IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP and ASTRAZENECA AB, Plaintiffs, v. XAVIER BECERRA, in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, *et al.* Defendants.	)	Civil Action No. 23-931-CFC

BRIEF IN OPPOSITION TO
DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

AND

REPLY IN SUPPORT OF PLAINTIFFS'
MOTION FOR SUMMARY JUDGMENT

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Dated: December 1, 2023

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INTRODUCTION

The Inflation Reduction Act grants extraordinary power to federal regulators over the prescription drug market. Under the law's Drug Price Negotiation Program, the Secretary of Health and Human Services selects drugs and biologics for purported "negotiation." Those products are then subject to a "Maximum Fair Price" dictated by CMS. There can be no challenge to the selection. There can be no challenge to the price. Manufacturers' only option is to withdraw from the Program—but only if they forfeit much or all of the market for *all* of their drug products—leaving vulnerable patients without access to important life-saving medicines.

The Government's cross-motion confirms its stark view on the scope of its administrative power: Courts should clear the way for the agency to implement the Program however it sees fit. The Government argues, at bottom, that the agency enjoys unfettered, unreviewable discretion to interpret the statute to its liking. That concept runs roughshod over due process from start to finish. It hands the agency absolute authority to unilaterally dictate prices. It permits the agency to promulgate and enforce unlawful interpretations of key statutory terms. All of this harms both AstraZeneca and patients who depend on its groundbreaking therapies. The Government argues that AstraZeneca has no means of redress. The law says otherwise.

The agency's Guidance is unlawful under the Administrative Procedure Act for two reasons. First, in its eagerness to sweep as many products as possible into the Program, CMS lumps multiple drug products (approved at different times and under different applications) within the statutory definition of a single "Qualifying Single Source Drug." Second, CMS redrafts the statute's text with a new, atextual requirement that the marketing of a competing generic product be "bona fide" in the eyes of the agency. These subjective standards contravene the plain terms of the Inflation Reduction Act.

The Government would prefer to avoid the tall task of defending the Program on the merits. Instead, it offers up various threshold arguments, none of which have merit. The Government argues that AstraZeneca lacks standing to sue. That is not correct. AstraZeneca takes on enormous risks in developing new uses for the active moieties of existing drug products. It takes vast amounts of time and the support of significant monetary investment to identify, test, and develop any new drug candidate. Even when a drug shows early promise in clinical trials, the rigorous drug approval process means very few of these research efforts result in a new drug or indication. CMS's Qualifying Single Source Drug definition diminishes incentives for AstraZeneca to invest in future treatments and therapies for FARXIGA's single-ingredient active moiety because such treatments or therapies will—immediately upon approval—be bound by the agency's compelled, below-market price for

FARXIGA. In addition, because FDA has already tentatively approved generic versions of FARXIGA, the drug will imminently be subject to CMS's unlawful "bona fide marketing" standard. These financial disincentives do more than harm AstraZeneca's bottom line; they also harm patients and the public good.

The Government also claims that the statute precludes AstraZeneca from seeking judicial review. The Government is wrong; the agency's unlawful interpretations are reviewable by this Court. There is a strong presumption favoring judicial review of administrative action, and the narrow statutory preclusions of judicial review do not apply to AstraZeneca's claims.

Finally, to be very clear: There is nothing voluntary about any of this. The only "choice" available to a manufacturer wishing to avoid draconian penalties under the Program is to withdraw *all* of its drug products from both Medicare and Medicaid. Because the Federal Government dominates the prescription drug market—serving as the gatekeeper to approximately 50% of the U.S. population, particularly those most in need of lifesaving drug therapies—no manufacturer has any meaningful choice but to accede to the Government's demands. The Program's watershed expansion of federal regulatory authority violates due process.

ARGUMENT

The Government devotes a large swath of its brief to procedural objections. D.I. 21-1 at 14–26. That speaks volumes, because the agency has little to say in support of its merits argument. Instead, the Government's essential position is that the agency may interpret the statutory however it sees fit—even in conflict with the plain text of the statute—while nonetheless escaping judicial review. That is a remarkable assertion, and the Court should reject it.

I. ASTRAZENECA HAS STANDING.

The Government acknowledges that AstraZeneca has standing to bring its due-process claim, but maintains that AstraZeneca lacks standing to bring its APA claims. That is not correct. The agency's unlawful policies, as codified in its Guidance Documents, have harmed and will continue to harm AstraZeneca in at least three ways. First, CMS's unlawful Qualifying Single Source Drug definition decreases the incentives for AstraZeneca to look for additional uses for FARXIGA's single-ingredient active moiety for patients in need. Second, AstraZeneca's FARXIGA will be subject to generic competition during the relevant period, triggering application of the agency's unlawful "bona fide marketing" standard. Third, AstraZeneca's decision-making about investment in other certain-to-be-selected drugs is negatively affected by both of the agency's unlawful policies.

AstraZeneca thus establishes "(1) an injury in fact, (2) that is fairly traceable to the challenged conduct of [CMS], and (3) that is likely redressed by a favorable judicial decision," *Yaw v. Delaware River Basin Comm'n*, 49 F.4th 302, 310 (3d Cir. 2022), satisfying the "constitutional minimum" for both of its APA claims, *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992).

Despite all this, the Government contends that AstraZeneca lacks Article III standing for its APA claims. D.I. 21-1 at 14–21.[1] The Government is wrong. The agency's unlawful actions cause AstraZeneca both actual and imminent injury that is redressable by the court.

A. AstraZeneca's injuries are plain.

An injury-in-fact is "an invasion of a legally protected interest" that is "concrete and particularized," and "actual or imminent, not conjectural or hypothetical." *Lujan*, 504 U.S. at 560. "That 'actual or imminent' is disjunctive is critical." *Clemens v. ExecuPharm Inc.*, 48 F.4th 146, 152 (3d Cir. 2022). AstraZeneca "need not wait until" it has "*actually* sustained the feared harm in order to seek judicial redress, but can file suit when the risk of harm becomes imminent." *Id.* (emphasis in original). A harm becomes imminent when either a threat of injury is " 'certainly impending,' " or there is at least " 'a substantial risk that the harm will

[1] The Government concedes that AstraZeneca has standing on its due process claim. D.I. 21-1 at 14.

occur.' " *National Shooting Sports Found. v. Attorney Gen. of N.J.*, 80 F.4th 215, 218 (3d Cir. 2023) (quoting *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 (2014)). AstraZeneca's injuries are "actual or imminent." *Lujan*, 504 U.S. at 560; *see also City of Los Angeles v. Lyons*, 461 U.S. 95, 105 (1983) (holding a plaintiff seeking injunctive relief must show it is "likely to suffer future injury").

First, the agency's unlawful definition of "Qualifying Single Source Drug" extinguishes AstraZeneca's demonstrated interest in investing in additional treatment options and therapies using the same single ingredient active moiety as an approved drug.[2] Declaration of Jim Ader (Ader Decl.) ¶ 26. As a core part of its business model, AstraZeneca invests tremendous resources into identifying, researching, and developing new and important treatment options for the active moiety of existing products. *Id.* ¶ 16.

CMS's unlawful Qualifying Single Source Drug definition eliminates any incentive for AstraZeneca—or any drug manufacturer—to invest in new single-ingredient treatment options for the active moiety of a selected drug. Under CMS's Guidance, the agency will effectively treat FARXIGA and any new product with the same single-ingredient active moiety approved under a distinct NDA as the same drug—even if that new product is approved years after FARXIGA and after

[2] The agency's definition of Qualifying Single Source Drug excludes combination therapies. D.I. 19, Ex. 2 (Final Guidance) 100.

extensive research and financial investment. Thus, a new drug product or therapy with the same single-ingredient active moiety as FARXIGA—even if it is approved under a different NDA or BLA under FDA's rules[3]—will *immediately* be subject to the Maximum Fair Price for FARXIGA, without regard to the statutory seven-year minimum that would otherwise apply before a drug is selected for price negotiation. D.I. 19 (AstraZeneca's Opening Br.), Ex. 1 (Initial Guidance) at 8; Ex. 2 (Final Guidance) 99. This eliminates incentives for AstraZeneca to further innovate new uses for FARXIGA's single-ingredient active moiety, which in turn will narrow patient access to new treatments.

