

The so-called “SAFE Drugs Act”: Two bills, two very different messages

Despite a name suggesting legislation aimed at fraudulent drugs, the so-called “SAFE Drugs Act” regulates legitimate pharmacies and outsourcing facilities already operating within rigorous federal and state regulatory systems. The Senate has substantially improved its bill. The House has not.

THE ISSUE

There are two so-called “SAFE Drugs Act” bills: **H.R. 6509 in the House** and **S. 3794 in the Senate**.

The original legislation imposed sweeping new restrictions on lawful pharmacy compounding – including provisions that would severely limit pharmacies’ ability to respond when FDA-approved drugs are in shortage.

That is particularly incongruous with the bill’s full name: the *Safeguarding Americans from Fraudulent and Experimental Drugs Act*. The legislation does not principally target counterfeiters, illicit online sellers or businesses peddling fraudulent drugs. It addresses regulation of state-licensed pharmacies and FDA-registered outsourcing facilities.

Those entities should be accountable when they violate the law. But calling lawful pharmacy compounding “fraudulent” does not make it so.

The House and Senate bills now require different responses.

THE DETAILS

The House: H.R. 6509 remains unacceptable

H.R. 6509 remains essentially the original so-called “SAFE Drugs Act.” Among its most problematic provisions, it would restrict the number of copies of commercially available drugs a 503A pharmacy could prepare – including when those drugs are on FDA’s shortage list.

That would gut the ability of pharmacies to respond meaningfully during a shortage. When a manufactured drug is unavailable, pharmacy compounding can serve as an essential bridge for patients. A shortage policy that arbitrarily limits how many patients a pharmacy may serve defeats the reason shortage compounding is permitted in the first place.

H.R. 6509 should not advance in its current form.

The Senate: S. 3794 has been substantially improved but still needs work

The Senate HELP Committee removed the original shortage-compounding restrictions and narrowed the bill to provisions including:

Serious adverse-event reporting. APC supports requiring 503A pharmacies to report serious adverse events that can reveal meaningful safety signals.

Clear patient disclosure. APC supports factual labeling stating that a medication is compounded and has not been FDA-approved.

Interstate reporting. APC supports a practical national reporting framework. But the amended bill may conflict with Section 503A's existing memorandum-of-understanding provisions and 5-percent interstate limitation. Those MOU provisions are obsolete and should be repealed as part of this legislation so pharmacies are not left subject to two inconsistent federal frameworks.

The Senate changes demonstrate that patient-safety concerns can be addressed without unnecessarily restricting access to compounded medications.

APC also supports **H.R. 5316, the Drug Shortage Compounding Patient Access Act**, which would improve FDA's shortage process and strengthen patient access when commercial supply cannot meet demand.

THE ASK

For House members:

- Oppose H.R. 6509 in its current form. Its shortage provisions would severely restrict patient access when FDA-approved drugs are unavailable.
- Support H.R. 5316, the Drug Shortage Compounding Patient Access Act.

For senators:

- Preserve the improvements made to S. 3794 by the HELP Committee.
- Do not restore the original shortage-compounding restrictions.
- Repeal the obsolete Section 503A MOU provisions so the bill's new interstate-reporting framework does not conflict with existing law.

Smart oversight should protect patients. It should not address a regulatory concern by taking needed medication away from them.

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