IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TEVA PHARMACEUTICALS USA, INC. 400 Interpace Pkwy #3, Parsippany, New Jersey 07054; and TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., 145 Brandywine Parkway, West Chester, Pennsylvania 19380; *Plaintiffs*, v. XAVIER BECERRA, in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, 200 Independence Avenue, S.W., Washington, D.C. 20201; and CHIQUITA BROOKS-LASURE, in her official capacity as ADMINISTRATOR OF THE CENTERS FOR MEDICARE & MEDICAID SERVICES, 7500 Security Boulevard, Baltimore, Maryland 21244, *Defendants*.	Civil Action No. 25-113

COMPLAINT

Teva Pharmaceuticals USA, Inc. and Teva Branded Pharmaceutical Products R&D, Inc. (collectively, Teva) bring this complaint challenging certain aspects of the drug-pricing provisions of the Inflation Reduction Act of 2022, Pub. L. 117-169 (the IRA), as well as guidance issued by the Centers for Medicare & Medicaid Services (CMS) purporting to implement the IRA.

PRELIMINARY STATEMENT

1. Much has been written about the IRA's impact on pharmaceutical innovation. This action seeks to ensure that the statute's unlawful negative impact on our country's public health, as supported by lower-cost generic and biosimilar medicines, is also addressed. This challenge to CMS's implementation of the IRA's drug-pricing provisions reflects Teva's unique position in the pharmaceutical ecosystem as a developer of innovative medicines as well as high-quality generic drugs and biosimilars. Teva provides not only new and needed therapies to American patients, but also lower-cost alternatives to existing branded medicines. That vantage point provides Teva with a singular perspective as to how CMS's unlawful implementation of the IRA, along with the IRA drug pricing program's unconstitutionality, upsets the delicate balance between innovation and affordability at the core of the American public health infrastructure.

2. The IRA's Drug Price Negotiation Program (DPNP) is a fiction. The statute empowers CMS to impose lower prices for Medicare's top-spend medicines, even when generic or biosimilar alternatives are already likely to bring those prices down through free-market competition. But the statute does its best to obscure its true nature, and CMS has further muddied the waters by promulgating guidance that gives the agency even more unchecked price-setting power without any statutory basis and under the guise of implementing statutory directives.

3. CMS's guidance re-writes two of the critical limitations imposed by Congress in the IRA. *First*, the IRA makes drugs eligible for price controls only after they have been marketed for a set number of years. *Second*, the IRA exempts drugs from price controls when a non-branded competitor—such as a generic or biosimilar—emerges. CMS rendered both of those Congressionally imposed limitations illusory by fabricating a new definition of a statutory term and by replacing a statutory test with one of CMS's own making.

4. CMS's novel definition is of a Qualifying Single Source Drug, which is the IRA's term for a drug that is eligible to be selected for the DPNP. Under the statute, each eligible drug corresponds to a particular FDA application to approve that drug. Under CMS's made-up definition, the agency can decide that two or more drugs approved under distinct FDA applications held by the same entity should be treated as one Qualifying Single Source Drug because they have the same active moiety—that is, the same active molecule. That guidance, which has no basis in the statutory text, warps the timing of the DPNP Congress established. Two drugs with the same active moiety may be approved years apart, but CMS's rule starts the negotiation eligibility clock with the first approval. CMS thus asserts that a second drug with same active moiety can be subject to a price control *immediately* after it is approved, despite the contrary statutory language.

5. CMS's novel test splices an atextual, discretionary exception into the IRA. Under the statute, a drug becomes ineligible for a price control based on when a non-branded competitor has been "approved" and "marketed." That test creates an objective, yes-or-no inquiry: Has a non-branded competitor's first sale occurred? CMS's guidance replaces that test with a subjective determination: whether the marketing of the non-brand competitor is "bona fide." As CMS's guidance readily admits, the "bona fide marketing" determination is subjective and standardless. CMS says it will consider the "totality of the circumstances" and any forms of evidence it wishes. And CMS has announced that it will apply that test on an "ongoing" basis, meaning it can change its mind at will about whether "bona fide marketing" has occurred.

6. Through CMS's expansions of the statutory text—that multiple different drugs can be one Qualifying Single Source Drug, and that CMS's assessment of what constitutes "bona fide marketing" may consider anything other than whether a non-branded drug has been "approved"

and "marketed"—the agency claims even more power over drug pricing than the already capacious IRA permits.

7. At bottom, the DPNP does not actually involve negotiation. A drug manufacturer receives an initial "offer" from CMS, with a putative opportunity to counter, but CMS in the end issues a final take-it-or-leave-it demand. That is a price control, not a negotiated agreement.

8. The promise of fairness is another mirage. The statute sets a ceiling for the initial offer but, for most drugs, no floor for CMS's ultimate demand, leaving manufacturers with no assurance that the price CMS imposes will be anything close to fair.

9. Nor does the IRA permit drug manufacturers any off-ramp. The statute offers two routes that appear to allow drug manufacturers to escape a CMS-imposed priced control. A drug manufacturer could "choose" to pay a set of steep, escalating fines capped at 95 percent of total *revenue*—not profit—for *all* sales of the drug, including commercial sales. Or a drug manufacturer could "choose" to withdraw from Medicare and Medicaid entirely—for all of its drugs. Either "choice" would bring swift financial ruin to a manufacturer and intolerable policy outcomes to the U.S. healthcare system. As Congress well knew, no rational drug manufacturer could accept those consequences.

10. The IRA permits CMS to write the "negotiation" script from start to finish. On the front end, the agency decides which drugs are included in the DPNP, what initial "offer" to make, what final price control to impose, and whether to later "renegotiate" a price control, to name only some examples. CMS's guidance expands that power by allowing it to select even more drugs than Congress permitted and to decide when its price controls can no longer apply. On the back end, Congress purported to preclude judicial review of many of these decisions *entirely*. CMS

gets the first, last, and only word. That is a far cry from the government's portrayal of the IRA as creating a process for voluntary negotiation.

11. For those reasons, the DPNP is unlawful. CMS's guidance contradicts the statute twice over and exceeds the agency's authority, in violation of the Administrative Procedure Act (APA), 5 U.S.C. § 706. And the IRA denies drug manufacturers due process by stripping them of protected property interests without giving them a meaningful opportunity to be heard or offering sufficient protections against erroneous deprivations of those interests.

12. As a leading manufacturer of both innovative therapies and generic and biosimilar drugs, Teva has a front-row seat to how the IRA operates in practice. And the harms to America's biotech ecosystem are clear: The IRA's legislative experiment in market manipulation undermines not just the innovation that creates next-generation therapies, but also the Congressionally created public health infrastructure that ensures those therapies transition to lower-cost options on a defined and predictable time frame.

13. Other drug manufacturers have brought challenges to the IRA's constitutionality and to the legality of CMS's guidance. But those cases have focused on the harms to manufacturers of branded drugs and biologics. Those harms are real, substantial, and equally relevant to this case. Branded drugs are directly subject to price controls that impose steep discounts, causing their manufacturers to lose massive revenue. Those harms are profound and wide-ranging because research and development of innovative drugs is expensive, risky, and fraught with failure. By destroying innovative manufacturers' ability to recoup their investments in the industry's most successful drugs, the IRA disincentivizes further innovation, ultimately harming patients, too.

14. This case, however, is different from the others. This case is about the unlawful way in which CMS implements the entire IRA system *as well as* the harms visited on non-branded drugs and biologics, as Teva also knows first-hand.

15. Federal law has long encouraged the development of generic small-molecule drugs. More recently, it began doing the same for non-brand versions of more-complex biologic products, called biosimilars. Under those legal regimes, the manufacturers of innovative drugs and biologics are permitted a period of exclusivity in which they can recoup their investments in research and development. Then, generics and biosimilars enter the market, bringing down costs for patients and payors. The predictability of non-branded entry, in turn, incentivizes brand name manufacturers to continue to develop new, innovative drugs and biologics to address yet unmet medical needs. It is a virtuous cycle of innovation, recoupment, low-cost competition, and further innovation.

16. For this system to work, though, generics and biosimilars must be able to compete on price by charging substantially less than their branded counterparts, capturing market share in the process. Otherwise, no patients or payors would choose them, and generic and biosimilar manufacturers such as Teva would not recover *their* investments, which in turn fund the development of future generic and biosimilar competitors and their public health benefits.

17. CMS's re-writing of the DPNP disrupts this process by forcing a generic or biosimilar manufacturer to compete—in ways not even contemplated by the scheme imposed by Congress in the IRA—with unlawful price controls rather than free-market prices.

18. CMS's unlawful definition of a Qualifying Single Source Drug pulls branded drugs and biologics into the "negotiation" process and forces price controls on them before their statutory due date. That expansion of price controls shortens—if not eliminates—the period during which

generic and biosimilar competitors can capture market share based on what should be their lower prices. CMS's dampening of non-branded competition in this way hurts not just the manufacturers of generics and biosimilars, but also weakens the U.S. healthcare system as a whole. Generics and biosimilars are the foundation of our public-health infrastructure, making up the vast majority of prescriptions written in the country. Generics' and biosimilars' commercial success funds the manufacturing capacity that ensures these low-cost medicines are available nationwide and protects against drug shortages—a bulwark that will be lost if manufacturers have no incentive to develop these products.

19. CMS's "bona fide marketing" standard overrides Congress's express direction that competition trumps price controls once a generic or biosimilar enters the market. By giving itself the power to retain price controls until "bona fide marketing" of a generic or biosimilar occurs—whatever that means—CMS has lengthened, and, in some cases, created the period in which a generic or biosimilar must struggle to compete with a price-controlled branded product.

20. For these reasons, Teva will suffer imminent irreparable harm from both the IRA as enacted and from CMS's unlawful guidance purporting to implement the IRA. Teva thus brings this action seeking injunctive relief, declaratory relief, and relief under the APA to prevent harm to both itself and its patients.

PARTIES

21. Plaintiff Teva Pharmaceuticals USA, Inc. is a corporation organized in Delaware with its principal place of business at 400 Interpace Pkwy #3, Parsippany, New Jersey 07054. Teva Pharmaceuticals USA, Inc. sells AUSTEDO and AUSTEDO XR and will sell the product described in Teva's applications for generic Enzalutamide, Nintedanib, Linagliptin, Rivaroxiban, and Linaclotide.

22. Plaintiff Teva Branded Pharmaceutical Products R&D, Inc. is a corporation organized in Delaware with its principal place of business at 145 Brandywine Parkway, West Chester, Pennsylvania 19380. Teva Branded Pharmaceutical Products R&D, Inc. is the application holder for AUSTEDO and AUSTEDO XR.

23. Defendant Xavier Becerra is the Secretary of the U.S. Department of Health and Human Services (HHS). Defendant Becerra maintains an office at 200 Independence Avenue, S.W., Washington, D.C. 20201. He is sued in his official capacity only.

24. Defendant Chiquita Brooks-LaSure is the Administrator of CMS. In that capacity, Defendant Brooks-LaSure is responsible for administering the guidance and statutory provisions challenged here on behalf of the HHS Secretary. Defendant Brooks-LaSure maintains an office at 7500 Security Boulevard, Baltimore, Maryland, 21244. She is sued in her official capacity only.

JURISDICTION AND VENUE

25. This Court has jurisdiction under the following statutes:

a. 28 U.S.C. § 1331, because this civil action arises under the laws of the United States;

b. 28 U.S.C. § 1346(a)(2), because Teva asserts claims against the United States;

c. 28 U.S.C. § 1361, because this is an action to compel officers of the United States to perform their duties; and

d. 28 U.S.C. §§ 2201–02, because this is an actual, justiciable controversy as to which Teva requires a declaration of its rights by this Court and injunctive relief to prohibit Defendants from violating laws and regulations.

26. Venue is proper in this Court under 28 U.S.C. § 1391(e)(1)(A) because this is a civil action in which Defendants are officers of the United States acting in their official capacities and at least one defendant resides in this judicial district.

FACTUAL BACKGROUND

I. Statutory and Regulatory Background

A. Medicare and FDA's Drug-Approval Process

27. The Medicare program provides health insurance for eligible individuals: people 65 or older; people with certain disabilities; and people with certain conditions, such as end-stage renal disease. As relevant here, Medicare Part B covers enrolled beneficiaries for drugs and biologics that are typically administered by healthcare providers. Medicare Part D, which is optional, helps cover beneficiaries' drugs that are not typically administered by healthcare providers. About 20 percent of Americans are covered by Medicare.

