No. 24-1819

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

ASTRAZENECA PHARMACEUTICALS LP et al.,

Plaintiffs-Appellants,

v.

SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,

Defendants-Appellees.

On Appeal from the United States District Court
for the District of Delaware

BRIEF FOR APPELLEES

Of Counsel:

SAMUEL R. BAGENSTOS
General Counsel

JOEL McELVAIN
Acting Deputy General Counsel

JANICE L. HOFFMAN
Associate General Counsel

MATTHEW A. CAMPBELL
BRIDGETTE L. KAISER
ANANT KUMAR
Attorneys
U.S. Department of Health & Human Services

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

DAVID C. WEISS
United States Attorney

MICHAEL S. RAAB
LINDSEY POWELL
STEVEN A. MYERS
DAVID L. PETERS
CATHERINE PADHI
Attorneys, Appellate Staff
Civil Division, Room 7712
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530
(202) 616-5372

TABLE OF AUTHORITIES

Page

COMBINED CERTIFICATIONS

ADDENDUM

TABLE OF AUTHORITIES

Cases: **Page(s)**

U.S. Constitution:

Statutes:

Regulations:

Rules:

Legislative Materials:

Other Authorities:

INTRODUCTION

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

As directed by Congress, CMS issued guidance interpreting certain statutory terms and explaining, among other things, how the agency would

select "qualifying single source drugs" for the first negotiation cycle. The guidance expressly applies only to that first cycle, for which negotiated prices will take effect in 2026, and does not govern subsequent cycles.

Plaintiffs AstraZeneca Pharmaceuticals LP and AstraZeneca AB (collectively, AstraZeneca) filed suit before CMS selected any drugs for negotiation. They challenge under the Administrative Procedure Act (APA) two aspects of the agency's interpretation of "qualifying single source drug," and they challenge under the Due Process Clause of the Fifth Amendment the IRA provisions establishing the Negotiation Program. While this suit was pending, CMS selected a single drug manufactured by AstraZeneca—Farxiga—for the first negotiation cycle.

As the district court held, AstraZeneca lacks standing to assert its APA claims because it has failed to identify a concrete harm that will actually or imminently result from the CMS guidance. It is undisputed that neither of the challenged interpretations had any bearing on the selection of Farxiga for the first negotiation cycle. AstraZeneca contends instead that, in making business decisions, it must account for the possibility that future application of the guidance could reduce the value of as-yet-undeveloped drugs or delay the deselection of a drug that has become

subject to generic competition. But it is well settled that a plaintiff may not establish standing by taking action to mitigate possible future harms that are themselves too speculative to support standing. And plaintiffs compound that shortcoming by failing to identify with specificity the decisions allegedly affected. Plaintiffs' theory also fails because the challenged guidance applies only to the first negotiation cycle and will not govern most of the future eligibility determinations with which plaintiffs are concerned. Although the district court did not reach the issue, the courts additionally lack jurisdiction to consider these APA claims because the IRA expressly precludes review of the challenged determinations.

The district court correctly rejected AstraZeneca's due process claim on the merits because AstraZeneca failed to identify a protected property interest affected by the challenged program. On appeal, AstraZeneca principally asserts that the Negotiation Program deprives it of "core property interests in its patented drugs" and "the right to determine the revenue it derives therefrom." Br. 43. But AstraZeneca has "never . . . explain[ed] how the IRA affects or could affect a patent right." JA41-42. And plaintiffs lack any "right to determine revenue" earned from participation in a government program.

To the extent that AstraZeneca asserts an interest in "the ability to sell products to Medicare beneficiaries at prices above" the negotiated price, its argument fails because no one "is entitled to sell the Government drugs at prices the Government won't agree to pay." JA42. As the courts of appeals have uniformly held, participation in Medicare is voluntary, and anyone dissatisfied with the prices offered by the government may choose to sell their products to other buyers. Just as a military contractor has no legally protected interest in charging the government a particular price for its goods, drug manufacturers have no right to dictate the price the government will pay. The profitability of selling drugs to Medicare in no way alters the analysis.

STATEMENT OF JURISDICTION

AstraZeneca invoked the district court's jurisdiction pursuant to 28 U.S.C. §§ 1331, 1346, 1361, 2201, and 2202. JA61. The district court's jurisdiction over AstraZeneca's APA claims is contested. *See infra*, pp. 28-41. On March 1, 2024, the district court granted the government's motion for summary judgment and entered a final judgment in the government's favor. JA48-50. AstraZeneca filed a timely notice of appeal

on April 29, 2024. JA51; *see* Fed. R. App. P. 4(a)(3). This Court has jurisdiction pursuant to 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES

1. Whether the district court correctly held that AstraZeneca lacks standing to assert its APA claims;

2. Whether, in the alternative, the APA claims are barred by the IRA's express limitations on judicial review of the agency's determination of qualifying single-source drugs, its determination of negotiation-eligible drugs, and its selection of drugs, 42 U.S.C. § 1320f-7(2); and

3. Whether the district court correctly held that AstraZeneca's Fifth Amendment due process claim fails on the merits because AstraZeneca has no constitutionally protected property interest in selling drugs to Medicare at prices above those the government is willing to pay.

STATEMENT OF THE CASE

A. Medicare and the Escalating Cost of Prescription Drug Coverage

Medicare provides federally funded health coverage for individuals who are 65 or older or who have certain disabilities or medical conditions. 42 U.S.C. § 1395 *et seq.* CMS administers Medicare on behalf of the Secretary of Health and Human Services.

Medicare is divided into "Parts" that set forth the terms by which Medicare will pay for specific benefits. *See Northeast Hosp. Corp. v. Sebelius*, 657 F.3d 1, 2 (D.C. Cir. 2011). Medicare Part B covers outpatient care as well as the cost of drugs administered as part of that care. *Cares Cmty. Health v. HHS*, 944 F.3d 950, 953 (D.C. Cir. 2019). Medicare Part D, which Congress added in 2003, 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.* In enacting Part D, Congress initially barred CMS from negotiating Part D drug prices or otherwise interfering in the arrangements between drug manufacturers and insurance plans. 42 U.S.C. § 1395w-111(i). But that model led to skyrocketing drug prices that saddled beneficiaries with unaffordable copays and threatened the long-term solvency of the program.

The cost to the federal government of providing prescription drug coverage under Medicare Part B and Part D is immense. In 2021 alone, the federal government spent more than $250 billion on drugs covered by these programs. *See* KFF, *10 Prescription Drugs Accounted for $48 Billion in*

Medicare Part D Spending in 2021, or More Than One-Fifth of Part D Spending That Year (July 12, 2023), https://perma.cc/4CYL-KYRM. That figure has risen dramatically over the last decade and is "projected to continue rising during the coming decade, placing increasing fiscal pressure[]" on the federal budget. Office of the Assistant Sec'y for Planning & Evaluation, HHS, *Report to Congress: Prescription Drug Pricing* 8 (May 20, 2020), https://perma.cc/5GEN-LZ7F (2020 HHS Report to Congress). Medicare Part D spending in particular "is projected to increase faster than any other category of health spending." S. Rep. No. 116-120, at 4 (2019).

In addition to its effects on the federal treasury, the high cost of prescription drug coverage directly burdens Medicare beneficiaries by affecting their premiums and out-of-pocket payments. Because Part B premiums are automatically set to cover 25% of aggregate Part B spending, higher total spending on prescription drug coverage results in higher premiums for individual enrollees. *See* 2020 HHS Report to Congress, at 11. Beneficiaries also pay 20% of their Part B prescription drug costs out of pocket. Part D premiums are similarly based on a plan's anticipated costs, and many Part D plans likewise require beneficiaries to pay additional cost-sharing amounts.

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

These rising costs are in large part attributable to manufacturers' considerable latitude in dictating the prices that Medicare pays for the most expensive drugs. Because formulas for drug prices under Medicare Part B and Part D were tied to the price manufacturers charged private buyers, *see* 42 U.S.C. §§ 1395w-3a(b), 1395w-101 *et seq.*, manufacturers of drugs with no generic competition could "effectively set[] [their] own Medicare payment rate[s]" by dictating sales prices in the broader market. Medicare Payment Advisory Comm'n, *Report to the Congress: Medicare and the Health Care Delivery System* 84 (June 2022), https://perma.cc/5X4R-KCHC. Drug companies' substantial leeway in this respect was compounded by the

significant legal and practical obstacles to market entry faced by generic competitors, along with the practice of many manufacturers of protecting their market share by entering into "settlements" with generic manufacturers to limit generic marketing. *See, e.g.*, Sarah M.E. Gabriele & William B. Feldman, *The Problem of Limited-Supply Agreements for Medicare Price Negotiation*, 330 JAMA 1223 (2023). As a result of these factors, there are in many instances "no market forces to apply downward pressure to provide lowered prices to the millions who have coverage for such medicines under Medicare." H.R. Rep. No. 116-324, pt. 2, at 37-38.

Other federal agencies, including the Departments of Defense and Veterans Affairs, operate their drug benefit programs differently and have not been subject to skyrocketing costs. Manufacturers that wish to sell drugs to the government through these programs have long been required to negotiate with the government and reach agreements subject to statutorily defined ceiling prices. *See* 38 U.S.C. § 8126(a)-(h). As a consequence, manufacturers often sell drugs to these agencies for roughly half as much as they charge Medicare Part D. *See* Cong. Budget Office, *A Comparison of Brand-Name Drug Prices Among Selected Federal Programs* 16 (Feb. 2021), https://perma.cc/ YY2E-GM97. "[I]f Medicare had received

the same discounts as the Departments of Defense and Veterans Affairs, taxpayers would have saved" billions. Staff of H. Comm. on Oversight & Reform, *Drug Pricing Investigation: AbbVie—Humira and Imbruvica* 13-15 (May 2021), https://perma.cc/Z2KG-ZKW3.

