IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ABBVIE INC.,
1 North Waukegan Road
North Chicago, IL 60064;

Plaintiff,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue, S.W.
Washington, DC 20201;

CENTERS FOR MEDICARE AND MEDICAID SERVICES,
7500 Security Boulevard
Baltimore, MD 21244;

ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the U.S. Department of Health and Human Services,
200 Independence Avenue, S.W.
Washington, DC 20201;

MEHMET OZ, in his official capacity as Administrator of the Centers for Medicare and Medicaid Services,
7500 Security Boulevard
Baltimore, MD 21244,

Defendants.

No. _____

COMPLAINT

Plaintiff AbbVie Inc. brings this action for declaratory and injunctive relief against the Department of Health and Human Services (HHS), the Centers for Medicare & Medicaid Services (CMS), and the heads of those agencies in their official capacities, and alleges as follows:

PRELIMINARY STATEMENT

1. This lawsuit challenges CMS's decision to select BOTOX® for the prescription-drug price controls established by the Inflation Reduction Act of 2022 (IRA). *See* 42 U.S.C.

§ 1320f *et seq*. Through the IRA, Congress for the first time granted the federal government the authority to place price controls on certain medications covered under Medicare. In so doing, Congress expressly *excluded* certain categories of medications from eligibility in the price-control program. *See* 42 U.S.C. § 1320f-1(e)(3). Unlike previous challenges related to the IRA, this lawsuit is the first that arises from CMS's violation of one of those express statutory exclusions established by Congress: namely, the IRA's exclusion of "plasma-derived products" from price controls.

2. While commonly known for its cosmetic uses, BOTOX was first developed as a medicine. It is approved by the Food and Drug Administration (FDA) to treat multiple serious and debilitating diseases, including chronic migraine, urinary incontinence, eye-and-neck movement disorders, and many other non-cosmetic medical conditions. BOTOX is the only FDA-approved product to treat the serious eye disorders blepharospasm (*i.e.*, uncontrollable eye blinking) in adolescents and strabismus (*i.e.*, crossed eyes) in adults and adolescents. BOTOX works by selectively blocking nerve communications to targeted muscles and sensory neurons involved in pain transmission, enabling highly precise administration to selected areas of the body. That targeted approach minimizes unwanted side effects and enables more effective treatment, particularly for patients who have not responded to other therapies. Medicare coverage for BOTOX only extends to its medical uses, and it is BOTOX's medical uses that are the subject of this litigation.

3. Since its first FDA approval in 1989, BOTOX has always consisted of just three ingredients: onabotulinumtoxinA (onabotA), human serum albumin (HSA), and sodium chloride. HSA is a protein extracted from human blood plasma. HSA makes up approximately one-third of BOTOX and plays a critical role in the safety and efficacy of the product.

4. Because HSA is sourced from donated human blood plasma, its supply is inherently constrained by donor supply and vulnerable to supply-chain interruptions. Natural variability among donors, as well as the chemical and physical processes required to isolate HSA from other plasma components, introduces additional variability that contributes to manufacturing challenges. Products that contain ingredients that come from human blood are also subject to strict regulatory requirements regarding their manufacturing and labeling. Such supply vulnerabilities and operational complexities are inherent to manufacturing plasma-derived products, as Congress implicitly acknowledged when it excluded plasma-derived products from IRA price controls.

5. BOTOX is a biological product derived from human blood plasma that should have been excluded from selection under the plain language of the IRA. Congress granted CMS authority to select a drug or biological product for price controls only if that drug or biological product meets certain conditions. Specifically, the product must satisfy the statutory definition of a "qualifying single source drug." 42 U.S.C. § 1320f-1(d)(1). The IRA expressly provides that the phrase "qualifying single source drug" does not include "[p]lasma-derived products"—that is, a "biological product that is derived from human whole blood or plasma." *Id.* § 1320f-1(e)(3)(C). BOTOX undoubtedly falls within that exclusion. Because HSA is sourced from plasma collected from human donors, BOTOX is a "plasma-derived product" that Congress excluded from the price-control program. In failing to apply this exclusion to BOTOX, CMS has exceeded its statutory authority under the IRA and thus violated the Administrative Procedure Act or, alternatively, acted *ultra vires*.

6. The plain text of the IRA's plasma-derived-products exclusion suffices to set aside the selection of BOTOX. In addition, CMS's actions will lead to the violation of AbbVie's constitutional rights in several ways. By selecting BOTOX and imposing a "maximum fair price,"

CMS will (1) force AbbVie, under threat of ruinous tax liability or exclusion from federal government programs, to turn over physical doses of the product to Medicare beneficiaries at confiscatory prices without just compensation in violation of the Takings Clause; (2) require AbbVie to express an untrue statement that it has acceded to a "fair" price in violation of the First Amendment; and (3) subject AbbVie to a one-sided price-setting process lacking the hallmarks of due process. Those constitutional violations also independently entitle AbbVie to declaratory and injunctive relief.

THE PARTIES

7. Plaintiff AbbVie Inc. (AbbVie) is a corporation organized and existing under the laws of Delaware with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064. AbbVie Inc. holds the biologics license application (BLA) for BOTOX.[1]

8. AbbVie is engaged in the discovery and delivery of innovative medicines and solutions that enhance people's lives. AbbVie develops, sells, and distributes a broad range of pharmaceutical products, including the finished biological products that are marketed under the name BOTOX.

