No.

In the Supreme Court of the United States

ASTRAZENECA PHARMACEUTICALS LP; ASTRAZENECA AB,
PETITIONERS,

v.

ROBERT F. KENNEDY, SECRETARY OF HEALTH AND HUMAN SERVICES; ADMINISTRATOR CENTERS FOR MEDICARE & MEDICAID SERVICES

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

In the Inflation Reduction Act of 2022 (IRA), Congress enacted the so-called "Drug Price Negotiation Program," which requires pharmaceutical manufacturers to sell certain selected drugs at steeply discounted prices mandated by the Secretary of Health and Human Services. A manufacturer whose drug is subject to this government-dictated price must—on pain of massive civil penalties—make that price available in private transactions with individuals, pharmacies, hospitals, and other non-governmental participants in Medicare.

Notably, the agency's key decisions interpreting and implementing the IRA are not subject to notice-and-comment rulemaking on the front end; nor are they judicially reviewable on the back end. There is accordingly no way for a manufacturer who objects to the selection of its drug, or to the price set for the drug by the agency, to ensure that its objections are taken into account.

Petitioners manufacture one of the drugs that will be subject to government-set prices in 2026. The price set for that drug will affect billions of dollars' worth of sales in private-party transactions. In the decision below, the court of appeals rejected petitioners' due process challenge—without even considering whether the IRA's complete lack of procedures falls below minimum constitutional standards—on the ground that the statute does not affect petitioners' constitutionally protected interests.

The question presented is:

Whether the IRA implicates an interest of pharmaceutical manufacturers that is protected by the Due Process Clause.

RULE 29.6 STATEMENT

Pursuant to Supreme Court Rule 29.6, petitioners make the following disclosures: 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.

RELATED PROCEEDINGS

United States District Court (D. Del.):

AstraZeneca Pharms. LP v. *Becerra*, No. 23-931-CFC (Mar. 1, 2024)

United States Court of Appeals (3d Cir.):

AstraZeneca Pharms. LP v. *Sec'y U.S. Dep't of Health & Hum. Servs.*, No. 24-1819 (May 8, 2025)

Supreme Court of the United States (U.S.):

AstraZeneca Pharms. LP v. *Kennedy*, No. 25A115 (July 28, 2025) (granting application for extension of time to file petition for writ of certiorari)

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OPINIONS BELOW

The opinion of the court of appeals (App. 1a-19a) is reported at 137 F.4th 116. The decision of the district court (App. 20a-56a) is reported at 719 F. Supp. 3d 377.

JURISDICTION

The judgment of the court of appeals was entered on May 8, 2025. App. 1a. On July 28, Justice Alito extended the time to file a petition for a writ of certiorari to September 20. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

Relevant provisions are reproduced in the Appendix. App. 57a-112a.

INTRODUCTION

This case concerns the fate of a new government program that will overhaul the $600-billion prescription drug market and affect the lives and health of the 68 million Americans enrolled in Medicare. On January 1, 2026, the Inflation Reduction Act of 2022 (IRA) will impose a regime of government price controls for critical medicines, upending the biopharmaceutical ecosystem and stalling innovation and patient care. As one court of appeals put it, the IRA's so-called "Drug Price Negotiation Program" (Drug Pricing Program or Program) "shifts the price-setting mechanism for many of America's highest-selling drugs from the free market to a government-run process." *Nat'l Infusion Ctr. Ass'n* v. *Becerra*, 116 F.4th 488, 494 (5th Cir. 2024) (*NICA*). The constitutionality of that process "is of great importance to consumers of pharmaceutical drugs, the companies that provide them, and the public at large." *Bristol Myers Squibb Co.* v. *HHS*, No. 24-1820, — F.4th —, 2025 WL 2537005, at *33 (3d. Cir. Sept. 4, 2025) (Hardiman, J., dissenting). Indeed, it is the most significant overhaul of the healthcare sector since the Affordable Care Act. See *Nat'l Fed'n of Indep. Bus.* v. *Sebelius*, 567 U.S. 519 (2012).

Here is how the Program works. Contrary to its statutory name, it involves no genuine "negotiation." Rather, it compels pharmaceutical manufacturers to sell their most innovative and widely used medicines at prices unilaterally chosen by the Centers for Medicare & Medicaid Services (CMS) on behalf of the Department of Health and Human Services (HHS). The agency could decide that a lifesaving medicine that cost $10 billion to develop is worth just $1 per dose. CMS has already used this authority to impose massive price cuts on ten drugs, which are scheduled to take effect in 2026, and is in the process of imposing similar price cuts on fifteen more drugs for 2027. Additional drugs will be added every year; and for 2028,

CMS is considering setting prices as low as the unit cost of production and distribution.

In a genuine negotiation, the seller could walk away from such a paltry offer. But the IRA forecloses that option. A manufacturer that declines to "negotiate" or to accede to the CMS-dictated price is subject to a crippling "excise tax," which rapidly escalates to 19 times the manufacturer's *total* U.S. revenues for the drug. The manufacturer's only alternative is to withdraw *all* its drugs from Medicare and Medicaid—depriving patients nationwide of access to critical medicines and foreclosing nearly half the U.S. prescription-drug market.

With the IRA's price-controls set to take effect on January 1, review is warranted now. Ten lawsuits challenging the Program are currently pending in the lower courts, see O'Neill Institute, *Medicare Drug Price Negotiation*, https://perma.cc/Q8EC-25B9, and three circuits have now issued five decisions addressing the IRA's constitutionality. Judge Hardiman recently concluded that the law is unconstitutional for multiple reasons, *Bristol Myers Squibb*, 2025 WL 2537005, at *33 (Hardiman, J., dissenting); and another court of appeals observed, in upholding the plaintiffs' standing, that the Program fails "the *Mathews* [v. *Eldridge*] test" for assessing constitutionally required due process, *NICA*, 116 F.4th at 503. Although the Program has survived these challenges so far, its fate ultimately rests with this Court.

Petitioners AstraZeneca Pharmaceuticals LP and AstraZeneca AB (together, "AstraZeneca") are among the numerous manufacturers to challenge the Drug Pricing Program. AstraZeneca's innovative drug Farxiga has been selected for "negotiation" under the IRA—and hence for a steep price cut. Like many manufacturers, AstraZeneca has challenged the statute under the Fifth Amendment's Due Process Clause, arguing that the agency's decision-making under the Program implicates

its protected interests without affording adequate procedures to guard against errors.

The government has not even attempted to defend the IRA's woefully deficient procedures, and for good reason: The statute shields the agency's decision-making under the Program from *any* meaningful external input or accountability. On the front end, it dispenses with notice-and-comment rulemaking, leaving CMS to make key implementation decisions without accounting for the views of affected parties. And on the back end, the IRA forecloses administrative and judicial review of critical agency decisions. As a result, the agency can make essentially any decision it wants—it could literally flip a coin to decide which drugs to select for the Program—and the affected manufacturers would have no recourse.

