No. 24-1819

IN THE

United States Court of Appeals for the Third Circuit

ASTRAZENECA PHARMACEUTICALS, LP, *ET AL.*,

Plaintiffs-Appellants,

v.

XAVIER BECERRA, *ET AL.*,

Defendants-Appellees.

On Appeal from the United States District Court
for the District of Delaware
No. 23-cv-00931-CFC, Chief Judge Colm F. Connolly

OPENING BRIEF FOR PLAINTIFFS-APPELLANTS

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July 15, 2024

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure and Rule 26.1 of this Court, Appellants AstraZeneca Pharmaceuticals LP and AstraZeneca AB disclose the following: AstraZeneca Pharmaceuticals LP is a Delaware limited partnership. AstraZeneca Pharmaceuticals LP's general partner is AstraZeneca AB, a Swedish corporation. AstraZeneca Pharmaceuticals LP's sole limited partner is Zeneca Inc., a Delaware corporation. AstraZeneca PLC, a publicly-held company, is the ultimate parent company of AstraZeneca Pharmaceuticals LP, AstraZeneca AB, and Zeneca, Inc. No other publicly held company owns 10% or more of the voting interest in AstraZeneca Pharmaceuticals LP or AstraZeneca AB.

July 15, 2024

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TABLE OF CONTENTS

TABLE OF CONTENTS—Continued

Page(s)

TABLE OF AUTHORITIES

Page(s)

CASES:

TABLE OF AUTHORITIES—Continued

Page(s)

TABLE OF AUTHORITIES—Continued

Page(s)

TABLE OF AUTHORITIES—Continued

Page(s)

TABLE OF AUTHORITIES—Continued

Page(s)

TABLE OF AUTHORITIES—Continued

Page(s)

CONSTITUTIONAL PROVISION:

STATUTES:

TABLE OF AUTHORITIES—Continued

Page(s)

TABLE OF AUTHORITIES—Continued

Page(s)

TABLE OF AUTHORITIES—Continued

Page(s)

REGULATIONS:

RULE:

OTHER AUTHORITIES:

INTRODUCTION

AstraZeneca is a world-leading pharmaceutical company that creates medicines to treat serious diseases. AstraZeneca aims to provide patients access to its medications today, and to continue funding innovative, life-saving medical advancements for tomorrow. That life-saving and innovative work requires tremendous investment: AstraZeneca spends billions on research and development, and any given drug can take years in the development pipeline before it is approved—if it is approved at all. In exchange for the investment and those attendant risks, AstraZeneca receives patents on its drugs. Those patents, alongside regulatory exclusivity periods, allow AstraZeneca to recoup its investments based on the prevailing market-dictated price.

In the last few years, the government has upended this regime, shifting from a market participant and arms-length negotiator to a market manipulator, using the cudgel of fines, penalties, and exclusion from government programs. In 2022, Congress enacted the so-called "Drug Pricing Negotiation Program," a Medicare price-fixing statute that forces manufacturers like AstraZeneca to sell their patented drugs to nearly half the market at government-dictated prices. And despite the program's label, there is no real "negotiation" here; declining the government's "offer" subjects a manufacturer to exorbitant penalties, which the manufacturer can only avoid by withdrawing *all of its products* from Medicare and Medicaid. The

statute authorizes the Centers for Medicare & Medicaid Services (CMS) to dictate whether a drug qualifies for "negotiation" and what constitutes a "fair price," without notice-and-comment and without judicial oversight to boot; the statute bars judicial or administrative review of those key decisions.

Wielding its newfound authority, CMS issued guidance that drastically expands the Program's already broad reach. The statute limits the Program to small-molecule drugs that have been on the market for at least seven years. CMS, however, re-wrote that limitation so it can control the price for a *new* drug as soon as it hits the market—as long as it shares an active moiety with a previously approved drug. The statute requires that the price control end once a generic competitor is approved and marketed. CMS instead adopted a nebulous "bona fide marketing" test, retaining complete discretion to determine when such generic competition occurs.

This government price-control program—augmented by CMS's standardless guidance—has harmed manufacturers like AstraZeneca. CMS has already selected for price control one of AstraZeneca's patented drugs: FARXIGA® (dapagliflozin), which treats diabetes, heart disease, and kidney disease. Other medications are likely to follow, including several critical cancer drugs. AstraZeneca has planned and invested in the development of these drugs for *years*. Yet the Program stands to disrupt AstraZeneca's investment-backed expectations by dictating the value of patented drugs like FARXIGA during the critical exclusivity period. What is more,

AstraZeneca must agree to a price for the drug now that will apply for years to come, and it must make drug portfolio decisions now that impact the company for the foreseeable future. The agency's unlawful policies thus cause AstraZeneca concrete and imminent harm.

Walking away from Medicare and Medicaid is not an option for AstraZeneca—or the millions of Medicare and Medicaid patients who rely on its drugs. So AstraZeneca filed this suit, arguing that CMS's guidance violates the Administrative Procedure Act (APA) and that both the Program and guidance violate the Fifth Amendment's Due Process Clause. The District Court granted summary judgment for the government, finding that AstraZeneca lacks standing to raise its APA claims and that the Due Process Clause does not apply here because participation in Medicare is "voluntary."

That decision is wrong on all fronts. Standing is supported by the record: AstraZeneca has been forced to reckon with CMS's unlawful interpretation of the statute while making decisions about how to develop its drug pipeline and in applying the agency's guidance *now* in deciding whether to agree on a price for FARXIGA that will presumably apply indefinitely. As for the due process claim, the District Court's invented "voluntariness" exception is as wrong as it is dangerous. There are scores of voluntary government programs, and the District Court's novel

rule provides a roadmap to price control by regulatory fiat, with no process due to anyone.

This Court should reverse.

JURISDICTIONAL STATEMENT

The District Court had jurisdiction under 28 U.S.C. §§ 1331, 1346, 1361, and 2201-2202. The District Court entered a final order denying AstraZeneca Pharmaceuticals LP's and AstraZeneca AB's (collectively, "AstraZeneca") motion for summary judgment and granting the Government's cross-motion on March 1, 2024, disposing of all claims. AstraZeneca timely appealed on April 29, 2024. This Court has jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF ISSUES

1. Whether AstraZeneca has standing to bring either or both of its APA claims, where CMS's Guidance directly affects AstraZeneca's ability to make current business decisions and to value its product in ongoing negotiations with the agency, that Guidance caused AstraZeneca's injuries, vacating that Guidance would redress AstraZeneca's injuries, and AstraZeneca is within the zone of interests protected by the statute? *See* JA20-36.; ECF 21-1, at 14-21; ECF 58, at 3-16; ECF 61, at 2-9.[1]

2. Whether the Inflation Reduction Act's (IRA) drug pricing provisions,

[1] All "ECF" cites refer to the District Court's docket.

as applied to AstraZeneca, violate the Fifth Amendment's Due Process Clause? JA36-46; ECF 19, at 28-32; ECF 21-1, at 44-48; ECF 58, at 44-50; ECF 61, at 24-27.

STATEMENT OF RELATED CASES AND PROCEEDINGS

Several cases in this Circuit and other courts involve challenges to the IRA's drug pricing provisions, although many of the cases involve claims that do not overlap with AstraZeneca's. Those cases are:

- *Bristol Myers Squibb Co. v. Becerra*, No. 3:23-cv-3335 (D.N.J.), appeal docketed, No. 24-1820 (3d Cir.) (Takings and First Amendment) – consolidated with *Janssen*
- *Janssen Pharms. v. Becerra*, No. 3:23-cv-3818 (D.N.J.), appeal docketed, No. 24-1821 (3d Cir.) (Takings, First Amendment, and unconstitutional conditions) – consolidated with *Bristol Myers Squibb*
- *Merck & Co. v. Becerra*, No. 1:23-01615 (D.D.C.) (Takings and First Amendment)
- *Dayton Area Chamber of Com. v. Becerra*, 2023 WL 6378423 (S.D. Ohio Sept. 29, 2023) (separation of powers, Procedural Due Process, Excessive Fines, lack of legislative authority, and First Amendment)
- *Boehringer Ingelheim Pharms., Inc. v. HHS*, 2024 WL 3292657 (D. Conn. July 3, 2024) (Procedural Due Process, Takings, First Amendment, Excessive Fines, Unconstitutional Conditions, and APA notice-and-comment)
- *Novartis Pharms. v. Becerra*, No. 3:23-cv-14221 (D.N.J.) (Takings, Excessive Fines, and First Amendment)
- *Novo Nordisk Inc., et al. v. Becerra*, No. 3:23-cv-20814 (D.N.J.) (First Amendment, APA, and ultra vires)
- *Nat'l Infusion Ctr. Ass'n v. Becerra*, No. 1:23-cv-707, 2024 WL

561860 (W.D. Tex. Feb. 12, 2024), appeal docketed, No. 24-50180 (5th Cir.) (argued May 1, 2024) (separation of powers, Excessive Fines, and Procedural Due Process)

STATEMENT OF THE CASE

A. STATUTORY AND REGULATORY FRAMEWORK

1. Medicare, drug pricing, and exclusivity periods.

"The federal government dominates the healthcare market" and "pays for almost half the annual nationwide spending on prescription drugs." *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 699 (3d Cir. 2023). Medicare is the nation's largest healthcare program with more than 67 million members overall. CMS, *Medicare Enrollment Dashboard*, https://perma.cc/2RBC-6FSH (last visited July 15, 2024). Medicare Part B covers outpatient prescription drugs administered at a doctor's office or in a hospital outpatient setting by a health care professional. *Prescription drugs (outpatient)*, Medicare.gov, https://perma.cc/8MN4-JT4J (last visited July 15, 2024). 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). Typically, Part D covers self-administered drugs dispensed through pharmacies. *See* CMS, *Medicare Prescription Drug Benefit Manual*, ch. 6, § 10.2 (rev. Jan. 15, 2016).