9. Defendant Department of Health and Human Services (HHS) is an executive department of the United States government headquartered in Washington, D.C. HHS is responsible for administering the Medicare program and the statutory provisions challenged here.

[1] The FDA's drug database lists "Allergan" as the "Company" under the BLA for BOTOX. *See* U.S. Food & Drug Administration, Drugs@FDA: FDA-Approved Drugs, <https://tinyurl.com/FDADrugsAllergan>. But AbbVie is the actual BLA holder of BOTOX. AbbVie acquired Allergan, Inc., in 2020, and, as agency correspondence and product labels posted to the FDA's drug database illustrate, AbbVie is the BLA holder of all BOTOX products.

10. Defendant Centers for Medicare & Medicaid Services (CMS) is an administrative agency within HHS that is headquartered in Baltimore, Maryland. It administers the Medicare program and the statutory provisions challenged here.

11. Defendant Robert F. Kennedy, Jr., is the Secretary of the Department of Health and Human Services. He oversees the Medicare program and is responsible for administering the statutory provisions challenged here. He is sued in his official capacity.

12. Defendant Mehmet Oz is the CMS Administrator. He administers the Medicare program and the statutory provisions challenged here on behalf of the Secretary of HHS. He is sued in his official capacity.

JURISDICTION AND VENUE

13. This Court has jurisdiction under 28 U.S.C. §§ 1331 and 1346 because this action arises under the laws of the United States, including the United States Constitution, and because an agency of the United States is a Defendant. Sovereign immunity is not an obstacle to this suit for injunctive and declaratory relief. *See* 5 U.S.C. § 702.

14. An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201(a), and this Court may grant declaratory relief, injunctive relief, and other appropriate relief pursuant to 28 U.S.C. §§ 2201-2202 and 5 U.S.C. §§ 703-706.

15. Venue is proper in this judicial district under 28 U.S.C. § 1391(e)(1) because this action is brought against officers and agencies of the United States and at least one defendant resides in this district.

BACKGROUND

I. Federal Healthcare Programs and Prescription Drugs

A. Medicare and Medicaid

16. The Medicare and Medicaid programs—two of the world's largest health insurance programs, both operated by the federal government—provide health insurance to over 100 million eligible Americans.

17. Medicare offers prescription drug coverage through Medicare Part B, which covers, among other things, physician-administered drugs, and through Medicare Part D, which covers self-administered prescription drugs. In addition, every state currently provides coverage for outpatient prescription drugs to most enrollees within their state Medicaid programs.

18. The federal government faces practically no competition from private insurers in markets served by Medicare and Medicaid. The two programs account for nearly 40% of the broader domestic health-care market.

19. Federal agencies have generally imposed an "all in" or "all out" requirement for these federal health care programs, forcing manufacturers either to participate in Medicare and Medicaid or to withdraw all of their products from those programs. Because Medicare and Medicaid dominate the health care market, withdrawing all of a manufacturer's products from these federal health care programs is not a viable option.

B. The Drug Price Negotiation Program

20. In 2022, Congress enacted the IRA, which included a directive to create the Drug Price Negotiation Program (Program). In so doing, Congress delegated authority to CMS to "negotiate" prices on certain drug and biological products pursuant to statutory requirements. *See* 42 U.S.C. § 1320f(a).

21. The IRA directs CMS to select a set number of drugs each year to subject to the Program. The number of drugs selected for the Program is cumulative: for initial price applicability year (IPAY) 2026, CMS selected 10 new drugs; for each of IPAY 2027 and IPAY 2028, the agency selected 15 new drugs; and for all future IPAYs, CMS must choose 20 new drugs each year. *See* 42 U.S.C. §§ 1320f(d), 1320f-1(a)(1)-(4). Given that cumulative selection process, projections show that, within ten years, half of all Medicare drug spending will be controlled by the IRA's new price-setting process under the Program.

22. The selected drugs are chosen out of a pool of "negotiation-eligible" drugs, which are then ranked based on "total expenditures" under Medicare over the previous 12-month period. 42 U.S.C. § 1320f-1(b)(1)-(2). To be "negotiation-eligible"—and thus subject to selection under the Program—a drug must be a "qualifying single source drug." 42 U.S.C. § 1320f-1(d), (e).

23. The term "qualifying single source drug" includes (1) drug products "approved" and "marketed" under a new drug application, that have been licensed for at least seven years, and that are not the listed drug for a marketed generic drug; and (2) biological products "licensed" and "marketed" under a BLA, that have been licensed for at least 11 years, and that are not the reference product for a marketed biosimilar product. 42 U.S.C. § 1320f-1(e)(1)(A), (B).

24. Congress excluded from the Program certain categories of drugs or biological products that would otherwise meet the definition of a "qualifying single source drug." 42 U.S.C. § 1320f-1(e)(3). As relevant here, the IRA limits CMS's authority to select drugs for the Program by specifying that "the term 'qualifying single source' drug does not include . . . [p]lasma-derived products," defined as "[a] biological product that is derived from human whole blood or plasma." 42 U.S.C. § 1320f-1(e)(3)(C).

25. In its final implementation guidance for IPAY 2028, CMS stated that, "[f]or purposes of this exclusion, 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." Centers for Medicare & Medicaid Services, 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 (Sept. 30, 2025) (IPAY 2028 Final Guidance). The guidance also states that CMS will refer to "product information available on the FDA Approved Blood Products website" and "databases such as FDALabel and the FDA Online Label Repository" to "identify plasma-derived products" for purposes of the plasma-derived-products exclusion. *Id*. at 27 (footnotes omitted); *accord id*. at 173. The guidance further provides that "CMS also will consult with FDA, as appropriate." *Id*. at 173.

