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

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| TEVA PHARMACEUTICALS USA, INC., *et al.*,<br><br>*Plaintiffs*,<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.* | No. 1:25-cv-00113-SLS |

**PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT**

Plaintiffs Teva Pharmaceuticals USA, Inc.; Teva Branded Pharmaceutical Products R&D LLC; and Teva Neuroscience, Inc. move for summary judgment. Fed. R. Civ. P. 56. In support of their motion, Plaintiffs submit the accompanying memorandum of law, declaration of Dell Faulkingham, and declaration of Carrie Groff. A proposed order is also attached.

Respectfully submitted,

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March 7, 2025

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

TEVA PHARMACEUTICALS USA, INC., *et al.*,

*Plaintiffs*,

v.

ROBERT F. KENNEDY JR., in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, *et al*.,

*Defendants.*

No. 1:25-cv-00113-SLS

**MEMORANDUM IN SUPPORT OF TEVA'S MOTION FOR SUMMARY JUDGMENT**

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## INTRODUCTION

The prescription-drug ecosystem rests on a delicate balance. The Centers for Medicare & Medicaid Services (CMS) has upset that balance through its unlawful implementation of the Inflation Reduction Act's (IRA) Drug Price Negotiation Program. CMS's extra-textual interpretations have usurped Congress's power and allowed CMS to select more drug products for the Program than the IRA's text dictates and subject those products to the Program's price controls for longer than the IRA's text allows. This case is therefore about CMS's unlawful actions, not just the underlying IRA.

Innovator medicines cost tremendous amounts of capital and other resources to develop, and for those investments to continue, manufacturers must recover the costs of developing not just the medicines that make it to market, but also the vast majority of drug candidates that end up being dead ends. Manufacturers receive patents and regulatory exclusivities for drug products that allow them to recoup their investments, incentivizing continued innovation. Generic versions of the innovator manufacturer's drugs are then permitted to enter the market, benefitting patients and payors alike by cutting costs and creating a more diverse and robust supply chain. This carefully calibrated ecosystem fosters a virtuous cycle: Patents and regulatory exclusivities incentivize manufacturers to develop innovator medicines and recoup their investments, generic competition drives down prices and makes supply more diverse and resilient, and the inevitability of generic competition incentivizes innovator manufacturers to continue developing new medicines for patients' unmet needs.

CMS's arbitrary efforts to implement the Drug Price Negotiation Program supplant that virtuous cycle with central planning, throwing the prescription-drug ecosystem into disarray. CMS's actions violate both the IRA and the Administrative Procedure Act (APA). The Program tasks CMS with imposing price controls—called "maximum fair prices" and reached through a

faux "negotiation"—on innovator manufacturers, forcing them to sell their drugs under Medicare Parts B and D at cut-rate prices. And CMS's implementing Guidance drastically expands the Program's already broad reach. The statute limits the Program to drugs that have been on the market for at least seven years. CMS, however, rewrote that limitation so that it can control the price for a *new* drug as soon as it hits the market—so long as that new drug shares an active moiety with one of the manufacturer's previously approved drugs. The statute also requires the price control to end once a generic competitor enters the market. But CMS has adopted a "bona fide marketing" standard that distorts this feature of the statute as well: CMS uses inherently time-delayed data to make its own subjective determination about whether a generic has been sufficiently "marketed" to sunset the price control, guaranteeing that some innovator drugs will remain subject to price controls despite timely generic entry.

Despite the Program's label, there is no real "negotiation" here: Declining CMS's "offer" subjects a manufacturer to exorbitant penalties, which the manufacturer can avoid only by withdrawing *all of its products* from Medicare and Medicaid, which no rational manufacturer can or would do. Moreover, the statute authorizes CMS to dictate whether a drug qualifies for "negotiation" and what constitutes a "fair price," without notice-and-comment and without judicial checks; the statute explicitly bars judicial or administrative review of those decisions.

CMS's price controls do not just damage the innovator medicines to which they directly apply; they also harm the generic products that would otherwise compete with those innovator medicines absent CMS's market intervention. Because generics are therapeutically equivalent to their innovator counterparts, they obtain market share through price competition. When an innovator medicine is price controlled, any generic manufacturer is similarly restricted, leaving it

with little or no ability to compete. The bottom line: less innovation, less competition, and a weaker supply chain, leaving American patients worse-off.

Teva understands these lessons better than anyone. Teva is a leading global pharmaceutical company that offers over 3,600 medicines and serves more than 200 million patients. Unlike many manufacturers, Teva develops both innovator therapies as well as high-quality and lower-cost generic medicines[1] that compete with innovator medicines—lowering costs for patients and the healthcare system. Teva's innovative and life-saving work requires tremendous investment: Teva spends billions of dollars on research and development, much of which is devoted to generic development. Teva receives patents on its innovator drugs and often receives temporary exclusivity for its first-to-market generic drugs. Teva has historically been able to capture significant portions of the generic market because it has been able to offer its generics at significant discounts to innovator drugs. Teva thus participates in the virtuous cycle: Teva's patents on its innovator medicines, alongside regulatory exclusivity periods, allow Teva to recoup its research-and-development investments and continue innovating. And Teva's generics compete with innovator products to increase supply and bring down prices for patients.

Enter the Drug Price Negotiation Program. CMS selected two of Teva's innovator drugs, AUSTEDO and AUSTEDO XR, for "negotiation" and price controls starting in 2027, even though AUSTEDO XR has been approved for only two years—far less than the seven years explicitly required by the IRA to subject a drug to price-controls. And CMS has selected six other non-Teva innovator drugs for the Program, with the result that Teva's generic versions of these same products will be forced to compete with artificially low innovator prices—depriving Teva of the ability to obtain market share by offering discounts to patients, and all without any

[1] Unless otherwise noted, we use "generic" to refer to both generic drugs and biosimilars.

chance for Teva to be heard. Teva has planned and invested in the development of these drugs for *years*. Yet CMS's implementation of the Program stands to disrupt Teva's investment-backed expectations by dictating the value of patented drugs like AUSTEDO XR during its critical exclusivity period and limiting Teva's ability to recoup its investment in licensing and developing effective generics. Teva must make decisions on the future of those generic launches *now*, and Teva is harmed each day that the Program and CMS's unlawful implementation of it remain in effect.

CMS's Guidance and the Program are unlawful several times over. By supplying its own definitions of a "qualified single source drug" and "marketed," CMS contradicts the IRA and exceeds its authority, in violation of the APA. And the Program denies drug manufacturers due process by stripping them of protected property interests without a meaningful opportunity to be heard or sufficient protections against erroneous deprivations of those interests. As part of the so-called negotiation, Teva will be forced to provide a counteroffer to CMS on the "maximum fair price" for AUSTEDO and AUSTEDO XR by June 30, 2025—even though the IRA prohibited CMS from selecting AUSTEDO XR in the first place. CMS's Guidance—and the Program as a whole—should be set aside and enjoined.

## STATUTORY AND REGULATORY BACKGROUND

### A. Medicare and FDA's Drug-Approval Process

"The federal government dominates the healthcare market" and "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). Within that market, Medicare is the largest healthcare program with 68 million members overall—20% of the U.S. population. CMS, *Medicare Enrollment Dashboard*, https://tinyurl.com/4arr9tpr (last visited Mar. 5, 2025). That program pays for prescription drugs in two ways. Medicare Part B covers prescription drugs administered at a doctor's office or in a

hospital outpatient setting, and for those who opt into it, Medicare Part D covers self-administered prescription drugs dispensed through pharmacies. CMS, *Parts of Medicare*, Medicare.gov, https://tinyurl.com/2pujvb9w (last visited Mar. 5, 2025).

Innovator manufacturers invest billions annually to discover, develop, and improve medicines that benefit Medicare patients. In light of FDA's arduous approval process, manufacturers must continually make difficult decisions about which new therapies and innovations to existing therapies to pursue, to subject to preclinical testing and clinical trials, and to ultimately submit for approval through a New Drug Application (NDA).[2] 21 U.S.C. § 355(b).

The average cost of this process is more than $2.5 billion for each new drug and often takes 10 to 15 years. *See, e.g.*, PhRMA, *Research & Development Policy Framework* https://perma.cc/7YKB-CUQN. The odds of approval are exceedingly low, and even then, there is no guarantee that manufacturers will recoup their costs: Just one-third of approved therapies manage to cover their cost of development, much less provide an economic return significant enough to allow for continued investment and innovation. *See* John A. Vernon et al., *Drug Development Costs When Financial Risk Is Measured Using the Fama-French Three-Factor Model*, 19 J. Health Econ. 1002, 1004 (2009).

Congress has established various patent and regulatory exclusivity periods during which innovator drugs are protected from generic competition, encouraging manufacturers to invest the substantial time and money needed to develop new drug products. *See, e.g.*, 21 U.S.C. § 355(c)(3)(E). These periods enable the manufacturer to commercialize the new medicine and

[2] A similarly rigorous process exists for biological products, which are approved pursuant to a Biologics License Application (BLA). *See* 42 U.S.C. § 262(a).

to recoup not only its investment in that therapy but also to generate the revenue needed to cover the costs of pursuing all of the products that never make it to approval.

**B. Generic Competition**

Federal law also provides a path for generic products to enter the market and reduce prices through competition: a generic manufacturer can file an Abbreviated New Drug Application (ANDA) with FDA, relying on the showings of safety and efficacy already made by the innovator manufacturer's NDA. *See* 21 U.S.C. § 355(j)(2)(A)(ii), (iv). The ANDA thus piggybacks off its corresponding NDA by certifying that "the generic has the 'same active ingredients as,' and is 'biologically equivalent' to, the already-approved brand-name drug." *FTC v. Actavis, Inc.*, 570 U.S. 136, 142 (2013) (citation omitted).

For drugs that enjoy patent protection, the Hatch-Waxman Act requires the applicant to identify every patent claiming the drug or its use that could reasonably be asserted in an infringement action related to the drug. 21 U.S.C. § 355(b)(1). FDA lists the identified patents in the "Orange Book." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405-406 (2012). FDA cannot authorize the marketing of a generic drug that would infringe an unexpired patent. *Id.* at 405. An ANDA applicant therefore must make specific certifications about each patent listed in the Orange Book that relates to its applied-for drug. 21 U.S.C. § 355(j)(2)(A)(vii), (viii); *see Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1318 (Fed. Cir. 2012). One example is a "paragraph IV certification," stating that the patents are "invalid or will not be infringed by the manufacture, use, or sale of the [generic] drug." 21 U.S.C. § 355(j)(2)(A)(vii)(IV), (j)(2)(B). An ANDA applicant making a Paragraph IV certification must notify the original NDA holder and patent owner of the certification; that, in turn, constitutes a technical act of patent infringement. *See id.*; *Caraco*, 566 U.S. at 406. The patent owner can then sue for infringement. 21 U.S.C. § 271(e)(2)(A); *Bayer*, 676 F.3d at 1318-

19. These cases may settle with an agreement that the generic manufacturer may enter the market before the patent expires. *See, e.g.*, Carrie Groff Decl. ¶¶ 22, 24-27.

The abbreviated ANDA approval pathway "speeds the introduction of low-cost generic drugs to market" and "thereby further[s] drug competition." *Actavis*, 570 U.S. at 142 (citation and brackets omitted). Those cost savings are enormous: In the last decade, generic drugs have saved patients and the healthcare system over $3 trillion—including $445 billion in 2023 alone. Ass'n for Accessible Meds., *The 2024 U.S. Generic & Biosimilar Medicines Savings Report Fact Sheet* (Sept. 2024), https://perma.cc/3FNK-FAL4. And cost-savings are not the only benefit: Generics also strengthen the healthcare system by increasing the available sources for a medicine, which "can help stabilize the supply." FDA, *Generic Drugs Can Help Promote Health Equity*, www.fda.gov/media/173765/download.

Critically, however, the "generic industry's financial viability" depends on whether manufacturers can "expect to generate sufficient volume and revenue to justify entering the market." Dana Goldman et al., *Mitigating the Inflation Reduction Act's Adverse Impacts on the Prescription Drug Market*, at 5 (Apr. 2023), https://perma.cc/FT4K-2JGW. To incentivize prompt generic entry, the first generic that files an ANDA with a paragraph IV certification receives 180 days of exclusivity during which no other generic can compete with either the first-filed generic or the innovator drug. *Actavis*, 570 U.S. at 143-144; *see* 21 U.S.C. § 355(j)(5)(B)(iv). But because generics are by definition equivalent to innovator drugs, even first-filed generics must compete with innovator drugs almost exclusively on price—both during and after the 180-day exclusivity period. That price competition by first and later-filed generics leads to lower prices overall, benefiting patients and the healthcare system more generally. *See* FDA, *Generic Competition & Drug Prices: New Evidence Linking Greater Generic Competition*

*& Lower Generic Drug Prices*, at 8 (Dec. 2019), https://www.fda.gov/media/133509/download (reporting a median "60% reduction in price" of generics compared to innovator drugs).

### C. The Medicare Drug Price Negotiation Program

In 2022, Congress enacted the Inflation Reduction Act and with it the Drug Price Negotiation Program, fundamentally transforming how prescription drug pricing works in this country. The Program authorizes CMS to bring the full coercive force of the government to bear in "negotiating" maximum prices under Medicare for a set number of drugs each year. Manufacturers that refuse to participate must pay a draconian penalty or withdraw every single one of their medicines from Medicare and Medicaid—not just the drug at issue.

***Drug Selection.*** First, the Program directs CMS to select a certain number of "negotiation-eligible" drugs for inclusion in the Program each year. 42 U.S.C. § 1320f–1(b). To be selected, a drug must be a "qualifying single source drug," which the statute defines as a "covered part D drug"—or a "drug or biological product" payable under Part B—that has been (i) FDA-approved; (ii) for at least seven years (or 11 years for biological products), and (iii) has no generic "that is approved and marketed." *Id.* § 1320f–1(e)(1). The definition of "covered part D drug" cross-references the definition for a "covered outpatient drug" under the Medicaid statute, which in turn is based on whether the product is approved pursuant to a distinct NDA or BLA. *Id.* §§ 1395w–102(e)(1)(A), 1396r–8(k)(2)(A)(i). So do the definitions of "drug product" and "biological product." *Id.* § 1320f–1(e)(1)(A)(i), (B)(i). The statute therefore defines a "qualifying single source drug" to mean individual products individually approved by FDA.

After identifying these "negotiation-eligible" drugs, the IRA directs CMS to rank the drugs in order of the highest total Medicare expenditures over a preceding 12-month period. *Id.* § 1320f–1(d)(1). The IRA directs CMS to select an increasing number of drugs for each "initial

price applicability year" (IPAY): ten drugs with the highest Part D expenditures for IPAY 2026;[3] 15 drugs with the highest Part D expenditures for IPAY 2027;[4] 15 drugs with the highest Part D or Part B expenditures for IPAY 2028; and 20 drugs with the highest Part D or Part B expenditures for IPAY 2029 and beyond. *Id.* § 1320f–1(a)-(b), (d)(1), (e).