Medicare Part D alone has about 54 million members. *Medicare Enrollment Dashboard*, *supra*. Although Part D began as a comparatively small part of the

prescription drug market, it now accounts for over $200 billion per year—more than 40% of prescription drug spending nationwide. GAO, No. GAO-23-105270, *Medicare Part D: CMS Should Monitor Effects of Rebates on Plan Formularies and Beneficiary Spending* (Sept. 2023); *Drug Spending*, HHS, Officer of Inspector General, https://oig.hhs.gov/reports-and-publications/featured-topics/drug-spending (last updated May 14, 2024).

Drug manufacturers invest billions annually into discovering, developing, and improving medications. Not every drug that a manufacturer invests in comes to market—far from it. Manufacturers must continually make difficult decisions about which compounds to pursue developing, put through preclinical testing and controlled clinical trials, and ultimately submit to FDA for approval. The average cost of bringing a single new drug to market is more than $2 billion and often takes 10 to 15 years. *See, e.g.*, PhRMA, *Research & Development Policy Framework* (last visited July 15, 2024), https://perma.cc/7YKB-CUQN; Deloitte, *Seize the Digital Momentum: Measuring the Return from Pharmaceutical Innovation 2022* at 12 (Jan. 2023). Only one-third of approved therapies manage to cover their cost of development, much less to provide an economic return significant enough to allow for continued investment and innovation. *See* John A. Vernon et al., *Drug Development Costs When Financial Risk Is Measured Using the FAMA-French Three-Factor Model*, 19 J. Health Econ. 1002, 1004 (2009).

The government has historically employed two primary strategies to encourage manufacturers to invest the substantial time and money needed to develop new drug products, including new uses of drugs subject to existing approvals: market-based pricing and exclusivity periods.

First, a market-based pricing approach ensures that manufacturers are fairly compensated for their products, thereby enabling them to continue investing in new products and innovations, which in turn provides improved outcomes for patients and lowers the government's long-term healthcare costs. Traditionally, Medicare Part B and Part D both looked to market-based payment amounts for prescription drugs—so much so that when Congress enacted Medicare Part D, it explicitly prohibited the government from "interfer[ing] with the negotiations between drug manufacturers and pharmacies and [private plan] sponsors." 42 U.S.C. § 1395w–111(i).

Second, Congress has established various patent and regulatory exclusivity periods during which brand-name drugs are protected from generic competition. *See, e.g.*, 21 U.S.C. § 355(c)(3)(E). Virtually all branded drugs eventually experience generic competition to some degree, and entry of a generic into the market typically results in an immediate decrease in the market share and pricing of the brand-name drug. *See* FDA, *Generic Competition and Drug Prices*, https://perma.cc/AY95-BTNM (last visited July 15, 2024). Rigorous enforcement of these protections is

therefore essential to foster the continued investment necessary to develop and market new drug products.

Although a generic cannot be marketed during an exclusivity or applicable patent period, the generic manufacturer can seek "tentative approval" of its drug. A "tentative approval" means the application meets the requirements for approval, but its final approval must be delayed until all patent or exclusivity periods have expired. *See* 21 C.F.R. § 314.3. Seeking a tentative approval allows a generic manufacturer to significantly expedite the final approval process once the exclusivity and patent periods lapse so that the generic can immediately begin competing with the branded drug. *See generally* FDA, *Paragraph IV Patent Certifications* (July 8, 2024), https://perma.cc/6CRQ-CMM5 (showing many generics are first marketed the same day they are approved); *see also* JA105 ¶ 27.

2. The IRA's Medicare Drug Price Negotiation Program.

The Medicare Drug Price Negotiation Program (the "Program") fundamentally transforms how prescription drug pricing works. The Program authorizes CMS to bring the full coercive force of the government to bear in "negotiating" maximum prices under Medicare for a set number of drugs each year. Manufacturers that refuse to participate in this process must pay a draconian penalty or withdraw every single one of their drugs from Medicare and Medicaid.

The statute mandates several specific steps that CMS and manufacturers must

follow leading up to the start of the price applicability period in order to select and set the price for a certain number of drugs each year.

First, CMS must identify "negotiation-eligible drugs." Only qualifying single source drugs are negotiation-eligible. The statute defines "qualifying single source drug" as a "covered part D drug" that (i) is FDA-approved and "is marketed pursuant to such approval"; (ii) has been FDA-approved for at least seven years; and (iii) "that is not the listed drug for any" generic drug "that is approved and marketed." 42 U.S.C. § 1320f-1(e)(1)(A). The definition of "covered part D drug" cross-references the definition for a "covered outpatient drug," which in turn is based on whether the product is approved pursuant to a distinct New Drug Application (NDA) or Biologics License Application (BLA). *Id.* §§ 1395w-102(e)(1); 1396r–8(k)(2), (k)(7)(A)(iv); *see also* 42 C.F.R. § 447.50.

Second, CMS ranks all negotiation-eligible drugs according to the highest total Medicare Part B or D expenditures over a designated 12-month period. *See* JA08. CMS must then select a specified number of drugs for negotiation: ten drugs with the highest Part D expenditures for 2026; 15 drugs with the highest Part D expenditures for 2027; 15 drugs with the highest Part D or Part B expenditures for 2028; and 20 drugs with the highest Part D or Part B expenditures for 2029 and beyond. 42 U.S.C. § 1320f-1(a)-(b), (d)(1), (e).

Third, the manufacturer of a selected drug "shall . . . negotiate" the drug's

price with CMS. *Id.* § 1320f-3(a)(1). Nothing about this negotiation mirrors a typical commercial negotiation, however. For one, negotiation is mandatory: Manufacturers must sign an agreement to participate in the negotiation process by a date certain and have no meaningful opportunity to opt out. *See id.* §§ 1320f-2, 1320f-6(a); 26 U.S.C. § 5000D; *infra* p.13. For another, although the IRA nominally allows CMS and the manufacturer to jointly determine the "maximum fair price," it directs CMS to design and implement a "methodology" to "achieve the lowest maximum fair price for each selected drug." 42 U.S.C. § 1320f-3(b)(1). Although that *maximum* price is capped at a fraction of certain reference prices, there is no statutory *minimum* price—CMS can offer a price as low as one penny. *Id.* § 1320f-3(c)(1)(A).

The statute sets forth a timeline dictating the dates on which CMS and manufacturers must submit offers and counteroffers. CMS first makes an initial written offer, which a manufacturer must accept or counter within 30 days. *Id.* § 1320f-3(b)(2). All negotiations "shall end" no later than August 31, 2024 for the 2026 initial price applicability year. *Id.* "If the parties have not agreed on a price by that date, the manufacturer is deemed to be noncompliant and subject to" a host of severe penalties. JA11.

Finally, after the "negotiation" concludes, the manufacturer must provide that drug at the "fair price" to a number of Medicare-eligible individuals and entities *in*

perpetuity. Once a drug has been "selected," it remains subject to the "negotiated" price control even if it would no longer rank in the top of all negotiation-eligible drugs. *See* 42 U.S.C. § 1320f-1(c)(2). Except for a very limited universe of circumstances, selected drugs are subject to the same negotiation price indefinitely, plus a nominal bump for inflation. *See id.* § 1320f-2(b), (3)(f). Any time a manufacturer fails to make its drug available to Medicare beneficiaries at CMS's designated "maximum fair price," the manufacturer is subject to a steep penalty of ten times the price differential between the price used and the CMS-mandated price. *Id.* § 1320f-6(a).

The only real way to avoid the price control, once imposed, is if a generic version of the drug "is approved or licensed" and "is marketed pursuant to such approval or licensure." *Id.* § 1320f-1(c)(1)(A). Even then, the generic must have met these criteria for "at least 9 months" of a price applicability year. *See id.* Thus, for a drug that was selected for inclusion in the 2026 list, if a generic is "approved and marketed" between August 2, 2024 and March 31, 2026, the branded drug remains subject to the price cap through December 31, 2026. JA109, 284. If the generic is first "approved and marketed" between April 1, 2026 to March 31, 2027, however, the branded drug remains subject to the price cap for an extra year—through December 31, 2027. *Id.*

Manufacturers that do not wish to participate in this Program are out of luck.

Refusing to negotiate with CMS or to agree to CMS's mandated price triggers a daily escalating penalty beginning at 185% of the drug's price and escalating to *1,900%*. *See* Cong. Rsch. Serv., No. R47202, Tax Provisions in the Inflation Reduction Act of 2022 (H.R. 5376), at 4 tbl. 2 (Aug. 10, 2022); *see* 26 U.S.C. § 5000D(a)-(b); *see also Excise Tax on Designated Drugs; Procedural Requirements*, 89 Fed. Reg. 55,507 (July 5, 2024). The only way to "suspen[d]" this oppressive penalty is to acquiesce to CMS's price or terminate "all applicable agreements" to sell *every single one of the manufacturer's drugs under Medicare and Medicaid*. *See* 26 U.S.C. § 5000D(c). That would substantially disrupt the manufacturer's ability to research and develop new products or to continue providing its existing products to the other half of the country, given that Medicare and Medicaid account for 40% of all U.S. prescription drug sales. *See* JA99-100 ¶ 11; *supra* p. 7. It would also leave over half the country without access to any of the manufacturer's medications.

To make matters worse, the IRA deprives manufacturers of important procedural protections on both the front and back ends of this process. The statute mandates implementation by regulatory fiat, directing CMS to implement the Program through guidance "for 2026, 2027, and 2028." 42 U.S.C. § 1320f note. CMS has interpreted this language to mean it is not required to provide notice or an opportunity for comment prior to promulgating guidance. *See* JA126-129. The IRA likewise withholds notice of the contents of the forced-sale "agreement." *See* 42

U.S.C. §§ 1320f-2(a), 1320f-3(a). Moreover, CMS—the agency with the clearest interest in negotiating the lowest price possible, no matter how "fair"—is the one charged with negotiating the price cap. *See id.* § 1320f-3.