28. Before a "new" drug can be marketed, FDA must approve it. 21 U.S.C. §§ 355(a), 331(d). A "new" drug may be one that has never been approved, or it may be an already-approved drug product with some innovation, such as a new intended use or indication, or a different strength or dosage form. *See id.* § 321(p). A manufacturer seeks approval of a new drug through a New Drug Application (NDA). Approval is an arduous, years-long process that few drug candidates survive.[1]

29. Innovator pharmaceutical companies invest vast resources into identifying and pursuing new drug candidates in the hopes of giving patients new therapeutic options for saving or improving their lives. Studies have found that it costs from hundreds of millions to well over $4

[1] A parallel process exists for licensing new biologics through a Biologics License Application. *See* 42 U.S.C. § 262(a). When used on its own in this complaint, the term "drug" refers collectively to both drugs and biologics, and the term "generic" refers collectively to both generics and biosimilars.

billion to bring a new drug to market, and more-recent drugs tend to run at the higher end of that range. *See* Michael Schlander, *et al.*, *How Much Does It Cost to Research and Develop a New Drug? A Systematic Review and Assessment*, 39 PharmacoEconomics 1243, 1264 (Aug. 9, 2021), *available at* https://link.springer.com/article/10.1007/s40273-021-01065-y (presenting estimates in 2019 U.S. dollars). But most of those resources are spent on dead ends because many early drug candidates never reach approval and commercialization. Innovator drugs are therefore typically rewarded with periods of marketing exclusivity and patent rights to make that innovation viable.

B. Generic and Biosimilar Competition

30. The exclusive marketing rights needed to enable and reward innovation typically result in high sticker prices for new medicines. That is the trade-off for American patients being the first in line to receive innovative therapies and for the need to recoup the high cost of drug development, including the cost of the many failed drug candidates. So federal law provides a path for generic competition to reduce prices once an innovator manufacturer has had a chance to recoup the research-and-development costs for both the approved product *and* those that never get across the finish line.

31. For decades, the Hatch-Waxman Act[2] has advanced the dual goals of encouraging innovation and reducing cost by, in part, streamlining the path for approval of generic drugs by eliminating the need for manufacturers to file an NDA. A generic manufacturer instead files an Abbreviated New Drug Application (ANDA), which relies on the demonstration of safety and efficacy already made by the brand manufacturer's NDA. An ANDA certifies "that the generic has the 'same active ingredients as,' and is 'biologically equivalent' to, the already-approved

[2] Formally known as the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355).

brand-name drug." *FTC v. Actavis, Inc.*, 570 U.S. 136, 142 (2013) (quoting *Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012)).

32. Hatch-Waxman's abbreviated approval pathway quickly transformed the healthcare market. By "making generic entry easier and less costly, the Hatch-Waxman Act helped increase the number of generic manufacturers producing the same drug," which reduced the "average prescription price of a generic drug." CBO, *How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* xiii (July 1998), *available at* https://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/6xx/doc655/pharm.pdf. In the last decade, generic drugs have saved U.S. patients and the U.S. healthcare system over $3 trillion, with $445 billion of those savings occurring in 2023 alone. Ass'n for Accessible Meds., *The 2024 U.S. Generic & Biosimilar Medicines Savings Report Fact Sheet* (Sept. 2024), https://accessiblemeds.org/wp-content/uploads/2024/09/AAM-2024-Generic-Biosimilar-Medicines-Savings-Report-Fact-Sheet.pdf (AAM 2024 Fact Sheet).

33. Those savings have contributed to generics' tremendous popularity. By 2023, 90 percent of all prescriptions were dispensed as generics, yet generics accounted for only about 13 percent of spending on drug products. AAM 2024 Fact Sheet, *supra*. State laws also drive widespread generic adoption. Since Hatch-Waxman's passage, every state has adopted laws that permit pharmacies to substitute generic equivalents for brand prescriptions; some such laws *require* generic substitution unless the prescriber specifically directs otherwise.

34. In the biologic market, Congress more-recently sought to replicate Hatch-Waxman's success in making small-molecule drugs affordable. Unlike "traditional [small-molecule] drugs, which are typically synthesized from chemicals," a "biologic is a type of drug derived from natural, biological sources such as animals or microorganisms." *Sandoz Inc. v. Amgen Inc.*, 582

U.S. 1, 6 (2017). These biologics "often represent the cutting-edge of biomedical research and, in time, may offer the most effective means to treat a variety of medical illnesses and conditions that presently have no other treatments available." FDA, *What Are "Biologics" Questions and Answers* (Feb. 6, 2018), *available at* https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers. To encourage competition among biologics, Congress passed the Biologics Price Competition and Innovation Act (BPCIA) in 2010.[3]

35. Like Hatch-Waxman, the BPCIA provides a streamlined path for the approval of non-branded versions of existing innovator biologics, commonly known as "biosimilars." The BPCIA authorizes shortened FDA review and approval of biologic products that a manufacturer shows are "highly similar" to, and have "no clinically meaningful differences" from, an existing FDA-licensed biologic product. 42 U.S.C. §§ 262(i)(2), (k). To spur innovation, the BPCIA also grants manufacturers of new biologics periods of market exclusivity, during which FDA cannot license any biosimilars that might otherwise compete with the innovator product. *Id.* § 262(k)(7).

36. Biosimilars, like generics, create significant cost savings because they introduce "robust . . . price competition." Ass'n for Accessible Meds., *The U.S. Generic & Biosimilar Medicines Savings Report* 9 (Sept. 2023), *available at* https://accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf. That competition results in lower prices both for brand biologics and for biosimilars. On average, brand biologics drop in price by over 25 percent after the entry of a biosimilar, and biosimilars are more than 50 percent cheaper than brand biologics. *Id.* Biosimilars have therefore already saved U.S. patients and the U.S. healthcare system almost $24 billion since the first biosimilar launched in 2015. *Id.*

[3] Formally known as the Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, § 7001, 124 Stat. 119, 804 (2010) (codified at 42 U.S.C. § 262).

37. Generics and biosimilars also strengthen the healthcare system by diversifying drug supply. Without the competition generics and biosimilars provide, the brand-name manufacturer would be the only source of a given product. But that arrangement leaves the drug supply vulnerable to shortages because one seller can encounter "manufacturing and quality problems, delays, [or] discontinuations." FDA, *Drug Shortages* (last updated Jan. 10, 2025), *available at* https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages. Regulatory hurdles may exacerbate those problems, and a new manufacturer cannot help address a shortage until it secures FDA approval, which takes time. FDA, *Drug Shortages: Root Causes and Potential Solutions* 6 (updated Feb. 21, 2020), *available at* https://www.fda.gov/media/131130/download?attachment.

38. Generics and biosimilars can guard against shortages by increasing the number of sources for a medicine, which "can help stabilize the supply." FDA, *Generic Drugs Can Help Promote Health Equity*, *available at* www.fda.gov/media/173765/download. Generics and biosimilars therefore play a critical role in providing access to lifesaving and life-improving medicines.

39. Although the processes for approving generics and biosimilars are streamlined compared to innovator drugs, they still require substantial resources. That means generic and biosimilar competition depends on manufacturers' ability to invest significant time and money to bring generic and biosimilar products to market and on manufacturers having sufficient incentives to do so. For instance, in 2020 alone, Teva "invested nearly $1 billion in R&D activities" across its entire portfolio of products, a "significant portion" of which went to generics, leading to "more than 1,160 generic products in its development pipeline." Teva, *Generic Medicines and R&D* (Nov. 11, 2021), www.tevapharm.com/news-and-media/feature-stories/generics-medicine-development/. Teva's "R&D activities for generic products" generate diverse expenses including

"product formulation, analytical method development, stability testing, management of bioequivalence and other clinical studies and regulatory filings," among others. Teva Pharmaceutical Indus. Ltd., *2023 Form 10-K* 69 (Feb. 12, 2024), https://d18rn0p25nwr6d.cloudfront.net/CIK-0000818686/f65dca04-a98d-454c-8a16-9bee7f8825d8.pdf (noting that in 2023, Teva again spent nearly $1 billion in R&D across its entire portfolio of products).

40. Biosimilars require especially intense development. Biologics tend to be "complex mixtures that are not easily identified and characterized," which makes R&D unusually expensive. *What Are "Biologics", supra*. And unlike most generics, biosimilars "must still be put through some clinical trials," which adds further expense. CBO, *Research and Development in the Pharmaceutical Industry* 22 (Apr. 2021), *available at* www.cbo.gov/system/files/2021-04/57025-Rx-RnD.pdf. For these reasons, shepherding the typical biosimilar to approval can cost between $100 million and $300 million and can take between 6 and 9 years. Miriam Fontanillo, *Three Imperatives for R&D in Biosimilars*, McKinsey & Co. (Aug. 19, 2022), *available at* https://www.mckinsey.com/industries/life-sciences/our-insights/three-imperatives-for-r-and-d-in-biosimilars.

41. FDA approval, however, does not end the investment needed to market a successful biosimilar. Patentholders often challenge the launch of a biosimilar by filing costly litigation. *See generally Sandoz*, 582 U.S. at 7–10 (summarizing the BPCIA's framework for resolving patent disputes). Even after launch, biosimilar manufacturers must actively market their products because, unlike generic drugs, most already-licensed and yet-to-be-marketed biosimilars do not qualify for state automatic-substitution laws. *See* 42 U.S.C. § 262(k)(4) (establishing criteria for an "interchangeable" biosimilar, which may qualify for automatic substitution); Sophia Humphreys, Am. J. of Managed Care, *Understanding Interchangeable Biosimilars at the Federal and State Levels* (Aug. 16, 2023) (discussing the consequences of an "interchangeable" designation under

state substation laws). The biosimilar industry is therefore particularly susceptible to changes in incentives.

42. Generics and biosimilar manufacturers cannot invest the resources needed to market their products if they cannot reliably expect to earn sufficient returns on their investments. To earn the necessary returns, generic-drug manufacturers must be able to gain sufficient market share.

43. Generics compete with branded drugs almost exclusively on price. That is because generics are—by Congressional design—essentially fungible with the corresponding brand products, leaving no room for other forms of differentiation. *See* Vega Econ., *The Modern Regulatory Framework for Generic Drugs Encourages Active Price Competition* 3 (Aug. 2021), *available at* https://vegaeconomics.com/webfiles/Regulatory-Framework-for-Generic-Pharmaceuticals.pdf. Still, some consumers prefer branded drugs. *See, e.g.*, Aaron S. Kesselheim et al., *Variations in Patients' Perceptions and Use of Generic Drugs: Results of a National Survey*, 31 J. Gen. Int'l Med. 609 (Feb. 16, 2016), *available at* https://pmc.ncbi.nlm.nih.gov/articles/PMC4870419/. Generic manufacturers therefore tend to price their products far below the equivalent branded product to obtain market share. *See* Tracy L. Regan, *Generic Entry, Price Competition, and Market Segmentation in the Prescription Drug Market*, 26 Int'l J. Indus. Org. 930, 939 (Aug. 14, 2007), *available at* https://tinyurl.com/4n3fj8vj; Ryan Conrad & Randall Lutter, FDA Center for Drug Evaluation & Research, *Generic Competition & Drug Prices: New Evidence Linking Greater Generic Competition & Lower Generic Drug Prices* 8 (Dec. 2019), *available at* https://www.fda.gov/media/133509/download (reporting a median "60% reduction in price" when comparing generics to brands). Brand manufacturers, by contrast, tend to maintain or increase prices after generic entry to maximize revenue from the small share of

price-insensitive, brand-loyal patients. Regan, *supra*, at 947; *see also* Atanu Saha & Yong Xu, *The 'Generic Competition Paradox' Revisited*, Int'l J. of Econ. of Business 1–2 (Mar. 10, 2021), *available at* https://stoneturn.com/wp-content/uploads/2021/03/Generic-Competition-Paradox-Revisited_SahaXu_Mar2021.pdf.

