The Partnership for SAFEMEDICINES®
1300 I Street NW, Suite 400E, Washington, D.C., 20005
www.safemedicines.org

December 10, 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

The Honorable Rudy Yakym
349 Cannon House Office Building
United States House of Representatives
Washington, D.C. 20515

The Honorable André Carson
2135 Rayburn House Office Building
United States House of Representatives
Washington, D.C. 20515

RE: Letter of Support for The SAFE Drugs Act of 2025

Dear Chairman Guthrie, Ranking Member Pallone, Rep. Rudy Yakym, Rep. André Carson, and Members of the House Energy & Commerce Committee:

On behalf of The Partnership for Safe Medicines (PSM), we write to express our strong support of the *Safeguarding Americans from Fraudulent and Experimental (SAFE) Drugs Act*. This legislation is a long-overdue step toward protecting the U.S. drug supply from unsafely compounded medication and restoring transparency to a rapidly growing segment of the U.S. prescription drug supply chain.

As we detail below, the bill aligns important rules for what can be compounded to focus on unique patient needs and provides important transparency in the compounded drug supply chain needed by FDA to ensure public safety. It does this all while **increasing the amount** of essentially copies of commercially available drugs that is considered inordinate for 503A pharmacies and **without new limits** on the amount that 503B outsourcing facilities and hospital pharmacies can make of allowed-to-be-compounded medications.

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.[1]

For decades, compounding pharmacies have played a crucial role in meeting unique patient needs and compounded medicines serve an important purpose in our healthcare system. However, what began as a practice of customized therapies for unique patient needs has, in many cases, evolved into mass production without the safeguards required of manufacturers.[2] When a pharmacy compounds copies of commercially available drug more than twenty times in a month, that pharmacy is no longer compounding patient-specific, customized therapies – it is manufacturing at scale. There are other regulatory frameworks better suited for compounding clinically necessary drugs at scale, such as becoming a 503B outsourcing facility.

The *SAFE Drugs Act* establishes a clear, enforceable boundary that preserves legitimate patient-specific compounding while closing loopholes that have fueled large-scale, high-risk practices to flourish. By creating a bright-line standard, it safeguards personalized care and ends the misuse of compounding as a backdoor for unregulated mass production – ensuring patients receive individualized medicines under proper oversight. In fact,

[1] A list of PSM's members list may be found here: www.safemedicines.org/about-us/members.
[2] "What is a 503B outsourcing facility, and why are so many of them uninspected by FDA?" by PSM, 503B article about vulnerabilities and policy recommendations.

the bill **raises the inordinate amount threshold** for compounding essentially copies of a commercially available drug product **to 20 prescriptions per month** – five times higher than the existing FDA guidance – so patients who truly need individualized therapy retain access, while preventing "personalization" from being exploited as a pretext for mass production.[3]

Transparency is another critical cornerstone of this legislation because compounded drugs operate in a blind spot within the U.S. prescription drug supply chain. Unlike FDA-approved medicines, compounded drugs are not reviewed for safety, effectiveness, or quality, nor are they subject to the rigorous reporting and inspection standards that apply to manufacturers.[4] This gap has allowed the practice to persist without the nation's top drug regulator being informed of the volume of these product being made, a critical need for their mandate to ensure patient safety.

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 sterile injectables like GLP-1 agonists.[5] Their concerns follow a long trend of FDA investigations into compounding pharmacies that have revealed instances of:

- Compounded medicines contaminated with bacteria in non-sterile conditions;
- Use of cheap ingredients that fail pharmaceutical purity standards; and
- Incorporation of unapproved substances never tested for human use. [6]

The consequences of not carefully overseeing patient safety in the compounded medicine arena are serious. Between 2001-2019, unsafe compounding practices have been linked to at least 1,562 adverse events and 116 deaths.[7] The 2012 fungal meningitis outbreak tied to the New England Compounding Center (NECC), which killed 55 patients and sickened over 700 more, remains the most tragic example of what happens when oversight fails.[8] That deadly 2012 outbreak underscored the dangers of unregulated drug compounding and the urgent need for federal oversight. In response, Congress passed the *Compounding Quality Act* in 2013, amending section 503A and codifying section 503B of the *Federal Food, Drug & Cosmetics (FD&C) Act*, to impose basic safeguards and keep illegal and unsafe drug compounding in check.[9]

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[3] 21 U.S.C. § 353a; https://www.fda.gov/media/92232/download (FDA Compounding Policy Overview – MOU).
[4] "Compounding and the FDA: Questions and Answers," FDA, September 16, 2025, www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers.
[5] "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.
[6] 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).
[7] "U.S. Illnesses and Deaths Association With Compounded or Repackaged Medications, 2001-2019", Pew Charitable Trusts, March 2, 2020
[8] "Lessons Learned from Compounding Tragedies", Eric S. Kastango, published in the Canadian Journal of Hospital Pharmacy, May 2013
[9] *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.

Yet, despite bipartisan efforts the FDA needs greater authority to require comprehensive reporting or monitoring of high-volume interstate compounding. Transparency is sorely needed, as research on the FDA's Adverse Event Reporting program shows that legally compounded GLP-1's are associated with higher odds of adverse events, safety concerns, and product quality issues compared to non-compounded products[10]. Greater FDA visibility into the compounded drug supply is critical for addressing this risk.

