Alliance for Natural Health Position Paper

FDA's Attack on Natural Desiccated Thyroid (NDT)

Why MAHA's Vision Depends on Preserving Patient Access to NDT

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Authors:

Robert Verkerk, Ph.D., Executive & Scientific Director
Jonathan Emord, Esq., General Counsel
Ron Hoffman, M.D., President & Medical Director
Michael Ames-Sikora, Editorial Director

Alliance for Natural Health USA
(anh-usa.org)

Executive Summary

Natural desiccated thyroid (NDT)—a time-tested, bioidentical hormone replacement therapy—is a critical lifeline for millions of Americans with hypothyroidism who do not sufficiently respond to synthetic T4-only medications. In August 2025, the FDA ruled NDT an unapproved biologic and ordered removal of compounded and commercial NDT products from the market. The Alliance for Natural Health (ANH) considers FDA's August 2025 ruling directly contrary to the Make America Healthy Again (MAHA) agenda endorsed by the President's executive order.[1] Because this issue is central to the health of millions, we have drafted this position paper specifically for NDT patient advocates, MAHA activists, and integrative practitioners who rely on NDT to support their patients and manufacturers and compounding pharmacies that produce NDT products.

[1] Trump, D. J. (2025, February 13). Establishing the President's Make America Healthy Again Commission (Executive Order No. 14212). The White House. *https://www.whitehouse.gov/presidential-actions/2025/02/establishing-the-presidents-make-america-healthy-again-commission*.

This position paper evaluates the FDA's August 2025 announcement,[2] underscores the urgency for action to reverse the announcement, and lays out a refined, evidence-rich, three-tiered advocacy strategy (short-, medium-, and long-term), designed to preserve patient access, safeguard compounding, and secure long-term regulatory protection.

1. Long-Standing Use, Safety, and Patient Choice

1.1 **Century-long track record**: Natural desiccated thyroid (NDT) has a uniquely long and well-documented history of safe therapeutic use. Its introduction in the late 1800s marked one of the first effective treatments for hypothyroidism, dramatically reducing morbidity and mortality associated with myxedema.[3] For more than half a century, NDT remained the standard of care worldwide, until synthetic levothyroxine (T4) became widely available in the 1950s.[4] Even with the arrival of synthetic monotherapy, many endocrinologists continued to prescribe NDT for its ability to deliver the full complement of thyroid hormones—thyroxine (T4), triiodothyronine (T3), diiodothyronine (T2), monoiodothyronine (T1), and calcitonin—thereby more closely replicating the natural secretory profile of the human thyroid gland.[5]

1.2 **Comprehensive hormone profile**: This broader hormone spectrum is clinically significant. While levothyroxine effectively normalizes thyroid-stimulating hormone (TSH) levels in most patients, a substantial subset—estimated at up to 29% of the roughly 30 million Americans with hypothyroidism—continue to experience residual symptoms such as fatigue, weight gain, and cognitive slowing despite "biochemical euthyroidism."[6] These patients often have impaired peripheral conversion of T4 to T3, the biologically active hormone, due to genetic polymorphisms, chronic illness, or other metabolic factors. For these individuals, NDT can provide symptom relief, improve quality of life, and normalize serum T3 levels more effectively than levothyroxine alone.

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[2] FDA. FDA's Actions to Address Unapproved Thyroid Medications, July 8, 2025: *https://www.fda.gov/drugs/enforcement-activities-fda/fdas-actions-address-unapproved-thyroid-medications*.

[3] Kendall EC. The development of desiccated thyroid therapy. *Endocrinology.* 1915;1(3):123-135.

[4] Jonklaas J, Bianco AC, Bauer AJ, et al. Guidelines for the treatment of hypothyroidism: prepared by the American Thyroid Association Task Force on Thyroid Hormone Replacement. *Thyroid*. 2014;24(12):1670-1751.

[5] Hoang TD, Olsen CH, Mai VQ, Clyde PW, Shakir MKM. Desiccated thyroid extract compared with levothyroxine in the treatment of hypothyroidism: a randomized, double-blind, crossover study. *J Clin Endocrinol Metab.* 2013;98(5):1982-1990.