Despite the IRA's complete lack of process, the court of appeals below rejected AstraZeneca's due process claim on the threshold ground that the Program does not implicate any interest protected by the Constitution. In the court's view, AstraZeneca lacks a protected interest in selling its patented products "at a price higher than what the government is willing to pay." App. 17a.

But that reasoning fundamentally misunderstands the IRA's radical design. The statute gives CMS authority to set prices that the government does *not* pay—or even directly reimburse. It controls the prices that manufacturers must offer in *private* transactions involving *private* parties like patients, hospitals, and pharmacies. The government is not a party to those transactions and never buys a single drug at issue. For drugs covered under Medicare Part D, the government does not even reimburse drug purchases by others; that is done by private insurance companies, whom the government in turn subsidizes and reinsures through a complex statutory formula.

But even if the court of appeals were right that the Drug Pricing Program sets prices only for drugs

purchased by the government—though it is not—that still would not strip manufacturers of all due process protections. The Due Process Clause forbids *all* arbitrary decision-making by the government. Making billion-dollar decisions by coinflip is constitutionally impermissible even when an administrative agency is choosing how to spend the government's own money.

The constitutionality of this massive, novel program would warrant this Court's review even without any split of authority. But the decision below contravenes this Court's precedent regarding the procedures the government must follow when imposing price controls. It also conflicts with decisions of other courts of appeals, which have concluded that the IRA deprives affected parties of protected interests, and that patentees have a federal right to set the prices at which they will sell their patented products.

Whether the IRA implicates manufacturers' constitutionally protected interests calls out for this Court's review. Although the Drug Pricing Program is still in its early stages, its consequences will proliferate as government-mandated prices go into effect in the coming months, and as the number of drugs subject to the Program expands each year. Unscrambling the egg will only become more difficult as time passes. This Court should take up the question now, before the IRA's lack of adequate process causes further irreparable consequences.

STATEMENT

A. Legal Background

1. Medicare is a federal program that provides health insurance coverage for those over the age of 65 and individuals with certain disabilities and medical conditions. "Medicare stands as the largest federal program after Social Security," *Azar* v. *Allina Health Servs.*, 587 U.S. 566, 569 (2019), and currently has over 68 million enrollees,

CMS, *Medicare Enrollment Dashboard* (May 2025), https://perma.cc/9KSR-ZPAA.

Medicare includes two major prescription drug programs. Part B covers medically necessary and preventive healthcare services, including drugs administered by a physician. 42 U.S.C. §§ 1395k(a)(1), 1395x(s)(2)(A). Part B is administered by CMS and, with certain exceptions, has long reimbursed healthcare providers based on market prices of the medicines they administer. Part B reimbursement rates generally reflect a drug's "average sales price," which is based on the volume-weighted average of all manufacturer sales prices to U.S. purchasers—plus a percentage (generally 6%). *Id.* § 1395w-3a.

Medicare Part D allows beneficiaries to enroll in privately operated insurance plans covering self-administered prescription drugs. *Id.* § 1395w-102. Drug prices in Part D also are market-based, reflecting negotiations among private plan sponsors, pharmacies, and manufacturers. "[T]o promote competition under [Part D]," HHS and CMS "may not interfere with the negotiations between drug manufacturers and pharmacies and [prescription drug plan] sponsors." *Id.* § 1395w-111(i)(1).

For decades, Medicare's market-driven approach has encouraged innovation. Although this approach benefits patients globally, it helps Americans most directly. Manufacturers generally launch new drugs in the United States first, so U.S. patients are often the first to receive lifesaving pharmaceuticals. For example, nearly 80% of medicines approved by the FDA in 2021 were available in the United States before any other country. See U.S. Food & Drug Admin., *Advancing Health Through Innovation: New Drug Therapy Approvals 2021* 21 (Jan. 2022), https://bit.ly/46Op0Dy. Foreign countries with drug-price controls, by contrast, have seen drastic reductions in research and investment, as well as delays in patients' access to advanced treatments. See Joe Kennedy,

The Link Between Drug Prices and Research on the Next Generation of Cures, Info. Tech. & Innovation Found. (Sept. 9, 2019), https://perma.cc/KZE3-53DC; PhRMA, *Global Access to New Medicines Report* 8, 11-36 (Apr. 2023), https://perma.cc/V4WB-CVMC.

2. The IRA upends Medicare's market-based system. Although the statute directs HHS to establish a "Drug Price *Negotiation* Program," 42 U.S.C. § 1320f(a) (emphasis added), the Program in reality empowers HHS to control drug prices not by negotiation, but by administrative *fiat*.

Price-setting under the IRA proceeds in several steps. First, HHS ranks "negotiation-eligible drugs," defined to encompass many of the most-innovative drugs and biological products available. *Id.* § 1320f-1(b)(1)(A). HHS must pick the 50 "qualifying single source drugs" with the highest total expenditures under Parts B and D. *Id.* § 1320f-1(d)(1). Qualifying drugs must have been approved and marketed for at least seven years and must have no generic competitor. *Id.* § 1320f-1(e)(1)(A).

The IRA then directs HHS to "select" an increasing number of the highest-ranked drugs for "negotiation." *Id.* § 1320f-1(a). HHS selected the first round of Part D drugs in 2023; Part B drugs will be added to the selection process beginning in 2026. *Id.* § 1320f-1(a)(1). Ten Part D drugs were selected for 2026 and fifteen for 2027; fifteen Part D and Part B drugs will be selected for 2028; and twenty Part D and Part B drugs will be selected for 2029 and each year thereafter. *Id.* § 1320f-1(a)(1)-(4). The process is cumulative: Once a drug has been selected, it remains on the list until it no longer qualifies. *Id.* § 1320f-1(c)(1).

After drugs are ranked and selected, the IRA directs HHS to "enter into agreements with manufacturers" to "negotiate to determine (and … agree to) a maximum fair price." *Id.* § 1320f-2(a). To conduct the "negotiations," the

statute directs HHS "to achieve the lowest maximum fair price for each selected drug." *Id.* § 1320f-3(b)(1). The process is designed to mimic a genuine negotiation—with what the statute describes as an HHS "offer," a manufacturer "counteroffer," and an HHS "[r]esponse." *Id.* § 1320f-3(b)(2)(B)-(D). But that is where any semblance of negotiation ends.

Most notably, the IRA sets no meaningful constraints on HHS's price-setting discretion. With one minor exception, the statute does not limit how low a price HHS can demand. See *id.* § 1320f-3(b)(2)(F). But it *does* place a "ceiling" on how high a price HHS can offer. *Id.* § 1320f-3(c). The ceiling generally ranges from 75% of the private market price for recently approved drugs to just 40% for drugs that have been approved for over 16 years. *Id.* § 1320f-3(b)(2)(F), (c)(1)(C). That means a *minimum* discount of 25-to-60%.

