No. 25-761

IN THE
Supreme Court of the United States

NOVO NORDISK INC., ET AL.,
Petitioners,
v.
ROBERT F. KENNEDY, JR., SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Third Circuit

BRIEF OF TEVA PHARMACEUTICALS USA, INC. AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

SEAN MAROTTA
Counsel of Record
DANIELLE DESAULNIERS STEMPEL
KATHERINE T. MCKAY
HOGAN LOVELLS US LLP
555 Thirteenth Street, N.W.
Washington, D.C. 20004
(202) 637-5600
sean.marotta@hoganlovells.com

Counsel for Teva Pharmaceuticals USA, Inc.

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES iii

INTERESTS OF AMICUS CURIAE 1

SUMMARY OF ARGUMENT 2

ARGUMENT 4

I. GENERICS AND BIOSIMILARS OFFER IMPORTANT BENEFITS TO THE NATION'S HEALTHCARE SYSTEM 4

A. Generics And Biosimilars Reduce Costs While Diversifying Supply 5

B. The Development Of Generics And Biosimilars Requires Substantial Investment And Therefore Depends On Market Incentives To Succeed 7

II. THE IRA, AS IMPLEMENTED BY CMS, WILL STIFLE GENERIC AND BIOSIMILAR COMPETITION THROUGH MARKET-DISTORTING COERCION 10

A. Government-Imposed Prices For Innovator Products Will Directly Impact The Generic And Biosimilar Markets 10

B. The IRA Fails To Protect Generics And Biosimilars From Market Disruption Caused By Government-Coerced Price Erosion 15

TABLE OF CONTENTS—Continued

Page

1. As implemented by CMS, the IRA lifts its price mandates only after the generic or biosimilar market is affected 15

2. The biosimilar delay provision is too limited and opaque to meaningfully protect competition 20

III. THE IRA'S MARKET-DISTORTING EFFECT BELIES THE GOVERNMENT'S CONTENTION THAT IT IS MERELY AN ORDINARY MARKET PARTICIPANT 21

CONCLUSION 25

TABLE OF AUTHORITIES

Page

CASES:

Azar v. *Allina Health Servs.*,
587 U.S. 566 (2019) 23

Bristol Meyers Squibb Co. v. *Secretary of HHS*,
155 F.4th 245 (3d Cir. 2025) 4, 22, 24

Cardinal Towing & Auto Repair, Inc. v. *City of Bedford*,
180 F.3d 686 (5th Cir. 1999) 23

Engquist v. *Oregon Dep't of Agric.*,
553 U.S. 591 (2008) 23

FTC v. *Actavis, Inc.*,
570 U.S. 136 (2013) 5

Loper Bright Enters. v. *Raimondo*,
603 U.S. 369 (2024) 16

Polymer Techs., Inc. v. *Bridwell*,
103 F.3d 970 (Fed. Cir. 1996) 18

Sandoz Inc. v. *Amgen Inc.*,
582 U.S. 1 (2017) 9

Sanofi Aventis U.S. LLC v. *U.S. Dep't of Health & Hum. Servs.*,
58 F.4th 696 (3d Cir. 2023) 2, 23, 25

South-Central Timber Dev., Inc. v. *Wunnicke*,
467 U.S. 82 (1984) 23

STATUTES:

21 U.S.C. § 355(c)(3)(E)(ii) 8, 11

21 U.S.C. § 355(j)(5)(F)(ii) 8, 11

26 U.S.C. § 5000D 22

26 U.S.C. § 5000D(c) 22

TABLE OF AUTHORITIES—Continued

Page

42 U.S.C. § 1320f-1(a) 10
42 U.S.C. § 1320f-1(c) 15
42 U.S.C. § 1320f-1(c)(1) 16, 17
42 U.S.C. § 1320f-1(d) 15
42 U.S.C. § 1320f-1(e) 15
42 U.S.C. § 1320f-1(e)(1) 16
42 U.S.C. § 1320f-1(e)(1)(A) 11, 12, 16
42 U.S.C. § 1320f-1(e)(1)(B) 11, 12, 16
42 U.S.C. § 1320f-1(f) 20
42 U.S.C. § 1320f-1(f)(1)(B)(i)(I) 21
42 U.S.C. § 1320f-1(f)(1)(B)(ii) 20
42 U.S.C. § 1320f-2 22
42 U.S.C. § 1320f-2(a)(1) 13
42 U.S.C. § 1320f-3(c) 13
42 U.S.C. § 1320f-6(a) 22
42 U.S.C. § 1320f-7(2) 21
42 U.S.C. § 1395w-111(i) (2003) 10
42 U.S.C. § 1395w-114c(g)(2) 14
42 U.S.C. § 1396r-8(a)(1) 22
42 U.S.C. § 262(i)(2) 6
42 U.S.C. § 262(k) 6
42 U.S.C. § 262(k)(7) 8 12
Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) 5

TABLE OF AUTHORITIES—Continued

Page

Inflation Reduction Act of 2022, Pub. L. 117-169, 136 Stat. 1818 14

LEGISLATIVE AUTHORITIES:

Cong. Budget Off., *How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (July 1998), https://perma.cc/KR6F-WQZB 5

Cong. Budget Off., *Research and Development in the Pharmaceutical Industry* (Apr. 2021), https://perma.cc/W43X-4YJC 8

Cong. Rsch. Serv., No. R46679, *The Role of Patents and Regulatory Exclusivities in Drug Pricing* (Jan. 30, 2024), https://perma.cc/4SAS-JUT6 12

Cong. Rsch. Serv., No. R47202, *Tax Provisions in the IRA of 2022 (H.R. 5376)* (Aug. 10, 2022), https://perma.cc/5TWK-RULD 22

EXECUTIVE MATERIALS:

CMS, *Medicare Drug Price Negotiation Program: Final Guidance for IPAY 2027* (Oct. 2, 2024), https://perma.cc/AJ33-F9U4 16

CMS, *Medicare Drug Price Negotiation Program: Final Guidance for IPAY 2028* (Sept. 30, 2025), https://perma.cc/78BF-LL9C 16

CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026* (Aug. 2024), https://perma.cc/2G25-LL63 ..... 13, 19

TABLE OF AUTHORITIES—Continued

Page

CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2027* (Nov. 2025), https://perma.cc/6YZB-AMDL 13, 19

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), https://perma.cc/BP7R-MMVM 16-18, 20, 21, 24

FDA, *CBER-Regulated Products: Current Shortages* (July 11, 2025), https://perma.cc/9PM7-KD4K 7

FDA, *Drug Shortages* (Oct. 23, 2025), https://perma.cc/L34Y-7GVT 6

FDA, *Generic Competition & Drug Prices: New Evidence Linking Greater Generic Competition & Lower Generic Drug Prices* (Dec. 2019), https://perma.cc/9Z9R-2VXW 6

FDA, *Generic Drugs Can Help Promote Health Equity*, https://perma.cc/495Y-TL85 7

FDA, *Review and Approval* (Dec. 13, 2022), https://perma.cc/ZL78-2XZ7 8

FDA, *What Are "Biologics" Questions and Answers* (Feb. 6, 2018), https://perma.cc/8Q97-R7K6 ..... 6, 8

Medicaid.gov, *March 2024 Medicaid & CHIP Enrollment Data Highlights* (updated Nov. 28, 2025), https://perma.cc/4PJ5-XU6Z 23

OTHER AUTHORITIES:

Alvotech, *Alvotech and Teva Secure U.S. License Date for AVT04, a Proposed Biosimilar to Stelara*

TABLE OF AUTHORITIES—Continued

Page

(June 12, 2023), https://perma.cc/7LTS-WUYW 18

Ass'n for Accessible Meds., *2025 U.S. Generic & Biosimilar Medicines Savings Report* (Sept. 2025), https://perma.cc/7UDL-HCMC 5, 6

BusinessWire, *Samsung Biopeis Announces US Launch of PYZCHIVA, Biosimliar to Stelara* (Feb. 24, 2025), https://perma.cc/6K3M-L7K4 19

Becky Davidson et al., Avalere, *How Will the IRA Impact the Future of Biosimilars?* (Aug. 17, 2023), https://perma.cc/Y88M-BJUW 14

Miriam Fontanillo, et al., McKinsey & Co., *Three Imperatives for R&D in Biosimilars* (Aug. 19, 2022), https://perma.cc/NSC3-B24S 8

Dana Goldman et al., *Mitigating the Inflation Reduction Act's Adverse Impacts on the Prescription Drug Market*, USC Schaeffer (Apr. 2023), https://perma.cc/JG3V-J8RL 9, 14

Aaron S. Kesselheim et. al, *Determinants of Market Exclusivity for Prescription Drugs in the United States* (Sept. 11, 2017), https://perma.cc/8EU2-8MWM 11

Laurie McGinley, *Low Prices of Some Lifesaving Drugs Make Them Impossible to Get*, Wash. Post (June 18, 2019), https://perma.cc/PSR7-3LAF 7

Merck, *Addressing the Global Shortage of TICE BCG* (May 30, 2025), https://perma.cc/R7PB-2A8E 7

TABLE OF AUTHORITIES—Continued

Page

Stephanie E. O'Byrne, *IPRs and ANDA Litigation: All a Matter of Timing*, Fed. Lawyer (Jan. 2015), https://perma.cc/YNU5-LBLF 9

Steven Scheer, *Teva Pharm CEO Calls on Trump for Faster US Drug Approvals*, Reuters (Feb. 17, 2025), https://perma.cc/8R8N-JZ4W 1

Teva, *Generic Medicines and R&D* (Nov. 11, 2021), https://perma.cc/USE3-QJFM 8

Teva, *Producing Quality Products That Support Better Health*, https://perma.cc/N9DT-L8J7 1

INTERESTS OF AMICUS CURIAE

Teva Pharmaceuticals USA, Inc. (Teva) submits this brief as *amicus curiae* in support of Petitioners.[1]

Teva is a global pharmaceutical company that supplies over 3,600 medicines to almost 200 million patients. Teva, *Producing Quality Products That Support Better Health*, https://perma.cc/N9DT-L8J7. Teva has invested billions in research-and-development activities across that product portfolio and is unique in that it develops both innovator therapies *and* high-quality, lower-cost generics—one in fourteen U.S. prescriptions is a Teva generic. Steven Scheer, *Teva Pharm CEO Calls on Trump for Faster US Drug Approvals*, Reuters (Feb. 17, 2025), https://perma.cc/8R8N-JZ4W.