26. Only if a drug or biological product meets the definition of a qualifying single source drug—and does not fall into one of the exclusions to that definition that Congress created—does CMS have the authority to select the product for the Program.

C. Consequences of Selection for the Program

27. For manufacturers of selected products, the consequences of selection are immediate. Once CMS publishes the list of selected drugs, the affected manufacturers have approximately one month to "enter into agreements" with CMS, under which they must agree to "negotiate to determine . . . a maximum fair price," submit "information that [CMS] requires to carry out the negotiation," and "compl[y] with requirements" that CMS determines "to be necessary for purposes of administering the program and monitoring compliance with the program." 42 U.S.C. § 1320f-2(a).

28. CMS released template manufacturer agreements that require manufacturers to express that the "manufacturer agree[s]" that it will "negotiate to determine . . . a maximum fair price," and that once "the manufacturer and CMS have engaged in negotiation of the price," that price will be "binding" upon the manufacturer. Medicare Drug Price Negotiation Program Agreement 1-2, 7-8, <https://tinyurl.com/ManufacturerAgreementTemplate> (Template Agreement). The Template Agreement contains a disclaimer: "Use of the term 'maximum fair price' and other statutory terms throughout this Agreement reflects the parties' intention that such terms be given the meaning specified in the statute and does not reflect any party's views regarding the colloquial meaning of those terms." *Id*. at 4.

29. If a manufacturer refuses to sign CMS's agreement to "negotiate," the manufacturer must pay an escalating daily excise tax that starts at 186% and increases to 1,900% of the drug's daily sales. 26 U.S.C. § 5000D; *see* Molly F. Sherlock et al., Congressional Research Service, R47202, Tax Provisions in the Inflation Reduction Act of 2022 (H.R. 5376), at 4 (Aug. 10, 2022). A manufacturer that does not agree to "negotiate" may avoid this excise tax only by withdrawing *all* of its products from Medicare and Medicaid. IPAY 2028 Final Guidance 257-259 & n.148.

30. As part of entering into an agreement with CMS to negotiate a "maximum fair price," a manufacturer must promise to "provide access to such price" for the "selected drug" to eligible individuals and entities. 42 U.S.C. § 1320f-2(a)(1). Failure to do so will trigger civil monetary penalties of ten times the difference between the price the manufacturer actually charges and the mandated price. 42 U.S.C. § 1320f-6(a). In addition, a manufacturer that violates the terms of its agreement with CMS will be subject to a statutorily specified civil monetary penalty of $1 million per day. *See* 42 U.S.C. § 1320f-6(c).

31. During the price-setting process, CMS "shall . . . aim[] to achieve the lowest maximum fair price for each selected drug," 42 U.S.C. § 1320f-3(b)(1), and in no case may agree to a price exceeding the ceiling established by statute, *see* 42 U.S.C. § 1320f-3(b)(2)(F)(i). For a drug that has been on the market for at least 16 years, that price ceiling may be no more than 40% of the wholesale price for the drug in the private market. For a drug that has been on the market for at least 16 years, that price ceiling may be no more than 40% of the wholesale price for the drug in the private market. 42 U.S.C. § 1320f-3(c)(3)(C). For drugs that have been on the market for between 12 and 16 years or for less than 12 years, that price ceiling may be no more than 65% and 75%, respectively, of the private market wholesale price. 42 U.S.C. § 1320f-3(c)(3)(A), (B). CMS has often set prices that are discounted at least 50% from the list price and has imposed discounts as high as 85% off of the list price. *See* Centers for Medicare & Medicaid Services, Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026, at 2 (2024); Centers for Medicare & Medicaid Services, Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2027, at 2 (2025). For drugs that have been on the market at least 16 years, CMS has imposed an average reduction of more than 70% off the list price. *Id*.

32. "[T]here is no limit to how low HHS's offer can be." *National Infusion Center Association* v. *Becerra*, 116 F.4th 488, 495 (5th Cir. 2024). And "[i]f the manufacturer fails to reach an agreement" on a "maximum fair price" or "walk[s] away from negotiations," the penalties described above will apply. *Id*. (internal quotation marks omitted).

33. Once a manufacturer enters an agreement with HHS to sell at the dictated price, sales must continue at that price until a specified time after a generic or biosimilar version of the

drug is approved and marketed, *see* 42 U.S.C. § 1320f-1(c)(1), or the drug is picked for "renegotiation," *see* 42 U.S.C. § 1320f-3(f).

34. The IRA bars both administrative and judicial review of various aspects of the drug-selection and price-setting process. *See* 42 U.S.C. § 1320f-7.

II. BOTOX

A. BOTOX Is An Innovative Biological Product

35. BOTOX is a biological product that was first approved by the FDA in 1989.[2] Although widely known for its cosmetic uses such as reducing wrinkles, BOTOX has received 12 FDA approvals to treat serious medical conditions. This case focuses on BOTOX's medical uses, which are reimbursed by Medicare and Medicaid and thus are implicated by its improper selection for governmental price-setting.