Below the "ceiling," HHS has free rein to set prices as it pleases. HHS must "consider" specified "factors," including research and development costs, production and distribution costs, prior federal financial support, data on patents and regulatory exclusivities, market data and revenue and sales volume data, and information about alternative treatments. *Id.* § 1320f-3(e). But the IRA sets no standards for how to weigh these considerations. Ultimately, HHS's only real mandate is "to achieve the lowest maximum fair price for each selected drug." *Id.* § 1320f-3(b)(1).

After a so-called "maximum fair price" becomes effective—two or three years after it has been set—the government does not buy any drugs at that price. Rather, the manufacturer must provide "access to such price to" a wide array of private individuals and entities participating in Medicare. *Id.* § 1320f-2(a)(1). Manufacturers that fail to do so must pay a penalty of ten times the difference

between the price charged and the HHS-imposed price, multiplied by the number of units sold. *Id.* § 1320f-6(a)(2).

3. In ordinary negotiations, parties that fail to agree can simply walk away. But the IRA does not give manufacturers that option. Instead, to force them to "agree[]" to whatever "maximum fair price" HHS chooses, the IRA uses a so-called "excise tax"—a steep, escalating penalty for every day a manufacturer has not, by the statutory deadline, entered into an "agreement" to negotiate or "agreed" to a maximum fair price. 26 U.S.C. § 5000D(b).

The scope of this tax is staggering. It applies to *all* U.S. sales of the drug in question—not just Medicare sales. *Id.* § 5000D(d). And the *rate* is astronomical: As the Congressional Research Service has explained, the "excise tax rate … range[s] from 185.71% to 1,900% of the selected drug's price depending on the duration of noncompliance." Cong. Rsch. Serv., *Tax Provisions in the Inflation Reduction Act of 2022 (H.R. 5376)* 4 (Aug. 10, 2022), bit.ly/3sbHYBy. In other words, the tax starts at nearly double the manufacturer's total daily U.S. revenue for the drug, then quickly skyrockets to *nineteen times* revenue.

Faced with this crippling tax, manufacturers have no choice but to "agree" to whatever "maximum fair price" HHS demands. While the IRA provides that the excise tax may be suspended, that can happen only if the manufacturer stops participating in Medicare Part B, Part D, and Medicaid—not just for drugs subject to the Drug Pricing Program, but for *all* of the manufacturer's drugs. See 26 U.S.C. § 5000D(c); 42 U.S.C. § 1396r-8(a)(1).

Withdrawing from Medicare and Medicaid altogether, of course, is not feasible for manufacturers. Medicare and Medicaid beneficiaries account for almost half of nationwide spending on prescription drugs and, hence, an immense share of most manufacturers' revenue. See Cong. Budget Off., *Prescription Drugs: Spending, Use,*

and Prices 8 (Jan. 2022), https://perma.cc/349Z-DUQ8. In addition, withdrawing from Medicare and Medicaid would deprive millions of patients of critical medicines, raise serious ethical concerns, and conflict with manufacturers' core values.

4. Despite the unprecedented burdens that the Drug Pricing Program imposes on manufacturers, they have no say in how HHS implements key parts of the Program. The IRA deprives manufacturers of any input into, or judicial review of, numerous critical decisions regarding the statute's interpretation and application.

On the front end, there is no right to participate in the implementation process. The IRA provides that HHS "shall implement [the Program] for 2026, 2027, and 2028 by program instruction or other forms of program guidance." *Id.* § 1320f Statutory Note. HHS has interpreted that language as exempting the Drug Pricing Program, during the Program's formative years, from notice-and-comment requirements under the Administrative Procedure Act (APA). See CMS, *Medicare Drug Price Negotiation Program: Initial Memorandum* 2 (Mar. 15, 2023), https://perma.cc/XL6X-ES3U; CMS, *Medicare Drug Price Negotiation Program: Revised Guidance* 8-11 (June 30, 2023), https://perma.cc/NPW4-UHXT.

On the back end, after the agency makes key implementation decisions, the IRA purports to insulate them from review. The statute provides that "[t]here shall be no administrative or judicial review" of, among other things, "[t]he selection of drugs," "the determination of negotiation-eligible drugs," "the determination of qualifying single source drugs," and "[t]he determination of a maximum fair price." 42 U.S.C. § 1320f-7(2)-(3). HHS reads this judicial-review bar as precluding courts from considering whether it has interpreted the statute correctly—even when a question of statutory interpretation determines

whether a particular drug is eligible for selection and "negotiation" in the first place. See Gov't C.A. Br. 41-47.

B. Factual Background and Procedural History

1. AstraZeneca is a global, science-led, patient-focused pharmaceutical company that manufactures numerous drugs. AstraZeneca currently has 196 projects in its drug-development pipeline. See AstraZeneca, *Our pipeline* (July 29, 2025), https://perma.cc/JG3S-B9PF. Many of AstraZeneca's products are tailored to patients who are most likely to be on Medicare and Medicaid—the elderly, chronically ill, and those with serious and rare conditions. See C.A. App. 100. "Medicare and Medicaid collectively account for approximately more than 40% of AstraZeneca's gross revenues in the U.S." *Ibid.* In the Drug Pricing Program's first year, CMS selected an AstraZeneca drug for "negotiation" that AstraZeneca developed and patented long before the IRA was enacted.

In August 2023, CMS selected the first ten drugs for the Program. CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026* (Aug. 2023), https://perma.cc/WFK4-9Z9H. Included on the list was AstraZeneca's product Farxiga (dapagliflozin)—a first-in-class, highly effective treatment for diabetes, heart disease, and chronic kidney disease. See C.A. App. 99, 102. In August 2024, CMS announced maximum prices for the selected drugs, which are scheduled to take effect on January 1, 2026. See CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026* (Aug. 15, 2024), https://perma.cc/94NA-L6VG. CMS slashed the list prices of these drugs by as much as 79%, with an average discount of 63%. See *ibid.* CMS determined that Farxiga will be subject to a mandated discount of 68%. See CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026* (Aug. 2024), https://perma.cc/66QF-9T8Y.

In January 2025, CMS selected the next fifteen drugs for the Program. CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2027* (Jan. 2025), https://perma.cc/7NWW-WNVT. CMS will publish the mandatory discounts for those drugs by November 2025, and the discounts will go into effect in January 2027. See 42 U.S.C. § 1320f-4(a)(1).

