UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TEVA PHARMACEUTICALS USA, INC., *et al.*, Plaintiffs, v. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of Health and Human Services, *et al.*, Defendants.[1]	Civil Action No. 25-113 (SLS)

DEFENDANTS' COMBINED MEMORANDUM OF LAW IN SUPPORT OF THEIR CROSS-MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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[1] Pursuant to Federal Rule of Civil Procedure 25(d), Robert F. Kennedy, Jr., Secretary of Health and Human Services, is automatically substituted as a defendant in his official capacity for his predecessor, Acting Secretary Dorothy A. Fink. Dr. Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, is likewise automatically substituted as a defendant in his official capacity for his predecessor, Acting Administrator Stephanie Carlton.

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INTRODUCTION

For more than 30 years, Congress has limited how much federal agencies will pay for prescription drugs. Manufacturers that wish to sell their drugs to the Departments of Defense and Veterans Affairs, for example, do so subject to statutorily defined ceiling prices, and both agencies have authority to negotiate prices below those ceilings. *See* 38 U.S.C. § 8126(a)-(h). In the Inflation Reduction Act of 2022, Pub. L. No. 117-169, 136 Stat. 1818 (IRA), Congress gave the Secretary of Health and Human Services (HHS) similar authority to address the extraordinary and unsustainable increase in the prices that Medicare pays for pharmaceutical products that lack generic competition and that account for a disproportionate share of Medicare's expenses. *See* 42 U.S.C. §§ 1320f(a), 1320f-1(b), (d), (e). Under the IRA's Drug Price Negotiation Program, the Centers for Medicare & Medicaid Services (CMS) can now negotiate the prices that Medicare will pay for a select group of drugs manufactured by companies that choose to sell drugs to Medicare and Medicaid.

Unsurprisingly, drug manufacturers—which have long profited from unrestricted growth in Medicare's prescription drug payments—lobbied hard against legislative efforts to introduce market discipline by giving the Secretary a seat at the negotiating table. After their lobbying failed, pharmaceutical companies and interest groups repackaged their policy disagreements into lawsuits, filing complaints around the country challenging the Negotiation Program on a wide variety of statutory and constitutional grounds. This case, brought by a manufacturer of both generic and branded prescription drugs, is lawsuit number 11 of 11. But it fares no better than the others.

As a threshold matter, the Court lacks subject-matter jurisdiction over both of Plaintiffs' Administrative Procedure Act (APA) claims, in which they contest how CMS has interpreted a single statutory term. That term—"qualifying single source drug"—identifies a set of threshold criteria for a drug to be potentially included in the Negotiation Program. 42 U.S.C. § 1320f-1(e). On Plaintiffs' telling, CMS misread that statutory definition in two different ways. But Congress provided expressly that there "shall be no administrative or judicial review" of certain

administrative actions—including CMS's "determination of qualifying single source drugs," its determination of "negotiation-eligible drugs," and its "selection of drugs" for negotiation. 42 U.S.C. § 1320f-7. By contesting CMS's application of the definition of a "qualifying single source drug," Plaintiffs walk directly into that explicit preclusion provision. Both the plain text of the IRA and case law analyzing similar bars to judicial review in other parts of the Medicare statute confirm that this Court cannot ignore Congress's choice to explicitly preclude judicial review.

Even if this Court had jurisdiction to consider them, Plaintiffs' statutory claims would also fail on the merits. CMS's interpretation straightforwardly implements the text of the statute, as well as its broader structure and purpose. Plaintiffs' dispute with those interpretations ultimately boils down to disagreements with policy choices made by Congress. Plaintiffs' preferred interpretations are not only atextual, but would open the Negotiation Program to easy gamesmanship by drug manufacturers, who would be able to avoid the Program's requirements by engaging in well-documented practices that are intended only to maintain market exclusivity and high prices. As the text of the statute shows, Congress sought to prevent manufacturers from thwarting the negotiation program's cost-saving measures through this sort of manipulation.

Disposing of Plaintiffs' statutory challenges leaves only their claim that the Negotiation Program violates the Due Process Clause. But the threshold "inquiry in every due process challenge is whether the plaintiff has been deprived of a protected interest" in liberty or property. *Am. Mfrs. Mut. Ins. v. Sullivan*, 526 U.S. 40, 59 (1999). So, as several courts have recognized in rejecting largely identical claims, Plaintiffs' due process claim does not even get off the ground because drug manufacturers have no constitutionally protected property interest in their unilateral desire to continue selling their drugs to the government at their preferred price.

BACKGROUND

I. Medicare and the IRA's Drug Negotiation Program

A. Congress created Medicare in 1965. *See* Social Security Amendments of 1965, Pub. L. No. 89-97, tit. I, 79 Stat. 286, 290-353. Medicare is a federal program that pays for covered healthcare items and services, including prescription drugs, for qualified beneficiaries. *See*

generally 42 U.S.C. § 1395 *et seq*. The Medicare statute encompasses several "Parts," which set forth the terms by which Medicare will pay for benefits. *See Ne. Hosp. Corp. v. Sebelius*, 657 F.3d 1, 2 (D.C. Cir. 2011).

"Traditional Medicare comprises Part A, which covers medical services furnished by hospitals and other institutional care providers, and Part B, which covers outpatient care like physician and laboratory services," as well as the cost of drugs administered as part of that care. *Cares Cmty. Health v. HHS*, 944 F.3d 950, 953 (D.C. Cir. 2019) (cleaned up). In 2003, Congress added Medicare Part D, which provides "a voluntary prescription drug benefit program that subsidizes the cost of prescription drugs and prescription drug insurance premiums for Medicare enrollees." *United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 749 (3d Cir. 2017); *see* 42 U.S.C. § 1395w-101 *et seq*. Prior to the IRA, Congress barred the Secretary from negotiating drug prices under Part D or otherwise interfering in the commercial arrangements between manufacturers and the private insurance plans that, in turn, enter into agreements with Medicare to provide benefits. *See* 42 U.S.C. § 1395w-111(i).

This model has contributed to rapidly rising costs to Medicare in recent years. Medicare Part D spending has doubled over the last decade, and it "is projected to increase faster than any other category of health spending." S. Rep. No. 116-120, at 4 (2019); *see also* Cong. Budget Off., *Prescription Drugs: Spending, Use, and Prices* 16 (Jan. 2022), https://perma.cc/9WPC-VLFC. Much of that increase is attributable to a "relatively small number of drugs [that] are responsible for a disproportionately large share of Medicare costs." H.R. Rep. No. 116-324, pt. II, at 37 (2019). Congressional reports have found that generic competitors face many legal and practical obstacles to market entry, sometimes leaving only a single manufacturer of a particular drug on the market for extended periods of time. *See* Staff of H. Comm. on Oversight & Reform, 117th Cong., *Drug Pricing Investigation: AbbVie—Humira and Imbruvica* 36 (May 2021), https://perma.cc/9L42-VRBK. For example, manufacturers of brand-name drugs often fend off generic competitors by introducing inconsequential changes to their drug and shifting patients to that new version, a strategy known as "product hopping." H.R. Rep. No. 116-695, at 3 (2020). Similarly, brand-name

manufacturers often protect their market share by entering into "settlements" with generic manufacturers that permit the generic to be marketed only nominally, without resulting in meaningful competition. *See, e.g.*, Sarah M.E. Gabriele, et al., *The Problem of Limited-Supply Agreements for Medicare Price Negotiation,* 330 JAMA 1223 (2023). And the payment formula for drugs covered under Part B permits a manufacturer of a drug without generic competition to "effectively set[] its own Medicare payment rate." Medicare Payment Advisory Comm'n, *Report to the Congress: Medicare and the Health Care Delivery System* 84 (June 2022), https://perma.cc/5X4R-KCHC. The result has been a shift of financial burden to Medicare, undermining the program's premise of using market competition to reduce prices for beneficiaries and costs for taxpayers. *Id.* at 120. Because of how cost-sharing and premiums function under Part D, high drug costs also increase out-of-pocket payments by Medicare beneficiaries.

B. The IRA seeks to address these concerns. *See* Pub. L. No. 117-169, §§ 11001-11003 (codified at 42 U.S.C. §§ 1320f-1320f-7 and 26 U.S.C. § 5000D). As relevant here, the IRA requires the Secretary, through CMS, to establish the Negotiation Program, through which he will negotiate the prices Medicare pays for certain covered drugs: those with the highest Medicare Parts B and D expenditures and no generic or biosimilar competitors, and that have been marketable for at least 7 years (*i.e.*, drugs that have long enjoyed little market competition). *See* 42 U.S.C. § 1320f *et seq.* The Negotiation Program applies only to the prices Medicare pays for selected drugs that it covers; the statute regulates neither the prices manufacturers may charge for drugs generally nor the conduct of manufacturers that do not participate in Medicare or Medicaid. *See, e.g.*, *id.* § 1320f-1(b), (d).

To carry out the Negotiation Program, the statute requires CMS to first identify a set of "negotiation-eligible drug[s]" from a set of "qualifying single source drugs." 42 U.S.C. § 1320f-1(d)–(e) (defining "negotiation-eligible drug" and "qualifying single source drug"). Congress directed CMS to select up to 10 such drugs for negotiation for initial price applicability year 2026, up to 15 drugs for initial price applicability years 2027 and 2028, and up to 20 drugs for initial price applicability year 2029 and for subsequent years. *Id.* § 1320f-1(a)–(b).

After selecting the drugs, CMS is directed to negotiate with the manufacturer of each selected drug in an effort to reach agreement on a "maximum fair price" for that drug. *Id.* § 1320f-3. In formulating offers during the course of those negotiations, the statute requires CMS to consider several categories of information, including (1) "[r]esearch and development costs of the manufacturer for the drug and the extent to which the manufacturer has recouped" those costs, (2) current "costs of production and distribution," (3) prior "Federal financial support for . . . discovery and development with respect to the drug," and (4) evidence about alternative treatments. *Id.* § 1320f-3(e). In hopes of achieving meaningful savings for the American people, Congress imposed a "[c]eiling for [the] maximum fair price," which it tied to specified pricing data. *Id.* § 1320f-3(c). But Congress also directed CMS to "aim[] to achieve the lowest maximum fair price" that manufacturers will accept. *Id.* § 1320f-3(b)(1).

