ABBVIE INC. v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES et al Doc. 54

**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF COLUMBIA**

ABBVIE INC.,

*Plaintiff*,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

*Defendants*.

Civil Action No. 1:26-cv-00431 (CJN)

# MEMORANDUM OPINION

Plaintiff AbbVie manufactures and sells BOTOX, an FDA-licensed biological product that is used for a variety of cosmetic and therapeutic treatments. From November 2024 to October 2025, BOTOX accounted for over a billion dollars in Medicare spending. Under the Inflation Reduction Act of 2022 (IRA), the Centers for Medicare & Medicaid Services selected BOTOX for price negotiations based on its significant Medicare expenditures, which would likely result in greatly reduced prices of BOTOX for Medicare beneficiaries. AbbVie challenges CMS's selection of BOTOX, contending that the agency failed to exclude BOTOX from negotiations as a "biological product . . . derived from human whole blood or plasma." 42 U.S.C. § 1320f-1(e)(3)(C). For the reasons discussed below, because CMS misinterpreted this plasma-derived products exclusion, AbbVie's motion for summary judgment is granted in part.

## I. Background

### A. Statutory and Regulatory Background

Millions of Americans receive healthcare coverage for prescription drugs through two federally funded programs known as Medicare and Medicaid. *See* ECF No. 28 ¶ 5 (Mahmoud



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Decl.). Medicare provides healthcare coverage for individuals who are 65 or older, or who have certain medical conditions or disabilities. *See* 42 U.S.C. § 1395 *et seq.* Medicaid in turn provides healthcare for certain individuals and families "whose income and resources are insufficient to meet the costs of necessary medical services." 42 U.S.C. § 1396-1. Together, these programs spend hundreds of billions of dollars each year on retail prescription drugs. *See, e.g.*, CMS, Table 4: National Health Expenditures by Source of Funds and Type of Expenditure: Calendar Years 2017–2024.

This case most centrally concerns the procedures for pricing prescription drugs under the Medicare program. Medicare is divided into five "Parts," only two of which are relevant here. *Ne. Hosp. Corp. v. Sebelius*, 657 F.3d 1, 2 (D.C. Cir. 2011). Part B covers outpatient care, including some limited coverage for prescription drugs that are administered by medical professionals. 42 U.S.C. §§ 1395j–1395w-6; *Cares Cmty. Health v. U.S. Dep't of Health & Hum. Servs.*, 944 F.3d 950, 953 (D.C. Cir. 2019). Part B historically did not cover prescription drugs that were self-administered. ECF No. 32-1 at 3 (Gov't MSJ Br.). In 2003, Congress enacted Part D, *see* 42 U.S.C. §§ 1395w-101–1395w-154, which altered this framework and expanded prescription drug coverage. *See United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 749 (3d Cir. 2017). Unlike Part B, Part D provides coverage through private insurers, referred to as "sponsors," that contract with CMS and receive reimbursement for covered Part D expenditures. 42 U.S.C. §§ 1395w-112(b), 1395w-115. Significantly, when Congress established Part D, it prevented CMS from negotiating Part D drug prices. *See id.* § 1395w-111(i). Part D's non-interference provision set it apart from the drug benefits programs administered by other federal entities, such as the Departments of Defense and Veterans Affairs, which have had some authority to negotiate drug prices directly with manufacturers. *See* 38 U.S.C. § 8126.

Part D's market-oriented approach has resulted in huge costs over the last decade, putting increasing strain on the federal fisc. *See* Off. of the Assistant Sec'y for Plan. & Evaluation, HHS, Report to Congress: Prescription Drug Pricing 8 (May 20, 2020), [https://perma.cc/R34A-GNWK]. Indeed, Part D expenditures are projected to rise "faster than any other category of health spending." S. Rep. No. 116-120, at 4 (2019). Despite Medicare covering thousands of prescription drugs, only "a relatively small number of drugs are responsible for a disproportionately large share of Medicare costs." H.R. Rep. No. 116-324, pt. 2, at 37 (2019). In 2021, for instance, the 10 top-selling drugs accounted for approximately one-fourth of gross Part D spending even though they made up just 0.3 percent of the total number of covered drugs. KFF, Juliette Cubanski & Tricia Neuman, A Small Number of Drugs Account for a Large Share of Medicare Part D Spending (July 12, 2023), [https://perma.cc/44Q9-4CGV].

To address those concerns, in 2022 Congress enacted the IRA, which established the Medicare Drug Price Negotiation Program. *See* 42 U.S.C. §§ 1320f–1320f-7; 26 U.S.C. § 5000D. The Negotiation Program empowers CMS, by delegation from the HHS Secretary, to negotiate the prices that Medicare pays for certain drugs for a particular drug-pricing year. *See* 42 U.S.C. § 1320f(a)(3), (b)(1)–(2). The Negotiation Program applies only to manufactures that have opted into Medicare and Medicaid and governs only drugs paid for by Medicare. *See id.* § 1320f-1(b), (d). It does not dictate the prices private insurers pay for drugs in the private marketplace.

