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

REPLY BRIEF FOR PLAINTIFFS-APPELLANTS

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INTRODUCTION

The IRA grants extraordinary power to federal regulators over the prescription drug market. Under the law's Drug Price Negotiation Program, there can be no challenge to CMS's selection of drugs for a purported "negotiation" or to the ultimate "negotiated" price. Manufacturers' only option is to refuse to negotiate—triggering fines that no manufacturer can afford to pay—or to withdraw every single one of its drugs from Medicare and Medicaid entirely—leaving vulnerable patients without access to important life-saving medicines. No ordinary market actor brings that kind of leverage to the "negotiating" table. Yet CMS was apparently not content with the existing scope of that already sweeping power, pushing these limits even further in its Guidance by unlawfully reinterpreting the statutory text to expand the scope of "qualifying single source drug" and adding an atextual "bona fide marketing" requirement.

To avoid the tall task of defending that unlawful Guidance on the merits, the government resorts to its customary threshold-argument playbook, contending that AstraZeneca lacks standing and that it is statutorily barred from seeking judicial review. Both of those arguments are meritless. As to standing, AstraZeneca has been forced to adapt its business decisions to account for the ways in which CMS's unlawful Guidance will affect drug development and valuation going forward. That is classic Article III injury-in-fact.

As to the judicial-review bar, the government urges this Court to hold that CMS enjoys unfettered, unreviewable discretion to interpret its authorizing statute as it likes. That is not what the judicial review-bar in 42 U.S.C. § 1320f-7 states. The Court should decline the government's request to rewrite the clear text of Section 1320f-7 in a bid to further expand CMS's authority by wholly insulating its unlawful Guidance from judicial review.

The government's insistence that CMS's Guidance is exempt from judicial review further compounds the already stark due process shortcomings with the Program. The government does not argue otherwise. It does not say the Program provides a constitutionally sufficient opportunity to be heard or that CMS is a neutral, detached adjudicator—nor could it. Instead, the government argues that AstraZeneca has no protected property interest to begin with and that participation in the Program is voluntary. To be clear: Patent rights are property rights, and patent holders like AstraZeneca have the inherent and exclusive right to determine what price to charge for their patented products. As for voluntariness, that is a takings concept that has no relevance here. But even if it did, there is nothing "voluntary" about the Program.

At bottom, the government's due process theory comes down to the idea that it is just another "buyer[] in the marketplace" and, like any other buyer, it has the right to "negotiate" with AstraZeneca. Response Br. 55. That is doubly wrong. To

begin with, the government is not *buying* AstraZeneca's products. The government is an insurer. It does not purchase any drugs directly from AstraZeneca, whether at the actual or "negotiated" price of the drug.

Nor does the government stand on the same footing as any other "market participant." Response Br. 50. As the Fifth Circuit recently observed, when the only other options are draconian penalties that "no manufacturer could afford to pay" or "walking away" and "losing the" entire Medicaid and "Medicare market for its drugs," thereby jeopardizing patients' access to life-saving medications, "basic economic rationality" dictates that manufacturers are "all but certain" to acquiesce to CMS's demands. *National Infusion Ctr. Ass'n v. Becerra*, No. 24-50180, __ F.4th __, 2024 WL 4247856, at *5 (5th Cir. Sept. 20, 2024). No ordinary market participant could leverage that type of coercive power and credibly claim the Program is "voluntary." The Program's watershed expansion of federal regulatory authority violates due process.

ARGUMENT

I. THE COURT HAS JURISDICTION OVER ASTRAZENECA'S APA CLAIMS.

The government's jurisdictional argument boils down to the idea that even though CMS's atextual statutory re-interpretation is presently affecting AstraZeneca's decisionmaking, AstraZeneca does not suffer any harm and, even if

it had, AstraZeneca has no judicial resource. The government is wrong on both counts.

A. AstraZeneca has standing to assert its APA claims.

AstraZeneca has established an injury-in-fact, traceable to the challenged agency action, that would likely be redressable by a judicial decision invalidating CMS's Guidance.

CMS's Guidance has impacted AstraZeneca's research, development, and marketing decisions, as well as its current ability to value FARXIGA in the context of the Program. Opening Br. 26-33. That is injury-in-fact. The government attempts to minimize these harms by disputing whether CMS's unlawful definition of qualifying single source drug and bona fide marketing requirement directly affect FARXIGA. *See* Response Br. 31-33. Because of the uncertainty created by CMS's Guidance, AstraZeneca faces present harm to its "business decision-making abilities," including research and development decisions, its ability to further innovate with FARXIGA, and its ability to value FARXIGA for purposes of deciding whether to participate in the Program. Opening Br. 27-33; *see* JA86-93 ¶¶ 104-138. That these scenarios are, in the government's estimation, "extremely unlikely to occur," illustrates the problem. Response Br. 31 (quoting JA24). As AstraZeneca's corporate declarant explained, "AstraZeneca has thus been forced to make decisions now based on the agency policies currently in place," assuming for

its decisionmaking processes that these otherwise-unlikely eventualities will come to pass. JA106 ¶ 32; Opening Br. 38.