CMS is directed to sign agreements to negotiate prices for selected drugs with willing manufacturers. *See id.* § 1320f-2. If those negotiations prove successful, a manufacturer will then sign an addendum agreement to establish the maximum price at which the drug will be made available to Medicare beneficiaries. *Id.* A manufacturer that does not wish to sign such an agreement—or to otherwise participate in the Negotiation Program—has several options. It can continue selling the selected drug to be dispensed or furnished to Medicare beneficiaries at non-negotiated prices and pay an excise tax on those sales. *See* 26 U.S.C. § 5000D. It can continue selling its other drugs to Medicare but transfer its interest in the selected drug to another entity, which can then make its own choices about negotiations. *See* CMS, *Medicare Drug Price Negotiation Program: Final Guidance* 236-27 (Oct. 2, 2024), http://perma.cc/D457-4V4E (2027 Guidance). Or it can withdraw from Medicare and Medicaid—in which case it will incur no excise tax and no other liability. *See id.* at 33-34, 120-21, 129-31; *see also* Pub. L. No. 117-169, § 11003 (codified at 26 U.S.C. § 5000D(c)(1)).

These conditions parallel those Congress has long attached to other government healthcare programs. For example, Congress has long required that any drug manufacturer wishing to participate in Medicaid enter into agreements with the Secretary of Veterans Affairs giving the

Department of Veterans Affairs, the Department of Defense, the Public Health Service, and the Coast Guard the option to purchase drugs at negotiated prices at or below statutory ceiling prices. *See* 38 U.S.C. § 8126(a)-(h). As in those statutes, the Negotiation Program gives manufacturers a choice: they can sell their products at prices the government is willing to pay, or they can take their business elsewhere.

II. CMS's Implementation of the Negotiation Program

Congress directed CMS to implement the Negotiation Program through "program instruction or other forms of program guidance" through 2028. Pub. L. No. 117-169, § 11001(c). Following that statutory mandate, CMS issued initial 2026 guidance on March 15, 2023, explaining how it intended to implement certain aspects of the statute and soliciting public input. *See* CMS, *Medicare Drug Price Negotiation Program: Initial Memorandum* (Mar. 15, 2023), https://perma.cc/8X4K-CVD8 (Initial Guidance). After considering more than 7,500 public comments "representing a wide range of views," CMS published revised 2026 guidance on June 30, 2023. *See* CMS, *Medicare Drug Price Negotiation Program: Revised Guidance* 1-2 (June 30, 2023), https://perma.cc/K6QB-C3MM (2026 Guidance). On October 24, 2024, after voluntarily soliciting another round of comments, CMS published guidance for initial price applicability year 2027. *See* 2027 Guidance 1-2.[2]

The 2027 Guidance describes several aspects of CMS's implementation of the second year of the Negotiation Program, including the methodologies by which CMS selects drugs for negotiation, the negotiation process, the types of data that CMS considers in making an offer, and the procedures for manufacturers to follow if they decide not to participate in the Negotiation Program. *Id.* at 160-62. As to that last point, the 2027 Guidance expressly provides that if a manufacturer "determines . . . that it is unwilling to continue its participation in the Negotiation Program," CMS will "facilitate an expedited Termination Date" of the manufacturer's Medicare agreements before the manufacturer would incur liability for any excise tax, so long as the

[2] For purposes of this brief, the 2027 Guidance is materially identical to the 2026 Guidance on all of the issues that Plaintiffs raise in this suit.

manufacturer notifies CMS of its desire to withdraw at least 30 days in advance of when that tax would otherwise begin to accrue. *Id.* at 235. The 2027 Guidance also notes that manufacturers that wish to remain in the Medicare and Medicaid programs but that do not wish to negotiate can divest their interest in the selected drug(s). *Id.* at 236-27.

On August 29, 2023, CMS published the list of drugs selected for negotiation for initial price applicability year 2026. *See* HHS, *HHS Selects the First Drugs for Medicare Drug Price Negotiation* (Aug. 29, 2023), https://perma.cc/A36P-Z88Z. The drugs selected accounted for more than $50 billion—or about 20%—of gross Medicare Part D spending between June 2022 and May 2023. *See* CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026* (Aug. 2023), https://perma.cc/X37F-RC94.

Manufacturers of selected drugs have challenged the constitutionality of the Negotiation Program in cases that are pending around the country.[3] To date, four district court judges have considered such constitutional claims on the merits, and each has rejected the claims. *See AstraZeneca Pharms. LP v. Becerra*, 719 F. Supp. 3d 377 (D. Del. 2024) (Connolly, C.J.), *appeal filed*, No. 24-1819 (3d. Cir. May 2, 2024); *Dayton Area Chamber of Com. v. Becerra*, 696 F. Supp. 3d 440 (S.D. Ohio 2023) (Newman, J.); *Boehringer Ingelheim Pharms., Inc. v. HHS*, No. 3:23-cv-01103, 2024 WL 3292657 (D. Conn. July 3, 2024) (Shea, J.), *appeal filed*, No. 24-2092 (2d Cir Aug. 8, 2024); *Bristol Myers Squibb Co. v. Becerra*, Nos. 23-cv-3335, 23-cv-3818, 2024 WL 1855054 (D.N.J. Apr. 29, 2024) (Quraishi, J.), *appeals filed*, Nos. 24-1820 & 24-1821 (3d Cir. May 6, 2024); *Novo Nordisk Inc. v. Becerra*, No. 23-20814, 2024 WL 3594413 (D.N.J. July 31,

[3] *See Merck & Co. v. Kennedy*, No. 1:23-cv-1615 (D.D.C. filed June 6, 2023); *Dayton Area Chamber of Com. v. Becerra*, No. 3:23-cv-156 (S.D. Ohio filed June 9, 2023); *Bristol Myers Squibb Co. v. Becerra*, No. 3:23-cv-3335 (D.N.J. filed June 16, 2023); *Janssen Pharms., Inc. v. Becerra*, No. 3:23-cv-3818 (D.N.J. filed July 18, 2023); *Boehringer Ingelheim Pharm., Inc. v. HHS*, No. 3:23-cv-1103, 2024 WL 3292657 (D. Conn. filed July 3, 2024); *AstraZeneca Pharms. LP v. Becerra*, No. 1:23-cv-931 (D. Del. filed Aug. 25, 2023); *Novartis Pharms. Corp. v. Becerra*, No. 3:23-cv-14221 (D.N.J. filed Sept. 1, 2023); *Novo Nordisk Inc. v. Becerra*, No. 3:23-cv-20814 (D.N.J. filed Sept. 29, 2023); *Teva Pharms. USA, Inc. v. Kennedy*, No. 1:25-cv-113 (D.D.C. filed Jan. 15, 2025).

2024) (Quraishi, J.), *appeal filed*, No. 24-2510 (3d Cir. Aug. 19 2024); *Novartis Pharms. Corp. v. Becerra*, No. 23-14221, 2024 WL 4524357, at *2 (D.N.J. Oct. 18, 2024) (Quraishi, J.).

In the meantime, for the first negotiation cycle, manufacturers of all the selected drugs executed agreements to negotiate the price of their respective drugs. *See* CMS, *Medicare Drug Price Negotiation Program: Manufacturer Agreements for Selected Drugs for Initial Price Applicability Year 2026* (Oct. 3, 2023), https://perma.cc/3222-VPEE (*Manufacturer Agreements*). In accordance with the schedule established by Congress, CMS presented the drug manufacturers of selected drugs with initial offers by February 1, 2024. *See* CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026* (Aug. 15, 2024), https://perma.cc/6MVG-BZP8. Each participating manufacturer responded with a counteroffer by March 2, 2024. *Id.* CMS subsequently held three negotiation meetings with each company to discuss the offers and relevant evidence. *Id.* Many companies proposed revised counteroffers during these meetings, and CMS accepted four of these revised counteroffers outright, and reached agreement with a fifth manufacturer on a negotiated price. *Id*. CMS then sent final offers to manufacturers of the five remaining drugs. By August 1, 2024, CMS and the participating manufacturers had agreed to a negotiated price for each of the 10 selected drugs. *See id.* Assuming that none of the 10 manufacturers withdraw from Medicare and Medicaid by December 2025, those prices take effect on January 1, 2026. 42 U.S.C. §§ 1320f(b), (d), 1320f-2(a), 1320f-3(b).

Earlier this year, CMS announced the list of selected drugs for the second negotiation cycle. CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2027* (Jan. 2025), https://perma.cc/3GTY-V2KL. The negotiation process is now underway.

III. Litigation Background

Plaintiffs—Teva Pharmaceuticals USA, Inc., Teva Branded Pharmaceutical Products R&D, Inc., and Teva Neuroscience, Inc. (collectively "Teva")—filed this suit on January 15, 2025, Compl., ECF No. 1, and filed an amended complaint (as of right) on February 10, 2025, Am. Compl., ECF No. 9. Teva sells both brand-name and generic pharmaceuticals. *See* Am. Compl. ¶¶ 21-23. One of Teva's products is Austedo, a brand-name drug that was selected for the

Negotiation program's second negotiation cycle. *See id.* ¶ 93. Austedo treats Tardive Dyskinesia and Huntington's Disease, and is also available in an "extended-release formulation," which Teva markets as "Austedo XR." *Id.* ¶¶ 87, 89. From November 2023 to October 2024, Austedo accounted for approximately $1,531,855,000.00 in Medicare Part D spending, for roughly 26,000 Medicare patients—just under $59,000 per patient. *See* CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2027* (Jan. 2025), *available at* https://tinyurl.com/5h7aka7x.

Teva moved for summary judgment on all claims. ECF No. 15. Defendants now cross-move for summary judgment and oppose Plaintiffs' motion for summary judgment.

ARGUMENT

Plaintiffs' statutory-interpretation claims (Counts I and II) should be dismissed for lack of subject-matter jurisdiction, because they challenge agency determinations over which Congress expressly provided that "[t]here shall be no administrative or judicial review." 42 U.S.C. § 1320f-7. Regardless, those claims would also fail on the merits. CMS appropriately considered the different forms of Teva's drug in selecting both Austedo and its "extended release formulation," 42 U.S.C. § 1320f-1(d)(3)(B), Austedo XR, just as Congress directed. CMS's bona-fide marketing standard is also faithful to the statute's text, structure, and purpose. Finally, Plaintiffs' due process claim (Count III) fails for several reasons, the most obvious of which is that the Negotiation Program does not deprive Plaintiffs of any protected constitutional interest in liberty or property, as several courts have concluded in rejecting materially identical claims.

