UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

ASTRAZENECA PHARMACEUTICALS LP, *et al.*,

Plaintiffs,

v.

ROBERT F. KENNEDY JR., in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants.

Case No. 1:25-cv-4212-MJM

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

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INTRODUCTION

AstraZeneca asks this Court to conclude that Congress enacted a statutory scheme in which any drug manufacturer can defeat the eligibility for price negotiations of its drug in perpetuity, merely by introducing multiple products with the same active moiety under separate new drug applications (NDAs). Unsurprisingly, Congress did not enact such a self-defeating scheme—as the plain text of the statute indicates, and as its structure and purpose put beyond any doubt. In selecting drugs for negotiation, the Centers for Medicare & Medicaid Services (CMS) is required to aggregate spending data "across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation." 42 U.S.C. § 1320f-1(d)(3)(B). This ensures that the Negotiation Program, as intended, captures the most expensive drugs across all their dosage forms, formulations, and strengths.

But this Court need not reach the merits of this statutory claim because Congress expressly provided that "[t]here shall be no administrative or judicial review" of the very sort of agency determinations that AstraZeneca challenges here: (1) CMS's "selection of drugs" for negotiation under Section 1320f-1(b); (2) its "determination of negotiation-eligible drugs" under Section 1320f-1(d); and (3) its "determination of qualifying single source drugs" under Section 1320f-1(e). *Id.* § 1320f-7(2). At bottom, AstraZeneca's qualm is with CMS's selection of Calquence for the Negotiation Program. That is precisely the type of decision that Congress sought to shield from "judicial review." *Id.*

The Court should thus dismiss AstraZeneca's sole claim for lack of subject-matter jurisdiction, or, in the alternative, enter summary judgment for Defendants on the merits.

ARGUMENT

I. CONGRESS EXPRESSLY PRECLUDED JUDICIAL REVIEW OVER ASTRAZENECA'S STATUTORY CLAIM.

The animating premise of AstraZeneca's sole claim is that CMS has selected the wrong drug for participation in the Negotiation Program. In particular, AstraZeneca laments that CMS treated two forms of AstraZeneca's Calquence—acalabrutinib (free base, 100 mg capsule) and

acalabrutinib (maleate salt, 100 mg tablet)—as a single "qualifying single source drug," even though they were approved through two separate NDAs. *See* Compl. ¶¶ 116-17, ECF No. 1. This claim turns out to be meritless, *see infra*, Section II, but regardless, it is not subject to review pursuant to Congress's decision to bar review of (1) CMS's "selection of drugs" for negotiation under Section 1320f-1(b); (2) its "determination of negotiation-eligible drugs" under Section 1320f-1(d); and (3) its "determination of qualifying single source drugs" under Section 1320f-1(e). 42 U.S.C. § 1320f-7(2). All AstraZeneca's arguments to the contrary lack merit.

a. AstraZeneca's primary theory, advanced in both its opening and reply briefs, is that 42 U.S.C. § 1320f-7 only "shields from review" "the specific 'determinations'" by CMS such as "CMS's 'determination' that any particular product is a 'qualifying single source drug,' its 'determination' that any drug is 'negotiation-eligible,' or its 'selection' of any drug." ECF No. 35 ("Pls.' Opp'n & Reply") at 12 (citation omitted); *see also* ECF No. 21-1 ("Pls.' Br.") at 27-30. In AstraZeneca's telling, subsidiary agency decisions along the way, even if they dictate those "specific 'determinations,'" Pls.' Opp'n & Reply at 12, remain subject to litigation. But, as explained below, neither the statute nor precedent supports AstraZeneca's attempt to so casually circumvent Congress's review bar. Besides, as also explained below, AstraZeneca's theory would effectively nullify the review bar altogether because the "specific determinations" at issue are inextricably tied to the subsidiary agency decisions made along the way.

AstraZeneca makes much of characterizing its claim as a challenge to CMS's "definition" of a "qualifying single source drug." *Id.* at 14. But that characterization is of no help to AstraZeneca where, as here, the precluded "determination[s]" *included* the agency defining key statutory terms. *Id.* In other words, the "definitional" challenge that AstraZeneca purports to bring is simply to one of the earlier steps in the agency's overall "determination of qualifying single source drugs," its "determination of negotiation-eligible drugs," and the ultimate "selection of drugs." 42 U.S.C. § 1320f-7(2). But the plain text of the statute precludes review of that entire "determination"—not just the final step, in which CMS identifies each selected drug by name. Put another way, in precluding review of the agency's "determination" of qualifying single source

drugs and its "determination" of negotiation-eligible drugs, Congress shielded from review both the agency's identification of such drugs "*and* the process by which [the agency] reaches this [identification]." *See Novo Nordisk Inc. v. HHS*, 154 F.4th 105, 111-13 (3d Cir. 2025), *cert. denied sub nom. Novo Nordisk Inc. v. Kennedy*, No. 25-761, 2026 WL 1377130 (U.S. May 18, 2026) (second alteration added) (citation omitted).

Another textual problem for AstraZeneca is that the preclusion provision does not apply to "the selection of a drug," singular, but to "[t]he selection of drugs," plural. 42 U.S.C. § 1320f-7(2). The same with CMS's "determination of qualifying single source drugs" and its "determination of negotiation-eligible drugs," which also use the plural "drugs." *Id.* So, AstraZeneca's central submission—that it has not challenged any specific determination with respect to "any particular product," singular, but rather that it challenges the way CMS defined "qualifying single source drugs" for *all* drugs, plural, Pls.' Opp'n & Reply at 12—leaves its claims equally precluded. If Congress meant to preclude only challenges to the selection of "any particular product," *id.*, then it is hard to see why the statute refers to "selection of drugs," plural.