The government's rebuttals betray this fundamental problem. The government contends that FARXIGA "in all likelihood" will face generic competition at some point in the future "and would thus no longer be eligible for selection" under the bona fide marketing requirement. Response Br. 32. That argument assumes the answer. As the Fifth Circuit just explained, CMS's "criteria for" deciding whether a drug meets the amorphous "bona fide marketing requirement" "are unclear." *National Infusion Ctr. Ass'n*, 2024 WL 4247856, at *4 & n.8. That uncertainty is one of the reasons AstraZeneca challenged the bona fide marketing requirement—AstraZeneca does not and cannot know whether FARXIGA will *in fact* "no longer be eligible for selection" due to "generic competition." Response Br. 32. So AstraZeneca must plan today as if FARXIGA will remain on the list in perpetuity. *See* JA99, 105-106 ¶¶ 11, 27-28, 31-32.

Likewise, the government draws exactly the wrong conclusion about the effect of CMS's re-definition of "qualifying single source drug" on the current clinical trials for FARXIGA. *See* Response Br. 32. Although clinical trials are currently focused on combination products, AstraZeneca is actively engaged in "other ongoing drug development efforts involving the same active moiety as FARXIGA," which "could result in" a new product that would be "treated as the

same [qualifying single source drug] as FARXIGA" under the Guidance—but not the statute. JA103 ¶ 23. AstraZeneca must consider the effect of CMS's Guidance in deciding whether to continue pursuing those development efforts into clinical trials. *See* JA104 ¶ 26. The same is true for "follow-on therapies for new indications and improvements" to other drugs. JA106 ¶ 30.

The government's objections (at 33, 40-41) regarding the Guidance's time-horizon face the same stumbling block. Regardless of whether CMS later decides to correct course and adhere to the statute's plain text, AstraZeneca "must make decisions now" as if CMS's atextual interpretations are in fact the law. JA106 ¶ 32. CMS, moreover, has demonstrated no intent to back down from its current approach; the just-released final guidance for program year 2027 is substantively identical. *See* CMS, *Medicare Drug Price Negotiation Program: Final 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 in 2026 and 2027*, at 167, 278-279, 292-293 (Oct. 2, 2024). That is not surprising—after all, as the government sees things, CMS's unlawful statutory interpretation is wholly insulated from judicial review. *See* Response Br. 41-47.

More to the point, any uncertainty is of the government's making, thanks to CMS's decision to adopt an unsupportable statutory interpretation implemented through a black-box process. Parroting the District Court, the government says the

only "uncertainty" is "the uncertainty created by this lawsuit." Response Br. 39-40; *see* JA35. As AstraZeneca has explained, this approach turns the usual Article III rule on its head by asking the Court to pre-judge the merits of AstraZeneca's suit; courts must assume the merits of the plaintiff's argument in assessing standing. *See* Opening Br. 34-35. The government says nothing—not one word—in response.

The government next argues that any injury AstraZeneca faces today is *still* too speculative, citing *National Shooting Sports Foundation v. Attorney General of New Jersey*, 80 F.4th 215 (3d Cir. 2013) and *Clapper v. Amnesty International USA*, 568 U.S. 398 (2013). *See* Response Br. 34-35. *National Shooting Foundation* involved the "specialized test" applicable to pre-enforcement challenges, which requires the plaintiff to show an "inten[t] to take action." 80 F.4th at 219. The plaintiff there failed to meet that test because it had asserted only a "subjective chill." *Id.* at 220 (quotation marks omitted). That is nothing like this case, where AstraZeneca is *already* being forced to adjust its decisionmaking in response to CMS's Guidance. As for *Clapper*, those plaintiffs feared they might be subject to ongoing surveillance under one of several such government programs. 568 U.S. at 406-407. Because those future fears were too speculative, plaintiffs could not manufacture standing by "tak[ing] costly and burdensome measures to" prevent that "hypothetical future harm" from coming to pass. *Id.* at 415-416.

"[T]he reality of the long-range economic planning involved in the sound management of an enterprise" sets this case apart. *Great Lakes Gas Transmission Ltd. P'ship v. FERC*, 984 F.2d 426, 431 (D.C. Cir. 1993). In *Clapper*, there was no need for the plaintiffs to proactively adjust their business practices based on speculative assumptions; plaintiffs maintained the ability to mount a near-immediate response should their fears come to pass. Whether to "talk in generalities rather than specifics," "avoid certain e-mail and phone conversations," or conduct "in-person conversations," is a decision that can be made moments, days, or even weeks before that correspondence takes place. *See* 568 U.S. at 415.