"The Negotiation Program sets out a two-phase process for each drug-pricing period." *AstraZeneca Pharms. LP v. Sec'y U.S. Dep't of Health & Hum. Servs.*, 137 F.4th 116, 120 (3d Cir. 2025); *see Teva Pharms. USA, Inc. v. Kennedy*, 187 F.4th 587, 596–97 (D.C. Cir. 2026) (describing the two-stage process).

1. The initial phase is "a narrowing process" in which CMS identifies the drugs subject to negotiation. *Teva*, 187 F.4th at 596. Before it can be considered for negotiation, a drug must first satisfy the definition of the term "qualifying single source drug" (QSSD). 42 U.S.C. § 1320f-1(e). A QSSD consists of two categories of products: (1) "Drug products" that are "approved" and "marketed" under new drug applications, 21 U.S.C. § 355, that have been approved for at least seven years, and that are not listed drugs for marketed generic drugs; and (2) "Biological products" that are "licensed" and "marketed" under biologics license applications, 42 U.S.C. § 262, that have been licensed for at least 11 years, and that are not reference products for marketed biosimilar products. *Id.* § 1320f-1(e)(1)(A), (B).

Congress excluded from the definition of QSSD three sub-categories of drugs and biological products: "[c]ertain orphan drugs," "[l]ow spend Medicare drugs," and, at issue in this case, "[p]lasma-derived products." *Id.* § 1320f-1(e)(3). A plasma-derived product is "[a] biological product that is derived from human whole blood or plasma." *Id.* § 1320f-1(e)(3)(C). Since the IRA's inception, CMS guidance has consistently provided that in applying this exclusion, CMS considers whether "a plasma-derived product is a licensed biological product that is derived from human whole blood or plasma, as indicated on the approved product labeling." *See, e.g.*, CMS, Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028, at 173 (2025) (2028 Guidance), [https://perma.cc/EUD8-DLXK]; ECF No. 25 at 13 & n.11 (AbbVie MSJ Br.). The guidance also states that CMS will refer to product information available on an FDA website and certain databases and will consult with the FDA as appropriate in making its exclusionary determination. *Id.*

After determining which drugs and biological products are QSSDs, CMS continues the narrowing process by identifying "negotiation-eligible drugs." *See* 42 U.S.C. § 1320f-1(d). As the Third Circuit cogently explained, CMS "rank-orders the [QSSDs] according to highest associated expenditures under Medicare Part B or Part D over a recent twelve-month period." *AstraZeneca*, 137 F.4th at 120. To calculate these expenditures, CMS aggregates data "across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation, and not based on the specific formulation or package size or package type of the drug." 42 U.S.C. § 1320f-1(d)(3)(B). "The [50] drugs that represent the highest total spending under each respective Part are 'negotiation-eligible drugs.'" *AstraZeneca*, 137 F.4th at 120 (citation omitted).

For the final step of the narrowing process, CMS publishes a list of "selected drugs"—the highest-ranked negotiation-eligible drugs that will "be subject to the negotiation process" for a drug-pricing period. 42 U.S.C. § 1320f-1(a)–(c). To create this list, CMS selects a statutorily prescribed number of negotiation-eligible drugs in accordance with their ranked total expenditures for a given pricing year. *Id.* § 1320f-1(a)–(b). For 2026, CMS selected 10 drugs. *Id.* § 1320f-1(a)(1). For 2027 and 2028, CMS must select 15 drugs. *Id.* § 1320f-1(a)(2), (3). And for every year thereafter, CMS must select 20 drugs. *Id.* § 1320f-1(a)(4).

As a final matter, and important to this case, Congress restricted judicial review at each step of the narrowing process. *See Teva*, 187 F.4th at 597. A court lacks subject matter jurisdiction over the "selection of drugs under section 1320f-1(b) of this title, the determination of negotiation-eligible drugs under section 1320f-1(d) of this title, and the determination of [QSSDs] under section 1320f-1(e) of this title." 42 U.S.C. § 1320f-7(2).

2. The second phase involves the drug-pricing negotiation and begins once CMS publishes the list of selected drugs. A manufacturer of a selected drug enters into an agreement with CMS and then negotiates the drug price with CMS. *Teva*, 187 F.4th at 597 (citing 42 U.S.C. §§ 1320f-2(a), 1320f-3(b)(2)). The goal of the negotiations is "to achieve the lowest maximum fair price for each selected drug." 42 U.S.C. § 1320f-3(b)(1). If the parties reach an agreed upon "maximum fair price," the manufacturer signs an addendum to its manufacturer agreement and makes that price available to Medicare beneficiaries. *Id.* § 1320f-3; CMS, Medicare Drug Price Negotiation Program Agreement, [https://perma.cc/P5ZL-Z4E3]; Gov't MSJ Br. 7–8. If the manufacturer "fails to enter the required agreement," "enters one but does not agree to a maximum fair price on time," or otherwise walks away from the process, "federal law imposes an excise tax on sales of the selected drug." *Teva*, 187 F.4th at 598 (citing 26 U.S.C. § 5000D(a)–(b)).

