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ISSUE BRIEF SEPTEMBER 2026

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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ISSUE BRIEF SEPTEMBER 2026

Real solutions for patient safety in pharmacy compounding

Patient-safety concerns that have emerged in the GLP-1 era deserve real answers. APC has developed five targeted policy proposals that address identifiable risks without unnecessarily restricting lawful pharmacy compounding, prescriber judgment or patient access.

THE ISSUE

The rapid growth of GLP-1 medications, telehealth, medical and wellness businesses, and online sellers has exposed gaps in the way prescription medications and drug ingredients are marketed, prescribed and provided to patients.

Some concerns involve pharmacy compounding. Many do not.

Too often, policy proposals treat state-licensed pharmacies, 503B outsourcing facilities, medical spas, telehealth platforms, research-chemical sellers and counterfeiters as though they present the same regulatory problem.

They do not.

Pharmacies already operate under federal and state law, state board of pharmacy oversight and applicable USP standards. Outsourcing facilities operate under a separate federal framework that includes FDA registration and cGMP requirements. Problems within those systems should be addressed. But restricting lawful pharmacy compounding does little to stop illicit sellers, improperly sourced ingredients, or medical spas operating outside meaningful pharmacy oversight.

APC's approach is straightforward: **Identify the risk. Target the conduct creating it. Protect patients without unnecessarily restricting lawful pharmacy practice or access.**

THE DETAILS

APC proposes five practical reforms. Except for medical-spa licensure and oversight, which is principally a state responsibility, these solutions can be pursued at either the federal or state level.

Require clear disclosure that compounded medications are not FDA-approved.
Patients should receive a straightforward, factual statement that their medication is compounded and has not been FDA-approved. The disclosure should inform, not stigmatize.

Require 503A pharmacies to report serious adverse events via FDA's MedWatch system.
APC supports reporting deaths, hospitalizations, life-threatening events, significant disability and other medically serious outcomes. That provides regulators meaningful safety signals without flooding reporting systems with minor symptoms and routine complaints.

Prohibit direct-to-consumer promotion of substances that cannot lawfully be compounded for human use.
Products labeled “research use only” or “not for human use” – or ingredients that otherwise do not meet legal sourcing requirements for human drug compounding – should not be marketed directly to consumers. The substances themselves are illegal. Marketing them to consumers should be, too.

Close oversight gaps involving medical spas and similar businesses.
States should require appropriate licensure or registration, practitioner accountability, product-source documentation and enforcement when these businesses handle prescription drugs. Prescription-drug activity should not become less accountable because it occurs outside a pharmacy.

Protect lawful pharmacies from deceptive legal intimidation.
Drug manufacturers have every right to protect intellectual property, pursue legally cognizable claims and report suspected violations to FDA, state boards of pharmacy or other regulators. But they should not knowingly or materially misrepresent the law or their own legal rights in order to pressure a pharmacy or outsourcing facility to stop otherwise lawful compounding. Good-faith legal arguments and legitimate disputes about unsettled law should remain protected.

The principle is straightforward: Lawful compounding should be governed by what federal and state law actually permit – not by a manufacturer’s ability to use a misleading legal threat to obtain a result the law itself does not provide.

THE ASK

- Use APC’s five proposals as a roadmap for addressing legitimate patient-safety and marketplace concerns.
- Pursue them federally or at the state level as appropriate, with medical-spa licensure principally addressed by states.
- Focus new requirements on the conduct creating the risk rather than broadly restricting lawful pharmacy compounding.
- **Contact APC for the detailed proposals and regulatory language.**

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ISSUE BRIEF SEPTEMBER 2026

Peptides: A regulated pathway is better than an illicit marketplace

Some peptides patients are seeking today cannot legally be compounded by pharmacies. Yet demand has not disappeared. Consumers can readily obtain "research use only" or improperly sourced products outside the regulated healthcare system. APC believes FDA should consider a carefully controlled pathway for appropriate peptides that brings patients and ingredients into a regulated healthcare framework.

THE ISSUE

Patient interest in peptides has grown rapidly, including products promoted for recovery, metabolism, anti-aging, weight management and other uses.

At the same time, an online market offers substances labeled "research use only" or "not for human use" – and ingredients from sources that may not meet federal requirements for human drug compounding – while plainly promoting their use in humans.

That is a genuine public-health concern.

For several peptides patients are seeking, there is currently no lawful pathway for a state-licensed pharmacy to compound them from bulk substance. Yet consumers can readily obtain those same substances from research-chemical sellers, overseas sources and others operating outside normal pharmacy and drug-supply-chain safeguards.

Simply saying "no" to pharmacy compounding does not make that market disappear.

APC is not advocating unrestricted peptide compounding. We have proposed to FDA a narrow, controlled interim pathway for selected peptides, with specific conditions designed to protect patients and move sourcing into a legitimate drug-supply chain.

THE DETAILS

Under APC's proposed framework, FDA would determine substance by substance which peptide APIs, if any, qualify for the pathway. Participating pharmacies would then operate under specific conditions:

API purchased only through a validated, FDA-registered intermediary.
A pharmacy could obtain the designated peptide API only through an FDA-registered repackager, relabeler or reseller that has performed and documented appropriate vendor validation of the API manufacturer and validation of the manufacturer's Certificate of Analysis. Direct pharmacy purchases from the API manufacturer or purchases through unvalidated channels would not qualify.