Courts consistently treat longer-term business decisions differently. Opening Br. 31-33 (collecting cases). For example, in *Great Lakes*, FERC "granted Great Lakes a certificate to expand its pipeline facility" on the condition that Great Lakes would have to cover the construction costs if, at any point in the next 33 years, Great Lakes' supplier did not have a license from the Canadian National Energy Board to export enough gas to meet the pipelines' expanded capacity. 984 F.2d at 428-429. The Canadian Board had already granted the requisite license for 15 years—the full length of Great Lakes' contract with its supplier. *Id.* at 428, 430 & n.3. The Commission thus argued that any potential risk of harm was many years down the line and relied on a chain of unlikely contingencies. *See id.* at 430. The D.C. Circuit disagreed, holding that FERC's order was presently affecting "Great Lakes' business

decisions," as the company had to "adjust its finances and investment strategy" now to account for that hypothetical future "risk of underutilization." *Id.* at 430-431.

The Fifth Circuit's recent decision finding standing for the National Infusion Center Association (NICA) is also instructive. There, the court held that NICA, which is comprised of members that provide treatments using certain drugs, had associational standing to challenge the Program as unconstitutional. *National Infusion Ctr. Ass'n*, 2024 WL 4247856, at *4-7. NICA argued that its members suffered injury-in-fact "because the Program currently impacts their projected revenue and their corresponding ability to . . . run their business." *Id.* at *7. The government objected that this was too speculative, but the court "disagree[d]," explaining that "the threat of regulation" had reduced NICA's members' "bargaining power" by affecting their present ability to "raise debt and equity capital." *Id.* Nothing about those current harms was "conjectural," the court concluded. *Id.*

Or consider *Biotechnology Industry Organization v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007). The Federal Circuit there found standing to challenge a D.C. law restricting prices for patented drugs where a pharmaceutical manufacturer "declared that in light of the Act, it 'will need to consider the impact of its decisions as to the timing and pricing of launches.' " *Id.* at 1371. "Even if" the manufacturer did not ultimately make any changes, "the need to monitor and consider" these issues "in light of the Act" was sufficient to confer standing. *Id.*

These cases reflect the common-sense reality that when companies must account for agency action in longer-range business planning, that can confer standing, even if the ultimate effects of that agency action remain unclear to some degree. Said differently, for the companies in *Great Lakes*, *National Infusion Center Association*, and *Biotechnology Industry Organization*, corporate realities made it necessary to consider the effect of the challenged action during the agency's existing decisionmaking cycles. That is precisely the type of injury AstraZeneca suffers.

The realities of the drug-development process and AstraZeneca's "science-led, patient-focused" approach require AstraZeneca to "invest[] significant time and money to identify, test, and develop new drug candidates." JA98 ¶¶ 6-7. That process "can take decades and hundreds of millions of dollars," meaning AstraZeneca must make decisions today about potential therapies to invest in for the future. JA98 ¶ 7. That decisionmaking process necessarily requires AstraZeneca to consider the risks imposed by CMS's Guidance today in making future investment decisions. The same is true with respect to AstraZeneca's present-day decisions about how to value FARXIGA—indeed, the Program's regimented deadlines mean AstraZeneca cannot put those decisions off. *See* Opening Br. 11.

Finally, the government re-treads the District Court's supposed slippery slope. Citing *New England Power Generations Ass'n v. FERC*, 707 F.3d 364 (D.C. Cir. 2013), the government posits that if AstraZeneca has standing here, so will any

plaintiff who merely "dislike[s] a law or government action." Response Br. 38-39 (quoting JA23). The government made that same argument in the Fifth Circuit, relying on that same case, and the court rejected it: "[A]dopting [plaintiff's] standing theory here would not confer standing in all circumstances. This case does not concern a statute that applies generally to all participants in a given market. It concerns a statute that picks out specific drugs for special treatment." 2024 WL 4247856, at *7. Just as in *National Infusion Center Association*, moreover, AstraZeneca does not allege a "marginal effect" on business; it argues that CMS's Guidance directly and currently "impacts" a "critically important" "aspect of [its] business," *id.* (quotation marks omitted)—decisions about which innovative, life-saving medical advancements to pursue now, to help the patients of tomorrow. That is more than enough to satisfy the "very generous" "injury-in-fact requirement." *Cottrell v. Alcon Lab'ys*, 874 F.3d 154, 162 (3d Cir. 2017) (quotation marks omitted).

For these same reasons, AstraZeneca's harms are traceable to CMS's unlawful Guidance and a decision setting that Guidance aside would likely redress the effects that Guidance has on AstraZeneca's business decisionmaking and ability to value FARXIGA. Opening Br. 40-41. Finally, with regard to prudential standing, the government does not dispute that AstraZeneca satisfies that test. *Id.* at 41-42. AstraZeneca has standing.