On the back end, manufacturers that disagree with the selection of their drug or with the price dictated by CMS have no recourse—judicial or otherwise. There is no process for manufacturers to ask CMS to reconsider its decision that a product meets the definition of "qualifying single source drug" or the price cap it has set. The IRA also expressly precludes "administrative or judicial review" for key aspects of the Program, including the "selection of drugs," the "determination of negotiation-eligible drugs," the "determination of qualifying single source drugs," the "determination of a maximum fair price," and the "determination of renegotiation-eligible drugs." 42 U.S.C. § 1320f-7.

3. CMS's Guidance.

On March 15, 2023, CMS issued an initial guidance document detailing how the agency planned to execute these changes for the first year of the program. *See* JA12. On June 30, 2023, CMS released another guidance document representing the agency's final word on implementation for the Program's first year. *See* JA119-316 (the "Guidance").

Two aspects of the Guidance are relevant here. *First*, CMS redefined the term "qualifying single source drug." The IRA defines that term as a drug that has been

approved and marketed under its own NDA, provided that "at least 7 years will have elapsed since the date of such approval" before the start of the relevant price applicability year. 42 U.S.C. § 1320f-1(e)(1)(A); *see* 21 U.S.C. § 355(c); *supra* p. 10. In other words—and consistent with Congress's recognition of the need to incentivize manufacturers to invest in bringing new drugs to market—only those drugs that have been on the market for at least seven years are eligible for a possible price cap.

In its Guidance, however, CMS expanded the definition of qualifying single source drug to include "all dosage forms and strengths of the drug with the same active moiety" (*i.e.*, active ingredient) that a manufacturer has developed, including "products that are marketed pursuant to *different NDAs*." JA217 (emphasis added). Drugs as disparate as those that treat irritable bowel syndrome with constipation and those designed to reduce serum phosphorus in adults with chronic kidney disease on dialysis uridine replacement will thus be collectively treated as one "qualifying single source drug." Ibsrela (NDA 211801), Prescribing Information (Apr. 2022), https://perma.cc/C23E-JBVZ; Xphozah (NDA 213931), Prescribing Information (Oct. 2023), https://perma.cc/G3ZL-YRA8; *see also* JA217. That means that Medicare expenditures on both products will be aggregated for purposes of ranking the qualifying single source drug for selection for negotiation. The negotiated "maximum fair price" will also apply across both products—including to a new

product as soon as it is approved, irrespective of the statutory seven-year waiting period.

Second, CMS altered the statutory requirements that must be met before a drug is deemed to have generic competition. Under the statute, a drug is not eligible for negotiation if a generic version "is approved and marketed," *i.e.*, available for purchase. 42 U.S.C. § 1320f-1(c)(1), (e)(1)(A)(iii); *see Marketed*, Merriam-Webster's Collegiate Dictionary 760 (11th ed. 2020).

CMS's Guidance adopts a new and fundamentally different test: CMS will subjectively assess whether, under the "totality of the circumstances," the generic has been the subject of "*bona fide* marketing." JA120 (emphasis added). To determine whether a drug meets CMS's new test, the agency will review various data, including Prescription Drug Event (PDE) data. JA124. CMS will also consider "[a]dditional relevant factors" which "may include" whether the generic "is regularly and consistently available for purchase through the pharmaceutical supply chain and whether any licenses or other agreements between a Primary Manufacturer and a generic drug . . . manufacturer limit the availability or distribution of the selected drug." JA283. CMS did not explain what else it might look to in assessing the "totality of the circumstances" or what threshold a manufacturer must meet to prove "bona fide marketing." Nor did CMS establish a set deadline by which it will decide whether a particular drug has been subject to "bone fide marketing," after the

drug has been approved. On the contrary, CMS proclaimed that it will monitor this data and retain discretion to determine *at any time* that a generic no longer satisfies the agency's amorphous "bona fide marketing" standard. JA196, 288.

Although the Guidance technically only applies to initial price applicability year 2026, CMS has since released a substantively identical draft guidance document for price applicability year 2027. *See* CMS, *Medicare Drug Price Negotiation Program: Draft Guidance Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027* (May 3, 2024). The final guidance for 2027 will issue this fall. *See* CMS, *Fact Sheet: Medicare Drug Price Negotiation Program Draft Guidance for 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027*, at 3 (May 2024).

B. FACTUAL AND PROCEDURAL HISTORY

1. The Program's effects on AstraZeneca's drug development and investment decisions.

AstraZeneca is a global, science-led, patient-focused pharmaceutical company that manufactures numerous drugs. AstraZeneca currently has 182 projects in its drug-development pipeline. AstraZeneca, *Our pipeline*, https://perma.cc/BU7Y-9F2L (last updated April 25, 2024). Many of AstraZeneca's products specifically serve those patients that are most likely to be on Medicare and Medicaid—the elderly, chronically ill, and those with serious and rare conditions.

See JA100 ¶ 12. "Medicare and Medicaid collectively account for approximately more than 40% of AstraZeneca's gross revenues in the U.S." JA100 ¶ 13.

AstraZeneca invests substantial time and resources to develop new drugs with active ingredients that have not previously been approved, known as innovator drugs. One example is FARXIGA® (dapagliflozin)—a first-in-class, highly effective treatment for diabetes, heart disease, and chronic kidney disease. *See* JA15. FDA originally approved FARXIGA in 2014 for use in treating Type 2 diabetes. JA101-102 ¶ 17. Since then, AstraZeneca has continued investing in FARXIGA, resulting in several subsequent FDA approvals to treat a variety of diseases. *Id*. At the time AstraZeneca filed suit, FDA had granted tentative approval to 17 generic versions of FARXIGA, slated to come to market between October 2025 and Summer 2026. *See* JA15. FDA subsequently granted tentative approval to one additional generic and extended the exclusivity period, such that a generic will now come to market between April 4, 2026 and Summer 2026. *See* FDA, *Product Details for NDA 202293, Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*, https://perma.cc/U82Z-UHR9.

AstraZeneca is also constantly looking for ways to improve other drug products. Take LYNPARZA® (olaparib), a cancer medication. LYNPARZA was initially approved in capsule form in 2014. JA104 ¶ 24. AstraZeneca subsequently developed a tablet formulation that was better tolerated by patients and more

convenient, which FDA approved under a separate NDA in 2017. *Id.* AstraZeneca's drug CALQUENCE® (acalabrutinib) has a similar story—it was first approved in 2017 in capsule form, but AstraZeneca later invested substantial resources to develop a tablet form which was approved under a separate NDA in 2022 in order to expand the patient population. *Id.* ¶ 25.

Drugs like FARXIGA, which has already been selected for the Program, and LYNPARZA and CALQUENCE, which may well be selected in the future, help "fund the bulk of AstraZeneca's research and development capabilities." JA90 ¶ 118; *see also* JA105-106 ¶¶ 29-30. In response to the Program, however, AstraZeneca has already been forced to "take significant steps to fundamentally reposition its business operations and investments in pipeline products." JA89 ¶ 113; *see also* JA 106 ¶ 30. This includes both current and future operations. For example, "[l]ike other manufacturers, AstraZeneca is making the painful decision to suspend ongoing research and development activities" because of diminished incentives to "research and develop[] new treatment applications for existing drugs." JA90 ¶ 118; *see also* JA104-106 ¶¶ 26, 28, 30. AstraZeneca has also been forced to "reckon[] with the delayed launch of cancer drugs" and to shelve other "product development plans . . . entirely." JA90 ¶ 119; *see also* JA106 ¶ 32.

2. CMS selects FARXIGA for price applicability year 2026.

In August 2023, CMS announced the ten drugs it had selected for 2026, the

first price applicability year. FARXIGA was on that list. JA15. As mandated by statute, AstraZeneca signed the negotiation agreement and has been "negotiating" with CMS. *See* JA17. The "maximum fair price" will become effective beginning January 1, 2026. *See* JA210.

3. AstraZeneca files suit and the District Court grants summary judgment for the Government.

AstraZeneca challenged CMS's Guidance as violating the APA and the Program itself as violating AstraZeneca's due process rights. AstraZeneca explained that CMS's Guidance contravenes the plain text of the IRA, and that it has been forced to account for CMS's Guidance in making important decisions about whether to pursue the research, development, and marketing of certain drugs and in deciding how to value its products when negotiating with CMS over FARXIGA's price cap. *See* JA67-91. AstraZeneca further explained that the Program deprives AstraZeneca of its "investment-backed patent rights" without providing "[e]ven the most rudimentary . . . procedural safeguards." JA94.

AstraZeneca moved for summary judgment. ECF 19. The government cross-moved for summary judgment, asserting that AstraZeneca lacked standing to pursue its APA claims, that those claims were subject to the judicial-review bar, and that all of AstraZeneca's claims failed on the merits. ECF 21-1. The government did not dispute that AstraZeneca has standing to pursue its due process claim. *See id.*; *see also* ECF 66.

The District Court granted the government's motion for summary judgment and denied AstraZeneca's. According to the court, AstraZeneca lacks standing for its APA claims because neither of the two challenged aspects of CMS's Guidance "have had any bearing on CMS's decision to designate Farxiga as a selected drug." JA21. The District Court waved away the company's concerns that it had been forced to adapt its investment and marketing strategies *today* on the assumption that CMS's Guidance would govern in the future, theorizing that it was unclear what effects CMS's decisions might have at some later point and that AstraZeneca could not "credibly argue that it is unable to understand the Guidance or how [it] applies." *See* JA22-35. The court did not reach the government's alternative argument that the IRA's judicial-review bar applied to AstraZeneca's APA claims or adjudicate those claims on the merits. *See* JA36.

The District Court also rejected AstraZeneca's procedural due process claim on the merits, theorizing that the Due Process Clause does not apply here because "participation in the Medicare program is a voluntary undertaking." JA43 (quotation omitted). In the District Court's view, the government may administer the Program without providing manufacturers like AstraZeneca due process because no law "requires" a manufacturer "to sell its drugs to Medicare beneficiaries." *Id.*

This appeal followed.

