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' REPLY IN SUPPORT OF THEIR MOTION TO DISMISS
(OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT)

ERIC J. HAMILTON
Deputy Assistant Attorney General

MICHELLE R. BENNETT
Assistant Branch Director

STEPHEN M. PEZZI (D.C. Bar 995500)
Chief Litigation Counsel
PARDIS GHEIBI (D.C. Bar 90004767)
Trial Attorney
United States Department of Justice
Civil Division, Federal Programs Branch
1100 L Street NW
Washington, DC 20005
Tel: (202) 305-8576
Email: stephen.pezzi@usdoj.gov

Counsel for Defendants

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INTRODUCTION

From November 2024 to October 2025, approximately 390,000 Medicare beneficiaries used Botox, at a cost of approximately $1,143,070,000 in Medicare Part B and Part D funds. *See* Fact Sheet, CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2028* (Jan. 2026), https://perma.cc/6YCF-WZEX. All of those Medicare beneficiaries used Botox because its active ingredient is Botulinum Toxin Type A—a powerful toxin that, according to AbbVie, has both cosmetic and medicinal benefits. But it is undisputed that Botulinum Toxin Type A is *not* "derived from human whole blood or plasma." 42 U.S.C. § 1320f-1(e)(3)(C). Accordingly, CMS correctly determined that "Botox; Botox Cosmetic" is a "qualifying single source drug" within the meaning of 42 U.S.C. § 1320f-1(e).

AbbVie disagrees with that determination. But this Court need not referee that dispute here, because Congress also provided expressly that "[t]here shall be no administrative or judicial review" of (among other things) CMS's "determination of qualifying single source drugs under [42 U.S.C. §] 1320f-1(e)." *Id.* § 1320f-7. And the Supreme Court recently reiterated that a preclusion provision that bars review of an agency "determination . . . under [a specified] subsection" should be given its ordinary meaning. *Mullin v. Doe*, 146 S. Ct. 2121, 2133-35 (2026). Here, as in *Mullin*, the ordinary meaning of the review bar precludes review of CMS's determination that Botox is a qualifying single source drug *and* of the relevant "subsidiary determinations" that led to that determination, *id.* at 2136—namely, CMS's decision that Botox does not qualify for the plasma-derived products exclusion to the definition of a qualifying single source drug.

AbbVie's statutory claim would also fail on its merits. CMS properly examined Botox's active ingredient to determine whether it falls within the exclusion for "[a] biological product that

is derived from human whole blood or plasma." 42 U.S.C. § 1320f-1(e)(3)(C). Congress's directive to engage in this analysis is embedded throughout the IRA's text and confirmed by the IRA's structure and purpose. In the alternative, CMS's determination that Botox does not qualify for the exclusion withstands scrutiny even if the Court assumes, as AbbVie argues, that CMS must engage in a *product*-specific analysis. By its own terms, the exclusion applies only to "[a] biological product that is *derived from* human whole blood or plasma." *Id.* (emphasis added). AbbVie does not dispute that the reason Botox is licensed as a "biological product" to begin with is because its active ingredient is Botulinum Toxin Type A. Thus, under an ordinary reading of the exclusion's text, Botox—as a "biological product"—is "derived from" its active ingredient Botulinum Toxin Type A, and not "human whole blood or plasma." *Id.*

Finally, AbbVie's constitutional theories have already been addressed in roughly a dozen other challenges to this same program. All have been rejected, in every case—a robust nationwide consensus that is extraordinarily rare in the modern era of litigation over significant government programs. AbbVie offers no basis for this Court to reject that now-settled understanding.

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." *Id.* § 1320f-7. But even if this Court reaches the merits of AbbVie's statutory claim, it should reject it. CMS properly applied the "[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)—by examining whether Botox's active ingredient is "derived from human

whole blood or plasma." This interpretation is consistent with the text, structure, and purpose of the IRA, which make clear that Congress directed CMS to identify "qualifying single source drug[s]"—and the biological products that fall within the "[p]lasma-derived products" exclusion—based on their active ingredients. Here, the only active ingredient in Botox is Botulinum Toxin Type A, which is indisputably not "derived from human whole blood or plasma." *Id.*

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

The animating premise of AbbVie's statutory claim is that CMS has selected the wrong drug for inclusion in the Negotiation Program. In particular, AbbVie argues that because Botox contains human serum albumin ("HSA") as an inactive ingredient, it should have been subject to the "[p]lasma-derived products" exclusion to the definition of a "qualifying single source drug" under Section 1320f-1(e)(3)(C). *See* Pl.'s Opp'n & Reply at 12-16, ECF No. 40 ("Pl.'s Opp'n & Reply"). This claim turns out to be meritless, *see* pp. 13-23, *infra*, but regardless, it is not subject to review under Section 1320f-7(2), which expressly bars review of CMS's "determination of qualifying single source drugs under section 1320f-1(e)." 42 U.S.C. § 1320f-7(2).

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

As explained in Defendants' opening brief, AbbVie's grievance is that CMS's determination that Botox is a "qualifying single source drug" under Section 1320f-1(e) is erroneous. *See* Defs.' Br. in Supp. of Mot. to Dismiss at 13-29, ECF No. 32-1 ("Defs.' Br."). But Section 1320f-7(2) plainly bars judicial review of any such "determination." 42 U.S.C. § 1320f-7(2); *see also* Defs.' Br. at 14-17. It is of no moment that AbbVie purports to challenge CMS's determination that the "[p]lasma-derived products" exclusion does not apply to Botox. *Id.* § 1320f-1(e)(3)(C). This determination is not subject to judicial review because it was a necessary subsidiary decision in the lead up to the unreviewable "determination" that Botox is "a qualifying

single source drug[] under section 1320f-1(e)." *Id.* § 1320f-7(2). And as the Supreme Court recently recognized in *Mullin*, where, as here, a judicial-review bar prohibits review of an agency "determination," it also bars review of "subsidiary determinations" prior to the unreviewable determination. 146 S. Ct. at 2136.

In *Mullin*, the Supreme Court interpreted the scope of 8 U.S.C. § 1254a(b)(5)(A), which "provides: 'There is no judicial review of any determination of the [Secretary of Homeland Security] with respect to the designation, or termination or extension of a designation, of a foreign state under this subsection.'" 146 S. Ct. at 2133 (quoting 8 U.S.C. § 1254a(b)(5)(A)) (alteration in original). The Court recognized that the term "'determination' in its ordinary sense" has a broad scope. *Id.* at 2136. Specifically, it emphasized that "it [is] common to use the term 'determination' in [a] broad sense" to include not just the ultimate "'decision'" itself but also "the chain of events leading up to a decision." *Id.* at 2133. The Court reasoned that the preclusion provision "barr[ed] respondents' non-constitutional claims," which challenged "discrete decision[s] made by the Secretary" as a "part of the process that led to her final decision to terminate these countries' [Temporary Protected Status (TPS)] designations." *Id.* at 2134.

This interpretation, the Court explained, was consistent with the principle that in agency-review cases, "an agency's subsidiary decisions merge into the final agency action, ... [i]f the final agency action is unreviewable, then so too are subsidiary determinations." *Id.* at 2136. "This important principle ensures that challengers cannot avoid a judicial-review bar by creative pleading or clever lawyering." *Id.* And while the Court acknowledged the "presumption in favor of judicial review," it explained that "the text of the TPS judicial-review bar very clearly overcomes [that] general presumption." *Id.* at 2134.

