IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, *et al.* v. XAVIER BECERRA, in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, *et al.*	Civ. No. 1:23-cv-931-CFC

DEFENDANTS' OPPOSITION TO PLAINTIFFS'
MOTION FOR SUMMARY JUDGMENT AND CROSS-MOTION

Defendants oppose Plaintiffs' motion for summary judgment and cross-move for summary judgment on all claims pursuant to Rule 56 of the Federal Rules of Civil Procedure. In support, Defendants rely on the attached declaration of Ms. Cheri Rice and memorandum of law.

Dated: November 1, 2023

Respectfully submitted,

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MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND CROSS-MOTION

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INTRODUCTION

For more than 30 years, Congress has imposed limits on how much federal agencies pay for prescription drugs. Manufacturers that wish to sell their drugs to the Department of Defense and the Department of Veterans Affairs do so at statutorily defined ceiling prices, and both agencies have authority to negotiate prices further below those ceilings. *See* 38 U.S.C. § 8126(a)-(h). Building on this model in last year's Inflation Reduction Act (IRA), Pub. L. No. 117-169, Congress granted the Secretary of Health and Human Services similar authority to negotiate how much Medicare will pay for pharmaceutical products that lack generic (or biosimilar) competition and account for a disproportionate share of Medicare's expense. *See* 42 U.S.C. § 1320f(a) (establishing the "Negotiation Program"); *id.* § 1320f-1(b), (d), (e) (specifying which drugs are eligible for negotiation). For the first time, Medicare will be able to decide how much it is willing to pay for certain prescription drugs it covers—just as it has long determined how much it is willing to reimburse doctors, hospitals, and other providers for medical services provided to Medicare beneficiaries.

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. And now that their lobbying has failed, pharmaceutical companies and interest groups have repackaged their policy disagreements into lawsuits, filing complaints around the country challenging the Negotiation Program on a variety of grounds. This case, brought by Plaintiffs AstraZeneca Pharmaceuticals LP and AstraZeneca AB, is just one such lawsuit. But it fares no better than the others.

As a threshold matter, Plaintiffs have not established—and cannot establish—Article III standing for their two Administrative Procedure Act (APA) claims, in which they contest how the Centers for Medicare & Medicaid Services (CMS) interpreted one statutory term for the first negotiation cycle. 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). In Plaintiffs' telling, CMS misread the statutory definition two different ways in the program guidance it published. *See* Pls. Mot. Sum. J., ECF 19 at 11-12 (Pls. Br.). But even if CMS had made *both* of Plaintiffs' preferred interpretive choices, that would have had no effect on the inclusion of AstraZeneca's drug Farxiga among the drugs CMS selected for negotiation. Moreover, CMS has explicitly stated that the program guidance that Plaintiffs challenge governs *only* the first negotiation cycle. As a result, Plaintiffs cannot show either present *or* future injury from CMS's current interpretation of the "qualifying single source drug" definition they challenge. They therefore lack standing to bring either of their APA claims.

Further, even aside from Article III, Plaintiffs' APA claims would also be explicitly barred by a provision of the IRA that limits judicial review. That provision expressly states 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 under 42 U.S.C. § 1320f-1. By contesting the manner in which CMS applied the "qualifying single source drug" definition, Plaintiffs seek review of the determinations that CMS has made, and will make in the future, about what drugs meet

that definition and what drugs can be selected for negotiation. 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 entertain Plaintiffs' claims.

In any event, even if this Court had jurisdiction to consider them, Plaintiffs' APA claims are meritless. The interpretations CMS articulated in its Revised Guidance are consistent with the plain text of the statute, as well as its broader structure and purpose. CMS explained in detail the reasons for adopting the approach it did. Plaintiffs' dispute with those interpretations ultimately comes down to a disagreement about policy choices made by *Congress* when it enacted the IRA. Adopting Plaintiffs' preferred readings of the statute would open the Negotiation Program to gamesmanship by drug manufacturers, who would be able to avoid the Program's requirements by engaging in well-documented practices that are intended to maintain market exclusivity and high prices. Permitting such gamesmanship is neither required by the IRA nor consistent with congressional intent. And CMS's decision to minimize incentives for manufacturers to engage in such behavior is neither arbitrary nor capricious.

Disposing of Plaintiffs' APA challenges leaves solely their claim that the Negotiation Program violates the Due Process clause. A judge presiding over another IRA case in the Southern District of Ohio recently rejected an analogous argument, holding that the Negotiation Program raises no due process concerns. *Dayton Area Chamber of Com. v. Becerra*, No. 3:23-cv-156, --- F. Supp. 3d ---, 2023 WL 6378423 (S.D. Ohio Sept. 29, 2023) (*Chamber*). As that court correctly recognized, Congress's authorization for the Secretary to negotiate Medicare prices "cannot be considered a constitutional violation" because drug manufacturers "are not legally compelled to

participate in the [Negotiation] Program . . . or in Medicare generally." *Id.* at *11. "[P]harmaceutical manufacturers who do not wish to" make their drugs available to Medicare beneficiaries at negotiated prices can "opt out" by, for example, withdrawing from the Medicare and Medicaid markets or by divesting their interests in the drugs subject to negotiation before 2026, when any negotiated prices would otherwise take effect. *Id.* The Negotiation Program—like Medicare more broadly—is thus "a completely voluntary" undertaking. *Id.* So although Plaintiffs may be dissatisfied with the conditions this program imposes on future Medicare spending, they are not being deprived of a protected property interest in a way that implicates the Due Process Clause.

In creating the Negotiation Program, Congress exercised its constitutional prerogative to ensure that federal funds are spent according to its view of the "general Welfare." U.S. Const. art. I, § 8, cl. 1. Plaintiffs' objections to that program are nothing more than "a dispute with the policy choices" made by Congress masquerading as legal theory. *Franklin Mem'l Hosp. v. Harvey*, 575 F.3d 121, 130 (1st Cir. 2009). Rather than arguing against established precedent, the "better course of action is to seek redress through the . . . political process." *Id.* Plaintiffs are not entitled to relief in court.

BACKGROUND

I. Medicare and the IRA's Drug Negotiation Program

A. Medicare is a federal program that pays for covered healthcare items and services, including prescription drugs, for qualified beneficiaries. *See generally* 42 U.S.C. § 1395 *et seq.* The Medicare statute encompasses several "Parts," which set forth the

terms by which Medicare will pay for benefits. *See Ne. Hosp. Corp. v. Sebelius*, 657 F.3d 1, 2 (D.C. Cir. 2011).

"Traditional Medicare comprises Part A, which covers medical services furnished by hospitals and other institutional care providers, and Part B, which covers outpatient care like physician and laboratory services," 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) (citation omitted). In 2003, Congress added Medicare Part D, which provides "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.* Prior to the IRA, Congress had not granted the Secretary authority to directly negotiate with drug manufacturers for the costs of covered medications under Medicare. To the contrary, Congress barred the Secretary from negotiating drug prices under Part D or otherwise interfering in the commercial arrangements between manufacturers and the private insurance plans that, in turn, enter into agreements with Medicare to provide benefits. *See* 42 U.S.C. § 1395w-111(i).

Although this model was relatively economical at first, it has contributed to rapidly rising costs to Medicare in recent years. Medicare Part D spending has doubled over the last decade, and it "is projected to increase faster than any other category of health spending." S. Rep. No. 116-120, at 4 (2019); *see also* Cong. Budget Office, *Prescription Drugs: Spending, Use, and Prices* 16 (Jan. 2022), https://perma.cc/9WPC-VLFC. Much of that increase is attributable to a "relatively small number of drugs [that] are responsible for a disproportionately large share of Medicare costs." H.R. Rep. No.

116-324, pt. II, at 37 (2019). Congressional reports have found that generic competitors face many legal and practical obstacles to market entry, sometimes leaving only a single manufacturer of a particular drug on the market for extended periods of time. *See* Staff of H. Comm. on Oversight & Reform, 117th Cong., *Drug Pricing Investigation: AbbVie—Humira and Imbruvica* at 36 (May 2021), https://perma.cc/9L42-VRBK. For example, manufacturers of brand-name drugs often fend off generic competitors by introducing inconsequential changes to their drug and shifting patients to that new version, a strategy known as "product hopping." H.R. Rep. No. 116-695, at 3 (2020). Similarly, brand-name manufacturers often protect their market share by entering into "settlements" with generic manufacturers that permit the generic to be marketed only nominally, without resulting in meaningful competition. *See, e.g.*, Sarah M.E. Gabriele, et al., *The Problem of Limited-Supply Agreements for Medicare Price Negotiation,* 2023 JAMA 1223 (2023). And the payment formula for drugs covered under Part B permits a manufacturer of a drug without generic competition to "effectively set[] its own Medicare payment rate." Medicare Payment Advisory Comm'n, *Report to the Congress: Medicare and the Health Care Delivery System* at 84 (June 2020), https://perma.cc/5X4R-KCHC. The result has been a shift of financial burden to the Medicare program, undermining the program's premise of using market competition to reduce prices for beneficiaries and costs for taxpayers. *Id.* at 120. Because of how cost-sharing and premiums function under Part D, high drug costs also increase out-of-pocket payments by Medicare beneficiaries.

B. The IRA seeks to address these concerns. Pub. L. No. 117-169, §§ 11001-11003 (codified at 42 U.S.C. §§ 1320f–1320f-7 and 26 U.S.C. § 5000D). As relevant

here, the IRA requires the Secretary, acting through CMS, to establish the Negotiation Program, through which he will negotiate the prices Medicare pays for certain covered drugs: those with the highest Medicare Parts B and D expenditures and no generic or biosimilar competitors, and that have been marketable for at least 7 years (*i.e.*, drugs that have long enjoyed little market competition). *See* 42 U.S.C. § 1320f *et seq.* The Negotiation Program applies only to the prices Medicare pays for selected drugs that it covers; the statute regulates neither the prices manufacturers may charge for drugs generally nor the conduct of manufacturers that do not participate in Medicare or Medicaid. *See, e.g.*, *id.* § 1320f-1(b), (d).

To carry out the Negotiation Program, the statute requires CMS to first identify a set of "negotiation-eligible drugs" from a set of "qualifying single source drugs." 42 U.S.C. § 1320f-1(d)-(e) (defining "negotiation-eligible drug" and "qualifying single source drug"). Congress explicitly required CMS to make these determinations by using "data that is aggregated across dosage forms and strengths of the drug." *Id.* § 1320f-1(d)(3)(B); *see also id.* § 1320f-5(a)(2). Using that data, the agency is then to select up to 10 such drugs for negotiation for initial price applicability year 2026, up to 15 drugs for initial price applicability years 2027 and 2028, and up to 20 drugs for initial price applicability year 2029 and for subsequent years. *Id.* § 1320f-1(a)-(b).

