

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

ABBVIE INC.,

Plaintiff,

v.

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

Defendants.

Case No. 1:26-cv-00431 (CJN)

**DEFENDANTS' MOTION TO DISMISS (OR, IN THE  
ALTERNATIVE, FOR SUMMARY JUDGMENT)**

For the reasons set forth in the accompanying combined memorandum of law, all Defendants hereby move to dismiss Plaintiff's complaint under Federal Rule of Civil Procedure 12(b)(1) and 12(b)(6). In the alternative, Defendants move for summary judgment under Federal Rule of Civil Procedure 56.

Date: June 23, 2026

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**DEFENDANTS' COMBINED MEMORANDUM OF LAW IN SUPPORT OF THEIR  
MOTION TO DISMISS (OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT)  
AND IN OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT**

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## INTRODUCTION

For over 30 years, Congress has limited the amount that federal agencies will pay for prescription drugs. Manufacturers that wish to sell their drugs to the Departments of Defense and Veterans Affairs, for example, do so subject to statutorily defined ceiling prices, and both agencies have authority to negotiate prices below those ceilings. *See* 38 U.S.C. § 8126(a)-(h). In 2022, Congress gave the Secretary of Health and Human Services (HHS) similar authority to address the extraordinary and unsustainable increase in the prices Medicare pays for pharmaceutical products that lack generic competition and that account for a disproportionate share of Medicare’s expenses. Inflation Reduction Act of 2022, Pub. L. No. 117-169, 136 Stat. 1818 (Act); *see* 42 U.S.C. §§ 1320f(a), 1320f-1(b), (d), (e). Under the Drug Price Negotiation Program, the Centers for Medicare & Medicaid Services (CMS) can now negotiate the prices that Medicare will pay for a select group of drugs sold by companies that choose to sell drugs to Medicare and Medicaid.

Unsurprisingly, drug manufacturers—which have long profited from unrestricted growth in Medicare’s prescription drug payments—lobbied hard against legislative efforts to introduce market discipline by giving the Secretary a seat at the negotiating table. After their lobbying failed, pharmaceutical companies and interest groups repackaged their policy disagreements into lawsuits, filing over a dozen complaints around the country challenging the Negotiation Program on a wide variety of statutory and constitutional grounds. This case, brought by AbbVie, is lawsuit number 13 of 13. But it fares no better than all the others that came before.

As a threshold matter, the Court lacks subject-matter jurisdiction over AbbVie’s statutory and ultra vires claims, in which it contests how CMS has applied the threshold statutory criteria for inclusion in the Negotiation Program. The IRA’s definition of “qualifying single source drug,” 42 U.S.C. § 1320f-1(e), excludes “[p]lasma-derived products,” *id.* § 1320f-1(e)(3)(C). In other

words, “[a] biological product that is derived from human whole blood or plasma” is not “a qualifying single source drug.” *Id.* On AbbVie’s telling, CMS erred in refusing to apply that exclusion to AbbVie’s most famous product: Botox. But whether CMS was right or wrong, Congress provided expressly that there “shall be no administrative or judicial review” of certain agency decisions—including CMS’s “determination of qualifying single source drugs,” its determination of “negotiation-eligible drugs,” and its “selection of drugs” for negotiation. *Id.* § 1320f-7. By contesting CMS’s application of the definition of a “qualifying single source drug” to Botox, AbbVie walks directly into that explicit review bar. Both the plain text of the IRA and case law analyzing similar bars to review in other parts of the Medicare statute confirm that this Court cannot ignore Congress’s choice to explicitly preclude judicial review.

Even if this Court had jurisdiction, AbbVie’s statutory claim would fail on the merits. The active ingredient in Botox is Botulinum Toxin Type A, and it is undisputed that Botulinum Toxin Type A is *not* “derived from human whole blood or plasma.” *Id.* § 1320f-1(e)(3)(C). Accordingly, the “[p]lasma-derived products” exclusion is inapplicable—even if one of Botox’s two *inactive* ingredients is “derived from human whole blood or plasma.” *Id.*

Disposing of AbbVie’s statutory claim leaves only a series of tacked-on constitutional claims: that the Negotiation Program violates the First Amendment, the Takings Clause of the Fifth Amendment, and the Due Process Clause of the Fifth Amendment. Every court to consider those theories has rejected them. For the most part, that is because if AbbVie “dislike[s] the prices the government is willing to pay,” it is always “free to stop doing business with the government.” *Bristol Myers Squibb Co. v. HHS*, 155 F.4th 245, 255 (3d Cir. 2025), *cert. denied*, No. 25-751 2026 WL 1377095 (May 18, 2026). Drug companies have no constitutional right to dictate the prices that Medicare is willing to pay for their drugs.

## BACKGROUND

### **I. Medicare and the Escalating Cost of Prescription Drug Coverage**

Congress created Medicare in 1965. Social Security Amendments of 1965, Pub. L. No. 89-97, tit. I, 79 Stat. 286, 290-353. Medicare provides federally funded health coverage for individuals who are 65 or older or who have certain disabilities or medical conditions. 42 U.S.C. § 1395 *et seq.* CMS administers Medicare on behalf of the Secretary of HHS.

Medicare is divided into “Parts,” which establish the terms under which Medicare pays for specific benefits. *See Ne. Hosp. Corp. v. Sebelius*, 657 F.3d 1, 2 (D.C. Cir. 2011). Medicare Part B covers outpatient care as well as the cost of drugs administered as part of that care. *Cares Cmty. Health v. HHS*, 944 F.3d 950, 953 (D.C. Cir. 2019). CMS generally pays Part B providers at a rate of 106% of the average sales price for most separately payable drugs or biologicals. 42 U.S.C. § 1395w-3a(b)(1); *see Am. Hosp. Ass’n v. Becerra*, 596 U.S. 724, 729 (2022). For nearly four decades, Medicare did not cover the cost of prescription drugs unless they were administered by medical professionals. That changed in 2003, when Congress enacted Medicare Part D to provide “a voluntary prescription drug benefit program that subsidizes the cost of prescription drugs and prescription drug insurance premiums for Medicare enrollees.” *United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 749 (3d Cir. 2017); *see* 42 U.S.C. § 1395w-101 *et seq.* Under Part D, CMS enters into contracts with private entities, known as “sponsors,” 42 U.S.C. § 1395w-112(b), and makes payments to them to provide prescription drug plans to Part D eligible individuals, *see id.* § 1395w-115. On average, the government subsidizes 74.5% of expected benefit costs. *See id.* § 1395w-115(a).

In enacting Part D, Congress initially barred CMS from negotiating Part D drug prices or otherwise interfering in the arrangements between drug manufacturers and insurance plans. 42

U.S.C. § 1395w-111(i); *see also* Michelle Singer, *Under the Influence*, CBS News (Mar. 29, 2007), <https://perma.cc/5U9Z-M2YS> (documenting extensive pharmaceutical industry efforts to lobby for price-negotiation bar in lead-up to enactment of Part D). But that model led to skyrocketing drug prices, which saddled beneficiaries with unaffordable copays and threatened the long-term solvency of the program.

The cost to the United States of providing prescription drug coverage under Medicare Parts B and D is immense. In 2021 alone, the federal government spent more than \$216 billion on drugs covered by these programs. *See* KFF, *10 Prescription Drugs Accounted for \$48 Billion in Medicare Part D Spending in 2021, or More Than One-Fifth of Part D Spending That Year* (July 12, 2023), <https://perma.cc/4CYL-KYRM>. That figure has risen dramatically over the last decade and is “projected to continue rising during the coming decade, placing increasing fiscal pressure[]” on the federal budget. Off. of the Assistant Sec’y for Plan. & Evaluation, HHS, *Report to Congress: Prescription Drug Pricing* 8 (May 20, 2020), <https://perma.cc/5GEN-LZ7F> (2020 Report). Medicare Part D spending in particular “is projected to increase faster than any other category of health spending.” S. Rep. No. 116-120, at 4 (2019).

In addition to its effects on the fisc, the high cost of prescription drugs directly burdens Medicare beneficiaries by affecting their premiums and out-of-pocket payments. Because Part B premiums are automatically set to cover 25% of aggregate Part B spending, higher total spending on prescription drugs results in higher premiums for individual enrollees. *See* 2020 Report 11. Beneficiaries also pay 20% of their Part B prescription drug costs out of pocket. Many Part D plans likewise require beneficiaries to pay cost-sharing amounts, *e.g.*, 42 C.F.R. § 423.104(d)(2), and Part D premiums are similarly based on a plan’s anticipated costs, *see id.* § 423.286.

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 2018, “the top ten highest-cost drugs by total spending accounted for 46 percent of spending in Medicare Part B” and “18 percent of spending in . . . Part D.” 2020 Report 7. By 2021, the top 10 drugs by total spending accounted for 22% of spending under Part D. See 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/2PF2-336Z>.

These rising costs are in large part attributable to manufacturers’ considerable latitude in dictating the prices that Medicare pays for the most expensive drugs. Because drug prices under Medicare Part B and Part D were tied to the price manufacturers charged private buyers, see 42 U.S.C. §§ 1395w-3a(b), 1395w-101 *et seq.*, manufacturers of drugs with no generic competition could “effectively set[] [their] own Medicare payment rate[s]” by dictating sales prices in the broader market. Medicare Payment Advisory Comm’n, *Report to the Congress: Medicare and the Health Care Delivery System* 84 (June 2022), <https://perma.cc/5X4R-KCHC>. Drug companies’ substantial leeway in this respect was compounded by the significant legal and practical obstacles to market entry faced by generic competitors, along with the practice of many manufacturers of protecting their market share by entering into “settlements” with generic manufacturers to limit generic marketing. See, e.g., Sarah M.E. Gabriele & William B. Feldman, *The Problem of Limited-Supply Agreements for Medicare Price Negotiation*, 330 JAMA 1223 (2023). As a result of these factors, there are in many instances “no market forces to apply downward pressure to provide lowered prices to the millions who have coverage for such medicines under Medicare.” H.R. Rep. No. 116-324, pt. 2, at 37-38.

Other federal agencies, including the Departments of Defense and Veterans Affairs, have long operated their drug benefit programs differently and have not been subject to skyrocketing costs. Manufacturers that wish to sell drugs to these and other specified government agencies have long been obligated, as a requirement for Medicaid payment for their products, to negotiate directly with the government and to reach agreements subject to statutorily defined ceiling prices. *See* 42 U.S.C. § 1396r-8(a)(1), (6); 38 U.S.C. § 8126(a)-(h). As a result, manufacturers often sell drugs to these agencies for roughly half as much as they charge Medicare Part D. *See* Cong. Budget Off., *A Comparison of Brand-Name Drug Prices Among Selected Federal Programs* 16 (Feb. 2021), <https://perma.cc/YY2E-GM97>. “[I]f Medicare had received the same discounts as the Departments of Defense and Veterans Affairs, taxpayers would have saved” billions. Staff of H. Comm. on Oversight & Reform, *Drug Pricing Investigation: AbbVie—Humira and Imbruvica* 13-15 (May 2021), <https://perma.cc/Z2KG-ZKW3>.

## **II. The Drug Price Negotiation Program**

Through the Drug Price Negotiation Program, Congress empowered the HHS Secretary, acting through CMS, to negotiate the prices Medicare pays for certain drugs, just as the Department of Defense, the Department of Veterans Affairs, and the Coast Guard have done for decades. *See* Act §§ 11001-11003, 136 Stat. at 1833-64 (*codified at* 42 U.S.C. §§ 1320f-1320f-7 and 26 U.S.C. § 5000D). The Negotiation Program applies only to manufacturers that choose to participate in Medicare and Medicaid, and even then, it governs only the prices that Medicare pays for certain drugs. *See* 42 U.S.C. § 1320f-1(b), (d). The Negotiation Program does not dictate the prices paid for sales outside of Medicare Parts B and D.

By statute, only certain drugs are eligible for selection in the Negotiation Program: those that account for the highest Medicare expenditures, that have no generic or biosimilar competitors,

and that have been on the market for at least seven years (or 11 for biological products). *See* 42 U.S.C. § 1320f-1(d), (e). For the first negotiation cycle, CMS selected 10 of these drugs with the highest Medicare expenditures for negotiations. *Id.* § 1320f-1(a). Additional drugs have and will be selected for future negotiation cycles. A selected drug is generally subject to negotiated prices until “the first year that begins at least 9 months after the date on which the Secretary determines at least one” generic competitor “is approved or licensed” by the Food and Drug Administration (FDA) and “is marketed pursuant to such approval or licensure.”<sup>1</sup> *Id.* § 1320f-1(c)(1).

