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VIA Electronic Submission at <http://www.regulations.gov>

United States Department of Health and Human Services
Food and Drug Administration
Docket No. FDA 2013-S-0610

Date: August 28, 2026

The undersigned submits this petition under 21 U.S.C. § 201(g) (section 201(g) of the Federal Food, Drug, and Cosmetic Act), 42 U.S.C. § 262(i)(1) (section 351 of the Public Health Service Act), and 21 C.F.R. § 10.30 to request the Commissioner of Food and Drugs to take the actions requested below.

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A. Actions Requested

The undersigned requests that the U.S. Food and Drug Administration (“*FDA*” or the “*Agency*”):

- (1) Revoke FDA’s determination that animal-derived thyroid (“*ADT*”) products are “biological product[s]” under section 351(i) of the Public Health Service Act;
- (2) Announce that FDA will classify ADT products as a drug, as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act; and
- (3) Withdraw the September 16, 2022 letter to the National Association of Boards of Pharmacy (“*NABP*”) and the August 6, 2025 letter to manufacturers, importers, and distributors of animal-derived thyroid products, and any other publication in which FDA describes ADT as being subject to the “biological product” definition.

B. Statement Of Grounds

I. Summary.

Approximately 1.5 million patients in the United States depend on ADT products to treat hypothyroidism. This includes patients who have had their thyroid removed, destroyed by Hashimoto’s disease, or irradiated during cancer treatment, and they suffer from debilitating symptoms: chronic and intense fatigue, cognitive impairment, weight gain, hair loss, autoimmune complications, and inflammation, among many others. Many of these patients have attempted to treat their condition with FDA-approved synthetic thyroid medications, but their symptoms persisted or deteriorated. The common refrain from these patients is that ADT is the only medication that restores their quality of life and allows them to feel like their normal selves again. Indeed, ADT is often the difference between severe illness and a functional, thriving life. FDA is now threatening to take away these patients’ ability to lead a normal life simply because it (wrongly) determined that ADT meets the statutory definition of “biological product” and therefore should not be regulated as a “drug.” This formalistic decision is not only divorced from the real impacts that it will have on patients; it is also incorrect as a matter of law.

To start, FDA is wrong that the product meets the statutory definition of a “biological product.” FDA’s determination that ADT meets this definition relied solely on the fact a component of ADT, the thyroglobulin, is a “protein” or is “analogous” to a protein. But the definition requires more than just identifying these components. The statute, controlling case law, and even FDA’s own guidance make clear that the protein or analogous protein must be an active pharmaceutical ingredient (“*API*”). Thyroglobulin is not an API. Rather, the scientific evidence demonstrates that the thyroglobulin is a carrier protein, which helps control the release of the drugs that are bound to it, but does not play a role in treating the condition. This is not unusual. A number of products contain proteins that play a pharmacokinetic role but do not furnish the pharmacological activity, and the Agency regulates these products as drugs.

Moreover, FDA’s determination violated the Administrative Procedure Act. FDA failed to follow rulemaking procedures by not seeking public comment before imposing such an impactful rule. The determination is also arbitrary and capricious because FDA:

- (1) misapplied the definition of “biological product”;
- (2) ignored its own policy that requires the biological component to be an API;

- (3) entirely failed to provide an explanation as to why the thyroglobulin is an API;
- (4) failed to explain why it classifies products with similar traits as drugs but refuses to classify ADT as a drug; and
- (5) failed to consider the reliance interests of the physicians who prescribe compounded ADT products, the pharmacies that compound the ADT products, and the patients who require the continued availability of compounded ADT products to maintain quality of life.

Finally, public policy reasons should compel the Agency to reconsider its stance. ADT is a well-researched product with over a hundred years of documented efficacy in patients who rely on it as the only available means to treat their thyroid condition. ADT is essential to these patients, and denying them access is not only unnecessary; it is harmful. For these reasons we ask that the Agency (1) revoke its decision to classify ADT as a biological product, (2) announce that ADT will be classified as a drug, and (3) withdraw all previous statements in which FDA describes ADT as being subject to requirements of “biological products” under the Public Health Service Act.

II. Background.

a. Animal-Derived Thyroid Products Are Critical to Treating Certain Patients with Hypothyroidism.

Hypothyroidism, a condition of decreased thyroid hormone production, affects approximately 2% of the U.S. adult population, and millions of Americans take thyroid hormone replacement therapy to maintain normal circulating thyroid hormone levels and to prevent or improve symptoms such as fatigue, weight gain, cold intolerance, and depressed mood.¹ Two categories of thyroid hormone replacement therapy are marketed in the United States: synthetic products containing either levothyroxine (“LT4”) or liothyronine (“LT3”), and ADT products, which are commonly described as desiccated thyroid extract.² ADT products are composed of thyroglobulin, an alpha amino acid polymer that acts as a carrier of the thyroid hormones thyroxine (“T4”) and triiodothyronine (“T3”)³ and are marketed under names including Armour Thyroid, NP Thyroid, Nature-Throid, and Natural Thyroid.⁴

ADT is the oldest pharmacological treatment for hypothyroidism, becoming the dominant therapy in the early 1900s.⁵ As of 1965, approximately four of every five prescriptions for thyroid

¹ FDA, *FDA’s Actions to Address Unapproved Thyroid Medications*, <https://www.fda.gov/drugs/enforcement-activities-fda/fdas-actions-address-unapproved-thyroid-medications> (last visited June 15, 2026) (hereinafter “*FDA Actions*”); Letter from Shannon Glueck, U.S. FDA, to Lemrey “Al” Carter, National Association of Boards of Pharmacy 1-2 (September 16, 2022) (hereinafter “*2022 Pharmacist Letter*”) (Notice from FDA determining that ADT is a biologic and not eligible for compounding).

² FDA Actions; 2022 Pharmacist Letter at 2.

³ Letter from FDA to Manufacturers, Importers, and Distributors of Animal-Derived Thyroid Products at 3 (Aug. 6, 2025), <https://www.fda.gov/media/188081/download>, (hereinafter “*2025 Notice to Industry*”).

⁴ 2022 Pharmacist Letter at 2.

⁵ Mohamed K.M. Shakir et al., *Comparative Effectiveness of Levothyroxine, Desiccated Thyroid Extract, and Levothyroxine+Liothyronine in Hypothyroidism*, 106 J. Clin. Endocrinol. & Metab. e4400, e4401 (2021); Matthew D. Ettleson & Antonio C. Bianco, *Individualized Therapy for Hypothyroidism: Is T4 Enough for Everyone?*, 105 J. Clin. Endocrinol. & Metab. e3090, e3090–91 (2020).

hormone in the United States were for ADT.⁶ Today, these products remain a common form of treatment even after the introduction of synthetic products containing LT4 and LT3, as an estimated 1.5 million patients receiving thyroid hormone replacement are prescribed ADT products.⁷ Further, many of these patients are prescribed and rely on a compounded ADT formulation, prepared by pharmacies pursuant to Section 503A of the Federal Food, Drug, and Cosmetic Act (“*FD&C Act*”)⁸ and consistent with the Thyroid U.S. Pharmacopeia (“*USP*”) drug monograph.⁹

The option to use ADT is particularly impactful for autoimmune or immunologically sensitive patients who cannot tolerate the dyes and filler ingredients prevalent in FDA-approved medications like Synthroid, Tirosint, Levoxyl, and Unithroid, all of which contain LT4 as the only active ingredient.¹⁰ FDA-approved LT4 products can also be ineffective in patients whose thyroids cannot convert T4 to the needed T3 hormone, or patients who have had their thyroid removed, destroyed by Hashimoto’s disease, or irradiated. These patients need a combination of LT4 and LT3 to restore thyroid function—a combination that does not exist in any single FDA-approved medication—but does in ADT.

Moreover, thyroid treatment is specific to the patient and there is no single dose or medication that fits every patient. With respect to dosing, precision is necessary in thyroid management but the FDA-approved products come in limited dosage strengths that make precise treatment difficult. Additionally, as previously stated, there is no FDA-approved medication that contains both LT4 and LT3 that many of those with hypothyroidism need. Yet, ADT combines both of these active ingredients and ADT is the only medication that makes it possible to replace what a patient without a thyroid has lost. Further, ADT, rather than pure T3 or pure T4, is better suited for compounding. As explained in more detail below, achieving the microgram-level precision patients require using only the pure T3 or pure T4, is difficult and inevitably introduces some imprecision, whereas ADT comes with a USP drug monograph that makes it straightforward and safe to compound.¹¹

The clinical record reflects meaningful patient benefit from ADT. A large online survey of hypothyroid patients reported higher median treatment satisfaction among respondents taking

⁶ Adrian H. Heald et al., *Natural Desiccated Thyroid for the Treatment of Hypothyroidism?*, 14 *Frontiers Endocrinol.* 1309159, at 1–2 (2024).

⁷ 2025 Notice to Industry at 2; FDA Actions.