44. The resulting generic pricing advantage is indispensable to generic manufacturers' ability 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* 5 (Apr. 2023), *available at* https://healthpolicy.usc.edu/wp-content/uploads/2023/04/2023.04_Schaeffer-White-Paper_Mitigating-Adverse-Impacts-of-the-IRA.pdf. By the same token, threats to this model "could effectively threaten the generic industry's financial viability." *Id.*

45. The ability to offer lower prices is similarly essential for biosimilars. Manufacturers of branded biologics sometimes respond to potential biosimilar entry by offering rebates that reduce the net prices of their products to certain payors. *See* Jennifer Carioto & Harsha Mirchandani, Milliman, *Barriers and Potential Paths for Biosimilars in the United States* 3 (Nov. 2018), https://us.milliman.com/-/media/milliman/importedfiles/uploadedfiles/insight/2018/biosimilars-united-states.ashx (Biosimilars Barriers). That strategy can prevent biosimilars from gaining significant market share, *id.*, which can cause them to "struggle to sustain production, leading to reduced competition." Skylar Jeremias, *The Rebate War: How Originator Companies Are Fighting Back Against Biosimilars* Ctr. for Biosimilars (Nov. 25, 2024), https://www.centerforbiosimilars.com/view/the-rebate-war-how-originator-companies-are-fighting-back-against-biosimilars.

46. Under this system, manufacturers of branded products have delivered patients countless breakthrough treatments, and manufacturers of generic and biosimilar products have

ensured the affordability of those treatments over the longer term. These outcomes were sustained by manufacturers' abilities to sell their products—both commercially and under Medicare—at prices dictated by market dynamics. The system struck a careful balance between spurring life-saving innovation and keeping drug prices as low as possible—until the IRA.

C. The IRA Becomes Law

47. President Biden signed the IRA into law in August 2022. As relevant here, the IRA created what it calls the DPNP, which lowers prices for certain drugs and biologics under Medicare Parts B and D. Inclusion in the program is supposed to be limited to drugs and biologics that lack generic or biosimilar competition, and the program is slated to begin imposing price controls starting in 2026.

Drug and Biologic Selection

48. Each year, the Secretary must select a specified number of "negotiation-eligible" drugs. 42 U.S.C. § 1320f-1(b). A drug is currently "negotiation-eligible" if it is among those with the 50 highest total Part D expenditures over a specified preceding 12-month period. *See id.* § 1320f-1(d)(1). CMS then ranks the "negotiation-eligible" drugs in order of the highest Medicare expenditures during that period and then selects the drugs with the "highest such rankings." *Id.* § 1320f-1(b)(1)(A)–(B).

49. The number of drugs to be selected as "negotiation-eligible" increases over time, for two reasons. *First*, the IRA directs the Secretary to select an increasing number of drugs for an "initial price applicability year" (aptly known as an "IPAY"). 42 U.S.C. § 1320f-1(a)(1)–(4). The Secretary selected ten Part D drugs for IPAY 2026. *Id.* § 1320f-1(a)(1). Then, for IPAY 2027, the Secretary must select fifteen more Part D drugs, on top of the ten already selected. *Id.* § 1320f-1(a)(2). That process continues with fifteen new selections in IPAY 2028—which may now include Part B drugs as well—and twenty new selections in IPAYs 2029 and later. *Id.*

§ 1320f-1(a)(3)–(4). *Second*, a drug's selection is sticky. A drug can retain its IPAY-selected status well after the drug faces generic or biosimilar competition. *Id.* § 1320f(c)(1). Under most circumstances, a drug cannot be deselected until the start of the first year that "begins at least 9 months after the date" on which generic or biosimilar competition begins. *Id.*

50. To be eligible for selection and negotiation, a drug must be a Qualifying Single Source Drug. 42 U.S.C. § 1320f-1(d)(1). The IRA defines the term, and the definition has four relevant parts. *First*, the drug must be eligible for Medicare coverage under Part B or Part D. *Id.* § 1320f-1(e)(1). *Second*, the drug must be approved by FDA. *Id.* §§ 1320f-1(e)(1)(A)(i). *Third*, sufficient time must have elapsed since the drug's approval. Small-molecule drugs become eligible for IPAYs beginning seven years after their approval. *Id.* § 1320f(e)(1)(A)(ii). *Fourth*, the drug must not be subject to generic competition. Small-molecule drugs are ineligible for selection if a generic has been "approved and marketed." *Id.* § 1320f-1(e)(1)(A)(iii).

Price "Negotiation"

51. A manufacturer whose product is selected must agree to participate in what the IRA calls the "the negotiation period." 42 U.S.C. § 1320f-2(a). During this period, CMS purportedly "negotiate[s] a maximum fair price" with the manufacturer. *Id.* § 1320f-3(a). The proceedings are negotiations in name only; CMS is directed not to work with each drug manufacturer to reach a genuine agreement, but to use "a consistent methodology" that will always "achieve the *lowest* maximum fair price." *Id.* § 1320f-3(b)(1) (emphasis added). After some token back-and-forth, the proceedings "shall end" with a final take-it-or-leave-it ultimatum from CMS. *Id.* § 1320f-3(b)(2)(B)–(E).

52. The term "maximum fair price" is another marketing fiction. The price is capped at a benchmark specified by statute: the lower of an average price calculated under Medicare Part D or a specified percentage of the non-federal average manufacturer price. *See* 42 U.S.C. §§ 1320f-

3(c)(1); 1395w-3a(b)(4). And that is only the cap; for most products, CMS is free to demand a "maximum fair price" *below* the cap. *Id.* § 1320f-3(c).

53. The IRA also limits the bases for manufacturers' nominal counteroffers to myopic "factors" specified by statute. 42 U.S.C. §§ 1320f-3(b)(2)(C)(ii), (e). For instance, a manufacturer may point to its "[r]esearch and development costs," but typically only those "for the drug" that has been selected. *Id.* § 1320f-3(e)(1)(A). That factor leaves out most of the enormous costs manufacturers incur identifying, researching, and developing the countless early drug candidates that never reach approval and that must be recouped through those drugs that *do* succeed.

54. Even if manufacturers were free to put forward all relevant evidence in support of their counteroffers, the "negotiations" would remain a pretext. Nothing in the IRA requires CMS to account for a manufacturer's counteroffer. It requires simply that CMS "respond in writing," which can include CMS reiterating its initial offer. *See* 42 U.S.C. § 1320f-3(b)(2)(D). And once CMS has made its final offer, the manufacturer must take or leave it.

55. Once CMS has imposed a "maximum fair price," a manufacturer must provide various Medicare participants "access to such price." 42 U.S.C. § 1320f–2(a)(1). Those participants include all eligible Medicare beneficiaries who are dispensed drugs under Medicare Part D; all "pharmacies, mail order services, and other dispensers" that dispense drugs to Medicare Part D beneficiaries; and all "hospitals, physicians, and other providers of services and suppliers" that furnish or administer drugs to Medicare Part B beneficiaries. *Id.* § 1320f–2(a)(1)(A)–(B); *see also id.* § 1320f(c)(2). Manufacturers must also extend the "maximum fair price" to all state Medicaid programs, and, through a requirement to offer the "maximum fair price" to participants in the 340B Drug Pricing Program, private parties as well. *Id.* § 1396r-8(c)(1)(C)(V) (including the "maximum fair price" in the best price when calculating the rebate manufacturers pay state Medicaid

programs, effectively ensuring those programs receive the "maximum fair price" as well); *id.* § 1320f-2(d) (specifying that manufacturers must offer the lower of the "maximum fair price" or the 340B ceiling price—but not both—to 340B covered entities).

56. Sales to all of these market participants must then continue at the "maximum fair price," adjusted only for inflation, until generic competition begins, or until CMS selects the drug for "renegotiation." 42 U.S.C. §§ 1320f–1(c)(1), 1320f–3(f), 1320f–4(b)(1)(A). As with the rest of this supposed "negotiation" process, failure to provide access to the "maximum fair price" leads to eye-popping penalties.

Penalties

57. A manufacturer's agreement to participate in "negotiations" and to acquiesce to CMS's "maximum fair price" are compelled by a punitive, escalating "tax." 42 U.S.C. §§ 1320f-2(a), 1320f-3(a); 26 U.S.C. § 5000D. Under the IRA, this "tax"—really a penalty—can reach up to 95 percent of the *total* U.S. revenues for the drug or biologic. 26 U.S.C. §§ 5000D(a), (d). The penalty continues to accrue daily until the manufacturer accedes to CMS's demands or until the drug is deselected. Thus, "[n]oncompliance," as the statute puts it, *id.* § 5000D(b), would vaporize multiples of the manufacturer's total revenues from the selected drug, not merely its profits.

58. The IRA provides for the "[s]uspension" of the penalty, but only if a manufacturer destroys itself. 26 U.S.C. § 5000D(c). Suspension requires the complete termination of the manufacturer's Medicare Part D agreements and Medicaid rebate agreement for *all* of its drugs—not merely the selected drug. *Id.* § 5000D(c)(1). Terminating the Medicaid rebate agreement would, in turn, cause *all* of a manufacturer's products to lose federal funding under Medicare Part B. 42 U.S.C. § 1396r–8(a)(1). Suspension of the noncompliance penalty therefore requires nothing short of absolute withdrawal from both Medicare and Medicaid, which means denying the manufacturer's products to potentially millions of patients.

59. No manufacturer could make that choice, as Congress well knew and intended. Medicare and Medicaid serve the Nation's most vulnerable communities, including elderly people, people with disabilities, and indigent people. Congress would not have accepted any genuine risk that these communities would lose access to critical medicines. Tellingly, Congress projected the IRA's so-called tax to have "no revenue effect." 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," as Passed by the House of Representatives, Fiscal Years 2022 – 2031* 8 (Nov. 19, 2021), *available at* https://www.jct.gov/publications/2021/jcx-46-21/. Congress understood that the "tax" would not raise a single penny of revenue because no rational manufacturer could choose to not comply and pay the penalty. Manufacturers must instead play along with CMS's sham negotiations and charge the price CMS demands.

60. Nor does the IRA allow courts to check CMS's near-unlimited power to select drugs and unilaterally impose price controls. Congress purported to preclude judicial review for key aspects of the DPNP, including the "selection of drugs," the "determination of qualifying single source drugs," and the "determination of a maximum fair price." 42 U.S.C. § 1320f-7.

CMS Issues Guidance Purporting to Implement the IRA

61. Congress directed that CMS implement the DPNP for IPAY 2026, 2027, and 2028 through "program instruction or other forms of program guidance." 42 U.S.C. § 1320f-1 note.

62. CMS issued its first guidance document in early 2023, announcing its plans for executing the DPNP for IPAY 2026. CMS, *Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2026* (Mar. 15, 2023) (the 2026 Initial Guidance).

63. CMS included its foundational policies governing the selection of drugs subject to negotiation in the 2026 Initial Guidance. CMS issued these policies in final form, with no opportunity for manufacturers or patients to comment. 2026 Initial Guidance at 2, 5.

64. A few months later—and just a few weeks before the selection of the first year's list of drugs—CMS released its final word on implementation of the DPNP for IPAY 2026. CMS, *Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2026* (June 30, 2023) (the 2026 Final Guidance). The 2026 Final Guidance doubled down on the 2026 Initial Guidance's most problematic aspects.

65. For the following year, IPAY 2027, CMS released its initial and final guidance in May 2024 and October 2024, respectively. CMS, *Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027* (May 3, 2024) (the 2027 Initial Guidance); CMS, *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027* (October 2, 2024) (the 2027 Final Guidance). In doing so, CMS again embraced the 2026 Guidance's worst aspects.

66. The Guidance Documents violate the IRA in at least two ways.

67. *First*, CMS overrode the statutory definition of a Qualifying Single Source Drug. The IRA makes clear that a Qualifying Single Source Drug is one drug, marketed under its own NDA. 42 U.S.C. § 1320f-1(e). But in the Guidance Documents, CMS lumps together multiple drugs, marketed under separate NDAs, as a single Qualifying Single Source Drug. CMS defines

a Qualifying Single Source Drug as any set of drugs "with the same active moiety"[4]—including "all dosage forms and strengths"—whose NDAs are held by the same entity. 2026 Final Guidance at 99; 2027 Final Guidance at 167–168. CMS's guidance adopts this definition even though the term "active moiety" does not appear anywhere in the IRA.

68. CMS's extra-statutory definition of a Qualifying Single Source Drug greatly expands and distorts the universe of products eligible for selection. By aggregating Medicare expenditures among multiple products, CMS is more likely to rank a drug highly. *See* 42 U.S.C. § 1320f(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 because its eligibility for selection will depend on the approval date for that earlier product. That change may drastically shorten—or even eliminate—the period in which a drug manufacturer may recoup its investment in developing a new and more patient-centric product.