The D.C. Circuit has applied this reasoning to another Medicare preclusion provision. In *Texas Alliance for Home Care Services v. Sebelius*, the statute precluded review over "the awarding of contracts under this section." 681 F.3d 402, 409 (D.C. Cir. 2012). The challengers argued that this "statutory language was meant to preclude only review of 'individual contracts.'" *Id.* at 410 (quoting Appellants' Br. 18). The court rejected that argument because, "by its terms," the statute "applie[d] not to the awarding of a single contract but to 'the awarding of contracts' generally." *Id.* So too here, for "[t]he selection of drugs," generally. 42 U.S.C. § 1320f-7(2).

Moving beyond the plain text of the preclusion provision, AstraZeneca faces another insurmountable problem: courts have repeatedly interpreted preclusion provisions in the Medicare statute in a manner that is inconsistent with AstraZeneca's approach. ECF No. 32-1 ("Defs.' Br.")

at 14-15.[1] Indeed, as outlined further below, the Third Circuit has already rejected the application of AstraZeneca's theory to 42 U.S.C. § 1320f-7(2). *See Novo*, 154 F.4th at 111-14. Although AstraZeneca struggles mightily to distinguish many of those cases in its brief, it cannot.

First, the plaintiffs in *Novo*, much like AstraZeneca, took issue with "CMS's decision to group products into a single potentially qualifying drug." *Id*. at 111. "CMS adopted a definition of qualifying single-source drug that led the agency to group [its] products together and ultimately select them for negotiation as one drug." *Id.* at 112. The at-issue preclusion provision barred review of such "CMS[] determinations or the internal processes CMS used to make them." *Id.*[2]

Second, in *Texas Alliance*, as discussed above in the context of AstraZeneca's singular-plural problem, the plaintiffs "challenge[d] a regulation addressing the 'applicable financial standards' that a . . . supplier must meet to be eligible for a Medicare contract." 681 F.3d at 404. The D.C. Circuit held that a challenge to the regulation was precluded, under a provision that barred review of "the awarding of contracts under this section." *Id.* at 409-11. The court reasoned

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[1] The only Fourth Circuit cases cited by AstraZeneca in support of its theory are *University of Maryland v. Cleland*, 621 F.2d 98 (4th Cir. 1980), which as explained in Defendants' opening brief, has little relevance here, *see* Defs.' Br. at 19 n.6, and *Garcia v. Neagle*, 660 F.2d 983 (4th Cir. 1981), which is similarly unhelpful. The preclusion provision in *Garcia* only barred review of the Parole Commission's "decision to grant or deny parole"; it did not bar plaintiff's "claim that the guidelines for exercising discretion [to grant or deny parole] . . . violate the intent and directives of the Parole Act." *Id.* at 988. Here, by contrast, the review bar precludes precisely the challenge AstraZeneca brings: "determination of qualifying single source drugs," its "determination of negotiation-eligible drugs," and the ultimate "selection of drugs." 42 U.S.C. § 1320f-7(2).

[2] On May 18, 2026, the Supreme Court denied petitions for writs of certiorari in six cases, including *Novo*, which unsuccessfully challenged the Negotiation Program. *See Novo*, 154 F.4th, *cert. denied sub nom. Novo Nordisk Inc. v. Kennedy*, 2026 WL 1377130; *AstraZeneca Pharms. LP v. Sec'y United States Dep't of Health & Hum. Servs*., 137 F.4th 116 (3d Cir. 2025), *cert. denied sub nom. AstraZeneca v. Kennedy*, No. 25-348, 2026 WL 1377100 (U.S. May 18, 2026); *Bristol Myers Squibb Co. v. Sec'y*, 155 F.4th 245 (3d Cir. 2025), *cert. denied sub nom. Bristol Myers Squibb Co. v. Kennedy*, No. 25-751, 2026 WL 1377095 (U.S. May 18, 2026), *and cert. denied sub nom. Janssen Pharms., Inc. v. Kennedy*, No. 25-749, 2026 WL 1377134 (U.S. May 18, 2026); *Boehringer Ingelheim Pharms., Inc. v. United States Dep't of Health & Hum. Servs.*, 150 F.4th 76 (2d Cir. 2025), *cert. denied sub nom. Boehringer Ingelheim, Inc. v. HHS*, No. 25-799, 2026 WL 1377142 (U.S. May 18, 2026); *Novartis Pharms. Corp. v. Sec'y United States Dep't of Health & Hum. Servs*., 155 F.4th 223 (3d Cir. 2025), *cert. denied sub nom. Novartis Pharms. Corp. v. Kennedy*, No. 25-902, 2026 WL 1377118 (U.S. May 18, 2026).

that "financial standards are indispensable to 'the awarding of contracts' as such standards determine whether or not a contract may be awarded to a bidder based on the financial documents submitted with its bid." *Id.* at 409-10.

Third, in *Florida Health Sciences Center, Inc. v. HHS*, 830 F.3d 515 (D.C. Cir. 2016), "[a]lthough the" preclusion provision at issue barred "judicial review of the Secretary's estimates," a hospital sought "to challenge the data underlying" those estimates. *Id.* at 517. The D.C. Circuit held "that the bar on judicial review of the Secretary's estimates precludes review of the underlying data as well." *Id.* In short, the hospital was "simply trying to undo the Secretary's estimate of the hospital's uncompensated care by recasting its challenge to the Secretary's choice of data as an attack on the general rules leading to her estimate." *Id.* at 522. It could not do so.

Fourth, in *Mercy Hospital, Inc. v. Azar*, 891 F.3d 1062, 1067 (D.C. Cir. 2018), plaintiffs challenged an agency calculation called the "LIP adjustment," which was related to a precluded determination called "the step-two rate." The D.C. Circuit explained that "[a]s both a textual and a practical matter, the LIP adjustment is inextricably intertwined with the step-two rate, and so the shield that protects the step-two rate from review protects the LIP adjustment as well." *Id.*; *see also id.* ("Because reviewing a formula used by the prospective payment rate would effectively review the rate itself, we cannot review the former if we cannot review the latter.").

Fifth, in *Knapp Medical Center v. Hargan*, the D.C. Circuit rejected the argument that, for preclusion purposes, "the 'process' is distinct from the CMS determination flowing from the process." 875 F.3d 1125, 1129 (D.C. Cir. 2017). The court explained that it had twice "rejected the 'categorical distinction between inputs and outputs'" that the plaintiff advanced. *Id.* at 1131 (quoting *Fla. Health*, 830 F.3d at 519). It did so again.

