[ORAL ARGUMENT NOT SCHEDULED]

No. 25-5425

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

TEVA PHARMACEUTICALS USA, INC., *et al.*,
Plaintiffs-Appellants,

v.

ROBERT F. KENNEDY, JR., *in his official capacity as Secretary of Health and Human Services*, *et al.*,
Defendants-Appellees.

On Appeal from the United States District Court
for the District of Columbia

BRIEF FOR APPELLEES

Of Counsel:

MICHAEL B. STUART
General Counsel

ELIZABETH C. KELLEY
Deputy General Counsel
Chief Legal Officer for CMS

JOCELYN S. BEER
Acting Deputy Associate General Counsel for Litigation

KENNETH R. WHITLEY
Attorneys

U.S. Department of Health and Human Services

ERIC J. HAMILTON
Deputy Assistant Attorney General

MICHAEL S. RAAB
MAXWELL A. BALDI
Attorneys, Appellate Staff
Civil Division, Room 7513
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530
(202) 532-0211

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Circuit Rule 28(a)(1), the undersigned counsel certifies as follows:

A. Parties and Amici

Plaintiffs-appellants are Teva Pharmaceuticals USA, Inc.; Teva Branded Pharmaceutical Products R&D LLC; and Teva Neuroscience, Inc.

Defendants-appellees are Robert F. Kennedy, in his official capacity as Secretary of Health and Human Services, and Mehmet Oz, in his official capacity as Administrator of the Centers for Medicare & Medicaid Services.

The following amici appeared in the district court in support of plaintiffs: Association for Accessible Medicines; Bausch Health Companies Inc.; Eli Lilly and Company; Johnson & Johnson; Pfizer Inc.; Sanofi-Aventis U.S. LLC; and Biotechnology Innovation Organization.

The following amici appeared in the district court in support of defendants: Richard G. Frank; Fiona M. Scott Morton; Aaron S. Kesslheim; Gerard F. Anderson; Rena M. Conti; David M. Cutler; Jack Hoadley; Public Citizen; Doctors for America; Protect Our Care; and Families USA.

The following amici appeared in this Court in support of plaintiffs: Association for Accessible Medicines, Bausch Health Companies, Inc.,

Bristol Myers Squibb Company, Eli Lilly and Company, Johnson & Johnson, Sanofi-Aventis U.S. LLC, and Biotechnology Innovation Organization.

B. Rulings Under Review

Plaintiffs appeal from the memorandum opinion (Dkt. 46) and order (Dkt. 47) issued by the district court (Sooknanan, J.) on November 20, 2025. The memorandum opinion is not yet published but is available at 2025 WL 3240267.

C. Related Cases

This case has not previously been before this Court or any court other than the district court. Counsel for defendants-appellees are unaware of any related cases within the meaning of D.C. Circuit Rule 28(a)(1)(C).

/s/ Maxwell A. Baldi
Maxwell A. Baldi

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Cases: **Page(s)**

U.S. Constitution:

Statutes:

Regulations:

Rule:

Legislative Materials:

Other Authorities:

GLOSSARY

Act	Inflation Reduction Act of 2022
CMS	Centers for Medicare & Medicaid Services
FDA	Food and Drug Administration
HHS	U.S. Department of Health and Human Services
NDA	New Drug Application

INTRODUCTION

For more than 30 years, Congress has limited the amount that 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 2022, Congress gave the Secretary of Health and Human Services (HHS) similar authority to address the extraordinary and unsustainable increase in the prices Medicare pays for pharmaceutical products that lack generic competition and that account for a disproportionate share of Medicare's expenses. Inflation Reduction Act of 2022, Pub. L. No. 117-169, 136 Stat. 1818 (Act); *see* 42 U.S.C. §§ 1320f(a), 1320f-1(b), (d), (e). Under the Act'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.

Teva Pharmaceuticals USA, Inc. and two related companies assert that CMS improperly selected one of its drugs for negotiation, that CMS improperly imposed a good-faith requirement on the exemption from the

Negotiation Program for drugs subject to generic competition, and that the Negotiation Program deprives them of property without due process of law. Congress expressly barred judicial review of Teva's statutory claims, and in any event they are meritless. The Act expressly requires CMS to aggregate different formulations of the same drugs together. Congress did not require CMS to accept bad-faith efforts to evade the Negotiation Program through sham marketing of generic alternatives. As for Teva's due process claim, drug manufacturers do not have a property right to dictate prices when they participate in a government spending program. Teva can accept the deal the government offers, or it can walk away. The district court properly rejected Teva's claims.

The Second and Third Circuits have rejected similar due process claims, and the Third Circuit has concluded that the Act's judicial review bar precludes the type of statutory challenge Teva mounts here. *See AstraZeneca Pharms. LP v. HHS*, 137 F.4th 116, 125-26 (3d Cir. 2025); *Boehringer Ingelheim Pharms., Inc. v. HHS*, 150 F.4th 76, 93-94 (2d Cir. 2025); *Novo Nordisk Inc. v. HHS*, 154 F.4th 105, 111-13 (3d Cir. 2025). This Court too should uphold the constitutionality of the Negotiation Program and decline to review CMS's implementation of it.

STATEMENT OF JURISDICTION

Plaintiffs invoked the jurisdiction of the district court under 28 U.S.C. §§ 1331, 1346(a)(2), 1361, and 2201-2202. Amended Complaint, JA81-82. The district court entered final judgment in favor of the government on November 20, 2025. Order, JA204. Plaintiffs filed a timely notice of appeal on November 20, 2025. Notice of Appeal, JA205; *see* Fed. R. App. P. 4(a)(1)(B). This Court has jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES

1. Whether Congress barred judicial review of Teva's statutory challenges to the Negotiation Program.

2. Whether the district court correctly rejected Teva's statutory challenges to the Negotiation Program.

3. Whether the district court correctly rejected Teva's due process challenge to the Negotiation Program.

PERTINENT STATUTES AND REGULATIONS

All applicable statutes are contained in the addendum to Teva's opening brief.

STATEMENT OF THE CASE

A. Medicare and the Escalating Cost of Prescription Drug Coverage

Congress created Medicare in 1965. Social Security Amendments of 1965, Pub. L. No. 89-97, tit. I, 79 Stat. 286, 290-353. Medicare provides federally funded health coverage for individuals who are 65 or older or who have certain disabilities or medical conditions. 42 U.S.C. § 1395 *et seq.* CMS administers Medicare on behalf of the Secretary of HHS.

Medicare is divided into "Parts," which establish the terms under which Medicare pays for specific benefits. *See Northeast Hosp. Corp. v. Sebelius*, 657 F.3d 1, 2 (D.C. Cir. 2011). Medicare Part B covers outpatient care 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). CMS generally pays Part B providers at a rate of 106% of the average sales price for most separately payable drugs or biologicals. 42 U.S.C. § 1395w-3a(b)(1); *see American Hosp. Ass'n v. Becerra*, 596 U.S. 724, 729 (2022). For nearly four decades, Medicare did not cover the cost of prescription drugs unless they were administered by medical professionals. That changed in 2003, when Congress enacted Medicare Part D to provide "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.* Under Part D, CMS enters into contracts with private entities, known as "sponsors," 42 U.S.C. § 1395w-112(b), and makes payments to them to provide prescription drug plans to Part D eligible individuals, *see id.* § 1395w-115. On average, the government subsidizes 74.5% of expected benefit costs. *See id.*

In enacting Part D, Congress initially barred CMS from negotiating Part D drug prices or otherwise interfering in the arrangements between drug manufacturers and insurance plans. 42 U.S.C. § 1395w-111(i); *see also* Michelle Singer, *Under the Influence*, CBS News (Mar. 29. 2007), https://perma.cc/5U9Z-M2YS (documenting extensive pharmaceutical industry efforts to lobby for price-negotiation bar in lead-up to enactment of Part D). But that model led to skyrocketing drug prices, which saddled beneficiaries with unaffordable copays and threatened the long-term solvency of the program.