STANDARD OF REVIEW

This Court "review[s] a district court's grant of summary judgment in a case brought under the APA de novo, applying the applicable standard of review to the underlying agency decision." *Louisiana Forestry Ass'n Inc. v. Sec'y U.S. Dep't of Lab.*, 745 F.3d 653, 668-669 (3d Cir. 2014) (quotation marks and brackets omitted). Under the APA, this Court "must set aside an agency action that is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.' " *Id.* at 669 (quoting 5 U.S.C. § 706(2)(A)).

SUMMARY OF ARGUMENT

I. AstraZeneca has standing to raise its APA claims. *First*, AstraZeneca has suffered injury-in-fact from CMS's unlawful Guidance. AstraZeneca faces injury to its ability to make business decisions about which products to invest in and market and has had to adjust its strategies accordingly. As a result of CMS's Guidance, AstraZeneca must consider whether to continue investing in developing additional uses of active moieties in already-approved drug products, knowing those products would not receive the benefit of the seven-year statutory exemption from the price cap. AstraZeneca must likewise account for the risk that CMS's subjective application of the extra-statutory "bona fide marketing test" will subject it to a simultaneous price cap and generic competition. The company must consider these risks *today* in making investment decisions for the future.

For these same reasons, CMS's Guidance directly affects AstraZeneca's negotiating position with respect to FARXIGA. The price set for FARXIGA will apply to the drug for years, and AstraZeneca has had to apply the agency's unlawful definitions *now* in deciding whether and how to negotiate with CMS. The District Court's contrary decision fundamentally misunderstood AstraZeneca's theory of injury and was legally incorrect.

Second, AstraZeneca's injuries are caused by CMS's Guidance and redressable by a decision vacating that Guidance. Where a plaintiff is the object of agency action, causation is straightforward. The same is true of redressability when the agency's rule causes the injury. That is the case here.

Third, AstraZeneca has prudential standing because it is within the zone of interests that the IRA regulates.

II. The Program violates the Due Process Clause because it deprives AstraZeneca of property interests without providing due process.

First, the Program deprives AstraZeneca of core property interests by reclaiming some of the rights conferred by FARXIGA's patent. A patent is a bargain between an inventor and the government: In return for investing in creating innovative products, an inventor obtains the exclusive right to sell a patented invention for a limited time to recoup its investment costs. AstraZeneca maintains a property interest in that patent right.

Second, the Program does not provide AstraZeneca due process. The Due Process Clause protects the opportunity to be heard at a meaningful time and in a meaningful manner, but the Program provides no such opportunity. On the front end, manufacturers do not sign up for participation in the Program; they are selected for negotiation by the government. On the back end, the Program bars administrative or judicial review of many of CMS's key decisions. The program also denies AstraZeneca an impartial adjudicator. CMS—the agency with a vested interest in paying the lowest price possible—is the one charged with adjudicating whether a drug qualifies for negotiation and setting the applicable price cap.

Third, the District Court's "voluntariness" exception to the Due Process Clause is both wrong and dangerous. Even if the Program, which functionally mandates compliance through oppressive fines and unrealistic opt-out requirements, could fairly be called "voluntary," the mere fact that participation in a government program is voluntary does not mean the government can dispense with due process. Indeed, the Supreme Court and this Court have repeatedly applied the Due Process Clause in the context of voluntary government programs. The District Court reached a contrary conclusion by relying on cases from the takings context, a different type of claim not at issue here. Moreover, accepting the District Court's "voluntariness" theory would fundamentally upend public-private relationships nationwide by

allowing the government to impose price controls by fiat with no due process whatsoever.

ARGUMENT

I. ASTRAZENECA HAS STANDING FOR ITS APA CLAIMS.

Courts assess standing as of the time the plaintiff filed suit and, in so doing, must assume the plaintiff will prevail on the merits. *Davis v. FEC*, 554 U.S. 724, 734 (2008); *Cottrell v. Alcon Lab'ys*, 874 F.3d 154, 162 (3d Cir. 2017). Article III standing requires (1) an injury-in-fact (2) that is fairly traceable to the challenged action, and (3) likely redressable by a favorable decision. *Davis*, 554 U.S. at 733. In APA cases, the challenger must also show prudential standing, meaning its interests are "arguably within the zone of interests to be protected or regulated by the statute that [it] says was violated." *Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak*, 567 U.S. 209, 224 (2012) (quotation marks and citation omitted). AstraZeneca satisfies all of these requirements.

A. AstraZeneca satisfies the injury-in-fact requirement.

Injury-in-fact requires showing "an invasion of a legally protected interest that is concrete and particularized and actual or imminent, not conjectural or hypothetical." *Cottrell*, 874 F.3d at 162-163 (cleaned up). "That 'actual or imminent' is disjunctive is critical: it indicates that a plaintiff need not wait until he or she has *actually* sustained the feared harm in order to seek judicial redress." *Clemens v. ExecuPharm Inc.*, 48 F.4th 146, 152 (3d Cir. 2022). Allegations of future injury

accordingly "suffice if the threatened injury is certainly impending or there is a substantial risk that the harm will occur." *Id.* (quotation marks and citation omitted).

"[T]he injury-in-fact requirement" is "very generous" to claimants, who need only allege some "specific, identifiable trifle of injury or a personal stake in the outcome of the litigation." *In re Glob. Indus. Techs., Inc.*, 645 F.3d 201, 210 (3d Cir. 2011) (en banc) (quotation marks and citations omitted). "[T]he question is simply whether" the plaintiff has a "legally protected interest[] that could be affected" by the challenged action. *Id.* at 212. AstraZeneca clears that minimal hurdle.

1. AstraZeneca's injuries are legally sufficient to confer standing.

AstraZeneca faces actual or imminent injury to its "ability to make business decisions about the products it will offer in the market" as a result of CMS's challenged decisions. *Sabre, Inc. v. Dep't. of Transp.*, 429 F.3d 1113, 1117 (D.C. Cir. 2005). A regulated entity suffers injury where agency action creates a present-day obligation to "adjust its finances and investment strategy to prepare for" future potential risks. *See Great Lakes Gas Transmission Ltd. P'ship v. FERC*, 984 F.2d 426, 431 (D.C. Cir. 1993). "[T]o find otherwise would ignore the reality of the long-range economic planning involved in the sound management of an enterprise," *id.*, especially in the pharmaceutical industry, given the substantial time and resources required to develop and market a new drug, *see* JA98-99 ¶7; *supra* p. 7.

CMS's unlawful Guidance causes actual and imminent injury to AstraZeneca's business decision-making abilities, both with respect to FARXIGA and AstraZeneca's broader portfolio. Start with the decision to treat multiple drugs approved under separate NDAs as one qualifying single source drug. The IRA's definition of "qualifying single source drug" cross-references the definition for a "covered part D drug" in the Medicare statute. 42 U.S.C. § 1320f-1(e)(1). That definition, in turn, cross-references the definition for a "covered outpatient drug" in the Medicaid Drug Rebate Program statute. *Id.* § 1395w-102(e)(1). Under *that* definition, whether a single source drug is a distinct "covered outpatient drug" is based on whether the product is approved pursuant to a distinct NDA or BLA. *Id.* §§ 1396r–8(k)(2), (k)(7)(A)(iv); *see also* 42 C.F.R. § 447.50. Under the IRA, a "qualifying single source drug" is therefore a drug that has been approved and marketed under its own NDA; such drugs cannot be selected for price negotiation for seven years following approval. 42 U.S.C. § 1320f-1(e)(1)(A).

CMS's Guidance, however, defines "a drug" to include *every* product that manufacturer markets that has the "same active moiety," even if approved under different NDAs. JA217. CMS's definition thus lumps together drugs that have different indications, strengths, or dosages, such that FDA has determined that they are fundamentally different products. As a result, where a drug manufacturer already has one drug under an existing NDA and invests the energy and funds to develop

and market a *different* drug under a *different* NDA, those two distinct products will now be considered one "drug" for purposes of the Program.

That directly affects AstraZeneca's ongoing research, development, and marketing activities. In line with its patient-focused, science-led approach, AstraZeneca has traditionally "invest[ed] significant time and money" in "explor[ing] new potential uses of the active moieties of its already-approved drug products." JA98-99, 101 ¶¶ 7, 16; *see also* JA104 ¶¶ 24-25. Indeed, AstraZeneca is currently engaged in such efforts for FARXIGA and other drugs, some of which are potential candidates for selection in upcoming program years. JA103-104, 106 ¶¶ 23-25, 30.

As noted, however, the average cost to bring a new drug to market exceeds $2 billion, and only one-third of therapies approved for patient use can cover their development costs—much less make enough money to fund further investment and innovation. *Supra* p. 7. CMS's Guidance further shifts that balance to manufacturers' disfavor because a new product marketed under a different NDA can immediately be subject to an existing price cap for a drug with the same active moiety. AstraZeneca must take this into account in making business decisions about its research and development pipeline, for FARXIGA and every other product. *See* JA101, 103-106 ¶¶ 15-16, 23-26, 29-32; *see, e.g.*, *Shays v. FEC*, 414 F.3d 76, 86 (D.C. Cir. 2005) (finding standing where challenged rule required "anticipat[ing] and respond[ing] to a broader range of competitive tactics than federal law would

otherwise allow"); *Vote Choice, Inc. v. DiStefano*, 4 F.3d 26, 37 (1st Cir. 1993) (same, where a "coerced choice . . . colored [the plaintiff's] strategy from the outset").