After selecting the drugs, CMS is directed to negotiate with the manufacturer of each selected drug in an effort to reach agreement on a "maximum fair price" for that drug. *Id.* § 1320f-3. In formulating offers during the course of those negotiations, the statute requires CMS to consider numerous categories of information, including (1) "[r]esearch and development costs of the manufacturer for the drug and the extent

to which the manufacturer has recouped" those costs, (2) current "costs of production and distribution," (3) prior "Federal financial support for . . . discovery and development with respect to the drug," and (4) evidence about alternative treatments. *Id.* § 1320f-3(e). In hopes of achieving meaningful savings for the American people, Congress imposed a "ceiling for [the] maximum fair price," which it tied to specified pricing data. *Id.* § 1320f-3(c). But Congress also directed CMS to "aim[] to achieve the lowest maximum fair price" that manufacturers will accept. *Id.* § 1320f-3(b)(1).

CMS is directed to sign agreements to negotiate prices for selected drugs with willing manufacturers. *Id.* § 1320f-2. If those negotiations prove successful, a manufacturer will then sign an addendum agreement to establish the maximum price at which the drug will be made available to Medicare beneficiaries. *Id.* A manufacturer that does not wish to sign such an agreement—or to otherwise participate in the Negotiation Program—has several options. It can continue selling the selected drug to be dispensed or furnished to Medicare beneficiaries at non-negotiated prices and pay an excise tax on those sales. 26 U.S.C. § 5000D. It can continue selling its other drugs to Medicare but transfer its interest in the selected drug to another entity, which can then make its own choices about negotiations. *See* Medicare Drug Price Negotiation Program: Revised Guidance at 131-32 (June 30, 2023), https://perma.cc/K6QB-C3MM (Revised Guidance). Or it can withdraw from Medicare and Medicaid—in which case it will incur no excise tax and no other liability. *See id.* at 33-34, 120-21, 129-31; *see also* Pub. L. No. 117-169, § 11003 (enacting 26 U.S.C. § 5000D(c)(1)).

These conditions parallel those Congress has long attached to other government healthcare programs. For example, Congress has long required that any drug

manufacturer wishing to participate in Medicaid enter into agreements with the Secretary of Veterans Affairs—agreements which give the Department of Veterans Affairs, the Department of Defense, the Public Health Service, and the Coast Guard the option to purchase drugs at negotiated prices at or below statutory ceiling prices. *See* 38 U.S.C. § 8126(a)-(h). Like those statutory provisions, the Negotiation Program thus gives manufacturers a choice: they can sell their products at prices the government is willing to pay, or they can take their business elsewhere.

II. CMS's Implementation of the Negotiation Program

Congress directed CMS to implement the Negotiation Program through "program instruction or other forms of program guidance" through 2028. Pub. L. No. 117-169, § 11001(c). Following that statutory mandate, CMS issued initial guidance on March 15, 2023, explaining how it intended to implement certain aspects of the statute and soliciting public input. *See* CMS, Medicare Drug Price Negotiation Program: Initial Memorandum (Mar. 15, 2023), https://perma.cc/8X4K-CVD8 (Initial Guidance). After considering more than 7,500 public comments "representing a wide range of views," CMS published a Revised Guidance on June 30, 2023. Revised Guidance at 1-2. The Revised Guidance applies only to initial price applicability year 2026. *Id.*

The Revised Guidance describes several aspects of CMS's implementation of the first year of the Negotiation Program, including the methodologies by which CMS selects drugs for negotiation, the negotiation process, and the types of data that CMS considers in making an offer. The Revised Guidance also explains how CMS makes the determination of whether a product constitutes a "qualifying single source drug"—

that is, a drug that can eventually be found eligible for negotiation and ultimately selected. 42 U.S.C. § 1320f-1(e).

As relevant here, the Revised Guidance explains that, consistent with 42 U.S.C. §§ 1320f-1(d)(3)(B) and 1320f-5(a)(2), 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."[1] Revised Guidance at 99. Similarly, the Revised Guidance considers a qualifying single source drug for biological products to include "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." *Id.*[2]

CMS's Revised Guidance also explains how the agency will apply the criteria for *excluding* a drug from the "qualifying single source drug" definition. Under the IRA, a drug or biological product is not considered a qualifying single source drug if an approved generic drug or licensed biosimilar product references it and that competitor product "is . . . marketed." 42 U.S.C. § 1320f-1(e)(1)(A)(iii), (B)(iii). The Revised Guidance explains that CMS will deem "a generic drug or biosimilar biological product [to be] marketed when the totality of the circumstances . . . reveals that the manufacturer of that drug or product is engaging in bona fide marketing of that drug

[1] Active moiety is "[t]he molecule or ion . . . responsible for the physiological or pharmacological action of the drug substance." *Kisor v. Wilkie*, 139 S. Ct. 2400, 2411 n.1 (2019) (quoting 21 C.F.R. § 314.3(b) (2018)).

[2] In order to market an innovator prescription drug or biological product in the United States, an applicant must receive FDA approval of an NDA pursuant to 21 U.S.C. § 355(c) or a BLA pursuant to 42 U.S.C. § 262, respectively.

or product." Revised Guidance at 102. CMS further explained that it will conduct "ongoing assessments of whether the manufacturer of the generic drug or biosimilar is engaging in bona fide marketing." *Id.* at 170. In doing so, "CMS will review both Prescription Drug Event (PDE) data and Average Manufacturer Price (AMP)[3] data reported by manufacturers," as well as potentially other sources as part of a holistic inquiry. *Id.* at 2, 101-02. For the initial selection of drugs in the first negotiation cycle, CMS stated that it "will review PDE data for the 12-month period beginning August 16, 2022 and ending August 15, 2023" along with AMP "data for the 12-month period beginning August 1, 2022 and ending July 31, 2023, using the AMP data available on August 16, 2023" to identify whether a relevant "generic drug or biosimilar biological product" is being marketed. Ultimately, CMS's bona-fide marketing inquiry asks "whether the generic drug or biosimilar biological product is regularly and consistently available for purchase through the pharmaceutical supply chain and whether any licenses or other agreements between a Primary Manufacturer and a generic drug or biosimilar manufacturer limit the availability or distribution of the selected drug." *Id.* at 170.

Separately, CMS's Revised Guidance also sets forth the procedures for manufacturers to follow if they decide not to participate in the Negotiation Program. *Id.* at 2-8. In doing so, the Revised Guidance expressly provides that if a manufacturer "decides not to participate in the Negotiation Program," CMS will "facilitate an

[3] AMP means "the average price paid to the manufacturer for the drug in the United States by: (i) wholesalers for drugs distributed to retail community pharmacies; and, (ii) retail community pharmacies that purchase drugs directly from the manufacturer, subject to certain exclusions." Revised Guidance at 101 n.37.

expeditious termination of" the manufacturer's Medicare agreements before the manufacturer would incur liability for any excise tax, so long as the manufacturer notifies CMS of its desire to withdraw at least 30 days in advance of when that tax would otherwise begin to accrue. *Id.* at 33-34. The Revised Guidance also notes that manufacturers that wish to remain in the Medicare and Medicaid programs but that do not wish to negotiate can divest their interest in the selected drug(s). *Id.* at 131-32.

On August 29, 2023, CMS published the list of drugs selected for negotiation for initial price applicability year 2026. *See HHS Selects the First Drugs for Medicare Drug Price Negotiation* (Aug. 29, 2023), https://perma.cc/A36P-Z88Z. The drugs selected accounted for more than $50 billion—or about 20%—of gross Medicare Part D spending between June 2022 and May 2023. *See Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026* (Aug. 2023), https://perma.cc/X37F-RC94. AstraZeneca's drug Farxiga was among the 10 drugs selected for negotiation. *Id.* No other AstraZeneca drug was selected.

AstraZeneca has now executed an agreement to negotiate the price of Farxiga. *See Manufacturer Agreements for Selected Drugs for Initial Price Applicability Year 2026* (Oct. 3, 2023), https://perma.cc/3222-VPEE (*Manufacturer Agreements*). Manufacturers of all the other selected drugs have likewise signed agreements to negotiate the price of their respective drugs. *Id.* Under the schedule established by Congress, negotiations are to conclude by August 1, 2024. 42 U.S.C. §§ 1320f(b), (d), 1320f-2(a), 1320f-3(b); *see generally* Revised Guidance at 91-92 (outlining statutory timetable). Any agreed-upon prices for the selected drugs will take effect on January 1, 2026—more than two years from now. 42 U.S.C. §§ 1320f(b), 1320f-2(a); Revised Guidance at 92.

III. Related Litigation

Prior to the deadline to execute negotiation agreements with CMS, drug manufacturers and interest groups filed multiple suits across the country challenging the constitutionality of the Negotiation Program. *See Bristol Myers Squibb Co. v. Becerra*, No. 3:23-cv-3335 (D.N.J. June 16, 2023); *Janssen Pharms, Inc. v. Becerra*, No. 3:23-cv-3818 (D.N.J. July 18, 2023); *Boehringer Ingelheim Pharms., Inc. v. HHS*, No. 3:23-cv-1103 (D. Conn. Aug. 18, 2023); *Nat'l Infusion Ctr. Ass'n v. Becerra*, No. 1:23-cv-707 (W.D. Tex. June 21, 2023); *Merck & Co., Inc. v. Becerra*, No. 1:23-cv-1615 (D.D.C. June 6, 2023); *Novartis Pharms. Corp. v. Becerra*, No. 3:23-cv-14221 (D.N.J. Sept. 1, 2023); *Novo Nordisk Inc., et al. v. Becerra*, No. 3:23-cv-20814 (D.N.J. Sept. 29, 2023); *Dayton Area Chamber of Com. v. Becerra*, No. 3:23-cv-156 (S.D. Ohio June 9, 2023).[4] Plaintiffs in one such case—brought by the U.S. Chamber of Commerce and its local affiliates—sought a preliminary injunction "to prevent the implementation of [the] Program." *Chamber,* 2023 WL 6378423, at * 1. In doing so, the Chamber argued that the Program violated the Fifth Amendment's Due Process Clause. *Id.* at *11. The court disagreed.

As the court detailed, the Chamber's arguments failed "as a matter of law" because manufacturers were "not legally compelled to participate in the [Negotiation] Program." *Id.* at *11. As a result, the court explained, the Negotiation "Program's eventual 'maximum fair price' cannot be considered confiscatory because pharmaceutical manufacturers who do not wish to participate in the Program have the ability—practical or not—to opt out[.]" *Id.* (citation omitted). The court thus denied

[4] Another case was filed, but voluntarily dismissed: *Astellas Pharma US, Inc. v. HHS*, No. 1:23-cv-4578 (N.D. Ill. July 14, 2023).

the Chamber's motion. *Id.* at *14. The Chamber decided not to appeal that decision. *Chamber*, No. 3:23-cv-156, ECF No. 56 at 2 (S.D. Ohio Oct. 12, 2023) (joint scheduling motion stating that plaintiffs do not intend to appeal).