36. BOTOX's first FDA approval was for the treatment of strabismus and blepharospasm, serious eye disorders caused by muscle dysfunction that substantially impact daily functioning, quality of life, and work productivity. Prior to BOTOX's approval, the only available medications were generally ineffective and not FDA-approved for these uses; some also caused intolerable side effects. Alan B. Scott et al., *Treatment of Strabismus and Blepharospasm with Botox (onabotulinumtoxinA): Development, Insights, and Impact*, 102 Medicine S23, S24 (2023). These conditions were thus often treated with eye muscle surgeries, but the surgeries were often unsuccessful or resulted in complications. *Id*. BOTOX, which allows for the targeted dosing of specific muscles, was developed to provide a less invasive, well-tolerated pharmacological

[2] The product known today as BOTOX was initially licensed by the FDA in 1989 under the name Oculinum. In 1991, Allergan acquired Oculinum and renamed it BOTOX a year later.

alternative. *Id.* at S24, S26. It was found to be an effective alternative to surgery and significantly reduced the risk of intolerable side effects linked to oral medicines. *Id.*

37. Since the initial approval of BOTOX, research and development efforts have resulted in this innovative therapy being used to address other severe, difficult-to-treat medical conditions. Today, BOTOX has 12 U.S. FDA approvals across 8 neurological diseases spanning both adult and pediatric populations. These are summarized in the table below:

<table>
<tr><th>BOTOX Indications</th><th>Approval Date</th><th colspan="2">Description</th></tr>
<tr><td>Blepharospasm</td><td>1989</td><td colspan="2">Involuntary, repeated blinking, or spasm of eyelid muscles resulting in uncontrollable blinking or eyelid closure</td></tr>
<tr><td>Strabismus</td><td>1989</td><td colspan="2">Eye misalignment due to poor control of eye muscles resulting in double vision, reduced depth perception, eye strain, and potential vision loss</td></tr>
<tr><td>Cervical dystonia</td><td>2000</td><td colspan="2">Painful neurological condition due to involuntary neck muscle contractions, causing the head to twist, turn, or tilt uncontrollably in various directions</td></tr>
<tr><td>Hyperhidrosis</td><td>2004</td><td colspan="2">Skin disorder resulting in excessive sweating due to overactive sweat glands</td></tr>
<tr><td rowspan="4">Spasticity*</td><td>2010</td><td>Adult Upper Limb</td><td rowspan="4">Debilitating neurological condition causing muscle stiffness and impaired movement that can interfere with movement and function, often seen after stroke, spinal cord injury, multiple sclerosis, traumatic brain injury, or cerebral palsy</td></tr>
<tr><td>2016</td><td>Adult Lower Limb</td></tr>
<tr><td>2019</td><td>Pediatric Upper Limb</td></tr>
<tr><td>2019</td><td>Pediatric Lower Limb</td></tr>
<tr><td>Chronic migraine</td><td>2010</td><td colspan="2">Headaches on 15 or more days per month, often severely impacting daily life due to pain and other symptoms</td></tr>
<tr><td rowspan="2">Neurogenic detrusor overactivity*</td><td>2011</td><td>Adult</td><td rowspan="2">Uncontrolled contraction of bladder muscles causing frequent, urgent urination or leakage, resulting from nerve damage from neurological conditions (e.g., spinal cord injury, multiple sclerosis)</td></tr>
<tr><td>2021</td><td>Pediatric</td></tr>
<tr><td>Overactive bladder</td><td>2013</td><td colspan="2">Uncontrolled contraction of bladder muscles causing frequent, urgent urination or leakage, without underlying neurological cause or infection</td></tr>
</table>

* = FDA approvals granted separately for different muscle groups and patient populations, each requiring additional clinical data to address variations in muscle type and injection methods, as well as differences in muscle size, function, treatment goals, and risk profiles.

38. While BOTOX was being used to treat overactive facial muscles, researchers discovered that BOTOX also decreased skin wrinkles at the site of injection. The FDA has since approved BOTOX—under the brand name BOTOX Cosmetic—for 4 cosmetic indications, including the smoothing of facial wrinkles in adults. BOTOX's cosmetic uses are not covered by Medicare and Medicaid and are not subject to government price controls.

39. BOTOX's broad range of medical uses are driven by its precise, targeted mechanism of action and strong safety profile, providing opportunities for continued innovation. In recent years, AbbVie has investigated new uses for BOTOX for additional severe and difficult-to-treat medical conditions. AbbVie has made—and continues to make—significant investments to advance toxin innovation, including discovering new uses and optimizing manufacturing processes. For example, AbbVie recently completed a $69 million expansion of its domestic toxins research and development capabilities to more effectively manage the scientific challenges, high security, and regulatory demands of an innovative toxins portfolio.

B. BOTOX Supply Depends On HSA

40. Since its original approval, BOTOX has always consisted of three ingredients: onabotulinumtoxinA (onabotA), human serum albumin (HSA), and sodium chloride. OnabotA is a natural, biological protein produced from *clostridium botulinum* bacteria. HSA is a protein present in human blood plasma and sourced from human blood donors. Sodium chloride, commonly known as salt, is included in BOTOX to produce an isotonic solution that is in balance with body fluids.

41. BOTOX is not made up of all three ingredients in equal proportion or volume. The product contains approximately 100,000 times more HSA than onabotA. This is roughly equivalent to onabotA occupying a single seat in the University of Michigan's football stadium—the

biggest stadium in the United States—while HSA occupies every other seat in the stadium. That has been the case since BOTOX launched in 1989.