Similarly, here, the IRA's review bar "clearly overcomes the general presumption in favor of judicial review." *Id.* Much like the provision at issue in *Mullin*, Section § 1320f-7(2) also bars review of "determination[s] . . . under [a specific subsection]." *Compare* 42 U.S.C. § 1320f-7(2) (barring review of CMS's "determination of qualifying single source drugs under Section 1320f-1(e)") *with* 8 U.S.C. § 1254a(b)(5)(A) (barring the Secretary of Homeland Security's "determination . . . with respect to the designation, or termination or extension of a designation, of a foreign state under this subsection"). Here, CMS's determination that Botox does not qualify under the plasma-derived products exclusion is a necessary "subsidiary determination[]," *Mullin*, 146 S. Ct. at 2136, in the lead up to its "determination" that Botox is a "qualifying single source drug[] under section 1320f-1(e)," 42 U.S.C. § 1320f-7(2); *see also Mullin*, 146 S. Ct. at 2136 ("In APA cases, an agency's subsidiary decisions merge into the final agency action."). Because CMS's determination that Botox is a qualifying single source drug "is unreviewable, then so too are [CMS's relevant] subsidiary determinations," *Mullin*, 146 S. Ct. at 2136, including its application of the plasma-derived products exclusion.

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

AbbVie does not dispute that it seeks to challenge CMS's determination that Botox is a qualifying single source drug.[1] But, AbbVie maintains, the review bar is nevertheless inapplicable

[1] On this score, AbbVie's argument is even more ambitious than other manufacturers who have tried to bring statutory challenges to this Program. Here, AbbVie directly challenges CMS's selection of Botox, whereas other manufacturers largely attempted to masquerade their challenges to CMS's selection of their drugs by purporting to target CMS's drug-selection *methodology*. Those attempts are meritless because CMS's methodologies were inextricably intertwined with CMS's unreviewable determinations. *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). AbbVie—in an attempt to shield itself from the same fate—distinguishes itself by claiming that it is not challenging "any agency decision that is 'inextricably intertwined' with an unreviewable determination." Pl.'s Opp'n & Reply at 2. Its transparency, however, only

because CMS's determination was unlawful. *See* Pl.'s Opp'n & Reply at 3 ("This Court Has Jurisdiction To Review The Unlawful Selection Of BOTOX."). As AbbVie sees it, only lawful determinations are subject to the review bar. *See id.* at 3-12. In support of its theory, AbbVie relies on a line of cases in the D.C. Circuit, which according to AbbVie, stand for the proposition that when a review bar is limited to certain agency actions, the court must first examine the lawfulness of those actions to determine whether the review bar is applicable in the first place. *See id.* 4-7. AbbVie's reading of the caselaw is unduly expansive and fails for several reasons.

1. To begin with, AbbVie's cases do not depart from the general proposition that a review bar only applies to agency actions that "qualify as the kind of action for which review is barred." *Am. Hosp. Ass'n v. Azar*, 964 F.3d 1230, 1238 (D.C. Cir. 2020); *see also Ardelyx, Inc. v. Kennedy*, 179 F.4th 947, 954 (D.C. Cir. 2026) (same). They merely illustrate that, in rare cases, "the preclusion and merits analysis" "merg[e]." *Am. Hosp. Ass'n*, 964 F.3d at 1238 (quotation marks omitted). Whether such merger occurs, however, turns on the specific text of the review bar and the relevant facts of the case. In *Am. Hosp. Ass'n*, for instance, the review bar "foreclose[d] judicial review of the agency's 'establishment of methods described in paragraph (2)(F).'" *Id.*

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makes its claim less palatable. After all, CMS's "determination" that Botox is a qualifying single source drug is not merely "inextricably intertwined" with an unreviewable determination—it *is* an unreviewable determination.

Contrary to AbbVie's contention, this distinction does not render reference to "the 'inextricably intertwined' doctrine . . . misplaced." *Id.* If anything, it makes the doctrine more potent because it exposes AbbVie's theory as incoherent. As AbbVie would have it, this Court has jurisdiction to review CMS's *individual* determination with respect to Botox but not the *methodology* that led to Botox's selection. That distinction belies common sense—challenges to individual determinations are narrower than those to methodologies. If the latter is barred, so is the former. Moreover, AbbVie's theory would allow litigants to try to evade the "inextricably intertwined" doctrine altogether by simply reframing their argument under this "merger" theory. Indeed, one litigant already has. *See AstraZeneca Pharms. LP v. Kennedy*, No. 1:25-cv-4212-MJM (D. Md. April 27, 2026), ECF No. 33 at 3-11. This Court should reject AbbVie's attempt to create an end-run around the "inextricably intertwined" doctrine.

(quoting 42 U.S.C. § 1395*l*(t)(12)(A)). The court concluded that in order to determine whether the review bar applies, it must first determine whether the purported method was, indeed, "*described* in paragraph (2)(F)." *Id.* (quoting 42 U.S.C. § 1395*l*(t)(12)(A)) (emphasis added). By contrast, here, nothing about the phrase "determination of qualifying single source drugs under Section 1320f-1(e)" requires that the court examine the *lawfulness* of the "determination." *See* Defs.' Br. at 17-22. We know this because the review bar in *Mullin* also barred review of an agency "'determination . . . under [a specified] subsection.'" 146 S. Ct. at 2133 (quoting 8 U.S.C. § 1254a(b)(5)(A)). And yet, the Supreme Court did not "merge" the preclusion and merits issues in the way that AbbVie wants this Court to do. Here, the Court can—and indeed, should—conclude that AbbVie's statutory challenge pertains to an "subsidiary determination" by CMS in the lead up to its "determination" that Botox is a qualifying single source drug. *Mullin*, 146 S. Ct. at 2136. Both determinations (right or wrong) are barred from review under Section 1320f-7(2).

AbbVie insists that this Court must first decide the *merits* of its claim to determine whether this Court has *jurisdiction*. Pl.'s Opp'n & Reply at 3-12. To advance this argument, AbbVie relies heavily on *Ardelyx, Inc. v. Kennedy*, which examined a review bar that precluded review of "'identification of renal dialysis services included in the bundled payment.'" 179 F.4th at 953 (quoting 42 U.S.C. § 1395rr(b)(14)(G)). Ardelyx's challenge targeted a CMS regulation, which defined "'renal dialysis services' to include oral-only drugs," and CMS's identification of Ardelyx's drug "'consistent with th[e] regulation.'" *Id.* at 951, 957 (citations omitted). The D.C. Circuit reasoned that it must examine the merits of Ardelyx's particular statutory claim to determine whether the challenged CMS conduct was precluded because it amounted to the "'identification of renal dialysis services included in the bundled payment'" "within the meaning of the bar to judicial review." *Id.* at 953 (citation omitted). The court ultimately held that CMS's

regulation and application of the regulation to Ardelyx's drug did constitute "identification of renal dialysis services included in the bundled payment" under the review bar, and thus was precluded from review. *Id.* at 953-61 (citation omitted). AbbVie argues that applying *Ardelyx*'s "logic" leads to the merger of the merits and preclusion issues here. Pl.'s Opp'n & Reply at 6. For the reasons outlined below, AbbVie reads too much into *Ardelyx*—which does not (and could not, particularly after *Mullin*) stand for the proposition that preclusion provisions like Section 1320f-7(2) can be so easily circumvented.

To begin with, *Ardelyx* did not discuss *Mullin*, which was issued just one day earlier. But regardless, Section 1320f-7(2) and the review bar in *Ardelyx* are textually distinct. The review bar in *Ardelyx* barred review of CMS's "*identification[s] . . . included* in the bundled payment." 42 U.S.C. § 1395rr(b)(14)(G) (emphases added). But here, Congress instead used the same formulation that was interpreted in *Mullin—i.e.*, barring judicial review of a "determination . . . under [specified subsection]." *Compare* 42 U.S.C. § 1320f-7(2) *with* 8 U.S.C. § 1254a(b)(5)(A). Applying *Mullin*'s logic, this formulation is broad enough to capture "the chain of events leading up to" CMS's "determination" that Botox is a qualifying single source drug. 146 S. Ct. at 2133. This textual distinction alone renders *Ardelyx*'s inapplicable here. As *Mullin* makes clear, the scope of a review bar is first and foremost determined by its "statutory text." 146 S. Ct. at 2134.