Sixth, in *DCH Regional Medical Center v. Azar,* the court held that it "cannot review the Secretary's method of estimation without also reviewing the estimate. And because the two are inextricably intertwined," the Medicare Act "precludes review of both." 925 F.3d 503, 507 (D.C. Cir. 2019). The plaintiff was "simply trying to undo the Secretary's estimate . . . by recasting its challenge to that estimate as an attack on the underlying methodology." *Id.* at 508.

AstraZeneca's primary response is that some of these cases were not "*genuinely* challenging 'general rules,'" and were "instead merely 'attempt[ing] to undo a shielded determination.'" Pls.' Opp'n & Reply at 15 (alteration in original) (citation omitted). But that is no distinction at all—it is an apt description of AstraZeneca's own claim. Regardless, as the precedent above confirms, framing its challenge as targeting a "general rule" is no help anyway. To the contrary, these sorts of preclusion provisions (at least in the Medicare statute) are equally applicable to agency decisions that are "indispensable or integral to, or inextricably intertwined with, the unreviewable agency action." *Fla. Health*, 830 F.3d at 519 (citation omitted); *accord DCH Reg'l*, 925 F.3d at 507 ("[B]ecause the two are inextricably intertwined, section 1395ww(r)(3)(A) precludes review of both."); *Mercy Hosp.*, 891 F.3d at 1067 ("As both a textual and a practical matter, the LIP adjustment is inextricably intertwined with the step-two rate, and so the shield that protects the step-two rate from review protects the LIP adjustment as well.").

Applying that "inextricably intertwined" principle here, AstraZeneca cannot reasonably dispute that the agency's *definition* of a "qualifying single source drug" is "indispensable or integral to, or inextricably intertwined with," *Fla. Health*, 830 F.3d at 519 (citation omitted), the agency's "determination of qualifying single source drugs," as well as its "determination of negotiation-eligible drugs" and its "selection of drugs," 42 U.S.C. § 1320f-7(2). Without a definition of "qualifying single source drug," there can be no "determination of qualifying single source drugs." Indeed, in rejecting a similar claim in *Novo*, the Third Circuit recognized that "CMS adopted a *definition* of qualifying single-source drug that led the agency to group [its] products together and ultimately select them for negotiation as one drug." 154 F.4th at 112 (emphasis added). Even so, the court concluded, that claim was subject to the review bar because it amounted to an unreviewable challenge to "CMS's determinations or the internal processes CMS used to make them." *Id*. So too here.

Next, like many of the unsuccessful Medicare-related plaintiffs that came before it, "[t]o support its argument for jurisdiction, [AstraZeneca] invokes *McNary v. Haitian Refugee Center, Inc.*, 498 U.S. 479 (1991)." *DCH Reg'l*, 925 F.3d at 507; *see* Pls.' Opp'n & Reply at 11-15. But

McNary is inapplicable here. There, the Supreme Court permitted a due process challenge despite a statutory bar on judicial review. *McNary*, 498 U.S. at 483-84. As the D.C. Circuit has subsequently explained, the "question before the [*McNary*] Court was a narrow one: whether a provision of [an immigration statute], which barred judicial review of individual [adjustment of] status determinations except in the context of deportation proceedings, foreclosed district court review of the plaintiffs' procedural due process claims." *Federal L. Enf't Officers Ass'n v. Ahuja*, 62 F.4th 551, 564 (D.C. Cir. 2023). *McNary* concluded that the challenged provision applied only to "a single act rather than a group of decisions or a practice or procedure employed in making decisions." 498 U.S. at 491-92. *McNary* does not stand for the general proposition that any judicial review bar applied to individual determinations permits broader challenges to underlying rules. When the judicial review provision covers more than a "particular kind of adjudicatory decision," *McNary*'s limited holding does not control. *See DCH Reg'l*, 925 F.3d at 508. And crucially, the claims in *McNary* "were collateral to review of a denied application." *Miriyeva v. USCIS*, 9 F.4th 935, 944 (D.C. Cir. 2021) (citing *McNary*, 498 U.S. at 494-99). Thus, if the plaintiffs in that case prevailed, "that victory would not have reversed the denial of their applications for special agricultural worker status. Rather, it would allow only for their applications to be reconsidered with new procedures in place." *Miriyeva*, 9 F.4th at 944 (citation omitted). Where deciding the challenge to the general rule would "decide the merits" of the individual adjudication, judicial review is barred. *Fornaro v. James*, 416 F.3d 63, 68 (D.C. Cir. 2005); *Palisades Gen. Hosp. Inc. v. Leavitt*, 426 F.3d 400, 405 (D.C. Cir. 2005). Both of these caveats render the *McNary* rule inapplicable here. For the same reasons, AstraZeneca' reliance on *Reno v. Catholic Social Services, Inc.*, 509 U.S. 43 (1993), is also unavailing. *Reno* relied heavily on *McNary*. Indeed, *Reno* explained that *McNary* involved a "virtually identical set of provisions governing judicial review." *Id.* at 55. Because the Court found "no reason to reverse course," it concluded that review was not precluded. *Id.* at 56.

Nor can AstraZeneca salvage its argument by relying on *Teva Pharmaceuticals USA, Inc. v. Kennedy,* which is currently on appeal. 2025 WL 3240267, at *12 (D.D.C. Nov. 20, 2025),

appeal pending, No. 25-5425 (D.C. Cir. Nov. 30, 2025). For the above reasons, the district court's refusal to apply the review-preclusion provision was, respectfully, based on the same misreading of the caselaw that AstraZeneca advances here. This Court should not follow that approach.

