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.	Civil Action No. 1:25-cv-4212-MJM

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

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For the reasons stated in the accompanying combined memorandum of law, the Court should dismiss this suit for lack of subject-matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1). In the alternative, the Court should dismiss this suit for failure to state a claim upon which relief can be granted under Federal Rule of Civil Procedure 12(b)(6). Further in the alternative, the Court should grant Defendants' motion for summary judgment

Date: March 27, 2026

Respectfully submitted,

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

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INTRODUCTION

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

Unsurprisingly, drug manufacturers—which have long profited from unrestricted growth in Medicare's prescription drug payments—lobbied hard against legislative efforts to introduce market discipline by giving the Secretary a seat at the negotiating table. After their lobbying failed, pharmaceutical companies and interest groups repackaged their policy disagreements into lawsuits, filing complaints around the country challenging the Negotiation Program on a wide variety of statutory and constitutional grounds. This is lawsuit number 12 of 13, and the second one filed by AstraZeneca alone. It fares no better than all the others.

As a threshold matter, this Court lacks statutory subject-matter jurisdiction over this suit. AstraZeneca's only claim contests how CMS has interpreted a single statutory term. That term—"qualifying single source drug"—identifies a set of threshold criteria for a drug to be potentially included in the Negotiation Program. 42 U.S.C. § 1320f-1(e). On AstraZeneca's telling, CMS misread that statutory definition by aggregating products with the same active moiety across multiple New Drug Applications (NDAs). But even if AstraZeneca were right about that, Congress provided expressly that there "shall be no administrative or judicial review" of certain

administrative actions—including CMS's "determination of qualifying single source drugs," its determination of "negotiation-eligible drugs," and its "selection of drugs" for negotiation. 42 U.S.C. § 1320f-7. By contesting CMS's application of the definition of a "qualifying single source drug," AstraZeneca walks directly into that explicit preclusion provision. Both the plain text of the IRA and case law analyzing similar bars to judicial review in other parts of the Medicare statute confirm that this Court cannot ignore Congress's choice to explicitly preclude judicial review.

Even if the Court had jurisdiction, AstraZeneca is wrong on the merits. CMS has correctly implemented the statute's text, structure, and purpose by treating products with the same active moiety and held by the same NDA holder as a single drug for purposes of selection and negotiation, even if they happen to be marketed under multiple NDAs. Plaintiffs' contrary reading—equating "drug" with each separate NDA approval and using that formality to defeat the substance of selection, ranking, and eligibility rules in the Act—is inconsistent with the statute's text and structure, and would frustrate Congress's design by inviting easy evasion through routine lifecycle-management maneuvers that preserve exclusivity and high prices without introduction of a genuinely new drug.

Ultimately, AstraZeneca remains free to sell two forms of Calquence under two different NDAs. But for purposes of the Negotiation Program, Calquence (NDA 210259) and Calquence (NDA 216387) are the same drug.

BACKGROUND

I. Medicare and the Escalating Cost of Prescription Drug Coverage

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

Medicare is divided into "Parts," which establish the terms under which Medicare pays for specific benefits. *See Ne. Hosp. Corp. v. Sebelius*, 657 F.3d 1, 2 (D.C. Cir. 2011). Medicare Part B covers outpatient care as well as the cost of drugs administered as part of that care. *Cares Cmty.*

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

In enacting Part D, Congress initially barred CMS from negotiating Part D drug prices or otherwise interfering in the arrangements between drug manufacturers and insurance plans. 42 U.S.C. § 1395w-111(i); *see also* Michelle Singer, *Under the Influence*, CBS News (Mar. 29, 2007), https://perma.cc/5U9Z-M2YS (documenting extensive pharmaceutical industry efforts to lobby for price-negotiation bar in lead-up to enactment of Part D). But that model led to skyrocketing drug prices, which saddled beneficiaries with unaffordable copays and threatened the long-term solvency of the program.

The cost to the federal government of providing prescription drug coverage under Medicare Parts B and D is immense. In 2021 alone, the federal government spent more than $250 billion on drugs covered by these programs. *See* KFF, *10 Prescription Drugs Accounted for $48 Billion in Medicare Part D Spending in 2021, or More Than One-Fifth of Part D Spending That Year* (July 12, 2023), https://perma.cc/4CYL-KYRM. That figure has risen dramatically over the last decade and is "projected to continue rising during the coming decade, placing increasing fiscal pressure[]" on the federal budget. Off. of the Assistant Sec'y for Plan. & Evaluation, HHS, *Report to Congress: Prescription Drug Pricing* 8 (May 20, 2020), https://perma.cc/5GEN-LZ7F (2020

Report). Medicare Part D spending in particular "is projected to increase faster than any other category of health spending." S. Rep. No. 116-120, at 4 (2019).

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

A "relatively small number of drugs are responsible for a disproportionately large share of Medicare costs." H.R. Rep. No. 116-324, pt. 2, at 37 (2019). In 2018, "the top ten highest-cost drugs by total spending accounted for 46 percent of spending in Medicare Part B" and "18 percent of spending in . . . Part D." 2020 Report 7. By 2021, the top 10 drugs by total spending accounted for 22% of spending under Part D. *See* KFF, Juliette Cubanski & Tricia Neuman, *A Small Number of Drugs Account for a Large Share of Medicare Part D Spending* (July 12, 2023), https://perma.cc/2PF2-336Z.

These rising costs are in large part attributable to manufacturers' considerable latitude in dictating the prices that Medicare pays for the most expensive drugs. Because drug prices under Medicare Part B and Part D were tied to the price manufacturers charged private buyers, *see* 42 U.S.C. §§ 1395w-3a(b), 1395w-101 *et seq.*, manufacturers of drugs with no generic competition could "effectively set[] [their] own Medicare payment rate[s]" by dictating sales prices in the broader market. Medicare Payment Advisory Comm'n, *Report to the Congress: Medicare and the Health Care Delivery System* 84 (June 2022), https://perma.cc/5X4R-KCHC. Drug companies' substantial leeway in this respect was compounded by the significant legal and practical obstacles to market entry faced by generic competitors, along with the practice of many manufacturers of protecting their market share by entering into "settlements" with generic manufacturers to limit generic marketing. *See, e.g.*, Sarah M.E. Gabriele & William B. Feldman,

The Problem of Limited-Supply Agreements for Medicare Price Negotiation, 330 JAMA 1223 (2023). As a result of these factors, there are in many instances "no market forces to apply downward pressure to provide lowered prices to the millions who have coverage for such medicines under Medicare." H.R. Rep. No. 116-324, pt. 2, at 37-38.

