IN THE 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)

ORAL ARGUMENT REQUESTED

COMBINED OPPOSITION TO DEFENDANTS' MOTION TO DISMISS (OR, IN THE ALTERNATIVE, CROSS-MOTION FOR SUMMARY JUDGMENT) AND REPLY IN SUPPORT OF PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

By enacting the Inflation Reduction Act of 2022 (IRA), Congress gave defendants unprecedented power to dictate the prices of prescription drugs administered to Medicare beneficiaries. But that power is not unlimited. Congress not only created statutory procedures with which defendants must comply when "selecting" eligible drugs for "negotiation"—that is, price controls—but also categorically excluded some drugs from selection in the first place. Most relevant here, Congress expressly provided that a "biological product that is derived from human whole blood or plasma" is not a "qualifying single source drug" (QSSD) that is eligible to be selected for price controls. 42 U.S.C. § 1320f-1(e)(3)(C). Defendants defied that express statutory prohibition when (without explanation and in violation of their own guidance) they selected BOTOX, a "biological product" that contains the plasma-derived protein human serum albumin.

The government attempts to lump this case together with out-of-circuit cases in which manufacturers have challenged the IRA's drug-pricing provisions on constitutional grounds—lifting arguments verbatim from its filings in those cases and devoting the majority of its brief to constitutional claims it admits get "less attention in AbbVie's brief[]." But the government thereby misses what makes this case different. While AbbVie *also* challenges the IRA's Drug Price Negotiation Program on constitutional grounds, this case presents the distinct question of whether defendants exceeded their authority under the IRA by selecting BOTOX, which is a plasma-derived biological product and thus cannot be a QSSD. The government attempts to group this case with other IRA challenges precisely because it has little to say in response to that question.

The most the government can muster is the argument that BOTOX was properly selected because its "active ingredient" is not itself made from plasma. But that made-for-litigation theory—first publicly announced in the preamble of a notice of proposed rulemaking issued only weeks ago and in the government's opposition brief—finds no support in the IRA. The IRA

contains no active-ingredient limitation, and it is not this Court's job to rewrite the plasma-derived-products exclusion by adding words to it. The government seeks to infer a "focus" on active ingredients from provisions of the IRA that apply only at subsequent stages of the "negotiation" process, after QSSDs have already been determined. Those provisions have no bearing on the question of which biological products can be QSSDs in the first place. The government also gestures at the IRA's purported broad purpose of reducing Medicare expenditures, but that purpose cannot trump the statutory text, nor does the government address why Congress expressly excluded plasma-derived products. If anything, statutory purpose confirms that the exclusion applies to *any* biological product derived from human plasma, regardless of whether its active ingredient is plasma-derived. Because the plasma-derived-products exclusion clearly bars defendants from treating BOTOX as a QSSD, and because only QSSDs may be selected for price controls, defendants' selection of BOTOX should be held unlawful and set aside.

In an attempt to evade review of its unlawful BOTOX selection, the government presses jurisdictional arguments that the D.C. Circuit has long rejected. As the D.C. Circuit reaffirmed just last month in *Ardelyx, Inc.* v. *Kennedy*, 2026 WL 1839261 (D.C. Cir. June 26, 2026), when deciding whether a judicial-review bar precludes a claim that an agency exceeded its statutory authority, the court's analysis of its jurisdiction and the merits of that claim "merge." Because Congress restricted judicial review of a "determination of a [QSSD] under section 1320f-1(e)," 42 U.S.C. § 1320f-7(2), this Court retains jurisdiction to determine whether defendants exceeded their statutory authority by treating BOTOX as a QSSD in the face of the plasma-derived-products exclusion. The government's invocation of the "inextricably intertwined" doctrine is misplaced; as the government concedes, AbbVie has not challenged any agency decision that is "inextricably intertwined" with an unreviewable determination. And even if review under the Administrative

Procedure Act (APA) were unavailable, the selection of BOTOX is the kind of flagrant statutory violation that *ultra vires* claims exist to correct.

This Court can set aside defendants' selection of BOTOX on statutory grounds without reaching AbbVie's constitutional claims. But if it does reach those claims, it should enjoin the enforcement of the IRA Drug Price Negotiation Program as to BOTOX based on AbbVie's rights under the First and Fifth Amendments. The government rests largely on the theory that participation in the Program is voluntary. But that theory misapprehends the IRA's text, and in any event, it is no answer to AbbVie's unconstitutional-conditions claim.

The Court should grant AbbVie's motion for summary judgment and deny defendants' motion to dismiss (or, in the alternative, for summary judgment).

ARGUMENT

As AbbVie has explained, AbbVie is entitled to summary judgment for the independent reasons that the selection of BOTOX is contrary to the IRA's express exclusion of plasma-derived products and that the Program violates or impermissibly burdens AbbVie's First and Fifth Amendment rights. The government has no persuasive response on the merits, and, as a threshold matter, its jurisdictional arguments are invalid as well.

I. This Court Has Jurisdiction To Review The Unlawful Selection Of BOTOX

The government does not dispute that AbbVie has standing or that this Court has subject-matter jurisdiction over AbbVie's constitutional claims. The government contends, however, that the IRA precludes review of AbbVie's APA and *ultra vires* claims that the selection of BOTOX violates the plasma-derived-products exclusion. *See*, *e.g.*, Defs.' Combined Mem. 14-17, Dkt. No. 33 (Opp.). In particular, the government cites the IRA's review-limiting provision, which provides that "[t]here shall be no administrative or judicial review" of several actions taken under the Program, including "[t]he selection of drugs under [42 U.S.C. § 1320f-1(b)], the determination of

negotiation-eligible drugs under [42 U.S.C. § 1320f-1(d)], and the determination of [QSSDs] under [42 U.S.C. § 1320f-1(e)]." 42 U.S.C. § 1320f-7(2). In effect, the government argues that the IRA prohibits this Court from resolving whether defendants' selection of BOTOX violated that very statute. Under longstanding D.C. Circuit precedent, however, this Court must review the merits of AbbVie's APA and *ultra vires* claims to determine whether the review-limiting provision even applies.

A. Longstanding Precedent Confirms That The IRA's Review-Limiting Provision Does Not Bar AbbVie's Statutory Claims

Given the "strong presumption favoring judicial review of administrative action," *Mach Mining, LLC* v. *EEOC*, 575 U.S. 480, 488-489 (2015), the D.C. Circuit has long interpreted jurisdiction-limiting statutory provisions not to bar judicial review of claims that agencies exceeded their statutory authority. *See* Pl.'s Mem. of Law in Supp. of Mot. for Summ. J. 17-19, Dkt. No. 25 (MSJ) (citing numerous additional cases). As those cases recognize, when a provision limits judicial review of agency action taken under a statute, the question of whether the review-limiting provision applies "merges" with the question of whether the agency exceeded its authority under the statute. *See COMSAT Corp.* v. *FCC*, 114 F.3d 223, 227 (D.C. Cir. 1997). If the agency acts within its authority, the review-limiting provision applies and the case is properly dismissed; if not, the provision is inapplicable and the agency action should be set aside. The D.C. Circuit has repeatedly taken that approach, cautioning that reading a review-limiting provision more broadly could enable an agency to break the law and evade accountability by styling its action as one for which review is barred. *See*, *e.g.*, *id.*; *Amgen, Inc.* v. *Smith*, 357 F.3d 103, 113 (D.C. Cir. 2004).

Under that controlling precedent, this Court has jurisdiction to consider whether defendants' selection of BOTOX exceeded their authority under the IRA. The review-limiting provision precludes review of "[t]he selection of drugs under section 1320f-1(b)," "the determination of

negotiation-eligible drugs under section 1320f-1(d)," and the "determination of [QSSDs] under section 1320f-1(e)." 42 U.S.C. § 1320f-7(2). But the plasma-derived-products exclusion is part of section 1320f-1(e) (42 U.S.C. § 1320f-1(e)(3)(C), to be precise), and if that exclusion applies, a product cannot be a QSSD. If defendants exceeded their statutory authority by treating BOTOX as a QSSD, they consequently never made a "determination of [a QSSD] under section 1320f-1(e)." And because a drug must be a QSSD to be "select[ed] . . . under section 1320f-1(b)" or treated as "negotiation-eligible . . . under section 1320f-1(d)," if BOTOX is not a QSSD, then there was neither a "selection" nor a "determination" under those provisions. Accordingly, this Court cannot determine whether the review-limiting provision applies without determining whether defendants' selection of BOTOX violated the relevant provisions of section 1320f-1. *See* MSJ 16-21.

