**ORAL ARGUMENT NOT YET SCHEDULED**

No. 25-5425

IN THE

# United States Court of Appeals for the District of Columbia Circuit

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

v.

ROBERT F. KENNEDY, JR., 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,
*Defendants-Appellees*.

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On Appeal from the United States District Court
for the District of Columbia, No. 1:25-cv-00113-SLS (Sooknanan, J.)

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## OPENING BRIEF FOR PLAINTIFFS-APPELLANTS

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January 9, 2026

## CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

### A. PARTIES AND AMICI

1. The following were parties in the District Court:

a. Plaintiffs-Appellants: Teva Pharmaceuticals USA, Inc.; Teva Branded Pharmaceutical Products R&D LLC; and Teva Neuroscience, Inc. (together, "Teva").

b. Defendants-Appellees: 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.[1]

c. Amici for 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.

Amici for Defendants: Richard G. Frank; Fiona M. Scott Morton; Aaron S. Kesselheim; Gerard F. Anderson; Rena M. Conti; David M. Cutler; Jack Hoadley; Public Citizen; Doctors for America; Protect Our Care; and Families USA.

[1] The current defendants have been automatically substituted for their predecessors in office, Dorothy Fink and Stephanie Carlton. *See* Fed. R. Civ. P. 25(d).

2. a. Teva Pharmaceuticals USA, Inc. is an indirect wholly owned subsidiary of Teva Pharmaceutical Industries Ltd., a publicly traded company. Teva Pharmaceutical Industries Ltd. is the only publicly traded company that owns 10% or more of Teva Pharmaceuticals USA, Inc.

b. Teva Branded Pharmaceutical Products R&D LLC is an indirect wholly owned subsidiary of Teva Pharmaceutical Industries Ltd., a publicly traded company. Teva Pharmaceutical Industries Ltd. is the only publicly traded company that owns 10% or more of Teva Branded Pharmaceutical Products R&D LLC.

c. Teva Neuroscience, Inc. is an indirect wholly owned subsidiary of Teva Pharmaceutical Industries Ltd., a publicly traded company. Teva Pharmaceutical Industries Ltd. is the only publicly traded company that owns 10% or more of Teva Neuroscience, Inc.

## B. RULINGS UNDER REVIEW

Teva appeals the District Court's November 20, 2025 memorandum opinion and order (JA168-204) denying Teva's motion for summary judgment and granting Defendants' cross-motion for summary judgment. *Teva Pharms. USA, Inc. v. Kennedy*, No. 1:25-cv-00113, 2025 WL 3240267 (D.D.C. Nov. 20, 2025) (Sooknanan, J.).

## C. RELATED CASES

The following cases are related to this action within the meaning of Circuit Rule 28(a)(1)(C):

1. *Merck & Co., Inc. v. Becerra*, No. 1:23-cv-01615 (D.D.C.) (challenge to same statute but no overlapping claims);

2. *AstraZeneca Pharms. LP v. Becerra*, No. 1:23-cv-00931, 719 F. Supp. 3d 377 (D. Del. 2024), *aff'd sub nom., AstraZeneca Pharms. LP v. Secretary of HHS*, No. 24-1819, 137 F.4th 116 (2025), *cert. petition docketed*, No. 25-348 (U.S. Sept. 24, 2025) (overlapping Due Process Clause claim);

3. *Novo Nordisk Inc. v. Becerra*, No. 3:23-cv-20814 (D.N.J. July 31, 2024), *aff'd sub nom., Novo Nordisk Inc. v. Secretary of HHS*, No. 24-2510, 154 F.4th 105 (3d Cir. 2025), *cert. petition docketed*, No. 25-761 (U.S. Dec. 29, 2025) (overlapping Due Process Clause claim);

4. *Bristol Meyers Squibb Co. v. Becerra*, No. 3:23-cv-03335 (D.N.J. Apr. 29, 2024), *aff'd sub nom., Bristol Meyers Squibb Co. v. Secretary of HHS*, No. 24-1820, 155 F.4th 245 (3d Cir. 2025), *cert. petition docketed*, No. 25-751 (U.S. Dec. 23, 2025) (challenge to same statute but no overlapping claims);

5. *Janssen Pharms., Inc. v. Becerra*, No. 3:23-cv-03818 (D.N.J. Apr. 29, 2024), *aff'd sub nom., Bristol Meyers Squibb Co. v. Secretary of HHS*, No. 24-

1821, 155 F.4th 245 (3d Cir. 2025), *cert. petition docketed*, No. 25-749 (U.S. Dec. 23, 2025) (challenge to same statute but no overlapping claims);

6. *National Infusion Ctr. Ass'n v. Becerra*, No. 1:23-cv-00707, 716 F. Supp. 3d 478 (W.D. Tex. 2024), *rev'd*, No. 24-50180, 116 F.4th 488 (5th Cir. 2024), *on remand sub nom.*, *National Infusion Ctr. Ass'n v. Kennedy*, No. 1:23-cv-00707, 798 F. Supp. 3d 748 (W.D. Tex. 2025), *on appeal*, No. 25-50661 (5th Cir.) (overlapping Due Process Clause claim);

7. *Boehringer Ingelheim Pharms., Inc. v. HHS*, No. 3:23-cv-01103 (D. Conn. July 3, 2024), *aff'd*, No. 24-2092, 150 F.4th 76 (2d Cir. 2025), *cert. petition docketed*, No. 25-799 (U.S. Jan. 7, 2026) (overlapping Due Process Clause claim);

8. *Novartis Pharms. Corp. v. Becerra*, No. 3:23-cv-14221 (D.N.J. Oct. 18, 2024), *aff'd sub nom.*, *Novartis Pharms. Corp. v. Secretary of HHS*, No. 24-2968, 155 F.4th 223 (3d Cir. 2025), *cert. petition due* January 23, 2026, No. 25A587 (U.S.) (challenge to same statute but no overlapping claims).

/s/ Sean Marotta
Sean Marotta

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**OTHER AUTHORITIES:**

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## GLOSSARY

| | |
|---|---|
| AMP: | Average Manufacturer Price |
| ANDA: | Abbreviated New Drug Application |
| APA: | Administrative Procedure Act |
| BLA: | Biologic License Application |
| CMS: | Centers for Medicare & Medicaid Services |
| FDA: | Food and Drug Administration |
| IPAY: | Initial Price Applicability Year |
| IRA: | Inflation Reduction Act |
| NDA: | New Drug Application |
| PDE: | Prescription Drug Event |
| Program: | Inflation Reduction Act's Medicare Drug Price Negotiation Program |

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*Defendants-Appellees*,

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## OPENING BRIEF FOR PLAINTIFFS-APPELLANTS

## JURISDICTIONAL STATEMENT

The District Court had subject-matter jurisdiction under 28 U.S.C. § 1331 and entered judgment on November 20, 2025. JA204. Teva appealed that day. JA205. This Court has jurisdiction under 28 U.S.C. § 1291.

## INTRODUCTION

For decades, the federal government has participated in and encouraged a free market for prescription drugs. That approach gives patients access to cutting-edge medications while allowing drug manufacturers—who pour hundreds of

millions annually into research and development—to earn competitive returns. The Inflation Reduction Act of 2022 (IRA) replaced that free marketplace with government-dictated prices through the Medicare Drug Price Negotiation Program, granting the Centers for Medicare & Medicaid Services (CMS) the power to fix prices on certain highest-spend drugs. This suit challenges CMS's unlawful guidance implementing the Program and the Program as a whole.

The IRA instructs CMS to impose price controls—called "maximum fair prices"—on select prescription drugs sold through Medicare using sham negotiations with manufacturers. The Program is not voluntary: Declining CMS's "offer" subjects manufacturers to exorbitant penalties, which they can avoid only by withdrawing *all* of their drugs—not just the selected drug—from Medicare and Medicaid. The IRA also authorizes CMS to make key decisions without public input and largely without administrative or judicial review.

Worse, CMS has rewritten the already harsh statute through guidance. By its plain terms, the IRA limits the Program to drugs that have been approved for at least seven years. CMS, however, blue-penciled that limitation so that it can control the price for a new drug the instant it hits the market so long as the new drug shares an "active moiety"—a term found nowhere in the statute—with an existing Program drug. The IRA also requires CMS's price cap to sunset once a generic competitor enters the market. But CMS replaced that straightforward yes-

no determination with a subjective, atextual "bona fide marketing" standard. And the Program as a whole violates due process by impairing manufacturers' protected property interests without adequate procedures.

The Program's price controls do not just harm the innovator medicines to which they directly apply. They also harm generic products that would otherwise compete with those innovator products. Generics are therapeutically equivalent to innovator reference drugs, so generics obtain market share primarily through price competition. But if an innovator medicine is price capped, the generic's manufacturer has little or no room to undercut it without being forced to sell at a significant loss. The result: less innovation, less competition, and a weaker supply chain because of the risk that generics manufacturers will not introduce medicines they cannot earn a profit on.

Teva understands these harms better than anyone. Teva is a leading global pharmaceutical company that makes over 3,600 medicines and serves hundreds of millions of patients through both its novel innovator therapies and high-quality, lower-cost generics. CMS selected two of Teva's innovator drugs, AUSTEDO® and AUSTEDO XR®, for price controls starting in 2027. AUSTEDO XR has been approved for only *three years*—four years shy of the statutorily mandated seven—but CMS nonetheless applied its invented active-moiety definition and selected the drug anyway. CMS has also selected non-Teva innovator drugs for the Program,

forcing Teva to choose between selling its generic versions of these products at a loss or not at all.

Teva's suit is "of great importance to consumers of pharmaceutical drugs, the companies that provide them, and the public at large." *Bristol Meyers Squibb Co. v. Secretary of HHS*, 155 F.4th 245, 289 (3d Cir. 2025) (Hardiman, J., dissenting). But the District Court fundamentally misunderstood the Program, Teva's medicines, and the applicable law. This Court should reverse to restore the IRA Congress wrote and afford Teva its constitutional due process rights.

## ISSUES PRESENTED FOR REVIEW

1. Whether CMS's definition of "qualifying single source drug" unlawfully rewrites the IRA's definition of that term.

2. Whether Teva's challenge to CMS's "bona fide marketing" standard is ripe.

3. Whether CMS's "bona fide marketing" standard unlawfully rewrites the IRA's definition of "marketed."

4. Whether the Program violates Teva's due process rights.

## PERTINENT STATUTES AND REGULATIONS

Pertinent statutes and regulations are reprinted in the Addendum.

## STATEMENT OF THE CASE

### A. Medicare And The Drug Approval Process

The federal government pays "for almost half the annual nationwide spending on prescription drugs." *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 699 (3d Cir. 2023). Much of that spending is through Medicare, which has 69 million members—20% of the U.S. population. CMS, *Medicare Enrollment Dashboard*, https://tinyurl.com/4arr9tpr (last visited Jan. 9, 2026).

The process of taking a drug from idea to an approved New Drug Application (NDA) can take 15 years and costs, on average, more than $2.5 billion. PhRMA, *Research & Development Policy Framework*, https://perma.cc/7YKB-CUQN. The odds of a drug receiving Food and Drug Administration (FDA) approval are exceedingly low; 99.9% of drugs that enter pre-clinical testing fail. *See* Sandra Kraljevic, *Accelerating Drug Discovery*, 5 Eur. Molecular Biology Org. Reps. 837, 837 (2004), https://perma.cc/9GNF-NX6R. To incentivize investment to discover new medicines, Congress established patent and regulatory exclusivity periods protecting innovator drugs from generic competition for defined periods of time. 21 U.S.C. § 355(c)(3)(E).

This market- and innovation-focused approach benefits patients by enabling manufacturers to invent and commercialize new medicines and cover the

substantial costs of pursuing products that never make it to FDA approval at the company's own economic risk. Countries with drug-price controls have less research and investment and face delays in patients' access to advanced treatments. Joe Kennedy, *The Link Between Drug Prices and Research on the Next Generation of Cures*, Info. Tech. & Innovation Found. (Sept. 2019), https://perma.cc/XS9G-FZ4T; PhRMA, *Global Access to New Medicines Report*, at 8, 11-36 (Apr. 2023), https://perma.cc/5CLX-AZHJ.

Federal law also provides a path for generic drug manufacturers to lower prices through competition by filing Abbreviated New Drug Applications (ANDAs). 21 U.S.C. § 355(j)(2)(A)(ii), (iv). Each ANDA is approved as the generic for only one reference drug, identified by its NDA. *Id.* § 355(j).

Over the past decade, generics have saved patients and the healthcare system over $3 trillion. Ass'n for Accessible Meds., *The U.S. Generic & Biosimilar Medicines Savings Report*, at 10 (Sept. 2025), https://perma.cc/HUV4-93EK. Generics also increase the available sources for a particular medicine, which "can help stabilize the supply." FDA, *Generic Drugs Can Help Promote Health Equity*, www.fda.gov/media/173765/download.

The "generic industry's financial viability" depends on whether generics manufacturers can "expect to generate sufficient volume and revenue to justify entering the market." Dana Goldman et al., *Mitigating the IRA's Adverse Impacts*

*on the Prescription Drug Market*, at 5 (Apr. 2023), https://perma.cc/FT4K-2JGW. Generics are therapeutically equivalent to their innovator counterparts, so they gain market share primarily through price competition. Richard Frank et al., *The Evolution of Supply and Demand in Markets for Generic Drugs*, 99 Milbank Quarterly 828, 829-833 (2021), https://perma.cc/CN63-AQH4. Manufacturers considering whether to launch a generic must therefore balance gaining market share through price cutting against generating sufficient revenue to cover their investments.

Manufacturers intending to market a generic must certify that the generic will not infringe any valid innovator patents. 21 U.S.C. § 355(j)(2)(A)(vii)-(viii). That certification often triggers patent litigation that "can run over $10 million." JA151; *see* 35 U.S.C. § 271(e)(2)(A). Innovators and generics manufacturers therefore often reach settlements or licensing agreements allowing the generic to launch at specific times. *E.g.*, JA155-160.

### B. The Medicare Drug Price Negotiation Program

The IRA's Drug Price Negotiation Program fundamentally transforms prescription drug pricing by authorizing CMS to bring the government's full coercive force to bear in "negotiating" maximum prices under Medicare for a set number of drugs each year.