B. The judicial-review bar does not preclude AstraZeneca's APA claims.

The government's alternative jurisdictional argument fares no better. In a bid to further expand its already vast power under the Program, the government contends that the judicial-review bar—which bars review of CMS's selection and determination-decisions with respect to particular drugs—precludes review of AstraZeneca's claims. That is wrong. The judicial-review bar does not apply to AstraZeneca's facial challenge to CMS's Guidance.

1. The Supreme Court "has long applied a strong presumption favoring judicial review of administrative action." *Mach Mining, LLC v. EEOC*, 575 U.S. 480, 489 (2015). "This default rule is well-settled, and Congress is presumed to legislate with it in mind." *Salinas v. United States Railroad Ret. Bd.*, 592 U.S. 188, 197 (2021) (quotation marks and citation omitted). The reason for this rule is simple: Congress knows "that legal lapses and violations occur," and "rarely intends to prevent courts from enforcing its directives to federal agencies." *Mach Mining*, 575 U.S. at 489, 486. The government bears a "heavy burden" to overcome that "strong presumption." *Id.* at 486 (quotation marks and citation omitted). It must produce "clear and convincing evidence of congressional intent" to exempt the executive from judicial oversight. *Guerrero-Lasprilla v. Barr*, 589 U.S. 221, 229 (2020) (quotation marks and citation omitted). Any "ambiguity . . . must be resolved in" favor of permitting judicial review. *Salinas*, 592 U.S. at 197.

The government does not mention this "strong presumption" once. Nor does it acknowledge that *it* bears the "heavy burden" of overcoming it. Its silence is understandable; the government cannot carry that burden here.

42 U.S.C. § 1320f-7 provides that "[t]here shall be no . . . judicial review of" eight specified actions under the Program: (1) "[t]he selection of drugs" for negotiation under section 1320f-1(b)"; (2) "the determination of negotiation-eligible drugs under section 1320f-1(d)"; (3) "the determination of qualifying single source drugs under section 1320f-1(e)"; (4) "the application of section 1320f-1(f)," which concerns delaying selection and negotiation of biologics; (5) "[t]he determination of a maximum fair price under" section 1320f-3(b), (f); (6) "[t]he determination of renegotiation-eligible drugs under section 1320f-3(f)(2)"; (7) "the selection of renegotiation-eligible drugs under section 1320f-3(f)(3)"; and (8) "[t]he determination of" what constitutes "a unit" of a drug, which affects how CMS negotiates "the maximum fair price of a selected drug pursuant to section 1320f(c)(6)." 42 U.S.C. § 1320f-7. Each of those carefully delineated categories involves CMS's decision about *which drugs* are subject to the program and *what price* to charge.

AstraZeneca did not challenge FARXIGA's selection, the determination that FARXIGA was negotiation-eligible or was a "qualifying single source drug," or any price determination. Rather, AstraZeneca challenged CMS's "unlawful definition

of a Qualifying Single Source Drug" and unlawful "interpretation of the statutory approved and marketed . . . requirement." JA91-92 ¶¶ 125, 133 (quotation marks and ellipses omitted). In other words, AstraZeneca did not challenge CMS's Guidance "as applied" to the selection of FARXIGA (or any other particular product); it brought a facial challenge arguing that CMS unlawfully re-defined "qualifying single source drug" and added a "bona fide marketing" requirement contrary to the IRA's plain text.

The government does not say otherwise. It does not contend that AstraZeneca's suit directly challenges any of the precluded agency actions, nor could it. Instead, it argues that AstraZeneca's APA claims are precluded because they "*implicate[]* the determinations for which Congress barred review." Response Br. 42 (emphasis added). As the government sees things, by precluding review of certain narrow categories of agency action, "Congress could not have made clearer its intent to preclude judicial review" of suits that more broadly "implicate" those agency actions. *Id.* at 42-43.

Beg to differ. Congress could have "made clearer its intent" by saying that judicial review is precluded over any decisions that "implicate" these eight narrow categories, rather than just the specific decisions themselves. It did not, and this Court must "assume Congress meant what it said" in creating "a jurisdictional bar." *National Union Fire Ins. Co. of Pittsburgh, Pa. v. City Sav., F.S.B.*, 28 F.3d 376,

389 (3d Cir. 1994). The Court will also recall that Congress explicitly instructed CMS to "implement [the Program]" using "guidance." 42 U.S.C. § 1320f (note). Congress could have specified in the judicial-review bar that any review of CMS's *guidance* was precluded; it did not do that either. *Compare. id.* § 1395ff(e)(1) (precluding review of "[a] regulation or instruction that relates to a method for determining the amount of payment under" Medicare Part B).