42. BOTOX is licensed and marketed under a biologics license application (BLA 103000) held by AbbVie in three strengths. FDA has only ever licensed BOTOX in its finished dosage forms, which have always included HSA, and AbbVie's ability to market BOTOX under this license depends on the presence of HSA. *See* 21 C.F.R. § 601.12 (setting forth FDA regulations governing changes to already-approved or licensed drug products).

43. The HSA in BOTOX is sourced from human plasma. The FDA-approved product labeling for BOTOX expressly states that the "product contains albumin, a derivative of human blood." United States BOTOX Prescribing Information § 5.14 (2023) (BOTOX Prescribing Information) (Exhibit 1).

44. Because plasma-derived products like BOTOX rely on human donations, these products are particularly vulnerable to variability in plasma donation supply. Plasma-derived products also pose unique manufacturing challenges. Plasma fractionation is a multi-step process that separates and purifies specific proteins (such as HSA) from human plasma. Slight variations in fractionation processes can alter the properties of HSA and other plasma proteins in ways that can affect products that contain these proteins. These manufacturing challenges result in heightened risk of shortage. To try to protect against these risks to BOTOX supply, AbbVie has qualified two different HSA suppliers.

45. Even minor changes in either of these supplier's HSA extraction processes or handling protocols can result in significant, costly changes to AbbVie's BOTOX manufacturing process to maintain product consistency. BOTOX manufacturing process changes take years to develop and require FDA pre-approval before implementation. *See* 21 U.S.C. § 356a; 21 C.F.R.

§ 601.12(b). As a plasma-derived product, BOTOX supply is vulnerable to precisely the manufacturing and regulatory risks that led Congress to exclude plasma-derived products from the IRA.

C. HSA Plays A Critical Role In BOTOX

46. HSA is a necessary, integral ingredient in achieving BOTOX's therapeutic effects. Specifically, and in addition to constituting approximately one-third of the volume of BOTOX, HSA plays a critical function in managing the activity of onabotA, and it directly contributes to the safety and efficacy of BOTOX.

47. The FDA-approved formulation for BOTOX has always (and continues) to include HSA. AbbVie initially formulated BOTOX with HSA to protect onabotA, an extremely potent and complex molecule, from environmental factors that can affect the quality, stability, and performance of BOTOX. For example, HSA minimizes protein aggregation (or "clumping") that would reduce the activity of onabotA or trigger unwanted immune responses. HSA also limits protein loss via adsorption, which occurs when the protein sticks to surfaces or syringes; adsorption can contribute to inconsistency in the delivered dose. Moreover, HSA protects against toxin oxidation (*i.e.*, the breakdown of onabotA into other compounds), which is particularly important given the minute quantities of onabotA present in each BOTOX dose.

48. In the years since BOTOX's approval, the scientific community's understanding of the relationship between HSA and toxins has further expanded. Over the last two decades, peer-reviewed studies have reported that the concentration of HSA affects the activity of toxins and enables the effective administration of lower dosages of toxin products. *See*, *e.g.*, Anna Kutschenko et al., *The Role of Human Serum Albumin and Neurotoxin Associated Proteins in the Formulation of BoNT/A products*, 168 Toxicon 158, 161 (2019); Jens D. Rollnik et al., *Low-Dose*

Treatment of Cervical Dystonia, Blepharospasm and Facial Hemispasm with Albumin-Diluted Botulinum Toxin Type A under EMG Guidance, 43 European Neurology 9, 11 (2000).

49. Building on those observations and using modern analytical tools, AbbVie recently conducted additional studies regarding how HSA impacts onabotA and the efficacy of BOTOX. AbbVie observed that HSA's presence leads to greater binding between onabotA and the targeted nerve cell receptors, resulting in greater toxin peak effect and duration. AbbVie's studies also demonstrated that, in the presence of HSA, onabotA remains longer near the injection site, increasing receptor binding. Overall, AbbVie's findings clarify HSA's significance in BOTOX and demonstrate that HSA directly contributes to the therapeutic effects of BOTOX. This has always been true—BOTOX's formulation has not changed since its original licensure. If HSA were removed from BOTOX, it would be a different product that would require new data to secure FDA approval.

D. BOTOX Is Selected For The Drug Price Negotiation Program

50. In 2025, AbbVie's internal projections suggested that, if not for the IRA's express exclusion for plasma-derived products, CMS might select BOTOX for the Program based on its methodology for calculating Medicare Part B and D expenditures.

51. To the best of AbbVie's knowledge, CMS has never applied the plasma-derived exclusion. Accordingly, AbbVie sought to engage with CMS regarding BOTOX's exemption from the Program as a plasma-derived product. AbbVie sent CMS multiple emails and letters, and AbbVie personnel met with CMS representatives on several occasions. In these communications and meetings, AbbVie explained that the plasma-derived exclusion precluded CMS from selecting BOTOX for the Program. CMS never refuted AbbVie's view. And despite these multiple letters

and meetings, CMS provided no feedback with respect to the application of the plasma-derived exclusion.

52. On January 27, 2026, CMS selected BOTOX and BOTOX Cosmetic for IPAY 2028 of the Program. CMS provided no explanation for its failure to apply the statute's plasma-derived exception to BOTOX.

CLAIMS FOR RELIEF

COUNT I

**(Challenge to CMS's Actions:
Violation of the Administrative Procedure Act—
Action in Excess of Statutory Authority)**

53. AbbVie realleges and incorporates by reference all prior and subsequent paragraphs.

54. The Administrative Procedure Act provides that a "reviewing court shall . . . 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).