AstraZeneca must likewise account for these risks in deciding whether to continue marketing existing products, like the one FDA approved in August 2022 that contains the same active moiety as CALQUENCE. *See* JA104-105 ¶¶ 25-26. FDA viewed those products as different enough to warrant unique NDAs, and by operation of the plain statutory text, the IRA would treat them as such. Under the IRA, that drug would therefore be exempt from the Program's price cap through 2032. *See* 42 U.S.C. § 1320f-1(e)(1)(A)(ii). Under CMS's Guidance, however, the price cap could apply as early as 2027. *See, e.g.*, *Shays*, 414 F.3d at 85 (finding standing where "basic economic logic" indicates agency's decision will affect litigant's strategy).

Applying CMS's definition also has the potential to affect products' placements on CMS's ranked list. Combining the gross covered drug costs of AstraZeneca's products approved under multiple distinct NDAs increases the odds CMS will select those drugs for "negotiation." *See* JA104-105 ¶¶ 24-27. On the flip side, separating other manufacturers' gross costs out by each discrete NDA, as the statute mandates, may well bump AstraZeneca's drugs further down—or even off—

the possible negotiation list. Absent a court order, however, AstraZeneca must proceed as if CMS's definition governs and structure its decisionmaking accordingly.

AstraZeneca has also suffered injury-in-fact by virtue of the 2026 Guidance's unlawful "bona fide marketing" requirement. By statute, when a generic is "approved and marketed," the branded drug is ineligible for price control. 42 U.S.C. § 1320f-1(e)(1)(A)(iii). A previously selected drug also becomes ineligible for continued price controls based on when a generic is "marketed." 42 U.S.C. § 1320f-1(c)(1)(B). "Marketing ordinarily refers to the act of holding forth property for sale" and "does not require that the promotional or merchandising activities connected with the selling be extensive." *Asgrow Seed Co. v. Winterboer*, 513 U.S. 179, 187 (1995); *see Marketed*, Merriam-Webster's Collegiate Dictionary 760 (available for purchase; up for sale). The key cut-off date is April 1, 2026—if a generic is available for purchase prior to that date, the selected drug is ineligible for the 2027 price-capped list; if it becomes available for purchase after that date, the selected drug can stay on the list until 2028. *See* JA284.

When AstraZeneca filed suit, it was all but certain that generic competition for FARXIGA would begin between October 2025 and Summer 2026. JA105 ¶ 27. A generic that came to market on March 31, 2026 should immediately trigger § 1320f-1(c)(1)'s de-selection provision. That is not the case under CMS's "bona fide marketing" standard, which CMS will assess based on "the totality of the

circumstances," including by relying on PDE data that can be delayed by months. *See* JA194 (admitting PDE data may not immediately capture generic sales). CMS's Guidance thus threatens to harm AstraZeneca by impermissibly resulting in a price cap on drugs that are also subject to generic competition, and by keeping drugs on the selected list longer than they should be under the statutory test.

AstraZeneca "must . . . account for" these risks in shaping its broader investment strategy. *See, e.g.*, *Shays*, 414 F.3d at 91. For FARXIGA and more generally, AstraZeneca must weigh whether it can withstand both a government-imposed price cap and stiff generic competition in evaluating future investment opportunities, whether to develop additional uses of existing drugs, and more. *See* JA105-106 ¶¶ 28, 32. *Cf. In re Glob. Indus. Techs.*, 645 F.3d at 213-214 (finding injury-in-fact where decision puts plaintiff at "a tangible disadvantage," even if "ultimate liability is contingent"); *Bristol-Myers Squibb Co. v. Shalala*, 91 F.3d 1493, 1498-99 (D.C. Cir. 1996) (same, where brand-name drug alleged injury from "exposure to competition" based on generic's tentative approval).

These are not mere "some day intentions." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 564 (1992). AstraZeneca is considering CMS's Guidance in "mak[ing] decisions *now*" as it plans for "drug development and commercialization for years to come," and there is at least a "substantial risk" that it will continue to do so moving forward. JA99-100 (emphasis added), 104-106 ¶¶ 11, 26, 28, 30, 32; *see also* JA90-

91 ¶¶ 119-120. As AstraZeneca's declarant explained, "[o]ver the next three years, CMS will select up to 50 additional drugs to be eligible for the Drug Price Negotiation Program. That selection process will very likely sweep up more of AstraZeneca's drug products." JA105-106 ¶ 29. "Thus, even pre-selection, AstraZeneca has to make investment decisions now on research [and] development of follow-on therapies for new indications and improvements to the drug itself," based on "the agency policies currently in place." JA 106 ¶¶ 30, 32; *see also, e.g.*, VitalTransformation, *IRA's Impact on the US Biopharma Ecosystem*, https://perma.cc/SXE6-WY84 (explaining that the Program has forced manufacturers to "significantly narrow investment opportunities," leaving "as many as 139 drugs over the next 10 years . . . at risk of not being developed at all").

For all these reasons, CMS's re-interpretation of the IRA's text also directly affects AstraZeneca's ability to value FARXIGA for purposes of deciding whether to participate in the Program.

When AstraZeneca filed suit, it was making decisions about whether to agree to the government's proffered "maximum fair price" that will apply to FARXIGA for years to come. JA99-100 ¶ 11. "[A]bsent judicial intervention, AstraZeneca" has "had no choice but to" base its decisions "on the policies that CMS has announced will apply." JA99-100, 106 ¶¶ 11, 31. That requires weighing (among other things): the financial implications of having a future drug approved under a

separate NDA immediately subjected to an existing price cap simply because it shares the same active moiety as FARXIGA; the risk that AstraZeneca will simultaneously be subject to a price cap and generic competition for an extended period of time; the "enormous financial consequence" and harms to patients of withdrawing all of AstraZeneca's drug products from Medicare and Medicaid if it refused to agree to the mandatory price cap for FARXIGA; the lead-time required to implement an opt-out decision; and the egregious penalties associated with failing to timely withdraw. *See* JA99-101, 104-105 ¶¶ 11-16, 26-28. The Guidance thus had "immediate[and] unavoidable" effects on AstraZeneca's negotiating position. *Sabre*, 429 F.3d at 1118; *id.* at 1119 (finding standing where agency's statutory interpretation "shapes the competitive environment"); *see, e.g.*, *Clinton v. City of New York*, 524 U.S. 417, 432 (1998) (deprivation of a "statutory bargaining chip" creates "a sufficient likelihood of economic injury to establish standing").

Because it is "reasonably certain" that CMS's Guidance is or will have "implications for [AstraZeneca's] business choices and investments," AstraZeneca satisfies the injury-in-fact requirement for its APA challenges. *Sabre*, 429 F.3d at 1118-19; *see also Shays*, 414 F.3d at 91 (where agency action "color[s]" a regulated entity's "strategy from the outset," "there is no need to wait for injury from specific transactions to claim standing") (quotation marks and citation omitted).

2. The District Court wrongly concluded that AstraZeneca had not shown injury-in-fact.

None of the District Court's four reasons for finding AstraZeneca lacked standing to raise its APA challenges withstand scrutiny.

First, the District Court devoted a spare two paragraphs to AstraZeneca's argument that, as a result of CMS's Guidance, it cannot fairly value its products as required to negotiate with CMS and engage in future planning. The court rejected that theory, decreeing that "[o]f course" AstraZeneca "understand[s] the Guidance or how the Guidance applies as written to Farxiga," given that AstraZeneca described these issues in detail in its complaint and briefing. JA35. In the court's view, "[t]he only uncertainty relating to the Guidance comes from the filing of this lawsuit." *Id*.

That misses the point. AstraZeneca *cannot* fairly value its product without a judicial determination of *whether* the Guidance is unlawful. Absent such a decision, AstraZeneca must operate under the assumption that CMS's Guidance will stand and act accordingly. CMS's flawed interpretation of the IRA therefore directly affects the company's ability to make decisions now and in the future. Moreover, insofar as the court suggested that the Guidance's interpretation of the IRA is clearly correct such that AstraZeneca could have fairly valued FARXIGA or made future decisions had it not filed suit, that violates black-letter law. Courts must accept the validity of the plaintiff's merits arguments in assessing standing, lest they "thwart a major

function of the standing doctrine—to avoid premature judicial involvement in . . . the merits." *Cottrell*, 874 F.3d at 164 (quotation marks and citation omitted).

Nor is this case like *Fair Housing Council of Suburban Philadelphia v. Montgomery Newspapers*, 141 F.3d 71 (3d Cir. 1998), the District Court's lone citation. JA35. In *Fair Housing Council*, this Court held that "litigation expenses alone do not constitute damage sufficient to support" organizational standing on a diversion-of-resources theory. 141 F.3d at 79. AstraZeneca is not claiming harm from the need to litigate this lawsuit; AstraZeneca needs to litigate this suit because, absent a judicial decision setting aside the Guidance, it will likely suffer harm from CMS's challenged decisions, both individually and combined.

Other portions of the District Court's analysis drive home the combined harm AstraZeneca faces from CMS's two unlawful actions. The District Court elsewhere theorized that, by the time a new NDA for the same active moiety as FARXIGA is approved, it is "highly []likely that Farxiga [will] have generic competition" and therefore no longer "meet the definition of a qualifying single source drug." JA26. Because of CMS's unlawful "bona fide marketing" requirement, however, AstraZeneca cannot be sure whether that speculative assertion will come to pass. In fact, under the Guidance, CMS could determine *at any time* that a generic no longer satisfies its subjective "totality of the circumstances" "bona fide marketing" requirement—even if CMS had previously decided a generic did meet that test. *See*

JA196, 288. More, the judicial-review bar would prevent AstraZeneca from challenging that determination, even if CMS has no supporting data, fundamentally misreads the data, or renders its decision mere minutes before the deadline. *See* 42 U.S.C. § 1320f-7(2). AstraZeneca must therefore proceed on the basis that FARXIGA and any drugs with the same active moiety approved under a new NDA will remain subject to the price cap indefinitely, even while facing generic competition.