⁸ 21 U.S.C. § 301 *et seq.*

⁹ 2022 Pharmacist Letter at 2; USP Monograph for Thyroid, United States Pharmacopeia (May 2016); 21 U.S.C. § 353a(b)(1)(A)(i)(I); 21 U.S.C.A. § 353a(b)(1)(A)(i)(I) (“A drug product may be compounded under [Section 503A] if the licensed pharmacist . . . compounds the drug product using bulk drug substances . . . that comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding”).

¹⁰ See Synthroid (Levothyroxine Sodium Tablets) Label, FDA, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021402s0171bl.pdf; see also Tirosint (Levothyroxine Sodium Capsules) Label, FDA, available at

https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/021924s0021bl.pdf; Levoxyl (Levothyroxine Sodium Tablets) Label, FDA, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021301s0261bl.pdf;

Unithroid (Levothyroxine Sodium Tablets) Label, FDA, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2000/212101bl.pdf.

¹¹ Peter Koshland, PharmD, Statement of Support, at p. 2 (hereinafter “*Koshland Statement*”).

ADT than among respondents taking LT4 alone or LT4+LT3.¹² In a prospective, randomized, double-blind, crossover study, outcomes for the overall group were similar across LT4, LT4+LT3, and ADT, while a subgroup of the most symptomatic participants on LT4 preferred and showed improvement on T3-containing therapy, including ADT.¹³ A 2024 review likewise identified a role for ADT in carefully selected patients who remain symptomatic despite treatment with an FDA-approved LT4 therapy.¹⁴

The consequences of inadequate thyroid management are profound and far-reaching, as the thyroid affects virtually every system in the body. Patients may experience energy loss, cognitive impairment and brain fog, weight gain leading to other chronic illnesses, systemic inflammation, and autoimmune reactions—symptoms that greatly impact patients’ day-to-day functioning and can render patients bedridden.¹⁵ However, when dosed appropriately, ADT products can mimic normal thyroid function and restore clinical euthyroidism. As such, ADT is not just a convenience for the patients that use it—it is essential to their overall wellbeing.¹⁶ It is therefore critical that these patients continue to have access to these products.¹⁷

b. FDA’s Regulation of Protein Products as Biologics Instead of Drugs.

FDA regulates medications under two parallel statutory regimes: the FD&C Act,¹⁸ which governs drugs approved through new drug applications (“NDAs”),¹⁹ and the Public Health Service Act (“PHS Act”),²⁰ which governs “biological products” licensed through biologics license applications (“BLAs”).²¹ In March of 2010, Congress passed the Biologics Price Competition and Innovation Act of 2009 (“BPCI Act”),²² which, among other things, amended the statutory definition of “biological product” (sometimes referred to herein as “*biologics*”) in the PHS Act to add the category “protein.”²³ As amended, the statute defines a “biological product” as “a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product . . . applicable to the prevention, treatment, or cure of a disease or condition of human beings.”²⁴ The BPCI Act adopted a ten-year waiting period before products newly incorporated into the definition of “biological product” with NDA approvals under

¹² Sarah J. Peterson et al., *An Online Survey of Hypothyroid Patients Demonstrates Prominent Dissatisfaction*, 28 *Thyroid* 707, 716 (2018).

¹³ Shakir et al., *supra* note 5, at e4400–01, e4413.

¹⁴ A. A. Patel, M. K. Shakir, F. Tuamokumo, A. C. Bianco & T. D. Hoang, *The Effect of Combination Thyroid Hormone Therapies on Symptoms in Patients with a Suboptimal Response to Levothyroxine: A Post-Hoc Analysis*, 8 *J. Endocrine Soc’y* (Supp. 1) bva163.2084 (2024), DOI: 10.1210/jendso/bvae163.2084.

¹⁵ Dawn Ipsen, PharmD, FACP, FACA, FAVCP, Statement of Support, p. 2 (hereinafter “*Ipsen Statement*”).

¹⁶ Brittany Bohinc Henderson, MD, ECNU, Statement of Support, p. 2 (hereinafter “*Henderson Statement*”).

¹⁷ Heald et al., *supra* note 6, at 1, 3.

¹⁸ 21 U.S.C. § 301 *et seq.*

¹⁹ FD&C Act § 505 (21 U.S.C. § 355).

²⁰ 42 U.S.C. § 201 *et seq.*

²¹ PHS Act § 351 (42 U.S.C. § 262).

²² Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, § 7002, 124 Stat. 119, 804 (2010).

²³ BPCI Act § 7002(b) & (e), 124 Stat. 814 & 817 (the BPCI originally amended the definition to exempt “any chemically synthesized polypeptide” from the definition of the “protein” but this exception was removed by the Further Consolidated Appropriations Act, 2020, Pub. L. No. 116-94, § 605, 133 Stat. 2534, 2758 (2019)).

²⁴ PHS Act § 351(i)(1).

section 505 of the FD&C Act would be deemed to be a license under the PHS Act.²⁵ This transition date was March 23, 2020.²⁶

Congress did not define “protein,” and the term lacks a scientific consensus on how to define it, so FDA took to notice-and-comment rulemaking to issue a definition. FDA defined “protein” to mean “any alpha amino acid polymer with a specific, defined sequence that is greater than 40 amino acids in size.”²⁷ Although FDA referred to this as a “bright-line” approach, FDA further clarified its thinking in March 2020, when it issued the guidance titled “The ‘Deemed To Be a License’ Provision of the BPCI Act, Questions and Answers” (herein “*Deemed QA Guidance*” or “*Guidance*”).²⁸ Of particular importance, the Guidance clarified that not all products containing proteins are regulated as biologics. Rather “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.”²⁹ In other words, the protein component of the product must be an API of the product for the product to fall within the PHS Act.

The distinction between drug and biologic is not merely one of form—rather, there are impactful differences. Importantly, one consequence of being classified as a biologic is that such products are not eligible for compounding by pharmacies under section 503A of the FD&C Act.³⁰

c. FDA’s Determination That ADT Is a Biological Product.

Soon after the BPCI Act’s ten-year transition period ended, FDA began referring to ADT as a biological product.³¹ For example, in 2020, FDA issued two warning letters to manufacturers of ADT products, alleging that the products are biological products because they contain thyroglobulin, an alpha amino acid polymer with a specific defined sequence consisting of 2770 amino acids, which meets the definition of “protein.”³² In the alternative, the warning letters also stated that the products are biological products because they are “‘analogous’ to a protein because the identified biological product (i.e., protein) component in these naturally derived mixtures is necessary for the activity of the product and contributes to achieving the intended therapeutic effect.”³³

In 2022, FDA issued a letter to the National Association of Boards of Pharmacy (hereinafter “*2022 Pharmacist Letter*”) to advise that FDA intends to regulate ADT as a biological product. Again, FDA took the position that ADT was a biological product because the thyroglobulin in the ADT exceeded the size threshold of amino acids in FDA’s definition of

²⁵ BPCI Act § 7002(e)(4).

²⁶ Deemed QA Guidance at 1.

²⁷ Biological Product Proposed Rule at 63,817; FDA, Final Rule, *Definition of the Term “Biological Product,”* 85 Fed. Reg. 10,057 (Feb. 21, 2020) (hereinafter “*Biological Product Final Rule*”) (codifying definition at 21 C.F.R. § 600.3(h)(6)).

²⁸ FDA, *The “Deemed To Be a License” Provision of the BPCI Act, Questions and Answers, Guidance for Industry*, Mar. 2020, <https://www.fda.gov/media/135838/download>.

²⁹ Deemed QA Guidance at 5.

³⁰ 2022 Pharmacist Letter.

³¹ See, e.g., Warning Letter to Acella Pharmaceuticals, LLC, CMS No. 604438 (Aug. 14, 2020); Warning Letter to RLC Labs, CMS No. 607596 (Oct. 9, 2020); 2022 Pharmacist Letter; August 2025 Notice to Industry at 1.

³² Warning Letter to Acella Pharmaceuticals, LLC, CMS No. 604438 (Aug. 14, 2020).

³³ *Id.*; see also Warning Letter to RLC Labs, CMS No. 607596 (Oct. 9, 2020) (same).