Nor did Congress use the capacious language it commonly relies on to signal a sweeping jurisdictional bar. For example, Congress has elsewhere "strip[ped] 'jurisdiction to review' . . . any other cause or claim *arising from or relating to* the implementation or operation of' " agency action. *United States v. Dohou*, 948 F.3d 621, 626 (3d Cir. 2020) (emphasis added) (quoting 8 U.S.C. § 1252(a)(2)(A)). "This 'relating to' language is 'typically construed as having a broad, expansive meaning' " to bar "claims indirectly connected to" the action for which review is barred. *Id.* (quotation marks and citation omitted). "But when a jurisdiction-stripping provision . . . omits capacious phrases like 'relating to,' it bars only direct review" of the agency's specific determination. *Id.* That "relating to" language is notably absent from the IRA.

So, too, is language saying review is precluded for the entire "process" surrounding the Program. Take 42 U.S.C. § 1395nn, where Congress instructed that " 'the Secretary shall promulgate regulations to carry out' " a particular "process"

and prohibited judicial review of "the process," full stop. *Id.* § 1395nn(i)(3)(A)(iv), (I). That type of "unqualified" judicial-review bar "preclud[es] review of 'the process' in its broadest sense," in stark contrast to narrower provisions that delineate a specific "list" of unreviewable actions. *Knapp Med. Ctr. v. Hargan*, 875 F.3d 1125, 1130-31 (D.C. Cir. 2017) (quoting 42 U.S.C. § 1395nn(i)(3)(I)). Congress adopted the narrower approach here, and the Court should honor that choice. *See, e.g.*, *American Clinical Lab'y Ass'n v. Azar*, 931 F.3d 1195, 1205 (D.C. Cir. 2019) (holding jurisdiction-stripping provision inapplicable where government's argument was "plausible, but the text does not compel it").

The government's other case citations fare no better. Relying on a string of decisions largely involving challenges to specific payment or reimbursement determinations, the government says there is no difference between a challenge to CMS's Guidance and one to CMS's " 'determination of qualifying single source drugs.' " Response Br. 43-44 (quoting 42 U.S.C. § 1320f-7(2)). As the D.C. Circuit has explained, however, "even if judicial review of a [specific] decision is barred," affected parties are still "free to challenge the general rules leading to" that decision. *Florida Health Sciences Center, Inc. v. Secretary of HHS*, 830 F.3d 515, 521 (D.C. Cir. 2016) (quotation marks and citation omitted). The question is whether the litigant is truly challenging a "general rule[]" or "is simply trying to undo" "a

shielded determination" "by recasting its challenge" as one to "the general rules leading to [that determination]." *Id.* at 522.

Each of the government's cited cases (at 43-44) falls into the latter category: They were challenges to a shielded determination dressed up in "general rule" garb. In *John Balko & Associates Inc. v. Secretary of HHS*, this Court confronted a statute that barred judicial review of the "determination[]" that a particular Medicare provider had a "high level of payment error." 555 F. App'x 188, 192-193 (3d Cir. 2014) (quoting 42 U.S.C. § 1395ddd(f)(3)). If an auditor determines there has been a "high level of payment error," the auditor may use a particular statistical method to calculate the amount of overpayment the provider owes. *Id.* at 189. The provider there "appealed from the determination that it was liable for [a certain] amount," arguing the auditor used the wrong "procedure[]" in determining the provider had "a high level of payment error." *Id.* at 193. This Court held that challenge unreviewable.

The government's remaining out-of-circuit citations are in accord. Three of them involved challenges under a provision precluding review of "[a]ny estimate of the Secretary for purposes of determining" "[a]djustments to" Medicare payments to disproportionate share hospitals. 42 U.S.C. § 1395ww(r)(3). The adjustment is the product of three statutory factors estimated by the Secretary. *Id.* § 11395ww(r)(2). For factor three, which was specific to "each . . . hospital,"

Congress instructed the Secretary to measure using "appropriate data." *Id.* § 1395ww(r)(2)(C).

In *Florida Health Sciences Center*, the hospital argued that the Secretary's estimate for factor three got the math wrong—according to the hospital, using the right numbers "established that it was entitled to $3 million more." 830 F.3d at 517-518. The D.C. Circuit held the hospital could not "challenge the Secretary's refusal to use" certain data the hospital had submitted in rendering that hospital-specific estimate, as that would eviscerate the bar against reviewing "any estimate of the Secretary." *Id.* at 518-521. The hospital had "not brought a challenge to any general rules leading to the Secretary's estimate," the court explained; it was "simply trying to undo the Secretary's estimate . . . by recasting its challenge to the Secretary's choice of data as an attack on the general rules leading to her estimate." *Id.* at 522.