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

II. The Drug Price Negotiation Program

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

By statute, only certain drugs are eligible for selection in the Negotiation Program: those that account for the highest Medicare expenditures, that have no generic or biosimilar competitors, and that have been on the market for at least seven years (or 11 for biological products). *See* 42 U.S.C. § 1320f-1(d), (e). For the first negotiation cycle, CMS selected 10 of these drugs with the highest Medicare expenditures for negotiations. *Id.* § 1320f-1(a). Additional drugs have and will be selected for future negotiation cycles. A selected drug is generally subject to the negotiated prices until "the first year that begins at least 9 months after the date on which the Secretary determines at least one" generic competitor "is approved or licensed" by the Food and Drug Administration (FDA) and "is marketed pursuant to such approval or licensure."[1] *Id.* § 1320f-1(c)(1).

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

In enacting the Negotiation Program, Congress revised the terms of the government's offer to continue purchasing drugs for Medicare and Medicaid. A drug manufacturer that does not wish to participate in the Negotiation Program has several options. Because participation in the Medicare program is a voluntary undertaking, the manufacturer can withdraw from Medicare and Medicaid and thus not be subject to any of the Negotiation Program's requirements. 26 U.S.C. § 5000D(c)(1); *see also Medicare Drug Price Negotiation Program: Final Guidance,*

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

Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027, at 189–90 (Oct. 2, 2024), https://perma.cc/4XGP-ZEEV ("2027 Guidance" or "the Guidance"). Alternatively, a manufacturer can transfer its ownership of the selected drug to another entity and continue to sell other drugs to Medicare and Medicaid. *See* 2027 Guidance 236. A manufacturer that pursues neither of these options may also continue to sell the selected drug to Medicare beneficiaries at non-negotiated prices subject to an excise tax. *See* 26 U.S.C. § 5000D(a)-(h); *see also Excise Tax on Designated Drugs*, 90 Fed. Reg. 31 (Jan. 2, 2025); Internal Revenue Serv., Notice No. 2023-52 (Aug. 4, 2023), https://perma.cc/B9JZ-ZG7P (IRS Notice).

III. Implementing the Negotiation Program

a. In addition to the statutory requirements set out above, Congress instructed CMS to implement the Negotiation Program through "program instruction or other forms of program guidance" for the first three negotiation cycles.[2] Act § 11001(c), 136 Stat. at 1854 (42 U.S.C § 1320f note). In June 2023, CMS published guidance that explains, among many other things, how CMS determines which drugs may be selected for negotiation and the procedures for participating in the negotiation process. *See* CMS, *Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028*, at 91-92 (June 30, 2023), https://perma.cc/K6QB-C3MM (2026 Guidance). On October 2, 2024, after voluntarily soliciting comments, CMS published guidance for initial price applicability year 2027. CMS, *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027*, at 120-21 (Oct. 2, 2024), https://perma.cc/4XGP-ZEEV ("2027 Guidance" or "the

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

Guidance"). The 2027 Guidance is materially indistinguishable from the 2026 Guidance with respect to all the issues AstraZeneca raises in this suit.

As relevant here, the Guidance explains how CMS determines what constitutes a "qualifying single source drug" that may be selected for negotiation. 42 U.S.C. § 1320f-1(e). The Act specifically "directs CMS to establish 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.'" 2026 Guidance 99 (quoting 42 U.S.C. § 1320f-5(a)(2)); *accord* 2027 Guidance 167. The Guidance explains that CMS will consider a qualifying single source drug to include "all dosage forms and strengths of the drug with the same active moiety and the same holder of a New Drug Application (NDA), inclusive of products that are marketed pursuant to different NDAs."[3] 2027 Guidance 167 (footnote omitted); *accord* 2026 Guidance 99. This means that if one manufacturer holds NDAs for several forms of a drug with the same active moiety, these various forms will be considered collectively under the provisions of the Act that require aggregation across dosage forms, package types, and formulations. 2026 Guidance 99-100 (citing 42 U.S.C. § 1320f-1(d)(3)(B)); *accord* 2027 Guidance 167-68.

CMS acknowledged that some commenters had suggested that a qualifying single source drug should instead be defined by reference to each distinct NDA. 2026 Guidance 11; 2027 Guidance 12. But CMS explained that such a definition would be inconsistent with the Act's aggregation requirements. 2026 Guidance 11; 2027 Guidance 12-13. "The aggregation rules under [the Act] are clear, and are designed to ensure that the Negotiation Program delivers benefits to the Medicare program and its beneficiaries as intended by the law." 2026 Guidance 11; *accord* 2027 Guidance 13. CMS also noted that its definition "will decrease incentives for pharmaceutical manufacturers to engage in 'product hopping'"—that is, making "modest or minor modifications"

[3] A similar definition applies to biologicals: CMS aggregates "all dosage forms and strengths of the biological product with the same active ingredient and the same holder of a Biologics License Application [BLA] . . . inclusive of products that are marketed pursuant to different [BLAs]." 2026 Guidance 99 (footnote omitted); *accord* 2027 Guidance 168.

to a drug to avoid regulations or the expiration of patent exclusivity. 2026 Guidance 11; *accord* 2027 Guidance 13.

b. In January 2025, CMS selected drugs for the second negotiation cycle. *See* CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2027* (Jan. 2025), https://perma.cc/BQG7-GC3W. The 15 drugs selected "accounted for about $41 billion in total gross covered prescription drug costs under Medicare Part D" between November 2023 and October 2024 and were used that year by "about 5.3 million people with Medicare Part D coverage." Press Release, CMS, *HHS Announces 15 Additional Drugs Selected for Medicare Drug Price Negotiations in Continued Effort to Lower Prescription Drug Costs for Seniors* (Jan. 17, 2025), https://perma.cc/TQ5V-PABY. That included Calquence, *see id.*, which is a drug manufactured by AstraZeneca UK LTD under two NDAs, *see* Compl. ¶ 79, ECF No. 1 (NDA 210259 for "acalabrutinib free base"), *id.* ¶ 86 (NDA 216387 for "acalabrutinib maleate salt").

In accordance with the schedule set by Congress, CMS presented the manufacturers of selected drugs with initial offers by June 1, 2025. *See* CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2027* (Nov. 2025), https://perma.cc/ZU7B-5PJ7. The manufacturers responded to the initial offers with counteroffers by July 1, 2025. *Id.* CMS held three negotiation meetings with each manufacturer to discuss the offers and relevant evidence. *Id.* CMS reached price agreements for eight of the selected drugs in connection with these meetings. *Id.* CMS sent final written offers to manufacturers of the seven remaining drugs by October 15, 2025. *Id.* By November 1, 2025, CMS and the participating manufacturers had agreed to a negotiated price for each of the 15 selected drugs. *Id.* Assuming that none of the manufacturers withdraw from the Negotiation Program by December 2026, these prices will take effect on January 1, 2027. 42 U.S.C. §§ 1320f(b), (d), 1320f-2(a), 1320f-3(b).