The cost to the federal government of providing prescription drug coverage under Medicare Parts B and D is immense. In 2021 alone, the federal government spent more than $250 billion on drugs covered by these

programs. *See* KFF, *10 Prescription Drugs Accounted for $48 Billion in Medicare Part D Spending in 2021, or More Than One-Fifth of Part D Spending That Year* (July 12, 2023), https://perma.cc/4CYL-KYRM. That figure has risen dramatically over the last decade and is "projected to continue rising during the coming decade, placing increasing fiscal pressure[ ]" on the federal budget. Off. of the Assistant Sec'y for Plan. & Evaluation, HHS, *Report to Congress: Prescription Drug Pricing* 8 (May 20, 2020), https://perma.cc/5GEN-LZ7F (2020 Report). Medicare Part D spending in particular "is projected to increase faster than any other category of health spending." S. Rep. No. 116-120, at 4 (2019).

In addition to its effects on the fisc, the high cost of prescription drug coverage directly burdens Medicare beneficiaries by affecting their premiums and out-of-pocket payments. Because Part B premiums are automatically set to cover 25% of aggregate Part B spending, higher total spending on prescription drug coverage results in higher premiums for individual enrollees. *See* 2020 Report 11. Beneficiaries also pay 20% of their Part B prescription drug costs out of pocket. Many Part D plans likewise require beneficiaries to pay cost-sharing amounts, *e.g.*, 42 C.F.R.

§ 423.104(d)(2), and Part D premiums are similarly based on a plan's anticipated costs, *see id.* § 423.286.

A "relatively small number of drugs are responsible for a disproportionately large share of Medicare costs." H.R. Rep. No. 116-324, pt. 2, at 37 (2019). In 2018, "the top ten highest-cost drugs by total spending accounted for 46 percent of spending in Medicare Part B" and "18 percent of spending in … Part D." 2020 Report 7. By 2021, the top 10 drugs by total spending accounted for 22% of spending under Part D. *See* Juliette Cubanski & Tricia Neuman, *A Small Number of Drugs Account for a Large Share of Medicare Part D Spending*, KFF (July 12, 2023), https://perma.cc/2PF2-336Z.

These rising costs are in large part attributable to manufacturers' considerable latitude in dictating the prices that Medicare pays for the most expensive drugs. Because drug prices under Medicare Part B and Part D were tied to the price manufacturers charged private buyers, *see* 42 U.S.C. §§ 1395w-3a(b), 1395w-101 *et seq.*, manufacturers of drugs with no generic competition could "effectively set[ ] [their] own Medicare payment rate[s]" by dictating sales prices in the broader market. Medicare Payment Advisory Comm'n, *Report to the Congress: Medicare and the Health Care Delivery*

System 84 (June 2022), https://perma.cc/5X4R-KCHC. Drug companies' substantial leeway in this respect was compounded by the significant legal and practical obstacles to market entry faced by generic competitors, along with the practice of many manufacturers of protecting their market share by entering into "settlements" with generic manufacturers to limit generic marketing. *See, e.g.*, Sarah M.E. Gabriele & William B. Feldman, *The Problem of Limited-Supply Agreements for Medicare Price Negotiation*, 330 JAMA 1223 (2023). As a result of these factors, there are in many instances "no market forces to apply downward pressure to provide lowered prices to the millions who have coverage for such medicines under Medicare." H.R. Rep. No. 116-324, pt. 2, at 37-38.

Other federal agencies, including the Departments of Defense and Veterans Affairs, operate their drug benefit programs differently and have not been subject to skyrocketing costs. Manufacturers that wish to sell drugs to these and other specified government agencies have long been obligated, as a requirement for Medicaid payment for their products, to negotiate directly with the government and to reach agreements subject to statutorily defined ceiling prices. *See* 42 U.S.C. § 1396r-8(a)(1), (6); 38 U.S.C. § 8126(a)-(h). As a consequence, manufacturers often sell drugs to these agencies for

roughly half as much as they charge Medicare Part D. *See* Cong. Budget Off., *A Comparison of Brand-Name Drug Prices Among Selected Federal Programs* 16 (Feb. 2021), https://perma.cc/YY2E-GM97. "[I]f Medicare had received the same discounts as the Departments of Defense and Veterans Affairs, taxpayers would have saved" billions. Staff of H. Comm. on Oversight & Reform, *Drug Pricing Investigation: AbbVie—Humira and Imbruvica* 13-15 (May 2021), https://perma.cc/Z2KG-ZKW3.

B. The Drug Price Negotiation Program

Through the Drug Price Negotiation Program, Congress empowered the HHS Secretary, acting through CMS, to negotiate the prices Medicare pays for certain drugs, just as the Department of Defense, the Department of Veterans Affairs, and the Coast Guard have done for decades. *See* Act §§ 11001-11003, 136 Stat. at 1833-64 (codified at 42 U.S.C. §§ 1320f-1320f-7 and 26 U.S.C. § 5000D). The Negotiation Program applies only to manufacturers that choose to participate in Medicare and Medicaid, and even then, it governs only the prices that Medicare pays for certain drugs. *See* 42 U.S.C. § 1320f-1(b), (d). The Negotiation Program does not dictate the prices paid for sales outside of Medicare Parts B and D.

By statute, only certain drugs are eligible for selection in the Negotiation Program: those that account for the highest Medicare expenditures, that have no generic or biosimilar competitors, and that have been on the market for at least seven years (11 for biological products). *See* 42 U.S.C. § 1320f-1(d), (e). For the first negotiation cycle, CMS selected 10 of these drugs with the highest Medicare expenditures for negotiations. *Id.* § 1320f-1(a). Additional drugs have and will be selected for future negotiation cycles. A drug is generally subject to the negotiated prices until "the first year that begins at least 9 months after the date on which the Secretary determines at least one" generic competitor "is approved or licensed" by the Food and Drug Administration (FDA) and "is marketed pursuant to such approval or licensure."[1] *Id.* § 1320f-1(c)(1).

After selecting the drugs, CMS signs a Manufacturer Agreement with those manufacturers that are willing to engage in the negotiation process. 42 U.S.C. § 1320f-2. The object of the negotiations is to reach agreement on what the Act terms a "maximum fair price" that Medicare will pay for each selected drug. *Id.* § 1320f-3. To guide the negotiation process, Congress

[1] Additionally, in some circumstances, not relevant here, a drug is eligible for renegotiation of the negotiated price. 42 U.S.C. § 1320f-3(f).

imposed a "[c]eiling for [the] maximum fair price," which is based on specified pricing data for each drug, *id.* § 1320f-3(c), and directed CMS to "aim[ ] to achieve the lowest maximum fair price" that the manufacturer will accept, *id.* § 1320f-3(b)(1). If negotiations prove successful, the manufacturer signs an addendum to the Manufacturer Agreement establishing the maximum price at which the drug will be made available to Medicare beneficiaries. *Id.* § 1320f-3.