The definition of a “qualifying single-source drug” includes a “biological product . . . that is licensed” and “marketed” under 42 U.S.C. § 262, “at least 11 years have elapsed since the date of [its] licensure[,]” and “is not the reference product for” a biosimilar or interchangeable product under the Public Health Service Act (PHSA). 42 U.S.C. § 1320f-1(e)(1)(B). That definition also contains an exclusion for “[p]lasma-derived products,” which means that “[a] biological product that is derived from human whole blood or plasma” is *not* “a qualifying single source drug,” *id.* § 1320f-1(e)(3)(C), even if it otherwise satisfies the statutory criteria.

After selecting the drugs, CMS signs a Manufacturer Agreement with those manufacturers that are willing to participate in the Negotiation Program. 42 U.S.C. § 1320f-2. The object of the negotiations is to reach agreement on what the Act terms a “maximum fair price” that Medicare will pay for each selected drug. *Id.* § 1320f-3. To guide the negotiation process, Congress imposed a “[c]eiling for [the] maximum fair price,” which is based on specified pricing data for each drug, *id.* § 1320f-3(c), and directed CMS to “aim[] to achieve the lowest maximum fair price” that the manufacturer will accept, *id.* § 1320f-3(b)(1). If negotiations prove successful, the manufacturer

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<sup>1</sup> Additionally, in some circumstances not relevant here, a drug is eligible for renegotiation of the negotiated price. 42 U.S.C. § 1320f-3(f).

signs an addendum to the Manufacturer Agreement establishing the maximum price at which the drug will be made available to Medicare beneficiaries. *Id.* § 1320f-3.

In enacting the Negotiation Program, Congress thus revised the terms of the government’s offer to continue purchasing drugs for Medicare and Medicaid. A drug manufacturer that does not wish to participate in the Negotiation Program has several options. Because participation in the Medicare program is a voluntary undertaking, the manufacturer can withdraw from Medicare and Medicaid and thus not be subject to any of the Negotiation Program’s requirements. 26 U.S.C. § 5000D(c)(1); *see also* 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* (Sep. 30, 2025) at 200-01 <https://perma.cc/RNP9-8U86> (“2028 Guidance” or “the Guidance”). Alternatively, a manufacturer can transfer its ownership of the selected drug to another entity and continue to sell other drugs to Medicare and Medicaid. *See id.* at 260-61. A manufacturer that pursues neither of these options may also continue to sell the selected drug to Medicare beneficiaries at non-negotiated prices subject to an excise tax. *See* 26 U.S.C. § 5000D(a)-(h); *see also* *Excise Tax on Designated Drugs*, 90 Fed. Reg. 31 (Jan. 2, 2025); Internal Revenue Serv., Notice No. 2023-52 (Aug. 4, 2023), <https://perma.cc/B9JZ-ZG7P> (IRS Notice).

### **III. Implementing the Negotiation Program**

**a.** In addition to the statutory requirements set out above, Congress instructed CMS to implement the Negotiation Program through “program instruction or other forms of program guidance” for the first three negotiation cycles.<sup>2</sup> Act § 11001(c), 136 Stat. at 1854 (42 U.S.C.

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<sup>2</sup> For 2029 and forward, CMS will pursue notice and comment rulemaking in implementing the Negotiation Program. *See* Act § 11001(c), 136 Stat. at 1854 (42 U.S.C. § 1320f note). *See*

§ 1320f note). In June 2023, CMS first published guidance that explains, among many other things, how CMS determines which drugs and biological products may be selected for negotiation and the procedures for participating in the negotiation process. *See CMS, Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026* (June 30, 2023), <https://perma.cc/K6QB-C3MM> (2026 Guidance). On September 30, 2025, after voluntarily soliciting comments, CMS published guidance for initial price applicability year 2028. The 2028 Guidance is materially indistinguishable from the 2026 Guidance and the 2027 Guidance with respect to the issues that AbbVie raises in this suit.

As relevant here, the Guidance discusses the statutory exclusion for “[p]lasma-derived products” from the statutory definition of qualifying single source drugs. Tracking the statutory text, CMS explains that in applying the “[p]lasma-derived products” exclusion, it will consider 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.” *Id.* at 173; *see also* 42 U.S.C. § 1320f-1(e)(3)(C) (excluding “[a] biological product that is derived from human whole blood or plasma” from the definition of “a qualifying single source drug”). CMS has further explained that it will “verify if [a] product is derived from human whole blood or plasma” by referring to the “product information available on the FDA Approved Blood Products website, including the listing of fractionated plasma products” and “databases such as FDALabel and the FDA Online Label Repository.” 2028 Guidance at 173. In making these determinations, CMS “will consult with FDA, as appropriate.” *Id.*

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HHS, *Medicare Drug Price Negotiation Program & Medicare Prescription Drug Benefit Program*, 91 Fed. Reg. 36236 (June 16, 2026) (notice of proposed rulemaking).

b. In January 2026, CMS selected drugs for the third negotiation cycle. *See* Fact Sheet, CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2028* (Jan. 2026), <https://perma.cc/6YCF-WZEX> (“Jan. 2026 Fact Sheet”). The 15 drugs selected “accounted for approximately \$27 billion in total prescription drug spending under Medicare Part B and Part D” between November 2024 and October 2025 and were used that year by “approximately 1.8 million people with Medicare Part D or Medicare Part B coverage.” Press Release, CMS, *CMS Announces Selection of Drugs for Third Cycle of Medicare Drug Price Negotiation Program, Including First-Ever Part B Drugs* (Jan. 27, 2026), <https://perma.cc/43A6-3MM3>. That included Botox, which is manufactured by AbbVie.<sup>3</sup> *See* Compl. ¶ 52. From November 2024 to October 2025, Botox accounted for approximately \$1,143,070,000 in Medicare Part B and Part D spending, for roughly 390,000 Medicare patients—just under \$3,000 per patient, per year. *See* Jan. 2026 Fact Sheet.

Under a schedule set by Congress, *see* 42 U.S.C. § 1320f-3, negotiations for the third cycle are now underway. By February 28, 2026, manufacturers of all 15 drugs selected for the third negotiation cycle had signed participation agreements, including AbbVie. *See* Fact Sheet, CMS, *CMS Announces Manufacturer Participation in Third Cycle of Medicare Drug Price Negotiation* (Mar. 13, 2026), <https://perma.cc/MH6T-M8VT>. By March 1, 2026, participating manufacturers (and the general public) “had an opportunity to submit data and information on the selected drugs and their therapeutic alternative(s) to CMS.” *Id.* After inviting “each participating drug company with a selected drug to engage in a meeting on its data submission,” CMS sent initial offers by June 1, 2026. *Id.* Participating manufacturers will respond to those offers later this summer, and

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<sup>3</sup> For purposes of the Negotiation Program, CMS refers to AbbVie’s selected drug as “Botox; Botox Cosmetic,” *see id.*, for reasons that are not relevant to this litigation. For the sake of simplicity and brevity, this brief will use the name “Botox.”

CMS will ultimately hold up to three negotiation meetings with each manufacturer to discuss the offers and relevant evidence. *See id.* The negotiation period ends on November 1, 2026. *Id.* If negotiations result in agreement on a maximum fair price, and assuming that none of the manufacturers withdraw from the Negotiation Program by December 2027, those prices would take effect approximately one additional year later, on January 1, 2028. 42 U.S.C. §§ 1320f(b), (d), 1320f-2(a), 1320f-3(b).

#### IV. Litigation Background

For almost three years now, manufacturers of selected drugs have challenged the constitutionality of the Negotiation Program (or the legality of CMS's implementing guidance) in over a dozen cases around the country.<sup>4</sup> To date, every court to address these claims has rejected them—some on threshold grounds, some on the merits.<sup>5</sup> That includes a prior lawsuit filed in the

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<sup>4</sup> *See Merck & Co. v. Kennedy*, No. 1:23-cv-1615 (D.D.C. filed June 6, 2023); *Dayton Area Chamber of Com. v. Becerra*, No. 3:23-cv-156 (S.D. Ohio filed June 9, 2023); *Bristol Myers Squibb Co. v. Becerra*, No. 3:23-cv-3335 (D.N.J. filed June 16, 2023); *Nat'l Infusion Ctr. Ass'n v. Becerra*, No. 1:23-cv-707 (W.D. Tex. Filed June 21, 2023); *Boehringer Ingelheim Pharm., Inc. v. HHS*, No. 3:23-cv-1103 (D. Conn. filed Aug. 18, 2023); *Janssen Pharms., Inc. v. Becerra*, No. 3:23-cv-3818 (D.N.J. filed July 18, 2023); *AstraZeneca Pharms. LP v. Becerra*, No. 1:23-cv-931 (D. Del. filed Aug. 25, 2023); *Novartis Pharms. Corp. v. Becerra*, No. 3:23-cv-14221 (D.N.J. filed Sept. 1, 2023); *Novo Nordisk Inc. v. Becerra*, No. 3:23-cv-20814 (D.N.J. filed Sept. 29, 2023); *Teva Pharms. USA, Inc. v. Kennedy*, No. 1:25-cv-113 (D.D.C. filed Jan. 15, 2025); *AstraZeneca Pharms. LP v. Kennedy*, No. 1:25-cv-4212 (D. Md. filed Dec. 19, 2025).

<sup>5</sup> *See Dayton Area Chamber of Com. v. Becerra*, 696 F. Supp. 3d 440 (S.D. Ohio 2023); *Boehringer Ingelheim Pharms., Inc. v. HHS*, No. 3:23-cv-01103, 2024 WL 3292657 (D. Conn. July 3, 2024), *aff'd* 150 F.4th 76 (2d Cir. 2025), *cert. denied*, No. 25-799, 2026 WL 1377142 (May 18, 2026); *Bristol Myers Squibb Co. v. Becerra*, Nos. 23-cv-3335, 23-cv-3818, 2024 WL 1855054 (D.N.J. Apr. 29, 2024), *aff'd*, 155 F.4th 245 (3d Cir. 2025), *cert. denied*, No. 25-751, 2026 WL 1377095 (May 18, 2026); *Novo Nordisk Inc. v. Becerra*, No. 23-20814, 2024 WL 3594413 (D.N.J. July 31, 2024), *aff'd* 154 F.4th 105 (3d Cir. 2025), *cert. denied*, No. 25-761, 2026 WL 1377130 (May 18, 2026); *Novartis Pharms. Corp. v. Becerra*, No. 23-14221, 2024 WL 4524357, at \*2 (D.N.J. Oct. 18, 2024), *aff'd* 155 F.4th 223 (3d Cir. 2025), *cert. denied*, No. 25-902, 2026 WL 1377118 (May 18, 2026); *Nat'l Infusion Ctr. Ass'n v. Kennedy*, 798 F. Supp. 3d 748 (W.D. Tex. 2025), *appeal pending*, No. 25-50661 (5th Cir. docketed Aug. 15, 2025); *Teva Pharm., USA, Inc. v. Kennedy*, No. 25-113, 2025 WL 3240267 (D.D.C. Nov. 20, 2025), *appeal pending*, No. 25-5425 (D.C. Cir. docketed Nov. 30, 2025).

Southern District of Ohio by the Chamber of Commerce of the United States and the Dayton Area Chamber of Commerce, in which the plaintiffs’ original theory of associational standing was premised entirely on AbbVie joining the Dayton Area Chamber of Commerce. *Dayton Area Chamber of Com. v. Becerra*, 696 F. Supp. 3d 440, 445-46 (S.D. Ohio 2023) (Newman, J.) (“Plaintiffs state that the biopharmaceutical company AbbVie—a member of the Dayton Area Chamber of Commerce and the U.S. Chamber of Commerce—‘markets the drug Imbruvica’ and will be injured by the Program.”).

