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APPENDIX A

PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 24-1819

ASTRAZENECA PHARMACEUTICALS LP;
ASTRAZENECA AB,

Appellants

v.

SECRETARY UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES;
ADMINISTRATOR CENTERS FOR MEDICARE &
MEDICAID SERVICES

On Appeal from the United States District Court
for the District of Delaware
(D.C. No. 1:23-cv-00931)
District Judge: Honorable Colm F. Connolly

Argued on October 30, 2024

Before: HARDIMAN, PHIPPS, and FREEMAN,
Circuit Judges

(Opinion filed: May 8, 2025)

Catherine E. Stetson [ARGUED]
Susan M. Cook
Danielle Desaulniers Stempel
Claire Adkins Rhodes
Hogan Lovells US LLP
555 Thirteenth Street NW
Washington, D.C. 20004
(202) 637-5600
Counsel for Appellants

Lindsey Powell [ARGUED]
Steven A. Myers
Catherine M. Padhi
David L. Peters
Michael S. Raab
Bridgette L. Kaiser
Anant Kumar
Matthew A. Campbell
United States Department of Justice, Appellate Section
Room 7259
950 Pennsylvania Avenue NW
Washington, DC 20530
Counsel for Appellees

Michael D. Lieberman
Fairmark Partners
1001 G Street NW
Suite 400 East
Washington, DC 20001
Counsel for Amicus Patients for Affordable Drugs

Ananda V. Burra
Robin F. Thurston
Democracy Forward Foundation
P.O. Box 34553
Washington, DC 20043

Counsel for Amici American Public Health Association, American College of Physicians, American Geriatrics Society, American Society of Hematology, and Society of General Internal Medicine

Charles L. Becker
Kline & Specter
1525 Locust Street
19th Floor
Philadelphia, PA 19102

Counsel for Amici Senators Amy Klobuchar, Peter Welch, Tammy Baldwin, Richard Blumenthal, Sherrod Brown, Catherine Cortez Mastro, Richard Durbin, John Fetterman, John Hickenlooper, Jack Reed, Jacky Rosen, Jeanne Shaheen, Debbie Stabenow, Chris Van Hollen, and Elizabeth Warren

Hannah W. Brennan
Sophia K. Weaver
Hagens Berman Sobol Shapiro
One Faneuil Hall Square, 5th Floor
Boston, MA 02109

Jamie Crooks
Fairmark Partners
400 7th Street NW
Suite 304
Washington, DC 20004

Counsel for Amici Center for American Progress, Century Foundation, UnidosUS Action Fund, and National Association for the Advancement of Colored People

Maame A. Gyamfi
AARP Foundation Litigation
B4-377
601 E Street NW

Washington, DC 20049
Counsel for Amici AARP, AARP Foundation, Center for Medicare Advocacy, Justice in Aging, and Medicare Rights Center

Alyssa H. Card
Margaret Dotzel
William B. Schultz
Zuckerman Spaeder
1800 M Street NW
Suite 1000
Washington, DC 20036
Counsel for Amici Stuart Altman, Robert Berenson, Donald Berwick, David Blumenthal, Francis J. Crosson, Paul Ginsburg, Marilyn Moon, and Bruce Vladeck

Deepak Gupta
Gupta Wessler
2001 K Street NW
Suite 850 North
Washington, DC 20006
Counsel for Amici Richard G. Frank, Fiona M. Scott Morton, Aaron S. Kesselheim, Gerard F. Anderson, Rena M. Conti, David M. Cutler, and Jack Hoadley

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OPINION OF THE COURT

FREEMAN, *Circuit Judge*.

The Inflation Reduction Act of 2022 ("IRA") created the Drug Price Negotiation Program ("Negotiation Program"). The Negotiation Program directs the Centers for Medicare & Medicaid Services ("CMS") to negotiate prices for certain drugs that have resulted in high

expenditures to Medicare. To implement that statutory directive, CMS issued guidance explaining how it would select the qualifying drugs for 2026—the first year of the Negotiation Program. CMS then selected the drugs that are subject to negotiation. One of the selected drugs is Farxiga, which is manufactured by AstraZeneca.[1]

AstraZeneca sued the Secretary of the Department of Health and Human Services and CMS's Administrator (collectively, "the government") to challenge the Negotiation Program and portions of CMS's guidance. AstraZeneca claims that the Negotiation Program deprives it of procedural due process and that two provisions of CMS's guidance violate the Administrative Procedure Act ("APA").

The District Court determined that AstraZeneca failed to state a due process violation to challenge the Negotiation Program and lacks standing to pursue its APA claims. Accordingly, the District Court entered judgment in favor of the government. For the following reasons, we will affirm the District Court's judgment.

I

Medicare is a federal medical insurance program for people ages sixty-five and older and for younger people with certain disabilities. *See* 42 U.S.C. § 1395 *et seq.* Medicaid is a joint federal and state program that provides medical coverage for people with limited incomes. *See id.* § 1396 *et seq*. "Through Medicare and Medicaid, [the federal government] pays for almost half the annual nationwide spending on prescription drugs." *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th 696, 699 (3d Cir. 2023) (citing Cong.

[1] We refer to AstraZeneca Pharmaceuticals LP, and AstraZeneca AB collectively as "AstraZeneca."

Budget Off., *Prescription Drugs: Spending, Use, and Prices* 8 (2022)).

Medicare is divided into Parts, two of which (Parts B and D) are relevant here. Part B is a voluntary supplemental insurance program that covers outpatient care, including certain prescription drugs that are typically administered by a physician. *See* 42 C.F.R. § 410.28. Part D "is 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). Part D works through prescription drug plans operated by private insurance companies that it calls "sponsors." Sponsors then work with subcontractors, including pharmacy benefit managers, who handle administrative tasks and process claims. *See id.* Those subcontractors in turn contract with the pharmacies that dispense prescription drugs to Medicare beneficiaries. *See id.*

When Congress enacted Medicare Part D in 2003, it included a "non-interference" provision. That provision states that CMS "may not interfere with the negotiations between drug manufacturers and pharmacies and ... sponsors" and "may not institute a price structure for the reimbursement of covered part D drugs." 42 U.S.C. § 1395w-111(i)(1), (3) (2003). Nineteen years later, when Congress enacted the IRA, it created an exception to the non-interference provision: the Negotiation Program directs CMS to "negotiate ... maximum fair prices" for certain drugs, *id.* § 1320f(a)(3), subject to price ceilings derived from the price on the private market, *id.* § 1320f-3(c). Each selected drug's "maximum fair price" applies beginning in a given drug-pricing period (a period of one calendar year), the first of which is 2026, until the drug is no longer eligible for negotiation or the price is

renegotiated. *Id.* §§ 1320f(b)(1)–(2), 1320f-1(c), and 1320f-3(f).

The Negotiation Program sets out a two-phase process for each drug-pricing period. First, CMS identifies the drugs subject to negotiation. Second, CMS negotiates with the manufacturer of each identified drug. We will refer to these as the Identification Phase and the Negotiation Phase.

During the Identification Phase for any given drug-pricing period, CMS first identifies "qualifying single source drugs," which are drugs approved by the FDA for at least seven years and not subject to competition from a generic "that is approved and marketed." *Id.* § 1320f-1(e)(1)(A)(i)–(iii). CMS then rank-orders the qualifying single source drugs according to highest associated expenditures under Medicare Part B or Part D over a recent twelve-month period. To determine the total spending on a drug, CMS looks to "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." *Id.* § 1320f-1(d)(3)(B). The fifty drugs that represent the highest total spending under each respective Part are "negotiation-eligible drugs." *Id.* § 1320f-1(d)(1).[2]

Next, CMS selects and publishes a list of the negotiation-eligible drugs that will be subject to negotiation for the relevant drug-pricing period, *id.* § 1320f-1(a), prioritizing negotiation for the drugs that

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[2] The Negotiation Program applies to drugs covered by Medicare Part D for the 2026 and 2027 drug-pricing periods. 42 U.S.C. § 1320f-1(a)(1)–(2), (d)(1). The Negotiation Program first applies to drugs covered by Medicare Part B during the 2028 drug-pricing period. *Id.* § 1320f-1(a)(3)–(4), (d)(1).

represent the largest expenditures to Medicare, *see id.* § 1320f-1(b)(1)(B). It selected ten drugs for drug-pricing period 2026, and the number of selected drugs will increase for subsequent drug-pricing periods. *Id.* § 1320f-1(a).

Once CMS publishes the list of drugs selected for negotiation, the Negotiation Phase begins. When negotiating, CMS "shall ... aim[] to achieve the lowest maximum fair price for each selected drug," *id.* § 1320f-3(b)(1), and is barred from offering or agreeing to a price that is more than 75 percent of the private market price for the drug, *see id.* § 1320f-3(c). Lower price ceilings (65 percent or 40 percent) apply to drugs that have been approved or licensed for a longer time (at least 12 years or at least 16 years, respectively). *Id.*

CMS must consider several factors during negotiations, including the manufacturer's production and distribution costs, the manufacturer's research and development costs (and the extent to which those costs have been recouped), federal funding for the drug's development, patent rights and statutory exclusivities, FDA product approvals, sales data, and alternative treatments. *See id.* § 1320f-3(e). Manufacturers supply information about these factors to CMS. *See id.* § 1320f-3(b)(2)(A). Based on the enumerated factors and the price ceilings, CMS makes an initial offer. *Id.* § 1320f-3(b)(2)(B). The manufacturer then has an opportunity to make a counteroffer, to which CMS will respond. *Id.* §§ 1320f-3(b)(2)(C)–(D). Negotiations must end by November 1 of the year two years prior to when the pricing will take effect, *id.* § 1320f-3(b)(2)(E), and CMS must publish the maximum fair price by November 30, *id.* § 1320f-4(a)(1). CMS then has until March 1 of the following year (i.e., ten months before the price goes into effect) to publish an

explanation of how the maximum fair price comports with the statutory factors. *Id.* § 1320f-4(a)(2).

Congress directed CMS to implement the Negotiation Program for drug-pricing periods 2026 through 2028 "by program instruction or other forms of program guidance." *Id.* § 1320f note. Accordingly, in March 2023 CMS issued an initial program guidance. After receiving more than 7,500 public comments, it made revisions and issued revised guidance ("the Guidance") in June 2023. By its terms, the Guidance applies only for drug-pricing period 2026, though CMS has stated that it may incorporate the comments it received when promulgating the Guidance into its program guidance for drug-pricing periods 2027 and 2028.

AstraZeneca challenges two aspects of the Guidance. The first is the Guidance's grouping of variations of the same drug. As noted above, the Negotiation Program requires CMS to determine total Medicare expenditures for negotiation-eligible drugs by using "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." *Id.* § 1320f-1(d)(3)(B). Relying on this language, the Guidance states that CMS "will identify a potential qualifying single source drug using ... all dosage forms and strengths of the drug with the same active moiety and the same holder of a New Drug Application (NDA), inclusive of products that are marketed pursuant to different NDAs."[3] App. 217 (footnotes omitted).

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[3] As defined by FDA regulations, a drug's active moiety is the core "molecule or ion … responsible for the physiological or pharmacological action of the drug substance." 21 C.F.R. § 314.3. An

The second challenge is to the Guidance's test for generic competition. Recall that the Negotiation Program states that drugs qualify for negotiation if they lack a generic competitor that "is approved and *marketed*." 42 U.S.C. § 1320f-1(e)(1)(A)(iii) (emphasis added). The Guidance states that CMS will consider an approved generic "to be marketed when the totality of the circumstances ... reveals that the manufacturer of the generic drug ... is engaging in bona fide marketing of that drug." App. 124. It explains that the statutory term "is marketed" contemplates "that a generic ... must have a continuing presence on the market." App. 190. It also explains that "manufacturers' past behavior warrants CMS review on an ongoing basis as to whether a generic drug ... is being bona fide marketed." *Id.* It reasons that, without that review, a generic-drug manufacturer "could launch into the market a token or de minimis amount of a generic drug" and the manufacturer of a drug selected for negotiation could "claim that the [maximum fair price] should no longer apply." *Id.* Accordingly, to determine whether a manufacturer is engaging in bona fide marketing, the Guidance says CMS will review data on prescriptions being filled and the average price a manufacturer offers to direct purchasers.

In August 2023, after CMS published the Guidance, AstraZeneca filed this lawsuit challenging the Guidance and the Negotiation Program. Four days after AstraZeneca filed suit, CMS published a list of the ten drugs it selected for negotiation for drug-pricing period 2026. AstraZeneca then amended its complaint to allege that CMS had selected one of the drugs AstraZeneca

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NDA is the FDA's approval of a pharmaceutical for sale and marketing; a drug can have multiple approved uses under one NDA and multiple NDAs for different uses. *See generally* 21 U.S.C. § 355.

manufactures: Farxiga, which is used to treat diabetes, heart disease, and kidney disease. While this case proceeded, AstraZeneca and CMS undertook the steps set out in the Negotiation Program's Negotiation Phase, and the parties agreed to a "maximum fair price" for Farxiga during drug-pricing period 2026.[4]

Meanwhile, the parties cross-moved for summary judgment, agreeing that their motions presented purely legal issues. In March 2024, the District Court denied AstraZeneca's motion and granted the government's motion. It determined that AstraZeneca lacked standing to challenge the Guidance under the APA and failed to state a procedural-due-process claim that could lead to relief from the Negotiation Program. AstraZeneca timely appealed.

II[5]

We exercise plenary review of summary-judgment orders, applying the same standard used by district courts. *Auto-Owners Ins. Co. v. Stevens & Ricci Inc.*, 835 F.3d 388, 402 (3d Cir. 2016). Under that standard, summary judgment is only appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a).

A

In its APA claims, AstraZeneca challenges how the Guidance defines a qualifying single source drug and how

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[4] The Negotiation Program defines the term "maximum fair price" to mean, with respect to a selected drug and a given drug-pricing period, "the price negotiated pursuant to [the Negotiation Program], … as applicable, for such drug and year." 42 U.S.C. § 1320f(c)(3).

[5] The District Court had jurisdiction under 28 U.S.C. §§ 1331, 1346, and 1361. We have jurisdiction under 28 U.S.C. § 1291.

it instructs CMS to determine whether a drug is subject to generic competition. It asserts that these Guidance provisions conflict with or exceed the terms of the Negotiation Program and must be set aside. But before we can address the merits of these claims, AstraZeneca must demonstrate that it has Article III standing. *Nat'l Shooting Sports Found. v. Att'y Gen. of N.J.*, 80 F.4th 215, 218 (3d Cir. 2023); *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 352 (2006) ("[A] plaintiff must demonstrate standing for each claim he seeks to press.").

