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UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT
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PHILADELPHIA, PA 19106-1790
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TELEPHONE
215-597-2995

May 2, 2024

Susan M. Cook, Esq.
Marlan Golden, Esq.
Catherine E. Stetson, Esq.
Hogan Lovells US
555 Thirteenth Street NW
Columbia Square
Washington, DC 20004

Alexandra M. Joyce, Esq.
Daniel M. Silver, Esq.
McCarter & English
405 N King Street
Renaissance Centre, 8th Floor
Wilmington, DE 19801

RE: AstraZeneca Pharmaceuticals LP, et al v. Secretary United States Department of Health and H, et al

Case Number: 24-1819

District Court Case Number: 1-23-cv-00931

PACER account holders are required to promptly inform the PACER Service Center of any contact information changes. In order to not delay providing notice to attorneys or pro se public filers, your information, including address, phone number and/or email address, may have been updated in the Third Circuit database. Changes at the local level will not be reflected at PACER. Public filers are encouraged to review their information on file with PACER and update if necessary.

Attorneys are required to file all documents electronically through the Court's Electronic Case Filing System. See 3d Cir. L.A.R. 113 and the Court's website at www.ca3.uscourts.gov/cmecf-case-managementelectronic-case-files.

To All Parties:

Enclosed is case opening information regarding the above-captioned appeal filed by **AstraZeneca Pharmaceuticals LP, AstraZeneca AB**, docketed at **No. 24-1819**. All inquiries should be directed to your Case Manager in writing or by calling the Clerk's Office at 215-597-2995. This Court's rules, forms, and case information are available on our website at http://www.ca3.uscourts.gov.

Please note: If any party has filed one of the motions listed in Fed.R.App.P 4(a)(4) after the notice of appeal has been filed, that party must immediately inform the Clerk of the Court of Appeals in writing of the date and type of motion that was filed. The case in the court of appeals will not be stayed absent such notification.

Counsel for Appellant

As counsel for Appellant(s), you must file:
1. Application for Admission (if applicable)
2. Appearance Form
3. Civil Information Statement
4. Disclosure Statement (except governmental entities)
5. Concise Summary of the Case
6. Transcript Purchase Order Form.

These forms must be filed within **fourteen (14) days** of the date of this letter.

Failure of Appellant(s) to comply with any of these requirements by the deadline will result in the DISMISSAL of the case without further notice. 3rd Circuit LAR Misc. 107.2.

Counsel for Appellee

As counsel for Appellee(s), you must file:
1. Application for Admission (if applicable)
2. Appearance Form
3. Disclosure Statement (except governmental entities)

These forms must be filed within **fourteen (14) days** of the date of this letter.

Parties who do not intend to participate in the appeal must notify the Court in writing. This notice must be served on all parties.

Attached is a copy of the full caption in this matter as it is titled in the district court. Please review the caption carefully and promptly advise this office in writing of any discrepancies.

Very truly yours,
Patricia S. Dodszuweit, Clerk

By: s/Alicia
Case Manager
267-299-4948

Cc: Christine L. Coogle, Esq.
Jacob Laksin, Esq.
Brian D. Netter, Esq.
Stephen M. Pezzi, Esq.
Cassandra Snyder, Esq.
Alexander V. Sverdlov, Esq.

ASTRAZENECA PHARMACEUTICALS LP; ASTRAZENECA AB,

Appellants

v.

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

STANDING ORDER REGARDING MOTIONS TO EXCEED THE PAGE LIMITATIONS OF THE FEDERAL RULES OF APPELLATE PROCEDURE

Effective Immediately

PRESENT: McKEE, **Chief Judge**, and SLOVITER, SCIRICA, RENDELL, AMBRO, FUENTES, SMITH, FISHER, CHAGARES, JORDAN, HARDIMAN, GREENAWAY, JR, VANASKIE, ALDISERT, WEIS, GARTH, STAPLETON, GREENBERG, COWEN, NYGAARD, ROTH, BARRY, and VAN ANTWERPEN, **Circuit Judges**

AND NOW, it being noted that motions to exceed the page/word limitations for briefs are filed in approximately twenty-five percent of cases on appeal, and that seventy-one percent of those motions seek to exceed the page/word limitations by more than twenty percent;

Notice is hereby given that motions to exceed the page or word limitations for briefs are strongly disfavored and will be granted only upon demonstration of extraordinary circumstances. Such circumstances may include multi-appellant consolidated appeals in which the appellee seeks to file a single responsive brief or complex/consolidated proceedings in which the parties are seeking to file jointly or the subject matter clearly requires expansion of the page or word limitations.

Accordingly, it is **ORDERED** that a three-judge Standing Motions Panel is hereby appointed to rule on all motions to exceed the page/word limitations for briefs since the page/word limitations, prescribed by Fed. R. App. P. 32(a)(7), should be sufficient to address all issues in an appeal.