In *Ardelyx, Inc.* v. *Kennedy*, 2026 WL 1839261 (June 26, 2026), the D.C. Circuit recently reaffirmed the proposition that, "to determine whether [a] judicial-review bar applies," a court "must decide whether the challenged agency action[s] are the sort of actions shielded from review." *Id*. at *5 (citation omitted). *Ardelyx* arose under a provision of the Social Security Act authorizing the Centers for Medicare & Medicaid Services (CMS) to "implement a payment system" that would provide a bundled "single payment" for the reimbursement of "renal dialysis services" under Medicare. 42 U.S.C. § 1395rr(b)(14)(A)(i). A pharmaceutical manufacturer challenged CMS's determination that the manufacturer's oral drug—a pill—qualified as a "renal dialysis service" subject to bundled payments. In response, CMS argued that the statute at issue, which precluded review of the "identification of renal dialysis services included in the bundled payment," barred review of the challenged determination. 2026 WL 1839261, at *4-*5 (discussing 42 U.S.C. § 1395rr(b)(14)(G)). Accordingly, the government argued, "the only question is whether the CMS

purported to identify or to 'recognize' a drug as a renal dialysis service." *Id*. at *6 (emphasis added).

The D.C. Circuit rejected CMS's argument and proceeded to the merits of the manufacturer's claim. Deciding whether the judicial-review bar at issue applied, the court explained, required the court to "merge consideration of the legality of the [agency's] action with consideration of [the] court's jurisdiction." *Ardelyx*, 2026 WL 1839261, at *7 (citation omitted). Because the judicial-review bar was keyed to the statutory phrase "renal dialysis service," the D.C. Circuit had to ascertain the meaning of that phrase to determine whether CMS made a shielded "identification" "within the meaning of the bar." *Id*. at *6. Although the D.C. Circuit ultimately found jurisdiction lacking, it did so only after concluding that, on the merits, the agency had not exceeded its statutory authority. *See id*. at *12.

Ardelyx confirms that this Court has jurisdiction to consider AbbVie's claim that the selection of BOTOX exceeded defendants' authority under the IRA. To determine whether the bar on review of the "identification of [a] renal dialysis service" precluded Ardelyx's claim, the D.C. Circuit needed first to decide whether Ardelyx's pill was a "renal dialysis service." *See* 2026 WL 1839261, at *6-*7. By the same logic, this Court cannot decide whether the IRA's review-limiting provision's bar on challenges to the "determination of [QSSDs] under section 1320f-1(e)" precludes AbbVie's claim without first determining whether BOTOX is a QSSD, which requires determining whether BOTOX is a plasma-derived product. Like in *Ardelyx*, this Court "must look to the definition in [section 1320f-1(e)] to determine the scope of [the review-limiting provision]." *See* 2026 WL 1839261, at *6.

If anything, this is an easier case than *Ardelyx*. There, the government unsuccessfully tried to distinguish the D.C. Circuit's earlier decisions on the ground that the jurisdiction-stripping

provisions in those cases "expressly cross-referenced other provisions of the Medicare statute" or "expressly incorporated [surrounding] statutory text." Br. for Appellees at 32-33, *Ardelyx*, *supra* (No. 24-5290) (Apr. 10, 2025). Because the IRA's review-limiting provision "express[ly] cross-reference[s] . . . other provisions of the Medicare statute," the jurisdictional and merits inquiries should "merge" in this case even by the government's lights.

B. The Government's Arguments Against Jurisdiction Fail

The government fails to distinguish this case from the long line of D.C. Circuit precedent holding that the scope of statutory bars on judicial review merge with the merits when an agency is alleged to have exceeded its statutory authority.

1. The government principally argues that, in D.C. Circuit cases that "merged" consideration of jurisdiction and the merits, the jurisdictional and merits inquiries were coextensive, whereas this case presents distinct questions of whether CMS made a "determination" of a QSSD versus whether that "determination" was correct. Opp. 18. But the same could have been said in any of those previous cases. The court in *Southwest Airlines Co.* v. *TSA*, 554 F.3d 1065 (D.C. Cir. 2009), could have asked whether TSA made a "determination" regarding limitations on air carrier fees without asking whether that determination was correct. *See id*. at 1071. In *American Hospital Association* v. *Azar*, 964 F.3d 1230, 1238 (D.C. Cir. 2020) (*AHA*), the court could have dismissed for lack of jurisdiction because HHS's challenged reduction in payments was arguably an "establishment of . . . methods" regardless of whether it "count[ed]" or "qualifie[d] as a method" under the governing statute. *Cf. id*. at 1238, 1239 (internal quotation marks and citation omitted). And in *Ardelyx*, the court could have asked only whether CMS "purported to identify or to 'recognize' a drug as a renal dialysis service," without asking whether the pill at issue was in fact a "renal dialysis service" within the meaning of the statute. 2026 WL 1839261, at *6. In those cases, however, the D.C. Circuit correctly asked whether the agency's action was "the kind of

action for which review is barred," *id*. (quoting *AHA*, 964 F.3d at 1238), rather than more narrowly asking whether the government purported to act under authority shielded by statute from review. *See also Amgen*, 357 F.3d at 112-113; *COMSAT*, 114 F.3d at 227.

2. The government's argument also misreads the review-limiting provision. As is relevant here, the IRA does not broadly preclude review of all agency action having anything to do with the selection of drugs for "negotiation," but only four distinct steps in that process: "[t]he selection of drugs under section 1320f-1(b) of this title," "the determination of negotiation-eligible drugs under section 1320f-1(d) of this title," "the determination of qualifying single source drugs under section 1320f-1(e) of this title" and "the application of section 1320f-1(f) of this title." The government contends that AbbVie's statutory-authority claim is unreviewable because AbbVie, in effect, challenges a "determination of [a QSSD] under section 1320f-1(e)." But by precluding judicial review only of that "determination . . . under [the statute]," Congress left the courthouse doors open to claims that defendants exceeded their authority under section 1320f-1(e) by erroneously treating as a QSSD a biological product that Congress excluded from the definition of QSSD and thus from selection.

The government struggles to explain away the fact that the review-limiting provision precludes review of only QSSD determinations "under section 1320f-1(e)." Although such an explicit cross-reference is not necessary for the jurisdictional and merits inquiries to "merge," *Ardelyx*, 2026 WL 1839261, at *6, the fact that the review-limiting provision specifically exempts only "the determination of [QSSDs] *under section 1320f-1(e)*" reinforces the conclusion that Congress never barred claims that defendants violated section 1320f-1(e) by treating ineligible products as QSSDs. 42 U.S.C. § 1320f-7(2) (emphasis added). That "under" clause—like the other "under" clauses in the review-limiting provision—would be superfluous if the government were correct that the

review-limiting provision precluded review of any determination relating to QSSDs, lawful or not. *See* MSJ 19-20.

The government has little to say on that score. Although the government contends that "under" does not create a "freestanding, threshold 'lawfulness' requirement," Opp. 20, the government does not cite a single decision interpreting a similarly worded provision to bar review of claims that an agency exceeded its statutory authority.[1] Instead, the government relies solely on a throwaway citation to 42 U.S.C. § 1983's "under color of [law]" requirement (Opp. 20-21), which has nothing to do with the reviewability of agency action. The government contends that the "under" clauses in the IRA's review-limiting provision merely clarify which agency actions are immune from review—distinguishing, for example, QSSD determinations from impositions of penalties under section 1320f-6. Opp. 21. But shorn of the "under" clauses, the review-limiting provision would still refer to (as relevant) "the selection of drugs," "the determination of negotiation-eligible drugs," and the "determination of [QSSDs]." The "under" clauses are in no way necessary to clarify that the review bar does not extend to actions such as the imposition of penalties.

3. The government also devotes several pages to cases standing for the proposition that, when Congress "precludes judicial review of a decision," it also "precludes review of any

[1] Although *Texas Alliance for Home Care Services* v. *Sebelius*, 681 F.3d 402, 409-411 (D.C. Cir. 2012), applied a provision barring any judicial review of "the awarding of contracts under this section," 42 U.S.C. § 1395w-3(b)(12)(B), the plaintiffs in that case challenged the agency's regulation as arbitrary and capricious and for violating notice-and-comment requirements, 681 F.3d at 408, and the court thus had no occasion to consider whether that provision would have precluded review of a claim that the agency exceeded its statutory authority. In any event, the review-limiting provision in *Texas Alliance* is far broader than that at issue here. Like the IRA's review-limiting provision, the provision in *Texas Alliance* precludes review of agency actions taken under enumerated statutory provisions (for example, "under section 1395ff of this title, section 1395*oo* of this title"), but it also adds the catch-all phrase "or otherwise," extending its reach even further. 42 U.S.C. § 1395w-3(b)(12). The IRA's review-limiting provision contains no comparably expansive language.

preceding issues that are 'inextricably intertwined' with the final decision." Opp. 16 (quoting *DCH Regional Medical Center* v. *Azar*, 925 F.3d 503, 507 (D.C. Cir. 2019)). But this case bears no resemblance to those in which the D.C. Circuit has concluded that courts lack jurisdiction over issues "inextricably intertwined" with agency action that "all agree *is* shielded from review." *Florida Health Sciences Center* v. *Secretary of HHS*, 830 F.3d 515, 521 (D.C. Cir. 2016); *see Mercy Hospital, Inc.* v. *Azar*, 891 F.3d 1062, 1066-1067 (D.C. Cir. 2018); *DCH*, 925 F.3d at 507. In each of those cases, plaintiffs barred from directly attacking some agency action instead challenged the inputs or methodologies used to make those decisions. *See DCH*, 925 F.3d at 507 (methodology used to generate estimates "inextricably intertwined" with unreviewable estimates); *Mercy Hospital*, 891 F.3d at 1066 (adjustments used to calculate payment rate "inextricably intertwined" with unreviewable payment rate); *Florida Health Sciences Center*, 830 F.3d at 518 (data used to determine estimate of uncompensated care "inextricably intertwined" with unreviewable estimate); *see also Mullin* v. *Doe*, 609 U.S. ___, 2026 WL 1825840, at *7-*10 (June 25, 2026) (concluding that a judicial-review bar precluded a challenge to the steps taken in reaching a "final decision to terminate" a program because the term "determination" covered the "chain of events leading up to a decision" and the phrase "with respect to" "has a broadening effect," where the plaintiffs did not dispute that the provision precluded judicial review of substantive challenges to the final decision).