***Price "Negotiations."*** A manufacturer whose innovator product is selected must agree to participate in what the statute calls "the negotiation period," during which CMS purportedly negotiates "a maximum fair price" with the manufacturer. *Id.* §§ 1320f–2(a), 1320f–3(a). Nothing about this negotiation mirrors a typical commercial negotiation, however. For one, negotiation is mandatory: Manufacturers must sign an agreement to participate in the negotiation process by a date certain or face draconian and escalating penalties. *See id.* §§ 1320f–2, 1320f–6(a); 26 U.S.C. § 5000D. For another, CMS is directed not to work with each drug manufacturer to reach a genuine agreement, but to use "a consistent methodology" designed to "achieve the *lowest* maximum fair price for each selected drug." 42 U.S.C. § 1320f–3(b)(1) (emphasis added). The potential "maximum fair price" is capped at a fraction of certain reference prices, but there is no lower bound, leaving CMS free to offer an initial price as low as one penny. *Id.* § 1320f–3(c)(1)(A). And although manufacturers are permitted to counteroffer under very limited statutory factors, *see id.* § 1320f–3(b)(2)(C)(ii), (e), nothing in the IRA requires CMS to accept or account for a manufacturer's counteroffer. It requires simply that CMS "respond in writing," which can include CMS reiterating its initial offer. *See id.* § 1320f–

[3] The ten selected drugs for IPAY 2026 are listed at CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026* (Aug. 2023), https://perma.cc/8KEK-AJ23 (Selected Drugs for IPAY 2026).

[4] The 15 selected drugs for IPAY 2027 are listed at CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2027* (Jan. 2025), https://perma.cc/2ZTC-PJTK (Selected Drugs for IPAY 2027).

3(b)(2)(D). And once CMS has made its final offer, the manufacturer must take it or leave it. *Id.* § 1320f–3(b)(2)(B)-(E).

After this "negotiation" concludes, the manufacturer must provide the drug at the imposed "fair price" to Medicare-eligible individuals *in perpetuity*. Except for a limited universe of circumstances, selected drugs are subject to the same negotiation price indefinitely, plus a nominal bump for inflation. *See id.* §§ 1320f–2(b), 1320f–3(f), 1320f–4(b). Any manufacturer that fails to make its drug available to Medicare beneficiaries at CMS's designated "maximum fair price" is subject to a steep penalty of ten times the price differential between the price charged and the CMS-mandated price. *Id.* § 1320f–6(a).

There is only one real way to avoid CMS's price control once the "negotiation" period has ended: A generic version of the drug must be "approved or licensed" and "marketed pursuant to such approval or licensure." *Id.* § 1320f–1(c)(1). Even then, the price control remains in effect for at least one year, and the generic must meet the "approved or licensed" and "marketed" criteria for "at least 9 months" of the year before the price control can sunset. *See id.* For example, for a drug that was selected for inclusion in the IPAY 2027 list, if a generic is "approved and marketed" between November 2, 2025—after the end of the "negotiation" period—through March 31, 2027, the innovator drug remains subject to the price cap through December 31, 2027. *See* CMS, *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191-1198 of the Social Security Act for IPAY 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027*, at 279-280 (Oct. 2, 2024), https://perma.cc/AJ33-F9U4 (2027 Guidance). If the generic is "approved and marketed" between April 1, 2027 and March 31, 2028, the innovator drug remains subject to the price cap for an extra year—through December 31, 2028. *Id.*

***Noncompliance Penalties.*** The IRA compels manufacturers of selected drugs to participate in "negotiations" and acquiesce to CMS's "maximum fair price" by a punitive, daily escalating "tax" until the manufacturer accedes to CMS's demands or the drug is deselected. 42 U.S.C. §§ 1320f–2(a), 1320f–3(a); 26 U.S.C. § 5000D. This "tax" begins at 185% of the drug's price and escalates to 1,900%. 26 U.S.C. § 5000D(a), (d); *see* Cong. Rsch. Serv., No. R47202, *Tax Provisions in the Inflation Reduction Act of 2022* (H.R. 5376), at 4 tbl. 2 (Aug. 10, 2022), https://crsreports.congress.gov/product/pdf/R/R47202.

The only way to "suspen[d]" this oppressive penalty is to acquiesce to CMS's demands or completely terminate the manufacturer's Medicare Part D agreements and its Medicaid rebate agreement for *all* of its products—not just the selected one. *See* 26 U.S.C. § 5000D(c)(1). Terminating the Medicaid rebate agreement would, in turn, render *all* of the manufacturer's products ineligible for reimbursement under Medicare Part B. 42 U.S.C. § 1396r–8(a)(1). Suspending the noncompliance penalty therefore requires nothing short of absolute withdrawal from both Medicare and Medicaid, denying the manufacturer's products to millions of patients.

No manufacturer could make that choice, as Congress well knew and intended. Congress projected the IRA's so-called tax to have "no revenue effect" because no rational manufacturer could choose to not comply and pay the penalty. Joint Comm. on Tax'n, *Estimated Budget Effects of the Revenue Provisions of Title XIII – Committee on Ways and Means, of H.R. 5376, the "Build Back Better Act"*, at 8 (Nov. 19, 2021), https://perma.cc/U9TQ-TMYS.

***Lack of Process.*** To make matters worse, the IRA deprives manufacturers of important procedural protections on both the front and back ends of this process. The statute mandates implementation by regulatory fiat, directing CMS to implement the Program through guidance that CMS has concluded does not include the protections of notice-and-comment rulemaking.

*See* 42 U.S.C. § 1320f note; 2027 Guidance at 100. Moreover, CMS—the agency with the clearest interest in obtaining the lowest price possible, no matter how "fair"—is also the agency charged with negotiating the price cap. *See* 42 U.S.C. § 1320f–3.

On the back end, manufacturers that disagree with the selection of their drug or with the price dictated by CMS have no recourse—judicial or otherwise. There is no process for manufacturers to ask CMS to reconsider its black-box decision that a product meets the definition of "qualifying single source drug" or the price cap it has set. The IRA also precludes "administrative or judicial review" for key aspects of the Program, including 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. But that bar does not apply to the claims asserted in this case.

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

Two aspects of CMS's Guidance are relevant here. *First*, CMS radically expanded the universe of drugs that are "negotiation-eligible" by overriding the statutory definition of "qualifying single source drug." The IRA makes clear that a qualifying single source drug is one single drug product, marketed under its own NDA, for at least seven years. 42 U.S.C. § 1320f–1(e)(1)(A); *see* 21 U.S.C. § 355(c); *supra* p. 8. But in the Guidance, CMS lumps together multiple drug products, marketed under separate NDAs, into a *single* qualifying single source drug. Specifically, CMS defines a qualifying single source drug as any set of drugs "with the same active moiety"[5]—including "all dosage forms and strengths"—if the NDAs are held by the same entity. 2027 Guidance at 167. Yet the term "active moiety" appears nowhere in the IRA.

[5] An active moiety is the core portion of a drug molecule that is "responsible for the [drug's] physiological or pharmacological action." 21 C.F.R. § 314.3. CMS adopted the same approach for biologics, lumping together products licensed under multiple BLAs. 2027 Guidance at 168.

CMS's extra-statutory definition greatly increases and distorts the pool of products eligible for selection. By aggregating Medicare expenditures across multiple products, CMS selects drugs that would not qualify on their own based on Medicare spend. *See* 42 U.S.C. § 1320f–1(b)(1)(A)-(B). CMS's definition also changes the selection clock for a newer drug that shares an active moiety with an earlier-approved drug: Under CMS's approach, a new drug's eligibility for selection depends on the approval date for an earlier product with the same active moiety—meaning drugs approved for less than seven years can be (and are) selected.

*Second*, CMS altered the statutory requirements for removing a drug from the Program. Under the statute, a drug is not eligible for negotiation if a generic version of that same drug has been "approved and marketed"—that is, available for purchase. *Id.* § 1320f–1(c)(1), (e)(1)(A)(iii). That is an objective yes-or-no determination: A generic drug is approved when FDA grants an ANDA for the product, and it is marketed when its manufacturer launches it in the commercial marketplace. According to CMS, however, that is not enough. Rather, the generic must be the subject of "bona fide marketing," such that "meaningful competition exists on an ongoing basis between a listed drug . . . and a generic drug." 2027 Guidance at 20, 170. This supposedly "holistic inquiry" will be based on the "totality of the circumstances" and "informed by" two specified data sources: Medicare Part D Prescription Drug Event (PDE) data and Medicaid Average Manufacturer Price (AMP) data. *Id.* at 171, 278, 293.

There are multiple problems with CMS's approach. For one, CMS has never explained what these data must show before CMS will conclude that a generic drug's marketing is "bona

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For biologics, the operative term is "same active ingredient," which has the same effect as the "same active moiety" language for small-molecule drugs. *See id.* An active ingredient "is any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals." 21 C.F.R. § 314.3.

fide." For another, both sources of data are inherently time lagged. CMS acknowledges the "time lag between" a generic drug's availability and CMS's "ability to detect it in PDE data resulting from coverage determinations and filled Part D prescriptions." *Id.* at 21. And given that Part D is generally "notably slower than commercial plans in coverage of first generics"[6] and that Medicare plans continue to block or delay coverage of new generics,[7] the initial months of PDE data reported after a drug faces generic competition reflect very limited generic uptake. Even if a plan covers the generic, plans have 30 days following the date a claim is received or the date of service, whichever is later, to submit data to CMS—causing yet further delay. 2027 Guidance at 21. The other source of data that CMS says it will look to—AMP data, or the average price wholesalers and retail pharmacies pay the manufacturer for the drug—is also inherently time lagged. *See* 42 U.S.C. § 1396r–8(b)(3)(A), (k).

CMS acknowledges that, because of this delay, it will not have relevant PDE or AMP data at the most critical juncture. CMS must decide if a generic drug's marketing is "bona fide" by March 31, 2027 to remove the innovator drug from the Program in 2028; by March 31, 2028 to remove the innovator drug from the Program in 2029; by March 31, 2029 to remove the innovator drug from the Program in 2030; and so on. 2027 Guidance at 279-280. Yet CMS concedes that it will not have any PDE or AMP data for the month of March, and no AMP data in February either. *Id.* at 278. Under CMS's approach, therefore, a generic drug launched in either February or March before the crucial March 31 cutoff has zero chance of being considered

[6] Ass'n for Accessible Meds., *New Generics Are Less Available in Medicare Than Commercial Plans: New Evidence Shows Medicare Part D Plans Continue to Fail to Get New Generics to Patients*, at 5 (July 2021), https://tinyurl.com/bdf2mzyv (capitalization altered).

[7] Ass'n for Accessible Meds., *Redesigned Medicare Drug Program Still Allows PBMs to Deny Patients Access to Lower-Cost Generics & Biosimilars* (Jan. 2025), https://perma.cc/D8VW-KMK2 ("For example, it appears to take roughly three years before new generics are covered by more than half of all Medicare drugs plans.").

"bona fide" marketed, because the data sources CMS says it will consider in making that decision will not reflect what has happened in February or March. And any generics launched earlier will have two months less time to capture whatever market share CMS might deem sufficiently "bona fide." Even for those generics that launch earlier, serious uncertainties remain about whether CMS will consider their marketing "bona fide," given CMS's amorphous standard and uncertainties in what PDE and AMP data will reflect—particularly given delays in Medicare coverage for generics and where generics launch with fewer presentations than the innovator drug, such as fewer strengths or a tablet form instead of both tablets and capsules. If CMS determines that a generic has not been "bona fide" marketed by the crucial March 31 cutoff-date, the innovator drug will be subject to price controls for the following year—forcing the generic to compete against a price-controlled innovator drug for an additional year.

Even if CMS determines that a generic has been "bona fide" marketed such that the innovator drug will be removed from the Program, CMS has stated that its "bona fide marketing" determination is an ongoing one, reserving for itself the right to change its mind at any time. "CMS will monitor the manufacturers of such generic drugs . . . to ensure they continue to engage in bona fide marketing of the generic," with the threat that the innovator drug could be added back to the Program if generic manufacturers are unable to maintain whatever part of the market CMS subjectively determines is necessary. *Id.* at 278. And all this is despite the fact that CMS's invented "bona fide" requirement appears nowhere in the statute itself.

## FACTUAL BACKGROUND

### A. Teva's Mission To Further Access To Quality Medicines

Teva is a leading global pharmaceutical company that offers over 3,600 medicines and serves more than 200 million patients. Teva, *Company Info: Teva in Facts and Figures*, https://www.tevapharm.com/our-company/teva-facts-figures/ (last visited Mar. 5, 2025). Teva

began over a century ago as a small drug wholesaler, and it has developed into an industry leader supplying patients around the world with life-improving medicines. Teva, *Improving Health Since 1901*, https://www.tevapharm.com/our-company/teva-history/ (last visited Mar. 5, 2025). Teva holds a unique position in the pharmaceutical ecosystem as both a developer of innovator therapies as well as high-quality and lower-cost generic and biosimilar medicines. Teva has invested billions of dollars in research-and-development activities across its entire portfolio of products—a significant portion of which has gone to generics, giving Teva more than a thousand generic products in its development pipeline. Groff Decl. ¶ 4.

Among the innovator drugs that Teva developed and now markets are AUSTEDO and AUSTEDO XR, which are indicated to treat two movement disorders: tardive dyskinesia, a disease associated with long-term use of antipsychotic medications; and Huntington's disease chorea, a rare, terminal genetic disease. Dell Faulkingham Decl. ¶¶ 10-11. AUSTEDO was approved by FDA in 2017 and is taken twice per day. *Id.* ¶ 10, 12. Teva then developed an extended-release, one-tablet-per-day formulation, called AUSTEDO XR, after substantial additional investments. *Id.* ¶¶ 12, 14. AUSTEDO XR uses osmotic pressure to deliver deutetrabenazine—the active ingredient—at a controlled rate throughout the day. *Id.* ¶ 12. Teva filed a distinct NDA for AUSTEDO XR, supported by additional clinical study data demonstrating that the extended-release formulation is just as effective as twice-daily dosing, which FDA approved in 2023. *Id.* ¶¶ 10, 14. AUSTEDO XR benefits patients by lessening their pill burden and helping to improve adherence in patient populations that 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. *Id.* ¶ 12.

Teva also invests hundreds of millions of dollars annually into developing and manufacturing generic medicines. Groff Decl. ¶ 5. The generics that Teva plans to launch over the next several years will provide essential competition to innovator drugs that treat serious and debilitating conditions, including advanced prostate cancer (XTANDI (Enzalutamide)); idiopathic pulmonary fibrosis (OFEV (Nintedanib)); blood clots (XARELTO (Rivaroxaban)); irritable-bowel syndrome (LINZESS (Linaclotide)), hepatic encephalopathy and irritable-bowel syndrome (XIFAXAN (Rifaximin)); and psoriatic arthritis and plaque psoriasis (OTEZLA (Apremilast)). *Id*. ¶¶ 22-27. Of these six examples, all but one are anticipated to be among the first generics to market. *Id*. ¶¶ 22(e), 23(e), 24(e), 25(e), 26(e), 27(e).