“protein.”³⁴ FDA added that, because they are biological products, ADT products are not eligible for the compounding exemptions afforded under sections 503A and 503B of the FD&C Act.³⁵

On August 6, 2025, FDA expanded on its classification rationale in its notice to manufacturers, importers, and distributors of ADT (hereinafter “2025 Notice to Industry” or “Notice”). The Notice announced that FDA “intends to take action against marketed unapproved” ADT products, asserting that such products “require an approved [BLA] under section 351 of the [PHS] Act in order to be legally marketed,” and that “[t]here are no FDA-approved BLAs for the ADT products currently on the market.”³⁶ FDA specified that its Notice was intended to “promote compliance with FDA’s premarket approval requirements” and as of August 2026, the Agency intends to “initiat[e] action against manufacturers, distributors, and importers of ADT and unapproved ADT products intended for commercial distribution.”³⁷

Like the warning letters and the 2022 Notice, the 2025 Notice to Industry offered two alternative grounds for treating ADT as a “biological product.” First, FDA reasoned that ADT is a “protein” because it “necessarily contains thyroglobulin, an alpha amino acid polymer with a specific defined sequence consisting of 2,770 amino acids,” and that a product “composed primarily of protein components (e.g., thyroglobulin)” falls within the Agency’s size-based interpretation of the statutory term “protein.”³⁸ Second, and in the alternative, FDA reasoned that ADT is “analogous” to a protein, and thus a biological product, because it “includes an identified biological product component (i.e., thyroglobulin) that is necessary for the activity of the product and contributes to achieving the intended therapeutic effect,” while also potentially including non-biological components such as free T3 and free T4.³⁹ Finally, the Letter announced a risk-based patient transition period of up to twelve months before the Agency would initiate action against manufacturers.⁴⁰

FDA has reiterated this position in other communications. On the same day it issued the 2025 Notice to Industry, FDA also responded to a citizen petition from AbbVie confirming that “a marketed unapproved ADT product requires a license under section 351 of the [PHS] Act in order to be legally commercially distributed.”⁴¹ In a February 2, 2026, response to a bipartisan congressional letter urging that ADT be classified as a drug rather than a biologic, FDA repeated that ADT meets the definition of a biological product and reaffirmed its intent to review and approve such products through the BLA process.⁴² On March 11, 2026, FDA issued a further notice to industry reiterating its risk-based enforcement approach and announcing that it plans to issue draft guidance before August 2026, describing both its compliance priorities and conditions of

³⁴ 2022 Pharmacist Letter.

³⁵ 2022 Pharmacist Letter.

³⁶ August 2025 Notice to Industry at 1.

³⁷ August 2025 Notice to Industry at 5.

³⁸ August 2025 Notice to Industry at 2-3.

³⁹ August 2025 Notice to Industry at 3.

⁴⁰ August 2025 Notice to Industry at 4-5.

⁴¹ Letter from FDA to Neal Parker & Raymond C. Votzmeyer, AbbVie Inc., Dkt. No. FDA-2024-P-1715, at 3 (Aug. 6, 2025) (hereinafter “*AbbVie Petition Response*”).

⁴² Letter from Martin A. Makary, Comm’r of FDA, to Hon. Diana Harshbarger 1 (Feb. 2, 2026) (hereinafter “*Harshbarger Response*”).

continued enforcement discretion for marketed unapproved ADT products, as well as draft guidance on the development of ADT products to support marketing applications.⁴³

Notably, in all of these public statements, FDA’s rationale rests entirely on the fact that the thyroglobulin is a “protein” component of ADT or that it is the “necessary” activity-contributing component of an “analogous” product.⁴⁴ At no point has FDA articulated why it believes that the thyroglobulin is an API. As set forth in the argument that follows, that rationale is in tension with FDA’s own interpretation of this term in guidance and in litigation, and with the undisputed physiology of the product, under which thyroglobulin functions only as a carrier that is enzymatically degraded before absorption while the small-molecule hormones T3 and T4 serve as the only APIs in this medication.

The practical consequence of FDA’s classification is significant: because biological products subject to licensure under the PHS Act are not eligible for the compounding exemptions of the FD&C Act, FDA’s position would render ADT products ineligible for compounding and, absent an approved BLA, subject to enforcement action. This interpretation has shut off supplies of ADT products to the millions of patients that rely on it, including those suffering from Hashimoto’s disease, or have had their thyroid removed or irradiated, many of whom only respond to ADT therapy after synthetic therapies have failed them.

III. Argument.

a. ADT’s Protein Component Is Not an Active Pharmaceutical Ingredient.

The scientific evidence demonstrates that FDA’s classification of ADT as a biological product cannot withstand scrutiny under the statutory definition, controlling case law, and FDA’s own guidance. FDA interprets products containing proteins or “analogous” proteins to be biological products only if the component is an API. As discussed below, evidence demonstrates that the protein component of ADT is not an API. Instead, the active ingredients in ADT are the T3 and T4 small molecules that do not meet the definition of a protein and are appropriately regulated as drugs. The protein component of ADT, the thyroglobulin, merely acts as a carrier of the active ingredients (T3 and T4) and does not furnish any pharmacological activity. Indeed, FDA regulates products with similar proteinaceous or animal-derived components as drug products. Accordingly, classifying ADT as a biologic is contrary to the law and FDA’s own practices. ADT must therefore be classified, and regulated, as a drug.

i. Legal Standard.

1. FDA’s Statutes, Regulations, and Guidance Make Clear That the Protein Component Must Be the API to Meet the Definition of Biological Product.

The statute defines “biological product” as a “virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product

⁴³ Letter from FDA to Mfrs., Imps. & Distribs. of Animal-Derived Thyroid (ADT) Prods. (Mar. 11, 2026) (hereinafter “March 2026 Notice to Industry”).

⁴⁴ August 2025 Notice to Industry.

... applicable to the prevention, treatment, or cure of a disease or condition of human beings.”⁴⁵

The qualifying phrase “applicable to the prevention, treatment, or cure of a disease” modifies each enumerated category, including “protein” and “analogous product.” The protein or protein analogous component itself must therefore be the component that treats the disease.

To account for this statutory limitation, as discussed in Part B.II.b above, FDA’s Deemed QA Guidance clarified that if a product contains a protein that functions only as an inactive ingredient, then the protein is not cause to regulate the product as a biologic. Specifically, the guidance states that “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.’”⁴⁶

FDA’s regulation defines “inactive ingredients” as “any component other than an active ingredient.”⁴⁷ The same regulation defines “active ingredient” as any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease.”⁴⁸ Thus, as FDA recognizes in the Deemed QA Guidance, for a drug with proteins to be regulated as a biologic the protein must furnish pharmacological activity.⁴⁹ FDA also has applied this principle in practice: for example, in albumin-bound paclitaxel, paclitaxel is the active ingredient and human albumin—a large plasma protein—is considered an inactive ingredient, and therefore FDA classifies the product as a drug.⁵⁰

2. Finished Dosage Form Is Not Relevant when Determining the Pharmacologically Active Component.

The API of a product is determined by how the product furthers the therapeutic purpose and is not determined by how the product is composed in its finished dosage form.⁵¹ In *Ipsen Biopharmaceuticals Inc. v. Becerra*, Ipsen, the sponsor of the product Somatuline Depot, argued that the product’s API was a protein and therefore FDA should classify the product as a biologic. While both the manufacturer and FDA agreed that the proper question is whether a protein was the API, they disagreed as to when the determination should be made.⁵² Ipsen argued that the determination should be made when the product was in its finished dosage form. Somatuline Depot’s API is lanreotide acetate, which is a molecule containing eight amino acids (referred to as an octapeptide).⁵³ In finished dosage form, the octapeptide is linked together to form nanotubes to allow for extended release of the lanreotide acetate octapeptides.⁵⁴ The nanotubes’ total amino acids far exceeds the forty amino acids needed to meet the definition of “protein.”

⁴⁵ 42 U.S.C. § 262(i)(1) (emphasis added).

⁴⁶ Deemed QA Guidance at 5 (emphasis added).

⁴⁷ 21 C.F.R. § 314.3(b).

⁴⁸ *Id.*

⁴⁹ *Ipsen Biopharmaceuticals v. Becerra*, 108 F.4th 836, 841 (D.C. Cir. 2024); see also *Ipsen Biopharmaceuticals Inc. v. Becerra*, 678 F.Supp.3d 20 (D.D.C. 2023).

⁵⁰ See, e.g., FDA, Labeling, Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound), NDA No. 216338 (2023), https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216338s000lbl.pdf.

⁵¹ *Ipsen*, 678 F. Supp. 3d at 37–38, *aff’d*, 108 F.4th 836 (D.C. Cir. 2024).

⁵² *Ipsen*, 108 F.4th at 841.

⁵³ *Ipsen*, 678 F.Supp.3d at 36.

⁵⁴ *Ipsen*, 678 F.Supp.3d at 27.

However, to FDA, the finished dosage form was irrelevant. Rather, the relevant inquiry was how the lanreotide acetate behaved to effectuate the therapeutic purpose.⁵⁵ For Somatuline Depot, once the therapy is administered, the lanreotide acetate octapeptides individually separated from the nanotube to bind to somatostatin receptors to exercise the drug's functions. Because the octapeptides contain less than forty amino acids when they bind to receptors, they did not meet the definition of a protein. In contrast, the nanotubes acted to control the release rate of the octapeptides, which FDA recognized as “‘alter[ing] the pharmacokinetics’ – movement of the drug, including distribution and absorption – ‘but does not change the active ingredient that is intended to furnish pharmacological activity.’”⁵⁶ Thus, according to FDA, the important inquiry is not the form in which the product is administered, ***including design features to affect dosing***, rather, the inquiry is what is the specific component of the product that “confers the pharmacological activity” upon administration of the therapy.⁵⁷

The D.C. District Court agreed that, based on the language in the definition of “biological product” that the protein must be “applicable to the prevention, treatment, or cure of a disease,” FDA was correct to examine what specific molecule furnished the therapeutic purpose, notwithstanding the form upon which it was initially administered.⁵⁸ The D.C. Circuit affirmed, confirming that FDA must focus on a product’s active ingredient, rather than its finished dosage form, when determining whether the product falls within the statutory “protein” category.