That "inextricably intertwined" rule is doubly inapplicable here. *First*, there is no agency action that "all agree *is* shielded from review." *Florida Health Sciences Center*, 830 F.3d at 521. Whether the review-limiting provision precludes AbbVie's statutory claims is squarely in dispute. *Second*, as the government apparently concedes, *see* Opp. 15-16, AbbVie challenges the selection of BOTOX, not just the "means by which drugs are determined to be a [QSSD]" as a backdoor

means of obtaining review of that selection.[2] Because defendants' selection of BOTOX in violation of the plasma-derived-products exclusion is not "shielded from review," this case does not present the question of whether any upstream actions and decisions are "inextricably intertwined" with some unreviewable decision. *Florida Health Sciences Center*, 830 F.3d at 518-521.

4. As a last line of defense, the government retreats to policy arguments for why the review-limiting provision should apply. But those arguments, too, are unavailing. Although the government grudgingly concedes that there is a presumption in favor of judicial review of agency action, *see* Opp. 14, it neglects to mention that this presumption is "particularly strong" when an agency is alleged to have acted "in excess of delegated authority." *Amgen*, 357 F.3d at 111. Brushing past that "particularly strong" presumption, the government contends that AbbVie's interpretation would "create an end-run" around the IRA's judicial-review bar. Opp. 19. But merging the jurisdictional question with the question of whether defendants have exceeded their statutory authority, as precedent requires, would not "render the judicial-review bar irrelevant" or superfluous. *Ardelyx*, 2026 WL 1839261, at *7. The review-limiting provision "still forecloses inquiry into whether the challenged agency action is arbitrary, capricious, or procedurally defective." *Id*. This Court can analyze whether the selection of BOTOX violated section 1320f-1(e)—and was thus not a "determination of [a QSSD] under" that provision—even if it would lack jurisdiction to review

[2] This Court would also have jurisdiction to review challenges to CMS's recently unveiled "policy"—first announced in the government's opposition brief and in the preamble of a notice of proposed rulemaking issued while this litigation was pending, *see* 91 Fed. Reg. 36,236, 36,263 (June 16, 2026)—of identifying QSSDs and applying the plasma-derived-products exclusion based on products' active ingredients. The IRA does not purport to limit judicial review over that general policy, which is not a "selection," "determination," or "application" under any relevant provision of the IRA and is not "inextricably intertwined" with any specific unreviewable agency action. *See Teva Pharmaceuticals USA, Inc.* v. *Kennedy*, 2025 WL 3240267, at *7 (D.D.C. Nov. 20, 2025), appeal pending, No. 25-5425 (D.C. Cir.).

a claim (which AbbVie does not bring) that defendants' selection of BOTOX without any explanation, and despite existing guidance to the contrary, was arbitrary and capricious.

Indeed, it is the *government's* position that would enable gamesmanship. As the D.C. Circuit has observed, if judicial-review bars are not construed to permit review of whether agencies acted within the scope of their statutory authority, agencies could attempt to "characterize reviewable or unauthorized action as falling within the scope of no-review provisions whose application to such action Congress did not intend" based solely on the agency's "say-so." *Ardelyx*, 2026 WL 1839261, at *6 (citation omitted); *see COMSAT*, 114 F.3d at 227. If this Court were to accept the government's interpretation of the review-limiting provision as precluding review of agency action "whether lawful or unlawful," Opp. 21, defendants would be free to disregard the IRA's other restrictions on their authority—for example, by imposing price controls on new drugs without waiting the required 7 or 11 years, by selecting drugs with generic or biosimilar competition, or by announcing "negotiated" prices for all prescription drugs at once. *See* 42 U.S.C. § 1320f-1(a), (e)(1)(A)(ii)-(iii), (B)(ii)-(iii). The D.C. Circuit has described such "bald assertion[s] of power by an agency" as "preposterous." *COMSAT*, 114 F.3d at 227 (citation omitted). This Court should thus reject the government's reading and analyze jurisdiction and the merits of AbbVie's statutory claims together.

II. The IRA Prohibits Defendants From Imposing Price Controls On BOTOX Because It Falls Within The Plasma-Derived-Products Exclusion

On the merits, this Court should set aside defendants' unlawful selection of BOTOX. BOTOX is undisputedly a biological product that in its licensed and marketed form contains human serum albumin (HSA), which is made from human plasma. Dkt. No. 27, ¶ 14. Because BOTOX is thus a "biological product that is derived from human . . . plasma," it cannot be a QSSD and cannot be selected for IRA price controls. 42 U.S.C. § 1320f-1(e)(3)(C). The

government argues that BOTOX is a QSSD because the IRA's plasma-derived-products exclusion reaches only products whose *active ingredient* is *itself* derived from human blood or plasma. *See* Opp. 2, 23-28. That theory cannot be reconciled with the IRA's text, structure, or purpose.

A. BOTOX Is A Plasma-Derived Product Not Subject To IRA Price Controls

Section 1320f-1(e)(3)(C) unambiguously prohibits defendants from selecting a product for "negotiations" if that product is a "biological product that is derived from human whole blood or plasma." The text, structure, and purpose of that provision all point to the conclusion that it applies to any "biological product" that—like BOTOX—is "derived from" plasma, regardless of whether the plasma component is the product's active ingredient.

1. The IRA prohibits defendants from imposing price controls on biological products derived from human blood or plasma. Under that statute, CMS may "select" a product for "negotiation[s]" only if that product is a QSSD. 42 U.S.C. § 1320f-1(d)(1) (defining "negotiation-eligible drug"). To be a QSSD, a biological product must meet several statutory criteria. It must be either a "covered Part D drug (as defined in [42 U.S.C. § 1395w-102(e)])" or a "biological product for which payment may be made under" Medicare Part B. § 1320f-1(e)(1). It must be licensed under 42 U.S.C. § 262(a), be marketed under section 262, have been licensed for at least 11 years, and not be the reference product for a biosimilar licensed and marketed under section 262(k). 42 U.S.C. § 1320f-1(e)(1)(B). Finally, it must not fall within any of three exclusions, including, as is relevant here, the exclusion for "plasma-derived products," *i.e.*, any "biological product that is derived from human whole blood or plasma." 42 U.S.C. § 1320f-1(e)(3). Products within those exclusions do not qualify as QSSDs and thus cannot be selected for price controls.

2. A "biological product" falls within the plasma-derived-products exclusion if the "biological product"—the whole, finished product licensed by FDA and sold by a manufacturer—is obtained from human whole blood or plasma. The IRA's text dictates that interpretation.

a. Section 1320f-1(e)(1) requires a QSSD to be either a "covered part D drug (as defined in [42 U.S.C. § 1395w-102(e)])" or a "biological product for which payment may be made under" Medicare Part B. And section 1320f-1(e)(2) provides that, if the drug is a "biological product," it must be "licensed under [42 U.S.C. § 262(a)]" and "marketed under [42 U.S.C. § 262]," have been licensed for at least 11 years, and not be the reference product for a biosimilar licensed and marketed under 42 U.S.C. § 262(k). Each of those elements makes sense only if, as used in the definition of "QSSD," "biological product" refers to the whole, finished product.

i. The requirement that a QSSD be a "covered part D drug" or a "biological product for which payment may be made under" Part B necessarily implies that a "biological product" refers to the whole, finished product, because Medicare Part B and Part D provide coverage only for whole products. To be a "covered part D drug," a "biological product" must be both "dispensed only upon a prescription" and "licensed under [42 U.S.C. §] 262." 42 U.S.C. §§ 1395w-102(e)(1)(A), (C), 1396r-8(*i*)(2)(B)(i), (ii). Only whole products are "dispensed" upon prescription. And while FDA considers a product's active ingredient in deciding whether to regulate the product as a drug or biological product, *see Ipsen Biopharmaceuticals, Inc.* v. *Becerra*, 108 F.4th 836, 838 (D.C. Cir. 2024), FDA ultimately *licenses* biological products in their whole, finished form—inclusive of not only their active ingredients, but also inactive ingredients and manufacturing processes. *See* 42 U.S.C. § 262(a)(2)(C); 21 C.F.R. § 601.2. Similarly, Medicare Part B provides coverage only for whole products. Specifically, it covers "medical and other health services," which include "drugs and biologicals which are not usually self-administered by the patient[,] furnished as an incident to a physician's professional service." 42 U.S.C. §§ 1395k(a)(2)(B), 1395x(s)(2)(A), (B). Again, physicians "furnish[]" patients with whole products, not active ingredients in isolation.