ARGUMENT

I. Plaintiffs Lack Article III Standing to Bring their APA Challenges

Article III of the Constitution confines federal courts to deciding actual "Cases" and "Controversies." U.S. Const. art. III, § 2; *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016). "[A]n essential and unchanging part of the case-or-controversy requirement" is that plaintiffs must demonstrate that they have standing to sue by, among other things, establishing—"with the manner and degree of evidence required at the [appropriate] stage[] of the litigation"—an (1) "invasion of a legally protected interest which is [] concrete and particularized . . . and [] actual or imminent, not conjectural or hypothetical," and that (2) is "fairly traceable to the challenged action of the defendant" and (3) redressable by a favorable court ruling. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560-61 (1992) (citations omitted). Further, because "'standing is not dispensed in gross,' a plaintiff who raises multiple causes of action 'must demonstrate standing for each claim he seeks to press.'" *In re Schering Plough Corp.*, 678 F.3d 235, 245 (3d Cir. 2012) (citation omitted) (quoting *Lewis v. Casey*, 518 U.S. 343, 358 n.6 (1996) and *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 352 (2006)). Plaintiffs fall far short of this "irreducible constitutional minimum" for both of their APA claims. *Lujan*, 504 U.S. at 560.

In those APA claims, Plaintiffs contest two aspects of CMS's Revised Guidance that articulated how CMS would make determinations about which products are

"qualifying single source drugs"—and thus potentially eligible for negotiation—for program year 2026. *See* Am. Compl. ¶¶ 123-38. First, Plaintiffs contend that, in identifying what constitutes a "qualifying single source drug," CMS improperly decided that it would include "all dosage forms and strengths of the drug with the same active moiety" (or in the case of the biologic, "the same active ingredient"), even if those different forms have been approved under different NDAs or BLAs. Revised Guidance at 99; *see also* Pls. Br. at 15; Am. Compl. ¶¶ 49, 59, 125. In Plaintiffs' view, a "qualifying single source drug" can have only one NDA or BLA, despite the fact that the number of NDAs or BLAs for a drug or biologic is, in many instances, a feature of how the applicant chooses to submit its application(s) to the Food and Drug Administration (FDA). Pls. Br. at 15. Second, Plaintiffs assert that CMS imposed an improperly high standard for when a drug should be excluded from the definition of "qualifying single source drug" on the grounds that it faces a generic or biosimilar competitor. *See* Pls. Br. at 19; Am. Compl. ¶¶ 51-52, 134. According to Plaintiffs, even a *de minimis* presence of a generic competitor in the market is sufficient—the generic need not be marketed in a "bona fide" manner. *See* Pls. Br. at 19-20. Crucially, however, Plaintiffs fail to even allege—much less to establish at summary-judgment—that *either* of those aspects of the "qualifying single source drug" definition affected the inclusion of AstraZeneca's drug Farxiga on the list of selected drugs for price applicability year 2026. *See generally* Pls. Br.; *see also* Am. Compl. ¶¶ 53, 61, 78. Nor can they.

As detailed by CMS Deputy Director of the Center for Medicare Cheri Rice in the attached declaration, Farxiga—which contains the active moiety dapagliflozin—is approved and marketed under a single NDA, which contains one dosage form in two

strengths, a 5 mg and a 10 mg tablet. *See* Decl. of Cheri Rice ¶ 9; *see also* U.S. FDA: Drugs@FDA, https://perma.cc/Z7JR-M7BL (search "Farxiga"). Because Farxiga has only one NDA, Plaintiffs' claims that CMS must consider products with distinct NDAs or BLAs to be different "qualifying single source drug[s]" are completely irrelevant: the approach Plaintiffs challenge did not affect Farxiga's designation as a "qualifying single source drug" or its eventual selection. *See* Rice Decl. ¶ 9 (explaining that, because "Farxiga is approved and marketed under a single NDA . . . the 'Total Expenditures' for Farxiga under Medicare Part D would be the same whether CMS aggregated expenditures by active moiety across multiple NDAs or not"). Indeed, as Deputy Director Rice details, "applying Plaintiffs' approach . . . could only ever have the effect of causing Farxiga to rise in the 'Total Expenditure' rankings (by, for example, causing a drug above Farxiga in the rankings to fall below it after disaggregating expenditures of multiple formulations of the other drug)." *Id.* Likewise, Farxiga has no FDA-approved generic competitor at all—so CMS's determination of when the presence of a generic competitor might or might not cause a drug to fall outside the "qualifying single source drug" definition likewise did not affect the drug's selection for negotiation. *See id.* ¶ 10 (explaining that "[b]ecause there are no approved generic versions of Farxiga, CMS' interpretation of the 'marketed' requirement as requiring bona fide marketing is irrelevant").

Thus, *neither* element of CMS's "qualifying single source drug" definition that Plaintiffs challenge mattered for Farxiga. *See id.* ¶ 11. As Deputy Director Rice explains, "even if CMS had applied either or both of the interpretations of the statute . . . Plaintiffs have advanced in this lawsuit, it would have had no effect on Farxiga's

selection for" negotiation in the program's first cycle. *Id.* And that means, in turn, that the challenged portions of the Revised Guidance caused Plaintiffs neither a cognizable injury with respect to Farxiga nor one that could be remedied with a favorable decision. *See, e.g.*, *California v. Texas*, 141 S. Ct. 2104, 2114 (2021) (no standing where the challenged provision was not enforced against plaintiffs). Plaintiffs thus cannot establish standing to challenge the Revised Guidance on the basis of CMS selecting Farxiga as one of the 10 negotiation drugs.

Nor can Plaintiffs establish standing by speculating that CMS might improperly keep Farxiga on the selected drug list in the future if a generic competitor emerges for that drug. *See* Pls. Br. at 28. To establish Article III standing, a plaintiff cannot rely merely on guesswork that it might be injured some day by the policy it challenges; rather, it must show an injury that is "certainly impending." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409-10 (2013). So, to establish injury arising from CMS's understanding of the statutory "is . . . marketed" standard, Plaintiffs would need to demonstrate that: (1) a generic competitor for Farxiga will be approved; (2) the competitor will begin to market that drug; (3) the competitor will do so only at a *de minimis* level, such that the statutory dispute between Plaintiffs and CMS would matter for the agency's determination; and (4) all of these events would happen at a point in time that would affect Farxiga's status as a selected drug. *See* 42 U.S.C. § 1320f-1(c) (describing standards for deselection from eligibility for negotiation). Plaintiffs have made no effort to prove any of these things, and their claim to standing accordingly must fail. *See Lujan,* 504 U.S. at 560.

Unable to establish standing for their APA claims on the basis of Farxiga, Plaintiffs speculate (without any evidence) that CMS's interpretation might affect some of their other drugs at some point in the future. *See, e.g.*, Pls. Br. at 16-17, 26, 28; Am. Compl. ¶¶ 53, 105-12. But these alternative theories also fail to establish a "certainly impending" injury traceable to the Revised Guidance, for several distinct reasons. *Clapper*, 568 U.S. at 409-10.

First, by its very terms, the Revised Guidance applies *only* for the first negotiation cycle. *See* Revised Guidance at 1-2 (noting that the Revised Guidance applies for the "initial price applicability year 2026" and that CMS will "develop[] [] program guidance for initial price applicability years 2027 [and] 2028" in the future); Rice Decl. ¶ 12 (explaining that the Revised Guidance "applies only for initial price applicability year 2026" and that "[i]n the future, CMS will issue new guidance to govern future price applicability years."). Accordingly, the Revised Guidance will not cause any harm to Plaintiffs (or have any effect at all) in future years. Even if CMS were to adopt a similar approach in a future guidance or rulemaking and Plaintiffs were injured by it, that injury would be the result of an entirely different administrative action—and would not be traceable to the Revised Guidance Plaintiffs challenge here. *See, e.g.*, *California*, 141 S. Ct. at 2119. And Plaintiffs cannot use a dispute over guidance that causes them no harm to obtain an advisory opinion from this Court about what interpretation CMS can or cannot adopt in a future year. *See, e.g.*, *Bond v. United States*, 564 U.S. 211, 225 (2011) (Plaintiffs "have 'no standing to complain simply that their Government is violating the law.'" (quoting *Allen v. Wright*, 468 U.S. 737, 755 (1984)).

Second, even if the Revised Guidance were not limited by its terms to the first negotiation cycle, "allegations of *possible* future injury are not sufficient" to establish standing. *Clapper*, 568 U.S. at 409 (cleaned up; emphasis in original). To constitute injury-in-fact, an injury must be "certainly impending" and cannot rely on a "highly attenuated chain of possibilities." *Id.* 409-10 (quoting *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990); *Lujan*, 504 U.S. at 565 n.2) (emphasis added); *City of Los Angeles v. Lyons*, 461 U.S. 95, 101–02 (1983) ("[I]njury or threat of injury must be both 'real and immediate,' not 'conjectural' or 'hypothetical.'" (citations omitted)). The concept is "stretched beyond the breaking point when . . . the plaintiff alleges only an injury at some indefinite future time" and that alleged injury depends on a host of contingent actions. *Penn. Prison Soc. v. Cortes*, 508 F.3d 156, 166 (3d Cir. 2007) (quoting *Lujan*, 504 U.S. at 564 n.2). Yet that is exactly what Plaintiffs offer here.