AbbVie either ignores these textual distinctions or mistakenly touts them as making "this . . . an easier case than *Ardelyx*." Pl.'s Opp'n & Reply at 6. This only further exposes the strikingly expansive nature of AbbVie's theory. As AbbVie would have it, its merger theory is freely applicable to any review bar so long as it references another statutory provision, phrase, or requirement. That theory would kneecap countless review bars that are formulated in that way. *See, e.g., Knapp Med. Ctr. v. Hargan*, 875 F.3d 1125 (D.C. Cir. 2017) (applying 42 U.S.C.

§ 1395nn(i)(3), which among other things, bars review "of the process *under this paragraph*" (emphasis added)); *Challa v. DHS*, 2026 WL 1983290, at *3 (D.D.C. July 9, 2026) (examining 8 U.S.C. § 1252(a)(2)(A)(i), which bars review of "any individual determination or to entertain any other cause or claim arising from or relating to the implementation or operation of an order of removal *pursuant to section 1225(b)(1)* of this title" (emphasis added)).

Moreover, unlike in *Ardelyx*, here, AbbVie's proposed application of the "merger" theory would effectively nullify the review bar altogether. Although AbbVie argues that its interpretation "would not render the judicial-review bar irrelevant," Pl.'s Opp'n & Reply at 11 (citation omitted), its sole attempt to hypothesize a claim that would still be subject to the preclusion under its interpretation only serves to undermine its argument. Specifically, AbbVie posits that under its interpretation, the review bar would still prohibit review of a claim that CMS's "selection of BOTOX without any explanation, and despite existing guidance to the contrary, was arbitrary and capricious." *Id.* at 12. For the reasons outlined below, any such purported prohibition on review would be immaterial because the drug-selection provisions of the IRA do not lend themselves to arbitrary-and-capricious review anyway.

As relevant here, under the IRA, the mechanism for the selection of drugs for participation in the Negotiation Program is formulaic. CMS is *required* to identify the top 15 most expensive "negotiation-eligible drugs" for selection for the Program for 2028. 42 U.S.C. § 1320f-1(a)(3). In other words, absent some kind of error of arithmetic, if Botox satisfies the IRA's statutory requirements, it *must* be selected for the Program—regardless of whether CMS has adequately "explain[ed]" the selection of Botox. *Cf.* Pl.'s Opp'n & Reply at 12.

Moreover, the *factual* inquiries under the IRA will rarely (if ever) be subject to genuine dispute—*e.g.*, there is no genuine dispute that more than 11 years have passed since Botox's

licensure. *See* 42 U.S.C. § 1320f-1(e)(1)(B)(ii). The only meaningful disputes will always be related to CMS's *interpretation* of the IRA's requirements—*e.g.*, how to define a "qualifying single source drug." So, to the extent CMS exercises any discretion, it does so with respect to its interpretation of the IRA. If, as AbbVie would have it, the review bar cannot shield CMS's interpretations of the IRA from judicial second-guessing, then the review bar serves no function at all. That logic cannot be squared with D.C. Circuit precedent rejecting interpretations of judicial-review bars that "would eviscerate [them]" altogether, contrary to congressional intent. *DCH Reg'l Med. Ctr. v. Azar*, 925 F.3d 503, 506 (D.C. Cir. 2019); *see also Fresno Cmty. Hosp. v. Cochran*, 987 F.3d 158, 162 (D.C. Cir. 2021) ("'disregard[ing] statutory bars on judicial review' when the agency has violated the underlying statute . . . . would essentially remove the statutory bar against judicial review" (quoting *DCH Reg'l*, 925 F.3d at 509)). In short, AbbVie cannot analogize its case to *Ardelyx* by arguing that in both cases, the review bar would still "foreclose[] inquiry into whether the challenged agency action is arbitrary, capricious, or procedurally defective." Pl.'s Opp'n & Reply at 11. Here, unlike in *Ardelyx*, any such limitation would be purely nominal.

2. AbbVie's interpretation of the review bar's text fares no better. As it did in its opening brief, AbbVie overreads Section 1320f-7(2)'s cross reference to "'determination[s] . . . *under section 1320f-1(e)*[.]'" *Id.* at 8 (quoting 42 U.S.C. § 1320f-7(2) (emphasis in original)). According to AbbVie, Congress included this cross reference to indirectly restrict the scope of the preclusion to determinations that are *lawful* under section 1320f-1(e). *Id.* at 8-9. In AbbVie's telling, the Court must adopt this reading to save the "'under' clauses" from superfluity. *Id.*

As outlined in the Government's opening brief, AbbVie's superfluity argument is meritless. Defs.' Br. at 21-22. The "under" clauses identify—via cross reference—the specific

categories of "determination[s]" or "selection[s]" that are precluded from review. 42 U.S.C. § 1320f-7(2). This interpretation is consistent with the approach taken by the D.C. Circuit in *Knapp*. There, the court examined a review bar, which, in part, barred "judicial review . . . of the process under this paragraph." *Knapp*, 875 F.3d at 1130 (quoting 42 U.S.C. § 1395nn(i)(3)) (emphasis removed). As the court explained, the review bar's reference to "the process *under this paragraph*" "clarif[ied] what process [Congress was] refer[ring] to"—namely, the process identified in paragraph 3 of the statute. *Id.* at 1130 (emphasis in original). Similarly, here, the cross reference to Section 1320f-1(e) in the review bar precludes review of AbbVie's statutory claim because the challenged CMS "determination" is the *type* of determination identified in Section 1320f-1(e)—*i.e.*, a "determination" that Botox is a "qualifying single source drug."

Notably, *Mullin* further undermines AbbVie's reading of the "under" clause in IRA's review bar. The text of the review bar there also precluded review of agency determinations "under" a specific subsection. *See* 8 U.S.C. § 1254a(b)(5)(A) ("There is no judicial review of any determination . . . *under this subsection*." (emphasis added)). On AbbVie's theory, the plaintiff in *Mullin* could have evaded the review bar by *directly* challenging the Secretary's "determination" to terminate the TPS designations. After all, according to AbbVie's theory, because the review bar prohibits review of "any determination . . . under this subsection," the jurisdictional inquiry demands that the court first ask whether the "determination" was *lawful* "under this subsection." Tellingly, neither the Supreme Court nor the parties in *Mullin* even entertained the possibility that the review bar could be so easily circumvented. This confirms that AbbVie puts more weight on the "under" clause than it can bear.

3. Lastly, AbbVie argues that "the government's position . . . would enable gamesmanship." Pl.'s Opp'n & Reply at 12 (emphasis removed). According to AbbVie, under

the government's theory, CMS "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." *Id.* (citation omitted). Of course, the same could be said in litigation over *any* preclusion provision—the entire purpose of such a provision is to implement Congress's intent to *preclude* some agency decisions from judicial scrutiny. And as *Mullin* makes clear, litigants cannot narrow the text by provoking apprehension based on "farfetched hypotheticals." 146 S. Ct. at 2137. There, the Court acknowledged hypothetical scenarios that present "shocking abuses of power"—*e.g.*, "a rogue Secretary issue[s] a 50-year TPS designation, contrary to the 18-month statutory cap" or "terminate[s] a TPS designation based on a coin-flip." *Id. at* 2136-37. Instead of weighing in on whether these abuses "could in fact be redressed by the courts," the Court explained that any obligation to "stop that abuse" would lie with Congress. *Id. at* 2137. So too here. "Congress may determine a lower federal court's subject-matter jurisdiction." *Kontrick v. Ryan*, 540 U.S. 443, 452 (2004). It has exercised that authority in the IRA. In doing so, "Congress decide[d] that the political process is the proper forum for remedying improper conduct." *Mullin*, 146 S. Ct. at 2137 (quoting *Nat'l TPS All. v. Noem*, 169 F.4th 796, 807 (9th Cir. 2026) (Bumatay, J., dissenting from denial of reh'g en banc)).

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

AbbVie also makes a passing attempt to support its ultra vires claim, again in hopes of persuading this Court to disregard Congress's choice to preclude judicial review. Pl.'s Opp'n & Reply at 27-28. Ultra vires review, however, is categorically unavailable when Congress has expressly precluded "all other forms of judicial review," *Nuclear Regul. Comm'n v. Texas*, 605

U.S. 665, 681 (2025) ("*NRC*") (citation omitted), as it has here.[2] In response, AbbVie repeats its preclusion arguments, which fail for the reasons identified above. *See* pp. 3-12, *supra*.