2. AstraZeneca filed suit challenging the Drug Pricing Program, arguing that CMS's guidance interpreting and implementing the Program violates the APA and that the IRA itself violates AstraZeneca's Fifth Amendment due process rights. C.A. App. 53-96. The district court granted summary judgment to the government. App. 20a-56a.

After concluding that AstraZeneca lacks standing to assert its APA claims, App. 33a-47a, the district court rejected AstraZeneca's procedural due process claim at the threshold. App. 47a-55a. The court reasoned that the Due Process Clause does not apply because "participation in the Medicare program is a voluntary undertaking," App. 53a (quotation marks and citation omitted), and because AstraZeneca lacks a constitutionally protected interest "in selling drugs to the Government at prices the Government will not agree to pay." App. 55a.

3. The court of appeals affirmed. App. 1a-19a.

The court of appeals did not endorse the district court's conclusion regarding "voluntariness." It nevertheless rejected AstraZeneca's due process claim on the ground that the Drug Pricing Program does not deprive it of any protected interest. App. 16a-19a. The court of appeals also acknowledged that "patent rights exist to permit greater profits during a product's exclusivity period to incentivize innovation." App. 17a (quoting *Eldred* v. *Ashcroft*, 537 U.S. 186, 215-216 (2003)). But it concluded that AstraZeneca's patent rights "do not confer a right to

sell at a particular price," or "at a price higher than what the government is willing to pay." *Ibid.*

In holding that AstraZeneca lacks a protected interest in selling its drugs at market prices to participants in Medicare, the court of appeals purported to distinguish this Court's decision in *Bowles* v. *Willingham*, 321 U.S. 503 (1944), which upheld a wartime rent-control statute against a procedural due process challenge on the ground that the statute provided definite standards for fixing rents and authorized judicial review. The court of appeals reasoned that those protections were necessary in *Bowles* because the statute at issue there "govern[ed] certain private housing transactions," whereas the Drug Pricing Program "only sets prices for drugs *that CMS pays for* when it reimburses sponsors." App. 18a (emphasis in original). In the court's view, "[t]hese are not private market transactions, regardless of the private hands through which CMS's funds pass." App. 19a.

The court of appeals below also sought to distinguish *Biotechnology Industry Organization* v. *District of Columbia*, 496 F.3d 1362, 1372 (Fed. Cir. 2007) (*BIO*), in which the Federal Circuit struck down a District of Columbia price-control statute aimed at patented drugs, finding it preempted by the federal patent laws. *BIO* reasoned that, through the patent laws, Congress granted patentees exclusive rights as "an incentive for innovation," and thus, "[u]pon grant of a patent, the only limitation" on a patentee's "economic rewards" "should be the dictates of the marketplace." *Id.* at 1372 (citation omitted). Here, the court of appeals found *BIO* inapplicable on the ground that "the federal patent laws do not create any affirmative right to make, use or sell anything" and thus "do not confer a right to sell at a particular price." App. 17a.

REASONS FOR GRANTING THE PETITION

In less than three months, the IRA is poised to wholly upend Medicare's market-based system for drug pricing, which for decades has made America the world leader in pharmaceutical research and development. Even today, the Drug Pricing Program is forcing manufacturers to make major decisions that will affect their businesses and patients for decades to come. Yet the court below declined even to consider the adequacy of the IRA's meager procedures, reasoning that a program mandating the price at which AstraZeneca may sell its patented products to private parties—if those private parties are later compensated by the government—does not implicate any constitutionally protected interest. That decision misunderstands the IRA's coercive regulation of the prices manufacturers charge in private transactions. It also contravenes this Court's precedent and the decisions of two courts of appeals.

Because review of this immensely consequential federal program will be most effective now, while the Drug Pricing Program is still in its early stages, the Court should grant certiorari.

I. THE DECISION BELOW IS WRONG

A. The IRA Deprives AstraZeneca of Constitutionally Protected Interests

The Fifth Amendment provides that no person shall "be deprived of life, liberty, or property, without due process of law." U.S. Const. amend. V. The government may not impair a protected interest without adequate procedures to prevent erroneous decision-making. See *Swarthout* v. *Cooke*, 562 U.S. 216, 219-220 (2011). The threshold "inquiry in every due process challenge is whether the plaintiff has been deprived of a protected interest." *Am. Mfrs. Mut. Ins. Co.* v. *Sullivan*, 526 U.S. 40, 59 (1999).

The Due Process Clause protects a "broad" class of property and liberty interests. *Bd. of Regents of State Colls.* v. *Roth*, 408 U.S. 564, 571-572 (1972). The government can create such protected interests through statutes, contracts, "policies and practices," or "rules and understandings" that are "promulgated and fostered by [government] officials." *Perry* v. *Sindermann*, 408 U.S. 593, 601-603 (1972). Protected "'property' interests … are not limited by a few rigid, technical forms," *id.* at 601, and "extend well beyond actual ownership of real estate, chattels, or money," *Roth*, 408 U.S. at 572. The liberty interests that the Due Process Clause protects are similarly broad, encompassing "not merely freedom from bodily restraint but also the right of the individual to contract, to engage in any of the common occupations of life, [and] to acquire useful knowledge." *Meyer* v. *Nebraska*, 262 U.S. 390, 399 (1923).

Here, the Drug Pricing Program implicates AstraZeneca's protected interests, including the "treasured" common-law right to offer access to its products to private parties at market prices. *Cedar Point Nursery* v. *Hassid*, 594 U.S. 139, 149 (2021). This Court has long recognized that private parties have a "right … to fix the price at which [they] will sell" their products. *Old Dearborn Distrib. Co.* v. *Seagram-Distillers Corp.*, 299 U.S. 183, 192 (1936). The IRA deprives AstraZeneca of that right, capping the prices at which it can sell its products to more than 68 million Medicare beneficiaries. The IRA thus directly impairs AstraZeneca's protected interest in selling its products to private parties at market prices.

That deprivation is particularly acute here because AstraZeneca holds patents on the affected products that entitle it to seek market-based profits. "The federal patent system … embodies a carefully crafted bargain": In return for "the creation and disclosure of new, useful, and nonobvious advances in technology," inventors obtain

"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). But the patent laws do not grant exclusivity for its own sake. Rather, "the encouragement of investment-based risk is the fundamental purpose of the patent grant," which in the pharmaceutical industry "provides incentive to … innovative drug companies to continue costly development efforts." *BIO*, 496 F.3d at 1372 (citation omitted).

"By penalizing high prices," the IRA "re-balance[s] the statutory framework of rewards and incentives … as it relates to inventive new drugs." *Id.* at 1374. Because of the long lead times for developing cutting-edge medicines, manufacturers like AstraZeneca must make investment decisions based on the prospect of future sales. See C.A. App. 104-105, 106. For products patented or in development before the IRA was enacted—including Farxiga—AstraZeneca invested in reliance on the principle that, "[u]pon grant of the patent, the only limitation on the size of the carrot should be the dictates of the marketplace." *King Instruments Corp.* v. *Perego*, 65 F.3d 941, 950 (Fed. Cir. 1995). The selection of its drugs for "negotiation" under the IRA accordingly has significant economic ramifications for AstraZeneca, see C.A. App. 105-106, depriving it of a key benefit of the bargain under which it obtained its patents.