**B. The Program Harms Teva**

CMS aggregated Teva's AUSTEDO and AUSTEDO XR into one drug for purposes of selecting 15 drugs for IPAY 2027—allowing CMS to select more than the 15 distinct drugs permitted by statute. Selected Drugs for IPAY 2027, *supra*. CMS also selected five other innovator drugs—XTANDI, OFEV, LINZESS, XIFAXAN, and OTEZLA—for which Teva has developed and plans to launch generics—Enzalutamide, Nintedanib, Linaclotide, Rifaximin, and Apremilast, respectively. *Id.*; *see* Groff Decl. ¶¶ 22-23, 25-27. Another innovator drug—XARELTO—for which Teva has developed and plans to launch a generic—Rivaroxaban—was selected for IPAY 2026. Groff Decl. ¶ 24; *see* Selected Drugs for IPAY 2026, *supra*.

As a result of AUSTEDO and AUSTEDO XR having been selected for the Program, Teva will be forced to sign the negotiation "agreement" and begin "negotiating" with CMS. Faulkingham Decl. ¶ 17. By June 30, 2025, Teva will be forced to provide a "counteroffer" to CMS on the "maximum fair price" for AUSTEDO and AUSTEDO XR. Because the IRA limits counteroffers to narrow grounds that depend on the specific selected drug, *see* 42 U.S.C. § 1320f–3(e), Teva's counteroffer would necessarily be different if CMS had not unlawfully

selected AUSTEDO XR. The "maximum fair price" that CMS ultimately imposes must be made available to the Medicare program starting January 1, 2027. Faulkingham Decl. ¶ 16. Based on the statutory formula, and the prices announced for the first round of the Program, CMS's price is certain to be lower than the prevailing market price for AUSTEDO and AUSTEDO XR. 42 U.S.C. § 1320f–3(c)(1)(A). And it will almost certainly be significantly lower, if the results of the "negotiations" for IPAY 2026 are any indication. For all but one of the products selected for IPAY 2026, CMS imposed discounts of more than 50 percent; for two products, CMS imposed discounts of more than 75 percent. CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for IPAY 2026*, at 2 (Aug. 2024), https://perma.cc/CB3E-GWX3 (IPAY 2026 Results). The smallest discount was just shy of 40 percent. *Id.*

As a result of these steep discounts, Teva's upcoming generic medicines will be forced to adopt a lower price to compete against price-controlled innovator products, hindering Teva's ability to compete. Groff Decl. ¶ 29; *see also* Goldman, *supra*, at 5 ("reduced branded prices will likely also reduce generics' pricing advantage relative to Medicare's negotiated prices"). Indeed, when Teva launches its generic Rivaroxaban on March 15, 2027, it will be forced to compete against the 62-percent discount on XARELTO that CMS has imposed, *see* IPAY 2026 Results, *supra*, at 2—hamstringing Teva's ability to offer a lower price capable of recouping Teva's development costs. Groff Decl. ¶ 29. Teva's other generics will likewise enter the market against price-controlled innovator drugs. *Id.* ¶ 28. And Teva will have no opportunity to be heard before CMS on the "fair" prices for those innovator drugs, even though those prices will set the market for Teva's generics. *Id.* ¶ 31.

CMS's Guidance compounds these injuries. But for CMS's definition of qualifying single source drug aggregating distinct, separately approved drug products, AUSTEDO XR

would not have been eligible for selection because the statute requires "at least 7 years [to] have elapsed since the date of [the drug's] approval," 42 U.S.C. § 1320f–1(e)(1)(A)(ii), and the AUSTEDO XR NDA was approved just two years ago, Faulkingham Decl. ¶¶ 10, 14. CMS's definition will also force Teva's generics to compete against innovator drugs that should not have been eligible for the Program: But for CMS's definition, neither the tablet form of XTANDI nor the suspension form of XARELTO would be eligible because their NDAs have been approved for less than seven years. Groff Decl. ¶¶ 35-36. Price controls on those innovator products, over which Teva had no opportunity for input, will hinder Teva's ability to compete when it launches its generic Enzalutamide capsules and its generic Rivaroxaban tablets, depriving Teva of the significant revenues it would have earned had the tablet form of XTANDI and the suspension form of XARELTO continued to be sold in arm's-length, market-rate transactions. *Id*.

CMS's "bona fide marketing" requirement likewise harms Teva. Teva plans to launch at least some its generics mere days, weeks, or months before the crucial March 31 cutoff date for the corresponding innovator drugs to be removed from the Program for the following year. *Id*. ¶ 44. Under the IRA's plain language, these generic launches before March 31 should and would result in the innovator drugs being removed from the Program by the end of that calendar year—thus allowing Teva to compete against market prices and not artificially low controlled prices. But under CMS's standard, Teva's generics launched in the weeks and months before March 31 will not be considered "bona fide" marketed, because the only two sources of data that CMS says it will consider—PDE and AMP data—will not be available for generics launched in February and March—effectively making the cutoff January 31. *Id*. ¶ 44; *see supra* pp. 14-15. Even for Teva's generics that are expected to launch earlier, delays and limitations in PDE and AMP data

make it exceedingly unlikely that CMS will deem these generics "bona fide" marketed by March 31. Groff Decl. ¶ 44; *see supra* pp. 13-15. Moreover, Teva's generic Enzalutamide and Rifaximin products will launch with fewer presentations than the innovator drugs against which they will compete—an Enzalutamide capsule when XTANDI is available in both capsules and tablets and a 550 mg Rifaximin product when XIFAXAN is available in 200 mg and 550 mg strengths—limiting the ability of Teva's products to obtain the kind of market share that CMS might consider "meaningful competition" against all the presentations of the innovator drugs. 2027 Guidance at 20; Groff Decl. ¶ 44(c)-(d). And by creating the "bona fide" definition, CMS also creates uncertainty about whether generic launches—whenever they occur—will be sufficiently robust to remove the Program's price controls for the innovator products. As a result of these dynamics, Teva's generics will be forced to compete against price-controlled innovator drugs for a full year longer than the statute would otherwise require, depriving Teva of the revenue it otherwise would have earned.

## STANDARD OF REVIEW

The APA requires courts to "hold unlawful and set aside agency action" that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law"; "contrary to constitutional right, power, privilege, or immunity"; or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2). In so doing, courts interpret the statute de novo, using all the traditional tools of statutory interpretation. *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 403 (2024).

## STANDING

Teva's standing is self-evident because it is the "object of the action." *Maine Lobstermen's Ass'n v. NMFS*, 70 F.4th 582, 592 (D.C. Cir. 2023) (citation omitted). Both the IRA and CMS's unlawful Guidance directly regulate Teva's innovator drugs, *see* Faulkingham

Decl. ¶¶ 16-26, and "there is ordinarily little question that a regulated individual or entity has standing to challenge an allegedly illegal statute or rule under which it is regulated." *Corbett v. TSA*, 19 F.4th 478, 483 (D.C. Cir. 2021) (citation and quotation marks omitted). Teva's "drugs will be subject to the Program," "the Program will lower the price for that drug," and "the lower price will lead to lower revenue" for Teva. *National Infusion Ctr. Ass'n v. Becerra*, 116 F.4th 488, 501 (5th Cir. 2024). The IRA and CMS's Guidance also operate "to the detriment of [Teva's] bottom line," *Sherley v. Sebelius*, 610 F.3d 69, 72 (D.C. Cir. 2010), by constraining Teva's pricing power for generics against innovator drugs that are price capped. *See* Groff Decl. ¶¶ 28-49; *Energy Future Coal. v. EPA*, 793 F.3d 141, 144 (D.C. Cir. 2015) (standing where manufacturers "seek an opportunity to compete in the marketplace" and "are being denied that opportunity because of [the agency's] regulation"). These harms are traceable to CMS's definitions of "qualifying single source drug" and "bona fide marketing" as well as the IRA itself, and are redressable by an order setting aside CMS's definitions and enjoining the Program in its entirety. *See* Faulkingham Decl. ¶¶ 16-26; Groff Decl. ¶¶ 30-31, 35-36, 44-49.

## ARGUMENT

### I. CMS's Definition Of Qualifying Single Source Drug Is Unlawful.

The IRA is clear: a "qualifying single source drug" means a drug that is eligible for Medicare coverage under Part B or Part D and has been approved and marketed under its own NDA, provided that "at least 7 years will have elapsed since the date of such approval"[8] and the drug "is not the listed drug for any [generic] drug that is approved and marketed." 42 U.S.C. § 1320f–1(e)(1)(A); *see* 21 U.S.C. § 355(j). That means that two drugs, approved under two

[8] For a biologic, it must be licensed and marketed under its own BLA, provided that "at least 11 years" have elapsed since the date of licensure. 42 U.S.C. § 1320f–1(e)(1)(B). We use the terms NDA, drug, and generic to include BLAs, biologics, and biosimilars, unless otherwise specified.

separate NDAs, cannot be considered one qualifying single source drug. CMS's Guidance, however, takes the opposite position: Multiple drugs with the same active moiety are *all* treated as one "qualifying single source drug," even if they have been approved "pursuant to different NDAs" at different times. 2027 Guidance at 167. That is unlawful; CMS cannot displace Congress's choice through guidance.

**1.** Several features of the IRA make clear that Congress adopted a product-specific definition of "qualifying single source drug." Start with the most obvious: the singular nature of "qualifying single source *drug*." The statute repeatedly speaks in such language, referring to "*a* qualifying single source *drug*," "*a drug*," "*a* selected *drug*," "*a* biological *product*." Indeed, Section 1320f–1 alone repeats those terms nearly 50 times. *See, e.g.*, 42 U.S.C. § 1320f–1(e) (defining "qualifying single source drug" as "*a* drug" or "*a* biological product" that meets certain criteria) (emphases added). Collectively, those terms appear nearly 100 times across the various provisions governing the Program. *See, e.g.*, *id.* § 1320f(b)(2) (defining "price applicability period" to mean, "with respect to *a qualifying single source drug*, the period beginning with the first initial price applicability year with respect to which such drug is *a selected drug* and ending with the last year during which the drug is *a selected drug*") (emphases added).

The IRA's "text, context, and structure" confirm that when Congress said "a drug," "singular, it meant singular." *Life Techs. Corp. v. Promega Corp.*, 580 U.S. 140, 141 (2017). The IRA defines "qualifying single source drug" by reference to the Medicare statute's definition of a "covered Part D drug." 42 U.S.C. § 1320f–1(e)(1). That definition explains a covered Part D drug is "a drug that may be dispensed only upon a prescription" and that constitutes a "covered outpatient drug" under the Medicaid Drug Rebate Program. *Id.* § 1395w–102(e)(1). A covered outpatient drug, in turn, is "a drug" that has been approved or licensed by FDA under a

distinct NDA. *Id.* § 1396r–8(k)(2), (k)(7)(A)(iv); *see* 21 U.S.C. § 355; 42 U.S.C. § 262(a). When Congress "employs a term of art," it "adop[ts] the cluster of ideas that were attached to each borrowed word." *George v. McDonough*, 596 U.S. 740, 753 (2022). And this Court has agreed with CMS's position that a distinct covered outpatient " 'drug' for Medicaid rebate purposes is defined by FDA's approval of a distinct NDA." *Ipsen Biopharmaceuticals v. Azar*, No. 1:16-cv-02372, 2020 WL 3402344, at *10 (D.D.C. June 19, 2020).

Congress's cross-references to FDA's approval framework provide further confirmation that "a drug" is defined by reference to its particular NDA for purposes of the IRA's selection process. The IRA *excludes* from the definition of qualifying single source drug "the listed drug for any drug that is approved and marketed under [21 U.S.C. §] 355(j)"—meaning 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) (a drug no longer qualifies as "a selected drug" when a generic is marketed for "the listed drug"). By statute, a generic sponsor must identify a single listed drug by its individually specified NDA. *See* 21 U.S.C. § 355(j)(2) (referring to "the listed drug"). FDA, in turn, approves a generic based on the specific NDA that it references. *See, e.g.*, *id.* § 355(j)(4)(B) (requiring FDA to compare a generic's "proposed conditions of use" to those "previously approved for the listed drug referred to in the" NDA); 42 U.S.C. § 262(i)(4) (defining the "reference product" for a biologic as "the single [licensed] biological product . . . against which a biological product is evaluated"). And the generic is a generic version of that specific listed drug under its particular NDA and no other. FDA's regulations confirm that this is a product-specific inquiry that has nothing to do with whether the reference drug shares an active moiety with other products. *See* 21 C.F.R. § 314.3 (defining "[d]rug product" to mean "a finished dosage form . . . that contains a drug substance, generally, but not necessarily, in association with one or more

other ingredients," not any set of dosage forms that contain the same active moiety, regardless of their other ingredients); *id.* § 600.3 (similar, for biological products).

Other textual clues abound. The IRA defines a qualifying single source drug as one where "at least 7 years will have elapsed from *the date of such approval*." 42 U.S.C. § 1320f–1(e)(1)(A) (emphasis added). The same is true for a biological product, except that "at least 11 years . . . have elapsed since *the date of such licensure*." *Id.* § 1320f–1(e)(1)(B) (emphasis added). This language necessarily focuses on the date of a singular approval—that is, the distinct NDA, not the dates of various approvals. *See Niz-Chavez v. Garland,* 593 U.S. 155, 166 (2021) (Congress's use of "a definite article with a singular noun" refers to "a discrete thing").

**2.** "Where a statute's language carries a plain meaning, the duty of an administrative agency is to follow its commands as written, not to supplant those commands with others it may prefer." *SAS Inst., Inc. v. Iancu*, 584 U.S. 357, 363 (2018). That is the case here, and yet CMS flouted Congress's commands at every step. Rather than looking to the date of the approval for a drug, then evaluating whether it is the listed drug for a generic, CMS has decided to determine the drug's "active moiety or active ingredient"; identify "all dosage forms and strengths of the drug with the same active moiety" approved under any number of NDAs; "investigate whether" those additional NDAs "are held by the same entity" as the original NDA or are "repackaged and relabeled" by another entity; identify the "earliest date of approval" for any NDA for a product containing that active moiety; then assess whether the first NDA was issued at least seven years prior to the start of the applicable price year. *See* 2027 Guidance 167-170. As CMS candidly admits, this system could easily lead the agency to define "*a* qualifying single source drug" to encompass *twelve or more* distinct NDAs. *See id.* at 168-169 & tbl. 1 (emphasis added). Not only does this allow CMS to aggregate multiple products' Medicare expenditures for purposes of

ranking negotiation-eligible qualifying single source drugs, it also allows CMS to subject multiple products, approved under different NDAs, to the same price-control cap.