Besides, even if ultra vires review was available, AbbVie's claim would still fail. Ultra vires review is exceedingly narrow. *See NRC*, 605 U.S. at 681-82 (explaining that an ultra vires claim is the equivalent of "a Hail Mary pass—and in court as in football, the attempt rarely succeeds" (citation omitted)). It applies only where "[a] defendant violates a clear and mandatory statutory command only when the error is so extreme that one may view it as jurisdictional or nearly so." *Glob. Health Council v. Trump*, 153 F.4th 1, 20 (D.C. Cir. 2025) (citation omitted).

AbbVie attempts to satisfy this high bar by repacking its merits argument. *See* Pl.'s Opp'n & Reply at 27-28. Putting aside the fact that AbbVie is wrong on the merits, *see* pp. 13-23, *infra*, it could not sustain an ultra vires claim by merely "dress[ing] up a typical statutory-authority argument as an ultra vires claim." *NRC*, 605 U.S. at 666. Because AbbVie "can point to no specific prohibition the defendants have violated to an extreme and nearly jurisdictional degree," its ultra vires claim fails outright. *Glob. Health Council*, 153 F.4th at 20.

C. Plaintiff's statutory claim lacks merit.

Even if this Court had jurisdiction over AbbVie's statutory claim, it should nevertheless reject it on its merits. CMS properly determined 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). The narrow "[p]lasma-derived products" exclusion, which applies to

[2] AbbVie seemingly misreads *NRC* as providing that "[u]ltra vires review is available . . . where the statutory scheme . . . 'forecloses all other forms of judicial review.'" Pl.'s Opp'n & Reply at 27 (quoting *NRC*, 605 U.S. at 681). That is wrong. *NRC* expressly states that "[u]ltra vires review is also *unavailable* if . . . a statutory review scheme forecloses all other forms of judicial review." 605 U.S. at 681 (emphasis added); *see also DCH Reg'l*, 925 F.3d at 509 (an ultra vires claim is only available if "the statutory preclusion of review is implied rather than express"). As explained above, that is the case here.

"[a] biological product that is derived from human whole blood or plasma," *id*., does not cover Botox because Botox's only active ingredient is Botulinum Toxin Type A, which is undisputedly not "derived from human whole blood or plasma." *Id.*; *see* Defs.' Br. at 23-27.

CMS's approach of identifying a "qualifying single source drug"—and implementing the plasma-derived products exclusion—based on the biological product's active ingredient properly accounts for the IRA's statutory text, structure, and purpose. As outlined in Defendants' opening brief, throughout the IRA, Congress instructed CMS to aggregate all dosage forms, strengths, and formulations of a "drug" in administering the Negotiation Program. Defs.' Br. at 23-27; *see also* 42 U.S.C. § 1320f-5(a)(2) (administrative duties include "[t]he establishment of procedures to compute and 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 such drug"); *id.* § 1320f-1(d)(3)(B) ("In determining whether a qualifying single source drug satisfies [specific criteria,] the Secretary shall use data that is aggregated across dosage forms and strengths of the drug . . . and not based on the specific formulation or package size or package type of the drug."); *id.* § 1320f-3(e)(1)(D) (requiring CMS to consider all "applications and approvals" of a drug). This directive to aggregate is consistent with CMS's active-ingredient analysis. Examining whether products share "active ingredients" allows CMS to distinguish truly new and innovative therapeutics from merely new versions of existing treatments.

Moreover, this approach is consistent with the goal of the Negotiation Program, which is to select the most expensive drugs for negotiation. By requiring aggregation across dosage forms, strengths, and formulations of a drug, Congress ensured that manufacturers could not circumvent participation in the Negotiation Program by introducing trivial changes to their products. *See Teva Pharms. USA, Inc. v. Kennedy*, 2025 WL 3240267, at *12 (D.D.C. Nov. 20, 2025) (explaining that

without such aggregation, manufacturers could easily engage in "product hopping" or other gamesmanship that would render the IRA "a 'self-defeating statute'" (quoting *Pugin v. Garland*, 599 U.S. 600, 607 (2023), *appeal pending*, No. 25-5425 (D.C. Cir. argued May 5, 2026))).

Thus, the text, structure, and purpose of the IRA make clear that CMS must look to the biological product's active ingredient when deciding whether it is a "qualifying single source drug" under 42 U.S.C. § 1320f-1(e). And so, the exclusions within the "qualifying single source drug" provision—including the "[p]lasma-derived products" exclusion—also turn on the biological product's active ingredient. After all, the exclusions merely identify subcategories of the drugs that would otherwise qualify as "qualifying single source drug[s]" under 42 U.S.C. § 1320f-1(e). If the former is identified using the biological product's active ingredients, then so is the latter. *See Lawson v. FMR LLC*, 571 U.S. 429, 435 (2014) (interpreting the relevant provision in a manner that is consistent with the assumptions embedded in other provisions of the same statute).

Here, because Botox's active ingredient is not "derived from human whole blood or plasma," it does not fall within the "[p]lasma-derived products" exclusion. *See* 42 U.S.C. § 1320f-1(e)(3)(C). AbbVie objects to this conclusion. According to AbbVie, the inquiry under the exclusion is not limited to the biological product's active ingredient. As AbbVie would have it, the exclusion is triggered even where, as here, Botox contains a human plasma derivative only as an *inactive* ingredient. But all of AbbVie's arguments lack merit.

1. AbbVie begins by protesting that "the IRA never uses the phrase 'active ingredient.'" Pl.'s Opp'n & Reply at 19. But CMS did not pluck the term "active ingredient" from thin air. The term has a long history and prominent role in FDA's regulatory scheme, where among other things, it is often used as a proxy for innovation in drug development. *See, e.g.*, 21 C.F.R. § 314.3 (defining the term for purposes of drugs); *see also, e.g.*, Erin H. Ward, Cong. Rsch. Serv., R46110,

Defining Active Ingredient (2023) at 2-4 (outlining "FDA's [H]istorical [I]nterpretation of [A]ctive [I]ngredient"). The IRA's directive to aggregate shows that Congress intended CMS to identify biological products based on their "active ingredient" in implementing this Program.

2. Next, AbbVie takes issue with the government's reliance on the IRA's statutory structure. But instead of arguing that its interpretation is consistent with the relevant provisions, AbbVie mainly dismisses the significance of those provisions altogether. It argues that Sections 1320f-1(d)(3)(B), 1320f-5(a)(2), and 1320f-3(e)(1)(D) are irrelevant to CMS's decision as to whether a biological product is a "qualifying single source drug" because those provisions only kick in after CMS has already identified whether the biological product is, indeed, a "qualifying single source drug." *See* Pl.'s Opp'n & Reply at 20-23.