ii. The requirements that, to be a QSSD, a "biological product" must be "licensed" and "marketed" under section 262 and have been licensed for at least 11 years are powerful proof that Congress used "biological product" in its whole-product sense. FDA undisputedly "licenses" whole products, not active ingredients in isolation. *See* p. 14, *supra*. And a manufacturer such as AbbVie likewise "market[s]" whole products. Accordingly, a "biological product" can be "licensed under section 262(a)" and "marketed under section 262" and have been licensed for at least 11 years only if "biological product" refers to the whole product.

iii. For similar reasons, the requirement that a "biological product" not be a "reference product" for a licensed biological product further confirms that Congress intended "biological product" in its whole-product sense. The Public Health Service Act (PHSA) defines a "reference product" as the "single biological product licensed under [section 262(a)] against which a biological product is evaluated in an application submitted under [section 262(k)]." 42 U.S.C. § 262(*i*)(4). Again, only the whole product is "licensed" under section 262. *See* p. 14, *supra*. "[R]eference product" thus refers to a whole product. And so the requirement that, to be a QSSD, a "biological product" not be a "reference product" likewise implies that "biological product" refers to a whole product.

Because section 1320f-1(e)(1) consistently uses "biological product" to refer to whole products, it follows that the plasma-derived-products exclusion, section 1320f-1(e)(3)(C), uses "biological product" the same way. It is a familiar interpretive principle that "identical words and phrases within the same statute should normally be given the same meaning." *Monsalvo* v. *Bondi*, 604 U.S. 712, 726 (2025) (citation omitted). That presumption of consistent usage is particularly powerful where, as here, the repeated term has "some heft and distinctiveness," *Pulsifer* v. *United States*, 601 U.S. 124, 149 (2024), and Congress uses the same term in "adjoining provisions,"

Nijhawan v. *Holder*, 557 U.S. 29, 39 (2009). Because section 1320f-1(e)(1) and the plasma-derived-products exclusion, section 1320f-1(e)(3)(C), are included in the same statutory subsection and as part of the same definition of "QSSD," it would impute a "schizophrenic intent" to Congress to assume that Congress meant "biological product" in its whole-product sense in subparagraph (e)(1) but meant it in a narrower sense in subparagraph (e)(3). *Janko* v. *Gates*, 741 F.3d 136, 142 (D.C. Cir. 2014) (internal quotation marks and citation omitted).

b. Under the same principles, the IRA's repeated usage of "biological product" in its whole-product sense confirms that the plasma-derived-products exclusion exempts any whole product "derived from" plasma. The subchapter of the Social Security Act housing the bulk of the Drug Price Negotiation Program, 42 U.S.C. §§ 1320f to 1320f-7, uses the term "biological product" nearly 100 times, and many of those references make sense only if "biological product" is understood as referring to whole products. For example, section 1320f(c)(6) defines the term "unit" to mean, with respect to a biological product, "the lowest identifiable amount (such as capsule or tablet, milligram or molecules, or grams) of the . . . biological product that is dispensed or furnished." And section 1320f-1(f)(4)(B) requires manufacturers of certain delayed-entry biological products to pay the government a rebate calculated based on, among other things, "the number of units" of the "biological product" that are "dispensed," "administered[,] or furnished." Providers dispense, furnish, or administer whole products, not active ingredients in isolation. *See* p. 14, *supra*. Moreover, numerous other provisions of the IRA refer to the amount the government pays for a "biological product" or discuss the "maximum fair price" for a "biological product." *See*, *e.g.*, 42 U.S.C. §§ 1320f(c)(5), 1320f-1(b)(1)(C), 1320f-1(e)(3)(B), 1320f-1(f)(4)(B), 1320f-3(c)(1)(B)(ii). But, as noted, Medicare pays for finished products, not active ingredients. *See* MSJ 25; p. 14, *supra*. Congress's repeated use of "biological product" to refer to whole products

connotes that the phrase has the same whole-product meaning when used in the plasma-derived-products exclusion.

3. Even if this Court were to inquire into Congress's purposes in creating the Program, those purposes cut squarely in favor of a whole-product reading of the plasma-derived-products exclusion. Plasma-derived products are subject to unique supply-chain vulnerabilities and additional manufacturing and regulatory challenges based on their reliance on donated human plasma. Dkt. No. 27-10, ¶¶ 10-11, 14; Dkt. No. 28, ¶ 11. In excluding plasma-derived products from selection under the IRA, Congress presumably wished to avoid the risk that price controls would disrupt access to such products due to the fragile supply of human plasma. *See* H.R. Rep. No. 696, 119th Cong., 2d Sess. 176-177 (2026). Because HSA is an essential "plasma-derived component" of BOTOX, those risks would exist as long as HSA is a necessary component of BOTOX, regardless of whether BOTOX's label lists HSA as an active or inactive ingredient. *See id*. The text and purpose of the plasma-derived-products exclusion thus support reading the exclusion as applying to *all* plasma-derived biological products.

4. BOTOX cannot be a QSSD because it falls squarely within the plasma-derived-products exclusion. Each dosage form of BOTOX "licensed" and "marketed" under 42 U.S.C. § 262 contains HSA. Dkt. No. 27, ¶ 12. HSA, in turn, plays an important role in facilitating BOTOX's therapeutic effects. Dkt. No. 27, ¶¶ 17-18.[3] As BOTOX's FDA-approved label

[3] The government asserts that AbbVie does not "dispute the fact that HSA functions as an inactive ingredient in BOTOX." Opp. 24. In fact, AbbVie has provided evidence that "HSA plays an important role in achieving BOTOX's therapeutic effects," including by facilitating greater binding between onabotA and targeted nerve cell receptors, resulting in greater toxin peak effect, duration, and overall effect, as well as leading to greater persistence of onabotA near the injection site. *E.g.*, Dkt. No. 27, ¶¶ 17-18; *see* MSJ 6. Because the IRA does not define biological products using a "focus" on active ingredients, however, it is immaterial whether HSA is identified as an active ingredient in BOTOX.

expressly states, HSA is obtained from human plasma. Dkt. No. 27, ¶ 14; Dkt. No. 27-5, § 5.14. Under a straightforward reading of the IRA, therefore, BOTOX is a "biological product that is derived from human . . . plasma," which cannot be designated as a QSSD or selected for price "negotiations" under the IRA. *See* MSJ 26-31.

B. The Government's Active-Ingredient Policy Is Contrary To The IRA

The government does not dispute that the IRA prohibits the imposition of price controls on a "biological product" that is "derived from human . . . plasma," that BOTOX is a biological product licensed and marketed under 42 U.S.C. § 262, or that every dosage form of BOTOX contains HSA obtained from human plasma. But the government defends the QSSD designation and selection of BOTOX on the ground that, when defendants apply the plasma-derived-products exclusion, the "focus" of their inquiry is "on the active ingredient of the biological product." Opp. 24. Because BOTOX's listed active ingredient, onabotA, is not *itself* derived from human plasma, the government maintains that BOTOX is a QSSD that can be selected for negotiation.[4] Nothing in the IRA supports that theory.

1. The IRA's plain text does not support a focus on 'active ingredients'

When a statute "speaks clearly," the court's inquiry "start[s] with the statutory text [and] end[s] there as well." *Allegheny Defense Project* v. *FERC*, 964 F.3d 1, 18 (D.C. Cir. 2020). Because the IRA requires a whole-product reading of the phrase "biological product" and offers no support for the government's contrary active-ingredient theory, the Court should give that phrase its ordinary, whole-product meaning.

[4] FDA-approved labeling and FDA databases list BOTOX's active ingredient as "onabotulinumtoxinA." In announcing its selection of BOTOX for price controls, however, CMS described BOTOX's active ingredient as "botulinum toxin type A"—the broader class to which onabotulinumtoxinA belongs.

a. The first problem with the government's theory is that the IRA never uses the phrase "active ingredient"—not in the plasma-derived-products provision, nor in the rest of subsection 1320f-1(e), nor anywhere else in the statute. Accordingly, for the government's theory to be correct, this Court would need to rewrite the statutory text to exclude from the definition of a QSSD any "biological product [*the active ingredient of which is*] derived from human whole blood or plasma." *Cf.* 42 U.S.C. § 1320f-1(e)(3)(C). But it is a bedrock proposition of statutory interpretation that a court should not "narrow a provision's reach by inserting words Congress chose to omit." *Lomax* v. *Ortiz-Marquez*, 590 U.S. 595, 600 (2020). As the Supreme Court has long recognized, "supply[ing] omissions" from the statutory text in this manner "transcends the judicial function." *Iselin* v. *United States*, 270 U.S. 245, 251 (1926). Had Congress wished CMS to limit the plasma-derived-products exclusion to biological products whose active ingredient was derived from human plasma, it could have easily done so. Because it did not, this Court should presume that the omission was intentional and decline the government's invitation to rewrite the plain text of the plasma-derived-products exclusion. *See*, *e.g.*, *Russello* v. *United States*, 464 U.S. 16, 23 (1983).

b. The government fails to come to grips with the fact that the IRA—and in particular, section 1320f-1's definition of "QSSD"—consistently uses "biological product" to refer to whole products. The government does not identify a single provision of the IRA that uses "biological product" in the narrow sense of referring only to a licensed product's active ingredient. And the government's cursory attempts to explain away the statute's repeated whole-product usage of the phrase are unpersuasive.