I. CONGRESS EXPRESSLY PRECLUDED JUDICIAL REVIEW OVER PLAINTIFFS' STATUTORY CLAIMS.

Congress expressly provided that "[t]here shall be no administrative or judicial review" of (1) CMS's "selection of drugs" for negotiation under § 1320f-1(b); (2) its "determination of negotiation-eligible drugs" under § 1320f-1(d); or (3) its "determination of qualifying single source drugs" under § 1320f-1(e). 42 U.S.C. § 1320f-7(2). Those prohibitions straightforwardly encompass Teva's statutory claims, which challenge the agency's determination of what

constitutes a "qualifying single source drug" and the resulting determination as to which drugs are eligible and may be selected.

It is well established that "Congress may determine a lower federal court's subject-matter jurisdiction." *Kontrick v. Ryan*, 540 U.S. 443, 452 (2004). Although there is a "strong presumption that Congress intends judicial review of administrative action," *Bowen v. Mich. Acad. of Fam. Physicians*, 476 U.S. 667, 670 (1986), when Congress "provides that 'there shall be no administrative or judicial review' of specified agency actions, its intent to bar review is clear," *DCH Reg'l Med. Ctr. v. Azar*, 925 F.3d 503, 505-06 (D.C. Cir. 2019) (citation omitted) (quoting 42 U.S.C. § 1395nn(i)(3)(I)); *see* 5 U.S.C. § 701(a)(1) (confirming that APA review is unavailable where "statutes preclude judicial review"). The only question in those circumstances is "whether the challenged action falls 'within the preclusive scope' of the statute." *DCH Regional*, 925 F.3d at 506 (quoting *Knapp Med. Ctr. v. Hargan*, 875 F.3d 1125, 1128 (D.C. Cir. 2017)).

Here, that is a straightforward inquiry. Plaintiffs' amended complaint and summary-judgment brief openly and directly challenge CMS's determination of what constitutes a "qualifying single source drug" under § 1320f-1(e). Specifically, Plaintiffs assert that CMS misinterpreted two aspects of the "qualifying single source drug" definition, namely (1) which products can be considered a single "qualifying single source drug"; and (2) which drugs can be excluded from the "qualifying single source drug" definition on the ground that they have a generic competitor.

Their first statutory claim (Count I) disparages CMS guidance as (in Plaintiffs' words) a "redefinition of a Qualifying Single Source Drug" that "changes the selection criteria" in the statute. Am. Compl. ¶ 135; *see also, e.g.*, Mem. in Supp. of Pls.' Mot. for Summ. J. at 18-19, ECF No. 15-1 ("Pls.' Br.") ("But for CMS's definition of qualifying single source drug aggregating distinct, separately approved drug products, AUSTEDO XR would not have been eligible for selection."). The first subject heading in the Argument section of Plaintiffs' brief leaves no doubt about the nature of Plaintiffs' theory: that "CMS's Definition Of Qualifying Single Source Drug

Is Unlawful." Pls.' Br. at 21. That is a straightforward challenge to CMS's "determination of qualifying single source drugs." 42 U.S.C. § 1320f-7(2).

Plaintiffs' second statutory claim (Count II) similarly protests that CMS's guidance on the "bona fide marketing" standard "means that even a drug with generic competition on the market may be selected for 'negotiation.'" Am. Compl. ¶ 150; *see also, e.g.*, Pls.' Br. at 28 (arguing that CMS's "bona fide marketing" standard improperly alters when "a drug is ineligible for negotiation or selection").

Plaintiffs are wrong about all of this on the merits, *see infra*, Section II—but right or wrong, both claims directly challenge CMS's "determination of qualifying single source drugs," and squarely implicate the agency's "determination of negotiation-eligible drugs" and its eventual "selection of drugs" for negotiation. 42 U.S.C. § 1320f-7(2). Congress expressly precluded judicial review of all of these determinations. *See id.*; *accord Novo Nordisk*, 2024 WL 3594413 at *3 ("Congress has divested this Court of jurisdiction to consider challenges under the APA to CMS's determinations under 1320f-1(b), (d), (e), and (f).").

To the extent Plaintiffs contend that the challenged interpretations are somehow ancillary to those for which Congress precluded review, the argument fails both because the statute expressly precludes review of CMS's "determination of qualifying single source drugs," 42 U.S.C. § 1320f-7(2), and because courts have consistently rejected attempts to distinguish between "the procedures used in arriving at [a] determination" and "the merits of the determination itself," *John Balko & Assocs., Inc. v. Sec'y of HHS*, 555 F. App'x 188, 193 (3d Cir. 2014). It is well established that preclusion provisions encompass decisions that are "indispensable or integral to, or inextricably intertwined with, the unreviewable agency action." *Fla. Health Scis. Ctr., Inc. v. Sec'y of HHS*, 830 F.3d 515, 519 (D.C. Cir. 2016) (cleaned up). Thus, any attempt to cast Plaintiffs' claims as a challenge to the means by which drugs are determined to be eligible for selection, rather than a challenge to the eligibility determination itself, would fail because the meaning of "qualifying single source drug" is indispensable to that determination.

Applying that principle, the D.C. Circuit construed a statute barring review of "the awarding of contracts" to preclude challenges to a regulation setting forth eligibility standards for such contracts because the challenged standards were "indispensable to 'the awarding of contracts.'" *Tex. All. for Home Care Servs. v. Sebelius*, 681 F.3d 402, 409 (D.C. Cir. 2012). Myriad other decisions accord with that view. *See, e.g.*, *DCH Reg'l*, 925 F.3d at 505-06 (bar on review of "[a]ny estimate of the Secretary for purposes of determining [specified statutory] factors" barred the plaintiffs from challenging "'the methodology adopted and employed' by HHS to calculate" one of those factors, as a "distinction between methodology and estimates would eviscerate the statutory bar" against review (first alteration in original) (citation omitted)); *Knapp Med. Ctr.*, 875 F.3d at 1130-31 (similar); *Mercy Hosp., Inc. v. Azar*, 891 F.3d 1062, 1066 (D.C. Cir. 2018) (statute barring judicial review of "prospective payment rates" covers "adjustments used to calculate th[ose] rate[s]"); *Yale New Haven Hosp. v. Becerra*, 56 F.4th 9, 13 (2d Cir. 2022) (prohibition against "judicial review" of "estimates" precluded claim that the Secretary "failed to abide by adequate notice-and-comment rulemaking procedures" in arriving at those estimates).

The text of the review bar confirms that reading, by expressly precluding review of the agency's key "determinations." 42 U.S.C. § 1320f-7(2). As the Third Circuit explained in the context of a different review bar, "[t]he word 'determine' means 'to fix conclusively or authoritatively' as well as 'to come to a decision concerning as the result of investigation or reasoning.'" *Bakran v. DHS*, 894 F.3d 557, 563 (3d Cir. 2018) (quoting Webster's Third New International Dictionary 616 (1993)). Thus, in precluding review of the agency's "determination" of qualifying single source drugs and its "determination" of negotiation-eligible drugs, Congress shielded from review both the agency's identification of such drugs and "the process by which the [agency] reache[d] this decision." *Id.* That § 1320f-7(2)'s reference to "drugs" is plural is also instructive, as the D.C. Circuit explained that a statute precluding review of "the awarding of contracts" is not limited to "the awarding of a single contract but" rather applies "to the 'awarding of contracts' generally" and thus encompasses the underlying process. *Texas Alliance*, 681 F.3d at 409-10 (discussing 42 U.S.C. § 1395w-3(b)(12)).

Even the scarce D.C. Circuit cases recognizing the limits of certain preclusion provisions underscore the problem with Plaintiffs' claims here. For example, in *American Clinical Laboratory Association v. Azar*, 931 F.3d 1195, 1205-07 (D.C. Cir. 2019), the D.C. Circuit concluded that the determination at issue was not "'inextricably intertwined' with" the unreviewable agency action and arose instead under a "distinct" statutory provision that imposed "new obligations" on third parties in a "bifurcated structure" and included a discrete notice-and-comment requirement that suggested the availability of review. The D.C. Circuit expressly distinguished the case from *Florida Health*, *Texas Alliance*, and *Mercy Hospital*, discussed above, which—like this case—did not entail challenges to determinations made pursuant to distinct authorities. *Id.* at 1206-07 (distinguishing cases); *see also Am. Hosp. Ass'n v. Azar*, 964 F.3d 1230, 1237 (D.C. Cir. 2020) (finding a challenge not precluded because the statute barred review only of certain "methods" not at issue). Here, Plaintiffs are not challenging some attenuated determination made in an adjacent agency proceeding but instead focus directly on the agency's determination of what constitutes a "qualifying single source drug"—a determination that is also fully intertwined with the agency's "determination of negotiation-eligible drugs" under § 1320f-1(d) and its "selection of drugs" for negotiation under § 1320f-1(b). 42 U.S.C. § 1320f-7(2). The IRA thus expressly precludes review of Plaintiffs' statutory claims. *Id.*

Finally, Plaintiffs cannot avoid this result by invoking the *ultra vires* doctrine. Such claims may proceed "only when three requirements are met: '(i) the statutory preclusion of review is implied rather than express; (ii) there is no alternative procedure for review of the statutory claim; and (iii) the agency plainly act[ed] in excess of its delegated powers and contrary to a specific prohibition in the statute that is clear and mandatory.'" *DCH Reg'l*, 925 F.3d at 509 (quoting *Nyunt v. Chairman, Broad. Bd. of Governors*, 589 F.3d 445, 449 (D.C. Cir. 2009)). "An ultra vires challenge, in other words, is 'essentially a Hail Mary pass.'" *Fed. Express Corp. v. Dep't of Com.*, 39 F.4th 756, 765 (D.C. Cir. 2022) (quoting *Nyunt*, 589 F.3d at 449)). Here, any *ultra vires* argument would fail at the first step because the IRA "express[ly]" bars review of Teva's challenge. *Id.*; *see Florida Health*, 830 F.3d at 519; *Texas All.*, 681 F.3d at 404; *see also Novo*

Nordisk, 2024 WL 3594413 at *3 ("[B]ecause it is an express statutory preclusion it also effectively prohibits this Court from reviewing those determinations on so-called *ultra vires* principles."). The argument would also fail at the third step because there is no contention that "the agency plainly act[ed] . . . contrary to a specific prohibition in the statute that is clear and mandatory.'" *DCH Reg'l*, 925 F.3d at 509 (citation omitted); *see Florida Health*, 830 F.3d at 522-23 (rejecting plaintiff's attempt "to 'couch[]' this type of reasonableness challenge 'in terms of the agency's exceeding its statutorily-defined authority'" (alteration in original) (quoting *Nw. Airlines, Inc. v. FAA*, 14 F.3d 64, 73 (D.C. Cir. 1994))).

Plaintiffs' statutory claims should thus be dismissed for lack of subject-matter jurisdiction.