"To establish standing, a plaintiff must show an injury in fact caused by the defendant and redressable by a court order." *United States v. Texas*, 599 U.S. 670, 676 (2023). The injury-in-fact must be "concrete, particularized, and actual or imminent." *TransUnion LLC v. Ramirez*, 594 U.S. 413, 423 (2021). "A concrete injury is real rather than abstract, and a particularized injury is one that affects the plaintiff in a personal and individual way." *Ellison v. Am. Bd. of Orthopaedic Surgery*, 11 F.4th 200, 205 (3d Cir. 2021). A plaintiff bears the burden of establishing standing "as of the time [it] brought [its] lawsuit," *Carney v. Adams*, 592 U.S. 53, 59 (2020), and it must do so "for each claim [it] seeks to press." *DaimlerChrysler Corp.*, 547 U.S. at 335.

AstraZeneca articulates two theories of injury stemming from both challenged aspects of the Guidance: (1) the impact on AstraZeneca's decision-making about research, development, and marketing, and (2) the company's difficulty valuing Farxiga in negotiations with CMS. Neither theory of injury is concrete or particularized.

1

We begin with AstraZeneca's asserted injury to its business decision-making. According to the company, the

Guidance's grouping of related drugs has caused or will cause AstraZeneca to make research, development, and marketing choices that account for the risk that its new drug products will be subject to price negotiation. Similarly, AstraZeneca contends that the Guidance's bona-fide-marketing requirement forces it to account for the risk that its drugs could be simultaneously subject to generic competition and negotiated pricing.

At summary judgment, a plaintiff cannot rely on mere allegations to demonstrate standing. It "must set forth by affidavit or other evidence specific facts demonstrating that [standing] requirements have been met." *Freeman v. Corzine*, 629 F.3d 146, 153 (3d Cir. 2010) (internal quotation marks and citation omitted). Seeking to satisfy this requirement, AstraZeneca submitted an affidavit from its Vice President of U.S. Market Access, Jim Ader. Ader stated that the grouping of different drug products "diminishes incentives for AstraZeneca to invest in future therapies and treatments for the active moiety of a selected drug product." App. 101. He continued:

> While clinical trials are currently focused on "combination product" therapies that would not be impacted by the agency's definition of Qualifying Single Source Drug, there are other ongoing drug development efforts involving the same active moiety as FARXIGA where one development pathway could result in the product being treated as the same QSSD as FARXIGA under CMS's position.

App. 103. He asserted that the Guidance "dramatically alters manufacturers' incentives to invest in ... follow-on therapies using a previously approved active moiety" and that "AstraZeneca would have no incentive to spend years and a steep financial investment researching alternative

treatment uses for the active moiety of a selected product." App. 104–05.

Ader's affidavit—the only evidence AstraZeneca submitted to support its theory of injury-in-fact—does not establish a concrete and particularized injury to AstraZeneca. Ader did not identify any actual decision about drug development or marketing that AstraZeneca has made or will make to avoid different drugs being grouped together. While he hypothesized that some unspecified "pathway" of AstraZeneca's ongoing drug-development efforts involving Farxiga's active moiety *could* result in a product that would be grouped with Farxiga in the future, he provided no evidence about how the company has been (or imminently will be) injured. *See Sherwin-Williams Co. v. Cnty. of Delaware, Pa.*, 968 F.3d 264, 269 (3d Cir. 2020) ("Allegations of possible future injury do not satisfy the requirements of Art. III." (quoting *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990))). Ader merely suggested a hypothetical scenario. But "[u]nder Article III, federal courts do not adjudicate hypothetical ... disputes." *TransUnion*, 594 U.S. at 423; *accord Trump v. New York*, 592 U.S. 125, 131 (2020) (recounting that standing requires "an injury that is concrete, particularized, and imminent rather than conjectural or hypothetical" (citation omitted)).[6] And Ader's statements about "broad-based market effects

[6] In his affidavit, Ader describes Calquence—a leukemia medicine approved under two different NDAs—and avers it is "a potential candidate for selection" for negotiation in pricing period 2027. App. 106. Ader states that the Guidance's definition "dramatically alters manufacturers' incentives to invest in such follow-on therapies," App. 104, but he provides no detail about how "AstraZeneca has to make investment decisions now on research development" related to Calquence, App. 106. Nor does the fact that CMS later selected Calquence for the 2027 pricing period demonstrate that AstraZeneca had a concrete and particularized injury at the time it sued.

stemming from regulatory uncertainty are quintessentially conjectural," *New Eng. Power Generators Ass'n v. FERC*, 707 F.3d 364, 369 (D.C. Cir. 2013), and thus insufficient to establish standing.[7]

2

AstraZeneca's asserted injury to its ability to value Farxiga in negotiations with CMS is not concrete or particularized either. AstraZeneca filed Ader's affidavit before CMS made an initial offer for Farxiga's "maximum fair price" for drug-pricing period 2026. It argues that it had to assume the Guidance applied, so the Guidance injured its business decisions even before any offers were made. But the only evidence presented is Ader's statement that "AstraZeneca ... is forced to make a number of decisions now about its willingness to go forward with its participation in the program." App. 99. This "general factual allegation[] of injury resulting from the defendant's conduct" is insufficient to establish

[7] While this appeal was pending, the Fifth Circuit held in *National Infusion Center Association v. Becerra*, 116 F.4th 488 (5th Cir. 2024) ("*NICA*"), that a medical trade organization had standing to bring constitutional challenges to the Negotiation Program. AstraZeneca asserts that *NICA* supports standing here. Not so. AstraZeneca's standing to challenge the Negotiation Program is not in dispute, and *NICA* says nothing about standing to challenge the Guidance provisions at issue here. And, of course, courts assess standing based on the record before them. In *NICA*, the plaintiff demonstrated how the Negotiation Program caused it both present and future injury. *See id.* at 502 ("NICA has specifically described the ways in which the [Negotiation] Program limits its members' ability to obtain necessary debt and equity capital."); *id.* at 501 ("NICA has shown that at least one of its members' drugs will be subject to the [Negotiation] Program, that the [Negotiation] Program will lower the price for that drug, and that the lower price will lead to lower revenue for the member."). Here, AstraZeneca has failed to demonstrate either actual or imminent injury caused by the Guidance.

standing. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992). AstraZeneca has introduced no "specific facts" about how the Guidance shaped its behavior before or during those negotiations.[8] *Id.*

Absent an injury-in-fact, AstraZeneca lacks Article III standing to challenge the Guidance. We will therefore affirm the District Court's order granting summary judgment in favor of the government with respect to AstraZeneca's APA claims.

III

In its due process claim, AstraZeneca argues that the Negotiation Program itself (not the Guidance) deprives the company of its property interests in drugs subject to negotiation and does not provide adequate procedural safeguards.

To state a procedural due process claim, "a plaintiff must allege that (1) he was deprived of an individual interest that is encompassed within the Fourteenth Amendment's protection of life, liberty, or property, and (2) the procedures available to him did not provide due process of law." *Hill v. Borough of Kutztown*, 455 F.3d 225, 233–34 (3d Cir. 2006) (internal quotation marks and citation omitted). "For a property interest to be protected, a plaintiff must show a legitimate claim of entitlement to it." *Coon v. Cnty. of Lebanon*, 111 F.4th 273, 275 (3d Cir. 2024) (internal quotation marks and citation omitted). The Due Process Clause protects property interests that are created and defined outside of the Constitution, such as

[8] AstraZeneca, of course, could have sought to file any confidential evidence under seal. *See, e.g.*, *Sabre, Inc. v. Dep't of Transp.*, 429 F.3d 1113, 1118 (D.C. Cir. 2005) (describing evidence of confidential marketing plans filed under seal that established injury-in-fact).

by federal statute or state law. *Bd. of Regents of State Colls. v. Roth*, 408 U.S. 564, 577 (1972).

AstraZeneca argues that the Negotiation Program limits its ability to sell its drugs at a market rate, thereby infringing on its property rights. It contends that those property rights derive from its patents and regulatory exclusivity periods. *See* Opening Br. 43 (asserting a deprivation of its "core property interests in its patented drugs and the right to determine the revenue it derives therefrom"); *id.* at 43–44 (suggesting regulatory exclusivity periods enhance its right to exclude); *accord id.* at 23 (describing the deprivation of "some of the rights conferred by Farxiga's patent").

AstraZeneca is correct that patent rights exist to permit greater profits during a product's exclusivity period to incentivize innovation. *See Eldred v. Ashcroft*, 537 U.S. 186, 215–16 (2003). But "the federal patent laws do not create any affirmative right to make, use, or sell anything." *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1372 (Fed. Cir. 2007) (citation omitted). And where federal patent laws do not confer a right to sell at all, they do not confer a right to sell at a particular price. (No other applicable provision of property law confers a right to sell goods at a particular price either.)

There is no protected property interest in selling goods to Medicare beneficiaries (through sponsors or pharmacy benefit plans) at a price higher than what the government is willing to pay when it reimburses those costs. AstraZeneca's asserted interest does not "resemble any traditional conception of property," *Town of Castle*

Rock, Colorado v. Gonzales, 545 U.S. 748, 766 (2005),[9] and AstraZeneca has no more than "a unilateral expectation" of that interest, *Roth*, 408 U.S. at 577.

AstraZeneca also contends that the Negotiation Program violates the Due Process Clause by imposing price controls on private market transactions while barring judicial review of CMS's price-setting decisions. For support, it relies on *Bowles v. Willingham*, 321 U.S. 503, 517–21 (1944). *Bowles* involved a wartime rent-control statute governing certain private housing transactions. The Supreme Court upheld the statute, noting that it provided for judicial review of the agency's price-setting decisions. *Id.* at 520–21. According to AstraZeneca, its drug sales to Medicare plan sponsors are private market transactions, so any price controls on those transactions must get judicial review as in *Bowles*. But the Negotiation Program only sets prices for drugs *that CMS pays for* when it reimburses sponsors. *See* 42 U.S.C. §§ 1395w-111–1395w-112 (establishing a scheme in which sponsors bid to be accepted into Medicare Part D and enter contracts with CMS for reimbursement); *see also* 42 C.F.R. § 423.301 *et seq.* (setting forth rules for

[9] In *Burns v. Pennsylvania Department of Corrections*, we looked to A. M. Honoré's eleven "standard incidents" of property ownership to determine whether a claimed interest qualified as property under the Due Process Clause. 544 F.3d 279, 287 (3d Cir. 2008) (citation omitted). Honoré's list of "standard incidents" of property ownership are "the right to possess, the right to use, the right to manage, the right to the income of the thing, the right to the capital, the right to security, the rights or incidents of transmissibility and absence of term, the prohibition of harmful use, liability to execution, and the incident of residuarity." *Id.* (quoting A. M. Honoré, *Ownership*, *in* Oxford Essays in Jurisprudence 107 (A.G. Guest, ed. 1961), *reprinted in* Tony Honoré, Making Law Bind: Essays Legal and Philosophical (1987) (emphasis omitted)). AstraZeneca's claimed interest does not align with any of these incidents of ownership.

reimbursing sponsors). These are not private market transactions, regardless of the private hands through which CMS's funds pass. *See Spay*, 875 F.3d at 749 (describing the public-private structure of Medicare Part D).

Because AstraZeneca does not articulate a protected property interest, we will affirm the District Court's grant of summary judgment in favor of the government on AstraZeneca's due process claim.

* * *

For the foregoing reasons, we will affirm the District Court's judgment.

APPENDIX B

[FILED: MARCH 1, 2024]

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP and ASTRAZENECA AB, Plaintiffs, v. XAVIER BECERRA, in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, and CHIQUITA BROOKS-LASURE, in her official capacity as ADMINISTRATOR OF THE CENTERS FOR MEDICARE & MEDICAID SERVICES, Defendants.	Civ. No. 23-931-CFC

Daniel M. Silver, Alexandra M. Joyce, MCCARTER & ENGLISH LLP, Wilmington, Delaware; Catherine E. Stetson, Susan M. Cook, Marian Golden, HOGAN LOVELLS US LLP, Washington, D.C.

Counsel for Plaintiffs

Jacob Laksin, UNITED STATES DEPARTMENT OF JUSTICE, Wilmington, Delaware; Brian D. Netter, Brian M. Boynton, Michelle R. Bennett, Alexander V.

Sverdlov, Stephen M. Pezzi, Christine L. Coogle, Cassandra M. Snyder, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C.

Counsel for Defendants

MEMORANDUM OPINION

/s/
COLM F. CONNOLLY
CHIEF JUDGE

March 1, 2024
Wilmington, Delaware

The plaintiffs in this action—AstraZeneca Pharmaceuticals LP and AstraZeneca AB (collectively, AstraZeneca)—challenge the constitutionality of the Drug Price Negotiation Program (the Program) created by the Inflation Reduction Act of 2022, Pub. L. No. 117-169, (the IRA or the Act) and the lawfulness of certain guidance promulgated by the Centers for Medicare and Medicaid Services (CMS) to implement the Program. They have sued the Secretary of Health and Human Services (the Secretary) and the Administrator of CMS (together with the Secretary, the Government).

Pending before me are the parties' cross motions for summary judgment. D.I. 18; D.I. 21. Because AstraZeneca does not have Article III standing to challenge the lawfulness of the guidance and because it has not identified a property interest protected by the Constitution that is put in jeopardy by the Program, I will deny AstraZeneca's motion and grant the Government's motion.

I.

A.

Medicare is a federally funded health insurance program administered by the Secretary through CMS for individuals who are 65 or older and for some younger individuals who have certain disabilities. *See generally* 42 U.S.C. § 1395 *et seq.* The Medicare statute is divided into five "Parts" labeled A through E. Two of those Parts are relevant here. Part B provides Medicare beneficiaries with, among other things, coverage for certain drugs administered as part of a physician's service and drugs furnished for use with certain durable medical equipment. 42 C.F.R. § 410.28. Drugs covered by Part Bare usually not self-administered. *See Part B Drugs and Biologicals,* CENTERS FOR MEDICARE & MEDICAID SERVICES, https://www.cms.gov/cms-guide-medical-technology-companies-andother-interested-parties/payment/part-b-drugs [https://perma.cc/7XR4-7 JGA] (last modified Sept. 6, 2023). Part D provides beneficiaries with prescription drug coverage. 42 U.S.C. § 1395w-101 *et seq.;* 42 C.F.R. pt. 423. In 2021, approximately 49 million Medicare beneficiaries filled prescriptions covered by Part D. The cost of those prescriptions totaled $200 billion. *See* John E. Dicken, *MEDICARE PART D: CMS Should Monitor Effects of Rebates on Drug Coverage and Spending,* Government Accountability Office, 1 (Sept. 19, 2023), https://www.gao.gov/assets/gao-23-107056.pdf [https://perma.ccNRW4-YNK4].

To access Part D's coverage, a Medicare beneficiary must enroll in a Part D plan established and administered by a private insurance company (referred to in Part D as a "sponsor"). *Pharm. Care Mgmt. Ass 'n v. Mulready,* 78 F.4th 1183, 1188 (10th Cir. 2023). As the court explained in *Mulready,*

> each plan sets terms for its beneficiaries to use the plan's prescription-drug benefits. These terms include what drugs the plan covers (the formulary), how much the plan will pay for those drugs (the cost-sharing terms), and at which pharmacies beneficiaries can have prescriptions filled (the pharmacy network). Together, the formulary, cost-sharing terms, and pharmacy network comprise the plan's prescription-drug-benefit design or structure.