The Drug Pricing Program overhauls the U.S. biopharmaceutical market and is projected to cost manufacturers like AstraZeneca hundreds of billions of dollars. Every day it remains in place means additional compliance costs from participating in sham "negotiations" and uncertainty that will limit investment in innovation and patient care. The notion that manufacturers lack any protected interest in how the Program operates blinks economic reality.

B. The Court of Appeals' Reasoning Is Mistaken

The court below rejected AstraZeneca's due process claim on the sole ground that AstraZeneca failed to "articulate a protected property interest." App. 19a. That conclusion does not withstand scrutiny.

1. The court of appeals accepted that the government violates the Due Process Clause if it "impos[es] price controls on private market transactions while barring judicial review of [agency] price-setting decisions." App. 18a. But the court concluded that the Drug Pricing Program "only sets prices for drugs *that CMS pays for* when it reimburses sponsors." *Ibid.* According to the court, manufacturers' sales to non-governmental parties are "not private market transactions, regardless of the private hands through which CMS's funds pass." App. 19a. That reasoning fundamentally misunderstands the IRA's radical design.

Contrary to the court of appeals' understanding, App. 18a, CMS does not "pay[] for" the drugs at issue. Once CMS sets prices, the IRA requires manufacturers like AstraZeneca to provide "access" to that price to "eligible individuals," to "pharmac[ies], mail order service[s], or other dispenser[s]," as well as to "hospitals, physicians, and other providers of services and suppliers." 42 U.S.C. § 1320f-2(a)(3). In other words, CMS dictates the prices that participating individuals, providers, and dispensers pay in *private* transactions to which the government is not a party.

Indeed, under Medicare Part D, CMS *never* buys or directly reimburses drugs, whether their prices are set by the Drug Pricing Program or not. See, *e.g.*, 42 U.S.C. § 1395w-112(b)(1). To participate in Part D, private health insurers—known as "plan sponsors"—submit bids, among which CMS then chooses. Medicare Payment Advisory Comm'n, *Report to the Congress: Medicare and the Health Care Delivery System* 123 (2020),

https://perma.cc/68D8-9TZH. Once plans go into effect, CMS does not reimburse plan sponsors for the actual or "negotiated" price of any drug. Instead, to reduce the premiums that plans charge Part D beneficiaries, CMS pays plan sponsors according to a complex statutory formula providing "subsid[ies]" and "reinsurance." 42 U.S.C. § 1395w-115(a), (b). But those subsidy and reinsurance payments do not directly turn on the prices paid by plan sponsors for individual drug sales.

The IRA thus authorizes CMS to set the prices that entities and individuals pay in *private* transactions. That stands in stark contrast to other federal drug-benefit programs, where the government acts as an actual market participant. Under 38 U.S.C. § 8126, for example, the Department of Veterans Affairs (VA) administers a "procurement" program allowing it and other federal agencies, including the Department of Defense (DOD), to purchase drugs from manufacturers at discounted prices. Unlike CMS, those agencies *do* "purchase" drugs in the marketplace, *id.* § 8126(a)(4), so it makes sense that they "negotiate" the prices that they pay as buyers.

The comparison with price-setting by the VA and DOD is telling in additional respects. Those agencies do not have any mechanism equivalent to the IRA's excise "tax" to force manufacturers to accede to their price demands. And, crucially, the VA's and DOD's decisions are subject to judicial review. See, *e.g.*, *Coal. for Common Sense in Gov't Procurement* v. *Sec'y of Veterans Affs.*, 464 F.3d 1306, 1312, 1316-1319 (Fed. Cir. 2006).

The IRA, by contrast, compels compliance through the threat of ruinous financial penalties. See p. 9, *supra*. And the lack of judicial review for key implementation decisions means that the agency can, with impunity, act in an unlawful or wholly arbitrary manner—a complete lack of process that, by definition, cannot satisfy minimum constitutional standards. See *Mathews* v. *Eldridge*, 424 U.S.

319, 333 (1976) ("The fundamental requirement of due process is the opportunity to be heard at a meaningful time and in a meaningful manner.") (quotation marks omitted).

AstraZeneca's interest in the non-arbitrary treatment of its products under the Drug Pricing Program is particularly acute given that the Program imposes price-controls for *patented* products. The court of appeals held that the Program does not implicate AstraZeneca's interest in its patents on the theory that if "the federal patent laws do not confer a right to sell at all," they cannot "confer a right to sell at a particular price." App. 17a. But that reasoning attacks a strawman.

AstraZeneca has never argued that it has a right to sell its products at a particular price. But AstraZeneca *does* have an interest in exercising its patent rights to seek higher prices "than could have been obtained if direct competition existed." *BIO*, 496 F.3d at 1373 (citation omitted). Indeed, allowing a patent-holder to pursue these kinds of "pecuniary rewards" is "the fundamental purpose of the patent grant." *Id.* at 1372 (citation omitted). By establishing "maximum fair prices" for products patented years before its enactment—including Farxiga—the IRA impairs AstraZeneca's protected interests.

2. Even if the court of appeals were correct that the Drug Pricing Program "only sets prices for drugs that CMS pays for when it reimburses sponsors," App. 18a (emphasis omitted), that *still* would not strip all due process protection from manufacturers whose products are selected under the Program. The Due Process Clause applies to *all* governmental decision-making, including when an administrative agency chooses how to spend the government's own money.

As this Court has explained, "the core of the concept" of due process is "protection against arbitrary [governmental] action." *Cnty. of Sacramento* v. *Lewis*, 523 U.S.

833, 845 (1998). Justice Johnson explained, in the early years following the Fifth Amendment's ratification:

> As to the words from Magna Charta, … after volumes spoken and written with a view to their exposition, the good sense of mankind has at length settled down to this: that they were intended to secure the individual from the arbitrary exercise of the powers of government, unrestrained by the established principles of private rights and distributive justice.

Bank of Columbia v. *Okely*, 17 U.S. 235, 244 (1819).

Arbitrary exercises of government power are not automatically consistent with the Due Process Clause merely because they concern an administrative agency's decision whether and how to commit the government's own funds. In *Goldberg* v. *Kelly*, 397 U.S. 254 (1970), for instance, this Court acknowledged that the government was not obligated to provide "public assistance benefits," which were "a privilege and not a right." *Id.* at 262 (quotation marks omitted). Yet the Court held that if the government *did* provide such benefits, it could not suspend them except through a constitutionally sufficient process designed to ensure, at minimum, that "payments [would] not be erroneously terminated." *Id.* at 266; see *id.* at 263-265.