Moreover, AstraZeneca cannot circumvent the preclusion provision by distancing itself from the selection of Calquence, in particular, for the Negotiation Program. In AstraZeneca's telling, the selection of Calquence gives it standing but does not define the "substance" of its claim. Pls.' Opp'n & Reply at 15 (citation omitted). But the substance of AstraZeneca's claim *is* a challenge to CMS's selection of Calquence. The concluding paragraphs of AstraZeneca's argument on the merits prove as much. *See* Pls.' Opp'n & Reply at 25. The crux of AstraZeneca's claim is that CMS erred in not treating acalabrutinib maleate salt and acalabrutinib free base as "distinct drug[s]" for purposes of the Negotiation Program. *See id.* This claim is—and only could be—a challenge to CMS's "selection of drugs," its "determination of negotiation-eligible drugs," and its "determination of qualifying single source drugs." 42 U.S.C. § 1320f-7(2).

AstraZeneca attempts to downplay its reliance on Calquence's selection by packaging its discussion of it as merely "illustrat[ive]." Pls.' Opp'n & Reply at 25. But AstraZeneca does not invoke Calquence as a mere example—it invokes it because it must. If AstraZeneca had sought an advisory opinion about the legality of CMS's guidance in the abstract—without seeking to remedy its concrete interest with respect to Calquence—the case would be dismissed for lack of standing. We know this because AstraZeneca already tried. In *AstraZeneca Pharms. LP v. Secretary U.S. Dep't of HHS* ("*AstraZeneca I*"), both the district court and a unanimous Third Circuit panel concluded that AstraZeneca's statutory claims—bringing an abstract challenge to CMS's guidance, which had not affected the selection of any AstraZeneca drug—had to be dismissed for lack of standing. 137 F.4th 116, 125-26 (3d Cir. 2025). Thus, here, AstraZeneca's invocation of its concrete interest in the selection of Calquence is not a mere box-checking exercise—it defines the nature of its claim.

Ultimately, this argument boils down to a plea that this Court ignore plain statutory text to achieve a policy result that drug manufacturers prefer, as AstraZeneca purports to be incredulous

that Congress could have meant what it said: that it will generally be up to CMS "to police its own conduct" on these issues, rather than federal courts. *Mach Mining, LLC v. EEOC*, 575 U.S. 480, 486 (2015) (cited in Pls.' Opp'n & Reply at 17). But that is what Congress wanted, as confirmed by the statutory text—at least with respect to CMS's "selection of drugs[,]" its "determination of negotiation-eligible drugs," and its "determination of qualifying single source drugs[.]" 42 U.S.C. § 1320f-7(2). Other courts have repeatedly enforced similar provisions in the Medicare statute as written. This Court should do the same.

b. Additionally, for the first time in its reply brief, AstraZeneca purports to identify a new theory as to why review of its claim is not precluded. *See* Pls.' Opp'n & Reply at 3-11. According to AstraZeneca, under what it calls the "merger rule," *id.* at 7, its challenge is reviewable because it "'raises the question of the [agency's statutory] authority,'" and thus "'merges consideration of the legality of [CMS's] action with consideration of this court's jurisdiction,'" *id.* at 4 (alterations in original) (quoting *COMSAT Corp. v. FCC*, 114 F.3d 223, 227 (D.C. Cir. 1997)). For the reasons identified below, this theory is—at best—a repackaged version of AstraZeneca's earlier (and futile) argument.

Under this so-called merger rule, "there is no preclusion of judicial review where . . . the [agency] has acted outside the scope of its [statutory] authority." *COMSAT*, 114 F.3d at 224. "Put differently, the jurisdiction-stripping provision does not apply if the agency's action fails to qualify as the kind of action for which review is barred." *Am. Hosp. Ass'n v. Azar*, 964 F.3d 1230, 1238 (D.C. Cir. 2020) (citation omitted). In *Azar*, for instance, the relevant provision barred review of "'establishment of methods,'" but plaintiffs argued "that the payment reduction at issue [was] *not* a 'method[]' . . . . within the meaning of the statute" to begin with. 964 F.3d at 1238 (first alteration added) (quoting 42 U.S.C. § 1395*l*(t)(12)(A)). So, "to determine whether the judicial-review bar applie[d]" in the first place, the court had to decide "whether the challenged agency action count[ed] as a 'method.'" *Id.* (citation omitted). That inquiry was essentially the same as the "merits issue presented." *Id.; see also Arlington Hospital v. Schweiker*, 547 F. Supp. 670, 676-77 (E.D. Va. 1982) (statute barred review of decisions to withhold payment for "personal comfort

items," but plaintiff's claim was reviewable because it challenged whether a telephone was a "personal comfort item" in the first place (citation omitted)), *reversed on other grounds sub nom. Arlington Hosp. v. Heckler,* 731 F.2d 171 (4th Cir. 1984).

By contrast, here, the merits issue does not turn on whether there was any "selection" or "determination" with respect to Calquence under 42 U.S.C. § 1320f-7(2). There plainly was because Calquence is currently part of the Negotiation Program. Tellingly, even AstraZeneca does not go so far as to argue that CMS did not reach any "determination" with respect to Calquence under 42 U.S.C. § 1320f-7(2). At most, it attempts to shoehorn its claim into the so-called merger rule by arguing that CMS's determination that Calquence is a "qualifying single source drug" is not a true "determination *'under' [Section 1320f-1(e)]*" because CMS "replace[d] Section 1320f-1(e)'s definition of 'qualifying single source drug' with a new definition based on 'active moiety.'" Pls.' Opp'n & Reply at 7 (emphases removed and added). Even this tortured phrasing only claims that the selection of Calquence for the Negotiation Program does not count as a *lawful* determination under 42 U.S.C. § 1320f-7(2) because it was premised on an erroneous application of the definition in Section 1320f-1(e). But that is not the same as claiming that CMS's selection of Calquence was not a "determination" under 42 U.S.C. § 1320f-7(2). Conflating the two would stretch any "merger rule" beyond its bounds and render meaningless Congress's decision to preclude judicial review. On AstraZeneca's theory, all meritless claims would be precluded, while all meritorious claims would proceed, which is exactly what would happen if Congress had omitted the review bar altogether. Besides, substantively, this argument merely regurgitates AstraZeneca's main theory—*i.e.*, that a challenge to the *definition* used to select Calquence is not a challenge to the selection of Calquence. For the reasons identified above, that argument fails.