Id.

As originally enacted in 2003, Part D barred the Secretary (and thus CMS) from "interfer[ing] with the negotiations between drug manufacturers and pharmacies and [prescription drug plan] sponsors" and from "requir[ing] a particular formulary or institut[ing] a price structure for the reimbursement of covered part D drugs." 42 U.S.C. § 1395w-111(i) (2003). But in 2022, in provisions contained in the IRA (codified in relevant part at 42 U.S.C. §§ 1320f-1320f-7 and 26 U.S.C. § 5000D), Congress directed the Secretary, through CMS, to "establish a Drug Price Negotiation Program." 42 U.S.C. § 1320f(a). To carry out the Program, the IRA requires CMS to "enter into agreements with manufacturers of selected drugs" and to "negotiate ... maximum fair prices for such selected drugs" for defined "price applicability period[s]." *Id.* Notwithstanding the Program's title and its mandates that CMS "negotiate" maximum fair prices and reach "agreements" with drug manufacturers, the IRA imposes ceilings on the maximum prices of the drugs selected for the Program, § 1320f-3(c); directs CMS to "aim to achieve the lowest maximum fair price for each selected drug," § 1320f-3(b)(l); and levies excise taxes on all sales of a drug selected for the Program in the event the manufacturer of the drug wants to continue to

participate in Medicare and Medicaid but won't agree with CMS's maximum fair price determinations for that drug, 26 U.S.C. § 5000D(b). Congress intended the price ceiling, negotiation, and tax provisions in the Program to result in lower prices for Part B and Part D drugs that lack generic competition and account for a disproportionate share of Medicare's expenses. *See* D.I. 19 at 5; D.I. 22 at 6-7.

The Program operates in cycles. Each price applicability period begins on January 1 of the "initial price applicability year" and ends "with the last year during which the drug is a selected drug" subject to the negotiated maximum fair price. 42 U.S.C. §§ 1320f(b)(l)-(2). The Program's first price applicability period—the period at issue in this case—begins on January 1, 2026. For ease of reference, I will call this period "the 2026 price period," and I will similarly identify all other price periods by reference to their initial price applicability year.

For each price period, the Act requires CMS to (1) use a mandated methodology to select a specific number of drugs for negotiating a maximum fair price, (2) publish a list of those selected drugs not later than a specified "selected drug publication date," and (3) engage with the manufacturers of the selected drugs in a negotiation process that has mandated steps and deadlines. *See§§* 1320f-1320f-3.

The Act directs CMS to begin the process of selecting the drugs for negotiation by identifying the universe of "qualifying single source drugs." As relevant here,§ 1320f-l(e)(l){A) of the Act defines a "qualifying single source drug" as a Part D drug

> (i) that is approved [by the United States Food and Drug Administration (FDA)] 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 [brand] drug for any [generic drug] that *is* approved [by the FDA] and *marketed* ....

§ 1320f-l(e)(l)(A) (emphasis added).[1]

The Act next requires CMS to identify within this universe of drugs "negotiation-eligible drugs." For the 2026 and 2027 price periods, the negotiation-eligible drugs are the 50 qualifying single source drugs with the highest total Medicare Part D expenditures over a specified 12-month period. § 1320f-l(d)(l)(A). For subsequent price periods, the negotiation-eligible drugs are the 50 qualifying single source drugs with the highest total Medicare Part B and Part D expenditures over a specified 12-month period. § 1320f-l(d)(l)(A).

The Act requires CMS to rank the negotiation-eligible drugs according to total expenditures (with the highest total expenditures having the highest ranking) and to select and publish a list of a specific number of the highest-ranking drugs no later than a selected drug publication date specified in the Act for each price period. The Act mandates that CMS base its total expenditure determinations using "data that is aggregated across dosage forms and strengths of the drug." § 1320f-l(d)(3)(B); *see also §* 1320f-5(a)(2). The number of drugs to be selected varies by year. CMS must select 10 drugs for

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[1] Qualifying single source drugs also include certain FDA-approved biological products. Because the IRA's provisions relating to biological products have no bearing on this case, I do not discuss them.

the 2026 price period, 15 drugs for the 2027 and 2028 price periods, and 20 drugs for all subsequent price periods. § 1320f-l(a)-(b). If the number of negotiation-eligible drugs for any price period is fewer than the specified number of selected drugs for that period, CMS is to select "all" negotiation-eligible drugs for negotiation. *See §* 1320f-l(a).

Congress took pains to ensure that CMS—and only CMS—selects the drugs covered by the Program. The IRA expressly states that "[t]here shall be no administrative or judicial review of ... [t]he selection of drugs under section 1320f-1(b) of this title, the determination of negotiation-eligible drugs under section 1320f-l(d) of this title, and the determination of qualifying single source drugs under section 1320f-l(e) of this title." § 1320f-7(2).

Once CMS publishes the list of selected drugs, the manufacturers of those drugs must decide whether to enter into an agreement with CMS to negotiate the maximum fair price of the drug. The Act requires CMS to enter into such negotiation agreements with willing manufacturers by dates specified in the statute for each price period. § 1320f-2(a). The Act does not require manufacturers to enter into negotiation agreements but it provides them a powerful incentive to negotiate a maximum fair price with CMS: If a manufacturer of a selected drug wants to continue to participate in Medicare, it must either agree to negotiate a maximum fair price for that drug or pay an excise tax of at least 65% and up to 95% on all (i.e., both Medicare and non-Medicare) sales of the drug. 26 U.S.C. § 5000D.

CMS and the manufacturers that do enter into negotiation agreements are required under the Act to follow a specified negotiation process that includes the making of offers and counteroffers by deadlines set by the

statute. The Act directs CMS to "develop and use a consistent methodology and process" that "accord[s]" with the Act's specified negotiation process and that "aims to achieve the lowest maximum fair price for each selected drug." 42 U.S.C. § 1320f-3(b)(l).

The negotiation process mandated by the Act begins with the submission of pricing and other related data by the manufacturer to CMS on a date prescribed by the statute. § 1320f-2(a)(4); § 1320f-3(b)(2)(A). CMS is then required—again by a date set by the statute for each price period—to make "a written initial offer that contains [its] proposal for the maximum fair price of the drug and a concise justification" of the proposal. § 1320f-3(b)(2)(B). "Not later than 30 days after" receiving the initial offer, the manufacturer must either accept such offer or propose a counteroffer. § 1320f-3(b)(2)(C). The Act requires CMS to "respond in writing to such counteroffer," § 1320f-3(b)(2)(D), but it does not say when CMS must do so.

For each price period, the Act specifies a date when the negotiations between CMS and the manufacturers of the selected drugs "shall end." § 1320f-3(b)(2)(E). If the parties have not agreed on a price by that date, the manufacturer is deemed to be noncompliant and subject to the excise tax penalties under 26 U.S.C. § 5000D.

If CMS and a manufacturer agree on a maximum fair price for a selected drug, the manufacturer must provide "access to such price" to Medicare beneficiaries beginning on January 1 of the initial price applicability year. 42 U.S.C. § 1320f-2(a)(l). Once a drug is selected for the Program, it remains in the Program for sale to Medicare beneficiaries at the negotiated price. Certain changes to the drug, not relevant here, can trigger renegotiation and a new maximum fair price beginning in 2028, or the drug

can be removed from the Program starting the first year that begins at least nine months after CMS determines that a generic version of the drug is approved and marketed. §§ 1320f-l{c)(l); 1320f-3(f).

If a manufacturer has agreed to a maximum fair price with the Government, but then fails to make the selected drug available to Medicare beneficiaries at that price, it is subject to civil penalties under § 1320f-6(a). Each time a manufacturer distributes a selected drug at a price above the drug's maximum fair price it "shall be subject to a civil monetary penalty equal to ten times the ... difference between the price for such drug ... and the maximum fair price." § 1320f-6(a)(2).

B.

Congress directed CMS to implement the Program through "instruction or other forms of program guidance." Pub. L. No. 117-169, § 1 l00l(c). CMS issued initial guidance in March 2023 and then, after receiving public comment, published revised guidance (the Guidance) on June 30, 2023. The Guidance expressly states that it applies only to the 2026 price period. D.I. 20-2 at 1-2.

Two provisions in the Guidance are relevant here. Both provisions address how CMS will determine whether a drug constitutes a qualifying single source drug. Under the first provision, CMS "will identify a potential qualifying single source drug using ... all dosage forms and strengths of the drug with the same active moiety and the same holder of a New Drug Application (NDA), inclusive of products that are marketed pursuant to different NDAs." D.I. 20-2 at 99 (footnote omitted). As explained in the Guidance, "[t]his approach to identifying a potential qualifying single source drug aligns with the requirement in [42 U.S.C. § 1320f-l(d)(3)(B)] of the Act to

use data aggregated across dosage forms and strengths of the drug, including new formulations of the drug." D.I. 20-2 at 100. CMS also deemed this approach "appropriate" based on its observation that "new dosage forms or different routes of administration of the same active moiety/active ingredient have been submitted by the same NDA[-]holder and approved under different NDAs ...." D.I. 20-2 at 100.

The second relevant Guidance provision explains how CMS will determine if a generic drug "is marketed" under § 1320f-l(e)(l)(A)(iii). As noted above, § 1320f-l(e)(l)(A)(iii) excludes a brand drug from being designated as a qualifying single source drug if an FDA-approved generic version of the brand drug "is marketed." The Guidance provides that CMS will deem a generic drug to be marketed "when the totality of the circumstances ... reveals that the manufacturer of that drug or product is engaging in bona fide marketing of that drug or product." D.I. 20-2 at 102. CMS explained in the Guidance that without this provision, a generic drug manufacturer "could launch into the market a token or de minimis amount of a generic drug ... for the selected drug and the manufacturer of that selected drug could claim that the [maximum fair price] should no longer apply." D.I. 20-2 at 72.

Under the Guidance, the "totality of the circumstances" CMS will consider in determining whether a generic drug has been bona fide marketed "includ[es]" Prescription Drug Event (PDE) data and Average Manufacturer Price (AMP) data, D.I. 20-2 at 3, 165. PDE data are drug cost and payment information submitted to CMS by drug plan sponsors every time a Medicare beneficiary fills a prescription under Medicare Part D. *See Questions and Answers on Obtaining PDE Data,* CENTERS FOR MEDICARE & MEDICAID SERVICES,

https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovgenin/downloads/partdclaimsdataqa.pdf [https://penna.cc/QJSE-ALKG]. AMP is "the average price paid to manufacturers by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturers." D.I. 20-2 at 76 n.23. It is calculated using manufacturer sales transaction data and is provided to CMS on a monthly and quarterly basis. D.I. 20-2 at 76 n.23. The Guidance expressly states that the "use of [PDE and AMP] data is not exhaustive, and [that] all data and other information will be reviewed in totality in monitoring if manufacturers of these applicable generic drugs ... engage in bona fide marketing." D.I. 20-2 at 7. The Guidance also provides that "[t]he determination [of] whether a generic drug or biosimilar is being bona fide marketed on an ongoing basis is a totality-of-the-circumstances inquiry that will not necessarily turn on any one source of data." D.I. 20-2 at 77.

II.

On August 25, 2023—almost two months after CMS published its Guidance—AstraZeneca Pharmaceuticals LP (but not AstraZeneca AB) initiated this lawsuit with the filing of the original Complaint. D.I. 1. Four days later, on August 29, 2023, CMS published the list of the Program's ten selected drugs for the 2026 price period. AstraZeneca's Farxiga is one of those drugs. It is the only AstraZeneca drug on the list. *See* D.I. 19 at 6; D.I. 21-2 at 3.

Farxiga was approved by the FDA and is marketed under a single NDA to treat indications relating to diabetes, heart disease, and chronic kidney disease. D.I. 19 at 6; D.I. 21-2 at 4. Its active moiety is dapagliflozin. D.I. 19 at 6. Between June 2022 and May 2023,

approximately 799,000 Medicare Part D enrollees used Farxiga, and Farxiga accounted for approximately $3,268,329,000 of Part D's gross covered prescription drug costs during that 12-month period. *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026,* CENTERS FOR MEDICARE & MEDICAID SERVICES, https://www.cms.gov/files/document/fact-sheet-medicare-selected-drug-negotiation-list-ipay-2026.pdf [https://perma.cc/T6W5-G6B U].

AstraZeneca alleges, and the Government does not dispute, that the FDA has granted tentative approval to 17 generic manufacturers to market generic versions of Farxiga and that Farxiga "will experience generic competition sometime between October 2025 and Summer 2026." D.I. 20 ¶ 27. The FDA grants a generic drug tentative approval if the generic drug is "ready for approval before the expiration of any patents or exclusivities accorded to the [brand] reference listed drug product[.]" *Drugs@FDA Glossary of Terms,* U.S. FOOD & DRUG ADMINISTRATION, https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms [https://perma.cc/Q88Y-KUWB] (last updated Nov. 14, 2017).

On September 26, 2023, AstraZeneca filed the operative Amended Complaint. The Amended Complaint is identical to the original Complaint in all material respects with two exceptions. First, the Amended Complaint added AstraZeneca AB as a Plaintiff. D.I. 16-2 at 1; D.I. 16-2 ¶ 24. Second, the Amended Complaint added an allegation that CMS had listed Farxiga as one of the ten selected drugs for the Program's 2026 price period. D.I. 16-2 ¶ 22.

The Amended Complaint has three claims. Counts I and II allege that CMS's Guidance violates the Administrative Procedure Act (APA), 5 U.S.C. § 706(2). D.I. 19 ¶¶ 49, 123-30. Count III alleges that the IRA is unconstitutional and violates AstraZeneca's Fifth Amendment right to due process.[2]

Pursuant to a stipulated order, on the same day it filed its Amended Complaint, AstraZeneca filed a motion for summary judgment in its favor on all counts in the Amended Complaint pursuant to Federal Rule of Civil Procedure 56. D.I. 18. Less than a week later—on October 1, 2023—AstraZeneca entered into an agreement with CMS to participate in the Program and negotiate a maximum fair price for Farxiga for the 2026 price period. *Medicare Drug Price Negotiation Program: Manufacturer Agreements for Selected Drugs for Initial Price Applicability Year 2026,* CENTERS FOR MEDICARE & MEDICAID SERVICES, https://www.cms.gov/files/document/fact-sheet-medicare-selected-drug-negotiation-list-ipay-2026.pdf [https://perma.cc/2F7N-4F5U].