In enacting the Negotiation Program, Congress revised the terms of the government's offer to continue purchasing drugs for Medicare and Medicaid. A drug manufacturer that does not wish to participate in the Negotiation Program has several options. Because participation in the Medicare program is a voluntary undertaking, the manufacturer can withdraw from Medicare and Medicaid and thus not be subject to any of the Negotiation Program's requirements. 26 U.S.C. § 5000D(c)(1); *see also* CMS, *Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026*, at 120-21 (June 30, 2023), https://perma.cc/K6QB-C3MM (2026 Guidance). Alternatively, a manufacturer can transfer its ownership of the selected drug to another

entity and continue to sell other drugs to Medicare and Medicaid. *See* 2026 Guidance 131-32. A manufacturer that pursues neither of these options may also continue to sell the selected drug to Medicare beneficiaries at non-negotiated prices subject to an excise tax. *See* 26 U.S.C. § 5000D(a)-(h); *see also Excise Tax on Designated Drugs*, 90 Fed. Reg. 31 (Jan. 2, 2025); Internal Revenue Serv., Notice No. 2023-52 (Aug. 4, 2023), https://perma.cc/B9JZ-ZG7P (IRS Notice).

C. Implementing the Negotiation Program

1. In addition to the statutory requirements set out above, Congress instructed CMS to implement the Negotiation Program through "program instruction or other forms of program guidance" for the first three negotiation cycles.[2] Act § 11001(c), 136 Stat. at 1854. In June 2023, CMS published guidance that explains, among other things, how CMS determines which drugs may be selected for negotiation and the procedures for participating in the negotiation process. *See* 2026 Guidance 91-92. On October 24, 2024, after voluntarily soliciting another round of comments, CMS published guidance for initial price applicability year 2027. CMS, *Medicare*

[2] For 2029 and subsequent years, CMS will pursue notice and comment rulemaking in implementing the Negotiation Program. *See* Act § 11001(c), 136 Stat. at 1854.

Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027, at 120-21 (Oct. 2, 2024), https://perma.cc/4XGP-ZEEV (2027 Guidance). While the 2027 Guidance governed CMS's selection of the drug at issue in this litigation, Teva challenges both the 2026 and 2027 Guidance. The 2027 Guidance is materially indistinguishable from the 2026 Guidance with respect to all the issues Teva raises in this suit.

As relevant here, the guidance explains how CMS determines what constitutes a "qualifying single source drug" that may be selected for negotiation. 42 U.S.C. § 1320f-1(e). The Act specifically "directs CMS to establish procedures 'to compute and 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 such drug.'" 2026 Guidance 99 (quoting 42 U.S.C. § 1320f-5(a)(2)); *accord* 2027 Guidance 167. The guidance explains that CMS 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."[3] 2026 Guidance 99 (footnote omitted); *accord* 2027 Guidance 167. This means that if one manufacturer holds NDAs for several forms of a drug with the same active moiety, these various forms will be considered collectively under the provisions of the Act that require aggregation across dosage forms, package types, and formulations. 2026 Guidance 99-100 (citing 42 U.S.C. § 1320f-1(d)(3)(B)); *accord* 2027 Guidance 167-68.

CMS acknowledged that some commenters had suggested that a qualifying single source drug must be defined by reference to a distinct NDA. 2026 Guidance 11; 2027 Guidance 12. But CMS explained that such a definition would be inconsistent with the Act's aggregation requirements. 2026 Guidance 11; 2027 Guidance 12-13. "The aggregation rules under [the Act] are clear, and are designed to ensure that the Negotiation Program delivers benefits to the Medicare program and its beneficiaries as intended by the law." 2026 Guidance 11; *accord* 2027 Guidance 13. CMS also noted that

[3] A similar definition applies to biological products, for which CMS aggregates "all dosage forms and strengths of the biological product with the same active ingredient and the same holder of a Biologics License Application … inclusive of products that are marketed pursuant to different [Biologics License Applications]." 2026 Guidance 99 (footnote omitted); *accord* 2027 Guidance 168.

its definition "will decrease incentives for pharmaceutical manufacturers to engage in 'product hopping'"—that is, making "modest or minor modifications" to a drug to avoid regulations or the expiration of patent exclusivity. 2026 Guidance 12; *accord* 2027 Guidance 13.

The guidance further explains when generic competition exempts a drug from the Negotiation Program. For this purpose, "CMS will consider a generic drug or biosimilar biological product to be marketed when the totality of the circumstances, including [specified sets of sales] data, reveals that the manufacturer of that drug or product is engaging in bona fide marketing of that drug or product." 2026 Guidance 102; *accord* 2027 Guidance 170. CMS noted that it would conduct a "holistic inquiry" including considering "whether the generic drug or biosimilar is regularly and consistently available for purchase through the pharmaceutical supply chain and whether any licenses or other agreements between a Primary Manufacturer … and a generic drug or biosimilar manufacturer limit the availability or distribution of the selected drug." 2027 Guidance 171; *see also* 2026 Guidance 101-02.

The guidance also sets out procedures for manufacturers that choose not to participate in the Negotiation Program. 2026 Guidance 118-21, 129-31;

2027 Guidance 187-90, 233-36. In those circumstances, CMS will "facilitate an expeditious termination of" a manufacturer's Medicare agreement before the manufacturer would incur liability for any excise tax, so long as the manufacturer notifies the agency of its desire to withdraw at least 30 days in advance of when the tax would otherwise begin to accrue. 2026 Guidance 33-34; *see also* 2026 Guidance 130; 2027 Guidance 235. The Treasury Department and the IRS issued a notice explaining that, when excise tax liability is triggered, the tax will be imposed only on the manufacturer's "sales of designated drugs dispensed, furnished, or administered to individuals under the terms of Medicare"—*i.e.*, not on drugs dispensed, furnished, or administered outside of Medicare. IRS Notice 3. That interpretation took effect immediately. *See* IRS Notice 5. The Treasury Department and the IRS have since reiterated their understanding of the application of the tax in a proposed rule. *See* 90 Fed. Reg. 31.

2. In January 2025, CMS selected drugs for the second negotiation cycle. *See* CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2027* (Jan. 2025), https://perma.cc/BQG7-GC3W. The 15 drugs selected "accounted for about $41 billion in total gross covered prescription drug costs under Medicare Part D" between November

2023 and October 2024 and were used during that period by "about 5.3 million people with Medicare Part D coverage." Press Release, CMS, *HHS Announces 15 Additional Drugs Selected for Medicare Drug Price Negotiations in Continued Effort to Lower Prescription Drug Costs for Seniors* (Jan. 17, 2025), https://perma.cc/TQ5V-PABY.

In accordance with the schedule established by Congress, CMS presented the manufacturers of selected drugs with initial offers by June 1, 2025. *See* CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2027* (Nov. 2025), https://perma.cc/ZU7B-5PJ7. The manufacturers responded to the initial offers with counteroffers by July 1. *Id.* CMS held three negotiation meetings with each manufacturer to discuss the offers and relevant evidence. *Id.* CMS reached price agreements for eight of the selected drugs in connection with these meetings. *Id.* CMS sent final written offers to manufacturers of the seven remaining drugs by October 15. *Id.* By November 1, 2025, CMS and the participating manufacturers had agreed to a negotiated price for each of the 15 selected drugs. *Id.* Assuming that none of the manufacturers withdraw from the negotiation agreement by December 2026, these prices

will take effect on January 1, 2027. 42 U.S.C. §§ 1320f(b), (d), 1320f-2(a), 1320f-3(b).

When the negotiated prices go into effect, they are projected to save Medicare beneficiaries $685 million in out-of-pocket costs and the federal fisc about $8.5 billion. *See* CMS, *Negotiated Prices for Initial Price Applicability Year 2027*, *supra*.