This concern is not a speculative one. The history of FARXIGA demonstrates how a foundational drug with a promising active moiety can be used to develop a variety of new treatment options for patients. FARXIGA was first approved in 2014 as an adjunct to diet and exercise to improve glycemic control in adults with Type 2 diabetes. Ader Decl. ¶ 17. Over time, AstraZeneca has developed multiple new uses

[3] The Government suggests that whether a new application is submitted under a different NDA or BLA is "in many instances, a feature of how the applicant chooses to submit its application(s) to [FDA]." D.I. 21-1 at 15. That is not how the FDA review process works. *See, e.g.*, 21 U.S.C. § 355(c)(4) (applicant may not file an sNDA if the application is for a product that qualifies as a different drug product); Ex. 1, FDA, *Guidance for Industry: Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees* (Dec. 2004), *available at* https://www.fda.gov/media/72397/download; *see also* Ex. 2, FDA, *Manual of Policies and Procedures 5018.2* (eff. Dec. 8, 2022), *available at* https://www.fda.gov/media/94381/download.

for FARXIGA, resulting in FDA approvals to treat heart disease and chronic kidney disease, in addition to diabetes. *Id.* ¶ 17–21. AstraZeneca is currently working on new uses with the active moiety in combination with other active ingredients. *Id.* ¶ 23. AstraZeneca's business model is to follow the science. While clinical trials are currently focused on "combination product" therapies that would not be impacted by the agency's definition of Qualifying Single Source Drug, Final Guidance 99, there are other ongoing drug development efforts involving the same active moiety as FARXIGA where one development pathway would result in the product being treated as the same Qualifying Single Source Drug as FARXIGA. Ader Decl. ¶ 23. The agency's unlawful definition would drastically limit AstraZeneca's incentive to follow the science with regard to any single-ingredient drug product using the same active moiety, limiting the company's ability to deliver life-saving therapies to patients in need. *Id*. ¶ 23, 26.

Second, and separately, AstraZeneca soon will be subject to CMS's unlawful bona fide marketing test. CMS has selected FARXIGA for "negotiation" for initial price applicability year (IPAY) 2026. The statute directs that if a generic product is "approved and marketed" before or during IPAY 2026, FARXIGA will be released from the Maximum Fair Price. 42 U.S.C. §§ 1320f-1(e)(1)(A)(iii)–(B)(iii). Generic versions of FARXIGA will enter the market sometime between October 2025 and Summer 2026. Ader Decl. ¶ 27.

The IRA's price control provisions begin to sunset once a generic drug "is marketed." 42 U.S.C. §§ 1320f-1(e)(1)(A)(iii)-(B)(iii). CMS has made clear, however, that it will not follow that statutory command. Instead, the agency has announced that it will determine, after examining various data, whether a generic drug is subject to "*bona fide* marketing." Initial Guidance 10; Final Guidance 102 (emphasis added). Because that data is delayed by numerous months, FARXIGA's generic competitor will not satisfy the agency's "bona fide marketing" standard for months *after* generic entry—assuming the agency finds the generic's marketing sufficiently "bona fide" even then. Initial Guidance 10; Final Guidance 102. AstraZeneca for that period will be subject both to generic competition *and* mandatory pricing. AstraZeneca thus faces imminent harm. Ader. Decl. ¶ 28.

The Government counters that AstraZeneca is merely "speculating" that CMS might improperly keep FARXIGA on the selected drug list after a generic competitor is marketed. D.I. 21-1 at 17. FDA, however, has already granted tentative approval to 17 generic manufacturers to market generic versions of FARXIGA. Ader Decl. ¶ 27.[4] All that is standing in the way of final approval of these generic drugs is the

[4] FDA issues tentative approval when the agency has already decided to approve the product, but patent or exclusivity periods must expire before it can issue a final approval. Once all patent and exclusivity periods have expired, the tentative approval is converted to final approval. *See* Ex. 3, FDA, Drugs@FDA Glossary of Terms, *available at* https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-

looming expiration of applicable patent rights and/or marketing exclusivity periods for FARXIGA, which will occur sometime between October 2025 and Summer 2026. *Id.* There is nothing speculative about the fact that FARXIGA will have generic competition.

Nor is there anything speculative about the fact that, once generic entry occurs, CMS's "bona fide marketing" standard will negatively impact AstraZeneca. CMS has announced its "bona fide marketing" standard through guidance—the procedural mechanism mandated by statute for implementation of IPAY 2026. 42 U.S.C. § 1320f. AstraZeneca does not need to guess how the agency will handle generic entry; the agency has already announced it. AstraZeneca therefore has standing to challenge the rule. *See Wynnewood Refin. Co. v. EPA*, *v.* 77 F.4th 767, 777 (D.C. Cir. 2023) (" '[T]here is ordinarily little question' that a regulated entity has standing to challenge a rule under which it is regulated.") (quoting *Lujan*, 504 U.S. at 560–561)); *Sierra Club v. EPA*, 292 F.3d 895, 899–900 (D.C. Cir. 2002) (noting a "petitioner's standing to seek review of administrative action is [often] self-evident . . . if the complainant is 'an object of the action (or forgone action) at issue' ") (quoting *Lujan*, 504 U.S. at 561)); *National Ass'n of Home Builders v. EPA*,

terms#:~:text=Tentative%20Approval&text=FDA%20delays%20final%20approval%20of,exclusivity%20issues%20have%20been%20resolved.

786 F.3d 34, 43 (D.C. Cir. 2015) (explaining "regulated entities' standing to challenge the rules that govern them is normally not an issue") (internal quotation marks omitted).[5]

Third, AstraZeneca's current decision-making about other drugs has been and will continue to be negatively affected by CMS's Guidance. Ader Decl. ¶¶ 31–32. CMS will select 15 more drugs for negotiation in 2024 for IPAY 2027, another 15 drugs in 2025 for IPAY 2028, and another 20 drugs in 2026 for IPAY 2029. *See* 42 U.S.C. § 1320f-1(c)(1). Within the next three years, 50 more drug products will be selected for negotiation. As a large U.S. pharmaceutical company, AstraZeneca will very likely have products on that list. Ader Decl. ¶¶ 29–30. As it makes plans to develop and commercialize new versions of these and other products, AstraZeneca has no rational choice but to take the agency's current policies into account. Ader Decl. ¶¶ 31–32. That causes AstraZeneca harm now. *See Sabre, Inc. v. Department of Transp.*, 429 F.3d 1113, 1117 (D.C. Cir. 2005) (petitioner "demonstrated a sufficiently concrete and particularized injury in fact due to the Final Rule's

[5] The Government implies that AstraZeneca must show its risk of harm will certainly occur. D.I. 21-1 at 17. In the very case cited by the Government, however, the Supreme Court explained that its "cases do not uniformly require plaintiffs to demonstrate that it is literally certain that the harms they identify will come about." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 414 n.5 (2013); *see also Susan B. Anthony List*, 573 U.S. at 158 ("An allegation of future injury may suffice if . . . there is a " 'substantial risk' that the harm will occur.").

immediate impact on [its] ability to make business decisions about the products it will offer in the market").

As one example of how AstraZeneca's core drug portfolio is impacted by CMS's unlawful interpretation, take AstraZeneca's cancer medication LYNPARZA® (olaparib). LYNPARZA was approved in capsule form in 2014. AstraZeneca invested years of dedicated research in developing a formulation that was better tolerated by patients, and a tablet form of the drug was approved by FDA under a separate NDA in 2017. Ader Decl. ¶ 24. The tablet product allowed patients to reduce the number of pills they must take per day, making it far more convenient for patients and improving adherence to the prescribed treatment, with the goal of improving patient outcomes. *Id*.[6]

CMS's definition of "Qualifying Single Source Drug," however, would render the LYNPARZA tablet and capsule *the same* Qualifying Single Source Drug, because the capsule and tablet forms of LYNPARZA contain "the same active moiety." Initial Guidance 8; Final Guidance 99. That is so even though the two products were approved under unique NDAs, and even though the capsule that started the negotiation clock is no longer marketed. Under CMS's test, the tablet

[6] *See also* Ex. 4, AstraZeneca, *Lynparza receives additional and broad approval in the US for ovarian cancer* (Aug. 17, 2017), *available at* https://www.astrazeneca.com/media-centre/press-releases/2017/lynparza-receives-additional-and-broad-approval-in-the-us-for-ovarian-cancer-17082017.html.

form would immediately be eligible for selection, even though it has not yet been approved for seven years as the statute requires.

LYNPARZA is not unique in this respect. AstraZeneca's drug CALQUENCE® (acalabrutinib), part of a treatment program for chronic lymphocytic leukemia and mantle cell lymphoma, was approved in capsule form in 2017, and in tablet form under a different NDA in 2022. Ader Decl. ¶ 25. The tablet formulation expanded the patient population able to benefit from CALQUENCE because, unlike the capsule, it may be taken with gastric acid-reducing agents, a commonly co-administered medication for many in the patient population. *Id.*[7] FDA viewed the products to be different enough that they warranted unique NDAs, and the IRA accordingly mandates that the products be treated as distinct drugs as well. *Id.* But *CMS's* definition would treat the two products as a single Qualifying Single Source Drug, *both* eligible for selection in 2025 for IPAY 2027, even though the tablet will not have been approved for seven years as the statute requires.