CMS starts by identifying and ranking "negotiation-eligible" drugs based on their total Medicare expenditures. It then selects a specified number for negotiation for each "initial price applicability year" (IPAY)—the year that the "negotiated" prices take effect: 10 drugs for IPAY 2026; 15 for IPAY 2027 and IPAY 2028; and 20 for IPAY 2029 and beyond. 42 U.S.C. § 1320f-1(a)-(b), (d)(1), (e). To be eligible for selection and negotiation, a drug must be a "qualifying single source drug," which the statute defines as a "covered [Medicare] part D drug" or a "drug" payable under Medicare Part B that has been (i) FDA-approved; (ii) for at least seven years, and (iii) has no existing generic "that is approved and marketed." *Id.* § 1320f-1(e)(1).[2]

A manufacturer whose innovator product is selected must "negotiate" with CMS to set what the agency deems "a maximum fair price" for that product. *Id.* §§ 1320f-2(a), 1320f-3(a). Nothing about an IRA negotiation mirrors a typical commercial bargaining session, however. For one, negotiation is mandatory: Manufacturers must agree to negotiate or face a crippling, punitive tax beginning at 185% of the drug's price and escalating to 1,900%. *See id.* §§ 1320f-2, 1320f-6(a); 26 U.S.C. § 5000D; Cong. Rsch. Serv., No. R47202, *Tax Provisions in the IRA of*

[2] The Program also covers biologics, which are complex medicines typically manufactured using biotechnology and approved pursuant to a Biologics License Application (BLA), the biologic equivalent of an NDA. 42 U.S.C. § 262(a). As relevant here, the Program treats drugs and biologics materially the same.

*2022 (H.R. 5376)*, at 4 tbl. 2 (Aug. 10, 2022), https://perma.cc/5TWK-RULD. For another, CMS is directed to set "the *lowest* maximum fair price for each selected drug." 42 U.S.C. § 1320f-3(b)(1) (emphasis added). The IRA caps this "maximum fair price" at a fraction of certain reference prices, but there is no lower bound, leaving CMS free to offer prices as low as a penny. *Id.* § 1320f-3(c)(1)(A).

A manufacturer that declines to offer its selected drug at CMS's "maximum fair price" is subject to civil monetary penalties of ten times the difference between the price charged and the CMS-mandated price. *Id.* § 1320f-6(a). The only way the manufacturer can avoid CMS's price-control regime is to withdraw *all* of its drugs from Medicare *and* Medicaid, denying access to millions of patients. 26 U.S.C. § 5000D(c); 42 U.S.C. § 1396r-8(a)(1). No manufacturer could or would make that choice.

Once in effect, the price caps continue indefinitely until a generic competitor is "approved" and "marketed pursuant to such approval." 42 U.S.C. § 1320f-1(c)(1). If a generic qualifies before the end of the CMS negotiation period, the innovator is never subject to a price cap. But if the generic is marketed even one day later, the price cap remains in effect for at least one full calendar year. *See id.* After that, the relevant cutoff is March 31 each year: If the generic is approved and marketed by March 31, the price cap sunsets at the end of that calendar year. But if the generic is marketed *after* March 31, the earliest the price cap can sunset

is the end of the *next* calendar year. Missing the cutoff thus means the innovator drug is subject to the price cap for significantly longer. So, for IPAY 2027:

| **Selected IPAY 2027 Drugs** | |
|---|---|
| **Date by which generic is marketed** | **Effect on price cap** |
| November 1, 2025 | No price cap goes into effect |
| November 2, 2025 through March 31, 2027 | Price cap effective January 1, 2027 through December 31, 2027 |
| April 1, 2027 through March 31, 2028 | Price cap effective January 1, 2027 through December 31, 2028 |
| April 1, 2028 through March 31, 2029 | Price cap effective January 1, 2027 through December 31, 2029 |
| April 1, 2029 through March 31, 2030 | Price cap effective January 1, 2027 through December 31, 2030 |
| . . . and so on | |

*See* 42 U.S.C. § 1320f-1(c)(1); CMS, *Medicare Drug Price Negotiation Program: Final Guidance for IPAY 2027*, at 279-280 (Oct. 2, 2024), https://perma.cc/AJ33-F9U4 (2027 Guidance).

The IRA deprives manufacturers of key procedural protections. Congress directed CMS to implement the Program using guidance without notice and comment through IPAY 2029. 42 U.S.C. § 1320f note. And CMS—the agency with the clearest interest in obtaining the lowest price possible, no matter how fair—is charged with setting the prices. *See id.* § 1320f-3. The IRA also precludes "administrative or judicial review" of key aspects of CMS's black-box process: the "selection of drugs," the "determination of negotiation-eligible drugs," the

"determination of a maximum fair price," and the "determination of renegotiation-eligible drugs." *Id.* § 1320f-7.

### C. CMS's Guidance Purporting To Implement The Program

Two aspects of CMS's Guidance are relevant here.

*First*, CMS radically expanded the universe of negotiation-eligible drugs through its construction of the term "qualifying single source drug." CMS's Guidance lumps together multiple different drugs—marketed under separate FDA-approved NDAs—into a *single* qualifying single source drug by defining the term as any set of drugs "with the same active moiety"[3] if the NDAs are held by the "same entity." 2027 Guidance 167. The words "active moiety" and "same entity" do not appear in the IRA.

*Second*, CMS limited the statutory generic-competition pathway for deselection. Under the IRA, a drug cannot be price controlled if a generic has been "approved and marketed"—that is, available for commercial purchase. 42 U.S.C. § 1320f-1(c)(1), (e)(1)(A)(iii). CMS's Guidance replaces that yes-no determination with a subjective requirement that the generic must be subject to "bona fide marketing," such that "meaningful competition exists on an ongoing basis between a listed drug . . . and a generic drug." 2027 Guidance 20, 170. CMS

[3] A drug's active moiety is the "molecule or ion . . . responsible for the physiological or pharmacological action of the drug substance." 21 C.F.R. § 314.3(b).

does not define what it means for marketing to be "bona fide" or competition to be "meaningful"—words that also do not appear in the IRA.

CMS's new definition means some innovator drugs will remain subject to price controls for longer than the statute requires. CMS admits that two key data sources it will look to in making its determination—Medicare Part D Prescription Drug Event (PDE) data and Medicaid Average Manufacturer Price (AMP) data—are inherently time-lagged. *Id.* at 21. Generics that enter the market close to one of CMS's critical cutoffs will therefore have to compete with price-controlled innovator drugs longer than they would otherwise.

### D. Harms To Teva From The Program And CMS's Guidance

Teva is a global pharmaceutical company that supplies over 3,600 medicines to almost 200 million patients. Teva, *Producing Quality Products That Support Better Health*, https://www.tevapharm.com/solutions/our-quality/. Teva has invested billions in research-and-development activities across that product portfolio, JA151, and is unique in that it develops both innovator therapies *and* high-quality, lower-cost generics—one in fourteen U.S. prescriptions is a Teva generic. Steven Scheer, *Teva Pharm CEO Calls on Trump for Faster U.S. Drug Approvals*, Reuters (Feb. 17, 2025), https://perma.cc/8R8N-JZ4W. Teva currently has over 1,000 generic products in development. JA151.

Among Teva's innovator drugs are AUSTEDO and AUSTEDO XR, which are indicated to treat tardive dyskinesia, a disease associated with long-term use of antipsychotic medications, and Huntington's disease chorea, a rare, terminal genetic disease. JA144-145. Teva Branded Pharmaceutical Products R&D LLC holds the NDA for AUSTEDO, a twice-daily tablet that FDA approved in 2017. JA144-145. After substantial additional investments, Teva developed AUSTEDO XR, a one-tablet-per-day formulation that delivers the active ingredient at a controlled rate. JA145-146. Teva Neuroscience, Inc. holds a separate NDA, supported by additional clinical-study data, for AUSTEDO XR, which FDA approved in 2023. JA144-146. AUSTEDO XR lessens patients' pill burden, which improves adherence because patients often have severe movement disorders, and—in the case of tardive dyskinesia—underlying mental illness that can make remembering to take AUSTEDO twice a day challenging. JA145.

AUSTEDO and AUSTEDO XR share the same active moiety, deutetrabenazine. *Id.* CMS therefore classified AUSTEDO and AUSTEDO XR as a single qualifying single source drug and selected them *together* for IPAY 2027—even though AUSTEDO XR was approved less than seven years before its selection under a separate NDA held by a different corporate entity. JA144-146, 148; *see* CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for IPAY 2027* (Jan. 2025), https://perma.cc/2ZTC-PJTK. CMS's "maximum fair

price" for both drugs is a mandatory 38% discount from their prevailing wholesale prices, effective January 1, 2027. CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2027*, at 2 (Nov. 2025), https://perma.cc/HKB7-KQZD (IPAY 2027 Results).

Teva also has developed generic versions of five innovator drugs selected for IPAY 2027 that were forced to accept CMS-mandated discounts ranging from 48% to 75%: Xtandi®, Ofev®, Linzess®, Xifaxan®, and Otezla®. JA155-160; IPAY 2027 Results, *supra*. As a generics manufacturer, Teva had no opportunity to participate in the "negotiation" over those price caps. Yet Teva's generics will still have to adopt much-lower prices to compete, hamstringing Teva's ability to recover its development costs. JA160-161.

CMS's bona fide marketing requirement keeps Teva's generics from knocking innovator drugs out of the program. Based on its negotiated agreements with innovator manufacturers and patent-expiration dates, Teva plans to launch its generics within months of—and, in one case, the same day as—the crucial March 31 cutoff. JA156-160. But under CMS's standard, generics cannot qualify as bona fide marketed the day they are first sold. *See* 2027 Guidance 278. And because Teva will have to compete against artificially low-priced innovator drugs longer, Teva will invariably lose revenue it otherwise would have earned.

### E. Procedural History

1. Teva challenged the Guidance and Program on three grounds. JA74-137. *First*, Teva challenged CMS's re-definition of "qualifying single source drug" under the Administrative Procedure Act (APA). JA132-133. *Second*, Teva challenged CMS's re-definition of "marketing" under the APA. JA133-134. And, *third*, Teva challenged the Program as a whole under the Fifth Amendment's Due Process Clause. JA134-136. Teva and the Government cross-moved for summary judgment. The District Court granted the Government's motion and denied Teva's without holding argument. JA168-203.

*First*, the District Court held that Section 1320f-7(2)'s bar on reviewing CMS's selection of individual drugs, determination of a "maximum fair price" for those drugs, and certain other drug-specific determinations did not apply to Teva's APA claims. JA179-186. The District Court explained that Teva's claims challenged the Guidance on its face, not its application to a particular determination. JA179-180. Indeed, Teva filed suit *before* AUSTEDO and AUSTEDO XR were selected for the Program. JA177; *see also* JA44 (Teva's original complaint). In so holding, the court emphasized the "strong presumption favoring judicial review of administrative action." JA180 (citation omitted). And it relied on this Court's "well-established" rule that "a statutory provision barring review of an individual determination 'leaves [regulated parties] free to challenge

the general rules' or policies 'leading to' those determinations." JA180-181 (quoting *ParkView Med. Assocs., L.P. v. Shalala*, 158 F.3d 146, 148 (D.C. Cir. 1998)).

*Second*, the District Court dismissed Teva's argument that the IRA defines "a qualifying single source drug" as a single drug approved under a discrete NDA, including any amendments or supplements. The court instead agreed with the Government that multiple drugs could be a single "qualifying single source drug" so long as they share the same active moiety and same manufacturer. JA192.

*Third*, the District Court *sua sponte* held that Teva's challenge to CMS's bona fide marketing standard was not prudentially ripe. Despite Teva's declaration swearing that its generic version of Xtandi was FDA-approved, JA156, the court faulted Teva for not "suggest[ing] that" any of its generics "have been 'approved' by the FDA," JA194. The court believed that CMS's future decisions about whether a generic version of an IPAY 2027 innovator drug is bona fide marketed would be governed by the then-latest guidance, JA195-196, even though the 2028 Guidance confirms that the 2027 Guidance governs the deselection of IPAY 2027 drugs, *see* CMS, *Medicare Drug Price Negotiation Program: Final Guidance for IPAY 2028*, at 317 (Sept. 30, 2025), https://perma.cc/78BF-LL9C (2028 Guidance). And the court concluded that Teva would not be harmed by delaying judicial review, because the company could bring piecemeal challenges to individual bona

fide marketing determinations, JA196, even though the court acknowledged elsewhere that the statute bars review of CMS's particular "drug determinations," JA179.

*Finally*, the District Court rejected Teva's due process claim, holding that the Program does not impair Teva's protected property interests. The court believed the Program determines only the price at which the government buys drugs and held that the government—like any other purchaser—can decide the price at which it will purchase Teva's drugs. JA197-203. The District Court also emphasized that Teva's participation in the Program is supposedly voluntary. JA201-203. The District Court did not address Teva's role as a generics manufacturer or Teva's property interests in licensing agreements for its generics. JA197-202.

Teva's appeal followed. JA205.

## SUMMARY OF ARGUMENT

I. The IRA defines a qualifying single source drug as "a covered part D drug" that is approved under an NDA for "at least 7 years" and is not the listed drug for a generic. The IRA's text, structure, and incorporated reliance on FDA's existing practices confirm that this definition is NDA-specific, meaning that two drugs, approved by FDA under two NDAs, cannot be one qualifying single source drug. The evidence all points in the same direction: Congress's concerted use of

the singular "*a* qualifying single source *drug*"; the IRA's interlinking cross-references to FDA's NDA-specific approval regime; the seven-year approval requirement; and the fact that generic approvals are NDA-specific. Yet CMS redefined "qualifying single source drug" through Guidance to permit itself to aggregate *every* NDA involving the same "active moiety" held by the "same entity," two terms that Congress certainly knew how to include if it wanted. The District Court erred in embracing CMS's expansionist approach, which elevates misplaced policy concerns over the IRA's plain text, context, and structure.

II. The District Court *sua sponte* concluded that Teva's challenge to CMS's unlawful definition of "marketed" was prudentially unripe. That was flat wrong. Teva brings a facial challenge to CMS's reinterpretation and expansion of the statutory text through Guidance—a purely legal argument that is presumptively reviewable. Nor is further factual development necessary; the District Court thought otherwise by misreading the record and CMS's Guidance. And hardship is both irrelevant and easily satisfied: Delaying review will harm Teva's bottom line and deter its continued investment in new generics.