D. Prior Proceedings

1. Teva manufactures prescription drugs including Austedo, which treats involuntary muscle movement associated with Huntington's disease and tardive dyskinesia. Faulkingham Declaration, JA144-45. Austedo contains a single active moiety: deutetrabenazine. *Id.*, JA145. Austedo is available as a tablet in both a regular-release formulation and an extended-release formulation. *See* Complaint, JA43 ("AUSTEDO XR is the extended-release formulation of AUSTEDO and gives patients the same benefits as AUSTEDO in a once-daily pill as opposed to the twice-a-day dosing and titration schedule for AUSTEDO."). From November 2023 to October 2024, Austedo accounted for approximately $1,531,855,000 in Medicare Part D spending for roughly 26,000 Medicare patients—just under $59,000 per patient. *See* CMS, *Selected Drugs for Initial Price Applicability Year 2027*,

supra. CMS selected Austedo (in both its regular and extended-release formulations) for negotiation in the second cycle of the negotiation program.[4] *Id.*

Teva also manufactures generic and biosimilar competitors to branded drugs. Groff Declaration, JA151. Teva alleges that it plans to launch generic competitors to several drugs that CMS has selected for negotiation. *Id.*, JA155-60. FDA has approved Teva to market generic versions of two of these drugs: enzalutamide, *id.*, JA156, and apremilast, Second Groff Declaration, Add. 5-6.

2. Together with two of its related companies, Teva sued. Amended Complaint, JA74-137. Teva alleged three causes of action: that CMS acted contrary to law in defining a qualifying single source drug, that CMS acted contrary to law in promulgating the bona fide marketing standard, and that the Negotiation Program deprives Teva of property without due process. *Id.*, JA132-36. Teva sought declaratory relief, vacatur of the qualifying single source drug definition and bona fide marketing standard, and injunctive relief barring application of "the drug-pricing provisions of the [Act] to Teva

[4] Subsequent mentions of Austedo refer to deutetrabenazine in both its regular and extended-release formulations unless express reference is made to one formulation.

or to the manufacturers of branded drugs or biologics with which Teva competes or will compete in the future." *Id.*, JA136-37.

The district court granted summary judgment to the government. Order, JA204. The court concluded that the Act's bar on judicial review does not preclude Teva's statutory challenges to the definition of a qualifying single source drug and to the bona fide marketing requirement because they "are facial challenges to policies and not as-applied challenges to drug determinations." Memorandum Opinion, JA179; *see id.*, JA179-86. The court, however, declined to reach Teva's bona fide marketing claim on ripeness grounds. *Id.*, JA192-97.

The court upheld CMS's definition of qualifying single source drug on the merits. Memorandum Opinion, JA186-92. The court explained that the Act expressly "instructs CMS to 'use data that is aggregated 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 size or package type of *the drug*' when 'determining whether a qualifying single source drug' has expenditures sufficient to be eligible for negotiations." *Id.*, JA190 (quoting 42 U.S.C. § 1320f-1(d)(3)(B)).

The court thus rejected Teva's argument for a definition tied to FDA's approval of an NDA. *Id.*, JA188, 192.

The court also rejected Teva's due process claim on the merits. Memorandum Opinion, JA197-203. The court concluded that neither the Medicare statute, past practice, common law, or patents conferred upon Teva a protected property interest implicated by the Negotiation Program. *See id.*

SUMMARY OF ARGUMENT

I. The Act expressly precludes review of Teva's statutory challenge to CMS's implementation of the Negotiation Program. The Act provides that there "shall be no administrative or judicial review" of CMS's "selection of drugs" or its predicate "determination of qualifying single source drugs." 42 U.S.C. § 1320f-7(2). These provisions squarely preclude judicial review of the claim that CMS erred in determining that multiple forms of Teva's drug Austedo should be selected for negotiation. *See Novo Nordisk Inc. v. HHS*, 154 F.4th 105, 111-13 (3d Cir. 2025). And they likewise preclude review of Teva's procedural challenge to the standard CMS will apply to determine whether a drug is no longer subject to a negotiated price due to generic competition.

II. A. CMS's selection of Teva's drug is in any event correct on the merits, as the Act directs CMS to consider all dosage forms, strengths, and "new formulations" of a drug together at every step of the negotiation process. 42 U.S.C. § 1320f-1(d)(3)(B); *see id.* §§ 1320f-3(e)(1)(D), 1320f-5(a)(2). That directive is consistent with the program goal of identifying and targeting the drugs that have the most significant financial impact on Medicare as a whole, regardless of variations in formulation and packaging. CMS appropriately followed this instruction in selecting both the regular and extended-release formulations of Austedo for negotiation.

B. Teva fares no better in its facial challenge to CMS's determination that a drug is no longer subject to the Negotiation Program due to generic competition only when a generic competitor is marketed in good faith. This is not a high bar: if a generic manufacturer is actually selling the drug in the market, the good-faith requirement is satisfied. But Congress did not intend to allow manufacturers to evade their Negotiation Program obligations through sham transactions, as Teva's "single sale" rule would permit.

III. Teva's due process arguments also lack merit. The threshold "inquiry in every due process challenge is whether the plaintiff has been deprived of a protected interest" in liberty or property, *American Mfrs.*

Mut. Ins. Co. v. Sullivan, 526 U.S. 40, 59 (1999), and Teva fails to identify any such deprivation. Put simply, "[t]here is no protected property interest in selling goods to Medicare beneficiaries (through sponsors or pharmacy benefit plans) at a price higher than what the government is willing to pay when it reimburses those costs." *AstraZeneca Pharms. LP v. HHS*, 137 F.4th 116, 125-26 (3d Cir. 2025).

Teva is likewise mistaken in asserting that it will suffer a cognizable deprivation when it sells its drug to Medicare at the negotiated price, or when it shares business information with CMS consistent with the program terms. "A company suffers no deprivation of its property interests by voluntarily submitting to a price-regulated government program." *Boehringer Ingelheim Pharms., Inc. v. HHS*, 150 F.4th 76, 94 (2d Cir. 2025). Teva is under no legal obligation to accept the terms of the government's offer to purchase its drug, and Teva's acceptance of that offer does not entail a deprivation of protected property rights.

STANDARD OF REVIEW

This court reviews de novo an order granting summary judgment. *See Novartis Pharms. Corp. v. Kennedy*, 156 F.4th 626, 629 (D.C. Cir. 2025).

ARGUMENT

I. Congress precluded judicial review of Teva's statutory claims.

1. Courts lack jurisdiction to resolve Teva's statutory claims because Congress expressly provided that there "shall be no administrative or judicial review" of CMS's "selection of drugs," its "determination of negotiation-eligible drugs," or its "determination of qualifying single source drugs." 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). While there is a "strong presumption that Congress intends judicial review of administrative action," *Bowen v. Michigan 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 Reg'l*, 925 F.3d at 506 (quoting *Knapp Med. Ctr. v. Hargan*, 875 F.3d 1125, 1128 (D.C. Cir. 2017)).

Plaintiffs directly challenge CMS's determination of what constitutes a "qualifying single source drug" under § 1320f-1(e). Amended Complaint, JA132-34. 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," *see* Br. 20-36; and (2) which drugs can be excluded from the "qualifying single source drug" definition on the ground that they have a generic competitor, *see* Br. 44-48. Both of these 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 these determinations. *See id.* § 1320f-7.