B. The IRA's Drug Price Negotiation Program

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

By statute, the only drugs eligible for selection in the Negotiation Program are "qualifying single source drugs"—*i.e.*, those that account for the highest Medicare expenditures, that have no generic or biosimilar competitors, and that have been on the market for at least seven years.

42 U.S.C. § 1320f-1(e). In determining which drugs are eligible for negotiation, the IRA directs CMS to use "data that is aggregated across dosage forms and strengths of the drug, including new formulations of the drug." *Id.* § 1320f-1(d)(3)(B); *see also id.* § 1320f-5(a)(2). From the resulting list of eligible drugs, the Act directs the agency to select up to 10 drugs for participation in the first negotiation cycle. *Id.* § 1320f-1(a)(1). Additional drugs are to be selected for future negotiation cycles. *Id.* § 1320f-1(a)(2)-(4). Drugs that were initially eligible for selection may become ineligible if, for example, an approved generic competitor or licensed biosimilar "is . . . marketed" by the relevant time. *Id.* § 1320f-1(e)(1).

After selecting the negotiation-eligible drugs with the highest Medicare expenditures, CMS signs agreements with manufacturers that are willing to engage in the negotiation process. 42 U.S.C. § 1320f-2. The object of the negotiations is to reach agreement on what the statute refers to as the "maximum fair price" that Medicare will pay for each selected drug. *Id.* § 1320f-3. To guide the negotiation process, Congress imposed a "[c]eiling for [the] maximum fair price," which is based on specified pricing data for each drug, *id.* § 1320f-3(c), and it directed the agency to "aim[] to achieve the lowest maximum fair price" that the manufacturer

will accept, *id.* § 1320f-3(b)(1). If negotiations are successful, the manufacturer signs an addendum to the negotiation agreement establishing the maximum price at which the drug will be made available to Medicare beneficiaries. *Id*. § 1320f-3.

Congress specified that, for drugs selected for the first negotiation cycle, any negotiated prices will take effect for Part D on January 1, 2026. 42 U.S.C. § 1320f(b)(1), (2).[1] To ensure that negotiated prices can be implemented by that date, Congress established a series of interim deadlines to govern the process. *Id*. § 1320f(d). And to ensure that litigation would not disrupt negotiations, Congress expressly prohibited judicial review of certain agency decisions, including the determination of qualifying single source drugs and negotiation-eligible drugs and the selection of drugs for negotiation. *Id.* § 1320f-7.

In enacting the Negotiation Program, Congress altered the terms of its offer to continue purchasing drugs for Medicare. A drug manufacturer that does not wish to participate in the Negotiation Program has several

[1] For Medicare Part B, the drug-selection and negotiations occur on a later timeframe, and any negotiated prices will take effect in 2028. *See* 42 U.S.C. § 1320f-1(a)(3).

options. Because "participation in the Medicare program is a voluntary undertaking," JA43 (quotation marks omitted), a manufacturer may withdraw from Medicare and Medicaid, and thus not be subject to any of the Negotiation Program's requirements. 26 U.S.C. § 5000D(c)(1); *see also* CMS, *Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2026*, at 120-21 (June 30, 2023) (Revised Guidance) (JA238-39). Alternatively, a manufacturer may transfer its ownership of the selected drug to another entity and continue to sell other drugs to Medicare. *See* JA249-50. A manufacturer that pursues neither of these options may continue to sell the selected drug to Medicare beneficiaries at the non-negotiated price subject to an excise tax. *See* 26 U.S.C. § 5000D(a)-(h); *see also* Internal Revenue Service Notice No. 2023-52, 2023-35 I.R.B. 650 (Aug. 4, 2023), https://perma.cc/B9JZ-ZG7P (IRS Notice).

C. The Negotiation Program's Implementation

1. In addition to establishing the statutory requirements above, Congress instructed the agency to implement the Negotiation Program through "program instruction or other forms of program guidance" for the first few negotiation cycles. IRA § 11001(c), 136 Stat. at 1854. In March

2023, CMS issued initial guidance explaining how it planned to implement certain aspects of the statute and soliciting public comment. *See* CMS, *Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments* (Mar. 15, 2023), https://perma.cc/8X4K-CVD8. After considering thousands of comments, CMS published the Revised Guidance in June 2023. JA119. The Revised Guidance applies only to the first negotiation cycle—*i.e.*, to selected drugs for which a negotiated price could first take effect in 2026 (referred to as "initial price applicability year 2026"). JA119. "CMS will issue new guidance to govern future price applicability years." JA321.

Several aspects of the Revised Guidance are relevant to this litigation. First, the Revised Guidance explains how CMS determines whether a product constitutes a "qualifying single source drug" that may be selected for negotiation. 42 U.S.C. § 1320f-1(e). The Act specifically "directs CMS to establish procedures 'to compute and apply the maximum fair price across different strengths and dosage forms of a selected drug.'" JA129 (quoting 42 U.S.C. § 1320f-5(a)(2)). The Revised Guidance explains that CMS will consider a qualifying single source drug to include "all dosage forms and

strengths of the drug with the same active moiety and the same holder of a New Drug Application (NDA), inclusive of products that are marketed pursuant to different NDAs." JA217 (footnote omitted).[2] Because "different dosage forms and strengths, as well as different formulations, . . . of an active moiety . . . can be approved . . . under multiple NDAs," considering products marketed pursuant to different NDAs in identifying a potential qualifying single source drug aligns with the statutory command to use data aggregated across different dosage forms and strengths of the drug. JA129 (citing 42 U.S.C. § 1320f-1(d)(3)(B)).

Second, the Revised Guidance explains the criteria for determining when generic competition excludes a drug from participation in the Negotiation Program. Under the IRA, a drug is excluded where an approved generic competitor "is . . . marketed," 42 U.S.C. § 1320f-1(e)(1)(A)(iii), (B)(iii), and the Revised Guidance explains that CMS will consider a generic drug to be marketed "when the totality of the

[2] Active moiety is "[t]he molecule or ion . . . responsible for the physiological or pharmacological action of the drug substance." *Kisor v. Wilkie*, 588 U.S. 558, 567 n.1 (2019) (first alteration in original) (quoting 21 C.F.R. § 314.3(b) (2018)). An NDA is an application that the U.S. Food and Drug Administration (FDA) must approve for a manufacturer to market an innovator prescription drug in the United States. *See* 21 U.S.C. § 355(c).

circumstances . . . reveals that the manufacturer of that drug or product is engaging in bona fide marketing of that drug or product," JA220. The bona fide marketing inquiry turns on "whether the generic drug . . . 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 . . . manufacturer limit the availability or distribution of the selected drug." JA288.

Finally, the Revised Guidance sets out procedures for manufacturers that choose not to participate in the Negotiation Program. JA247-49. In those circumstances, CMS will "facilitate an expeditious termination of" a manufacturer's Medicare agreements before the manufacturer would incur liability for any excise tax, so long as the manufacturer notifies the agency of its desire to withdraw at least 30 days in advance of when the tax would otherwise begin to accrue. JA151-52. The Treasury Department and the Internal Revenue Service issued a notice explaining that, when excise tax liability is triggered, the tax will be imposed only on the manufacturer's "sales of designated drugs dispensed, furnished, or administered to individuals under the terms of Medicare" — *i.e.*, not on drugs dispensed, furnished, or administered outside of Medicare. IRS Notice 3. Although

the Treasury Department intends to undertake rulemaking on this subject, the interpretation in the notice is effective immediately. *See id.* at 5.

2. In August 2023, CMS published the list of drugs selected for the first negotiation cycle. *See* HHS, *HHS Selects the First Drugs for Medicare Drug Price Negotiation* (Aug. 29, 2023), https://perma.cc/A36P-Z88Z. The 10 drugs selected accounted for more than $50 billion of gross Medicare Part D spending between June 2022 and May 2023, and Medicare beneficiaries paid a total of $3.4 billion in out-of-pocket costs for those drugs in 2022 alone. *See* CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026* (Aug. 2023), https://perma.cc/X37F-RC94. Among the drugs selected for negotiation was AstraZeneca's drug Farxiga, *id.*, which contains the active moiety dapagliflozin and is approved and marketed under a single NDA, JA320. No other NDA is approved for a drug containing dapagliflozin as its only active moiety. AstraZeneca executed an agreement to negotiate the price of Farxiga. *See* CMS, *Medicare Drug Price Negotiation Program: Manufacturer Agreements for Selected Drugs for Initial Price Applicability Year 2026* (Oct. 3, 2023), https://perma.cc/3222-VPEE.

In accordance with the schedule established by Congress, CMS presented AstraZeneca and the other manufacturers of selected drugs with initial offers by February 1, 2024. *See* CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026* (Aug. 15, 2024), https://perma.cc/6MVG-BZP8. Each participating manufacturer responded with a counteroffer by March 2, 2024. *Id.* CMS subsequently held three negotiation meetings with each company to discuss the offers and relevant evidence. *Id.* Many companies proposed revised counteroffers during these meetings, and CMS accepted four of these revised counteroffers outright. *Id.* By August 1, 2024, CMS and the participating manufacturers had agreed to a negotiated price for each of the 10 selected drugs. *Id.* Assuming that none of the 10 manufacturers withdraws from Medicare and Medicaid by December 2025, these prices will take effect on January 1, 2026. 42 U.S.C. §§ 1320f(b), (d), 1320f-2(a), 1320f-3(b). *See generally* JA209-10.

D. Prior Proceedings

In August 2023, before CMS published the list of selected drugs, AstraZeneca filed this suit, asserting claims under the APA and the Due Process Clause of the Fifth Amendment. Dkt. No. 1; JA319. The APA

claims challenge two aspects of the Revised Guidance's interpretation of "qualifying single source drug": (1) the determination that such a drug includes all dosage forms and strengths of the drug with the same active moiety, even if approved under separate NDAs; and (2) the determination that a generic competitor must be marketed in a bona fide manner to exclude a drug from selection. The due process claim asserts that the Negotiation Program deprived AstraZeneca of a protected property interest without adequate procedural protections. The parties filed cross-motions for summary judgment, and the district court denied AstraZeneca's motion and granted the government's motion in full.

