Alliance for Pharmacy Compounding
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ISSUE BRIEF SEPTEMBER 2025

FDA says natural thyroid medicine is a biologic drug.

That's not right, and the implications are serious for patients who rely on that compounded therapy.

THE ISSUE

FDA has arbitrarily reclassified Desiccated Thyroid Extract (DTE) as a biologic drug, prohibiting it from use in compounding and clearing the field for a drugmaker to have a monopoly on the therapy (and surely raise the price). DTE has been prescribed and used safely for more than a hundred years to treat millions of Americans with hypothyroidism. Patients depend on it when synthetic options don't work for them. Now, *based on dubious science, contrary to FDA's own policy on what ingredients may be considered biologics, and without following any formal process*, FDA is reclassifying this trusted medicine as a biologic drug. This move will disrupt care, reduce competition, and hand market control to a single manufacturer. It's a small niche in compounding, but hundreds of thousands of patients will be left without therapy.

THE DETAILS

1. **Bad science that contradicts FDA's own policy**

- The FDA's rationale hinges on the presence of *thyroglobulin*, a protein in pig thyroid glands. But thyroglobulin is an ***inactive*** **ingredient** — it's broken down in the stomach and does not treat hypothyroidism.
- The active ingredients in DTE are levothyroxine (T4) and liothyronine (T3), well-studied small molecules that have been used in thyroid care for generations.
- No precedent exists for reclassifying a drug solely because it contains an *inactive* protein.
- FDA's reclassification **contradicts its own guidance document***, which states that a drug product that contains a protein only as an inactive ingredient is not considered to be a "protein" for purposes of the statutory definition of "biological product."
- FDA has acted unilaterally, with **no rulemaking and no public comment period**, via an unorthodox series of letters to the National Association of Boards of Pharmacy and to DTE suppliers. This is not how such decisions should be made.

2. **Patient impact: Impeded access to an essential therapy + likely higher cost**

- Reclassification would force DTE into the biologics approval pathway. Unlike regular drug approval, the biologics pathway is far more expensive and restrictive, with no true generics—only costly "biosimilars"—an expensive, lengthy process designed for complex, protein-based drugs, not established small-molecule therapies.
- Up to **1.9 million patients** could lose access to DTE and face soaring prices after one pharma company becomes an exclusive manufacturer and compounded options become unavailable.
- Many patients who don't tolerate FDA-approved synthetic thyroid hormones would be left with no effective alternative.

**The "Deemed to be a License" Provision of the BPCI Act: Questions and Answers, Guidance for Industry; March 2020. Available at https://www.fda.gov/media/119274/download*

3. Monopoly by corporate petition

- This decision by FDA comes not as a result of a scientific evaluation of DTE, but from a petition by drugmaker **AbbVie**, manufacturer of commercial DTE product Armour Thyroid. AbbVie asked FDA to prohibit other manufacturers from selling unlicensed DTE products unless they had an investigational new drug application and a clinical development program aimed at eventual approval. AbbVie has these things in place and is working towards a Biologics License Application (BLA).
- If FDA's decision stands, AbbVie likely will be the only company with a biologics license for DTE, effectively giving it a monopoly.
- That would eliminate competition, undermine prescriber and patient choice, and almost certainly increase costs to patients.

Bottom line: FDA's reclassification of DTE as a biologic is unnecessary, scientifically flawed, and demonstrably harmful to patients. It strips away choice, likely increases prices, and hands control of a critical therapy to a single drugmaker.

THE ASK

Representative Diana Harshbarger (TN) is circulating a sign-on letter to FDA asking the agency to justify and reconsider its arbitrary decision related to natural thyroid products so that patients are not collateral damage in a policy change that effectively clears the field to create a monopoly for one drugmaker. Contact Peter Stein in Rep. Harshbarger's office to sign on to the letter by emailing peter.stein@mail.house.gov or calling (202) 225-6356.

The letter tells FDA to:

- **Keep DTE regulated as a small-molecule drug — not a biologic —** consistent with science and decades of precedent.
- **Reject a reclassification** that limits treatment options and drives up prices for patients.
- **Protect patient/provider decision-making** by preserving access to DTE alongside synthetic alternatives.

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ISSUE BRIEF SEPTEMBER 2025

The Drug Shortage Compounding Patient Access Act of 2025

THE ISSUE

Introduced by Representative Diana Harshbarger (TN), the *Drug Shortage Compounding Patient Access Act of 2025* delivers clarity and common-sense reforms to help FDA, pharmacies, and outsourcing facilities respond proactively and effectively to drug shortages, strengthen supply chain transparency, and protect patient care. By codifying previous "temporary" FDA policies, modernizing outdated provisions of the Food, Drug, and Cosmetic Act, and clarifying FDA's authority, the bill preserves patient access to medications their prescriber judges they need, even during shortages. It ensures that both 503A state-licensed pharmacies and 503B outsourcing facilities can meet essential patient needs while maintaining rigorous safety standards.