To be sure, the Court also explained that "consideration of what procedures due process may require under any given set of circumstances must begin with a determination of the precise nature of the government function involved as well as of the private interest that has been affected by governmental action." *Id.* at 263 (quoting *Cafeteria & Rest. Workers Union* v. *McElroy*, 367 U. S. 886, 895 (1961)). In some circumstances, the Court observed, "the private interest infringed is reasonably deemed to be of less importance," such that the government "can take summary action pending a later hearing." *Id.* at 263 n.10 (citation omitted). And notably, as an example, the Court

identified the interests of "a contractor [doing] business with the Government." *Ibid.* But the Court did not suggest that the "government contractor" had *no* constitutionally protected interest—only that its interest could be terminated "pending resolution of a controversy over eligibility." *Id.* at 264; cf. *Mathews*, 424 U.S. at 331 (recognizing right of Social Security disability benefit recipients to constitutionally adequate procedures to review termination decisions, though concluding that pre-termination hearing was not required where "full relief [could] be obtained at a postdeprivation hearing").

Unlike the contractor discussed in *Goldberg*, manufacturers subject to price-setting under the IRA do not have even the right to "a later hearing." 397 U.S. at 263 n.10. As a result, HHS may misapply the statute—or rewrite its terms wholesale—without any check on the agency's authority.

If the court of appeals were correct that participants in the Drug Pricing Program have "no protected property interest," App. 17a, then nothing would stop the government from choosing drugs for negotiation by a coinflip, or setting maximum fair prices by throwing darts at a dartboard. Indeed, beyond the Program, the government could adopt a similarly capricious approach to its contracting decisions generally—for example, by suspending the APA or other statutory review mechanisms. This Court's due process decisions do not countenance such arbitrariness, particularly for drug-selection and pricing decisions under the IRA that have billion-dollar implications.

II. THE DECISION BELOW CONFLICTS WITH DECISIONS OF THIS COURT AND OTHER COURTS OF APPEALS

Review is warranted now because this case concerns the constitutionality of a massive new federal program that deprives manufacturers of protected interests without even a semblance of due process. But in finding that manufacturers lack any protected interest, the court of

appeals provided another reason to take up this case: It flouted this Court's decision in *Bowles*, departed from the Fifth Circuit's due process analysis in *NICA*, and rejected longstanding patent principles that the Federal Circuit articulated in *BIO*.

A. The Decision Below Contravenes *Bowles*

The decision below is irreconcilable with this Court's decision in *Bowles*. There, the Court upheld a rent-control statute against a procedural due process challenge, not because the challenger lacked a protected interest, but instead because the statute provided sufficiently definite standards for fixing rents and—crucially—authorized judicial review.

Bowles involved a wartime statute that empowered a federal agency to "fix maximum rents for the housing" in designated "defense rental area[s]." 321 U.S. at 512-513. After the agency notified a landlord in Georgia that it would decrease the maximum rents of apartments she owned, the landlord sued, arguing that the statute deprived her of protected interests without adequate procedures. *Id.* at 509-510.

The Court agreed with the plaintiff that Congress was required, in authorizing an executive agency to set rental prices, to provide the landlord with sufficient process to ensure that rates were set appropriately. *Id.* at 519-521. The Court thus acknowledged repeatedly that the statute affected the landlord's "property rights." *Id.* at 518; see *id.* at 520. The Court further explained that even a wartime exigency sufficient to justify price-fixing "does not remove constitutional limitations safeguarding essential liberties." *Id.* at 521 (citation omitted).

The Court ultimately determined that the rent-fixing statute had "done all that due process under the war emergency requires." *Ibid.* But importantly, it reached that determination because the statute "provided for

judicial review after [rent-fixing] regulations or orders [became] effective." *Ibid.* "Where only property rights are involved, mere postponement of the judicial enquiry is not a denial of due process," the Court explained, provided that "the opportunity given for the ultimate judicial determination of the liability is adequate." *Ibid.* (quoting *Phillips* v. *Comm'r of Internal Revenue*, 283 U.S. 589, 596-597 (1931)).

The decision below contravenes *Bowles*. In contrast to the rent-fixing statute there, the IRA eliminates judicial review of HHS's price-fixing decisions. 42 U.S.C. § 1320f-7. The IRA thus delegates to HHS the same price-setting authority that the agency possessed in *Bowles*, while removing the essential procedural guardrail that allowed the Court to uphold the statute.

The court of appeals below did not dispute that empowering an agency to set below-market prices deprives affected sellers of a protected interest. Instead, the court purported to distinguish *Bowles* on the ground that it involved "private … transactions," whereas the Drug Pricing Program supposedly does not. App. 18a. But for the reasons already discussed, see pp. 17-19, *supra*, that distinction misunderstands the basic design of the Drug Pricing Program and its interaction with Medicare. By its plain terms, the Program *does* regulate "private market transactions" between manufacturers like AstraZeneca and non-governmental providers, pharmacies, and patients. CMS does not buy any drug for which it sets a "maximum fair price"; and, under Part D, CMS does not even directly reimburse that price after it is paid by others. Rather, CMS fixes prices that private parties pay and receive—just as the agency did in *Bowles*.

B. The Decision Below Conflicts with Decisions of the Fifth and Federal Circuits

The decision below also conflicts with decisions of two courts of appeals, which have recognized that drug

manufacturers *do* have interests in selling their patented products that are protected by the Due Process Clause.

1. In *NICA*, associations representing healthcare providers (among others) challenged the Drug Pricing Program on various grounds, including that it violates due process. 116 F.4th at 496. The government argued—and one member of the panel agreed—that the providers lacked standing to raise a due process claim because they "have not been … deprived of any protected interests." *Id.* at 514 (Ramirez, J., concurring in part and dissenting in part). But the majority disagreed, concluding that the Program puts "important property interests" at stake. *Id.* 503.

In so ruling, the majority explained that "key determinations [under the IRA] are made without notice and comment and insulated from administrative or judicial review." *Ibid.* As a result, "there is a substantial risk that [the plaintiffs'] members will be erroneously deprived of important property interests." *Ibid.* The majority then concluded that the associations had "alleged sufficient facts to satisfy the *Mathews* test" for identifying a due process violation. *Ibid.* Because the Drug Pricing Program deprives providers "of input regarding unanswered implementation questions" and also bars them from "challeng[ing] particular determinations," the court held that the Program "create[s] a substantial risk of erroneous deprivation" of the providers' interest in obtaining "revenue and … stay[ing] in business." *Ibid.*

The decision below is irreconcilable with *NICA*. Indeed, the conclusion that AstraZeneca has a constitutionally protected interest here follows *a fortiori* from the Fifth Circuit's conclusion there that the provider associations had standing to raise a due process claim. As all sides recognized, the Drug Pricing Program affects manufacturers *more* directly than it does providers. See *id.* at 504

n.12; accord *id.* at 514 (Ramirez, J., concurring in part and dissenting in part).