In that case, the U.S. District Court for the Southern District of Ohio (Newman, J.) denied a motion for a preliminary injunction on the theory that plaintiffs were not likely to succeed on the merits of similar constitutional claims as those presented here. *See id.* at 456 (“The law established in the Sixth Circuit and beyond is clear: participation in Medicare, no matter how vital it may be to a business model, is a completely voluntary choice.”). Eventually, the district court granted the government’s motion to dismiss that suit for lack of venue, concluding that AbbVie had “attempted to manipulate the system and manufacture standing to obtain a favorable venue” by joining the Dayton Area Chamber of Commerce “for the purpose of forum shopping.” *Dayton Area Chamber of Com. v. Becerra*, No. 3:23-cv-156, 2024 WL 3741510, at \*9 (S.D. Ohio Aug. 8, 2024). The Sixth Circuit affirmed. *See Dayton Area Chamber of Com. v. Kennedy*, 147 F.4th 626, 633 (6th Cir. 2025) (discussing AbbVie’s efforts to use the Dayton Chamber as a “stalking horse” to “seek[] a perceived favorable venue” that it “could not obtain on [its] own”).

This case, by contrast, is brought by AbbVie, Inc. (“AbbVie”) directly, in its own name. AbbVie’s primary argument is that CMS erred in determining that Botox is a “qualifying single source drug,” on the theory that it should have been excluded as a “biological product that is derived from human whole blood or plasma.” 42 U.S.C. § 1320f-1(e)(3)(C). AbbVie advances

that theory both under the Administrative Procedure Act (APA), *see* Compl. ¶¶ 54-62 (Count I), and as an ultra vires claim, *see id.* ¶¶ 64-67 (Count II).

Although they get less attention in AbbVie’s briefs, AbbVie also brings three constitutional claims: a First Amendment compelled-speech claim, *see id.* ¶¶ 79-88 (Count IV); a physical takings claim under the Takings Clause of the Fifth Amendment, *see id.* ¶¶ 69-77 (Count III); and a due process claim under the Fifth Amendment, *see id.* ¶¶ 90-95 (Count V). AbbVie seeks a series of declaratory judgments, an order that would “[v]acate and set aside CMS’s selection of BOTOX” for the Negotiation Program, and “a permanent injunction enjoining CMS from applying the drug-pricing provisions of the IRA to BOTOX.” Compl., Prayer for Relief.

## ARGUMENT

### **I. PLAINTIFF’S STATUTORY CLAIM FAILS (COUNTS I AND II).**

AbbVie’s statutory-interpretation claim (Counts I and II) should be dismissed for lack of subject-matter jurisdiction because it challenges an agency determination over which Congress expressly provided that “[t]here shall be no administrative or judicial review.” 42 U.S.C. § 1320f-7. Ultimately, AbbVie’s statutory claim boils down to its disagreement with CMS’s determination that Botox is a “qualifying single source drug” and not, as AbbVie argues, subject to the “[p]lasma-derived products” exclusion. That claim is plainly a challenge to CMS’s “determination of qualifying single source drugs” under § 1320f-1(e), which is explicitly barred from “judicial review.” 42 U.S.C. § 1320f-7(2).

Regardless, AbbVie’s statutory claim would also fail on the merits. CMS appropriately refused to apply the “[p]lasma-derived products” exclusion to Botox. *See* 42 U.S.C. § 1320f-1(e)(3)(C). As explained below, that exclusion only applies where the drug contains an active ingredient that “is derived from human whole blood or plasma.” *Id.* As AbbVie admits, the only

active ingredient in Botox is Botulinum Toxin Type A, which—although a “biological product”—is not derived from human whole blood or plasma. Thus, the exclusion is inapplicable.<sup>6</sup>

**A. Congress explicitly precluded judicial review of AbbVie’s statutory claims.**

Congress expressly provided that “[t]here shall be no administrative or judicial review” of (1) CMS’s “selection of drugs” for negotiation under § 1320f-1(b); (2) its “determination of negotiation-eligible drugs” under § 1320f-1(d); or (3) its “determination of qualifying single source drugs” under § 1320f-1(e). 42 U.S.C. § 1320f-7(2). Those prohibitions straightforwardly encompass AbbVie’s statutory claim, which challenges CMS’s “determination” that Botox is a “qualifying single source drug.” *Id.* AbbVie’s arguments to the contrary lack merit.

*i. CMS’s determination that Botox is a “qualifying single source drug” is precluded from review under the IRA.*

It is well established that “Congress may determine a lower federal court’s subject-matter jurisdiction.” *Kontrick v. Ryan*, 540 U.S. 443, 452 (2004). Although there is a “strong presumption that Congress intends judicial review of administrative action,” *Bowen v. Mich. Acad. of Fam. Physicians*, 476 U.S. 667, 670 (1986), when Congress “provides that ‘there shall be no administrative or judicial review’ of specified agency actions, its intent to bar review is clear,” *DCH Reg’l Med. Ctr. v. Azar*, 925 F.3d 503, 505-06 (D.C. Cir. 2019) (citation modified) (quoting 42 U.S.C. § 1395nn(i)(3)(I)); *see* 5 U.S.C. § 701(a)(1) (confirming that APA review is unavailable where “statutes preclude judicial review”). The only question in those circumstances is “whether the challenged action falls ‘within the preclusive scope’ of the statute.” *DCH Reg’l*, 925 F.3d at 506 (quoting *Knapp Med. Ctr. v. Hargan*, 875 F.3d 1125, 1128 (D.C. Cir. 2017)).

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<sup>6</sup> To be precise, AbbVie’s filings refer to the active ingredient of Botox as “onabotulinumtoxinA” rather than (as CMS does) “Botulinum Toxin Type A.” Nothing turns on that distinction here, however, as it is undisputed that neither Botulinum Toxin Type A nor onabotulinumtoxinA is derived from human whole blood or plasma.

Here, that is a straightforward inquiry. AbbVie’s filings openly and directly challenge CMS’s determination of whether or not Botox qualifies as a “qualifying single source drug” under § 1320f-1(e). AbbVie asserts that CMS misapplied the IRA’s definition of “qualifying single source drug”—specifically, by erring in refusing to exclude Botox from that definition on the basis that it is a “[p]lasma-derived product” under § 1320f-1(e)(3)(C).

In its own words, AbbVie’s statutory claim takes issue with CMS’s determination that Botox is a “qualifying single source drug” because, according to AbbVie, Botox should have been excluded from the list of qualifying single source drugs under the “[p]lasma-derived products” exclusion. Mem. in Supp. of Pl.’ Mot. for Summ. J. at 26, ECF No. 25 (“Pl.’s MSJ Br.”) (“In its whole, finished form as a licensed biological product, Botox is ‘derived from human whole blood or plasma.’ (citation omitted)). Indeed, the subject headings in the Argument section of AbbVie’s brief leave no doubt about the nature of AbbVie’s theory: “Under The IRA’s Plain Text, BOTOX Is A ‘Plasma-Derived Product’ That Is Ineligible For Price Controls.” *Id.* at 23; *see also id.* at 24 (“BOTOX Is A ‘Biological Product’ Within The Meaning Of The IRA”); *id.* at 26 (“BOTOX Is ‘Derived From Human Whole Blood Or Plasma’”). That is a straightforward challenge to CMS’s “determination of qualifying single source drugs.” 42 U.S.C. § 1320f-7(2).

AbbVie is wrong about this claim on the merits, *see infra* Section I.C—but right or wrong, the claim directly challenges CMS’s “determination of qualifying single source drugs.” 42 U.S.C. § 1320f-7(2). Congress expressly precluded judicial review of this determination. *See id.*; *accord Novo Nordisk*, 2024 WL 3594413 at \*3 (“Congress has divested this Court of jurisdiction to consider challenges under the APA to CMS’s determinations under 1320f-1(b), (d), (e), and (f).”).

Notably, unlike other litigants, AbbVie does not argue that the IRA’s review bar is inapplicable by recasting its claim as a challenge to the means by which drugs are determined to

be a “qualifying single source drug,” rather than a challenge to the determination itself.<sup>7</sup> That omission was prudent. In construing the Medicare statute’s other review bars, the D.C. Circuit has already explained that when Congress precludes judicial review of a decision, it also precludes review of any preceding issues that are “inextricably intertwined” with the final decision. *DCH Reg’l*, 925 F.3d at 507 (first citing *Fla. Health Scis. Ctr., Inc. v. HHS*, 830 F.3d 515, 521 (D.C. Cir. 2016); then citing *Tex. All. for Home Care Servs. v. Sebelius*, 681 F.3d 402, 411 (D.C. Cir. 2012); and then citing *Mercy Hosp., Inc. v. Azar*, 891 F.3d 1062, 1066-67 (D.C. Cir. 2018)). For example, a statute precluding administrative and judicial review of “the awarding of contracts,” 42 U.S.C. § 1395w-3(b)(12), is not limited to “the awarding of a single contract but” rather applies “to ‘the awarding of contracts’ generally.” *Texas All.*, 681 F.3d at 410. Thus, because the process of awarding contracts “requires the formulation and application of financial standards,” the statute’s bar on review extends to an agency rule adopting such standards. *Id.*

In another context, the D.C. Circuit similarly held that a statutory bar on judicial review of “[a]ny estimate of the Secretary for purposes of determining [specified] factors” precluded review of a challenge to “‘the methodology adopted and employed’ by HHS to calculate” one of those factors. *DCH Reg’l*, 925 F.3d at 505 (first alteration in original) (quoting 42 U.S.C. § 1395ww(r)(3)(A)). The court explained that a “distinction between methodology and estimates

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<sup>7</sup> A version of that theory was accepted by another district court in this district, in a case that is currently on appeal. *Teva Pharms., USA, Inc. v. Kennedy*, No. 25-113, 2025 WL 3240267 (D.D.C. Nov. 20, 2025) (Sooknanan, J.), *appeal pending*, No. 25-5425 (D.C. Cir. Nov. 30, 2025). Although the district court in *Teva* ultimately sided with CMS on the merits, it concluded that it had jurisdiction to review CMS’s determination that Teva’s drug was a qualifying single source drug. *Id.* at \*7-9. In doing so, the court interpreted Supreme Court and D.C. Circuit precedent as permitting review of “policies ‘leading to’ . . . determinations” even where Congress “barr[ed] review of an individual determination.” *Id.* at \*7 (citation omitted). For the reasons discussed here, the district court’s refusal to apply the review-preclusion provision was, respectfully, based on a misreading of precedent.

would eviscerate the statutory bar” against review because “almost any challenge to an estimate could be recast as a challenge to its underlying methodology.” *Id.* at 506. Because the “method” used by the agency and challenged by the plaintiff was “inextricably intertwined” with the “estimate,” this Court held that the statute “precludes review of both.” *Id.* at 507; *see Florida Health*, 830 F.3d at 519.

The same logic governs here. Congress precluded review of CMS’s “determination of qualifying single source drugs.” 42 U.S.C. § 1320f-7(2). The means by which CMS determines the list of qualifying single source drugs is by applying the statutory definition. CMS has no discretion over which drugs it determines are qualifying. *See id.* § 1320f-1(e). Determining the drugs, in effect, means generating the list of drugs that meet the definition. Put another way, in precluding review of the agency’s “determination” of qualifying single source drugs and its “determination” of negotiation-eligible drugs, Congress shielded from review both the agency’s identification of such drugs “and ‘the process by which [the agency] reaches this [identification].” *See Novo Nordisk Inc. v. HHS*, 154 F.4th 105, 111-13 (3d Cir. 2025), *cert. denied sub nom. Novo Nordisk Inc. v. Kennedy*, No. 25-761, 2026 WL 1377130 (U.S. May 18, 2026) (emphasis and first alteration in original) (quoting *Bakran v. DHS*, 894 F.3d 557, 563 (3d Cir. 2018)).

Thus, any attempt by AbbVie to recast its claim as a challenge to CMS’s definition of “a qualifying single source drug” (as opposed to its determination regarding the same) would fail because the meaning of “qualifying single source drug” is indispensable to that determination.

- ii. AbbVie cannot circumvent the review bar by arguing that the jurisdictional inquiry requires this Court to examine the merits.*

AbbVie attempts to circumvent the review bar by arguing that “the judicial-review bar ‘merges consideration of the legality of [Defendants’] action with consideration of the court’s

jurisdiction.” Pl.’s MSJ Br. at 17 (quoting *Am. Hosp. Ass’n v. Azar*, 964 F.3d 1230, 1238 (D.C. Cir. 2020) (alteration in original)). This merger, AbbVie argues, requires that this Court “consider the merits of [its] claims to decide whether the judicial-review bar applies in the first place.” *Id.* at 16. This theory fails.