These are not hypothetical harms, as the Government suggests. D.I. 21-1 at 18–21. The Guidance Documents say on their face that they apply in IPAY 2026, but the agency has yet to announce (nor do its counsel suggest) any change in policy

[7] *See also* Ex. 5, AstraZeneca, *Calquence tablet formulation approved in the US across current indications* (Aug. 5, 2022), *available at* https://www.astrazeneca.com/media-centre/press-releases/2022/calquence-tablet-formulation-approved-in-the-us-across-current-indications.html.

for IPAY 2027 or beyond. As a result, AstraZeneca is forced to structure its developmental and commercial planning around the agency's current policy positions on Qualifying Single Source Drug and "bona fide marketing." Ader Decl. ¶¶ 31–32.[8] If anyone's position is "speculative," it is the Government's position that the agency *might* change its policy in the future, such that AstraZeneca *might not* suffer harm if another one of its drugs is selected next year for IPAY 2027.

The Government also is wrong to suggest that the harms to AstraZeneca's product development planning are somehow "self-inflicted." D.I. 21-1 at 20. They are a rational action in response to a radical market change. FARXIGA is in the drug price negotiation program. It will be subject to the policies announced by the agency. AstraZeneca has no choice but to try to mitigate its financial risk with those policies in mind.[9]

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[8] Other drug manufacturers have already canceled or halted promising research on treatments because of the Drug Price Negotiation Program. *See* Ex. 6, Nacha Cattan, *Seagen Ended a Bladder Cancer Drug Program Due to IRA, CEO Says*, Bloomberg (Oct. 26, 2023), *available at* https://news.bloomberglaw.com/health-law-and-business/seagen-ended-a-bladder-cancer-drug-program-due-to-ira-ceo-says; *see also* Ex. 7, Joe Grogan, *The Inflation Reduction Act Is Already Killing Potential Cures*, Wall Street Journal (Nov. 3, 2022), *available at* https://www.wsj.com/articles/the-inflation-reduction-act-killing-potential-cures-pharmaceutical-companies-treatment-patients-drugs-prescriptions-ira-manufacturers-11667508291.

[9] The Government also argues that AstraZeneca's harm is solely tied to orphan drugs. D.I. 21-1 at 20–21. The IRA's draconian provisions do indeed run headlong into the policies underlying the Orphan Drug Act, *see* Am. Compl. ¶¶ 20, 36, 98–

In addition to showing "actual or imminent" injuries, AstraZeneca's injuries also are particularized and concrete. These injuries directly affect the company and are "real, and not abstract." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 339-340 (2016) (internal quotation marks omitted). AstraZeneca does not simply claim CMS's Guidance violated the APA. *See Cottrell v. Alcon Lab'ys*, 874 F.3d 154, 167 (3d Cir. 2017) ("Bare procedural or technical violations of a statute alone will not satisfy the concreteness requirement."). The agency's APA violations pose imminent tangible economic harm to AstraZeneca. *See TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2204 (2021) (providing that "certain harms readily qualify as concrete injuries under Article III," such as "monetary harms").

B. AstraZeneca's injuries are fairly traceable to CMS's qualifying single source drug definition and "bona fide marketing" standard.

The causation prong of the constitutional standing test requires that the defendant's "challenged actions, not the actions of some third party, caused" AstraZeneca's injuries. *Freeman v. Corzine*, 629 F.3d 146, 153 (3d Cir. 2010). "[T]his causal connection need not be as close as the proximate causation needed to succeed on the merits of a tort claim," *id.*; an "indirect causal relationship will suffice." *Id.* And "[w]hen a petitioner itself is the object of the challenged agency

102—but AstraZeneca's harm is by no means limited to orphan drugs. *See id.* ¶¶ 48–96.

action," "there usually is little doubt of causation." *Exhaustless Inc. v. Federal Aviation Admin.*, 931 F.3d 1209, 1212 (D.C. Cir. 2019). There is no such doubt here; AstraZeneca's ongoing and future injuries flow directly from the agency's Qualifying Single Source Drug definition and "bona fide marketing" standard.

C. AstraZeneca's injuries are redressable.

Redressability requires showing an injury will likely be "redressed by a favorable decision." *Lujan*, 504 U.S. at 561. AstraZeneca need only show "a substantial likelihood that the judicial relief requested will prevent or redress the claimed injur[ies]." *Duke Power Co. v. Carolina Env't Study Grp., Inc.*, 438 U.S. 59, 79 (1978).

AstraZeneca easily satisfies this prong; indeed, the Government does not argue otherwise. If the Court vacates the Guidance Documents as requested, FARXIGA would be entitled under the statute to removal from the program following launch of a generic product. And AstraZeneca would have the certainty that the statutory definition of Qualifying Single Source Drug applies—freeing it to develop and commercialize products sharing FARXIGA's single-ingredient active moiety that are approved under a new NDA or BLA. AstraZeneca's injuries will plainly be redressed by a favorable decision.

II. THE COURT MAY REVIEW ASTRAZENECA'S APA CLAIMS.

The Government next argues that AstraZeneca's APA claims are shielded from judicial review. D.I. 21-1 at 21–26.[10] Nothing in the IRA prohibits this Court from engaging in its traditional function and reviewing the claims presented here. The Court should see the agency's arguments for what they are: a transparent attempt to avoid having to defend its unlawful actions on the merits.

A. It is CMS's burden to defeat the strong presumption in favor of judicial review.

"Federal agencies are accountable to the public and their actions subject to review by the courts." *Franklin v. Massachusetts*, 505 U.S. 788, 796 (1992). Congress also "rarely intends to prevent courts from enforcing its directives to federal agencies." *Mach Mining, LLC v. EEOC*, 575 U.S. 480, 486 (2015). There is accordingly a "strong presumption favoring judicial review of administrative action." *Salinas v. United States R.R. Ret. Bd.*, 141 S. Ct. 691, 698 (2021); *see also American Disabled for Attendant Programs Today v. United States Dep't of Hous. & Urb. Dev.*, 170 F.3d 381, 384 (3d Cir. 1999) ("Agency actions are typically presumed to be reviewable under the APA."). This principle is entrenched in administrative law. "Because the presumption favoring interpretations of statutes

[10] The Government does not argue that this Court is barred from reviewing the merits of AstraZeneca's due process claim. D.I. 21-1 at 44.

[to] allow judicial review of administrative action is well-settled," courts fairly presume that "Congress legislates with knowledge of the presumption." *Kucana v. Holder*, 558 U.S. 233, 251–252 (2010) (cleaned up).

To overcome the "strong presumption" in favor of reviewing agency actions, *Bowen v. Michigan Acad. of Fam. Physicians*, 476 U.S. 667, 670 (1986), CMS bears a " 'heavy burden' in attempting to show that Congress 'prohibit[ed] all judicial review' of the agency's compliance with a legislative mandate," *Mach Mining*, 575 U.S. at 486 (quoting *Dunlop v. Bachowski*, 421 U.S. 560, 567 (1975)). The presumption in favor of judicial review is even stronger where—as here—the agency is alleged to have strayed from its governing statute. *See Williams v. Metzler*, 132 F.3d 937, 944 (3d Cir. 1997). And despite CMS's protestations, D.I. 21-1 23, the burden "to dislodge the presumption" in favor of judicial review rests squarely on the Government, *Kucana*, 558 U.S. 233 at 252. Before finding that Congress intended to strip a federal court of its authority to perform its Article III function, courts require "clear and convincing evidence" of that legislative objective. *Bowen*, 476 U.S. at 671. That evidence is lacking here.

B. The IRA does not foreclose judicial review of AstraZeneca's APA claims.

In urging dismissal, the Government leans heavily on three provisions of the IRA: one shielding CMS's "selection of drugs" for negotiation, and two addressing decisions made by the agency earlier in the selection process: "the determination of

negotiation-eligible drugs" under section 1192(d), and the "determination of qualifying single source drugs" under section 1192(e). D.I. 21-1 at 21 (citing 42 U.S.C. § 1320f-7(2)). All three purport to preclude judicial review of those "selection[s]" or "determination[s]."

None of these provisions applies here. AstraZeneca does not challenge the "selection" of a particular drug. Nor is this a challenge to a "determination of negotiation-eligible drugs under section 1192(d)" or a "determination of qualifying single source drugs under section 1192(e)." These "determinations" refer to the agency's identification of particular drugs as available for selection through discretionary calculations of Medicare expenditures.

In retreat, the Government next argues that the "plain text" of the statute not only bars judicial review of the "ultimate selection of individual drugs," but also of "the manner in which the agency makes those individual selections." D.I. 21-1 at 24. That is simply not so. The plain language of the statute's preclusion of judicial review does not extend to the "manner in which the agency makes those individual selections."