[6] Peterson SJ, McAninch EA, Bianco AC. Is a normal TSH synonymous with "euthyroidism" in levothyroxine monotherapy? *J Clin Endocrinol Metab.* 2016;101(12):4964-4973.

1.3 **Safety**: The safety profile of NDT has been extensively documented across more than a century of clinical use. Multiple retrospective and prospective studies have found no increased risk of cardiovascular disease, osteoporosis, or mortality compared with synthetic T4 therapy when dosed appropriately.[4,5] In fact, a randomized, double-blind crossover trial found that nearly half of patients preferred NDT over levothyroxine, citing improvements in mood, energy, and general well-being, without significant adverse effects.[5] This enduring patient preference highlights the importance of maintaining access to NDT as a therapeutic option, respecting both patient autonomy and the principles of personalized medicine. Eliminating NDT from the U.S. market would remove a critical choice for millions of patients who depend on this therapy to maintain optimal thyroid function and quality of life.

2. FDA's August 2025 Enforcement Campaign

2.1 Official Decision & Timeline

On August 6, 2025, the FDA issued a formal letter[7] to manufacturers, importers, and distributors of animal-derived thyroid products, declaring such therapies—commonly marketed as Armour Thyroid, NP Thyroid, Nature-Thyroid, and Natural Thyroid—as "unapproved biological products" under the Public Health Service Act, Section 351. As no Biologics License Applications (BLAs) exist for these products, the agency ordered enforcement with a 12-month risk-based transition to complete removal of NDTs from the market.

Despite allowing a grace period to "transition" patients to FDA-approved synthetic alternatives, the FDA emphasizes compounding of NDT is presently not permitted.

2.2 Agency Justification

The FDA bases its action on "public safety" concerns:

- **Unreviewed safety and effectiveness**: These products haven't undergone FDA premarket evaluation, including scrutiny of manufacturing, potency, labeling, or purity.
- **Inconsistent potency and purity**: Batch-to-batch variation, flawed manufacturing compliance, inconsistent labeling (e.g., measuring "grains"

[7] FDA formal letter to manufacturers, importers, and distributors of animal-derived thyroid products, August 6, 2025: *https://www.fda.gov/drugs/enforcement-activities-fda/fdas-actions-address-unapproved-thyroid-medications#:~:text=FDA%20sent%20letters%20to%20manufacturers,unapproved%20animal%2Dderived%20thyroid%20medication*.

ranging from 60–65 mg), and potential for viral or other contamination pose tangible patient risks.
- **Adverse events**: The agency cites over 500 adverse event reports between 1968 and early 2025, with notable elevation during 2019–2020 following voluntary recalls.

2.3 ANH-USA's Response: A Crucial Stand for Health Freedom

Following news of the announcement, we at ANH decried the move as "a devastating blow to health freedom." Our coverage on August 15 stated:

"The FDA has announced its intention to ban natural desiccated thyroid medicines used safely by millions of hypothyroid patients, leaving them with only a synthetic version that is much less effective."

In contrast to the FDA perspective, we argue that NDT has a long history of safe use (see above), with comparatively few adverse events—according to the FDA's own FAERS system, only ~500 since 1968,[8] or on average about nine per year—hardly evidence requiring urgent removal.

2.4 Media Voices & Political Reaction

- **Politico** highlighted NDT as a "MAHA flashpoint," illustrating how the Trump-era regulatory approach is now resurging under new leadership.[9]
- **NBC News** reported that the FDA is warning about unapproved thyroid pills but claims that access will be "ensured" as approval pathways proceed.[10]
- **Congressman Abe Hamadeh** questioned the FDA: patients had reported better outcomes on NDT than synthetics, raising alarms about limiting effective treatments.[11]
- **FDA Commissioner Dr. Marty Makary** publicly stated via social media that the agency is "committed to pursuing the first-ever approval of desiccated thyroid extract, pending results of the ongoing clinical trials," and affirmed access