The cases cited by AbbVie stand for the unremarkable proposition that 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.” *Am. Hosp. Ass’n*, 964 F.3d at 1238 (citation omitted). In *American Hospital Association*, for instance, the relevant provision barred review of “‘establishment of methods,’” but plaintiffs argued “that the payment reduction at issue [was] *not* a ‘method[]’ . . . within the meaning of the statute” to begin with. *Id.* (first alteration added) (quoting 42 U.S.C. § 1395l(t)(12)(A)). So, “to determine whether the judicial-review bar applie[d]” in the first place, the court had to decide “whether the challenged agency action count[ed] as a ‘method.’” *Id.* (citation omitted). At least in that case, that inquiry was essentially the same as the “merits issue presented.” *Id.*

But here, the jurisdictional and merits inquiries raise *different* questions. The merits of AbbVie’s claim turns on the *lawfulness* of CMS’s determination that Botox is a qualifying single source drug under section 1320f-1(e)—*e.g.*, whether CMS was right or wrong in determining that Botox did not qualify as a plasma-derived product (and thus *did* qualify as a “qualifying single source drug”). That inquiry is about the *merits* of the agency’s decision. But the jurisdictional inquiry only looks to the *nature* of the challenged agency decision, by asking whether the challenged CMS action was (regardless of its correctness) a “determination” as to whether Botox was a “qualifying single source drug[] under section 1320f-1(e).” 42 U.S.C. § 1320f-7(2). This Court can answer the latter question in the affirmative without examining the former. And

tellingly, even AbbVie does not dispute that it is challenging CMS’s “determination” that Botox was a “qualifying single source drug.” It simply takes issue with the merits of that determination. Pl.’s MSJ Br. at 20. But right or wrong, a “determination” that Botox is a “qualifying single source drug[] under section 1320f-1(e)” is precisely “the kind of [determination] for which review is barred.” *Am. Hosp. Ass’n*, 964 F.3d at 1238 (citation omitted); *see also* 42 U.S.C. § 1320f-7(2).

Hoping to shoehorn its merits arguments into this Court’s *jurisdictional* analysis, AbbVie essentially argues that the review bar only bars review of *lawful* “determination[s] of qualifying single source drugs under section 1320f-1(e).” 42 U.S.C. § 1320f-7(2); *see* Pl.’s MSJ Br. at 17 (arguing that the “review bar is inapplicable unless” the agency “complied with” section 1320f-1(e)). So, AbbVie reasons, this Court must first examine the lawfulness of CMS’s “determination” to determine whether the review bar applies at all. Putting aside the fact that this argument misconstrues the text of the review bar, *see infra* 20-22, it is a transparent attempt to create an end-run around Congress’s review bar through a tortured reframing of the claim. It also overreads the D.C. Circuit caselaw by conflating a challenge to the legality of CMS’s determination with a claim that “the [determination] fails to qualify as the kind of action for which review is barred.” *Am. Hosp. Ass’n*, 964 F.3d at 1238 (citation omitted). As explained above, those two claims can be adjudicated independently here, and are not “coextensive.” *DCH Reg’l*, 925 F.3d at 510.

AbbVie’s theory would also render meaningless Congress’s decision to preclude judicial review. That is because, on AbbVie’s theory, all meritless challenges would be precluded, while all meritorious challenges would proceed—which is exactly what would happen if Congress had omitted the review bar altogether. Any such reading would be inconsistent with the very precedent on which AbbVie relies. *See, e.g., COMSAT Corp. v. FCC*, 114 F.3d 223, 227 (D.C. Cir. 1997) (explaining that its “construction of [the review preclusion],” which permitted review of merits

questions that merge with the jurisdictional inquiry “d[id] not strip the [preclusion] of meaning” because some government actions remained shielded from review). The undeniable fact that AbbVie’s reading would “strip [the IRA’s review bar] of meaning,” *id.*, highlights that its theory stretches the caselaw beyond its bounds.

Putting aside its misapplication of the caselaw, AbbVie’s argument is also entirely detached from the text of the review bar. Again, AbbVie’s position is, effectively, that the review bar only applies to *lawful* determinations of qualifying single source drugs “under” section 1320f-1(e). Pl.’s MSJ Br. at 17 (quoting 42 U.S.C. § 1320f-7(2)). But the text imposes no such condition; it bars judicial review of *all* “determination[s]” “under section 1320f-1(e)”—including mistaken ones. Indeed, the entire point of the review bar is to prevent the judiciary from second-guessing the lawfulness of such determinations. Reading it AbbVie’s way would effectively strike that provision from the statute’s text. *See Pugin v. Garland*, 599 U.S. 600, 607 (2023) (courts “should not lightly conclude that Congress enacted a self-defeating statute” (citation omitted)).

In an effort to find some textual hook for its argument, AbbVie latches on to the word “under.” *See* Pl.’s MSJ Br. at 17. As AbbVie sees it, a determination “under section 1320f-1(e)” is not truly “*under* section 1320f-1(e)” unless it is also *lawful* “under section 1320f-1(e).” 42 U.S.C. § 1320f-7(2) (emphasis added); *see* Pl.’s MSJ Br. at 17. Again, this reading is at odds with the text’s ordinary meaning. After all, even an *erroneous* “determination” by CMS that a drug is (or is not) a “qualifying single source drug[] under section 1320f-1(e)” is still *a* “determination” that a drug is (or is not) a “qualifying single source drug[] under section 1320f-1(e).” 42 U.S.C. § 1320f-7(2). Nothing about the word “under” creates a freestanding, threshold “lawfulness” requirement. Indeed, Congress routinely uses the phrase “under [provision]” without first assuming the legality of the relevant action. *See, e.g.*, 42 U.S.C. § 1983 (providing that a litigant

can bring a civil-rights claim challenging action “under color of” state law regardless of whether the claim is meritorious “under” that state law).

AbbVie nevertheless insists that the Court must inject this sort of lawfulness requirement into the review bar because otherwise, “the limiting phrases ‘under section 1320f-1(b),’ ‘under section 1320f-1(d),’ and ‘under section 1320f-1(e)’ would be . . . ‘superfluous.’” Pl.’s MSJ Br. at 20 (quoting *Feliciano v. Dep’t of Transp.*, 605 U.S. 38, 53 (2025)). That is wrong. The limiting phrases have a clear purpose as written: they cabin the review bar in Section 1320f-7(2) to the categories of CMS “determination[s]” and “selection[s]” identified in sections 1320f-1(b), 1320f-1(d), and 1320f-1(e)—while excluding *other* unlisted CMS decisions such as (for example) the imposition of a civil penalty under section 1320f-6. See *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 114 (2014) (under the statutory canon of *expressio unius est exclusio alterius*, Congress’s express inclusion of some limitations implies that it did not intend to impose unidentified limitations). The limiting phrases play an important role in clarifying that agency decisions under sections 1320f-1(b), 1320f-1(d), and 1320f-1(e)—whether lawful or unlawful—“qualify as the kind of action[s] for which review is barred,” while decisions under unlisted sections of the IRA, such as section 1320f-6, “fail[] to qualify as [such].” *Am. Hosp. Ass’n*, 964 F.3d at 1238 (citation omitted).

Notably, despite purporting to save the provision from a superfluity problem, AbbVie’s interpretation creates one. As AbbVie would have it, any manufacturer can short-circuit the review bar by arguing that CMS’s determinations and selections are not *true* determinations or selections under sections 1320f-1(b), 1320f-1(d), and 1320f-1(e) because they are unlawful under sections 1320f-1(b), 1320f-1(d), and 1320f-1(e). Under this theory, virtually every grievance with CMS’s determinations and selections—if phrased cleverly enough—can slip past the review bar. Thus, it

is AbbVie’s reading—not the government’s—that leads to “superfluous language.” *Feliciano*, 605 U.S. at 53. This Court should reject AbbVie’s theory, which is not only detached from the text of the review bar, but would effectively render the review bar a nullity.

**B. Plaintiff cannot evade the statutory review bar through an ultra vires claim.**

AbbVie cannot avoid this result by invoking the ultra vires doctrine. Such claims may proceed “only when three requirements are met: ‘(i) the statutory preclusion of review is implied rather than express; (ii) there is no alternative procedure for review of the statutory claim; and (iii) the agency plainly act[ed] in excess of its delegated powers and contrary to a specific prohibition in the statute that is clear and mandatory.’” *DCH Reg’l*, 925 F.3d at 509 (quoting *Nyunt v. Chairman, Broad. Bd. of Governors*, 589 F.3d 445, 449 (D.C. Cir. 2009)). It is the equivalent of “a Hail Mary pass—and in court as in football, the attempt rarely succeeds.” *Nuclear Regul. Comm’n v. Texas*, 605 U.S. 665, 681-82 (2025) (citation omitted). This case is no exception.

Here, any ultra vires argument would fail at the first step because the IRA “express[ly]” bars review of AbbVie’s challenge. *DCH Reg’l*, 925 F.3d at 509; *see also Nuclear Regul. Comm’n*, 605 U.S. at 681 (ultra vires review is not available if “a statutory review scheme forecloses all other forms of judicial review”); *Novo Nordisk*, 2024 WL 3594413 at \*3 (“[B]ecause it is an express statutory preclusion it also effectively prohibits this Court from reviewing those determinations on so-called *ultra vires* principles.”).

The argument would also fail at the third step, which requires a showing that “the agency plainly act[ed] . . . contrary to a specific prohibition in the statute that is clear and mandatory.” *DCH Reg’l*, 925 F.3d at 509 (citation omitted). Under this standard, AbbVie cannot sustain an ultra vires claim even if CMS “has arguably reached ‘a conclusion which does not comport with the law.’” *Nuclear Regul. Comm’n*, 605 U.S. at 681 (citation omitted). An ultra vires claim

requires a showing that “an agency has taken action entirely ‘in excess of its delegated powers and contrary to a *specific prohibition*’ in a statute.” *Id.* (citation omitted). AbbVie has not identified any such “specific prohibition”—let alone shown that CMS violated it. *Id.* (emphasis omitted) (citation omitted).

AbbVie’s statutory claim should thus be dismissed for lack of subject-matter jurisdiction.

**C. Plaintiff’s statutory claim lacks merit.**

Even if this Court had jurisdiction, CMS was correct to determine that Botox does not fit within the “[p]lasma-derived products” exclusion to the IRA’s definition of a “qualifying single source drug.” *See* 42 U.S.C. § 1320f-1(e)(3)(C).

Under the IRA, “a qualifying single source drug” includes a “biological product . . . that is licensed under [42 U.S.C. §] 262(a) and is marketed under [42 U.S.C. §] 262,” “at least 11 years will have elapsed since the date of [its] licensure[,]” and “is not the reference product for” a biosimilar or interchangeable product under 42 U.S.C. § 262(k). *Id.* § 1320f-1(e)(1)(B). AbbVie does not dispute that Botox satisfies all of these conditions. Instead, it argues only that Botox falls into the narrow “[p]lasma-derived products” exclusion, which provides that “[a] biological product that is derived from human whole blood or plasma” is not “a qualifying single source drug.” *Id.* § 1320f-1(e)(3)(C). AbbVie is wrong.

As explained below, whether a biological product is plasma-derived under section 1320f-1(e)(3)(C) turns on its active ingredient. Here, the only active ingredient in Botox is Botulinum Toxin Type A, which is undisputedly not “derived from human whole blood or plasma.” *Id.* And although Botox also contains human serum albumin (HSA), which is derived from human plasma, that ingredient is an inactive ingredient in Botox. The “[p]lasma-derived products” exclusion is

thus inapplicable to Botox, because the Botulinum Toxin Type A it contains is not “derived from human whole blood or plasma” and because the HSA it contains is an inactive ingredient. *Id.*

For its part, AbbVie does not dispute the fact that Botulinum Toxin Type A is not “derived from human whole blood or plasma,” nor does it dispute the fact that HSA functions as an inactive ingredient in Botox. Instead, it argues that Botox itself—*i.e.*, the finished product—is “[a] biological product that is derived from human whole blood or plasma” because it *contains* HSA. 42 U.S.C. § 1320f-1(e)(3)(C); *see* Pl.’s MSJ Br. at 23-31. For the reasons below, AbbVie’s argument relies on an interpretative theory that is detached from the statutory text and structure.