Likewise, in *DCH Regional Medical Center v. Azar*, the hospital nominally challenged "the methodology adopted and employed" to calculate the hospital-specific estimate for factor three but also sought an order vacating the Secretary's calculation and directing the agency to recalculate the estimated amount owed. 925 F.3d 503, 505 (D.C. Cir. 2019) (quotation marks omitted). The D.C. Circuit found that challenge similarly precluded: "In this statutory scheme, a challenge to the methodology for" determining those estimates "is unavoidably a challenge to the estimates themselves." *Id.* at 506. A ruling in the plaintiff's favor on the

"methodology" challenge would thus inevitably give the plaintiff what it "explicitly" sought—and what the statute forbid—an order "undo[ing]" the estimate itself. *Id.* at 508.

The Second Circuit applied that same logic in *Yale New Haven Hospital v. Becerra*, declining to review an argument that a hospital-specific estimate "should be set aside" because the Secretary failed to abide by notice and comment in choosing what data to use. 56 F.4th 9, 15-20 (2d Cir. 2022). And the government's remaining citations follow in this same vein. *See Mercy Hosp., Inc. v. Azar*, 891 F.3d 1062, 1067 (D.C. Cir. 2018) (hospital's challenge to its specific reimbursement rate-adjustment under 42 U.S.C. § 1395ww(j) barred where the statute precluded review of the ultimate rate, expressly "tie[d] together" the adjustment and rate determinations, and any ruling that the adjustment was flawed would necessarily "ask[] the court to remand the [final rate] to be recalculated" using the correct adjustment); *Texas All. for Home Care Servs. v. Sebelius*, 681 F.3d 402, 410 (D.C. Cir. 2012) (challenge to rule articulating financial standards for contract-bidders was precluded under provision barring review of "the awarding of contracts," where the statute specifically "require[d] the formulation and application" of such standards).[1]

[1] The government describes *Knapp Medical Center* as "similar" to *DCH Regional Medical Center*. Response Br. 44. That is incorrect. The court's decision in *Knapp* rested primarily on the fact that the judicial-review bar was "unqualified" and explicitly encompassed "review of the process in its broadest sense." *Knapp Med. Ctr.*, 875 F.3d at 1130-31 (quotation marks omitted); *see supra* pp. 15-16.

AstraZeneca's challenge is nothing like those. AstraZeneca has not sought an order setting aside FARXIGA's "selection" or "vacating" CMS's determination of the so-called "maximum fair price" for a specific drug. *See* 42 U.S.C. § 1320f-7(2)-(3); *compare, e.g.*, *Yale New Haven Hosp.*, 56 F.4th at 18; *DCH Reg'l Med. Ctr.*, 925 F.3d at 505. AstraZeneca's suit is a challenge to a "general rule"—not a challenge made "solely in order to reverse an individual decision that [the Court] otherwise cannot review." *Florida Health Scis. Ctr.*, 830 F.3d at 521 (quotation marks, ellipses, and citation omitted). AstraZeneca challenged the Guidance because it violates the plain text of the IRA and thereby exceeds CMS's authority under the Program. *See* ECF 16 ¶¶ 49-53, 59-89, 123-138. Indeed, as the government elsewhere notes, it is "undisputed" that CMS's Guidance "had no bearing on Farxiga's selection for negotiation." Response Br. 30. Nor does the statute directly and intimately link the challenged determinations with the issue for which review is barred, making it impossible to review AstraZeneca's challenge "without reviewing the [barred decision] itself." *Compare, e.g., Yale New Haven Hosp.*, 56 F.4th at 20 (quotation marks and citation omitted). AstraZeneca's APA challenge is accordingly reviewable.

2. CMS's Guidance is also reviewable as *ultra vires*. CMS's Guidance was plainly "unauthorized" in that it exceeded "the scope of power allowed or granted by law" by re-interpreting the plain text of the IRA. *See Bakran v. Secretary, DHS*,

894 F.3d 557, 561 n.2 (3d Cir. 2018) (quoting *Ultra Vires*, Black's Law Dictionary (10th ed. 2014)) (ellipses, brackets, and quotation marks omitted). The government's contrary argument rests on a three-factor test articulated by the D.C. Circuit, which this Court has never adopted. *See* Response Br. 46. Even assuming that test applies, however, the government's arguments fail. Having conceded that there is no alternative procedure available to review AstraZeneca's claims, the government focuses on whether "the statutory preclusion of review is implied rather than express" and whether "the agency plainly acted in excess of its delegated powers." Response Br. 46 (quoting *DCH Reg'l Med. Ctr.*, 925 F.3d at 509). Both favor AstraZeneca. For the reasons explained, the statutory preclusion bar does not expressly prohibit review of challenges to CMS's Guidance; it only bars review of specific "selection" or "determination" decisions, none of which AstraZeneca challenges. *Supra* pp. 12-20; *see* Response Br. 42-43 (arguing AstraZeneca's challenge "implicates" or is "intertwined with" the barred determinations) (quotation marks omitted).