Indeed, contrary to the Government's suggestion, D.I. 21-1 at 22, the agency's unlawful definition of Qualifying Single Source Drug is not even solely relevant to selection; it also will affect the agency's treatment of the drug during the negotiation process and the agency's treatment of any future therapies using the same active

moiety as FARXIGA. 42 U.S.C. §§ 1320f(b)(2); 1320f-1(d); 1320f-1(e); 1320f-3(d). Likewise, the agency's "bona fide marketing" standard will influence whether generic competition for FARXIGA (expected before the end of IPAY 2026) will remove the drug from the program. 42 U.S.C. §§ 1320f-1(c)(1)(B); 1320f-1(e)(1)(A); 1320f-1(e)(1)(B); 1320f–1(e)(2)(B)(ii)(II); 1320f-1(f)(1)(A); 1320f-1(f)(1)(B)(ii)(III)(bb); 1320f-1(f)(2)(B); 1320f–1(f)(3)(B). The Government essentially suggests that the statute's targeted preclusion provisions should be read broadly, to create a sweeping bar to judicial review of *any* aspects of the Drug Price Negotiation Program. D.I. 21-1 at 22–25. That assertion runs counter to the "traditional presumption in favor of judicial review of administrative action," *American Hosp. Ass'n v. Becerra*, 596 U.S. 724, 734 (2022). The balance weighs in favor of judicial review in cases where "the wording of a preclusion clause is less than absolute." *Amgen, Inc. v. Smith*, 357 F.3d 103, 112 (D.C. Cir. 2004).

When Congress *does* contemplate a sweeping bar, the statutory preclusion on judicial review is framed in far broader terms. For example, a statute that "strip[s] 'jurisdiction to review' or 'to entertain any other cause or claim *arising from or relating to* the implementation or operation of' " agency action is often a reliable sign that Congress mean to preclude all such judicial review. *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.' " *Id.* (quoting *Osorio-Martinez v. Attorney Gen.*, 893 F.3d 153, 160, 165 (3d Cir. 2018)). Conversely, "when a jurisdiction-stripping provision" in a statute "omits capacious phrases like 'relating to,' it bars only direct review" of the agency's underlying determination. *Dohou*, 948 F.3d at 626. Notably absent from the IRA's judicial-review provision is any language declaring that judicial review is barred for any action "relating to" the selection or determination of particular drugs. *See id.* That omission is telling.

Cases interpreting the judicial-review provisions of other statutes governing CMS are instructive. Take *Baxter Healthcare Corp. v. Weeks*, 643 F. Supp. 2d 111 (D.D.C. 2009), for example. The review preclusion there was narrow, like the preclusion provisions here; it barred review of two related issues: "determinations of payment amounts" and the "assignment" of drug products to "billing and payment codes." *Id.* at 115. The *Baxter* court found that the lawsuit raised a related but distinct regulatory question—whether the product was a single source drug or multiple source drug within the meaning of the statute—the answer to which dictated the outcome of the other two issues. *Id.* While the issues were all related, the court concluded that the preclusion of judicial review was focused on the agency's calculation of payment amounts, not the more fundamental regulatory question of what counts as a single source drug under the statute. *Id.* at 115–116.

In *American Hospital Ass'n v. Azar*, 964 F.3d 1230, 1238 (D.C. Cir. 2020), the D.C. Circuit noted that although the statute in question there "forecloses judicial review of the agency's 'establishment of methods described in paragraph 2(F),' the Hospitals' claim is that the payment reduction at issue is *not* a 'method[] described in paragraph 2(F)' within the meaning of the statute." *Id.* The Court explained that by its very terms, "the jurisdiction-stripping provision does not apply" if "the agency's action fails to qualify as the kind of action for which review is barred." *Id.*. That is precisely the case here. Both of the IRA's statutory references to "determinations" require that the shielded determinations be made "under" the cross-referenced statutory provisions. 42 U.S.C. § 1320f-7(2). Agency actions that *violate* those cross-referenced statutory provisions—as AstraZeneca has alleged here—are not shielded from judicial review.

AstraZeneca's APA claims perhaps most closely resemble the claims the D.C. Circuit held were not precluded in *American Clinical Lab'y Ass'n v. Azar*, 931 F.3d 1195 (D.C. Cir. 2019). In that case, the Court held that a Medicare provision precluding judicial review of "the establishment of payment rates" did not strip the district court from hearing a challenge to a data collection requirement that "precede[d] and inform[ed] the setting of those amounts," noting that "the two are not one and the same." *Id.* at 1205–1206. The same is true here. While policies governing the definition of a Qualifying Single Source Drug and what it means to

be "marketed" may ultimately *inform* the criteria CMS uses to select a drug product (and, importantly, how it regulates the product post-selection), a challenge to these policies is not a challenge to the "selection of drugs."

The cases cited by the Government do not support its position. D.I. 21-1 at 24–26. *Texas Alliance for Home Care Services v. Sebelius*, 681 F.3d 402 (D.C. Cir. 2012), for example, involved a statute barring review of "the awarding of contracts," which the D.C. Circuit found encompassed eligibility standards "indispensable to the awarding of contracts." The lawsuit challenged an agency regulation promulgating the applicable financial standards to be considered in awarding contracts. *Id.* Unlike the case presented here, the lawsuit presented a pure arbitrary-and-capricious challenge to the promulgation of regulatory standards that Congress had plainly left to the agency's discretion as part-and-parcel of the shielded agency action. The same is true of the other cases cited by the Government. D.I. 21-1 at 25–26. *See, e.g.*, *DCH Reg'l Med. Ctr. v. Azar*, 925 F.3d 503, 505–506 (D.C. Cir. 2019) (statutory bar on judicial review of "[a]ny estimate of the Secretary" fairly encompassed challenges to the methodology used to *make* those estimates because the two could not "be separated"); *Florida Health Scis. Ctr., Inc. v. Secretary of HHS*, 830 F.3d 515 (D.C. Cir. 2016) (bar on judicial review of an estimate encompassed the choice of data underlying that estimate); *Mercy Hosp., Inc. v. Azar*,

891 F.3d 1062 (D.C. Cir. 2018) (bar on reviewing prospective payment rate includes the adjustments used to calculate that rate).

The issues raised in this lawsuit are readily separated from the actions shielded by statute from judicial review—all of which involve the identification of particular drugs as eligible for or subject to selection. AstraZeneca's claims implicate standards that have importance unrelated to the mere selection of drugs—including the treatment of a selected drug during the negotiation period and whether new therapies are immediately bound by an existing Maximum Fair Price for a previously selected drug. This lawsuit seeks to bring the agency into compliance with non-discretionary statutory requirements. These are all hallmarks of a reviewable APA challenge. If Congress had intended that a challenge to any aspect of the Drug Price Negotiation Program be shielded from judicial review, it would have said so. It did not.

C. CMS's actions are alternatively reviewable as ultra vires.

The Government's exceptionally broad reading of the statutory-preclusion bar is not sustainable. But even if the statute could be read that broadly, judicial review would still be available, for a different reason: The agency's action here was ultra vires. *Cf. Xcel Energy Servs. Inc. v. FERC*, 815 F.3d 947, 955 (D.C. Cir. 2016) ("When the [agency] acts contrary to the statute its action is ultra vires.").

The Government argues that AstraZeneca did not denominate an ultra vires claim as an independent cause of action, and that CMS's actions survive that standard in any event. D.I. 21-1 at 26 n.6. The Government is mistaken on both scores.

To begin with, the Third Circuit has acknowledged that the specific provision of the APA that AstraZeneca invokes in support of its statutory challenges, 5 U.S.C. § 706(2)(c), incorporates the ultra vires theory. *See Bakran v. Secretary, United States Dep't of Homeland Sec.*, 894 F.3d 557, 561 n.2 (3d Cir. 2018) (explaining that an "ultra vires claim" is authorized by the APA's right of action to challenge agency actions "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right"); Am. Compl. ¶¶ 125, 133 (AstraZeneca challenges "agency action in excess of statutory jurisdiction, authority, or limitations, or short of statutory right"). There was no need for AstraZeneca to set forth an independent "ultra vires" claim in its complaint.

On the merits, the Government's arguments come up just as short. The Government concedes that AstraZeneca satisfies one element of an ultra vires theory, as "there is no alternative procedure for review of the statutory claim." D.I. 21-1 at 26 n.6 (quoting *DCH Reg'l Med. Ctr.*, 925 F.3d at 509). So it hangs its hat on the other two elements: that the statutory preclusion of review is "implied rather than express," and that "the agency plainly acts in excess of its delegated powers."

D.I. 21-1 at 26 n.6 (quoting *DCH Reg'l Med. Ctr.*, 925 F.3d at 509). Both of these factors cut in AstraZeneca's favor, not the Government's.

The statutory preclusion bar is express only as to certain agency "selections" or "determinations," none of which AstraZeneca challenges. *See supra* at 19–20. CMS's preclusion claim thus rests on an argument that Congress *also* "implicitly granted" the agency unreviewable discretion to implement the IRA's Drug Price Negotiation Program writ large. *AHA v. Becerra*, 596 U.S. at 733. The agency tried a similar express-includes-implicit tactic in *AHA v. Becerra*, to no avail. *See id.* at 731 (rejecting agency's argument that an express statutory bar on challenges to its "authority to 'adjust' the average price for each drug" also "implicitly" barred challenges to its actions "vary[ing] the reimbursement rates by hospital group").