1. The IRA’s text, structure, and underlying purpose confirm that for purposes of identifying a “qualifying single source drug” under 42 U.S.C. § 1320f-1(e), and its corresponding exclusion for “[p]lasma-derived products” in section 1320f-1(e)(3)(C), the focus of the inquiry is on the active ingredient of the biological product.

The IRA’s overarching goal is to identify the most expensive drugs and biological products for participation in the Negotiation Program. In order to achieve this goal, the IRA requires CMS to consider all dosage forms, strengths, and formulations of a “drug” (referring to both “drug” and “biological product”) together,<sup>8</sup> “and not based on the specific formulation or package size or package type of such drug.” *id.* § 1320f-5(a)(2); *see also id.* § 1320f-1(d)(3)(B). This requirement applies at each stage of the process—from the identification and selection of negotiation-eligible drugs to the negotiations themselves and finally (if negotiations succeed) to the application of a negotiated price.

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<sup>8</sup> Under the IRA, “qualifying single source *drug[s]*,” *id.* 42 U.S.C. § 1320f-1(e) (emphasis added), include both “*drug[s]*” under section 1320f-1(e)(1)(A), and “*biological product[s]*,” under section 1320f-1(e)(1)(B).

Congress expressly directed CMS to identify “negotiation-eligible drugs” according to Medicare spending data, to rank these drugs according to this data, and then select the top drugs on the list for negotiation. When calculating Medicare expenditures for a drug at each of these steps, CMS must aggregate the spending 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 type* of the drug.” *Id.* § 1320f-1(d)(3)(B) (emphases added). By requiring CMS to consider the total expenditures for a drug across its variations, the statute ensures that CMS identifies and selects the drugs that have the most significant financial impact on Medicare as a whole.

The next steps in the process are in keeping with this approach. Once CMS selects a drug for negotiation, CMS is required to consider all “applications and approvals,” in the plural, “for the drug,” in the singular, when determining how much to offer in negotiations. *Id.* § 1320f-3(e)(1)(D). This step, like the earlier ones, contemplates that one drug may be offered in a number of forms that may correspond to different applications or approvals. And CMS is expressly required to consider all “applications and approvals” (plural) “for the drug” (singular) when determining how much to offer in negotiations. *Id.* Finally, after negotiations are completed and a price is established, CMS must “apply the maximum fair price across different strengths and dosage forms of a selected drug and not based on the specific formulation or package size or package type” of the drug. *Id.* § 1320f-5(a)(2).

Simply put, the structure and purpose of the IRA require CMS to aggregate together all formulations of the same “biological product” across multiple formulations, Biologics License Applications (BLAs), dosages, and strengths in order to identify the most expensive and eligible “biological products” for participation in the Negotiation Program. Based on this structure, CMS

aggregates “biological products” based on active ingredient to determine whether such products are a “qualifying single source drug,” *id.* § 1320f-1(e), and thus similarly applies the corresponding “[p]lasma-derived products” exclusion, *id.* § 1320f-1(e)(3)(C), based on the active ingredient.

2. AbbVie’s interpretation, however, effectively requires a product-specific interpretation of “biological product” as a “qualifying single source drug” based on a different statute: the Public Health Service Act (PHSA). *See* Pl.’s MSJ at 24-25. But the IRA and the PHSA are different statutes with fundamentally different objectives and functions. AbbVie’s reliance on FDA’s product-specific approval framework to argue for a product-specific approach by CMS misunderstands the statutory design and cannot be reconciled with the text of the IRA.

FDA approves drugs and biologics on a product-by-product basis, including their route of administration, dosage form, strength, formulation, and manufacturing process (among other things) to ensure each product’s safety, effectiveness, and quality. *See* 42 U.S.C. § 262(a) (providing for a “[b]iologics license”). Ignoring distinctions between dosage forms, strengths, and formulations would thus be inappropriate in the context of FDA approvals. But in the context of the Negotiation Program, considering biological products with the same active ingredient together permits CMS to identify the biological products with the greatest financial impact on Medicare overall, consistent with the purpose of the program.

In any event, Congress’s repeated instruction to aggregate “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 type of the drug,” 42 U.S.C. § 1320f-1(d)(3)(B), confirms that for purposes of identifying a “qualifying single source drug” (and its exclusions), the relevant inquiry turns on the active ingredient.

AbbVie nonetheless attempts to infer a contrary command from other IRA provisions. For instance, AbbVie observes that the IRA “sets forth the methodology for calculating the rebate that a manufacturer must pay when the Secretary delays selection of ‘a biological product that is a covered part D drug.’” *See* Pl.’s MSJ at 25-26 (quoting 42 U.S.C. § 1320f-1(f)(4)(B)(i)). According to AbbVie, “[a] biological product cannot be a ‘covered part D drug’ unless ‘biological product’ refers to the whole finished product, as Part D provides coverage for finished drugs, not active ingredients.” *See* Pl.’s MSJ at 25-26 (citing 42 U.S.C. § 1395w-102(e)(1); *id.* §§ 1396r-8(k)(2)(A)-(B)). But AbbVie overreads the cross-referenced provision, which merely requires that a biological product be FDA-approved to be eligible for Medicare reimbursement. In any event, AbbVie’s reading of these attenuated cross-references cannot be reconciled with the IRA’s express statutory language directing CMS to consider all dosage forms, strengths, and formulations of a biological product together, *see* 42 U.S.C. § 1320f-1(d)(3)(B), which inherently assumes that a “qualifying single source drug” includes the same active ingredient “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 type of the drug,” *id.*

In sum, consistent with the structure of the IRA and CMS’s approach to the definition of “qualifying single-source drug” more generally, CMS implements the “[p]lasma-derived products” exclusion based on a product’s active ingredient. As such, Botox would only qualify for the exclusion if Botulinum Toxin Type A “is derived from human whole blood or plasma.” 42 U.S.C. § 1320f-1(e)(3)(C). It is not. Thus, CMS correctly concluded that Botox does not satisfy the “[p]lasma-derived products” exclusion to the definition of “qualifying single source drug.” *Id.*

So, AbbVie's remaining statutory arguments, which are premised on the flawed assumption that the entire formulation of Botox is the relevant focus of the plasma-derived exclusion, *see* Pl.'s MSJ Br. at 26-30, all lack merit.

3. In the alternative, even if this Court adopts AbbVie's interpretive approach, which defines "biological product" in a way that examines the entire formulation of Botox as the finished product, the "[p]lasma-derived products" exclusion is still inapplicable. This exclusion applies only to "[a] biological product that is *derived* from human whole blood or plasma." 42 U.S.C. § 1320f-1(e)(3)(C) (emphasis added). And, as even AbbVie admits, Botox is regulated as a "biological product" under the PHSA *because* its active ingredient is Botulinum Toxin Type A. *See* Pl.'s MSJ at 24 (explaining that "[w]hen initially determining whether to classify . . . a biological product requiring approval of a biologics license application under 42 U.S.C. § 262, 'FDA analyzes the product's active ingredient'" and Botox's active ingredient is Botulinum Toxin Type A (quoting *Ipsen Pharmaceuticals, Inc. v. Becerra*, 108 F.4th 836, 838 (D.C. Cir. 2024) and then citing Brin Decl., Ex. 4 at 1)). Thus, in determining whether the "[p]lasma-derived products" exclusion applies to Botox, CMS focuses on the Botulinum Toxin Type A because that is active ingredient that causes Botox to be regulated under the PHSA.

Thus, at least in the context of the "[p]lasma-derived products" exclusion, Botox is not a "biological product that is derived" from human plasma because Botox does not "derive[]" its status as a "biological product" from HSA; rather, it "derive[s]" it from Botulinum Toxin Type A, which is not "human whole blood or plasma." 42 U.S.C. § 1320f-1(e)(3)(C). Botox is a "biological product" (as opposed to a "drug" product), because its active ingredient Botulinum Toxin Type A is a "toxin." 42 U.S.C. § 262(i)(1).

AbbVie’s arguments to the contrary are unavailing. As AbbVie sees it, because Botox contains HSA, Botox is “derived from” human plasma. *See* Pl.’s MSJ Br. at 26-30. But that interpretation is devoid of proper context—namely, that the exclusion only applies to “[b]iological products,” not *all* final products. 42 U.S.C. § 1320f-1(e)(3)(C). If, as AbbVie suggests, IRA sought to apply the exclusion to final products that merely *contain* “human whole blood or plasma,” it would have exempted *all* final products that are “derived from human whole blood or plasma.” *Id.* It did not. Instead, it only exempted “[b]iological products.” *Id.* Naturally, any exclusion that only applies to “[b]iological products” looks to the thing that made the product a “biological product” in the first place. *Id.*

What is more, Congress explicitly instructed CMS to look to the ingredient that the “biological product” “is *derived* from.” *Id.* Although not defined in the IRA, the word “derive” is defined in the dictionary as “to take, receive, or obtain especially from a specified source.” *Derive*, Merriam-Webster’s Dictionary, at <https://www.merriam-webster.com/dictionary/derive>. Here, Congress’s use of the word “derived” in conjunction with “biological product,” 42 U.S.C. § 1320f-1(e)(3)(C), further confirms that CMS must look to the “source” from which a product “take[s], receive[s], or obtain[s]” its status as a “biological product.” Here, the “source” that Botox—as a “biological product”—is “derived from” is Botulinum Toxin Type A.

## **II. PLAINTIFF’S CONSTITUTIONAL CLAIMS FAIL (COUNTS III, IV, AND V).**

Roughly three years after creation of the Negotiation Program by Congress, over a dozen drug manufacturers have filed lawsuits bringing a variety of constitutional challenges to the statute. To date, every single claim has failed, in every single case. AbbVie offers no reason for this Court to depart from that nationwide consensus.

**A. The Negotiation Program is consistent with the Fifth Amendment.**

AbbVie asserts that Congress violated the Fifth Amendment in two different ways when it authorized CMS to negotiate the prices it will pay for certain prescription drugs: first as a physical or “categorical” taking in violation of the Takings Clause, and also as a violation of the Due Process Clause. Both of AbbVie’s Fifth Amendment theories are meritless.

**1. The Negotiation Program does not effect a physical taking of Botox in violation of the Takings Clause.**

Courts have long recognized that government actions that adjust economic relationships, without a physical invasion or appropriation of property, do not amount to a physical taking. In the IRA, Congress established a framework for voluntary negotiations over certain drug prices that fits squarely within this well-established precedent. The Negotiation Program adjusts the terms of the government’s offer to pay for drugs for Medicare beneficiaries, but it does not physically appropriate any manufacturer’s drugs or otherwise compel their surrender or transfer. After all, if AbbVie prefers not to sell Botox to Medicare on the terms established by Congress, it need not sell Botox to Medicare at all.

**a.** The Fifth Amendment provides that private property shall not “be taken for public use, without just compensation.” U.S. Const. amend. V. A “physical appropriation[ ]” occurs when the government “physically takes” or authorizes “possession of property.” *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 147-48 (2021). The government can also effect a “regulatory taking[ ]” by, for example, imposing a regulation so burdensome that it effectively deprives the owner of the property’s economic use. *See Lingle v. Chevron USA Inc.*, 544 U.S. 528, 537 (2005). AbbVie alleges only the first type of taking—a physical appropriation of its personal property. *See Pl.’s MSJ Br.* at 33-34.

To establish a physical takings claim, a plaintiff must show that the government has forcibly appropriated or otherwise compelled the transfer of private property. The Supreme Court analyzed one such claim in *Horne v. Department of Agriculture*, 576 U.S. 350, 364 (2015), which concerned a requirement that raisin growers “physical[ly] surrender” a percentage of their raisin crop to the government as a condition of selling raisins on the open market. The Court held that the requirement constituted a physical taking because it required the transfer of “[a]ctual raisins” from the growers to the government, and growers lost “any right to control the[ ] disposition” of the raisins. *Id.* at 361, 364.