For example, the government does not dispute that FDA licenses whole products; indeed, it concedes that it would be "inappropriate" for FDA to consider only active ingredients when

licensing biological products under the PHSA, 42 U.S.C. § 262(a). Opp. 27. Nor does the government dispute that the biological products "marketed under section 262" are whole products. *Cf. id*. The government argues, however, that this fact is immaterial because "the IRA and PHSA are different statutes with fundamentally different objectives." *Id*. That argument is beside the point because the IRA itself makes clear that the term "biological product" refers to the whole product. Moreover, the IRA expressly defines the term "QSSD" by reference to the PHSA's licensing and marketing provisions, which are focused on whole products, as the government concedes. *See* 42 U.S.C. § 1320f-1(e)(1)(B)(i) (requiring biological product to be "licensed under section 262(a)" and "marketed under section 262" to be QSSD). Even if the government were correct that the IRA has distinct purposes from the PHSA, statutory purpose "cannot overcome the plain meaning of the statute's text." *Young* v. *United States*, 943 F.3d 460, 464 (D.C. Cir. 2019).

The government also lacks a valid explanation for the provisions of the IRA describing how much Medicare pays for a "biological product." *See* MSJ 25; p. 14, *supra*. The government contends that the provision equating a "biological product" with a "covered part D drug" "merely requires that a biological product be FDA-approved to be eligible for Medicare reimbursement." Opp. 27. That contention ignores that the phrase "covered part D drug" has a specific statutory definition that the IRA cross-references and that uses "biological product" in its whole-product sense. *See* p. 14, *supra*. In any event, the government's contention gives the game away. Because FDA licenses whole products, the admission that a product must be licensed to be covered by Medicare effectively concedes that the IRA—which authorizes the selection only of products covered by Medicare Parts B or D—uses "biological product" to refer to whole products.

2. The IRA's structure does not support a focus on 'active ingredients'

Lacking support in the plain text of the IRA, the government attempts to ground its active-ingredient policy primarily in an inference drawn from three provisions of the statute: section

1320f-1(d)(3)(B), which requires CMS to aggregate data "across dosage forms and strengths of the drug" when ranking negotiation-eligible drugs; section 1320f-5(a)(2), which uses similar language to describe CMS's obligation to establish procedures for computing and applying the maximum fair price to selected drugs; and section 1320f-3(e)(1)(D), which directs CMS, when formulating "offers," to consider all "applications and approvals" for the "drug." From these provisions, the government infers that, when CMS identifies QSSDs, the "focus" of the inquiry is on active ingredients. *See* Opp. 24. That argument misunderstands the IRA's structure.

a. The IRA authorizes CMS to select a product for price controls only after a sequence of determinations is made. Each of these determinations must be made according to distinct criteria. As is relevant here, CMS must *first* determine whether a product is a QSSD (including whether the product is an exempt plasma-derived product). *See* 42 U.S.C. § 1320f-1(e). Only after that determination is made may CMS then proceed to determine whether the QSSD satisfies additional criteria that render it a "negotiation-eligible drug" that may be selected and subjected to a "maximum fair price." 42 U.S.C. §§ 1320f-1(d), 1320f-3. The first two provisions to which the government points—sections 1320f-1(d)(3)(B) and 1320f-5(a)(2)—are aggregation provisions that come into play only *after* CMS has already determined which drugs and biological products are QSSDs—which is the issue here. Section 1320f-1(d)(3)(B) prescribes how defendants are supposed to rank QSSDs when identifying negotiation-eligible drugs, and section 1320f-5(a)(2) applies to CMS's computation and application of a "maximum fair price" for a selected drug that is, by definition, already deemed a QSSD. Neither provision says anything about the antecedent question of whether a biological product qualifies as a QSSD.

If anything, these provisions underscore that the IRA generally uses a whole-product approach. The fact that Congress required an aggregation rule in these specific contexts not only

fails to support the government's claim that the statute requires an active-ingredient "focus" "at each stage of the process," Opp. 24, but implies that Congress did *not* intend defendants to classify products according to their active ingredients at other steps of the process. *See Russello*, 464 U.S. at 23. Indeed, if Congress intended an active-ingredient approach to apply throughout the IRA, as the government suggests, it would have had no reason to spell out that an "aggregation" approach applies when determining whether a QSSD is negotiation-eligible.

b. The third provision to which the government points, section 1320f-3(e)(1)(D), also offers little support for its active-ingredient limitation. That provision directs CMS, when formulating its "offers" for a selected drug, to consider all "applications and approvals" for the "drug." Like sections 1320f-1(d)(3)(B) and 1320f-5(a)(2), section 1320f-3(e)(1)(D) is inapposite because it governs the procedures for formulating a price for "a selected drug," which occurs after a drug is deemed a QSSD (which a plasma-derived product by law cannot be). In any event, section 1320f-3(e)(1)(D) does not support the government's active-ingredient interpretation for additional reasons. The government attempts to summon support for its policy from the fact that this provision refers to "applications and approvals," in the plural, for a singular "drug." *See* Opp. 25. Under the general principles of construction applicable to federal statutes, however, the singular includes the plural and vice versa, 1 U.S.C. § 1, so any internal inconsistency in grammatical number is not a reliable tool for interpreting the statute. *See Monsalvo*, 604 U.S. at 726 n.2.

Even if distinctions between the singular and plural could be meaningful elsewhere, they are not here. Read in full, section 1320f-3(e)(1)(D) provides that CMS must consider, among other things, "applications and approvals under section 355(c) of title 21 or section 262(a) of [Title 42] for the drug." A manufacturer can obtain multiple approvals for the same product under either 21 U.S.C. § 355(c) (for new small-molecule drugs) *or* 42 U.S.C. § 262(a) (for new biological

products). For example, a manufacturer may seek approval for multiple dosages or indications of a single product, thus generating multiple "applications and approvals." 42 U.S.C. § 1320f-3(e)(1)(D). Indeed, BOTOX is licensed under a single biologics license application but has received dozens of approvals, *e.g.*, to treat different diseases and conditions. Congress's use of the plural in this provision does not suggest that CMS may ignore those distinct "applications and approvals" and instead look solely to a product's active ingredient. Rather, Congress's acknowledgement that a single product may have multiple "applications and approvals" signifies that a single product may have multiple licensed forms to which CMS may look. And as to BOTOX in particular, this provision is irrelevant, because all dosage forms of BOTOX are licensed and marketed under a single biologics license application. Section 1320f-3(e)(1)(D) thus offers no support for the government's active-ingredient limitation.

3. The IRA's purpose does not support a focus on 'active ingredients'

In arguing for an active-ingredient limitation, the government repeatedly invokes the IRA's supposedly broad purpose of controlling Medicare spending. *See*, *e.g.*, Opp. 1, 24-26. The government's claim that the Program has a single ascertainable purpose is doubtful, for "no legislation pursues its purposes at all costs." *Rodriguez* v. *United States*, 480 U.S. 522, 525-526 (1987) (per curiam). Nor did Congress pursue the single goal of reducing Medicare spending on all drugs: to the contrary, it excluded numerous drugs from being eligible for "negotiation." But even if the government's characterization of the Program's purpose were correct, "it is quite mistaken to assume . . . that whatever might appear to further[] the statute's primary objective must be the law." *Henson* v. *Santander Consumer USA Inc.*, 582 U.S. 79, 89 (2017) (internal quotation marks and citation omitted). In particular, to the extent the government suggests that the plasma-derived-products exclusion should be narrowly construed in light of the IRA's purported broad purpose, precedent holds otherwise. Courts "normally 'have no license to give [statutory] exemption[s]

anything but a fair reading.'" *Food Marketing Institute* v. *Argus Leader Media*, 588 U.S. 427, 439 (2019) (quoting *Encino Motorcars, LLC* v. *Navarro*, 584 U.S. 79, 89 (2018)). Because the plasma-derived-products exclusion prohibits the government from selecting BOTOX, it is irrelevant whether the selection of BOTOX for price controls would advance a broad policy goal of reducing Medicare expenditures.