1. As a threshold matter, the district court held that AstraZeneca lacks standing to assert its APA claims. The court first observed that "AstraZeneca does not allege that CMS's selection of Farxiga for negotiation under the Program constitutes the injury for which it seeks redress." JA21. That "makes sense" because "Farxiga is approved and marketed under a single NDA and no generic version of Farxiga is marketed in any manner or quantity," making the drug eligible for selection even under "*AstraZeneca's* interpretation." JA21. The court then explained why plaintiffs' theories of injury fail to establish standing.

First, AstraZeneca argued that CMS's interpretation of "qualifying single source drug" to encompass drug products with the same active moiety, even if approved under separate NDAs, "decreases the incentives for AstraZeneca to look for additional uses for Farxiga's single-ingredient active moiety." JA22 (quotation marks omitted).[3] The district court explained that "[a] loss or diminishment of an incentive to do something . . . is not a concrete injury." JA22. And it found that the challenged interpretation is in any event "extremely *unlikely*" to affect the value of an as-yet-undeveloped "additional use[]" of Farxiga because the concern is "premised on a hypothetical scenario that could only be realized *if* AstraZeneca were to develop a new formulation or use of Farxiga's active moiety, *if* the FDA approved that new formulation or use under a new NDA, and *if* Farxiga were still a selected drug for the Program at that (unknown) time." JA24, 26 (quotation marks omitted). The court observed that there is significant uncertainty in each part of that premise, not least because of the likelihood that a generic competitor will be marketed long before these events could transpire. JA24-26.

[3] Throughout this brief, references to "FARXIGA" in quoted materials are altered to "Farxiga."

The district court also found "many flaws in th[e] argument" that the bona fide marketing requirement could improperly delay the removal of Farxiga as a selected drug, JA28, and cause "an injury-in-fact in the form of simultaneous 'generic competition *and* mandatory pricing' 'for months' after generic versions of Farxiga enter the market," JA26. The court explained that it is the IRA's timing provisions, rather than the Revised Guidance, that creates the possibility that a drug could be subject to a negotiated price for a period of time after it faces generic competition. *See* JA29. Because it is "undisputed that no generic version of Farxiga will enter the market before October 2025," there is no question as to the drug's statutory eligibility for selection in the first negotiation cycle and thus no harm attributable to the Revised Guidance. JA29-30.

The court next rejected as "too vague to establish a cognizable injury" the contention that the agency's interpretations could negatively affect AstraZeneca's decision-making about drugs other than Farxiga. JA32-33. The Revised Guidance applies only to the first negotiation cycle, for which prices take effect in 2026, and "Farxiga is the only AstraZeneca drug selected for" that cycle. JA33. Moreover, "AstraZeneca does not say or suggest in any way how its decision-making about other drugs has been or

could be 'negatively affected' by the [Revised] Guidance. Nor does it say or suggest in any way how 'tak[ing] the agency's current policies into account' causes it harm as it 'makes plans to develop and commercialize' other drugs." JA33 (second alteration in original).

Finally, the district court rejected the only theory of standing that AstraZeneca advanced at oral argument—*i.e.*, that the company cannot accurately value Farxiga, as needed for effective negotiation, without knowing whether the challenged aspects of the Revised Guidance are lawful. JA34. The court explained that, "[o]f course, AstraZeneca *does* 'know the impact'" of the challenged guidance on the value of its drug. JA35. "The only uncertainty relating to the [Revised] Guidance comes from the filing of this lawsuit" and the attendant question as to whether the guidance may stand. JA35. But, of course, AstraZeneca cannot use the uncertainty created by litigation to manufacture standing. JA35.

Because the court concluded that AstraZeneca lacks standing to assert its APA claims, it declined to reach the government's argument that the IRA's express limits on judicial review independently deprive the court of jurisdiction to consider those claims. JA35.

2. The district court rejected the due process claim on the merits because the "first inquiry in every due process challenge is whether the plaintiff has been deprived of a protected interest in 'property' or 'liberty,'" and AstraZeneca fails to identify such an interest. JA39 (quoting *American Mfrs. Mut. Ins. Co. v. Sullivan*, 526 U.S. 40, 59 (1999)). "Distilled to its essence, the property interest AstraZeneca" invokes "is the ability to sell its drugs to Medicare at prices above the ceiling prices and negotiated maximum fair prices established by the IRA." JA40. But "AstraZeneca has no legitimate claim of entitlement to sell its drugs to the Government at any price other than what the Government is willing to pay." JA44.

Participation in Medicare "'is a voluntary undertaking,'" and nothing in the IRA or any other law "requires AstraZeneca to sell its drugs to Medicare beneficiaries." JA43 (quoting *Livingston Care Ctr., Inc. v. United States*, 934 F.2d 719, 720 (6th Cir. 1991)). Although there are "powerful incentive[s]" to participate in Medicare, "it does not follow" that the government's exercise of its market power "requires a drug manufacturer to participate" in the Negotiation Program "or any other Medicare program." JA46. Because AstraZeneca has no protected property interest in "sell[ing] the Government drugs at prices the Government won't agree

to pay," JA42, the court held that the "due process claim fails as a matter of law," JA44.

3. Other drug manufacturers and interest groups have filed related suits challenging the constitutionality and implementation of the Negotiation Program. To date, district courts in three other cases have considered such claims on the merits, and all have rejected them. *Novo Nordisk Inc. v. Becerra*, No. 23-20814, 2024 WL 3594413 (D.N.J. July 31, 2024), *appeal pending*, No. 24-2510 (3d Cir.); *Boehringer Ingelheim Pharm., Inc. v. HHS*, No. 23-1103, 2024 WL 3292657 (D. Conn. July 3, 2024), *appeal pending*, No. 24-2092 (2d Cir.); *Bristol Myers Squibb Co. v. Becerra*, Nos. 23-3335, 23-3818, 2024 WL 1855054 (D.N.J. Apr. 29, 2024), *appeals pending*, Nos. 24-1820 & 24-1821 (3d Cir.). Courts rejected two other challenges on threshold grounds. *Dayton Area Chamber of Commerce v. Becerra*, No. 23-156, 2024 WL 3741510 (S.D. Ohio Aug. 8, 2024); *National Infusion Ctr. Ass'n v. Becerra*, No. 23-707, 2024 WL 561860 (W.D. Tex. Feb. 12, 2024), *appeal pending*, No. 24-50180 (5th Cir.). Two district court cases raising related issues remain pending. *Merck & Co. v. Becerra*, No. 23-1615 (D.D.C. June 6, 2023); *Novartis Pharms. Corp. v. Becerra*, No. 23-14221 (D.N.J. Sept. 1, 2023).

SUMMARY OF ARGUMENT

I.A. The district court correctly held that AstraZeneca lacks standing to assert its APA claims because it fails to identify a concrete harm that will actually or imminently result from either of the challenged aspects of the Revised Guidance. It is undisputed that the agency's interpretation of "qualifying single source drug" had no bearing on the selection of Farxiga for the first negotiation cycle—the only cycle to which the Revised Guidance applies. AstraZeneca contends instead that the possible future application of the challenged interpretations could potentially reduce the value of its investments in as-yet-undeveloped products or delay a determination that a drug is subject to generic competition. But the possibility of such harm is entirely speculative.

Evidently recognizing that such harms are too conjectural to support standing, the principal injury AstraZeneca asserts is the need to take those ill-defined possibilities into account in its current decision-making. But a plaintiff cannot establish standing by taking present-day measures to avoid future harms that are themselves too speculative to establish standing. *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 415 (2013). AstraZeneca's arguments in any event suffer from lack of specificity, as plaintiffs identify

no particular decision affected by the challenged interpretations. That failure distinguishes this case from those on which plaintiffs rely, in which the injured parties identified a specific plan or transaction directly affected by the challenged action. A plaintiff could in every case make vague allegations about the need to account for agency action in its decision-making, and such assertions have never been found sufficient to support standing. AstraZeneca's contention that it was harmed by the need to consider the possible future effects of the Revised Guidance when negotiating the price of Farxiga fails for the same reasons.

Plaintiffs' theory additionally falls short because most of the harms alleged are not fairly traceable to the Revised Guidance and would not be redressed by a ruling in plaintiffs' favor given that the Revised Guidance applies only to the first negotiation cycle and will not govern the possible future determinations with which plaintiffs are concerned.

B. Although the district court did not reach the question, the Court also lacks jurisdiction to review AstraZeneca's APA claims because the IRA provides that "[t]here shall be no administrative or judicial review" of CMS's "selection of drugs" for negotiation under § 1320f-1(b), its "determination of negotiation-eligible drugs" under § 1320f-1(d), or its

"determination of qualifying single source drugs" under § 1320f-1(e). 42 U.S.C. § 1320f-7(2). That prohibition squarely encompasses AstraZeneca's challenge to CMS's means of determining "qualifying single source drugs."

II. The district court correctly rejected AstraZeneca's due process claim on the merits because AstraZeneca failed to identify a protected property interest affected by the Negotiation Program. On appeal, plaintiffs principally assert that the "Program deprives AstraZeneca of core property interests in its patented drugs and the right to determine the revenue it derives therefrom." Br. 43. But, as the district court held, AstraZeneca "never . . . explains how the IRA affects or could affect a patent right." JA41-42. Instead, AstraZeneca's argument distills to a claim that it has a protected interest in selling drugs to Medicare at prices above the negotiated price. That argument fails because no one "is entitled to sell the Government drugs at prices the Government won't agree to pay." JA42. Just as military contractors have no right to sell their products to the Department of Defense at prices it is unwilling to pay, pharmaceutical companies have no right to sell drugs to Medicare at a particular price.