That argument misses the point. "[S]tatutory construction 'is a holistic endeavor.'" *United States v. Cleveland Indians Baseball Co*., 532 U.S. 200, 217 (2001) (quoting *United Sav. Assn. of Tex. v. Timbers of Inwood Forest Associates, Ltd.,* 484 U.S. 365, 371 (1988)). And here, "the meaning of [qualifying single source drug] is clarified by the remainder of the statutory scheme." *Cleveland Indians Baseball Co*., 532 U.S. at 217 (citation omitted). The requirement that CMS aggregate all dosage forms, strengths, and formulations of a drug together is embedded throughout the statutory provisions that create the Negotiation Program. *See* 42 U.S.C. § 1320f-5(a)(2); *id.* § 1320f-1(d)(3)(B); *id.* § 1320f-3(e)(1)(D); *see also* Defs.' Br. 23-27. The selection of a "qualifying single source drug" under § 1320f-1(e) is no exception. Indeed, Section 1320f-1(d)(3)(B) makes the application of the aggregation requirement to the selection of "qualifying single source drug" explicit. It provides that "[i]n determining whether a *qualifying single source drug* satisfies [the criteria for negotiation-eligible drug or its exclusion], the Secretary shall use data that is aggregated across dosage forms and strengths of *the drug*." *Id.* § 1320f-1(d)(3)(B)

(emphases added). That provision plainly contemplates that a "qualifying single source drug" is subject to aggregation based on its active ingredient "across dosage forms and strengths." *Id.*

3. AbbVie also argues that the government's reliance on statutory purpose is misplaced. According to AbbVie, the Court lacks the authority to adopt an interpretation broader than the exclusion's "'fair reading'" to "advance a broad policy goal of reducing Medicare expenditures." Pl.'s Opp'n & Reply 23-24 (quoting *Food Mktg. Inst.* v. *Argus Leader Media*, 588 U.S. 427, 439 (2019)). But the government is not asking that the Court advance a policy goal instead of adopting a "fair reading" of the text. To the contrary, the government maintains that the IRA's overall statutory purpose confirms that its interpretation *is* a "fair reading" of the text. *See Texas Dep't of Hous. & Cmty. Affs. v. Inclusive Cmtys. Project, Inc.*, 576 U.S. 519, 539 (2015) (interpreting the statute in a way that "is consistent with the [Act]'s central purpose").

As already explained, the government's active-ingredient analysis is consistent with the IRA's purpose of identifying the drugs with the greatest financial impact on Medicare overall. By contrast, AbbVie's *product*-specific analysis—which is untethered to active ingredients—would open the door to various forms of trivial gamesmanship that would erode the statutory scheme altogether. Under a product-specific analysis, CMS must always treat each formulation of the same active ingredient as its own stand-alone "qualifying single source drug," no matter how minor the variations between the final products. For example, as Judge Sooknanan explained in *Teva*, that view would mean that any "manufacturer could avoid selection by simply balancing its sales of capsules and tablets such that neither reaches the selection threshold—even though both drugs are materially identical in their active effect," which would "render[] the statute nonsensical." 2025 WL 3240267, at *12 (D.D.C. Nov. 20, 2025) (cleaned up). In this way, the IRA's statutory purpose confirms that the government's active-ingredient analysis is "[t]he better reading." *Id.*

Brushing aside the IRA's overarching purpose, AbbVie argues that "Congress had specific reasons for enacting the plasma-derived-products exclusion, which favor AbbVie." Pl.'s Opp'n & Reply at 24. Specifically, AbbVie relies on one paragraph in a House Report that postdates the enactment of the IRA to argue that the purpose of the exclusion was to "avoid the risk that price controls would disrupt access to such products due to the fragile supply of human plasma." *Id.* at 17 (citing H.R. Rep. No. 696, 119th Cong., 2d Sess. 176-177 (2026)). And, AbbVie further argues, "those risks would exist . . . regardless of whether BOTOX's label lists HSA as an active or inactive ingredient." Pl.'s Opp'n & Reply at 17. This analysis cannot withstand scrutiny. For starters, "[p]ost-enactment legislative history (a contradiction in terms) is not a legitimate tool of statutory interpretation" because it, "by definition[,] could have had no effect on the congressional vote." *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 242 (2011) (citation omitted). Besides, the purported "purpose" identified by AbbVie is inconsistent with the text of the exclusion. The exclusion only applies to biological products—not to *all* products (including drugs). *See* 42 U.S.C. § 1320f-1(e)(3)(C). If, as AbbVie suggests, the purpose of the exclusion is to address the "risk that price controls would disrupt access to" products that contain human plasma, Pl.'s Opp'n & Reply at 17, then, presumably, Congress would have excluded all products that contain ingredients derived from human plasma (not just biological products). In other words, AbbVie's interpretation of the text is not even consistent with the purported purpose it has *itself* identified for the exclusion (let alone consistent with the overarching purpose of the IRA).

4. Lastly, and in the alternative, even if this Court accepts AbbVie's theory—namely, that the term "biological product" in the plasma-derived product exclusion refers to the "whole product," *see* Pl.'s Opp'n & Reply at 25, Botox would still fail to qualify under the exclusion. By its own terms, the exclusion only covers "[a] biological product that is *derived from* human whole

blood or plasma." 42 U.S.C. § 1320f-1(e)(3)(C) (emphasis added). Although the word "derive" is not defined in the IRA, its dictionary definition supports the common-sense conclusion that biological products are "derived from" their source. *See Derive*, Merriam-Webster's Dictionary, at https://www.merriam-webster.com/dictionary/derive ("derive" means "to take, receive, or obtain especially from a specified source"). Applying this dictionary definition of "derive" here, the "source" from which a biological product is "take[n], receive[d], or obtain[ed]" is its active ingredient. After all, it is the product's active ingredient that can qualify it as a licensed "biological product" in the first place. *See Ipsen Pharmaceuticals, Inc. v. Becerra*, 108 F.4th 836, 838 (D.C. Cir. 2024). It is thus natural to conclude that a "biological product" is "derived from" its active ingredient—*i.e.*, the only ingredient that can qualify it as a "biological product."

The government's interpretation is also consistent with the exclusion's core textual limitation—namely, that it only applies to biological products (not to drugs). *See* 42 U.S.C. § 1320f-1(e)(3)(C) (covering only a "biological product"). Although "human whole blood or plasma" can appear in both drugs and biological products as *inactive* ingredients, if they are *active* ingredients in a product, that product is regulated as a biological product. *See* 42 U.S.C. § 262(i)(1) (encompassing "blood, blood component or derivative . . . that is applicable to the prevention, treatment, or cure of a disease or condition of human beings"). If, as AbbVie suggests, the application of the exclusion does not turn on whether "human whole blood or plasma" is in active or inactive form, the exclusion's biological-product limitation would be arbitrary. Unlike AbbVie's theory, however, CMS's interpretation provides an explanation for this biological-product limitation: Congress intended to exclude products in which "human whole blood or plasma" or ingredients derived from them function as active ingredients—and that only occurs in biological products, not drugs. In this light, it is not a coincidence that human whole blood or

plasma are among the list of ingredients that can qualify a product as a "biological product" if they function as active ingredients. *Id.* This overlap contemplates that the excluded product is a "biological product" *because* of its "human whole blood or plasma."

Relatedly, AbbVie's interpretation leads to odd results. Consider, for instance, a "drug product" that—just like Botox—contains a human plasma derivative as an inactive ingredient. Because the "drug product" is not a "biological product," it would not be subject to the exclusion even though it contains the *same* ingredient that appears in Botox. *See* 42 U.S.C. § 1320f-1(e)(3)(C) (covering only a "biological product"). In other words, under AbbVie's interpretation, Congress sought to exclude products with a human plasma derivative as an inactive ingredient but *only* for biological products, not drug products. But AbbVie provides no explanation for such inconsistent treatment of a human plasma derivative as an inactive ingredient.[3] *Cf. Ipsen*, 108 F.4th at 843 (rejecting plaintiff's interpretation in part because it "compel[led]" a "killer contradiction": its own drug "qualifies as a biological product when it is evaluated in its finished dosage form . . . . [even though] other products, with the *same* active ingredient, would remain as drug products" (emphasis added)). The government's interpretation, however, treats like products alike: *no* product (whether a "drug product" or a "biological product") that contains a human plasma derivative as an *inactive* ingredient is subject to the exclusion, but *all* products that contain a human plasma derivative as an *active* ingredient are subject to the exclusion. After all, *only* biological products contain human plasma derivatives as active ingredients. *See* 42 U.S.C.

[3] If anything, the justification AbbVie provides for its interpretation is undermined by this form of inconsistent treatment. As explained above, AbbVie argues that the purpose behind the exclusion is "to avoid the risk that price controls would disrupt access to such products due to the fragile supply of human plasma." Pl.'s Opp'n & Reply at 17. That purported goal, however, is inconsistent with Congress's choice to limit the exclusion to *only* biological products. *See* pp. 18, *supra*.