The government's focus on the IRA's purported general purpose ignores that Congress had specific reasons for enacting the plasma-derived-products exclusion, which favor AbbVie. *See* p. 17, *supra*. The plasma-derived-products exclusion is every bit "as much a part of the [IRA's] purpose" as the overall goal of reducing Medicare drug spending. *Encino Motorcars*, 584 U.S. at 89. The evident purposes of that exclusion are served only by a whole-product reading: price controls risk interfering with sensitive supply chains and undermining research and development regardless of whether the biological product's active ingredients or inactive components are obtained from human plasma. *See* p. 17, *supra*. The government has yet to explain how its active-ingredient theory can be reconciled with the rationale for the plasma-derived-products exclusion.[5] The government's active-ingredient interpretation is thus self-defeating: in pursuing one of the IRA's "purposes at all costs," the government asks the Court to disregard or undermine Congress's purpose in enacting the plasma-derived-products exclusion. *Rodriguez*, 480 U.S. at 526.

[5] There is no basis for thinking that AbbVie added HSA to BOTOX for anything other than legitimate reasons. *See* MSJ 6-7, 29 (noting that BOTOX has included HSA since it was first approved in 1989). Nor has the government argued or provided any evidence that the active-ingredient policy is necessary to prevent evasion of Program requirements. The addition of HSA is no small manufacturing endeavor (given the supply-chain constraints discussed above), and FDA has adequate tools to police market entry of reformulated products. *See*, *e.g.*, 21 C.F.R. § 601.12(b)(2)(i) (requiring FDA preapproval for "major change[s]" to previously approved products, including changes in "inactive ingredients").

C. The Government's Fallback Argument Lacks Merit

The government argues that, even if the plasma-derived-products exclusion uses "biological product" in the ordinary sense of a whole product, BOTOX was nevertheless properly designated because "BOTOX does not derive its status as a biological product from HSA" but rather from onabotA, "which is not human whole blood or plasma." Opp. 28 (internal quotation marks and citation omitted; capitalization altered). That argument simply repackages the government's primary argument and fails for many of the same reasons.

To begin with, the government's argument disregards the statute Congress wrote. Congress excluded from the definition of a QSSD any "biological product that is derived from human whole blood or plasma." 42 U.S.C. § 1320f-1(e)(3)(C). As the government does not dispute, the D.C. Circuit has broadly interpreted the phrase "derived from" to mean that a product is obtained from another source, whether directly or by means of a component derived from that source. *See* MSJ 28 (noting that, under the D.C. Circuit's and FDA's interpretations of the Family Smoking Prevention and Tobacco Control Act of 2009, a product is "derived from tobacco"—and thus a regulated "tobacco product"—if it contains tobacco, nicotine, or any tobacco derivative). But on the government's telling, the plasma-derived-products exclusion would need to be rewritten to prohibit selection only of a "biological product *that* . . . derive[*s*] [*its regulatory status as a biological product*] from human whole blood or plasma." *Cf.* 42 U.S.C. § 1320f-1(e)(3)(C) (emphasis added). The Court's task is to interpret the IRA, however, not to "add words to the law to produce what is thought to be a desirable result." *Equal Employment Opportunity Commission* v. *Abercrombie & Fitch Stores, Inc.*, 575 U.S. 768, 774 (2015); *see* pp. 18-19, *supra*. In any event, it is hardly "natural[]" to think that Congress intended the plasma-derived-products exclusion to apply based on how products *derived their regulatory status*, as opposed to what those products *are*. *Cf.* Opp. 29.

The government gestures at two textual arguments, but neither has merit. *First*, the government contends that, if Congress wanted to apply the plasma-derived-products exclusion to whole products, it could have stated that the exemption applied to "final products," not "biological products." Opp. 29. No such formulation was necessary, however, because the IRA consistently uses "biological products" to refer to whole products. *See* pp. 13-16, *supra*. The government offers no reason to believe Congress naturally would have used "final product"—which appears in only two sections in all of Titles 21 and 42 of the U.S. Code—had it intended "biological product" to refer to whole products. *Cf.* 21 U.S.C. § 350a(b)(3) (using "final product stage" to refer to a "point in the manufacturing process" of infant formula at which point "an infant formula is homogenous and is not subject to further degradation"); 21 U.S.C. § 353b(b)(2)(A)(ii) (using "final product" in describing a report required to be submitted by registered drug-outsourcing facilities).

Second, the dictionary definition of "derive" on which the government relies only confirms that the plasma-derived-products exclusion applies to BOTOX. The cited dictionary defines "derive" to mean "to take, receive, or obtain especially from a specified source." Opp. 29. BOTOX is thus "derived" from human plasma because it is "take[n]" or "obtain[ed]" from HSA, regardless of where it "derived" its regulatory status. *See* pp. 17-18, *supra*. To the extent the government suggests that BOTOX cannot be derived from HSA because it is derived from onabotA, that is a false dichotomy: BOTOX is made of—and thus "derived from"—both. No further inquiry into the source of BOTOX's regulatory classification is necessary in order to conclude that the product is a "biological product that is derived from human . . . plasma." 42 U.S.C. § 1320f-1(e)(3)(C).

* * * * *

When Congress enacted the IRA, it expressly prohibited CMS from setting prices for biological products derived from human plasma. Because BOTOX is such a product, defendants

exceeded their statutory authority when they purported to select BOTOX for "negotiation." This Court should hold that selection unlawful and set it aside.

D. Alternatively, Defendants' Action Was *Ultra Vires*

For many of the same reasons that defendants' selection of BOTOX exceeded their statutory authority and must be set aside, that action was also *ultra vires*. *Ultra vires* review is available where an agency "has taken action entirely in excess of its delegated powers and contrary to a specific prohibition in a statute" and where the statutory scheme does not provide "a meaningful and adequate opportunity for judicial review" or "forecloses all other forms of judicial review." *Nuclear Regulatory Commission* v. *Texas*, 605 U.S. 665, 681 (2025) (*NRC*) (internal quotation marks, citations, and emphasis omitted).

Even if defendants' selection of BOTOX could not be reviewed under the APA, the Court should nevertheless review and enjoin that selection as *ultra vires*. *See* MSJ 32-33. By selecting BOTOX, defendants overstepped their "delegated powers" and acted "contrary to [the] specific prohibition" in the IRA on the selection of plasma-derived products like BOTOX. *Nyunt* v. *Chairman, Broadcasting Board of Governors*, 589 F.3d 445, 449 (D.C. Cir. 2009) (Kavanaugh, J.) (quoting *Leedom* v. *Kyne*, 358 U.S. 184, 188 (1958)). The government's construction of the plasma-derived-products exclusion, which imports an active-ingredient component, "requires adding text to the [IRA] that Congress pointedly omitted." *National Association of Postal Supervisors* v. *United States Postal Service*, 26 F.4th 960, 977 (D.C. Cir. 2022). "[N]onstatutory review [must be] available" to examine and set aside defendants' selection of BOTOX, which attempts to exercise a power Congress "specifically withheld" under the IRA. *NRC*, 605 U.S. at 681 (citation omitted).

The government's arguments to the contrary are unavailing. The government argues that *ultra vires* review is unavailable because the IRA expressly precludes review of AbbVie's claim.

See Opp. 22. But the statute "expressly" precludes only "determination[s] of [QSSDs] under section 1320f-1(e)," which does not bar claims that defendants acted *contrary to* section 1320f-1(e). *See* pp. 4-9, *supra*. There is accordingly no preclusion of review here—whether express or otherwise.

The government also contends that AbbVie cannot show that CMS "plainly" acted "contrary to a specific prohibition." Opp. 22-23 (citation omitted). But the plasma-derived-products exclusion is precisely the kind of "specific prohibition" that supports *ultra vires* review. *NRC*, 605 U.S. at 681-682 (citation omitted). Congress forbade the selection of plasma-derived products, leaving defendants no discretion to select BOTOX. The selection of BOTOX was not just unlawful, but *ultra vires*.

III. The Drug Price Negotiation Program Violates AbbVie's Constitutional Rights

By selecting BOTOX for the Program, defendants not only ignored the IRA's plain text, but also subjected AbbVie to a price-control scheme that violates several constitutional provisions. The IRA forces AbbVie to hand over "access" to BOTOX for whatever the government decides to pay following a sham "negotiation" lacking any of the essentials of due process. Worse still, the IRA forces AbbVie falsely to declare that this mandated price is "fair," that it "agrees" to the price, and that the price results from "negotiations." Should this Court reach AbbVie's constitutional claims, it should conclude that the Program violates the First and Fifth Amendments. *See* MSJ 33-44.

Despite dismissing AbbVie's constitutional claims as "tacked-on," the government devotes over half of its argument to addressing those claims. *See* Opp. 2, 29-50. Yet the government ultimately fails to justify the constitutional defects in the Program's design. The government defends the novel price-control scheme as the price that AbbVie must pay for providing its products to Medicare and Medicaid beneficiaries, but the IRA's structure and economic reality leave

AbbVie no way to exit that scheme. And even if it did, the Constitution prohibits the government from withholding benefits to coerce individuals into ceding their constitutional rights. The government thus falls back on a syllogism: because a handful of other courts have dismissed other manufacturers' constitutional claims, this Court should do the same. But the Supreme Court has yet to address those constitutional claims, and Judge Hardiman has forcefully explained the constitutional problems with the Program's design. *See Bristol Myers Squibb Co.* v. *Secretary, HHS*, 155 F.4th 245, 269 (3d Cir. 2025) (Hardiman, J., dissenting) (*BMS*). If this Court reaches the constitutional questions, it should conclude that the Program violates the First and Fifth Amendments.