**B. Factual Background**

This litigation arises from CMS's placement of BOTOX on the selected drug list for the 2028 drug-pricing year. While BOTOX is most often thought of as a cosmetic treatment, it treats various serious medical conditions. AbbVie has licenses for BOTOX for both therapeutic and cosmetic indications. ECF No. 27 ¶¶ 6–7 (Brin Decl.). At issue here is the version of BOTOX licensed for therapeutic indications.[1] A brief history of BOTOX and its chemistry is helpful to understanding the parties' dispute.

[1] As indicated above, BOTOX has a license for four cosmetic indications under the name BOTOX Cosmetic. Brin Decl. ¶ 7. These cosmetic uses are not covered by Medicare or Medicaid, and BOTOX Cosmetic is not otherwise at issue in this case. *See* AbbVie MSJ Br. 5. While CMS refers to the selected drug as "Botox; Botox Cosmetic," according to the government, it does so for reasons that do not matter to this litigation. Gov't MSJ Br. 10 n.3. Consistent with the parties' filings, the Court will use the name BOTOX.

In 1989, BOTOX was first licensed by the FDA to treat "eye disorders caused by muscle dysfunction." Brin Decl. ¶ 10. As it stands today, BOTOX has twelve therapeutic indications across eight diseases, and it is "the only FDA-licensed biological product providing localized treatment of chronic migraine, bladder disorders, involuntary eye dysfunctions, and hyperhidrosis." *Id.* ¶¶ 5–6.

Since the FDA first licensed it, BOTOX has always had the same three ingredients: onabotulinumtoxinA (onabotA), sodium chloride, and human serum albumin (HSA).[2] *Id.* ¶ 12. OnabotA is the only active ingredient. Brin Decl. Ex. 4 at 1. It is a natural, biological protein toxin, which makes BOTOX a "biological product" for purposes of FDA licensing. *See* 42 U.S.C. § 262(i); Brin Decl. ¶ 13. OnabotA serves to inhibit the release of acetylcholine, "a neurotransmitter nerve cells use to communicate with muscles and sweat glands." AbbVie MSJ Br. 5 (citing Brin Decl. Ex. 4 § 12.1). OnabotA is not derived from human blood or plasma. Sodium chloride, one of BOTOX's two inactive ingredients, is utilized to produce an isotonic solution with the same osmotic balance as fluids in the human body, which protects cells from damage and minimizes patient discomfort. Brin Decl. ¶ 15. Sodium chloride is also not derived from human blood or plasma.

The remaining inactive ingredient in BOTOX is HSA—a protein obtained from human blood plasma. *Id.* ¶ 14. It plays an important role in absorption, preventing the breakdown of onabotA, and minimizes protein clumping that could reduce efficacy or trigger immune responses. *Id.* ¶ 16. HSA accounts for nearly all of BOTOX's protein content, substantially exceeding the

[2] The government refers to BOTOX's active ingredient as botulinum toxin type A, a broader category that encompasses onabotA. Gov't MSJ Br. 2; ECF No. 40 at 18 n.4 (AbbVie Reply). Because the distinction does not matter to this case, the Court uses the term onabotA, which appears on BOTOX's FDA-approved label.

amount attributable to onabotA. *Id.* ¶ 14. For reference, there is about 100,000 times more HSA by mass than onabotA in each BOTOX vial. *Id.* It is undisputed that HSA is a necessary ingredient for BOTOX, that BOTOX cannot be marketed without the presence of HSA, and that HSA appears on the label of BOTOX. *See, e.g.*, Brin Decl. ¶¶ 12, 16, Ex. 4 § 5.14; 21 C.F.R. § 601.12(b).

AbbVie notes that HSA is uniquely susceptible to supply-chain disruptions. *See, e.g.*, Brin Decl. ¶ 21 ("BOTOX supply is heavily reliant on qualified HSA supply."). According to AbbVie, as "a complex natural mixture containing various proteins and phospholipids from human donors," HSA's composition "can be impacted by changes in the vendor's commercial process to extract and isolate the HSA protein." Brin Decl. Ex. 9 ¶ 11. As AbbVie explains, "variability in HSA supply has directly affected BOTOX supply." *Id.* ¶ 14.