In their amended complaint and summary judgment papers, Plaintiffs provide nothing but the most general speculation about the effects that the Revised Guidance may have on manufacturers generally or on Plaintiffs' drug "portfolio" in subsequent years. *See, e.g.*, Pls. Br. at 16-17, 26; Am. Compl. ¶¶ 105-12. Plaintiffs assert, for example, that CMS's interpretation may lead to other AstraZeneca products being selected, or Farxiga remaining a selected drug longer than what AstraZeneca believes is appropriate if a generic version gains FDA approval. Am. Compl. ¶¶ 108-11. All of these hypothetical harms depend on a long series of uncertain future contingencies—including, for example, the entry of a generic competitor on the market and sufficient utilization of AstraZeneca's other drugs to warrant their inclusion in the selected drug list. Yet Plaintiffs fail to provide *any* evidence to substantiate that any (let alone all) of

these speculative possibilities will actually occur. And absent such evidence, Plaintiffs' bare assumptions about an increased risk of possible future injuries are insufficient to establish Article III standing—especially at summary judgment. *See, e.g.*, *Penn. Prison Soc.*, 508 F.3d at 161 (although "generalized allegations of injury may suffice at the pleading stage, a plaintiff can no longer rest on such 'mere allegations' in response to a summary judgment motion, but must set forth 'specific facts' by affidavit or other evidence" (quoting *Lujan*, 504 U.S. at 561)).[5]

Finally, Plaintiffs assert in general terms that, given CMS's current interpretation, they may decline to pursue possible future investments out of a fear that the risk-reward calculation may not pay off. *See, e.g.*, Pls. Br. at 3, 12, 18. But even setting aside the extensive speculation required to indulge such a theory, that would be a classic form of self-inflicted injury. *See Clapper*, 568 U.S. at 418 ("[R]espondents' self-inflicted injuries are not fairly traceable to the Government's purported activities[.]"). The Supreme Court has been emphatic that such injury is insufficient for Article III purposes generally. And it is likewise insufficient here. This is all the more true given that Plaintiffs' alleged injuries along these lines are focused on the possible future selection of certain "orphan" drugs, Pls. Br. at 2, 5; Compl. ¶¶ 2-12, 20, 35, 68, 97-101, 106-07. But many of these drugs are expressly *excluded* from the "qualifying single source drug" definition. 42 U.S.C. § 1320f-1(e)(3)(A) (excluding drugs that are

[5] Indeed, it would be just as easy to posit that Plaintiffs might *benefit* in the future from CMS's interpretative choices, if another manufacturer's drug were to place ahead of one of Plaintiffs' drugs as a result of the interpretations Plaintiffs currently challenge. *See, e.g.*, Rice Decl. ¶ 9 (noting that, in the case of Farxiga, Plaintiffs' preferred approach "could only ever have the effect of causing Farxiga to rise" in the selection rankings).

"designated . . . for only one rare disease or condition" and only approved for the relevant indication). And, even absent that exclusion, the possible future selection of an orphan drug (in particular, one manufactured by AstraZeneca) is highly uncertain, because (in Plaintiffs' own words) "the patient populations for these diseases are so small," Pls. Br. at 2-3. Under these circumstances, even more additional layers of speculation are required to imagine that any of the legal objections raised in Plaintiffs' filings will ever matter for any orphan drug that Plaintiffs manufacture.

Plaintiffs' standing arguments thus do not come close to establishing the existence of a present or certainly impending future injury traceable to the aspects of the Revised Guidance they challenge and that is redressable by a Court order. In the absence of such evidence, Plaintiffs' challenge amounts to nothing more than a request for an advisory opinion on the legality of CMS's current interpretations. But the "oldest and most consistent thread in the federal law of justiciability is that the federal courts will not give advisory opinions." *Flast v. Cohen*, 392 U.S. 83, 96 (1968) (citation omitted). Plaintiffs' APA challenges should therefore be dismissed for lack of subject-matter jurisdiction.

II. Plaintiffs' APA Claims Are Statutorily Barred

Article III is not the only jurisdictional bar to Plaintiffs' APA challenges. In crafting the Negotiation Program, Congress explicitly provided that "[t]here shall be no administrative or judicial review" of certain CMS decisions, including its "selection of drugs" for negotiation. 42 U.S.C. § 1320f-7(2) (referring to the selection of drugs under 42 U.S.C. § 1320f-1(b)). And, to ensure that bar is not easily evaded, Congress also expressly foreclosed review of several precursor determinations, including the

"determination of qualifying single source drugs" under § 1320f-1(e). *Id.* § 1320f-7(2). Thus, even if Plaintiffs could demonstrate Article III standing to bring their APA claims in the context of some concrete and particularized injury relating to the actual selection of AstraZeneca's drugs, Congress has precluded judicial review over such claims.

1. As the Supreme Court has emphasized, "[o]nly Congress may determine a lower federal court's subject-matter jurisdiction." *Kontrick v. Ryan*, 540 U.S. 443, 452 (2004) (citing U.S. Const. art. III, § 1). And "what the Congress gives, the Congress may take away." *Knapp Med. Ctr. v. Hargan*, 875 F.3d 1125, 1128 (D.C. Cir. 2017). Given the "'strong presumption that Congress intends judicial review of administrative action,'" courts look for "'clear and convincing evidence' that Congress intended to preclude" a lawsuit. *Amgen, Inc. v. Smith*, 357 F.3d 103, 111 (D.C. Cir. 2004) (quoting *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 670 (1986) and *Abbott Laboratories v. Gardner*, 387 U.S. 136, 141 (1967)). But "[w]hen Congress provides that 'there shall be no administrative or judicial review' of specified agency actions . . . its intent to bar review is clear," and the only appropriate inquiry is "whether the challenged action falls 'within the preclusive scope' of the statute." *DCH Reg'l Med. Ctr. v. Azar*, 925 F.3d 503, 505–06 (D.C. Cir. 2019) (quoting *Knapp Med. Ctr.*, 875 F.3d at 1128).

Here, that is a straightforward inquiry. Plaintiffs' amended complaint and summary-judgment brief could not be clearer that they are challenging CMS's determination of what constitutes a "qualifying single source drug" under the provisions of § 1320f-1(e)—which Congress made unreviewable. Pls. Br. at 11, 14; Am. Compl. ¶¶ 125, 133. Specifically, Plaintiffs assert that CMS's Revised Guidance

misinterprets two aspects of the "qualifying single source drug" definition, namely (1) which products can be considered a single "qualifying single source drug;" and (2) which drugs can be excluded from the "qualifying single source drug" definition on the ground that they have a generic competitor. *See, e.g.*, Pls. Br. at 11-12, 14, 18-19. As Plaintiffs explain, their first APA challenge (in Count I of the Amended Complaint) contests CMS's decision to "aggregate different drug products approved under different NDAs or BLAs into the same Qualifying Single Source Drug," Pls. Br. at 14, which will allegedly make AstraZeneca's "later-approved drug products . . . eligible for the" Negotiation Program "as soon as they are approved," Pls. Br. at 17. And their second APA challenge (presented in Count II) disputes the conditions CMS articulated for when "a drug that faces generic competition in the market will [] be treated as a Qualifying Single Source Drug," Pls. Br. at 20, which will also allegedly affect how long AstraZeneca's drug is subject to the Negotiation Program's prices, Pls. Br. at 28. Both claims are precluded under the plain text of the statute.

Although it was Plaintiffs' burden to establish subject-matter jurisdiction, they do not even attempt to explain how their APA challenges survive in the face of the IRA's preclusion-of-review provisions. Nor could they do so; Plaintiffs are explicitly alleging harm from the potential *inclusion* of their drugs in the "qualifying single source drug" definition—and ultimately seek the *exclusion* of their drugs from that definition in the coming years. *See, e.g.*, Am. Compl. ¶¶ 108-11 (alleging the ways in which CMS's interpretation will prolong Plaintiffs' drugs inclusion in the statutory definition); *id.* at 43 (seeking an "order vacating and setting aside the definitions of 'Qualifying Single Source Drug'"). Granting such relief would threaten to overturn CMS's "selection of

drugs," its "determination of negotiation-eligible drugs," and its "determination of qualifying single source drugs"—all of which Congress shielded from judicial review—either in this negotiation cycle or in future ones. 42 U.S.C. § 1320f-7(2). The plain text of the preclusion provision bars this result—both with respect to the ultimate selection of individual drugs, and with respect to the manner in which the agency makes those individual selections.

2. This conclusion is reinforced by considering how courts have analyzed similar preclusion bars in other parts of the Medicare statute. Such bars are not unusual and—unsurprisingly—plaintiffs have long sought creative ways to argue around their application. But courts have consistently rejected such efforts.

For example, in *Texas Alliance for Home Care Services v. Sebelius*, 681 F.3d 402 (D.C. Cir. 2012), the D.C. Circuit construed a statute barring review of "the awarding of contracts" to cover challenges to a regulation setting forth eligibility standards for contracts, which it found to be "indispensable to 'the awarding of contracts.'" *Id.* at 409 (citation omitted). In doing so, the court specifically declined to "distinguish between an upfront attack . . . by suppliers not yet injured by [the rule] and a challenge brought after-the-fact by a frustrated bidder." *Id.* at 410.

Likewise, the D.C. Circuit recently affirmed that a statutory bar against "administrative or judicial review" of "[a]ny estimate of the Secretary for purposes of determining [specified statutory] factors" barred plaintiffs from challenging "'the methodology adopted and employed' by HHS to calculate" one of those factors. *DCH Reg'l Med. Ctr.*, 925 F.3d at 505. As the court explained, a "distinction between methodology and estimates would eviscerate the statutory bar" against review "for

almost any challenge to an estimate could be recast as a challenge to its underlying methodology." *Id.* at 506. Because the "method" used was "inextricably intertwined" with the "estimate," the court concluded that the statute "precludes review of both." *Id.* at 507.

This approach is not an aberration. Courts regularly find that preclusion provisions bar decisions that are "'indispensable' or 'integral' to, or 'inextricably intertwined' with, the unreviewable agency action." *Fla. Health Scis. Ctr., Inc. v. Sec'y of HHS*, 830 F.3d 515, 519 (D.C. Cir. 2016) (citing *Tex. All. for Home Care Servs.*, 681 F.3d at 409-10); *see also Knapp Med. Ctr.*, 875 F.3d at 1130-31 (applying same standard); *Mercy Hosp., Inc. v. Azar*, 891 F.3d 1062, 1066 (D.C. Cir. 2018) (a statute barring judicial review of "prospective payment rates" covers "adjustments used to calculate th[ose] rate[s]"); *DCH Reg'l Med. Ctr.*, 925 F.3d at 507 (canvassing cases); *Yale New Haven Hosp. v. Becerra*, 56 F.4th 9, 13 (2d Cir. 2022) (prohibition against "judicial review" of "estimates" precluded a claim that the Secretary "failed to abide by adequate notice-and-comment rulemaking procedures" before selecting underlying data).

Much the same could be said here. Because Plaintiffs challenge the potential inclusion of their drugs in, and seek the exclusion of their drugs from, the "qualifying single source drug" definition, the aspects of CMS's Revised Guidance that Plaintiffs contest are "'inextricably intertwined' with the" precluded determinations. *DCH Reg'l Med. Ctr.*, 925 F.3d at 507 (citation omitted). Accordingly, "the bar on judicial review applies to both." *Id.*; *see also Yale New Haven Hosp.*, 56 F.4th at 23 (noting that the Court can "presume 'that Congress was adopting, rather than departing from,' [this]

'established assumption[] about how [review-preclusion provisions in the Medicare Act] work[ ].'" (citation omitted)).[6]

In short, this Court lacks statutory subject-matter jurisdiction to consider Plaintiffs' APA challenges because the IRA contains a "provision that precludes [such] judicial review.'" *Yale New Haven Hosp.*, 56 F.4th at 16-17 (quoting *Knapp Med. Ctr.*, 875 F.3d at 1128). Those claims must therefore be dismissed.