§ 262(i)(1). So, the mere fact that the exclusion is limited to biological products does not prevent it from capturing *all* products with human plasma derivatives as their active ingredients.

In sum, as a matter of ordinary meaning, a "biological product" is "derived from" the "source" that made it a "biological product" in the first place. This reading is confirmed by the definition of the word "derive," as well as Congress's textual choice to limit the exclusion to biological products.

In response, AbbVie makes a puzzling objection to the government's invocation of biological products' "regulatory status." Pl.'s Opp'n & Reply at 25 (emphasis omitted). But it is AbbVie—not the government—that insists that "biological product," as used in the IRA's plasma-derived products exclusion, refers to "the whole, finished product licensed by FDA and sold by a manufacturer." *Id.* at 13. The government's at-issue interpretation of the phrase "derived from" simply assumes *AbbVie's* formulation that the phrase "biological product" in the exclusion refers to the product that is "licensed by FDA." *Id.* But as explained above, even under AbbVie's own formulation, its interpretation fails because it is inconsistent with the ordinary meaning of the phrase "derived from."

Next, AbbVie effectively asks the Court to replace the phrase "derived from" with "contains." *Id.* at 25. According to AbbVie, Botox meets the plasma-derived products exclusion because it "contains" a human plasma derivative. *See id.*; *see also id.* at 1. Contrary to AbbVie's analysis, however, the ordinary meanings of "derived from" and "contains" are not freely interchangeable. As a way of analogy, consider the difference between a scarf that merely "contains wool" versus a scarf that is "derived from wool." The former is much broader. It could, for instance, refer to a cotton scarf that contains wool stitching. The latter, however, is materially

narrower. Under the most natural reading, a scarf that is "derived from wool" is a scarf whose *main* fabric is made of wool.

So too here. "A biological product that is derived from human whole blood or plasma" is much more specific than one that merely "[contains] human whole blood or plasma." 42 U.S.C. § 1320f-1(e)(3)(C). And yet, AbbVie barely defends its attempt to rewrite the provision. Instead, it suggests that the meaning of the phrase "derived from" has already been settled by the D.C. Circuit. Pl.'s Opp'n & Reply at 25 (citing Mem. in Supp. of Pl.' Mot. for Summ. J. at 28, ECF No. 25 ("Pl.'s MSJ Br."), which, in turn, cites *Sottera, Inc. v. FDA*, 627 F.3d 891 (D.C. Cir. 2010), and *Nicopure Labs, LLC v. FDA*, 944 F.3d 267 (D.C. Cir. 2019)). AbbVie is wrong.

As for *Nicopure*, it has no bearing on the statutory-interpretation issue here. The D.C. Circuit appeal in that case did not raise any statutory questions, let alone turn on the meaning of the phrase "derived from." *Nicopure*, 944 F.3d at 280. *Sottera* does not help AbbVie, either. There, the court examined the statutory term "tobacco product," which (at that time) was defined in the Family Smoking Prevention and Tobacco Control Act of 2009 as "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product." 21 U.S.C. § 321(rr) (2009). In reasoning that certain e-cigarettes satisfied this definition, the court did not engage in any meaningful analysis of the phrase "derived from." There was no need, as the parties did not dispute that the "electronic cigarettes use a liquid nicotine mixture derived from tobacco." *Sottera*, 627 F.3d at 898. So, *Sottera* is of little relevance here. This is especially true given the textual differences between the statutory text at issue in *Sottera* and the text of the plasma-derived products exclusion. *See Mullin*, 146 S. Ct. at 2134 (dismissing a prior interpretation of the same term in a different statute because the analysis

"turned on the specific wording of the provision at issue[,]" and the court "did not adopt [a] broad principle" about the term's meaning).

In sum, as a matter of ordinary meaning, Botox—as a "biological product"—is "derived from" the ingredient that qualifies it as a "biological product" in the first place. That ingredient is Botox's active ingredient, Botulinum Toxin Type A, not its human plasma derivative. Thus, CMS correctly determined that Botox does not qualify for the plasma-derived product exclusion under Section 1320f-1(e)(3)(C).

II. PLAINTIFF'S CONSTITUTIONAL CLAIMS FAIL (COUNTS III, IV, AND V).

Every court to consider the question of whether the Negotiation Program violates the Constitution has concluded that it does not.[4] This Court should join that nationwide consensus.

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

AbbVie argues that Congress violated the Fifth Amendment by authorizing CMS to negotiate the prices it will pay for certain drugs: first as a physical taking in violation of the Takings Clause, and also as a violation of the Due Process Clause. Both theories are meritless.

[4] *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); *AstraZeneca Pharms. v. Becerra*, 719 F. Supp. 3d 377 (D. Del. 2024), *aff'd* 137 F.4th 116 (3d Cir. 2025), *cert. denied*, No. 25-348, 2026 WL 1377100 (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. argued Oct. 7, 2025); *Teva Pharm., USA v. Kennedy*, No. 25-113, 2025 WL 3240267 (D.D.C. Nov. 20, 2025), *appeal pending*, No. 25-5425 (D.C. Cir. argued May 5, 2026).

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

The Negotiation Program adjusts the government's offer to pay for drugs for Medicare beneficiaries, but it does not physically appropriate any drugs or otherwise compel their surrender or sale. And participation in the Negotiation Program (as with participation in Medicare generally) is voluntary, as no manufacturer is obligated to sell drugs to the government in the first place.

Primarily, AbbVie responds by resisting the premise that participation in the Negotiation Program (or even Medicare in general) is voluntary, asserting that its options to withdraw are both "legally and practically illusory." Pl.'s Opp'n & Reply at 30. AbbVie is wrong on the former, as it can "legally" withdraw from the Program with ease. And the latter is irrelevant—by "practically illusory," AbbVie just means that it is more profitable to continue selling drugs to Medicare than it would be to withdraw. But that economic reality has nothing to do with the Takings Clause—especially where (as here) AbbVie brings only a *physical* takings claim.

a. As for whether the notion of voluntariness is "legally . . . illusory," Pl.'s Opp'n & Reply at 30, AbbVie's argument hinges on the assertion—accompanied by no citation—that "[b]y 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." *Id.* at 30. But that is wrong. As AbbVie acknowledges elsewhere, Pl.'s MSJ Br. at 39-40,; Pl.'s Opp'n & Reply at 30, CMS has confirmed that a manufacturer may withdraw in as little as 30 days. *See* 42 U.S.C. § 1395w-114c(b)(4)(B)(i); Guidance at 199-201; *accord Boehringer Ingelheim*, 150 F.4th at 86 ("[A] manufacturer could withdraw from Medicare and Medicaid in as few as thirty days after providing notice to CMS."); *Bristol Myers Squibb*, 155 F.4th at 260 ("CMS announced in a regulatory guidance—one that has the force of law—that it will find 'good cause' to use the speedier path to termination whenever a manufacturer submits notice of its decision not to participate in the Drug

Price Negotiation Program."). That is more than enough to resolve AbbVie's stated concern that it will be (or has been) trapped in Medicare against its will.

AbbVie's only response is that "CMS cannot supersede the IRA's statutory requirements through nonbinding guidance." Pl.'s Opp'n & Reply at 30. But AbbVie does not actually challenge that aspect of the Negotiation Program in this litigation, nor could it—after all, AbbVie has no Article III standing to challenge an interpretation of the statute that could only possibly benefit it. *See* Defs.' Br. at 40 n.10. Given AbbVie's obvious policy concerns with the Negotiation Program, increasing AbbVie's flexibility to withdraw from the Program more quickly "would ordinarily be cause for celebration, not a lawsuit." *TransUnion LLC v. Ramirez*, 594 U.S. 413, 437 (2021). And AbbVie does not actually seek to withdraw anyway, so the question is academic.