On November 1, 2023, the Government filed an opposition to AstraZeneca's summary judgment motion and "cross-move[d] for summary judgment on all claims

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[2] The IRA addressed a broad array of topics such as energy production, carbon emissions, and corporate taxes that have nothing to do with the Drug Price Negotiation Program. Although AstraZeneca's challenge to the IRA focuses solely on the constitutionality of the Program, AstraZeneca asks in its Amended Complaint for "[a] declaration pursuant to 28 U.S.C. § 2201 that the IRA is unconstitutional and violates the Due Process Clause of the United States Constitution." D.I. 16 at 43-44. Neither party addressed the issue of severability. Since I conclude that AstraZeneca's due process claim fails as a matter of law, I need not and do not address severability.

pursuant to Rule 56." D.I. 21. I heard oral argument on the competing motions on January 31, 2024. D.I. 64.

III.

A court must grant summary judgment "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The parties agree that there are no disputes with respect to any material fact and that their motions present purely legal questions. D.I. 13.

IV.

I turn first to AstraZeneca's APA claims. Both claims challenge how CMS interpreted in its Guidance the Act's definition of "qualifying single source drug" in § 1320f-l(e)(l)(A). In Count I, AstraZeneca alleges that the Guidance's interpretation of that term "improperly overrode the statutory definition" by "embrac[ing] *all* dosage forms and strengths of *any* drug marked by the manufacturer with the same active moiety or ingredient" even if those different forms and strengths were approved under different NDAs. D.I. 16 ¶¶ 49, 59, 60, 126 (emphasis in the original). In AstraZeneca's view, § 1320f-l(e)(l)(A) "directs that each Qualifying Single Source Drug must be identified by reference to its *individual* approval ..., i.e., its distinct NDA" and "[a]ny other reading—including the one based on common active moiety or common active ingredient espoused by CMS—contradicts the plain text of the statute and therefore must be set aside." D.I. 19 at 16 (emphasis in the original).

In Count II, AstraZeneca alleges that CMS's requirement that a generic drug be marketed in a bona fide way to be deemed "is marketed" under § 1320f-l(e)(l)(A)(iii) "impermissibly expanded the requirements

that must be met before a drug is deemed to have generic competition such that it is ineligible for selection or negotiation." D.I. 16 ¶ 52; *see also* D.I. 16 ¶¶ 51, 134; D.I. 19 at 19. According to AstraZeneca, the ordinary and accepted meaning of "marketing" is "exposure for sale in a market," and if a generic drug is exposed for sale in any way or quantity the reference brand drug cannot be a selected drug for negotiation under the Program. D.I. 19 at 20.

The Government argues that I lack jurisdiction over these claims for two reasons: first, because AstraZeneca has not established and cannot establish Article III standing to assert the claims; and second, because § 1320f-7 of the IRA expressly precludes judicial review of CMS's selection of a drug for negotiation under the Program and its underlying determinations that a drug is a qualifying single source drug and a negotiable-eligible drug.

A.

Article III of the Constitution limits the jurisdiction of federal courts to "Cases" and "Controversies." *Lujan v. Deft. of Wildlife,* 504 U.S. 555, 559 (1992). "Part of the case-or-controversy requirement is the requirement that plaintiffs have standing to sue." *Yaw v. Delaware River Basin Comm 'n,* 49 F.4th 302,310 (3d Cir. 2022). To establish standing "a plaintiff must show (i) that he suffered an injury in fact that is concrete, particularized, and actual or imminent; (ii) that the injury was likely caused by the defendant; and (iii) that the injury would likely be redressed by judicial relief." *Trans Union LLC v. Ramirez,* 594 U.S. 413,423 (2021).

The plaintiff, as the party invoking federal jurisdiction, bears the burden of establishing standing. *Id.* And "[w]hile generalized allegations of injury may suffice at the pleading stage [to meet that burden], a plaintiff can

no longer rest on such mere allegations in response to a summary judgment motion, but must set forth specific facts by affidavit or other evidence." *Pa. Prison Soc y v. Cortes,* 508 F .3d 156, 161 (3d Cir. 2007) (internal quotation marks and citation omitted). Because "standing is not dispensed in gross, a plaintiff who raises multiple causes of action must demonstrate standing for each claim he seeks to press." *In re Schering Plough Corp.,* 678 F.3d 235,245 (3d Cir. 2012) (internal quotation marks and citation omitted).

As an initial matter, AstraZeneca does not allege that CMS's selection of Farxiga for negotiation under the Program constitutes the injury for which it seeks redress in this action. That makes sense, because neither element of the Guidance's "qualifying single source drug" definition challenged by AstraZeneca could have had any bearing on CMS's decision to designate Farxiga as a selected drug. Farxiga is approved and marketed under a single NDA and no generic version of Farxiga is marketed in any manner or quantity. Thus, Farxiga satisfies *AstraZeneca's* interpretation of the statutory definition of "qualified single source drug," and, as a result, the selection of Farxiga is not a cognizable injury that could be remedied with a decision in AstraZeneca's favor.

In its briefing, AstraZeneca argued that it has standing to pursue its APA claims because the Guidance "ha[s] harmed and will continue to harm" it in three other ways. D.I. 58 at 5. At oral argument, AstraZeneca barely mentioned these three alleged harms and instead argued that a fourth harm it suffered gives it standing to assert Counts I and II. I address the four harms AstraZeneca has alleged in turn.

1.

AstraZeneca contends first that it has standing to bring Count I because CMS's interpretation of "qualifying single source drug" "decreases the incentives for AstraZeneca to look for additional uses for FARXIGA's single-ingredient active moiety for patients in need." D.I. 58 at 19. In AstraZeneca's telling:

> Under CMS's Guidance, the agency will effectively treat FARXIGA and any new product with the same single-ingredient active moiety approved under a distinct NDA as the same drug—even if that new product is approved years after FARXIGA and after extensive research and financial investment. Thus, a new drug product or therapy with the same single-ingredient active moiety as FARXIGA—even if it is approved under a different NDA ... under FDA's rules-will immediately be subject to the Maximum Fair Price for FARXIGA, without regard to the statutory seven-year minimum that would otherwise apply before a drug is selected for price negotiation. This eliminates incentives for AstraZeneca to further innovate new uses for FARXIGA's single-ingredient active moiety, which in turn will narrow patient access to new treatments.

D.I. 61 at 6-7 (citations and footnote omitted).

A loss or diminishment of an incentive to do something, however, is not a concrete injury. To determine whether an alleged intangible harm is sufficiently concrete to constitute an injury-in-fact, courts "assess whether the alleged injury to the plaintiff has a 'close relationship' to a harm 'traditionally' recognized as providing a basis for a lawsuit in American courts." *Trans*

Union, 594 U.S. at 424 (quoting *Spokeo, Inc. v. Robins*, 578 U.S. 330,340 (2016)). "That inquiry asks whether plaintiffs have identified a close historical or common-law analogue for their asserted injury." *Id.* AstraZeneca has not identified, and I am not aware of, any court decision that has recognized a tort for loss or diminishment of an incentive to do something. Nor has AstraZeneca identified any harm traditionally recognized as providing a basis for a lawsuit that is analogous to or has a close relationship with a loss or diminishment of an incentive. This failure should come as no surprise. AstraZeneca's theory of injury is unprecedented and understandably so. Were courts to adopt AstraZeneca's "disincentivizing" theory of standing, they would open their doors to plaintiffs whose only complaint was that they disliked a law or government action. If AstraZeneca had its way, the merits of every "sin tax" could be challenged in never-ending lawsuits brought by disgruntled smokers, gamblers, oenophiles, and (at least in Philadelphia) soda drinkers.

But even if AstraZeneca's alleged "decreases in incentives" to develop new uses of Farxiga could be deemed sufficiently concrete, it would still not satisfy the "actual or imminent" requirement for an injury-in-fact. To be an imminent harm, the "threatened injury must be *certainly impending." Clapper v. Amnesty Int'l USA,* 568 U.S. 398, 409 (2013) (emphasis in the original). "[A]llegations of *possible* future injury are not sufficient." *Id.* (internal quotation marks and citation omitted) (emphasis in the original). As the Court held in *Clapper,* a plaintiff "cannot manufacture standing merely by inflicting harm on [itself] based on [its] fears of hypothetical future harm that is not certainly impending." 568 U.S. at 416. In this case, AstraZeneca's alleged injury 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. The fact that the word "if" is required to describe AstraZeneca's alleged injury demonstrates that the harm it complains of is neither actual nor certainly impending. *See Reilly v. Ceridian Corp.*, 664 F.3d 38, 43 (3d Cir. 2011) (finding plaintiffs failed to allege an imminent injury-in-fact where "we cannot now describe how [plaintiffs] will be injured in this case without beginning our explanation with the word 'if.'"); *Storino v. Borough of Point Pleasant Beach*, 322 F.3d 293, 297-98 (3d Cir. 2003) (finding plaintiffs failed to allege imminent injury-in-fact where "one cannot describe how the [plaintiffs] will be injured without beginning the explanation with the word 'if'").

In addition, the record evidence shows that the hypothetical scenario upon which AstraZeneca's stated harm is premised is extremely *unlikely* to occur. For starters, the odds of winning FDA approval are slim for any new drug. AstraZeneca itself acknowledges that "very few early drug candidates are ever approved or commercialized," D.I. 19 at 2, and "[e]ven when a drug shows early promise in clinical trials, the rigorous drug approval process means very few of these research efforts result in a new drug or indication," D.I. 58 at 2. According to the declarant of the sole affidavit submitted by AstraZeneca in support of its motion, "[i]t can take decades ... to shepherd a single potential new therapy through clinical trials" and "only one of every 5,000 compounds that enters preclinical testing will achieve FDA approval-a failure rate of 99.98%." D.I. 60 ¶ 7.

The odds of the FDA approving a new indication of Farxiga in the near future appear especially unlikely, as

AstraZeneca concedes that its only clinical trials involving Farxiga's active moiety are "focused on 'combination product' therapies that would not be impacted by [the Guidance's] definition of a Qualifying Single Source Drug." D.I. 60 ¶ 23. But even if AstraZeneca could eventually win FDA approval of a new indication for Farxiga's active moiety at some future date, the record evidence provides no basis to believe that any new indication would be approved in a new NDA; and thus there is no basis to believe that CMS's definition of a qualifying single source drug would come into play if a new indication were approved. If anything, the record suggests the opposite, as AstraZeneca says it "has developed multiple new uses for FARXIGA, resulting in FDA approvals to treat heart disease and chronic kidney disease, in addition to diabetes," D.I. 58 at 7-8, but none of these new uses were approved in a new NDA, D.I. 21-2 at 4. Finally, even if AstraZeneca could eventually obtain FDA approval for a new indication that met the criteria for a new NDA—perhaps "decades" from now—it would be highly unlikely that Farxiga would not have generic competition at that time and thus highly unlikely that it would still meet the definition of a qualifying single source drug. AstraZeneca insists, and the Government does not dispute, that 17 generic manufacturers have already received tentative approval to launch a Farxiga generic drug and that Farxiga "will experience generic competition sometime between October 2025 and Summer 2026." D.I. 60 ¶ 27.

For all these reasons, AstraZeneca's alleged harm in the form of decreases in incentives to develop new uses of Farxiga does not give it standing to assert Count I.

2.

AstraZeneca next argues that it has standing to assert Count II because the Guidance's bona fide marketing test will soon cause it an injury-in-fact in the form of simultaneous "generic competition *and* mandatory pricing" "for months" after generic versions of Farxiga enter the market. D.I. 58 at 9 (emphasis in the original). According to AstraZeneca, "[t]he statute directs that if a generic product is 'approved and marketed' before or during [initial price applicability year] 2026, FARXIGA will be released from the Maximum Fair Price." D.I. 58 at 8 (citing §§ 1320f-l(e)(l)(A)(iii)–(B)(iii)). In AstraZeneca's words:

> The IRA is a heavy-handed statute that imposes a significant burden on manufacturers. The one critical concession the statute gives to AstraZeneca and other manufacturers is that when a drug product faces generic competition, the drug is no longer subject to the IRA's price controls. CMS's "bona fide marketing" test annihilates that statutory protection. Under the agency's test, AstraZeneca will have to sell FARXIGA at the agency's compelled below-market price, despite also facing generic competition for that same product between October 2025 and Summer 2026, unless and until the agency decides the generic product has been marketed in a sufficiently "robust and meaningful" manner.

D.I. 58 at 43-44. AstraZeneca says that CMS cannot comply with this statutory directive if it applies the bona fide marketing test because the reporting of the PDE data that CMS has said it will rely on to determine if there has been bona fide marketing of a generic drug "moves at

a glacial pace." D.I. 19 at 27. In AstraZeneca's view, "[b]ecause that data is delayed by numerous months, FARXIGA's generic competitor will not satisfy the agency's 'bona fide marketing' standard for months after generic entry—assuming the agency finds the generic's marketing sufficiently 'bona fide' even then." D.I. 58 at 9.

There are many flaws in this argument. To begin with, its legal premises are wrong. Neither § 1320f-l(e)(l) nor any other section of the Act requires the "release" of a drug selected for negotiation for the 2026 price period from the Program's maximum fair price if a generic version of that drug is approved and marketed before or during 2026. It is also not accurate to say that the Act "conce[des]" or even suggests in any way that a selected drug is not subject to the Act's price controls if it faces generic competition.

As discussed above, § 1320f-l{e)(l) defines the universe of qualifying single source drugs from which the negotiation-eligible drugs and ultimately the selected drugs are chosen. Section 1320f-l(c)—not § 1320f-l(e)(l)—governs the removal of drugs from the Program once they have been selected. Section 1320f-l(c)(2) provides that a selected drug "shall not be subject to the negotiation process" if CMS determines that a generic version of the drug has been approved by the FDA and marketed "before or during the negotiation period." 42 U.S.C. § 1320f-l(c)(2)(B). Under § 1320f-l{c)(l), if no generic version of the selected drug has been approved and marketed by the end of the negotiation period, then that selected drug is deemed a selected drug for the initial price applicability year *and* for "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" has been approved and marketed.

The negotiation period for the 2026 price period began on October 1, 2023, and ends on August 1, 2024. *See §§* 1320f(b)(4); 1320(d)(2)(A)-(B). Thus, under the express terms of the Act, if no generic version of a drug selected for the 2026 price period enters the market before August 1, 2024, then the selected drug is subject to any negotiated maximum fair price for the entirety of 2026 even if a generic drug later enters the market before or during 2026. And if no generic drug enters the market before April 1, 2026, then the selected drug is subject to any negotiated maximum fair price for the entirety of 2027 even if a generic drug enters the market between April 1, 2026 and December 31, 2027. In both scenarios, the selected drug is simultaneously subject to generic competition and mandatory pricing.

In this case it is undisputed that no generic version of Farxiga will enter the market before October 2025. Accordingly, since there will not be an approved generic version of Farxiga on the market by August 1, 2024, it is not the "agency's test" but rather the Act itself that requires AstraZeneca to "have to sell FARXIGA at the agency's compelled below-market price, despite also facing generic competition for that same product between October 2025 and Summer 2026." D.I. 58 at 43-44. That alleged harm, therefore, cannot meet the causation and redressability requirements for standing, as it was not caused by the Guidance and could not be remedied by vacating the Guidance.