c. Finally, AstraZeneca 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. Pls.' Opp'n & Reply at 18-19. Ultra vires review, however, is categorically unavailable when Congress has expressly precluded "all other forms of judicial review," *Sustainability Inst. v. Trump*, 165 F.4th 817, 830 (4th Cir. 2026) (citation omitted), as it has here. Further ultra vires review is

"necessarily narrow." *Id.* (citation omitted); *see also Nuclear Regul. Comm'n v. Texas*, 605 U.S. 665, 681 (2025) (explaining that the Supreme Court has "strictly limited nonstatutory ultra vires review"). It "applies only when an agency has taken action entirely in excess of its delegated powers and contrary to a specific prohibition in a statute." *Sustainability Inst.*, 165 F.4th at 830 (citation omitted) (emphasis removed). It is the equivalent of "a Hail Mary pass—and in court as in football, the attempt rarely succeeds." *Nuclear Regul. Comm'n*, 605 U.S. at 681-82 (citation omitted). This case is no exception.

AstraZeneca attempts to satisfy this high bar by coupling a two-sentence summary of its merits argument with a swift declaration that the statutory violation "could hardly be clearer." Pls.' Opp'n & Reply at 18. Putting aside the fact that AstraZeneca is wrong on the merits, *see infra* Section II, it could not sustain an ultra vires claim even if CMS "ha[d] arguably reached a conclusion which does not comport with the law." *Sustainability Inst.*, 165 F.4th at 830 (citation omitted). An ultra vires claim requires "a strong and clear demonstration that a clear, specific and mandatory statutory provision has been violated." *Long Term Care Partners, LLC v. United States*, 516 F.3d 225, 234 (4th Cir. 2008) (citation modified). Far from satisfying that standard, AstraZeneca's argument on the merits turns on a statutory theory that was rejected by the only court that reached it. *See Teva*, 2025 WL 3240267, at *10-12.

II. ASTRAZENECA'S STATUTORY CLAIM LACKS MERIT.

Even if this Court had jurisdiction over AstraZeneca's statutory claim, it should nevertheless reject it on its merits. CMS properly determined that two forms of the same drug—namely, Calquence—are, indeed, the same drug. AstraZeneca's interpretation to the contrary, which treats Calquence (NDA 210259) and Calquence (NDA 216387) as two different drugs—is detached from the statutory text, structure, and overarching design of the statute. For that matter, it is likewise detached from AstraZeneca's own marketing materials, which generally refer only to "Calquence" without any further differentiation. *See* Defs.' Br. at 25.

CMS properly determined that it will identify a "qualifying single source drug" as including all "dosage forms and strengths" of a drug with the same active moiety, consistent with

the plain language of the Inflation Reduction Act (IRA). CMS, *Medicare Drug Price Negotiation Program: Final Guidance* at 167 (Oct. 2, 2024), https://perma.cc/J6JE-HHRS ("2027 Guidance"). By contrast, AstraZeneca's interpretation of "qualifying single source drug" would require CMS to consider all dosage forms and strengths of a drug, *except* when the different dosage form or strength was approved under a different NDA. *See* Pls.' Opp'n & Reply at 19. There is no basis for AstraZeneca's atextual reading.

a. As CMS has explained, its intent to consider all "dosage forms and strengths" of a drug with the same active moiety and the same holder of an NDA, *see* 2027 Guidance at 167, is consistent with the IRA's plain language directing CMS to consider all the different "dosage forms," "strengths," and "formulations" of the drug, 42 U.S.C. § 1320f-1(d)(3)(B); *id.* § 1320f-5(a)(2), and all "applications and approvals" of a drug, *id.* § 1320f-3(e)(1)(D).[3]

For its part, instead of arguing that its interpretation is consistent with the relevant provisions, AstraZeneca dismisses the significance of those provisions altogether. It argues that Sections 1320f-1(d)(3)(B) and 1320f-5(a)(2) are irrelevant to CMS's decision as to whether a drug is a "qualifying single source drug" because those provisions only kick in after CMS has already identified whether the drug is, indeed, a "qualifying single source drug." *See* Pls.' Opp'n & Reply at 22-23. AstraZeneca is wrong. The requirement that CMS consider all dosage forms, strengths, and formulations of a drug together, "and not based on the specific formulation or package size or package type of such drug," 42 U.S.C. § 1320f-5(a)(2); *see also id.* § 1320f-1(d)(3)(B), applies at each stage of the process—from the identification and selection of negotiation-eligible drugs to the negotiations themselves and finally (if negotiations succeed) to the application of a negotiated price. Congress expressly directed CMS to identify "negotiation-eligible drugs" according to Medicare spending data, to rank these drugs according to this data, and then select the top drugs on the list for negotiation. When calculating Medicare expenditures for a drug at each of these

[3] Similarly, for biologics, the 2027 Guidance explains that a "qualifying single source drug" includes "all dosage forms and strengths" of a biologic with the same active ingredient and the same holder of a biologics license application (BLA). 2027 Guidance at 168.

steps, CMS must aggregate the spending data "across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation, and *not based on the specific formulation* or … package type of the drug." 42 U.S.C. § 1320f-1(d)(3)(B) (emphasis added). By requiring CMS to consider the total expenditures for a drug across its variations, the statute ensures that CMS identifies and selects the drugs that have the most significant financial impact on Medicare as a whole.

The next steps in the process are in keeping with this approach. Once CMS selects a drug for negotiation, CMS is required to consider all "applications and approvals[,]" in the plural, "for the drug," in the singular, when determining how much to offer in negotiations. 42 U.S.C. § 1320f-3(e)(1)(D). This step, like the earlier ones, contemplates that one drug may be offered in a number of forms that may correspond to different applications or approvals. And CMS is expressly required to consider all "applications and approvals" (plural) "for the drug" (singular) when determining how much to offer in negotiations. *Id.* Finally, after negotiations are completed and a price is established, CMS must "apply the maximum fair price across different strengths and dosage forms of a selected drug and not based on the specific formulation or package size or package type" of the drug. *Id.* § 1320f-5(a)(2). The Act thus contemplates expressly that there may be multiple forms of a selected drug, with multiple approvals, and it directs CMS to apply the negotiated price to each form.