When the negotiated prices go into effect, they are projected to save Medicare beneficiaries $685 million in out-of-pocket costs and the federal fisc about $8.5 billion. *See* CMS, *Negotiated Prices for Initial Price Applicability Year 2027*, *supra.*

IV. Litigation Background

For almost three years now, manufacturers of selected drugs have challenged the constitutionality of the Negotiation Program (or the legality of CMS's implementing guidance) in over a dozen cases around the country.[4] To date, every court to address these claims has rejected them—some on threshold grounds, some on the merits.[5] That includes a prior lawsuit from AstraZeneca, which raised the same statutory-interpretation claim that is at issue here, as well as another statutory-interpretation claim (not included here), and a facial challenge to the statute under the Due Process Clause. In that first *AstraZeneca* case, the U.S. District Court for the District of Delaware dismissed AstraZeneca's statutory claims for lack of Article III standing, and rejected its due process claim on the merits. *See AstraZeneca Pharms. LP v. Becerra*, 719 F. Supp. 3d 377 (D. Del. 2024). The Third Circuit unanimously affirmed. *AstraZeneca Pharms. LP v. Becerra*, 137 F.4th 116 (3d Cir. 2025). AstraZeneca has now filed a petition for a writ of certiorari with the Supreme Court of the United States, though its petition presents only the due process

[4] *See Merck & Co. v. Kennedy*, No. 1:23-cv-1615 (D.D.C. filed June 6, 2023); *Dayton Area Chamber of Com. v. Becerra*, No. 3:23-cv-156 (S.D. Ohio filed June 9, 2023); *Bristol Myers Squibb Co. v. Becerra*, No. 3:23-cv-3335 (D.N.J. filed June 16, 2023); *Nat'l Infusion Ctr. Ass'n v. Becerra*, No. 1:23-cv-707 (W.D. Tex. Filed June 21, 2023); *Boehringer Ingelheim Pharm., Inc. v. HHS*, No. 3:23-cv-1103, 2024 WL 3292657 (D. Conn. filed July 3, 2024); *Janssen Pharms., Inc. v. Becerra*, No. 3:23-cv-3818 (D.N.J. filed July 18, 2023); *AstraZeneca Pharms. LP v. Becerra*, No. 1:23-cv-931 (D. Del. filed Aug. 25, 2023); *Novartis Pharms. Corp. v. Becerra*, No. 3:23-cv-14221 (D.N.J. filed Sept. 1, 2023); *Novo Nordisk Inc. v. Becerra*, No. 3:23-cv-20814 (D.N.J. filed Sept. 29, 2023); *Teva Pharms. USA, Inc. v. Kennedy*, No. 1:25-cv-113 (D.D.C. filed Jan. 15, 2025); *AbbVie Inc. v. HHS*, No. 1:26-cv-431 (D.D.C. filed Feb. 11, 2026).

[5] *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. pending*, No. 25-799 (filed Jan. 5, 2025); *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. pending*, No. 25-751 (filed Dec. 19, 2025); *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. pending*, No. 25-761 (filed Dec. 22, 2025); *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. pending*, No. 25-902 (filed Jan. 23, 2026); *Nat'l Infusion Ctr. Ass'n v. Kennedy*, 798 F. Supp. 3d 748 (W.D. Tex. 2025), *appeal pending*, No. 25-50661 (5th Cir. docketed Aug. 15, 2025); *Teva Pharm., USA, Inc. v. Kennedy*, No. 25-113, 2025 WL 3240267 (D.D.C. Nov. 20, 2025), *appeal pending*, No. 25-5425 (D.C. Cir. docketed Nov. 30, 2025).

issue. *See* Pet. for a Writ of Cert., *AstraZeneca Pharms. LP v. Kennedy*, No. 25-348 (filed Sep. 19, 2025). As of this filing, AstraZeneca's petition remains pending.

In this case, Plaintiffs—AstraZeneca Pharmaceuticals LP, AstraZeneca AB, and AstraZeneca UK LTD (collectively "AstraZeneca")—filed suit on December 19, 2025. AstraZeneca brings one (and only one) claim: a statutory-interpretation claim under the Administrative Procedure Act (APA), challenging CMS's Guidance. AstraZeneca contests CMS's implementation of the statutory term "qualifying single source drug" by aggregating products that share the same active moiety across multiple NDAs.

In particular, AstraZeneca alleges that CMS improperly treated AstraZeneca's Calquence products—acalabrutinib (free base, 100 mg capsule) and acalabrutinib (maleate salt, 100 mg tablet)—as a single "qualifying single source drug." *See* Compl. ¶ 116. Both forms of Calquence treat certain forms of lymphoma and leukemia; the acalabrutinib maleate salt tablet—approved by FDA five years after the acalabrutinib free base capsule—was allegedly developed to allow for easier co-administration alongside gastric-acid reducing agents (*e.g.*, Pepcid). *Id.* ¶¶ 75-83. Both versions are marketed by AstraZeneca under the same trade name: Calquence. *Id.* ¶ 116; *see also id.* ¶ 76 (citing AstraZeneca, *How Does Calquence Work?*, https://perma.cc/U42V-H5SM). And both contain 100 milligrams of acalabrutinib per pill: the first version (NDA 210259) in a capsule, and the second (NDA 216387) in a tablet. *See* FDA, *Drugs@FDA* (search for "Calquence"), https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm (last visited Mar. 27, 2026).

From November 2023 to October 2024, Calquence accounted for approximately $1,614,250,000.00 in Medicare Part D spending, for roughly 15,000 Medicare patients—just over $107,000 per patient, per year. *See* CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2027* (Jan. 2025), https://perma.cc/964W-MPDV.

ARGUMENT

Congress expressly precluded review over AstraZeneca's statutory challenge to CMS's selection of drugs. The Act provides that there "shall be no administrative or judicial review" of CMS's "selection of drugs" or its predicate "determination of qualifying single source drugs." 42

U.S.C. § 1320f-7(2). These provisions squarely preclude judicial review of the claim that CMS erred in determining that both forms of Calquence should be selected for negotiation. *See Novo Nordisk v. HHS*, 154 F.4th 105, 111-13 (3d Cir. 2025), *cert. pending*, 25-761 (U.S. Dec. 29, 2025).

CMS's selection of Calquence was in any event correct on the merits, as the Act requires CMS to use "data that is aggregated 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 size or package type of the drug." 42 U.S.C. § 1320f-1(d)(3)(B); *see id.* §§ 1320f-3(e)(1)(D), 1320f-5(a)(2). That directive is consistent with the program goal of identifying and targeting the drugs that have the most significant financial impact on Medicare as a whole, regardless of variations in formulation or packaging or strength. CMS appropriately followed this instruction in selecting both forms of Calquence for negotiation. AstraZeneca's contrary interpretation is untethered from the text of the statute, and would allow the very sort of trivial gamesmanship that Congress prohibited. In short, at least for purposes of the IRA's drug-selection provisions, Calquence and Calquence are the same drug.