### C. Litigation History

On January 27, 2026, CMS selected BOTOX as one of the 15 drugs for negotiation for drug-pricing year 2028. *See* Mahmoud Decl. ¶ 23 & Ex. 3. For the relevant statutory period, roughly $1,143,070,000 in Medicare Part B and Part D expenditures were attributable to BOTOX. *See* CMS, Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2028 (Jan. 2026), [https://perma.cc/K9VS-QNHE]. On February 11, 2026, AbbVie filed this lawsuit, alleging that CMS exceeded its statutory authority under the IRA by selecting BOTOX for negotiation in violation of 5 U.S.C. § 706(2)(C). ECF No. 1 ¶¶ 53–62 (Compl.). AbbVie also asserts an ultra vires claim and three constitutional claims. *Id.* ¶¶ 63–95.

## II. Standard of Review

Summary judgment is proper "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In the administrative context, "summary judgment 'serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise

consistent with the APA standard of review.'" *Cap. Area Immigrants' Rts. Coal. v. Trump*, 471 F. Supp. 3d 25, 37 (D.D.C. 2020) (citation omitted). Courts are required to "hold unlawful and set aside agency action . . . found to be . . . in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C).

## III. Analysis

### A. Jurisdiction

The threshold issue the Court must address is whether it has subject matter jurisdiction over AbbVie's statutory claim. Recall that the IRA provides that "[t]here shall be no administrative or judicial review of," among other actions, "the determination of [QSSDs] under section 1320f-1(e)." 42 U.S.C. § 1320f-7(2). The government contends that this case involves CMS's determination that BOTOX is a QSSD, and therefore that this provision forecloses judicial review. Gov't MSJ Br. 1–2, 14–22. Whatever its initial appeal, however, that argument is foreclosed by the Court of Appeals' recent decision in *Teva Pharmaceuticals USA, Inc. v. Kennedy*, 187 F.4th 587 (D.C. Cir. 2026).

There, a drug manufacturer (Teva) challenged CMS's guidance that resulted in two of its drug products, the applications for which were separately approved by the FDA, constituting a single QSSD. *Id.* at 599. In formulating this grouping rule, CMS interpreted a provision of the IRA concerning the aggregation of drug data for purposes of calculating expenditures for negotiation-eligible and selected drugs. *Id.* at 598 (citing 42 U.S.C. § 1320f-1(d)(3)(B)). Considering that language, CMS's guidance treated drugs with the same active moiety and manufacturer as a single QSSD even if the products were approved under different FDA applications. *Id.* at 598. This overarching grouping policy is referred to as aggregation, or more simply bundling, because it groups multiple licensed drugs together to be treated as a single product for purposes of the Negotiation Program. Because Teva's two products met that

definition, CMS determined that those products constituted a single QSSD. *Id.* at 599. Teva sued, claiming that CMS's interpretation of QSSD rested on an erroneous view of the IRA and that CMS had acted in excess of its statutory authority. *Id.*

Before turning to the merits, the Court of Appeals rejected the government's argument that the judicial review bar foreclosed Teva's challenge. *Id.* at 601. The government had argued, as it does here, that even though Teva purported to challenge CMS's interpretation of the statute rather than a specific QSSD determination, the judicial review bar precluded that challenge because CMS's interpretation was inextricably linked to an unreviewable, drug-specific determination. *Compare Teva*, 187 F.4th at 605–06, *with* ECF No. 42 at 3–5 (Gov't Reply).

After discussing the various presumptions in favor of judicial review in the administrative context that are equally applicable here, the Court of Appeals construed the review bar "as precluding review of CMS's drug-specific determinations while leaving its interpretation of the relevant IRA provisions reviewable." *Id.* at 603; *see also id.* at 595 (The review bar "covers CMS's drug-specific determinations, not the generally applicable legal standards that govern them."). In drawing that distinction, the Court reasoned that a "determination" is a "single, discrete act rather than 'a group of decisions or a practice or procedure employed in making decisions.'" *Id.* at 603 (quoting *McNary v. Haitian Refugee Ctr., Inc.*, 498 U.S. 479, 492 (1991)). And because "the determination" was "the object of the review bar," Congress "tasked CMS with deciding whether a particular drug satisfies its [QSSD] definition" but left reviewable "CMS's construction of the incorporated definitions." *Id.* at 603, 606.

In reaching this conclusion, the Court of Appeals explained that while "CMS's interpretation and its drug determinations are connected," as "[o]ne supplies the governing legal rule, and the other applies that rule to a particular drug," *id.* at 606, those inherently "distinct tasks"

have different jurisdictional outcomes—the former reviewable, the latter not. *Id.* at 603. The Court cautioned that "CMS cannot collapse those tasks by embedding its interpretation of the relevant term into each drug evaluation and then calling the whole package a 'determination.'" *Id.* If that were the case, "CMS could shield even an interpretation exceeding its delegated authority simply by using it to make an unreviewable decision." *Id.* at 603–04.