That leaves whether "the agency plainly acts in excess of its delegated powers and contrary to a specific prohibition in the statute that is clear and mandatory." *DCH Reg'l Med. Ctr.*, 925 F.3d at 509. That is exactly what AstraZeneca's claims allege. The agency's sole defense on this front is that its unlawful definition of "Qualifying Single Source Drug" and atextual bona fide marketing standard are mere "[g]arden-variety errors of law." D.I. 21-1 at 26 n.6. That is impossible to square with the Government's heralding of the program, of which these are key components, as a "historic" regulatory project that has already affected drugs comprising "20%" of all "Part D gross prescription drug costs" over the last year.

D.I. 19, Ex. 3 at 1, 3. The agency's interpretive errors are glaring, and review should be had of them.

III. CMS ACTED UNLAWFULLY.

Before turning to the merits, it is necessary to discuss two important predicate issues that bear on the nature of this Court's review.

First, the Government complains that AstraZeneca's arguments are insufficiently focused on "the statute's purpose." *See, e.g.*, D.I. 21-1 at 34, 43. "Purpose first" was indeed the prevailing approach to statutory interpretation—in the 1800s. Courts once elevated legislative purpose over statutory text in service of the belief that "a thing may be within the letter of the statute and yet not within the statute, because not within its spirit, nor within." *Church of Holy Trinity v. United States*, 143 U.S. 457, 459 (1892). In the modern day, however, "we start with the text of the statute." *Babb v. Wilkie*, 140 S. Ct. 1168, 1172 (2020).

That fact seems lost on CMS, which seeks refuge in the equally outmoded reasoning of *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402 (1971), *abrogated by Califano v. Sanders*, 430 U.S. 99 (1977), to support its argument that "the agency's decision is presumed valid." D.I. 21-1 at 30. *Overton Park*, however, was a decision so singularly focused on legislative purpose that the majority finally remarked, after uncovering scant evidence of congressional intent, that "[b]ecause of this ambiguity it is clear that we must look primarily to the statutes themselves to

find the legislative intent." 401 U.S. at 412 n.29. These days, we look to the statute first, foremost, and—if the text is clear—exclusively. *See In re Telegroup, Inc.*, 281 F.3d 133, 137 (3d Cir. 2002) (noting that "we begin, as we must, with the text of the statute" and that the inquiry then "must cease" if the statutory language is unambiguous).

The next preliminary item has to do with whether this Court should defer to the agency. The answer is "no." CMS does not argue for *Chevron* deference to its interpretations of "Qualifying Single Source Drug" or "marketed." The agency's decision "to eschew reliance on this doctrine" means this Court should interpret those statutory terms according to their ordinary meaning, without any deference to the agency's interpretations. *Center for Biological Diversity v. EPA*, 75 F.4th 174, 179 n.2 (3d Cir. 2023) (declining to afford *Chevron* deference where agency "conspicuously makes no mention of *Chevron* in its briefing"); *Neustar, Inc. v. FCC*, 857 F.3d 886, 893–894 (D.C. Cir. 2017) (FCC's failure to invoke *Chevron* meant it had "forfeited any claims to *Chevron* deference").

A. CMS's Qualifying Single Source Drug Definition Is Unlawful.

A key statutory term in the IRA is "Qualifying Single Source Drug." 42 U.S.C. § 1320f-1(d)(1). Much hinges on the meaning of that statutorily defined term: a product is eligible for selection and negotiation under the IRA's Drug Price Negotiation Program if—and only if—a product is a Qualifying Single Source Drug.

CMS has flouted the controlling statutory language in fashioning its own definition of Qualifying Single Source Drug. For that reason, its position is unlawful under the APA. At a minimum, the agency's definition is arbitrary and capricious and should be set aside on that basis.

1. Statutory Violation.

As AstraZeneca explained in its opening brief, the meaning of "Qualifying Single Source Drug" is secured through cross-reference to the definition of "a covered part D drug" under Medicare, which cross-references the definition of "covered outpatient drug" under Medicaid. D.I. 19 at 14–17 (citing 42 U.S.C. §§ 1320f-1(e)(1); 1395w-102(e)(1)). Under the Medicaid statute, whether a drug is a separate "covered outpatient drug" is expressly tied to whether the drug was approved under a separate New Drug Application (NDA) or Biologics License Application (BLA). 42 U.S.C. § 1396r-8(k)(2), (k)(7)(A)(iv). Not long ago, CMS agreed. *See Ipsen Biopharmaceuticals v. Azar*, No. 16-CV-2372 (DLF), 2020 WL 3402344, at *10 (D.D.C. June 19, 2020) (agreeing with CMS's position at the time that a distinct covered outpatient " 'drug' for Medicaid rebate purposes is defined by FDA's approval of a distinct NDA pursuant to section 505").

Here, however, CMS paid no heed to that intricate statutory structure. It instead lumps together, as one Qualifying Single Source Drug, "all dosage forms and strengths of the drug *with the same active moiety* and *the same holder* of a New

Drug Application (NDA), *inclusive of products that are marketed pursuant to different NDAs" or "BLAs."* Final Guidance 99 (emphases added). That sweeping interpretation does not square with the statutory text, nor the cross-referenced statutory definitions, none of which mentions the "active moiety" concept. That is why the Government has to engage in overly gymnastical explanations about the statute's purportedly plain text. Rather than starting with the definition of "Qualifying Single Source Drug," the Government begins with another statutory provision directing the agency to aggregate data "across dosage forms and strengths of *the drug*, including new formulations of *the drug*." D.I. 21-1 at 27 (citing 42 U.S.C. § 1320f-1(d)(3)(B))(emphases added). That provision, however, does not answer the critical question; it merely directs aggregation of data for different dosage forms and strengths *of the same drug*. If the drug is a different drug, then the statute does not direct aggregation of data.

The same is true of the Government's argument that the maximum fair price applies across different "strengths and dosage forms *of a selected drug*." D.I. 21-1 at 28 (citing 42 U.S.C. § 1320f-5(a)(2)). That language only applies if the products at issue first count as the same Qualifying Single Source Drug.

When the Government does get around to acknowledging the statutory definition, it argues that AstraZeneca "overread[s] the significance of the cross-referenced provision," which the Government suggests "merely" implies that the

drug must have been deemed safe and effective. D.I. 21-1 at 29. But *all* FDA-approved drugs that reach the market must be safe and effective for their intended use. Under the Government's reading, "Congress would not have needed to cross-reference" the Medicare or Medicaid Drug Rebate statutes at all. *National Ass'n of Mfrs. v. Department of Def.*, 583 U.S. 109, 126 (2018).

There are other textual clues as well. The statute says that if a new drug is approved by FDA "under section 355(c) of title 21," and "at least 7 years . . . have elapsed since the date of such approval"—or, in the case of a BLA approval, "at least 11 years . . . have elapsed since the date of such approval"—then that product counts as a Qualifying Single Source Drug. 42 U.S.C. §§ 1320f-1(e)(1)(A)-(B). If the Government were correct, D.I. 21-1 at 29, that two products approved under two different NDAs could count as a single Qualifying Single Source Drug, this provision would be impossible to apply. By definition, the two drugs would have two *different* approval dates. That would make no sense.

Nor is it relevant that Congress elsewhere in the statute recognized that a single drug might be approved under different "applications and approvals." D.I. 21-1 at 28, 29 (citing 42 U.S.C. § 1320f-3(e)(1)(D)). Manufacturers commonly file multiple supplemental applications to a single NDA or BLA—and thus, there are often multiple "applications" and "approvals" relating to a single drug under a single NDA. In fact, FARXIGA has over 20 supplemental applications filed to a single

NDA.[11] That is neither here nor there when it comes to interpreting the "such approval" language in 42 U.S.C. § 1320f-1(e)(1)(A), which plainly refers to when the "drug" itself "is approved."

CMS does not claim *Chevron* deference for its interpretation of Qualifying Single Source Drug, *see supra* at 29, nor could it. The agency maintains that its preferred reading "flows naturally from the provisions of the IRA," D.I. 21-1 at 27; *see also* Final Guidance 11 ("The aggregation rules under sections 1192(d)(3)(B) and 1196(a)(2) are clear."). That means deference is inappropriate even if the Court finds ambiguity where the agency detects none. Courts "cannot defer" to a "position [that] mistakenly advances an interpretation" the agency believes is "*compelled* by Congress when the statute is in fact ambiguous." *Secretary of Lab. v. KC Transp., Inc.*, 77 F.4th 1022, 1030 (D.C. Cir. 2023).

Congress provided an express definition of the statutory term "Qualifying Single Source Drugs." In the Guidance Documents, CMS offers its own definition, ignoring the statutory text and contradicting its own interpretation of the cross-referenced definition of "covered outpatient drug" in recent prior litigation. *See supra* at 29. That is unlawful under the APA.

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[11] *See* Ex. 8, FDA, *Approval Date(s) and History, Letters, Labels, Reviews for NDA 202293, available at* https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process.

2. Arbitrary and Capricious.

Putting aside the statutory violation, CMS's Qualifying Single Source Drug definition also is arbitrary and capricious. The agency's policy makes no sense: It disincentivizes manufacturers from investing in new uses for existing products, or new products involving the same active moiety. That in turn will harm patients and the public good.