Contrary to AstraZeneca's suggestion, the Negotiation Program does not compel it to sell any drug at a specified price. Participation in

Medicare is voluntary, and a manufacturer dissatisfied with the prices the government offers may choose instead to sell its products to other buyers. That withdrawing from Medicare would carry financial consequences does not change the well-established fact that participation is a choice.

STANDARD OF REVIEW

This Court "review[s] the grant or denial of summary judgment de novo." *Canada v. Samuel Grossi & Sons, Inc.*, 49 F.4th 340, 345 (3d Cir. 2022) (quotation marks omitted).

ARGUMENT

I. The Court lacks jurisdiction over AstraZeneca's APA claims.

AstraZeneca's claims challenging CMS's interpretation of the statutory term "qualifying single source drug" fail for lack of subject matter jurisdiction. As the district court concluded, AstraZeneca has not carried its burden of establishing Article III standing to assert these claims. In addition, the IRA's express limitations on judicial review independently deprive the courts of jurisdiction over these claims.

A. AstraZeneca lacks standing to assert its APA claims.

1. To establish the "'irreducible constitutional minimum' of standing," AstraZeneca must show that it "(1) suffered an injury in fact,

(2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016) (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992)). A cognizable legal injury must be "concrete and particularized" and "actual or imminent, not conjectural or hypothetical." *Lujan*, 504 U.S. at 560 (quotation marks omitted). The plaintiff bears the burden of establishing these elements "for each claim [it] seeks to press and for each form of relief that is sought." *Town of Chester v. Laroe Estates, Inc.*, 581 U.S. 433, 439 (2017) (quotation marks omitted). And "each element must be supported . . . with the manner and degree of evidence required at the successive stages of the litigation." *Lujan*, 504 U.S. at 561.

AstraZeneca misstates the governing standard in suggesting that a plaintiff suffers an injury in fact if its interests "*could be* affected" by the challenged action. Br. 26 (alteration in original) (emphasis added) (quoting *In re Global Indus. Techs., Inc.*, 645 F.3d 201, 212 (3d Cir. 2011) (en banc). It is well established that "[a]llegations of possible future injury do not satisfy the requirements of Art[icle] III." *Sherwin-Williams Co. v. County of Delaware*, 968 F.3d 264, 269 (3d Cir. 2020) (quotation marks omitted). "A threatened injury must be 'certainly impending' to constitute injury in

fact," *id.* (quoting *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990)), and plaintiffs fail to make that showing.

The harms that AstraZeneca alleges are far too abstract and remote to establish standing as to either (1) the agency's interpretation of "qualifying single source drug" or (2) its standard for determining when a generic drug "is marketed" so as to make the name-brand competitor ineligible for selection. The undisputed evidence establishes that these aspects of the Revised Guidance had no bearing on Farxiga's selection for negotiation. Farxiga was approved and marketed under a single NDA, making it irrelevant that some drug products marketed pursuant to separate NDA's may be eligible for selection as a "qualifying single source drug." JA21. And Farxiga does not yet have generic competitors that are marketed in any form. JA21. Thus, Farxiga was eligible for selection even under plaintiffs' preferred interpretation of the statute. And no other AstraZeneca drug was selected for negotiation in the first cycle—which is the only cycle to which the Revised Guidance applies.

2.a. In urging that it nevertheless has standing, AstraZeneca contends that it is harmed by having to "consider[] CMS's [Revised] Guidance in 'mak[ing] decisions *now*' as it plans for 'drug development

and commercialization for years to come.'" Br. 31 (third alteration in original) (quoting JA99, 106). AstraZeneca posits a variety of scenarios in which it contends that the challenged aspects of the Revised Guidance could conceivably affect the future value of not-yet-developed products with the same active moiety as Farxiga or as other AstraZeneca drugs that might be selected for negotiation in the future. For example, plaintiffs speculate that, by including products with separate NDAs in the definition of "qualifying single source drug," CMS's interpretation could potentially make as-yet-undeveloped "additional uses" of Farxiga or other drugs less lucrative by making them immediately subject, upon approval of a new NDA, to the negotiated price for an existing drug with the same active moiety. Br. 22, 27-28. AstraZeneca also contends that the bona fide marketing provision could conceivably delay a drug's deselection, thereby increasing the likelihood that a drug could be subject for a period of time to both generic competition and a negotiated price. Br. 30-31.

As the district court explained, each of these possible future consequences depends on a series of events that is "extremely *unlikely* to occur." JA24. With respect to Farxiga, the future harm that AstraZeneca contemplates as a result of the inclusion of products with separate NDAs in

the definition of "qualifying single source drug" "could only be realized *if* AstraZeneca were to develop a new formulation or use of Farxiga's active moiety, *if* the FDA approved that new formulation or use under a new NDA, and *if* Farxiga were still a selected drug for the Program at that (unknown) time." JA24.

AstraZeneca's own submissions emphasize that these events are highly unlikely to transpire: In general, "very few . . . drug candidates are ever approved and commercialized," JA54, and "it can take decades . . . to shepherd a single potential new therapy through clinical trials," JA98. Here, the only ongoing clinical trials involving Farxiga are "focused on 'combination product' therapies that would not be impacted by the agency's definition of Qualifying Single Source Drug," JA103, making the possible development of drug products affected by the definition entirely speculative. Moreover, even if AstraZeneca were eventually to develop an additional use of Farxiga's active moiety that was approved under a separate NDA, Farxiga in all likelihood would face generic competition by that time and would thus no longer be eligible for selection. *See* Br. 18 (noting that, at the time AstraZeneca filed suit, manufacturers had already received tentative approval for 17 generic competitors to Farxiga and

predicting that "a generic will now come to market between April 4, 2026 and Summer 2026"). In addition, because the Revised Guidance applies only to the first negotiation cycle, it does not govern the future-year eligibility determinations that underlie plaintiffs' concerns. JA120, 321.

AstraZeneca's suggestion (Br. 30-31) that the bona fide marketing provision could conceivably delay Farxiga's deselection is likewise conjectural. Because the bona fide marketing of *any* generic competitor suffices to bring a drug outside the definition of "qualifying single source drug," plaintiffs' argument is premised on a scenario in which CMS's approach delays a marketing determination with respect to *each* of Farxiga's approximately 17 potential generic competitors. But there is no evidence indicating that the agency's approach would delay one, much less all, such determinations. *See* JA 31. Plaintiffs' argument also depends on further speculation that any potential delay would be timed in such a way that it would affect the drug's deselection for a particular price year. *See* JA284. For example, because a drug would need to be subject to generic competition by April 1, 2026, to affect its eligibility for price year 2027, *see* JA30, a delay in finding that a generic competitor is marketed could harm plaintiffs only if it pushed the determination beyond the cutoff date.

b. Evidently conceding that such highly speculative future harms do not constitute injuries in fact, AstraZeneca's opening brief does not cite these harms as themselves supplying the basis for standing. Instead, AstraZeneca contends that it is injured by the need to "consider these risks *today* in making investment decisions for the future." Br. 22; *see* Br. 29, 31, 37. But *Clapper v. Amnesty International USA*, 568 U.S. 398, 415 (2013), confirms that a plaintiff cannot establish standing by taking present-day measures to avoid speculative future harms that are themselves insufficient to establish standing. After rejecting as too conjectural the plaintiffs' concern that their communications might be surveilled under the challenged program, *id.* at 410, the *Clapper* Court also rejected the plaintiffs' contention that "the threat of surveillance" caused them "ongoing injuries" by leading them, *e.g.*, "to avoid certain e-mail and phone conversations, to talk in generalities rather than specifics, or to travel so that they can have in-person conversations," *id.* at 415 (alteration and quotation marks omitted). The Court explained that the plaintiffs could not establish standing by taking present-day actions to avoid a future harm that "is not certainly impending." *Id.* at 416.

The same is true here. Indeed, the ongoing injuries AstraZeneca alleges are even more vague and abstract than those in *Clapper*. AstraZeneca's assertion that it has "been forced to make decisions now based on the agency policies currently in place," JA106, lacks any specificity as to which decisions have been affected, and how. AstraZeneca states only that it must "account for these risks in shaping its broader investment strategy," Br. 31 (quotation marks omitted), and does not "say or suggest in any way how 'tak[ing] the agency's current policies into account' causes it harm as it 'makes plans to develop and commercialize' other drugs," JA33 (alteration in original). All businesses must account for new regulatory information in their decision-making, and "vague," "generalized" assertions concerning that need do not constitute a cognizable harm. *National Shooting Sports Found. v. Attorney Gen. of N.J.*, 80 F.4th 215, 220 (3d Cir. 2023) (quotation marks omitted).

The cases that AstraZeneca cites underscore the insufficiency of its allegations. Without acknowledging the facts of these cases, AstraZeneca asserts that effects on an entity's "ability to make business decisions about the products it will offer" can suffice to establish injury in fact, *Sabre, Inc. v. Department of Transp.*, 429 F.3d 1113, 1117 (D.C. Cir. 2005), and that there is

thus "no need to wait for injury from specific transactions to claim standing," *Shays v. FEC*, 414 F.3d 76, 91 (D.C. Cir. 2005) (quotation marks omitted). Plaintiffs similarly assert that a party suffers a cognizable harm when "agency action creates a present-day obligation to 'adjust its finances and investment strategy to prepare for' future potential risks." Br. 26 (quoting *Great Lakes Gas Transmission Ltd. P'ship v. FERC*, 984 F.2d 426, 431 (D.C. Cir. 1993)). And they cite *Clinton v. City of New York*, 524 U.S. 417, 432 (1998), for the proposition that any effect on a party's investments or negotiating position creates "a sufficient likelihood of economic injury to establish standing." Br. 33 (quoting *Clinton*, 524 U.S. at 432).