On the merits, CMS's bona fide marketing requirement is unlawful. The statute asks a commonsense question—is an FDA-approved generic of the selected drug marketed?—which has a commonsense answer that CMS has consistently applied in other programs: If one unit of the generic has been sold, it has been

marketed. But CMS's Guidance grafts an additional "bona fide" barrier onto the unadorned text, leaving manufacturers at the agency's whim. And because the data CMS has chosen to review are inherently time delayed, generics that launch close to the critical statutory cutoffs will be forced to compete with price-controlled innovator drugs for longer than under the plain text.

III. The Program as a whole violates Teva's due process rights by impairing Teva's protected property interests without affording Teva sufficient process. The Program's price-control regime interferes with Teva's property interests in three respects: *First*, it degrades the value of the patent licenses Teva has negotiated with innovator manufacturers that allow Teva to manufacture and sell generics. *Second*, it impairs Teva's common-law right to sell products at prices set without arbitrary government interference. And, *third*, it interferes with Teva's property interest in the patents it holds for innovator drugs. Yet the Program provides *no process* whatsoever to Teva as a generics manufacturer. And the limited process afforded Teva as an innovator manufacturer is so constitutionally deficient that the Government has never argued otherwise. The District Court evaded this straightforward conclusion only by ignoring Teva's unique role as a generics manufacturer, misconstruing the government's role in the Program, and deeming the Program's coercive structure "voluntary."

## STANDARD OF REVIEW

"In a case . . . in which the District Court reviewed an agency action under the APA," this Court "review[s] the administrative action directly, according no particular deference to the judgment of the District Court." *Safari Club Int'l v. Zinke*, 878 F.3d 316, 325 (D.C. Cir. 2017) (citation omitted). The Court also interprets the IRA *de novo*, using all the traditional tools of statutory interpretation. *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 403 (2024). And the Court reviews dismissal of Teva's due process claim *de novo*. *Tri Cnty. Indus., Inc. v. District of Columbia*, 104 F.3d 455, 458 (D.C. Cir. 1997).

## ARGUMENT

### I. CMS'S DEFINITION OF "QUALIFYING SINGLE SOURCE DRUG" IS UNLAWFUL.

#### A. "Qualifying Single Source Drug" Means One Drug Approved By FDA Under One NDA.

Under the IRA, a "qualifying single source drug" is "a covered part D drug" that (i) "is approved" under an NDA "and is marketed pursuant to such approval"; (ii) for which "at least 7 years . . . have elapsed since the date of such approval"; and (iii) "is not the listed drug" for a generic. 42 U.S.C. § 1320f-1(e)(1)(A). That means that two drugs, approved under two NDAs, cannot be one qualifying single source drug.

CMS's Guidance takes the opposite position: Under the Guidance, a "qualifying single source drug" includes "all dosage forms and strengths of the

drug with the same active moiety and the same holder of an NDA, inclusive of products that are marketed pursuant to different NDAs." 2027 Guidance 167. That is unlawful; CMS cannot change Congress's definition.

1. Several IRA features make clear that Congress adopted an NDA-specific definition of "a qualifying single source drug." Start with the most obvious: the repeated use of the singular in referring to "*a* qualifying single source *drug*," "*a drug*," and "*a* selected *drug*." *E.g.*, 42 U.S.C. § 1320f-1(e). Those terms appear more than 100 times throughout the IRA, including dozens of times in Section 1320f-1 alone.

Every aspect of Section 1320f-1(e)'s definition of qualifying single source drug confirms that when Congress said "a drug," "singular, it meant singular." *Life Techs. Corp. v. Promega Corp.*, 580 U.S. 140, 151 (2017). The IRA defines "qualifying single source drug" using a series of interlinking cross-references:

- 42 U.S.C. § 1320f-1(e)(1) defines "qualifying single source drug" as "a covered Part D drug" under the Medicare statute.
- "A covered Part D drug" is a "covered outpatient drug" under the Medicaid Drug Rebate Program statute. 42 U.S.C. § 1395w-102(e)(1).
- "A covered outpatient drug" is "a drug" "which is approved" by FDA under 21 U.S.C. § 355. *Id.* § 1396r-8(k)(2)(A)(i).

- 21 U.S.C. § 355 specifies the process for FDA approval of "an application" for a "new drug"—a distinct NDA.[4]

This chain of references thus confirms that when Congress defined "a qualifying single source drug," it meant *a drug* approved under *an NDA*. *See George v. McDonough*, 596 U.S. 740, 753 (2022) (when Congress "employs a term of art," it "adop[ts] the cluster of ideas that were attached to each borrowed word").

The IRA's other cross-references to FDA's approval framework further confirm that "a drug" is defined by reference to its particular NDA. The statute excludes from its definition of qualifying single source drug any drug that is "the listed drug for any drug that is approved and marketed under" 21 U.S.C. § 355(j)—that is, the reference drug for an approved and marketed generic. 42 U.S.C. § 1320f-1(e)(1)(A)(iii); *see id.* § 1320f-1(c)(1). Under Section 335(j), a generic's sponsor must identify a single "listed drug" by its individually specified NDA, and FDA will approve a generic based on the specific NDA that the generic references. *E.g.*, 21 U.S.C. § 355(j)(4)(B) (requiring FDA to compare a generic's "proposed conditions of use" to those "previously approved for the listed drug"). In other

[4] Section 355 also sets out how FDA approves supplemental NDAs and ANDAs, but neither can result in selection of "a drug." A supplemental NDA allows a company to obtain FDA approval for changes to an already-approved drug. *See* Drugs@FDA Glossary of Terms, https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms (updated Nov. 2017). An ANDA is used to approve a generic of a single product approved under a single corresponding NDA. *Supra* p. 6.

words, a generic is the generic version of a specific drug approved under a particular NDA, and no other.

Congress's decision tying the definition of qualifying single source drug to the period a particular drug has been approved is further evidence of an NDA-specific approach. A qualifying single source drug is one where "at least 7 years will have elapsed since the date of such approval." 42 U.S.C. § 1320f-1(e)(1)(A). Congress's repeated use of "a definite article"—"the"—with a "singular noun"—"approval"—necessarily focuses on "a discrete thing": the approval of a distinct NDA. *Niz-Chavez v. Garland*, 593 U.S. 155, 166 (2021). That makes good sense; specifying a set exemption period ensures that innovator manufacturers have sufficient time to recoup the value of their multi-billion investments before they are subjected to the IRA's price controls.

The IRA's reference to a "listed drug" also confirms the NDA-specific approach. The statute defines a qualifying single source drug by what it is not: It is "not the listed drug" for a generic. 42 U.S.C. § 1320f-1(e)(1)(A)(iii); *see id.* § 1320f-1(c)(1)(A)(i). FDA has long defined "listed drug" as "*a* new drug product that has been approved under" 21 U.S.C. § 355(c) (emphasis added), and "[l]isted drug status is evidenced by *the* drug product's identification in" FDA's Orange Book "as *an* approved drug," 21 C.F.R. § 314.3(b) (emphases added). And the Orange Book—FDA's database listing all approved drugs—identifies drugs by

their NDA. An amalgamation of many different drugs with many distinct NDAs cannot be a single "listed drug." "When Congress adopts a new law against the backdrop of a 'longstanding administrative construction,' " courts "presume the statute employs the same understanding." *Monsalvo Velazquez v. Bondi*, 604 U.S. 712, 725-726 (2025) (citation omitted). Here, that's an NDA-specific approach.

2. "Where a statute's language carries a plain meaning, the duty of an administrative agency is to follow its commands as written." *SAS Inst., Inc. v. Iancu*, 584 U.S. 357, 363 (2018). Rather than looking to the date FDA approved an innovator drug's NDA and then determining whether the NDA is the listed drug for a marketed generic, CMS has gone on a frolic and detour. CMS will determine the drug's "active moiety"; identify "all dosage forms and strengths of the drug with the same active moiety" approved under any number of NDAs; "investigate whether" those NDAs "are held by the same entity"; identify the "earliest date of approval" for any NDA for a product containing that active moiety; and then assess whether the first NDA issued at least seven years prior to the drug's selection. *See* 2027 Guidance 167-170. As CMS admits, this could result in 12 or more distinct drugs, all approved under different NDAs, counting as just *one* qualifying single source drug. *See id.* at 168-169 & tbl.1.

That result runs headlong into the IRA's language specifying the number of drugs to include for each IPAY and the amount of time they must be approved

before selection. Congress instructed CMS to select 15 qualifying single source drugs for IPAY 2027. 42 U.S.C. § 1320f-1(a). CMS instead selected drugs and biologics approved and marketed pursuant to 24 distinct NDAs and BLAs.[5] *See* Selected Drugs for IPAY 2027, *supra*; Drugs@FDA: FDA-Approved Drugs, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm (search for each selected drug and add the NDAs and BLAs). And eight of those NDAs and BLAs have not been approved for the requisite number of years, in direct contravention of the IRA's reticulated approval timeframe requirements. 42 U.S.C. § 1320f-1(e)(1)(A)-(B). There is no textual evidence that when Congress said 15 drugs it actually meant 24. Nor is there any evidence that when Congress said "at least 7 years [must] have elapsed since the date of such approval," *id.* § 1320f-1(e)(1)(A), it actually meant that three years would suffice, or that CMS was free to look at various approval dates and pick the "earliest" one. *Contra* 2027 Guidance 170.

CMS's interpretation requires grafting language onto the statute. The IRA does not use term "active moiety" anywhere—not once—across its 270-plus pages. *See generally* Pub. L. 117-169, 136 Stat. 1818 (2022). Nor is "active moiety" interchangeable with the term that Congress did use: "a drug." FDA's regulations

[5] This includes two recently FDA-approved NDAs: Wegovy tablets NDA 218316 (Dec. 2025) and Otezla XR tablets NDA 210745 (Aug. 2025). *See* 2027 Guidance 274. It excludes four supplements or administratively closed NDAs: Rybelsus NDA 213182, AUSTEDO NDA 209885, Xifaxan NDA 022554, and Otezla NDA 206088.

define a "[d]rug product" as "a finished dosage form, e.g., tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients." 21 C.F.R. § 314.3(b). The term "drug" therefore encompasses "information about the drug's formulation, route of administration, labeling, inactive ingredients, bioavailability, and manufacturing processes." 86 Fed. Reg. 28,605, 28,606 (May 27, 2021). By contrast, a drug's "[a]ctive moiety" is just "the molecule or ion . . . responsible for the physiological or pharmacological action of the drug substance." 21 C.F.R. § 314.3(b). FDA and the Supreme Court have thus long "interpreted the word 'drug' in the term 'new drug' to refer to the entire drug product." 86 Fed. Reg. at 28,606; *accord United States v. Generix Drug Corp.*, 460 U.S. 453, 454 (1983).

Congress understands these differences, too. Unlike the IRA, several other statutes focus on whether one drug has the same "active moiety" as another. *E.g.*, 21 U.S.C. § 360n(a)(4)(C) (for priority review scheme, defining "tropical disease product application" to exclude a product whose "active moiety" has "been approved in" another NDA); *id.* § 360ff(a)(4)(B) (same, for priority review of "rare pediatric disease product application"); *id.* § 360bbb-4a(a)(4)(D) (same, for priority review of "material threat medical countermeasure application"). In fact, the year before it enacted the IRA, Congress amended 21 U.S.C. § 355(c) to tell FDA to look to the active moiety in assessing new-chemical-entry exclusivity.

Pub. L. 117-9, 135 Stat. 256 (2021). Under that provision, a newly approved drug is entitled to a five-year exclusivity period, provided its active moiety had not previously been approved under a separate NDA. 21 U.S.C. § 355(c)(3)(E)(ii), (iii).

Congress could have done the same here, specifying that a "qualifying single source drug" includes any product with the same "active moiety" that "has been approved in" an NDA. The Court should reject CMS's attempt to "add[ ] words that are not in the statute that the legislature enacted," *Public Citizen, Inc. v. Rubber Mfrs. Ass'n*, 533 F.3d 810, 816-817 (D.C. Cir. 2008), especially when Congress recently "chose to use" the language in another statute but "saw fit to leave [it] out of" the IRA, *Clark-Cowlitz Joint Operating Agency v. FERC*, 826 F.2d 1074, 1088 n.14 (D.C. Cir. 1987).

Blue penciling "active moiety" into the statute also creates another complication: Logically, under CMS's "active moiety" test, drugs that share the same active moiety but are approved under separate NDAs held by different companies would and should be aggregated as a single qualifying single source drug. After all, the IRA says nothing about whether aggregation turns on *who* happens to hold the NDA. To avoid that result, CMS had to add another caveat onto its definition of qualifying single source drug: It will aggregate drugs with the same active moiety only if the NDAs are "held by the same entity." 2027

Guidance 167. But the term "the same entity" is not in the IRA, either. That CMS must add yet more words to the IRA to fix the problem with its active-moiety approach is further proof that cannot be the definition Congress adopted.

Finally, CMS's approach leads to absurd results about when generic entry deselects a selected drug. Under CMS's many-NDAs-but-one-drug definition, a single generic can now disqualify 12 (or more) different innovator products from selection—even if there has been no generic approved for 11 of those 12 products. *See id.* at 171.

That makes no sense. Once there is a competing lower-priced product available, the "listed drug" that the generic competes with should no longer be subject to price controls. And "listed drug" is measured NDA by NDA. *See supra* pp. 22-24. CMS's redefinition writes the words "listed drug" out of the IRA and is contrary to the IRA's purpose of allowing generic competition to deselect drugs. *See, e.g.*, *Marx v. Gen. Revenue Corp.*, 568 U.S. 371, 386 (2013) ("the canon against surplusage is strongest when an interpretation would render superfluous another part of the same statutory scheme"). To take one example, there is no rational reason why both the capsule *and* tablet versions of Xtandi should no longer be controlled if only a capsule generic is available. *See* JA156 (explaining FDA approved Teva's generic capsule version). With the IRA's price cap lifted, the Xtandi manufacturer can raise the tablet's price, leaving patients who take the

tablet without a more-affordable generic to undercut the market-price drug. That is at odds with the purpose behind the Program's generic-deselection provision.