To be sure, *NICA* addressed the providers' standing to raise a due process claim, rather than the merits of that claim. But the Fifth Circuit specifically held that the plaintiffs had "allege[d] sufficient facts to satisfy the *Mathews* test," a prerequisite to which is a protected property interest. *Id.* at 503. The Fifth Circuit could not have reached that conclusion if it agreed with the court below that "[t]here is no protected property interest" at stake under the Drug Pricing Program. App. 17a.

2. The decision below is also inconsistent with the Federal Circuit's decision in *BIO*. There, the District of Columbia had enacted a statute that made it "unlawful for any drug manufacturer … to sell or supply for sale … a patented prescription drug that results in the prescription drug being sold in the District for an excessive price." 496 F.3d at 1365. Pharmaceutical-industry associations argued that the statute was preempted because it deprived "pharmaceutical patent holders [of] the pecuniary reward that follows from the right to exclude granted by a patent." *Id.* at 1372.

The Federal Circuit agreed and upheld an injunction against the statute's enforcement. The court explained that the "procurement of a patent" entitles the patentee to, among other things, "an opportunity to obtain above-market profits during the patent's term." *Ibid.* The court recognized that the "economic rewards during the period of exclusivity are the carrot" that the patent system uses to "incentiv[ize] … innovation." *Ibid.* (quoting *King Instruments Corp.*, 65 F.3d at 950). After obtaining a patent, therefore, "the only limitation on the size of the carrot should be the dictates of the marketplace." *Ibid.* And by "penalizing high prices," the D.C. statute "limit[ed] the full exercise of the exclusionary power that derives from a patent." *Id.* at 1374.

Like the D.C. statute at issue in *BIO*, the Drug Pricing Program deprives manufacturers of their federally protected interest in setting prices based on "the dictates of the marketplace." Below, the court of appeals addressed *BIO* only superficially, quoting its statement that "the federal patent laws do not create any affirmative right to make, use, or sell anything." App. 17a (quoting *BIO*, 496 F.3d at 1372). But the court ignored *BIO*'s more relevant conclusion—from the same paragraph—that a statute setting the price of patented products nevertheless "conflicts with Congress's intention to provide … pharmaceutical patent holders with the pecuniary reward that follows from the right to exclude granted by a patent." 496 F.3d at 1372. Under *BIO*'s logic, the Drug Pricing Program similarly deprives manufacturers like AstraZeneca of an interest in charging market prices for their already-patented drugs.

III. THIS CASE IS AN IDEAL VEHICLE FOR DECIDING AN IMMENSELY IMPORTANT AND RECURRING QUESTION

Whether the IRA deprives manufacturers of a constitutionally protected interest—and hence whether HHS is constrained in implementing the Drug Pricing Program by the Due Process Clause's prohibition on arbitrary governmental action—is a question of national importance. As the Fifth Circuit recently observed, the IRA seeks to replace the "free market" system with "a government-run process" for drug pricing. *NICA*, 116 F.4th at 494. That "process" is still in its infancy, but the more it progresses, the more extensive and irreparable the consequences of erroneous agency decisions will become. This Court's review is warranted now.

A. The Question Presented Is Highly Significant

The constitutionality of the Drug Pricing Program "is of great importance to consumers of pharmaceutical drugs, the companies that provide them, and the public at

large." *Bristol Myers Squibb Co.* v. *HHS*, No. 24-1820, — F.4th —, 2025 WL 2537005, at *33 (3d. Cir. Sept. 4, 2025) (Hardiman, J., dissenting). Indeed, the Program makes "the IRA … the largest and most consequential piece of legislation affecting the healthcare and pharmaceutical industries since the passage of the [Affordable Care Act] back in 2009." Magnolia, *Inflation Reduction Act Payer Insights Report* 2 (2024), https://perma.cc/B7VX-XH88. The IRA's "effects on the life sciences industry and ultimately to patient treatment [will be] profound." Luke Greenwalt, *The Impact of the Inflation Reduction Act on the Economic Lifecycle of a Pharmaceutical Brand*, IQVIA (Sept. 17, 2024).

With more than 68 million enrollees, Medicare accounts for a massive segment of the healthcare economy in the United States, CMS, *Medicare Enrollment Dashboard* (2025), https://perma.cc/9KSR-ZPAA, and underpins the $600 billion pharmaceutical market, see Grand View Research, *U.S. Pharmaceutical Market Size & Trends* (2024), https://bit.ly/3K4qsbs. The Drug Pricing Program is poised to radically transform that market: The Congressional Budget Office estimates that the Program will reallocate "about $100 billion" in healthcare payments in just its first ten years. CMS, *Negotiating for Lower Drug Prices Works, Saves Billions* (Aug. 15, 2024), https://perma.cc/63XP-AUPX.

CMS clearly intends to make good on that estimate. After the first round of "negotiations," CMS slashed the list prices of some of the nation's most innovative and widely prescribed medicines by as much as 79%, with an average discount of 63%. See CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026* (Aug. 15, 2024), https://perma.cc/94NA-L6VG. And CMS says it is considering setting the 2028 price for selected drugs even lower—as low as the "unit cost of production and

distribution of the selected drug," eliminating all marginal profit. CMS, *Medicare Drug Price Negotiation Program: Draft Guidance* 131 (May 12, 2025), https://perma.cc/VYM9-FFDR.

Manufacturers like AstraZeneca foot the bill for these cuts under the Drug Pricing Program. Yet under the decision below, HHS need not provide even the most rudimentary safeguards against erroneous decision-making. The agency could literally flip a coin or throw a dart to decide key implementation questions—such as which drugs to select—and affected manufacturers with billions of dollars on the line would be unable to challenge that process as impermissibly arbitrary. Given that HHS has interpreted the IRA as exempting the Program from the APA's notice-and-comment and judicial-review provisions, preserving a constitutional backstop is imperative.

B. Further Percolation Is Unnecessary

Parties throughout the country adversely affected by the Drug Pricing Program have challenged its constitutionality, including manufacturers, healthcare providers, and patient groups. "Whatever the outcome" of this wave of litigation, it "will undoubtedly have major implications for the pharmaceutical industry, those who are enrolled in Medicare, as well as the state of healthcare policy in the U.S., specifically regarding the pricing of drugs." Cornell In Washington, *Major Pharmaceutical Industry Players Sue the U.S. Government Over Medicare Drug Price Negotiation*, CIW Reports (2023), https://perma.cc/M7YX-SF36.