The facts of those cases, however, demonstrate the specificity that Article III demands. Rather than vague allegations that a plaintiff's present-day decisions must account for future possibilities, each of those cases entailed specific and concrete evidence regarding the way the challenged actions affected the plaintiff's operations. In *Sabre*, for example, the plaintiff proffered evidence showing "the present existence of marketing plans, which it could otherwise implement presumably at considerable profit" but that were prohibited by the challenged agency action. 429 F.3d at 1118. Similarly, in *Great Lakes*, the challenged action

required the operator of a natural gas pipeline to incur substantial liability by accepting responsibility for the full cost of recovery of the new facilities it sought to build. 984 F.2d at 429. By contrast, AstraZeneca has identified no specific way in which the Revised Guidance will affect particular business decisions, asserting only that it must consider the challenged interpretations in deciding whether to invest in the development of possible "additional uses" of existing drugs. *See* JA22.

Plaintiffs' other authorities likewise underscore the need for specific and substantiated allegations of harm. In *Clinton*, the plaintiff "had concrete plans to utilize" the relevant tax provision in specific transactions. 524 U.S. at 432. The plaintiff proffered evidence that it "was engaged in ongoing negotiations with the owner of a processing plant who had expressed an interest in structuring a tax-deferred sale when" the tax benefit was cancelled, and the plaintiff was also "actively searching for other processing facilities for possible future purchase if the President's cancellation" of the tax benefit was "reversed." *Id.* It was on the basis of those specific and concrete allegations that the Court found "a sufficient likelihood of economic injury to establish standing." *Id.* Similarly in *Shays*, the court found it "indisputable" that regulated parties would seize specific

opportunities created by the challenged rules, with direct consequences for the plaintiffs. 414 F.3d at 90-91.

The shared feature of these cases is a showing of the specific and immediate way in which the plaintiff would be injured by the challenged action. There is no suggestion, much less any evidence, of a similarly specific and concrete harm in this case. *See Lujan*, 504 U.S. at 561 (emphasizing that at summary judgment a "plaintiff can no longer rest on . . . 'mere allegations'" to establish standing "but must 'set forth' by affidavit or other evidence 'specific facts'" (citing Fed. R. Civ. P. 56(e)). The district court correctly held that "[a] loss or diminishment of an incentive to do something . . . is not a concrete injury." JA22. And it rightly refused to accept AstraZeneca's "unprecedented" theory of injury, which "would open [the court's] doors to plaintiffs whose only complaint was that they disliked a law or government action," JA23, as any objection to government action, no matter how generalized or abstract, could always be framed as a disincentive to do something. *Cf. New England Power Generators Ass'n v. FERC*, 707 F.3d 364, 369 (D.C. Cir. 2013) (explaining that "broad-based market effects stemming from regulatory uncertainty are quintessentially

conjectural, and it is difficult to imagine a[n] [agency] action that would not confer standing under this theory").

c. AstraZeneca's contention that the Revised Guidance "affect[ed] [its] ability to value Farxiga for purposes of deciding whether to participate in the [Negotiation] Program," Br. 32, largely repeats the arguments above and fails for the same reasons. According to AstraZeneca, whether to participate in these negotiations "require[d] weighing (among other things): the financial implications of having a future drug approved under a separate NDA immediately subjected to an existing price cap simply because it shares the same active moiety as Farxiga," and "the risk that AstraZeneca will simultaneously be subject to a price cap and generic competition." Br. 32-33. To the extent AstraZeneca contends that it is harmed by the need to take these highly speculative possibilities into account in its current decision-making regarding its valuation of Farxiga, the argument fails because these contingent events are highly unlikely to transpire, *see Clapper*, 568 U.S. at 416, and AstraZeneca in any event fails to explain the effect on its negotiations.

At bottom, it appears that the uncertainty with which AstraZeneca is concerned is the uncertainty created by this lawsuit because the company

"*cannot* fairly value its product without a judicial determination of *whether* the [Revised] Guidance is unlawful." Br. 34. As the district court observed, "AstraZeneca *does* 'know the impact of CMS's [allegedly] flawed guidance." JA35 (alteration in original). "The only uncertainty relating to the [Revised] Guidance comes from the filing of this lawsuit" and its attendant questions about whether the Revised Guidance may stand. JA35. But every APA challenge creates similar uncertainty for the party seeking to upset the status quo of the challenged action, and a plaintiff cannot use the fact of litigation to manufacture standing. *See, e.g.*, *Fair Hous. Council of Suburban Phila. v. Montgomery Newspapers*, 141 F.3d 71, 80 (3d Cir. 1998). Plaintiffs' contrary view "would eviscerate the Constitutional requirement of standing." JA35.

3. AstraZeneca's theory of standing fails for the additional reason that most of the harms alleged are not fairly traceable to the Revised Guidance and would not be redressed by a favorable ruling in this action. *See* JA33. By its terms, the Revised Guidance applies only to the first negotiation cycle, for which prices will take effect in 2026. The harms AstraZeneca contends that it must consider in its decision-making concern the application of eligibility criteria in future cycles that will be governed

by agency guidance that has not yet been issued. As the district court explained, "AstraZeneca cannot trace an injury it might suffer in price periods that begin in 2027 and beyond to guidance that by its express terms governs only the 2026 price period." JA33. "And vacating the [Revised] Guidance could not provide AstraZeneca any relief with respect to its decision-making regarding other drugs that might be selected under future guidance that has not been released." JA33.

B. The Court also lacks jurisdiction over the APA claims because Congress expressly precluded review of such claims.

Even if AstraZeneca had standing to assert its APA claims, the Court would lack jurisdiction to resolve them because Congress expressly provided that "[t]here shall be no administrative or judicial review" of (1) CMS's "selection of drugs" for negotiation under § 1320f-1(b); (2) its "determination of negotiation-eligible drugs" under § 1320f-1(d); or (3) its "determination of qualifying single source drugs" under § 1320f-1(e). 42 U.S.C. § 1320f-7(2). Those prohibitions squarely encompass AstraZeneca's APA claims, which challenge the agency's determination of what constitutes a "qualifying single source drug" and the resulting determination as to which drugs are eligible and may be selected.

It is well established that "Congress may determine a lower federal court's subject-matter jurisdiction." *Kontrick v. Ryan*, 540 U.S. 443, 452 (2004). "When 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 question 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) (citation omitted) (quoting *Knapp Med. Ctr. v. Hargan*, 875 F.3d 1125, 1128 (D.C. Cir. 2017)); *see* 5 U.S.C. § 701(a)(1) (APA review is unavailable where "statutes preclude judicial review").

Plaintiffs' APA claims fall squarely within the statute's preclusive scope because the meaning of "qualifying single source drug" directly implicates the determinations for which Congress barred review. AstraZeneca's amended complaint confirms its view that the challenged interpretations "will directly impact" when a drug becomes eligible for selection, as well as when it stops being eligible as a result of generic marketing. JA87, ¶108; *see* JA87-88, ¶¶110-11. Plaintiffs thus challenge CMS's "determination of qualifying single source drugs," and their claims directly implicate the agency's "determination of negotiation-eligible drugs" and its eventual "selection of drugs" for negotiation. 42 U.S.C.

§ 1320f-7(2). Congress could not have made clearer its intent to preclude judicial review of these determinations. *See id.*

To the extent plaintiffs contend that the challenged interpretations are ancillary to those for which Congress precluded review, the argument fails both because the statute expressly precludes review of CMS's "determination of qualifying single source drugs," 42 U.S.C. § 1320f-7(2), and because courts have consistently rejected attempts to distinguish between "the procedures used in arriving at [a] determination" and "the merits of the determination itself," *John Balko & Assocs., Inc. v. Secretary of HHS*, 555 F. App'x 188, 193 (3d Cir. 2014). It is well established that preclusion provisions encompass decisions that are "indispensable or integral to, or inextricably intertwined with, the unreviewable agency action." *Florida Health Scis. Ctr., Inc. v. Secretary of HHS*, 830 F.3d 515, 519 (D.C. Cir. 2016) (quotation marks omitted). Thus, any attempt to cast plaintiffs' claims as a challenge to the means by which drugs are determined to be eligible for selection, rather than a challenge to the eligibility determination itself, would fail because the meaning of "qualifying single source drug" is indispensable to that determination.

Applying that principle, the D.C. Circuit construed a statute barring review of "the awarding of contracts" to preclude challenges to a regulation setting forth eligibility standards for such contracts because the challenged standards were "indispensable to 'the awarding of contracts.'" *Texas All. for Home Care Servs. v. Sebelius*, 681 F.3d 402, 409 (D.C. Cir. 2012). Myriad other decisions accord with that view. *See, e.g.*, *DCH Reg'l*, 925 F.3d at 505-06 (bar on review of "[a]ny estimate of the Secretary for purposes of determining [specified statutory] factors" barred the plaintiffs from challenging "'the methodology adopted and employed' by HHS to calculate" one of those factors, as a "distinction between methodology and estimates would eviscerate the statutory bar" against review (first alteration in original) (quotation marks omitted)); *Knapp Med. Ctr.*, 875 F.3d at 1130-31 (similar); *Mercy Hosp., Inc. v. Azar*, 891 F.3d 1062, 1066 (D.C. Cir. 2018) (statute barring judicial review of "prospective payment rates" covers "adjustments used to calculate th[ose] rate[s]"); *Yale New Haven Hosp. v. Becerra*, 56 F.4th 9, 13 (2d Cir. 2022) (prohibition against "judicial review" of "estimates" precluded claim that the Secretary "failed to abide by adequate notice-and-comment rulemaking procedures" in arriving at that estimate).