The Third Circuit held that a near identical challenge was precluded under the Act's judicial review bar. *See Novo Nordisk Inc. v. HHS*, 154 F.4th 105, 111-13 (3d Cir. 2025). In that case, a pharmaceutical manufacturer

challenged "CMS's decision to group products into a single potentially qualifying drug"—there, the manufacturer's insulin aspart products. *Id.* at 111; *see id.* (noting that manufacturer offered the same active ingredient in six formulations). The Third Circuit held that it lacked jurisdiction to consider the manufacturer's challenge to CMS's "definition of qualifying single-source drug" because the Act precluded judicial review of "determination of negotiation-eligible drugs" and thus of the process CMS used to make that determination. *Id.* at 111-12 (quoting 42 U.S.C. § 1320f-7(2)). The same logic applies here.

2. Teva cannot avoid Congress's express preclusion of judicial review by framing its attack as a facial challenge to a rule rather than as an as-applied challenge to an individual drug selection. The plain text of the Act makes clear that "[t]here shall be no administrative or judicial review" of CMS's drug selection determinations. 42 U.S.C. § 1320f-7. The preclusive scope of that provision is broad insofar as it covers all aspects of the agency's "selection of drugs" for negotiation—including the steps that precede selection, such as the agency's "determination of qualifying single source drugs" and its "determination of negotiation-eligible drugs." *Id.* § 1320f-7(2). Congress thus made clear its intent to preclude review not just of individual

drug-selection decisions but also of the administrative steps leading to the selection. *See Novo*, 154 F.4th at 112.

As this Court has explained in construing the Medicare statute's other review bars, when Congress precludes judicial review of a decision, it also precludes review of any preceding issues that are "inextricably intertwined" with the final decision. *DCH Reg'l*, 925 F.3d at 507 (first citing *Florida Health Scis. Ctr., Inc. v. HHS*, 830 F.3d 515, 521 (D.C. Cir. 2016); then citing *Texas All. for Home Care Servs. v. Sebelius*, 681 F.3d 402, 411 (D.C. Cir. 2012); and then citing *Mercy Hosp., Inc. v. Azar*, 891 F.3d 1062, 1066-67 (D.C. Cir. 2018)). For example, a statute precluding administrative and judicial review of "the awarding of contracts," 42 U.S.C. § 1395w-3(b)(12), is not limited to "the awarding of a single contract but" rather applies "to 'the awarding of contracts' generally." *Texas All.*, 681 F.3d at 410. Thus, because the process of awarding contracts "requires the formulation and application of financial standards," the statute's bar on review extends to an agency rule adopting such standards. *Id.*

In another context, this Court similarly held that a statutory bar on administrative or judicial review of "[a]ny estimate of the Secretary for purposes of determining [specified] factors" precluded review of a challenge

to "'the methodology adopted and employed' by HHS to calculate" one of those factors. *DCH Reg'l*, 925 F.3d at 505 (first alteration in original) (quoting 42 U.S.C. § 1395ww(r)(3)(A)). This Court explained that a "distinction between methodology and estimates would eviscerate the statutory bar" against review because "almost any challenge to an estimate could be recast as a challenge to its underlying methodology." *Id.* at 506. Because the "method" used by the agency and challenged by the plaintiff was "inextricably intertwined" with the "estimate," this Court held that the statute "precludes review of both." *Id.* at 507; *see Florida Health*, 830 F.3d at 519.

The same logic governs here. Congress precluded review of CMS's "determination of qualifying single source drugs." 42 U.S.C. § 1320f-7(2). The means by which CMS determines the list of qualifying single source drugs is by applying the statutory definition. CMS has no discretion over which drugs it determines are qualifying. *See id.* § 1320f-1(e). Determining the drugs, in effect, means generating the list of drugs that meet the definition. And whether different formulations of a drug are aggregated together or whether a drug is ineligible because of generic competition are two key elements of how the list takes shape.

3. The district court improperly reached the merits of one of Teva's statutory claims because it misunderstood a line of cases permitting some collateral attacks on general rules even when challenges on individual determinations are barred. Memorandum Opinion, JA180-82. In *McNary v. Haitian Refugee Center, Inc.*, the Supreme Court permitted a due process challenge despite a statutory bar on judicial review. 498 U.S. 479 (1991). As this Court has explained, the "question before the [*McNary*] Court was a narrow one: whether a provision of [an immigration statute], which barred judicial review of individual [adjustment of] status determinations except in the context of deportation proceedings, foreclosed district court review of the plaintiffs' procedural due process claims." *Federal L. Enf't Officers Ass'n v. Ahuja*, 62 F.4th 551, 564 (D.C. Cir. 2023). *McNary* concluded that the challenged provision applied only to "a single act rather than a group of decisions or a practice or procedure employed in making decisions." 498 U.S. at 491-92.

McNary does not stand for the general proposition that any judicial review bar applied to individual determinations permits broader challenges to underlying rules. *Contra* Memorandum Opinion, JA180-81. When the judicial review provision covers more than a "particular kind of adjudicatory

decision," *McNary*'s limited holding does not control. *See DCH Reg'l*, 925 F.3d at 508. And crucially, the claims in *McNary* "were collateral to review of a denied application." *Miriyeva v. U.S. Citizenship & Immigr. Servs.*, 9 F.4th 935, 944 (D.C. Cir. 2021) (citing *McNary*, 498 U.S. at 494-99). Thus, if the plaintiffs in that case prevailed, "that victory would not have reversed the denial of their applications for special agricultural worker status. Rather, it would allow only for their applications to be reconsidered with new procedures in place." *Id.* (citation omitted). Where deciding the challenge to the general rule would "decide the merits" of the individual adjudication, judicial review is barred. *See id.*; *Fornaro v. James*, 416 F.3d 63, 68 (D.C. Cir. 2005); *Palisades Gen. Hosp. Inc. v. Leavitt*, 426 F.3d 400, 405 (D.C. Cir. 2005). Both of these caveats render the *McNary* rule inapplicable here.

The Act's judicial review provision does not apply to individual adjudications only. Instead, as relevant here, it covers "[t]he selection of drugs under section 1320f-1(b)," "the determination of negotiation-eligible drugs under section 1320f-1(d)," and "the determination of qualifying single source drugs under section 1320f-1(e)." 42 U.S.C. § 1320f-7(2). Each of the statutory cross-references in that provision refers to a process. When CMS

determines whether drugs are qualifying single source drugs, § 1320f-1(e) calls for it to determine whether the drug is described by a set of criteria and then to exclude certain drugs from the list. *Id.* § 1320f-1(e)(1), (3). The selection of drugs, therefore, is not some sort of individualized adjudication like adjusting a person's immigration status. It is a generalized process based on the meaning of "qualifying single source drug." Thus, the judicial review bar extends to CMS's determination of whether to aggregate various forms of a drug.

Nor is Teva's challenge collateral to the merits of determining whether a drug is a qualifying single source drug. Teva instead challenges the framework under which CMS identifies the universe of drugs that could be potentially selected. That challenge is inseparable from the merits. Because their "challenge is no more than an attempt to undo an individual decision," it cannot fit within the *McNary* collateral attack exception. *DCH Reg'l*, 925 F.3d at 508 (cleaned up). The district court further misunderstood the nature of Teva's challenge when it asserted that "Teva only seeks forward-looking vacatur of the challenged guidance." Memorandum Opinion, JA184 (citing Amended Complaint, JA 136, ¶ C). Teva in fact also sought injunctive relief against enforcement of the Act's "drug-pricing provisions." Amended

Complaint, JA 137, ¶ E. And nowhere did Teva limit its prayer for vacatur to prospective relief only.[5] Teva challenges the guidance under which its drug was selected for negotiation, and that challenge is not collateral to the selection decision.