[8] FDA letter to industry, August 7, 2025: *https://www.fda.gov/media/188081/download*.
[9] POLITICO. How thyroid drugs became a MAHA flashpoint. August 15, 2025: https://www.politico.com/newsletters/prescription-pulse/2025/08/15/how-thyroid-drugs-became-a-maha-flashpoint-00510284
[10] NBC News. FDA warns about unapproved thyroid pills — then says it'll 'ensure access' to them. August 14, 2025: *https://www.nbcnews.com/health/health-news/fda-warns-unapproved-thyroid-pills-says-ll-ensure-access-rcna224972*.
[11] Congressman Abe Hamadeh Questions FDA About Availability of Popular Thyroid Medications August 18, 2025. *https://hamadeh.house.gov/congressman-abe-hamadeh-questions-fda-about-availability-popular-thyroid*.

would be maintained during the process.[12]

3. Key Risks Despite FDA's Reassurances

Despite Commissioner Makary's assurance and media mitigations, several profound threats remain:

1. **Compounding Access Undermined**
   Given NDT's BLA-classified biologic status, compounded formulations—essential for dosage flexibility—cannot legally be produced without a BLA, effectively eliminating access to custom treatments.

2. **Market Monopoly & Reduced Therapeutic Fidelity**
   Approval pathways (like new drug applications or BLAs) are prohibitively expensive. Only large manufacturers (e.g., NP Thyroid, Armour/AbbVie) can realistically pursue them, risking monopolistic pricing and formulations that may not mirror historic NDT products.

3. **Uncertain Approved Formulations**
   Even if approved, the resulting NDT products may differ in hormone ratios, excipients, or manufacturing, potentially leaving many patients with inferior or non-equivalent therapies.

4. **Timeline Delays**
   Clinical trials and approvals may span years, creating critical gaps in patient acc and stability in thyroid control.

4. ANH-USA's Strategic Framework: Protecting NDT Access

To secure patient access and deter FDA overreach, ANH-USA will pursue a 3-tiered strategy:

4.1 Short-Term Strategy: Reclassification from Biologic to Drug

[12] Graves Disease & Thyroid Foundation. U.S. Food and Drug Administration Threatens Enforcement Action over Desiccated Thyroid Extract (DTE) Products. August 12, 2025: *https://gdatf.org/u-s-food-and-drug-administration-threatens-enforcement-action-over-desiccated-thyroid-extract-dte-products*.

Objective: Urgently petition **HHS** and **FDA leadership** to reclassify NDT as a **drug**, not a biologic, thereby reactivating compounding exemptions (e.g., 503A, 503B) and returning burden of proof to the agency rather than providers.

Rationale:

- NDT's decades-long safe history and biochemical comparability to synthetic thyroid hormones reinforce its eligibility for drug status.
- Reclassification would have immediate effect, preserving the critical compounding pipeline and patient choice.
- Natural NDTs are unpatentable, making biologic approval impossibly expensive and thus unrealistic.

Action Plan:

- Build consortium of practitioner groups, manufacturers, and compounding pharmacists to increase breadth and diversity of advocacy base
- Direct advocacy to HHS Secretary and FDA leadership.
- Draft federal legislation to reverse FDA's NDT biologic decision and protect NDT compounding in the states.
- Draft model state legislation to protect the availability of NDTs as compounded drugs.
- Deploy Congressional champions to prompt agency action.
- Use patient testimonials and network messaging to reinforce urgency.

4.2 Medium-Term Strategy: Enforcement Discretion for GMP-Manufactured NDT

Objective: Secure **FDA guidance** granting enforcement discretion for compounded and commercial NDT products manufactured under stringent GMP standards, while approval processes unfold.

Rationale:

- Provides legal breathing room for compounding pharmacies and manufacturers.
- Aligns with FDA's own risk-based enforcement approach—allowing patient access despite lack of formal approval.

Action Plan:

- Coordinate with compounding laboratories and pharmaceutical partners to validate and document GMP protocols.
- Launch media campaigns featuring patient stories and clinical urgency.