II. PLAINTIFFS' STATUTORY CLAIMS LACK MERIT.

Even if the Court had jurisdiction, there is no merit to Teva's arguments that CMS's implementation of the Negotiation Program exceeds the agency's statutory authority. CMS appropriately considered the different forms of Teva's drug in selecting both Austedo and its "extended release formulation," 42 U.S.C. § 1320f-1(d)(3)(B), Austedo XR, just as Congress directed; as well as in selecting the different forms of Xtandi and Xarelto. And CMS's bona-fide marketing standard is likewise faithful to the statute's text, structure, and purpose.

A. CMS appropriately considered different forms of the same drug in the negotiation process, as required by the IRA.

The 2027 Guidance explains that, in identifying a "qualifying single source drug," CMS will consider "all dosage forms and strengths of the drug with the same active moiety" (or in the case of a biologic, "the same active ingredient"), even if those different forms have been approved under different New Drug Applications (NDA) (or different Biologics License Applications (BLA)).[4] 2027 Guidance at 167-68. Teva contests this definition, arguing instead that the IRA takes a "product-specific" interpretation of "qualifying single source drug." Pls.' Br. at 21-22.

[4] Active moiety is "[t]he molecule or ion . . . responsible for the physiological or pharmacological action of the drug substance." *Kisor v. Wilkie*, 588 U.S. 558, 568 n.1 (2019) (quoting 21 C.F.R. § 314.3(b) (2018)).

But, as CMS explained, the 2027 Guidance's conclusion that a "qualifying single source drug" encompasses different formulations of a drug flows directly from the text, structure, and purpose of the IRA.

a. The Negotiation Program targets for negotiation those drugs that impose the highest cost burden on Medicare, regardless of variations in formulation or packaging. To achieve this goal, Congress directed CMS to consider all dosage forms, strengths, and formulations of a drug together, "and not based on the specific formulation or package size or package type of such drug." 42 U.S.C. § 1320f-5(a)(2); *see also id.* § 1320f-1(d)(3)(B). This requirement applies at each stage of the process—from the identification and selection of negotiation-eligible drugs to the negotiations themselves, and finally (if negotiations succeed) to application of a negotiated price.

Congress expressly directed CMS to identify "negotiation-eligible drugs" according to Medicare spending data, rank these drugs according to this data, and then select the top 10 drugs on the list for negotiation. When calculating Medicare expenditures for a drug at each of these steps, CMS must aggregate the spending data "across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation, and not based on the specific formulation . . . of the drug." 42 U.S.C. § 1320f-1(d)(3)(B). By requiring CMS to consider the total expenditures for a drug across its variations, the statute ensures that CMS identifies and selects the drugs that have the most significant financial impact on Medicare as a whole.

The next steps in the process are in keeping with this approach. Once CMS selects a drug for negotiation, CMS is required to consider all "applications and approvals," in the plural, "for the drug," in the singular, when determining how much to offer in negotiations. 42 U.S.C. § 1320f-3(e)(1)(D). This step, like the earlier ones, contemplates that one drug may be offered in multiple forms that may correspond to different applications or approvals. And CMS is expressly required to consider all of those forms together in calculating an offer price. Finally, after negotiations are completed and a price is established, CMS must "apply the maximum fair price across different strengths and dosage forms of a selected drug and not based on the specific formulation or package

size or package type" of the drug. *Id.* § 1320f-5(a)(2). The IRA thus contemplates expressly that there may be multiple formulations of a selected drug, with multiple approvals, and it directs CMS to apply the negotiated price to each formulation.

Following this statutory framework, CMS explained in the 2027 Guidance that it will consider a qualifying single source drug to include "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." 2027 Guidance at 167 (footnote omitted).[5] Applying that interpretation, CMS determined that Austedo and Austedo XR accounted for some of the highest Medicare expenditures when considered together, and CMS thus properly selected them for negotiation. Austedo XR is "the extended release formulation of AUSTEDO," and both have the same active moiety (deutetrabenazine). Decl. of Dell Faulkingham ¶ 12, ECF No. 15-2. Given the IRA's instruction that CMS should consider information "aggregated across dosage forms and strengths of the drug, including new formulations of the drug, *such as an extended release formulation*," 42 U.S.C. § 1320f-1(d)(3)(B) (emphasis added), CMS did not err in selecting multiple forms of the same drug for negotiation.

Similarly, even assuming that Teva is an appropriate plaintiff to challenge CMS's treatment of drugs manufactured by its competitors,[6] CMS determined that the different dosage forms of

[5] For biological products, a qualifying single source drug includes "all dosage forms and strengths of the biological product with the same active ingredient and the same holder of a [BLA]." 2027 Guidance 168. Each of the selected drugs that Teva discusses is a drug, rather than a biological product.

[6] Teva does not manufacture Xtandi or Xarelto. Rather, Astellas Pharma Inc. ("Astellas") manufactures Xtandi and Janssen Pharmaceuticals ("Janssen") manufactures Xarelto. *See* Astellas Pharma US, Inc., Xtandi: Prescribing Information at 32 (rev. Mar. 2025), https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/203415s024,213674s012lbl.pdf (combined prescribing information for different dosage forms and strengths of Xtandi); Janssen, Xarelto: Prescribing Information at 22 (issued Nov. 2024), https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/215859s002lbl.pdf (combined prescribing information for different dosage forms and strengths of Xarelto). Notably, however, neither Astellas nor Janssen have challenged the selection of their respective drugs for Initial Price Applicability Year 2027. Both manufacturers have proven themselves capable of asserting their own rights should they seek to challenge the selection of their drugs. Indeed, both manufacturers

Xtandi (tablet and capsule) accounted for some of the highest Medicare expenditures when considered together; and the different dosage forms of Xarelto (tablet and liquid suspension) accounted for some of the highest Medicare expenditures when considered together—and CMS thus properly selected Xtandi and Xarelto for negotiation. The tablet and capsule forms of Xtandi have the same active moiety (enzalutamide) and are available in different dosage forms and strengths (40 mg in the capsule form; and 40 mg and 80 mg in the tablet form) to suit various patient needs. *See* Decl. of Carrie Groff ¶ 22, ECF No. 15-3 ("Groff Decl."); Astellas Pharma US, Inc., Xtandi: Prescribing Information at 1. The tablet and liquid suspension forms of Xarelto likewise have the same active moiety (rivaroxaban) and are available in different dosage forms and strengths (2.5 mg, 10 mg, 15 mg, and 20 mg in the tablet form; and 1 mg/mL for the liquid suspension form). *See* Groff Decl. ¶ 24; Janssen Pharms., Inc., Xarelto: Prescribing Information at 1. Given the IRA's instruction that CMS should select drugs based on information "aggregated across dosage forms and strengths of the drug," 42 U.S.C. § 1320f-1(d)(3)(B), CMS did not err in selecting these multiple forms of Xtandi and Xarelto, respectively, for negotiation.

b. Despite the IRA's statutory mandate, Teva invokes what it calls a "product-specific" interpretation of "qualifying single source drug" based on a different statutory scheme: the Food,

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have previously brought their own lawsuits against the Negotiation Program. *See, e.g.*, *Janssen Pharms., Inc. v. Becerra*, No. 3:23-cv-3818 (D.N.J. filed July 18, 2023) (challenging selection of drug for Initial Price Applicability Year 2026); *Astellas Pharma US, Inc. v. HHS*, No. 23-cv-4578 (D. N. Ill. filed July 14, 2023) (same). But neither lawsuit shared Teva's theory that "qualifying single source drug" must be interpreted on a product- or application-specific basis. *See Bristol Myers Squibb Co.*, 2024 WL 1855054, *2 (noting that Bristol Myers Squibb and Janssen each allege three constitutional claims in their respective complaint, including a takings claim, a First Amendment claim, and an unconstitutional condition claim); Compl. ¶¶ 122-52, *Astellas Pharma US, Inc. v. HHS*, No. 23-cv-4578 (D. N. Ill. July 14, 2023), ECF No. 1 (bringing three constitutional claims, including a takings claim, a due process claim, and a First Amendment claim). Indeed, of the ten other cases challenging the Negotiation Program across the country, *see supra* n.3, only two have raised arguments echoing Teva's theory of "qualifying single source drug," *see AstraZeneca Pharms. LP*, 719 F. Supp. 3d at 386; *Novo Nordisk Inc.*, 2024 WL 3594413, *2.

Drug, and Cosmetic Act (FDCA).[7] Pls.' Br. at 22-24, 25. But the IRA and the FDCA are different statutes with fundamentally different objectives and functions. Teva's reliance on FDA's product-specific approval framework to argue for a product- or application-specific approach by CMS misunderstands the statutory design and cannot be reconciled with the text of the IRA.

FDA approves drugs and biologics on a product-by-product basis to ensure the safety, efficacy, and quality of each specific formulation, package type, and manufacturing process (among other things). *See* 21 U.S.C. § 355(a) (approval requirement for "new drugs"); 21 C.F.R. § 314.3(b) (defining "drug product" as "a finished dosage form, e.g., tablet, capsule, or solution, that contains a drug substance"). Ignoring distinctions between dosage forms, strengths, and formulations would thus be inappropriate in the context of FDA approvals, as it would prevent FDA from evaluating the safety of these various aspects of each finished product. But in the context of the Negotiation Program, considering those forms of a drug together permits CMS to identify the drugs with the greatest financial impact on Medicare overall, consistent with the purpose of the program.

In any event, any debate about aggregation across products for the purposes of IRA negotiations is fully resolved by Congress's repeated instruction to aggregate "across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation, and not based on the specific formulation or . . . package type of the drug." 42 U.S.C. § 1320f-1(d)(3)(B); *see id.* § 1320f-5(a)(2). Teva nonetheless attempts to infer a contrary

[7] Notably, however, Teva's argument is not truly "product-specific." Pls.' Br. at 22. Rather, Teva appears to argue for an application-specific approach, in which a distinct NDA is the defining feature of a "qualifying single source drug." Pls.' Br. at 21-28 (focusing on the "distinct NDA"); *id.* at 27-28 (arguing that different products in different supplemental applications to NDAs (sNDAs) may be aggregated). The difference between product-specific and application-specific is material because, as Teva's own submissions indicate, multiple "drug products" are often approved within a single original NDA, and through sNDAs. *See, e.g.*, Groff Decl. ¶¶ 22, 24 (multiple approved strengths of Xarelto tablet form under one NDA); Faulkingham Decl. ¶¶ 10, 13 (same regarding Austedo and Austedo XR). Thus, to the extent Teva truly argues for a strict "product-specific" (rather than an NDA- and/or sNDA-specific) interpretation, its argument is internally inconsistent.

command from other IRA provisions that reference the FDA approval process. For example, Teva urges that its view is compelled by the statute's requirement that a drug is not eligible for negotiation unless at least seven years have elapsed since approval (or eleven for biologics). *See* Pls.' Br. at 24 (citing 42 U.S.C. § 1320f–1(e)(1)(A), (B)). In Teva's view, each new product approval triggers a new clock, even when the "new" product is just a slightly different formulation of the same drug. But Teva's argument is irreconcilable with the IRA's command to aggregate "across . . . *new* formulations of the drug" for this purpose. 42 U.S.C. § 1320f-1(d)(3)(B) (emphasis added). CMS reasonably determined that the relevant date is the earliest approval date of a product in the set, 2027 Guidance at 170, ensuring that the introduction of subtle variations of the drug does not alter its eligibility. The alternate interpretation urged by Teva, by contrast, would force CMS to exclude newer formulations of high-expenditure drugs where they are approved in different NDAs despite the statutory command to "includ[e]" them. 42 U.S.C. § 1320f-1(d)(3)(B).