A. The IRA Effects An Unconstitutional Taking

As AbbVie has explained, *see* MSJ 33-34, the IRA violates the Fifth Amendment's Takings Clause because it requisitions AbbVie's property—doses of BOTOX—for less than "just compensation." U.S. Const. Amend. V. The Program "imposes a clear physical taking." *BMS*, 155 F.4th at 273 (Hardiman, J., dissenting). After CMS imposes a "maximum fair price" for BOTOX, AbbVie must "provide access to such price" to Medicare enrollees and dispensing providers. 42 U.S.C. § 1320f-2(a)(1). That requirement "forc[es] [AbbVie] to turn over physical doses of [BOTOX]," *BMS*, 155 F.4th at 273 (Hardiman, J., dissenting), and deprives AbbVie of its fundamental right to exclude others from its property, *see Horne* v. *Department of Agriculture*, 576 U.S. 350, 364-365 (2015); *Cedar Point Nursery* v. *Hassid*, 594 U.S. 139, 144, 149-150 (2021).

1. The government's contrary arguments lack merit. The government frames the Program as a "government action[] that adjust[s] economic relationships, without a physical invasion or appropriation of property." Opp. 30. The government does not dispute, however, that the Program is economically coercive. *See* Opp. 35. Rather, the government argues that AbbVie's participation in the Program is voluntary; as the government puts it, "if AbbVie prefers not to sell

BOTOX to Medicare on the terms established by Congress, it need not sell BOTOX to Medicare at all." *Id*. (capitalization altered). But that notion is legally and practically illusory. *See* MSJ 38-42 & n.16. By the time a manufacturer's drug is selected, the manufacturer cannot withdraw its drugs from Medicare and Medicaid in time to avoid the Program's crushing excise tax. Thus, "[a]lthough participation in Medicare and Medicaid is voluntary, participation in the Program is not." *BMS*, 155 F.4th at 273 (Hardiman, J., dissenting). The government's only response is to point in a footnote to CMS guidance purporting to allow manufacturers to withdraw within 30 days. *See* Opp. 40 n.10. But CMS cannot supersede the IRA's statutory requirements through nonbinding guidance. *See* MSJ 39-40 & n.16; *BMS*, 155 F.4th at 278 (Hardiman, J., dissenting).

In any event, the government effects a per se taking when it requires an owner to "relinquish specific, identifiable property as a condition on permission to engage in commerce," even where the owner "voluntarily choose[s] to participate in the . . . market." *Horne*, 576 U.S. at 364-365 (internal quotation marks and citation omitted). Selling a product "in interstate commerce, although certainly subject to reasonable government regulation, is . . . not a special governmental benefit that the [g]overnment may hold hostage, to be ransomed by waiver of constitutional protection." *Id*. at 366. Moreover, requiring a party to open its property to third parties is every bit as much of a taking as if the government seizes the property itself. *See Cedar Point*, 594 U.S. at 149-150; *Loretto* v. *Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 440 (1982). And government action imposes a taking—not a permissible condition of a government benefit—if failure to abide by the condition results in penalties beyond loss of the benefit. *See Valancourt Books, LLC* v. *Garland*, 82 F.4th 1222, 1232-1233 (D.C. Cir. 2023).

2. The government tries to shield its "voluntariness" argument behind dated out-of-circuit cases rejecting challenges to other Medicare provisions. Opp. 32-33. Those cases, which

predate the Supreme Court's decision in *Horne*, are inapposite. None involved a program in which the government singled out select providers for participation and imposed ruinous penalties on those who did not comply. Instead, for the most part, those cases upheld the government's right to determine "the amount it will pay for . . . services" (Opp. 32-33) without *requiring* sellers to provide those services or *punishing* them for their refusal to do so. And the plaintiffs' claims of *regulatory takings* failed because the plaintiffs had chosen to take on the obligations they complained about. *See*, *e.g.*, *Garelick* v. *Sullivan*, 987 F.2d 913, 916-917 (2d Cir. 1993). Regardless, in the wake of *Horne*, the government cannot require an owner to sell or transfer its property as a condition of being allowed to engage in lawful commerce, then maintain that the owner chose to accept that condition.

3. The government argues that the Program "does not mandate any physical appropriation" of BOTOX doses, because it "does not require [AbbVie] to sell its drugs to Medicare in the first instance or to give anyone physical access to its drugs over its objection." Opp. 33-34. But the Program gives manufacturers that participate in Medicare no legal or practical way to walk away once their drugs are selected. *See* MSJ 38-42; pp. 29-30, *supra*. And the government does not explain how a manufacturer could "provide access" to the "maximum fair price" for Medicare beneficiaries and providers, 42 U.S.C. § 1320f-2(a)(1), (3), without "turn[ing] over physical doses of their drugs," *BMS*, 155 F.4th at 281 (Hardiman, J., dissenting). The government need not send trucks to AbbVie's warehouses under cover of night for the Program to effect a taking. *See Cedar Point*, 594 U.S. at 149; *Loretto*, 458 U.S. at 440.

4. The government also contends that there is no taking because CMS acts only as a "market participant." Opp. 36. That argument ignores the basic realities of the government's role in the health-care industry. In 2024, for example, Medicare and Medicaid together accounted for

nearly 40% of domestic health-care consumption expenditures and nearly half of prescription-drug spending. *See* CMS, Table 4: National Health Expenditures by Source of Funds and Type of Expenditure: Calendar Years 2017-2024 <tinyurl.com/NHE-Tables> (last visited July 24, 2026); *Sanofi-Aventis U.S. LLC* v. *U.S. Department of Health & Human Services*, 58 F.4th 696, 699 (3d Cir. 2023). Moreover, the Program not only wields the government's tremendous purchasing power—a fact the government acknowledges, *see* Opp. 36—but also backs up that power with sovereign regulatory authority to fine and tax non-participating manufacturers. Those features make the Program materially different from the drug-pricing programs run by the Department of Defense, the Department of Veterans Affairs, and the Coast Guard. *See* 38 U.S.C. § 8126; *The Coalition for Common Sense in Government Procurement* v. *Secretary of Veterans Affairs*, 464 F.3d 1306, 1312, 1316-1318 (Fed. Cir. 2006). Unlike those programs, the IRA's price-control regime does not permit manufacturers to "choose whether to do business with the government." Opp. 37. Instead, it "creat[es] a de facto mandate to participate" that no ordinary market participant could impose. *BMS*, 155 F.4th at 273 (Hardiman, J., dissenting).

B. The IRA Deprives AbbVie Of Property Without Due Process

The Program unconstitutionally deprives AbbVie of its protected property interest in BOTOX without due process of law. That property interest encompasses "the rights to possess, use and dispose of" its products, *Horne*, 576 U.S. at 361 (citation omitted); the "right to exclude" others from them, *Cedar Point*, 594 U.S. at 149-150; and the right "to fix the price at which [it] will sell" them, *Old Dearborn Distributing Co.* v. *Seagram-Distillers Corp.*, 299 U.S. 183, 192 (1936). The Program violates the Due Process Clause by requiring AbbVie to "provide access to" the "maximum fair price" to third parties, 42 U.S.C. § 1320f-2(a)(1), (3), without first providing AbbVie "the opportunity to be heard at a meaningful time and in a meaningful manner," *Mathews* v. *Eldridge*, 424 U.S. 319, 333 (1976) (internal quotation marks and citation omitted), by a "neutral

and detached" decisionmaker, *Concrete Pipe & Products of California, Inc.* v. *Construction Laborers Pension Trust for Southern California*, 508 U.S. 602, 618 (1993).

The government fails to rebut AbbVie's showing of a protected property interest. The government insists that AbbVie does not have a right to "sell to the government that which the government does not wish to buy." Opp. 38 (quoting *Coyne-Delany Co.* v. *Capital Development Board*, 616 F.2d 341, 342 (7th Cir. 1980) (per curiam)). But the Program not only slashes Medicare reimbursement rates for selected drugs but also uses a combination of civil monetary penalties, an extortionate excise tax, and prohibition on reimbursement for *any* of a manufacturer's drugs to coerce manufacturers into providing products to third parties at below-market prices. Contrary to the government's claim that the Program "does not control any private market transactions," Opp. 41, the Program dictates the price at which AbbVie may sell BOTOX that will be administered to private Medicare-eligible individuals and the providers who administer drugs to such individuals.[6] Those sales are private-market transactions even if Medicare reimburses buyers for part or all of what they pay.

The government defends the Program's procedures, Opp. 41-42, but those procedures remain constitutionally inadequate. CMS is neither a neutral nor detached decisionmaker, given its statutory mandate to set "the *lowest* maximum fair price for each selected drug." 42 U.S.C. § 1320f-3(b)(1) (emphasis added). Nor does the Program give a manufacturer a meaningful opportunity to be heard, given that CMS may set a maximum fair price based on evidence not shared with a manufacturer and without considering manufacturer input. *See* MSJ 35-36. The government contends that these procedures are "neither unusual nor unlawful, standing alone." Opp. 42.