Taken together, the statute, the rulemaking, FDA’s guidance, and the *Ipsen* precedent support an analytical focus on the active ingredient and the component or components that actually furnish pharmacological activity, rather than on the finished dosage form or structural complexity. *Ipsen* further supports the narrower proposition that ***a structural or formulation feature affecting drug release is not the active ingredient*** when it has not been shown to confer pharmacological activity. As discussed below, ADT’s APIs are the T3 and T4 molecules, whereas the thyroglobulin does not confer any pharmaceutical therapeutic purpose, rather it serves as a carrier protein. Therefore, the product should be classified as a drug.

3. Products Analogous to Proteins Must Meet the API Standard.

The PHS Act’s definition of “biological products” also includes products that are “analogous” to proteins and the other enumerated categories of products. FDA has declined to define “analogous” protein product. In its final rule issuing the definition of a protein, FDA merely stated it is not a product that is “specifically excluded from this final rule.”⁵⁹ In litigation, FDA has stated that a product is analogous to a protein when it shares a “critical characteristic” such as the size of the amino acid polymer and specific defined sequence.⁶⁰ An example FDA provided is “naturally derived mixtures that include one or more identified biological product component(s) (e.g., protein), as well as one or more non-biological product component(s) (e.g., lipids) that can contribute to the product’s activity.”⁶¹ In other non-binding communications, it has stated that ADT is analogous to a protein product because the thyroglobulin is a “biological component” that

⁵⁵ *Id.* at 38.

⁵⁶ *Id.* at 39.

⁵⁷ *Id.* at 36.

⁵⁸ *Id.* at 37.

⁵⁹ 85 Fed. Reg. at 10061.

⁶⁰ *Ipsen*, 108 F.4th at 839, 844.

⁶¹ *Id.* at 844.

is “necessary for the activity of the product and contributes to achieving the intended therapeutic effect.”⁶²

At bottom, however, remains the PHS Act’s definitional provision that requires the “analogous” protein to be “applicable to the prevention, treatment, or cure of a disease.”⁶³ The reasoning of *Ipsen* thus still holds true that for a product to be “analogous” to a protein product, the analogous feature must be an API regardless of the finished dosage form.⁶⁴

ii. *The T3 and T4 Molecules, Not the Protein, are the Active Pharmaceutical Ingredients of ADT, and Therefore ADT Is a Drug.*

The scientific record establishes that the protein component of ADT (thyroglobulin) is a carrier for the drug components (T3 and T4), which functions by delivering the drugs to the body and controlling the release. Importantly, thyroglobulin has no independent receptor-mediated pharmacological activity and thus there is no identified pathway in which the thyroglobulin could further the therapeutic purpose. Understanding the distinction between carrier and API requires examining thyroglobulin’s molecular structure, its role in thyroid hormonogenesis, the mechanism by which it releases thyroid hormones during digestion, and the pharmacological activity of the released hormones.

The published scientific literature characterizes thyroglobulin as a carrier for thyroid hormones, while identifying T3 and T4 as the molecules responsible for the downstream thyroid-hormone effects.⁶⁵ Thyroglobulin specifically serves as the macromolecular carrier on which thyroid hormones are synthesized and stored.⁶⁶ Select tyrosine residues within the thyroglobulin polypeptide chain undergo iodination by thyroid peroxidase in the presence of hydrogen peroxide to form moniodotyrosine (MIT) and diiodotyrosine (DIT).⁶⁷ Coupling of two DIT residues yields thyroxine (T4), while coupling of one MIT and one DIT yields triiodothyronine (T3).⁶⁸ These iodinated residues remain covalently incorporated within the thyroglobulin polypeptide until released by proteolysis.⁶⁹ Thyroglobulin thus functions as a biosynthetic precursor and intracellular storage reservoir for thyroid hormones.⁷⁰

The fate of thyroglobulin after oral administration further confirms its carrier roles, as opposed to serving any therapeutic purpose. Following oral administration, the thyroglobulin component of ADT, a large protein containing covalently incorporated iodothyronine residues, is

⁶² 2025 Letter to Industry at 3; *see also* Warning Letter to Acella Pharmaceuticals, LLC, CMS No. 604438 (Aug. 14, 2020); *see also* Warning Letter to RLC Labs, CMS No. 607596 (Oct. 9, 2020) (same).

⁶³ PHS Act § 351(i)(1).

⁶⁴ *See supra* Part B.III.a.ii.

⁶⁵ *See* Bruno Di Jeso & Peter Arvan, *Thyroglobulin From Molecular and Cellular Biology to Clinical Endocrinology*, 37 *Endocr. Rev.* 2 (2016); Francesca Coscia et al., *The Structure of Human Thyroglobulin*, 578 *Nature* 627 (2020); Bassett et al. at 1-3.

⁶⁶ Cintia E. Citterio et al., *The Role of Thyroglobulin in Thyroid Hormonogenesis*, 15 *Nat. Rev. Endocrinol.* 323, 323-24 (2019).

⁶⁷ *Id.* at 324.

⁶⁸ *Id.* at 323.

⁶⁹ *Id.* at 324.

⁷⁰ *Id.* at 323-24.

subjected to gastrointestinal proteolysis.⁷¹ This process releases the protein-bound iodothyronines, including T3 and T4.⁷² The resulting hormones, together with T3 and T4 already present in free form, become bioavailable after oral administration.⁷³ Following release of the hormones, hydrolysis breaks the thyroglobulin into oligopeptides and amino acids, which are further broken down in the body.⁷⁴ Although limited absorption of larger intact proteins cannot be excluded, there is no identified independent catalytic or receptor-mediated therapeutic activity for thyroglobulin.⁷⁵ Rather the evidence demonstrates that it remains a storage protein for T3 and T4, whereas T3 is the primary endogenous ligand that mediates thyroid hormone receptor activation.⁷⁶ The 2025 Letter to Industry appears to acknowledge this process, where it states that following oral administration, “proteolytic enzymes of the gastrointestinal tract release iodothyronines and iodotyrosines (including T3 and T4) from the thyroglobulin.”⁷⁷ Importantly, the 2025 Letter to Industry identifies no therapeutic activity that is attributed to the thyroglobulin.

In contrast to thyroglobulin, bioavailable T3 and T4, whether released from thyroglobulin or already present in free form, are the pharmacologically active moieties responsible for the therapeutic effect of ADT.⁷⁸ In their free form, T3 and T4 contain no peptide bonds and are not amino acid polymers.⁷⁹ Rather, they are iodinated diphenyl ether derivatives.⁸⁰ They therefore do not, and cannot, satisfy FDA’s regulatory definition of a “protein.” T3 and T4 are the same thyroid hormone molecules that provide the pharmacological activity of the synthetic levothyroxine (“LT4”) and liothyronine (“LT3”) that FDA regulates as drugs. Indeed, FDA has approved multiple NDAs for synthetic LT3 and LT4 products,⁸¹ confirming that T3 and T4 are drug substances, not biological products. FDA has never suggested that these molecules are proteins or analogous to proteins, consistent with treating these hormones as small-molecule drug substances rather than proteins.

The pharmacological mechanism through which T3 and T4 treat hypothyroidism is well established. T3 and T4 released during digestion, together with hormones already present in free form, are absorbed through the intestinal epithelium into the portal circulation.⁸² T4 serves

⁷¹ Hugh James Freeman, *Clinical Relevance of Intestinal Peptide Uptake*, 6 World J. Gastrointest. Pharmacol. & Ther. 22, 23 (2015) (“Protein digestion and absorption in humans depends on initial enzymatic hydrolysis in the stomach and proximal small intestine. The hydrolytic products include oligopeptides and amino acids that ultimately undergo small intestinal uptake into the portal vein.”).

⁷² LeBoff MS et al., *Bioavailability of thyroid hormones from oral replacement preparations*, Metabolism 31(9): 900-905 (1982).

⁷³ *Id.*

⁷⁴ Freeman, *supra* note 71, at 23; Warren M. Miner-Williams, Bruce R. Stevens & Paul J. Moughan, *Are Intact Peptides Absorbed from the Healthy Gut in the Adult Human?*, 27 Nutrition Res. Revs. 308, 308, 311 (2014).