Similarly, Teva resorts to a series of attenuated cross-references that ends with a reference to FDA approval. *See* Pls.' Br. at 22-23. Teva observes that the IRA's definition of "qualifying single source drug" cross-references "the Medicare statute's definition of a 'covered part D drug,'" which Teva claims, in turn, defines a drug based on whether the product is approved pursuant to a distinct NDA. *Id.* (quoting 42 U.S.C. § 1320f-1(e)(1)) (citing 42 U.S.C. § 1395w-102(e); *id.* §§ 1396r–8(k)(2), (k)(7)(A)(iv)). But Teva overreads the significance of the cross-referenced provision, which provides merely that a "covered outpatient drug" must be "approved for safety and effectiveness" under an appropriate application. 42 U.S.C. § 1396r–8(k)(2). These provisions do not mean that FDA approval creates a distinct, *new* "covered outpatient drug." Indeed, contrary to Teva's characterization, *see* Pls.' Br. at 23, Judge Friedrich recently held that a new NDA alone does *not* suffice to establish a "new 'covered outpatient drug'" for Medicaid-rebate purposes. *Ipsen Biopharmaceuticals, Inc. v. Azar*, No. 16-cv-2372, 2020 WL 3402344, at *10 (D.D.C. June 19, 2020); *see also id.* (agreeing with government's position that "a new NDA (absent changes to the drug's dosage form or strength) is necessary, *but not always sufficient*, to establish new base date information for Medicaid rebate purposes"). In any event, Teva's reading of these attenuated

cross-references cannot be reconciled with the IRA's express statutory language directing CMS to consider all dosage forms, strengths, and formulations of a drug together.

Teva also reads great import into the IRA's language excluding brand-name drugs with generic versions from being a "qualifying single source drug." Specifically, the IRA excludes drugs that are "the listed drug for any drug that is [an approved and marketed generic drug]." 42 U.S.C. § 1320f–1(e)(1)(A)(iii). Teva argues that the reference to "*the* listed drug" necessarily means that the IRA contemplates a product-specific view of "qualifying single source drug." Pls.' Br. 23, 26-27 (emphasis added) (citation omitted). But Teva fails to explain how this inference overcomes the express statutory text directing aggregation. *See* 42 U.S.C. § 1320f-1(d)(3)(B); *id.* § 1320f-3(e)(1)(D); *id.* § 1320f-5(a)(2). In any event, it is easy to harmonize § 1320f–1(e)(1)(A)(iii) with § 1320f-1(d)(3)(B) and the other provisions directing aggregation. As CMS has explained: "If *any strength or dosage form* of a potential qualifying single source drug is the listed drug or reference product, as applicable, for one or more generic or biosimilar biological products that CMS determines are approved or licensed, as applicable, and marketed based on the process described in this final guidance, the potential qualifying single source drug will not be considered a qualifying single source drug for initial price applicability year 2027." 2027 Guidance at 171 (emphasis added).

Contrary to Teva's assertion, this does not "render[] the generic carveout nonsensical." Pls.' Br. 27. Indeed, the implications of *Teva's* proposed approach are striking, as Teva insists that CMS must treat each drug product as a separate drug, no matter how minor the differences between them. For example, Teva intends to market enzalutamide capsules, which is a generic version of the capsule form of Xtandi. Groff Decl. ¶ 22. According to Teva, the capsule form of Xtandi is to be treated as distinct from the tablet form of Xtandi for purposes of the Negotiation Program—even though they are different dosage forms of the drug containing the same moiety (enzalutamide). This interpretation is fundamentally inconsistent with the statutory framework—it would render meaningless the statute's requirement to aggregate data across "dosage forms," "strengths," and "formulations" of a drug in the selection process, and it would prevent the

Negotiation Program from identifying the drugs responsible for the greatest Medicare expenditures. Moreover, it would incentivize manufacturers to serially introduce slight variations or formulations of a drug that would otherwise qualify for negotiation in order to circumvent the negotiation. Congress was aware of such tactics and drafted the statute accordingly.

c. None of Teva's remaining arguments overcome the IRA's explicit text. That the IRA refers to a "qualifying single source *drug*," in the singular, *see* Pls.' Br. at 22, 26, is entirely consistent with the IRA's instruction that each individual "drug" is an aggregation of all dosage forms, strengths, and formulations of that drug. *See* 42 U.S.C. § 1320f-1(d)(3)(B) (selection of negotiation-eligible drugs); *id.* § 1320f-3(e)(1)(D) (determination of negotiation offer amount); *id.* § 1320f-5(a)(2) (application of maximum fair price (MFP)). Teva's attempt to replace "drug" with "drug product" is contrary to that statutory mandate.

Teva protests that Congress did not "mention the term 'active moiety' or 'active ingredient'" in the IRA. Pls.' Br. at 25. But by that logic, neither does the IRA mandate that CMS follow the FDA's product-specific approach (or a different, application-specific approach). *See* 42 U.S.C. § 1320f(a)-(c). In any event, CMS did not pluck the terms "active moiety" and "active ingredient" from thin air. The terms have a long history and prominent role in FDA's practice, where, among other things, the term "active moiety" is used as a proxy for innovation in drug development. *See, e.g.*, 21 C.F.R. § 314.3 (defining both terms); An Act to Amend the Federal Food, Drug, & Cosmetic Act, Pub. L. No. 117-9, 135 Stat. 256 (2021) (codifying FDA's definition); *see also, e.g.*, Erin H. Ward, Cong. Rsch. Serv., R46110, *Defining Active Ingredient: The U.S. Food and Drug Administration's Legal Interpretation of Regulatory Exclusivities* (2023), https://crsreports.congress.gov/product/pdf/R/R46110; *see also* Pls.' Br. at 25 (recognizing that FDA has used term "active moiety"). Contrary to Teva's suggestion, Congress need not specify

the precise terms "active moiety" or "active ingredient" for CMS to rely upon them in describing the necessary features of products that can be considered together under the statute.[8]

Finally, Teva's surplusage argument misses the point. Teva asserts that interpreting "qualifying single source drug" to include "all dosage forms and strengths" of a drug would render "redundant" the IRA provisions requiring aggregation of "dosage forms and strengths of the drug" in selecting negotiation-eligible drugs under 42 U.S.C. § 1320f-1(d)(3)(B) and in applying the MFP "across different strengths and dosage forms of a selected drug" under 42 U.S.C. § 1320f-5(a)(2). Pls.' Br. at 28 (citations omitted). But these provisions are not "redundant," *id.*; rather, each provision applies to a different step of the negotiation process, *see* 42 U.S.C. § 1320f-1(d)(3)(B) (selection of negotiation-eligible drugs); *id.* § 1320f-3(e)(1)(D) (determination of negotiation offer amount); *id.* § 1320f-5(a)(2) (application of MFP). It is the combined direction from each provision from which the aggregation requirement flows. And Plaintiffs fail to explain how their approach can be reconciled with these clear directives.

B. CMS's bona fide marketing standard is consistent with the statutory language.

Plaintiffs' second statutory claim—which contests CMS's standard for determining when a drug should be excluded from the definition of "qualifying single source drug" due to the entry of generic or biosimilar competition—fares no better.

The IRA provides that a drug will not be considered a "qualifying single source drug" if it has a generic "that is approved and marketed" (or, in the case of a biosimilar biological product, "that is licensed and marketed") under the FDCA. 42 U.S.C. § 1320f-1(e)(1)(A)(iii), (B)(iii). Implementing that statutory directive, CMS explained that "a generic drug or biosimilar [is] marketed when the totality of the circumstances . . . reveals that the manufacturer of that approved

[8] Notably, the Congressional Budget Office appeared to understand that CMS would use an active-ingredient standard. *See* Letter from Phillip L. Swagel, Dir., Cong. Budget Off. to Hon. Jodey Arrington, Chairman, Comm. on the Budget, U.S. House of Reps., and to Hon. Michael C. Burgess, U.S. House of Reps (Dec. 21, 2023), https://perma.cc/9A9B-6SM6. While certainly not dispositive of Congress's intent, this understanding demonstrates that the concepts were familiar and CMS's use of them not unexpected.

generic drug or licensed biosimilar is engaging in *bona fide* marketing of that drug or biosimilar." 2027 Guidance at 170 (emphasis added).

This understanding of the statute, CMS explained, addresses "situations in which a manufacturer of a brand name drug or biologic has entered into a market-limiting agreement with a manufacturer of a generic drug or biosimilar," under which "the generic drug or biosimilar manufacturer agrees to limit production or distribution of the generic drug or biosimilar, such that only a nominal quantity of product is allowed to enter the market." *Id.* at 20. The statutory directive of the Negotiation Program—which is designed to reduce Medicare expenditures on drugs that otherwise do not face meaningful competition in the market—"would not be met if a qualifying single source drug were to avoid selection or be removed from the selected drug list where generic drug or biosimilar availability is limited by the Primary Manufacturer." *Id.*; *see also* 2026 Guidance at 72 (noting that "a generic drug or biosimilar manufacturer could launch into the market a token or de minimis amount of a generic drug or biosimilar for the selected drug and the manufacturer of that selected drug could claim that the MFP should no longer apply"). Accordingly, CMS stated that it would conduct "ongoing assessments of whether the manufacturer of the generic drug or biosimilar is engaging in bona fide marketing," consistent with congressional intent. *See* 2027 Guidance at 292.

There is no substance to Plaintiffs' argument that this interpretation departs from the IRA's language. Pls. Br. at 28-36.