III. AstraZeneca's APA Claims Fail on the Merits

Even if the Court had jurisdiction to evaluate the substance of Plaintiffs' APA claims, those claims would fail on the merits. As noted above, Plaintiffs protest two elements of how CMS identifies "qualifying single source drugs" within the meaning of 42 U.S.C. § 1320f-1(e). Contrary to what Plaintiffs claim, however, CMS's interpretations are consistent with the language and structure of the IRA and supported by a reasoned explanation. Nothing more is required.

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[6] Nor would Plaintiffs be able to avoid this bar by characterizing their claim as contesting an "ultra vires" construction of the statute—which, notably, they have not done. As the D.C. Circuit has clarified, "[a]t most," such claims may proceed "only when three requirements are met: '(i) the statutory preclusion of review is implied rather than express; (ii) there is no alternative procedure for review of the statutory claim; and (iii) the agency plainly acts in excess of its delegated powers and contrary to a specific prohibition in the statute that is clear and mandatory.'" *DCH Reg'l Med. Ctr.*, 925 F.3d at 509 (quoting *Nyunt v. Chairman, Broad. Bd. of Governors*, 589 F.3d 445, 449 (D.C. Cir. 2009), (cleaned up)); *see also Yale New Haven Hosp.*, 56 F.4th at 26 (same). Here, of course, the statute *expressly* precludes review of the challenged determination—so the first requirement is lacking. And Plaintiffs do not come close to meeting the third factor, which "covers only 'extreme' agency error, not merely '[g]arden-variety errors of law or fact.'" *DCH Reg'l Med. Ctr.*, 925 F.3d at 509 (quoting *Griffith v. Fed. Labor Rels. Auth.*, 842 F.2d 487, 493 (1988)).

A. CMS's Approach to Multiple Forms of the Same Drug Correctly Interprets the IRA

The Revised 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" (or in the case of the biologic, "the same active ingredient"), even if those different forms have been approved under different NDAs or BLAs. Revised Guidance at 99. Plaintiffs protest this interpretation, arguing that various contextual clues in the IRA implicitly prohibit "aggregat[ing] different drug products approved under different NDAs or BLAs into the same Qualifying Single Source Drug." Pls. Br. at 14-15. Not so.

As CMS explained in its Revised Guidance, this aggregation requirement flows naturally from the provisions of the IRA. Congress expressly mandated that CMS aggregate certain data for a singular "drug" at various points in the drug-selection process. Specifically, 42 U.S.C § 1320f-1(d)(3)(B) provides that, "in determining whether a qualifying single source drug" is "negotiation eligible" under section 1320f-1(d), 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) (emphasis added); Revised Guidance at 99. In some cases, a drug or biological product with multiple dosage forms and strengths may have been approved in a single NDA or BLA, but that is not invariably true. A manufacturer may decide to submit multiple applications for a drug with the same active ingredient, such as a drug with both an immediate release and an extended release

formulation.[7] Yet Congress expressly referred to these different formulations—which may have been approved under more than one application—as a singular "drug." *See* 42 U.S.C. § 1320f-1(d)(3)(B). And Congress specifically required CMS to aggregate data across these different formulations in choosing negotiation-eligible drugs out of the pool of qualifying single source drugs. *See id.* So the fact that manufacturers might seek multiple NDAs (or BLAs) for different dosage forms, strengths, or formulations of a drug is simply irrelevant under the plain text of the statute.

Similarly, Congress provided that—once CMS selects a drug for negotiation and negotiations are completed—CMS would "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." 42 U.S.C. § 1320f-5(a)(2) (emphasis added). This reference to a price being applied to a singular drug—notwithstanding the fact that its "different strengths and dosage forms," *id.*, may be spread across different NDAs or BLAs—once again confirms that Congress did not view a drug to be necessarily limited to a single application.

Plaintiffs ignore these explicit statutory mandates. Instead, they observe that the IRA's definition of "single source drug" "cross-references the definition for a 'covered part D drug' in the Medicare statute," which they claim defines a drug "based on whether the product is approved pursuant to a distinct NDA or BLA." Pls. Br. at 15

[7] *See, e.g.*, Viramune (nevirapine) (NDA 020636) and Viramune XR (NDA 201152), FDA, Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, https://perma.cc/629Y-FDE6 (search "Viramune"); Nucynta (tapentadol hydrochloride) (NDA 022304) and Nucynta ER (NDA 200533), *id.* (search "Nucynta"); Lamictal (lamotrigine) (NDA 020241) and Lamictal **X**R (NDA 022115), *id.* (search "Lamictal").

(citing 42 U.S.C. §§ 1396r–8(k)(2), (k)(7)(A)(iv)). But Plaintiffs overread the significance of the cross-referenced provision, which provides merely that the drug must be "approved for safety and effectiveness" under an appropriate application. 42 U.S.C. § 1396r–8(k)(2). In the IRA, Congress explicitly instructed that CMS consider all "*applications and approvals* [plural]. . . for the *drug* [singular]" as a relevant factor when devising the government's price offer for that drug. *See* 42 U.S.C. § 1320f-3(e)(1)(D) (emphases added). Plaintiffs' purported bar against aggregating multiple NDAs or BLAs into a single "drug" would disregard this language and render it a nullity.

In light of this statutory structure, Plaintiffs' suggestion that Congress could have explicitly specified that a single drug could have multiple NDAs or BLAs, which they claim Congress did in a completely separate provision of the Affordable Care Act, falls flat. *See* Pls. Br. at 15 (citing 42 U.S.C. § 1396r–8(c)(2)(C)). Contrary to Plaintiffs' claims, Congress did not need to include any more explicit "exception" to Plaintiffs' supposed rule when the statute already clearly manifested Congress's intent. Pls. Br. at 15. Likewise without merit is Plaintiffs' attempt to find hidden "clue[s]" in the IRA's reference to a drug's approval or licensure dates. *Id.* at 15-16. Contrary to what Plaintiffs claim, the fact that the IRA defines a qualifying single source drug as one approved by the FDA and for which "at least 7 years will have elapsed since the date of such approval" (or 11 years for BLA licensure), does not mean that the IRA necessarily contemplates only a singular "approval." Pls. Br. at 16. A qualifying single source drug may have several different NDAs or BLAs yet still have a single *relevant* approval or licensure date. As CMS explained, it "will use the earliest date of approval or licensure of the initial FDA application number assigned to the NDA / BLA holder."

Revised Guidance at 101. This explanation properly reflects the interplay between sections 1320f-1(d)(3)(B) and 1320f-5(a)(2) on the one hand and section 1320f-1(e)(1) on the other. Plaintiffs' statutory challenge to CMS's interpretation thus fails.

B. CMS Properly Explained its Approach

Plaintiffs separately complain that CMS's aggregation approach is "arbitrary and capricious," Pls. Br. at 17-18, but this argument gets them no further.

As the Supreme Court has recently summarized, the "APA's arbitrary-and-capricious standard requires that agency action be reasonable and reasonably explained." *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021) (citations omitted). "Judicial review under that standard is deferential . . . [and a] court simply ensures that the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision." *Id.* Even if a reviewing court disagrees with the agency's conclusions, the court "may not substitute its own policy judgment for that of the agency." *Id.* Rather, the agency's decision is presumed valid, and a court considers only whether it "was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 416 (1971).

Here, the Revised Guidance expressly explains that "the suggestion from commenters to define a qualifying single source drug in reference to a distinct NDA or BLA is inconsistent with sections 1192(d)(3)(B) and 1196(a)(2) of the Act" "[b]ecause different dosage forms and strengths, as well as different formulations, of an active moiety / active ingredient can be approved or licensed under multiple NDAs or BLAs." Revised Guidance at 11. These provisions thereby "necessarily establish[] that the

statutory negotiation procedures apply more broadly than to a distinct NDA or BLA." *Id.* CMS's approach cannot be arbitrary when it aligns with the statute's text and structure.

Plaintiffs thus fail to establish that there is anything arbitrary about a "new product [] be[ing] deemed eligible for selection *immediately* upon approval, if it comes more than 7 years after approval of the initial product (11 years for a biological product)." Pls. Br. at 17–18. That is an intentional feature of the IRA, and the choices that *Congress* made. And as CMS explained in the Revised Guidance, aggregating across different dosage forms and strengths for the same drug, including new products of that same drug, "will decrease incentives for pharmaceutical manufacturers to engage in 'product hopping,'" Revised Guidance at 12—a practice that occurs when manufacturers introduce inconsequential changes to their drug and shift patients to that new version, potentially maintaining market exclusivity and high prices. *See* H.R. Rep. No. 116-695, at 3 (2020). Under Plaintiffs' interpretation, a manufacturer of a selected drug could attempt to evade the Negotiation Program by shifting production over to a product with the same active moiety or active ingredient in a separate NDA or BLA (which the manufacturer might seek if, for example, it wishes to market a slightly different formulation). Doctors would thus continue to prescribe what is essentially the same drug and Medicare would continue to reimburse it at current prices, solely because a manufacturer sought a new NDA. This sort of gamesmanship would undermine Congress's goals in crafting the IRA, and CMS appropriately effectuated congressional instruction to prevent this abuse.

Plaintiffs separately protest that CMS's approach "incentivizes manufacturers not to innovate." Pls. Br. at 18. Once again, however, this grievance fails to establish any arbitrariness or caprice—the same could be said of *any* statutory or regulatory change that places *any* downward pressure on future pharmaceutical profits. And CMS has taken this concern into account, explaining that it will "adjust[] the starting point for an initial offer based on clinical benefit," including unmet medical need and the impact of a selected drug on specific populations. Revised Guidance at 12, 147–51. Further, as courts have recognized, adopting an approach that allows manufacturers to product hop "may *deter* significant innovation by encouraging manufacturers to focus on switching the market to trivial or minor product reformulations rather than investing in the research and development necessary to develop riskier, but medically significant innovations." *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 659 (2d Cir. 2015) (emphasis added). In any event, this objection is nothing more than a policy disagreement with the IRA generally—and Plaintiffs cannot premise an arbitrary-and-capricious challenge in federal court on mere disagreement with how Congress and CMS weighed these competing policy concerns. The only appropriate forum for that argument is Congress.

C. CMS's Bona Fide Marketing Standard is Consistent with the Statutory Language

Plaintiffs' second statutory challenge—which contests CMS's standard for determining when a drug should be excluded from the definition of "qualifying single source drug" due to the entry of generic or biosimilar competition—fares no better.

