No. 25-348

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

REPLY BRIEF FOR THE PETITIONERS

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The government concedes that the IRA's Drug Price Negotiation Program is already affecting billions of dollars in healthcare spending and that its constitutionality "is of great importance." *Bristol Myers Squibb Co.* v. *HHS*, 155 F.4th 245, 289 (3d Cir. 2025) (*BMS*) (Hardiman, J., dissenting). But the government barely attempts to defend the statute's deficient procedures. Though the government gestures at the IRA's mechanics, it does not dispute that, under the decision below, CMS could flip a coin to select the drugs subject to price caps or set prices by throwing darts. Indeed, the government recently admitted to the Fifth Circuit that, under the IRA, "there's not process." Oral Arg. 18:43-19:10, *Nat'l Infusion Ctr. Ass'n* v. *Kennedy*, No. 25-50661 (5th Cir. Oct. 7, 2025).

The government instead insists (at 18) that it is just a "market participant" "negotiating" how much it pays for drugs, so AstraZeneca has no protected interests at stake and is entitled to *no* process. But no "market participant" has a tool like the "excise tax," a sovereign regulatory

power the IRA deploys to *prevent* manufacturers from engaging in genuine "negotiation." And regardless, the government admits (at 17) that it does not actually buy drugs under the Program, but only indirectly "subsidizes" a *portion* of what *private* buyers pay. Genuine market participants decide what they will pay their own counterparties; they do not dictate the prices charged in *other* parties' transactions. And even if the IRA controlled prices only for drugs CMS "pays for" in a "voluntary" program, it still deprives AstraZeneca of a protected interest in the non-arbitrary implementation of the Program in accordance with the statute.

The IRA's deficient procedures warrant review this Term. The first round of price caps took effect last week; and for the second round, prices are scheduled to take effect next year. Time is of the essence.

I. THE DECISION BELOW IS WRONG

A. AstraZeneca has a "right … to fix the price at which [it] will sell" its products. *Old Dearborn Distrib. Co.* v. *Seagram-Distillers Corp.*, 299 U.S. 183, 192 (1936). The Program impairs that right by preventing AstraZeneca from selling its patented products to nearly 70 million Medicare beneficiaries at market prices, with *no* process to ensure that prices are set in a non-arbitrary manner that comports with statutory requirements.

First, the government argues (at 15) that it "regularly negotiates the prices it pays for goods," and AstraZeneca has no protected interest "in forcing the government to pay for prescription drugs on specific terms." But AstraZeneca does not claim a right to payment "on specific terms." Instead, due process requires that "opportunity [be] given for [an] ultimate judicial determination" regarding whether government-set price caps are "adequate"—*i.e.*, consistent with statutory constraints and non-arbitrary. *Bowles* v. *Willingham*, 321 U.S. 503, 520 (1944).

The government argues (at 18) that under the IRA, it is simply a "market participant" that "negotiat[es]" drug prices with manufacturers, just as it does in other contexts. But that ignores the IRA's radical design. If Congress wanted the government to act as a market participant, it would not have added the IRA's "penalty phase," which applies if a manufacturer "fails to reach an agreement with HHS." *Nat'l Infusion Ctr. Ass'n* v. *Becerra*, 116 F.4th 488, 495 (5th Cir. 2024) (*NICA*). Private buyers cannot fine sellers into oblivion for "noncompliance" with their demands—as the government can via the IRA's "excise tax." 26 U.S.C. § 5000D(a). Similarly, even when private parties negotiate a price agreement, the agreed-upon price generally applies *only* in transactions between the negotiating parties. Under the IRA, by contrast, manufacturers must provide millions of *other* parties with "access" to discounted prices, on pain of massive civil money penalties. 42 U.S.C. § 1320f-2(a)(1)-(3).

In these ways, "to fulfill [its] goals," Congress chose "tool[s] … which only a government can wield." *Am. Trucking Ass'ns, Inc.* v. *City of Los Angeles*, 569 U.S. 641, 651 (2013). The government was unwilling to accept the risks of acting as a mere market participant—namely, that manufacturers might reject government-dictated prices, or that pharmacies and other intermediaries might not pass on all of the savings to patients. So the government deployed its sovereign regulatory power through "coercive mechanism[s] available to no private party." *Ibid.*

The *reason* the government could not simply act as a market participant, moreover, is that it does not actually buy any drugs at issue. Under the Program, CMS sets the prices charged to nearly 70 million *private* Medicare "eligible individuals," millions of *private* providers, and thousands of *private* pharmacies. 42 U.S.C. § 1320f-2(a)(1)-(3). In its own telling (at 17), the government does not buy *any*

drugs under the Program, but merely "subsidizes" a portion (74.5%) of those private purchases.

