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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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