The agency issued final guidance without inviting comment, but the comments poured in anyway from concerned citizens, patient access organizations, industry groups, and manufacturers outlining the many problems with the Qualifying Single Source Drug definition. Among other things, commenters explained the irrationality of CMS sweeping in products that have not yet been on the market for the required seven or eleven years. Assume two products, Product A and newly approved Product B, share the same active moiety. As one non-profit patient advocacy organization explained, the agency's definition makes it possible for the new product B to be eligible for selection immediately upon FDA approval, because product A was approved under a separate NDA years before Product B even came on the market. Ex. 9 (Haystack Project Comment Letter). The same commenter observed that it would have "expected that CMS would look to the statutory language" instead. *Id.* In response, the agency doubled down, reiterating that "CMS will use the earliest date of approval of the initial FDA application number assigned

to an NDA for the active moiety for which the manufacturer is the holder of the NDA." Final Guidance 13 n.4; *see id.* n.5 (same for BLAs).

Nor did CMS adequately explain in the rulemaking record its decision to adopt a Qualifying Single Source Drug definition that promises to undermine the very patient access that Congress sought to promote. This failure will work a real detriment to AstraZeneca and patients alike. AstraZeneca now has no incentive to invest in follow-on therapies that might benefit patients if those therapies share FARXIGA's same active moiety. The problem will recur with other products. As AstraZeneca explained to CMS before the agency issued the Final Guidance document, its products LYNPARZA, CALQUENCE, and FASENRA will face the same issue: The incentive to innovate further is all but squelched now that the selection clock for those products will run based on the approval or licensure date of the earlier approved product. *See* Ex. 10 (AstraZeneca Comment Letter).

The Government calls all of this a "policy disagreement." D.I. 21-1 at 32. That characterization overlooks the core legal defect in the agency's process: CMS "entirely failed to consider an important aspect of the problem." *Sierra Club v. EPA*, 972 F.3d 290, 298 n.47 (3d Cir. 2020). And to the extent this legal question implicates policy, the agency implemented a policy at odds with the statute's purpose. The statute was enacted with the aim of promoting patient access to prescription drugs; CMS has achieved the opposite effect with its Qualifying Single

Source Drug policy, which discourages manufacturers from innovating. The agency's failure to adequately explain that irrational result is arbitrary and capricious. *See SecurityPoint Holdings, Inc. v. Transportation Sec. Admin.*, 769 F.3d 1184, 1189 (D.C. Cir. 2014) (agency policy that works against desired goals was arbitrary and capricious). At minimum, CMS should have reasonably explained in the rulemaking record why it followed a path at cross-purposes with the statute's goals. *Music Choice v. Copyright Royalty Bd.*, 970 F.3d 418, 429 (D.C. Cir. 2020) ("[A]n agency's ipse dixit cannot substitute for reasoned decisionmaking.").[12]

B. CMS's "bona fide marketing" standard is unlawful.

The agency also has impermissibly edited the statutory test for determining whether a generic drug disqualifies a reference drug from participation in the Drug Price Negotiation Program. Under the IRA, a drug is ineligible for selection if an FDA-approved generic drug is "approved and marketed" (or, in the case of a biologic, "licensed and marketed"). 42 U.S.C. §§ 1320f-1(e)(1)(A)(iii)-(B)(iii). Congress provided no qualifying language in the statute that might narrow or

[12] It is no answer that the Government's lawyers attempt to justify the agency's policy in their legal briefs. *See* D.I. 21-1 at 30–32. Litigation briefs may not be used to backfill an inadequate agency record. *See Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962) (declining to accept counsel's "*post hoc* rationalizations for agency orders"); *see also Maine Pub. Utils. Comm'n v. FERC*, 625 F.3d 754, 759 (D.C. Cir. 2010) (courts cannot conclude an agency "counsel's current position is reasonable under the APA" where the agency never articulated that rationale).

otherwise change the ordinary meaning of the word "marketed." *Id.* The agency nevertheless interpreted the statutory term to mean "*bona fide* market[ed]," creating a new "totality of the circumstances" test that supplants the statute's objective inquiry. Initial Guidance 10, 62; Final Guidance 72, 101–102. That "bona fide marketing" standard violates the agency's statutory mandate; it is also arbitrary and capricious. The Government's arguments to the contrary lack merit.

1. Statutory Violation.

Congress created a simple test in the IRA for determining whether a drug subject to generic competition is ineligible for selection. CMS must ask and answer a simple question: Has the generic drug or biosimilar been "approved and marketed"? If yes, the reference listed drug (the innovator product upon which generic competitors' FDA approvals are based) is ineligible for selection. 42 U.S.C. §§ 1320f-1(e)(1)(A)(iii)-(B)(iii). And if the generic or biosimilar launches after the reference listed drug has been selected for negotiation, the "marketing" of that generic or biosimilar product either stops the negotiation process for the selected drug or cuts short the time period to which an MFP applies, depending on when that competitor goes to market. 42 U.S.C. § 1320f-1(c)(1)(B).

As AstraZeneca explained in its opening brief, CMS attempted to override this statutory mandate. Under the agency's interpretation, a drug that faces generic competition will still be treated as a Qualifying Single Source Drug, and any

applicable MFP will remain in place, *unless* the marketing of the generic products rises to the level of "bona fide marketing," meaning that sellers must sell the product in a "robust and meaningful" manner as determined in CMS's sole discretion. Initial Guidance 67–68; Final Guidance 73. Far from a yes/no inquiry, CMS's "bona fide marketing" test is a subjective, multi-factor inquiry; the agency plans to review data over a 12-month period and make a "holistic inquiry" based on the "totality of the circumstances" about "whether a generic drug or biosimilar is marketed on a bona fide basis." Initial Guidance 62; Final Guidance 101–102. The end result is that even a drug with generic competition on the market may be selected for negotiation and, if it is already subject to a Maximum Fair Price, remain subjected to that price, if CMS concludes in its discretion that the drug's generic competition is not "bona fide" enough. *None* of that comes from the statute.

In response, the Government argues that AstraZeneca "cite[s] no 'accepted ordinary meaning' of the phrase 'is marketed' establishing that *de minimis* sales necessarily satisfy the concept." D.I. 21-1 at 34. That is wrong: AstraZeneca explained in its opening brief that the term "marketed" has an accepted ordinary meaning. It means to "expose for sale in a market," D.I. 19, Ex. 5 (Merriam-Webster Dictionary), or "to bring or send to a market," D.I. 19, Ex. 6 (Oxford English Dictionary). *See United States v. Adair*, 38 F.4th 341, 350–351 (3d Cir. 2022) (explaining "it is permissible to consult contemporary dictionaries" when

"discern[ing] the common ordinary meaning" of terms). A generic drug product thus is "marketed" under the IRA when its manufacturer exposes it for sale in a market. No further showing of "robust and meaningful" marketing is required.

The agency's interpretation here also departs from its own previous approaches. CMS proposed to determine when a product is "marketed" by reference to its "market date" as reported under the Medicaid Drug Rebate Program (MDRP) for IRA's Part D inflation rebates. D.I. 19, Ex. 4. Yet CMS's longstanding policy under the MDRP has been to define "marketed" by reference to the date on which a product "is available for sale." Ex. 11, *Announcement of Medicaid Drug Rebate Program*, 83 Fed. Reg. 12,770, 12,784 (Mar. 23, 2018) (MDRP National Rebate Agreement); *see also* 42 C.F.R. § 447.502. Similarly, in the agency's pending proposed MDRP rule, CMS has proposed to define a drug's "market date" as the "date on which the . . . drug was first sold." Ex. 12, *Updates Under the Medicaid Drug Rebate Program*, 88 Fed. Reg. 34,238, 34,292 (May 26, 2023).