Teva's innovator drugs AUSTEDO and AUSTEDO XR highlight the differences between the IRA and CMS's Guidance. AUSTEDO's NDA was approved in August 2017; AUSTEDO XR's separate NDA was approved in April 2023. Faulkingham Decl. ¶ 10. By statute, that means that only AUSTEDO was eligible for selection for IPAY 2027. *Id.* ¶ 26. Yet CMS instead selected both AUSTEDO and AUSTEDO XR for price controls even though AUSTEDO XR has been approved and on the market for less than two years. *See id.* ¶¶ 10, 26; *see also* Groff Decl. ¶ 35 (outlining similar scenario involving XTANDI and XARELTO).

None of this makes sense. *First*, nothing in the IRA's definition of qualifying single source drug or the intricate provisions it incorporates by reference mention the term "active moiety" or "active ingredient." Indeed, the IRA does not use those terms even once across some 270-plus pages. *See generally* Pub. L. No. 117-169, 136 Stat. 1818 (Aug. 16, 2022). Nor are those terms interchangeable. As FDA has explained, "[a]n active ingredient can have different effects on the body depending on the formulation of the drug and its route of administration . . . among other things." 86 Fed. Reg. 28,605, 28,606 (May 27, 2021). "For decades," FDA has accordingly "interpreted the word 'drug' in the term 'new drug' to refer to the entire drug product and not just its active ingredient." *Id.* The Supreme Court has long agreed. *United States v. Generix Drug Corp.*, 460 U.S. 453, 454 (1983) (holding the term "drug" in the federal Food, Drug, and Cosmetic Act refers to "the entire product"—not just "the active ingredient"). Congress also understands this difference, and has passed other legislation that, unlike the IRA, focuses on whether one drug has the same "active moiety" as another. 21 U.S.C.

§ 355(c)(3)(E)(ii), (iii) (instructing FDA to look to the active moiety in assessing new chemical entry exclusivity).

*Second*, there is no textual evidence that Congress intended CMS to pick and choose between various approval dates, or to select the "earliest" one. *Contra* 2027 Guidance at 170. Congress instead again spoke in the singular: "at least" seven or eleven years must "have elapsed" since "the date" of "the selected" drug's approval. 42 U.S.C. § 1320f–1(e)(1)(A)-(B). Specifying a set exemption period ensures that innovator manufacturers have several years of exclusivity in which to recoup the value of their initial investments. *See supra* pp. 5-6. CMS's Guidance reads that protection out of the statute, allowing innovator drugs approved under distinct NDAs to be swept up into the statutory price-control scheme well before the deadline.

*Third*, CMS's interpretation runs headlong into the statutory language specifying the number of drugs to include for each initial price applicability year. By statute, CMS may only impose price-controls on ten drugs in IPAY 2026, 15 in IPAY 2027 and 2028, and 20 in IPAY 2029 and beyond. 42 U.S.C. § 1320f–1(a). But by inventing a new definition for "qualifying single source drug," CMS was able to select at least *14* drugs for IPAY 2026 and *22* drugs for IPAY 2027—well beyond the limits Congress set. Selected Drugs for IPAY 2026, *supra*; Selected Drugs for IPAY 2027, *supra*.[9]

*Fourth*, CMS's decision to treat multiple drugs approved under distinct NDAs as one "qualifying single source drug" renders other parts of the IRA superfluous and leads to absurd results. As explained, once a generic has been "approved and marketed," the "listed [innovator] drug for" that generic is no longer eligible for selection or price controls. 42 U.S.C. § 1320f–

[9] Excluding supplements, FDA's drug-approval database lists at least 14 and 22 unique NDAs or BLAs for the selected drugs for 2026 and 2027, respectively. *See* Drugs@FDA: FDA-Approved Drugs, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm.

1(e)(1)(A)(iii); *see id.* § 1320f–1(c)(1). And a generic's approval is specific to one listed product under one distinct NDA. *Supra* pp. 6-7. But under CMS's many-NDAs-in-one definition, a single generic can now disqualify twelve (or more) different innovator products from selection or negotiation—even if there has been no generic approved (much less marketed) for eleven of those twelve products. *See* 2027 Guidance at 171.

But the point of the generic carveout is that once there is a competing lower-priced product available, the "listed drug" with which that generic competes should no longer be subject to price controls. 42 U.S.C. § 1320f–1(e)(1)(A)(iii). CMS's redefinition of qualifying single source drug writes the "listed drug" limit out of the statute and renders the generic carveout nonsensical. *See, e.g.*, *Marx v. General 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"); *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1068 (D.C. Cir. 1998) ("a statute should not be construed to produce an absurd result").

**3.** CMS's claimed statutory hook for its interpretation cannot bear the weight CMS puts on it. In the 2027 Guidance, CMS defended its atextual interpretation on the ground that the IRA instructs it to "aggregate [spending] data across dosage forms and strengths of the drug, including new formulations of the drug," and "different dosage forms and strengths, as well as different formulations, containing the same active moiety / active ingredient may be approved or licensed under multiple NDAs or BLAs." 2027 Guidance at 12-13, 170; *see* 42 U.S.C. § 1320f–1(d)(3)(B).

But there is a far easier reading of this language—one that is consistent with the IRA's other textual indicia. Manufacturers commonly file multiple supplemental applications to a single NDA, including for different dosage forms and strengths. *See, e.g.*, Faulkingham Decl.

¶ 10 nn. 3-4; *see also* Drugs@FDA Glossary of Terms, https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms (last visited Mar. 5, 2025) (defining a "supplement" as "an application to allow a company to make changes in a product that already has an approved" NDA and defining "supplement type" as a supplemental application "[t]o change a label, market a new dosage or strength of a drug, or change the way it manufactures a drug"). Congress understood as much, and therefore instructed CMS to consider data from "applications and approvals" (plural) for "the drug" (singular). 42 U.S.C. § 1320f–3(e)(1)(D).

CMS's interpretation, by contrast, would render the statute redundant. If "a qualifying single source drug" meant "all dosage forms and strengths of the drug with the same active moiety" approved under any number of NDAs, 2027 Guidance at 167, there was no need to specify that data must be "aggregated across dosage forms and strengths of the drug," 42 U.S.C. § 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 drug products with the same active moiety. The fact that CMS's reading would render another part of the same statutory scheme superfluous is yet another reason to reject it. *See, e.g.*, *Marx*, 568 U.S. at 386.

## II. CMS's Subjective, Atextual "Bona Fide Marketing" Standard Is Unlawful.

Under the IRA, a drug is ineligible for negotiation or selection once an FDA-approved generic version of that drug is "approved and marketed." 42 U.S.C. § 1320f–1(e)(1)(A)(iii). The plain meaning of that term is clear: has the generic been made available for sale? The sale of even a single unit of the generic is sufficient to clear that hurdle. Yet CMS's Guidance imposes an artificial, subjective "bona fide marketing" requirement and creates a new "totality of the circumstances" test that supplants the statute's objective inquiry. *See* 2027 Guidance at 170-171. CMS's atextual definition cannot stand.

**1.** The IRA's inquiry is straightforward: is an approved generic "marketed"? If so, the reference listed drug is ineligible for selection or negotiation. 42 U.S.C. § 1320f–1(e)(1)(A)(iii), (B)(iii); *see id.* § 1320f–1(d)(1) (defining a negotiation-eligible drug); *id.* § 1320f–1(c)(1) (defining selected drug). A previously selected drug also becomes ineligible for continued price controls if and when a generic version of that drug "is marketed." *Id.* § 1320f–1(c)(1)(B).

Whether a generic drug is "marketed" is an objective, point-in-time determination based on when the product enters the commercial marketplace. "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. July 2023); *see Sandifer v. U.S. Steel Corp.*, 571 U.S. 220, 227-228 (2014) (using contemporary dictionaries to ascertain ordinary, contemporary, common meaning). As the Supreme Court has put it, "[m]arketing ordinarily refers to the act of holding forth property for sale." *Asgrow Seed Co. v. Winterboer,* 513 U.S. 179, 187 (1995) (rejecting argument that " 'marketing' requires 'extensive or coordinated selling activities' "). These definitions do not include any quantitative or qualitative requirement as to how *much* of the product must be brought to market or how *long* it must be exposed for sale. So long as even one unit of the generic has been sold, that is enough to satisfy the requirement Congress imposed, and the reference product cannot be included in the Program.

CMS, however, demands more—although precisely how much more is unclear. Contrary to the IRA, CMS insists on proof that the generic's marketing is "bona fide." 2027 Guidance at 20. CMS alternatively defines "bona fide" to mean that the generic has "more than solely token or *de minimis* availability," has "a continuing presence on the market," is being sold in a "robust and meaningful" manner and is generating "meaningful competition . . . on an ongoing basis" with the listed drug. *Id.* at 19-21 (quotation marks omitted). This amorphous language offers no

guideposts as to what degree of "presence," "availability," or "competition" is sufficient, nor does CMS define vague terms like "robust" or "meaningful." *See Robust*, Oxford English Dictionary (3rd ed. Sept. 2024) ("[s]trong and hardy"); *Meaningful*, Oxford English Dictionary (3rd ed. Sept. 2024) ("significant"); *see, e.g.*, *West Palm Beach Firefighters' Pension Fund v. Conagra Brands, Inc.*, 495 F. Supp. 3d 622, 653 (N.D. Ill. 2020) (explaining that terms like "robust" are merely "vague" "puffery" insufficient to trigger liability for a false or misleading statement), *aff'd sub nom. National Elevator Indus. Pension Fund v. Conagra Brands, Inc.*, No. 21-1155, 2022 WL 1449184 (7th Cir. May 9, 2022); *Bodri v. GoPro, Inc.*, 252 F. Supp. 3d 912, 924 (N.D. Cal. 2017) (same). CMS instead says it will make these decisions based on "the totality of the circumstances." 2027 Guidance at 20-21, 30.

"[T]hose are not the words that Congress wrote." *National Assn. of Mfrs. v. Department of Def.*, 583 U.S. 109, 127 (2018). And just like "this Court," CMS "is not free to rewrite the statute to [its] liking." *Id.* (quotation marks omitted). Indeed, Congress knows how to include a subjective "bona fide" qualifier when it sees fit. Congress used that term in 471 different sections of the U.S. Code governing programs—everything from intern compensation, to cotton futures contracts, to affordable housing. *See, e.g.*, 2 U.S.C. § 5322(b)(1) (intern must be a "bona fide student" to qualify for certain compensation); 7 U.S.C. § 15b(d) (restricting "cotton futures contracts" to "bona fide spot markets," meaning "markets in which spot cotton is sold in such volume and under such conditions as customarily to reflect accurately the value of middling cotton and the differences between the prices or values of middling cotton and of other grades of cotton for which standards shall have been established by the Secretary"); 12 U.S.C. § 1831q(c)(2), (d)(4)-(5) (requiring a "bona fide offer to purchase the property").

In fact, Congress used the term "bona fide" 82 times in Title 42, the portion of the U.S. Code that governs "the public health and welfare." *See generally* 42 U.S.C. § 1 *et seq.* For example, Congress has specified that only "bona fide service fees" are exempt from the calculation of the "average manufacturer price for a covered outpatient drug," 42 U.S.C. § 1396r–8(k)(1)(B)(i)(II); Congress has prohibited certain physician referrals in the absence of a "[b]ona fide employment relationship," which the statute defines as a relationship in which the "amount of the remuneration" is consistent with "fair market value," among other things, *id.* § 1395nn(e)(2); and Congress has specified a "bona fide" standard in another part of the Inflation Reduction Act—but not the Drug Price Negotiation Program. *See* Pub. L. No. 117-169, § 1310(f)(8)(E)(i)(II), 136 Stat. 1910 (defining "labor hours" to include only those hours worked by "persons employed in a bona fide executive, administrative, or professional capacity"). Simply put, Congress knows how to impose "bona fide" requirements, and it could have imposed a similar requirement on the Program's generic "marketing" trigger. But it chose not to. Congress also knows how to mandate totality-of-the-circumstances tests. *See, e.g.*, 52 U.S.C. § 10301(b) (establishing "totality of the circumstances" test for Voting Rights Act violations); 11 U.S.C. § 707(b)(3)(B) (same, in considering whether to dismiss a bankruptcy case under Chapter 11). But, again, Congress chose not to.

Congress's silence on these issues has meaning, because "where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposefully." *Russello v. United States*, 464 U.S. 16, 23 (1983) (quotation marks and brackets omitted). More broadly, as Judge Sutton has explained, when "Congress opts not to include a well known and frequently used approach in drafting a statute, the courts should hesitate to pencil it back in under the guise of

interpretation." *Prewett v. Weems*, 749 F.3d 454, 461 (6th Cir. 2014). Justice Scalia similarly observed that, unless Congress "makes clear that the totality of the circumstances is always to be considered," "courts properly assume that 'categorical decisions may be appropriate and individual circumstances disregarded.' " Antonin Scalia, *The Rule of Law As A Law of Rules*, 56 U. Chi. L. Rev. 1175, 1183 (1989) (quoting *DOJ v. Reporters Comm. for Freedom of Press*, 489 U.S. 749, 776 (1989)). Exactly right; this Court should reject CMS's attempts to graft atextual qualifiers onto the plain meaning of "marketed."

**2.** CMS's "bona fide marketing" standard also unlawfully alters the temporal nature of the statutory inquiry. The date on which a generic "is marketed" is significant: CMS must cease "negotiations" if, after a drug has been selected but before the end of the "negotiation period," a generic version is approved and "marketed." 42 U.S.C. § 1320f–1(c)(2). The IRA thus mandates that CMS remove a previously selected drug from the price-control list for the next price applicability year beginning at least nine months after a generic has been approved and is "marketed." *Id.* § 1320f–1(c)(1). A drug selected on February 1, 2025 for price controls in IPAY 2027 "will remain a selected drug for" 2027 "unless" a generic is "marketed" "on or before November 1, 2025," which marks the end of the negotiation period. 2027 Guidance at 131. If a generic is "marketed" between November 2, 2025 and March 31, 2027, the selected drug remains subject to price controls in 2027, but not 2028. *Id.* If the generic is not "marketed" until April 1, 2027, the selected drug remains subject to price controls in 2028. *Id.*

Under the IRA's text, this inquiry is simple: have any sales of the generic occurred by the cutoff date? If so, the innovator drug is ineligible for price controls, full stop; the statute does not provide any mechanism to later restore the innovator drug to the negotiation or selection list.

CMS's "bona fide marketing" standard unlawfully alters that straightforward inquiry in two respects. *First*, under CMS's Guidance, a generic may take many months to reach whatever level of "marketing" CMS considers "bona fide." That delay is the difference between an extra *year* of price controls if CMS finds—in its unreviewable discretion—that "bona fide marketing" has occurred the day after the cutoff, even if the generic's first sale occurred months earlier.