That is a far cry from an ordinary buyer "negotiating" the price it is willing to pay for its own purchases. Indeed, if partially and indirectly subsidizing transactions permitted the government to fix prices arbitrarily and without any process—as the government's argument suggests—the consequences would be staggering. After all, the government partially subsidizes numerous markets. Consider the Supplemental Nutrition Assistance Program (SNAP), in which the government subsidizes eligible individuals' food expenses. See 7 U.S.C. § 2011 *et seq.* In the government's view, it is a "market participant" whenever an individual buys milk or bread at a grocery store using even one dollar of SNAP benefits, such that Congress could empower the U.S. Department of Agriculture to set prices for fruits and vegetables—and harshly penalize those who offer higher prices—without providing any review process for stores or farmers. Or because many students receive Pell Grants, Congress could empower the Department of Education to set tuition costs without any administrative or judicial review for statutory compliance.

The VA and DOD examples (at 15-16) further undermine the government's position, because those agencies *do* purchase drugs. For instance, "the VA does not simply reimburse claims filed by pharmacies or other providers" (as CMS does) but "is itself the provider, operating an integrated network of … medical centers, … outpatient clinics, … brick-and-mortar pharmacies, … and mail-order pharmacies." Health Affairs, *Prescription Drug Pricing, Veterans Health Admin.* 1 (2017), https://bit.ly/4pmvr6a. Because the VA actually buys drugs, it is precisely the type of "market participant" that CMS is not.

Second, the government goes even further in arguing (at 19) that manufacturers have no protected interest in setting prices even for private transactions. Though

stopping short of claiming that *Old Dearborn* has been overturned, the government argues (at 19) that this Court has "clarified that the Constitution does not substantively constrain a legislature's ability to fix the price of goods." But AstraZeneca does not challenge "a *legislature's* ability to fix the price of goods." If Congress sets prices itself, it impairs a protected interest, but "[t]he legislative determination provides all the process that is due." *Atkins* v. *Parker*, 472 U.S. 115, 130 (1985) (citation omitted).

Under the Program, by contrast, CMS selects drugs and sets prices—not Congress. An administrative agency may not engage in price-setting without additional protections to ensure the agency makes non-arbitrary determinations within statutory bounds. See *Goldberg* v. *Kelly*, 397 U.S. 254, 262 (1970).

Finally, the government argues (at 19-20) that federal patent laws do not create a right to sell a product at a particular price. But as the government concedes (at 20), "a patentee may use its exclusive right to sell a drug as leverage in the marketplace." By imposing price caps for products (like Farxiga) that were patented years before the IRA's enactment, the IRA authorizes CMS to strip AstraZeneca of that leverage, thereby impairing its interests. AstraZeneca therefore is entitled to constitutionally adequate process.

B. Even if the government were right that the IRA controls prices only for drugs that CMS "pays for" through a "voluntary" program, AstraZeneca *still* has a protected interest in having the Program implemented in a lawful, non-arbitrary manner. See Pet. 19-21.

Contrary to the government's contention (at 21), manufacturers are similarly situated to the plaintiffs in *Goldberg* v. *Kelly*, whose statutory entitlement to welfare benefits required constitutionally sufficient pre-deprivation process. The government itself recognizes that the IRA "establishe[s] detailed criteria for the selection of

negotiation-eligible drugs" and additional "detailed criteria that CMS 'shall consider'" in setting prices. Gov't Br. at 11-12, *Nat'l Infusion Ctr. Ass'n* v. *Becerra*, No. 23-CV-707 (W.D. Tex. Apr. 21, 2025). Thus, under *Goldberg*, the IRA entitles manufacturers to lawful, non-arbitrary drug "selection" and pricing decisions. Yet the IRA offers *no* meaningful procedures—such as judicial review—to ensure statutory compliance. CMS could simply ignore or rewrite the law with impunity.

This concern is not merely hypothetical. Recall, for example, that the IRA limits the number of "qualifying single source drugs" CMS may "select" each year. 42 U.S.C. § 1320f-1(a). Although the IRA provides that each "qualifying single source drug" must be a *single* drug approved under a New Drug Application, *id.* § 1320f-1(e)(1)(A), CMS has lumped *multiple* drugs together whenever they share an "active moiety," a term that appears nowhere in the statute, CMS, *Medicare Drug Price Negotiation Program: Revised Guidance* 99 (June 30, 2023), https://perma.cc/NPW4-UHXT. For example, CMS grouped six Novo Nordisk drugs approved under separate NDAs into one qualifying single source drug, and then selected nine *more* drugs, circumventing the statutory limit of ten. See CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026* (Aug. 2023), https://perma.cc/WFK4-9Z9H. Yet when Novo challenged this extra-statutory power-grab, the government successfully invoked the IRA's judicial-review bar. See *Novo Nordisk Inc.* v. *HHS*, 154 F.4th 105, 111 (3d Cir. 2025).