### B. The District Court's Contrary Conclusion Ignores The IRA's Text And Structure.

The District Court endorsed CMS's approach ignoring the IRA's text and structure. JA186-192. But its analysis was flawed top to bottom.

1. The District Court rejected Teva's argument that the IRA's 100-plus references to "a drug"—singular—preclude CMS's reading. *See* JA188. The court cited the Dictionary Act's axiom that singular words generally include the plural. *Id.* But "[t]he Dictionary Act does not transform every use of the singular 'a' into the plural 'several.' " *Niz-Chavez*, 593 U.S. at 164. As the District Court recognized, the singular-plural presumption applies only "unless the context indicates otherwise." JA188 (quoting 1 U.S.C. § 1). And because context often indicates which Congress meant, courts "rare[ly] . . . rel[y]" on the presumption. *United States v. Hayes*, 555 U.S. 415, 422 n.5 (2009).

So too here. Congress knew how to use the plural—"drugs"—when it wanted to; it did so more than 70 times throughout 42 U.S.C. §§ 1320f to 1320f-7, including to describe the list of "selected drugs" and "the determination of qualifying single source drugs under section 1320f-1(e)." Congress's decision to use the singular "qualifying single source drug" should be presumed a deliberate choice. *See Life Techs.*, 580 U.S. at 150-151 (emphasizing Congress's decision to

use both the singular and plural in the same statute in declining to apply Dictionary Act's presumption).

2. None of the District Court's other glosses on the IRA's text withstand scrutiny. The court first pointed to Section 1320f-3(e)(1)(D), which does not define "qualifying single source drug" but instead states that CMS should consider manufacturer-submitted "data on . . . applications and approvals under" 21 U.S.C. § 355(c) "for the drug" when determining the drug's "maximum fair price." *See* JA188. Echoing the 2027 Guidance, the District Court concluded that this language proves "that a single 'drug' can have multiple corresponding 'approvals' and 'applications,' " because portions of Section 355(c) discuss the NDA-approval process. JA188-189; *see* 2027 Guidance 12-13, 170.

Section 1320f-3(e)(1)(D)'s use of the plural "applications" and "approvals" has a ready explanation consistent with an NDA-specific approach. Manufacturers commonly file—and FDA commonly approves—multiple supplemental applications to a single NDA, including for different dosage forms and strengths. *E.g.*, JA145. As FDA explains, a supplemental NDA "allow[s] a company to make changes in a product that already has an approved" NDA, and supplements can include "market[ing] a new dosage or strength." Drugs@FDA Glossary of Terms, *supra*. Congress incorporated this longstanding FDA practice into the IRA by instructing CMS to consider data from "applications and approvals" (plural) for

"the drug" (singular), when determining the "maximum fair price." 42 U.S.C. § 1320f-3(e)(1)(D).

The District Court apparently believed Teva's argument was that "applications and approvals under section 355(c)" should "be narrowly construed to apply *only* to supplemental applications." JA189 (emphasis added). According to the District Court, Teva's argument reads the statute to say "applications and approvals under section 355(c)**(5)**"—a subparagraph pertaining to supplements—which would lead to the " 'absurd result' that only drugs that needed further supplementation under" Section 355(c)(5) "would be eligible for selection." JA189 (citation omitted).

That *would* be absurd, but it was not Teva's argument. As Teva explained, the reference to "applications and approvals under section 355(c)" in Section 1320f-3(e) merely reflects that Congress intended CMS to consider data relevant to both the NDA *and* any "amendments and modifications" to that single NDA in formulating a selected drug's maximum fair price. *See* Dist. Ct. Dkt. No. 36 at 19-20. For example, when CMS developed its offer price for Xifaxan for IPAY 2027, the IRA instructed the agency to consider both the original 2004 NDA for a 200 mg dose, as well the 2015 supplemental approval for a new indication available in a 550 mg dose. *See* Xifaxan, Drugs@FDA, https://tinyurl.com/28nuhfr9 (last visited Jan. 9, 2026).

The IRA's reference to Section 355(c) in the definition of "qualifying single source drug" likewise encompasses any amendments or supplements to a single drug's single NDA. So too with the IRA's other references to Section 355(c), which tie decisions to the time that has "elapsed since the date of approval of such drug under section 355(c)"—the NDA-approval date controls, but "drug" includes supplements. 42 U.S.C. § 1320f-3(c)(4)(A) (extended-monopoly drug), (5)(A) (long-monopoly drug).

The District Court's other cited provisions work the same way as Section 1320f-1(e)(1)(D). JA190-191. Section 1320f-5(a)(2) directs CMS to establish "procedures to compute and apply the maximum fair price across different strengths and dosage forms of a selected drug." And Section 1320f-1(d)(3)(B) 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." Like Section 1320f-3(e)(1)(D), these provisions confirm that CMS should aggregate data across both an NDA and its supplements without regard to differences in packaging size or dosage.

The District Court worried Teva's reading would render its cited provisions surplusage. JA190-191. But where Congress includes language "to remove doubt," it is not "superfluous." *Marx*, 568 U.S. at 385. Here, FDA defines a "drug

product" as "a finished dosage form, e.g., tablet, capsule, or solution." 21 C.F.R. § 314.3(b). The command to aggregate across dosage forms and strengths ensures that "a drug" is not wrongly limited to "a drug product."

The District Court's interpretation has far worse surplusage problems, and in fact makes surplusage the very statutory language the court thought was extraneous under Teva's interpretation. Suppose CMS is right that "qualifying single source drug" means "all dosage forms and strengths of the drug with the same active moiety" approved under any number of NDAs. 2027 Guidance 167. If so, Congress had no reason to specify that CMS should consider "applications and approvals under section 355(c) . . . for the drug," 42 U.S.C. § 1320f-3(e)(1)(D); that data must be "aggregated across dosage forms and strengths of the drug," *id.* § 1320f-1(d)(3)(B); or that the "maximum fair price" should apply "across different strengths and dosage forms of a selected drug," *id.* § 1320f-5(a)(2). Those requirements would already have been swept in by the specification that a "drug" includes all drugs with the same active moiety.

The District Court did not engage with these problems and the many others inherent in its interpretation, even though "the canon against surplusage assists only where a competing interpretation gives effect to every clause and word of a statute." *Marx*, 568 U.S. at 385 (citation and quotation marks omitted). The District Court's reading relies on ancillary subsections to render Congress's

definition of qualifying single source drug nonsensical. Teva's reading adheres to the term's plain meaning while acknowledging that Congress at places may have taken a belt-and-suspenders approach. The latter is "far more faithful to the statutory scheme." *Cook Inlet Tribal Council, Inc. v. Dotomain*, 10 F.4th 892, 896 (D.C. Cir. 2021).

3. That leaves just the District Court's policy concern that accepting the NDA-specific approach would prompt manufacturers to file new NDAs with only "inconsequential changes" to avoid selection. JA191. Of course, "no amount of policy-talk" can overcome a statute's plain text. *Niz-Chavez*, 593 U.S. at 171. But the District Court's policy concerns are misplaced on their own terms.

For one, the District Court's fears ignore manufacturers' significant costs in developing new indications and routes of administration for pre-existing active moieties approved under a new NDA. Teva, for instance, had to submit new clinical-study data to support its NDA for AUSTEDO XR. *See* JA146. Moreover, contrary to the District Court's apparent belief (at JA191), manufacturers cannot unilaterally control their "balanc[e]" of sales across drugs approved under various NDAs. Doctors and their patients decide what dosage, indication, form, and route of administration work best for a patient's illness and circumstances.

FDA also has ample power to combat perceived manufacturer gamesmanship. FDA can refuse to accept an NDA and can reclassify an NDA that

FDA believes should be a supplement.[6] The power is not hypothetical: FDA commonly directs that certain changes—although filed under a new NDA number—are better deemed a supplement to the original NDA. AUSTEDO is proof: FDA originally approved AUSTEDO as indicated for Huntington's disease chorea. JA144-145. Months later, FDA approved AUSTEDO for tardive dyskinesia under a different NDA number, "administratively closed" the separate NDA, and stated that all subsequent "submissions should be addressed to the original NDA." CDER, Letter from Mitchell V. Mathis (Aug. 30, 2017), https://perma.cc/43NC-L6C2; *see* JA144-145. As a consequence, both indications for AUSTEDO are "marketed pursuant to [the original] approval," 42 U.S.C. § 1320f-1(e)(1)(A), and AUSTEDO is a single qualifying single source drug. That stands in contrast to AUSTEDO XR, which FDA approved under a distinct NDA owned by a different entity and is therefore a distinct qualifying single source drug.

The District Court's and CMS's interpretation, meanwhile, creates other concerns. The District Court thought it "self-defeating" for the capsule and tablet versions of Xtandi to be treated as "different drugs . . . because they are approved under distinct NDAs." JA191 (citation omitted). But under CMS's approach, only

[6] *See* FDA, *Guidance for Industry, Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees*, at 2 (Dec. 2004), https://www.fda.gov/media/72397/download (discussing factors FDA considers when "determining whether separate applications should be submitted").

those NDAs held by the "same entity" may be treated as one qualifying single source drug, 2027 Guidance 167, such that even a parent company and its subsidiary are not the same entity, *see* Gov't Mot. Summ. J. at 1, *Merck & Co., Inc. v. Becerra*, No. 1:23-cv-01615 (D.D.C. Sept. 11, 2023), ECF No. 24-1. If, after CMS issued its Guidance, Xtandi's manufacturer had created a separate subsidiary to hold the tablet form's NDA, CMS's Guidance would treat the capsules and tablets as different drugs. And FDA would be powerless to stop it; FDA is notified of, but does not approve or reject, NDA transfers. *See* 21 C.F.R. § 314.72. Teva pointed out this even-greater potential for gamesmanship below. Dist. Ct. Dkt. No. 35 at 26-27. But as with many of Teva's arguments, the District Court never grappled with it.

## II. CMS'S SUBJECTIVE, ATEXTUAL "BONA FIDE MARKETING" STANDARD IS UNLAWFUL.

The District Court did not reach CMS's unlawful definition of "marketed" after *sua sponte* holding Teva's challenge prudentially unripe—a decision rife with factual errors and misunderstandings of black-letter law. With that obstacle cleared, this Court should reject CMS's atextual "bona fide marketing" standard as contrary to law.

### A. Teva's Bona Fide Marketing Challenge Is Ripe.

Ripeness's "basic rationale" is to avoid "abstract disagreements over administrative policies" and "to protect agencies from judicial interference until an

administrative decision has been formalized." *National Ass'n of Home Builders v. Army Corps of Eng'rs*, 417 F.3d 1272, 1281 (D.C. Cir. 2005) (citation omitted). Teva's challenge to CMS's fixed—and illegal—decision to rewrite the statutory definition of "marketed" implicates neither concern. And the two factors courts consider in evaluating prudential ripeness—"the fitness of the issues for judicial decision and the hardship of withholding court consideration"—cannot justify delay. *Stolt-Nielsen S.A. v. AnimalFeeds Int'l Corp.*, 559 U.S. 662, 670 n.2 (2010) (citation and quotation marks omitted). The District Court reached a contrary conclusion by overlooking undisputed facts and misconstruing the law.

*1. Teva's challenge is fit for review.*

An issue is fit for review if it is "purely legal," does not require further factual development, and if "the agency's action is sufficiently final." *Energy Future Coal. v. EPA*, 793 F.3d 141, 146 (D.C. Cir. 2015). But here, the Court need not run the checklist. The District Court properly recognized that Teva brings "a facial challenge to set aside CMS's guidance," JA180, and this Court has "often observed" that "a purely legal claim in the context of a facial challenge" is "presumptively reviewable," *National Ass'n of Home Builders*, 417 F.3d at 1282 (quoting *National Mining Ass'n v. Fowler*, 324 F.3d 752, 757 (D.C. Cir. 2003)).

This Court's repeated observation about facial challenges is well-taken, because Teva's challenge to CMS's illegal bona fide marketing requirement ticks

all three fit-for-review boxes. *First*, it is "well-established" that challenges to agency action as "contrary to law present purely legal issues." *Energy Future*, 793 F.3d at 146 (citation omitted). *Second*, factual development is unnecessary; the parties agreed that Teva's claims could be resolved without an administrative record or discovery. *See* JA138-140. And, *third*, it makes no difference that CMS has not yet applied its illegal bona fide marketing definition to Teva's generics. When "a suit presents a purely legal question of whether [the agency's] final action violates" a statute, "it is unnecessary to wait for [the agency's] legal conclusion to be applied in order to determine its legality." *Energy Future*, 793 F.3d at 146 (citation and quotation marks omitted). Teva detailed its concrete plans to launch five generics that have as their reference drug innovator drugs selected for IPAY 2027. JA155, 157-160. Under the IRA's text, Teva's generics would be marketed on the date they are first sold; under CMS's definition, they will not.

The District Court did not address any of this. The court instead believed that Teva's claims suffered from two finality-related problems. JA194. *First*, the District Court thought it was a problem that Teva's generics have supposedly not been FDA-approved. *Id.* But the court misread the record. Teva's declarant swore that "FDA has approved" Teva's generic Xtandi capsules. JA155. Many of Teva's other generics have been approved or tentatively approved, too—

information that FDA's public databases reflect and that Teva could have shared if the District Court had asked. Add. 2-6 (Second Decl. of Carrie Groff).[7]

*Second*, the District Court mistakenly believed the 2027 Guidance would not apply to Teva's generics. The court observed that CMS issues guidance for each IPAY and assumed that whichever guidance is "in place when a generic to a selected drug is launched" would apply to a drug's deselection. JA196 (citation and brackets omitted). And the court held that any challenge to future guidance that may apply to Teva's generics was unripe because "agency consideration remains ongoing." JA195 (citation and brackets omitted).