I. CONGRESS EXPRESSLY PRECLUDED JUDICIAL REVIEW.

a. This Court lacks statutory subject-matter jurisdiction over this suit because Congress expressly provided that there "shall be no administrative or judicial review" of CMS's "selection of drugs," its "determination of negotiation-eligible drugs," or its "determination of qualifying single source drugs." 42 U.S.C. § 1320f-7(2). Those prohibitions straightforwardly encompass AstraZeneca's only claim here, which challenges the agency's determination of what constitutes a "qualifying single source drug" and the resulting determination as to which drugs are eligible and may be selected.

It is well established that "Congress may determine a lower federal court's subject-matter jurisdiction." *Kontrick v. Ryan*, 540 U.S. 443, 452 (2004). While there is a "strong presumption that Congress intends judicial review of administrative action," *Bowen v. Mich. Acad. of Fam. Physicians*, 476 U.S. 667, 670 (1986), when Congress "provides that 'there shall be no

administrative or judicial review' of specified agency actions, its intent to bar review is clear." *DCH Reg'l Med. Ctr. v. Azar*, 925 F.3d 503, 505-06 (D.C. Cir. 2019) (quoting 42 U.S.C. § 1395nn(i)(3)(I)); *see* 5 U.S.C. § 701(a)(1) (confirming that APA review is unavailable where "statutes preclude judicial review"). The only question in those circumstances is "whether the challenged action falls 'within the preclusive scope' of the statute." *DCH Reg'l*, 925 F.3d at 506 (quoting *Knapp Med. Ctr. v. Hargan*, 875 F.3d 1125, 1128 (D.C. Cir. 2017)); *see also, e.g.*, *Shaiban v. Jaddou*, 97 F.4th 263, 268 (4th Cir. 2024) (even if "there are valid public policy arguments to maintain judicial review," those "policy concerns cannot trump the best interpretation of the statutory text" of a preclusion provision (quoting *Patel v. Garland*, 596 U.S. 328, 346 (2022)), *cert. denied*, 145 S. Ct. 1046 (2025); *Lee v. USCIS*, 592 F.3d 612, 619-20 (4th Cir. 2010) (after acknowledging the "basic presumption of judicial review," explaining that "the first issue we must address" is the text of the preclusion provision).

Here, that is a straightforward inquiry. AstraZeneca openly and directly challenges CMS's determination of what constitutes a "qualifying single source drug" under § 1320f-1(e). Specifically, it asserts that CMS misinterpreted the definition of "qualifying single source drug" by aggregating products with the same active moiety, even if approved in different NDAs. AstraZeneca's only claim disparages CMS guidance as (in Plaintiffs' words) a "redefinition" of the term "qualifying single source drug" that "exceeds the agency's statutory authority." Compl. ¶ 125. Plaintiffs are wrong about all of this on the merits—but right or wrong, the claim directly challenges CMS's "determination of qualifying single source drugs," its "determination of negotiation-eligible drugs," and its eventual "selection of drugs" for negotiation. 42 U.S.C. § 1320f-7(2). Congress expressly precluded judicial review of all of these determinations. *See id.*

Last year, the Third Circuit held that a nearly identical challenge was precluded under the Act's judicial review bar. *See Novo Nordisk Inc. v. HHS*, 154 F.4th 105, 111-13 (3d Cir. 2025). In that case, another drug manufacturer challenged "CMS's decision to group products into a single potentially qualifying drug"—there, the manufacturer's various insulin products. *Id.* at 111; *see id.* (explaining that the manufacturer sold six insulin aspart products). The Third Circuit held that

it lacked jurisdiction to consider the manufacturer's challenge to CMS's "definition of qualifying single-source drug" because the Act precluded judicial review of "determination of negotiation-eligible drugs" and thus of the process CMS used to make that determination. *Id.* at 111-12 (quoting 42 U.S.C. § 1320f-7(2)). So too here.

b. AstraZeneca cannot avoid Congress's express preclusion of judicial review by framing its attack as a facial challenge to a rule rather than as an as-applied challenge to an individual drug selection. *See* Pls.' Mem. in Supp. of Mot. for Summ. J. ("Pls.' Br.") at 27-30, ECF No. 21-1. The plain text of the Act confirms that "[t]here shall be no administrative or judicial review" of CMS's drug selection determinations. 42 U.S.C. § 1320f-7. The preclusive scope of that provision is broad insofar as it covers all aspects of CMS's "selection of drugs" for negotiation—including the necessary steps that precede selection, such as the agency's "determination of qualifying single source drugs" and its "determination of negotiation-eligible drugs." *Id.* § 1320f-7(2). Congress thus made clear its intent to preclude review not just of individual drug-selection decisions but also of the related administrative steps leading to the selection. *See Novo*, 154 F.4th at 112.

As courts have repeatedly explained in construing the Medicare statute's many other review bars, when Congress precludes judicial review of a decision, it also precludes review of any preceding issues that are "inextricably intertwined" with the final decision. *DCH Reg'l*, 925 F.3d at 507 (first citing *Fla. Health Scis. Ctr., Inc. v. HHS*, 830 F.3d 515, 521 (D.C. Cir. 2016); then citing *Tex. All. for Home Care Servs. v. Sebelius*, 681 F.3d 402, 411 (D.C. Cir. 2012); and then citing *Mercy Hosp., Inc. v. Azar*, 891 F.3d 1062, 1066-67 (D.C. Cir. 2018)). For example, a statute precluding administrative and judicial review of "the awarding of contracts," 42 U.S.C. § 1395w-3(b)(12)(B), is not limited to "the awarding of a single contract but" rather applies "to 'the awarding of contracts' generally." *Tex. All.*, 681 F.3d at 410. Thus, because the process of awarding contracts "requires the formulation and application of financial standards," the statute's bar on review extends to an agency rule adopting such standards. *Id.*; *see also, e.g.*, *U.S. Anesthesia Partners of Texas, P.A. v. HHS*, 126 F.4th 1057, 1062-64 (5th Cir. 2025) (statute barring judicial review of HHS's "identification of measures and activities" also bars challenges

to how agency determines and implements measures); *Skagit Cnty. Pub. Hosp. Dist. No. 2 v. Shalala*, 80 F.3d 379, 386 (9th Cir. 1996) ("if a procedure is challenged only in order to reverse the individual reclassification decision, judicial review is not permitted").

In another context, the D.C. Circuit similarly held that a statutory bar on administrative or judicial review of "[a]ny estimate of the Secretary for purposes of determining [specified] factors" precluded review of a challenge to "'the methodology adopted and employed' by HHS to calculate" one of those factors. *DCH Reg'l*, 925 F.3d at 505 (first alteration in original) (quoting 42 U.S.C. § 1395ww(r)(3)(A)). The court explained that a "distinction between methodology and estimates would eviscerate the statutory bar" against review because "almost any challenge to an estimate could be recast as a challenge to its underlying methodology." *Id.* at 506. Because the "method" used by the agency and challenged by the plaintiff was "inextricably intertwined" with the "estimate," the D.C. Circuit held that the statute "precludes review of both." *Id.* at 507; *see Fla. Health*, 830 F.3d at 519.