69. *Second*, CMS distorted the criteria that make a drug ineligible for price controls due to generic competition. The IRA relies on two pathways to moderate prices of the drugs with the highest levels of Medicare spending: market-based competition by a generic competitor, or, failing that, price controls via the IRA. A brand-name drug is ineligible for selection and any previously imposed price control must be lifted if the brand-name product has a generic that is "approved" and "marketed." 42 U.S.C. §§ 1320f-1(e)(1)(A), (B). Both of these requirements are

[4] 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. 2026 Final Guidance at 99; 2027 Final Guidance at 168. 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. The term "active ingredient" also does not appear anywhere in the IRA.

simple yes-or-no determinations. A generic drug is approved when FDA grants an ANDA for the product, and it is marketed when its manufacturer launches it and the generic drug enters the commercial marketplace.

70. But CMS's Guidance Documents jettison the IRA's statutorily mandated objective determinations in favor of an unworkable subjective test. CMS grafted onto the statute a requirement that a generic or biosimilar must have been the subject of "bona fide marketing." 2026 Final Guidance at 102; 2027 Final Guidance at 170. Whether "bona fide marketing" has occurred, CMS explains, is a "holistic inquiry" based on the "totality of the circumstances." 2027 Final Guidance at 171.

71. CMS's "bona fide marketing" standard appears to be an attempt to evade a consequence of CMS's broadening of Congress's definition of Qualifying Single Source Drug. CMS's broadened definition combining multiple products into a single Qualifying Single Source Drug means that a generic or biosimilar that lists *any* of the grouped-together products as a reference would be enough to render *all* products with the same active moiety ineligible for the DPNP, as CMS grudgingly acknowledges. 2026 Final Guidance at 102; 2027 Final Guidance at 171. In that scenario, one of the branded products may have its price moderated by generic competition, but the other branded products would not, and yet all the products would be beyond CMS's reach. CMS therefore replaced the plain statutory text with a qualitative and subjective standard—never contemplated or enacted by Congress—that preserves its ability to impose price controls on a greater number of drugs than Congress specified.

D. The Stifling Effects on Generic and Biosimilar Competition Created by the IRA and CMS's Guidance

72. The IRA's price controls will disrupt generic and biosimilar competition for selected drugs by distorting the market effects that have allowed generic and biosimilar competition

to thrive since Hatch-Waxman and BPCIA's passage. When branded drugs and biologics must be sold at a government-mandated steep discount, a generic or biosimilar competitor cannot undercut the branded drug or biologic's price enough to recoup its substantial investment. The IRA therefore disincentivizes manufacturers to develop generics and biosimilars for drugs and biologics selected for the DPNP.

73. The IRA's distorting effect on the marketplace will be significant. When a drug or biologic is selected for an IRA price control, its manufacturer must make it available to Medicare beneficiaries at that price starting on the first day of the drug's IPAY. 42 U.S.C. § 1320f-2(a)(l). Of course, the CMS-mandated price will be far below the drug's market price; that is the point of the IRA's regime. The IRA thus requires CMS to set the price of a selected drug or biologic at the lower of an average Part D price or a specified percentage of the non-federal average manufacturer price. *See id.* §§ 1320f-3(c)(1); 1395w-3a(b)(4).

74. CMS's price controls will effectively bind generic and biosimilar manufacturers for as long as the branded drug remains selected and subject to its "maximum fair price." As noted above, biosimilars have historically launched at a discount of about 50 percent compared to the reference biologic. Ass'n for Accessible Meds., *The U.S. Generic & Biosimilar Medicines Savings Report* 23 (Sept. 2023), *available at* https://accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf. But if CMS has already ordered the biologic to charge that price, biosimilars have no room to compete. *See* Biosimilars Barriers, *supra*, at 3 (noting that brand manufacturers' rebates of around 50 percent of the biologic's list price have prevented some biosimilars from gaining substantial market share). So the DPNP "erode[s] the value proposition for a potential biosimilar [or generic] entrant," possibly leading them to "exit the market or never launch." Mark Von Eisenburg, Avalere, *How Will the IRA*

Impact the Future of Biosimilars? (Aug. 17, 2023), *available at* https://avalere.com/insights/how-will-the-ira-impact-the-future-of-biosimilars.

75. The results of "negotiations" for IPAY 2026 confirm that conclusion. CMS has published the discounts it will impose on the drugs selected for that year. CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026* 2 (Aug. 2024) (IPAY 2026 Results), *available at* https://www.cms.gov/files/document/fact-sheet-negotiated-prices-initial-price-applicability-year-2026.pdf. For all but one of those products, CMS will impose discounts of more than 50 percent. *Id.* For two, CMS will impose discounts of more than 75 percent. *Id.* Those prices are at or below what manufacturers of new generics or biosimilars can realistically charge.

76. CMS's unlawful guidance exacerbates these problems in two ways relevant to this case. *First*, CMS's expansion of what counts as a Qualifying Single Source Drug inflates the universe of price-controlled branded drugs and biologics that generics and biosimilars have to compete with. By aggregating multiple drug or biologic products together, CMS's definition makes the resulting conglomerate of drugs more likely to be selected for the DPNP and therefore more likely to stymie non-brand competition. *See* 42 U.S.C. §§ 1320f-1(b)(1)(A)–(B), (d)(1). Including more drugs in the program than the specific number prescribed by Congress facially violates the statute.

77. *Second*, CMS's Qualifying Single Source Drug definition erases the IRA's statutory protections for branded drugs by allowing those drugs to be selected sooner. Branded small-molecule drugs cannot be selected for the DPNP until they have been approved for seven years, 42 U.S.C. § 1320f(e)(1)(A)(ii), and biologics cannot be selected until they have been approved for eleven years, *id.* § 1320f(e)(1)(B)(ii).

78. Under CMS's Qualifying Single Source Drug definition, however, a drug or biologic approved under an NDA or a BLA may be treated as though it were approved under a much older NDA or BLA. One generic or biosimilar may be forced to compete against multiple distinct drugs or biologics that share a single moiety or active ingredient and are therefore price-controlled. The resulting proliferation of price-controlled competitors makes it difficult for a generic or biosimilar to secure market share. At the same time, it vitiates incentives for brand name manufacturers to build innovation based on existing active ingredients.

79. In addition, CMS's "bona fide marketing" standard overrides Congress's carefully specified judgment as to when a generic can be forced to compete with a price-controlled branded drug or biologic. The IRA reflects Congress's policy decision that generic and biosimilar competition should prevent or end a branded product's inclusion in the DPNP. *See, e.g.*, 42 U.S.C. §§ 1320f(e)(1)(A)(iii), 1320f(e)(1)(B)(iii).

80. If generic or biosimilar competition begins before a drug or biologic is selected, it is simply not eligible for the program. 2027 Final Guidance 278–80. If generic or biosimilar competition begins after CMS publishes its list of selections, but before the "negotiation" period ends, the drug or biologic remains selected, but no price control is imposed, and the drug or biologic's selection terminates in the year after its IPAY. *Id.* If generic or biosimilar competition begins after the end of the negotiation period, but before April 1 of the IPAY, the IRA's price control applies during the IPAY, but the drug's selection terminates in the year after its IPAY. *Id.* Finally, if generic or biosimilar competition begins after April 1 of the IPAY, the IRA's price control applies during the IPAY *and* the first year after its IPAY, terminating only in the following year. *Id.*

81. CMS's "bona fide marketing" standard dramatically increases the odds that a branded drug or biologic will be price controlled during its IPAY or in the first year after an IPAY. That is because a generic or biosimilar may launch shortly before the end of the branded drug or biologic's negotiation period, or shortly before April 1 of the branded drug's IPAY. Those launch dates are usually determined well in advance, governed by the expiration of a patent or by a settlement agreement resolving Hatch-Waxman or BPCIA litigation. Under the IRA's yes-or-no standard for whether a generic or biosimilar has been "marketed," those launch dates would pose no problem; sale of a single bottle of a generic or dose of a biosimilar would trigger removal from the DPNP. 21 C.F.R. § 314.3(b) (defining "[c]ommercial marketing" as "the introduction or delivery for introduction into interstate commerce of a drug product").

82. Under CMS's "bona fide marketing" standard, by contrast, a generic or biosimilar may take many months to reach whatever level of sales CMS will ultimately deem bona fide, a result that seems pre-determined by CMS's selected methodology, which relies exclusively on the evaluation of time-lagged utilization data. That delay may be the difference between an additional *year* of the branded drug's being subject to an IRA price control if CMS finds—in its unreviewable discretion—that "bona fide marketing" occurs after April 1 of the branded drug's IPAY, even if the generic or biosimilar's first sale occurred before that April 1. 2027 Final Guidance 278–280.

83. CMS relies on Part D Prescription Drug Event (PDE) data and Medicaid Average Manufacturer Price (AMP) data when making its "bona fide marketing" determinations. 2027 Final Guidance 170–71, 278, 293. The PDE data are inherently time lagged because of the delay between when a generic drug or biosimilar becomes available and when CMS can detect it in PDE data resulting from coverage determinations and filled Part D prescriptions. *Id.* at 21–22 (acknowledging this time lag). Part D generally is "notably slower than commercial plans in coverage of

first generics," such that in the 2021 Medicare Part D plan year, only 21 percent of first generics that launched in 2020 were covered by plan formularies—the list of drugs or biologics that the plan will cover. Association for Accessible Medicines, *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* (July 2021), https://tinyurl.com/bdf2mzyv. Moreover, "it takes nearly three years before first generics are covered on more than half of Medicare Part D formularies." *Id.* at 5. CMS allows Part D plans' Pharmacy and Therapeutics Committees a long period to review new drugs before deciding whether to place them on formulary. *See* Medicare Prescription Drug Benefit Manual, ch. 6, § 30.1.5 (rev. Jan. 15, 2016). As a result, the first six months of PDE data reported after a drug faces generic competition necessarily reflect very limited uptake. CMS has also acknowledged that it will not have AMP data from the two months preceding April 1 of a drug's IPAY—a critical date—when it makes its relevant "bona fide marketing" determination. 2027 Final Guidance 278. This gradual uptake could delay CMS's "bona fide marketing" determinations for months or years after a generic drug or biosimilar enters the market, subjecting the branded drug or biologic to the IRA price controls long after generic or biosimilar entry.

84. Trying to compete for an extra year—or more—with a price-controlled branded drug may dissuade a generic or biosimilar manufacturer from launching at all. Manufacturers of generic drugs or biosimilars often choose not to launch, despite having the legal right to do so, if they determine that the competitive landscape makes launching uneconomical. The uncertainty created by CMS's subjective "bona fide marketing" redefinition of the IRA's objective "marketed" standard will increase the probability that generic or biosimilar manufacturers will decide not to launch or even begin development of generic or biosimilar versions of the highest-priced and most-used branded pharmaceuticals on the market.

II. Teva and Its Mission to Further Access to Quality Medicine

85. 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/. Teva began over a century ago as a small drug wholesaler, and it has developed into an industry leader supplying patients across the world with life-improving medicines. Teva, *Improving Health Since 1901*, https://www.tevapharm.com/our-company/teva-history/. After Hatch-Waxman's enactment in 1984, Teva helped create the modern market for generic pharmaceuticals and became the largest North American generic manufacturer, saving the American healthcare system over $36 billion. *Id.* Unlike most generic manufacturers, Teva also develops and manufactures innovator drugs, which empower patients to live healthier lives. In this way, Teva offers the "world's largest medicine cabinet." *Id.*

AUSTEDO and AUSTEDO XR

86. Teva markets several innovative drugs, two of which are called AUSTEDO and AUSTEDO XR. AUSTEDO is indicated for two movement disorders: Tardive Dyskinesia and Huntington's Disease chorea. Tardive Dyskinesia is characterized by involuntary muscle movements. The disease 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. *See* Rakesh Jain & Christopher U. Correll, *Tardive Dyskinesia: Recognition, Patient Assessment, and Differential Diagnosis*, 79 J. Clin. Psychiatry 16, 16 (2018), *available at* https://doi.org/10.4088/JCP.nu17034ah1c. 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, and can inhibit a patient's ability to move voluntarily.

87. AUSTEDO reduces involuntary body movements in a majority of patients with both Tardive Dyskinesia and Huntington's Disease chorea and helps patients perform daily activities of living, such as climbing stairs, dressing, and bathing. FDA approved AUSTEDO with an indication for Huntington's Disease chorea in April 2017 (NDA 208082). FDA added an approved indication for Tardive Dyskinesia in August 2017.