[6] Indeed, CMS itself does not purchase any drugs under Medicare Part D. Under Medicare Part D, drug manufacturers generally negotiate prices with private plans that have contracted with CMS to participate in the Medicare Part D program. *See*, *e.g.*, 42 U.S.C. § 1395w-112(b)(1).

But the flaws with the Program's design do not "stand[] alone": rather, the absence of a neutral decisionmaker, lack of opportunity to be heard, and limitations on judicial review all work together to deprive manufacturers such as AbbVie of their property without any meaningful process at all.

C. The IRA Unconstitutionally Compels Speech

Beyond forcing AbbVie to sell its product at whatever price the government decides to charge, the IRA also requires AbbVie to state that the government's preferred price is "fair," that it "agree[s]" to that price, and that the price resulted from a "negotiation." 42 U.S.C. § 1320f-2(a). Forcing AbbVie to express these messages with which it disagrees violates the First Amendment. *See*, *e.g.*, *303 Creative LLC* v. *Elenis*, 600 U.S. 570, 586-587 (2023); *Hurley* v. *Irish-American Gay, Lesbian & Bisexual Group of Boston*, 515 U.S. 557, 573-574 (1995). The government's contrary arguments are unpersuasive.

1. The government stakes much on the premise that participation in the Program is voluntary, but that premise is incorrect. The government does not argue that the Program is narrowly tailored to serve a compelling government interest, or that the Program could survive any form of heightened scrutiny. Instead, it argues only that the First Amendment does not apply because AbbVie's participation in the Program is "voluntary." Opp. 42. As AbbVie has explained (MSJ 38-42), given the government's extraordinary market power, the IRA compels AbbVie's participation in the scheme. "By requiring [manufacturers] to profess a specific belief" in order to avoid paying extortionate excise taxes or banishment from the entire Medicare and Medicaid markets, the Program compels AbbVie's speech. *Agency for International Development* v. *Alliance for Open Society International, Inc.*, 570 U.S. 205, 218 (2013) (*AID*). That would be true even if the compelled speech were not "actually coercive, in the sense of an offer that cannot be refused." *Id*. at 214.

2. The government then argues that the messages it compels AbbVie to express are not "constitutionally protected speech," but rather "only non-expressive conduct." Opp. 43. Specifically, the government contends that the Program is only an "ordinary price regulation" that "poses no First Amendment problem." Opp. 44 (citation omitted). But the Program is "not like a typical price regulation," which "would simply regulate the amount that [AbbVie] could collect" for its products. *Expressions Hair Design* v. *Schneiderman*, 581 U.S. 37, 47 (2017). By contrast—and unlike the laws at issue in *44 Liquormart, Inc.* v. *Rhode Island*, 517 U.S. 484 (1996), and *Nicopure Labs, LLC* v. *FDA*, 944 F.3d 267 (D.C. Cir. 2019)—the Program regulates both the prices of drugs *and* the messages manufacturers must convey about those prices. The "agreements" thus are not "incidental" to the Program, *Expressions Hair Design*, 581 U.S. at 47, but expressive political messaging, *see BMS*, 155 F.4th at 285-286 & n.14 (Hardiman, J., dissenting).

The government likewise suggests that the "agreements" are non-expressive because they are "ordinary commercial contract[s]." Opp. 45. Not so. The "agreements" memorialize not commercial exchanges, but manufacturers' compelled assent to the government's preferred policy, which is protected expression. *See AID*, 570 U.S. at 213, 218-219. Indeed, because defendants could have imposed price controls without requiring manufacturers to "agree" to anything, those "agreements" serve no purpose other than creating the misleading appearance that manufacturers have participated voluntarily in the program and agree that the resulting prices are "fair."

D. The IRA Is Unconstitutional Even If The Drug Price Negotiation Program Is Voluntary

The government repeatedly asserts that the Program poses no constitutional problem because manufacturer participation in Medicare is "voluntary." That premise is neither correct nor dispositive. The unconstitutional-conditions doctrine forbids the government from coercing parties to forgo their constitutional rights through the "process of requiring a surrender, which, though,

in form voluntary, in fact lacks none of the elements of compulsion." *Frost & Frost Trucking Co.* v. *Railroad Commission of California*, 271 U.S. 583, 593 (1926); *see Koontz* v. *St. Johns River Water Management District*, 570 U.S. 595, 606, 608 (2013). Under that doctrine, even if participation in the Program were in some sense "voluntary," the Program would still be unconstitutional because it impermissibly burdens AbbVie's rights under both the First Amendment and the Takings Clause.

In response, the government primarily argues that the Program's conditions do not violate the unconstitutional-conditions doctrine because they "directly relate to the [P]rogram's goal of controlling costs and do not impede AbbVie's ability to exercise its rights outside the scope of the Program." Opp. 47. But the Supreme Court has rejected the view that the unconstitutional-conditions doctrine applies only "when the condition is not relevant to the objectives of the program" or "when the condition is actually coercive." *AID*, 570 U.S. at 214. The government "cannot recast a condition on funding as a mere definition of its program in every case, lest [the doctrine] be reduced to a simple semantic exercise." *Id*. at 215 (citation omitted). Otherwise, "the definition of a particular program [could] always be manipulated to subsume the challenged condition." *Id*.

Regardless, the Program's conditions sweep far beyond the goal of "controlling costs." *Contra* Opp. 47. Forcing manufacturers to choose between exercising their constitutional rights and selling *any* drugs to Medicare beneficiaries has an insufficient nexus to the Program's permissible goal of lowering Medicare spending on specific drugs. Even if the Program's conditions were relevant to the Program's goals, they are egregiously disproportionate: Congress just as easily could have regulated drug prices without requisitioning AbbVie's property and compelling AbbVie to endorse the government's preferred messages. The Program is thus "doing something more" than what is necessary to achieve its stated goals, and in so doing it "affects 'protected

conduct outside the scope of the federally funded program.'" *AID*, 570 U.S. at 218 (quoting *Rust* v. *Sullivan*, 500 U.S. 173, 197 (1991)).

The government suggests that the Program's compelled-speech tactics do not impermissibly burden AbbVie's free-speech rights because the "agreements" provide "the source of the enforceable obligation" between the parties, and because AbbVie remains "free to speak out against the Negotiation Program" in other contexts. Opp. 49. But the fact that AbbVie remains able to speak out against the Program does nothing to cure the First Amendment violation. The Supreme Court has consistently recognized that the government cannot "require speakers to affirm in one breath that which they deny in the next." *Pacific Gas & Electric Co.* v. *Public Utilities Commission of California*, 475 U.S. 1, 16 (1986) (plurality opinion). Were it otherwise, there would have been no First Amendment problem in *Miami Herald Publishing Co.* v. *Tornillo*, 418 U.S. 241 (1974), where "the statute in question" did "not prevent[] the *Miami Herald* from saying anything it wished." *Id*. at 256 (citation omitted). Nor would there have been a First Amendment violation in *Wooley* v. *Maynard*, 430 U.S. 705 (1977), where drivers could disavow a required license-plate motto with "a conspicuous bumper sticker." *Id*. at 722 (Rehnquist, J., dissenting). The Program's "agreements" thus burden AbbVie's First Amendment rights even if AbbVie remains free to repudiate "in one breath" the message it is forced to convey in another.

The government is also mistaken in arguing (Opp. 50) that the nexus-and-proportionality test applies only in the context of land-use exactions. *See Nollan* v. *California Coastal Commission*, 483 U.S. 825, 834-837 (1987); *Dolan* v. *City of Tigard*, 512 U.S. 374, 386, 391 (1994). The Supreme Court has rejected the argument that the Takings Clause offers greater protection against physical appropriation of real property than of personal property. *Horne*, 576 U.S. at 357-361. Moreover, the government's argument ignores *Sheetz* v. *County of El Dorado*, 601 U.S. 267

(2024), which clarified that the nexus-and-proportionality test is "rooted" in and "modeled on" the "unconstitutional conditions doctrine" and rejected an effort to limit that test to the facts of *Nollan* and *Dolan*. *Id*. at 275, 278. The *Nollan-Dolan* framework thus represents an application of the "overarching principle . . . that vindicates the Constitution's enumerated rights by preventing the government from coercing people into giving them up." *Koontz*, 570 U.S. at 604. The Program violates that principle by requiring a manufacturer to parrot the government's preferred messages and accept the government's arbitrary price controls on selected products if the manufacturer wishes to sell *any* drugs for administration to Medicare beneficiaries. Those requirements "amount to an out-and-out plan of extortion" that the unconstitutional-conditions doctrine prohibits. *Sheetz*, 601 U.S. at 275 (quoting *Nollan*, 483 U.S. at 837).

CONCLUSION

For the foregoing reasons, the Court should grant AbbVie's motion for summary judgment and deny defendants' motion to dismiss (or, in the alternative, for summary judgment).

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Respectfully submitted,

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