55. By selecting BOTOX for the Program, CMS acted in excess of its statutory authority. Through the IRA's specific eligibility requirements, Congress expressly limited CMS's authority to select drugs and biological products for inclusion in the Program. As relevant here, only a "qualifying single source drug" may qualify as a "negotiation-eligible drug" subject to selection under the Program. 42 U.S.C. § 1320f-1(d)(1).

56. In the IRA, Congress expressly provides that "the term 'qualifying single source drug' does not include" certain excluded products. 42 U.S.C. § 1320f-1(e)(3). One such exclusion is for a "plasma-derived product[]," which the IRA defines as a "biological product that is derived from human whole blood or plasma." 42 U.S.C. § 1320f-1(e)(3)(C).

57. That straightforward language makes clear that the plasma-derived-products exclusion applies when a biological product is "derived from"—*i.e.*, "obtain[ed]" from—"human whole blood or plasma." *See* The New Oxford Dictionary of English 498 (2001).

58. BOTOX undoubtedly satisfies the exclusion's requirement because one of its components, HSA, is sourced from plasma collected from human donors.

59. FDA licensed BOTOX in its finished dosage forms, which include HSA, and BOTOX's approved product labeling confirms that it contains "albumin, a derivative of human blood." BOTOX Prescribing Information § 5; *see id.* § 11. BOTOX thus falls under the exclusion's plain text based on its composition and labeling.

60. Because BOTOX satisfies the plasma-derived-products exclusion, CMS has no authority under the IRA to select BOTOX. CMS's decision to select BOTOX thus violates the express statutory mandate of the IRA.

61. The IRA's judicial-review bar does not apply to AbbVie's APA claim. The IRA precludes judicial review of "the determination of qualifying single source drugs under section 1320f–1(e) of this title." 42 U.S.C. § 1320f-7(2). But the IRA states that a "qualifying single source drug" does not include "[p]lasma-derived products" such as BOTOX. 42 U.S.C. § 1320f-1(e)(3). Under well-established circuit precedent, a "jurisdiction-stripping provision does not apply if the agency's action fails to qualify as the kind of action for which review is barred." *American Hospital Association* v. *Azar*, 964 F.3d 1230, 1238 (D.C. Cir. 2020). Consideration of the IRA's judicial-review bar thus "merges" with "the legality of [agency] action," and this Court thus may adjudicate this claim. *Id.*

62. CMS's selection of BOTOX for price setting constitutes final agency action for which AbbVie has no other adequate remedy under 5 U.S.C. § 704.

COUNT II

**(Challenge to CMS's Actions:
Ultra Vires and Unlawful Conduct)**

63. AbbVie realleges and incorporates by reference all of the allegations contained in the preceding paragraphs of this complaint as though set forth fully herein.

64. "Administrative agencies are creatures of statute," and they "possess only the authority that Congress has provided." *NFIB* v. *Department of Labor*, 595 U.S. 109, 117 (2022). "Judicial review for *ultra vires* agency action rests on the longstanding principle that if an agency action is unauthorized by the statute under which [the agency] assumes to act, the agency has violated the law and the courts generally have jurisdiction to grant relief." *Federal Express Corp.* v. *Department of Commerce*, 39 F.4th 756, 763 (D.C. Cir. 2022) (internal quotation marks and citation omitted).

65. Courts have identified *ultra vires* action when an agency attempts to exercise "power that had been specifically withheld" in a "specific prohibition" of a statute. *Leedom* v. *Kyne*, 358 U.S. 184, 188-189 (1958). An agency also acts *ultra vires* when it "ignore[s] [a] limitation" in a statute and "totally pervert[s] the meaning of the statute." *Aid Association for Lutherans* v. *USPS*, 321 F.3d 1166, 1175 (D.C. Cir. 2003). And an agency acts *ultra vires* when it "choose[s] to ignore" "Congress's directives"; "fails to meet its statutory obligation"; or adopts a statutory "construction [that] requires adding text to the Act that Congress pointedly omitted." *National Association of Postal Supervisors* v. *USPS*, 26 F.4th 960, 974, 977 (D.C. Cir. 2022).

66. This Court retains jurisdiction to set aside CMS's selection of BOTOX as *ultra vires* action. *See Leedom*, 358 U.S. at 185. Such "nonstatutory review [is] available" because, as explained above, the selection of BOTOX is "an attempted exercise of power that had been

specifically withheld" under a "specific prohibition" in the IRA—namely, the plasma-derived-products exclusion. *Nuclear Regulatory Commission* v. *Texas*, 605 U.S. 665, 681 (2025) (quoting *Leedom*, 358 U.S. at 188-189)).

67. Accordingly, if this Court does not set aside CMS's selection of BOTOX as unlawful under the APA, it should do so on the alternative basis that the agency's action was *ultra vires*. *See Chamber of Commerce* v. *Reich*, 74 F.3d 1322, 1327 (D.C. Cir. 1996) (noting that, even when "a plaintiff is unable to bring his case predicated on either a specific or a general statutory review provision, he may still be able to institute a non-statutory review action").

COUNT III

(Challenge to CMS's Actions:
Violation of the Fifth Amendment—Categorical Taking)

68. AbbVie realleges and incorporates by reference all of the allegations contained in the preceding paragraphs of this complaint as though set forth fully herein.

69. The Fifth Amendment prohibits the government from taking "private property . . . for public use, without just compensation."