1. As a starting point, Plaintiffs' suggestion that the phrase "is . . . marketed" in § 1320f-(1)(e) necessarily means being "expose[d] for sale in a market" in *any* capacity—even if only *de minimis*—finds no support in the very dictionaries they cite. *See* Pls.' Br. at 29. Instead, these definitions suggest the actual availability of a product for sale. *See, e.g.*, *Market* (v.), Merriam-Webster, https://perma.cc/VWL4-LMQZ ("to expose for sale in a market"; "[to] sell"; "to deal in a market"); *Market* (v.), Oxford English Dictionary, https://www.oed.com/dictionary/market_v?tab=meaning_and_use&tl=true#38116584 (last visited Apr. 28, 2025) ("[t]o sell in a market; to bring or send to a market"; "to place or establish

(a product) on the market; *esp.* to seek to increase sales of (a product) by means of distribution and promotion strategies"; "to buy and sell"). Plaintiffs' preferred definition—to "expose for sale in a market"—does not foreclose CMS from considering whether a generic drug was "expose[d] for sale" so as to be actually accessible by market participants. Pls.' Br. at 29 (citation omitted). On its face, the phrase "marketed" reflects actual and ongoing commercial activity—not a token presence or even (in Plaintiffs' telling) a single sham transaction.[9]

Further, the narrow interpretation that Plaintiffs offer cannot be reconciled with the IRA's provisions. Pls.' Br. at 19-20. Congress explicitly instructed CMS to de-select drugs that are otherwise selected for the Negotiation Program once "the Secretary *determines*" that a generic competitor "is marketed." 42 U.S.C. § 1320f-1(c)(1)(B) (emphasis added). This language acknowledges that CMS must exercise at least some judgment in applying this standard; there would be no need for Congress to entrust the Secretary to make a "determin[ation]" if it saw "market[ing]" as an entirely non-discretionary standard. *See, e.g.*, *Transitional Hosps. Corp. of La. v. Shalala*, 222 F.3d 1019, 1025 (D.C. Cir. 2000) (explaining that the phrase "as determined by the Secretary" is an "express delegation of authority" to exercise "discretion" (citation omitted)). Such discretion is the antithesis of the kind of binary, yes-or-no inquiry Plaintiffs claim is required. *See* Pls.' Br. at 28-29.

Notably, Congress's language about the Inflation Rebate Program—elsewhere in the IRA—highlights that Congress knew how to expressly cabin CMS's discretion when it wished to do so. In the Inflation Rebate Program, which requires manufacturers to provide rebates for some of their high-cost (and high-selling drugs), there is no concern about "marketing" being genuine;

[9] Plaintiffs summarily reference *Asgrow Seed Co. v. Winterboer*, 513 U.S. 179, 187-88 (1995), in which the Supreme Court addressed the meaning of "marketing" in the context of the Plant Variety Protection Act. Plaintiffs' reliance on that decision is misplaced. *Asgrow* did not consider whether "marketing" encompassed *de minimis* marketing, because there was no dispute in that case that the defendants were engaged in a bona fide effort to sell the product at issue. *Id.* at 182. The question instead was whether the plaintiff needed to show not only that the defendants were engaged in sale of the product at issue (seeds), but also that the defendants had engaged in "extensive or coordinated selling activities, such as advertising, using an intervening sales representative, or similar extended merchandising or retail activities." *Id.* at 187 (citation omitted).

in that context, Congress required CMS to determine whether a drug is "being marketed, as identified in the Food and Drug Administration's National Drug Code Directory." 42 U.S.C. 1395w-114b(g)(1)(C)(ii). That database "contains information on active and certified finished and unfinished drugs submitted to FDA" and includes marketing "start" and "end" dates, as relevant, for all listed drugs. *See, e.g.*, FDA, *National Drug Code Directory*, https://perma.cc/LYW5-7DGG (current through Apr. 24, 2025) (search for "Austedo" in the "Proprietary Name" field and select drug). By directing CMS to that specific source, Congress made clear that, in *that* context, the statute called for a simple yes-or-no inquiry. That Congress did not include a similar instruction in § 1192(e)(1)'s definition of "qualifying single source drug" shows that Congress contemplated a different inquiry in the context of drug selection and deselection and expected CMS to exercise broader discretion—where the possibility of gamesmanship in generic marketing is real and of significant concern. *See Weichsel v. JP Morgan Chase Bank, N.A.*, 65 F.4th 105, 113 (3d Cir. 2023) ("Where a statute or regulation uses specific language in one provision but different language in another, the Court presumes different meanings were intended.") (cleaned up).

Plaintiffs separately assert that CMS must cabin any determination as to whether a drug "is 'marketed'" to a single "point-in-time" and never again revisit that determination. Pls.' Br. at 35 (citation omitted). But the statute provides that a drug should not be identified as a qualifying single source drug if it "*is* marketed." 42 U.S.C. § 1320f-1(e)(1) (emphasis added). The statute does not refer to a drug that "was marketed" or "has been marketed" or "was marketed at least one time." This choice of verb tense must be presumed to be meaningful. *See Carr v. United States*, 560 U.S. 438, 448 (2010). Congress clearly contemplated that a generic drug or biosimilar product would have a continuing presence on the market in order to affect the status of the listed drug or reference product. This language is especially meaningful given that other provisions of the IRA use different language. *See, e.g.*, 42 U.S.C. § 1395w-114B(b)(5)(A) (referring to the date that a drug "was first marketed").

As a practical matter, Plaintiffs' interpretation of the IRA would also render the "marketed" requirement of § 1192(e)(1) meaningless. Under Plaintiffs' interpretation, "a generic drug or

biosimilar manufacturer could launch into the market a token or de minimis amount of a generic drug or biosimilar for the selected drug and the manufacturer of that selected drug could claim that the [maximum fair price] should no longer apply." 2026 Guidance at 72. That result would flout Congress's purpose. Section 1192(e)(1)'s "marketed" standard was adopted to promote competition between listed and generic drugs (and between reference products and biosimilar products) and thus to bring down the price of expensive pharmaceuticals. *See id.* at 72. Consistent with this goal, "Congress contemplated that a generic or biosimilar would have a continuing presence on the market"—otherwise, the purpose of meaningful price competition would not be achieved. 2027 Guidance at 20. CMS's bona fide marketing standard properly accounts for Congress's policy goals and the IRA's text. *See, e.g.*, *Wis. Dep't of Revenue v. William Wrigley, Jr., Co.*, 505 U.S. 214, 231-32 (1992) ("*[D]e minimis non curat lex* . . . is part of the established background of legal principles against which all enactments are adopted"; whether "a particular activity is a *de minimis* deviation from a prescribed standard must, of course, be determined with reference to the purpose of the standard"); *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 309 n.1 (2014) (recognizing EPA's authority to establish *de minimis* threshold for facility's emissions of a pollutant and increases thereof).

2. Attempting to resist this common-sense result, Plaintiffs try to show that Congress intentionally excluded the term "bona fide" from the IRA by noting the use of the term "bona fide" in other statutes, including within Title 42. Pls.' Br. at 30-31. But the use of "bona fide" in different statutes defining different terms for different purposes shows nothing about Congress's intent in the IRA—and is a particularly thin reed on which to rest the idea that Congress intended to hobble the Negotiation Program by allowing sham marketing of generics to foreclose the selection of high-cost name-brand drugs. Indeed, Plaintiffs' rule of interpretation—that any term is necessarily a yes-or-no inquiry unless it expressly includes a term like "bona fide"—would undermine agencies' ability to enforce myriad statutes and finds no support in the case law. The same goes for Plaintiffs' attempt to show that Congress did not intend to allow a totality-of-the-circumstances test. Pls.' Br. at 31-32. That CMS intends to consider multiple forms of data in

determining whether a manufacturer has engaged in meaningful, non-*de minimis* marketing, *see* 2027 Guidance at 170-71, is consistent with the IRA's instruction that the Secretary "determine[]" whether a generic competitor "is marketed." 42 U.S.C. § 1320f-1(c)(1)(B).

In asserting that Congress implicitly precluded any inquiry into "good faith" marketing efforts, Plaintiffs necessarily embrace the idea that bad faith marketing suffices. *See Bunge Corp. v. Recker*, 519 F.2d 449, 452 (8th Cir. 1975) (noting that *bona fide* "is the precise opposite of bad faith") (quotation marks omitted); *see also Wallace v. NCL (Bahamas) Ltd.*, 733 F.3d 1093, 1104 (11th Cir. 2013) (emphasizing that the two concepts are "two sides of the same coin." (citation omitted)). Reduced to those terms, Plaintiffs' argument is self-defeating. Because "[t]he law has regard for substance, rather than 'shades or shadows,'" *First Nat. Bank v. Phalen*, 62 F.2d 21, 23 (7th Cir. 1932), Congress cannot be presumed to countenance conduct undertaken in bad faith, as Plaintiffs urge here—particularly when the presumption runs counter to the text and purpose of the statute.

Plaintiffs also seek to draw parallels between CMS's use of the term "marketed" in the Negotiation Program and other contexts. But those parallels collapse upon closer examination. For instance, Plaintiffs reference CMS's practices under the IRA's Medicare Part B and Part D inflation rebates, and under the Medicaid Drug Rebate Program. Pls.' Br. at 35-36. But neither of these contexts define the concept of "marketed" in a context where *de minimis* marketing is a plausible concern. *See id.* As with the Inflation Rebate Program under the IRA, it makes sense to refer to the "date of first sale," CMS, *Medicare Part B Inflation Rebates Paid by Manufacturers: Revised Guidance* 57 (Dec. 14, 2023), https://perma.cc/HEC6-7EKQ; the date on which a product "is available for sale," *Medicaid Program; Announcement of Medicaid Drug Rebate Program National Rebate Agreement*, 83 Fed. Reg. 12,770, 12,784 (Mar. 23, 2018); or "the date on which the . . . drug was first sold," *Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program*, 89 Fed. Reg. 79,020, 79,082 (Sept. 26, 2024), in settings where the existence of such marketing is undisputed (and there is therefore no need to determine whether the marketing is bona fide).

The same is true for Plaintiffs' attempted analogy to FDA regulations under the Hatch-Waxman Act. *See* Pls.' Br. at 36. To identify "the date of the first commercial marketing of [a] drug," 21 U.S.C. § 355(j)(5)(B)(iv)(I), for the purpose of beginning a generic drug's 180-day period of exclusivity, the FDA has defined "commercial marketing" to mean "the introduction or delivery for introduction into interstate commerce of a drug *product*," 21 C.F.R. § 314.3(b) (emphasis added). It is unsurprising that Congress would have established different standards in these statutes given the different purpose of these provisions. There is no concern that a generic drug manufacturer may not be engaged in *legitimate* marketing when identifying "the date of the first commercial marketing" for the purpose of determining when to begin a generic drug's 180-day period of exclusivity.