The Government dismisses this litany, asserting that those definitions were not "in a context where *de minimis* marketing would plausibly be a concern." D.I. 21-1 at 38. But prior to enacting the IRA, Congress would have been aware of CMS's interpretations of the terms "marketing" and "marketed." *Lorillard v. Pons*, 434 U.S. 575, 580 (1978) ("Congress is presumed to be aware of an administrative . . . interpretation of a statute."). And if Congress was concerned that CMS's prior

interpretations would be insufficient in this context, it could have added qualifying language. It did not. This leads to a more logical conclusion than the one the Government proposes: Congress did not intend for CMS to adopt a new definition of "marketed" inconsistent with the term's accepted ordinary meaning and CMS's prior interpretations.[13]

Congress also knows how to write in a subjective "bona fide" standard or its equivalent. *See* 42 U.S.C. § 1396r-8(k)(1)(B)(i)(II) (as amended by § 2503(a)(2), Pub. L. No. 111-148, 124 Stat. 119) (amending the Medicaid Drug Rebate Program statute to specify that only "bona fide" service fees are exempt from the calculation of average manufacturer price); § 1396r-8(e)(5) (as amended by § 2503(a)(1), Pub. L. No. 111-148, 124 Stat. 119) (amending the MDRP statute to direct the calculation of a drug's federal upper limit using "pharmaceutically and therapeutically equivalent multiple source drug products . . . available for purchase by retail

[13] As AstraZeneca noted in its opening brief, the Supreme Court has addressed this same word in a similar context. In *Asgrow Seed Co. v. Winterboer*, the Supreme Court addressed whether an Iowa farming couple had planted and harvested seeds "as a step in marketing" under the Plant Variety Protection Act. 513 U.S. 179, 186 (1995). The Court explained that the word "marketing" refers to "the act of holding forth property for sale." *Id.* at 187 (citing dictionary definitions). The Court rebuffed the Federal Circuit's attempt to read into the statute's use of "marketing" a requirement that the marketing be "extensive." *Id.* The Government contends that *Asgrow Seed Co.* involved a different statute. D.I. 21-1 at 39–40. That is true enough, and it is also irrelevant. The Court's approach to the same statutory term is noteworthy.

community pharmacies on a nationwide basis"). The absence of "bona fide" in the IRA says something important: "Omitting a phrase from one statute that Congress has used in another statute with a similar purpose 'virtually commands the . . . inference' that the two have different meanings." *Prewett v. Weems*, 749 F.3d 454, 461 (6th Cir. 2014) (quoting *United States v. Ressam*, 553 U.S. 272, 276–277 (2008)). That is why when "Congress opts not to include a well known and frequently used approach in drafting a statute, the courts"—to say nothing of an agency—"should hesitate to pencil it back in under the guise of interpretation." *Id.* The Government suggests that Congress vested CMS with free-range discretion through its use of a single word: "determine." The Government argues that because CMS must "determine" whether a generic competitor "is marketed," CMS therefore "must exercise some judgment in applying this standard," D.I. 21-1 at 34–35—including, apparently, making a "holistic inquiry," based on review of extensive data from multiple sources and taking into account the "totality of the circumstances," into whether a generic competitor is "marketed" in a sufficiently "robust and meaningful" way. *Supra* at 38–39. That is far too much weight to place on the word "determine." The word "determine" means to ascertain or establish something. What *follows* the verb is what dictates whether the inquiry is absolute or discretionary. *See Whitman v. American Trucking Ass'n*, 531 U.S. 457, 475 (2001) ("[T]he degree of agency discretion that is acceptable varies according to the scope

of the power congressionally conferred."); 42 U.S.C. § 1395w-114c(E)(1) (specifying a penalty "in an amount the Secretary determines is equal to the sum" of two amounts). Where the statute requires the Secretary to "determine" whether a generic drug has been "marketed," the Secretary determines if the generic went to market. Nowhere in the statute does Congress instruct CMS to make a "holistic" determination about "robust and meaningful" marketing.

The IRA also provides CMS no statutory basis to conduct ongoing monitoring after a generic competitor is approved and marketed. Initial Guidance 67–68; Final Guidance 74, 170. The Government contends that Congress's verb choice of "is marketed," rather than "was marketed" or "has been marketed," permits CMS to continually monitor the marketing of generic competitors. D.I. 21-1 at 36. Again, if Congress wanted CMS to *continuously* monitor the marketing of a generic drug to make sure it was being marketed sufficiently "meaningful[ly]," it could have expressly delegated CMS such authority. It did not.

The Government also asserts that AstraZeneca's interpretation of the IRA "would flout Congress's purpose." D.I. 21-1 at 36, 41 (arguing that "CMS's common-sense efforts" are to "prevent obvious workarounds of congressional intent"). As explained above, however, the Court's inquiry should start and end with the text of the statute—not the purported statutory "purpose."

The agency's approach has real-world consequences for AstraZeneca. The statute mandates that generic competition will remove a drug from selection and exempt it from the Maximum Fair Price. AstraZeneca will face generic competition during the first IPAY year for which drugs have been selected, 2026. Under the Guidance, however, CMS purports to hand itself discretion to refuse to recognize generic competition when it feels like it. The agency's "bona fide marketing" test is a blatant overreach.

2. Arbitrary and Capricious.

Under the APA, agency action is arbitrary and capricious when the agency entirely "fail[s] to consider an important aspect of the problem, offer[s] an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n of United States v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

The agency's "bona fide marketing" standard is fundamentally unfair for AstraZeneca. The agency has signaled its intent to rely on Prescription Drug Event (PDE) data when making its "bona fide marketing" judgment calls. Initial Guidance 10; Final Guidance 101–102. PDE data reporting contains exclusively Medicare

Part D plans and moves at a glacial pace.[14] *See* D.I. 19 at 27. As a result, the first six months of PDE data reported after a drug faces generic competition necessarily reflect very limited uptake.

In response, the Government claims that CMS does not intend to rely exclusively on PDE data to show how many units of a generic or biosimilar product are sold. D.I. 21-1 at 41. According to the Government, CMS also will consider Average Manufacturer Price (AMP) data and "multiple" other sources as appropriate. D.I. 21-1 at 42. CMS's potential use of "multiple" other unknown sources just further supports the conclusion that the agency's standard is arbitrary and capricious. An agency "should provide regulated parties 'fair warning of the conduct [a regulation or guidance] prohibits or requires.' " *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 156 (2012).

The IRA is a heavy-handed statute that imposes a significant burden on manufacturers. The one critical concession the statute gives to AstraZeneca and other manufacturers is that when a drug product faces generic competition, the drug is no longer subject to the IRA's price controls. CMS's "bona fide marketing" test annihilates that statutory protection. Under the agency's test, AstraZeneca will have

[14] The Government purports that AstraZeneca "exaggerate[s] the delay in PDE data." D.I. 21-1 at 42 n.8. No matter; *any* amount of delay violates the statute and causes harm to AstraZeneca. The Government also offers no support, besides citing CMS's own Guidance documents, for its claim that PDE data is not all *that* delayed.

to sell FARXIGA at the agency's compelled below-market price, despite also facing generic competition for that same product between October 2025 and Summer 2026, unless and until the agency decides the generic product has been marketed in a sufficiently "robust and meaningful" manner. That outcome is both illogical and fundamentally unfair. It therefore is unlawful under the APA. *See American Fed'n of Gov't Emps., Loc. 2924 v. Federal Lab. Rels. Auth.*, 470 F.3d 375, 380 (D.C. Cir. 2006) (explaining that an agency's action is arbitrary and capricious "if the result reached is illogical on its own terms") (internal quotation marks omitted).

IV. THE PROGRAM VIOLATES DUE PROCESS.

AstraZeneca has detailed how the Drug Price Negotiation Program violates core principles of procedural due process. *See* D.I. 19 at 28–32. In response, the Government does not refute much of what AstraZeneca has argued, including that (1) AstraZeneca has legally cognizable, protected property interests in its patented drug products; (2) the IRA deprives AstraZeneca of its property interests by forcing its products to be sold at below-market prices; while (3) implementing a far-reaching regulatory program without any meaningful opportunity to be heard at any point in the process—a conclusion the Government's brief helpfully reinforces by arguing that (4) *all* of the agency's decisions pertinent to the negotiation scheme are exempt from administrative or judicial scrutiny; all under the threat of (5) civil monetary penalties; and (6) a draconian excise tax.

The Government's due process defense reduces to two points. Neither has merit.

CMS first points to an Ohio district court ruling that business-group plaintiffs could not obtain preliminary injunctive relief on a due process claim they have asserted against the IRA's Drug Price Negotiation Program. D.I. 21-1 at 44 (citing *Dayton Area Chamber of Com. v. Becerra*, No. 3:23-cv-156, 2023 WL 6378423, at *11 (S.D. Ohio Sept. 29, 2023)). That Ohio case is not the universal solvent the Government thinks it is. It largely turned on the application of a particular Sixth Circuit precedent. Observing that the "[p]laintiffs rel[ied] heavily on *Mich. Bell Tel. Co. v. Engler*, 257 F.3d 587 (6th Cir. 2001)," the Ohio trial court explained that in *Michigan Bell*, the Sixth Circuit weighed whether customer-fee and rate-freeze provisions of a state statute should be preliminarily enjoined because they imposed confiscatory rates in violation of due process. *Chamber*, 2023 WL 6378423, at *11. The statute at issue in *Michigan Bell* "compelled participation" by the plaintiff telephone companies and "denied them of their right to a fair and reasonable rate of return" such that the "utility rates imposed by the State were so unreasonable and unjust that they were considered confiscatory." *Id.* (quoting *Michigan Bell*, 257 F.3d at 593). The Sixth Circuit held in those circumstances that a preliminary injunction should issue as to the plaintiff utilities' claims. The Ohio district court, by contrast, was unpersuaded "at this initial stage in the litigation process" that the business-

organization plaintiffs were similarly entitled to immediate injunctive relief. *Id.* at *12.