Second, the District Court was wrong to reject AstraZeneca's injuries to its decision-making abilities as divorced from the Guidance. The court's one-paragraph explanation was that "[t]he Guidance is only for the 2026 price period, and Farxiga is the only AstraZeneca drug selected for that period," so it cannot affect AstraZeneca's "decision-making about other drugs." JA33.

That reasoning is as faulty as it is thin. Although the *consequences* of AstraZeneca's decisions may not directly manifest until 2027 or beyond, AstraZeneca is *making* those decisions now. For example, AstraZeneca must account for CMS's Guidance in "mak[ing] investment decisions now on research [and] development of follow-on therapies for new indications and improvements" to CALQUENCE, a leading leukemia medicine. JA104, 106 ¶¶ 25, 30; *accord* JA106 ¶ 32. Because the company must rely on CMS's Guidance today in making future-focused business decisions, and there is at least a substantial risk that will continue

in the future, AstraZeneca has suffered injury-in-fact. *See Great Lakes Gas Transmission Ltd. P'ship*, 984 F.2d at 431; *Sabre*, 429 F.3d at 1117.[2]

Third, the District Court's treatment of AstraZeneca's specific injuries from CMS's redefinition of "qualifying single source drug" fares no better. The District Court rejected this argument on the theory that AstraZeneca had merely alleged a diminished "incentive" to "look for additional uses of FARXIGA's single-ingredient active moiety," which was neither sufficiently concrete nor "certainly impending." JA22-23 (quotation marks and citation omitted).

The court's concreteness analysis misunderstands AstraZeneca's theory. As explained, the harm is to AstraZeneca's business decision-making, not its incentives to carry those decisions through. The District Court's insistence on certainly impending injury also misstates the law. As this Court has held, "allegations of future injury 'suffice if the threatened injury is certainly impending *or there is a substantial risk that the harm will occur*.' " *Clemens*, 48 F.4th at 152 (quoting *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 (2014)) (emphasis added). In other words, "plaintiffs are not required to demonstrate that it is literally certain that the harms they identify will come about"; "a realistic danger of sustaining a direct injury" will suffice. *Id.* at 152-153 (quotation marks and citations omitted).

[2] The court's conclusion that any negative effect on decisionmaking occurring "beyond 2026 also fails to meet the causation and redressability requirements" fails for the same reasons. JA33.

There is a substantial risk that CMS's unlawful interpretation of qualifying single source drug has harmed or will harm AstraZeneca's ability to make business decisions—including which products to invest in researching and developing and its valuation of FARXIGA. The District Court did not address this theory, instead rejecting AstraZeneca's arguments as based on a series of "ifs" about whether and when FDA might approve an NDA based on the same active moiety as FARXIGA. JA24-25. To be clear: this is not a question of *ifs*; CMS's unlawful interpretation *is* directly affecting AstraZeneca's decision-making abilities—with respect to FARXIGA and a host of other products. *See* JA101, 105-106 ¶¶ 16, 29; ECF 58 at 7-8; *supra* pp. 27-33.

The District Court's acknowledgment that it can take decades to go from development to approval and that "very few early drug candidates are ever approved or commercialized" proves the point. JA25. The court invoked this as support for the idea that "AstraZeneca's stated harm is . . . extremely *unlikely* to occur," but the opposite is true. *See* JA24. Because drug development has such a long lead time and is not guaranteed to succeed, AstraZeneca must evaluate the costs and benefits of investing in pipeline products well in advance. By restricting AstraZeneca's ability to price and value its product, CMS's Guidance is affecting those decisions *today*, even if the consequences will not immediately come to pass. *See* JA101 ¶ 16; *see, e.g.*, *Vill. of Bensenville v. FAA*, 376 F.3d 1114, 1119 (D.C. Cir. 2004) (finding

injury-in-fact where agency authorized a fee that would affect petitioner's budget planning, even though the fee would not be collected for thirteen years).

For these same reasons, it is immaterial whether certain of FARXIGA's development efforts have not yet reached the clinical-trial phase. *See* JA25-26. In fact, that is—again—precisely the point: AstraZeneca must make decisions *now* about which of its many products to put into clinical trials. That decisionmaking will look different under the statute as opposed to CMS's Guidance.

Fourth, the District Court erred in analyzing AstraZeneca's injuries from CMS's unlawful imposition of a bona fide marketing requirement. According to the court, (1) AstraZeneca had not shown "that a generic version of Farxiga will be on the market before April 1, 2026"; (2) AstraZeneca had not shown that "a delay in PDE [data] reporting would affect the timing of CMS's" bona-fide marketing determination because it was not clear that CMS would rely on that data or that this data delay "would affect the timing of CMS's determination that a generic drug met" the statutory "marketed" requirement; and (3) AstraZeneca had not "established[] that Farxiga will experience generic competition" at a "level insufficient to qualify as bona fide marketing." JA30-31.

That is wrong—legally, factually, and logically. Legally, AstraZeneca is not required to show that a generic "will" come to market on a specific date, that a delay "would affect" CMS's decision, or that FARXIGA "will experience" a specific level

of competition. This Court has never demanded that level of certainty in analyzing standing. *See, e.g.*, *Clemens*, 48 F.4th at 152 (explaining that substantial risk suffices).

Factually, a delay in the PDE data will affect CMS's determination. A generic can immediately go to market once FDA converts its approval from temporary to final, *supra* pp. 30-31, and nothing in the statutory text or plain meaning of "marketed" requires CMS to consult PDE data. Under the Guidance, however, CMS "will . . . review[] the PDE" data before determining whether a generic has engaged in bona fide marketing. *See* JA283.

Logically, it is impossible for AstraZeneca to "establish[]" that some generics will be available on the market but may not meet CMS's know-it-when-you-see-it test. That is, after all, one of the very reasons AstraZeneca challenged CMS's amorphous standard to begin with. Thus, even if the ultimate "outcome" of CMS's bona fide marketing inquiry is "speculative," CMS's decision to fundamentally alter the key decision-making framework caused a sufficient injury. *See Clinton*, 524 U.S. at 430-431 (decision imposing "contingent liability" that "directly affects . . . fiscal planning" constitutes injury-in-fact, even if the liability could ultimately be waived).

B. AstraZeneca's injuries are traceable to CMS's Guidance and redressable by a decision setting aside that Guidance.

AstraZeneca's injuries are traceable to CMS's qualifying single source drug definition and "bona fide marketing" requirement. "When a petitioner itself is the

object of the challenged agency action, there usually is little doubt of causation." *Exhaustless Inc. v. FAA*, 931 F.3d 1209, 1212 (D.C. Cir. 2019) (citing *Lujan*, 504 U.S. at 561-562). CMS's Guidance directly regulates companies like AstraZeneca whose drugs have been selected for inclusion in the Program. That Guidance is causing AstraZeneca harm now. The causation requirement is accordingly met.

Likewise, a decision setting aside CMS's Guidance would "likely redress[]" AstraZeneca's injuries. *Yaw v. Delaware River Basin Comm'n*, 49 F.4th 302, 310 (3d Cir. 2022). "Where an agency rule causes the injury, as here, the redressability requirement may be satisfied by vacating the challenged rule." *Ctr. for Energy & Econ. Dev. v. EPA*, 398 F.3d 653, 657 (D.C. Cir. 2005) (quotation marks and alterations omitted). An order setting aside the Guidance and declaring it unlawful would provide AstraZeneca clarity for the Program negotiations and its business decisions.

C. AstraZeneca has prudential standing.

The prudential standing test is "not meant to be especially demanding," *Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians*, 567 U.S. at 225 (quotation marks and citation omitted), and AstraZeneca easily satisfies it. Congress enacted the IRA to force manufacturers, like AstraZeneca, into a "negotiation" with CMS over price caps for their products. In crafting the statute, Congress set specific, calculated limits on which drugs would qualify for price caps and when the presence

of a generic would trigger an exemption. AstraZeneca's interests are therefore protected and regulated by the IRA.

II. THE PROGRAM VIOLATES THE DUE PROCESS CLAUSE.

A. The Program deprives AstraZeneca of property interests without providing due process.

Under the Fifth Amendment's Due Process Clause, "[n]o person shall be . . . deprived of life, liberty, or property, without due process of law." U.S. Const. amend. V. The government violates due process when: (1) it "deprive[s]" a person of a "liberty or property interest," and (2) the "procedures [it] followed" in effecting that deprivation were insufficient. *Swarthout v. Cooke*, 562 U.S. 216, 219 (2011).

The Program violates the Due Process Clause. *First*, it infringes the rights conferred by FARXIGA's patents and statutory exclusivity periods. *Second*, in committing those property deprivations, the government provided none of the process the Constitution requires.

1. The Program deprives AstraZeneca of protected property interests.

The " 'property' interests subject to procedural due process protection are not limited by a few rigid, technical forms." *Perry v. Sindermann*, 408 U.S. 593, 601 (1972). "Rather, 'property' denotes a broad range of interests," *id.*, that are "not limited to . . . real or personal property." *Klein v. Califano*, 586 F.2d 250, 257 (3d Cir. 1978) (en banc). Due process property interests include legal "entitlements," which are benefits conferred by statutes, regulations, and the "existing rules or

understandings" against which those statutes and regulations operate. *Bd. of Regents of State Colls. v. Roth*, 408 U.S. 564, 571-572 (1972); *see also Town of Castle Rock, Colo. v. Gonzales*, 545 U.S. 748, 756 (2005).

The Program deprives AstraZeneca of core property interests in its patented drugs and the right to determine the revenue it derives therefrom. Patents "have long been considered a species of property," and "they are surely included within the 'property' of which no person may be deprived . . . without due process of law." *Fla. Prepaid Postsec. Educ. Expense Bd. v. Coll. Sav. Bank*, 527 U.S. 627, 642 (1999). The rights inherent in a patent "embod[y] a carefully crafted bargain": In return for "the creation and disclosure of new, useful and nonobvious advances in technology," an inventor is entitled to "the exclusive right to practice the invention for a period of years." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-151 (1989). By statute, drug manufacturers are often also entitled to a so-called regulatory exclusivity period during which the FDA cannot approve a generic competitor. *See* 21 U.S.C. § 355(c). Though this "complex balance" between patent exclusivity and regulatory exclusivity, Congress provided "pharmaceutical innovation even greater statutory protection than other types of innovation," thus promoting "an industry vital to our national interests." *Pharm. Research & Mfrs. of Am. v. District of Columbia*, 406 F. Supp. 2d 56, 65-67 (D.D.C. 2005), *aff'd sub*

nom., *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007) ("*BIO*").