The government incorrectly argues (at 20) that AstraZeneca has "forfeited" its arbitrariness argument. AstraZeneca has always argued that the IRA's lack of procedures facilitates arbitrary, lawless decision-making. AstraZeneca's arbitrariness arguments merely underscore the logical consequence of *the government's*

position: If manufacturers lack any protected interest (as the government insists), and if the IRA affords no process (as the government concedes), then the statute allows CMS to exceed statutory constraints and set prices arbitrarily.[1]

II. THE DECISION BELOW CONFLICTS WITH OTHER AUTHORITY

A. The government fails to reconcile the decision below with *Bowles*, where this Court upheld a price-fixing statute against a landlord's challenge only because it provided ample process, including judicial review. The government dismisses *Bowles* (at 22) because it focused on the adequacy of the process provided, rather than on "whether there is a due-process interest." But *Bowles* addressed what "due process … requires" precisely *because* the rent-fixing statute there (like the IRA here) deprived the plaintiff of "property rights" and "essential liberties." 321 U.S. at 520-521. With that due-process prerequisite satisfied, the statute survived constitutional scrutiny only because (unlike the IRA) it provided procedural guardrails. *Id.* at 518. Indeed, to the extent *Bowles* treated the landlord's protected interest as *self-evident*, that only further undermines the government's theory.

The government also attempts (at 22-23) to distinguish *Bowles* by repeating its argument that the IRA only

[1] The government argues that "Petitioners challenge legislation (the Act) on its face, so they must show that Congress's decision was 'clearly wrong, a display of arbitrary power, not an exercise of judgment.'" Opp. 20-21 (quoting *Bowen* v. *Gilliard*, 483 U.S. 587, 598 (1987)). But that standard governs claims challenging the *substantive* scope of a statutory program as being insufficiently tailored to the program's rationale. See *Bowen*, 483 U.S. at 598-603. AstraZeneca instead argues that the IRA enables CMS to deprive manufacturers of their interests arbitrarily and in excess of statutory constraints. That *procedural* due process claim is governed by *Goldberg*, *Mathews* v. *Eldridge*, 424 U.S. 319 (1976), and their progeny.

governs transactions indirectly subsidized through Medicare. But that is wrong—and irrelevant—for the reasons discussed.

B. The government urges the Court (at 23-24) to ignore the Fifth Circuit's decision in *NICA* because it addressed standing. But the challengers there had standing *because* they "allege[d] sufficient facts to satisfy the *Mathews* test." *NICA*, 116 F.4th at 503. That test requires a protected interest; that is why *the dissent* argued the challengers lacked "protected interests." *Id.* at 514 (Ramirez, J., concurring in part and dissenting in part). Nor does the government claim that the facts "allege[d]" in *NICA* materially differ from the undisputed facts here.

C. The decision below also contravenes *Biotechnology Industry Org.* v. *District of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007) (*BIO*). The government notes (at 24) that *BIO* involved preemption. But *BIO* recognized that statutes "penalizing high prices"—like the IRA—"limit[] the full exercise of the exclusionary power that derives from a patent." *Id.* at 1374. That holding contradicts the decision below that the IRA has no bearing on AstraZeneca's patent rights. See Pet. App. 17a.

The government asserts (at 25) that *BIO* "essentially rejected petitioners' claimed property interest." Yet while *BIO* noted that "the federal patent laws do not create any affirmative right to … sell anything," it *held* that a statute setting prices for patented products "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. That holding is irreconcilable with the government's position that manufacturers lack even an *interest* in having the IRA applied to patented products in a textually faithful and non-arbitrary manner.

III. THIS CASE IS AN IDEAL VEHICLE TO DECIDE AN IMPORTANT ISSUE

A. The government does not dispute that the question presented is immensely important. Indeed, the government emphasizes (at 9-10) that many billions of dollars are at stake. The IRA "shifts the price-setting mechanism for many of America's highest-selling drugs from the free market to a government-run process," *NICA*, 116 F.4th at 494. Its consequences are already manifesting, and will become progressively more difficult to unscramble as statutory deadlines tick by.