Contrary to Plaintiffs' suggestion, CMS's standard is not "amorphous" or "vague." Pls.' Br. at 29-30. Consistent with Congress's grant of authority, the agency has explained how it will determine whether a generic or biosimilar is marketed on a bona fide basis: CMS will consider "the totality of the circumstances," including Prescription Drug Event (PDE) data[10] and Average Manufacturer Price (AMP) data,[11] which would reveal whether there is a regular and consistent volume of sales of any relevant generic or biosimilar product. 2027 Guidance at 170–71; *see also id.* at 171 (considering "whether the generic drug or biosimilar product is regularly and consistently available for purchase through the pharmaceutical supply chain"). There is nothing amorphous about that standard. Ultimately, manufacturers of drugs that face genuine—or, in other words, bona fide—generic competition have nothing to fear from CMS's common-sense efforts to prevent obvious workarounds of congressional intent.

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[10] PDE data is a summary record submitted to CMS by a prescription drug plan sponsor "[e]very time a beneficiary fills a prescription under Medicare Part D." CMS, *Questions and Answer on Obtaining PDE Data*, https://perma.cc/4F3B-MQ6S.

[11] AMP means "the average price paid to the manufacturer for the drug in the United States by: (i) wholesalers for drugs distributed to retail community pharmacies; and (ii) retail community pharmacies that purchase drugs directly from the manufacturer, subject to certain exclusions." 2027 Guidance at 171 n.67.

Teva's complaint that CMS has "alter[ed]" the timeline for the marketing inquiry cherry-picks from the Guidance. Pls.' Br. at 32. Teva asserts that it "may take many months" to establish bona fide marketing, but that is unsupported speculation. *Id.* at 33; *see also AstraZeneca Pharms. LP*, 719 F. Supp. 3d at 389-90 (manufacturer's allegation "that CMS will 'delay'" bona fide marketing determination "'for months' . . . is . . . speculative"). Manufacturers need only establish that marketing is "more than solely token or de minimis availability of the products." 2027 Guidance at 20. There is no reason that legitimate marketing should take "many months" to establish. And to the extent Teva is concerned about alleged "inherent time lags associated" with PDE data and AMP data, Pls.' Br. at 33, CMS has explicitly clarified that consideration of bona fide marketing "will not necessarily turn on any one source of data," and "[m]anufacturers of selected drugs can provide evidence to CMS regarding the market for the generic drug or biosimilar versions," 2027 Guidance at 21-22.[12] Thus, for example, Teva's ability "to prove 'bona fide marketing' in the two weeks" between when it plans to launch its generic version of Xarelto on March 15, 2027, and the negotiation cutoff date on March 31, 2027, may depend on Teva's own ability to collect data. Pls.' Br. at 34.

As a final resort, Plaintiffs allege that the "bona fide marketing" standard "will force generics to compete with more price-controlled innovator drugs and for longer periods of time." *Id.* at 37. But the standard requires only that a generic drug or biosimilar is marketed at more than

[12] In any event, Plaintiffs also exaggerate the alleged delay. CMS notes that "generally this timing lag [for PDE data] is relatively short as Part D plans are instructed to submit original PDEs to CMS within 30 days following the date the claim is received or date of service (whichever is greater) and the average turnaround time to date of submission is fewer days." 2027 Guidance at 21-22. Moreover, as CMS explained in the 2026 Guidance, "Part D rules allow for relatively quick formulary substitution of generic drugs for selected drugs and the addition of generic drug and biosimilar versions of selected drugs such that both should be evident in the PDE data relatively quickly." *Id.* at 76. And AMP data is reported to CMS on a monthly basis pursuant to a manufacturer's reporting responsibilities under the Medicaid Drug Rebate Program. *See* 2026 Guidance at 77. CMS expressly included reliance on AMP data to bridge any possible delays in a generic or biosimilar showing up in PDE data. *See* 2027 Guidance at 22 ("[AMP] data may capture sales transactions in the supply chain in situations when coverage and use of the generic drugs in Part D plans has not yet become evident in the PDE data.").

a "token or *de minimis*" amount. 2027 Guidance at 20. This is necessary to be consistent with the text and purpose of the statute, which is to lower drug prices for Medicare through negotiation or price competition. *See id*. If a generic drug or biosimilar is being marketed in only a token or *de minimis* amount, the listed drug is not subject to "meaningful competition" and thus does not fulfill the statute's purpose. *Id.* at 292. Plaintiffs cannot seriously allege that requiring more than mere token or *de minimis* marketing—*i.e.*, requiring more than non-meaningful competition—"vitiat[es] incentives for generic manufacturers to develop" drugs. Pls.' Br. at 37. In fact, the standard should have no effect on generic manufacturers at all, assuming they intend to engage in genuine (rather than sham) marketing.

Token or *de minimis* marketing is not merely a theoretical worry. The 2027 Guidance expressly noted that CMS was aware of real-world examples of manufacturers of brand-name drugs or biologics entering into sham agreements with generic-drug manufacturers like Teva to provide mere token or *de minimis* competition. *See* 2027 Guidance at 20. In such sham agreements, the generic drug manufacturer "agrees to limit production or distribution of the generic drug or biosimilar, such that only a nominal quantity of product is allowed to enter the market," which results in "a lack of meaningful price competition." *Id.* The "bona fide marketing" inquiry is thus necessary to implement the IRA's text and purpose.

III. PLAINTIFFS' DUE PROCESS CLAIMS LACK MERIT.

Finally, the IRA provisions establishing the Negotiation Program do not violate Plaintiffs' due process rights. The Due Process Clause protects against the deprivation "of life, liberty, or property, without due process of law." U.S. Const. amend. V. The threshold "inquiry in every due process challenge is whether the plaintiff has been deprived of a protected interest" in liberty or property. *Am. Mfrs. Mut. Ins.*, 526 U.S. at 59. Teva alleges that the Negotiation Program deprives manufacturers, providers, and patients of due process, but—as every other court to have addressed a due process challenge to the Negotiation Program has held—none of Teva's theories establish a deprivation of any constitutionally protected interest. At bottom, Teva wants to sell its drugs at prices higher than the government is offering to pay, and it has no protected interest in

doing so. Without a cognizable interest in liberty or property, the Court need not address whether the statute's "procedural safeguards are 'constitutionally sufficient.'" Pls.' Br. at 42; *see Gen. Elec. Co. v. Jackson*, 610 F.3d 110, 128 (D.C. Cir. 2010) ("Thus, because we have held that these consequential effects do not qualify as constitutionally protected property interests, we need not—indeed, we may not—apply *Mathews v. Eldridge* to determine what process is due." (internal citation omitted)).

Teva advances various theories of due process violations, but none entails a deprivation of a constitutionally protected interest.

1. Teva begins by asserting that the Negotiation Program deprives it of its alleged right "to be free from governmental price strictures." Pls.' Br. at 38. But even accepting that framing of the Negotiation Program, there is no such constitutional right. In support of this theory, Teva cites the original, pre-IRA provisions of Medicare Part D. As noted above, *see supra* at 3, Congress initially barred the Secretary from negotiating drug prices under Part D or otherwise interfering in the commercial arrangements between manufacturers and the private insurance plans that, in turn, enter into agreements with Medicare to provide benefits, *see* 42 U.S.C. § 1395w-111(i)(1), (3) (prohibiting the Secretary from "interfere[ing] with the negotiations between drug manufacturers and pharmacies and [prescription drug plan] sponsors," or "institut[ing] a price structure for the reimbursement of covered part D drugs"). But, as Teva recognizes, Congress has since amended those features of the Medicare statute, Pls.' Br. at 39, and the statute now requires the Secretary, acting through CMS, to negotiate the prices Medicare pays for certain covered drugs: those with the highest Medicare Parts B and D expenditures and no generic or biosimilar competitors, and that have been marketable for at least 7 years (*i.e.*, drugs that have long enjoyed little market competition), *see* 42 U.S.C. § 1320f *et seq.*

Statutory rights are not granted in perpetuity, and what the Congress gives, the Congress may take away. *See Davis v. Passman*, 442 U.S. 228, 241 (1979) ("Statutory rights and obligations are established by Congress . . . ."); *Omar v. McHugh*, 646 F.3d 13, 22-23 (D.C. Cir. 2011) (Congress may "undo . . . statutory rights that it has created"). Pursuant to the IRA, Teva thus no

longer has the statutory right under 42 U.S.C. § 1395w-111(i)(1) "to be free from governmental price strictures" in connection with the price of covered Part D drugs. Pls.' Br. at 38. [13]

Teva's cited cases are not to the contrary. *Rock River Health Care, LLC v. Eagleson* held only that Medicare and Medicaid providers have a property interest in "the legally prescribed rate [of reimbursement]," *i.e.*, the reimbursement amount due under the governing statutory formula. 14 F.4th 768, 774 (7th Cir. 2021). Here, the IRA establishes the procedures for determining the amount the government will pay for high-expenditure drugs under Medicare, and Plaintiffs have no right "to be free from [those] governmental price strictures." Pls.' Br. at 38. Nor, unlike in *O'Bannon v. Town Ct. Nursing Ctr.*, 447 U.S. 773, 785 (1980), do Plaintiffs cite any other statutory entitlement to "be free from government interference," Pls.' Br. at 38. In *O'Bannon*, 447 U.S. at 785, the Supreme Court recognized Medicaid recipient's statutory "right to choose among a range of *qualified* providers, without government interference" based on 42 U.S.C. § 1396a(a)(23), which provided that Medicaid recipients "may obtain [medical] assistance from any [provider] qualified to perform the service or services required." But even in *O'Bannon*, the Court confirmed that the government may decide what products and services it will pay for through Medicare and Medicaid by determining which providers are qualified (within statutory bounds that are not implicated here). 447 U.S. at 785 (explaining that 42 U.S.C. § 1396a(a)(23) confers on Medicaid

[13] Nor does Teva have a freestanding right to "fix the price at which [it] will sell" property. Pls.' Br. at 38 (quoting *Old Dearborn Distrib. Co. v. Segram-Distillers Corp.*, 299 U.S. 183, 192 (1936)). Citing a line of cases that have since been overruled, *Old Dearborn* asserted that legislatures generally may not impair "the right of the owner of property to fix the price at which he will sell" his property in the broader marketplace. 299 U.S. at 192. But the Supreme Court has since held that the Constitution does not substantively constrain a legislature's ability to fix the price of goods. *Olsen v. Nebraska ex rel. Western Reference & Bond Ass'n*, 313 U.S. 236, 247 (1941); *see also Nebbia v. New York*, 291 U.S. 502, 516 (1934) ("So far as the requirement of due process is concerned, and in the absence of other constitutional restriction, a state is free to adopt whatever economic policy may reasonably be deemed to promote public welfare, and to enforce that policy by legislation adapted to its purpose."). And *Old Dearborn* itself expressly affirmed the validity of legislation that allowed parties to fix the price of goods by contract. 299 U.S. at 192. Even on its terms, it did not recognize a freestanding property right to force a price on an unwilling buyer.

recipients "the right to choose among a range of *qualified* providers, without government interference," but does not "limit the Government's right to . . . decertify[] a facility").