The same logic applies here. Congress precluded review of CMS's "determination of qualifying single source drugs." 42 U.S.C. § 1320f-7(2). The means by which CMS determines the list of qualifying single source drugs is by applying the statutory definition. CMS has no discretion over which drugs it determines are qualifying. *See id.* § 1320f-1(e). Determining the drugs, in effect, means generating the list of drugs that meet the definition. And whether different forms of a drug are aggregated together is a key element of how the list takes shape.

In any event, to the extent AstraZeneca had tried to bring a facial challenge to the Guidance in the abstract—without seeking concrete relief tied to any real-world drug-selection decision—it would have lacked Article III standing to do so. Nobody knows that better than AstraZeneca: that is exactly what the District of Delaware and the Third Circuit both already held in *AstraZeneca I*. There, as here, "AstraZeneca challenge[d] how the Guidance defines a qualifying single source drug," arguing that "Guidance provisions conflict with or exceed the terms of the [Act] and must be set aside." *AstraZeneca I*, 137 F.4th at 122-23. But the complaint in that case did not offer anything concrete "about how the company has been (or imminently will be) injured" by the

definition of a qualifying single source drug, so (at that time, based on that complaint) "AstraZeneca lack[ed] Article III standing to challenge the Guidance." *Id.* at 124-25. Defendants have not raised the same standing argument here, because CMS's interpretation of the Act's aggregation requirements *was* relevant to the selection of Calquence. But in the absence of a concrete application of these policies in the selection of an AstraZeneca drug, this lawsuit could not proceed. That is another reason why labeling this a "facial challenge" cannot get AstraZeneca out from under the statute's preclusion provision—ultimately, this lawsuit is (and only ever could be) a challenge to CMS's "selection of drugs," 42 U.S.C. § 1320f-7(2), including the selection of Calquence specifically.

c. In seeking to evade the Act's preclusion provision, AstraZeneca relies heavily on a recent district court decision that reached the merits of a similar challenge brought by another drug manufacturer (albeit ultimately ruling in favor of the government, on the merits). *See* Pls.' Br. at 27, 29-30 (citing *Teva*, 2025 WL 3240267). But in exercising jurisdiction, the district court in *Teva*—in an opinion that is currently on appeal—misunderstood a line of cases permitting some collateral attacks on general rules even when challenges to individual determinations are barred. *See* 2025 WL 3240267, at *7-9. Plaintiffs rely on those very same cases here. *See* Pls.' Br. at 27-30. This Court should not make the same mistake.

In *McNary v. Haitian Refugee Center, Inc.*, the Supreme Court permitted a due process challenge to reach the merits despite a statutory bar on judicial review. 498 U.S. 479 (1991). But 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) (citing *McNary*, 498 U.S. at 491). *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. *Contra Teva*, 2025 WL 3240267, at *7-9. When a 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." *Id.* at 945 (internal citation omitted). In other words, where deciding the challenge to the general rule would decide the merits of the individual adjudication, judicial review is still barred. *See id.*; *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. *See, e.g.*, *Am. Soc'y of Cataract & Refractive Surgery v. Thompson*, 279 F.3d 447, 453-54 (7th Cir. 2002) (distinguishing *McNary* to apply another judicial-review bar in the Medicare statute); *Fischer v. Berwick*, 503 F. App'x 210, 213 (4th Cir. 2013) (applying *Thompson*); *see also Yale New Haven Hosp. v. Becerra*, 56 F.4th 9, 20 (2d Cir. 2022) (holding that a procedural challenge that would undo a substantive determination is not collateral to that determination for purposes of Medicare preclusion).

Here, the Act's judicial review provision does not apply to individual adjudications only. Instead, as relevant here, it covers "[t]he selection of drugs under section 1320f-1(b)," "the determination of negotiation-eligible drugs under section 1320f-1(d)," and "the determination of qualifying single source drugs under section 1320f-1(e)." 42 U.S.C. § 1320f-7(2). Each of the statutory cross-references in that provision refers to a process. When CMS determines whether drugs are qualifying single source drugs, § 1320f-1(e) calls for it to determine whether the drug is described by a set of criteria and then to exclude certain drugs from the list. *Id.* § 1320f-1(e)(1), (3). The selection of drugs, therefore, is not some sort of individualized adjudication like adjusting one person's immigration status. It is a generalized process based on the meaning of the term

"qualifying single source drug." The judicial review bar thus extends to CMS's determination of whether to aggregate various forms of a drug.

Nor is this suit collateral to the merits of determining whether a drug is a qualifying single source drug. AstraZeneca challenges the framework under which CMS identifies the universe of drugs that could be potentially selected. That challenge is inseparable from the merits of any individual selection decision. Because its "challenge is no more than an attempt to undo an individual decision," it cannot fit within the *McNary* collateral attack exception. *DCH Reg'l*, 925 F.3d at 508 (cleaned up); *see also John Balko & Assocs., Inc. v. Sec'y of HHS*, 555 F. App'x 188, 193 (3d Cir. 2014) (in interpreting another preclusion provision in the Medicare statute, rejecting an attempt to distinguish between "the procedures used in arriving at [a] determination" and "the merits of the determination itself").

Were there any doubt, the text of the review bar itself confirms this reading, by expressly precluding review of the agency's key "determination[s]." 42 U.S.C. § 1320f-7(2). As the Third Circuit explained in the context of a different review bar, "[t]he word 'determine' means 'to fix conclusively or authoritatively' as well as 'to come to a decision concerning as the result of investigation or reasoning.'" *Bakran v. DHS*, 894 F.3d 557, 563 (3d Cir. 2018) (quoting Webster's Third New International Dictionary 616 (1993)). Thus, 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] reache[d] this decision." *Id.* That § 1320f-7(2)'s reference to "drugs" is plural is also instructive. For example, the D.C. Circuit has held that a Medicare provision precluding review of "the awarding of contracts" is not limited to "the awarding of a single contract but" rather applies "to the 'awarding of contracts' generally" and thus also

encompasses the underlying process. *Tex. All.*, 681 F.3d at 409-10 (discussing 42 U.S.C. § 1395w-3(b)(12)). The same logic applies here.[6]

d. In one page at the end of its brief, AstraZeneca also tries to avoid application of the Act's preclusion provision by invoking principles of nonstatutory ultra vires review. Pls.' Br. at 30. But "[t]he implied nonstatutory exception for claims alleging that a federal actor has violated a federal statute—often called ultra vires claims—is 'necessarily narrow.'" *Sustainability Inst. v. Trump*, 165 F.4th 817, 830 (4th Cir. 2026) (quoting *Ancient Coin Collectors Guild v. U.S. Customs & Border Prot.*, 698 F.3d 171, 179 (4th Cir. 2012)). So, "[a]s the Supreme Court recently explained, 'because ultra vires review could become an easy end-run around' limitations imposed by statutes, the Court's 'cases have strictly limited nonstatutory ultra vires review.'" *Sustainability Institute*, 165 F.4th at 830 (quoting *Nuclear Regul. Comm'n v. Texas*, 605 U.S. 665, 681 (2025)). Ultra vires review "is not available 'simply because an agency has arguably reached a conclusion which does not comport with the law.'" *Id.* (quoting *Texas*, 605 U.S. at 681). "Rather, ultra vires review 'applies only when an agency has taken action entirely in excess of its delegated powers and contrary to a *specific prohibition* in a statute." *Id.*; *see also, e.g.*, *Long Term Care Partners, LLC v. United States*, 516 F.3d 225, 234 (4th Cir. 2008) (explaining that ultra vires review is "appropriate only where there is a strong and clear demonstration that a clear, specific and mandatory statutory provision has been violated") (cleaned up). "Given all that," an ultra vires claim "is essentially a Hail Mary pass—and in court as in football, the attempt rarely succeeds." *Texas*, 605 U.S. at 681-82.