⁷⁵ Citterio et al., *supra* note 66, at 323-24; Gregory A. Brent, *Mechanisms of Thyroid Hormone Action*, 122 J. Clin. Investigation 3035, 3035-36 (2012); Amy Schroeder et al., *The Ability of Thyroid Hormone Receptors to Sense T4 as an Agonist Depends on Receptor Isoform and on Cellular Cofactors*, 28 Molecular Endocrinology 745, 745-46 (2014).

⁷⁶ *Id.*

⁷⁷ 2025 Letter to Industry at 3 (citing LeBoff, *supra* note 72).

⁷⁸ Mahmoud Nassar et al., *Evaluating the Effectiveness of Combined T4 and T3 Therapy or Desiccated Thyroid Versus T4 Monotherapy in Hypothyroidism: A Systematic Review and Meta-Analysis*, 24 BMC Endocr. Disorders 90, at 2, 10 (2024).

⁷⁹ Mary B. Dratman & Joseph V. Martin, *The Many Faces of Thyroxine*, 7 AIMS Neuroscience 17, 27 (2020).

⁸⁰ *Id.* at 17.

⁸¹ FDA Actions; 2022 Pharmacist Letter at 2.

⁸² Josef Kohrle, *The Colorful Diversity of Thyroid Hormone Metabolites*, 8 Eur. Thyroid J. 115, 124 (2019).

predominantly as a circulating prohormone that is converted to T3 by type 1 and type 2 iodothyronine deiodinases (D1 and D2). T3 has substantially higher affinity for thyroid hormone receptors and is the principal receptor-active thyroid hormone.⁸³ It enters target cells, binds to nuclear thyroid hormone receptors, and modulates the transcription of genes governing basal metabolic rate, thermogenesis, cardiac output,⁸⁴ lipid metabolism, bone turnover, and neurocognitive function.⁸⁵

No comparable downstream role has been established for intact thyroglobulin after oral ADT administration.⁸⁶ This reality is exemplified by the fact that the therapeutic endpoints monitored in patients receiving ADT do not measure an independent pharmacological effect of thyroglobulin, rather they measure serum thyrotropin, free T3, and free T4 concentrations, circulating thyroid hormone concentrations and pituitary feedback.⁸⁷

Regulatory, pharmacopeial, labeling, and clinical standards support the conclusion that ADT dosing and clinical monitoring are based on T3 and T4 content and effects rather than measured thyroglobulin content. Since 1985, the USP standard has been keyed to thyroid hormone content rather than iodine content, making T3 and T4 content the compendial measure of product potency. Marketed ADT products such as Armour Thyroid and NP Thyroid are labeled by the mass of thyroid in grains or milligrams and specify the corresponding T3 and T4 content in micrograms; they are not labeled by thyroglobulin quantity. Clinical dosing and monitoring use labeled product strength and serum TSH, free T4, and free T3 rather than measured thyroglobulin content. Indeed, in a citizen petition submitted by the manufacturer of Amour Thyroid, the manufacturer explained that the thyroglobulin in their product is hydrolyzed in the body to yield T4 and T3, and states that those hormones provide the therapeutic effect.⁸⁸

Applying the regulatory framework to the available scientific evidence, the relevant scientific question is whether intact thyroglobulin furnishes an independent pharmacological activity, rather than whether it is simply present in the product or participates upstream in hormone storage and release.⁸⁹ As demonstrated above, the molecules that mediate the established pharmacological effects of ADT are bioavailable T3 and T4, which are small-molecule hormones that bind thyroid hormone receptors and mediate the thyroid hormone replacement effect. There is no evidence that Thyroglobulin furnishes an independent receptor-mediated pharmacological effect; instead, the evidence demonstrates that it serves as a carrier and storage protein from which iodothyronines are released during digestion.

Therefore, the controlling precedent in *Ipsen* is on all fours. FDA's explanations for why ADT is a biologic rest entirely on the fact that the product contains a protein that exceeds the forty amino acid requirement in the definition of protein. But FDA makes the same mistake that Ipsen made when arguing that Somatuline Depot was a biological product. Both analyses rest on the

⁸³ Citterio et al., *supra* note 66, at 323, 326.

⁸⁴ *Id.* at 323.

⁸⁵ Angela D. Mazza, *Personalized Approaches to Hypothyroidism: The Role of Triiodothyronine (T3) in Thyroid Hormone Replacement*, 17 *Cureus* e90685, at 2, 5 (2025).

⁸⁶ Citterio et al., *supra* note 66, at 324, 327; Bassett et al., *supra* note 65, at 1-3.

⁸⁷ Nassar et al., *supra* note 78, at 3-5, tbl.1, tbl.2.

⁸⁸ Heald et al., *supra* note 6, at 2; USP Monographs, *Thyroid Tablets*, *supra* note 9; Citizen Petition from AbbVie Inc., Docket No. FDA-2024-P-1715 (Apr. 2024), <https://www.regulations.gov/document/FDA-2024-P-1715-0001>.

⁸⁹ 21 C.F.R. § 314.3(b).

finished dosage form of the product rather than on how the product confers the pharmacological activity upon administration of the therapy. FDA has identified no pharmacological activity attributable to the thyroglobulin in any of the various notices describing its position (because there is none). Much like Somatuline Depot, the protein element of ADT acts to control the release rate of the T3 and T4, which may “alter the pharmacokinetics . . . but does not change the active ingredient that is intended to furnish pharmacological activity.”⁹⁰ FDA cannot have it both ways. Short of providing sound evidence that adequately trumps the evidence described above that thyroglobulin does not confer pharmacological activity, FDA must classify ADT as a drug.

iii. *ADT Is Not “Analogous” to a Protein and Therefore Is Not a Biological Product under the PHS Act.*

FDA’s alternative theory that ADT is “analogous” to a protein is equally flawed. FDA contends that ADT is “analogous” to a protein because thyroglobulin is “necessary for the activity of the product and contributes to achieving the intended therapeutic effect.”⁹¹ This argument fails for several reasons.

FDA’s alternative theory cannot rest on the mere presence of substances that are analogous to a protein in the finished dosage form. As discussed in Part B.III.a.i.3, to satisfy the definition of biological product, the protein analogous feature must be an API.⁹² The only “analogous” feature that FDA has identified in its various notices is the thyroglobulin.⁹³ As discussed in Part B.III, the thyroglobulin portion of ADT provides no pharmacological activity, and therefore ADT cannot be considered analogous to a protein such that it would cause it to meet the definition of a biological product.

Additionally, to the extent FDA considers other portions of the ADT to be “analogous” to a protein, as recognized by the D.C. Circuit, a product “analogous” to a protein must share the “critical characteristics” of proteins.⁹⁴ The APIs, T3 and T4, are iodinated diphenyl ether derivatives with molecular weights below 800 daltons and share none of the defining characteristics of proteins.

Finally, FDA’s argument is illogical. The thyroglobulin portion of ADT is a protein,⁹⁵ as it meets the amino acid size threshold in the definition of a protein in FDA’s regulation.⁹⁶ The same component cannot also be “analogous” to a protein because it *is* a protein. Analogous means having “similar function but different structure and origin.”⁹⁷ Here, there are no substances that have similar function to a protein but different structure or origin. Rather, the only component that has a protein function is the protein thyroglobulin, which is an inactive ingredient in the ADT.

⁹⁰ *Ipsen*, 678 F. Supp. 3d at 36.

⁹¹ August 2025 Notice to Industry at 3.

⁹² See *supra* Part B.III.a.iii.

⁹³ See 2025 Letter to Industry at 3.

⁹⁴ *Ipsen*, 678 F. Supp. 3d at 41; *Ipsen*, 108 F.4th at 840.

⁹⁵ But it is “not considered to be a ‘protein’ for purposes of the statutory definition of ‘biological product.’” Deemed QA Guidance at 5.

⁹⁶ 21 C.F.R. § 600.3(h)(6).

⁹⁷ See Merriam Webster, <https://www.merriam-webster.com/dictionary/analogous#medicalDictionary>.