88. AUSTEDO XR is the extended-release formulation of AUSTEDO and gives patients the same benefits as AUSTEDO in a once-daily pill as opposed to the twice-a-day dosing and titration schedule for AUSTEDO. AUSTEDO XR particularly benefits patients with Tardive Dyskinesia, who, as noted, often have underlying mental illnesses, which can make remembering to take AUSTEDO twice a day according to a titration schedule challenging. *See* Leah Kuntz & Rakesh Jain, *Why Clinicians Should Be Excited About Austedo XR*, Psychiatric Times (June 3, 2024), *available at* https://www.psychiatrictimes.com/view/why-clinicians-should-be-excited-about-austedo-xr. FDA approved AUSTEDO XR in April 2023 (NDA 216354). Most patients pay less than $10 per month for AUSTEDO XR.

89. Teva 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 Tardive Dyskinesia and Huntington's Disease chorea patients at double the rate of a placebo. And Teva continues to invest in addressing these patients' unmet needs. 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.

90. Teva's therapies promise large cost-saving opportunities, too. Patients with Tardive Dyskinesia and Huntington's Disease incur significant healthcare costs that increase as their diseases progress. *See, e.g.*, Benjamin Carroll & Debra E. Irwin, *Health Care Resource Utilization*

and Costs for Patients with Tardive Dyskinesia, 25 J. Manag. Care Spec. Pharm. 810, 814–15 (2019), *available at* https://pmc.ncbi.nlm.nih.gov/articles/PMC10398273/; Anisha M. Patel, Eunice Chang, Caleb Paydar, & Shiela R. Reddy, *Healthcare Utilization and Direct Medical Costs of Huntington's Disease Among Medicaid Beneficiaries in the United States*, 26 J. of Med. Econ. 811, 813–15 (2023), *available at* https://www.tandfonline.com/doi/epdf/10.1080/13696998.2023.2222561.

91. AUSTEDO is one of only two FDA-approved and Medicaid guideline-preferred treatments for Tardive Dyskinesia and Huntington's Disease chorea.

92. AUSTEDO is eligible to be selected for inclusion in the DPNP in 2025. Among eligible drugs, AUSTEDO ranked thirteenth in gross Medicare Part D spending in 2022. Emma M. Cousin et al., *Drugs Anticipated to be Selected for the Medicare Drug Price Negotiation Program in 2025*, 30 J. of Managed Care. & Spec. Pharmacy 1203, 1205 (Nov. 2024) (2025 Drug Selections), *available at* https://www.jmcp.org/doi/10.18553/jmcp.2024.24167. AUSTEDO is therefore reasonably expected to be selected for "negotiations" in 2025, leading to a price control in IPAY 2027. Under CMS's definition of a Qualifying Single Source Drug, AUSTEDO XR is eligible for selection, too, even though it has been approved for well under seven years, because it shares an active moiety with AUSTEDO and Teva holds both NDAs.

93. If AUSTEDO and AUSTEDO XR are selected for inclusion in the DPNP, Teva's revenue for those drugs will be lower than would be the case if no MFP were applied to those products.

Teva's generics that will compete with selected drugs

94. Teva invests hundreds of millions of dollars annually into developing and manufacturing generic medicines. These products help lower healthcare costs for American patients

and payors, including CMS. A typical generic medicine for which Teva files an ANDA can take up to 7 years to develop. Depending upon the complexity of the generic product, the cost to file an ANDA can amount to tens of millions of dollars in research-and-development costs, and even more if capital expenditures are required. If an ANDA product is subject to patent litigation under the Hatch-Waxman Act, there can be multiple rounds of litigation, and those cases can exceed $10 million to litigate through appeals.

95. A typical ANDA can take two-to-five years or more to be approved for sale in the United States.

96. Once Teva has legal and regulatory clearance to launch a generic medicine, it must invest significant sums into the medicine's launch. That investment is often more than $1 million, representing the cost of ingredients and manufacturing. And even once Teva has legal and regulatory clearance, it can take two years or more to prepare to launch a generic medicine.

97. In the next few years, Teva plans to launch multiple generics whose launches—and Teva's significant investment in those launches—will be harmed by both the IRA and CMS's guidance purporting to implement the IRA.

XTANDI (Enzalutamide)

98. XTANDI (Enzalutamide) is a branded drug that treats advanced prostate cancer. 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. XTANDI is eligible for inclusion in the DPNP in 2025. Based on publicly available analyses of Medicare Part D expenditures, XTANDI is ranked third-highest in gross expenditures and is therefore reasonably expected to be selected for "negotiation" in 2025, leading to an IPAY in 2027. 2025 Drug Selections, *supra*, at 1205.

99. But for CMS's redefinition of a Qualifying Single Source Drug, the tablet form of XTANDI would not be eligible for inclusion in the DPNP in 2025 because it has been approved for fewer than seven years.

100. Teva filed its ANDA for a generic version of XTANDI capsules on August 31, 2016. That ANDA contained a certification that the patents listed in FDA's Orange Book were either invalid, not infringed, or unenforceable. Teva was sued on August 31, 2016, as a result of filing its ANDA. The lawsuit against Teva was dismissed against Teva pursuant to a settlement on June 18, 2018. On that day, the latest expiring patent in the Orange Book was U.S. Patent No. 7,709,517, which expires on August 13, 2027.

101. Pursuant to the terms of the settlement referenced in the dismissal of the lawsuit, Teva plans to launch a generic capsule form of Enzalutamide that will compete with XTANDI before the expiration of the '517 patent. Teva's generic will be among the first generic forms of Enzalutamide to launch, all of which are expected to enter the market before that patent expires. Teva reasonably anticipates that its generic Enzalutamide launch will occur on or before March 31, 2028. Under FDA's regulations, Teva's generic will be deemed to be "marketed" on the date of its first sale. *See* 21 C.F.R. §§ 314.3(b), 314.107(c)(2).

102. CMS's redefinition of a Qualifying Single Source Drug will harm Teva by forcing Teva's generic capsule to compete with the tablet price-controlled form of XTANDI. All other things being equal, patients and prescribers tend to prefer tablets to capsules because they are more shelf stable, easier to split, and sometimes easier to ingest. Tablets are also more difficult to manufacture. Prescribers and patients are therefore likely to prefer the tablet form of XTANDI unless Teva's capsule form of Enzalutamide can offer significant price savings over the tablet form. But because the tablet form of XTANDI will be unlawfully price controlled, Teva's capsule form of

Enzalutamide cannot be priced at a significant discount to the price-controlled tablet form of XTANDI. Teva therefore will lose significant market share that it would otherwise achieve if CMS's guidance did not unlawfully impose a price control on the tablet version of XTANDI.

103. CMS's "bona fide marketing" standard will harm Teva by making it both more difficult for Teva to stop an IRA price control from applying to XTANDI in 2029, and less certain that CMS will conclude that Teva and other generics have done so. A launch on or before the expiration of the '517 patent will give Teva and other launching generic manufacturers only about eight months (or less) to sell enough product to satisfy CMS's standard for price-applicability year 2029. In Teva's experience, that will not be enough time to generate the utilization levels required by CMS's subjective "bona fide marketing" standard. But if Teva and other generics do not meet that standard by March 31, 2028, Teva will be forced to compete against two price-controlled versions of XTANDI throughout all of 2029, rather than just 2027 and 2028.

OFEV (Nintedanib)

104. OFEV (Nintedanib) is a branded drug that treats a lung disease called idiopathic pulmonary fibrosis. OFEV has been approved under NDA No. 205832 since October 2014. OFEV is eligible for inclusion in the DPNP in 2025. Based on publicly available analyses of Medicare Part D expenditures, OFEV is ranked fourth-highest in gross expenditures and is therefore reasonably expected to be selected for "negotiation" in 2025, leading to an IPAY in 2027. 2025 Drug Selections, *supra*, at 1205.

105. Teva filed its ANDA for a generic version of OFEV capsules on July 30, 2024. Teva's ANDA contained a certification that the patents listed in FDA's Orange Book were either invalid, not infringed, or unenforceable. Teva was not sued as a result of filing its ANDA, and so the only current barrier to final approval of Teva's ANDA for a generic version of OFEV is an

orphan-drug exclusivity period that expires on September 6, 2026, with a pediatric extension that expires on March 6, 2027.[5]

106. Teva plans to launch a generic form of Nintedanib that will compete with OFEV starting as early as September 6, 2026, and no later than March 6, 2027. Teva's generic is expected to be the first generic form of Nintedanib to launch. Under FDA's regulations, Teva's generic will be deemed to be "marketed" on the date of its first sale. *See* 21 C.F.R. §§ 314.3(b), 314.107(c)(2).

107. CMS's imposition of the "bona fide marketing" standard will harm Teva by making it both more difficult for Teva to stop an IRA price control from applying to OFEV in 2028, and less certain that CMS will conclude that Teva has done so. A launch on September 6, 2026, would give Teva and any other generic manufacturer only about six months to sell enough product to satisfy CMS's standard for price-applicability year 2028. If Teva is unable to launch until March 6, 2027, it will have only five *days* to satisfy that standard. In Teva's experience, six months will not be enough time to generate the utilization levels required by CMS's subjective "bona fide marketing" standard. But if Teva and other generics do not meet that standard by March 31, 2027, Teva will be forced to compete against a price-controlled version of OFEV beyond 2027 and throughout all of 2028 as well.

XARELTO (Rivaroxiban)

108. XARELTO (Rivaroxaban), a branded drug that treats blood clots, is approved under three NDAs. FDA approved NDA Nos. 22406 and 202430 for tablet forms of XARELTO in July and November 2011, respectively. FDA approved NDA No. 215859 on December 20, 2021,

[5] An orphan-drug exclusivity period of "seven years from the date of the approval" of an NDA is provided by statute to manufacturers of drugs indicated for certain "rare disease[s] or condition[s]." 21 U.S.C. § 360cc(a)(2). An orphan-drug manufacturer may earn an additional six months of exclusivity, called pediatric exclusivity, by completing pediatric studies in response to an FDA request. *See* 21 U.S.C. § 355a(c)(1)(A)(ii).

authorizing a liquid suspension form of XARELTO. XARELTO was selected for inclusion in the DPNP and for "negotiations" in 2024, leading to an IPAY in 2026. CMS has imposed a price control amounting to a 62 percent discount on branded XARELTO. IPAY 2026 Results, *supra*, at 2.

109. But for CMS's redefinition of a Qualifying Single Source Drug, the suspension form of XARELTO—approved more than ten years after the tablet forms—would not have been eligible for inclusion in the DPNP in 2024. That is because it had been approved for fewer than seven years.

110. Teva filed its ANDA for a generic version of XARELTO 10, 15, and 20 mg tablets on August 30, 2018, and an ANDA for a generic version of XARELTO 2.5 mg tablets on October 12, 2018. Those ANDAs contained certifications that the patents listed in FDA's Orange Book were either invalid, not infringed, or unenforceable. Teva was sued as a result of filing its ANDAs. The lawsuit against Teva with respect to the 10, 15, and 20 mg ANDAs was dismissed pursuant to a settlement on April 8, 2020. Teva was also sued on July 7, 2021, with respect to its ANDA for a generic version of the 2.5 mg strength of Xarelto. On July 28, 2023, the patent in that lawsuit was found unpatentable by the United States Patent and Trademark Office. An appeal with respect to that decision is pending.

111. Pursuant to the terms of the settlement agreement covering the ANDA for the 10, 15, and 20 mg strengths, Teva plans to launch a generic form of Rivaroxaban that will compete with XARELTO starting in March 2027. Teva's generic will be a tablet form of Rivaroxaban. Under FDA regulations, Teva's generic will be deemed "marketed" as of the date of its first sale. *See* 21 C.F.R. §§ 314.3(b), 314.107(c)(2).

112. CMS's imposition of the "bona fide marketing" standard will harm Teva by making it both more difficult for Teva and other generics to stop an IRA price control from applying to XARELTO in 2028, and less certain that CMS will conclude that generic manufacturers have done so. A launch in March 2027 will give Teva only *weeks* to generate enough utilization data to satisfy CMS's "bona fide marketing" standard for price-applicability year 2028. In Teva's experience, that will not be enough time to generate the utilization levels required by CMS's subjective "bona fide marketing" standard. But if Teva and other generics do not meet that standard by March 31, 2027, they will be forced to compete against three price-controlled versions of XARELTO not just for 2027, but also throughout all of 2028.