The inherent time lags associated with the data CMS considers in making this decision further exacerbate the problem. Although CMS has asserted "the right" to consider whatever data it sees fit, the agency has committed to reviewing at least two types of data: Part D PDE data and Medicaid AMP data. *Id.* at 170-171, 278-279, 293. PDE data are summary claims data generated when a Part D plan sponsor fills a prescription under Medicare Part D. *See id.* at 21; *see generally* CMS Guide to Requests for Medicare Part D Prescription Drug Event (PDE) Data 12 (Mar. 2008), https://perma.cc/3WWJ-4939. As CMS has acknowledged, PDE data are inherently time lagged because there is a delay between when a drug becomes available, when Part D prescriptions for that drug are filled, and when those prescriptions are reported in coverage determinations. 2027 Guidance at 21-22. That is particularly true with respect to generics. In the 2021 Medicare Part D plan year, only 21 percent of first generics launched in 2020 were covered. New Generics Are Less Available in Medicare, *supra*, at 4. Moreover, "it takes nearly three years before first generics are covered on more than half of Medicare Part D formularies." *Id.* at 5. As a result, the first six months of PDE data reported after a drug faces generic competition necessarily reflect very limited generic uptake. CMS has also acknowledged that AMP data—the other category of data CMS has committed to use in making its "bona fide marketing" determinations—are on a two-month delay. So "[w]hen CMS

performs this assessment in March 2025," it will look to AMP data from "February 2024 through January 2025." 2027 Guidance at 278.

These data delays will force generics to compete with price-controlled innovator drugs for months or years longer than Congress intended, which affects Teva's decisions today as to whether to continue to invest in the launch of those generic products. *See* Groff Decl. ¶¶ 39-45. CMS attempted to downplay these risks in its Guidance, *see* 2027 Guidance at 21-22, but even a one- or two-month data delay can be pivotal. Teva's products provide prime examples. The company is poised to launch several generics in the coming years on dates that are pre-determined by various patent and settlement agreements. *See, e.g.*, Groff Decl. ¶¶ 22-27. Consider XARELTO (Rivaroxaban), which is on the selected drug list for IPAY 2026. Teva plans to launch its generic version on March 15, 2027, the entry date specified in its patent settlement with the innovator. *Id.* ¶ 24(e). But because even CMS concedes that PDE and AMP data are unavailable for the month of March, it will be impossible for Teva to prove "bona fide marketing" in the two weeks before the March 31, 2027 cutoff under those metrics. That means Teva will be forced to compete with a price-controlled version of XARELTO and any other drugs with the same active moiety approved on separate NDAs for at least one extra year—through December 31, 2028. *Id.* ¶ 44(a). The issue is even more acute for LINZESS (Linaclotide), another drug selected for 2027. Teva anticipates launching its generic version of that product on March 31, 2029—the entry date specified in its patent settlement with the innovator. But March 31, 2029 is also the cutoff date to remove a drug from the Program in 2030. *Id.* ¶ 25(e). Under the IRA, generic entry on March 31 would and should trigger LINZESS's de-listing effective January 1, 2030; that will not be possible under CMS's atextual standard. *Id.* ¶ 44(b).

*Second*, CMS claimed the authority to continually reassess whether a generic has cleared its amorphous "bona fide marketing" threshold. In other words, if CMS determines that a generic drug manufacturer is no longer engaged in "bona fide marketing" (whatever that means), the innovator product could become re-eligible for negotiation and selection. 2027 Guidance at 292; *see* Groff Decl. ¶ 48.

Nothing in the statute authorizes this type of reassessment. The IRA lays out a reticulated scheme with specific date targets for various determinations throughout the selection and negotiation cycle. *Supra* p. 10. Because no manufacturer could afford to withdraw its products from Medicare and Medicaid or pay CMS's extreme tax penalty, there is only one viable escape hatch for selected products: a generic coming to market. *Id.* at 11; *see* 42 U.S.C. § 1320f–1(c)(1). Nowhere does the IRA contemplate *reselecting* a *deselected* drug. Congress was clear: once a generic is marketed, the innovator drug can no longer be part of the Program, and that is the end of the inquiry. The Court should reject CMS's attempt to "read[ ] words or elements into a statute that do not appear on its face." *Dean v. United States*, 556 U.S. 568, 572 (2009) (citation omitted).

**3.** An objective, point-in-time definition of "marketed" also matches CMS's approach in related contexts. For example, 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" that the manufacturer must report for Average Sales Price purposes or "the date the drug was first available for sale." CMS, *Medicare Part B Inflation Rebates Paid by Manufacturers: Initial Memorandum* 57 (Dec. 14, 2023), https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-revised-guidance.pdf. CMS has likewise long defined "marketed" for purposes of the Medicaid Drug Rebate Program by reference to the date on which a product "is

available for sale." 83 Fed. Reg. 12,770, 12,784 (Mar. 23, 2018); *see also* 42 C.F.R. § 447.502. CMS echoed that meaning in a recent rule defining the "market date" as "the date on which the . . . drug was first sold." 89 Fed. Reg. 79,020, 79,082 (Sept. 26, 2024).

This objective, point-in-time definition of "marketed" is also consistent with analogous FDA regulations. Under the Hatch-Waxman Act, the first generics to file an ANDA with a paragraph IV certification are entitled to 180 days of exclusivity during which other ANDAs cannot be approved, beginning "the date of the first commercial marketing of the drug." 21 U.S.C. § 355(j)(5)(B)(iv)(I); *see supra* pp. 6-7. FDA has long defined "commercial marketing" to mean "the introduction or delivery for introduction into interstate commerce of a drug product," full stop. 21 C.F.R. § 314.3(b). That is yet further confirmation that Congress "meant what it said" when it used the term "marketed." *Optimal Wireless LLC v. IRS*, 77 F.4th 1069, 1074 (D.C. Cir. 2023) (quotation marks omitted); *see also Lorillard v. Pons*, 434 U.S. 575, 580 (1978) ("Congress is presumed to be aware of an administrative . . . interpretation of a statute.").

* * *

CMS's redefinition of a "qualifying single source drug" and its "bona fide marketing" standard are each contrary to the IRA's plain text in their own right. But it is worth underscoring how the two interact: By expanding the universe of what constitutes a "qualifying single source drug," CMS has vastly inflated the number of price-controlled innovator drugs with which generics must compete. But because CMS has expanded the definition of qualifying single source drug to include multiple products approved under distinct NDAs, any generic that lists *any* of those grouped-together products as a reference would render *all* products with the same active moiety ineligible for negotiation. 2027 Guidance at 171. In other words, because CMS has elected to treat twelve distinct NDAs as one "qualifying single source drug," if one innovator

product has a generic competitor but the eleven other innovator products do not, *all twelve products would be ineligible for price controls*. To avoid these consequences of its many-NDAs-in-one definition, CMS replaced the IRA's objective "marketing" inquiry with its own subjective "bona fide marketing" standard, allowing CMS to delay the point at which all twelve NDAs drop off the price-control list.

The combined effect of CMS's actions will be devastating to manufacturers like Teva and the patients they serve. CMS's interpretations will force generics to compete with more price-controlled innovator drugs and for longer periods of time. That will make it difficult for generic manufacturers to secure market share and recoup their investments, particularly during the critical first months after launch, while simultaneously vitiating incentives for generic manufacturers to develop competing formulations of other innovator drugs. *See* Groff Decl. ¶¶ 4-9, 18, 28-29, 32. A generic manufacturer also has no way to know whether it will be able to satisfy CMS's amorphous "bona fide marketing" test year after year. And although some might think that generic competition matters less in the IRA's price-controlled regime, generics' availability protects against drug shortages, and competition from those low-cost medicines remains an important component of the private healthcare market. *See id.* ¶ 16. Moreover, for manufacturers like Teva that make both innovator and generic products, declining revenue from generics threatens to hamper their ability to develop innovator products, to the detriment of patients nationwide. *See id.* ¶ 46. The Court should set aside CMS's unlawful re-definition of "qualifying single source drug" and atextual "bona fide marketing" standard.

## III. The Program Violates The Due Process Clause.

The government denies due process when it "deprive[s]" a person or entity of a "liberty or property interest," and the "procedures [it] follow[s]" in effectuating that deprivation are insufficient. *Swarthout v. Cooke*, 562 U.S. 216, 220 (2011). Both are true here. The IRA's

price-setting scheme deprives Teva of its protected property interest in its drug products and its right to sell its products at a fair market value. And CMS affords Teva none of the process the Constitution requires.

**A. The Program Deprives Teva Of Protected Property Interests.**

"[P]roperty interests subject to procedural due process protection are not limited by a few rigid, technical forms." *Perry v. Sindermann*, 408 U.S. 593, 601 (1972) (quotation marks omitted). The government can create these constitutionally protected interests statutorily, contractually, or via "policies," "practices," "rules" or "understandings" that are "promulgated and fostered by [government] officials." *Id.* at 601-603. For economic actors, property interests include legal "entitlement[s]" and arise from longstanding legal rights and commercial practices. *See Board of Regents of State Colls. v. Roth*, 408 U.S. 564, 571, 576-577 & n.15 (1972).

Here, Teva, as a manufacturer of innovator as well as generic drugs, maintains several cognizable, constitutionally protected property interests: its property right to its innovator drug products; its contractual right to sell certain generics pursuant to licenses and settlement agreements with innovator manufacturers; and the inherent right to set the prices for its products without government interference. The government "may not constitutionally authorize the deprivation" of these interests "without appropriate procedural safeguards." *Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 541 (1985) (cleaned up). That is so even when a party claims that it is eligible for an entitlement and the government believes otherwise. *See, e.g.*, *Roth*, 408 U.S. at 577-578; *Goldberg v. Kelly*, 397 U.S. 254, 262 (1970).

*First*, for the pharmaceutical industry, the government's longstanding, codified approach of letting the market dictate prices creates an entitlement among manufacturers to be free from governmental price strictures. It is a "well-settled general principle that the right of the owner of property to fix the price at which he will sell it is an inherent attribute of the property itself, and

as such is within the protection of the Fifth [Amendment]." *Old Dearborn Distrib. Co. v. Seagram-Distillers Corp.*, 299 U.S. 183, 192 (1936).

Courts have long recognized that Medicare and Medicaid provisions may create entitlements protected by due process. For example, the Seventh Circuit has held that, where a Medicaid statute prescribes a reimbursement rate to all providers that meet certain "substantive criteria," the government has created an entitlement "to payment at the legally prescribed rate." *Rock River Health Care, LLC v. Eagleson*, 14 F.4th 768, 774 (7th Cir. 2021). Similarly, where a statute gives Medicaid recipients "the right to choose among a range of qualified providers[ ] without government interference," the Due Process Clause protects a recipient's entitlement to "be free from government interference" in her choice of qualified provider. *O'Bannon v. Town Court Nursing Ctr.*, 447 U.S. 773, 785 (1980). Thus, so long as the provision in question guarantees a benefit to someone "qualif[ied] under eligibility" rules, and officials "are not given the power to arbitrarily" deny that benefit "for any reason," the government has created an entitlement protected by due process. *Klein v. Califano*, 586 F.2d 250, 258 (3d Cir. 1978).

This case involves a similar statutory entitlement. Under the Medicare Part D statute's "noninterference" provision, the government "may not institute a price structure for the reimbursement of covered part D drugs," and it "may not interfere with the negotiations between drug manufacturers and pharmacies and [prescription drug plan] sponsors." 42 U.S.C. § 1395w–111(i). The IRA created an exception to that noninterference regime: Now, the government cannot institute price structures for the reimbursement of Part D drugs, "*except*" as to qualifying single source drugs, as defined by the statute. *Id.* § 1395w–111(i)(3) (emphasis added); *see id.* § 1320f–1. In other words, the statute entitles a drug manufacturer to be free from government price structures in the reimbursement of Part D drugs so long as (1) the drug is "covered" under

Medicare Part D, and (2) the drug is not a "qualifying single source drug." When these statutory criteria are met, the government has *no* discretion to impose price structures. And because the right to be free from government price structures is an entitlement guaranteed to any manufacturer "qualified to receive it," *Goldberg*, 397 U.S. at 262, "the administrative process determining eligibility" for that entitlement must *itself* "comply with due process," *Kelly v. Railroad Ret. Bd.*, 625 F.2d 486, 489 (3d Cir. 1980).

*Second*, manufacturers of novel drug products are also entitled to a guaranteed exclusivity period. By statute, "patents shall have the attributes of personal property," 35 U.S.C. § 261, and the Supreme Court has long affirmed that patents "are surely included within the 'property' of which no person may be deprived . . . without due process of law," *Florida Prepaid Postsec. Educ. Expense Bd. v. College Sav. Bank*, 527 U.S. 627, 642 (1999); *accord William Cramp & Sons Ship & Engine Bldg. Co. v. International Curtis Marine Turbine Co.*, 246 U.S. 28, 39-40 (1918). "The federal patent system . . . embodies a carefully crafted bargain": In return for "the creation and disclosure of new, useful, and nonobvious advances in technology," inventors obtain "the exclusive right to practice the invention for a period of years." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-151 (1989). This exclusivity period yields "economic rewards," subject only to "the dictates of the marketplace." *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1372 (Fed. Cir. 2007) (citation omitted).

*Third*, for these same reasons, Teva as a generic manufacturer also has a protected Fifth Amendment right in its patent settlement agreements and licenses. *See Ralls Corp. v. Committee on Foreign Inv. in the U.S.*, 758 F.3d 296, 316 (D.C. Cir. 2014) ("Valid contracts are property under the Fifth Amendment") (citation omitted and alteration adopted).

The Program directly implicates all of these protected property interests. As explained, CMS selected two of Teva's innovator drug products, AUSTEDO and AUSTEDO XR for negotiation in 2025. Selected Drugs for 2027 IPAY, *supra*. And six innovator drugs for which Teva will launch generics have also been selected, which will force Teva's generics to compete against artificially low prices. *See supra* pp. 17-20. Under the statutory definition of "qualifying single source drug," AUSTEDO XR and two of the innovator products with which Teva's generics will compete—the tablet form of XTANDI and the suspension form of XARELTO—would not have been eligible for selection. *Supra* pp. 17-19. With respect to those products, Teva has been deprived of its statutorily guaranteed noninterference right. And more broadly, the selection of Teva's patented drugs, and the price-caps imposed on the innovator drugs against which Teva's generic drugs will compete, disrupts Teva's "treasured" common-law right to offer access to its products at prices set by voluntary agreements, not government dictates, and to choose not to sell its product at prices it deems insufficient. *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 149 (2021).