*Teva* ensures the Court of its jurisdiction. Like Teva, AbbVie contends that CMS exceeded the scope of its statutory authority. *See* Compl. ¶ 55 (alleging that "[b]y selecting BOTOX for the Program, CMS acted in excess of its statutory authority"). And like Teva, AbbVie contends that that CMS exceeded its authority by having an erroneous interpretation of the IRA. In *Teva*, the allegedly erroneous interpretation concerned the definition of QSSD; here it is an allegedly flawed view of the plasma-derived products exclusion. Compl. ¶¶ 53–62; AbbVie Reply 18–27. Under *Teva*, the Court has jurisdiction to review those interpretations. *Id.* at 607 (The statute permits a court to review "the generally applicable legal standards that govern" CMS's determination.).

The government nevertheless argues that the judicial review bar applies here because interpreting and applying the exclusion are necessary, subsidiary decisions in the lead-up to an unreviewable QSSD determination. But *Teva* rejected that position. *See* 187 F.4th at 605 ("[A]n agency cannot make its statutory interpretation unreviewable simply by using it in an unreviewable determination."); *see id*. at 606 ("[W]e reject the Government's argument that CMS's interpretation of qualifying single source drug is 'inextricably intertwined' with its individual determination under that interpretation.").

The government also argues that *Teva* concerned a challenge to CMS guidance, which AbbVie has not raised. But *Teva* was not so limited; it states that CMS's "interpretation of the relevant IRA provisions" is reviewable, not just interpretations contained in guidance. *Id.* at 603.

There was also no guidance for AbbVie to challenge when it filed this action, as the notice of proposed rulemaking containing CMS's plasma-derived products interpretation issued while this litigation was already pending. *See* 91 Fed. Reg. 36,236, 36,263 (June 16, 2026). And at the earliest opportunity to do so, AbbVie has contended that "[t]his Court would also have jurisdiction to review challenges to CMS's recently unveiled 'policy.'" AbbVie Reply 11 n.2.[3]

The government likewise proposes a narrow reading of *Teva* that turns on the nature of the relief sought. ECF No. 43 at 1–2. To the government, *Teva* applies only when a party seeks prospective vacatur of challenged legal standards but not when it requests an order reversing a completed determination. *See* 187 F.4th at 607. But it is hard (if not impossible) to divine that principle from the opinion. While the Court of Appeals did distinguish *Novo Nordisk Inc. v. Secretary United States Department of Health & Human Services*, 154 F.4th 105 (3d Cir. 2025), in part based on the prospective nature of the relief sought by Teva, the Court of Appeals also explained that its judicial-review precedent "has long differed from our sister circuit's." *See id.* at 606–07. Indeed, the Court explained at length its doctrinal departure from the Third Circuit's view that "when a statute prohibits review of a particular determination, the bar extends to the ultimate decision and the process by which [the agency] reaches this decision." *Id.* (internal quotation marks omitted) (quoting *Novo Nordisk*, 154 F.4th at 111–12)).

[3] This disposes of a related point—the contention that AbbVie waived any reliance on a *Teva*-like challenge. ECF No. 43 at 3. The Court finds no such waiver or forfeiture. AbbVie has consistently argued that the Court has jurisdiction to review its statutory claim that CMS exceeded its authority under the IRA by not applying the plasma-derived products exclusion. *See, e.g.*, Compl. ¶¶ 53–62. As the litigation here has unfolded, it has become clear that the government interprets the exclusion to apply only when a biological product's active ingredient is derived from human whole blood or plasma. Whether AbbVie or the government is correct on that question, the parties have sufficiently preserved this question of statutory interpretation. And it does not change the jurisdictional analysis under *Teva* that CMS may have embedded its now-public interpretation of the plasma-derived products exclusion in determining that BOTOX was a QSSD. *See Teva*, 187 F.4th at 603–04.

In any event, this argument is hard to square with the rest of *Teva*. After all, the Court of Appeals stated that "CMS cannot collapse [interpretation and application] by embedding its interpretation of the relevant term into each drug evaluation and then calling the whole package a 'determination.'" 187 F.4th at 603. That statement did not turn on the nature of the relief sought. In fact, in the very next sentence, the Court discussed a hypothetical that dispenses with any relief-based distinction:

> Suppose subsection (e) requires that a qualifying single source drug be approved for at least seven years, but CMS decides that five will do. Once CMS applies that interpretation to a five-year-old drug, the Government's theory would place its interpretation beyond review because it now forms part of an unreviewable determination. A neat trick, but not one Congress authorized.