[6] On the issue of preclusion, the only Fourth Circuit authority that Plaintiffs cite (*see* Pls.' Br. at 29) is *University of Maryland v. Cleland*, 621 F.2d 98 (4th Cir. 1980). But that opinion was applying a materially different preclusion provision that had already been interpreted in two prior opinions of the Supreme Court. *See Cleland*, 621 F.2d at 100. The opinion itself contains almost no reasoning on this issue, other than a reference to a 1978 opinion of the Sixth Circuit, and (heavily dated) reliance on legislative history that is specific to the statute at issue in that case. *See id.* at 100-01. It also makes several references to potential constitutional constraints on the preclusion review of constitutional claims, *see id.*—an issue that does not arise in this case, due to the absence of any constitutional claims. *Cleland* thus has minimal relevance here.

Here, AstraZeneca "basically dress[es] up a typical statutory-authority argument as an ultra vires claim." *Id.* at 682. "That is a fairly common maneuver," which "is in large part why those claims rarely succeed." *Id.* And especially where, as here, the only court to reach the merits of AstraZeneca's statutory-interpretation theory has squarely rejected it, *see Teva*, 2025 WL 3240267, at *10-12, AstraZeneca cannot come close to the requisite "strong and clear demonstration that a clear, specific and mandatory statutory provision has been violated." *Long Term Care Partners*, 516 F.3d at 234; *see generally infra*, Section II. Nor is ultra vires review available where, as here, the statute expressly "forecloses all other forms of judicial review"; in those circumstances, it also forecloses ultra vires review. *Texas*, 605 U.S. at 681.

II. ASTRAZENECA'S ONLY CLAIM LACKS MERIT.

If the Court reaches the merits, AstraZeneca's interpretation of the statute is incorrect, because the Act requires CMS to aggregate different forms of the same drug. And so, CMS's Guidance explains that, in identifying a "qualifying single source drug," CMS will consider "all dosage forms and strengths of the drug with the same active moiety," even if those different forms have been approved under different NDAs.[7] 2027 Guidance 167. AstraZeneca contests this definition, arguing instead that the Act requires a "product-specific" or NDA-specific interpretation of "qualifying single source drug." Compl. ¶¶ 13, 34; Pls.' Br. at 22-23. But as CMS has explained, the Guidance's conclusion that a "qualifying single source drug" encompasses different forms of a drug flows directly from the text, structure, and purpose of the Act. In this case, the end result is an intuitive one: that "Calquence" and "Calquence" count as one drug for purposes of the Negotiation Program's drug-selection provisions, not two.

a. The Act targets for negotiation those drugs that impose the highest costs on Medicare, regardless of variations like differences in formulation or packaging. To achieve this goal, the Act

[7] *See Otsuka Pharm. Co. v. Price*, 869 F.3d 987, 991 (D.C. Cir. 2017) (explaining that "FDA's approach to determining a drug's active moiety . . . starts with the molecule that comprises that active ingredient in the drug product, and excludes the ester and salt-bonded portions of the molecule. . . . The remaining molecule or ion is the drug's active moiety."); *see also* 21 C.F.R. § 314.3(b) (defining the terms "active ingredient" and "active moiety").

requires CMS to 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). This requirement applies at each stage of the process—from the identification and selection of negotiation-eligible drugs to the negotiations themselves and finally (if negotiations succeed) to the application of a negotiated price.

Congress expressly directed CMS to identify "negotiation-eligible drugs" according to Medicare spending data, to rank these drugs according to this data, and then select the top drugs on the list for negotiation. When calculating Medicare expenditures for a drug at each of these steps, CMS must aggregate the spending data "across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation, and not based on the specific formulation or . . . package type of the drug." 42 U.S.C. § 1320f-1(d)(3)(B). By requiring CMS to consider the total expenditures for a drug across its variations, Congress ensured that CMS would identify and select 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, explicitly contemplates that one "drug" may be offered in a number of forms that may correspond to different applications or approvals. Then, after negotiations are completed and a price is agreed upon, 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 and repeatedly that there may be multiple forms of one selected drug—with multiple approvals—and it directs CMS to apply the negotiated price to each one.

Following this statutory framework, CMS explained in the Guidance that it will consider a qualifying single source drug to include "all dosage forms and strengths of the drug with the same active moiety and the same holder of a[n] [NDA], inclusive of products that are marketed pursuant

to different NDAs." 2027 Guidance 167 (footnote omitted).[8] Applying that interpretation, CMS determined that Calquence accounts for some of the highest Medicare expenditures, and CMS thus properly selected it for negotiation. Both forms of Calquence have the same active moiety (acalabrutinib) and strength (100 mg), with the primary differences being (1) approval via two separate NDAs, (2) the second NDA approving a maleate salt tablet version (rather than free base, in a capsule). *See supra* at 11. Given the IRA's instruction that CMS "shall use data that is aggregated 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), CMS did not err in selecting Calquence for negotiation.

b. AstraZeneca sidesteps the IRA's repeated commands for CMS to aggregate all forms of a drug, insisting instead that the key question is whether *FDA* has approved the products in separate NDAs for various formulations of the same drug for purposes of the Food, Drug, and Cosmetic Act. *See* Compl. ¶¶ 7-10; Pls.' Br. at 15-17. But the IRA and the Food, Drug, and Cosmetic Act are different statutes with fundamentally different objectives and functions. AstraZeneca's reliance on FDA's product-specific approval framework to argue for a product-specific approach by CMS misunderstands the statutory design and cannot be reconciled with the text of the Act.