The District Court overlooked that CMS's IPAY Guidance is IPAY specific; the 2027 Guidance governs the deselection of the innovator drugs selected for IPAY 2027, no matter when a generic version launches. *See* 2027 Guidance 131, 279 (setting out when IPAY 2027 price caps sunset based on when CMS determines "bona fide marketing exists for the generic" for certain dates in 2025, 2027, 2028, and in "each subsequent year"). Even CMS's IPAY 2028 Guidance confirms that "the final guidance for [IPAY] 2027" governs the deselection of

[7] Teva submits this declaration on appeal because the District Court's *sua sponte* prudential-ripeness dismissal denied Teva the chance to develop the record. *See Buchanan v. Manley*, 145 F.3d 386, 388 (D.C. Cir. 1998). Much of the information comes from public FDA databases this Court can take judicial notice of. *See Yellow Taxi Co. of Minneapolis v. NLRB*, 721 F.2d 366, 375 n.29 (D.C. Cir. 1983).

IPAY 2027 drugs. 2028 Guidance 317. The District Court was therefore wrong to think Teva's generics would have to launch "early enough to affect [2027] prices" in order for the 2027 Guidance to apply to them. JA194-195.[8] Because Teva's generics are for IPAY 2027-selected innovator drugs, the 2027 Guidance applies.

The District Court's mistake meant it ignored the three generics for IPAY 2027-selected drugs that Teva plans to launch in 2028 and 2029: Xifaxan, Otezla, and Linzess. JA194-195; *see* JA158-160. And the court's mistaken belief about a March 2026 cutoff for IPAY 2027 left it confused about Teva's Xtandi and Ofev generics. Teva's declarant also provided the "specifics" of when Teva's generic Xtandi will launch, *contra* JA195—shortly before August 13, 2027, *see* JA156, 165—and there is no "barrier" to Teva's Ofev generic entry, *contra* JA195, which is unaffected by one limited exclusivity extension, *see* JA156-157.

With the District Court's misperceptions corrected, the ripeness analysis is straightforward. Teva challenges CMS's "Final Guidance" for IPAY 2027, under which a "generic drug or biosimilar is not 'marketed' " on the date it is first sold. 2027 Guidance 20. The IPAY 2027 Guidance governs the deselection of IPAY 2027 drugs in perpetuity. *Id.* at 131, 279. And "[w]here, as here, the agency has

[8] All IPAY 2027 drugs will be price controlled at least one year, through December 31, 2027, because no generics referencing them were marketed by November 1, 2025. *Supra* p. 10. The court thought March 31, 2026, was a relevant cutoff for IPAY 2027, JA194-195, but it is not. After November 1, 2025, the next relevant cutoff is March 31, *2027*. 2027 Guidance 131, 279.

stated that the action in question governs and will continue to govern its decisions, such action must be viewed as final in [the court's] analysis of ripeness." *Better Gov't Ass'n v. Department of State*, 780 F.2d 86, 93 (D.C. Cir. 1986) (emphasis omitted).

*2. Hardship is irrelevant, and, in any event, Teva is harmed by withholding review.*

The District Court believed that Teva would not be harmed by delaying judicial review of Teva's bona fide marketing challenge. JA196. But when a purely legal question like Teva's is "clearly fit for review, there is no need to consider the hardship to the parties of withholding court consideration." *Cohen v. United States*, 650 F.3d 717, 735 (D.C. Cir. 2011) (en banc) (citation and quotation marks omitted). The Court can reverse the District Court's ripeness holding without going further.

But if the Court does reach this issue, there are "no significant agency or judicial interests militating in favor of delay." *Energy Future*, 793 F.3d at 146 (citation and quotation marks omitted). The Government did not assert any harms to CMS from immediate review, and forcing Teva "to bring separate actions at separate times" as each of its generics is launched is "piecemeal litigation at its nadir." *Consolidation Coal Co. v. Federal Mine Safety & Health Rev. Comm'n*, 824 F.2d 1071, 1083 (D.C. Cir. 1987).

Moreover, any interest in delay is outweighed by at least three distinct harms to Teva. *First*, Teva suffers economic harm when its generics are forced to compete with price-capped innovator drugs for a longer period than the IRA would otherwise require. Teva plans to launch five generics for IPAY 2027 selected drugs within months of—or even the same day as—the IRA's crucial March 31 cutoffs. JA156-160. Under the IRA, a single sale on March 31 ends the price cap on the innovator drug effective December 31 of that year; under CMS's 2027 Guidance, it cannot. Forcing Teva to compete longer with price-controlled innovator drugs is a textbook economic harm. *See Clinton v. City of New York*, 524 U.S. 417, 433 (1998) (courts "routinely recognize[] probable economic injury resulting from governmental actions that alter competitive conditions") (citation and quotation marks omitted); *Diamond Alt. Energy, LLC v. EPA*, 606 U.S. 100, 116 (2025) (recognizing " 'familiar' circumstance where government regulation of a business 'may be likely' to cause injuries to other linked businesses") (citation omitted).

*Second*, CMS's illegal bona fide marketing standard impairs the licensing agreements Teva negotiated with the manufacturers of competing innovator drugs, under which Teva has the right to sell its generic on a date certain. JA161. CMS's Guidance ensures a delay between when Teva first sells its generic and when CMS deems that generic bona fide marketed. This guaranteed delay devalues Teva's

licenses *today*. JA167. A final decision holding CMS's bona fide marketing requirement unlawful would give Teva "an immediate, concrete, and valuable benefit: certainty" that Teva's generic launch will terminate the price controls on the listed innovator. *VanderKam v. VanderKam*, 776 F.3d 883, 889 (D.C. Cir. 2015).

*Third*, CMS's unlawful bona fide marketing qualifier deters Teva's development of generics. *See Cablevision Sys. Corp. v. FCC*, 649 F.3d 695, 716 (D.C. Cir. 2011) ("[A]n incentive for petitioners to alter their business affairs[] establish[es] at least some degree of hardship."); *Exxon Mobil Corp. v. FERC*, 501 F.3d 204, 208 (D.C. Cir. 2007) (hardship prong satisfied where postponing review would cause "uncertainty" and "tend to inhibit or delay investment" by prospective applicant). The Guidance has already led Teva to reconsider whether to continue to invest in new generics. JA153-155, 160-161, 166-167. So long as CMS's unlawful qualifier is effective, Teva must continue to factor it into its decision making. JA167.

The one reason the District Court thought Teva "suffers no hardship" was that Teva could simply sue in the "nine months before a 'marketed' determination

has any effect." JA196.[9] But Teva's ability to bring a future lawsuit "cannot tip the balance against judicial review." *Energy Future*, 793 F.3d at 146 (citation omitted). And in a related context, this Court "has held that agency actions of less than *two years*' duration cannot be 'fully litigated' prior to cessation or expiration." *Del Monte Fresh Produce Co. v. United States*, 570 F.3d 316, 322 (D.C. Cir. 2009) (citation omitted and emphasis added). Nine months is too short for Teva to receive effectual relief. The Court should decide Teva's bona fide marketing challenge now.

### B. CMS's Bona Fide Marketing Requirement Is Unlawful.

1. A drug is ineligible for price controls if an FDA-approved generic is "marketed." 42 U.S.C. § 1320f-1(e)(1)(A)(iii); *see id.* § 1320f-1(c)(1), (d)(1). "Marketed" means "expose for sale in a market," *Marketed*, Merriam-Webster's Collegiate Dictionary (11th ed. 2020), or "bring or send to a market," *Marketed*, Oxford English Dictionary (3rd ed. 2023). These definitions do not include any quantitative or qualitative qualifiers as to how much product must be brought to market, how long it must be exposed for sale, or how strong the manufacturer's

[9] To the extent the District Court meant that Teva could wait until March 31, 2026, to see whether any of Teva's generics are found to be bona fide marketed and sue if they are not, the District Court fell prey to its misunderstanding about the cutoffs for IPAY 2027. *See supra* p. 40 n.8. March 31, 2026, is not a cutoff for IPAY 2027.

marketing efforts must be. If even one unit of a generic has been sold, it has been marketed.

That matches CMS's and FDA's approach in related contexts. For the IRA's Medicare Part B and Part D inflation rebates, CMS determines when a product is "marketed" by reference to the "date of first sale." CMS, *Medicare Part B Inflation Rebates Paid by Manufacturers: Revised Guidance*, at 57 (Dec. 14, 2023), https://perma.cc/366Q-QNU7. CMS likewise defines "marketed" for the Medicaid Drug Rebate Program using the date on which a product "is available for sale." 83 Fed. Reg. 12,770, 12,784 (Mar. 23, 2018). And for FDA, under the Hatch-Waxman Act, certain first-to-file generics are entitled to an exclusivity period beginning "the date of the first commercial marketing of the drug," 21 U.S.C. § 355(j)(5)(B)(iv)(I), defined as when the drug is introduced "into interstate commerce," 21 C.F.R. § 314.3(b).

CMS's Guidance eschews this bright-line definition, instead insisting marketing must be "bona fide," a know-it-when-we-see-it standard satisfied entirely at CMS's discretion. *See* 2027 Guidance 19-21 (attempting to provide various alternative definitions of the term). But "those are not the words that Congress wrote," and CMS "is not free to rewrite the statute to [its] liking." *National Ass'n of Mfrs. v. DOD*, 583 U.S. 109, 123 (2018) (citation omitted).

Congress knows how to include a "bona fide" qualifier when it wants. Congress used that term in 471 different sections of the U.S. Code governing many different programs, including more than 70 times in Title 42 alone—tacking it onto everything from cotton futures contracts, to physician relationships, to covered outpatient drug service fees. *E.g.*, 7 U.S.C. § 15b(d) (restricting "cotton futures contracts" to "bona fide spot markets"); 42 U.S.C. § 1396r-8(k)(1)(B)(i)(II) (exempting "bona fide service fees" from the calculation of the "average manufacturer price for a covered outpatient drug"); *id.* § 1395nn(e)(2) (prohibiting certain physician referrals absent a "[b]ona fide employment relationship").

Congress even included a "bona fide" qualifier in a different part of the IRA, defining "labor hours" to exclude hours worked by "persons employed in a bona fide executive, administrative, or professional capacity." Pub. L. 117-169, § 13101(f)(8)(E)(i)(II), 136 Stat. 1910. But Congress left the word "marketed" in the Program unadorned. This Court "presume[s]" Congress did so "intentionally and purposely." *Russello v. United States*, 464 U.S. 16, 23 (1983) (citation omitted).

Before the District Court, the Government protested that, for purposes of the Inflation Rebate Program, Congress instructed CMS to assess whether a drug is "being marketed, as identified in [FDA's] National Drug Code Directory" database. Dist. Ct. Dkt. No. 29 at 25 (quoting 42 U.S.C. § 1395w-

114b(g)(1)(C)(ii)). On the Government's telling, that proves that Congress knows how to mandate "a simple yes-or-no inquiry" when it sees fit and did not do so for the Program. *Id.* But the Government's comparison backfires. Manufacturers self-update FDA's directory twice per year. FDA merely does its best to verify the information afterwards, meaning the marketing "start date" for drugs in the directory may well be incorrect. FDA, *National Drug Code Database Background Information* (updated Mar. 20, 2017), https://perma.cc/CV7S-GPD7. It is therefore not surprising that Congress deemed FDA's directory unsuitable to determine whether a generic "is marketed" for Program purposes.

2. The date on which a generic "is marketed" is significant. If a generic is marketed after a drug has been selected but before the negotiation period ends, no IRA price cap takes effect. 42 U.S.C. § 1320f-1(c)(2). If a generic is marketed after the negotiation period ends, meanwhile, the price control will be effective for at least a year. After that, the relevant cutoff is March 31 each year: If the generic is marketed by March 31, the price control ends effective December 31 that same year, but if the generic launches April 1 or later, the earliest the price cap can sunset is the end of the following calendar year. *Id.* § 1320f-1(c)(1).

The IRA implements this complex timetable by asking a straightforward question: Have any sales of the generic occurred by the relevant deadline? If so, the innovator drug cannot be price controlled. But under CMS's Guidance, a

generic cannot be "marketed" on the date it is first sold. Indeed, a generic will inevitably take months to reach bona fide marketing. The delays associated with the Part D PDE data and Medicaid AMP data CMS considers exacerbate the problem. PDE data are generated when a Part D plan sponsor fills a prescription under Medicare Part D. But there is necessarily a delay between when a drug becomes available, when Part D prescriptions for that drug are filled, and when those prescriptions are reported, as CMS admits. 2027 Guidance 21-22. For example, in 2025, Medicare Part D covered only 24% of generics first launched in 2024. Ass'n for Access. Meds., *Breaking Barriers: Harnessing the Potential of Generics in Medicare and Commercial Market Drug Spending*, at 2 (June 2025) https://perma.cc/YRA7-7UK3. CMS has also acknowledged that AMP data are on a two-month delay. 2027 Guidance 278. These delays make it essentially impossible for a generic approved in February or March to end a price control on its referenced innovator drug by the March 31 cutoff. *See* JA158, 164. That, in turn, harms Teva and the patients it serves by preventing Teva from obtaining market share after launch and denying patients a resilient supply of affordable medications. *See* JA151-152, 154-155, 160-161, 166.

## III. THE PROGRAM VIOLATES DUE PROCESS.

### A. The Program Deprives Teva Of Protected Interests Without Due Process.

The IRA's price-control program impairs Teva's protected interests in both its generics licenses and innovator products without providing the constitutional protections Teva is due.

1. The Due Process Clause protects a broad class of property interests, including those created through statutes, contracts, "policies and practices," or through "rules and understandings" that are "promulgated and fostered by [government] officials." *Perry v. Sindermann*, 408 U.S. 593, 601-603 (1972). The Program impairs Teva's protected interests in three respects. *First*, the Program's price caps degrade the value of Teva's licenses to manufacture generic drugs. When Teva files an ANDA, Teva must certify it will not infringe a valid patent. 21 U.S.C. § 355(j)(2)(A)(vii)-(viii). Teva's certification often triggers expensive patent litigation that results in a settlement agreement allowing Teva's generic to launch before the innovator's patents expire. The value of Teva's license depends on the price and market share that Teva can expect to achieve. JA152-153. Teva invests significant resources in forecasting market conditions before agreeing to a license versus continuing to litigate against the innovator's patents. JA153. As the price or market share Teva's generic can command declines, the value of its license accordingly declines, too. JA161.