And make no mistake—having a drug selected *is* a deprivation, not just for the innovator manufacturer, but also for the generic manufacturer that is excluded from the "negotiation" process altogether. Selection forces a manufacturer to sell its product at far below market value to a broad plurality of the market—including Medicaid, given the requirement that manufacturers offer Medicaid the lowest price available. 42 C.F.R. § 447.505. The IRA attempts to create an illusion of fairness in what it calls "the negotiation period," during which CMS purportedly negotiates a "maximum fair price" with the selected drug's manufacturer. 42 U.S.C. §§ 1320f–2(a), 1320f–3(a). But the proceedings are negotiations in name only: CMS is directed to work with each manufacturer *not* to reach a genuine agreement, but instead to use a

"consistent methodology" that the statute promises will "achieve the *lowest* maximum fair price." *Id.* § 1320f–3(b)(1) (emphasis added). The phrase "maximum fair price" is also a legal fiction—CMS's obligation to reach the "lowest" price emphasizes the Program's failure to protect manufacturers against confiscatory prices. *See Michigan Bell Tel. Co. v. Engler*, 257 F.3d 587, 593-595 & n.4 (6th Cir. 2001) (price-control rule is unconstitutional absent "adequate[ ] safeguards against confiscatory rates" to ensure a "fair and reasonable return on investment"). To top it off, the statute denies Teva the right to seek judicial review of the selection of its products or the other products with which Teva's generics will compete.

**B. The Program Does Not Provide Teva Due Process.**

Because Teva has been deprived of a constitutionally protected property right, the next question is whether the government's procedural safeguards are "constitutionally sufficient." *Swarthout*, 562 U.S. at 219. Asked another way, did the government follow procedures designed to prevent "substantively unfair and simply mistaken deprivations of property"? *Fuentes v. Shevin*, 407 U.S. 67, 81 (1972); *see also Gilbert v. Homar*, 520 U.S. 924, 930-932 (1997). That requires providing a meaningful opportunity to be heard and an impartial adjudicator. The Program fails both requirements.

*First*, the Program deprives Teva of notice and an opportunity to be heard "at a meaningful time and in a meaningful manner." *Armstrong v. Manzo*, 380 U.S. 545, 552 (1965). Only in "rare and extraordinary" cases may the government "postpon[e] the hearing until after the event." *Roth*, 408 U.S. at 570 n.7 (citation omitted). What the government may never do, however, is deprive a party of its property interests without any hearing at all. *See, e.g.*, *Bowles v. Willingham*, 321 U.S. 503, 521 (1944) (due process requires at least a hearing "after the regulations or orders have been made effective"—even during a "war emergency"). That is precisely what the Program does, several times over.

Start where CMS should have—rulemaking. In cases involving property deprivations by agency action, due process "requires an opportunity for interested parties to be heard in rulemaking proceedings." *Westinghouse Elec. Corp. v. Nuclear Regul. Comm'n*, 555 F.2d 82, 95 (3d Cir. 1977). The government denied Teva that opportunity here, as the IRA exempts the Program from standard notice-and-comment rulemaking, and instead prescribes implementation via agency guidance. *See* 2027 Guidance at 1-2.

CMS's drug-selection methodology is also completely opaque, with no clear criteria or standardized formula. Once a drug is selected, the IRA forces innovator manufacturers to engage in purported "negotiations," but gives them no leverage, no meaningful opportunity to walk away, and no ability to protect their interests. And generic manufacturers have no place at the table at all. The IRA then directs CMS to unilaterally impose a "maximum fair price" for selected drugs that is drastically below the actual fair-market value of both the innovator product and the generic. If a manufacturer declines to agree to CMS's price, it is subject to a steep, escalating daily penalty until it acquiesces to CMS's demands or the drug ceases to be selected. *Supra* pp. 10-11. The penalty maxes out at 95 percent of total U.S. product *revenue*, and the only pathway to suspend the penalty is for the manufacturer to terminate its Medicare Part D and Medicaid rebate agreements—not just for the drug in question, but for *all* of its products. 26 U.S.C. § 5000D(c)-(d). That makes declining to negotiate impossible, a conclusion Congress was counting on when it estimated the penalty would raise no revenue. *Supra* p. 11.

Generic manufacturers like Teva lack even the theoretical option of walking away. Only the manufacturer of the innovator drug participates in the "negotiation," so only it may decide how to respond to a drug's selection or to CMS's "offer." When innovator manufacturers inevitably accede to CMS's demands, generic manufacturers suffer the consequences because

they must then compete with price-controlled drugs, effectively ceding their pricing decisions to the outcome of a "negotiation" between the innovator manufacturer and CMS that generic manufacturers had no role in.

CMS also does not provide the required process on the back end. When the government fails to provide process up front, the Constitution requires a judicial or administrative hearing to review the agency's action. *See, e.g.*, *Hodel v. Virginia Surface Min. & Reclamation Ass'n*, 452 U.S. 264, 299-301 (1981). But the statute forbids even that. Under the IRA, "[t]here shall be no administrative or judicial review" of any government decision the Program entails—including CMS's decision about whether a product is a "qualifying single source drug" and its determination of reimbursement prices. *See* 42 U.S.C. § 1320f–7. These prohibitions on review apply to CMS's decisionmaking processes to intentionally keep stakeholders in the dark. And although Congress may define the scope of judicial review, that power cannot be exercised to "cut off all review of an allegedly unconstitutional statute" that may result in a property deprivation. *Feinberg v. FDIC*, 522 F.2d 1335, 1341-42 (D.C. Cir. 1975); *see also Marozsan v. United States*, 852 F.2d 1469, 1478-79 (7th Cir. 1988). By not allowing Teva to meaningfully participate in the price-setting process for its innovator drugs—as well as its generic products, for which Teva is denied any participation at all—*and* of any review once a drug is selected and its price is determined, the Program denies Teva due process.

*Second*, the Program denies Teva an impartial adjudicator. When the government deprives a party of a "protected interest," due process requires "a neutral and detached adjudicator" "in the first instance." *Concrete Pipe & Prods. of Cal., Inc. v. Construction Laborers Pension Tr. for S. Cal.*, 508 U.S. 602, 617-618 (1993) (citation and quotation marks omitted). This neutrality requirement "preserves both the appearance and reality of fairness,

generating the feeling, so important to a popular government, that justice has been done." *Marshall v. Jerrico, Inc.*, 446 U.S. 238, 242 (1980) (citation and quotation marks omitted). That requirement applies even "more strictly" to agency action because the administrative process lacks "procedural safeguards normally available in judicial proceedings"—especially when the agency maintains an "active role" in the process. *Ventura v. Shalala*, 55 F.3d 900, 902 (3d Cir. 1995). And when an adjudicator has a "pecuniary interest" in the outcome of the case, it is not neutral. *Ward v. Vill. of Monroeville*, 409 U.S. 57, 60-61 (1972) (citation omitted).

The Program checks all of these boxes. It vests CMS with the power to unilaterally dictate which drugs qualify for the program and the corresponding price caps. It explicitly bars any "administrative or judicial review" of CMS's decisions. *See* 42 U.S.C. § 1320f–7. And CMS, which acts as the adjudicator in this space, is anything but neutral. CMS is the agency primarily responsible for paying Medicare Part D reimbursements. So when CMS decides the reimbursement rate for a drug, it decides how much money will flow directly from its coffers. CMS thus has a profound "pecuniary interest" in setting low rates—as its statutory directive confirms—regardless of whether those prices are actually "fair," are based on the statutorily mandated factors, or adhere to CMS's standard methodology. *See Ward*, 409 U.S. at 60-61; *see generally* 42 U.S.C. § 1320f–3. No amount of process on the back end could cure that fatal flaw, but the Program does not provide even that. *See Concrete Pipe*, 508 U.S. at 617.

## CONCLUSION

For the foregoing reasons, Teva's motion for summary judgment should be granted. CMS's definitions of "qualifying single source drug" and "marketed" should be set aside, and the Government should be enjoined from implementing the Program in its entirety.

Respectfully submitted,

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March 7, 2025

**CERTIFICATE OF SERVICE**

I hereby certify that on March 7, 2025, I caused a true and correct copy of the foregoing to be filed with the Court electronically and served by the Court's CM/ECF System upon the listed counsel of record.

*/s/ Sean Marotta*
Sean Marotta

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

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| TEVA PHARMACEUTICALS USA, INC., *et al.*,<br><br>*Plaintiffs*,<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*. | No. 1:25-cv-00113-SLS |

**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.

**TEVA'S INVESTMENTS IN ITS GENERIC PORTFOLIO**

4. Teva invests substantial resources into creating and marketing its portfolio of medicines—both innovator new drugs and high-quality and lower-cost generic drugs. In 2023, Teva invested nearly $1 billion into research and development across its entire portfolio of products. A significant portion of those investments went to generics,[1] and Teva has more than a thousand generic products in its development pipeline.

5. Developing generics requires substantial investments: Teva invests hundreds of millions of dollars annually into developing and manufacturing generic medicines. From start to finish, Teva's development of a generic medicine may take up to seven years. The cost often amounts to tens of millions of dollars, and even more if capital expenditures are required. If the product is subject to patent litigation against the sponsor of the referenced innovator product, litigation expenses add to the cost of development, and those litigation expenses can run over $10 million if a case must be litigated through appeals.

6. Biosimilars are especially costly to develop. They are subject to many of the same costs as generics. But unlike generics, sponsors of biosimilars must also conduct expensive clinical trials to demonstrate safety. And biosimilar manufacturers may also invest additional

[1] Unless otherwise noted, I use "generics" to refer to both generic drugs and biosimilars.

money into advertising their products—again unlike AB-rated generics, which are substituted at the pharmacy counter—adding still further expense.

7. To recoup its investments in developing generics, Teva must be able to sell a sufficient volume of those products. Teva's products must therefore gain enough market share, which requires Teva to convince its customers, including wholesalers, pharmacies, hospitals and clinics, to switch from a branded product to a generic.

8. Generics compete with branded drugs on price. By law, a generic must be therapeutically equivalent to the reference product. That means generic manufacturers must differentiate their products from branded equivalents by offering lower prices. Of course, that is by design: The purpose of generic competition is to bring down prices.

9. If a generic cannot compete on price, it is unlikely to gain substantial market share. Similarly, in my experience, payors and pharmacy benefit managers are unlikely to add generic products to their formularies—meaning they will not provide insurance coverage for those products—if they will not save any money by doing so. Even if payors and pharmacy benefit managers were to add a generic that costs about the same as a branded drug to their formularies, in my experience they would be unlikely to give such a generic favorable placement, leaving consumers and their prescribers with no incentive to choose it.

10. I am aware of studies and government reports demonstrating that generic prices are strongly and negatively correlated with the number of generic competitors. According to some such estimates, generics tend to be sold at about a 25 to 50 percent discount to the branded drug when there is only one generic seller, but that discount can rise to well over 90 percent when there are 6 or more generic sellers.[2] Teva's experience matches those findings: The first generic entrant

[2] FDA, *Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices*, at 9 (Dec. 2019), https://www.fda.gov/media/133509/download.

is priced at a significant discount to the branded drug and the generic price declines significantly as more generics enter the market.

11. Under such circumstances, it is doubly difficult for generic manufacturers to recoup their investments in developing their products. Very low prices mean that manufacturers will earn little revenue for each sale, and a large number of competitors means that each generic will attain less market share.

12. For these reasons, Teva closely monitors expected market conditions upon generic entry when deciding whether it will continue developing, and ultimately launch, a generic product. In doing so, Teva forecasts the likely generic prices upon launch, given Teva's expectations about potential competitors' behavior. When Teva determines that generic prices will likely be too low to make launching economical, it decides not to launch a generic product, even if it has the legal right to do so.

13. Uncertainty also plays a key role in those decisions. If there appears to be a strong chance that launching a generic product will ultimately not be economical because of excessively low generic prices, Teva ceases developing that product so that it may commit those resources elsewhere. Teva cannot justify committing the substantial funds needed to prepare a generic product for launch unless it can be reasonably sure that launching will generate sufficient revenue to recover those funds, enabling Teva to invest in further product development.

14. Biosimilar competition relies on similar dynamics. Although biosimilars are not necessarily fungible with their reference biologics, evidence suggests that biosimilars must be priced substantially lower than their reference products to gain market share. For example, I have reviewed evidence that manufacturers of biologics have prevented biosimilars from gaining substantial market share by offering large rebates on their branded products. In those

circumstances, a biosimilar cannot undercut the price of the biologic by a sufficient margin to induce consumers, payors, and pharmacy benefit managers to switch to the biosimilar without offering prices so low that the biosimilar would incur losses.

15. If Teva projected that a biosimilar product in its development pipeline would not gain sufficient market share to recoup Teva's costs in developing that product, Teva would cease investing in its development and decide not to launch the product. When faced with substantial uncertainty about whether a biosimilar product in its development pipeline will gain sufficient market share to recoup Teva's costs in developing that product, Teva would likely elect to devote its scarce resources toward developing other products instead.

16. Loss of generic competition would have serious adverse consequences for patients and the whole American healthcare system. I am aware of statistics demonstrating that over 90 percent of all prescriptions dispensed in the United States are filled with generic drugs, yet those drugs account for only a small fraction of total spending.

**THE DRUG PRICE NEGOTIATION PROGRAM**

17. When an innovator product is subject to a price cap under the Drug Price Negotiation Program, generic competition against that innovator product is undermined because the generic is forced to compete against an artificially low price. CMS's price caps have resulted in much lower prices for selected innovator drugs: Most of the price caps the agency has announced so far are greater than 50 percent.

18. When the prices of innovator products are forcibly reduced to those levels, generics will have little or no room to compete. To attract substantial market share, generic manufacturers must try to price their products significantly below the price of the innovator product. But when the innovator product is already priced at a large discount to the prevailing market price, a generic manufacturer will likely be unable to do so while still earning a profit on its sales. Of course, if a

generic manufacturer cannot earn a profit on its sales, it cannot rationally sell its product, and doing so would not enable the manufacturer to recoup its research and development costs. At a minimum, generics will have to be sold at prices far lower than they would be if the innovator products had not been selected. Generic competitors will therefore earn far less revenue than they would but for a given innovator product's selection.

19. Selection of an innovator product for the Drug Price Negotiation Program also creates substantial uncertainty regarding the status of generic competition. It is not possible to know, at the time of selection, what price CMS will ultimately impose on the product. That indeterminacy is compounded by the difficulty of predicting how other potential generic entrants may react to the imposition of a price cap under the Drug Price Negotiation Program.

20. For that reason, when the reference drug for one of Teva's forthcoming generic products is, or is likely to be, selected for the Drug Price Negotiation Program, Teva may elect to invest its scarce resources in other ways instead. If it does so, patients and payors will be deprived of important generic products they would otherwise have access to.

