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Alliance for Pharmacy Compounding

November 5, 2025

The Honorable Marty Makary, M.D., M.P.H.
Commissioner, U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Re: Urgent request to freeze and reverse FDA's classification of desiccated thyroid extract as a biologic

Dear Commissioner Makary:

Recent allegations concerning former CDER Director George Tidmarsh—described in the complaint *Aurinia Pharmaceuticals Inc. v. Tidmarsh*, Case No. 25-CIV-00788 (filed Oct. 10, 2025)—raise grave concerns about potential personal animus, undisclosed conflicts, and misuse of regulatory authority. Indeed, the timing and context of the FDA's biologic reclassification of animal-derived thyroid products, including desiccated thyroid extract (DTE), heighten concern that such alleged conduct by Dr. Tidmarsh may have influenced policy in a manner inconsistent with FDA's own guidance and statutory framework.

FDA's August 6, 2025, notice to industry asserts that animal-derived thyroid (ADT/DTE) products are "biological products" because they contain thyroglobulin, a large protein naturally present in animal thyroid tissue. Yet, FDA's guidance implementing the Biologics Price Competition and Innovation Act of 2009 expressly states that a product is not considered a "biological product" merely because it contains a protein *as an inactive ingredient*.[1]

The labeled active ingredients for marketed animal-derived thyroid products are the thyroid hormones T3 and T4. *Thyroglobulin is not identified as an active ingredient*. Classifying DTE as a biologic based solely on the presence of thyroglobulin, therefore, conflicts with FDA's stated policy. Moving forward on that basis would create a significant and unnecessary disruption to patient care for individuals who have long relied on DTE when synthetic

[1] "Moreover, a drug product that contains a protein only as an inactive ingredient (e.g., a drug product formulated with human serum albumin as an inactive ingredient) is not considered to be a 'protein' for purposes of the statutory definition of 'biological product' and the transition provision of the BPCI Act." See FDA, The "Deemed To Be a License" Provision of the BPCI Act – Questions and Answers (March 2020), Section A, Q1.

alternatives prove insufficient. It also contradicts FDA's stated intention to ground regulatory actions in law, guidance, evidence, and patient safety.

Accordingly, to protect patients, uphold FDA's standards, and ensure confidence that agency policy is driven not by personal animus but solely by science and statute, we respectfully request that FDA immediately:

1. Reverse its position that animal-derived thyroid products (including DTE) are biological products; and
2. Freeze any related enforcement action or implementation activities regarding ADT/DTE while FDA realigns its approach with the March 2020 guidance and applicable statutory definitions.

These measured steps will prevent avoidable harm, restore alignment with FDA's own guidance, and reinforce public trust in the Agency's impartial decision-making.

Thank you for your prompt attention. I stand ready to answer questions about these requests and the impacts on affected patients.

Sincerely,

Scott Brunner, CAE
Chief Executive Officer
Alliance for Pharmacy Compounding
scott@a4pc.org

cc: HHS Office of the Inspector General

Senate Health, Education, Labor and Pensions Committee, Chair and Ranking Member

House Energy and Commerce Committee, Chair and Ranking Member

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The Alliance for Pharmacy Compounding is the industry trade association and the voice for pharmacy compounding, representing more than 600 compounding small businesses — including more than 7,000 compounding pharmacists and technicians in both 503A and 503B settings — as well as prescribers, educators, researchers, and suppliers. Learn more at compounding.com or a4pc.org.