The provisions at issue here are unlike those in *American Clinical Laboratory Ass'n v. Azar*, in which this Court held that a statute providing for no administrative or judicial review "of the establishment of payment amounts" did not preclude review of a separate rule that "detailed the framework for data collection" even though the data collected would be used in establishing payment amounts. 931 F.3d 1195, 1204-05 (D.C. Cir. 2019) (quotation marks omitted). The Court explained that the challenged rulemaking implemented a separate statutory provision that "imposes new obligations on private parties," thereby addressing a distinct subject from "the rate-setting provisions affect[ing] reimbursements for Medicare

[5] To the extent Teva seeks only prospective vacatur of CMS's guidance, it would lack standing to raise this claim because such relief would not redress any of the harms Teva asserts from the selection of Austedo. *See Dobbin Plantersville Water Supply Corp. v. Lake*, 108 F.4th 320, 326-27 (5th Cir. 2024) (no standing where party fails to seek retrospective relief and prospective relief would be ineffectual); *see also Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 107 (1998) ("Relief that does not remedy the injury suffered cannot bootstrap a plaintiff into federal court; that is the very essence of the redressability requirement.").

services" for which Congress precluded review. *Id.* at 1205-06. "Congress also required that the parameters for that data collection be established through notice and comment rulemaking," part of the purpose of which "is to ensure the parties develop a record for judicial review." *Id.* at 1206. In those circumstances, where the challenged rule was promulgated pursuant to separate authority to address a discrete subject, and where Congress required procedures suggesting the availability of review, the Court declined to hold that review was precluded. By contrast, Teva challenges the framework under which CMS made the substantive determinations for which Congress precluded review. Those challenges are barred.

4. To the extent Teva continues to maintain that ultra vires review is available, *see* Dkt. 35, at 26-28, those arguments fail as well. 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 (quotation marks omitted); *see also Nuclear Regul. Comm'n v. Texas*, 605 U.S. 665, 681 (2025). Teva's ultra vires argument cannot surmount the first hurdle because the

Act expressly bars review of its claims. The argument also fails to satisfy the third prong 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 (quotation marks omitted); *see infra* pp. 34-50.

II. Teva's statutory claims fail on the merits.

If the Court reaches plaintiffs' statutory challenges, both lack merit. The Act expressly requires CMS to aggregate different forms of the same drug. And the Act's exception for drugs subject to generic competition is triggered when a generic alternative is "approved and marketed." That provision requires that the drug actually be marketed.

A. CMS appropriately grouped together different formulations of the same drug as the Act requires.

The 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," even if those different forms have been approved under different NDAs.[6] 2027 Guidance 167. Teva contests this definition, arguing instead that the Act takes an "NDA-specific" interpretation of

[6] Active moieties are "roughly[ ] active ingredients"; active moiety refers to "'the molecule or ion … responsible for the physiological or pharmacological action of the drug substance.'" *Otsuka Pharm. Co. v. Price*, 869 F.3d 987, 989-90 (D.C. Cir. 2017) (quoting 21 C.F.R. § 314.3(b)).

"qualifying single source drug." Br. 21-22. But, as CMS explained, the 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 Act.

1. The Negotiation Program targets for negotiation those drugs that impose the highest cost burden on Medicare, regardless of variations like differences in formulation or packaging. To achieve this goal, the Act requires 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 the application of a negotiated price.

Congress expressly directed CMS to identify "negotiation-eligible drugs" according to Medicare spending data, to rank these drugs according to this data, and then select the top 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* or … *package type* of the drug." 42 U.S.C. § 1320f-1(d)(3)(B) (emphases added). 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 a number of forms that may correspond to different applications or approvals. And CMS is expressly required to consider all "applications and approvals" (plural) "for the drug" (singular) when determining how much to offer in negotiations. *Id.* 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 Act 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 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[n] [NDA], inclusive of products that are marketed pursuant to different NDAs." 2027 Guidance 167 (footnote omitted). Applying that interpretation, CMS determined that Austedo (in both its regular and extended-release formulations) accounted for some of the highest Medicare expenditures, and CMS thus properly selected it for negotiation. Austedo XR is "the extended release formulation of AUSTEDO," and both have the same active moiety (deutetrabenazine). Faulkingham Declaration, JA 145. Given the Act's instruction that CMS "shall use data that is 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 aggregating across dosage forms and strengths to determine whether Teva's drug satisfied the criteria for selection.

2. Teva sidesteps the Act's repeated commands to aggregate all forms of a drug, insisting instead that the key question is whether FDA has approved the drugs in separate NDAs for various formulations of the same drug under the Food, Drug, and Cosmetic Act. But the Act and the Food, Drug, and Cosmetic Act are different statutes with fundamentally different objectives and functions. Teva's reliance on FDA's product-specific approval framework to argue for a product-specific approach by CMS misunderstands the statutory design and cannot be reconciled with the text of the Act.

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 be inappropriate in the context of FDA approvals, as it would prevent FDA from evaluating the safety and efficacy 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. That a manufacturer often controls whether its drug has one NDA or multiple NDAs based on how it chooses to submit its application(s) to FDA only underscores that Teva's approach conflicts with Congress's design. *See Mallinckrodt ARD LLC v. Verma*, 444 F. Supp. 3d 150, 173 (D.D.C. 2020) (recognizing the risk of product-hopping "by simply manipulating how a submitted drug application was administratively categorized").

In any event, any debate about aggregation across products for the purposes of negotiations is fully resolved by the Act'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 command from other Act provisions that reference the FDA approval process. For example, Teva urges (Br. 23) 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. In Teva's view, each new product approval triggers a new clock, even when the product is just a different package type or formulation of the same drug. But Teva's argument

is irreconcilable with the Act'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 170, ensuring that the introduction of 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 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* Br. 21-22. Teva observes that the Act'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.* (first citing 42 U.S.C. § 1395w-102(e); and then citing *id.* § 1396r-8(k)(2), (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)(A)(i). These provisions do not mean that FDA approval creates a distinct, *new* "covered outpatient drug." Teva's

reading of these attenuated cross-references cannot be reconciled with the Act's express statutory language directing CMS to consider all dosage forms, strengths, and formulations of a drug together. *See* Memorandum Opinion, JA190-91.

Teva also reads great import into the Act's language excluding brand-name drugs with generic versions from being a "qualifying single source drug." Specifically, the Act excludes drugs that are "the listed drug for any [generic] drug that is approved and marketed." 42 U.S.C. § 1320f-1(e)(1)(A)(iii). Teva argues that the reference to "*the* listed drug" necessarily means that the Act contemplates a product-specific view of "qualifying single source drug." Br. 23 (emphasis added) (quotation marks 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 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 171 (emphasis added).

Contrary to Teva's assertion, this interpretation does not lead to absurd results in applying the generic carveout. Br. 28. Indeed, the implications of Teva's proposed approach are striking, as Teva insists that CMS must treat each drug product as separate drugs, no matter how minor the differences between them. *See* Memorandum Opinion, JA191-92. For example, Teva intends to market enzalutamide capsules, which is a generic version of the capsule form of Xtandi. Groff Declaration, JA 155-56. 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. 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, including changes to the formulations, to 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.

None of Teva's remaining arguments overcome the Act's explicit text. That the Act refers to a "qualifying single source *drug*," in the singular, *see* Br. 21-22, is entirely consistent with the Act's instruction that each individual "drug" is an aggregation of all dosage forms, strengths, and formulations. *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 negotiated price). Teva's attempt to replace "drug" with "drug product" is contrary to that statutory mandate. *Cf.* Br. 25-26.