As for AstraZeneca's interpretation of 42 U.S.C. § 1320f-3(e)(1)(D), it is particularly forced. That provision directs CMS to consider all "applications and approvals under section 355(c) of Title 21 or section 262(a) of [Title 42] for the drug" when determining how much to offer in negotiations. 42 U.S.C. § 1320f-3(e)(1)(D). AstraZeneca dismisses this provision in passing by arguing that the provision merely references "the drug's original NDA and any supplemental applications and approvals under the same NDA number." Pls.' Opp'n & Reply at 24. In other words, as AstraZeneca sees it, Section 1320f-3(e)(1)(D) references multiple supplements within a single NDA or BLA rather than multiple NDAs or BLAs. *See id*.

But this argument ignores the fact that Section 1320f-3(e)(1)(D) cross-references 21 U.S.C. § 355(c) and 42 U.S.C. § 262(a), which provide procedures related to the base-level approval process for *all* applications—including both new NDAs or BLAs and supplemental NDAs or BLAs. *See* 21 U.S.C. § 355(c); 42 U.S.C. § 262(a); *see also, e.g.*, 21 C.F.R. § 314.3(b) (defining "[a]pplication, new drug application, or NDA" as "the application" plus "all amendments and supplements to the application").[4] It would make little sense for Congress to cross-reference the approval processes used for all applications, including new NDAs and BLAs, if Congress had meant to cabin CMS to considering only applications and approvals within a single NDA or BLA. Had Congress so intended, Congress easily could have specified. *See Jama v. ICE*, 543 U.S. 335, 341 (2005) ("We do not lightly assume that Congress has omitted from its adopted text requirements that it nonetheless intends to apply[.]").

b. AstraZeneca nevertheless insists that the NDA-specific requirement is embedded in the IRA by latching on to the statute's cross-references to an entirely different statute—namely, the Food, Drug, and Cosmetic Act (FDCA). Pls.' Opp'n & Reply at 19-20. AstraZeneca emphasizes that the IRA provides that a qualifying single source drug is "'a covered part D drug . . . that is approved under Section 355(c) of Title 21,' which is the provision of the [FDCA] governing NDA-approval," and that "[t]he drug must be 'marketed pursuant to such approval,' meaning pursuant to *that* NDA." *Id.* (quoting 42 U.S.C. §§ 1320f-1(e)(1) & 1320f-1(e)(1)(A)). These provisions, AstraZeneca argues, tie a qualifying single source drug to one specific "approval"—*i.e.*, a singular NDA. Pls.' Opp'n & Reply at 19.

AstraZeneca overreads these cross-references. The definition of a qualifying single source drug includes "approv[al] under section 355(c) of Title 21" because, unsurprisingly, a qualifying

[4] For example, Section 355(c) addresses the timing for approval or hearing on an application, *see* 21 U.S.C. § 355(c)(1); instructs an applicant to submit the relevant patent information to the FDA, *see id.* § 355(c)(2); provides the effective date of approval for certain NDAs, including in case of a patent-infringement lawsuit, *see id.* § 355(c)(3); and allows applicants to rely on drugs manufactured in "a pilot or other small facility" to show the safety and effectiveness of the drugs and obtain approval for the drugs before their manufacture in a larger facility, *see id.* § 355(c)(4).

single source drug must be FDA-approved, 42 U.S.C. § 1320f-1(e)(1)(A)—rather than, for example, an experimental drug, or a drug approved only in Europe. Similarly, the IRA's cross-reference to the definition of a "covered part D drug" in section 1395w-102(e) ensures that a qualifying single source drug is a drug eligible for reimbursement under Medicare Part D. The definition of a "covered part D drug," in turn, cross-references the general Medicaid definition of a "covered outpatient drug" in section 1396r-8(k)(2), which—again—unsurprisingly requires that a drug be FDA-approved to be eligible for Medicaid reimbursement. These provisions do not mean that each FDA approval of each NDA creates a distinct, *new* "covered outpatient drug."

Regardless, is it unlikely that Congress would have buried a critical feature of the IRA beneath multiple layers of obscure cross-references to another statute with different purposes. *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001) (cautioning that courts should not assume that Congress "hide[s] elephants in mouseholes"); *see also* Defs.' Br. at 22-23 (explaining that "the IRA and the [FDCA] are different statutes with fundamentally different objectives and functions"). Had Congress intended that a qualifying single source drug be NDA-specific, it could have just said so. *See Jama*, 543 U.S. at 341.

Indeed, the Fourth Circuit recently came to a similar conclusion in an adjacent context. In *Vanda Pharmaceuticals, Inc. v. CMS*, the Fourth Circuit determined that "line extension" drugs—which are subject to additional rebates under the Medicaid Drug Rebate Program—are not limited to new formulations of drugs marketed and approved pursuant to supplemental NDAs, but instead also include drugs marketed and approved under new NDAs. 98 F.4th 483, 495-96 (4th Cir. 2024), *cert. denied*, 145 S. Ct. 1047 (2025). In doing so, the Fourth Circuit held that cross-references to the FDA approval process in definitions of the Medicaid Drug Rebate Program were meant only to limit Medicaid drug coverage to drugs that the FDA considers safe and efficacious—not to create a hidden, implicit constraint on-line extensions. *See id.* ("If Congress had meant to limit line extensions to drugs approved via supplemental [NDAs], we think it would have done so explicitly within the definition of the term 'line extension.'"). Much the same could be said here.