Meanwhile, compounded drugs have grown into a major segment of the supply chain. Today, more than 7,500 compounding pharmacies operate in the United States, most without FDA inspection or FDA reporting obligations because they are primarily overseen by state Boards of Pharmacy. Though state BOPs are hardworking entities, they obviously lack the resources and depth of expertise of the FDA and there is a distinct lack of uniform requirements for reporting in all 50 states. This lack of visibility leaves federal regulators unable to track production or identify risks before harm occurs. The *SAFE Drugs Act* closes this gap by mandating reporting for high-volume interstate compounding and strengthening oversight of large-scale operations, critical steps to protecting patients and restoring accountability throughout the entire prescription drug supply chain.[11]

The *SAFE Drugs Act* builds on the FDA's current regulatory and oversight frameworks with practical tools it has long sought:

- Clear definitions of "commercially available;"
- Reportable thresholds for interstate activity related to compounding products that are essentially copies of commercially available drugs; and
- Risk-based inspections that start before large-scale shipments leave a facility.

Importantly, the *SAFE Drugs Act* is a reasonable, pragmatic solution to solving the high-risk issues that currently exist with compounded medicines while preserving the prescriber's authority to determine the best course of care. The "significant difference" provision provides flexibility to physicians with patients who have a clinical need for compounded medications. At the same time, the reporting requirements ensure that when compounding crosses state lines at scale, the FDA has visibility into what is being produced and for whom. This balance between clinical autonomy and regulatory oversight is essential for patient safety.[12]

The *SAFE Drugs Act* also strengthens oversight of large-scale outsourcing – or 503B – facilities, which can produce thousands of sterile prescriptions annually yet can ship products without ever undergoing an FDA inspection.[13] As we measured in early 2025, since 2021 many of newly registered 503B facilities have never been inspected, underscoring the urgent need for reform.[14] Because the FDA has prioritized inspections of 503B's in the last twelve months, this number has been brought down quite a bit, but it should never have gotten that high.

To close this gap, the *SAFE Drugs* Act requires an initial inspection before any product is shipped and biennial reinspections thereafter. These measures are not excessive; they simply align compounding oversight with the standards applied to every other link in the prescription drug supply chain. By enforcing these inspections, the *SAFE Drugs Act* ensures that facilities engaged in mass production are inspected under regular timelines, all without disrupting access during drugs shortages. [15]

The bill also includes commonsense exemptions. Specifically, hospital pharmacies are explicitly excluded,

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[10] "Safety analysis of compounded GLP-1 receptor agonists: a pharmacovigilance study using the FDA adverse event reporting system", Dr. Kenneth L. McCall et al, Expert Opinion on Drug Safety, 29 April 2025
[11] https://www.fda.gov/drugs/human-drug-compounding/fda-compounders-know-your-bulks-and-excipients-suppliers;
[12] https://www.safemedicines.org/wp-content/uploads/2024/05/PSM-Patient-Harm-Compounding-v3.pdf
[13] See PSM analysis of 503B outsourcing facilities.
[14] PSM Patient Harm Report
[15] https://www.fda.gov/drugs/human-drug-compounding/compounding-inspections-and-oversight-frequently-asked-questions; https://www.safemedicines.org/wp-content/uploads/2024/05/PSM-Patient-Harm-Compounding-v3.pdf

ensuring that bedside care within hospitals continues uninterrupted while broader market-facing compounding is subject to transparency and oversight.[16]

Finally, the bill sets a clear threshold – 100 compounded doses per year – for when a 503B outsourcing facility must be inspected more frequently based on risk. This bright-line rule protects patients by requiring entities engaged in mass production to be more regularly inspected for compliance with current good manufacturing practices. Importantly, the *SAFE Drugs Act* does not alter existing 503B provisions for drug shortages, nor does it limit 503B compounding when a drug is on the FDA Drug Shortage list.

By contrast, other legislative proposals on compounding would roll back key safeguards of the *Compounding Quality Act* and the *FD&C Act* by extending distribution of unapproved compounded drugs for months after a shortage ends; repealing interstate limits and reporting that FDA and states need to see volume; permitting mass manufacturing without patient-specific prescriptions; weakening labeling protections for 503Bs ("Not for Resale," "For Office Use Only"); and allowing non-pharmaceutical-grade ingredients in sterile injectables.[17]
Rather than protecting patients, such proposals would increase diversion, obscure traceability (compounded drugs lack serial numbers under DSCSA), and ultimately elevate patient risk when FDA-approved alternatives are available.

FDA has repeatedly warned patients to avoid compounded versions when an FDA-approved product is available. The FDA has made clear there is a role for compounded medications in our drug supply, but as the practice has exploded, transparency and accountability for oversight have not kept up. The *SAFE Drugs Act* is a commonsense, bipartisan solution that strengthens oversight without compromising access. It empowers prescribers, enhances transparency, and closes dangerous loopholes that have persisted for more than 25 years.

PSM has consistently advocated for strong oversight and transparency within our prescription drug supply chain, and we urge Congress to pass the *SAFE Drugs Act* swiftly to protect American patients while ensuring access and personalized care remain top priorities for healthcare providers.

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
Executive Director
The Partnership for Safe Medicines

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

[16] https://www.safemedicines.org/wp-content/uploads/2024/05/PSM-Patient-Harm-Compounding-v3.pdf
[17] "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.