To the extent AstraZeneca meant to imply in its briefing that it would be injured by having to face generic competition and mandatory pricing simultaneously in 2027 because delays in PDE data reporting will prevent CMS from determining before April I, 2026 that Farxiga had been subjected to bona fide marketing of generic competition, that harm does not constitute an actual or

imminent injury sufficient to create standing. First, a generic version of Farxiga would have to be on the market before April 1, 2026 for Farxiga to be exempted from the negotiated maximum price in 2027. But whether a generic would be on the market by that date is speculative. AstraZeneca says that Farxiga "will experience generic competition *sometime* between October 2025 and Summer 2026." D.I. 20 ¶ 27 (emphasis added). AstraZeneca has not alleged, let alone established, that a generic version of Farxiga *will* be on the market before April 1, 2026. *See Clapper*, 568 U.S. at 409 ("Although imminence is concededly a somewhat elastic concept, it cannot be stretched beyond its purpose, which is to ensure that the alleged injury is not too speculative for Article III purposes—that the injury is certainly impending.").

Second, AstraZeneca's allegation that CMS will "delay" "for months" after the market entry of a Farxiga generic competitor its determination of whether that competitor was bona fide marketed is also speculative. The Guidance expressly states that CMS's totality-of-the-circumstances inquiry "will not necessarily turn on any one source of data" and that "all data and other information will be reviewed in totality" to determine whether a manufacturer has engaged in bona fide marketing. D.I. 20-2 at 6, 77. AstraZeneca does not allege or suggest that CMS's receipt of these alternative sources of information would be "delayed." AstraZeneca also does not allege—and there is no reason to infer from the record evidence—that a delay in PDE reporting would affect the timing of CMS's determination that a generic drug had been bona fide marketed any more than such a delay would affect the timing of CMS's determination that a generic drug met AstraZeneca's definition of marketed. AstraZeneca does not allege, for example, that CMS would not consider PDE data to determine whether a

generic drug had been exposed for sale (AstraZeneca's definition of "marketing").

Third, AstraZeneca has not alleged, let alone established, that Farxiga will experience generic competition that is exclusively marketed at a de minimis level insufficient to qualify as bona fide marketing. And accepting as true AstraZeneca's allegations that 17 manufacturers have received tentative FDA approval to enter the market and that Farxiga will experience generic competition no later than Summer 2026, it is highly unlikely that all 17 of those manufacturers would market their drugs in only a de minimis manner.

In sum, AstraZeneca has not established that the harm it alleges it has suffered and will continue to suffer from CMS's bona fide marketing requirement creates standing to assert Count II.

3.

AstraZeneca also argues that it has standing to assert both of its APA claims because its "current decision-making about other drugs has been and will continue to be negatively affected by CMS's Guidance." D.I. 58 at 11. In AstraZeneca's words:

> Within the next three years, 50 more drug products will be selected [by CMS] for negotiation. As a large U.S. pharmaceutical company, AstraZeneca will very likely have products on that list. As it makes plans to develop and commercialize new versions of these and other products, AstraZeneca has no rational choice but to take the agency's current policies into account. That causes AstraZeneca harm now.

D.I. 58 at 11 (citations omitted).

The harm alleged here is too vague to establish a cognizable injury. *Nat'l Shooting Sports Found. v. Att'y Gen. of New Jersey,* 80 F.4th 215, 219 (3d Cir. 2023). The Guidance is only for the 2026 price period, and Farxiga is the only AstraZeneca drug selected for that period. 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 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.

This alleged harm of negatively affected decision-making for price periods beyond 2026 also fails to meet the causation and redressability requirements for standing. 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. And vacating the 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.

4.

At oral argument, AstraZeneca effectively abandoned the standing arguments it made in its briefing. Instead, it argued that the counteroffer of a maximum fair price for Farxiga that the Act requires it to submit to CMS on March 2, 2024 "supplies the basis for [AstraZeneca's] standing." D.I. 64 at 8:5-9. Its counsel explained this standing theory as follows:

> ... [I]n order to make a counteroffer to the Government's price offer ..., AstraZeneca needs to know what is the value of this product [Farxiga] that we have.

> The value of that product, among other things, depends on a couple of key components. One of them is, what is coming down the pipeline ... that might, under the Government's construction of the guidance, be treated as the exact same drug and shunted into the same price? That's going to affect our valuation of the product right now, this product, Farxiga.
>
> The exact same calculus comes into play with respect to our other merits APA argument, which is the bona fide marketing requirement. If this drug, as should be, is taken back out of the price negotiation after generics come on the market, which 17 of them are poised to do as our declarant points out, that affects our valuation of the drug right now because we will understand that, in the world of the statute, this drug should be taken back out of the price program after a year.
>
> But *because the CMS has chosen to interpret the statute in two very faulty ways, we are not able to make that kind of valuation. We have no idea whether the value will be higher or lower because we don 't know the impact of CMS's flawed guidance on our ability to negotiate.*
>
> *So we, essentially, have to walk in over the next 30 days to this counteroffer, based on a flawed definition that affects our ability to value our product. That is the reason that we have standing.*

D.I. 64 at 8:15-9:21 (emphasis added).

Of course, AstraZeneca *does* "know the impact of CMS's [allegedly] flawed guidance on [its] ability to

negotiate." AstraZeneca described in detail in a 44-page Amended Complaint and 100 pages of briefing the content of the Guidance it challenges and the reasons why it contends that Guidance is unlawful. It cannot credibly argue that it is unable to understand the Guidance or how the Guidance applies as written to Farxiga.

The only uncertainty relating to the Guidance comes from the filing of this lawsuit. Because AstraZeneca seeks by this lawsuit a declaration that the IRA is unconstitutional and vacatur of the Guidance, so long as the suit is pending, AstraZeneca can say with a straight face that it has "no idea whether the value [of Farxiga] will be higher or lower." A plaintiff, however, cannot create standing to file a suit by filing the suit. *See Fair Hous. Council of Suburban Phila. v. Montgomery Newspapers*, 141 F.3d 71, 80 (3d Cir. 1998) ("[T]he pursuit of litigation alone cannot constitute an injury sufficient to establish standing under Article III."). To hold otherwise would eviscerate the Constitutional requirement of standing.

Accordingly, the injury articulated by AstraZeneca at oral argument is insufficient to confer standing for either of its APA claims.

* * * *

Because AstraZeneca has failed to identify a cognizable injury-in-fact that is caused by the Guidance and could be redressed by vacatur of the Guidance, it has not established the requisite standing to allege Counts I and II of the Amended Complaint and I will therefore dismiss those claims for lack of jurisdiction.

B.

Having determined that I lack jurisdiction over Counts I and II under Article III, I need not (and

arguably cannot) address whether § 1320f-7 precludes judicial review of those claims.

V.

I turn next to AstraZeneca's claim that the IRA violates its Fifth Amendment due process rights. The Fifth Amendment prohibits the government from depriving a person of "life, liberty, or property, without due process of law." U.S. Const. amend. V.

AstraZeneca alleges in Count III that the IRA violates its right to due process "by directing the Secretary to fix [selected drug] prices at the 'lowest' level, without affording adequate procedural safeguards," D.I. 16 ¶ 143; "strip[ping] manufacturers of any ability to meaningfully negotiate a reasonable price for their products," D.I. 16 ¶ 144; "dispens[ing] with traditional hearing and notice-and-comment rulemaking procedures," D.I. 16 ¶ 144; and "vest[ing] [CMS] with unchecked authority to finalize its decisions without any process for administrative or judicial review," D.I. 16 ¶ 144. The Government does not challenge AstraZeneca's standing to assert this claim, *see* D.I. 66, but it says that I should grant it summary judgment on Count III because AstraZeneca is not legally compelled to provide Medicare beneficiaries with drugs and therefore the IRA's imposition of caps on the amount the Government will reimburse AstraZeneca for drugs sales does not deprive AstraZeneca of a protected property interest for purposes of the Fifth Amendment. *See* D.I. 22 at 44-45.

A.

Before addressing the merits of Count III, I consider whether I have the authority to do so. Even if jurisdiction is not contested, I am obligated to assure myself of jurisdiction under Article III. *Trump v. Hawaii,* 585 U.S.

667, 697 (2018); *Wayne Land & Min. Grp., LLC v. Del. River Basin Comm'n,* 959 F.3d 569, 574 (3d Cir. 2020). For that reason, after oral argument, I ordered the parties to submit supplemental briefs "addressing whether Plaintiffs have standing to assert Count III." D.I. 65. Unfortunately, the Government ignored my order, and instead of addressing in its supplemental brief whether AstraZeneca has standing, it merely reiterated that it "ha[s] not argued (and do[es] not now argue) that Plaintiffs lack standing to bring Count III." D.I. 66 at 2.

I had ordered the supplemental briefing because I had thought it might help me navigate the fine line between standing and the merits with respect to AstraZeneca's due process claim. As the Seventh Circuit observed in *Protect Our Parks, Inc. v. Chicago Park District,* 971 F.3d 722, 736 (7th Cir. 2020), "it is not unusual for the distinction between standing and the merits to cause conceptual trouble when a plaintiff alleges the deprivation of a dubious property or liberty interest." The court noted in *Protect Our Parks* that "when the existence of a protected property interest is an element of the claim, deciding whether the interest exists *virtually always* goes to the merits rather than standing." *Id.* (emphasis added). Notably, the court did not say that deciding whether the interest exists *always* goes to the merits. But unfortunately, the court in *Protect Our Parks* did not provide, and I have not been able to find in any other case, helpful guidance to determine *when* the question of whether the interest exists goes to the merits as opposed to *when* that question goes to standing. In this case, at the summary judgment stage of the litigation, distinguishing the issue of whether AstraZeneca has established a deprivation of a property interest that meets the injury-in-fact, causation, and redressability requirements for standing from the issue of whether

AstraZeneca has established a deprivation without due process of a property interest protected by the Constitution poses an epistemological question I'm not capable of answering. This being "one of those cases where the line between standing and the merits is rather fine but makes little practical difference," *Matushkina v. Nielsen*, 877 F.3d 289, 291 (7th Cir. 2017), I will assume I have jurisdiction and proceed to the merits. *Cf Trump*, 585 U.S. at 682-83 ("assum[ing] without deciding that plaintiffs' statutory claims [were] reviewable" and that Court "ha[d] authority" to "address[] the merits of plaintiffs' statutory claims" when "[t]he justiciability of plaintiffs' challenge under the [statute] present[ed] a difficult question"); *but see id.* (noting that "[t]he Government d[id] not argue that [its justiciability] argument goes to the Court's jurisdiction").

B.

"[T]he first inquiry in every due process challenge is whether the plaintiff has been deprived of a protected interest in 'property' or 'liberty.'" *Am. Mfrs. Mut. Ins. Co. v. Sullivan*, 526 U.S. 40, 59 (1999). To have a protected property interest, "a person clearly must have more than an abstract need or desire" and "more than a unilateral expectation of it. He must, instead, have a legitimate claim of entitlement to it." *Town of Castle Rock, Colo. v. Gonzales*, 545 U.S. 748, 756 (2005) (quoting *Bd of Regents of State Colls. v. Roth*, 408 U.S. 564, 577 (1972)).

Distilled to its essence, the property interest AstraZeneca contends merits protection under the Fifth Amendment's due process clause is the ability to sell its drugs to Medicare at prices above the ceiling prices and negotiated maximum fair prices established by the IRA. The central and oft-repeated allegation in the Amended Complaint is that "the Program is designed to coerce

manufacturers to submit to government-imposed price controls." D.I. 16 ¶ 94. *See also* D.I. 16 ¶ 1 ("This case is about a statute and guidance designed to cut costs to the federal government at great cost to innovation and the country's most vulnerable patients. The Inflation Reduction Act enacted sweeping changes to drug pricing under Medicare, jettisoning a market-based approach in favor of a new scheme of price controls established by the federal government."); D.I. 16 ¶ 13 ("The IRA jettisons ... market-based solutions in favor of price controls set by the federal government."); D.I. 16 ¶ 16 ("Selected products are subject to statutory price ceilings defined to require deep cuts from the current, market-based prices. For nearly all drugs, there is no floor. The Secretary could decide that Medicare should pay only a penny for a particular drug, and the manufacturer would have to sell at that price ...."); D.I. 16 ¶ 19 ("[T]he IRA forces manufacturers to engage in purported 'negotiations' but affords them no bargaining power, no meaningful opportunity to walk away, and no ability to protect their interests against a so-called 'maximum fair price' capped at an amount drastically below actual fair market value."); D.I. 16 ¶ 32 ("Historically, innovator manufacturers have been able to sell their products both commercially and under Medicare at prices dictated by market dynamics. That market-driven dynamic has now come to a crashing halt with the passage of the IRA."); D.I. 16 ¶ 38 ("The price is capped at a fraction of reference prices specified by statute and defined by the Guidance to be as low as possible, and the agency can insist that the 'maximum fair price' be set lower than the cap."); D.I. 16 ¶ 117 ("The IRA's design mandates that its targeted price controls must be trained on the most revolutionary therapies ...."); D.I. 16 ¶ 142 ("The IRA deprives AstraZeneca of ... [its] common law right to sell its products at market prices free

from arbitrary and inadequately disclosed governmental constraints."); D.I. 16 ¶ 143 ("The IRA deprives AstraZeneca of those property interests by directing the Secretary to fix prices at the 'lowest' level, without affording adequate procedural safeguards.").

AstraZeneca alleges in two paragraphs of the Amended Complaint that it also has a protected interest in undefined "patent rights." D.I. 16 ¶¶ 91, 142. But it never identifies a patent or explains how the IRA affects or could affect a patent right. AstraZeneca does not allege that the IRA authorizes or will result in the seizure or threatened seizure of its patents, and it could not credibly allege that the Government's refusal to purchase a drug at the price demanded by AstraZeneca constitutes patent infringement. Although I pressed AstraZeneca on the issue at oral argument, its counsel was unable to articulate a coherent theory of why or how the IRA affects patent rights. *See* D.I. 64 at 38:6-39:8; D.I. 64 at 54:19-55:5; D.I. 64 at 62:15-65:5. But in any event, AstraZeneca alleges in the Amended Complaint that the IRA deprives it of these putative patent rights "by directing the Secretary to fix prices at the 'lowest level,' without affording adequate procedural safeguards" and "strip[ping] manufacturers of any ability to meaningfully negotiate a reasonable price for their products." D.I. 16 ¶¶ 143-44. And in its briefing, AstraZeneca similarly argues that the IRA deprives it of "protected interests in its patented drugs and the revenue it derives therefrom ... by compelling sales of its products at well-below market prices." D.I. 19 at 29. Thus, the property interest encompassed by AstraZeneca's alleged "patent rights" is at bottom the ability to sell products to Medicare beneficiaries at prices above what the IRA requires.