THE DETAILS

The Drug Shortage Compounding Patient Access Act of 2025:

1. **Equips FDA to better anticipate drug shortages and pharmacies to help mitigate those shortages within regulatory guardrails.**
   - Broadens the sources from which FDA is required to draw drug shortage data and requires manufacturers to report supply issues, including demand surges.
   - Allows 503A pharmacies to provide hospitals/clinics compounded drugs in shortage for urgent administration when the hospital/clinic documents it cannot source the drug from the manufacturer or from a 503B outsourcing facility.
2. **Stimulates cGMP-compliant bulk drug compounding by 503B outsourcing facilities.**
   - Improves clarity for 503Bs by mandating annual FDA updates to the 503B bulks list.
   - Implements a 180-day transition period for 503B outsourcing facilities to continue compounding medications after a shortage is resolved.
3. **Clarifies certain provisions and labeling.**
   - Establishes a mandatory, uniform prescription label disclosure for compounded medications, noting that the drug is not FDA-approved.
   - Clarifies that monographed dietary supplements are permissible substances for use in compounded drugs.
   - Repeals a 1997 law directing FDA to create an interstate distribution MOU with states (never finalized, made obsolete with passage of DQSA in 2013) and placing a mandatory 5% cap on interstate shipments of compounded drugs without a prescription in states that don't sign that MOU.

THE ASK

- **House:** Co-sponsor the Drug Shortage Compounding Patient Access Act of 2025. To co-sponsor the bill, contact Peter Stein in Rep. Harshbarger's office at peter.stein@mail.house.gov or (202) 225-6356.
- **Senate:** Consider introducing companion legislation to the Drug Shortage Compounding Patient Access Act of 2025 in the Senate.

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ISSUE BRIEF SEPTEMBER 2025

The practice of pharmacy compounding requires rigorous regulation. But it needs to be the right regulation.

Our Blueprint provides 14 recommendations for eliminating ineffective rules and practices that impede patient access to drugs their prescriber judges they need.

THE ISSUE

Pharmacy compounding plays a vital and time-honored role in American healthcare, offering customized medication solutions when FDA-approved drugs are in shortage or a prescriber judges a custom formulation is needed for an individual patient. Compounded medications are prepared in state-licensed pharmacies by trained professionals under rigorous oversight from state pharmacy boards and in general accordance with compounding standards established by the U.S. Pharmacopeia.

The practice of compounding requires a rigorous regulatory framework. Indeed, the measure of good regulation is how well it keeps patients safe without impeding patients' access to therapies their prescriber judges they need. Unfortunately, some current compounding-related regulations and policies don't meet that standard, to the detriment of patients.

Under President Trump's 10:1 Executive Order requiring the elimination of unnecessary federal rules, we believe pharmacy compounding presents a clear opportunity for reform. APC's '**Blueprint for Eliminating Redundant, Unauthorized, or Ineffective Regulation that Impedes Patient Access to Compounded Drugs**' identifies key federal policies or proposals that are obsolete, unauthorized by statute, or unproven in their benefit to public health. The document is by no means a call for de-regulation. Rather, it offers constructive recommendations for smarter, more effective regulatory approaches – ones that preserve safety without undermining access or innovation.

THE DETAILS

Key priorities for removal or reform:

- **Support** legislation requiring FDA to rely on a broader range of data in determining drug shortages so the agency can better anticipate drug shortages and marshal resources accordingly.
- **Mandate** that both drug and dietary supplement USP monographs are considered "applicable" in law and regulation so that supplements may be compounded pursuant to a prescription.
- **Demand** balance and evidence in FDA communication about compounded therapies.

- **Correct** overt overreach in FDA's draft "Demonstrably Difficult to Compound" rules for 503A pharmacies.
- **Reject** drugmaker petitions to add GLP-1 APIs to the DDC list and ensure that decisions about items added to the DDC list are rooted in science and facts.
- **Reject** any effort to restrict patient access to compounded hormone therapy and disqualify using the 2020 NASEM report in future policy making.
- **Eliminate** the 1997 MOU requirement in Section 503A of the FD&C Act.
- **Overhaul** the FDA Pharmacy Compounding Advisory Committee to include pharmacists with current patient-facing experience and to allow for a fair and balanced deliberative process.
- **Repair** or rescind FDA's GFI 256 regarding animal drug compounding.
- **Instruct** DEA to clarify "constructive transfer" policies to allow for the delivery of controlled substance prescriptions to provider offices for administration.
- **Amend** FDA's "Insanitary Conditions" guidance to include bright-line standards for compliance.
- **Instruct** FDA to finalize a robust 503B bulks list with all deliberate speed.

THE ASK

- Download and read the Blueprint at **a4pc.org/blueprint**.
- Share the Blueprint with administration and agency officials who can act on its recommendations.
- Support compounding legislation and regulation that ensures both patient safety and patient access.

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