These exclusivity periods yield "economic rewards," limited only by "the dictates of the marketplace." *BIO*, 496 F.3d at 1372 (quoting *King Instruments Corp. v. Perego*, 65 F.3d 941, 950 (Fed. Cir. 1995)). Indeed, it is well understood that the opportunity to recoup investment is the "central" function of the right to exclude. *Id.* at 1372-73. That right is meaningless if the government can restrict the manufacturer's price, whether by prematurely denying exclusivity or by artificially limiting the ability to sell the product at the prevailing market rate. *Id.*

A law that authorizes the government to limit prices for an innovative drug during the exclusivity period thus "limit[s] the full exercise of the exclusionary power" to which the manufacturer is entitled. *Id.* at 1374. That is why, for example, a state law barring high prices for patented drugs is preempted by federal patent law—because limiting prices during the exclusivity period "re-balance[s] the statutory framework of rewards and incentives" that is inherent in a patent on an "inventive new drug[]." *Id.* Indeed, a statute "designed to force drug manufacturers" "to limit the wholesale price" of patented drugs during the exclusivity period undermines the "very purpose" for which the exclusivity right was conferred. *Pharm. Research*, 406 F. Supp. 2d at 65-66; *see also United States v. Gen. Elec. Co.*, 272 U.S. 476, 490 (1926) ("One of the valuable elements of the exclusive right of a

patentee is to acquire profit by the price at which the article is sold."); *United States v. Studiengesellschaft Kohle, m.b.H.*, 670 F.2d 1122, 1131 (D.C. Cir. 1981) ("[T]he patentee's reward include[s] the right to fix prices at which products [a]re sold.").

AstraZeneca is entitled to the inherent "economic rewards" that accompany its patents on FARXIGA and its statutory right to regulatory exclusivity periods. *BIO*, 496 F.3d at 1374. That means AstraZeneca has a right to "profit by the price at which [FARXIGA] is sold," *General Electric*, 272 U.S. at 490—a right which can be limited only by the "dictates of the marketplace," *BIO*, 496 F.3d at 1374. By leveraging its coercive power to force AstraZeneca to sell FARXIGA at a government-dictated rate, the Program "limit[s] the full exercise" of these rights. *BIO*, 496 F.3d at 1374. That deprivation of property rights cannot be carried out without due process of law.

2. The Program does not provide AstraZeneca due process.

Once a property deprivation is established, courts "ask whether the procedures followed by the [government] were constitutionally sufficient." *Swarthout*, 562 U.S. at 219. To meet that standard, the government must follow procedures designed to prevent "substantively unfair and simply mistaken deprivations of property." *Elsmere Park Club, L.P. v. Town of Elsmere*, 542 F.3d 412, 417 (3d Cir. 2008) (quotation marks and citation omitted). That includes providing a meaningful

opportunity to be heard and an impartial adjudicator to evaluate those claims. The Program explicitly denies AstraZeneca both.

First, the Program provides AstraZeneca no hearing on its property deprivation. It is "fundamental" that due process protects the "opportunity to be heard . . . at a meaningful time and in a meaningful manner." *Armstrong v. Manzo*, 380 U.S. 545, 552 (1965). Thus, when the state deprives a person of his property interests, "the right to some kind of prior hearing is paramount." *Roth*, 408 U.S. at 569-570. Only in "rare and extraordinary" cases may the government "postpon[e] the hearing until after the event." *Id.* at 570 n.7.

What the government may never do, however, is deprive a party of its property interests without any hearing at all. Simply put, the government violates due process when it affords a person "no hearing, either before or after" the property deprivation. *Bradley v. Pittsburgh Bd. of Educ.*, 913 F.2d 1064, 1078 (3d Cir. 1990). Even when a federal agency acts during a "war emergency," due process requires at least a hearing "after the regulations or orders have been made effective." *Bowles v. Willingham*, 321 U.S. 503, 521 (1944); *see also Lawrence v. Reed*, 406 F.3d 1224, 1233 (10th Cir. 2005) (a property deprivation with "no hearing whatsoever" is unconstitutional); *Schepers v. Comm'r, Indiana Dep't of Correction*, 691 F.3d 909, 915 (7th Cir. 2012) (when a law "provides *no process* whatsoever," "[t]his deficiency alone" violates the Due Process Clause) (emphasis in original).

Here, the government has deprived AstraZeneca of property interests with "no hearing, either before or after" the deprivation. *Bradley*, 913 F.2d at 1078. The IRA provides that CMS "shall implement [the Program] for 2026, 2027, and 2028, by program instruction or other forms of program guidance." 42 U.S.C. § 1320f note. CMS has read that language to exempt the Program from notice-and-comment requirements. *See* JA126-129. The IRA also withholds advance notice to AstraZeneca of the forced-sale "agreement," let alone the opportunity to comment or negotiate its contents. 42 U.S.C. §§ 1320f-2(a)(1), 1320f-3(a). Indeed, the pattern manufacturer "agreement" was not even published until after CMS issued its final Guidance. *See* JA107-118.

CMS also did not provide the requisite process on the back end. When there is no front-end process, the Constitution requires a judicial or administrative hearing at which agency action can be reviewed. *See, e.g.*, *Hodel v. Va. Surface Min. & Reclamation Ass'n, Inc.*, 452 U.S. 264, 299-301 (1981). Yet the statute forbids even that. Under the IRA, "[t]here shall be no administrative or judicial review" of any meaningful government decision the Program entails—including what counts as a "qualifying single source drug" and the price-capped rate itself. *See* 42 U.S.C. § 1320f-7. That violates due process.

Second, the Program denies AstraZeneca an impartial adjudicator. When the government deprives a party of a "protected interest," that party "is entitled as a

matter of due process of law to . . . a neutral and detached adjudicator" "in the first instance." *Concrete Pipe & Prods. of Cal., Inc. v. Constr. Laborers Pension Tr. for S. Cal.*, 508 U.S. 602, 617-618 (1993) (quotation marks and citation omitted). This neutrality requirement "has been jealously guarded by [the Supreme] Court" as it "preserves both the appearance and reality of fairness, generating the feeling, so important to a popular government, that justice has been done." *Marshall v. Jerrico, Inc.*, 446 U.S. 238, 242 (1980) (quotation marks and citation omitted). That requirement applies even "*more strictly*" to agency action because the administrative process lacks "procedural safeguards normally available in judicial proceedings"—especially when the agency maintains an "active role" in the process. *Ventura v. Shalala*, 55 F.3d 900, 902 (3d Cir. 1995) (emphasis added).

An adjudicator is not neutral when he has a "pecuniary interest" in the outcome of the case. *See, e.g.*, *Ward v. Vill. of Monroeville*, 409 U.S. 57, 60-61 (1972). For instance, a mayor is not a neutral adjudicator over challenges to civil fines that generate income for the mayor's budget. *Id.* "[T]he mayor's executive responsibilities for [government] finances" may tempt him to assess greater fines, and that "possible temptation" violates due process. *Id.* Likewise, a government agency cannot be a neutral adjudicator when it has a "pecuniary interest in the outcome" of an administrative proceeding—for example, if "any fine imposed will flow directly to the [agency's] budget." *Esso Standard Oil Co. v. Cotto*, 389 F.3d

212, 219 (1st Cir. 2004); *see also, e.g.*, *United Church of the Med. Ctr. v. Med. Ctr. Comm'n*, 689 F.2d 693, 699 (7th Cir. 1982).

When an agency functions in a "prosecutorial or plaintiff-like capacity," however, de novo review of the agency action by a neutral decisionmaker, like an administrative law judge or an Article III court, can satisfy due process. *See, e.g.*, *Marshall*, 446 U.S. at 247-248. In that situation, the agency does not sit as a judge over "disputed factual or legal questions"—rather, it "acts as a complaining party and bears the burden of proof on contested issues," which are ultimately decided by a separate, neutral adjudicator. *Id.* at 248-250. So long as that independent check exists, the agency need not be "entirely neutral and detached." *Id.* at 248 (quotation marks and citation omitted).

Applying these principles, the Program violates due process. The IRA vests CMS with the power to unilaterally dictate which drugs qualify for the program and the corresponding price caps. The statute explicitly bars any "administrative or judicial review" of CMS's decisions. *See* 42 U.S.C. § 1320f-7. CMS is therefore acting as an adjudicator, not a prosecutor. CMS does not "bear[] the burden of proof on contested issues"—it makes the "final decision" on those issues itself, subject to review from no one. *Marshall*, 446 U.S. at 247-248, 250. In that adjudicative role, CMS is subject to the Due Process Clause's "rigid requirements" for neutrality. *Id.*

Here, CMS is anything but neutral. CMS is the agency primarily responsible for paying Medicare Part D reimbursements. So when CMS decides the reimbursement rate for a drug like FARXIGA, the agency decides how much money will "flow directly" from its coffers. *Cotto*, 389 F.3d at 219. It thus has a profound "pecuniary interest" in setting low rates—as its statutory directive confirms—regardless of whether they are actually "fair," are based on the statutorily mandated factors, or adhere to CMS's standard methodology. *Ward*, 409 U.S. at 60-61; *see generally* 42 U.S.C. § 1320f-3. No amount of process on the back end could cure that fatal flaw. *See Concrete Pipe*, 508 U.S. at 617.