Accordingly, FDA cannot rely on the “analogous product” clause to force ADT into the PHS Act’s jurisdiction.

iv. *FDA’s Treatment of Comparable Products Supports Regulating ADT as a Drug.*

FDA’s treatment of other products containing proteinaceous or animal-derived components supports regulating ADT as a drug. Across these products, FDA has focused on the identity and pharmacological function of the active ingredient rather than treating animal origin, molecular complexity, or the presence of a protein as determinative. For example:

- **Somatuline Depot:** As discussed in Part B.III.a.i.3, FDA regulates Somatuline Depot under an NDA. Its active ingredient, lanreotide acetate, is an eight-amino-acid peptide that self-assembles into nanotube structures in the finished dosage form to provide extended release. These nanotube structures far exceed the required amino acid count to meet FDA’s definition of a protein. FDA nevertheless determined, and the D.C. Circuit upheld, that the relevant active ingredient is the individual lanreotide acetate molecule that furnishes the pharmacological activity, rather than the larger self-assembled nanotube structure. Somatuline Depot therefore supports focusing on the component that furnishes pharmacological activity rather than on the size or structural complexity of the finished dosage form.
- **Paclitaxel protein-bound particles for injectable suspension (albumin-bound):** FDA regulates this product under an NDA, identifying paclitaxel as the active ingredient and human albumin, a large plasma protein, as an inactive ingredient. The product demonstrates that a large protein may be integral to a formulation without becoming the active ingredient or requiring regulation of the product as a biologic.⁹⁸
- **DefenCath:** FDA approved DefenCath under an NDA with taurolidine and heparin sodium as active ingredients. FDA-approved labeling describes heparin as a heterogeneous group of straight-chain anionic mucopolysaccharides, called glycosaminoglycans, derived from porcine intestinal mucosa. DefenCath therefore demonstrates that an animal-derived, structurally complex polymer may be regulated under the drug framework.⁹⁹
- **Conjugated Estrogens:** Similarly, FDA regulates conjugated estrogens (e.g., Premarin), a naturally derived hormone mixture purified from pregnant mares’ urine, under the drug framework.¹⁰⁰ The product demonstrates that a naturally derived, heterogeneous mixture of small-molecule hormones remains subject to the drug framework. This example is relevant to the product’s animal origin and mixture complexity.

Taken together, these products support focusing on the components that furnish pharmacological activity, not merely the presence of a protein, animal origin, or molecular complexity. Somatuline Depot and albumin-bound paclitaxel confirm that FDA may distinguish a protein formulation component from the drug active ingredient. DefenCath and conjugated

⁹⁸ FDA, Labeling, Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound), NDA No. 216338 (2023), https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216338s000lbl.pdf.

⁹⁹ FDA, Labeling DefenCath (Taurolidine and Heparin) Catheter Lock Solution, NDA No. 214520 (2023), https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/214520s003lbl.pdf.

¹⁰⁰ FDA, Product-Specific Guidance for Conjugated Estrogens (Naturally Sourced); see FDA, Labeling, Premarin (conjugated estrogens tablets, USP), https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/004782s142lbl.pdf.

estrogens further confirm that complex and naturally derived products remain subject to the drug framework when their pharmacologically active components are not proteins. In ADT, bioavailable T3 and T4 furnish the established receptor-mediated effects, while no independent catalytic or receptor-mediated therapeutic activity has been established for intact thyroglobulin. These comparators therefore support regulating ADT as a drug.

b. FDA’s Classification Violates the Administrative Procedure Act.

Beyond the substantive classification errors described above, FDA’s decision is independently defective under the Administrative Procedure Act (“APA”).¹⁰¹ FDA’s decision to utilize the incorrect standard when assessing whether to regulate ADT under the PHS Act meant that it relied on factors Congress did not intend for FDA to consider. FDA also ignored its own guidance without providing a rational justification. Moreover, FDA did not consider important factors such as reliance interests of patients, physicians and other health care providers, and pharmacies that reasonably relied on FDA’s Deemed QA Guidance indicating that FDA would regulate ADT as a drug and therefore ADT would remain available for compounding. Finally, FDA’s determination was a legislative rule requiring notice-and-comment rulemaking pursuant to section 505(b) of the APA. FDA’s actions therefore are not legally supportable and any planned enforcement must be stayed until these defects are cured.

i. FDA’s Determination That ADT Is a Biologic Is Arbitrary and Capricious Because It Is Inconsistent with the Statute and FDA’s Own Guidance, and Failed to Consider Important Factors Impacting Patients and Providers.

An agency rule is arbitrary and capricious if the agency “failed to consider an important aspect of the problem,” “relied on factors which Congress has not intended it to consider,” produced a decision that is “unreasoned,” or “is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.”¹⁰² The requirement of a reasoned decision also means the agency cannot contradict its prior rules or existing policy sub silentio and, importantly, that it must meaningfully consider any reliance interests that may be at stake if it consciously decides to change its position.¹⁰³

FDA’s decision failed to consider factors that Congress intended it to consider by misinterpreting the statutory definition. By classifying ADT as a biologic based upon its finished dosage form, instead of the API, FDA ignored the statutory requirement that the protein or analogous product must be “applicable to the prevention, treatment, or cure of a disease or condition of human beings.”¹⁰⁴ As discussed in Part B.III.a.i., this language required FDA to

¹⁰¹ 5 U.S.C. §§ 551-559, 701-706.

¹⁰² *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983); *U.S. Sugar Corp. v. Env’t Protection Agency*, 830 F.3d 579, 606 (D.C. Cir. 2016).

¹⁰³ *See FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) (citing *Smiley v. Citibank (South Dakota), N.A.*, 517 U.S. 735, 742 (1996)); *see also Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016) (“Agencies are free to change their existing policies as long as they provide a reasoned explanation for the change. . . . In explaining its changed position, an agency must also be cognizant that longstanding policies may have engendered serious reliance interests that must be taken into account.”) (citation modified).

¹⁰⁴ PHS Act § 351(i)(a).

classify products based upon their API, rather than their finished dosage form.¹⁰⁵ By misapplying the statute, FDA failed to consider the key question that Congress intended, which caused the decision to be arbitrary and capricious.¹⁰⁶

FDA’s classification decision also ignored its own policy outlined in the Deemed QA Guidance that proteins must be the API to cause a product to be classified as a biologic. At no point in the various notices and letters has FDA explained why it believes that the thyroglobulin is the API. By ignoring its own guidance, FDA fails to provide reasoned decision making or justify why it is departing from its policy—the epitome of arbitrary decision making.¹⁰⁷

Moreover, even if FDA was of the position that the thyroglobulin was an API, FDA never attempted to justify this position. In all of the various notices FDA has provided, the Agency only addresses whether thyroglobulin is a protein or analogous to a protein. It never addresses whether the protein plays any role outside of pharmacokinetics. The APA requires reasoned decision making, and the complete lack of an explanation provides no basis upon which to conclude that the Agency’s determination was reasonable.¹⁰⁸

FDA’s decision is also inconsistent with FDA’s practices of regulating like-products as drugs. As discussed in Part B.III.a.i.3, FDA has treated Somatuline Depot, albumin-bound paclitaxel, conjugated estrogens, and DefenCath—all of which contain proteinaceous, animal-derived, or naturally derived components—as drugs. Yet FDA classifies ADT as a biologic without articulating a principled basis for the disparate treatment. An agency that treats like cases differently must provide a reasoned explanation; failure to do so renders the action arbitrary.¹⁰⁹

Finally, when an agency changes course, it must “be cognizant that longstanding policies may have engendered serious reliance interests that must be taken into account.”¹¹⁰ Here, the reliance interests are substantial: approximately 1.5 million patients currently use ADT, and prescribers, pharmacists, and compounders have relied on its availability under the drug framework for over a century.

For patients, ADT is a lifetime medication; it is not a “band-aid” product that improves a patient’s condition until such a point that the patient can ease off. Rather, patients will perpetually require this medication in order for their thyroids to function at optimal levels. Dr. Sarah Zielsdorf,

¹⁰⁵ See *supra* Part B.III; *Ipsen*, 108 F.4th at 841.

¹⁰⁶ See *Genus Med. Techs., LLC v. FDA*, 427 F. Supp. 3d 74, 87 (D.D.C. 2019), *aff’d*, 994 F.3d 631 (D.C. Cir. 2021) (holding that FDA’s decision was arbitrary where it chose to regulate contrast agent as a drug instead of a device because it violates the statutory definitions).

¹⁰⁷ See *FDA v. Wages and White Lion Invests., L.L.C.*, 604 U.S. 542, 568 (2025) (“Agencies are free to change their existing policies as long as they provide a reasoned explanation for the change, display awareness that they are changing position, and consider serious reliance interests.”) (citation modified).

¹⁰⁸ See *State Farm*, 463 U.S. at 43 (“the agency must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made”) (quotation marks omitted).

¹⁰⁹ See *Burlington N. & Santa Fe Ry. Co. v. Surface Transp. Bd.*, 403 F.3d 771, 776–77 (D.C. Cir. 2005) (citations and quotation marks omitted); see *Prairie Band Potawatomi Nation v. Yellen*, 63 F.4th 42, 47 (D.C. Cir. 2023) (finding that Agency’s decision was arbitrary and capricious because it treated similar cases differently without providing a legitimate reason for doing so).