## TEVA'S AFFECTED GENERIC PRODUCTS

21. Teva plans to launch the following generics that will be affected by the Drug Price Negotiation Program.

***XTANDI (Enzalutamide)***

22. CMS selected XTANDI (Enzalutamide) for the Drug Price Negotiation Program in January 2025. XTANDI will therefore be subject to a price cap beginning January 1, 2027.

a. XTANDI is a branded drug that treats advanced prostate cancer.

b. XTANDI is approved under two NDAs. FDA approved NDA No. 203415 in August 2012, which authorizes a capsule form of XTANDI. FDA approved NDA No. 213674 in August 2020, which authorizes a tablet form of XTANDI.

c. Teva filed an application on August 31, 2016 to market generic Enzalutamide capsules, which FDA has approved. Teva's application contained a certification that the patents listed in FDA's Orange Book were invalid, not infringed, or unenforceable.

d. Teva was sued as a result of filing its application to market generic Enzalutamide capsules. The lawsuit against Teva was dismissed pursuant to a settlement agreement on June 18, 2018. That settlement left intact certain patents covering XTANDI, the latest of which expires on August 13, 2027 (U.S. Patent No. 7,709,517).

e. Pursuant to the terms of the settlement, Teva plans to launch a generic capsule form of Enzalutamide that will compete with XTANDI before the expiration of the '517 patent. Teva was among the first filers of generic Enzalutamide capsules and Teva's product is anticipated to be among the first to launch.

***OFEV (Nintedanib)***

23. CMS selected OFEV (Nintedanib) for the Drug Price Negotiation Program in January 2025. OFEV will therefore be subject to a price cap beginning January 1, 2027.

a. OFEV is a branded drug that treats a lung disease called idiopathic pulmonary fibrosis.

b. OFEV has been approved under NDA No. 205832 since October 2014.

c. Teva filed an application on July 30, 2024, to market generic Nintedanib capsules. Teva's application contained a certification that the patents listed in FDA's Orange Book were invalid, not infringed, or unenforceable.

d. Teva was not sued as a result of filing its application to market generic OFEV capsules, so the only barrier to Teva's marketing generic Nintedanib is a statutory-

exclusivity period that expires on September 26, 2026, with a six-month extension covering certain potential versions of generic Nintedanib that expires on March 26, 2027.

e. Teva plans to launch a generic form of Nintedanib that will compete with OFEV. Teva is not among the first filers for generic Nintedanib, so Teva will launch its generic six months after the first generic enters the market due to various exclusivity provisions. Teva anticipates the first generic to be launched in April 2026, which would mean Teva's generic is expected to launch in October 2026.

***XARELTO (Rivaroxaban)***

24. CMS selected XARELTO (Rivaroxaban) for the first year of the Drug Price Negotiation Program. XARELTO will therefore be subject to a price cap amounting to a 62 percent discount beginning January 1, 2026.

a. XARELTO is a branded drug that treats blood clots.

b. XARELTO has been approved under NDA Nos. 22406 and 202430 for tablet forms of XARELTO since July and November 2011, respectively. A liquid suspension form of XARELTO has also been approved under NDA No. 215859 since December 20, 2021.

c. Teva filed an application on August 30, 2018, to market 10, 15, and 20 mg generic versions of Rivaroxaban tablets. Teva's applications contained certifications that the patents listed in FDA's Orange Book were either invalid, not infringed, or unenforceable.

d. Teva was sued as a result of filing its applications to market generic versions of XARELTO. The lawsuit as to the 10, 15, and 20 mg Rivaroxaban tablets was dismissed pursuant to a settlement on April 8, 2020.

e. Pursuant to the terms of the settlement agreement, Teva plans to launch a generic tablet form of Rivaroxaban that will compete with XARELTO starting on March 15, 2027. Teva's generic is expected to be among the first to market.

***LINZESS (Linaclotide)***

25. CMS selected LINZESS (Linaclotide) for the Drug Price Negotiation Program in January 2025. LINZESS will therefore be subject to a price cap beginning January 1, 2027.

a. LINZESS is a branded drug that treats irritable-bowel syndrome.

b. LINZESS has been approved under NDA No. 202811 since August 2012.

c. Teva filed an application on August 30, 2016, to market 145 and 290 mcg Linaclotide capsules. Teva filed an application on November 7, 2017, to market a 72 mcg Linaclotide capsule. Teva's applications contained certifications that the patents listed in FDA's Orange Book were invalid, not infringed, or unenforceable.

d. Teva was sued as a result of filing its applications to market generic versions of LINZESS. The lawsuits were dismissed against Teva pursuant to settlements in February 2020 and May 2021, respectively.

e. Teva plans to launch a generic form of Linaclotide that will compete with LINZESS on March 31, 2029. Teva was among the first filers on the 145 mcg and 290 mcg Linaclotide capsules, and is the sole first filer on the 72 mcg Linaclotide capsules. Teva's generic for all strengths is expected to be among the first to launch, all of which are expected to enter the market on March 31, 2029.

***XIFAXAN (Rifaximin)***

26. CMS selected XIFAXAN (Rifaximin) for the Drug Price Negotiation Program in January 2025. XIFAXAN will therefore be subject to a price cap beginning January 1, 2027.

a. XIFAXAN is a branded drug that treats irritable bowel syndrome with diarrhea and hepatic encephalopathy.

b. XIFAXAN has been approved under NDA No. 22554 (550 mg) since March 2010, and NDA No. 21361 (200 mg) since May 2004.

c. Teva filed an application on December 17, 2015, to market 550 mg strength of Rifaximin. Teva's application contained a certification that the patents listed in FDA's Orange Book were either invalid, not infringed, or unenforceable.

d. Teva was sued on March 23, 2016, as a result of filing its application to market a generic version of XIFAXAN. The lawsuit was dismissed pursuant to a settlement on September 17, 2018.

e. Pursuant to the terms of the settlement, Teva plans to launch its 550 mg Rifaximin product that will compete with XIFAXAN starting on January 1, 2028. Teva was the first-filed generic and is anticipated to be the first and only generic to launch on that date; FDA has confirmed that Teva has retained its 180-Day exclusivity as the first company to file a Paragraph IV challenge to XIFAXAN.

***OTEZLA (Apremilast)***

27. CMS selected OTEZLA (Apremilast) for the Drug Price Negotiation Program in January 2025. OTEZLA will therefore be subject to a price cap beginning January 1, 2027.

a. OTEZLA is a branded drug that treats psoriatic arthritis and plaque psoriasis.

b. OTEZLA has been approved under NDA Nos. 205437 and 206058 since March 2014 and September 2014, respectively. OTEZLA comes in a titration pack, containing combinations of 10 mg, 20, mg, and 30 mg strength tablets, as well as bottles

of the 20 mg and 30 mg tablets. All approved indications for OTEZLA provide for the patient to start treatment with the appropriate titration pack and be followed by maintenance dosing using the 20 mg or 30 mg strength tablets.

c. Teva filed an application on March 21, 2018 to market Apremilast tablets. Teva's application contained a certification that the patents listed in FDA's Orange Book were either invalid, not infringed, or unenforceable.

d. Teva was sued on June 28, 2018, as a result of filing its application to market a generic version of Apremilast. The lawsuit was dismissed pursuant to a settlement on January 26, 2021.

e. Pursuant to the terms of the settlement, Teva plans to launch generic Apremilast tablets that will compete with OTEZLA starting in August 2028. Teva's generic is expected to be among the first generics to launch.

**THE DRUG PRICE NEGOTIATION PROGRAM HARMS TEVA**

28. When XTANDI, OFEV, XARELTO, LINZESS, XIFAXAN, and OTEZLA are subject to price caps, Teva will be prevented from launching its generic Enzalutamide, Rivaroxaban, Nintedanib, Linaclotide, Rifaximin, and Apremilast products at the arm's-length, free-market rates that would prevail absent price caps on the corresponding innovator products. In fact, if price caps are sufficiently low for any of those innovator products, Teva may be unable to launch its corresponding generic product at all. As a result, Teva will be deprived of revenue that it would have earned absent CMS's price caps.

29. Teva's ability to compete with brand-name products will be hindered by price controls on those products. When Teva launches its generic Rivaroxaban on March 15, 2027, it will be forced to compete against the 62-percent discount on branded XARELTO that CMS has

imposed, which significantly decreases Teva's ability to offer a lower price capable of recouping Teva's investment costs.

30. When XTANDI, XARELTO, LINZESS, XIFAXAN, and OTEZLA are subject to price caps, Teva's license agreements to sell Enzalutamide, Rivaroxaban, Linaclotide, Rifaximin, and Apremilast will also be impaired because the right to sell those generic products according to Teva's settlement agreements with the brand-name manufacturers will become less valuable.

31. Teva will also suffer a distinct injury when it is deprived of that revenue and those contractual rights without any opportunity to participate or otherwise be heard in the process that is responsible for depriving Teva of its property.

32. Finally, the Drug Price Negotiation Program creates uncertainty that impairs Teva's ability to invest in its pipeline of new generic products. Teva cannot be reasonably sure that it will be afforded the opportunity to recoup its investments in research and development, creating a disincentive to invest resources in those endeavors.

**CMS'S GUIDANCE FURTHER HARMS TEVA**

33. CMS has issued guidance that purports to implement the Drug Price Negotiation Program. At least two aspects of that guidance inflict additional harms on Teva.

***Qualifying Single Source Drug***

34. I understand that the IRA's statutory term for a drug that is eligible to be selected for the Drug Price Negotiation Program is a Qualifying Single Source Drug. I further understand that one consequence of that statutory definition is that a small-molecule drug cannot be selected until it has been approved for at least seven years, but that CMS's guidance effectively removes that limitation so that certain drugs can be selected sooner.

35. But for CMS's guidance, the tablet form of XTANDI could not have been selected for the Drug Price Negotiation Program because it has been approved for less than seven years.

As a result, Teva's Enzalutamide *capsule* product will be forced to compete against a price-controlled *tablet* version of XTANDI, on top of a price-controlled *capsule* version of XTANDI.

a. All other things being equal, patients and prescribers may prefer tablets to capsules because, for example, they are more shelf stable, able to be split, and sometimes easier to swallow. Prescribers and patients may well prefer the tablet form of XTANDI unless Teva's capsule form of Enzalutamide can offer significant price savings over the tablet form.

b. Because the tablet form of XTANDI will be subject to an IRA price cap as a result of CMS's guidance, Teva's capsule form of Enzalutamide will likely be unable to offer significant price savings over the tablet form of XTANDI. As a result, Teva will be deprived of revenue it would earn if the tablet form of XTANDI could continue to be sold in arm's-length, market-rate transactions.

36. But for CMS's guidance, the suspension form of XARELTO could not have been selected for the Drug Price Negotiation Program because it had been approved for less than seven years when it was selected. Teva's generic tablet form of Rivaroxaban will therefore be forced to compete against an additional price-capped version of XARELTO. As a result, Teva will be deprived of revenue it would earn if the suspension form of XARELTO could continue to be sold in arm's-length, market-rate transactions.

***"Bona Fide" Marketed***

37. I understand that the IRA provides for price caps to be lifted upon generic entry according to the following schedule: If generic competition begins after CMS publishes its list of selections, but before the "negotiation" period ends, the drug or biologic remains selected, but no price cap is imposed, and the drug or biologic's selection terminates in the year after its price cap

would otherwise have taken effect. If generic competition begins after the end of the negotiation period, but before April 1 of the year in which the drug's price cap takes effect, the price cap applies during that year, but the drug's selection terminates in the following year. Finally, if generic competition begins after March 31 of any year in which the drug's price cap applies, the price cap applies during that year *and* the following year, terminating only thereafter.

38. Thus, for a drug that was selected for inclusion in the 2027 list, if a generic is "approved and marketed" between November 2, 2025 through March 31, 2027, the branded drug remains subject to the price cap through December 31, 2027. If the generic is "approved and marketed" between April 1, 2027 and March 31, 2028, the branded drug remains subject to the price cap for an extra year—through December 31, 2028.

39. For these reasons, the timing of generic entry has significant consequences for the duration of price caps. Generic entry on or before March 31 of a year in which a drug's price cap applies is the difference between 9 and 21 additional months of price caps.

40. I understand that the IRA defines generic entry sufficient to terminate price caps as the date on which the first sale of a generic product occurs. I further understand that CMS's guidance effectively rewrites that definition to give CMS the power to determine when generic competition is sufficiently "bona fide" to terminate price caps.

41. CMS has stated publicly that it will determine whether a generic is "bona fide" marketed based on sales data reflected in Medicare Part D Prescription Drug Event (PDE) data and Medicaid Average Manufacturer Price (AMP) data.

42. I understand that CMS has acknowledged that PDE and AMP data are inherently time-lagged. In my experience, AMP and PDE data contain a significant lag, such that they do not reflect the extent of generic uptake until many months after generic marketing begins.

43. I also understand that CMS has acknowledged that AMP data will be unavailable for the two months preceding the crucial March 31 cutoff, and no PDE data for the month preceding the cutoff. Therefore, any generic launched in the months preceding March 31 cannot—under CMS's guidance—qualify as bona fide marketed in time to remove an innovator drug from price controls for the following year. The result is that the generic will be forced to compete against a price-controlled branded drug for an additional year.

44. As a result of CMS's guidance, there is a significant chance that XARELTO LINZESS, XIFAXAN, XTANDI, OTEZLA, and OFEV will be subject to at least an additional year of price caps.

a. Pursuant to the terms of its settlement agreement, Teva intends to launch its 10, 15, and 20 mg Rivaroxaban tablets on March 15, 2027, just two weeks before the crucial March 31, 2027 cutoff date for XARELTO to be removed from the Program for the following year. Because CMS's guidance is clear that its determination of "bona fide marketing" depends on PDE and AMP data, and those data will not exist for generics launched in March, it is virtually certain that XARELTO will be subject to an additional year of price controls.

b. Pursuant to the terms of its settlement agreements, Teva plans to launch its Linaclotide product on March 31, 2029, the same day as the cutoff for removing a drug from the Program for the following year. Because CMS's guidance is clear that its determination of "bona fide marketing" depends on PDE and AMP data, and those data will not exist for generics launched in March, it is virtually certain that LINZESS will be subject to an additional year of price controls.

c. Pursuant to the terms of its settlement agreement, Teva plans to launch its 550 mg Rifaximin product on January 1, 2028, just three months before the critical March 31 cutoff. At best, that would provide just one month of AMP data and two months of PDE data for CMS to review. In Teva's experience, that is insufficient time to generate significant utilization levels reflected in PDE or AMP data. That is particularly true because Teva's generic will compete against only the 550 mg strength of XIFAXAN, and not the 200 mg. If CMS deems those utilization levels insufficient as of March 31, 2028, Teva will be forced to compete against a price-controlled version of XIFAXAN for an additional year.

d. Pursuant to the terms of its settlement agreement, Teva anticipates launching its generic Enzalutamide capsules before the expiration of XTANDI's '517 patent on August 13, 2027. That would provide Teva less than eight months to sell enough product to satisfy CMS's "bona fide marketing" standard by March 31, 2028 such that XTANDI is removed from the Program for the following year. In Teva's experience, even eight months may not be enough time to generate significant utilization levels reflected in PDE or AMP data, particularly because Teva's generic is a capsule, not the tablet form of XTANDI which dominates the market. If CMS deems those utilization levels insufficient as of March 31, 2028, Teva will be forced to compete against a price-controlled version of XTANDI for an additional year.

e. Pursuant to the terms of its settlement agreement, Teva plans to launch its generic Apremilast product in August 2028. That would provide Teva only about seven months to sell enough product to satisfy CMS's "bona fide marketing" standard by March 31, 2029 such that OTEZLA is removed from the Program for the following year. Like

with XTANDI, in Teva's experience seven months on the market may be an insufficient amount of time to generate significant utilization levels. If CMS deems those utilization levels insufficient as of March 31, 2029, Teva will be forced to compete against a price-controlled version of OTEZLA for an additional year.

f. Teva anticipates launching is generic Nintedanib product six months after the first generic enters the market. Teva currently anticipates the first generic to be launched in April 2026, which would make Teva's entry in October 2026. If the first generic delays entry, however, Teva's entry date will be similarly delayed. Delays in generic entry will make it more difficult to generate significant utilization levels reflected in PDE or AMP data by March 31, 2027. And if CMS deems those utilization levels insufficient by that date, Teva will be forced to compete against a price-controlled version of OFEV for an additional year.