No one, however, is entitled to sell the Government drugs at prices the Government won't agree to pay. *See*

Coyne-Delany Co. v. Cap. Dev. Bd., 616 F.2d 341, 342 (7th Cir. 1980) ("No one has a 'right' to sell to the government that which the government does not wish to buy."). 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.*" *Perkins v. Lukens Steel Co.*, 310 U.S. 113, 127 (1940) (emphasis added). Neither the IRA nor any other federal law requires AstraZeneca to sell its drugs to Medicare beneficiaries. On the contrary, "participation in the Medicare program is a voluntary undertaking." *Livingston Care Ctr., Inc. v. United States*, 934 F.2d 719, 720 (6th Cir. 1991); *see also Dayton Area Chamber of Com. v. Becerra*, 2023 WL 6378423, at *11 (S.D. Ohio Sept. 29, 2023) ("[P]articipation in Medicare, no matter how vital it may be to a business model, is a completely voluntary choice.").

The IRA simply establishes maximum prices the Government will pay for selected drugs. These prices are lower than the prices CMS has been paying for the selected drugs. The whole point of the Program is to lower the prices of selected drugs that lack generic competition and account for a disproportionate share of Medicare's expenses. Understandably, drug manufacturers like AstraZeneca don't like the IRA. Lower prices mean lower profits. Drug manufacturers like AstraZeneca desire the old pricing regime, and they lobbied and perhaps expected Congress not to pass the IRA in 2022. Yeganeh Torbati and Jeff Stein, *Lobbyists are Rushing to Influence the Democrats 'Spending Bill*, THE WASHINGTON POST (Aug. 5, 2022), https://www.washingtonpost.com/business/2022/08/05/inflation-reduction-act-lobbyists/ [https://perma.cc/N5DNR5FP]. But AstraZeneca's

"desire" or even "expectation" to sell its drugs to the Government at the higher prices it once enjoyed does not create a protected property interest. *Castle Rock*, 545 U.S. at 756. And 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. *Id.*

AstraZeneca insists that "participation in the Drug Price Negotiation Program is anything but voluntary" and that the Third Circuit "intimated as much" in *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696 (3d Cir. 2023). In support of this assertion, it points to dicta in *Sanofi* that "[t]he federal government dominates healthcare" and "uses [its] market power to get drug makers to subsidize healthcare." D.I. 58 at 48 (quoting *Sanofi*, 58 F.4th at 699). But neither that dicta nor anything else the Third Circuit said in *Sanofi* suggests in any way that drug manufacturers are required to participate in the Program or any other part of Medicare.

Sanofi did not mention let alone discuss the IRA or the Program. At issue in *Sanofi* was the lawfulness of regulations issued to implement the so-called 340B Program created by the Veterans Health Care Act of 1992, Pub. L. No. 102-585, 106 Stat. 4943 (1992), codified at 42 U.S.C. §§ 256b; 1396r-8. Like the IRA's Program, the 340B Program conditions drug manufacturers' participation in Medicare on their offering certain drugs at capped prices. In the case of the 340B Program, "drug makers that want to take part in Medicare or Medicaid must offer their drugs at a discount to certain healthcare providers … that typically care for low-income and rural persons." *Sanofi*, 58 F.4th at 699. The court took note in *Sanofi* of the fact that Medicare and Medicaid account "for almost half the annual nationwide spending on prescription drugs," and that the Government "uses that

market power to get drug makers to subsidize healthcare" by conditioning their participation in Medicare on selling drugs to the healthcare providers of low-income and rural patients at below-market prices. *Id.* This observation makes sense, and there is nothing sinister in the Government wielding its market power to obtain lower prices or set "conditions upon which it will make needed purchases." *Perkins,* 310 U.S. at 127. The opportunity.to sell drugs to 50% of the potential market for prescription drugs provides a powerful incentive for a manufacturer to agree to sell certain drugs to certain healthcare providers at below-market prices. The Government can offer that incentive because of its market power. But it does not follow, and the court did not say or imply in *Sanofi,* that the 340B Program or any other law requires a drug manufacturer to participate in the 340B Program or any other Medicare program.

The IRA's Drug Price Negotiation Program operates much like the 340B Program. The IRA offers a powerful incentive—the opportunity to sell products to more than 49 million Medicare and Medicaid beneficiaries—to induce drug manufactures to participate in the Program and negotiate with CMS maximum fair prices for selected drugs. That incentive is not, as AstraZeneca contends, "a gun to the head." D.I. 58 at 50. It is a potential economic opportunity that AstraZeneca is free to accept or reject.

Because AstraZeneca's participation in Medicare is not involuntary, AstraZeneca does not have a protected property interest in selling drugs to the Government at prices the Government will not agree to pay. Accordingly, AstraZeneca's due process claim fails as a matter of law.

VI.

For the reasons stated above, I lack jurisdiction to hear Counts I and 11; and, because AstraZeneca has not

identified the deprivation of a constitutionally protected property interest, Count III fails as a matter of law. I will therefore deny AstraZeneca's Motion for Summary Judgment (D.I. 18) and grant Defendants' Motion for Summary Judgment (D.I. 21).

The Court will enter an order consistent with this Memorandum Opinion.

APPENDIX C

26 U.S.C. § 5000D
Designated drugs during noncompliance periods

(a) In general.--There is hereby imposed on the sale by the manufacturer, producer, or importer of any designated drug during a day described in subsection (b) a tax in an amount such that the applicable percentage is equal to the ratio of—

(1) such tax, divided by

(2) the sum of such tax and the price for which so sold.

(b) Noncompliance periods.--A day is described in this subsection with respect to a designated drug if it is a day during one of the following periods:

(1) The period beginning on the March 1st (or, in the case of initial price applicability year 2026, the October 2nd) immediately following the date on which such drug is included on the list published under section 1192(a) of the Social Security Act and ending on the earlier of--

(A) the first date on which the manufacturer of such designated drug has in place an agreement described in section 1193(a) of such Act with respect to such drug, or

(B) the date that the Secretary of Health and Human Services has made a determination described in section 1192(c)(1) of such Act with respect to such designated drug.

(2) The period beginning on the November 2nd immediately following the March 1st described in paragraph (1) (or, in the case of initial price applicability year 2026, the August 2nd immediately following the October 2nd described in such paragraph) and ending on the earlier of--

(A) the first date on which the manufacturer of such designated drug and the Secretary of Health and Human Services have agreed to a maximum fair price under an agreement described in section 1193(a) of the Social Security Act, or

(B) the date that the Secretary of Health and Human Services has made a determination described in section 1192(c)(1) of such Act with respect to such designated drug.

(3) In the case of any designated drug which is a selected drug (as defined in section 1192(c) of the Social Security Act) that the Secretary of Health and Human Services has selected for renegotiation under section 1194(f) of such Act, the period beginning on the November 2nd of the year that begins 2 years prior to the first initial price applicability year of the price applicability period for which the maximum fair price established pursuant to such renegotiation applies and ending on the earlier of--

(A) the first date on which the manufacturer of such designated drug has agreed to a renegotiated maximum fair price under such agreement, or

(B) the date that the Secretary of Health and Human Services has made a determination described in section 1192(c)(1) of such Act with respect to such designated drug.

(4) With respect to information that is required to be submitted to the Secretary of Health and Human Services under an agreement described in section 1193(a) of the Social Security Act, the period beginning on the date on which such Secretary certifies that such information is overdue and ending on the date that such information is so submitted.

(c) Suspension of tax.--

(1) In general.--A day shall not be taken into account as a day during a period described in subsection (b) if such day is also a day during the period--

(A) beginning on the first date on which—

(i) the notice of terminations of all applicable agreements of the manufacturer have been received by the Secretary of Health and Human Services, and

(ii) none of the drugs of the manufacturer of the designated drug are covered by an agreement under section 1860D-14A or 1860D-14C of the Social Security Act, and

(B) ending on the last day of February following the earlier of--

(i) the first day after the date described in subparagraph (A) on which the manufacturer enters into any subsequent applicable agreement, or

(ii) the first date any drug of the manufacturer of the designated drug is covered by an agreement under section 1860D-14A or 1860D-14C of the Social Security Act.

(2) Applicable agreement.--For purposes of this subsection, the term "applicable agreement" means the following:

(A) An agreement under--

(i) the Medicare coverage gap discount program under section 1860D-14A of the Social Security Act, or

(ii) the manufacturer discount program under section 1860D-14C of such Act.

(B) A rebate agreement described in section 1927(b) of such Act.

(d) Applicable percentage.--For purposes of this section, the term "applicable percentage" means--

(1) in the case of sales of a designated drug during the first 90 days described in subsection (b) with respect to such drug, 65 percent,

(2) in the case of sales of such drug during the 91st day through the 180th day described in subsection (b) with respect to such drug, 75 percent,

(3) in the case of sales of such drug during the 181st day through the 270th day described in subsection (b) with respect to such drug, 85 percent, and

(4) in the case of sales of such drug during any subsequent day, 95 percent.

(e) Definitions.--For purposes of this section--

(1) Designated drug.--The term "designated drug" means any negotiation-eligible drug (as defined in section 1192(d) of the Social Security Act) included on the list published under section 1192(a) of such Act which is manufactured or produced in the United States or entered into the United States for consumption, use, or warehousing.

(2) United States.--The term "United States" has the meaning given such term by section 4612(a)(4).

(3) Other terms.--The terms "initial price applicability year", "price applicability period", and "maximum fair price" have the meaning given such terms in section 1191 of the Social Security Act.

(f) Special rules.--

(1) Coordination with rules for possessions of the United States.--Rules similar to the rules of paragraphs (2) and (4) of section 4132(c) shall apply for purposes of this section.

(2) Anti-abuse rule.--In the case of a sale which was timed for the purpose of avoiding the tax imposed by this section, the Secretary may treat such sale as occurring during a day described in subsection (b).

(g) Exports.--Rules similar to the rules of section 4662(e) (other than section 4662(e)(2)(A)(ii)(II)) shall apply for purposes of this chapter.

(h) Regulations.--The Secretary shall prescribe such regulations and other guidance as may be necessary to carry out this section.

APPENDIX D

42 U.S.C. § 1320f-1
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

(A) In general

Subject to subparagraph (C), the term "negotiation-eligible drug" shall not include, with respect to the initial price applicability years 2026, 2027, and 2028, a qualifying single source drug that meets either of the following:

(i) Part D drugs

The total expenditures for the qualifying single source drug under part D of subchapter

XVIII, as determined by the Secretary in accordance with paragraph (3)(B), during 2021--

(I) are equal to or less than 1 percent of the total expenditures under such part D, as so determined, for all covered part D drugs (as defined in section 1395w-102(e) of this title) during such year; and

(II) are equal to at least 80 percent of the total expenditures under such part D, as so determined, for all covered part D drugs for which the manufacturer of the drug has an agreement in effect under section 1395w-114a of this title during such year.

(ii) Part B drugs

The total expenditures for the qualifying single source drug under part B of subchapter XVIII, as determined by the Secretary in accordance with paragraph (3)(B), during 2021--

(I) are equal to or less than 1 percent of the total expenditures under such part B, as so determined, for all qualifying single source drugs for which payment may be made under such part B during such year; and

(II) are equal to at least 80 percent of the total expenditures under such part B, as so determined, for all qualifying single source drugs of the manufacturer for which payment may be made under such part B during such year.

(B) Clarifications relating to manufacturers

(i) Aggregation rule

All persons treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 shall be treated as one manufacturer for purposes of this paragraph.

(ii) Limitation

A drug shall not be considered to be a qualifying single source drug described in clause (i) or (ii) of subparagraph (A) if the manufacturer of such drug is acquired after 2021 by another manufacturer that does not meet the definition of a specified manufacturer under section 1395w-114c(g)(4)(B)(ii) of this title, effective at the beginning of the plan year immediately following such acquisition or, in the case of an acquisition before 2025, effective January 1, 2025.

(C) Drugs not included as small biotech drugs

A new formulation, such as an extended release formulation, of a qualifying single source drug shall not be considered a qualifying single source drug described in subparagraph (A).

(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; 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.

(f) Special rule to delay selection and negotiation of biologics for biosimilar market entry

(1) Application

(A) In general

Subject to subparagraph (B), in the case of a biological product that would (but for this subsection) be an extended-monopoly drug (as defined in section 1320f-3(c)(4) of this title) included as a selected drug on the list published under subsection (a) with respect to an initial price applicability year, the rules described in paragraph (2) shall apply if the Secretary determines that there is a high likelihood (as described in paragraph (3)) that a biosimilar biological product (for which such biological product will be the reference product) will be licensed and marketed under section 262(k) of this title before the date that is 2 years after the selected drug publication date with respect to such initial price applicability year.

(B) Request required

(i) In general

The Secretary shall not provide for a delay under--

(I) paragraph (2)(A) unless a request is made for such a delay by a manufacturer of a biosimilar biological product prior to the selected drug publication date for the list published under subsection (a) with respect to the initial price applicability year for which the biological product may have been included as a selected drug on such list but for subparagraph (2)(A); or

(II) paragraph (2)(B)(iii) unless a request is made for such a delay by such a

manufacturer prior to the selected drug publication date for the list published under subsection (a) with respect to the initial price applicability year that is 1 year after the initial price applicability year for which the biological product described in subsection (a) would have been included as a selected drug on such list but for paragraph (2)(A).

(ii) Information and documents

(I) In general

A request made under clause (i) shall be submitted to the Secretary by such manufacturer at a time and in a form and manner specified by the Secretary, and contain--

> **(aa)** information and documents necessary for the Secretary to make determinations under this subsection, as specified by the Secretary and including, to the extent available, items described in subclause (III); and
>
> **(bb)** all agreements related to the biosimilar biological product filed with the Federal Trade Commission or the Assistant Attorney General pursuant to subsections (a) and (c) of section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

(II) Additional information and documents

After the Secretary has reviewed the request and materials submitted under subclause (I), the manufacturer shall submit any additional information and documents requested by the Secretary necessary to make determinations under this subsection.

(III) Items described

The items described in this clause are the following:

> **(aa)** The manufacturing schedule for such biosimilar biological product submitted to the Food and Drug Administration during its review of the application under such section 262(k) of this title.
>
> **(bb)** Disclosures (in filings by the manufacturer of such biosimilar biological product with the Securities and Exchange Commission required under section 78*l*(b), 78*l*(g), 78m(a), or 78*o*(d) of Title 15 about capital investment, revenue expectations, and actions taken by the manufacturer that are typical of the normal course of business in the year (or the 2 years, as applicable) before marketing of a biosimilar biological product) that pertain to the marketing of such biosimilar biological product, or comparable documentation that is

distributed to the shareholders of privately held companies.

(C) Aggregation rule

(i) In general

All persons treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986, or in a partnership, shall be treated as one manufacturer for purposes of paragraph (2)(D)(iv).

(ii) Partnership defined

In clause (i), the term "partnership" means a syndicate, group, pool, joint venture, or other organization through or by means of which any business, financial operation, or venture is carried on by the manufacturer of the biological product and the manufacturer of the biosimilar biological product.