¹¹⁰ *Dep’t of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1913 (2020) (quoting *Encino Motorcars*, 579 U.S. at 222).

a board-certified internal medicine physician and Institute for Functional Medicine Certified Practitioner (FMCP-M), explained that she:

fear[s] for the lives of some of [her] patients if they cannot get access to ADT. Some of [her] patients may be forced back onto therapies they cannot tolerate or cannot use effectively. For others with severe hypothyroid symptoms that need ADT to maintain daily basic functioning, loss of access will not be a mere inconvenience; ***it will be a profound medical crisis.***¹¹¹

Dr. Brittany Bohinc Henderson, MD, ECNU, who has dedicated her career to advancing the diagnosis and treatment of thyroid disease, has also relied on the availability of ADT so that she can prescribe compounded versions of the medication that fit the individual needs of her patients. To her, “uninterrupted access to compounded ADT is critical. Compounded ADT allows [her] to prescribe slight variations in LT3 and LT4 that create meaningful differences for [her] patients.”¹¹²

Compounding pharmacies have also relied on the availability of ADT so that they can fill the many prescriptions issued by providers like Dr. Henderson and Dr. Zielsdorf. These pharmacies traditionally have filled hundreds of compounded ADT prescriptions for patients each year.¹¹³ FDA’s classification—which forecloses compounding under section 503A—directly disrupts those interests without acknowledgment.

When FDA acknowledged in the Deemed QA Guidance that the protein elements of product must be the API for it to be regulated as a biological product, it implicitly acknowledged that ADT would continue to be regulated as a drug. FDA violated the APA by reversing course without acknowledging and responding to the interests of those who relied on the continued availability of these products under the drug pathway. These interests demanded consideration, and the failure to do so resulted in an arbitrary decision.

ii. The Classification Required Notice-and-Comment Rulemaking.

FDA’s classification is also procedurally invalid. FDA’s determination that ADT products are biological products constitutes a legislative rule that was required to undergo notice-and-comment rulemaking under 5 U.S.C. § 553. Although section 553(b)(A) exempts “interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice” from notice-and-comment requirements, FDA’s classification does not fall within any of these exemptions. The classification imposes new, binding legal obligations on regulated parties: it requires manufacturers to obtain BLA approval under section 351 of the PHS Act, and it forecloses compounding under FD&C Act sections 503A and 503B, eliminating a legal pathway on which pharmacies, prescribers, and patients have relied for decades. A rule that changes the legal obligations of regulated parties, restricts the availability of an established drug product, and alters the conditions under which that product may be manufactured or dispensed is substantive in nature, not merely interpretive.¹¹⁴ An interpretive rule merely “advises the public of the agency’s

¹¹¹ Sarah J. Zielsdorf, MD, MS, Statement of Support, p. 2 (hereinafter “Zielsdorf Statement”) (emphasis added).

¹¹² Henderson Statement, at p. 2.

¹¹³ See, e.g., Ipsen Statement at p. 2.

¹¹⁴ See *City of Billings v. Transportation Sec. Admin.*, 153 F.4th 46, 52 (D.C. Cir. 2025); *N.H. Hosp. Ass’n v. Azar*, 887 F.3d 62, 74 (1st Cir. 2018).

construction of the statutes and rules which it administers” without creating new rights or obligations.¹¹⁵

By contrast, the August 2025 Notice creates new obligations (BLA requirement), extinguishes existing rights (compounding eligibility), and prescribes enforcement consequences. It is therefore a legislative rule, and FDA’s failure to provide notice and an opportunity for public comment before issuing it renders the classification procedurally invalid under the APA.¹¹⁶ The absence of any notice-and-comment process is particularly significant here because the classification implicates the health and welfare of approximately 1.5 million patients and raises complex scientific questions that would have benefited from public input by affected stakeholders, including physicians, pharmacists, compounders, patient advocacy organizations, and scientific experts.

c. Patient Access to Life-Altering Medications Must Be Protected.

“The first dose of ADT felt like going from a world in black and white to a world of color.”¹¹⁷

This is the kind of life-altering impact ADT has had on the lives of countless patients across the United States. FDA’s classification of ADT as a biological product threatens to cause significant harm to the many patients that have relied on this vital medication for years. It is therefore in the best interest of the public that FDA ensure the availability of ADT by revoking its classification of ADT as a biological product and regulate ADT as a drug.

As discussed in Part B.II., hypothyroidism is associated with a wide range of symptoms that can profoundly affect nearly every aspect of daily life. Common manifestations include persistent fatigue and energy depletion, cold intolerance, unexplained weight gain, hair loss, dry skin, brittle nails, gastrointestinal dysfunction, cardiovascular complications, musculoskeletal pain, joint inflammation and myxedema, fibromyalgia and reproductive harm, not to mention the cognitive symptoms such as intense brain fog, depression, and anxiety. When thyroid function is poorly managed through suboptimal treatment, patients often continue to suffer diminished quality of life, feeling unheard by medical professionals and inadequately treated. Poorly controlled hypothyroidism can also serve as a gateway to additional autoimmune conditions, including celiac disease, rheumatoid arthritis, and Type 1 Diabetes, compounding the already heavy burden on patients’ physical and emotional health. Ultimately, effective thyroid management requires attentive, patient-centered care that prioritizes symptom resolution and overall well-being, and this care can only be offered when providers have access to all viable treatment options. This must include ADT.

i. Physicians That Specialize in Hypothyroidism Rely on Compounded ADT Products.

In support of this petition, two prominent physicians known for their practice of treating patients with thyroid conditions provided statements explaining the critically important nature of

¹¹⁵ *City of Billings*, 153 F.4th at 52 (quoting *Shalala v. Guernsey Mem’l Hosp.*, 514 U.S. 87, 99 (1995)).

¹¹⁶ See *N.H. Hosp. Ass’n*, 887 F.3d at 70-74; *Am. Acad. of Pediatrics v. Food & Drug Admin.*, 379 F. Supp. 3d 461, 497 (D. Md. 2019) (FDA’s enforcement discretion guidance was a legislative rule requiring notice and comment rulemaking).

¹¹⁷ Zielsdorf Statement, at p. 1.

ADT.¹¹⁸ One, Dr. Brittany Bohinc Henderson, MD, ECNU, has dedicated her career to advancing the diagnosis and treatment of thyroid disease.¹¹⁹ She developed an interest in ADT when she realized that the FDA-approved thyroid medications (i.e., Synthroid, Tirosint, Levoxyl, and Unithroid, all of which contain Levothyroxine as the only active ingredient) were insufficient to fully control thyroid disease in many of her patients. And although many of these patients could tolerate the manufactured ADT products (e.g., NP Thyroid and Armour Thyroid), some could not tolerate the fillers or the pharmacodynamics of an instant release, manufactured product, and they required a compounded ADT formulation that is slower release. The ability to have various medication formulations available is essential to quality of life and resolution of thyroid symptoms in this patient population. When dosed appropriately, ADT products can mimic normal thyroid function and restore clinical euthyroidism. For these patients, there is often no adequate FDA-approved or commercially manufactured substitute.

To Dr. Henderson, FDA's classification of ADT as a biologic product "has become a human rights issue." She has patients who have had their thyroid removed due to cancer, multinodular goiter, Graves' Disease or due to other reasons and require lifelong thyroid replacement medicine. Many of these patients also have autoimmune thyroiditis, the most common reason for thyroid disease in the developed world, and thus have sensitivities to many of the FDA-approved drug excipients. Many of the ADT products have no dyes and fewer excipients, allowing for improved tolerability. Importantly, many patients report substantially improved well-being and markedly fewer side effects on ADT products. Because the science of why some patients do better on one formulation vs. another is still evolving, Dr. Henderson believes it is *imperative* that individual clinical judgement be respected and preserved.

The second provider, Dr. Sarah J. Zielsdorf, MD, MS, is a board-certified internal medicine physician and Institute for Functional Medicine Certified Practitioner (FMCP-M) with over ten years of experience in functional and internal medicine.¹²⁰ Her experience with ADT is both professional and personal. On a professional level, her practice actively treats around 2,000 patients, the strong majority of whom are being treated for thyroid management. But on a personal level, Dr. Zielsdorf is also intimately familiar with thyroid management. She was diagnosed with hypothyroidism at age 19. Despite being prescribed FDA-approved Synthroid, her condition continued to deteriorate because her body was not converting T4 to T3. Dr. Zielsdorf was eventually bedbound, gained 50 pounds, lost her menstrual cycle, developed severe liver problems, was told she could never have children, and, at the worst, had difficulty speaking her own name. Upon being treated with ADT, she "felt like going from a world in black and white to a world of

¹¹⁸ Zielsdorf Statement, at p. 1-2; Henderson Statement, at p. 1-3.

¹¹⁹ Henderson Statement, at p. 1. Dr. Henderson currently serves as Chief Medical Officer and owner of the Charleston Thyroid Center and as Chief Medical Officer of MyThyroidDoctor.com, a telemedicine thyroid practice. She has held faculty and medical director roles in endocrinology at Duke University and Wake Forest Baptist Health, where she directed the Thyroid & Endocrine Neoplasia Clinic and the Fellows Thyroid Ultrasound and Biopsy Clinic, and is the author of 20 peer-reviewed publications on thyroid-related topics. At any given time, her practice has 20,000 active patients from across the U.S. who are seeking treatment for thyroid management, and approximately 15% of these patients are being successfully treated with ADT medications.