LINZESS (Linaclotide)

113. LINZESS (Linaclotide), a branded drug that treats irritable-bowel syndrome, has been approved under NDA No. 202811 since August 2012. LINZESS is eligible for inclusion in the DPNP in 2025. Again, based on publicly available analyses of Medicare Part D expenditures, LINZESS is ranked seventh-highest in expenditures and is therefore reasonably expected to be selected for "negotiation" in 2025, leading to an IPAY in 2027. 2025 Drug Selections, *supra*, at 1205.

114. Teva filed its ANDA for a generic version of the 145 and 290 mcg strengths of LINZESS capsules on August 30, 2016, and for the 72 mcg strength on November 7, 2017. Those ANDAs contained certifications that the patents listed in FDA's Orange Book were either invalid, not infringed, or unenforceable. Teva was sued as a result of filing its ANDAs on November 30 2016, and February 2, 2018, respectively. The lawsuits were dismissed as against Teva pursuant to settlements in February 2020 and May 2021, respectively.

115. Pursuant to the terms of the settlements, Teva plans to launch a generic form of Linaclotide that will compete with LINZESS starting March 31, 2029. Teva's generic is expected to be among the first generic forms of Linaclotide to launch, all of which are expected to enter the market on March 31, 2029. Under FDA regulations, Teva's generic will be deemed "marketed" as of the date of its first sale. *See* 21 C.F.R. §§ 314.3(b), 314.107(c)(2).

116. CMS's imposition of the bona fide marketing standard will harm Teva by making it both more difficult for Teva and other generics to stop an IRA price control from applying to LINZESS in 2030, and less certain that CMS will conclude that generic manufacturers have done so. A launch on March 31, 2029, will give Teva and other generics only *one day* to sell enough product to satisfy CMS's bona fide marketing standard for price-applicability year 2030. In Teva's experience, that will not be enough time to generate the utilization levels required by CMS's subjective "bona fide marketing" standard. But if Teva and other generics do not meet that standard on their launch date, they will be forced to compete against a price-controlled version of LINZESS throughout all of 2030.

117. The drugs listed above are merely illustrative examples of the harms to innovator manufacturers and their generic and biosimilar competition created by the IRA and CMS's guidance purporting to implement the IRA. Teva maintains a vast portfolio of innovator drugs, prospective innovator drugs, generics, biosimilars, and prospective generics and biosimilars. But the IRA and CMS's guidance both disincentivize Teva from continuing to invest in research and development and from launching products that it has invested substantial resources into developing.

118. Given Teva's broad exposure to the innovator-drug and generic-and-biosimilar markets, Teva is virtually certain to suffer imminent harm traceable to the IRA's price controls and to CMS's guidance purporting to implement the DPNP.

III. CMS's Guidance Violates the Administrative Procedure Act.

119. Agency action violates the APA if it contravenes the text of an agency's governing statute. *See Natural Res. Def. Council v. EPA*, 643 F.3d 311, 323 (D.C. Cir. 2011); *Orion Rsrvs. Ltd. P'ship v. Salazar*, 553 F.3d 697, 703 (D.C. Cir. 2009); *Bennett v. Donovan*, 4 F. Supp. 3d 5, 13 (D.D.C. 2013); *Lone Mountain Processing, Inc. v. Secretary of Labor*, 709 F.3d 1161, 1164 (D.C. Cir. 2013). And courts "may not defer to an agency interpretation of the law simply because a statute is ambiguous." *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2273 (2024).

120. 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). Agency action is arbitrary and capricious if the agency fails to adequately explain a deviation from prior policy, *Steenholdt v. FAA*, 314 F.3d 633, 639 (D.C. Cir. 2003), or ignores relevant evidence, *Butte County v. Hogen*, 613 F.3d 190, 194 (D.C. Cir. 2010). Agency action is also arbitrary and capricious if the agency "fail[s] to consider an important aspect of the problem, offer[s] an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

121. CMS violated all of these maxims here.

Qualifying Single Source Drug

122. CMS's definition of a Qualifying Single Source Drug violates the IRA by impermissibly aggregating different drug products approved under different NDAs, or in the case of biologics, licensed under different BLAs.

123. In its Guidance Documents, CMS provided that two drug products with the same active moiety are treated as the same Qualifying Single Source Drug, even if they were approved under distinct NDAs. 2026 Final Guidance at 99; 2027 Final Guidance at 167–68. Similarly, two biologic products with the same active ingredient are treated as the same Qualifying Single Source Drug, even if they were licensed under distinct BLAs. *Id.* CMS's gloss on the statutory term Qualifying Single Source Drug has no basis in the IRA or any accepted principle of statutory interpretation. But because of it, the DPNP will now sweep in *sets* of drugs, rather than single drugs.

124. CMS's definition of a Qualifying Single Source Drug has profound implications for multiple drugs and biologics approved under different applications that share the same active moiety or active ingredient. These products will all run on the same seven- or eleven-year selection clock—including those approved years after the first product. Some products may even be subject to selection and negotiation *immediately* after their approval.

125. That result contradicts the IRA's prohibition on selecting small-molecule drugs until "at least 7 years will have elapsed since the date of [FDA] approval," 42 U.S.C. § 1320f–1(e)(1)(A)(i)–(ii), or biologics until "at least 11 years will have elapsed since the date of [FDA] licensure," *id.* § 1320f–1(e)(1)(B)(i)–(ii).

126. CMS's redefinition of a Qualifying Single Source Drug also changes the selection criteria Congress established. By conflating distinct drugs approved in different applications, CMS will aggregate Medicare expenditures across those products for purposes of ranking the Qualifying Single Source Drug for selection for negotiation. And the resulting price control will apply across all products.

127. Congress intended none of these consequences. Under the IRA's plain language, two products are the same Qualifying Single Source Drug only if those products share the same NDA or BLA. This statutory mandate is expressed in several ways.

128. For starters, the statute defines the term Qualifying Single Source Drug by reference to "a covered part D drug," as that term is defined in the Medicare statute. 42 U.S.C. § 1320f-1(e)(1). The definition of a "covered Part D drug," in turn, cross-references the definition of a "covered outpatient drug" in the Medicaid Drug Rebate Program (MDRP) statute. *Id.* § 1395w-102(e)(1). Under that definition, whether a single source drug is a distinct "covered outpatient drug" is based on whether the product is approved pursuant to a distinct NDA or BLA. *Id.* §§ 1396r–8(k)(2), (k)(7)(A)(iv).

129. There is only one exception to the MDRP standard that a drug or biologic is defined by its NDA or BLA. Congress amended the MDRP statute to treat line extensions—new formulations of an existing drug or biologic—as the same "covered outpatient drug" even if they were approved under different NDAs or BLAs. Patient Protection and Affordable Care Act of 2010, § 2503, Pub. L. No. 111-148, 124 Stat. 119, 310 (codified at 42 U.S.C. § 1396r–8(c)(2)(C)).

130. Congress knew about this "line extension" exception to the one-NDA-one-drug standard when it created the IRA. It included the exception in the new law, but only selectively: Congress did not include the exception in the IRA's DPNP, even as it included the exception in the IRA's Part D inflation-rebate provision. *See* 42 U.S.C. § 1395w-114a(b)(5)(B). Congress therefore must be presumed to have specifically chosen *not* to include that exception in connection with the DPNP. *See Jama v. ICE*, 543 U.S. 335, 341 (2005) ("We do not lightly assume that Congress has omitted from its adopted text requirements that it nonetheless intends to apply, and

our reluctance is even greater when Congress has shown elsewhere in the same statute that it knows how to make such a requirement manifest.").

131. The IRA further defines a Qualifying Single Source Drug as a drug approved by FDA and for which "at least 7 years will have elapsed since the date of *such approval*." 42 U.S.C. § 1320f-1(e)(1)(A) (emphasis added). The definition is the same for a biologic product, except the applicable time period is "at least 11 years . . . since the date of *such licensure*." *Id.* § 1320f-1(e)(1)(B) (emphasis added). This language directs that each Qualifying Single Source Drug be identified by reference to its individual approval or licensure, and approvals and licenses are granted on a NDA- and BLA-specific basis. FDA does not approve active moieties or active ingredients; it approves and licenses finished products under individual NDAs and BLAs. Any other reading—including CMS's construction based on common active moieties or active ingredients—contradicts the statute's plain text.

132. The statutory definition of Qualifying Single Source Drug is grounded in FDA's Congressionally created framework for approving and licensing drugs and biologics, and that framework distinguishes among drugs and biologics through distinct applications. By cross-referencing the FDA framework in the Qualifying Single Source Drug definition, Congress directed CMS to rely on that framework in distinguishing among Qualifying Single Source Drugs. By excluding from selection "the listed drug for any drug that is approved and marketed under section 355(j)"—that is, the reference drug for an approved and marketed generic—the IRA necessarily uses the term "drug" in reference to a single, specific NDA. *See* 42 U.S.C. § 1320f-1(e)(1)(A)(iii). That is because, under the Federal Food, Drug, and Cosmetic Act, sponsors of generics apply for approval by identifying a single reference listed drug by its individually specified NDA. *See* 21 U.S.C. § 355(j)(2). FDA, in turn, approves a generic based on that specific NDA. *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). The generic is in turn deemed a generic version of that specific listed drug and no other. By excluding listed drugs from the Qualifying Single Source Drug definition, therefore, the IRA confirms that "drug" means "drug marketed pursuant to a specific NDA."

133. Finally, comparing the IRA's language to pre-existing FDA regulations reinforces the conclusion that Congress intended to preserve distinctions between products approved or licensed at different times. Congress defined a Qualifying Single Source Drug using the terms "drug products" and "biological products." 42 U.S.C. § 1320f-1(e)(1) (capitalization altered). FDA has defined both of those terms by regulation. The term "[d]rug product" means "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. *See* 21 C.F.R. § 314.3. Similarly, the term "[b]iological product" refers to "a product" meeting certain criteria, not to a *set* of products that share the same qualifying criterion. *See* 21 C.F.R. § 600.3. CMS's sham definition of the term Qualifying Single Source Drug cannot be squared with those well-settled meanings of the terms Congress chose to include in the IRA. But "[i]t is a cardinal rule of statutory construction that, when Congress employs a term of art, it presumably knows and adopts the cluster of ideas that were attached to each borrowed word in the body of learning from which it is taken." *Air Wis. Airlines Corp. v. Hoeper*, 571 U.S. 237, 248, (2014) (quotation omitted).

134. CMS's rule creates an unlawful "relation-back" regime, under which CMS will pull drugs into the queue for "negotiation" significantly earlier than the time permitted by Congress.

Manufacturers of generics and biosimilars must therefore compete with price-controlled products much earlier than the IRA permits.

135. CMS's rule also makes drugs approved under different applications more likely to be selected for negotiation by aggregating sales data for separate products, again subjecting manufacturers of generics and biosimilars to price-controlled competition they otherwise would not face.

136. CMS's definition of a Qualifying Single Source Drug violates the IRA, exceeds CMS's statutory authority, and should be set aside.

Bona Fide Marketing

137. CMS also purported to overwrite the statutory requirements governing the kind of generic or biosimilar competition that renders a drug ineligible for selection or negotiation.

138. Whether a generic has been "marketed" has far-reaching consequences for the DPNP. Under the IRA, a drug that is the reference listed product for an approved and "marketed" generic cannot be a Qualifying Single Source Drug, and therefore cannot be selected for "negotiation." *See* 42 U.S.C. § 1320f–1(e)(1). The IRA also requires CMS to remove a selected drug from the selected drug list on January 1 of the first "subsequent year"—that is, a year after the drug's IPAY—that begins at least 9 months after CMS determines that a generic has been approved and "marketed." *Id.* § 1320e(c)(1). CMS also 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." *Id.* § 1320f–1(c)(2).

139. The statutory test for these off-ramps is simple. The IRA requires that a generic drug be "approved and marketed," or in the case of a biosimilar product, "licensed and marketed." 42 U.S.C. §§ 1320f-1(e)(1)(A) & (B). In other words, the IRA requires that a manufacturer launch its approved or licensed product and place it into commerce for sale. But CMS's made-up "bona

fide marketing" standard turns the IRA's "marketed" test into a false promise that CMS can manipulate as it sees fit.