The government nevertheless calls (at 26) for "further percolation." But the Program has already generated years of litigation, with numerous appellate judges disagreeing about its constitutionality. Compare App. 1a-19a (upholding Program), with *BMS*, 155 F.4th at 269-289 (Hardiman, J., dissenting) (finding Program unconstitutional); *NICA*, 116 F.4th at 503 (Program fails "the *Mathews* test"). The longer the Program persists, the more it "will impact [manufacturers'] drug development and commercialization," C.A. App. 106, impose irrecoverable compliance costs, Pet. 31, and threaten America's preeminence in pharmaceutical innovation, Pet. 2. The marginal benefit of additional lower-court opinions here "should count[] for little." Henry J. Friendly, *The "Law of the Circuit" and All That*, 46 St. John's L. Rev. 406, 407 (1972) (cleaned up).

B. The government argues (at 25-26) that this case is a "poor vehicle" because it expects to prevail on the "alternative ground[]" that AstraZeneca's participation in the Program is "voluntary." But as the government has often observed, the possibility that a respondent "could still prevail on alternative grounds on remand" is "no reason to deny review." Gov't Cert. Reply at 10, *Garland* v. *Singh*, 602 U.S. 447 (2024) (No. 22-884); see, *e.g.*, Cert. Reply at 9, *United States* v. *Taylor*, 142 S. Ct. 2015 (2022)

(No. 20-1459). That includes cases where the district court ruled for the respondent on the alternative ground. See, *e.g.*, *United States ex rel. Polansky* v. *Exec. Health Res., Inc.*, 599 U.S. 419 (2023); *Minerva Surgical, Inc.* v. *Hologic, Inc.*, 141 S. Ct. 2298 (2021). The government itself often obtains review in this posture, noting (correctly) that "the existence of a potential alternative ground relied upon by the district court, but not addressed by the court of appeals, is not a barrier to [this Court's] review." Gov't Cert. Reply Br. at 3, *United States* v. *Bean*, 2002 WL 32101203 (Jan. 2002) (No. 01-704) (collecting examples).

Regardless, the government's "voluntariness" argument is *not* an "alternative" ground here; it is merely another way of framing the government's central theory that AstraZeneca lacks a protected interest because it "choose[s] to participate in Medicare and Medicaid." Opp. 23. The government can press that point in arguing the question presented.

The government's "voluntariness" theory also is incorrect. *Goldberg* held that due process bars the government from terminating voluntary "public assistance benefits" without sufficient process. 397 U.S. at 264. Indeed, *Goldberg* expressly contrasted a welfare-benefit recipient with a "contractor [doing] business with the Government," which *would* be entitled to a "hearing" in the event of disqualification, albeit only after-the-fact. *Id.* at 263 n.10. Here, the IRA offers manufacturers *no* process *at all*.

The government also relies (at 7) on the incorrect premise that withdrawal from Medicare and Medicaid is an "option[]." In fact, under the IRA's deadlines, manufacturers could not have withdrawn during the Program's first year without incurring the excise tax. 42 U.S.C. § 1320f(b)(4), (d)(2)(A). Doing so was "*impossible*" because the withdrawal window closed before the IRA was

enacted. *BMS*, 155 F.4th at 272 (Hardiman, J., dissenting).[2]

For the Program's later years, there is nothing "voluntary" about choosing between acceding to price controls and withdrawing from nearly half of the national market for prescription drugs. Even if withdrawal were feasible in business terms (but see Pet. 9), doing so would deprive millions of patients of critical medicines. The Program is at least as "coercive" as the provision of the Affordable Care Act that "threaten[ed] to withhold … States' existing Medicaid funds" if they declined "new conditions." *NFIB* v. *Sebelius*, 567 U.S. 519, 579-580 (2012). For manufacturers who lack States' tax-and-spend powers, it is "a gun to the head." *Id.* at 581.

C. The government finally suggests (at 27) consolidating AstraZeneca's petition with other petitions challenging the IRA's constitutionality. While those petitions raise different issues, AstraZeneca agrees that they also warrant review.

But *only* AstraZeneca's petition can be set for argument this Term. The IRA is already being implemented, and its harmful effects will only multiply as time passes. The Court should not put off deciding the law's constitutionality for another year.

CONCLUSION

The petition should be granted.

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[2] "Apparently recognizing this Catch-22," *id.* at 276 (Hardiman, J., dissenting), the government claims (at 8) that manufacturers could "withdraw at least 30 days in advance." But "CMS lacks authority to offer this expedited exit option." *BMS*, 155 F.4th at 277 (Hardiman, J., dissenting).

Respectfully submitted.

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