Before the IRA, Teva negotiated licenses to sell generic versions of multiple innovator drugs. JA156, 158-160. Teva's "[v]alid contracts are property under the Fifth Amendment" that "fully vested upon the completion of the transaction[s]" with the innovator manufacturers. *Ralls Corp. v. Committee on Foreign Inv. in U.S.*, 758 F.3d 296, 316 (D.C. Cir. 2014) (citation and brackets omitted); *see Greene v. McElroy*, 360 U.S. 474, 493 n.22 (1959) (acknowledging "legally protected right to be free from arbitrary interference with private contractual relationships"). CMS then imposed price caps on the innovator drugs that are 48% to 75% off the wholesale price. IPAY 2027 Results, *supra*. Teva will therefore have to charge even less for its generics to have any chance at obtaining market share or forego marketing its generics of IRA-selected drugs entirely. JA154-155.

*Second*, the Program impairs Teva's "treasured" common-law right to sell its products at market prices free from arbitrary and undisclosed governmental constraints. *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 149 (2021); *Old Dearborn Distrib. Co. v. Seagram-Distillers Corp.*, 299 U.S. 183, 192 (1936) (private parties have a "right . . . to fix the price at which" they "sell" products). That right is reinforced by "policies and practices" and "rules and understandings" "promulgated and fostered by [government] officials." *Perry*, 408 U.S. at 601-603. Until the IRA, federal law affirmatively prohibited interference with market rates for pharmaceutical products. *See* 42 U.S.C. § 1395w-111(i). Pharmaceutical

manufacturers entered Medicare and Medicaid against that backdrop, allowing the federal government to build these programs into the behemoths they are today. Teva's right to sell its products at prices set by voluntary agreements is therefore more than "a mere subjective 'expectancy.' " *Perry*, 408 U.S. at 603 (citation omitted). But the Program upends all of that, forcing Teva to sell its drugs to Medicare beneficiaries, to "pharmacies, mail order services, and other dispensers," and to "hospitals, physicians, and other providers of services and suppliers," 42 U.S.C. § 1320f-2(a)(1), at a price directly or effectively determined by CMS. Government programs "in the nature of a contract" may not "surpris[e] [participants] with post-acceptance or 'retroactive' conditions." *National Fed'n of Indep. Bus. (NFIB) v. Sebelius*, 567 U.S. 519, 577, 584 (2012) (citation and emphasis omitted). And the government cannot impose price controls on private market transactions without adequate procedural safeguards. *See Bowles v. Willingham*, 321 U.S. 503, 520-521 (1944) (government cannot mandate rent control even during wartime without affording landlords due process).

*Third*, the Program impairs Teva's property interest in the patents it holds for innovator drugs. Patents are " 'property' of which no person may be deprived . . . without due process of law." *Florida Prepaid Postsecondary Educ. Expense Bd. v. College Sav. Bank*, 527 U.S. 627, 642 (1999). Patents permit patent-holders to charge more for products during the exclusivity period.

*Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1372 (Fed. Cir. 2007); *see Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-151 (1989) (patentees obtain "the exclusive right to practice the invention for a period of years"); *United States v. Studiengesellschaft Kohle, m.b.H.*, 670 F.2d 1122, 1131 (D.C. Cir. 1981) ("patentee's reward include[s] the right to fix prices at which products [a]re sold"); JA144. Innovator manufacturers accordingly "make most of their revenue on their products during those exclusivity periods because they sell a higher volume of their product at market prices when no generic version is available." JA144. If the government coerces lower prices on patented medicines during the protected period, the patent is worth less—a deprivation that must be preceded by due process. *E.g.*, *PhRMA v. District of Columbia*, 406 F. Supp. 2d 56, 65-67 (D.D.C. 2005) (holding unlawful a state statute "designed to force drug manufacturers" "to limit the wholesale price" of patented drugs during the exclusivity period), *aff'd*, 496 F.3d at 1371-74; *Delano Farms Co. v. California Table Grape Comm'n*, No. 1:07-cv-01610, 2010 WL 2952358, at *26 (E.D. Cal. July 26, 2010) (similar). That principle applies to Teva's patents for AUSTEDO and AUSTEDO XR, which are worth less because the drugs were selected for IPAY 2027. And the patents will be worth even less when CMS's 38% discount goes into effect.

2. Once Teva is understood to have a property interest, the rest follows. Due process requires "the opportunity to be heard at a meaningful time and in a meaningful manner." *Mathews v. Eldridge*, 424 U.S. 319, 333 (1976) (citation and quotation marks omitted). But the Program provides no process to Teva in its role as a generics manufacturer: Teva has no say in what innovator drugs are selected for the Program or the price caps CMS imposes, even though the caps affect whether Teva's generics can effectively compete. JA155. A government program that provides "no process whatsoever" is unconstitutional. *Schepers v. Commissioner*, 691 F.3d 909, 915 (7th Cir. 2012); *see Gray Panthers v. Schweiker*, 652 F.2d 146, 165-173 (D.C. Cir. 1980).

Nor does the Program sufficiently protect Teva as an innovator manufacturer. The Program directly affects the prices Teva can charge for AUSTEDO and AUSTEDO XR. The "lack of input" and inability to obtain judicial review of particular determinations "create a substantial risk of erroneous deprivation." *National Infusion Ctr. Ass'n (NICA) v. Becerra*, 116 F.4th 488, 503 (5th Cir. 2024). CMS's price-setting methodology is opaque, with no objective criteria or standardized formula guiding CMS's offers. Once a drug is selected, the Program forces manufacturers to "negotiate," but gives manufacturers no leverage, no meaningful opportunity to walk away, no ability to protect their interests, and no access to an impartial adjudicator. The risk of mistake in that deliberately one-

sided process is high, *see Mathews*, 424 U.S. at 335, and the IRA's review bar stops manufacturers from seeking administrative or judicial review of key determinations, 42 U.S.C. § 1320f-7. The government does not have any legitimate interest in insulating CMS's mistakes from third-party review. But even if it did, giving interested parties the opportunity for legitimate input would impose only minimal "fiscal and administrative burdens" on CMS and would substantially reduce the likelihood that Teva will experience "the erroneous deprivation" of its protected interests. *NICA*, 116 F.4th at 503; *Mathews*, 424 U.S. at 335. All these flaws render the Program unconstitutional.

### B. The District Court Erred In Concluding Teva Lacks Protected Interests.

The District Court, like the Government, did not contend that the Program provides adequate process. It instead dodged the issue by concluding that the Program does not impair Teva's cognizable property interests. JA197-203.

To begin, the court ignored Teva's protected interests in its generic licenses and agreements, brushing aside Teva's challenge as "near identical" to *Boehringer Ingelheim Pharmaceuticals, Inc. v. HHS*, 150 F.4th 76 (2d Cir. 2025), *AstraZeneca Pharmaceuticals LP v. Secretary of HHS*, 137 F.4th 116 (3d Cir. 2025), and *NICA v. Kennedy*, No. 1:23-cv-00707, 2025 WL 2380454 (W.D. Tex. Aug. 7, 2025), *appeal pending*, No. 25-50661 (5th Cir.). JA197. But none of those cases involved generics manufacturers like Teva.

The District Court's unquestioning adoption of those cases also meant it committed many of their same errors. The court concluded that the Program only sets prices for drugs that CMS pays for in its capacity as an ordinary "buyer on the market." JA200-202. But the Program controls the price at which Teva may sell to Medicare-eligible individuals, providers, and dispensers in completely private transactions. *See* 42 U.S.C. § 1320f-2(a)(3). When your grandmother buys AUSTEDO XR, she is the purchaser; she does not act as an "agent" or "private intermediar[y]" of the federal government. *Contra* JA202. And unlike your grandmother, CMS never buys a single drug under Medicare Part D. *See*, *e.g.*, 42 U.S.C. § 1395w-112(b)(1). Nor does CMS directly reimburse insurers for the actual or "negotiated" price of drugs; reimbursement rates are set by a complex statutory formula consisting of direct subsidies and reinsurance. *Id.* § 1395w-115(a), (b).

The Third Circuit in *AstraZeneca* accepted that the government violates due process if it "impos[es] price controls on private market transactions while barring judicial review of [agency] price-setting decisions." 137 F.4th at 126. That principle applies here. To be sure, the Third Circuit—like the District Court—erroneously believed that the Program sets prices only for drugs that the government buys. *See id.* But when that misperception is corrected, the Program's unconstitutionality follows inexorably.

Nor is the government acting just "like any buyer on the market." *Contra* JA201-202. Where the government exercises powers "tantamount to regulation," it is not entitled to market-participant treatment. *Cardinal Towing & Auto Repair, Inc. v. City of Bedford*, 180 F.3d 686, 691 (5th Cir. 1999); *see Engquist v. Oregon Dep't of Agric.*, 553 U.S. 591, 598 (2008); *South-Central Timber Dev., Inc. v. Wunnicke*, 467 U.S. 82, 97 & n.10 (1984) (plurality op.). The government is a monopsonist that so dominates the prescription-drug market that manufacturers cannot avoid doing business with it. *See Sanofi Aventis*, 58 F.4th at 699. And no ordinary buyer could impose exorbitant excise taxes or ruinous civil monetary penalties on recalcitrant suppliers. *E.g.*, 26 U.S.C. § 5000D(d); 42 U.S.C. § 1320f-6(a); *see also Maryland Dredging & Contracting Co. v. United States*, 241 U.S. 184, 187 (1916) (government, in contracting, "has no right to retain [a] sum" imposed as "a penalty" on its counterparty).

The District Court's reasoning that the Program is voluntary is wrong. *See* JA200-202. Choosing between acceding to price controls, incurring crippling penalties, and withdrawing from Medicare and Medicaid—which constitute nearly half the prescription drug market—is as voluntary as giving your wallet to a mugger who has jabbed his pistol between your ribs. Indeed, "[m]anufacturers are all but certain to adopt the price" CMS imposes—as they have all done, *see* IPAY 2027 Results, *supra*—even when doing so is "unprofitable." *NICA*, 116 F.4th at

500. The Supreme Court rejected a similar "threat[ ] to withhold . . . Medicaid grants" as an unconstitutionally coercive "gun to the head," even though participation in Medicaid is also technically voluntary. *NFIB*, 567 U.S. at 575, 581. This Court should do the same here.

None of the out-of-circuit cases the District Court relied on prove otherwise. *See* JA201. Those cases asked whether participation in Medicaid was voluntary for individual nursing homes, hospitals, and physicians. *See, e.g.*, *Shah v. Azar*, 920 F.3d 987, 998 (5th Cir. 2019) (physicians); *Baptist Hosp. E. v. Secretary of HHS*, 802 F.2d 860, 869-870 (6th Cir. 1986) (hospitals); *Minnesota Ass'n of Health Care Facilities, Inc., v. Minnesota Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984) (nursing homes).[10] Those facts bear no resemblance to this case, where drug companies are being asked to abandon half the marketplace on pain of "enterprise-crippling excise taxes." *Bristol Myers Squibb*, 155 F.4th at 280-281 (Hardiman, J., dissenting).

Regardless, voluntariness is not dispositive. Due process applies equally to voluntary benefit programs. *E.g.*, *Goldberg v. Kelly*, 397 U.S. 254, 262-266 (1970) (government cannot terminate public assistant benefits without sufficient process); *Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 535, 538 (1985) (eliminating

[10] *Cummings v. Premier Rehab Keller, PLLC*, 596 U.S. 212 (2022), which asked what remedies are available in discrimination suits against the government, is even less applicable.

"property right in continued employment" requires due process). If voluntariness matters at all, it is only for takings claims. There is a fundamental difference between a company voluntarily subjecting its property to the government's power "in exchange for . . . economic advantages," and the kind of diverse and flexible "claim of entitlement" that the Due Process Clause protects. *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1007 (1984); *see Hignell-Stark v. City of New Orleans*, 46 F.4th 317, 323 (5th Cir. 2022).

The District Court's remaining objections likewise miss the mark. The court dismissed Teva's right to sell its products at prices free from government interference on the theory that the IRA undid Teva's prior statutory rights. JA199. But the government cannot "surpris[e]" participants in quasi-contractual programs with "post-acceptance or 'retroactive' conditions." *NFIB*, 567 U.S. at 577, 584. And statutes aside, Teva has a *common-law* right to sell its products at market prices free from arbitrary and inadequately disclosed governmental constraints. When Congress amends a statutory or common-law entitlement in a manner that impedes those rights, it must provide adequate process. The IRA does not. And Teva has never claimed a right to sell AUSTEDO and AUSTEDO XR at a particular price. *Contra* JA203. Teva instead argued that its common-law and statutory rights, together with its patents, protect its interest in "above-market profits during the patent's term." *Biotechnology Indus. Org.*, 496 F.3d at 1372.

CMS's deliberately opaque and highly coercive process of establishing drugs' price caps deprives manufacturers of core interests in setting their prices during the patented period without any meaningful notice or opportunity to be heard.

## CONCLUSION

The Court should reverse and remand with instructions for the District Court to vacate CMS's definitions of "qualifying single source drug" and "marketed" and enjoin the government from implementing the Program as to Teva.

Respectfully submitted,

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## CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(g)(1), the undersigned hereby certifies that this brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B)(i).

1. Exclusive of the exempted portions of the brief, as provided in Fed. R. App. P. 32(f), the brief contains 12,998 words.

2. The brief has been prepared in proportionally spaced typeface using Microsoft Word in 14-point Times New Roman font. As permitted by Fed. R. App. P. 32(g)(1), the undersigned has relied upon the word count feature of this word processing system in preparing this certificate.

/s/ Sean Marotta
Sean Marotta

January 9, 2026

# ADDENDUM

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

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| TEVA PHARMACEUTICALS USA, INC., *et al.*,<br><br>*Plaintiffs-Appellants*,<br><br>v.<br><br>ROBERT F. KENNEDY, JR., in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, *et al.*,<br><br>*Defendants-Appellees*. | No. 25-5425 |

**DECLARATION OF CARRIE GROFF**

I, Carrie Groff, declare as follows:

1. I am over the age of 18. Except as expressly indicated, the facts stated herein are based on my personal knowledge, including my experience in the pharmaceutical industry, my work at Teva Pharmaceuticals USA, Inc. (Teva), and my review of the business records of the company. If called to testify, I could truthfully and competently testify to those facts.