The *Chamber* decision tells us, then, that one district court has denied a trade association a preliminary injunction because the Sixth Circuit public-utility precedent those plaintiffs "rel[ied] heavily" on did not squarely demonstrate their entitlement to Rule 65 relief. *Id.* at *11. AstraZeneca, however, does not need to demonstrate it is entitled to a preliminary injunction to obtain relief on its due process claim at the summary-judgment stage. And AstraZeneca does not invoke a *Michigan Bell*-like precedent to support its procedural due process claim, much less does it need to satisfy that out-of-circuit standard. The Government's overreliance on the *Chamber* decision proves too much.

AstraZeneca's due process claim succeeds under the Third Circuit's unequivocal legal standard. "The core of due process is an 'opportunity to be heard at a meaningful time and in a meaningful manner.' " *Frein v. Pennsylvania State Police*, 47 F.4th 247, 257 (3d Cir. 2022) (quoting *Mathews v. Eldridge*, 424 U.S. 319, 333 (1976)). That usually means a pre-deprivation hearing: "In the typical situation, the hearing should come before the Government deprives a person of his property." *Elsmere Park Club, L.P. v. Town of Elsmere*, 542 F.3d 412, 417 (3d Cir. 2008); *see also Westinghouse Elec. Corp. v. U.S. Nuclear Regul. Comm'n*, 555 F.2d 82, 95 (3d Cir. 1977) ("[D]ue process requires an opportunity for interested parties

to be heard in rulemaking proceedings in many circumstances."). In certain cases where a pre-deprivation hearing is not " 'feasibl[e],' it may give process after the deprivation." *Frein*, 47 F.4th at 257 (quoting *Zinermon v. Burch*, 494 U.S. 113, 132 (1990)).

The Government may not, under these principles, simply refuse to allow AstraZeneca any opportunity to be heard before *or* after depriving the company of its protected property interest in the products it has developed—at least not without violating due process. And paying below-market rates for AstraZeneca's products is no answer, either, as "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).

CMS's second attempt to pivot away from its duty to afford due process is to argue that AstraZeneca's participation in the Drug Price Negotiation Program is voluntary. D.I. 21-1 at 44–48. To begin with, the vast majority of the cases cited by the Government involved takings claims.[15] *See* D.I. 21-1 at 44–48 (citing cases). Those cases arose under a different legal framework and, unlike AstraZeneca's claims, dealt with asserted injuries that were compensable in damages.

[15] The primary exception was the *Chamber* case, dispensed with above.

In any event, participation in the Drug Price Negotiation Program is anything but voluntary. The Third Circuit itself intimated as much just months ago, observing that "[t]he federal government dominates the healthcare market. Through Medicare and Medicaid, it pays for almost half the annual nationwide spending on prescription drugs." *Sanofi Aventis U.S. LLC v. HHS*, 58 F. 4th 696, 699 (3d Cir. 2023). As the Third Circuit explained, the federal government "uses that market power to get drug makers to subsidize healthcare" by making their products available to federal payers. *Id.*

The Government's drug-payment umbrella covers much more than just one IRA-selected drug reimbursed under Medicare Part B and Part D. The obligation to participate, which encompasses both Medicare and Medicaid, is all-or-nothing: A manufacturer either has all of its drugs in the federal programs, or none of them. *See* 42 U.S.C. § 1396r-8(a)(1) *see also* Ex. 11, 83 Fed. Reg. 12,770, 12,785 (Oct. 1, 2018); 42 U.S.C. § 1395w-153(a); 42 C.F.R. § 423.2315(b)(5); CMS, Medicare Part D Manufacturer Discount Program Final Guidance at 42 (Nov. 17, 2023). Thus, if a manufacturer withdraws from Medicare Part D and the Medicaid Drug Rebate Program to avoid the IRA's below-market price-fixing and ruinous penalties, *see* 26 U.S.C. § 5000D(c), its drugs will no longer be covered under Medicare Part B, Medicare Part D, or Medicaid with respect to all of its products. *Id.* That Medicare and Medicaid one-two punch is an all-or-nothing proposition for a pharmaceutical

manufacturer with many products: AstraZeneca could not withdraw only FARXIGA from only Medicare Part D—it would need to withdraw *its entire product portfolio* from Medicare Parts B and D and Medicaid. *See id.* § 5000D(c)(1).

That would result in losses of 40% of AstraZeneca's gross U.S. revenue. Medicare is the behemoth in the prescription drug market. It is responsible for covering 30% of prescription drug sales; when Medicaid is added in, that number rises to nearly 50%.[16] This market dominance is baked-in. Medicare Part A is mandatory for all Americans who are eligible for coverage. In turn, Part A beneficiaries are automatically enrolled in Part B (which covers physician-administered drugs) unless they opt out, and few do: approximately 90% choose to remain enrolled in Part B.[17] Part D (which covers other drugs) is voluntary but also has a high enrollment rate.[18] The resulting market dominance wielded by the

[16] Ex. 13, *Table 04 National Health Expenditures by Source of Funds and Type of Expenditures*, Ctrs. for Medicare & Medicaid Services, at row 111, *available at* https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet (download "NHE Tables" zip folder; open Table 4) (last visited Dec. 1, 2023); *see also Sanofi-Aventis*, 58 F.4th at 696.

[17] Ex. 14, Medicare Beneficiary Enrollment Trends and Demographic Characteristics, U.S. Dep't of Health & Human Servs., at 4 tbl.1 (Mar. 2, 2022), *available at* https://aspe.hhs.gov/sites/default/files/documents/f81aafbba0b331c71c6e8bc66512e25d/medicare-beneficiary-enrollment-ib.pdf (34 of 38.7 million Part A beneficiaries also participated in Part B in 2019).

[18] *Id.* at 1–2, 4. (74.4% of all Medicare beneficiaries enrolled in Part D in 2019).

Government is so powerful that it would readily support an antitrust violation if the Government were a private market participant.[19] The problem is especially dire for physician-administered drugs that treat conditions more commonly found in older Americans, where Medicare Part B makes up a disproportionately high percentage of their payer mix. Take AstraZeneca's product IMFINZI® (durvalumab), an immunotherapy designed to treat certain cancers. The majority of its patient population—over 50%—is comprised of Medicare beneficiaries. Ader Decl. ¶ 12.

There are other, non-financial reasons that manufacturers cannot leave the Medicare and Medicaid programs with all of their products. Consider, above all else, the patient impact: AstraZeneca's portfolio includes oncology products and those that treat rare diseases. Removal of these products from Medicare and Medicaid would result in significant harm to patients, quite apart from the reputational and financial harm to a manufacturer from withdrawing.

In short, AstraZeneca's "choice" to withdraw all its products from participation in Medicare and Medicaid is not a choice; "it is a gun to the head." *National Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 581 (2012).

[19] Ex. 15, *Monopolization Defined*, Fed. Trade Comm'n, *available at* https://www.ftc.gov/advice-guidance/competition-guidance/guide-antitrust-laws/single-firm-conduct/monopolization-defined (explaining Section 2 of the Sherman Act, 15 U.S.C. § 2).

CONCLUSION

For these reasons, as well as those in AstraZeneca's opening brief, the Court should grant AstraZeneca's motion for summary judgment, deny the Government's cross-motion for summary judgment, vacate the relevant portions of the Initial Guidance and the Final Guidance, and declare that the IRA Drug Price Negotiation Program violates due process.

Respectfully submitted,

Dated: December 1, 2023

MCCARTER & ENGLISH, LLP

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP and ASTRAZENECA AB, Plaintiffs, v. XAVIER BECERRA, in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, and CHIQUITA BROOKS-LASURE, in her official capacity as ADMINISTRATOR OF THE CENTERS FOR MEDICARE & MEDICAID SERVICES, Defendants.	Civil Action No. 23-931-CFC

WORD COUNT CERTIFICATION

Pursuant to the Stipulated Order Regarding Cross-Motions for Summary Judgment (D.I. 15), the undersigned counsel hereby certifies that Plaintiffs' Brief In Opposition to Defendants' Cross-Motion for Summary Judgment and Reply In Support of Plaintiffs' Motion for Summary Judgment was prepared in 14-point Times New Roman font, and contains 11,894 words (excluding the caption, title,

tables of contents and authorities, and signature blocks), which were counted using the word count feature in Microsoft Word.

DATED: December 1, 2023

/s/ *Daniel M. Silver*
Daniel M. Silver (#4758)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP and ASTRAZENECA AB, Plaintiffs, v. XAVIER BECERRA, in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, and CHIQUITA BROOKS-LASURE, in her official capacity as ADMINISTRATOR OF THE CENTERS FOR MEDICARE & MEDICAID SERVICES, Defendants.	Civil Action No. 23-931-CFC

[PROPOSED] ORDER DENYING DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

Upon consideration of Defendants' Cross-Motion for Summary Judgment, the briefs in support thereof and in opposition thereto, arguments of counsel, and the entire record in this case, it is hereby

ORDERED, this _____ day of _____, 2024, that Defendants' Cross-Motion for Summary Judgment is **DENIED**.

The Honorable Colm F. Connolly
Chief United States District Judge