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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