(2) Rules described

The rules described in this paragraph are the following:

(A) Delayed selection and negotiation for 1 year

If a determination of high likelihood is made under paragraph (3), the Secretary shall delay the inclusion of the biological product as a selected drug on the list published under subsection (a) until such list is published with respect to the initial price applicability year that is 1 year after the initial price applicability year for which the biological product would have been included as a selected drug on such list.

(B) If not licensed and marketed during the initial delay

(i) In general

If, during the time period between the selected drug publication date on which the biological product would have been included on the list as a selected drug pursuant to subsection (a) but for subparagraph (A) and the selected drug publication date with respect to the initial price applicability year that is 1 year after the initial price applicability year for which such biological product would have been included as a selected drug on such list, the Secretary determines that the biosimilar biological product for which the manufacturer submitted the request under paragraph (1)(B)(i)(II) (and for which the Secretary previously made a high likelihood determination under paragraph (3)) has not been licensed and marketed under section 262(k) of this title, the Secretary shall, at the request of such manufacturer--

(I) reevaluate whether there is a high likelihood (as described in paragraph (3)) that such biosimilar biological product will be licensed and marketed under such section 262(k) before the date that is 2 years after the selected drug publication date for which such biological product would have been included as a selected drug on such list published but for subparagraph (A); and

(II) evaluate whether, on the basis of clear and convincing evidence, the manufacturer of such biosimilar biological product has made a significant amount of

progress (as determined by the Secretary) towards both such licensure and the marketing of such biosimilar biological product (based on information from items described in subclauses (I)(bb) and (II) of paragraph (1)(B)(ii)) since the receipt by the Secretary of the request made by such manufacturer under paragraph (1)(B)(i)(I).

(ii) Selection and negotiation

If the Secretary determines that there is not a high likelihood that such biosimilar biological product will be licensed and marketed as described in clause (i)(I) or there has not been a significant amount of progress as described in clause (i)(II)—

(I) the Secretary shall include the biological product as a selected drug on the list published under subsection (a) with respect to the initial price applicability year that is 1 year after the initial price applicability year for which such biological product would have been included as a selected drug on such list but for subparagraph (A); and

(II) the manufacturer of such biological product shall pay a rebate under paragraph (4) with respect to the year for which such manufacturer would have provided access to a maximum fair price for such biological product but for subparagraph (A).

(iii) Second 1-year delay

If the Secretary determines that there is a high likelihood that such biosimilar biological

product will be licensed and marketed (as described in clause (i)(I)) and a significant amount of progress has been made by the manufacturer of such biosimilar biological product towards such licensure and marketing (as described in clause (i)(II)), the Secretary shall delay the inclusion of the biological product as a selected drug on the list published under subsection (a) until the selected drug publication date of such list with respect to the initial price applicability year that is 2 years after the initial price applicability year for which such biological product would have been included as a selected drug on such list but for this subsection.

(C) If not licensed and marketed during the year two delay

If, during the time period between the selected drug publication date of the list for which the biological product would have been included as a selected drug but for subparagraph (B)(iii) and the selected drug publication date with respect to the initial price applicability year that is 2 years after the initial price applicability year for which such biological product would have been included as a selected drug on such list but for this subsection, the Secretary determines that such biosimilar biological product has not been licensed and marketed--

(i) the Secretary shall include such biological product as a selected drug on such list with respect to the initial price applicability year that is 2 years after the initial price applicability year for which such biological product would have been included as a selected drug on such list; and

(ii) the manufacturer of such biological product shall pay a rebate under paragraph (4) with respect to the years for which such manufacturer would have provided access to a maximum fair price for such biological product but for this subsection.

(D) Limitations on delays

(i) Limited to 2 years

In no case shall the Secretary delay the inclusion of a biological product on the list published under subsection (a) for more than 2 years.

(ii) Exclusion of biological products that transitioned to a long-monopoly drug during the delay

In the case of a biological product for which the inclusion on the list published pursuant to subsection (a) was delayed by 1 year under subparagraph (A) and for which there would have been a change in status to a long-monopoly drug (as defined in section 1320f-3(c)(5) of this title) if such biological product had been a selected drug, in no case may the Secretary provide for a second 1-year delay under subparagraph (B)(iii).

(iii) Exclusion of biological products if more than 1 year since licensure

In no case shall the Secretary delay the inclusion of a biological product on the list published under subsection (a) if more than 1 year has elapsed since the biosimilar biological product has been licensed under section 262(k) of

this title and marketing has not commenced for such biosimilar biological product.

(iv) Certain manufacturers of biosimilar biological products excluded

In no case shall the Secretary delay the inclusion of a biological product as a selected drug on the list published under subsection (a) if Secretary determined that the manufacturer of the biosimilar biological product described in paragraph (1)(A)--

> **(I)** is the same as the manufacturer of the reference product described in such paragraph or is treated as being the same pursuant to paragraph (1)(C); or
>
> **(II)** has, based on information from items described in paragraph (1)(B)(ii)(I)(bb), entered into any agreement described in such paragraph with the manufacturer of the reference product described in paragraph (1)(A) that--
>
> > **(aa)** requires or incentivizes the manufacturer of the biosimilar biological product to submit a request described in paragraph (1)(B); or
> >
> > **(bb)** restricts the quantity (either directly or indirectly) of the biosimilar biological product that may be sold in the United States over a specified period of time.

(3) High likelihood

For purposes of this subsection, there is a high likelihood described in paragraph (1) or paragraph (2), as applicable, if the Secretary finds that--

(A) an application for licensure under section 262(k) of this title for the biosimilar biological product has been accepted for review or approved by the Food and Drug Administration; and

(B) information from items described in sub clauses[1] (I)(bb) and (III) of paragraph (1)(B)(ii) submitted to the Secretary by the manufacturer requesting a delay under such paragraph provides clear and convincing evidence that such biosimilar biological product will, within the time period specified under paragraph (1)(A) or (2)(B)(i)(I), be marketed.

(4) Rebate

(A) In general

For purposes of subparagraphs (B)(ii)(II) and (C)(ii) of paragraph (2), in the case of a biological product for which the inclusion on the list under subsection (a) was delayed under this subsection and for which the Secretary has negotiated and entered into an agreement under section 1320f-2 of this title with respect to such biological product, the manufacturer shall be required to pay a rebate to the Secretary at such time and in such manner as determined by the Secretary.

(B) Amount

Subject to subparagraph (C), the amount of the rebate under subparagraph (A) with respect to a

biological product shall be equal to the estimated amount--

(i) in the case of a biological product that is a covered part D drug (as defined in section 1395w-102(e) of this title), that is the sum of the products of--

(I) 75 percent of the amount by which--

(aa) the average manufacturer price, as reported by the manufacturer of such covered part D drug under section 1396r-8 of this title (or, if not reported by such manufacturer under section 1396r-8 of this title, as reported by such manufacturer to the Secretary pursuant to the agreement under section 1320f-2(a) of this title) for such biological product, with respect to each of the calendar quarters of the price applicability period that would have applied but for this subsection; exceeds

(bb) in the initial price applicability year that would have applied but for a delay under—

(AA) paragraph (2)(A), the maximum fair price negotiated under section 1320f-3 of this title for such biological product under such agreement; or

(BB) paragraph (2)(B)(iii), such maximum fair price, increased as described in section 1320f-4(b)(1)(A) of this title; and

(II) the number of units dispensed under part D of subchapter XVIII for such covered part D drug during each such calendar quarter of such price applicability period; and

(ii) in the case of a biological product for which payment may be made under part B of subchapter XVIII, that is the sum of the products of--

(I) 80 percent of the amount by which--

(aa) the payment amount for such biological product under section 1395w-3a(b) of this title, with respect to each of the calendar quarters of the price applicability period that would have applied but for this subsection; exceeds

(bb) in the initial price applicability year that would have applied but for a delay under—

(AA) paragraph (2)(A), the maximum fair price negotiated under section 1320f-3 of this title for such biological product under such agreement; or

(BB) paragraph (2)(B)(iii), such maximum fair price, increased as described in section 1320f-4(b)(1)(A) of this title; and

(II) the number of units (excluding units that are packaged into the payment amount for an item or service and are not separately payable under such part B) of the billing and

payment code of such biological product administered or furnished under such part B during each such calendar quarter of such price applicability period.

(C) Special rule for delayed biological products that are long-monopoly drugs

(i) In general

In the case of a biological product with respect to which a rebate is required to be paid under this paragraph, if such biological product qualifies as a long-monopoly drug (as defined in section 1320f-3(c)(5) of this title) at the time of its inclusion on the list published under subsection (a), in determining the amount of the rebate for such biological product under subparagraph (B), the amount described in clause (ii) shall be substituted for the maximum fair price described in clause (i)(I) or (ii)(I) of such subparagraph (B), as applicable.

(ii) Amount described

The amount described in this clause is an amount equal to 65 percent of the average non-Federal average manufacturer price for the biological product for 2021 (or, in the case that there is not an average non-Federal average manufacturer price available for such biological product for 2021, for the first full year following the market entry for such biological product), increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from September 2021 (or December of such first full year following the market entry), as applicable,

to September of the year prior to the selected drug publication date with respect to the initial price applicability year that would have applied but for this subsection.

(D) Rebate deposits

Amounts paid as rebates under this paragraph shall be deposited into--

(i) in the case payment is made for such biological product under part B of subchapter XVIII, the Federal Supplementary Medical Insurance Trust Fund established under section 1395t of this title; and

(ii) in the case such biological product is a covered part D drug (as defined in section 1395w-102(e) of this title), the Medicare Prescription Drug Account under section 1395w-116 of this title in such Trust Fund.

(5) Definitions of biosimilar biological product

In this subsection, the term "biosimilar biological product" has the meaning given such term in section 1395w-3a(c)(6) of this title.

APPENDIX E

42 U.S.C. § 1320f-2
Manufacture 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, to such covered entity if such selected drug is subject to an agreement described in section 340B(a)(1) of such Act and the ceiling price (defined in section 340B(a)(1) of such Act) 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.

APPENDIX F

42 U.S.C. § 1320f-3
Negotiation and renegotiation process

(a) In general

For purposes of this part, under an agreement under section 1320f-2 of this title between the Secretary and a manufacturer of a selected drug (or selected drugs), with respect to the period for which such agreement is in effect and in accordance with subsections (b), (c), and (d), the Secretary and the manufacturer--

(1) shall during the negotiation period with respect to such drug, in accordance with this section, negotiate a maximum fair price for such drug for the purpose described in section 1320f-2(a)(1) of this title; and

(2) renegotiate, in accordance with the process specified pursuant to subsection (f), such maximum fair price for such drug for the purpose described in section 1320f-2(a)(2) of this title if such drug is a renegotiation-eligible drug under such subsection.

(b) Negotiation process requirements

(1) Methodology and process

The Secretary shall develop and use a consistent methodology and process, in accordance with paragraph (2), for negotiations under subsection (a) that aims to achieve the lowest maximum fair price for each selected drug.

(2) Specific elements of negotiation process

As part of the negotiation process under this section, with respect to a selected drug and the negotiation period with respect to the initial price applicability year with respect to such drug, the following shall apply:

(A) Submission of information

Not later than March 1 of the year of the selected drug publication date, with respect to the selected drug, the manufacturer of the drug shall submit to the Secretary, in accordance with section 1320f-2(a)(4) of this title, the information described in such section.

(B) Initial offer by Secretary

Not later than the June 1 following the selected drug publication date, the Secretary shall provide the manufacturer of the selected drug with a written initial offer that contains the Secretary's proposal for the maximum fair price of the drug and a concise justification based on the factors described in subsection (e) that were used in developing such offer.

(C) Response to initial offer

(i) In general

Not later than 30 days after the date of receipt of an initial offer under subparagraph (B), the manufacturer shall either accept such offer or propose a counteroffer to such offer.

(ii) Counteroffer requirements

If a manufacturer proposes a counteroffer, such counteroffer—

(I) shall be in writing; and

(II) shall be justified based on the factors described in subsection (e).

(D) Response to counteroffer

After receiving a counteroffer under subparagraph (C), the Secretary shall respond in writing to such counteroffer.

(E) Deadline

All negotiations between the Secretary and the manufacturer of the selected drug shall end prior to the first day of November following the selected drug publication date, with respect to the initial price applicability year.

(F) Limitations on offer amount

In negotiating the maximum fair price of a selected drug, with respect to the initial price applicability year for the selected drug, and, as applicable, in renegotiating the maximum fair price for such drug, with respect to a subsequent year during the price applicability period for such drug, the Secretary shall not offer (or agree to a counteroffer for) a maximum fair price for the selected drug that—

(i) exceeds the ceiling determined under subsection (c) for the selected drug and year; or

(ii) as applicable, is less than the floor determined under subsection (d) for the selected drug and year.

(c) Ceiling for maximum fair price

(1) General ceiling

(A) In general

The maximum fair price negotiated under this section for a selected drug, with respect to the first initial price applicability year of the price

applicability period with respect to such drug, shall not exceed the lower of the amount under subparagraph (B) or the amount under subparagraph (C).

(B) Subparagraph (B) amount

An amount equal to the following:

(i) Covered part D drug

In the case of a covered part D drug (as defined in section 1395w-102(e) of this title), the sum of the plan specific enrollment weighted amounts for each prescription drug plan or MA-PD plan (as determined under paragraph (2)).

(ii) Part B drug or biological

In the case of a drug or biological product for which payment may be made under part B of subchapter XVIII, the payment amount under section 1395w-3a(b)(4) of this title for the drug or biological product for the year prior to the year of the selected drug publication date with respect to the initial price applicability year for the drug or biological product.

(C) Subparagraph (C) amount

An amount equal to the applicable percent described in paragraph (3), with respect to such drug, of the following:

(i) Initial price applicability year 2026

In the case of a selected drug with respect to which such initial price applicability year is 2026, the average non-Federal average manufacturer price for such drug for 2021 (or, in the case that there is not an average non-Federal average

manufacturer price available for such drug for 2021, for the first full year following the market entry for such drug), increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from September 2021 (or December of such first full year following the market entry), as applicable, to September of the year prior to the year of the selected drug publication date with respect to such initial price applicability year.

(ii) Initial price applicability year 2027 and subsequent years

In the case of a selected drug with respect to which such initial price applicability year is 2027 or a subsequent year, the lower of—

(I) the average non-Federal average manufacturer price for such drug for 2021 (or, in the case that there is not an average non-Federal average manufacturer price available for such drug for 2021, for the first full year following the market entry for such drug), increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from September 2021 (or December of such first full year following the market entry), as applicable, to September of the year prior to the year of the selected drug publication date with respect to such initial price applicability year; or

(II) the average non-Federal average manufacturer price for such drug for the

year prior to the selected drug publication date with respect to such initial price applicability year.