Teva protests that Congress did not mention the term "active moiety" in the Act. Br. 25-26. But by that logic, neither does the Act mandate that CMS follow FDA's product-specific approach in implementing the Food, Drug, and Cosmetic Act. *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); Act of Apr. 23, 2021, Pub. L. No. 117-9, 135 Stat. 256 (codifying

FDA's definition). 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.

Teva also objects (Br. 27-28) that CMS's guidance only includes NDAs held by the same entity. Teva asserts that CMS grafted this "same holder" requirement onto the statute and "[l]ogically" drugs with the same active ingredient made by different manufacturers should be grouped together. *Id.* But the Act presumes that CMS will negotiate with a single manufacturer, thus establishing that different dosage forms and strengths of a drug with the same active moiety are the same qualifying single source drug only when the NDA is held by the same manufacturer. *See, e.g.*, 42 U.S.C. §§ 1320f(c)(1), 1320f-2(a)(1), (4)(A).

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 surplusage the Act's 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 negotiated price "across different strengths and dosage forms

of a selected drug" under 42 U.S.C. § 1320f-5(a)(2). Br. 33 (quotation marks omitted). But these provisions are not redundant; 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 negotiated price). It is the combined direction from each provision from which the aggregation requirement flows. And Teva fails to explain how its approach can be reconciled with these clear directives.

B. CMS is not required to allow manufacturers to evade their Negotiation Program obligations through bad-faith marketing of generic alternatives.

1. The Act provides that a drug will not be considered a "qualifying single source drug" when "at least one" generic competitor "is approved or licensed" by FDA and "is marketed pursuant to such approval or licensure." 42 U.S.C. § 1320f-1(c)(1). Implementing that statutory directive, CMS explained that "a generic drug or biosimilar to be marketed when the totality of the circumstances … reveals that the manufacturer of that drug or product is engaging in *bona fide* marketing of that drug or product." 2027 Guidance 170 (emphasis added); *see also* 2027 Guidance 292. CMS's common-sense interpretation ensures only that a generic drug or biosimilar is subject

to some amount of "meaningful competition" before a selected drug is removed from the Negotiation Program. 2027 Guidance 20.

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 … manufacturer agrees to limit production or distribution of the generic drug … such that only a nominal quantity of product is allowed to enter the market." 2027 Guidance 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 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 [negotiated price] should no longer apply."); Gabriele & Feldman, *supra*. 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. 2027 Guidance 170; *see also* 2027 Guidance 292.

CMS's guidance properly applies Congress's statutory scheme. When a generic drug is actually marketed, a manufacturer can escape the strictures of the Negotiation Program while continuing to reap the benefits of participation in Medicare and Medicaid. But a manufacturer cannot free itself from its obligations by engaging in subterfuge.

2. Teva brings a facial challenge to the good-faith obligation. Br. 37. Thus, to prevail Teva must show that the regulation "itself is inconsistent with the statute on its face," not merely potentially "invalid as applied." *Bondi v. VanDerStok*, 604 U.S. 458, 467 (2025) (quotation marks omitted); *see also INS v. National Ctr. for Immigrants' Rts., Inc.*, 502 U.S. 183, 188 (1991). Put another way, to succeed Teva must show that the statute requires CMS to accept bad-faith marketing. Teva has not met that weighty burden.

Teva's position is that a drug is marketed when the manufacturer makes a single sale. *See* Br. 45 ("If even one unit of a generic has been sold, it has been marketed."). That position leaves a brand-name manufacturer free to enter an agreement with a generic manufacturer "to limit production or

distribution of the generic drug … such that only a nominal quantity of product is allowed to enter the market." 2027 Guidance 20. Teva's argument against a *bona fide* marketing requirement is remarkable. *Bona fide*—literally, in good faith—"is the precise opposite of bad faith." *Bunge Corp. v. Recker*, 519 F.2d 449, 452 (8th Cir. 1975) (quotation marks omitted). The two concepts are "two sides of the same coin." *Wallace v. NCL (Bahamas) Ltd.*, 733 F.3d 1093, 1104 n.11 (11th Cir. 2013) (quotation marks omitted). In asserting that Congress did not require "good faith" marketing efforts, Teva necessarily embraces the idea that bad-faith marketing suffices. And reduced to those terms, its argument becomes 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) (quotation marks omitted), Congress cannot be presumed to countenance bad-faith evasion of statutory requirements unless it expressly includes the phrase "good faith."

Teva's argument turns on its wooden reading of the word "marketed" to mean "'expose for sale in a market' or 'bring or send to a market.'" Br. 44 (citation omitted) (first quoting *Marketed*, Merriam-Webster's Collegiate Dictionary (11th ed. 2020); and then quoting *Marketed*, Oxford English Dictionary (3d ed. 2023)). But even the dictionaries Teva cites do not support

such a narrow definition. *Compare id., with Market*, Merriam-Webster's Collegiate Dictionary 760 (11th ed. 2020) ("to expose for sale in a market"; "[to] sell"; "to deal in a market"), *and Market*, Oxford English Dictionary (3d ed. 2023) ("[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").[7] As the broader context makes clear, to "market" a product means not just to bring a product to market for the first time but to actually sell the product. And the structure of the sentence ("is marketed") confirms that the marketing must be ongoing. This understanding accords with common usage. No one would say that a *pièce unique* "is marketed" because its watchmaker sold it to a buyer. The one-of-a-kind watch was once sold; it is not marketed.

Teva's understanding of the statute gives the marketing requirement practically no work to do. Congress set out a pair of criteria for drugs to fall into the generic carve-out, each embodied in a separate subparagraph of § 1320f-1(c)(1). In subparagraph (A), Congress required that the drug be approved by FDA. If all Congress cared about was the theoretical possibility

[7] *Accord Market*, The American Heritage Dictionary of the English Language 1075 (5th ed. 2011) ("[t]o offer for sale"; "[t]o deal in a market; engage in buying or selling").

of generic competition, it would have stopped there. But instead, Congress added subparagraph (B), which contains the requirement that the drug "is marketed pursuant to such approval." Plaintiffs offer no explanation for why Congress would have gone out of its way to detail this separate requirement if it did not care whether the generic drugs were actually sold. Courts, however, disfavor readings like Teva's that would render a statutory provision ineffective. *See Finnbin, LLC v. Consumer Prod. Safety Comm'n*, 45 F.4th 127, 134 (D.C. Cir. 2022); *Sault Ste. Marie Tribe of Chippewa Indians v. Haaland*, 25 F.4th 12, 23 (D.C. Cir. 2022).

Teva also raises (Br. 47-48) practical concerns about how CMS will implement the bona fide marketing requirement. These concerns, however, have no place in a facial challenge. They are also ill-conceived. If Teva actually intends to sell generic competitors to drugs subject to negotiation, the negotiated price will no longer apply. Unless Teva intends to collude with a name-brand manufacturer to market generic drugs in bad faith, there is no reason to believe that the good-faith requirement will ever come into play. As it asserts that it "intends to market [its] generics to the maximum extent possible[ ] as permitted by law," Dkt. 35, at 47, Teva has nothing to fear from CMS's interpretation.

III. Teva's due process claim fails because the Negotiation Program does not deprive it of a protected property interest.

As every court to consider the issue has concluded, the Negotiation Program does not deprive pharmaceutical manufacturers of any protected property interest. *See, e.g.*, *AstraZeneca Pharms. LP v. HHS*, 137 F.4th 116, 125-26 (3d Cir. 2025) ("There is no protected property interest in selling goods to Medicare beneficiaries (through sponsors or pharmacy benefit plans) at a price higher than what the government is willing to pay when it reimburses those costs."); *Boehringer Ingelheim Pharms., Inc. v. HHS*, 150 F.4th 76, 94 (2d Cir. 2025) ("A company suffers no deprivation of its property interests by voluntarily submitting to a price-regulated government program."). Teva offers no good reason to diverge from this consensus view.