The IRA provides that a drug will not be considered a "qualifying single source drug" if it has an approved generic "that is approved and marketed" (or, in the case of a biosimilar biological product, "that is licensed and marketed") under the Food Drug and Cosmetic Act. 42 U.S.C. § 1320f-1(e)(1)(A)(iii), (B)(iii). Implementing that statutory directive, CMS explained that "a generic drug or biosimilar biological product [is] marketed when the totality of the circumstances . . . reveals that the manufacturer of that drug or product is engaging in *bona fide* marketing of that drug or product." Revised Guidance at 102 (emphasis added). This approach, CMS explained, was designed to address "situations in which a manufacturer of a brand name drug or biologic has entered into a market-limiting agreement with a manufacturer of a generic drug or biosimilar," under which "the generic manufacturer agrees to limit production or distribution of the generic version of the drug, such that only a nominal quantity of product is allowed to enter the market." Revised Guidance at 74. The statutory directive of the Negotiation Program—which is designed to reduce Medicare expenditures on drugs that otherwise do not face meaningful competition in the market—"would not be met if a qualifying single source drug were to avoid selection or be removed from the selected drug list where generic drug or biosimilar availability is limited by the Primary Manufacturer." *Id.*; *see also id.* at 72 (noting that "a generic drug or biosimilar manufacturer could launch into the market a token or *de minimis* amount of a generic drug or biosimilar for the selected drug and the manufacturer of that selected drug could claim that the MFP should no longer apply."). Accordingly, CMS stated that it would conduct "ongoing assessments of whether the manufacturer of the

generic drug or biosimilar is engaging in bona fide marketing," consistent with congressional intent. *Id.* at 170.

Disregarding the statutory purpose, Plaintiffs protest that this interpretation departs from the IRA's language. Pls. Br. at 19-26. None of their objections finds its mark.

1. As a starting point, Plaintiffs' suggestion that the phrase "is . . . marketed" in § 1320f-(1)(e) means only being "expose[d] for sale in a market" in any capacity—even if only *de minimis*—finds no support even in the very dictionaries they cite. *See* Pls. Br. at 20; *see also, e.g.*, "Market" ("to deal in a market"), https://perma.cc/LJ4X-FEFF; "Market," ("To deal in a market; engage in buying or selling."), https://perma.cc/GMY2-4J5E. Plaintiffs cite no "accepted ordinary meaning" of the phrase "is marketed" establishing that *de minimis* sales necessarily satisfy the concept. *See* Pls. Br. at 19-20. On its face, the phrase reflects actual and ongoing commercial activity—not a token presence or even (in Plaintiffs' telling) a single sham transaction.

Further, the narrow interpretation that Plaintiffs offer is difficult to reconcile with the IRA's provisions. Pls. Br. at 19-20. Congress explicitly instructed CMS to de-select drugs that are otherwise selected for the Negotiation Program once "the Secretary *determines*" that a generic competitor "is marketed." 42 U.S.C. § 1320f-1(c)(1)(B) (emphasis added). This language acknowledges that CMS must exercise some judgment in applying this standard; there would be no need for Congress to entrust the Secretary to make a "determin[ation]" if it saw "market[ing]" as an entirely non-discretionary standard. *See, e.g.*, *Transitional Hosps. Corp. of La. v. Shalala*, 222 F.3d 1019, 1025 (D.C. Cir. 2000) (explaining that the phrase "as determined by the Secretary" is an "express

delegation of authority" to exercise "discretion" (citation omitted)). Such discretion is the antithesis of the kind of binary, "check-the-box inquiry" Plaintiffs claim is required. Pls. Br. at 19.

Notably, Congress's language in the Inflation Rebate Program—established elsewhere in the IRA—highlights that Congress knew how to expressly cabin CMS's discretion when it wishes to do so. In the Inflation Rebate Program, which requires manufacturers to provide rebates on some of their high-cost (and high-selling drugs), there is no concern about "marketing" being genuine; in that context, Congress required CMS to determine whether a drug is "being marketed, as identified in the Food and Drug Administration's National Drug Code Directory." 42 U.S.C. 1395w-114b(g)(1)(C)(ii). That database "contains information on active and certified finished and unfinished drugs submitted to FDA" and includes marketing "start" and "end" dates, as relevant, for all listed drugs. *See, e.g.*, FDA, *National Drug Code Directory*, https://perma.cc/P27C-9BRZ (current through Oct. 19, 2023) (search for "Farxiga" in the "Proprietary Name" field and select drug). By directing CMS to that specific source, Congress made clear that, in *that* context, a simple check-the-box inquiry was sufficient. *See* Pls. Br. at 23. By contrast, the fact that Congress didn't include a similar instruction in § 1192(e)(1)'s definition of qualifying single source drug suggests that it expected CMS to exercise broader discretion in the context of drug selection and deselection—where the possibility of gamesmanship in generic marketing is real. *See Weichsel v. JP Morgan Chase Bank, N.A.*, 65 F.4th 105, 113 (3d Cir. 2023) ("Where a statute or regulation uses specific language in one provision but different language in

another, the Court presumes different meanings were intended.") (alterations and citations omitted).

Plaintiffs separately assert that CMS must cabin any determination as to whether a drug "is . . . marketed" to a single "point-in-time" and never again revisit that determination. Pls. Br. at 20. But the statute provides that a drug should not be identified as a qualifying single source drug if it "*is* marketed." 42 U.S.C. § 1320f-1 (e)(1) (emphasis added). The statute does not refer to a drug that "was marketed" or "has been marketed" or "was marketed at least one time." This choice of verb tense must be presumed to be meaningful. *See Carr v. United States*, 560 U.S. 438, 448 (2010). Congress clearly contemplated that a generic drug or biosimilar product would have a continuing presence on the market in order to affect the status of the listed drug or reference product. This language is especially meaningful given that other provisions of the IRA use different language. *See, e.g.*, 42 U.S.C. § 1395w-114B(b)(5)(A) (referring to the date that a drug "was first marketed").

As a practical matter, Plaintiffs' interpretation of the IRA would also render the "marketed" requirement of section 1192(e)(1) meaningless. Under Plaintiffs' interpretation, "a generic drug or biosimilar manufacturer could launch into the market a token or de minimis amount of a generic drug or biosimilar for the selected drug and the manufacturer of that selected drug could claim that the [maximum fair price] should no longer apply." Revised Guidance at 72. That result would flout Congress's purpose. As CMS observed in its guidance, § 1192(e)(1)'s "marketed" standard was adopted to promote competition between listed and generic drugs (and between reference products and biosimilar products) and thus to bring down the price of expensive

pharmaceuticals. *See id.* at 72. Consistent with this goal, "Congress contemplated that a generic or biosimilar must have a continuing presence on the market"—otherwise, the purpose of meaningful price competition would not be achieved. *Id.* at 72–73. CMS's bona fide marketing standard properly accounts for Congress's policy goal. *See, e.g.*, *Wisc. Dep't of Revenue v. William Wrigley, Jr., Co.,* 505 U.S. 214, 231-32 (1992) ("*[D]e minimis non curat lex* . . . is part of the established background of legal principles against which all enactments are adopted"; whether "a particular activity is a de minimis deviation from a prescribed standard must, of course, be determined with reference to the purpose of the standard"); *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 309 n.1 (2014) (recognizing EPA's authority to establish *de minimis* threshold for facility's emissions of a pollutant and increases thereof).

2. Attempting to resist this common-sense result, Plaintiffs seek to draw parallels between Congress's use of the term "marketed" in § 1320f-1(e)(1) and other contexts. But those parallels collapse upon closer examination. For instance, Plaintiffs protest that CMS had previously articulated a different definition in its *Initial* Guidance. Pls. Br. at 23 (citing Initial Guidance at 82). But the portion of the Initial Guidance Plaintiffs reference—Appendix C—discussed "[m]arket data" as one of the factors that CMS must consider when determining CMS's initial price offer for a selected drug. 42 U.S.C. § 1320f-3(e)(1)(E); Initial Guidance at 82. In that context, dealing with a brand-name drug selected for negotiation, the marketing will necessarily have been genuine—otherwise the drug could not possibly have come anywhere near the top of the list of drugs with the highest Medicare expenditures for a given year (as required for selection). That CMS saw no need to account for the possibility of *de minimis* marketing in that

distinct regulatory context thus does not shed any light on the "marketed" standard under section 1192(e)(1). And the fact that CMS did not carry that definition forward into the *Revised* Guidance does not suggest that the Revised Guidance was improper—rather, it indicates that CMS reached a different conclusion about the appropriate definition, for this different context, after public input and deliberation.

Plaintiffs' reference to CMS's practices under the Medicaid Drug Rebate Program fail for essentially the same reason. Pls. Br. at 23. None of the authorities that Plaintiffs cite attempt to define the concept of "marketed" in a context where *de minimis* marketing would plausibly be a concern. *See id.* As with the Inflation Rebate Program under the IRA, it makes sense to refer to the "first marketed date," Pl.'s Ex. 4 at 18–19, ECF No. 20-4, or "market date," *Updates Under the Medicaid Drug Rebate Program*, 88 Fed. Reg. 34,238, 34,292 (May 26, 2023), in settings where the existence of such marketing is undisputed (and there is therefore no need to determine whether the marketing is bona fide).

Plaintiffs next cite language in two different statutes in an attempt to show that Congress intentionally excluded the phrase "bona fide" from the IRA. In particular, Plaintiffs contend that Congress must have intentionally excluded the phrase "bona fide" from section 1192(e) because a different Medicaid-related statute refers to "bona fide service fees." Pls. Br. at 25 (quoting 42 U.S.C. § 1396r-8(k)(1)(B)(i)(II) (as amended by § 2503(a)(2), Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010))). But the single use of "bona fide" in a different statute defining a different term for different purposes shows nothing about Congress's intent in the IRA—and is a particularly thin reed on which to assume that Congress would have

intended to hobble the Negotiation Program by allowing sham marketing of generics to foreclose the selection of high-cost name-brand drugs. Indeed, Plaintiffs' rule of interpretation—that any term is necessarily a yes-or-no "check-the-box inquiry," Pls. Br. at 19, unless it expressly includes a term like "bona fide"—would hobble an agency's ability to enforce nearly *any* statute.

Finally, Plaintiffs appeal to *Asgrow Seed Co. v. Winterboer*, 513 U.S. 179, 187-88 (1995), in which the Supreme Court addressed the meaning of "marketing" in the context of the Plant Variety Protection Act. Plaintiffs' reliance on that decision is misplaced. There was no dispute there that the defendants were engaged in a bona fide effort to sell the product at issue; indeed, the impetus for the suit was that they "were making a business out of selling [the plaintiff's] protected seed." *Id.* at 182. The question instead was whether, in addition to just showing that the defendants had built a business out of selling its seeds, the plaintiff also needed to show "extensive or coordinated selling activities, such as advertising, using an intervening sales representative, or similar extended merchandising or retail activities." *Id.* at 187 (citation omitted). Observing that interpreting "marketing" to "demand extensive promotion" would undermine the purpose of the Plant Variety Protection Act, the Court held that no such additional showing was needed when a farmer undisputedly sold thousands of bushels of soybeans. *Id.* at 187-88. At the same time, the Court recognized that whether the farmer was engaged in "marketing" within the relevant provision of the Act depended upon whether "the seed was intentionally grown for the purpose of" a particularly-defined type of "sale." *Id.* at 189-91.