140. CMS "will consider a generic drug . . . to be market*ed*" only if certain sources of data "reveal[ ] that the manufacturer of that drug or product is engaging in bona fide market*ing* of that drug." 2026 Final Guidance at 102 (emphases added); 2027 Final Guidance at 170 (emphases added). CMS's purported interpretation operates as an ongoing test—a subjective, multifactor inquiry based on the "totality of the circumstances." 2026 Final Guidance at 101–02; 2027 Final Guidance at 170–71. And that inquiry will occur over a "12-month period." *Id.*

141. CMS's test means that even a drug with generic competition on the market may be selected for "negotiation" and subject to a price control if CMS concludes that the generic competition is not sufficiently "bona fide." This expanded qualitative standard enables CMS to slow-walk a drug's removal from the DPNP. These delays, dressed up for the public as "bona fide" determinations, become particularly important to CMS because of the agency's Qualifying Single Source Drug definition that gloms together products subject to multiple NDAs or BLAs. Without the "bona fide marketing" test CMS invented, the resulting sets of drugs or biologics could no longer be subject to negotiation or price controls when a generic or biosimilar for any of the included products is marketed. To evade that snag, CMS created a novel test to give itself total (and supposedly unreviewable) discretion to keep price controls in place—even though the statute requires the sets of drugs and biologics to be treated distinctly in the first place.

142. That problem is compounded by the agency's further decision to monitor, "after such [bona fide marketing] determination is made, whether meaningful competition *continues* to exist in the market by *ongoing* assessments of whether the manufacturer of the generic drug . . . is engaging in bona fide marketing." 2026 Final Guidance at 170 (emphasis added); 2027 Final

Guidance at 292 (emphasis added). The IRA uses "marketed" in only the past tense, and there is no statutory basis for the agency to conduct ongoing monitoring after a generic competitor is approved and marketed. *See* 42 U.S.C. §§ 1320f-1(e)(1)(A) & (B). Yet CMS threatens to withdraw its prior determination that a drug or biologic is disqualified from selection or price controls based on the agency's unilateral (and unreviewable) determination at some later time that there is insufficiently "meaningful" competition between the brand and generic versions of a drug or biologic.

143. CMS has also announced a non-exhaustive multifactor test for conducting its evaluations. The agency says it will review "whether the generic drug or biosimilar is regularly and consistently available for purchase through the pharmaceutical supply chain and whether any licenses or other agreements between a Primary Manufacturer and a generic drug or biosimilar manufacturer limit the availability or distribution of the selected drug." 2026 Final Guidance at 170; 2027 Final Guidance at 292. CMS also intends to "analyze the share of generic drug or biosimilar biological product units identified in [Medicare claims] data as a percentage of total units of Part D expenditures, as well as whether manufacturers are reporting units of the selected drug as part of their [Average Manufacturer Price (AMP)] reporting responsibilities . . . , and the trend in reporting of such AMP units." 2026 Final Guidance at 170; 2027 Final Guidance at 293.

144. To support its ongoing-monitoring process, CMS purports to "reserve[ ] the right to also use other available data and informational sources on market share and relative market competition of the generic drug or biosimilar." 2026 Final Guidance at 170; 2027 Final Guidance at 293. If CMS determines through its monitoring that a generic or biosimilar manufacturer is not engaged in "bona fide marketing" after a previous determination that there was an approved and marketed generic, "the drug/biologic could be eligible for negotiation in a future price applicability year." 2026 Final Guidance at 78.

145. None of that ongoing monitoring has any basis or authorization in the statute. Congress established a clear reference point—the date a product is "marketed." 42 U.S.C. §§ 1320f-1(e)(1)(A) & (B). CMS cannot supplant that statutory provision with a made-up standard tied to the agency's subjective, ongoing assessments of unverified data not subject to any review. Whether a product is "marketed" is an objective, point-in-time determination based on when the product enters the commercial marketplace. *See* Oxford English Dictionary (defining "marketing" as "[t]he action or business of bringing or sending a product or commodity to market"). Once the product has entered the marketplace, it has been "marketed." Nothing about a product's later utilization can change that fact.

146. CMS's own actions have confirmed that conclusion. In the provision of its 2026 Initial Guidance listing the data manufacturers must give CMS, the agency first defined "marketing" consistently with the term's plain meaning: "the introduction or delivery for introduction into interstate commerce of a drug product." 2026 Initial Guidance at 82. But CMS then silently deleted that definition from the 2026 Final Guidance and from both iterations of the 2027 Guidance Documents, implicitly acknowledging the sharp contrast between the ordinary meaning of "marketed" and CMS's adoption of the "bona fide marketing" standard.

147. An objective, point-in-time definition of "marketed" is consistent with CMS's approach in related contexts. For example, for the IRA's Medicare Part B inflation rebate, 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, which likewise is an objective, point-in-time determination. CMS, *Medicare Part B Inflation Rebates Paid by Manufacturers: Initial Memorandum* 57 (Dec. 14, 2023), *available at* https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-revised-guidance.pdf.

148. The same is true for CMS's guidance regarding the IRA's Medicare Part D inflation rebate. To determine a product's "first marketed" date, CMS will look to "the date the drug was first available for sale." *See* CMS, *Medicare Part D Inflation Rebates Paid by Manufacturers: Initial Memorandum* 51 & n.40 (Dec. 14, 2023), *available at* https://www.cms.gov/files/document/medicare-part-d-inflation-rebate-program-revised-guidance.pdf. The standard differs slightly from the corresponding Medicare Part B determination because of an existing reporting requirement found in the Social Security Act. *See id.* at 51 n.40; 42 U.S.C. § 1396r-8(b)(3)(A)(v). But the standards share an essential feature: they establish objective, historical inquiries.

149. The MDRP provides a further example. Under that program, CMS's longstanding policy has been to define "marketed" by reference to the date on which a product "is available for sale." Announcement of Medicaid Drug Rebate Program, 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 MDRP rule, where it defined the "market date" as "the date on which the . . . drug was first sold." Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program, 89 Fed. Reg. 79,020 79,082 (Sept. 26, 2024). CMS's IRA guidance reinforces the relevance of those MDRP definitions by explaining that CMS will evaluate "bona fide marketing" using sales volume and AMP data reported under the MDRP. 2026 Final Guidance at 101–102; 2027 Final Guidance at 170–171. CMS therefore highlighted the paradox of its "bona fide marketing" standard: CMS will evaluate whether a drug is "marketed" for purposes of the DPNP by reference to MDRP data that can be reported to the MDRP only once the drug has *already* qualified as being "marketed"—such that its sales volume can be reported in the first place.

150. That same problem plays out in reference to the second dataset CMS will rely upon in determining whether a drug is "marketed." In addition to Medicaid data, CMS has stated it will also evaluate Part D program PDE data in effectuating its bona fide marketing standard. 2026 Final Guidance at 101–102; 2027 Final Guidance at 170–171. PDE data is summary claims data generated when a Part D plan sponsor fills a prescription under Medicare Part D. CMS has recognized that the date on which a product is "release[d] onto the market" triggers certain coverage-related obligations on the part of Part D plans. Prescription Drug Benefit Manual ch. 6 § 30.1.5 (rev. Jan. 15, 2016). CMS requires that Part D plan sponsors' Pharmacy & Therapeutics committees "make a reasonable effort to review a new FDA approved drug product (or new FDA approved indication) within 90 days of its release onto the market and . . . make a decision on each new FDA approved drug product (or new FDA approved indication) within 180 days of its release onto the market, or a clinical justification will be provided if this timeframe is not met." *Id.* All of this means that, like with the MDRP data, CMS will have already recognized that a product has been marketed by the time PDE data show product utilization.

151. An objective, point-in-time definition of "marketed" is also consistent with analogous FDA regulations. Under the Hatch-Waxman Act, the first generic to file an ANDA is entitled to 180 days of exclusivity during which other ANDAs cannot be deemed approved. *See* 21 U.S.C. § 355(j)(5)(iv)(I). That exclusivity is triggered by "commercial marketing of the drug." *Id.* By regulation, FDA has long defined "commercial marketing" to mean "the introduction or delivery for introduction into interstate commerce of a drug product." 21 C.F.R. § 314.3(b). That "introduction or delivery" occurs upon the sale of even a single bottle of the generic, a simple yes-or-no standard that generic manufacturers simply notify the FDA has been satisfied. *See id.* § 314.107(c)(2).

152. In sum, by purporting to override Congress's bright-line "marketed" test with a test of its own creation, CMS spawned significant tension with other aspects of federal drug-pricing law and drug-approval laws. A proper reading of the IRA would harmonize an interpretation of the term "marketed" with how that term is used in the statutes and regulations just discussed. *See Burrage v. United States*, 571 U.S. 204, 212 (2014). And adhering to the IRA's statutory text erases all of the interpretive problems that CMS's guidance creates. That confirms that Congress used the phrase "approved . . . and . . . marketed" to refer to the first time a generic or biosimilar is sold.

153. Congress has shown that it knows how to create a subjective "bona fide" standard if it wishes to do so. *See, e.g.*, 42 U.S.C. § 1396r–8(k)(1)(B)(i)(II) (as amended by Pub. L. No. 111–148, § 2503(a)(2) (2010)) (amending the MDRP statute to specify that only "bona fide" service fees are exempt from the calculation of average manufacturer price). Similarly, Congress knows how to set a standard that is triggered only by the broad availability of a drug nationwide. *See, e.g.*, *id.* § 1396r-8(e)(5) (as amended by Pub. L. No. 111-148 § 2503(a)(1)) (amending the MDRP statute to direct the calculation of a drug's federal upper limit using "pharmaceutically and therapeutically equivalent multiple source drug products . . . available for purchase by retail community pharmacies on a nationwide basis"). Congress did neither here. Because Congress "knew how to say" that CMS should use its subjective judgement and consider nationwide availability, but "did not express such a desire" in the IRA, CMS's guidance "ignore[d] [its] duty to pay close heed to both what Congress said and what Congress did not say." *Union of Concerned Scientists v. U.S. Nuclear Regul. Comm'n*, 824 F.2d 108, 115 (D.C. Cir. 1987).

154. One final note about the Qualifying Single Source Drug and "bona fide marketing" guidance: These provisions do not operate wholly independently. CMS's insistence on combining

drugs approved under separate NDAs as a single Qualifying Single Source Drug and then evaluating whether a generic product is sufficiently marketed exacerbates the problems created by both unlawful interpretations. A generic drug references a particular NDA. If FDA approves a generic drug that references one NDA, the generic will not be rated therapeutically equivalent to another product approved under a different NDA or automatically substitutable for that product under state substitution laws. In these circumstances, only the form of the innovative drug with an approved generic competitor will face price competition, but the single generic entrant will disqualify *all* forms of the drug from DPNP price controls. CMS's addition of the qualitative and subjective "bona fide" overlay to the "marketed" determination thus allows the agency to further control (and delay) the date by which any generic entrant disqualifies a drug from negotiation. By seizing that discretionary power over the period during which it may control prices, and the market, under the guise of a faithful interpretation of the IRA, CMS further obscured the standardless price setting that its guidance enables.

155. CMS's atextual "bona fide marketing" standard violates the IRA, exceeds CMS's statutory authority, and should be set aside.

IV. The IRA and CMS's Guidance Violate the Due-Process Clause.

156. CMS's unlawful guidance purporting to implement the IRA compounds an already unlawful statutory scheme.

157. The Fifth Amendment prevents the federal government from depriving drug manufacturers of "property[ ] without due process of law." U.S. Const. amend. V.

158. Drug manufacturers have at least two property interests implicated by the IRA: their property rights in their drug products and, as to certain generics and biosimilars, their contractual rights to sell those drugs pursuant to licenses and settlement agreements with brand manufacturers. *See Ralls Corp. v. Committee on Foreign Inv. in the U.S.*, 758 F.3d 296, 316 (D.C. Cir. 2014)

(recognizing that "[v]alid contracts are property under the Fifth Amendment") (quoting *Lynch v. United States*, 292 U.S. 571, 579 (1934)) (alteration adopted).

159. The IRA undermines both property interests without providing notice or an opportunity to be heard, either before or after drug manufacturers suffer these deprivations. Agency action that deprives a person or entity of a property interest without "a *meaningful opportunity* to be heard" is unconstitutional. *See Propert v. District of Columbia*, 948 F.2d 1327, 1333 (D.C. Cir. 1991).

160. The IRA's selection and "negotiation" process is riddled with due-process problems from start to finish. On the front end, the statute contemplates that the first few years of the DPNP will be instituted through agency guidance rather than the standard notice-and-comment rulemaking. The overreach evidenced by CMS's adoption of its Qualifying Single Source Drug and bona fide marketing interpretations demonstrates CMS's embrace of this expansive authority.