AstraZeneca similarly overreads the "exemption for 'the listed drug' for a generic competitor." Pls.' Opp'n & Reply at 21 (quoting 42 U.S.C. §§ 1320f-1(e)(1)(A)(iii)). It claims that because a "generic competitor relie[s] [on a specific NDA] for its own approval," the IRA intended to impose an NDA-specific limitation on the selection of a "qualifying single source drug." Pls.' Opp'n & Reply at 21. This reading puts more weight on the text than it can bear, and in any event, conflicts with the IRA's unambiguous directive to consider all the different "dosage forms," "strengths," and "formulations" of the drug, 42 U.S.C. § 1320f-1(d)(3)(B); *id.* § 1320f-5(a)(2), and all "applications and approvals" of a drug, *id.* § 1320f-3(e)(1)(D).

Nor can AstraZeneca support its specific-NDA theory by emphasizing that the seven-year eligibility clock starts from "the date of such approval[.]" *Id.* § 1320f-1(e)(1)(A)(ii); *see* Pls.' Opp'n & Reply at 20. AstraZeneca argues that the text of this provision supports the conclusion that the IRA intended to restart the seven-year clock for the same drug with every new NDA. *See* Pls.' Opp'n & Reply at 20. But once again, AstraZeneca's argument is detached from an explicit directive from Congress to the contrary to "includ[e]" new forms of the same drug in making eligibility determinations. *See* 42 U.S.C. § 1320f-1(d)(3)(B). Besides, restarting the clock with every new NDA would undermine the IRA's statutory scheme altogether. Under AstraZeneca's theory, "the manufacturer could extend its seven-year grace period from selection in the Program . . . by introducing inconsequential changes to the drug in new NDAs and shifting patients to that new version." *Teva*, 2025 WL 3240267, at *12 ("The statutory text gives [the Court] no reason to conclude that Congress enacted such a 'self-defeating statute.'" *Id.* (quoting *Pugin v. Garland*, 599 U.S. 600, 607 (2023)).

AstraZeneca also attempts to salvage its argument by latching on to Congress's use of the singular in explaining that a "qualifying single source drug" is "*a* covered part D drug . . . that *is* approved under Section 355(c) of Title 21 and *is* marketed pursuant to *such* approval," becomes eligible "7 years [after] *the* date of *such* approval," and is not "*the* listed drug" for a generic drug. Pls.' Opp'n & Reply at 19, 21 (alteration in original) (quoting 42 U.S.C. §§ 1320f–1(e)(1) & 1320f–1(e)(1)(A)(ii)-(iii)). This argument is also unavailing. Section 320f–1(e)'s use of the word

"drug," in its singular form to refer to the aggregation of the drug's various dosage forms, strengths, and formulations is in line with the IRA's use of "drug" elsewhere. *See, e.g.*, 42 U.S.C. § 1320f-1(d)(3)(B) (selection of negotiation-eligible drugs); *id.* § 1320f-3(e)(1)(D) (determination of negotiation offer amount); *id.* § 1320f-5(a)(2) (application of negotiated price).

Unable to find any statutory support for its desired interpretation, AstraZeneca reverts to scrutinizing CMS's reliance on the drug's "active moiety" to determine that different forms of a drug with the same active moiety are the same qualifying single source drug. As AstraZeneca sees it, because "Congress [was] well aware of that term" and "regularly uses it in *other* statutes" but did not do so in the IRA, the appropriate inference is that Congress did *not* intend to incorporate this well-established term into the IRA. Pls.' Opp'n & Reply at 21. This argument gets it backward. Congress told CMS to look to "[a] drug," 42 U.S.C. § 1320f-1(e)(1)(A)—*i.e.*, "[a] substance used in the diagnosis, treatment, or prevention of a disease or as a component of a medication," drug (n), *The American Heritage Dictionary of the English Language* (5th ed. 2018)—that meets certain characteristics. Looking to the active moiety—which FDA has historically done—is a basic way to determine whether the drug contains a new chemical entity. In that context, there was no need for Congress to further detail the ordinary definition of a drug. "Longstanding practices of the Executive Branch can place a gloss on Congress's action in enacting a particular provision." *United States v. Wilson*, 290 F.3d 347, 356 (D.C. Cir. 2002) (cleaned up). And "Congress is unlikely to intend any radical departures from past practice without making a point of saying so." *Jones v. United States*, 526 U.S. 227, 234 (1999).

c. Moreover, AstraZeneca's argument that a "qualifying single source drug" can have only one NDA or BLA is counterintuitive at best, given that the number of NDAs or BLAs for a drug or biologic may be affected by various factors, including FDCA provisions, FDA regulations, and FDA guidance, as well as how an applicant chooses to submit its application(s) to FDA. In some cases, a drug or biologic with multiple dosage forms and strengths may have been approved in a single NDA or BLA, but that is often not the case. A manufacturer may decide to submit multiple applications for a drug with the same active moiety, such as a drug with both an immediate

release and an extended-release formulation. *See* 2027 Guidance at 169 ("CMS is aware that existing NDA / BLA holders have obtained approval for new dosage forms or different routes of administration of the same active moiety / active ingredient under different NDAs or BLAs.").

It is precisely these circumstances that allow for the possibility of "product hopping," *see id.* at 13, which is a strategy to fend off generic competition by introducing changes to an existing drug and shifting patients to that new version, *see* Defs.' Br. at 8-9. AstraZeneca waves away this argument as a "policy concern" detached from the IRA. Pls.' Opp'n & Reply at 25. But far from a mere policy concern, the "product-hopping" problem has interpretative relevance: it exposes AstraZeneca's interpretation of the statute as "self-defeating." *Pugin*, 599 U.S. at 607 (citation omitted); *see also Teva*, 2025 WL 3240267, at *12 (rejecting this interpretation in part because it would allow for "product hopping," which would render the IRA "a 'self-defeating statute'"(quoting *Pugin*, 599 U.S. at 607)).

d. To further criticize CMS's interpretation, AstraZeneca strains to construct a problem related to the requirement that a qualifying single source drug consists only of products held by "the same holder of a[n] [NDA]." 2027 Guidance at 167. AstraZeneca's argument is that CMS's definition is illogical without this "same-NDA-holder" qualifier, because it would sweep in products held by different entities; yet, argues AstraZeneca, the "same holder" qualifier itself lacks statutory authority. *See* Pls.' Opp'n & Reply at 22.