The authorities on which AstraZeneca relied in district court, by contrast, involved actions that arose under provisions distinct from those that precluded review. For example, the court explained in *American Clinical Laboratory Ass'n v. Azar*, 931 F.3d 1195, 1205-07 (D.C. Cir. 2019), that the determination at issue was not "inextricably intertwined with" the unreviewable agency action and arose instead under a "distinct" statutory provision that imposed "new obligations" in a "bifurcated structure" and included a discrete notice-and-comment requirement. The D.C. Circuit expressly distinguished the case from *Florida Health*, *Texas Alliance*, and *Mercy Hospital*, discussed above, which—like this case—did not entail challenges to determinations made pursuant to distinct authorities. *Id.* at 1206-07 (distinguishing cases); *see also American Hosp. Ass'n v. Azar*, 964 F.3d 1230, 1237 (D.C. Cir. 2020) (finding a challenge not precluded because the statute barred review only of certain "methods" not at issue). Here, the challenged interpretations include the agency's "determination of qualifying single source drugs" under § 1320f-1(e), and they are fully intertwined with the agency's "determination of negotiation-eligible drugs" under § 1320f-1(d) and its "selection of drugs" for negotiation

under § 1320f-1(b). 42 U.S.C. § 1320f-7(2). The IRA thus expressly precludes review. *Id.*

Plaintiffs cannot avoid this result by invoking the *ultra vires* doctrine. 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 act[ed] in excess of its delegated powers and contrary to a specific prohibition in the statute that is clear and mandatory.'" *DCH Reg'l*, 925 F.3d at 509 (quoting *Nyunt v. Chairman, Broad. Bd. of Governors*, 589 F.3d 445, 449 (D.C. Cir. 2009)). Here, an *ultra vires* argument would fail at the first step because the IRA "express[ly]" bars review of AstraZeneca's challenge. *Id.*; *see Florida Health*, 830 F.3d at 519; *Texas All.*, 681 F.3d at 404. The argument would also fail at the third step because there is no contention that "the agency plainly act[ed] . . . contrary to a specific prohibition in the statute that is clear and mandatory.'" *DCH Reg'l*, 925 F.3d at 509 (quotation marks omitted); *see Florida Health*, 830 F.3d at 522-23 (rejecting plaintiff's attempt "to 'couch[]' this type of reasonableness challenge 'in terms of the agency's exceeding its statutorily-defined

authority'" (alteration in original) (quoting *Northwest Airlines, Inc. v. FAA*, 14 F.3d 64, 73 (D.C. Cir. 1994))).

II. The district court correctly held that the Negotiation Program does not violate AstraZeneca's Fifth Amendment right to due process.

The IRA provisions establishing the Negotiation Program do not implicate plaintiffs' due process rights. The Due Process Clause protects against the deprivation "of life, liberty, or property, without due process of law." U.S. Const. amend. V. The threshold "inquiry in every due process challenge is therefore whether the plaintiff has been deprived of a protected interest" in liberty or property. *American Mfrs. Mut. Ins. Co. v. Sullivan*, 526 U.S. 40, 59 (1999); *see* JA39. AstraZeneca asserts that the Negotiation Program deprives it of "property interests in its patented drugs" and "the right to determine the revenue it derives therefrom." Br. 43. But as the district court correctly held, AstraZeneca's claim fails as a matter of law because it does not identify any constitutionally protected property interest threatened by the statute. JA 44.

1. There is no dispute here that patents are a form of property, but AstraZeneca "never . . . explains how the IRA affects or could affect a patent right." JA41-42. There is no allegation that the IRA "authorizes or

will result in the seizure" of AstraZeneca's patents, nor is there any suggestion that "the Government's refusal to purchase a drug at the price demanded by AstraZeneca constitutes patent infringement." JA42.

"Distilled to its essence, the property interest AstraZeneca contends merits protection . . . is the ability to sell its drugs to Medicare at prices above" those established through the Negotiation Program. JA40. Plaintiffs urge that the Negotiation Program threatens the "full exercise of the exclusionary power" that a patentee enjoys, Br. 44 (quotation marks omitted), including the "right to determine the revenue it derives" from its patented drugs, Br. 43, and "the opportunity to recoup investment," Br. 44. But "the federal patent laws do not create any affirmative right to . . . sell anything," *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1372 (Fed. Cir. 2007) (quoting *Leatherman Tool Grp. Inc. v. Cooper Indus., Inc.*, 131 F.3d 1011, 1015 (Fed. Cir. 1997)), much less a right to command a particular price. While a patentee may use its exclusive right to sell a drug as leverage in the marketplace, the freedom from competitive pressure conferred by the period of exclusivity does not entitle the patentee to any particular revenue from any particular buyer.

The same holds true when the government is the buyer. "[N]o one has a 'right' to sell to the government that which the government does not wish to buy." *Coyne-Delany Co. v. Capital Dev. Bd.*, 616 F.2d 341, 342 (7th Cir. 1980) (per curiam); *see Perkins v. Lukens Steel Co.*, 310 U.S. 113, 127 (1940) (emphasizing the government's authority to "determine those with whom it will deal"). "Just like private individuals and businesses, 'the Government enjoys the unrestricted power to produce its own supplies, to determine those with whom it will deal, and to fix the terms and conditions upon which it will make needed purchases.'" JA 43 (emphasis omitted) (quoting *Perkins*, 310 U.S. at 127). There is no overriding right inherent in a patent that entitles the holder to compel the government or anyone else to purchase a good or to pay more for a good than they are willing to pay.

Pursuant to the government's power to determine the prices it will pay for goods and services, other federal agencies have for decades negotiated with drug manufacturers over the price paid for patented drugs in other government programs. *See* 38 U.S.C. § 8126(a)-(h). Similarly, as a condition of Medicaid participation, drug manufacturers including AstraZeneca have long entered into agreements to provide patented drugs to certain healthcare facilities subject to statutory price ceilings. *See Astra*

USA, Inc. v. Santa Clara County, 563 U.S. 110, 113 (2011) (describing requirements under Section 340B of the Public Health Service Act). And the government regularly negotiates the price it will pay for other goods. *See, e.g.*, 48 C.F.R. pts. 15, 215. Just as military contractors have no right to sell their patented products to the Department of Defense at prices above what the government is willing to pay, pharmaceutical companies have no right to sell drugs to Medicare at a particular price.

AstraZeneca's acknowledgement that "the dictates of the marketplace" can affect its revenues without threatening any patent rights, Br. 44 (quoting *Biotechnology Indus.*, 496 F.3d at 1372), is fatal to its claim. In negotiating the price that Medicare will pay for drugs, the government is acting as a market participant. The IRA sets the terms of the government's offer to pay for certain drugs, and AstraZeneca has no right to force the government to pay for its drugs on different terms. AstraZeneca's contrary view does not reflect how the marketplace works, nor is it consistent with Congress's clear authority to control federal spending. The Negotiation Program reflects Congress's judgment that American taxpayers have been spending far too much on high-cost prescription drugs, and the government has a strong interest in controlling federal spending to

promote the general welfare. *See Sabri v. United States*, 541 U.S. 600, 608 (2004) ("The power to keep a watchful eye on expenditures . . . is bound up with congressional authority to spend in the first place . . . ."). Because "AstraZeneca has no legitimate claim of entitlement to sell its drugs to the Government at any price other than what the Government is willing to pay, its due process claim fails as a matter of law." JA44.

2. Plaintiffs are incorrect in asserting that the IRA "force[s] AstraZeneca to sell Farxiga at a government-dictated rate." Br. 45. The IRA does not limit the prices that AstraZeneca may charge other buyers for its patented drugs, Br. 44; it "simply establishes maximum prices the Government will pay for selected drugs" that are dispensed, furnished, or administered to Medicare beneficiaries, JA43. AstraZeneca may choose not to sell its drugs to Medicare if it does not agree with the offered price. The terms of the Negotiation Program apply only to entities that choose to participate in Medicare and Medicaid, and it regulates only the prices the government will pay for certain drugs sold to Medicare beneficiaries. As the Revised Guidance explains, "the IRA expressly connects a . . . [m]anufacturer's financial responsibilities under the voluntary Negotiation Program to that manufacturer's voluntary participation" in Medicare.

JA238; *see* 26 U.S.C. § 5000D(c)(1) (making the applicability of the excise tax contingent on such participation).

Drug manufacturers are under no obligation to participate in Medicare or Medicaid. "Neither the IRA nor any other federal law requires AstraZeneca to sell its drugs to Medicare beneficiaries." JA43. On the contrary, it is well established that participation in Medicare and Medicaid "is a voluntary undertaking." JA43 (quoting *Livingston Care Ctr., Inc. v. United States,* 934 F.2d 719, 720 (6th Cir. 1991)); *see Baptist Hosp. E. v. Secretary of HHS*, 802 F.2d 860, 869-70 (6th Cir. 1986); *see also Baker Cty. Med. Servs., Inc. v. U.S. Attorney Gen.*, 763 F.3d 1274, 1279-80 (11th Cir. 2014); *Garelick v. Sullivan*, 987 F.2d 913, 917 (2d Cir. 1993).[4] Accordingly, drug

[4] Many of these cases address claims under the Takings Clause of the Fifth Amendment, rather than the Due Process Clause, but that context does not affect the conclusion that the economic incentive to participate in Medicare and Medicaid does not make such participation involuntary. AstraZeneca errs in urging that the district court created a "'voluntariness' exception" to the Due Process Clause on the basis of such cases. Br. 51. AstraZeneca itself put the voluntariness of its participation at issue by arguing that government coercion is the mechanism by which it is deprived of its purported interest in determining the revenues it earns from sales of its drugs. *See* Br. 45 ("By leveraging its coercive power to force AstraZeneca to sell Farxiga at a government-dictated rate, the Program 'limit[s] the full exercise' of these rights." (alteration in original)). The absence of coercion responds directly to that argument.

manufacturers that do not wish to make their drugs available to Medicare beneficiaries at negotiated prices need not do so. *See* JA151-52, 238-39, 247-49. The Negotiation Program in no way alters the fact that a provider dissatisfied with the prices that Medicare offers "may withdraw from participation." *Baptist Hosp.*, 802 F.2d at 869-70.