As for whether CMS "plainly acted in excess of its delegated powers and contrary to a specific prohibition in the statute that is clear and mandatory," Response Br. 46 (citation omitted), that is exactly what AstraZeneca alleges. Where the statute expressly defines "qualifying single source drug" and does not include a "bona fide marketing" requirement, CMS cannot re-interpret the text to mean

something different. *See* Opening Br. 14-17, 27-30; ECF 16 ¶¶ 49-53, 59-89, 123-138. For this reason, too, AstraZeneca's challenge is reviewable.

II. THE PROGRAM VIOLATES THE DUE PROCESS CLAUSE.

The government does not dispute that the Program fails to provide any of the process the Constitution requires. The government does not contend that the Program provides AstraZeneca with a meaningful opportunity to be heard, on either the front-end or the back-end, or that CMS is a "neutral and detached adjudicator." *Concrete Pipe & Prods. of Cal., Inc. v. Construction Laborers Pension Tr. for S. Cal.*, 508 U.S. 602, 617-618 (1993) (quotation marks and citation omitted). Nor could it—particularly given its view that judicial review of CMS's unlawful Guidance is impermissible.

Instead, the government's due process defense reduces to two points: AstraZeneca has no property interest in its patents, and participation in Medicare is voluntary. Neither has merit.

1. The government denies that AstraZeneca has any protected property interest to begin with. That is flat wrong. Patent rights are property rights, and patent holders have the inherent and exclusive right to determine what price to charge for their patented products. Opening Br. 42-45. As Congress explained in enacting the Hatch-Waxman Act, which established the U.S. system of generic-drug regulation, "[p]atents are designed to promote innovation by providing the right to

exclude others from making, using, or selling an invention. They enable innovators to obtain greater profits than could have been obtained if direct competition existed. These profits act as incentives for innovative activities." *Biotechnology Indus. Org.*, 496 F.3d at 1373 (quoting H.R. Rep. No. 98–857, at 17 (1984)). Laws "limiting the full exercise of the exclusionary power that derives from a patent" upset that "framework of rewards and incentives." *Id.* at 1374. That describes the Program to a T. Even outside the patent context, the Supreme Court has long analyzed price-control regimes under a procedural due process lens, confirming those regimes implicate property interests even where there is no compelled sale. *Bowles v. Willingham*, 321 U.S. 503, 517 (1944); *Yakus v. United States*, 321 U.S. 414, 438 (1944).

The government maintains that the IRA's price-control program is an ordinary example of "how the marketplace works," and that AstraZeneca is "free to negotiate pricing with any buyers in the marketplace, including the government." Response Br. 50, 55. This is a curious argument. The government has intentionally constructed this market so that it is not a "buyer" of drugs under Medicare. It is a buyer of insurance—and a buyer-once-removed at that, because it contracts out responsibility for Medicare Part D to private plans. *See, e.g.*, 42 U.S.C. § 1395w-112(b)(1). Under Medicare Part D, the drug manufacturer offers discounts to the private plans, those plans bid to be accepted into the Medicare Part D program, and

CMS selects the eligible plans based on costs. At no point does CMS buy drugs directly from the manufacturer. Nor does CMS reimburse the insurer directly for the actual or "negotiated" price of the drug; reimbursement rates are set by a separate statutory formula. The more apt analogy is of a market actor using its dual role as regulator to reach out and direct the behavior of certain cherry-picked entities elsewhere in the drug distribution chain as a round-about way to influence the behavior of the parties with whom they directly contract.

And even then, the government is not remotely just "any" participant in the marketplace. Response Br. 55. As the Fifth Circuit recently explained, "[m]anufacturers who fail to reach an agreement with [CMS] are subject to escalating fines ranging from 187.5% to 1,900% of the drug's price that can only be suspended if the manufacturer terminates Medicare coverage for all drugs that it produces." *National Infusion Ctr. Ass'n*, 2024 WL 4247856, at *1. Indeed, "[t]he Congressional Budget Office estimated that the tax on selected drugs for which no agreement was reached would raise no revenue because no manufacturer could afford to pay it." *Id.* at *2 (citation omitted). No ordinary "buyer[] in the marketplace" has the power to fine into oblivion a private party that declines to agree to its dictated terms. *See* Response Br. 55. As for the "opt-out" option, that is no option at all. "[B]asic economic rationality" dictates that a manufacturer is more likely to agree to an unprofitable price for a selected drug than to refuse and "lose[]

the Medicare [and Medicaid] market for all of its drugs." *National Infusion Ctr. Ass'n*, 2024 WL 4247856, at *5. No ordinary "buyer[] in the marketplace" can exert that kind of monopsonistic leverage, either. *See* Response Br. 55; JA100 ¶ 13 ("Medicare and Medicaid collectively account for approximately more than 40% of AstraZeneca's gross revenues in the U.S.").

