply Chain," April 14, 2025, www.fda.gov/drugs/drug-safety-and-availability/fda-warns-consumers-not-use-counterfeit-ozempic-semaglutide-found-us-drug-supply-chain.
[5] See, for example, Form 483s issued to Pacifico National, Inc. in 2019 (www.fda.gov/media/128709/download); Empower Clinic Services in 2023 (web.archive.org/web/20250322113535/www.fda.gov/media/176194/download) and a warning letter issued to Amazing Meds in September 2025 (www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/amazing-meds-09092025).

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Congress passed the *Compounding Quality Act*, sections 503A and 503B of the *Federal Food, Drug, and Cosmetic (FD&C) Act*, to establish requirements that keep illegal and unsafe drug compounding in check after a deadly 2012 fungal meningitis outbreak linked to the New England Compounding Center (NECC) claimed over 100 lives and injured hundreds more.[6] That event underscored the dangers of unregulated drug compounding and the urgent need for federal oversight.

Viewed from PSM's patient safety perspective, H.R. 5316 would roll back key provisions of the *Compounding Quality Act*. Specifically, it would:

- Extend the distribution of unapproved compounded drugs for up to 180 days – or six months – after a shortage ends, exposing patients to risk even when FDA-approved alternatives are available, simply to benefit compounding pharmacies' profit margins. As drafted in the legislation, this six-month duration would apply regardless of how long a drug shortage lasts.
    - Patients deserve access to medicines that are safe and effective. That's why the FDA approval system exists. Compounding was intended as a narrow exception for patients whose unique medical needs cannot be met by approved drugs, not a backdoor for unregulated mass production of untested drugs. Further permitting compounding when FDA-approved alternatives are available (i.e., post-shortage) unnecessarily increases risk of patient harm. Compounders are sidestepping federal law by mass producing so-called "personalized" knockoffs to profit off vulnerable patients, not to meet special patient needs.
    - The bill would also allow what should be last-resort compounders to continue selling compounded drugs that are not subject to *Drug Supply Chain Security Act (DSCSA)* requirements for up to six months after a shortage, even if that shortage only lasted for one or two months. Meanwhile, manufacturers of FDA-approved drugs are required to adhere to strict, patient-safety focused rules and regulations that ensure patients receive the highest quality medicines. This implicitly favors unapproved and unsafe compounded alternatives over FDA-approved safe and effective medicines.

- Repeal interstate shipment limits and reporting requirements, eliminating restrictions on the volume of compounded drugs that 503A pharmacies can introduce into interstate commerce.
    - This critically weakens state boards of pharmacies' ability to facilitate volume and prescription reporting by 503As distributing compounded medicines out of state.
    - Mass illegal manufacturing of compounded drugs would introduce unlimited and untraceable interstate sales, obscure the true volume of drugs being compounded, and seriously undermine FDA's Gold Standard for prescription drug quality and patient safety.

- Enable mass manufacturing under the guise of compounding by allowing 503A compounding pharmacies to produce drugs without patient-specific prescriptions during and for 60 days after a declared shortage. This would open the door to widespread anticipatory compounding of non-FDA approved drugs.
    - Telehealth companies and compounders are already skirting the law by making knockoff versions of branded products, offering "custom" doses and "personalized" formulations, often with additives that are commercially available and do not need to be compounded. Patients should not receive altered doses of medicines unless their care providers indicate a legitimate medical reason.

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[6] *Compounding Quality Act*," 21 U.S.C. 351 et seq., www.fda.gov/drugs/human-drug-compounding/text-compounding-quality-act; "Multistate Outbreak of Fungal Meningitis and Other Infections," U.S. Centers for Disease Control and Prevention, October 30, 2015, archive.cdc.gov/www_cdc_gov/hai/outbreaks/meningitis.html; and "Former Owner of Defunct New England Compounding Center Resentenced to 14 Years in Prison in Connection with 2012 Fungal Meningitis Outbreak," U.S. Department of Justice, July 7, 2021, www.justice.gov/usao-ma/pr/former-owner-defunct-new-england-compounding-center-resentenced-14-years-prison.

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  - Mass compounding under lax regulation risks another tragedy like the NECC fungal meningitis outbreak.

- Increase the risk of drug diversion and contamination in the supply chain by removing important labeling requirements for 503B outsourcing facilities.
  - The bill would remove current requirements that 503B compounded drugs always be labeled "Not for Resale" and, in most circumstances, "For Office Use Only." These current requirements are critical because compounded drugs do not have serial numbers and they are not subject to the DSCSA.[7] When a patient receives a substandard compounded product with no serial number, regulators will not be able to trace it back to the source. This hamstrings enforcement against bad actors, exposing more patients to potential harm. Ultimately, removing the current labeling requirements will result in degraded safety in the U.S. drug supply chain and the potential for increased diversion of controlled substances.
  - Unlike FDA-approved drugs manufactured under stricter standards, compounded drugs are not subject to FDA approval and are not reviewed by FDA for safety, efficacy, or quality. Compounding pharmacies are not required to meet the same standards as manufacturers of FDA-approved drugs nor are they subject to the same safety reporting requirements. For example, FDA routinely inspects manufacturing sites prior to approving a drug, but many 503B facilities have never been inspected by the FDA.

- Allow the use of non-pharmaceutical grade ingredients, including in sterile injectable drugs, which poses a direct threat to patient safety.
  - The FDA has repeatedly warned patients not to use compounded medicine if an FDA-approved version is available, citing concerns about misbranded, unapproved or unsafe ingredients. Over 250 online sites selling unapproved products have been shut down after authorities received reports of adverse events and unapproved ingredients from compounded medications.[8]

H.R. 5316 would dismantle the guardrails Congress put in place to prevent illegal drug manufacturing and protect patients from unsafe compounded medications. PSM has consistently advocated for strong oversight and transparency within our prescription drug supply chain, and we believe this bill would reverse hard-won progress.

PSM urges the Committee to oppose and reject H.R. 5316, the *Drug Shortage Compounding Patient Access Act*. Patient safety must remain the cornerstone of any policy addressing drug access and shortages. We welcome the opportunity to work with you on solutions that preserve access without compromising the integrity of our drug supply.

Sincerely,

Shabbir Safdar

Shabbir Safdar
Executive Director
The Partnership for Safe Medicines

[7] "Drug Supply Chain Security Act Product Tracing Requirements | Frequently Asked Questions," FDA, August 14, 2024, www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-product-tracing-requirements-frequently-asked-questions.
[8] "Hundreds of websites are selling fake Ozempic, says company. Doctors say it's only going to get worse," Canadian Broadcasting Company, April 19, 2024, www.cbc.ca/radio/asithappens/fake-ozempic-report-1.7176597.

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cc: U.S. House Energy & Commerce Committee Members
U.S. Senate Health, Education, Labor, and Pensions Committee Members
Marty Makary, Commissioner, The Food and Drug Administration