The Supreme Court has distinguished this sort of direct, physical appropriation of personal property from laws that merely restrict the use or limit the value of such property, and which therefore do not effect a *physical* taking. The Court has held, for example, that a law prohibiting the sale of eagle feathers did not effect a taking—even though the law sapped the feathers of all commercial value—because the law neither “compel[led] the surrender of the artifacts” nor resulted in any “physical invasion or restraint upon them,” and the feather owners “retained the rights to possess, donate, and devise their property.” *Horne*, 576 U.S. at 364 (citation omitted) (describing the holding in *Andrus v. Allard*, 444 U.S. 51 (1979)). Relying on that analysis, *Horne* explained that although a regulation limiting the production of raisins might well have “the same economic impact” on a farmer as a requirement to surrender raisins to the government, the former does not constitute a physical taking because it does not entail an appropriation. *Id.* at 362.

The Supreme Court recently reiterated in *Cedar Point* that a physical appropriation is an essential element of a physical takings claim. 594 U.S. 139. The plaintiffs in that case challenged a regulation “grant[ing] union organizers a right to physically enter and occupy” private farmland for up to three hours per day, 120 days a year. *Id.* at 149. In determining whether the regulation

was a physical taking, the Court explained that the “essential question” is “whether the government has physically taken property for itself or someone else.” *Id.* Because the challenged provision granted third parties a right to “literally,” “physically invade the growers’ property,” the Court held that this government-authorized occupation was a physical taking. *Id.* at 152; *see also Lingle*, 544 U.S. at 539; *Bowles v. Willingham*, 321 U.S. 503, 517-18 (1944).

By contrast, courts have long held that when an entity “voluntarily participates in a price-regulated program or activity, there is no legal compulsion to provide” goods or services, “and thus there can be no taking.” *Garelick v. Sullivan*, 987 F.2d 913, 916 (2d Cir. 1993) (citing cases); *see Franklin Mem’l Hosp. v. Harvey*, 575 F.3d 121, 129 (1st Cir. 2009). The Second Circuit, for example, applied these principles to reject a takings challenge to other Medicare pricing restrictions. *Garelick*, 987 F.2d at 918. In that case, physicians challenged statutory caps on the amount they could charge Medicare beneficiaries for services. *Id.* at 914-15. The Second Circuit rejected the challenge because the physicians “voluntarily choose to provide services in the price-regulated Part B program.” *Id.* at 916.

Other courts of appeals have also rejected similar takings challenges on the grounds that “participation in the Medicare program is a voluntary undertaking.” *Livingston Care Ctr., Inc. v. United States*, 934 F.2d 719, 720 (6th Cir. 1991). Unlike public utilities, which “generally are compelled” by statute “to employ their property to provide services to the public,” *Garelick*, 987 F.2d at 916, no statute or regulation requires entities to sell their products or services to Medicare. As a result, when addressing regulations limiting physician fees, nursing-home payments, or hospital reimbursements, courts have been unequivocal: Because providers are not required to offer services to Medicare beneficiaries, the government deprives them of no property interest for purposes of the Fifth Amendment when it limits the amount it will pay for such

services. *See Se. Ark. Hospice, Inc. v. Burwell*, 815 F.3d 448, 450 (8th Cir. 2016) (“[The plaintiff] voluntarily chose to participate in the Medicare hospice program. ‘This voluntariness forecloses the possibility that the statute could result in an imposed taking of private property which would give rise to the constitutional right of just compensation.’” (alteration omitted) (quoting *Minnesota Ass’n of Health Care Facilities v. Minnesota Dep’t of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984))); *Franklin Mem’l Hosp.*, 575 F.3d at 129; *Burditt v. HHS*, 934 F.2d 1362, 1376 (5th Cir. 1991) (rejecting takings challenge to reimbursement under Medicare because “[o]nly hospitals that voluntarily participate in the federal government’s Medicare program must comply”); *Baptist Hosp. E. v. HHS*, 802 F.2d 860, 869-70 (6th Cir. 1986); *Whitney v. Heckler*, 780 F.2d 963, 972 (11th Cir. 1986); *St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 875-76 (7th Cir. 1983) (per curiam); *Baker Cty. Med. Servs., Inc. v. DOJ*, 763 F.3d 1274, 1279-80 (11th Cir. 2014).

Those background principles have now been repeatedly applied to reject Takings Clause challenges to the Negotiation Program that are indistinguishable from AbbVie’s here. *See, e.g., Boehringer Ingelheim Pharms., Inc. v. HHS*, 150 F.4th 76, 91 (2d Cir. 2025) (“[B]ecause Boehringer voluntarily chose to participate in the Negotiation Program, no taking has occurred.”); *Bristol Myers Squibb*, 155 F.4th at 2545 (“If the Companies dislike the prices the government is willing to pay, they are free to stop doing business with the government. So the Companies’ participation in the Program is voluntary, and there is no physical taking.”). This Court should take the same approach.

**b.** In contending that the Negotiation Program effects a physical taking, AbbVie points to physical doses of Botox. *See* Pls.’ MSJ Br. at 34. But the Negotiation Program does not mandate any physical appropriation of any Botox. That alone defeats AbbVie’s physical takings claim.

AbbVie cannot allege, for example, that CMS will “sen[d] trucks to [its] facility” to haul away its products as in *Horne*. 576 U.S. at 356. Nor is there any plausible suggestion that AbbVie must otherwise physically turn over its drugs to the government or Medicare beneficiaries. Instead, AbbVie asserts only that the Negotiation Program effects a physical taking by “impos[ing] a ‘maximum fair price’ for BOTOX” and then requiring AbbVie to “‘provide access to such price’ to Medicare enrollees” if the company participates in Medicare. Pl.’s MSJ Br. at 34 (quoting 42 U.S.C. § 1320f-2(a)(1), (3)). But “access” to a “price” for Botox is an entirely different thing from physical access to Botox—particularly when the price is determined through a series of offers and counteroffers made after the manufacturer elects to participate in Medicare and agrees to negotiate.

The requirement to provide “access to [the negotiated] price,” 42 U.S.C. § 1320f-2(a)(1), (3), means only that a manufacturer that chooses to participate in Medicare may not charge Medicare beneficiaries who are dispensed, furnished, or administered the drug more than that price. *See* Guidance § 40.4, p. 208 (“Although the Primary Manufacturer is obligated to provide access to the [maximum fair price (MFP)] for these dosage forms, strengths, and package sizes of the selected drug that are dispensed, furnished, or administered to MFP-eligible individuals, the Primary Manufacturer is not obligated to make any sales of the selected drug.”); *see also id.* § 90.2, p. 321; *id.* § 100.1, p. 338-39.

Contrary to AbbVie’s suggestion, the statute does not require it to sell its drugs to Medicare in the first instance or to give anyone physical access to its drugs over its objection. The Negotiation Program altered what Medicare will pay for certain drugs, but it does not require any pharmaceutical company to accept that offer to pay. Instead, the Negotiation Program gives companies a choice whether to continue doing business with the government on the terms the government is presently offering. A manufacturer is subject to the negotiated price only if it

chooses to sell its drugs to Medicare beneficiaries. As CMS has explained, “the IRA expressly connects a . . . [m]anufacturer’s financial responsibilities under the voluntary Negotiation Program to that manufacturer’s voluntary participation” in Medicare and Medicaid. Guidance § 40.6, p. 259; *see also* 26 U.S.C. § 5000D(c)(1). Thus, as with other restrictions on Medicare spending, providers may choose whether to accept participation on these terms. If AbbVie is dissatisfied with the terms of the government’s offer, it can decline to sell its drugs to Medicare. If it chooses instead to accept the offer and provide its drugs on those terms, it cannot then complain that the government has effected a physical taking of its drugs.

c. AbbVie’s takings argument ultimately rests on the erroneous assumption that it is being coerced to sell its drugs to the government on the terms established by the Negotiation Program because it cannot afford to forgo the profits it accrues through participation in Medicare and Medicaid. In other words, AbbVie argues that, because “Medicare and Medicaid account for a significant percentage of AbbVie’s gross sales,” it would be economically irrational not to participate. Pl.’s MSJ Br. at 41. But the courts of appeals have uniformly held that the economic pressures on the healthcare industry to participate in Medicare do not make such participation involuntary. In other words, economic or other practical “hardship is not equivalent to legal compulsion for purposes of [a] takings analysis.” *Garelick*, 987 F.2d at 917. Thus, even where “business realities” create “strong financial inducement to participate”—*e.g.*, as where Medicaid provides the vast majority of a nursing home’s revenue—the decision to participate in the program “is nonetheless voluntary.” *Minnesota Ass’n*, 742 F.2d at 446; *see also St. Francis Hosp. Ctr.*, 714 F.2d at 875 (the “fact that practicalities may in some cases dictate participation does not make participation involuntary”); *Whitney*, 780 F.2d at 972 n.12 (same). That the government spends significant money on drugs for Medicare and Medicaid, and that this money translates into

substantial (but highly regulated) commercial opportunities for pharmaceutical companies, does not in any relevant sense mandate participation in those programs. *See, e.g., Bristol Myers Squibb*, 155 F.4th at 257 (“Economic factors may have a strong influence on a company’s choice to do business with the government, but a company that chooses to do so still acts voluntarily.”).

This widespread recognition that economic incentives to do business with the government, regardless of their magnitude, do not raise Takings Clause concerns is unsurprising: The fundamental question in a takings case is whether the government has “taken” or appropriated property. When a company retains the option not to sell its products on the offered terms—but chooses to anyway because the alternative is less profitable—nothing has been “taken.”

After all, the government exercises considerable market power across a range of contexts—indeed, in some circumstances, such as defense spending, it may be the only market participant—and that fact has never been understood to transform the government’s bargaining terms into matters of constitutional concern. *Cf. Perkins v. Lukens Steel Co.*, 310 U.S. 113, 127-28 (1940) (observing that “[j]udicial restraint of those who administer the Government’s purchasing would constitute a break with settled judicial practice and a departure into fields hitherto” entrusted to other branches of government). Accordingly, the government has for decades offered to purchase drugs subject to an extensive set of statutory and regulatory requirements that AbbVie has previously accepted. For example, as a condition on its participation in Medicaid, AbbVie has long been required to enter into agreements that give the Department of Defense, the Department of Veterans Affairs, and the Coast Guard the option to purchase drugs at negotiated prices at or below statutory ceilings. *See* 38 U.S.C. § 8126(a)-(h). Pursuant to another condition on Medicaid participation, AbbVie has likewise been required to enter into agreements to provide drugs to

certain healthcare facilities subject to statutory price ceilings. *See Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 113 (2011) (describing requirements under Section 340B of the PHSA).

For each of these programs, providers must choose whether to do business with the government on the terms the government is offering. And these choices have long been held to be voluntary even though the financial incentives to participate are great. The Negotiation Program works the same way. And any company that rejects the government's offer can continue to sell its drugs to any other purchaser. AbbVie's view that the Program is nevertheless mandatory runs counter to longstanding precedent and would have sweeping implications across a wide range of industries and programs.

**2. The Negotiation Program does not deprive AbbVie of a protected property interest in violation of the Due Process Clause.**

As every court to consider the issue has also concluded, the Negotiation Program does not deprive pharmaceutical manufacturers of any protected property interest. *See, e.g., AstraZeneca Pharms. LP v. HHS*, 137 F.4th 116, 125-26 (3d Cir. 2025) ("There is no protected property interest in selling goods to Medicare beneficiaries (through sponsors or pharmacy benefit plans) at a price higher than what the government is willing to pay when it reimburses those costs."), *cert. denied*, No. 25-348, 2026 WL 1377100 (U.S. May 18, 2026); *Boehringer Ingelheim*, 150 F.4th at 94 ("A company suffers no deprivation of its property interests by voluntarily submitting to a price-regulated government program."); *Teva*, 2025 WL 3240267, at \*17 ("In sum, there is no protected property interest in selling goods to Medicare beneficiaries at a price higher than what the government is willing to pay when it reimburses those costs.") (cleaned up). AbbVie offers no good reason to diverge from this consensus view.<sup>9</sup>

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<sup>9</sup> Because this precise question is currently pending before the D.C. Circuit, the Court might wish to consider waiting for the D.C. Circuit's opinion in *Teva* before resolving the parties'

a. The Due Process Clause protects against the deprivation “of life, liberty, or property, without due process of law.” U.S. Const. amend. V. Therefore, the threshold “inquiry in every due process challenge is whether the plaintiff has been deprived of a protected interest” in liberty or property. *Am. Mfrs. Mut. Ins. Co. v. Sullivan*, 526 U.S. 40, 59 (1999). Property interests arise from an independent source, such as state or federal law. *See Bd. of Regents v. Roth*, 408 U.S. 564, 577 (1972). To have a constitutionally protected property interest, “a person clearly must have more than an abstract need or desire for it” and “more than a unilateral expectation of it.” *Id.* Rather, he must have an “individual entitlement” to the property, which “cannot be removed except ‘for cause.’” *Logan v. Zimmerman Brush Co.*, 455 U.S. 422, 430 (1982) (quoting *Memphis Light, Gas & Water Div. v. Craft*, 436 U.S. 1, 11-12 (1978)).