2. Teva next asserts that the IRA deprives it of its rights in both its brand-name and generic products. Teva's arguments boil down to an effort to use the Due Process Clause to expand (and constitutionalize) their patent rights. *See* Pls.' Br. at 41 (arguing that "Teva has been deprived of its statutorily guaranteed noninterference right" with respect to Austedo, Austedo XR, and Teva's generic versions of Xtandi and Xarelto). As to its brand-name products, Teva argues that it is entitled "to a guaranteed exclusivity period." Pls.' Br. at 38, 40. Similarly, as to its generic products, Teva argues that it has a "right in its patent settlement agreements and licenses." *Id.* Patents are, of course, a form of property. But Teva fails to explain how the Negotiation Program deprives it of any patent rights, as to either its brand-name or generic products. The IRA simply does not infringe on any right that is protected by any patent.

Teva urges that the selection of its brand-name product deprives it of its exclusivity period and "forces [it] to sell its product at far below market value to a broad plurality of the market," and, similarly, that the selection of the brand-name drugs for which Teva intends to launch generics "will force Teva's generics to compete against artificially low prices." *Id*. at 41. But "the federal patent laws do not create any affirmative right to . . . sell anything," *Biotechnology Indus. Org. v. Dist. of Columbia*, 496 F.3d 1362, 1372 (Fed. Cir. 2007) (quoting *Leatherman Tool Grp. Inc. v. Cooper Indus., Inc.*, 131 F.3d 1011, 1015 (Fed. Cir. 1997)), much less to command a particular price. While a patentee may use its exclusive right to sell a drug as leverage in the marketplace, the freedom from competitive pressure conferred by the period of exclusivity does not entitle the patentee to any particular revenue from any particular buyer.

The same holds true when the buyer is the government. "[N]o one has a 'right' to sell to the government that which the government does not wish to buy." *Coyne-Delany Co. v. Cap. Dev. Bd*., 616 F.2d 341, 342 (7th Cir. 1980) (per curiam); *see Perkins v. Lukens Steel Co.*, 310 U.S. 113, 127 (1940) (emphasizing the government's authority to "determine those with whom it will deal"). "Just like private individuals and businesses, 'the Government enjoys the unrestricted power to

produce its own supplies, to determine those with whom it will deal, and to fix the terms and conditions upon which it will make needed purchases.'" *AstraZeneca*, 719 F. Supp. 3d at 395 (emphasis omitted) (quoting *Perkins*, 310 U.S. at 127). There is no overriding right inherent in a patent that entitles the holder to compel anyone, including the government, to pay more for a good than they are willing to pay.

Indeed, pursuant to the government's power to determine the prices it will pay for goods and services, other federal agencies have for decades negotiated with drug manufacturers over the price paid for patented drugs in other government programs. *See* 38 U.S.C. § 8126(a)-(h). Similarly, as a condition of Medicaid participation, drug manufacturers have long entered into agreements to provide patented drugs to certain healthcare facilities subject to statutory price ceilings. *See Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011) (describing requirements under Section 340B of the Public Health Service Act). And the government regularly negotiates the price it will pay for other goods. *See, e.g.*, 48 C.F.R. pts. 15, 215. Just as military contractors have no right to sell their patented products to the Department of Defense at prices above what the government is willing to pay, pharmaceutical companies have no right to sell drugs to Medicare at any particular price.

In negotiating the price that Medicare will pay for drugs, the government is acting as a market participant. The Negotiation Program sets the terms of the government's offer to pay for certain drugs, and manufacturers have no right to force the government to pay for its drugs on different terms. Teva's contrary view is inconsistent both with how the marketplace works and with Congress's clear authority to control federal spending. The Negotiation Program reflects Congress's judgment that the federal government has been spending far too much on high-cost prescription drugs, and the government has a strong interest in controlling federal spending to promote the general welfare. *See Sabri v. United States*, 541 U.S. 600, 608 (2004) ("The power to keep a watchful eye on expenditures . . . is bound up with congressional authority to spend in the first place . . . ."). Because Teva "has no legitimate claim of entitlement to sell its drugs to the

Government at any price other than what the Government is willing to pay, [its] due process claim fails as a matter of law." *AstraZeneca*, 719 F. Supp. 3d at 396.

3. Teva is also incorrect that the Negotiation Program deprives it of an alleged "right to offer access to its products at prices set by voluntary agreements" rather than "government dictates." Pls.' Br. at 41. The Negotiation Program does not require any sales of drugs but rather "simply establishes maximum prices the Government will pay for selected drugs" that are dispensed, furnished, or administered to Medicare beneficiaries. *AstraZeneca*, 719 F. Supp. 3d at 396.

To the extent Teva contends that the Negotiation Program requires manufacturers to provide access to their physical drugs, the argument runs counter to a large body of case law holding that that participation in Medicare and Medicaid "is a voluntary undertaking." *Livingston Care Ctr., Inc. v. United States*, 934 F.2d 719, 720 (6th Cir. 1991)); *see Baptist Hosp. E. v. HHS*, 802 F.2d 860, 869-70 (6th Cir. 1986); *see also Baker Cnty. Med. Servs., Inc. v. U.S. Att'y Gen.*, 763 F.3d 1274, 1279-80 (11th Cir. 2014); *Garelick v. Sullivan*, 987 F.2d 913, 917 (2d Cir. 1993).[14] Indeed, every district court to have addressed a Fifth Amendment challenge to the Negotiation Program has concluded that participation is voluntary. *See supra* at 7-8 (listing cases).

As those courts have explained, "[n]either the IRA nor any other federal law requires [manufacturers] to sell [their] drugs to Medicare beneficiaries." *AstraZeneca*, 719 F. Supp. 3d at 395-96; *see also, e.g.*, *Bristol Myers Squibb Co.*, 2024 WL 1855054, at *7 ("[T]he parties have not identified any authority holding that participation in the Medicare system is involuntary. The Court, despite diligent efforts, was likewise unable to identify any such authority." (citations omitted)). Manufacturers may choose not to sell their drugs to Medicare if they do not agree with the offered price. And the Negotiation Program applies only to entities that choose to participate

[14] Many of these cases address claims under the Takings Clause of the Fifth Amendment, rather than the Due Process Clause, but that context does not affect the conclusion that the economic incentive to participate in Medicare and Medicaid does not make such participation involuntary.

in Medicare and Medicaid, and regulates only the prices the government will pay for certain drugs sold to Medicare beneficiaries. *See* 2027 Guidance at 234 ("[T]he IRA expressly connects a . . . [m]anufacturer's financial responsibilities under the voluntary Negotiation Program to that manufacturer's voluntary participation [in Medicare.]"); 26 U.S.C. § 5000D(c)(1) (making the applicability of the excise tax contingent on such participation). The Program does not limit the price that non-beneficiaries pay, nor does it limit the price that a beneficiary pays if he chooses to obtain drugs without using his Medicare benefits (*i.e.*, pays cash). Thus, drug manufacturers that do not wish to make their drugs available to Medicare beneficiaries at negotiated prices need not do so. The Negotiation Program in no way alters the fact that a provider dissatisfied with the prices that Medicare offers "may withdraw from participation." *Baptist Hosp.*, 802 F.2d at 869-70.

To the extent Teva contends that the financial benefits of Medicare participation make withdrawal involuntary because it would be impractical, "[c]ourts have roundly rejected such arguments." *Bristol Myers Squibb Co.*, 2024 WL 1855054, at *7 (collecting cases). Rather, "participation in Medicare, no matter how vital it may be to a business model, is a completely voluntary choice." *Dayton Area Chamber of Com.,* 696 F. Supp. 3d at 456; *see also, e.g.*, *AstraZeneca*, 719 F. Supp. 3d at 397 (participation in Medicare "is a potential economic opportunity that [manufacturers are] free to accept or reject"). This is because practical "hardship is not equivalent to legal compulsion for purposes of" a Fifth Amendment analysis. *Garelick*, 987 F.2d at 917; *cf. St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 875 (7th Cir. 1983) (per curiam) (the "fact that practicalities may in some cases dictate participation does not make participation involuntary"). Thus, even where "business realities" create a "strong financial inducement to participate" in a government program—*e.g.*, when Medicaid provides the vast majority of a nursing home's revenue—courts have uniformly held that participation "is nonetheless voluntary." *Minnesota Ass'n of Health Care Facilities, Inc. v. Minnesota Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984); *Whitney v. Heckler*, 780 F.2d 963, 972 n.12 (11th Cir. 1986) ("[T]he fact that Medicare patients comprise a substantial percentage of [the plaintiffs'] practices does not render their participation 'involuntary.'"). Courts have likewise rejected the suggestion that participation

in a voluntary program becomes involuntary if it may take some time to withdraw. *See Yee v. City of Escondido*, 503 U.S. 519, 527-28 (1992) (finding no violation of a protected property interest where a property owner could choose to leave a price-capped market with "6 or 12 months notice").

Far from "forc[ing]" Teva to sell its products at a government-dictated rate, the IRA leaves Teva free to negotiate pricing with any buyers in the marketplace, including the government. Pls.' Br. 41. Just as defense contractors remain free to accept or reject the government's contractual terms despite the government's dominant market position, so too are pharmaceutical companies that participate in Medicare and Medicaid, which occupy a far less significant portion of the prescription drug market. While Teva cannot require the government to buy its drugs at its preferred price, it may avail itself of the leverage resulting from its exclusive right to sell its products. Teva also remains free to negotiate different prices with other buyers and to choose not to sell its drugs to any buyer, including the government, if the parties do not agree on a price.

CONCLUSION

For these reasons, the Court should dismiss Plaintiffs' statutory claims for lack of subject-matter jurisdiction and enter summary judgment for Defendants on Plaintiff's due process claims.

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