- Mobilize medical organizations and compounding networks to advocate for formal FDA guidance to ensure high quality manufacturing standards are met.

4.3 Long-Term Strategy: Regulatory Carve-Out

Objective: Secure federal statutory protection for NDTs via legislation that recognizes NDTs as an approved drug class, and explicitly permits compounding.

Rationale:

- Legislative action ensures durable protections, immune to shifting agency priorities or leadership.
- A carve-out aligns with MAHA principles, reinforcing patient, medical, and practice freedoms.

Action Plan:

- Engage sympathetic lawmakers to introduce targeted legislation.
- Build bipartisan support emphasizing health freedom, patient rights, and affordability.
- Frame NDT as a broader emblem of integrative medicine and choice.

5. Why the FDA's Action is Part of a Broader Threat to Health Autonomy

ANH-USA frames the current assault on NDT as part of a larger pattern of natural, compounded, or bioidentical medical option suppression—restricting access and limiting clinician choice to consolidate Big Pharma anti-competitive control and dominance.

Other examples:

- Restrictions on estriol (natural estrogen).
- Pressure on compounded peptides, homeopathic remedies, and supplement claims under FTC/FDA scrutiny.
- Mandated randomized controlled trials (RCTs)—exclusively suitable for patentable pharmaceuticals, but inaccessible for natural therapies—effectively silencing many health product options.

  Find out more about threats to natural health at anh-usa.org.

6. Call to Action to Save NDT

1. **Policymakers**: Introduce and support legislation protecting NDT; elevate constituent concerns.
2. **FDA/HHS**: Reclassify NDT as a drug; issue safeguarding enforcement guidance for GMP-compliant products.
3. **Compounding & Pharmaceutical Makers**: Collaborate on quality standards; support ANH-USA's advocacy efforts.
4. **Patients & Advocates**: Share experience, contact legislators, join ANH-USA's campaigns to preserve access.

7. Conclusion

Natural desiccated thyroid is far more than a legacy therapy—it's an irreplaceable, patient-preferred option rooted in safety, efficacy, autonomy. It is also the option preferred by many integrative medicine physicians who specialize in supporting whole person health and approaches that work with, rather than in contest with, natural systems.

The FDA's August 2025 enforcement threatens the health, functional stability, and autonomy of millions. It removes a safe, effective, and low-cost tool from the 'medicine chest' of integrative medicine physicians and practitioners.

ANH-USA proposes a three-tiered strategy which offers practical, rights-based, and durable solutions: reclassification, enforcement discretion, and legislative protection, that is fully aligned with the MAHA agenda.

We must act swiftly and collaboratively to ensure that NDT remains accessible today—and protected for the long run.

8. Call To Action

TO INDIVIDUALS: If you strongly oppose the FDA's action, please send our Action Alert below to Secretary Kennedy, FDA Commissioner Dr. Marty Makary, and Congress.

TO PRACTITIONER ASSOCIATIONS, COMPOUNDERS AND MANUFACTURERS OF NDT: if you believe our strategy will facilitate your mission or objectives, we would love to hear from you so you can consider partnering with us on our three-tier strategy.

TO ALL: Please get the word out in any way that suits your network. You may find some of the wording in the Appendix of use in social media posts.

APPENDIX

Examples for use in NDT campaign messaging

Audience	Message Highlights
Policymakers (Congress)	Protect constituent health and freedom; avoid corporate capture, monopolies and rationed access; support MAHA-backed regulatory approaches.
FDA/HHS Leadership	An NDT ban is unjustified from a safety standpoint (it is driven by corporate capture of the FDA). NDT has unmatched safety and patient value compared with synthetic T4; reasonable reclassification and discretion policies uphold public trust. Need for patient access is critical millions are affected.
Compounding Industry	Encourage unified quality standards and stakeholder engagement with FDA; prepare for enforcement buffers; partner in advocacy.
Supporters/Patients	Inform your networks of the FDA's plan to ban NDT; mobilize personal stories; fuel public outreach and engagement with FDA/HHS and legislators.