2. I am the Vice President of Portfolio and New Product Launch at Teva. Teva is a wholly owned, indirect subsidiary of Teva Pharmaceuticals Industries, Ltd., a global pharmaceutical company headquartered in Israel. Teva is an industry

leader in the development, manufacture, and marketing of generic pharmaceutical products in the United States.

3. In my capacity as Vice President of Portfolio and New Product Launch, I lead Teva's U.S. generic product portfolio and launch teams, which includes responsibility for selecting new generic products for development, and overseeing Teva's generic product-development strategy from the time Teva chooses to develop a given product through the time Teva launches that product into the market. My team and I value new product opportunities, coordinate with Teva's regulatory affairs personnel to ensure that our strategies align, and make decisions about which products to prioritize based on the company's goals, projections, manufacturing capacity, and pertinent regulatory developments. My responsibilities for Teva's generic products include timeline alignment, taking into consideration product approval, operational readiness, and legal status. My team also coordinates internal decision-making regarding inventory preparation activities.

4. FDA approved Teva's application (ANDA No. 209614) in May 2021 to market generic XTANDI (Enzalutamide) capsules, which is publicly available in FDA's Orange Book: https://tinyurl.com/27jms69u. XTANDI capsules are available in a single strength, 40 mg. FDA's database lists the company that submitted the ANDA as Actavis Laboratories FL, Inc. Teva acquired Actavis in

2016, and it is now a wholly owned subsidiary of Teva. Teva Pharmaceuticals USA, Inc. holds the marketing rights for Teva's generic Enzalutamide capsules. FDA's database reflects that the marketing status of Teva's Enzalutamide capsules is "discontinued." The "discontinued" status means only that that Teva was not going to market the product within 180 days of approval—here, because of a remaining patent. *See* Drugs@FDA, Glossary of Terms, https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms (updated Nov. 2017) ("Products listed in Drugs@FDA as 'discontinued' " include "approved products that have never been marketed"). Under its settlement agreement, Teva anticipates that its generic Enzalutamide capsules will enter the market shortly before the expiration of a patent on the innovator drug on August 13, 2027. Teva will reactivate the marketing status for generic Enzalutamide capsules before the capsules enter the market.

5. FDA tentatively approved Teva's application (ANDA No. 218187) in April 2024 to market generic XTANDI (Enzalutamide) tablets in both strengths (40 mg and 80 mg), which is publicly available in FDA's Orange Book at: https://tinyurl.com/yxtr77u3. Teva Pharmaceuticals USA, Inc. holds the marketing rights for Teva's generic Enzalutamide tablets. FDA's Orange Book explains that "FDA issues a tentative approval" "[i]f a generic drug product is ready for approval before the expiration of any patents or exclusivities accorded to the

reference listed drug product," and "FDA delays final approval of the generic drug product until all patent or exclusivity issues have been resolved." Drugs@FDA Glossary of Terms, https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms (updated Nov. 2017); *see also* 21 C.F.R. § 314.105(d). Because of patents protecting the innovator drug and confidential settlement agreements, Teva does not anticipate that generic Enzalutamide tablets will enter the market before March 31, 2028.

6. FDA tentatively approved Teva's application (ANDA No. 219371) in August 2025 to market generic OFEV (Nintedanib) capsules in all strengths, which is publicly available in FDA's Orange Book at: https://tinyurl.com/7nupjwra. Teva Pharmaceuticals USA, Inc. holds the marketing rights for Teva's generic Nintedanib capsules. I explained in my previous declaration that Teva planned to launch its generic Nintedanib capsules in October 2026, six months after the first-to-file generic was anticipated to enter the market in April 2026. Groff Decl. ¶ 23(e). But the first-to-file generic did not retain its 180-day exclusivity rights, so Teva now anticipates that its generic Nintedanib capsules will enter the market on April 2, 2026, when the final remaining patent protecting the innovator drug expires. At the time of my previous declaration, Teva's anticipated October 2026 launch for adult indications would not have been affected by a pediatric orphan exclusivity period set to expire on March 26, 2027. Groff Decl. ¶ 23(d)-(e).

7. FDA tentatively approved Teva's application (ANDA No. 211255) in June 2022 to market generic LINZESS (Linaclotide) 72 mcg capsules, which is publicly available in FDA's Orange Book at: https://tinyurl.com/4x6j4cs4. Teva's applications to market the other two strengths, 145 mcg and 290 mcg capsules, are pending. Teva Pharmaceuticals USA, Inc. holds the marketing rights for Teva's generic Linaclotide capsules. As the sole first filer on 72 mcg capsules, Teva has a 180-day statutory exclusivity period on that strength. Under its settlement agreement, Teva anticipates that its Linaclotide capsules will enter the market on March 31, 2029. Because of patents protecting the innovator drug and confidential settlement agreements, Teva does not anticipate that other generic Linaclotide capsules of any strength will enter the market before this date.

8. Teva's application to market generic XIFAXAN (Rifaximin) 550 mg tablets is pending. Teva Pharmaceuticals USA, Inc. holds the marketing rights for Teva's generic Rifaximin 550 mg tablets. Teva has not applied to market the other strength, 200 mg. Under its settlement agreement, Teva anticipates that its generic Rifaximin 550 mg tablets will enter the market on January 1, 2028. FDA determined that Teva has an 180-day exclusivity period to market generic Rifaximin 550 mg tablets.

9. FDA approved Teva's application (ANDA No. 211897) in August 2022 to market generic OTEZLA (Apremilast) tablets in 10, 20, and 30 mg

strengths,[*] which is publicly available in FDA's Orange Book at: https://tinyurl.com/bp93pknh. Teva Pharmaceuticals USA, Inc. holds the marketing rights for Teva's generic Apremilast tablets. Under its settlement agreement, Teva anticipates that its generic Apremilast tablets will enter the market in August 2028.

10. My previous declaration explained that Teva has a pending application to market generic XARELTO (Rivaroxaban) tablets in 10, 15, and 20 mg strengths, which Teva expects to market starting on March 15, 2027 and anticipates will be among the first to market for those strengths. Groff Decl. ¶ 24. Teva Pharmaceuticals USA, Inc. holds the marketing rights for Teva's generic Rivaroxaban tablets. CMS selected XARELTO for the first year of the Drug Price Negotiation Program, IPAY 2026.

11. XARELTO is also available in a 2.5 mg strength, which Teva has not applied to market. XARELTO 2.5 mg tablets were protected by different patents than the other strengths. One patent on the 2.5 mg strength expired in February 2025. *See* FDA Letter (June 2022), https://tinyurl.com/2w4hvn2m. The Patent Trial and Appeals Board also found certain claims in a different patent protecting the 2.5 mg strength unpatentable. *Mylan Pharms. Inc. v. Bayer Pharma Aktiengesellschaft*, No. IPR2022-00517, 2023 WL 5110340, at *18 (P.T.A.B. July

[*] In August 2025, FDA approved an OTEZLA extended release 75 mg tablet.

28, 2023), *aff'd in part, vacated in part, and remanded, sub nom.*, *Bayer Pharma Aktiengesellschaft v. Mylan Pharms. Inc.*, 152 F.4th 1400 (Fed. Cir. 2025). Generic Rivaroxaban 2.5 mg tablets launched "at risk" in March 2025 while an appeal of the Patent Trial and Appeals Board's ruling was pending. On November 25, 2025, CMS announced that it had determined that generic Rivaroxaban "is being bona fide marketed" such that the price cap on all XARELTO strengths would terminate on December 31, 2026. *See* CMS Memo (Nov. 25, 2025), https://perma.cc/V3E2-658D.

I declare under penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct.

DocuSigned by:
Carrie Groff
6F8E8416229842A...

Carrie Groff

January 9, 2026

## 42 U.S.C. § 1320f-1. Selection of negotiation-eligible drugs as selected drugs

### (a) IN GENERAL

Not later than the selected drug publication date with respect to an initial price applicability year, in accordance with subsection (b), the Secretary shall select and publish a list of—

**(1)** with respect to the initial price applicability year 2026, 10 negotiation-eligible drugs described in subparagraph (A) of subsection (d)(1), but not subparagraph (B) of such subsection, with respect to such year (or, all (if such number is less than 10) such negotiation-eligible drugs with respect to such year);

**(2)** with respect to the initial price applicability year 2027, 15 negotiation-eligible drugs described in subparagraph (A) of subsection (d)(1), but not subparagraph (B) of such subsection, with respect to such year (or, all (if such number is less than 15) such negotiation-eligible drugs with respect to such year);

**(3)** with respect to the initial price applicability year 2028, 15 negotiation-eligible drugs described in subparagraph (A) or (B) of subsection (d)(1) with respect to such year (or, all (if such number is less than 15) such negotiation-eligible drugs with respect to such year); and

**(4)** with respect to the initial price applicability year 2029 or a subsequent year, 20 negotiation-eligible drugs described in subparagraph (A) or (B) of subsection (d)(1), with respect to such year (or, all (if such number is less than 20) such negotiation-eligible drugs with respect to such year).

Subject to subsection (c)(2) and section 1320f-3(f)(5) of this title, each drug published on the list pursuant to the previous sentence and subsection (b)(3) shall be subject to the negotiation process under section 1320f-3 of this title for the negotiation period with respect to such initial price applicability year (and the renegotiation process under such section as applicable for any subsequent year during the applicable price applicability period).

### (b) SELECTION OF DRUGS

#### (1) IN GENERAL

In carrying out subsection (a), subject to paragraph (2), the Secretary shall, with respect to an initial price applicability year, do the following:

**(A)** Rank negotiation-eligible drugs described in subsection (d)(1) according to the total expenditures for such drugs under parts B and D of

subchapter XVIII, as determined by the Secretary, during the most recent period of 12 months prior to the selected drug publication date (but ending not later than October 31 of the year prior to the year of such drug publication date), with respect to such year, for which data are available, with the negotiation-eligible drugs with the highest total expenditures being ranked the highest.

**(B)** Select from such ranked drugs with respect to such year the negotiation-eligible drugs with the highest such rankings.

***

**(c) SELECTED DRUG**

**(1) IN GENERAL**

For purposes of this part, in accordance with subsection (e)(2) and subject to paragraph (2), each negotiation-eligible drug included on the list published under subsection (a) with respect to an initial price applicability year shall be referred to as a "selected drug" with respect to such year and each subsequent year beginning before the first year that begins at least 9 months after the date on which the Secretary determines at least one drug or biological product--

**(A)** is approved or licensed (as applicable)--

**(i)** under section 355(j) of Title 21 using such drug as the listed drug; or

**(ii)** under section 262(k) of this title using such drug as the reference product; and

**(B)** is marketed pursuant to such approval or licensure.

**(2) CLARIFICATION**

A negotiation-eligible drug--

**(A)** that is included on the list published under subsection (a) with respect to an initial price applicability year; and

**(B)** for which the Secretary makes a determination described in paragraph (1) before or during the negotiation period with respect to such initial price applicability year;

shall not be subject to the negotiation process under section 1320f-3 of this title with respect to such negotiation period and shall continue to be considered a selected drug under this part with respect to the number of

negotiation-eligible drugs published on the list under subsection (a) with respect to such initial price applicability year.

**(d) NEGOTIATION-ELIGIBLE DRUG**

**(1) IN GENERAL** For purposes of this part, subject to paragraph (2), the term "negotiation-eligible drug" means, with respect to the selected drug publication date with respect to an initial price applicability year, a qualifying single source drug, as defined in subsection (e), that is described in either of the following subparagraphs (or, with respect to the initial price applicability year 2026 or 2027, that is described in subparagraph (A)):

**(A) Part D high spend drugs**

The qualifying single source drug is, determined in accordance with subsection (e)(2), among the 50 qualifying single source drugs with the highest total expenditures under part D of subchapter XVIII, as determined by the Secretary in accordance with paragraph (3), during the most recent 12-month period for which data are available prior to such selected drug publication date (but ending no later than October 31 of the year prior to the year of such drug publication date).

**(B) Part B high spend drugs**

The qualifying single source drug is, determined in accordance with subsection (e)(2), among the 50 qualifying single source drugs with the highest total expenditures under part B of subchapter XVIII, as determined by the Secretary in accordance with paragraph (3), during such most recent 12-month period, as described in subparagraph (A).

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**(3) CLARIFICATIONS AND DETERMINATIONS**

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**(B) Use of data**

In determining whether a qualifying single source drug satisfies any of the criteria described in paragraph (1) or (2), the Secretary 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, and not based on the specific formulation or package size or package type of the drug.

**(e) QUALIFYING SINGLE SOURCE DRUG**

**(1) IN GENERAL**

For purposes of this part, the term "qualifying single source drug" means, with respect to an initial price applicability year, subject to paragraphs (2) and (3), a covered part D drug (as defined in section 1395w-102(e) of this title) that is described in any of the following or a drug or biological product for which payment may be made under part B of subchapter XVIII that is described in any of the following:

**(A) Drug products**

A drug—

**(i)** that is approved under section 355(c) of title 21 and is marketed pursuant to such approval;

**(ii)** for which, as of the selected drug publication date with respect to such initial price applicability year, at least 7 years will have elapsed since the date of such approval; and

**(iii)** that is not the listed drug for any drug that is approved and marketed under section 355(j) of such title.

**(B) Biological products** A biological product—

**(i)** that is licensed under section 262(a) of this title and is marketed under section 262 of this title;

**(ii)** for which, as of the selected drug publication date with respect to such initial price applicability year, at least 11 years will have elapsed since the date of such licensure; and

**(iii)** that is not the reference product for any biological product that is licensed and marketed under section 262(k) of this title.