45. When XTANDI, OFEV, XARELTO, LINZESS, XIFAXAN, and OTEZLA are subject to price caps for longer than they would be absent CMS's guidance, Teva's generic Enzalutamide, Nintedanib, Rivaroxaban, Linaclotide, Rifaximin, and Apremilast products will be forced to compete with price-capped innovator drugs for longer than they would be absent CMS's guidance, therefore gaining less revenue and market share. CMS's guidance will therefore harm Teva by costing it revenue that it would otherwise earn if XTANDI, OFEV, XARELTO, LINZESS, XIFAXAN, and OTEZLA could be sold in arm's-length, market-rate transactions sooner.

46. For manufacturers like Teva, which makes both branded and generic products, declining revenue from generics also threatens to hamper the company's ability to develop innovative products, to the detriment of patients nationwide.

47. CMS's guidance also impairs Teva's contractual rights to sell its generic Enzalutamide, Rivaroxaban, Linaclotide, Rifaximin, and Apremilast products by reducing the expected value of those rights.

48. I understand that CMS also claims the authority to continually reassess whether a generic clears its "bona fide marketing" threshold, such that if CMS determines that a generic drug manufacturer is no longer engaged in "bona fide marketing," the branded product could become re-eligible for negotiation and selection. Teva must factor into its decisions whether to invest in and launch generic products both the uncertainty of whether CMS will determine that a generic is "bona fide" marketed in the first place, as well as the ever-present possibility that CMS will re-subject a branded drug to price caps and stifle generic competition. If Teva cannot be confident that it will be able to receive a return on its investment, it is likely to discontinue research and development on that product or even cancel a planned launch, depriving Teva of its investments.

49. Finally, CMS's guidance independently injures Teva by depriving it of revenue and the value of its contractual rights without any opportunity to be heard. CMS's "bona fide" standard is largely opaque, subjective, and leaves Teva without any meaningful way to persuade the agency that the competition created by its generic products is "bona fide" and should be deemed sufficient to lift price caps imposed on innovator products.

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

Carrie Groff

February 20 2025

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

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| TEVA PHARMACEUTICALS USA, INC., *et al.*,<br><br>*Plaintiffs*,<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*. | No. 1:25-cv-00113-SLS |

**DECLARATION OF DELL FAULKINGHAM**

I, Dell Faulkingham, 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 Senior Vice President, U.S. Innovative Medicines 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 innovator, generic, and biosimilar pharmaceutical products in the United States.

3. In my capacity as Senior Vice President, U.S. Innovative Medicines, I lead the team in charge of the commercialization of innovative products at Teva, including AUSTEDO and AUSTEDO XR. My team coordinates the sales and marketing of innovative products at Teva and in that capacity we coordinate with Teva's research and development as well as regulatory affairs

personnel to ensure that our strategies align. We also make decisions about which products to prioritize based on the company's goals, projections, manufacturing capacity, and pertinent regulatory developments. My team also coordinates internal decision-making regarding inventory preparation activities for innovative products.

**TEVA'S INVESTMENTS IN ITS MEDICINE PORTFOLIO**

4. Teva invests substantial resources into creating and marketing its portfolio of medicines—both innovator new drugs and high-quality, lower-cost generic drugs.

5. To develop its innovator products, Teva must begin by identifying and pursuing new drug[1] candidates, in the hopes of creating new therapeutic options for patients. That process is extremely expensive, and it is riddled with dead-ends: most drug candidates never receive FDA approval. From start to finish, Teva's development of a new drug may take up to 5-10 years.

6. Even once Teva identifies a potential drug candidate, it still must invest further resources to bring that product to patients. For example, Teva must develop a scalable manufacturing process, subject the drug candidate to rigorous clinical trials, secure FDA approval to market the product,[2] and protect its intellectual property with patents, including the potential for costly patent litigation.

7. To enable continued investment in research and development, Teva must be able to recoup the costs incurred in researching and developing all its new drug candidates with revenue it receives from marketing the few products that survive the entire process. When Teva does so,

[1] Unless otherwise indicated, I use the terms "drug" and "medicine" to include both small-molecule and biologic products.

[2] Even after a manufacturer files a New Drug Application (NDA) or Biologics License Application (BLA), manufacturers commonly file multiple supplemental applications to a single NDA or BLA, including for different dosage forms and strengths.

it creates a virtuous cycle: Teva can use the revenue it gains from marketing new life-improving therapies it has already developed to fund the development of even more therapies, and so on.

8. That cycle relies on Teva's ability to market its innovator products at market prices during statutory-exclusivity periods. Federal law provides sponsors of innovator drugs with various statutory-exclusivity periods, during which they may market their products free from competition by generic versions of those products. Innovator manufacturers 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.

9. Without the ability to rely on those statutory-exclusivity periods to recoup its investments, the virtuous cycle of research and development would become a vicious cycle instead: If Teva does not earn sufficient revenue by marketing its products to cover the costs of researching and developing those products—including those related to the many drug candidates that never made it to market—Teva must reduce or terminate its investments in further research and development. If Teva does not invest sufficient funds in further research and development, its pipeline of new products will dry up, and Teva will be deprived of the revenue it would otherwise have earned by marketing those products. And patients will never receive new therapies that would otherwise have improved or extended their lives.

**TEVA'S AFFECTED INNOVATOR PRODUCTS**

10. AUSTEDO and AUSTEDO XR are life-changing medicines that benefit patients with certain movement disorders. FDA approved AUSTEDO in April 2017 (NDA 208082) with an indication for Huntington's disease chorea; an additional indication for tardive dyskinesia was

approved in August 2017.[3] Teva Branded Pharmaceutical Products R&D LLC is the application holder for AUSTEDO. FDA approved AUSTEDO XR in April 2023 (NDA 216354).[4] Teva Neuroscience, Inc. is the application holder for AUSTEDO XR.

11. Huntington's disease is a rare, terminal genetic disease that tends to cause uncontrollable movements of all muscles in the body, called chorea. Huntington's disease chorea particularly affects muscles in patients' arms, legs, face, and tongue. Tardive dyskinesia is charactered by involuntary movements and is associated with long-term use of antipsychotic medications, and therefore many tardive dyskinesia patients have underlying mental illness that can be exacerbated by suboptimal treatment of tardive dyskinesia. AUSTEDO and AUSTEDO XR are indicated in adults for the treatment of chorea associated with Huntington's disease and tardive dyskinesia. The active ingredient is deutetrabenazine, a vesicular monoamine transporter 2 (VMAT2) inhibitor.

12. AUSTEDO XR is the extended-release formulation of AUSTEDO. It gives patients the same benefits as AUSTEDO in a once-daily pill as opposed to the twice-a-day dosing schedule for AUSTEDO. AUSTEDO XR uses osmotic pressure to deliver deutetrabenazine at a controlled rate throughout the day. AUSTEDO XR particularly benefits patients with HD and tardive dyskinesia by lessening pill burden and helping to improve adherence in patient populations that often have severe movement disorders, and, in the case of TD, underlying mental illness.

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[3] FDA has approved nine supplements to AUSTEDO's NDA, from June 2018 through November 2024. FDA, Approval Date(s) and History, Letters, Labels, Reviews for NDA 208082, *available at* https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm.

[4] FDA has approved two supplements to the NDA for AUSTEDO XR, in May 2024 and July 2024. FDA, Approval Date(s) and History, Letters, Labels, Reviews for NDA 216354, *available at* https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm.

13. AUSTEDO is available in 6 mg, 9 mg, and 12 mg tablets. AUSTEDO XR is available in 6 mg, 9 mg, 12 mg, 18 mg, 24 mg, 30 mg, 36 mg, 42 mg, and 48 mg extended-release tablets. AUSTEDO XR is also available in 4-week titration kits in 12 mg, 18 mg, 24 mg, and 30 mg configurations.

14. Teva (and its predecessors) invested significant resources in researching and developing both AUSTEDO and AUSTEDO XR. Those efforts were rewarded with medicines that work: AUSTEDO successfully reduces movement symptoms in Huntington's disease chorea and tardive dyskinesia and patients when compared with placebo. Teva committed substantial additional investments in developing AUSTEDO XR and seeking FDA approval. Teva's NDA for AUSTEDO XR was supported by additional clinical study data demonstrating that the extended-release formulation is just as effective as twice-daily dosing.

15. Teva continues to invest in addressing the unmet needs of patients who benefit from AUSTEDO and AUSTEDO XR. For example, Teva conducted a 3-year IMPACT-TD Registry study, the largest of its kind, to evaluate tardive dyskinesia patients outside a clinical-study setting.

**THE DRUG PRICE NEGOTIATION PROGRAM HARMS TEVA**

16. Teva must comply with the requirements of the Inflation Reduction Act's (IRA's) Drug Price Negotiation Program. On January 17, 2025, the Centers for Medicare & Medicaid Services (CMS) announced that it had selected two of Teva's innovator products—AUSTEDO and AUSTEDO XR—for inclusion in the Drug Price Negotiation Program. That selection means CMS will impose price caps on those products beginning January 1, 2027.

17. As a result of CMS's selection of AUSTEDO and AUSTEDO XR, Teva must engage in a process with CMS that the IRA calls a "negotiation." In fact, the process will not involve any genuine negotiation. Even though there are opportunities for initial "informational" meetings with CMS and some back-and-forth until the final price is "set," the practical reality is

that CMS will "propose" a price cap for Teva's products; Teva will have one written opportunity to request a higher price cap; and CMS will respond with its final "offer."

18. Teva takes seriously CMS's representation that it will consider the manufacturer's counteroffer "as CMS reviews data and develops its final offer." 2027 Guidance at 62. But the statutory reality is that Teva will have no choice but to accept CMS's final offer. If Teva were to attempt to resist that offer, I understand that Teva would be subject to a penalty of up to 95 percent of its total U.S. revenues for AUSTEDO and AUSTEDO XR. That penalty would be financially ruinous.

19. Teva also has no way to avoid paying this penalty. I understand that the IRA provides for "suspension" of this 95-percent penalty if a manufacturer terminates its Medicare Part D agreements and its Medicaid rebate agreement for all of its drugs—which would also make Teva's products ineligible for federal reimbursements under Medicare Part B. In other words, the statute's supposed "suspension" of the penalty demands complete withdrawal from Medicare and Medicaid.

20. Teva cannot take that step. Withdrawing all of Teva's thousands of products from Medicare and Medicaid would cause Teva to lose an unsustainable amount of revenue and jeopardize Teva's future. It would also deprive vulnerable patient populations served by those programs of the critical therapies that Teva offers. Teva cannot accept either result, so it must participate in the Drug Price Negotiation Program and accede to CMS's demanded price.

21. Teva has no meaningful opportunity—that is, an opportunity that could materially affect the outcome—to participate in the Drug Price Negotiation Program's process of selecting or setting prices for AUSTEDO and AUSTEDO XR.

22. When CMS subjects AUSTEDO and AUSTEDO XR to price caps under the Drug Price Negotiation Program, Teva will earn less revenue for those products than it would if CMS had not selected AUSTEDO or AUSTEDO XR. Teva will also suffer a distinct injury when it is deprived of that revenue as a result of an illusory negotiation—one that forces Teva to accept the government-dictated price, with no meaningful way for Teva to participate or object to CMS's ultimate decision.

23. The Drug Price Negotiation Program also creates uncertainty that impairs Teva's ability to invest in its pipeline of new and improved innovator products. Teva cannot be reasonably sure that it will be afforded the opportunity to recoup its investments in research and development of both new medicines and improvement on existing therapies, creating a disincentive to invest resources in those endeavors. For every discontinued investment, patients lose an opportunity for a newer and/or better therapy.

**CMS'S GUIDANCE FURTHER HARMS TEVA**

24. CMS has issued guidance that purports to implement the Drug Price Negotiation Program.

25. I understand that the IRA's statutory term for a drug that is eligible to be selected for the Drug Price Negotiation Program is a Qualifying Single Source Drug. I further understand that one consequence of that statutory definition is that a small-molecule drug cannot be selected until it has been approved for at least seven years, but that CMS's guidance effectively removes that limitation so that certain drugs can be selected sooner.

26. But for CMS's guidance, AUSTEDO XR could not have been selected for the Drug Price Negotiation Program because it was approved pursuant to a different NDA than AUSTEDO and has been approved for fewer than seven years. As a result, Teva will be deprived of revenue it would earn if it remained free to sell AUSTEDO XR in arm's-length, market-rate transactions.

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

Dell Faulkingham

February 21, 2025

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

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| TEVA PHARMACEUTICALS USA, INC., *et al.*,<br><br>*Plaintiffs*,<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.* | No. 1:25-cv-00113-SLS |

**[PROPOSED] ORDER ON MOTIONS FOR SUMMARY JUDGMENT**

Upon consideration of Plaintiffs' motion for summary judgment, Defendants' cross-motion for summary judgment, and all responses and replies thereto, the Court **ORDERS** as follows:

Plaintiffs' motion for summary judgment is **GRANTED**; and

Defendants' cross-motion for summary judgment is **DENIED**; and

The Inflation Reduction Act's Drug Price Negotiation Program and the Centers for Medicare & Medicaid Services' guidance documents purporting to implement the Program are **DECLARED** unconstitutional under the Fifth Amendment's Due Process Clause; and

The Inflation Reduction Act's Drug Price Negotiation Program and the Centers for Medicare & Medicaid Services' guidance documents purporting to implement the Program are **ENJOINED**, and Defendants; their officers, agents, servants, employees, and attorneys; and other persons in active concert or participation with any of the foregoing are **ENJOINED** from implementing the Program or the guidance documents; and

The Centers for Medicare & Medicaid Services' guidance documents' "qualified single source drug" definition and "bona fide marketing" standard are **DECLARED** arbitrary, capricious, and contrary to law; and

The Centers for Medicare & Medicaid Services' guidance documents' "qualified single source drug" definition and "bona fide marketing" standard are **VACATED** and **SET ASIDE**.

**IT IS SO ORDERED.**

Dated: _____

_____
Honorable Sparkle L. Sooknanan
United States District Judge