70. CMS has violated the Fifth Amendment by forcing AbbVie to turn over physical doses of BOTOX to Medicare beneficiaries at confiscatory prices set by CMS without paying just compensation. *See Horne* v. *Department of Agriculture*, 576 U.S. 350, 360-363 (2015).

71. CMS is in the process of taking AbbVie's personal property by requiring the company, under threat of devastating penalties or total withdrawal of all of its drugs from Medicare and Medicaid, to sign an agreement to hand over its BOTOX products at a confiscatory price to which AbbVie would never voluntarily agree. The IRA's threat of crippling penalties is a "sword of Damocles" hanging over AbbVie's head, compelling it to participate in the Program and turn

over its BOTOX products to Medicare beneficiaries at prices dictated by CMS. *Bristol Myers Squibb Co.* v. *Secretary*, 155 F.4th 245, 273 (3d Cir. 2025) (Hardiman, J., dissenting).

72. The "maximum fair price" that CMS will impose—which will almost certainly be lower than the statutory ceiling price—will be both arbitrary and confiscatory and impermissibly below the threshold for just compensation set by the Constitution.

73. CMS has thus taken AbbVie's property without providing the just and adequate compensation required by the Fifth Amendment.

74. Even supposing that AbbVie could avoid this taking by removing all of its products from Medicare and Medicaid—something that is not a viable option for multiple reasons already discussed—the selection of BOTOX is nevertheless unconstitutional because it impermissibly conditions AbbVie's ability to participate in those programs on the surrendering of its constitutional rights. *See Koontz* v. *St. Johns River Water Management District*, 570 U.S. 595, 606 (2013). Conditioning benefits on the relinquishment of constitutional rights runs afoul of the unconstitutional-conditions doctrine, which applies even if "a person has no 'right' to a valuable governmental benefit and even though the government may deny him the benefit for any number of reasons." *Perry* v. *Sindermann*, 408 U.S. 593, 597 (1972).

75. AbbVie seeks declaratory relief with respect to its Takings Clause claim. Such relief is appropriate for two reasons.

76. *First*, a damages suit would be "utterly pointless." *Eastern Enterprises* v. *Apfel*, 524 U.S. 498, 521 (1998) (plurality opinion) (internal quotation marks and citation omitted). AbbVie would need to bring a suit regarding each instance of a taking of a BOTOX product. "Congress could not have contemplated" that "[e]very dollar [saved] pursuant to [the IRA] would

be presumed to generate a dollar of . . . compensation." *Id*. (internal quotation marks and citation omitted).

77. *Second*, declaratory relief for a Takings Clause claim is appropriate when a statute does not provide "advance assurance of adequate compensation in the event of a taking." *Duke Power Co.* v. *Carolina Environmental Study Group, Inc.*, 438 U.S. 59, 71 n.15 (1978). Here, the IRA does not provide any such assurances.

COUNT IV

(Challenge to CMS's Actions:
Violation of the First Amendment—Free Speech)

78. AbbVie realleges and incorporates by reference the foregoing paragraphs as though set forth fully herein.

79. The First Amendment protects against laws "abridging the freedom of speech."

80. Freedom of speech "includes both the right to speak freely and the right to refrain from speaking at all." *Wooley* v. *Maynard*, 430 U.S. 705, 714 (1977).

81. The First Amendment does not permit laws that "[c]ompel[] individuals to mouth support for views they find objectionable." *Janus* v. *American Federation of State, County, and Municipal Employees, Council 31*, 585 U.S. 878, 892 (2018).

82. As the IRA's text provides, AbbVie must express in a contract that it has "agreed" to receive a "maximum fair price" for BOTOX. 42 U.S.C. § 1320f-2(a). AbbVie must accede to these statements *before* the so-called negotiation has begun. *See* 42 U.S.C. § 1320f-2(a)(1). "[W]hen a deprivation of First Amendment rights is at stake, a plaintiff need not wait for the damage to occur before filing suit." *Mahmoud* v. *Taylor*, 606 U.S. 522, 560-561 (2025) (citing *Susan B. Anthony List* v. *Driehaus*, 573 U.S. 149, 158 (2014)).

83. Moreover, as CMS's template manufacturer agreement illustrates, AbbVie will be forced to state that it "agree[s]" to "negotiate to determine . . . a maximum fair price" and that the resulting price was "[n]egotiated," "fair," and something to which AbbVie "agree[s]." Template Agreement at 2, 7.

84. AbbVie strongly disagrees with those statements but will be forced to make them anyway. Specifically, AbbVie does not believe that any price achieved through the Program would be the result of a negotiation or voluntary agreement—let alone that the final price would be "fair," given the government's ability to pick the price unilaterally. But AbbVie has no choice in whether to participate in the Program because it would face potentially catastrophic economic consequences if it declined to do so. AbbVie will thus be converted into a "vehicle for spreading a message with which it disagrees." *Pacific Gas & Electric Co.* v. *Public Utilities Commission*, 475 U.S. 1, 17 (1986) (plurality opinion); *see Bristol Myers Squibb*, 155 F.4th at 284-286 (Hardiman, J., dissenting).

85. To the extent CMS seeks to include a disclaimer in AbbVie's agreement, it would not cure any First Amendment violation. That is because a disclaimer would not eliminate the pressure on AbbVie to express statements with which it disagrees and would not otherwise make. *See Pacific Gas & Electric*, 475 U.S. at 15 n.11 (plurality opinion). The taint of compelled speech still leaves its mark when the government "require[s] speakers to affirm in one breath that which they deny in the next." *Id*. at 16.