(2) Plan specific enrollment weighted amount

For purposes of paragraph (1)(B)(i), the plan specific enrollment weighted amount for a prescription drug plan or an MA-PD plan with respect to a covered Part D drug is an amount equal to the product of—

(A) the negotiated price of the drug under such plan under part D of subchapter XVIII, net of all price concessions received by such plan or pharmacy benefit managers on behalf of such plan, for the most recent year for which data is available; and

(B) a fraction—

(i) the numerator of which is the total number of individuals enrolled in such plan in such year; and

(ii) the denominator of which is the total number of individuals enrolled in a prescription drug plan or an MA-PD plan in such year.

(3) Applicable percent described

For purposes of this subsection, the applicable percent described in this paragraph is the following:

(A) Short-monopoly drugs and vaccines

With respect to a selected drug (other than an extended-monopoly drug and a long-monopoly drug), 75 percent.

(B) Extended-monopoly drugs

With respect to an extended-monopoly drug, 65 percent.

(C) Long-monopoly drugs

With respect to a long-monopoly drug, 40 percent.

(4) Extended-monopoly drug defined

(A) In general

In this part, subject to subparagraph (B), the term "extended-monopoly drug" means, with respect to an initial price applicability year, a selected drug for which at least 12 years, but fewer than 16 years, have elapsed since the date of approval of such drug under section 355(c) of Title 21 or since the date of licensure of such drug under section 262(a) of this title, as applicable.

(B) Exclusions

The term "extended-monopoly drug" shall not include any of the following:

(i) A vaccine that is licensed under section 262 of this title and marketed pursuant to such section.

(ii) A selected drug for which a manufacturer had an agreement under this part with the Secretary with respect to an initial price applicability year that is before 2030.

(C) Clarification

Nothing in subparagraph (B)(ii) shall limit the transition of a selected drug described in paragraph (3)(A) to a long-monopoly drug if the selected drug meets the definition of a long-monopoly drug.

(5) Long-monopoly drug defined

(A) In general

In this part, subject to subparagraph (B), the term "long-monopoly drug" means, with respect to an initial price applicability year, a selected drug for which at least 16 years have elapsed since the date of approval of such drug under section 355(c) of Title 21 or since the date of licensure of such drug under section 262(a) of this title, as applicable.

(B) Exclusion

The term "long-monopoly drug" shall not include a vaccine that is licensed under section 262 of this title and marketed pursuant to such section.

(6) Average non-Federal average manufacturer price

In this part, the term "average non-Federal average manufacturer price" means the average of the non-Federal average manufacturer price (as defined in section 8126(h)(5) of Title 38) for the 4 calendar quarters of the year involved.

(d) Temporary floor for small biotech drugs

In the case of a selected drug that is a qualifying single source drug described in section 1320f-1(d)(2) of this title and with respect to which the first initial price applicability year of the price applicability period with respect to such drug is 2029 or 2030, the maximum fair price negotiated under this section for such drug for such initial price applicability year may not be less than 66 percent of the average non-Federal average manufacturer price for such drug (as defined in subsection (c)(6)) for 2021 (or, in the case that there is not an average non-Federal average manufacturer price

available for such drug for 2021, for the first full year following the market entry for such drug), increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from September 2021 (or December of such first full year following the market entry), as applicable, to September of the year prior to the selected drug publication date with respect to the initial price applicability year.

(e) Factors

For purposes of negotiating the maximum fair price of a selected drug under this part with the manufacturer of the drug, the Secretary shall consider the following factors, as applicable to the drug, as the basis for determining the offers and counteroffers under subsection (b) for the drug:

(1) Manufacturer-specific data

The following data, with respect to such selected drug, as submitted by the manufacturer:

(A) Research and development costs of the manufacturer for the drug and the extent to which the manufacturer has recouped research and development costs.

(B) Current unit costs of production and distribution of the drug.

(C) Prior Federal financial support for novel therapeutic discovery and development with respect to the drug.

(D) Data on pending and approved patent applications, exclusivities recognized by the Food and Drug Administration, and applications and approvals

under section 355(c) of Title 21 or section 262(a) of this title for the drug.

(E) Market data and revenue and sales volume data for the drug in the United States.

(2) Evidence about alternative treatments

The following evidence, as available, with respect to such selected drug and therapeutic alternatives to such drug:

(A) The extent to which such drug represents a therapeutic advance as compared to existing therapeutic alternatives and the costs of such existing therapeutic alternatives.

(B) Prescribing information approved by the Food and Drug Administration for such drug and therapeutic alternatives to such drug.

(C) Comparative effectiveness of such drug and therapeutic alternatives to such drug, taking into consideration the effects of such drug and therapeutic alternatives to such drug on specific populations, such as individuals with disabilities, the elderly, the terminally ill, children, and other patient populations.

(D) The extent to which such drug and therapeutic alternatives to such drug address unmet medical needs for a condition for which treatment or diagnosis is not addressed adequately by available therapy.

In using evidence described in subparagraph (C), the Secretary shall not use evidence from comparative clinical effectiveness research in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value

than extending the life of an individual who is younger, nondisabled, or not terminally ill.

(f) Renegotiation process

(1) In general

In the case of a renegotiation-eligible drug (as defined in paragraph (2)) that is selected under paragraph (3), the Secretary shall provide for a process of renegotiation (for years (beginning with 2028) during the price applicability period, with respect to such drug) of the maximum fair price for such drug consistent with paragraph (4).

(2) Renegotiation-eligible drug defined

In this section, the term "renegotiation-eligible drug" means a selected drug that is any of the following:

(A) Addition of new indication

A selected drug for which a new indication is added to the drug.

(B) Change of status to an extended-monopoly drug

A selected drug that—

(i) is not an extended-monopoly or a long-monopoly drug; and

(ii) for which there is a change in status to that of an extended-monopoly drug.

(C) Change of status to a long-monopoly drug

A selected drug that—

(i) is not a long-monopoly drug; and

(ii) for which there is a change in status to that of a long-monopoly drug.

(D) Material changes

A selected drug for which the Secretary determines there has been a material change of any of the factors described in paragraph (1) or (2) of subsection (e).

(3) Selection of drugs for renegotiation

For each year (beginning with 2028), the Secretary shall select among renegotiation-eligible drugs for renegotiation as follows:

(A) All extended-monopoly negotiation-eligible drugs

The Secretary shall select all renegotiation-eligible drugs described in paragraph (2)(B).

(B) All long-monopoly negotiation-eligible drugs

The Secretary shall select all renegotiation-eligible drugs described in paragraph (2)(C).

(C) Remaining drugs

Among the remaining renegotiation-eligible drugs described in subparagraphs (A) and (D) of paragraph (2), the Secretary shall select renegotiation-eligible drugs for which the Secretary expects renegotiation is likely to result in a significant change in the maximum fair price otherwise negotiated.

(4) Renegotiation process

(A) In general

The Secretary shall specify the process for renegotiation of maximum fair prices with the

manufacturer of a renegotiation-eligible drug selected for renegotiation under this subsection.

(B) Consistent with negotiation process

The process specified under subparagraph (A) shall, to the extent practicable, be consistent with the methodology and process established under subsection (b) and in accordance with subsections (c), (d), and (e), and for purposes of applying subsections (c)(1)(A) and (d), the reference to the first initial price applicability year of the price applicability period with respect to such drug shall be treated as the first initial price applicability year of such period for which the maximum fair price established pursuant to such renegotiation applies, including for applying subsection (c)(3)(B) in the case of renegotiation-eligible drugs described in paragraph (3)(A) of this subsection and subsection (c)(3)(C) in the case of renegotiation-eligible drugs described in paragraph (3)(B) of this subsection.

(5) Clarification

A renegotiation-eligible drug for which the Secretary makes a determination described in section 1320f-1(c)(1) of this title before or during the period of renegotiation shall not be subject to the renegotiation process under this section.

(g) Clarification

The maximum fair price for a selected drug described in subparagraph (A) or (B) of paragraph (1)[1] shall take effect no later than the first day of the first calendar quarter that begins after the date described in subparagraph[2] (A) or (B), as applicable.

APPENDIX G

42 U.S.C. § 1320f-4
Publication of maximum fair prices

(a) In general

With respect to an initial price applicability year and a selected drug with respect to such year—

(1) not later than November 30 of the year that is 2 years prior to such initial price applicability year, the Secretary shall publish the maximum fair price for such drug negotiated with the manufacturer of such drug under this part; and

(2) not later than March 1 of the year prior to such initial price applicability year, the Secretary shall publish, subject to section 1320f-2(c) of this title, the explanation for the maximum fair price with respect to the factors as applied under section 1320f-3(e) of this title for such drug described in paragraph (1).

(b) Updates

(1) Subsequent year maximum fair prices

For a selected drug, for each year subsequent to the first initial price applicability year of the price applicability period with respect to such drug, with respect to which an agreement for such drug is in effect under section 1320f-2 of this title, not later than November 30 of the year that is 2 years prior to such subsequent year, the Secretary shall publish the maximum fair price applicable to such drug and year, which shall be—

(A) subject to subparagraph (B), the amount equal to the maximum fair price published for such drug for the previous year, increased by the annual percentage increase in the consumer price index for

all urban consumers (all items; United States city average) for the 12-month period ending with the July immediately preceding such November 30; or

(B) in the case the maximum fair price for such drug was renegotiated, for the first year for which such price as so renegotiated applies, such renegotiated maximum fair price.

(2) Prices negotiated after deadline

In the case of a selected drug with respect to an initial price applicability year for which the maximum fair price is determined under this part after the date of publication under this section, the Secretary shall publish such maximum fair price by not later than 30 days after the date such maximum price is so determined.

APPENDIX H

42 U.S.C. § 1320f-5
Administrative duties and compliance monitoring

(a) Administrative duties

For purposes of section 1320f(a)(4) of this title, the administrative duties described in this section are the following:

(1) The establishment of procedures to ensure that the maximum fair price for a selected drug is applied before—

> **(A)** any coverage or financial assistance under other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of maximum fair price eligible individuals; and
>
> **(B)** any other discounts.

(2) The establishment of procedures to compute and apply the maximum fair price across different strengths and dosage forms of a selected drug and not based on the specific formulation or package size or package type of such drug.

(3) The establishment of procedures to carry out the provisions of this part, as applicable, with respect to--

> **(A)** maximum fair price eligible individuals who are enrolled in a prescription drug plan under part D of subchapter XVIII or an MA-PD plan under part C of such subchapter; and
>
> **(B)** maximum fair price eligible individuals who are enrolled under part B of such subchapter, including who are enrolled in an MA plan under part C of such subchapter.

(4) The establishment of a negotiation process and renegotiation process in accordance with section 1320f-3 of this title.

(5) The establishment of a process for manufacturers to submit information described in section 1320f-3(b)(2)(A) of this title.

(6) The sharing with the Secretary of the Treasury of such information as is necessary to determine the tax imposed by section 5000D of the Internal Revenue Code of 1986, including the application of such tax to a manufacturer, producer, or importer or the determination of any date described in section 5000D(c)(1) of such Code. For purposes of the preceding sentence, such information shall include—

> **(A)** the date on which the Secretary receives notification of any termination of an agreement under the Medicare coverage gap discount program under section 1395w-114a of this title and the date on which any subsequent agreement under such program is entered into;
>
> **(B)** the date on which the Secretary receives notification of any termination of an agreement under the manufacturer discount program under section 1395w-114c of this title and the date on which any subsequent agreement under such program is entered into; and
>
> **(C)** the date on which the Secretary receives notification of any termination of a rebate agreement described in section 1396r-8(b) of this title and the date on which any subsequent rebate agreement described in such section is entered into.

(7) The establishment of procedures for purposes of applying subsections (d)(2)(B) and (f)(1)(C) of section 1320f-1 of this title.

(b) Compliance monitoring

The Secretary shall monitor compliance by a manufacturer with the terms of an agreement under section 1320f-2 of this title and establish a mechanism through which violations of such terms shall be reported.

APPENDIX I

42 U.S.C. § 1320f-6
Civil monetary penalties

(a) Violations relating to offering of maximum fair price

Any manufacturer of a selected drug that has entered into an agreement under section 1320f-2 of this title, with respect to a year during the price applicability period with respect to such drug, that does not provide access to a price that is equal to or less than the maximum fair price for such drug for such year--

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

(2) to a hospital, physician, or other provider of services or supplier with respect to maximum fair price eligible individuals who with respect to such drug is described in subparagraph (B) of such section and is furnished or administered such drug by such hospital, physician, or provider or supplier during such year;

shall be subject to a civil monetary penalty equal to ten times the amount equal to the product of the number of units of such drug so furnished, dispensed, or administered during such year and the difference between the price for such drug made available for such year by such manufacturer with respect to such individual or hospital, physician, provider of services, or supplier and the maximum fair price for such drug for such year.

(b) Violations relating to providing rebates

Any manufacturer that fails to comply with the rebate requirements under section 1320f-1(f)(4) of this title shall be subject to a civil monetary penalty equal to 10 times the amount of the rebate the manufacturer failed to pay under such section.

(c) Violations of certain terms of agreement

Any manufacturer of a selected drug that has entered into an agreement under section 1320f-2 of this title, with respect to a year during the price applicability period with respect to such drug, that is in violation of a requirement imposed pursuant to section 1320f-2(a)(5) of this title, including the requirement to submit information pursuant to section 1320f-2(a)(4) of this title, shall be subject to a civil monetary penalty equal to $1,000,000 for each day of such violation.

(d) False information

Any manufacturer that knowingly provides false information pursuant to section 1320f-5(a)(7) of this title shall be subject to a civil monetary penalty equal to $100,000,000 for each item of such false information.

(e) Application

The provisions of section 1320a-7a of this title (other than subsections (a) and (b)) shall apply to a civil monetary penalty under this section in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

APPENDIX J

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]

(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.

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[1] So in original. The word "and" probably should not appear.

[2] So in original. Probably should be preceded by ", and".

[3] So in original.

APPENDIX K

42 U.S.C. § 1396r-8
Payment for covered outpatient drugs

(a) Requirement for rebate agreement

(1) In general

In order for payment to be available under section 1396b(a) of this title or under part B of subchapter XVIII for covered outpatient drugs of a manufacturer, the manufacturer must have entered into and have in effect a rebate agreement described in subsection (b) with the Secretary, on behalf of States (except that, the Secretary may authorize a State to enter directly into agreements with a manufacturer), and must meet the requirements of paragraph (5) (with respect to drugs purchased by a covered entity on or after the first day of the first month that begins after November 4, 1992) and paragraph (6). Any agreement between a State and a manufacturer prior to April 1, 1991, shall be deemed to have been entered into on January 1, 1991, and payment to such manufacturer shall be retroactively calculated as if the agreement between the manufacturer and the State had been entered into on January 1, 1991. If a manufacturer has not entered into such an agreement before March 1, 1991, such an agreement, subsequently entered into, shall become effective as of the date on which the agreement is entered into or, at State option, on any date thereafter on or before the first day of the calendar quarter that begins more than 60 days after the date the agreement is entered into.