FDA approves drugs on a more granular product-by-product basis to ensure the safety, efficacy, and quality of each specific formulation, package type, and manufacturing process (among other things). *See* 21 U.S.C. § 355(a) (approval requirement for "new drugs"); 21 C.F.R. § 314.3(b) (defining "drug product" as "a finished dosage form, *e.g.*, tablet, capsule, or solution, that contains a drug substance"). Ignoring distinctions between dosage forms, strengths, and formulations would be inappropriate in the context of FDA approvals, as it would prevent FDA from evaluating the safety and efficacy of these various aspects of each finished product—no matter how minor the variation. But in the context of the Negotiation Program, considering those

[8] For biological products, a qualifying single source drug includes "all dosage forms and strengths of the biological product with the same active ingredient and the same holder of a [BLA]." 2027 Guidance 168. Calquence is a drug, not a biological product.

forms of a drug together permits CMS to identify the drugs with the greatest financial impact on Medicare overall, consistent with the purpose of the program. That manufacturers often control whether a drug has one NDA or multiple NDAs based on how it chooses to submit its application(s) to FDA only underscores that AstraZeneca's approach conflicts with Congress's design. *See Mallinckrodt ARD LLC v. Verma*, 444 F. Supp. 3d 150, 173 (D.D.C. 2020) (recognizing the risk of drug manufacturers circumventing their statutory obligations "by simply manipulating how a submitted drug application was administratively categorized").

In any event, any debate about aggregation across products for the purposes of negotiations is resolved by the Act's repeated instruction to aggregate "across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation, and not based on the specific formulation or . . . package type of the drug." 42 U.S.C. § 1320f-1(d)(3)(B); *see id.* § 1320f-5(a)(2). AstraZeneca nonetheless attempts to infer a contrary command from other provisions that reference the FDA approval process. For example, AstraZeneca urges that its view is compelled by the statute's requirement that a drug is not eligible for negotiation unless at least seven years have elapsed since approval. *See* Pls.' Br. at 21. In AstraZeneca's view, each new product approval triggers a new clock—even when the new product is just a different package type or dosage form of the same drug. But that position is irreconcilable with the Act's command to aggregate "across . . . *new* formulations of the drug" for this purpose. 42 U.S.C. § 1320f-1(d)(3)(B) (emphasis added). CMS reasonably determined that the relevant date is the earliest approval date of a product in the set, 2027 Guidance 170, ensuring that the introduction of minor, serial variations of the drug does not alter its eligibility. The alternate interpretation urged by AstraZeneca, by contrast, would force CMS to exclude newer formulations of the same high-expenditure drugs despite the statutory command to "includ[e]" them, 42 U.S.C. § 1320f-1(d)(3)(B).

Similarly, AstraZeneca resorts to a series of attenuated cross-references that ends with a reference to FDA approval. AstraZeneca observes that the Act's definition of "qualifying single source drug" makes "reference to the Medicare statute," which AstraZeneca claims, in turn, defines a drug based on whether the product is approved pursuant to a distinct NDA. Pls.' Br. at

15 n.9 (first citing 42 U.S.C. § 1395w-102(e); and then citing *id.* § 1396r-8(k)(2)(A)(i)). But AstraZeneca overreads the significance of the cross-referenced provision, which provides merely that a "covered outpatient drug" must be "approved for safety and effectiveness" under an appropriate application to FDA. 42 U.S.C. § 1396r-8(k)(2)(A)(i). These provisions do not mean that FDA approval creates a distinct, new "covered outpatient drug." AstraZeneca's reading of these attenuated cross-references cannot be reconciled with the Act's express statutory language directing CMS to consider all dosage forms, strengths, and formulations of a drug together. *See Teva*, 2025 WL 3240267, at *10-12.

AstraZeneca also reads great import into the Act's language excluding brand-name drugs facing generic competition from being a "qualifying single source drug." Specifically, the Act excludes drugs that are "the listed drug for any [generic] drug that is approved and marketed." 42 U.S.C. § 1320f-1(e)(1)(A)(iii). AstraZeneca suggests that the reference to "*the* listed drug" necessarily means that the Act contemplates an NDA-specific view of "qualifying single source drug." Pls.' Br. at 20 (emphasis added). But AstraZeneca fails to explain how this inference overcomes the statutory text directing aggregation. *See* 42 U.S.C. § 1320f-1(d)(3)(B); *id.* § 1320f-3(e)(1)(D); *id.* § 1320f-5(a)(2). In any event, it is easy to harmonize § 1320f-1(e)(1)(A)(iii) with § 1320f-1(d)(3)(B) and the other provisions directing aggregation. As CMS has explained: "If any strength or dosage form of a potential qualifying single source drug is the listed drug or reference product, as applicable, for one or more generic or biosimilar products that CMS determines are approved or licensed, as applicable, and marketed based on the process described in this final guidance, the potential qualifying single source drug will not be considered a qualifying single source drug." 2027 Guidance 171. That resolves AstraZeneca's concern.

Contrary to AstraZeneca's assertion, CMS's interpretation does not "make a mess" of the statute's generic carveout. Pls.' Br. at 20. Indeed, the implications of AstraZeneca's proposed approach are striking, as it insists that CMS must always treat each separately approved drug product as its own stand-alone drug, no matter how minor the variations between them. As Judge Sooknanan explained in *Teva*, adopting 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 (cleaned up).

Tellingly, AstraZeneca's marketing materials for Calquence often fail to distinguish between Calquence (NDA 210259) and Calquence (NDA 216387)—for the most part, AstraZeneca simply markets the drug as "Calquence." *See* Compl. ¶ 116; *see also id.* ¶ 76 (citing AstraZeneca, *How Does Calquence Work?*, https://perma.cc/U42V-H5SM). This Court is "not required to exhibit a naiveté from which ordinary citizens are free." *Dep't of Com. v. New York*, 588 U.S. 752, 785 (2019) (quoting *United States v. Stanchich*, 550 F.2d 1294, 1300 (2d. Cir. 1977) (Friendly, J.)). Ultimately, AstraZeneca's interpretation is fundamentally inconsistent with the statutory framework—it would render meaningless the requirement to aggregate data across "dosage forms," "strengths," and "formulations" of a drug in the selection process, and it would prevent CMS from identifying the drugs responsible for the greatest Medicare expenditures. Moreover, it would incentivize manufacturers to serially introduce slight variations to a drug that would otherwise qualify for negotiation in order to circumvent the negotiation. Congress was aware of such tactics and drafted the statute accordingly.

None of AstraZeneca's remaining arguments overcome the Act's plain text. That the Act refers to a "qualifying single source drug," in the singular, *see* Pls.' Br. at 15 & n.8, 21-22, is entirely consistent with the Act's instruction that each individual "drug" is an aggregation of all dosage forms, strengths, and formulations. *See* 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). And AstraZeneca's repeated attempts to replace "drug" with "drug product" is contrary to Congress's drafting choices. *Cf.* Compl. ¶¶ 40, 44, 51, 75, 91, 95.

AstraZeneca protests that Congress did not use the specific term "active moiety" in the Act. Pls.' Br. at 22-23. But by that logic, neither does the Act mandate that CMS follow FDA's product-specific approach in implementing the Food, Drug, and Cosmetic Act. *See* 42 U.S.C.