*Id.* at 604. Under *Teva*, that CMS has *applied* an allegedly incorrect interpretation of the statute to a drug determination does not mean the interpretation is shielded from review. *See id.* (rejecting the position that "CMS could rewrite the statute and then shield its rewrite merely by applying it"). And regardless, AbbVie seeks more than just vacatur of CMS's selection of BOTOX. *See* Compl. at 26 (seeking declaratory relief that is not BOTOX specific).

**B. Merits**

The Court turns next to AbbVie's statutory claim—that BOTOX is a "biological product that is derived from human whole blood or plasma" excluded from the price-negotiation scheme. 42 U.S.C. § 1320f-1(e)(3)(C). That language turns on two inquiries: whether (or really, why) BOTOX is a biological product within the meaning of the statutory exclusion; and if so, whether it is derived from human whole blood or plasma.

**1. Biological Product**

The FDA's licensing framework, referenced by the IRA, *see* 42 U.S.C. § 1320f-1(e)(1)(B), defines a "biological product"—within the context of that statute at least—to mean a "toxin

. . . applicable to the prevention, treatment, or cure of a disease or condition of human beings." 42 U.S.C. § 262(i). Under this definition, since BOTOX's active ingredient onabotA is a biological protein toxin, BOTOX is a licensed biological product. *See Ipsen Biopharmaceuticals, Inc. v. Becerra*, 108 F.4th 836, 838 (D.C. Cir. 2024) (explaining that FDA analyzes a product's active ingredient to determine a biological product for licensing).

Although the parties agree that BOTOX is a "biological product" within the meaning of the IRA's exclusion, the government disagrees that that's *because* (or only because) BOTOX is a "biological product" under 42 U.S.C. § 262(i). The Court interprets the relationship between these positions to be that while the § 262(i) licensing definition may supply an initial, necessary element for being considered "[a] biological product that is derived from human whole blood or plasma" in the IRA, there is more to the term "biological product" in the IRA, which provides generally for the aggregation or bundling of products throughout the Negotiation Program. 42 U.S.C. § 1320f-1(e)(3)(C). In other words, the FDA's licensing definition—which focuses on a specific product rather than bundled ones—cannot directly map onto the term biological product in the IRA without also accounting for the concept of aggregation.

Here again the decision in *Teva* is relevant. There, on the merits, the Court of Appeals upheld CMS's aggregation policy, which in that case treated all drug products that share the same active moiety and manufacturer as a single QSSD. 187 F.4th at 598, 607–10. The Court rejected Teva's argument that each drug approved by the FDA under a new drug application should be considered a separate statutory drug for purposes of identifying a QSSD. *Id.* at 607. Instead, the Court of Appeals explained, such a "one-[application], one-drug rule would . . . create substantial tension with" other provisions of the IRA that support the bundling of drug products throughout various stages of the Negotiation Program. *Id.* at 608; *see also id.* at 609 ("Congress . . . carried

the same aggregation principle through each stage of the process."). For instance, the IRA directs "CMS to aggregate expenditures across dosage forms, strengths, and 'new formulations of the drug,' rather than calculate them by 'specific formulation.'" *Id.* at 608 (quoting 42 U.S.C. § 1320f-1(d)(3)(B)). This provision (and others), the Court of Appeals reasoned, "makes more sense if a single statutory drug may include formulations approved under different" drug applications. *Id.*

*Teva* further held that CMS's active-moiety and same-manufacturer requirements comported with the statutory scheme. Active moiety, the Court explained, is a well-accepted "marker for the pharmacologically active substance that remains constant across changes in strength, dosage form, or release mechanism." *Id.* at 609. And the same-manufacturer limitation "accords with the IRA's repeated direction that CMS negotiate with 'the manufacturer' of the selected drug." *Id.*

This reasoning informs this Court's interpretation of "biological product" in the plasma-derived products exclusion. The exclusion is located in the same statutory subsection as the term "qualifying single source drug." *See* 42 U.S.C. § 1320f-1(e)(1), (e)(3)(C). And it excludes a subset of drugs from the overarching category of QSSDs. *Id.* Given the conceptual similarity between drugs and biological products and their placement in the same subsection, it makes sense to interpret the terms in an aligned fashion. *See Lawson v. FMR LLC*, 571 U.S. 429, 459 (2014) ("The provisions' parallel text and purposes counsel in favor of interpreting the two provisions consistently."). Because the IRA permits CMS to treat as a QSSD all drugs with the same active moiety and manufacturer no matter the formulation, the IRA also allows CMS to treat as a biological product the bundle of products with the same active ingredient across all changes in

strength, dosage form, or release mechanism owned by the same manufacturer.[4] That is, a biological product is a single manufacturer's bundle of biological products licensed and marketed under 42 U.S.C. § 262 that contain the same active ingredient across all dosage forms, strengths, and formulations.