AstraZeneca is mistaken, because the "same holder" limitation also follows from the IRA's text. In particular, the statute repeatedly and consistently directs CMS to negotiate with "the manufacturer" of the selected drug, in the singular. As relevant here, the IRA defines "manufacturer" as "the manufacturer" "with respect to a drug or biological." 42 U.S.C. § 1320f(c)(1); *id.* § 1395w-3a(c)(6)(A)).[5] And the IRA directs CMS to negotiate with "the

[5] Section 1395w-3a(c)(6)(A) further cross-references the definition of "manufacturer" in 42 U.S.C. § 1396r-8(k)(5), which defines "manufacturer" as "any entity which is engaged in" either (1) "the production, preparation, propagation, compounding, conversion, or processing of prescription drug products," or (2) "the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products."

manufacturer" to reach "a maximum fair price for such selected drug of the manufacturer." *Id.* § 1320f-2(a)(1). After entering into an agreement to negotiate, "the manufacturer" must submit certain information to CMS. *See id.* § 1320f-2(a)(4)(A) (directing "the manufacturer" to submit "information on the non-Federal average manufacturer price . . . for the drug" (citing 38 U.S.C. § 8126(h)(5))); *see also* 38 U.S.C. § 8126(h)(5) (defining "non-Federal average manufacturer price" as "the weighted average price of a single form and dosage unit of the drug that is paid by wholesalers in the United States to *the manufacturer*" (emphasis added)); 42 U.S.C. § 1320f-3(c)(1)(A), (C) (directing CMS to use "average non-Federal average manufacturer price" for determining ceiling on maximum fair price). And the IRA directs CMS to provide an initial offer to "the manufacturer of the selected drug." *Id.* § 1320f-3(b)(2)(B).[6] Because the IRA directs CMS to negotiate a maximum fair price with "the manufacturer" of the selected drug, in the singular, *see* 2027 Guidance at 187, CMS recognizes that different dosage forms and strengths of a drug with the same active moiety (or active ingredient) are the same qualifying single source drug only when the NDA(s) or BLA(s) are held by the same manufacturer, *see id.* at 167. CMS's inclusion of the "same holder" qualifier in the definition of a qualifying single source drug is thus explicitly contemplated by the text of the statute.

In any event, AstraZeneca cannot complain that CMS's interpretation is improper based on the "same holder" qualifier because the need for that qualifier also applies to AstraZeneca's interpretation. As CMS explains, multiple entities may meet the statutory definition of a "manufacturer," 42 U.S.C. § 1320f-2(a)(4)(A), for a single NDA or BLA, *see* 2027 Guidance at 187.[7] Thus, even under AstraZeneca's "one NDA" interpretation of a qualifying single source

[6] There are more examples. *See, e.g.*, 42 U.S.C. § 1320f(b)(4)(A)(i) (defining "negotiation period" as beginning on, as one alternative, "the date on which *the manufacturer of the drug* and the Secretary enter into an agreement . . . with respect to such drug" (emphasis added)); *id.* § 1320f-1(d)(2)(B)(ii) ("A drug shall not be considered to be a qualifying single source drug . . . if *the manufacturer of such drug* is acquired after 2021 by another manufacturer that does not meet the definition of a specified manufacturer . . . ." (emphasis added)).

[7] Multiple entities may meet the statutory definition of "manufacturer" where, for example, multiple manufacturers have entered into royalty, licensing, revenue-sharing, marketing, supply,

drug, Pls.' Opp'n & Reply at 19, there might otherwise be multiple different entities that meet the definition of "manufacturer." And given that the IRA directs CMS to negotiate with "the manufacturer" of a drug, *see supra* at 18-19, CMS has explained that in such circumstances, CMS will enter into agreements and negotiations with the *holder* of the relevant NDA(s) or BLA(s) (also known as the "Primary Manufacturer"), 2027 Guidance at 187 (quoting 42 U.S.C. § 1320f-2(a)(1)). So, even AstraZeneca's interpretation of the statute would require a "same holder" qualifier to ensure consistency with the IRA's plain text.

At bottom, AstraZeneca's interpretation is contrary to the plain language of the IRA. Despite claiming that "[t]he IRA defines Qualifying Drug by reference to the drug's NDA," Pls.' Opp'n & Reply at 19, AstraZeneca fails to identify any provision in the IRA specifying that consideration of all the different "dosage forms," "strengths," "formulations," and "applications and approvals" of the drug must be limited to the *same* NDA, 42 U.S.C. § 1320f-1(d)(3)(B); *id.* § 1320f-5(a)(2); *id.* § 1320f-3(e)(1)(D). Had Congress intended CMS to impose an NDA-specific limitation, it could have said so far more easily than through the interpretative scavenger-hunt suggested by AstraZeneca. Moreover, any such NDA-specific limitation would be contrary to the goal of the Negotiation Program, which is to select the most expensive drugs. By requiring that CMS calculate the total cost of a drug (across its various dosage forms, strengths, and formulations), Congress ensured that differing forms of the same drug did not undermine its goal of facilitating price negotiation of drugs that imposed the greatest financial burden on Medicare.

CONCLUSION

For these reasons, the Court should dismiss AstraZeneca's sole claim for lack of subject-matter jurisdiction, or, in the alternative, enter summary judgment for Defendants on its merits.

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purchasing, or affiliate agreements for a particular NDA or BLA. 2027 Guidance at 187. In such cases, CMS refers to the entity that holds the NDA or BLA as the "Primary Manufacturer." *Id*. CMS uses the term "Secondary Manufacturer" for any other entity that also meets the statutory definition of "manufacturer" *and* "either (1) is listed as a manufacturer in an NDA or BLA for the selected drug; or (2) markets the selected drug pursuant to an agreement with the Primary Manufacturer." *Id*. There is only ever one Primary Manufacturer.

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CERTIFICATE OF SERVICE

I hereby certify that on June 11, 2026, I electronically filed this document with the Court by using the CM/ECF system, and that this document was distributed via the Court's CM/ECF system.

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