To the extent AstraZeneca contends that the significant financial benefits of Medicare participation make withdrawal impractical, that does not serve to make participation legally mandated. As the district court explained, participation in Medicare "is a potential economic opportunity that AstraZeneca is free to accept or reject." JA46. Every other court to consider constitutional challenges to the Negotiation Program has agreed. *See Novo Nordisk Inc. v. Becerra*, No. 23-20814, 2024 WL 3594413 (D.N.J. July 31, 2024), *appeal pending*, No. 24-2510 (3d Cir.); *Boehringer Ingelheim Pharm., Inc. v. HHS*, No. 23-01103, 2024 WL 3292657 (D. Conn. July 3, 2024), *appeal pending*, No. 24-2092 (2d Cir.); *Bristol Myers Squibb Co. v. Becerra*, Nos. 23-3335, 23-3818, 2024 WL 1855054 (D.N.J. Apr. 29, 2024), *appeals pending*, Nos. 24-1820 & 24-1821 (3d Cir.).

The possibility that non-participation would be financially disadvantageous does not bear on the constitutional inquiry because

practical "hardship is not equivalent to legal compulsion for purposes of" a Fifth Amendment analysis. *Garelick*, 987 F.2d at 917; *cf. St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 875 (7th Cir. 1983) (per curiam) (the "fact that practicalities may in some cases dictate participation does not make participation involuntary"). Thus, even where "business realities" create a "strong financial inducement to participate" in a government program—*e.g.*, when Medicaid provides the vast majority of a nursing home's revenue—courts have uniformly held that participation "is nonetheless voluntary." *Minnesota Ass'n of Health Care Facilities v. Minnesota Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984); *Whitney v. Heckler*, 780 F.2d 963, 972 n.12 (11th Cir. 1986) ("[T]he fact that Medicare patients comprise a substantial percentage of [the plaintiffs'] practices does not render their participation 'involuntary.'"). Courts have likewise rejected the suggestion that participation in a voluntary program becomes involuntary if it may take some time to withdraw. *Yee v. City of Escondido*, 503 U.S. 519, 527-28 (1992) (finding no violation of a protected property interest where a

property owner could choose to leave a price-capped market with "6 or 12 months' notice").[5]

Far from "forc[ing] AstraZeneca to sell Farxiga at a government-dictated rate," Br. 45, the IRA leaves AstraZeneca free to negotiate pricing with any buyers in the marketplace, including the government. While AstraZeneca cannot force the government to buy its drugs or unilaterally insist on its preferred price, it may avail itself of the leverage resulting from its exclusive right to sell Farxiga. And it remains free to choose not to sell its drugs to any buyer, including the government, if the parties do not agree on a price.

For all of these reasons, the Negotiation Program does not infringe any property interest that would trigger a due process inquiry. "Drug manufacturers like AstraZeneca desire the old pricing regime, and they lobbied and perhaps expected Congress not to pass the IRA in 2022." JA43.

---

[5] Plaintiffs suggested in district court that withdrawal from Medicare might take 11 months, Dkt. No. 19, at 39, but any of the options for withdrawal can be accomplished much more quickly. As explained in the Revised Guidance, "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." JA151-52.

But "[n]o one . . . is entitled to sell the Government drugs at prices the Government won't agree to pay," JA42, and manufacturers' dissatisfaction with a voluntary program in which prices are negotiated does not give rise to a constitutional claim. The district court therefore correctly rejected AstraZeneca's due process claim as a matter of law.[6]

[6] Although the operative complaint states its request for relief broadly, asking for a declaration "that the IRA is unconstitutional," JA16, AstraZeneca's arguments focus solely on those portions of the IRA that enacted the Negotiation Program, and its opening brief acknowledges that the Program is severable from the remainder of the IRA, which would be fully operable without the Program provisions, Br. 51 n.3.

CONCLUSION

For the foregoing reasons, the judgment of the district court should be affirmed.

Respectfully submitted,

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

DAVID C. WEISS
United States Attorney

MICHAEL S. RAAB
s/ Lindsey Powell

LINDSEY POWELL
STEVEN A. MYERS
DAVID L. PETERS
CATHERINE PADHI
Attorneys, Appellate Staff
Civil Division, Room 7712
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530
(202) 616-5372
lindsey.e.powell@usdoj.gov

Of Counsel:

SAMUEL R. BAGENSTOS
General Counsel

JOEL McELVAIN
Acting Deputy General Counsel

JANICE L. HOFFMAN
Associate General Counsel

MATTHEW A. CAMPBELL
BRIDGETTE L. KAISER
ANANT KUMAR
Attorneys
U.S. Department of Health & Human Services

SEPTEMBER 2024

COMBINED CERTIFICATIONS

1. Government counsel are not required to be members of the bar of this Court.

2. This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B)(i) because it contains 11,374 words. This brief also complies with the typeface and type-style requirements of Rule 32(a)(5)-(6) because it uses Book Antiqua 14-point font, a proportionally spaced typeface.

3. On September 12, 2024, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Third Circuit by using the appellate CM/ECF system. Service will be accomplished by the appellate CM/ECF system.

4. The text of the electronic version of this document is identical to the text of the hard copies that will be provided.

5. This document was scanned for viruses, and no virus was detected.

s/ Lindsey Powell
LINDSEY POWELL

ADDENDUM

TABLE OF CONTENTS

42 U.S.C. § 1320f-1 (excerpt) – Selection of negotiation-eligible drugs as selected drugs

(a) In general

Not later than the selected drug publication date with respect to an initial price applicability year, in accordance with subsection (b), the Secretary shall select and publish a list of—

(1) with respect to the initial price applicability year 2026, 10 negotiation-eligible drugs described in subparagraph (A) of subsection (d)(1), but not subparagraph (B) of such subsection, with respect to such year (or, all (if such number is less than 10) such negotiation-eligible drugs with respect to such year);

(2) with respect to the initial price applicability year 2027, 15 negotiation-eligible drugs described in subparagraph (A) of subsection (d)(1), but not subparagraph (B) of such subsection, with respect to such year (or, all (if such number is less than 15) such negotiation-eligible drugs with respect to such year);

(3) with respect to the initial price applicability year 2028, 15 negotiation-eligible drugs described in subparagraph (A) or (B) of subsection (d)(1) with respect to such year (or, all (if such number is less than 15) such negotiation-eligible drugs with respect to such year); and

(4) with respect to the initial price applicability year 2029 or a subsequent year, 20 negotiation-eligible drugs described in subparagraph (A) or (B) of subsection (d)(1), with respect to such year (or, all (if such number is less than 20) such negotiation-eligible drugs with respect to such year).

Subject to subsection (c)(2) and section 1320f–3(f)(5) of this title, each drug published on the list pursuant to the previous sentence and subsection (b)(3) shall be subject to the negotiation process under section 1320f–3 of this title for the negotiation period with respect to such initial price applicability year (and the renegotiation process under such section as applicable for any subsequent year during the applicable price applicability period).

(b) Selection of drugs

(1) In general

In carrying out subsection (a), subject to paragraph (2), the Secretary shall, with respect to an initial price applicability year, do the following:

(A) Rank negotiation-eligible drugs described in subsection (d)(1) according to the total expenditures for such drugs under parts B and D of subchapter XVIII, as determined by the Secretary, during the most recent period of 12 months prior to the selected drug publication date (but ending not later than October 31 of the year prior to the year of such drug publication date), with respect to such year, for which data are available, with the negotiation-eligible drugs with the highest total expenditures being ranked the highest.

(B) Select from such ranked drugs with respect to such year the negotiation-eligible drugs with the highest such rankings.

(C) In the case of a biological product for which the inclusion of the biological product as a selected drug on a list published under subsection (a) has been delayed under subsection (f)(2), remove such biological product from the rankings under subparagraph (A) before making the selections under subparagraph (B).

(2) High spend part D drugs for 2026 and 2027

With respect to the initial price applicability year 2026 and with respect to the initial price applicability year 2027, the Secretary shall apply paragraph (1) as if the reference to "negotiation-eligible drugs described in subsection (d)(1)" were a reference to "negotiation-eligible drugs described in subsection (d)(1)(A)" and as if the reference to "total expenditures for such drugs under parts B and D of subchapter XVIII" were a reference to "total expenditures for such drugs under part D of subchapter XVIII".

(3) Inclusion of delayed biological products

Pursuant to subparagraphs (B)(ii)(I) and (C)(i) of subsection (f)(2), the Secretary shall select and include on the list published under subsection (a) the biological products described in such subparagraphs. Such biological products shall count towards the required number of drugs to be selected under subsection (a)(1).

(c) Selected drug

(1) In general

For purposes of this part, in accordance with subsection (e)(2) and subject to paragraph (2), each negotiation-eligible drug included on the list published under subsection (a) with respect to an initial price applicability year shall be referred to as a "selected drug" with respect to such year and each subsequent year beginning before the first year that begins at least 9 months after the date on which the Secretary determines at least one drug or biological product—

(A) is approved or licensed (as applicable)—

(i) under section 355(j) of title 21 using such drug as the listed drug; or

(ii) under section 262(k) of this title using such drug as the reference product; and

(B) is marketed pursuant to such approval or licensure.

(2) Clarification

A negotiation-eligible drug—

(A) that is included on the list published under subsection (a) with respect to an initial price applicability year; and

(B) for which the Secretary makes a determination described in paragraph (1) before or during the negotiation period with respect to such initial price applicability year;

shall not be subject to the negotiation process under section 1320f–3 of this title with respect to such negotiation period and shall continue to be considered a selected drug under this part with respect to the number of negotiation-eligible drugs published on the list under subsection (a) with respect to such initial price applicability year.