Thus, consistent with both parties' positions, the biological product here is BOTOX in all of its forms. BOTOX is licensed in three strengths under a single biologics license application held by AbbVie. Brin Decl. ¶ 12, Ex. 1, Ex. 7 § I.B. Each formulation of BOTOX has the same three ingredients—onabotA, HSA, and sodium chloride—even though each formulation differs in strength. *Id.* ¶ 12. The biological product for purposes of the plasma-derived products exclusion encompasses each of these formulations.

**2. Derived from human plasma**

But is BOTOX (in its bundled formulations) "derived from human . . . plasma"? 42 U.S.C. § 1320f-1(e)(3)(C). The IRA doesn't define this phrase, and therefore the Court gives the language its ordinary meaning understood in context. *Feliciano v. Dep't of Transp.*, 605 U.S. 38, 45–46 (2025). "Derive" is commonly understood to mean "to take, receive, or obtain especially from a specified source." *Derive*, Merriam-Webster's Dictionary, https://www.merriam-webster.com/dictionary/derive; *see also Derivative*, Merriam-Webster's Medical Dictionary, https://www.merriam-webster.com/dictionary/derivative#medicalDictionary (Derivative is defined as "made up of or marked by derived elements"). The question then becomes whether BOTOX is "made up of" or "obtained from" human plasma. Common sense and parlance dictate that it is.

[4] The analog to active moiety for a biological product is the active ingredient. *See* 2028 Guidance, at 165–66; ECF No. 43 at 5.

It is undisputed that all versions of BOTOX are made up of only onabotA, sodium chloride, and HSA. Brin Decl. ¶ 12. It is undisputed that without HSA, one cannot make BOTOX. *Id.* ¶¶ 12, 16. In fact, HSA "constitutes the vast majority of the protein content in BOTOX," as in each vial of BOTOX, there is "100,000 times more HSA by mass than onabotA." *Id.* ¶ 14. And it is undisputed that HSA is a protein obtained from human plasma. *Id.* As a matter of ordinary usage, where as here, a substantial, necessary component of a product comes from a source, the product as a whole is also best understood as being obtained from that source. The Court thus concludes that BOTOX is derived from human plasma because HSA, a significant and necessary ingredient, comes from human plasma.

The government reads the exclusion differently. On its view, whether "[BOTOX] is derived from human . . . plasma" turns on whether BOTOX's *active ingredient* is derived from human plasma. Gov't MSJ Br. 28. The government reasons that Congress implicitly incorporated an active-ingredient limitation into the exclusion because biological products obtain their regulatory status under 42 U.S.C. § 262 based on their active ingredient. *Id.* Under this interpretation, because BOTOX's active ingredient, onabotA, is not derived from human plasma, BOTOX would fall outside the exclusion.

The words "active ingredient," however, are nowhere to be found in the plasma-derived products exclusion—or anywhere in the IRA, for that matter. To adopt the government's reading, the Court would have to essentially insert "active ingredient" into § 1320f-1(e)(3)(C), which would read as: "biological product [whose active ingredient] is derived from human whole blood or plasma." The Court is reluctant to do so absent compelling reason for "[w]hen the language is plain, [courts] have no right to insert words and phrases, so as to incorporate in the statute a new and distinct provision." *United States v. Temple*, 105 U.S. 97, 99 (1881). While this longstanding

proposition is not necessarily dispositive, it presents a substantial obstacle for the government's interpretation.

To be sure, the Court recognizes that a drug's active moiety and a biological product's active ingredient are important for aggregation under the reasoning of *Teva*, even though the words "active ingredient" and "active moiety" are not included in the IRA. *Teva*, 187 F.4th at 609 ("Certainly, the IRA does not use the phrase 'active moiety.'"). As *Teva* explains, active moiety (and here active ingredient) is the pharmacological consideration that enables bundling across different drug formulations consistent with Congress's commands to aggregate expenditures no matter the dosage, strength, or formulation. *Id.*; *see* 42 U.S.C. § 1320f-1(d)(3)(B). But it does not necessarily follow that this concept also supplies a further limitation in the context of the exclusion for plasma-derived biological products. Rather, numerous considerations cut in the other direction.

As an initial matter, various provisions of the IRA and the FDA licensing regime conceptualize biological products in a whole-product sense, not just by their active ingredient. *See Teva*, 187 F.4th at 609 (recognizing that the Supreme Court has "held that a 'drug' could encompass the finished product, including its active and inactive ingredients," whether or not "products containing the same active ingredients could 'under some circumstances be the same drug'" (quoting *United States v. Generix Drug Corp.*, 460 U.S. 453, 459–61 (1983))). For example, and as discussed above, the IRA explicitly references biological products under 42 U.S.C. § 262, which provides for the licensing and marketing of biological products in their whole, finished sense. *See* 42 U.S.C. § 1320f-1(e)(1)(B)(i). Even though the FDA analyzes the active ingredient in determining whether to classify a product as a drug or biological product for licensing, the FDA ultimately licenses the entire finished product, composed of all its ingredients,

as a single "biological product." AbbVie MSJ Br. 24–25; 42 U.S.C. § 262(a)(1), (a)(2)(C); 21 C.F.R. § 601.2.