Lot-specific provenance and documentation.
The intermediary would provide the pharmacy documentation establishing the source of the API, the specific lot, the validated Certificate of Analysis and information sufficient to establish provenance and traceability. Research-grade or laboratory-use-only material would not qualify.

Patient-specific prescribing.
Compounding would remain within Section 503A's patient-specific prescription framework, subject to otherwise applicable anticipatory-compounding provisions. This is not a pathway for mass production or general office stock.

Clear patient disclosure.
Patients would receive a standardized disclosure explaining that the preparation is compounded and not FDA-approved, that FDA has not reviewed the finished preparation for safety, effectiveness or quality, and – where applicable – that FDA has not determined the API to be safe and effective for the intended use.

Serious adverse-event reporting.
Participating pharmacies would report serious adverse events through FDA's MedWatch system so FDA can identify emerging safety signals.

Limited real-world utilization reporting.
APC has proposed pairing adverse-event information with limited aggregate dispensing data so FDA can understand the denominator behind reported events. The data would be analyzed through an independent academic partner and would not provide FDA raw patient-level information or competitively sensitive pharmacy data.

Existing applicable USP standards, state pharmacy laws and board-of-pharmacy oversight would continue to apply. The proposed pathway does not replace those requirements; it adds sourcing, transparency and surveillance safeguards for this limited category of peptide APIs.

THE ASK

APC is not asking Congress to authorize specific peptides for compounding. Those scientific determinations belong with FDA.

We are asking policymakers to recognize the public-health reality: the choice is not between pharmacy compounding and no peptide use. An illicit marketplace already exists.

APC's proposed pathway would give FDA a controlled option between an unrestricted market and a prohibition that leaves patients seeking these substances outside the regulated healthcare system.

The question is whether appropriate patients who seek these substances can be served within a framework of legitimate sourcing, prescriber oversight, pharmacy standards and regulatory visibility – or whether demand will continue to be pushed into the illicit marketplace.

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Desiccated thyroid extract: Restore a workable pathway

About 1.5 million Americans rely on animal-derived thyroid medications, including patients for whom synthetic thyroid medications have not adequately addressed their needs. FDA's decision to classify these products as biologics threatens continued access to patient-specific compounded DTE. Congress and FDA can help correct that result.

THE ISSUE

Desiccated thyroid extract, or DTE, has been used to treat hypothyroidism for more than a century. FDA estimates that approximately **1.5 million patients** received prescriptions for animal-derived thyroid medications in 2024.

For many patients, FDA-approved synthetic thyroid medications work well. But some patients continue to experience symptoms, cannot tolerate available formulations, or require individualized combinations or doses of the thyroid hormones T3 and T4. For those patients, animal-derived thyroid products, including compounded formulations, can be an important treatment option.

The immediate problem is FDA's regulatory classification.

FDA has determined that animal-derived thyroid products are biological products because they contain thyroglobulin, a protein. But a recently filed Citizen Petition argues that thyroglobulin is not the active pharmaceutical ingredient in DTE. Rather, it acts as a carrier for T3 and T4, the small-molecule thyroid hormones that provide the product's pharmacological effect.

That distinction matters because biological products subject to licensure under the Public Health Service Act are not eligible for pharmacy compounding under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act.

FDA's classification therefore threatens access to compounded DTE for patients who rely on individualized formulations.

THE DETAILS

FDA initially signaled that it might begin enforcement against marketed animal-derived thyroid products after August 2026. It subsequently announced that it would apply a risk-based enforcement approach while manufacturers pursue FDA approval, reducing the immediate threat to commercially manufactured products.

But the underlying problem remains: FDA continues to classify DTE as a biological product.

On August 27, 2026, a Citizen Petition was filed with FDA challenging that classification. The petition asks FDA to:

- Revoke its determination that animal-derived thyroid products are biological products;
- Announce that animal-derived thyroid products will instead be classified as drugs under the Federal Food, Drug, and Cosmetic Act; and
- Withdraw its September 2022 letter to the National Association of Boards of Pharmacy, its August 2025 notice to manufacturers, importers, and distributors, and other publications describing animal-derived thyroid products as biological products.

The petition argues that FDA's classification is inconsistent with the statute, FDA's own guidance, and relevant case law because the protein component of DTE does not furnish the product's pharmacological activity. T3 and T4 do. It also argues that FDA failed to adequately consider the reliance interests of patients, prescribers, and pharmacies and adopted its classification without the notice-and-comment process required for a substantive regulatory change.

The petition also documents why preserving access matters. Some patients cannot tolerate available synthetic products, require individualized doses or formulations, or have not achieved adequate symptom control with other therapies. Compounding allows prescribers and pharmacists to tailor DTE formulations to those patient-specific needs.

Congress also has a direct legislative solution.

H.R. 8630, the Protecting Equal Access to Thyroid Act of 2026, introduced by Rep. Michael Rulli (Ohio), would clarify that the presence of a protein alone does not make a product a biological product when that protein is not the component responsible for the therapeutic effect.

That approach addresses the core regulatory issue while preserving FDA's authority to address legitimate product quality and safety concerns.

THE ASK

- Co-sponsor H.R. 8630, the Protecting Equal Access to Thyroid Act of 2026.
- Urge FDA to respond promptly to the August 27 Citizen Petition and reconsider its classification of animal-derived thyroid products as biologics.
- Ask FDA to preserve patient access to compounded DTE while establishing a durable regulatory pathway for animal-derived thyroid products.

Congress and FDA do not need to choose between product quality and patient access. A sound regulatory pathway can protect both while preserving individualized treatment options for patients who rely on them.

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