The government's comparison (at 9-10, 49-50) to the Departments of Defense and Veterans Affairs' drug-pricing program similarly backfires. Unlike CMS, those agencies actually *are* purchasers of drugs in the marketplace, so it is perhaps unsurprising that they negotiate the prices that they pay as buyers. Nor can the government wield the cudgel of oppressive fines under the Departments of Defense and Veterans Affairs' program to force manufacturers to acquiesce to its pricing demands. *Cf.* Opening Br. 13. The government's decisions in that program also are subject to judicial review. *See, e.g.*, *Coalition for Common Sense in Gov't Procurement v. Secretary of Veterans Affs.*, 464 F.3d 1306, 1312, 1316-18 (Fed. Cir. 2006) (finding jurisdiction to review letter providing guidance on 38 U.S.C. § 8126's applicability under 38 U.S.C. § 502, which authorizes review of "substantive and interpretive rules").

2. The government's argument that there is no due process right at issue because participation in Medicare is "voluntary" fails out of the gate. "Voluntariness" is a takings concept; it has no bearing on a due process inquiry. Opening Br. 52-56.

The reason for this distinction is simple: The government cannot "take" property that has been voluntarily relinquished. *See, e.g.*, *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1007 (1984). The essence of procedural due process, however, is that the government must turn square corners when depriving its citizens of a protected interest. Holding that a private citizen forfeits that constitutional right when voluntarily engaging with a government program would be nonsensical. Otherwise, the government could take away citizens' rights to social security benefits, healthcare, utilities, or disability benefits with no hearing, no oversight, and no judicial review. *Contra Goldberg v. Kelly*, 397 U.S. 254 (1970); *Memphis Light, Gas & Water Div. v. Craft*, 436 U.S. 1 (1978); *Kelly v. Railroad Ret. Bd.*, 625 F.2d 486, 488 (3d Cir. 1980). That is not and should not be the law.

In response, the government doubles down on the argument that there is no meaningful difference between the Takings Clause and Due Process Clause . . . citing more takings decisions. *See* Response Br. 52-54 (citing *Baker Cty. Med. Servs., Inc. v. U.S. Atty. Gen.*, 763 F.3d 1274, 1279-80 (11th Cir. 2014); *Garelick v. Sullivan*, 987 F.2d 913, 917 (2d Cir. 1993); *Whitney v. Heckler*, 780 F.2d 963, 972 n.12 (11th Cir. 1986); and *St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 875 (7th Cir. 1983)). The government does not even try to distinguish the many cases explaining that property rights and voluntariness are different in these distinct contexts. *See* Opening Br. 53-55 (collecting cases). Nor does it explain *why*

voluntariness should have any bearing on the due process inquiry; it just says again and again that "participation in Medicare is voluntary." *E.g.*, Response Br. 4.

Unable to muster a substantive response, the government resorts to pointing fingers, blaming AstraZeneca for introducing the voluntariness issue to this case. *See id.* at 52 n.4. The record reflects otherwise: The *government* raised this concept for the first time in the District Court, citing the same takings cases it invokes here. ECF 21-1, at 44-48; *see also* ECF 61, at 24-27. The District Court adopted that theory without explaining how or why it translated to a due process challenge, either. *See* JA42-46.

Nor is it any answer for the government to say it will continue to pay AstraZeneca for its products. *See* Response Br. 53-55. "[T]he deprivation of private property without due process is likewise a constitutional violation even if compensation is paid." *Theodorou v. Measel*, 53 F. App'x 640, 643 (3d Cir. 2002). Again, the reason is simple: If you are entitled to $100 in benefits under a voluntary government program, but the government instead gives you only $25, the Due Process Clause guarantees a "constitutionally sufficient" opportunity to challenge that decision before an impartial adjudicator. *See Swarthout v. Cooke*, 562 U.S. 216, 219 (2011). That is why the Supreme Court has held that price-control programs are still subject to procedural due process requirements, whether or not the decision to

join the price-controlled program was voluntary in the first place. *Bowles*, 321 U.S. 503; Opening Br. 54-55. The government has no answer to *Bowles*, either.

In the end, the government's argument comes down to the idea that "no one has a 'right' to sell the government that which it does not wish to buy." Response Br. 49 (quoting *Coyne-Delany Co. v. Capital Dev. Bd.*, 616 F.2d 341, 342 (7th Cir. 1980) (per curiam)). Again, the government is not *buying* from AstraZeneca. *Supra* pp. 23-24. But even where the government does "wish to buy" a product, it does not have the right to use its coercive power to artificially restrict the property owner's right to profit from their product, without adequate due process protections. That is what happened here, and the Court should find it unconstitutional.

CONCLUSION

For the foregoing reasons and those in AstraZeneca's opening brief, AstraZeneca respectfully requests that this Court reverse the judgment below and remand for further proceedings.

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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 6,476 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 October 7, 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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