In any event, the exit options CMS articulated in its Guidance are expressly grounded in statutory provisions authorizing the "Secretary [to] provide for termination" of the relevant agreement "for a knowing and willful violation of the requirements of the agreement or *other good cause shown*." 42 U.S.C. § 1395w-114c(b)(4)(B)(i) (emphasis added). AbbVie reads the phrase "other good cause shown" as effectively limited to "knowing and willful violations of the requirements of the agreements," Pl.'s Br. at 40. But tellingly, AbbVie does not volunteer what type of circumstance would be covered by that interpretation—likely because any example would emphasize that its construction would reduce the "good cause" clause to a nullity. Yet "one of the most basic interpretive canons" is that "[a] statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant." *Corley v. United States*, 556 U.S. 303, 314 (2009) (quoting *Hibbs v. Winn*, 542 U.S. 88, 101 (2004)). And it is hard to see how a manufacturer indicating that it wishes to withdraw early—which would be inconsistent with the agreements' terms—would not be "good cause" here, particularly when

AbbVie itself claims that the absence of a speedy exit option would (at least) raise serious constitutional questions. *See, e.g.*, *United States ex rel. Polansky v. Exec. Health Res., Inc.*, 599 U.S. 419, 429 n.2 (2023) ("good cause" is "a uniquely flexible and capacious concept, meaning simply a legally sufficient reason" (citation omitted)); *see also Boehringer Ingelheim*, 150 F.4th at 96 (agreeing with CMS's interpretation); *Bristol Myers Squibb*, 155 F.4th at 261 (same).

b. As for whether AbbVie's withdrawal options are "practically illusory," Pl.'s Opp'n & Reply at 30, the answer to that question doesn't matter. Indeed, that legal proposition is sufficiently well-settled that the government need only cite Medicare cases. In short, 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 also, e.g.*, *Se. Ark. Hospice, Inc. v. Burwell*, 815 F.3d 448, 450 (8th Cir. 2016); *Franklin Mem'l Hosp. v. Harvey*, 575 F.3d 121, 129 (1st Cir. 2009); *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); *Whitney v. Heckler*, 780 F.2d 963, 972 (11th Cir. 1986). Even where "business realities" create "strong financial inducement to participate"—such as, for example, when Medicare or Medicaid provides the vast majority of a nursing home's revenue—courts have emphasized that the decision to participate in the program "is nonetheless voluntary." *Minn. Ass'n of Health Care Facilities, Inc. v. Minn. Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984); *see also Livingston Care Ctr., Inc. v. United States*, 934 F.2d 719, 720 (6th Cir. 1991) (explaining that "participation in the Medicare program is a voluntary undertaking" even for nursing homes).

AbbVie dismisses this wall of precedent as "dated out-of-circuit cases" that "predate the Supreme Court's decision in *Horne*." Pl.'s Opp'n & Reply at 31. For one thing, the Eighth Circuit rejected a takings claim (after *Horne*) on the theory that the plaintiff "voluntarily chose to

participate in the Medicare hospice program" and that "voluntariness forecloses the possibility that the statute could result in an imposed taking of private property." *Ark. Hospice*, 815 F.3d at 450 (explicitly distinguishing *Horne*). And, of course, the Second Circuit and the Third Circuit have also recently rejected the same arguments about *Horne* that AbbVie advances here—in the context of this very Program. The Third Circuit explained that "*Horne* does not disturb our conclusion that the voluntary nature of Medicare participation precludes takings liability," noting that (unlike in *Horne*) drug manufacturers "remain free to participate in the pharmaceutical market" even if they withdraw from Medicare and Medicaid, "including by selling" drugs selected for the Negotiation Program "to private parties." *Bristol Myers Squibb*, 155 F.4th at 258. And the Second Circuit's explanation—that "*Horne* is materially different from both *Garelick*," its prior Medicare precedent, "and this case"—is equally applicable here. *Boehringer Ingelheim*, 150 F.4th at 92. "Whereas the *Horne* plaintiffs challenged an actual seizure of their personal property (raisins) without compensation, the *Garelick* plaintiffs challenged regulations that merely limited the price they could charge under Medicare." *Id.* So too here.

c. AbbVie also notes that some of the government's cases were about regulatory takings. *See* Pl.'s Opp'n & Reply at 31. But voluntariness is equally fatal to a physical takings claim. *See, e.g.*, *Valancourt Books, LLC v. Garland*, 82 F.4th 1222, 1232 (D.C. Cir. 2023) ("A demand for personal property would not be a taking, however, if it involved a voluntary exchange for a governmental benefit."). And overall, AbbVie's focus on physical takings can only hurt its cause—by abandoning any regulatory takings theory, AbbVie can only prevail by showing an actual physical appropriation. *See, e.g.*, *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 149 (2021) (challenged regulation "appropriates a right to physically invade the growers' property—to literally 'take access,'" and "is therefore a *per se* physical taking"); *Horne*, 576 U.S. at 364

(physical taking because "the raisin program requires physical surrender of the raisins and transfer of title" without just compensation); *Andrus v. Allard*, 444 U.S. 51, 65 (1979) (no physical taking of eagle feathers because challenged regulations "do not compel the surrender of the artifacts, and there is no physical invasion or restraint"). In short, when it comes to *physical* takings, "[t]he essential question is . . . whether the government has physically taken property for itself or someone else—by whatever means—or has instead restricted a property owner's ability to use his own property." *Cedar*, 594 U.S. at 149. And here, at best, AbbVie can show only the latter.

To be clear, the government is not arguing that it must "send trucks to AbbVie's warehouses under cover of night for the Program to effect a taking." Pl.'s Opp'n & Reply at 31. But to be a *physical* taking, there must be at least some kind of physical appropriation, or (at the very least) a compelled transfer or forced sale. AbbVie can't even show that much. AbbVie's continued references to "BOTOX doses" only underscore how this case *differs* from *Horne*—where the government *did* "sen[d] trucks to the Hornes' facility at eight o'clock one morning to pick up the raisins" subject to physical appropriation. 576 U.S. at 356. And those facts mattered—as *Horne* itself explains, there is a "settled difference in our takings jurisprudence between appropriation and regulation." *Id.* at 362. Even if "[a] physical taking of raisins and a regulatory limit on production may have the same economic impact on a grower," one raises takings problems and the other does not. *Id.* "The Constitution . . . is concerned with means as well as ends." *Id.*

To try and fit within *Horne*, AbbVie states (without citation) that "[t]he IRA forces AbbVie to hand over 'access' to BOTOX for whatever the government decides to pay." Pl.'s Opp'n & Reply at 28. Again, if that were true, this case might be different. But it isn't. When the statute discusses "access," it is (as AbbVie recognizes on the next page of its brief) only in the context of the requirement to "provide access *to such price*," for sales of the drug through Medicare. Pl.'s

Opp'n & Reply at 29 (quoting 42 U.S.C. § 1320f-2(a)(1)) (emphasis added). As is obvious from the statutory text, 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 more than that price for sales to Medicare beneficiaries. *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.

Requiring "access" to a particular *price* for sales to Medicare beneficiaries is not the same thing as requiring "access" to "doses of BOTOX." *Id.* That is why, respectfully, Judge Hardiman erred in his dissent in *Bristol Myers Squibb*—it is simply not correct that the IRA "forc[es] [AbbVie] to turn over physical doses of" Botox to anyone. 155 F.4th at 273 (Hardiman, J., dissenting). It is undisputed that AbbVie, for example, could refuse to sell Botox to Medicare beneficiaries entirely, charge whatever price it wants to all other buyers (including the rest of the U.S. market and the entire international market), and in doing so retain full ownership over every single "dose of Botox" that it has.

In sum, a statutory limit on the price that manufacturers may charge for drugs sold to Medicare beneficiaries may have an "economic impact" on AbbVie—but even if it does, that still falls squarely on the other side of the "settled difference in [] takings jurisprudence between appropriation and regulation," and thus cannot be a "physical taking." *Horne*, 576 U.S. at 362.

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

"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 v. Lukens Steel Co.*, 310 U.S. 113, 127 (1940). And so, as every court to consider the question has concluded, the Negotiation Program does not deprive pharmaceutical manufacturers of any protected property interest. *See, e.g.*, *AstraZeneca*, 137 F.4th at 125-26 ("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."); *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.").