161. Once a drug is selected, the IRA forces manufacturers to engage in purported "negotiations," but gives them no leverage, no meaningful opportunity to walk away, and no ability to protect their interests. It then directs CMS to unilaterally impose a "maximum fair price" for selected drugs that is drastically below the actual fair-market value of the product.

162. Manufacturers have no way to resist selection of their products or the price controls that CMS imposes. The DPNP covers itself in the trappings of a negotiation—using terms like "offer," "counteroffer," and "negotiation," 42 U.S.C. § 1320f–3—but the reality is plain. The DPNP coerces manufacturers to submit to government-dictated pricing.

163. That conclusion is evident from the severity of the threatened penalties. The DPNP is enforced through an "excise tax imposed on drug manufacturers" for "noncompliance. 26 U.S.C. § 5000D(b)(1)–(4) (capitalization altered). A manufacturer that fails to comply—either at

the initiation of the "negotiation" period or by declining to "agree[ ]" to the ultimate price that CMS sets—is subject to a steep and escalating daily penalty, *id.* § 5000D(b), which the statute suggests applies to each sale of the subject drug or biologic, *id.* § 5000D(a). The penalty continues to accrue every day until the manufacturer acquiesces to CMS's demands or until the drug or biologic in question ceases to be selected. The penalty maxes out at 95 percent of total U.S. revenues—not just profits—for the product. *Id.* § 5000D(d).

164. The IRA does not give manufacturers a genuine off-ramp. The IRA nominally allows for the "[s]uspension" of this penalty, but only if the manufacturer terminates both its Medicare Part D agreements and Medicaid rebate agreement—not just for the drug in question, but for *all* of the manufacturer's drugs. 26 U.S.C. § 5000D(c).

165. Drug manufacturers cannot plausibly withdraw from participation in Medicare Part D or in Medicaid. Medicare is "the largest federal program after Social Security" and, as of 2019, "spends about $700 billion annually to provide health insurance for nearly 60 million aged or disabled Americans, nearly one-fifth of the Nation's population." *Azar v. Allina Health Servs.*, 587 U.S. 566, 569 (2019). Medicaid likewise serves more than 72 million patients. CMS, August 2024 Medicaid & CHIP Enrollment Data Highlights (last updated Nov. 27, 2024), *available at* https://www.medicaid.gov/medicaid/program-information/medicaid-and-chip-enrollment-data/reporthighlights/index.html. Given that enormous size, the "federal government dominates the healthcare market," and it "uses that market power to get drug makers to subsidize healthcare." *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 699 (3d Cir. 2023). Congress therefore understood that drug manufacturers would not withdraw from Medicare Part D or Medicaid, and it was counting on that conclusion. Otherwise, large and vulnerable portions of the public would lose access to important medicines.

166. Generic and biosimilar manufacturers lack even these theoretical ways to avoid being harmed by the DPNP. Only the manufacturer of the branded drug participates in the program, so only it may decide how to respond to a drug's selection or to CMS's "offer." When branded manufacturers inevitably accede to CMS's demands, manufacturers of generics and biosimilars suffer the consequences because they must then compete with a price-controlled drug or biologic, effectively ceding their pricing decisions to the outcome of the "negotiation" between the branded manufacturer and CMS.

167. On the back end, the IRA purports to preclude affected manufacturers from exercising their right to judicial review of several critical inputs, including a drug's selection and the price CMS demands. 42 U.S.C. § 1320f-7. 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 (7th Cir. 1988).

168. CMS's Guidance Documents multiply the IRA's unconstitutional deprivations. For example, Teva has protected property interests in AUSTEDO and AUSTEDO XR. Teva also has property interests in its upcoming generic products Enzalutamide and Rivaroxaban, as well as protected property interests in its license agreements with the manufacturers of the reference listed drugs XTANDI and XARELTO. Under the IRA's definition of a Qualifying Single Source Drug, AUSTEDO XR, the tablet form of XTANDI, and the suspension form of XARELTO would not be eligible for inclusion in the DPNP in 2025 because they have not been approved for long enough to qualify. But under CMS's definition of a Qualifying Single Source Drug, all of those products are reasonably expected to be subject to price controls. Those price controls will undermine Teva's property interests by diminishing the prices at which Teva's products can be sold and impair

Teva's contractual rights to sell Enzalutamide and Rivaroxaban. As to AUSTEDO XR, Teva has only an illusory chance to be heard before CMS does as it pleases; as to Enzalutamide and Rivaroxaban, Teva has no chance at all to be heard.

169. CMS's "bona fide marketing" standard provides even less process. Again, Teva has protected property interests, including contractual rights under license agreements with manufacturers of the reference listed drugs, to sell its upcoming generic products Enzalutamide, Rivaroxaban, and Linaclotide. Under the IRA's "approved . . . and . . . marketed" standard, the date of the first sale of Teva's generic products should trigger the end of IRA price controls on the reference listed drugs. But under CMS's invented "bona fide marketing" standard, the agency can choose to devalue all of Teva's property interests by maintaining price controls for additional months or years, diminishing the prices at which Teva's products can be sold. And Teva has no opportunity to be heard before CMS decides what it will do.

170. For all these reasons, when a drug is selected for inclusion in the DPNP and subject to price controls under the guise of a "maximum fair price," both the manufacturer of the selected drug and manufacturers of generics and biosimilars that compete or will compete with the selected drug are deprived of property interests without due process of law.

COUNT I
(Administrative Procedure Act—Qualifying Single Source Drug)

171. Teva realleges, reasserts, and incorporates by reference each of the foregoing allegations as though set forth fully herein.

172. The APA prohibits CMS from implementing the IRA's statutory mandate in a manner that is unlawful, arbitrary, capricious, an abuse of discretion, or contrary to law. 5 U.S.C. § 706(2)(A).

173. CMS's unlawful definition of a Qualifying Single Source Drug constitutes agency action in excess of statutory jurisdiction, authority, or limitations, or short of statutory right, in violation of 5 U.S.C. § 706(2)(C).

174. The IRA establishes that two drugs approved under separate NDAs or BLAs count as two separate Qualifying Single Source Drugs. CMS's Guidance Documents, however, purport to lump multiple Qualifying Single Source Drugs together for purposes of selection and assessment of a price control. That is unlawful.

175. CMS's finalized Guidance Documents for both IPAY 2026 and IPAY 2027 constitute final agency action for which Teva has no other adequate remedy within the meaning of 5 U.S.C. § 704.

176. Both Teva and the patients Teva serves will suffer irreparable harm unless CMS's definition of a Qualifying Single Source Drug is set aside. Teva lacks access to any mechanism by which it could otherwise be made whole for its injuries.

177. Congressional intent and the public interest would be served by an order vacating and setting aside CMS's unlawful definition of a Qualifying Single Source Drug.

COUNT II
(Administrative Procedure Act—Bona Fide Marketing)

178. Teva realleges, reasserts, and incorporates by reference each of the foregoing allegations as though set forth fully herein.

179. The APA prohibits CMS from implementing the IRA's statutory mandate in a manner that is unlawful, arbitrary, capricious, an abuse of discretion, or contrary to law. 5 U.S.C. § 706(2)(A).

180. CMS's unlawful "bona fide marketing" standard constitutes agency action in excess of statutory jurisdiction, authority, or limitations, or short of statutory right, in violation of 5 U.S.C. § 706(2)(C).

181. The IRA's phrase "approved . . . and . . . marketed" creates a point-in-time inquiry keyed to a product's initial launch. It does not permit a backward-looking—and ongoing—subjective inquiry into a generic drug's or a biosimilar's utilization after being marketed.

182. CMS's finalized Guidance Documents for both IPAY 2026 and IPAY 2027 constitute final agency action for which Teva has no other adequate remedy within the meaning of 5 U.S.C. § 704.

183. Both Teva and the patient population will suffer irreparable harm unless CMS's "bona fide marketing" standard is set aside. Teva lacks access to any mechanism by which it could otherwise be made whole for the injuries described in this complaint.

184. Congressional intent and the public interest would be served by an order vacating and setting aside CMS's unlawful "bona fide marketing" standard.

COUNT III
(Fifth Amendment—Due Process)

185. Teva realleges, reasserts, and incorporates by reference each of the foregoing allegations as though set forth fully herein.

186. The Fifth Amendment's Due Process Clause prohibits the government from depriving an entity of a constitutionally protected property interest without following constitutionally sufficient procedures.

187. The Due Process Clause requires 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); *see also Mathews v. Eldridge*, 424 U.S. 319, 333 (1976). Due process requires procedural protections

to prevent, to the extent possible, an erroneous deprivation of property. *See Gilbert v. Homar*, 520 U.S. 924, 930–932 (1997).

188. The IRA deprives Teva of two constitutionally protected property interests: its common-law property rights in its drug products and its contractual rights to sell certain generics and biosimilars pursuant to licenses and settlement agreements with manufacturers of the reference products.

189. The IRA deprives Teva of those property interests involuntarily and without any meaningful opportunity to be heard. The IRA also deprives Teva of those property interests by directing the Secretary to set prices at the "lowest" level without adequate procedural safeguards.

190. When AUSTEDO and AUSTEDO XR are selected for the DPNP, the IRA will strip Teva of any ability to meaningfully negotiate a reasonable price for those products. CMS's decision to select those drugs, and the prices CMS imposes on Teva, will be unchecked by any administrative or judicial review. 42 U.S.C. § 1320f-7.

191. Teva's supposed "option" to avoid those consequences by foregoing reimbursements from Medicare and Medicaid is no option at all. And if Teva were to somehow withdraw anyway, the resulting scarcity of its medicines would have disastrous public health consequences for patients.

192. When XTANDI, OFEV, XARELTO, and LINZESS are subject to IRA price controls, Teva will be deprived of its property interests in its competing generic products: Enzalutamide, Nintedanib, Rivaroxaban, and Linaclotide. As a generic manufacturer, Teva will have *no* opportunity to be heard before that deprivation occurs, not even the simulacrum of opportunity that the IRA affords to manufacturers of branded drugs.

193. Absent CMS's definition of a Qualifying Single Source Drug, Teva could not be deprived of its property interests in AUSTEDO XR in 2025, and the deprivations of Teva's property interests in Enzalutamide and Rivaroxaban would be less extensive. Absent CMS's invented "bona fide marketing" standard, CMS would not have the discretionary ability to keep price controls in place even after the entry of Teva's Enzalutamide, Nintedanib, Rivaroxaban, and Linaclotide products, further undermining Teva's property interests in those products. Further, CMS affords Teva no meaningful opportunity to be heard before it impairs Teva's property interests.

194. The risk of an erroneous deprivation of property interests resulting from the IRA's lack of procedural protections is substantial. And the government has no legitimate interest in shielding CMS's arbitrary decisions from judicial review.

195. The IRA's price-control scheme is therefore unlawful under the Fifth Amendment and should be enjoined. CMS's definition of a Qualifying Single Source Drug and its "bona fide marketing" standard are likewise unlawful under the Fifth Amendment, and they should be vacated and set aside.

PRAYER FOR RELIEF

For the foregoing reasons, Teva prays for the following relief:

A. A declaration under 28 U.S.C. § 2201 that CMS's definition of a Qualifying Single Source Drug is unlawful, arbitrary, and capricious under the APA;

B. A declaration under 28 U.S.C. § 2201 that CMS's "bona fide marketing" standard is unlawful, arbitrary, and capricious under the APA;

C. An order vacating and setting aside the Guidance Documents' Qualifying Single Source Drug definition and "bona fide marketing" standard;

D. A declaration under 28 U.S.C. § 2201 that the DPNP and CMS's Guidance Documents purporting to implement the Program violate the Fifth Amendment's Due Process Clause;

E. Injunctive relief barring Defendants from applying the drug-pricing provisions of the IRA to Teva or to the manufacturers of branded drugs or biologics with which Teva competes or will compete in the future;

F. An order under 28 U.S.C. § 2412 awarding Teva its costs, expenses, and attorney's fees incurred in these proceedings; and

G. Such other and further relief as the Court deems proper.

Respectfully submitted,

/s/ Sean Marotta
Sean Marotta (D.C. Bar No. 1006494)
Jacob T. Young (D.C. Bar No. 90014334)
HOGAN LOVELLS US LLP
555 Thirteenth Street, N.W.
Washington, D.C. 20004
(202) 637-4881
sean.marotta@hoganlovells.com

Attorney for Plaintiffs
Teva Pharmaceuticals USA, Inc. and Teva Branded Pharmaceutical Products R&D, Inc.

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