The same concept carries through in the IRA, which requires CMS to "use data that is aggregated across dosage forms and strengths of the drug, including *new formulations of the drug*, . . . and *not based on the specific formulation* or package size or package type of the drug." 42 U.S.C. § 1320f-1(d)(3)(B) (emphasis added). By requiring CMS to consider all formulations of a drug—which includes every active and inactive ingredient—the IRA focuses on a drug in its entirety, not just its active ingredient. And as the Court of Appeals put it in *Teva*, "[t]hat instruction makes more sense if a single statutory drug may include *formulations* approved under different [applications]." 187 F.4th at 608 (emphasis added). In sum, although the active ingredient provides the glue for aggregation, it does not further constrain a biological product as being defined only by its active ingredient. "Patients take drugs, not [just active ingredients]." *Id.* at 609.

The government's reading is also at odds with the exclusion's apparent purpose to safeguard the market of plasma-derived products, which face unique supply-chain vulnerabilities. *See* Mahmoud Decl. ¶ 11 ("That exclusion recognizes that manufacturers of plasma-derived products are especially vulnerable to shocks to the supply of donated blood and plasma."). As AbbVie explains, BOTOX's supply is heavily reliant on qualified HSA supply, Brin Decl. ¶ 21, Ex. 9 ¶¶ 10, 14, because "HSA is a recognized source of variability due to its human origin and the chemical and physical conditions of the manufacturing process used to separate HSA from other plasma components." *Id.* Ex. 9 ¶ 8; *see also id.* ¶ 11 ("[T]he composition of the final HSA material can be impacted by changes in the vendor's commercial process to extract and isolate the HSA protein."). In light of these unique challenges, it makes sense that Congress would intend to exclude all bundled products that are made up of human plasma, not just those that have an active

ingredient derived from human plasma. That is especially the case because, as the government roughly estimated at oral argument, on its view of the exclusion only a dozen or so biological products would fit within it—and none of them is one on which the government currently spends significant Medicare funds. ECF No. 53 at 71–72 (Transcript). It is not obvious to the Court why Congress would have enacted such an exclusion (one of only three) if such a small number of inexpensive products fell within it.

The government also points out concerns regarding workability and gamesmanship. *See* Gov't Reply 17; Transcript 14–20. As the government sees it, some bundled biological products may have formulations with a plasma-based ingredient while others may not, making it difficult for CMS to apply the exclusion in those circumstances. And the government fears that sophisticated drug manufacturers could subvert the Negotiation Program by adding HSA or a different inactive plasma-based ingredient to its product and thereby qualify as an excluded plasma-derived product. But neither concern is present here. Since the FDA licensed BOTOX in 1989, BOTOX has always had the same three ingredients and has always had HSA in all of its forms. Brin Decl. ¶¶ 12, 16.

Nor has the government provided sufficient reason to think that this scenario is likely to occur, as the government cited only one such example, and it did so for the first time at oral argument. Transcript 14–20. Indeed, AbbVie has provided unrebutted evidence that human plasma increases the complexity in the drug manufacturing process, reducing any concern that a manufacturer would intentionally add such an ingredient for the purpose of avoiding the Drug Negotiation Program. Brin Decl. ¶ 24, Ex. 9 ¶¶ 10–11, 14. And even assuming an attempted end-run, the FDA has its own mechanisms for policing strategic reformulations of products. *See* 21 C.F.R. § 601.12(b)(2)(i) (dictating that a drug manufacturer must seek FDA approval for "major

changes," including changes in "inactive ingredients," to previously approved products). For these reasons, the Court will not prejudge how the exclusion would apply to a bundled biological product that has some formulations containing a plasma-based inactive ingredient and others that do not.[5]

* * *

In sum, one of BOTOX's core components, HSA, is derived from human plasma, so BOTOX as an aggregated biological product is derived from human plasma and subject to exclusion under the IRA. Because CMS applied an erroneous interpretation of that exclusion, AbbVie's motion for summary judgment is granted in part, and the Government's motion to dismiss or alternatively for summary judgment, is denied in part.[6]

DATE: October 29, 2026

CARL J. NICHOLS
United States District Judge

[5] A potential answer to the government's related concerns might be that the exclusion would not apply to a bundled biological product that has only some formulations with a plasma-based ingredient. Such a product might not be "derived from" human plasma since, as an aggregated whole, not every form of the product comes from human plasma.

[6] Because the Court concludes that AbbVie should prevail on its statutory claim (Count One of the Complaint), it does not reach at this time its ultra vires or constitutional claims.