“[N]o one has a ‘right’ to sell to the government that which the government does not wish to buy.” *Coyne-Delany Co. v. Capital Dev. Bd.*, 616 F.2d 341, 342 (7th Cir. 1980) (per curiam). “Like private individuals and businesses, the Government enjoys the unrestricted power to produce its own supplies, to determine those with whom it will deal, and to fix the terms and conditions upon which it will make needed purchases.” *Perkins*, 310 U.S. at 127.

Pursuant to the government’s power to determine the prices it will pay for goods and services, other agencies have for decades negotiated with drug manufacturers over the price paid for drugs in other government programs. *E.g.*, 38 U.S.C. § 8126(a)-(h). Similarly, as a condition of Medicaid participation, manufacturers have long entered into agreements to provide drugs to certain healthcare facilities subject to statutory price ceilings. *See Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011) (describing requirements under Section 340B of the Public Health

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pending motions in this case. Oral argument before the D.C. Circuit was held on May 5, 2026. *See Teva v. Kennedy*, No. 25-5425 (D.C. Cir.).

Service Act). And the government regularly negotiates the price it will pay for other goods. *See, e.g.*, 48 C.F.R. pts. 15, 215. Just as military contractors have no right to sell their products to the Department of Defense at prices above what the government is willing to pay, “[t]here is no protected property interest in selling goods to Medicare beneficiaries (through sponsors or pharmacy benefit plans) at a price higher than what the government is willing to pay when it reimburses those costs.” *AstraZeneca*, 137 F.4th at 125-26; *see Teva*, 2025 WL 3240267, at \*17.

In negotiating the price that Medicare will pay for drugs, the government is acting as a market participant. The Act sets the terms of the government’s offer to pay for certain drugs. While manufacturers may use their market power to negotiate with the government, they have no right to force the government to pay for their drugs on specific terms. Plaintiffs’ contrary view does not reflect how the market works, nor is it consistent with Congress’s undoubted authority to control federal spending. The Negotiation Program reflects Congress’s judgment that American taxpayers have been spending too much on high-cost prescription drugs, and the government has a strong interest in controlling federal spending to promote the general welfare. *See Sabri v. United States*, 541 U.S. 600, 608 (2004) (“The power to keep a watchful eye on expenditures . . . is bound up with congressional authority to spend in the first place . . .”).

**b.** Even if manufacturers could establish the existence of a protected property interest, the Negotiation Program does not *deprive* them of any property. No manufacturer is compelled to participate in the Negotiation Program. Again, as courts have repeatedly stressed, participation in Medicare is a voluntary choice. *See, e.g., Burditt v. HHS*, 934 F.2d 1362, 1376 (5th Cir. 1991); *Baptist Hosp. E. v. HHS*, 802 F.2d 860, 869-70 (6th Cir. 1986). Participation does not become involuntary just because participation is particularly lucrative. *See, e.g., Garelick*, 987 F.2d at 917. A manufacturer with a drug selected for the Negotiation Program has a choice: it may remain in

Medicare because it concludes that the benefits still outweigh the burdens, or it may withdraw in as little as 30 days, *see* 42 U.S.C. §§ 1395w-114a(b)(4)(B)(i), 1395w-114c(b)(4)(B)(i); Guidance 199-201; *Bristol Myers Squibb*, 155 F. 4th at 256-57.<sup>10</sup>

Plaintiffs' insistence that manufacturers' participation in Medicare is involuntary is relevant to the due process analysis only to the extent they argue that government coercion is the mechanism by which manufacturers are deprived of their purported interests. Because "no one has a 'right' to sell to the government that which the government does not wish to buy," *Coyne-Delany Co.*, 616 F.2d at 342, there is no protected property right implicated in a manufacturer's expectancy of further participation in a government spending program. *See also Perkins*, 310 U.S. at 127. Thus, a manufacturer that chooses voluntarily to participate in a government program cannot complain that the sheer act of participation deprives it of a property right. *See Boehringer Ingelheim*, 150 F.4th at 94.

c. AbbVie's arguments to the contrary all lack merit. *First*, there is no due process right on the part of a manufacturer to dictate the price at which it sells products—at the very least, not to the federal government. *Old Dearborn Distrib. Co. v. Seagram-Distillers Corp.*, 299 U.S. 183 (1936) (cited at Pl.'s MSJ Br. at 34-35), is not to the contrary. Citing a line of cases that have long since been overruled, *Old Dearborn* asserted that legislatures generally may not impair "the right of the owner of property to fix the price at which he will sell" his property in the broader

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<sup>10</sup> While AbbVie claims to fear that withdrawal from Medicare might take 11 to 23 months, it ultimately acknowledges that CMS's guidance confirms that a manufacturer may withdraw in as little as 30 days. *See* Pl.'s MSJ Br. at 39-40. AbbVie suggests that the 30-day withdrawal option is inconsistent with the statute, *see id.*, but AbbVie does not challenge that aspect of the Negotiation Program in this litigation, and does not actually seek to withdraw anyway. Nor would AbbVie have Article III standing to challenge an interpretation of the statute that can only possibly benefit it. Regardless, AbbVie is incorrect, for reasons well explained by the Third Circuit. *See Bristol Myers Squibb*, 155 F.4th at 260-61 ("[G]ood cause is a uniquely flexible and capacious concept, meaning simply a legally sufficient reason.") (cleaned up).

marketplace. *Id.* at 192. But the Supreme Court has since made clear that the Constitution does not substantively constrain a legislature’s ability to fix the price of goods. *See Olsen v. Nebraska ex rel. W. Reference & Bond Ass’n*, 313 U.S. 236, 246-47 (1941); *see also Nebbia v. New York*, 291 U.S. 502, 516 (1934) (“So far as the requirement of due process is concerned, and in the absence of other constitutional restriction, a State is free to adopt whatever economic policy may reasonably be deemed to promote public welfare . . .”). And *Old Dearborn* itself expressly affirmed the validity of legislation that allowed parties to fix the price of goods by contract. 299 U.S. at 192. Even on its terms, it did not recognize a freestanding property right to force a price on an unwilling buyer.

Critically, the Negotiation Program does not control any private market transactions. Unlike the provisions challenged in *Bowles v. Willingham*, 321 U.S. 503, 519-21 (1944) (cited in Pl.’s MSJ Br. at 36), in which Congress sought to regulate the price at which anyone could lease property to *any* buyer, the Negotiation Program does not regulate the price at which manufacturers may sell their drugs except in circumstances where a buyer uses Medicare Part B or D to pay for the drugs. *See AstraZeneca*, 137 F.4th at 126 (“These are not private market transactions, regardless of the private hands through which CMS’s funds pass.”). And AbbVie offers no sound reason to extend the analysis that applies to market-wide price restrictions to a law that governs only the procedures used to determine the price the government itself is willing to pay.

Finally, AbbVie offers a series of conclusory assertions that the agency is “biased” or that the statute offers insufficient procedural protections. The Court need not address those arguments due to the threshold problem of AbbVie’s failure to identify any protected property interest (which is the approach that has been taken by every other court to be faced with similar arguments). Even so, Plaintiffs’ suggestion that CMS is “biased” cannot state a due process claim, Pl.’s MSJ Br. at

35—CMS is no more “biased” than any other regulator, and the Supreme Court has long blessed various forms of (often far more prescriptive) price regulation by the federal government. *See, e.g., Yakus v. United States*, 321 U.S. 414, 444 (1944) (rejecting due process challenge to the Emergency Price Control Act). And the absence of judicial review over some (but not all) of CMS’s decisions is neither unusual nor unlawful, standing alone. *See, e.g., Kontrick*, 540 U.S. at 452 (“Congress may determine a lower federal court’s subject-matter jurisdiction.”); *DCH Reg’l*, 925 F.3d at 505-06 (enforcing preclusion provision in the Medicare statute). Nor can AbbVie combine multiple failed theories into one omnibus unconstitutional “combination” theory, Pl.’s MSJ Br. at 36—the Supreme Court squarely rejected that approach just last year. In short, “[t]wo wrong claims do not make one that is right.” *FCC v. Consumers’ Rsch.*, 606 U.S. 656, 697 (2025); *see also id.* (“Contra the Fifth Circuit, a meritless public nondelegation challenge plus a meritless private nondelegation challenge cannot equal a meritorious ‘combination’ claim.”).

**B. The Negotiation Program is consistent with the First Amendment.**

1. The Negotiation Program does not compel manufacturers’ speech by requiring that participants sign a Manufacturer Agreement memorializing their decision to negotiate and—if negotiations succeed—the maximum amount that Medicare will pay for a selected drug. As several courts have recognized in rejecting identical claims, AbbVie’s compelled speech claims fail at the outset because “[a] violation of the First Amendment right against compelled speech occurs only in the context of actual compulsion.” *Bristol Myers Squibb*, 155 F.4th at 266-67 (cleaned up); *see also Boehringer Ingelheim*, 150 F.4th at 95 (same). AbbVie faces no “actual compulsion” to engage in any speech because its participation in the Negotiation Program, like its participation in Medicare and Medicaid, is voluntary. *See supra* Section II.A.

As discussed, manufacturers are subject to the Negotiation Program’s terms—including the requirement to sign a Manufacturer Agreement—only if they choose to do business with the government by selling their drugs to Medicare and Medicaid. Just as nothing compels AbbVie to participate in these programs in the first instance, nothing compels it to engage in any form of protected speech. The voluntariness of the Negotiation Program and any attendant “speech” requirements is thus independently fatal to these claims. *See, e.g., Bristol Myers Squibb*, 155 F.4th at 266-67. In short, “[b]ecause [AbbVie’s] assent to the Manufacturer Agreement did not occur in the context of actual compulsion, the company suffered no First Amendment violation.” *Boehringer Ingelheim*, 150 F.4th at 96.

2. The First Amendment claims also fail for the independent reason that the Negotiation Program regulates only non-expressive conduct and does not regulate AbbVie’s constitutionally protected speech. Although the constitutionally protected “freedom of expression” extends beyond the “the spoken or written word,” *Texas v. Johnson*, 491 U.S. 397, 404, 406 (1989) (quotation marks omitted), the Supreme Court has “rejected the view that ‘conduct can be labeled “speech” whenever the person engaging in the conduct intends thereby to express an idea,’” *Rumsfeld v. Forum for Acad. & Instl. Rights, Inc. (FAIR)*, 547 U.S. 47, 65-66 (2006) (quoting *United States v. O’Brien*, 391 U.S. 367, 376 (1968)). First Amendment protections for conduct cover only the “inherently expressive.” *Id.* at 66. “It is possible to find some kernel of expression in almost every activity a person undertakes—for example, walking down the street or meeting one’s friends at a shopping mall—but such a kernel is not sufficient to bring the activity within the protection of the First Amendment.” *City of Dallas v. Stanglin*, 490 U.S. 19, 25 (1989).

Consistent with this principle, it is well established that “the First Amendment does not prevent restrictions directed at commerce or conduct from imposing incidental burdens on speech.”

*Sorrell v. IMS Health Inc.*, 564 U.S. 552, 567 (2011). A “typical price regulation” is one such example. *Expressions Hair Design v. Schneiderman*, 581 U.S. 37, 47 (2017). Such a “law—by determining the amount charged—would indirectly dictate the content” of speech about the product’s price, but the price regulation poses no First Amendment problem because any “effect on speech would be only incidental to its primary effect on conduct.” *Id.*; *see also 44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 507 (1996) (plurality opinion) (noting that minimum prices or taxes would not restrict speech); *id.* at 524 (Thomas, J., concurring in part and concurring in the judgment); *id.* at 530 (O’Connor, J., concurring in the judgment). In other words, as the D.C. Circuit has explained, “ordinary price regulation does not implicate constitutionally protected speech.” *Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 292 (D.C. Cir. 2019).