86. The government has no compelling or important interest in forcing AbbVie to speak these untruths about the purportedly "negotiated" price of BOTOX. The most that can be said for the IRA's regime is that the government has an interest in convincing the public that the IRA brings the government and manufacturers together in good faith for a fair negotiation. But that is

not the reality; rather, at the risk of catastrophic economic consequences, manufacturers are forced to the table to accept the government's non-negotiable negotiation offer.

87. An injunction is necessary because manufacturers would suffer irreparable harm to their constitutional rights if forced to submit to the Program. *See*, *e.g.*, *eBay Inc.* v. *MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006); *Elrod* v. *Burns*, 427 U.S. 347, 373 (1976) (plurality opinion). Moreover, the equities and public interest favor injunctive relief, because the government has no meaningful justification for maintaining the IRA's unconstitutional faux-negotiation scheme. *See Karem* v. *Trump*, 960 F.3d 656, 668 (D.C. Cir. 2020).

88. The Court should thus declare unconstitutional the IRA's requirement that manufacturers "agree" to "maximum fair prices." 42 U.S.C. § 1320f-2(a). The Court should enjoin CMS from forcing AbbVie to sign a "[m]anufacturer agreement[]" or "agree to" a "maximum fair price." *Id*. Further, to the extent AbbVie is forced to sign such a "[m]anufacturer agreement[]" during the pendency of this lawsuit, the Court should declare any such agreement null and void.

COUNT V

(Challenge to CMS's Actions:
Violation of the Fifth Amendment—Due Process)

89. AbbVie realleges and incorporates by reference the foregoing paragraphs as though set forth fully herein.

90. The Fifth Amendment provides that "[n]o person shall be deprived of life, liberty, or property, without due process of law."

91. Under the Fifth Amendment's Due Process Clause, the government may not deprive a person of property without first following constitutionally sufficient procedures. *See Kentucky Department of Corrections* v. *Thompson*, 490 U.S. 454, 460 (1989). Those procedures

include notice and an opportunity to be heard "at a meaningful time and in a meaningful manner," *Armstrong* v. *Manzo*, 380 U.S. 545, 552 (1965); *see also Mathews* v. *Eldridge*, 424 U.S. 319, 333 (1976), as well as other protections that work to prevent, to the extent possible, an erroneous deprivation of property, *see Gilbert* v. *Homar*, 520 U.S. 924, 930-932 (1997).

92. In imposing a "maximum fair price" on BOTOX, CMS will not follow constitutionally sufficient procedures. CMS's negotiation process is arbitrary and does not comply with basic requirements of due process. CMS has not created any forum in which AbbVie may be heard and may lodge any objections, including objections related to the plasma-derived-products exclusion. As this case illustrates, moreover, CMS is not required under the IRA to provide an explanation, much less a reasoned explanation, for why it has selected a drug to be subject to the Program in the first place. Those concerns are aggravated by the fact that CMS's actions are largely insulated from judicial and administrative review.

93. Further, CMS will act as both the arbiter of the "negotiated" price and a party with a pecuniary interest in that price being as low as possible. This conflict of interest and the lack of a neutral arbiter violate longstanding due-process precedents.

94. AbbVie has multiple property interests related to BOTOX that are intruded upon by CMS's unlawful actions, including its interests in physical BOTOX doses; the regulatory exclusivities and patents covering BOTOX and related intellectual property rights; the loss of the expected market value AbbVie invested in BOTOX; and the confidential and proprietary data AbbVie will be forced to provide to CMS.

95. AbbVie has a constitutionally protected property interest in its BOTOX products and substantial investment-backed expectations to be free from price controls that are "arbitrary, discriminatory, or demonstrably irrelevant to the policy the legislature is free to adopt." *In re*

Permian Basin Area Rate Cases, 390 U.S. 747, 769-770 (1968) (quoting *Nebbia* v. *New York*, 291 U.S. 502, 539 (1934)). As has been the experience with other manufacturers under the Program, CMS's price controls, coupled with its faux-negotiation regime, will take away AbbVie's property interests, without affording it a meaningful opportunity to be heard before suffering significant economic losses.

PRAYER FOR RELIEF

Wherefore AbbVie prays for the following relief:

A. Declare that CMS has violated the Administrative Procedure Act (or, alternatively, acted *ultra vires*) by exceeding the limitations on its statutory authority set forth in the Inflation Reduction Act of 2022;

B. Vacate and set aside CMS's selection of BOTOX under the Administrative Procedure Act (or, alternatively, as an *ultra vires* action);

C. Declare that CMS has violated the Fifth Amendment by physically taking AbbVie's property without providing just and adequate compensation;

D. Declare that CMS has violated the First Amendment by compelling AbbVie to express agreement that it is receiving a "fair price" for BOTOX products under the IRA's price-negotiation program;

E. Declare that CMS's selection of BOTOX violates the Due Process Clause of the Constitution's Fifth Amendment;

F. Enter a permanent injunction enjoining CMS from applying the drug-pricing provisions of the IRA to BOTOX, including in any administrative proceeding;

G. Award AbbVie reasonable attorneys' fees and costs, plus interest accruing thereon, under 28 U.S.C. § 2412; and

H. Grant such other and further relief as the Court may deem appropriate.

Dated: February 11, 2026
Washington, DC

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