It is further **ORDERED** that Counsel are advised to seek advance approval of requests to exceed the page/word limitations whenever possible or run the risk of rewriting and refiling a compliant brief. Any request to exceed page/word limitations submitted in the absence of such an advance request shall include an explanation of why counsel could not have foreseen any difficulty in complying with the limitations in time to seek advance approval from the panel.

This order shall not apply to capital habeas cases.

By the Court,

/s/ Theodore A. McKee
Chief Judge

Date: January 9, 2012

A True Copy:

Marcia M. Waldron

Marcia M. Waldron, Clerk

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.	Civil Action No. 23-931-CFC

NOTICE OF APPEAL

Notice is hereby given that Plaintiffs AstraZeneca Pharmaceuticals LP and AstraZeneca AB hereby appeal to the United States Court of Appeals for the Third Circuit from the Court's March 1, 2024 Memorandum Opinion (D.I. 70), Order denying Plaintiffs' motion for summary judgment and granting Defendants' cross-motion for summary judgment (D.I. 71), and corresponding Judgment (D.I. 72), and

from all orders, opinions, decisions, and rulings prior to the entry of the order that merge therein.

Respectfully submitted,

Dated: April 29, 2024

McCarter & English, LLP

Catherine E. Stetson*
Susan M. Cook*
Marlan Golden*
HOGAN LOVELLS US LLP
555 Thirteenth Street, NW
Washington, D.C. 20004
Tel: (202) 637-5600
cate.stetson@hoganlovells.com
susan.cook@hoganlovells.com
marlan.golden@hoganlovells.com

*admitted pro hac vice

/s/ Daniel M. Silver
Daniel M. Silver (#4758)
Alexandra M. Joyce (#6423)
Renaissance Centre
405 North King Street, 8th Floor
Wilmington, DE 19801
(302) 984-6300
dsilver@mccarter.com
ajoyce@mccarter.com

Attorneys for Plaintiffs

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 SEVICES, 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, Marlan 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

March 1, 2024
Wilmington, Delaware

COLM F. CONNOLLY
CHIEF JUDGE

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 B are usually not self-administered. *See Part B Drugs and Biologicals*, CENTERS FOR MEDICARE & MEDICAID SERVICES, https://www.cms.gov/cms-guide-medical-technology-companies-and-other-interested-parties/payment/part-b-drugs [https://perma.cc/7XR4-7JGA] (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.cc/VRW4-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)(1); 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)(1)–(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-1(e)(1)(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-1(e)(1)(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-1(d)(1)(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-1(d)(1)(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-1(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 the 2026 price period, 15 drugs for the 2027 and 2028 price periods, and 20 drugs for all subsequent price periods.

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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.

§ 1320f-1(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-1(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-1(d) of this title, and the determination of qualifying single source drugs under section 1320f-1(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)(1).

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)(1). 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-1(c)(1); 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, § 11001(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-1(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-1(e)(1)(A)(iii). As noted above, § 1320f-1(e)(1)(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://perma.cc/QJ5E-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-G6BU].

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]

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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

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

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.

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-1(e)(1)(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-1(e)(1)(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-1(e)(1)(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. Defs. 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." *TransUnion 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." *TransUnion*, 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-1(e)(1)(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-1(e)(1) 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-1(e)(1) defines the universe of qualifying single source drugs from which the negotiation-eligible drugs and ultimately the selected drugs are chosen. Section 1320f-1(c)—not § 1320f-1(e)(1)—governs the removal of drugs from the Program once they have been selected. Section 1320f-1(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-1(c)(2)(B). Under § 1320f-1(c)(1), 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 1, 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/N5DN-R5FP]. 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 II; 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.

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 SEVICES, and CHIQUITA BROOKS-LASURE, in her official capacity as ADMINISTRATOR OF THE CENTERS FOR MEDICARE & MEDICAID SERVICES, Defendants.	Civ. No. 23-931-CFC

ORDER

At Wilmington on this First day of March in 2024, having considered the parties' cross-motions for summary judgment, it is hereby ORDERED that Plaintiffs' Motion for Summary Judgment (D.I. 18) is DENIED; and it is further

ORDERED that Defendants' Cross-Motion for Summary Judgment (D.I. 21) is GRANTED.

CHIEF UNITED STATES DISTRICT JUDGE

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 SEVICES, and CHIQUITA BROOKS-LASURE, in her official capacity as ADMINISTRATOR OF THE CENTERS FOR MEDICARE & MEDICAID SERVICES, Defendants.	Civ. No. 23-931-CFC

JUDGMENT IN A CIVIL CASE

For the reasons stated in the Court's Memorandum Opinion and Order of March 1, 2024;

IT IS ORDERED that judgment is entered in favor of Defendants and against Plaintiffs.

Dated: 3.1.24

Chief Judge

(By) Deputy Clerk