This principle holds true when commercial conduct is carried out through written contracts. “[I]t has never been deemed an abridgment of freedom of speech” to regulate conduct “merely because the conduct was in part initiated, evidenced, or carried out by means of language, either spoken, written, or printed.” *FAIR*, 547 U.S. at 62 (quoting *Giboney v. Empire Storage & Ice Co.*, 336 U.S. 490, 502 (1949)); *see also Lowe v. SEC*, 472 U.S. 181, 232 (1985) (White, J., concurring in the result) (emphasizing that “offer and acceptance are communications incidental to the regulable transaction called a contract”).

In requiring the parties to sign documents memorializing their intent to negotiate and their agreement upon the maximum price that Medicare will pay for selected drugs, the Negotiation Program regulates only non-expressive, commercial conduct, and any effects on speech are “plainly incidental.” *FAIR*, 547 U.S. at 62; *accord Bristol Myers Squibb*, 155 F.4th at 263 (holding that the Negotiation Program “permissibly regulates conduct, with only an incidental effect on speech”). Manufacturers that choose to participate in the Program engage in negotiations with the

government and agree to make any negotiated prices available when Medicare beneficiaries purchase selected drugs, and the Manufacturer Agreement memorializes those program terms. Because the Negotiation Program “simply regulate[s] the amount that a [manufacturer] c[an] collect” when selling drugs to Medicare, its effect on speech is the same as an ordinary commercial contract. *Expressions Hair Design*, 581 U.S. at 47. Such commercial arrangements between the government and private parties to document agreed-upon prices raise no First Amendment concerns. Healthcare providers and other entities regularly execute similar agreements with the government to memorialize their acceptance of the terms of participation across a range of federal healthcare programs. *See, e.g.*, 42 U.S.C. §§ 1395cc, 1396r-8(b), (c), 1395w-102(b)(1); *see also* CMS, HHS, Form CMS-460, *Medicare Participating Physician or Supplier Agreement* (Nov. 2022), <https://perma.cc/WG64-ZNPL>.

3. There is no merit to AbbVie’s objection (*see* Pl.’s MSJ at 36-37) to the Manufacturer Agreement’s use of statutory terms of art that are defined in the IRA. The use of statutory terms in the Manufacturer Agreement promotes consistency and clarity. For example, the IRA defines the term “maximum fair price,” 42 U.S.C. § 1320f(c)(3), and when that term is used in the Agreement, its meaning reflects its statutorily defined definition. *See Meese v. Keene*, 481 U.S. 465, 484-85 (1987) (construing statutory terms as defined by Congress, “not as it might be read by a layman”). These terms of art accurately describe the operation of the Negotiation Program and do not convey or require AbbVie to endorse any view regarding the value of its drugs. *Cf. Milavetz, Gallop & Milavetz, P.A. v. United States*, 559 U.S. 229, 251 (2010) (holding that use of the term “debt relief agency” was necessarily accurate because it was a statutory term of art that defined the scope of a statutory requirement).

Indeed, the template Manufacturer Agreement states explicitly that a manufacturer's signature reflects neither an "endorsement of CMS'[s] views" nor a representation of the manufacturers' views concerning the fairness of prices. *See CMS, Medicare Drug Price Negotiation Program Agreement (Template)*, <https://perma.cc/N7AJ-C2JM>. And it explains that the use "of the term 'maximum fair price' and other statutory terms throughout th[e] 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.* This language confirms that the Manufacturer Agreement uses statutory terms as a way of ensuring a consistent understanding of the parties' obligations by reference to the statute, not as a means of compelling manufacturers to express a view about the value of their drugs.

Language in a government contract describing a price as "fair" is not at all atypical. Government contracting is premised on the government obtaining a "fair and reasonable price." 48 C.F.R. § 15.402(a); *see* 2 Karen L. Manos, *Government Contract Costs & Pricing* § 84:19, Westlaw (database updated Dec. 2025) ("The Government's stated pricing policy is to award contracts at fair and reasonable prices."). Every government contractor entering a fixed-price contract implicitly agrees that the price is fair; were it otherwise, the contractor could never defend its contract award against a bid protest. Nor is the IRA the first scheme to require a contractor to agree expressly that a price charged is "fair." *See, e.g., United States v. General Dynamics Corp.*, 19 F.3d 770, 771 (2d Cir. 1994) (statute requires that in order to obtain a federal subsidy "the proposed ship purchaser and the shipyard submit backup cost details and evidence that the negotiated price is fair and reasonable" (citation modified)); *Air Borealis Ltd. P'ship v. United States*, 167 Fed. Cl. 370, 389 (2023) (contractor allowed to certify that price is "fair and reasonable" in lieu of providing cost data to government purchaser (citation modified)); *Sea-Land*

*Serv., Inc. v. United States*, 493 F.2d 1357, 1360 (Ct. Cl. 1974) (agreement to sell ships to purchaser at “fair and reasonable values”).

In short, as other courts have recognized, “the terms of the contracts are meant to effectuate the Program, not to force the Companies to endorse a government-mandated message.” *Bristol Myers Squibb*, 155 F.4th at 266. So AbbVie’s First Amendment claim fails.

**C. The Negotiation Program does not violate the unconstitutional conditions doctrine.**

Finally, AbbVie also repackages several of its constitutional claims under the rubric of the unconstitutional conditions doctrine, arguing that “[e]ven if participation in the Program were in some sense ‘voluntary,’ that would not render the Program constitutional.” Pl.’s MSJ Br. at 42-44. But Congress acted well within any constraints that the unconstitutional conditions doctrine imposes in this context by making the government’s offer to pay for drugs through Medicare and Medicaid contingent on manufacturers’ agreement to negotiate the price of certain high-expenditure drugs. And although AbbVie “will lose certain revenues from Medicare and Medicaid if they decide not to participate in the Program, Congress can permissibly leverage funding in this way.” *Bristol Myers Squibb*, 155 F.4th at 267.

The unconstitutional conditions doctrine prevents the government from requiring a person to give up a constitutional right in order to receive an unrelated benefit. *See Rust v. Sullivan*, 500 U.S. 173, 196-98 (1991). Even assuming the doctrine applies here, where AbbVie is neither a beneficiary of discretionary benefits nor a government employee or independent contractor, *see* Pl.’s MSJ Br. at 42-44 (citing cases from those contexts), the requirements imposed by the Negotiation Program directly relate to the program’s goal of controlling costs and do not impede AbbVie’s ability to exercise its rights outside the scope of the Program.

As the Supreme Court explained in *Rust*, the government may condition the receipt of federal funds on compliance with program-specific requirements without violating the unconstitutional conditions doctrine, so long as the conditions are relevant to the program's purpose and "leave the grantee unfettered in its other activities." 500 U.S. at 196. The "'unconstitutional conditions' cases involve situations in which the Government has placed a condition on the recipient of the subsidy rather than on a particular program or service, thus effectively prohibiting the recipient from engaging in the protected conduct outside the scope of the federally funded program." *Id.* at 197 (emphasis omitted). This jurisprudence has thus consistently distinguished between provisions that set the terms of and define the scope of government programs, on the one hand, and provisions that impose external conditions on the recipient of a government benefit, on the other. *See id.*

In *Rust*, the Court upheld regulations that prohibited the use of federal funds for abortion counseling, emphasizing that the conditions were directly connected to the purpose of the funding, and that they did not prevent recipients from engaging in protected speech through affiliates funded by non-federal sources. *See* 500 U.S. at 196-98. Conversely, in *Agency for International Development v. Alliance for Open Society International, Inc. (AID)*, the Supreme Court struck down a condition that required non-governmental organizations receiving federal HIV/AIDS funding to adopt a policy announcing their opposition to prostitution and sex trafficking that extended well beyond the scope of the funded program. 570 U.S. 205, 217-18 (2013).

These cases underscore the permissibility of the Negotiation Program terms. The IRA sets the terms of the government's offer to pay for drugs for Medicare beneficiaries and does not set an external "condition" on manufacturers' ability to sell drugs. The government has a substantial interest in curbing the rising costs of public spending on prescription drugs. *See Lyng v. Int'l*

*Union, United Auto., Aerospace & Agric. Implement Workers of Am.*, 485 U.S. 360, 373 (1988) (acknowledging the government’s legitimate interest in “protecting the fiscal integrity of [g]overnment programs, and of the [g]overnment as a whole”). And the establishment of the Negotiation Program furthers that interest and promotes the long-term fiscal integrity of the government’s drug-procurement program. The terms that AbbVie challenges—agreeing to participate in price negotiations, signing contracts reflecting agreed-upon prices, and ultimately selling drugs to Medicare at such prices—are integral to the functioning of this drug-payment program, and they do not impede AbbVie’s ability to exercise its rights outside of the government’s prescription drug spending.

To the extent that AbbVie objects to signing (1) an agreement to negotiate or (2) an addendum stipulating the agreed price after a deal is reached, *see* Pl.’s MSJ Br. at 36-37, those requirements are central to the operation of the Negotiation Program as they are the mechanisms by which the government and manufacturers establish prices for the selected drugs, as well as the source of the enforceable obligation for both parties to honor those terms, *see* Guidance 197-201. In this way, the Manufacturer Agreement “define[s] the federal program” and does not “reach outside it.” *AID*, 570 U.S. at 217. AbbVie is entirely free to speak out against the Negotiation Program. *Cf.* AbbVie Earnings Call: Q4 2025 (Feb. 4, 2026), <https://stockanalysis.com/stocks/abbv/transcripts/394826-q4-2025/> (AbbVie’s CEO stating that he believes Botox “should have been excluded,” even as AbbVie was aware “that it could be selected based on CMS spend” and that Botox’s “selection does not impact our long-term growth guidance at all”). Thus, even if the Manufacturer Agreement implicated AbbVie’s speech interests, Congress has not impermissibly leveraged its spending “to regulate speech outside the contours of the program itself.” *AID*, 570 U.S. at 214-15.

AbbVie’s contention that the Negotiation Program impermissibly conditions participation on the relinquishment of Fifth Amendment rights likewise fails because the terms to which AbbVie objects are central to the operation of the program and “leave [AbbVie] unfettered in its other activities.” *Rust*, 500 U.S. at 196. The negotiation of prices is the central point of Congress’s decision to establish the Program and cannot reasonably be described as an extrinsic condition imposed on manufacturers. And because AbbVie remains free to sell its drugs to other purchasers at any price, this Medicare-specific requirement does not infringe on AbbVie’s rights “outside the scope of the federally funded program.” *Id.* at 197.

Finally, AbbVie’s reliance (Pl.’s MSJ Br. at 43) on the “nexus-and-proportionality test from *Dolan v. City of Tigard*, 512 U.S. 374, 391 (1994),” and *Nollan v. California Coastal Commission*, 483 U.S. 825, 834-37 (1987), is misplaced, as the Supreme Court has made clear that this test is reserved for the “‘special application’ of . . . land-use permits,” *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013); *see also Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 538 (2005) (noting the “special context of land-use exactions”). As the Third Circuit explained in rejecting this same argument, “the realities of land-use permitting have no bearing on Medicare contracts,” so this Court should “decline [AbbVie’s] invitation to subject the Program to scrutiny under *Nollan-Dolan*.” *Bristol Myers Squibb*, 155 F.4th at 262.

Ultimately, “Supreme Court precedent makes clear that laws establishing conditions on spending under federally funded programs without implicating recipients’ activity in the private market do not run afoul of the unconstitutional conditions doctrine.” *Boehringer Ingelheim*, 150 F.4th at 97. So AbbVie’s unconstitutional-conditions theories fail.

**CONCLUSION**

For these reasons, the Court should dismiss Counts I and II for lack of statutory subject-matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1). All remaining claims should be dismissed for failure to state a claim upon which relief can be granted under Federal Rule of Civil Procedure 12(b)(6). In the alternative, the Court should enter summary judgment for Defendants on all remaining claims.

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