***

## 42 U.S.C. § 1320f-2. Manufacturer agreements

### (a) IN GENERAL

For purposes of section 1320f(a)(2) of this title, the Secretary shall enter into agreements with manufacturers of selected drugs with respect to a price applicability period, by not later than February 28 following the selected drug publication date with respect to such selected drug, under which—

**(1)** during the negotiation period for the initial price applicability year for the selected drug, the Secretary and the manufacturer, in accordance with section 1320f-3 of this title, negotiate to determine (and, by not later than the last date of such period, agree to) a maximum fair price for such selected drug of the manufacturer in order for the manufacturer to provide access to such price—

**(A)** to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (A) of section 1320f(c)(2) of this title and are dispensed such drug (and to pharmacies, mail order services, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed such drugs) during, subject to paragraph (2), the price applicability period; and

**(B)** to hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (B) of such section and are furnished or administered such drug during, subject to paragraph (2), the price applicability period;

***

**(3)** subject to subsection (d), access to the maximum fair price (including as renegotiated pursuant to paragraph (2)), with respect to such a selected drug, shall be provided by the manufacturer to—

**(A)** maximum fair price eligible individuals, who with respect to such drug are described in subparagraph (A) of section 1320f(c)(2) of this title, at the pharmacy, mail order service, or other dispenser at the point-of-sale of such drug (and shall be provided by the manufacturer to the pharmacy, mail order service, or other dispenser, with respect to such maximum fair price eligible individuals who are dispensed such drugs), as described in paragraph (1)(A) or (2)(A), as applicable; and

**(B)** hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with

respect to such drug are described in subparagraph (B) of such section and are furnished or administered such drug, as described in paragraph (1)(B) or (2)(B), as applicable;

***

**(b) AGREEMENT IN EFFECT UNTIL DRUG IS NO LONGER A SELECTED DRUG**

An agreement entered into under this section shall be effective, with respect to a selected drug, until such drug is no longer considered a selected drug under section 1320f-1(c) of this title.

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## 42 U.S.C. § 1320f-3. Negotiation and renegotiation process

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### (b) NEGOTIATION PROCESS REQUIREMENTS

#### (1) METHODOLOGY AND PROCESS

The Secretary shall develop and use a consistent methodology and process, in accordance with paragraph (2), for negotiations under subsection (a) that aims to achieve the lowest maximum fair price for each selected drug.

***

### (c) CEILING FOR MAXIMUM FAIR PRICE

#### (1) GENERAL CEILING

##### (A) IN GENERAL

The maximum fair price negotiated under this section for a selected drug, with respect to the first initial price applicability year of the price applicability period with respect to such drug, shall not exceed the lower of the amount under subparagraph (B) or the amount under subparagraph (C).

***

#### (4) EXTENDED-MONOPOLY DRUG DEFINED

##### (A) IN GENERAL

In this part, subject to subparagraph (B), the term "extended-monopoly drug" means, with respect to an initial price applicability year, a selected drug for which at least 12 years, but fewer than 16 years, have elapsed since the date of approval of such drug under section 355(c) of title 21 or since the date of licensure of such drug under section 262(a) of this title, as applicable.

***

#### (5) LONG-MONOPOLY DRUG DEFINED

##### (A) IN GENERAL

In this part, subject to subparagraph (B), the term "long-monopoly drug" means, with respect to an initial price applicability year, a selected drug for which at least 16 years have elapsed since the date of approval of such drug under section 355(c) of title 21 or since the date

of licensure of such drug under section 262(a) of this title, as applicable.

***

**(e) FACTORS**

For purposes of negotiating the maximum fair price of a selected drug under this part with the manufacturer of the drug, the Secretary shall consider the following factors, as applicable to the drug, as the basis for determining the offers and counteroffers under subsection (b) for the drug:

**(1) MANUFACTURER-SPECIFIC DATA**

The following data, with respect to such selected drug, as submitted by the manufacturer:

**(A)** Research and development costs of the manufacturer for the drug and the extent to which the manufacturer has recouped research and development costs.

**(B)** Current unit costs of production and distribution of the drug.

**(C)** Prior Federal financial support for novel therapeutic discovery and development with respect to the drug.

**(D)** Data on pending and approved patent applications, exclusivities recognized by the Food and Drug Administration, and applications and approvals under section 355(c) of title 21 or section 262(a) of this title for the drug.

**(E)** Market data and revenue and sales volume data for the drug in the United States.

***

## 42 U.S.C. § 1320f-5. Administrative duties and compliance monitoring

### (a) ADMINISTRATIVE DUTIES

For purposes of section 1320f(a)(4) of this title, the administrative duties described in this section are the following:

***

**(2)** The establishment of 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.

***

## 42 U.S.C. § 1320f-6. Civil monetary penalties

### (a) VIOLATIONS RELATING TO OFFERING OF MAXIMUM FAIR PRICE

Any manufacturer of a selected drug that has entered into an agreement under section 1320f-2 of this title, with respect to a year during the price applicability period with respect to such drug, that does not provide access to a price that is equal to or less than the maximum fair price for such drug for such year—

**(1)** to a maximum fair price eligible individual who with respect to such drug is described in subparagraph (A) of section 1320f(c)(2) of this title and who is dispensed such drug during such year (and to pharmacies, mail order services, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed such drugs); or

**(2)** to a hospital, physician, or other provider of services or supplier with respect to maximum fair price eligible individuals who with respect to such drug is described in subparagraph (B) of such section and is furnished or administered such drug by such hospital, physician, or provider or supplier during such year;

shall be subject to a civil monetary penalty equal to ten times the amount equal to the product of the number of units of such drug so furnished, dispensed, or administered during such year and the difference between the price for such drug made available for such year by such manufacturer with respect to such individual or hospital, physician, provider of services, or supplier and the maximum fair price for such drug for such year.

***

**42 U.S.C. § 1320f-7. Limitation on administrative and judicial review**

There shall be no administrative or judicial review of any of the following:

**(1)** The determination of a unit, with respect to a drug or biological product, pursuant to section 1320f(c)(6) of this title.

**(2)** The selection of drugs under section 1320f-1(b) of this title, the determination of negotiation-eligible drugs under section 1320f-1(d) of this title, and the determination of qualifying single source drugs under section 1320f-1(e) of this title the application of section 1320f-1(f) of this title,.

**(3)** The determination of a maximum fair price under subsection (b) or (f) of section 1320f-3 of this title.

**(4)** The determination of renegotiation-eligible drugs under section 1320f-3(f)(2) of this title and the selection of renegotiation-eligible drugs under section 1320f-3(f)(3) of this title.

**26 U.S.C. § 5000D. Designated drugs during noncompliance periods**

**(a) IN GENERAL.**--There is hereby imposed on the sale by the manufacturer, producer, or importer of any designated drug during a day described in subsection (b) a tax in an amount such that the applicable percentage is equal to the ratio of--

**(1)** such tax, divided by

**(2)** the sum of such tax and the price for which so sold.

***

**(c) SUSPENSION OF TAX.--**

**(1) IN GENERAL.**--A day shall not be taken into account as a day during a period described in subsection (b) if such day is also a day during the period--

**(A)** beginning on the first date on which--

**(i)** the notice of terminations of all applicable agreements of the manufacturer have been received by the Secretary of Health and Human Services, and

**(ii)** none of the drugs of the manufacturer of the designated drug are covered by an agreement under section 1860D-14A or 1860D-14C of the Social Security Act, and

**(B)** ending on the last day of February following the earlier of--

**(i)** the first day after the date described in subparagraph (A) on which the manufacturer enters into any subsequent applicable agreement, or

**(ii)** the first date any drug of the manufacturer of the designated drug is covered by an agreement under section 1860D-14A or 1860D-14C of the Social Security Act.

**(2) APPLICABLE AGREEMENT.**--For purposes of this subsection, the term "applicable agreement" means the following:

**(A)** An agreement under--

**(i)** the Medicare coverage gap discount program under section 1860D-14A of the Social Security Act, or

**(ii)** the manufacturer discount program under section 1860D-14C of such Act.

**(B)** A rebate agreement described in section 1927(b) of such Act.

**(d) APPLICABLE PERCENTAGE.**--For purposes of this section, the term "applicable percentage" means--

**(1)** in the case of sales of a designated drug during the first 90 days described in subsection (b) with respect to such drug, 65 percent,

**(2)** in the case of sales of such drug during the 91st day through the 180th day described in subsection (b) with respect to such drug, 75 percent,

**(3)** in the case of sales of such drug during the 181st day through the 270th day described in subsection (b) with respect to such drug, 85 percent, and

**(4)** in the case of sales of such drug during any subsequent day, 95 percent.

**(e) DEFINITIONS.**--For purposes of this section--

**(1) DESIGNATED DRUG.**--The term "designated drug" means any negotiation-eligible drug (as defined in section 1192(d) of the Social Security Act) included on the list published under section 1192(a) of such Act which is manufactured or produced in the United States or entered into the United States for consumption, use, or warehousing.

***

## 42 U.S.C. § 1395w-102. Prescription drug benefits

***

### (e) COVERED PART D DRUG DEFINED

#### (1) IN GENERAL

Except as provided in this subsection, for purposes of this part, the term "covered part D drug" means--

**(A)** a drug that may be dispensed only upon a prescription and that is described in subparagraph (A)(i), (A)(ii), or (A)(iii) of section 1396r-8(k)(2) of this title;

***

## 42 U.S.C. § 1396r-8. Payment for covered outpatient drugs

***

### (k) DEFINITIONS

In this section--

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#### (2) COVERED OUTPATIENT DRUG

Subject to the exceptions in paragraph (3), the term "covered outpatient drug" means--

**(A)** of those drugs which are treated as prescribed drugs for purposes of section 1396d(a)(12) of this title, a drug which may be dispensed only upon prescription (except as provided in paragraph (4)), and--

**(i)** which is approved for safety and effectiveness as a prescription drug under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act or which is approved under section 505(j) of such Act;

***

## 21 U.S.C. § 355. New drugs

### (a) NECESSITY OF EFFECTIVE APPROVAL OF APPLICATION

No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug.

***

### (c) PERIOD FOR APPROVAL OF APPLICATION; PERIOD FOR, NOTICE, AND EXPEDITION OF HEARING; PERIOD FOR ISSUANCE OF ORDER

***

**(3)** The approval of an application filed under subsection (b) which contains a certification required by paragraph (2) of such subsection shall be made effective on the last applicable date determined by applying the following to each certification made under subsection (b)(2)(A):

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**(E)**

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**(ii)** If an application submitted under subsection (b) for a drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under subsection (b), is approved after September 24, 1984, no application which refers to the drug for which the subsection (b) application was submitted and for which the investigations described in subsection (b)(1)(A)(i) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted may be submitted under subsection (b) before the expiration of five years from the date of the approval of the application under subsection (b), except that such an application may be submitted under subsection (b) after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in clause (iv) of subsection (b)(2)(A). The approval of such an application shall be made effective in accordance with this paragraph except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months

after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (C) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

**(iii)** If an application submitted under subsection (b) for a drug, which includes an active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) that has been approved in another application approved under subsection (b), is approved after September 24, 1984, and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under subsection (b) for the conditions of approval of such drug in the approved subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) if the investigations described in subsection (b)(1)(A)(i) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

**(iv)** If a supplement to an application approved under subsection (b) is approved after September 24, 1984, and the supplement contains reports of new clinical investigations (other than bioavailabilty studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under subsection (b) for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) if the investigations described in subsection (b)(1)(A)(i) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

***

**(5)(A)** The Secretary may rely upon qualified data summaries to support the approval of a supplemental application, with respect to a qualified indication for a drug, submitted under subsection (b), if such supplemental application complies with subparagraph (B).

**(B)** A supplemental application is eligible for review as described in subparagraph (A) only if--

**(i)** there is existing data available and acceptable to the Secretary demonstrating the safety of the drug; and

**(ii)** all data used to develop the qualified data summaries are submitted to the Secretary as part of the supplemental application.

***

**(j) ABBREVIATED NEW DRUG APPLICATIONS**

**(1)** Any person may file with the Secretary an abbreviated application for the approval of a new drug.

**(2)(A)** An abbreviated application for a new drug shall contain--

**(i)** information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7) (hereinafter in this subsection referred to as a "listed drug");

**(ii)(I)** if the listed drug referred to in clause (i) has only one active ingredient, information to show that the active ingredient of the new drug is the same as that of the listed drug;

**(II)** if the listed drug referred to in clause (i) has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or

**(III)** if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the other active ingredients of the new drug are the same as the active ingredients of the listed drug, information to show that the different active ingredient is an active ingredient of a listed drug or of a drug which does not meet the requirements of section 321(p) of this title, and such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

**(iii)** information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

**(iv)** information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

**(v)** information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

**(vi)** the items specified in clauses (ii) through (vi) of subsection (b)(1)(A);

**(vii)** a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c)--

**(I)** that such patent information has not been filed,

**(II)** that such patent has expired,

**(III)** of the date on which such patent will expire, or

**(IV)** that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

**(viii)** if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) for a method of use patent which

does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).

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**(4)** Subject to paragraph (5), the Secretary shall approve an application for a drug unless the Secretary finds--

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**(B)** information submitted with the application is insufficient to show that each of the proposed conditions of use have been previously approved for the listed drug referred to in the application;

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**(5)** ***

**(B)** The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined by applying the following to each certification made under paragraph (2)(A)(vii):

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**(iv) 180-DAY EXCLUSIVITY PERIOD**

**(I) EFFECTIVENESS OF APPLICATION**

Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.

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**21 C.F.R. § 314.3. Definitions**

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**(b)** The following definitions of terms apply to this part and part 320 of this chapter:

***

Active moiety is the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance.

***

Commercial marketing is the introduction or delivery for introduction into interstate commerce of a drug product described in an ANDA, outside the control of the ANDA applicant, except that the term does not include transfer of the drug product for investigational use under part 312 of this chapter or transfer of the drug product to parties identified in the ANDA for reasons other than sale. Commercial marketing includes the introduction or delivery for introduction into interstate commerce of the reference listed drug by the ANDA applicant.

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Drug product is a finished dosage form, e.g., tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients.

***

Listed drug is a new drug product that has been approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act for safety and effectiveness or under section 505(j) of the Federal Food, Drug, and Cosmetic Act, which has not been withdrawn or suspended under section 505(e)(1) through (5) or section 505(j)(6) of the Federal Food, Drug, and Cosmetic Act, and which has not been withdrawn from sale for what FDA has determined are reasons of safety or effectiveness. Listed drug status is evidenced by the drug product's identification in the current edition of FDA's "Approved Drug Products With Therapeutic Equivalence Evaluations" (the list) as an approved drug. A drug product is deemed to be a listed drug on the date of approval for the NDA or ANDA for that drug product.

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## CERTIFICATE OF SERVICE

I certify that on January 9, 2026, the foregoing was electronically filed through this Court's CM/ECF system, which will send a notice of filing to all registered users.

/s/ Sean Marotta
Sean Marotta