1. The Due Process Clause protects against the deprivation "of life, liberty, or property, without due process of law." U.S. Const. amend. V. Therefore, the threshold "inquiry in every due process challenge is whether the plaintiff has been deprived of a protected interest" in liberty or property. *American Mfrs. Mut. Ins. Co. v. Sullivan*, 526 U.S. 40, 59 (1999). Property interests arise from an independent source, such as state or federal law. *See Board of Regents v. Roth*, 408 U.S. 564, 577 (1972). To have a constitutionally protected property interest, "a person clearly must have more than an

abstract need or desire for it" and "more than a unilateral expectation of it." *Id.* Rather, he must have an "individual entitlement" to the property, which "cannot be removed except 'for cause.'" *Logan v. Zimmerman Brush Co.*, 455 U.S. 422, 430 (1982) (quoting *Memphis Light, Gas & Water Div. v. Craft*, 436 U.S. 1, 11 (1978)).

"[N]o one has a 'right' to sell to the government that which the government does not wish to buy." *Coyne-Delany Co. v. Capital Dev. Bd.*, 616 F.2d 341, 342 (7th Cir. 1980) (per curiam). "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." *Perkins v. Lukens Steel Co.*, 310 U.S. 113, 127 (1940).

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 drugs in other government programs. *E.g.*, 38 U.S.C. § 8126(a)-(h). Similarly, as a condition of Medicaid participation, drug manufacturers have long entered into agreements to provide drugs to certain healthcare facilities subject to statutory price ceilings. *See Astra USA, Inc. v. Santa Clara County*, 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 products to the Department of Defense at prices above what the government is willing to pay, "[t]here is no protected property interest in selling goods to Medicare beneficiaries (through sponsors or pharmacy benefit plans) at a price higher than what the government is willing to pay when it reimburses those costs." *AstraZeneca*, 137 F.4th at 125-26.

In negotiating the price that Medicare will pay for drugs, the government is acting as a market participant. The Act sets the terms of the government's offer to pay for certain drugs. While manufacturers may use their market power to negotiate with the government, they have no right to force the government to pay for their drugs on specific terms. Plaintiffs' contrary view does not reflect how the market works, nor is it consistent with Congress's undoubted authority to control federal spending. The Negotiation Program reflects Congress's judgment that American taxpayers have been spending 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 ….").

2. Teva makes three arguments in support of its effort to find a protected property interest; all three lack merit.

First, the Negotiation Program does not interfere with any of Teva's existing contracts to sell generic drugs. *Contra* Br. 50. That the government has negotiated lower prices for some drugs does not deprive Teva of a property right because it might become less profitable to sell other drugs. Teva identifies no case in support of its contrary view.

Second, there is no right on the part of a manufacturer to dictate the price at which it sells products. *Contra* Br. 50-51. *Old Dearborn Distrib. Co. v. Seagram-Distillers Corp.*, 299 U.S. 183 (1936), is not to the contrary. 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. *Id.* at 192. But the Supreme Court has since made clear that the Constitution does not substantively constrain a legislature's ability to fix the price of goods. *Olsen v. Nebraska ex rel. W. Reference & Bond Ass'n*,

313 U.S. 236, 246-47 (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 *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.

Critically, the Negotiation Program does not control any private market transactions. *Contra* Br. 51. Unlike the provisions challenged in *Bowles v. Willingham*, 321 U.S. 503, 519-21 (1944), in which Congress sought to regulate the price at which any person could lease his property to *any* buyer, the Negotiation Program does not regulate the price at which manufacturers may sell their drugs except in circumstances where a buyer uses Medicare Part B or D to pay for the drugs. *See AstraZeneca*, 137 F.4th at 126 ("These are not private market transactions, regardless of the private hands through which CMS's funds pass."). And plaintiffs offer no sound reason to extend the analysis that applies to market-wide price restrictions

to a law that governs only the procedures used to determine the price the government itself is willing to pay.[8]

Third, the Negotiation Program does not implicate Teva's patent rights. *Contra* Br. 51-52. "[F]ederal patent laws do not create any affirmative right to … sell anything," *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1372 (Fed. Cir. 2007) (quotation marks omitted), much less a right to command a particular price, *AstraZeneca*, 137 F.4th at 125. 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 including the federal government. Teva fails to allege any deprivation of patent rights, so those rights may not form the basis of a due process claim.

3. Even if manufacturers could establish the existence of a protected interest, the Negotiation Program does not deprive them of anything. No manufacturer is compelled to participate in the Negotiation Program. As

[8] Teva similarly errs in asserting (Br. 51) that it has been subjected to an unfair retroactive condition on government spending. The Negotiation Program operates only prospectively, and Teva is free to opt-out of further participation if it so chooses.

courts have repeatedly stressed, participation in Medicare is a voluntary choice. *See, e.g.*, *Burditt v. HHS*, 934 F.2d 1362, 1376 (5th Cir. 1991); *Baptist Hosp. E. v. HHS*, 802 F.2d 860, 870 (6th Cir. 1986). Participation does not become involuntary just because participation is particularly lucrative. *See, e.g.*, *Garelick v. Sullivan*, 987 F.2d 913, 917 (2d Cir. 1993). A manufacturer with a drug selected for the Negotiation Program has a choice: it may remain in Medicare because it concludes that the benefits still outweigh the burdens, or it may withdraw in as little as 30 days, *see* 42 U.S.C. §§ 1395w-114a(b)(4)(B)(i), 1395w-114c(b)(4)(B)(i); 2026 Guidance 33-34; *Bristol Myers Squibb Co. v. HHS*, 155 F.4th 245, 256-57 (3d Cir. 2025).

Plaintiffs' insistence that manufacturers' participation in Medicare is involuntary is relevant to the due process analysis only to the extent they argue that government coercion is the mechanism by which manufacturers are deprived of their purported interests. Because "no one has a 'right' to sell to the government that which the government does not wish to buy," *Coyne-Delany Co.*, 616 F.2d at 342, there is no protected property right implicated in a manufacturer's expectancy of further participation in a government spending program. *See also Perkins*, 310 U.S. at 127. Thus, a manufacturer that chooses voluntarily to participate in a government program cannot

complain that the sheer act of participation deprives it of a property right. *See Boehringer Ingelheim*, 150 F.4th at 94.

CONCLUSION

For the foregoing reasons, the judgment of the district court should be affirmed.

Respectfully submitted,

ERIC J. HAMILTON
Deputy Assistant Attorney General [*]

MICHAEL S. RAAB

/s/ Maxwell A. Baldi
MAXWELL A. BALDI
Attorneys, Appellate Staff
Civil Division, Room 7513
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530
(202) 532-0211
maxwell.baldi@usdoj.gov

Of Counsel:

MICHAEL B. STUART
General Counsel

ELIZABETH C. KELLEY
Deputy General Counsel
Chief Legal Officer for CMS

JOCELYN S. BEER
Acting Deputy Associate General Counsel for Litigation

KENNETH R. WHITLEY
Attorneys

U.S. Department of Health and Human Services

MARCH 2026

[*] The Assistant Attorney General is recused in this matter.

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 11,789 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Word for Microsoft 365 in Century Expanded BT 14-point font, a proportionally spaced typeface.

/s/ Maxwell A. Baldi
Maxwell A. Baldi