AbbVie responds by insisting that the Negotiation Program "coerce[s] manufacturers into providing products to third parties at below-market prices" as part of what it describes as "private-market transactions." Pl.'s Opp'n & Reply at 33; *see also id.* at 33 n.6. But that argument largely rests on a misunderstanding of the relationship between the Negotiation Program and the rest of the market for prescription drugs. A negotiated price applies only to drugs purchased through Medicare Parts B, C, or D. 42 U.S.C. §§ 1320f(c)(2); 1320f-2(a)(3). Thus, the Negotiation Program does not control the price paid for a drug by any person who is not a Medicare beneficiary or by any private insurance plan. Nor does the Negotiation Program even control the price paid for Medicare beneficiaries who, for whatever reason, choose to purchase their drugs without using their Medicare benefits—*i.e.*, who choose to pay cash when filling their prescriptions. *See, e.g.*, 42 C.F.R. § 423.120(c)(3) (permitting an individual at an in-network pharmacy to request that the pharmacy not bill the individual's Part D plan). Instead, "the Negotiation Program only sets prices for drugs *that CMS pays for* when it reimburses sponsors" of Medicare plans. *AstraZeneca*, 137

F.4th at 126. When the government decides how much the government is willing to spend on prescription drug coverage, it implicates no interest protected by the Due Process Clause.

AbbVie's responds by restating what its opening brief explicitly referred to as a theory of unconstitutional "combination," Pl.'s Br. at 36, and what AbbVie now describes more carefully as multiple "flaws with the Program's design" that "all work together to deprive manufacturers such as AbbVie of their property," Pl.'s Opp'n & Reply at 33-34. But leaving the word "combination" out of its reply brief doesn't solve AbbVie's problem, which is that the Supreme Court explicitly rejected this sort of "combination theory" just last year, explaining that "[t]wo wrong claims do not make one that is right." *FCC v. Consumers' Rsch.*, 606 U.S. 656, 697 (2025). And regardless, here, the Court need not decide whether any particular procedures (or lack thereof) pass constitutional muster, *but see* Defs.' Br. at 41-42 (explaining why each component is routine and lawful)—because AbbVie cannot make the threshold showing of a protected property interest. And without a protected property interest in the price the government is willing to pay to purchase drugs, AbbVie cannot state a due process claim.

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

Congress did not compel manufacturers' speech by requiring that participants sign an agreement memorializing their decision to negotiate and—if negotiations succeed—the maximum amount that Medicare will pay for their drug. AbbVie's arguments to the contrary lack merit.

A compelled speech claim under the First Amendment necessarily fails if no speech is compelled—essentially, by definition. In other words, as multiple courts have recognized in rejecting identical claims, "[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). And so, as AbbVie seems

not to dispute (other than in the context of its unconstitutional-conditions theory, addressed separately below, *see infra* at 34), the voluntariness of AbbVie's participation in the program is also independently fatal to any First Amendment claim. *See supra* at 24-27 (explaining why participation is voluntary); *see also* Defs.' Br. at 32-37 (same).

Even if AbbVie had established "actual compulsion," *Bristol Myers Squibb*, 155 F.4th at 266-67, here, what is allegedly being compelled is not speech at all, but non-expressive conduct. As the D.C. Circuit has explained, "ordinary price regulation does not implicate constitutionally protected speech." *Nicopure*, 944 F.3d at 292. And even if AbbVie were correct that this regulatory scheme imposes some ancillary or incidental burden on speech—for example, by using statutory terms of art for the sake of clarity and consistency, *see* Defs.' Br. at 45-46 (explaining why using terms of art is permissible)—"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).

AbbVie responds that "[t]he 'agreements' memorialize not commercial exchanges, but manufacturers' compelled assent to the government's preferred policy, which is protected expression." Pl.'s Opp'n & Reply at 35. But as Defendants already explained, *see* Defs.' Br. at 45-47, that understanding of the agreement cannot be squared with the text of the document itself. 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.* at 4. This language resolves any doubt that "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. To that point, AbbVie offers no response at all.

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

Finally, AbbVie continues to repackage its Takings Clause and First Amendment claims (but not its due process claim) 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 Opp'n & Reply at 35-38. These claims fare no better than the direct versions of these same constitutional claims that Defendants have already refuted.

As a threshold matter, tellingly, AbbVie entirely ignores (save one parenthetical) one of the government's primary authorities: *Rust v. Sullivan*, 500 U.S. 173, 197 (1991). In *Rust*, the Supreme 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 id.* at 196-98. On the other hand, in *Agency for International Development v. Alliance for Open Society International, Inc.*, 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) ("*AID*"). Taken together, these decisions distinguish between regulatory requirements 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. The Negotiation Program sits comfortably within

that framework. The IRA sets the terms of the government's offer to pay for drugs for Medicare beneficiaries and does not set any external "condition" on manufacturers' ability to sell drugs.

As for the First Amendment, AbbVie offers only one argument in response, and it is against a strawman. All agree that, at least as a general matter, the government cannot "require speakers to affirm in one breath that which they deny in the next." *Pac. Gas & Elec. Co.* v. *Public Utilities Comm'n of Cal.*, 475 U.S. 1, 16 (1986) (plurality opinion). But that is not what was happening in *Rust*, and it is not what is happening here. In *Rust*, the Supreme Court relied explicitly on the fact that the challenged "regulations [did] not force the Title X grantee to give up abortion-related speech; they merely require[d] that the grantee keep such activities separate and distinct from Title X activities." 500 U.S. at 196. The Negotiation Program, if anything, is far more accommodating of any speech-related interests that AbbVie may have here. After all, whether or not it participates in the Negotiation Program, AbbVie can say whatever it wants, whenever it wants, to whomever it wants. The only (even arguably) speech-related requirement for participation in this program is that AbbVie needs to sign (1) an agreement to negotiate, and (2) an addendum specifying the agreed-upon price (if any) after a deal is reached. Because those documents "define the federal program" and do not "reach outside it," *AID*, 570 U.S. at 217, they do not run afoul of the unconstitutional-conditions doctrine. That straightforward conclusion does not require that "the definition of" the program "be manipulated to subsume the challenged condition," Pl.'s Opp'n & Reply at 36 (quoting *AID*, 570 U.S. at 215)—after all, AbbVie does not even argue (nor could it) that the agreement is somehow external to operation of the Negotiation Program.

As for the Takings Clause, AbbVie's only response is to continue to insist that the *Nollan-Dollan* framework applies here. *See* Pl.'s Br. at 37-38. But as Defendants explained, *see* Defs.' Br. at 50, that 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). AbbVie protests that the government's position "ignores *Sheetz v. County of El Dorado*, 601 U.S. 267 (2024)," Pl.'s Opp'n & Reply at 37-38. Hardly. If anything, the Supreme Court's uncontroversial observation in *Sheetz* that the "*Nollan/Dolan* test is rooted" in "the unconstitutional conditions doctrine" highlights that that test reflects a *special* application of the unconstitutional conditions doctrine, not a universal one. *Sheetz*, 601 U.S. at 278. Regardless, *Sheetz* is yet another case about the "potential abuse of the permitting process" in the "complicated" context of "land use" and "building permits." *Id.* at 274-75. *Sheetz* thus cannot be a counterexample to Defendants' core point, well explained by the Third Circuit: "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.

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.

Date: August 14, 2026

Respectfully submitted,

ERIC J. HAMILTON
Deputy Assistant Attorney General
Civil Division

MICHELLE R. BENNETT
Assistant Branch Director
Federal Programs Branch

/s/ Stephen M. Pezzi
STEPHEN M. PEZZI (D.C. Bar 995500)
Chief Litigation Counsel
PARDIS GHEIBI (D.C. Bar 90004767)
Trial Attorney
United States Department of Justice
Civil Division, Federal Programs Branch
1100 L Street NW
Washington, DC 20005
Tel: (202) 305-8576
Email: stephen.pezzi@usdoj.gov

Counsel for Defendants