Even assuming that the Supreme Court's interpretation of the Plant Variety Protection Act has anything useful to say about how this Court should interpret the Inflation Reduction Act, the Supreme Court's analysis does not assist Plaintiffs. The totality-of-the-circumstances inquiry called for by CMS's Revised Guidance seeks to determine whether another manufacturer is actually making a bona fide effort to "mak[e] a business out of selling" a generic drug that will compete with the listed drug and thereby exert meaningful price pressure, *id.* at 182, or instead is attempting only to make a *de minimis* number of sales so that it can profit through a means *other than* actually selling the drug (such as through payments from the manufacturer of the listed drug in exchange for refraining from more extensive sales of the generic competitor). That holistic inquiry is fully consistent with the Court's distinction in *Asgrow Seed Co.* between those who are genuinely competing with the producers of the original protected seeds (and are thus involved in "market[ing]") and those who are making only incidental sales without intending actually to compete in that market (and who are thus not involved in "market[ing]").

Contrary to Plaintiffs' suggestion, applying CMS's interpretation will not improperly require courts to "ponder the difficult question of how much promotion is necessary to constitute marketing." Pls. Br. at 24–25 (quoting *Asgrow Seed Co.*, 513 U.S. at 187). Congress granted the agency both the authority and the discretion to make that determination. And, exercising that authority, the agency has explained how it will determine whether a generic or biosimilar is marketed on a bona fide basis: CMS will consider "the totality of the circumstances," including PDE and AMP data, which would reveal whether there is a regular and consistent volume of sales of any relevant

generic or biosimilar product. Revised Guidance at 101–02; *see also id.* at 170 (considering "whether the generic drug or biosimilar biological product is regularly and consistently available for purchase through the pharmaceutical supply chain"). There is nothing imponderable about that standard (even if it were subject to judicial review). Ultimately, manufacturers of drugs that face genuine—or, in other words, bona fide—generic competition have nothing to fear from CMS's common-sense efforts to prevent obvious workarounds of congressional intent.

D. CMS Properly Explained Its Reasoning for Its Approach to Marketing

Plaintiffs also challenge the "bona fide marketing" standard as arbitrary and capricious—in their telling, because it relies on PDE data, which Plaintiffs allege "moves at a glacial pace." Pls. Br. at 27. But Plaintiffs' argument fails at its premise.

As CMS explained in the Revised Guidance, CMS does not intend to rely exclusively on PDE data to show how many units of a generic or biosimilar product are sold. Rather, CMS will also review AMP data, which "is the average price paid to manufacturers by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturers." Revised Guidance at 76 & n.23, 101. As CMS noted, AMP "is calculated using manufacturer sales transaction data," so it would likewise show the volume of sales for the relevant drug. *Id.* at 76 n.23. And AMP data is reported to CMS on a monthly basis pursuant to a manufacturer's reporting responsibilities under the Medicaid Drug Rebate Program. *See id.* at 77. CMS expressly included reliance on AMP data to bridge any possible delays in a generic or biosimilar showing up in PDE data. *See id.* at 76 ("AMP

data may capture sales transactions in the supply chain in situations when use of the generic drugs in Part D plans has not yet become evident in the PDE data.").

Moreover, CMS explained that it will also consider "multiple" other sources as appropriate. *See id.* at 77 (explaining that CMS will determine whether a generic or biosimilar is being bona fide marketed on a continuing basis based on "a totality-of-the-circumstances inquiry that will not necessarily turn on any one source of data"); *see id.* at 165 (considering "the totality of the circumstances, including" "PDE and AMP data"); *id.* at 170 (considering "whether the generic drug or biosimilar biological product is regularly and consistently available for purchase through the pharmaceutical supply chain and whether any licenses or other agreements between a Primary Manufacturer and a generic drug or biosimilar manufacturer limit the availability or distribution of the selected drug"); *id.* ("CMS reserves the right to also use other available data and informational sources on market share and relative market competition of the generic drug or biosimilar.").[8]

As a final resort, Plaintiffs allege that the "bona fide marketing" standard "obliterates the statutory protection" afforded to manufacturers by excluding drugs which face generic competition. Pls. Br. at 28. But the standard requires only that a generic drug or biosimilar is marketed at more than a "token or de minimis amount."

[8] In any event, Plaintiffs also exaggerate the delay in PDE data. CMS notes that "generally this timing lag is relatively short as Part D plans are instructed to submit original PDEs to CMS within 30 days following the date the claim is received or date of service (whichever is greater) and the average turnaround time to date of submission is fewer days." Revised Guidance at 76. Moreover, as CMS explains, "Part D rules allow for relatively quick formulary substitution of generic drugs for selected drugs and the addition of generic drug and biosimilar versions of selected drugs such that both should be evident in the PDE data relatively quickly." *Id.*

Revised Guidance at 72. This is necessary to be consistent with the text and purpose of the statute, which is to lower drug prices for Medicare through negotiation or price competition. *See id.* If a generic drug or biosimilar is being marketed only a token or *de minimis* amount, the listed drug is not subject to "meaningful competition" and thus does not fulfill the statute's purpose. *Id.* at 74. Plaintiffs cannot seriously allege that requiring more than mere token or *de minimis* marketing—*i.e.*, requiring more than non-meaningful competition—"obliterates [their] statutory protection." Pls. Br. at 28. In fact, it will not affect them at all, in the event that they ever face genuine generic competition.

Nor is token or *de minimis* marketing merely a theoretical worry. The Revised Guidance expressly cites situations in which CMS was aware of manufacturers of brand-name drugs or biologics entering into sham agreements with generic-drug manufacturers to provide mere token or *de minimis* competition. *See* Revised Guidance at 74. In such sham agreements, the generic drug manufacturer "agrees to limit production or distribution of the generic version of the drug, such that only a nominal quantity of product is allowed to enter the market," which results in "a lack of meaningful price competition." *Id.* The "bona fide marketing" inquiry is thus necessary to implement the IRA's text and purpose. Doing so is neither arbitrary nor capricious. Like CMS's aggregation requirement, CMS's adoption of the "bona fide marketing" standard is the product of reasoned decision-making and consistent with the statute. It should therefore be upheld.

* * *

In bringing their APA claims, Plaintiffs have failed to satisfy threshold Article III requirements and have sought to challenge a determination that does not affect them and that Congress explicitly shielded from review. The Court lacks subject matter jurisdiction to entertain those claims—which would, in any event, fail on the merits. Counts I and II of Plaintiffs' complaint should therefore be dismissed for lack of jurisdiction, and Plaintiffs' motion for summary judgment should be denied.

IV. The Negotiation Program Does Not Violate The Due Process Clause Because It Is Voluntary

Disposing of AstraZeneca's APA challenges on either jurisdictional or merits grounds leaves solely its argument that the IRA violates the Due Process Clause. But this argument is likewise unavailing. The *Chamber* court recently rejected an analogous due process claim brought by the U.S. Chamber of Commerce, finding that it failed "as a matter of law." *See Chamber*, 2023 WL 6378423, at *11. And for good reason.

The Due Process Clause protects against the deprivation "of life, liberty, or property, without due process of law." U.S. Const. amend. V. But the threshold "inquiry in every due process challenge is whether the plaintiff has been deprived of a protected interest." *Am. Mfrs. Mut. Ins. Co. v. Sullivan*, 526 U.S. 40, 59 (1999). And it is well established that a "property owner must be *legally compelled* to engage in price-regulated activity for regulations to" impugn a property interest that the Fifth Amendment protects. *Garelick v. Sullivan*, 987 F.2d 913, 916 (2d Cir. 1993) (emphasis added); *see, e.g., Bowles v. Willingham*, 321 U.S. 503, 517-18 (1944) (rent controls do not constitute prohibited taking because statute did not require landlords to offer their

apartments for rent). When an entity "voluntarily participates in a price-regulated program or activity, there is no legal compulsion to provide service and thus there can be no" deprivation of property. *Garelick*, 987 F.2d at 916 (citing cases); *Franklin Mem'l Hosp.*, 575 F.3d at 129 ("Of course, where a property owner voluntarily participates in a regulated program, there can be no unconstitutional taking.").

That is the case with Medicare conditions generally. As courts have repeatedly explained, "participation in the Medicare program is a voluntary undertaking." *Livingston Care Ctr., Inc. v. United States*, 934 F.2d 719, 720 (6th Cir. 1991); *see Baptist Hosp. E. v. Sec'y of Health & Hum. Servs.*, 802 F.2d 860, 869-70 (6th Cir. 1986) (same); *see also Baker Cnty. Med. Servs., Inc. v. U.S. Att'y Gen.*, 763 F.3d 1274, 1279-80 (11th Cir. 2014) (surveying cases); *Garelick*, 987 F.2d at 917 (same); *see generally Chamber*, 2023 WL 6378423, at *11 (discussing this precedent). Unlike public utilities, which "generally are compelled" by statute "to employ their property to provide services to the public," no statutory provision *requires* entities to participate in Medicare or to sell their property to Medicare beneficiaries. *Garelick*, 987 F.2d at 916. So, whether confronting regulations limiting physician fees, nursing-home payments, or hospital reimbursements, courts have been unequivocal and consistent: entities are not required to serve Medicare beneficiaries, and thus the government deprives them of no property interest for purposes of the Fifth Amendment when it imposes caps on the amount the government will reimburse. *Baptist Hosp.*, 802 F.2d at 869-70; *see also Se. Ark. Hospice, Inc. v. Burwell*, 815 F.3d 448, 450 (8th Cir. 2016) (no taking because plaintiff "voluntarily chose to participate in the Medicare hospice program"); *Baker Cnty.*, 763 F.3d at 1279-80 (rejecting hospital's "challenge [to] its rate of compensation in a regulated industry for

an obligation it voluntarily undertook . . . when it opted into Medicare"); *Franklin Mem'l Hosp.*, 575 F.3d at 129-30; *Garelick*, 987 F.2d at 916-19; *Burditt v. HHS*, 934 F.2d 1362, 1376 (5th Cir. 1991); *Whitney v. Heckler*, 780 F.2d 963, 972 (11th Cir. 1986) ("[A]ppellants are not required to treat Medicare patients, and the temporary freeze is therefore not a taking within the meaning of the Fifth Amendment."). If a provider dislikes the conditions offered by the government, it can simply withdraw from the program. *Baptist Hosp.*, 802 F.2d at 869-70. There is no legal compulsion to participate.