(d) Negotiation-eligible drug

(1) In general

For purposes of this part, subject to paragraph (2), the term "negotiation-eligible drug" means, with respect to the selected drug publication date with respect to an initial price applicability year, a qualifying single source drug, as defined in subsection (e), that is described in either of the following subparagraphs (or, with respect to the initial price applicability year 2026 or 2027, that is described in subparagraph (A)):

(A) Part D high spend drugs

The qualifying single source drug is, determined in accordance with subsection (e)(2), among the 50 qualifying single source drugs with the highest total expenditures under part D of subchapter XVIII, as determined by the Secretary in accordance with paragraph (3), during the most recent 12-month period for which data are available prior to such selected drug publication date (but ending no later than October 31 of the year prior to the year of such drug publication date).

(B) Part B high spend drugs

The qualifying single source drug is, determined in accordance with subsection (e)(2), among the 50 qualifying single source drugs with the highest total expenditures under part B of subchapter XVIII, as determined by the Secretary in accordance with paragraph (3), during such most recent 12-month period, as described in subparagraph (A).

(2) Exception for small biotech drugs

* * *

(3) Clarifications and determinations

(A) Previously selected drugs and small biotech drugs excluded

In applying subparagraphs (A) and (B) of paragraph (1), the Secretary shall not consider or count—

(i) drugs that are already selected drugs; and

(ii) for initial price applicability years 2026, 2027, and 2028, qualifying single source drugs described in paragraph (2)(A).

(B) Use of data

In determining whether a qualifying single source drug satisfies any of the criteria described in paragraph (1) or (2), the Secretary 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, and not based on the specific formulation or package size or package type of the drug.

(e) Qualifying single source drug

(1) In general

For purposes of this part, the term "qualifying single source drug" means, with respect to an initial price applicability year, subject to paragraphs (2) and (3), a covered part D drug (as defined in section 1395w–102(e) of this title) that is described in any of the following or a drug or biological product for which payment may be made under part B of subchapter XVIII that is described in any of the following:

(A) Drug products

A drug—

(i) that is approved under section 355(c) of title 21 and is marketed pursuant to such approval;

(ii) for which, as of the selected drug publication date with respect to such initial price applicability year, at least 7 years will have elapsed since the date of such approval; and

(iii) that is not the listed drug for any drug that is approved and marketed under section 355(j) of such title.

(B) Biological products

A biological product—

(i) that is licensed under section 262(a) of this title and is marketed under section 262 of this title;

(ii) for which, as of the selected drug publication date with respect to such initial price applicability year, at least 11 years will have elapsed since the date of such licensure; and

(iii) that is not the reference product for any biological product that is licensed and marketed under section 262(k) of this title.

(2) Treatment of authorized generic drugs

(A) In general

In the case of a qualifying single source drug described in subparagraph (A) or (B) of paragraph (1) that is the listed drug (as such term is used in section 355(j) of title 21) or a product described in clause (ii) of

subparagraph (B), with respect to an authorized generic drug, in applying the provisions of this part, such authorized generic drug and such listed drug or such product shall be treated as the same qualifying single source drug.

(B) Authorized generic drug defined

For purposes of this paragraph, the term "authorized generic drug" means—

(i) in the case of a drug, an authorized generic drug (as such term is defined in section 355(t)(3) of title 21); and

(ii) in the case of a biological product, a product that—

(I) has been licensed under section 262(a) of this title; [1] and

(II) is marketed, sold, or distributed directly or indirectly to retail class of trade under a different labeling, packaging (other than repackaging as the reference product in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trade mark than the reference product.

(3) Exclusions

In this part, the term "qualifying single source drug" does not include any of the following:

(A) Certain orphan drugs

A drug that is designated as a drug for only one rare disease or condition under section 360bb of title 21 and for which the only approved indication (or indications) is for such disease or condition.

(B) Low spend medicare drugs

A drug or biological product with respect to which the total expenditures under parts B and D of subchapter XVIII, as determined by the Secretary in accordance with subsection (d)(3)(B)—

(i) with respect to initial price applicability year 2026, is less than, during the period beginning on June 1, 2022, and ending on May 31, 2023, $200,000,000;

(ii) with respect to initial price applicability year 2027, is less than, during the most recent 12-month period applicable under subparagraphs (A) and (B) of subsection (d)(1) for such year, the dollar amount specified in clause (i) increased by the annual percentage increase in the consumer price index for all urban consumers (all items; United States city average) for the period beginning on June 1, 2023, and ending on September 30, 2024; or

(iii) with respect to a subsequent initial price applicability year, is less than, during the most recent 12-month period applicable under subparagraphs (A) and (B) of subsection (d)(1) for such year, the dollar amount specified in this subparagraph for the previous initial price applicability year increased by the annual percentage increase in such consumer price index for the 12-month period ending on September 30 of the year prior to the year of the selected drug publication date with respect to such subsequent initial price applicability year.

(C) Plasma-derived products

A biological product that is derived from human whole blood or plasma.

* * *

42 U.S.C. § 1320f-2 – Manufacturer agreements

(a) In general

For purposes of section 1320f(a)(2) of this title, the Secretary shall enter into agreements with manufacturers of selected drugs with respect to a price applicability period, by not later than February 28 following the selected drug publication date with respect to such selected drug, under which—

(1) during the negotiation period for the initial price applicability year for the selected drug, the Secretary and the manufacturer, in accordance with section 1320f–3 of this title, negotiate to determine (and, by not later than the last date of such period, agree to) a maximum fair price for such selected drug of the manufacturer in order for the manufacturer to provide access to such price—

(A) to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (A) of section 1320f(c)(2) of this title and are dispensed such drug (and to pharmacies, mail order services, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed such drugs) during, subject to paragraph (2), the price applicability period; and

(B) to hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (B) of such section and are furnished or administered such drug during, subject to paragraph (2), the price applicability period;

(2) the Secretary and the manufacturer shall, in accordance with section 1320f–3 of this title, renegotiate (and, by not later than the last date of the period of renegotiation, agree to) the maximum fair price for such drug, in order for the manufacturer to provide access to such maximum fair price (as so renegotiated)—

(A) to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (A) of section 1320f(c)(2) of this title and are dispensed such drug (and to pharmacies, mail order services, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed such drugs) during any year during the

price applicability period (beginning after such renegotiation) with respect to such selected drug; and

(B) to hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (B) of such section and are furnished or administered such drug during any year described in subparagraph (A);

(3) subject to subsection (d), access to the maximum fair price (including as renegotiated pursuant to paragraph (2)), with respect to such a selected drug, shall be provided by the manufacturer to—

(A) maximum fair price eligible individuals, who with respect to such drug are described in subparagraph (A) of section 1320f(c)(2) of this title, at the pharmacy, mail order service, or other dispenser at the point-of-sale of such drug (and shall be provided by the manufacturer to the pharmacy, mail order service, or other dispenser, with respect to such maximum fair price eligible individuals who are dispensed such drugs), as described in paragraph (1)(A) or (2)(A), as applicable; and

(B) hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (B) of such section and are furnished or administered such drug, as described in paragraph (1)(B) or (2)(B), as applicable;

(4) the manufacturer submits to the Secretary, in a form and manner specified by the Secretary, for the negotiation period for the price applicability period (and, if applicable, before any period of renegotiation pursuant to section 1320f–3(f) of this title), and for section 1320f–1(f) of this title, with respect to such drug—

(A) information on the non-Federal average manufacturer price (as defined in section 8126(h)(5) of title 38) for the drug for the applicable year or period;

(B) information that the Secretary requires to carry out the negotiation (or renegotiation process) under this part; and

(C) information that the Secretary requires to carry out section 1320f–1(f) of this title, including rebates under paragraph (4) of such section; and

(5) the manufacturer complies with requirements determined by the Secretary to be necessary for purposes of administering the program and monitoring compliance with the program.

(b) Agreement in effect until drug is no longer a selected drug

An agreement entered into under this section shall be effective, with respect to a selected drug, until such drug is no longer considered a selected drug under section 1320f–1(c) of this title.

(c) Confidentiality of information

Information submitted to the Secretary under this part by a manufacturer of a selected drug that is proprietary information of such manufacturer (as determined by the Secretary) shall be used only by the Secretary or disclosed to and used by the Comptroller General of the United States for purposes of carrying out this part.

(d) Nonduplication with 340B ceiling price

Under an agreement entered into under this section, the manufacturer of a selected drug—

(1) shall not be required to provide access to the maximum fair price under subsection (a)(3), with respect to such selected drug and maximum fair price eligible individuals who are eligible to be furnished, administered, or dispensed such selected drug at a covered entity described in section 340B(a)(4) of the Public Health Service Act [42 U.S.C. 256b(a)(4)], to such covered entity if such selected drug is subject to an agreement described in section 340B(a)(1) of such Act [42 U.S.C. 256b(a)(1)] and the ceiling price (defined in section 340B(a)(1) of such Act [42 U.S.C. 256b(a)(1)]) is lower than the maximum fair price for such selected drug; and

(2) shall be required to provide access to the maximum fair price to such covered entity with respect to maximum fair price eligible individuals who are eligible to be furnished, administered, or dispensed such selected drug at such entity at such ceiling price in a nonduplicated amount to the ceiling price if such maximum fair price is below the ceiling price for such selected drug. [Add text].

42 U.S.C. § 1320f-7 – Limitation on administrative and judicial review

There shall be no administrative or judicial review of any of the following:

(1) The determination of a unit, with respect to a drug or biological product, pursuant to section 1320f(c)(6) of this title.

(2) The selection of drugs under section 1320f–1(b) of this title, the determination of negotiation-eligible drugs under section 1320f–1(d) of this title, and [1] the determination of qualifying single source drugs under section 1320f–1(e) of this title the [2] application of section 1320f–1(f) of this title.

(3) The determination of a maximum fair price under subsection (b) or (f) of section 1320f–3 of this title.

(4) The determination of renegotiation-eligible drugs under section 1320f–3(f)(2) of this title and the selection of renegotiation-eligible drugs under section 1320f–3(f)(3) of this title.