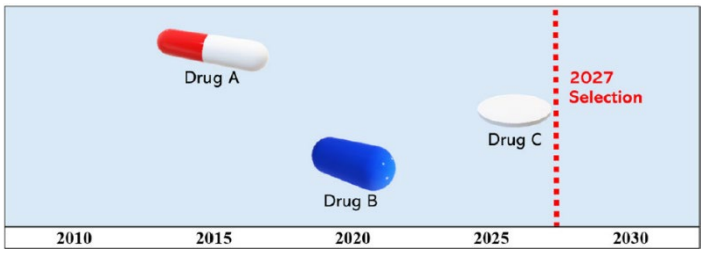
§ 1320f(a)-(c). In any event, CMS did not pluck the terms "active moiety" and "active ingredient" from thin air. The terms have a long history and prominent role in FDA's practice, where the term "active moiety" is used as a proxy for innovation in drug development. *See, e.g.*, 21 C.F.R. § 314.3 (defining both terms); Act of Apr. 23, 2021, Pub. L. No. 117-9, 135 Stat. 256 (codifying FDA's definition); *see also, e.g.*, Erin H. Ward, Cong. Rsch. Serv., R46110, *Defining Active Ingredient: The U.S. Food and Drug Administration's Legal Interpretation of Regulatory Exclusivities* (2023), https://perma.cc/627K-ZXND. Congress need not specify the precise terms "active moiety" or "active ingredient" for CMS to reference them in describing the necessary features of products that can be considered together under the statute.

AstraZeneca also objects (Pls.' Br. at 23-24) that CMS's guidance only includes NDAs held by the same entity. AstraZeneca asserts that CMS added this "same holder" requirement as a "workaround" to avoid an outcome where different manufacturers' "drugs would be treated as *one*" qualifying single source drug, which "would render the IRA's negotiation provisions incoherent." *Id.* at 23-24. But as AstraZeneca itself seems to acknowledge, the Act repeatedly presumes that CMS will engage in negotiations with a drug's manufacturer, not a consortium of competitive manufacturers. *See id.* (quoting 42 U.S.C. § 1320f–2(a)-(b)). Those provisions make clear that different dosage forms and strengths of a drug with the same active moiety are the same qualifying single source drug only when the NDA is held by the same manufacturer. *See, e.g.*, 42 U.S.C. §§ 1320f(c)(1), 1320f-2(a)(1), (a)(4)(A). So the "same holder" requirement is not a "workaround" at all, Pls.' Br. at 24—it is a faithful interpretation of the Act as a whole.

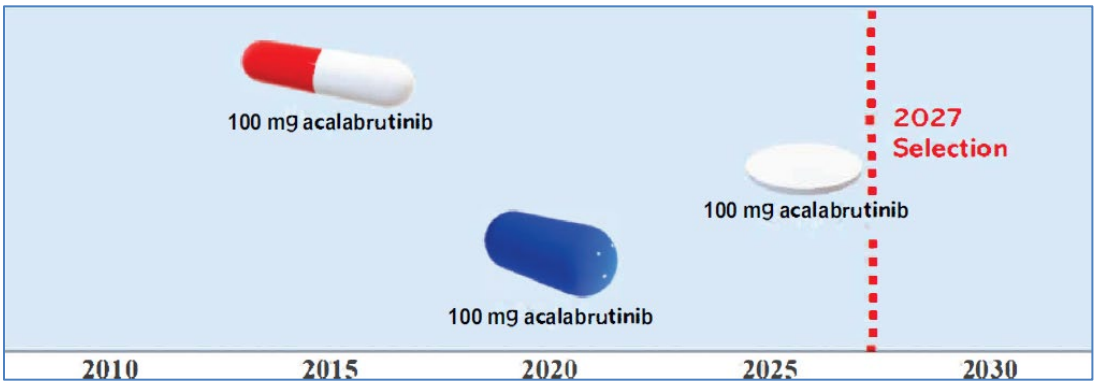
AstraZeneca's surplusage argument (made only in a footnote) also misses the mark. It suggests that interpreting "qualifying single source drug" to include "all dosage forms and strengths" of a drug would render surplusage the Act's provisions requiring aggregation of "dosage forms and strengths of the drug" in selecting negotiation-eligible drugs under 42 U.S.C. § 1320f-1(d)(3)(B) and in applying the negotiated price "across different strengths and dosage forms of a selected drug" under 42 U.S.C. § 1320f-5(a)(2). *See* Pls.' Br. at 25-26 n.10. But these provisions are not redundant; rather, each applies to a different step of the negotiation process, *see* 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). It is the combined direction from each provision from which the aggregation requirement flows. And AstraZeneca fails to explain how its approach can be reconciled with these clear directives. *See Teva*, 2025 WL 3240267, at *11 (explaining the surplusage problems created by Teva's (and now AstraZeneca's) interpretation).

Finally, AstraZeneca includes a series of hypothetical graphics in its brief, purportedly demonstrating the problems with CMS's interpretation. *See* Pls.' Br. at 18-19. But the force of those hypotheticals turns entirely on the conclusory labels chosen by AstraZeneca, which suggest that each pill on each chart represents a genuinely different drug—rather than *one* drug in a new "dosage form or strength" or "new formulation." 42 U.S.C. § 1320f-1(d)(3)(B). For example, on Page 18, AstraZeneca uses the labels Drug A, Drug B, and Drug C in the following chart:



But of course, one could draw the same chart, but this time showing the *same* drug in three different forms (one in a skinny red-and-white capsule, one in a thick blue capsule, and one in a white tablet). That version illustrates the untenable nature of AstraZeneca's position. For example, consider the following alteration, which shows one drug in three forms, approved in three NDAs:



Ultimately, if anything, AstraZeneca's charts are a powerful demonstration of how variations in form or packaging should not be permitted to defeat congressional intent in identifying the drugs that create the highest cost burden on Medicare beneficiaries and the American taxpayer. CMS's interpretation, by contrast, faithfully implements the statute's text, structure, and purpose.

CONCLUSION

For these reasons, the Court should dismiss this suit for lack of subject-matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1), and then deny Plaintiffs' motion for summary judgment as moot. In the alternative, the Court should dismiss this suit for failure to state a claim upon which relief can be granted under Federal Rule of Civil Procedure 12(b)(6), and then deny Plaintiffs' motion for summary judgment as moot. Further in the alternative, the Court should grant Defendants' motion for summary judgment and deny Plaintiffs' motion for summary judgment.

Date: March 27, 2026

Respectfully submitted,

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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.	Civil Action No. 1:25-cv-4212-MJM

[PROPOSED] ORDER AND FINAL JUDGMENT

Upon consideration of Defendants' motion to dismiss (or, in the alternative, for summary judgment), the parties' briefing, and the entire record herein, it is hereby

ORDERED that Defendants' motion is **GRANTED**; it is further

ORDERED that this case is dismissed, in its entirety, for lack of subject-matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1); it is further

ORDERED that Plaintiffs' motion for summary judgment is **DENIED** as moot; and it is further

ORDERED that this case is now closed. This is a final and appealable order.

SO ORDERED.

Date:

_____
Matthew J. Maddox
United States District Judge