The process afforded likewise falls short of the constitutional goalposts if the Court views CMS's role as more akin to a plaintiff or prosecutor. Although CMS need not be "entirely neutral" when acting in that role, due process still requires the government to "provid[e] for a neutral adjudicator to conduct a de novo review" of the agency's decision. *Id.* at 618 (quotation marks and citation omitted). Otherwise, the target of the agency action would "be deprived . . . of the impartial adjudication in the first instance to which it is entitled under the Due Process Clause." *Id.* at 626. Here, however, the statute expressly bars the very review that due process requires—

CMS's biased decision is the end of the line. 42 U.S.C. § 1320f-7. That is flat-out unconstitutional.[3]

B. This Court should reject the District Court's "voluntariness" exception to the Due Process Clause.

Rather than engaging with these issues, the District Court instead adopted the government's theory that AstraZeneca is not entitled to due process because "participation in the Medicare program is a voluntary undertaking." JA43 (quotation marks and citation omitted); *see* ECF 21-1, at 44-48.

That voluntariness theory finds no footing here. For one, participation in the Program is hardly "voluntary" in light of the draconian fines manufacturers face if they refuse to sell their products at CMS's chosen rate and the practical impossibility of withdrawing all their products from Medicare and Medicaid entirely, which is the only way to avoid the price cap. *Supra* pp. 12-13; *see also, e.g.*, *Doe v. Univ. of Scis.*, 961 F.3d 203, 213 (3d Cir. 2020) (acknowledging that the "total withdrawal of federal funding" is "economic dragooning," akin to "a gun to the head") (quotation marks omitted).

[3] The Drug Price Negotiation Program is severable from the remainder of the IRA. *See* JA16-17 n.2 (raising but not deciding this issue). The remainder of the statute would be "fully operative" without it, and there is no evidence that Congress would have refused to enact the remainder of this bill without this Program. *See, e.g.*, *Alaska Airlines, Inc. v. Brock*, 480 U.S. 678, 684 (1987).

More to the point, the District Court's voluntariness framing misunderstands the relevant due process principles. The mere fact that participation in a government program is voluntary does not mean the government can dispense with due process in administering that program. Indeed, the Supreme Court and this Court have repeatedly applied the Due Process Clause in the context of voluntary government programs. The plaintiffs in *Goldberg v. Kelly*, for instance, were not *required* to seek out social security benefits, but that did not mean the government could deny benefits "without affording . . . due process." 397 U.S. 254, 263-264 (1970). Rather, for due process purposes, the relevant question is whether the government has created a "statutory entitlement" guaranteed to any person who qualifies under the statutory criteria. *Id.* at 262. If so, the government must afford due process in administering that benefit. *Id.* The fact that a person is not required to seek out that benefit is irrelevant. *See also, e.g.*, *Memphis Light, Gas & Water Div. v. Craft*, 436 U.S. 1 (1978) (voluntary utility services); *Kelly v. R.R. Ret. Bd.*, 625 F.2d 486, 488 (3d Cir. 1980) (voluntary disability benefits).

In reaching the opposite conclusion, the District Court relied heavily on dicta from a Southern District of Ohio opinion denying a preliminary injunction of the Program. *Dayton Area Chamber of Com. v. Becerra*, __ F.3d __, 2023 WL 6378423, at *11 (S.D. Ohio Sept. 29, 2023). That decision, in turn, rested on Sixth and Eighth Circuit cases rejecting challenges to Medicare provisions under the Takings Clause.

Id. (citing *Baptist Hosp. East v. HHS*, 802 F.2d 860, 869 (6th Cir. 1986); *Minnesota Ass'n of Health Care Facilities, Inc. v. Minnesota Dep't of Pub. Welfare*, 742 F.2d 442 (8th Cir. 1984)).

"Voluntariness" applies differently in the takings context. Where the submission of property to the government is truly "voluntary," it "can hardly be called a taking." *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1007 (1984). Thus, the government commits a taking "only where it *requires*" a person to relinquish property interests, *see Yee v. City of Escondido*, 503 U.S. 519, 527-28 (1992), whether directly or through economic coercion. The Takings Clause therefore "does not extend . . . to statutory entitlements" under voluntary government programs. *Pittman v. Chicago Board of Education*, 64 F.3d 1098, 1104 (7th Cir. 1995). By contrast, the Supreme Court has repeatedly held that the Due Process Clause *does* apply to the administration of such voluntary government programs. *See, e.g.*, *Goldberg*, 397 U.S. at 263-264.

This Court and others have accordingly recognized that property interests are "defined somewhat differently" in takings and due process cases. *Midnight Sessions, Ltd. v. City of Philadelphia*, 945 F.2d 667, 679 (3d Cir. 1991), *abrogated on other grounds by United Artists Theatre Cir., Inc. v. Twp. of Warrington, PA*, 316 F.3d 392 (3d Cir. 2003). Indeed, "entitlements are often referred to as 'property interests' within the meaning of the Due Process Clause," "but such references have no

relevance to whether they are 'property' under the Takings Clause." *Adams v. United States*, 391 F.3d 1212, 1220 n.4 (Fed. Cir. 2004); *accord Roth v. King*, 449 F.3d 1272 (D.C. Cir. 2006); *see also, e.g.*, *Hignell-Stark v. City of New Orleans*, 46 F.4th 317, 323 (5th Cir. 2022) ("there's a big difference between saying that something is property for purposes of procedural due process and saying that it is property for purposes of the Takings Clause"); *Corn v. City of Lauderdale Lakes*, 95 F.3d 1066, 1075 (11th Cir. 1996) (" 'Property' as used in the Just Compensation Clause is defined much more narrowly than in the due process clauses."); *Hoffman v. City of Warwick*, 909 F.2d 608, 620 n.11 (1st Cir. 1990) ("Our holding that plaintiffs have not been deprived of a property interest for Takings Clause purposes is not determinative of the issue whether they had a property interest for procedural due process purposes.").

The Supreme Court's holding in *Bowles v. Willingham*, 321 U.S. 503 (1944), illustrates the distinction. That case involved a rent control statute enacted to reduce wartime inflation. The Court held that the statute did not effect a "taking" because the landlord plaintiffs voluntarily submitted to rent regulation by choosing to lease their apartments: "There is no requirement that the apartments in question be used for purposes which bring them under the Act." *Id.* at 517. Voluntary or not, however, the Court still held that the government was required to provide landlords due process in setting the rent prices. *Id.* at 519-522. The Due Process Clause, the Court

reasoned, is a "constitutional limitation[] safeguarding essential liberties" "that even the war power does not remove." *Id.* (quotation marks and citation omitted). The rent control statute satisfied those constitutional requirements only because it "provided for judicial review"—and that is precisely what the IRA fails to do. *Id.*

For its part, the District Court cited *Livingston Care Center, Inc. v. United States*, 934 F.2d 719 (6th Cir. 1991), but that case similarly shows that "voluntariness" is not a bar to due process claims. That opinion notes in its background discussion that Medicare "is a voluntary undertaking." *Id.* at 720. When analyzing the plaintiff's due process claim, however, the court did not hold that due process is irrelevant because Medicare is "voluntary." Instead, it held that the Medicare provision at issue provided sufficient process because it allowed for adequate "judicial review." *Id.* at 722-723. That analysis would make little sense if no process is *ever* due in the administration of voluntary government programs like Medicare.

The District Court's unprecedented and unfounded theory would fundamentally upend public-private relationships nationwide. The District Court touted the government's "unrestricted power . . . to fix the terms and conditions upon which it will make needed purchases" as a reason for ruling against AstraZeneca, JA43 (quotation marks and citation omitted), but the fact that this process is *unrestricted* is what is so alarming. A host of laws empower the federal and state

governments to impose price caps. *See, e.g.*, 50 U.S.C. § 4514(a) (permitting the president to impose wartime "price controls" with congressional authorization); 15 U.S.C. § 764 (similar "pricing authority" for oil prices); N.Y.C. Admin. Code §§ 26-401-26-415 (rent control). What separates those programs from this one is not "voluntariness"—it is the provision of a constitutionally sufficient check to ensure the price cap is legitimate, reasonable, and unbiased. Even the Emergency Price Control Act of 1942, which authorized sweeping authority to set price controls over agricultural commodities, goods and services, and real property during World War II, ensured adjudication by a neutral administrator and review by an Article III court. 50 U.S.C.A. §§ 902, 905, 921, 924, 56 Stat. 23. The District Court's decision would upend all of that, allowing the government to impose price controls by fiat with no due process whatsoever.

CONCLUSION

For the foregoing reasons, AstraZeneca respectfully requests that this Court reverse the judgment below and remand for further proceedings.

July 15, 2024

Respectfully submitted,

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CERTIFICATION OF BAR MEMBERSHIP

Pursuant to Local Rules 28.3(d) and 46.1(e), I certify that I, Catherine E. Stetson, am admitted as an attorney and counselor of the United States Court of Appeals for the Third Circuit.

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(g) and Local Rule 31.1, I certify the following:

1. This brief complies with the type-volume limits of Federal Rule of Appellate Procedure 32(a)(7) because it contains 12,935 words, excluding those parts exempted by Federal Rule of Appellate Procedure 32(f).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the typestyle requirements of Federal Rule of Appellate Procedure 32(a)(6) because the brief has been prepared in Times New Roman 14-point font using Microsoft Word 2010.

3. This brief complies with the electronic filing requirements of Local Rule 31.1(c) because the text of the electronic brief is identical to the text of the paper copies and because Symantec Endpoint Protection version 14 was run on the file containing the electronic version of the brief and no viruses were detected.

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CERTIFICATE OF SERVICE

I certify that the foregoing was filed with the Clerk using the appellate CM/ECF system on July 15, 2024. All counsel of record are registered CM/ECF users, and service will be accomplished by the CM/ECF system. I also hereby certify that pursuant to Third Circuit Local Appellate Rule 31.1, ten paper copies of the foregoing brief were sent on today's date via overnight Federal Express to the Clerk of this Court.

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