¹²⁰ Zielsdorf Statement, at p. 1. Dr. Zielsdorf is the owner and medical director of Motivated Medicine, PLLC, a functional and translational/internal medicine practice in Illinois, which focuses on complex chronic and autoimmune-driven illnesses, including thyroid disease, sex hormone management, and adrenal disorders. Dr. Zielsdorf has specifically addressed thyroid conditions in her clinical and educational work and has authored numerous publications on thyroid disease management and presented on the topic at many professional conferences.

color.” Within just months her health improved, her menstrual cycle returned, and she became pregnant. Dr. Zielsdorf fights for the availability of ADT because this particular medication has the ability to be the difference between profound, debilitating illness and a vibrant, thriving life.

ii. Compounding Pharmacies Safely Produce Customized ADT Therapies.

Many compounding pharmacies dispense prescriptions for ADT, and several pharmacists were eager to contribute to the statements of support for this petition. It is the shared hope of these pharmacists to preserve the practice of compounding ADT to ensure that those patients who rely on these medications are able to get the treatment they need. In response to growing prescription volume and patient demand, these pharmacies have each dispensed hundreds of, and in some cases more than 1,000, ADT prescriptions in a given year. These statistics reflect a fraction of the pharmacies in the U.S. that serve thyroid patients, but they demonstrate a clear and sustained clinical need for compounded ADT.

The pharmacies recognize FDA’s concerns with ADT’s potency, content uniformity, labeling, impurity, and manufacturing quality in the 2025 Notice to Industry. The pharmacies do not seek to dismiss those concerns—thyroid medications require careful dosing and monitoring and appropriate quality controls, and FDA is right to consider them. However, the Agency’s concerns do not support a categorical conclusion that ADT products are unsuitable for continued patient access through compounding. Instead, the quality system concerns identified by FDA in the 2025 Notice are already adequately addressed through targeted, risk-based measures.

Specifically, pharmacies already employ rigorous quality and safety controls to ensure the safety of compounded medications. Their processes include vendor qualification to ensure that API manufacturers are registered with and inspected by FDA, Certificate of Analysis review, and verification of acceptance criteria and internal specifications for the USP monograph for thyroid, among many others. For example, VLS Pharmacy performs weighted calculations for every capsule and maintains a method of validation from lowest to highest dose, with all compounding performed in strict accordance with USP standards.¹²¹ As part of the quality assurance practice for Clark’s Compounding Pharmacy and Kusler’s Compounding Pharmacy, the pharmacies screen for allergies, drug interactions, and recalls, source exclusively from FDA-registered manufacturers and state-licensed wholesalers, and screen Certificates of Analysis for microbial growth, residual solvents, mold, and yeast as part of the USP monograph process.¹²² Notably, none of these pharmacies has ever received a patient or provider complaint related to the quality of a compounded ADT product, and has never received a report of a serious adverse event related to compounded ADT.

Moreover, it is safer to compound with ADT as an API than with pure T4 or T3 on its own. From a potency standpoint, pure T3 and pure T4 are each extremely potent and are dosed in micrograms (i.e., one one-thousandth of a single milligram). Even with the most diligent processes, there is still a far greater risk of inconsistent potencies in individual capsules of T3 or T4 than there is in compounding with ADT, which is dosed in milligrams. Further, ADT also has a monograph,

¹²¹ Gopesh Patel, R.Ph., Statement of Support, at p. 1-2 (hereinafter “*Patel Statement*”).

¹²² Ipsen Statement, at p. 2; *see also* Steve Hoffart, PharmD, FAAMM, ABAHP, Statement of Support, p. 1-2; Koshland Statement, at p. 1-2.

which makes it more straightforward and easier to compound with than pure T3 or T4.¹²³ Accordingly, classification of ADT as a biologic causes more problems than it solves by failing to provide a reasonable alternative for patients who will be harmed by the lack of access.¹²⁴

These pharmacists demand access to ADT because they share a common interest—they want what is best for their patients. And, what is best for their patients is the ability to dispense the medication that is the best fit for the patient. In many cases, this best fit is compounded ADT.

iii. Patients Will Suffer Without Compounded ADT.

Classifying ADT as a biological product will result in clinically meaningful deterioration for patients who cannot tolerate FDA-approved alternatives or for whom these alternatives simply do not work. The classification removes a vital treatment option that is genuinely life-altering for the patients who depend on it; patients who have likely already exhausted all FDA-approved alternatives and only arrive at a compounding pharmacy when nothing else on the market has worked for them. Those who cannot access proper thyroid treatment cannot live normal lives—they experience energy loss, cognitive impairment and brain fog, weight gain leading to other chronic illnesses, systemic inflammation, and autoimmune reactions, which can render patients bedridden.¹²⁵ One pharmacist believes that this classification will cause “one hundred percent of affected patients [to] seek these medications from unregulated overseas pharmacies or from the black market,” thereby profoundly harming patients whose quality of life will diminish significantly without proper dosing from a licensed pharmacy under physician supervision.¹²⁶

For example, one patient reported that, despite working in the fitness industry for 15 years, she experienced complete lethargy, unexplained and unexpected weight gain, inflammation, and brain fog. She felt like she lost control of her life. When she was diagnosed with a thyroid issue, however, she was prescribed a combination of FDA-approved synthetic levothyroxine and Armour Thyroid, which she took for eight years. Unfortunately, her symptoms prevailed and she did not get better. However, everything changed when she was prescribed a compounded ADT medication. Thanks to the compounded formulation, her thyroid levels stabilized and she only has to get bloodwork done every six months rather than every three months (which was the frequency when she was on synthetic levothyroxine and Armour Thyroid). Importantly, her brain fog vanished, her energy returned, and her weight gain resolved.¹²⁷

Another patient was living with Hashimoto’s disease for almost 20 years and was initially prescribed FDA-approved Synthroid. He took Synthroid for nine to ten years but continued to feel worse. Synthroid was not working for him because of its rapid release nature once it is ingested. By contrast, when he was eventually prescribed a compounded ADT medication, it was formulated to be slow-release and better mimic his body’s natural thyroid pattern. This medication “genuinely gave [him his] life back.” He transitioned from an obese, inactive individual to an athlete and his ability to function day to day was restored. Now, he is more physically active than ever before, and he participates in competitive events like triathlons and ultra marathons.¹²⁸ This is not a minor

¹²³ Koshland Statement, at p. 2.

¹²⁴ Jerry Beamer, R.Ph., Statement of Support, p. 2.

¹²⁵ Ipsen Statement, at p. 2-3.

¹²⁶ Patel Statement, at p. 2.

¹²⁷ Amanda Murdock, Statement of Support, p. 1.

¹²⁸ Ashley Neboschick, Statement of Support, p. 1.

difference—in his words, “it is literally the difference between me taking a medication that simply keeps me alive and a medication that allows me to function and thrive on a daily basis.”¹²⁹

A third patient shared these experiences. When she was first diagnosed, she was prescribed Synthroid, but this medication did not help her. She experienced brain fog, fatigue, weight gain, puffy eyes, cold hands and feet, dry hair, constipation, and bloating. When she was finally switched to an ADT medication, her condition significantly improved. Her weight returned to normal, her digestion improved, she experienced relief from chronic fatigue, and her energy levels stabilized. She had been on some form of thyroid medication for over 15 years, and ADT is the only medication that has worked for her. As a Certified Physician Assistant with over 11 years of experience in thoracic surgery and functional medicine, she often sees these same results in her patients.¹³⁰

Classifying ADT as a biologic and thus revoking access to compounded ADT formulations will cause serious, tangible harm to patients who have no viable alternative. In many cases, these patients have already endured years on FDA-approved synthetic medications that failed them, yet FDA seems inclined to effectively force patients back on these drugs that will certainly diminish these patients’ quality of life. ADT is a life-changing medication, and it is in the best interest of the public that FDA revoke its classification of ADT as a biological product and regulate ADT as a drug.

IV. Conclusion.

For the reasons stated above, we ask that FDA revoke the Agency’s determination that ADT products are classified as biological products; announce that FDA will classify ADT as a drug; and withdraw the September 16, 2022 letter to NABP and the August 6, 2025 letter to manufacturers, importers, and distributors of animal-derived thyroid products, and any other publication in which FDA describes ADT as being subject to the “biological product” definition. FDA’s decision to classify ADT as a biologic is defective because it is inconsistent with the statutory requirements for a biological product, it was determined in an arbitrary and capricious manner and failed to use the required notice-and-comment process, and puts consumers into harm’s way by providing no other pathway to address their critical needs.

C. Environmental Impact

Petitioner claims a categorical exclusion under 21 C.F.R. § 25.30.

D. Economic Impact

The following information is to be submitted only when requested by the Commissioner.

¹²⁹ *Id.*

¹³⁰ Larisa Baldwin, PA-C, Statement of Support, p. 1-2.

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D. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.



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