



April 23, 2026

RE: Opposition to the SAFE Drugs Act of 2026 (H.R. 6509/S. 3794)

Dear Representative/Senator:

On behalf of the Alliance for Pharmacy Compounding (APC), representing more than 600 compounding small businesses and thousands of pharmacists nationwide, as well as the National Community Pharmacy Association (NCPA), the voice of community pharmacists representing over 18,000 community pharmacies, we are writing to express our strong opposition to the Safeguarding Americans from Fraudulent and Experimental (SAFE) Drugs Act of 2025.

Our concerns begin with the misleading title of the bill, as the legislation does nothing to address problems associated with fraudulent or experimental drugs while insulting and maligning the thousands of legitimate state licensed pharmacies and FDA registered outsourcing facilities serving critical patient needs. While we support the goal of ensuring patient safety, this legislation—as currently drafted—threatens to severely disrupt the drug supply chain, exacerbate ongoing drug shortages, and block patient access to essential, customized medications.

APC and NCPA are particularly concerned that the legislation would dramatically alter the current regulatory framework at FDA for drug shortage compounding and replace flexible FDA guidance based on clinical need with rigid new statutory language that will not allow prescribers and pharmacists the ability to meet their patients' medical needs. We are particularly concerned with the following provisions of the SAFE Drugs Act:

- **Arbitrary Limits on "Essentially a Copy" Drugs:** The SAFE Drugs Act would codify a restrictive definition of "essentially a copy" of a commercially available drug and impose a strict monthly limit of 20 units per month for 503A pharmacies compounding these medications. This rigid cap fails to account for emergency situations, medical necessity or physician-guided care, effectively stripping healthcare providers of their ability to prescribe tailored treatments for more than a handful of patients.
- **Worsening of Drug Shortages:** The SAFE Drugs Act would codify a definition of "commercially available" that would not exclude drugs on the FDA drug shortage list as the current FDA guidance for industry does. Compounding pharmacies serve as a critical safety net when FDA-approved drugs are in short supply. By creating new regulatory barriers and "bright-line" standards that restrict compounding based on commercial availability rather than clinical need, this bill would prevent pharmacies from stepping in to provide medications that patients literally cannot obtain elsewhere.
- **Onerous Interstate Reporting Requirements:** The bill mandates that pharmacies shipping more than 20 out-of-state prescriptions monthly report detailed product and volume data to the FDA. This creates a significant administrative burden on small-business pharmacies and could discourage the interstate distribution of specialized drugs to patients in rural or underserved areas.
- **Increased Costs for Providers:** By significantly increasing the base outsourcing facility fee, the bill may force smaller 503B facilities out of the market, further consolidating the supply chain and reducing the availability of critical medications for hospitals and clinics.

By codifying inflexible "essentially a copy" and "commercially available" definitions and imposing a strict 20-unit-per-month limit on such medications, this legislation would effectively ban pharmacies from providing life-sustaining alternatives when FDA-approved supplies vanish. For example, as of April 2026, the following critical medications remain on the [FDA Drug Shortages List](#), and the SAFE Drugs Act would directly block patients from accessing compounded versions:

- **Critical Acute Care Injectables:** Essential hospital medications like **Dextrose (25% and 50% injections)**, **Lidocaine**, and **Epinephrine** are currently facing limited availability. Under the SAFE Drugs Act, a local compounding pharmacy would be

legally prohibited from filling more than 20 prescriptions for these items per month—even if a local hospital or clinic has completely run out.

- **Specialized Treatments:** Medications like **Acetazolamide Injection** (used for glaucoma and altitude sickness) and **Acyclovir Injection** (for severe viral infections) are currently in shortage. Restricting the compounding of these "copies" would leave patients with zero viable treatment options.

Instead of the sweeping and restrictive approach of this legislation, APC and NCPA urge Congress to support common-sense reforms like [H.R. 5316](#), the **Drug Shortage Compounding Patient Access Act**. That legislation provides a balanced pathway for compounders to respond proactively to shortages while maintaining rigorous safety standards, ensuring that patients—not bureaucrats—remain the priority.

We urge you to oppose H.R. 6509/S.3794 to protect patient access and the integrity of the American healthcare safety net.

Sincerely,



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