As the *Chamber* court correctly recognized in rejecting a due process claim, the Negotiation Program is no different. *See Chamber*, 2023 WL 6378423, at *11. The IRA regulates neither the prices manufacturers may charge for drugs generally nor the conduct of manufacturers that elect not to participate in Medicare and Medicaid. *See, e.g.*, 42 U.S.C. § 1320f-1(b), (d). Rather, Congress established the Negotiation Program in an effort to reduce how much Medicare pays for selected drugs provided to Medicare beneficiaries. *See id.* § 1320f-2(a)(2). As CMS noted, "the IRA expressly connects a . . . [m]anufacturer's financial responsibilities under the voluntary Negotiation Program to that manufacturer's voluntary participation" in Medicare and Medicaid. Revised Guidance at 120; *see also* 26 U.S.C. § 5000D(c)(1) (providing that tax consequences are only applicable if the manufacturer continues to participate in Medicare and Medicaid).

Drug manufacturers that do not wish to make their drugs available to Medicare beneficiaries at negotiated prices can avoid doing so by withdrawing from the Medicare and Medicaid programs. *See Chamber*, 2023 WL 6378423, at *11; *see also* Revised Guidance at 33-34, 120-21, 129-31. The Social Security Act provides that the relevant Medicare-participation agreements (which trigger withdrawal from the Negotiation

Program) can be terminated by CMS in 30 days for "good cause." *See* 42 U.S.C. §§ 1395w-114a(b)(4)(B)(i), 1395w-114c(b)(4)(B)(i); *see generally United States ex rel. Polansky v. Exec. Health Res., Inc.*, 143 S. Ct. 1720, 1730 n.2 (2023) ("good cause" is "a uniquely flexible and capacious concept, meaning simply a legally sufficient reason"). Relying on this provision, CMS's Revised Guidance explains that if a "[m]anufacturer determines . . . that it is unwilling to continue its participation in the Negotiation Program and provides a termination notice," CMS will treat that determination as providing "good cause to terminate the . . . Manufacturer's agreement(s) . . . and thus facilitate an expedited" termination in 30 days. Revised Guidance at 130. As a result, "any manufacturer that declines to enter an Agreement for the Negotiation Program may avoid incurring excise tax liability by submitting the notice and termination requests . . . 30 days in advance of the date that excise tax liability otherwise may begin to accrue." *Id.* at 33-34. Alternatively, a manufacturer can divest its interest in the selected drug to a separate entity—or otherwise stop selling it to Medicare beneficiaries, either permanently or temporarily, which would expose it to no penalty or tax. *Id.* at 131-32. Any of these options can be accomplished far faster than the "11 months" timeline Plaintiffs posit. Pls. Br. at 31.

Notably, the Supreme Court has found no violation of a property right where a property owner could choose to leave a price-capped market with "6 or 12 *months* notice." *Yee v. City of Escondido*, 503 U.S. 519, 527-28 (1992) (emphasis added). Manufacturers have far more flexibility here. And, contrary to what Plaintiffs claim, Pls. Br. at 29-32, manufacturers "are not legally compelled to participate in the Program" at all, nor forced to make sales they don't want to make. *Chamber*, 2023 WL

6378423, at *11. Unlike laws requiring utilities to serve the public, the IRA does not "compel[] [manufacturers] to employ their property to provide [drugs] to" Medicare beneficiaries—at any price. *Garelick*, 987 F.2d at 916. As courts have explained in rejecting Fifth Amendment challenges to other Medicare conditions, "[i]f any provider fears that its participation [in the program] will drive it to insolvency, it may withdraw from participation." *Baptist Hosp.*, 802 F.2d at 869-70.

Simply put, Plaintiffs cannot establish that the Negotiation Program is anything other than "completely voluntary." *Chamber*, 2023 WL 6378423, at *11. And because it is completely voluntary, the Program "simply does not involve a forced taking of property" or any other infringement of a property interest that would trigger a due process inquiry at all. *Minn. Ass'n of Health Care Facilities, Inc. v. Minn. Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984). As the *Chamber* court correctly observed, because "there is no constitutional right (or requirement) to engage in business with the government, the consequences of that participation cannot be considered a constitutional violation." *Chamber*, 2023 WL 6378423, at *11 (citing *Livingston Care*, 934 F.2d at 720). Plaintiffs may be dissatisfied with the policy choices that Congress made in creating the Negotiation Program. But Plaintiffs' dissatisfaction does not establish a constitutional claim.

CONCLUSION

For these reasons, the Court should dismiss Counts I and II of Plaintiffs' complaint for lack of subject-matter jurisdiction, and enter judgment for Defendants on Count III.

Dated: November 1, 2023

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, *et al.* v. XAVIER BECERRA, in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, *et al.*	Civ. No. 1:23-cv-931-CFC

DECLARATION OF CHERI RICE

I, Cheri Rice, pursuant to 28 U.S.C. § 1746, and based upon my personal knowledge and information made known to me in the course of my employment, hereby make the following declaration with respect to the above-captioned matter:

1. I currently serve as the Deputy Director of the Center for Medicare at the Centers for Medicare & Medicaid Services ("CMS"). In my role as Deputy Director, I oversee implementation of the Medicare Drug Price Negotiation Program including the process by which CMS selected the first 10 drugs for negotiation.

2. The Inflation Reduction Act ("IRA") (Pub. L. 117-169) established the Medicare Drug Price Negotiation Program to enable Medicare to negotiate maximum fair prices with willing manufacturers for certain high expenditure, single source drugs and biological products. Under section 1192(a)(1) of the Social Security Act ("Act"), for the first year of the Negotiation Program (the "initial price applicability year 2026"), the Secretary is required to select and publish a list of the 10 negotiation-eligible drugs

with the highest "Total Expenditures" under Medicare Part D. The Secretary has delegated this authority to CMS. Under Section 1192(d) of the Act, to be a negotiation-eligible drug, a drug must be, among other things, a "Qualifying Single Source Drug." In accordance with section 1192(e)(1) of the Act, a drug or biological product is not a Qualifying Single Source Drug if it is the listed drug for any drug approved and marketed under an Abbreviated New Drug Application ("ANDA") under section 505(j) of the Food, Drug & Cosmetic Act or the referenced biological product for any biological product that is licensed and marketed under section 351(k) of the Public Health Service Act. Drugs approved and marketed under section 505(j) of the FD&C Act are colloquially referred to as generic drugs.

3. Section 1192(d)(3)(B) of the Act states that CMS shall use data that are 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, package size, or package type of the drug for purposes of determining whether a Qualifying Single Source Drug is a negotiation-eligible drug under section 1192(d)(1) of the Act and applying the exception for small biotech drugs under section 1192(d)(2) of the Act. Similarly, section 1196(a)(2) of the Act 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."

4. On March 15, 2023, CMS published an initial memorandum to provide interested parties with information regarding CMS' implementation of the first year of the Negotiation Program, including CMS' process for identifying selected drugs. On June 30, 2023, CMS published revised guidance for initial price applicability year 2026, which addressed public comments received in response to the initial memorandum and set forth CMS' final policies on the topics discussed for initial price applicability year 2026.

5. The Revised Guidance provided, among other things, that for the purposes of identifying the 10 selected drugs for initial price applicability year 2026, CMS would identify potential Qualifying Single Source Drugs, in accordance with sections 1192(d)(3)(B) and 1196(a)(2) of the Act, by using 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. *See* Revised Guidance at 99. The Revised Guidance also provided that in determining whether a drug is the listed drug for any [generic] drug that is approved and marketed under section 505(j) of such Act, CMS will consider a generic drug to be marketed when the totality of the circumstances and data reveals that the manufacturer of that drug is engaging in bona fide marketing of that drug. *See id.* at 102.

6. On August 29, 2023, CMS announced the 10 drugs for which it would seek to negotiate prices during the Negotiation Program's first year. One of those 10 selected drugs is Farxiga (dapagliflozin), which is manufactured by AstraZeneca AB.

7. I understand that Plaintiffs in this action challenge CMS's interpretation of the IRA in two respects. According to Plaintiffs, the statute prohibits CMS from (a) treating all dosage forms and strengths of the drug with the same active moiety as part of the same Qualifying Single Source Drug if those different forms of the drug are approved and marketed under different NDAs, or (b) considering whether a generic drug is being marketed on a bona fide basis.

8. Adopting either of Plaintiffs' interpretations of the statute, however, would have had no effect on Farxiga's selection by the Secretary as one of the 10 selected drugs for initial price applicability year 2026.

9. First, Farxiga is approved and marketed under a single NDA (NDA #202293). Thus, the "Total Expenditures" for Farxiga under Medicare Part D would be the same whether CMS aggregated expenditures by active moiety across multiple NDAs or not. Moreover, the aggregation of expenditures by active moiety of other drugs did not affect Farxiga's inclusion on the list of top 10 drugs by "Total Expenditures" for initial price applicability year 2026. Indeed, in this case, applying Plaintiffs' approach of disaggregating expenditures for different drug formulations with the same active moiety if those formulations are approved and marketed under different NDAs could only ever have the effect of causing Farxiga to rise in the "Total Expenditure" rankings (by, for example, causing a drug above Farxiga in the rankings to fall below it after disaggregating expenditures of multiple formulations of the other drug). Accordingly, the Revised Guidance interpretation of "Qualified Single Source

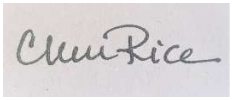
Drug" as requiring aggregation of expenditures by active moiety had no effect on Farxiga's selection for initial price applicability year 2026.

10. Second, there are no approved ANDAs for a generic version of Farxiga. Thus, Farxiga "is not the listed drug for any drug that is approved and marketed under section 505(j)" of the Food, Drug & Cosmetic Act and thus is a Qualifying Single Source Drug under section 1192(e)(1) of the Act. Accordingly, CMS' bona fide marketing interpretation had no effect on Farxiga's selection for initial price applicability year 2026. Because there are no approved generic versions of Farxiga, CMS' interpretation of the "marketed" requirement as requiring bona fide marketing is irrelevant.

11. In sum, even if CMS had applied either or both of the interpretations of the statute I understand Plaintiffs have advanced in this lawsuit, it would have had no effect on Farxiga's selection for initial price applicability year 2026.

12. As the Revised Guidance itself makes clear, CMS's Revised Guidance applies only for initial price applicability year 2026. *See* Revised Guidance at 2. In the future, CMS will issue new guidance to govern future price applicability years.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.



Executed on November 1, 2023

Cheri Rice
Deputy Director
Center for Medicare
Centers for Medicare & Medicaid Services

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, *et al.* v. XAVIER BECERRA, in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, *et al.*	Civ. No. 1:23-cv-931-CFC

[PROPOSED] ORDER

Upon consideration of the parties' cross-motions for summary judgment, it is hereby **ORDERED** that Plaintiffs' motion for summary judgment is **DENIED**; and it is further **ORDERED** that Defendants' cross-motion for summary judgment is **GRANTED**.

Date:

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Colm F. Connolly
United States District Judge