Among the recurring claims in these challenges is that the IRA fails to provide due process, which invariably raises the same threshold question presented here: whether manufacturers have protected interests at stake. Indeed, the government has raised that threshold argument in response to every due process challenge to the Drug Pricing Program, telling courts throughout the

country to simply ignore the details of the IRA's procedures on the theory that they do not matter—the IRA does not deprive manufacturers of any protected interest in the first place. See Gov't Br. at 31, *Teva Pharms. USA, Inc.* v. *Becerra*, No. 25-CV-113 (D.D.C. Apr. 29, 2025) ("Without a cognizable interest in liberty or property, the Court need not address whether the statute's procedural safeguards are constitutionally sufficient.") (quotation marks omitted); Gov't Br. at 37, *Nat'l Infusion Ctr. Ass'n* v. *Becerra*, No. 23-CV-707 (W.D. Tex. Apr. 21, 2025) (similar); Gov't Br. at 56, *Novo Nordisk, Inc.* v. *HHS*, No. 23-CV-20814 (D.N.J. Jan. 26, 2024) (similar); Gov't Br. at 39, *Boehringer Ingelheim Pharms., Inc.* v. *HHS*, No. 23-CV-1103 (D. Conn. Dec. 20, 2023) (similar); Gov't Br. at 54, *Dayton Area Chamber of Commerce* v. *Becerra*, No. 23-CV-156 (S.D. Ohio Dec. 15, 2023) (similar).

Given the nationwide recurrence of the question presented, this Court's review is not a matter of *if* but *when*. While "[s]ome legal analysts endorse" the constitutional challenges to the IRA, and "others argue they're specious," they all agree on one thing: It "seems likely that these cases will end up before the Supreme Court." Larry Levitt, *The 4 Arguments You Will Hear Against Drug Price Negotiation*, N.Y. Times (Sept. 6, 2023), https://perma.cc/7GD2-5VVJ; see, *e.g.*, Michael Erman, *Merck sues US government to halt Medicare drug price negotiation*, Reuters (June 6, 2023) (litigation over the Program "is likely headed to the Supreme Court"), https://perma.cc/JR2X-FFBY; Cong. Research Serv., *Constitutional Challenges to the Medicare Drug Price Negotiation Program* (Oct. 10, 2024) (noting "predict[ions] that the litigation could eventually reach the U.S. Supreme Court"); Erica N. White, et al. *Medicare Drug Pricing Negotiations: Assessing Constitutional Structural Limits*, 51 J. L., Med. & Ethics 956 (2024) (IRA's "fate may rest with the Supreme Court"); Duane

Morris, *Forging Ahead to the Supreme Court? Drug Company Sues U.S. Over Inflation Reduction Act Pricing* (June 8, 2023) ("These lawsuits matter because they may reach the U.S. Supreme Court relatively quickly before the new prices for the first round of 10 drugs take effect starting on January 1, 2026.").

The reasons for granting review now, rather than awaiting further "percolation," are overwhelming. There is little benefit to delaying review of important constitutional questions about major federal statutes just to enable additional lower-court judges to weigh in first. See Henry J. Friendly, *The "Law of the Circuit" and All That*, 46 St. John's L. Rev. 406, 407 (1972) ("If a case involves questions of federal law of such importance as to be reviewed by the Supreme Court, the views of the court of appeals count, and should count, for little."); see also Michael Coenen, Seth Davis, *Percolation's Value*, 73 Stan. L. Rev. 363, 367 (2021) ("reject[ing] the idea that the need to foster percolation generally provides a good reason for denying certiorari on (or otherwise declining to decide) an issue that the Court would otherwise be inclined to take on").

In any event, the question presented here has already been thoroughly ventilated. The issue has received extensive briefing and argument in the lower courts. And, including the decision below, three circuits have now issued five decisions addressing the IRA's constitutionality. See *NICA*, 116 F.4th at 494; *Boehringer Ingelheim Pharms., Inc.* v. *United States Dep't of Health & Hum. Servs.*, No. 24-2092, — F.4th —, 2025 WL 2248727, at *10 (2d Cir. Aug. 7, 2025); *Bristol Myers Squibb*, 2025 WL 2537005, at *1; *Novartis Pharms. Corp.* v. *Sec'y United States Dep't of Health & Hum. Servs.*, No. 24-2968, — F.4th —, 2025 WL 2619133, at *1 (3d Cir. Sept. 11, 2025). The Court need not await further views.

C. Delaying Review Will Only Compound the Due Process Problem

Although the Drug Pricing Program is still in its infancy, the irreparable consequences of insulating the Program from due process review will multiply as the statutory timeline progresses. The first ten IRA-imposed prices are scheduled to take effect in less than three months, on January 1, 2026. "Negotiations" over the next fifteen drugs are ongoing, and the resulting price caps are scheduled to take effect at the start of 2027. Fifteen more drugs are scheduled for "negotiation" in 2026 and for IRA-imposed prices starting in 2028. And another twenty are scheduled for "negotiation" and price-setting every year after that. 42 U.S.C. § 1320f-1(a)(1)-(4).

As long as the Drug Pricing Program continues without constitutionally adequate procedures, manufacturers must make significant, long-term business decisions in the shadow of arbitrary governmental action. For example, manufacturers must decide on R&D investments years in advance. Every day, they are being "forced to make decisions" that "will impact [their] drug development and commercialization for years to come." C.A. App. 106. Manufacturers also must invest substantial time and resources in the sham "negotiations" themselves. Even if AstraZeneca or another manufacturer ultimately prevails in challenging the IRA, it will not be able to recover these costs from the government. Cf. *Thunder Basin Coal Co.* v. *Reich*, 510 U.S. 200, 220-221 (1994) (Scalia, J., concurring in part and in the judgment) ("[C]omplying with a regulation later held invalid almost *always* produces the irreparable harm of nonrecoverable compliance costs."). And because the IRA creates an "unconstitutionally structured decisionmaking process," mandatory participation subjects manufacturers to a "here-and-now injury." *Axon Enter., Inc.* v. *FTC*, 598 U.S. 175, 191, 192 (2023).

D. This Case Is an Ideal Vehicle

This case is an ideal vehicle to decide the question presented. The court of appeals denied AstraZeneca's due process claim on a single legal ground: that AstraZeneca lacks a constitutionally protected interest. App. 19a. The court did not provide any alternative basis for its decision, nor did the government offer any case-specific arguments.

If AstraZeneca prevails, therefore, this Court's decision will allow the lower courts to address the next logical question: whether the Drug Pricing Program's procedures satisfy the constitutional minimum and, if not, whether that deficiency can be remedied. This case accordingly offers a clean vehicle to resolve the question presented at a time when its resolution will be most valuable. Review is warranted now.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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