Teva's work as both an innovator and generic and biosimilar drug manufacturer makes it well-positioned to address the market-distorting effects of the Inflation Reduction Act's (IRA's) Drug Price Negotiation Program. This background explains why the government's assertions that participation in its price-control program is voluntary and that the Centers for Medicare & Medicaid Services (CMS) should be treated like an ordinary market participant with respect to the Program ring hollow.

---

[1] No party or counsel for a party authored this brief in whole or in part. No party, counsel for a party, or person other than *amicus curiae* or its counsel made any monetary contribution intended to fund the preparation or submission of this brief. Teva filed a materially identical brief in support of certiorari in *Janssen Pharmaceuticals, Inc.*. v. *Kennedy*, and *Bristol Myers Squibb Company v. Kennedy*, Nos. 25-749, 25-751.

SUMMARY OF ARGUMENT

The "federal government dominates the healthcare market" and "uses that market power to get drug makers to subsidize healthcare." *Sanofi Aventis U.S. LLC* v. *U.S. Dep't of Health & Hum. Servs.*, 58 F.4th 696, 699 (3d Cir. 2023). But in the IRA's Drug Price Negotiation Program, the government has done much more than wield its already impressive bargaining strength. CMS instead mandates that manufacturers supply selected drugs at significantly reduced prices—potentially as low as a penny—even when lower-cost generic drugs have launched or are certain to launch before the agency's price cap takes effect. The same is true for biosimilars, the generic equivalent of biologics, which are complex medicines typically manufactured using biotechnology. Perversely, CMS's price controls—which are ostensibly intended to benefit patients and bring down healthcare spending—will undercut competition from generic and biosimilar medicines, leading to a more-fragile market and an increased risk of drug shortages.

Patients and the healthcare system as a whole benefit enormously from generic and biosimilar competition, which help reduce prices and diversify the available sources for critical medicines. But developing these medicines can cost millions of dollars and take years. And because generics and biosimilars are therapeutically equivalent to their branded counterparts, they gain market share primarily by competing on price. That means companies will only undertake the substantial investments needed to develop and secure approval for generic and biosimilar

products if there are robust market opportunities to reward their efforts.

The IRA jeopardizes all of that. As Petitioner explains, the Program fundamentally upends the healthcare market and its incentive structure for innovator products by subjecting certain high-spend drugs and biologics to a government-dictated "maximum fair price." The only meaningful way out is for the manufacturer to withdraw completely from Medicare and Medicaid, a penalty so steep that no rational manufacturer could bear it. And the Program's market-distorting effects extend to generics and biosimilars, too. Under the Program, CMS will impose price caps on innovator drugs even if generic or biosimilar competition is imminent. Nor can generic and biosimilar products generally launch before the price caps are set, because the IRA can subject innovator products to selection before the expiration of exclusivity periods that block generic and biosimilar competition. The CMS-dictated price therefore functionally sets the market for *all* products—innovator and generic alike. But generic and biosimilar manufacturers have no opportunity to participate in the putative negotiation setting the "maximum fair price," further highlighting the Program's severe constitutional shortcomings.

The IRA purports to offer relief from the government-dictated price control upon generic or biosimilar entry, but that is often illusory. Selected innovator products remain subject to the government's price cap unless and until CMS determines that a generic or biosimilar competitor has been "bona fide" marketed, an arbitrary requirement found nowhere in the statute. And even if a generic or biosimilar

can satisfy that amorphous and atextual test, the innovator product's price cap generally remains in effect for at least one full calendar year—ample time for the government's artificially low prices to permanently alter the market. Moreover, the narrow statutory path theoretically available for biosimilar manufacturers to ask CMS to delay the selection of biological products for the Program is too limited, opaque, and unreliable to mitigate the negative effects on biosimilar development. The IRA's sweeping impact on the market also gives lie to the government's rationalization that CMS is merely an ordinary market participant engaged in voluntary commercial transactions with a willing counterparty.

The issues raised in the petition are "of great importance to consumers of pharmaceutical drugs, the companies that provide them, and the public at large." *Bristol Meyers Squibb Co.* v. *Secretary of HHS*, 155 F.4th 245, 289 (3d Cir. 2025) (Hardiman, J., dissenting). The petition should be granted.

ARGUMENT

I. GENERICS AND BIOSIMILARS OFFER IMPORTANT BENEFITS TO THE NATION'S HEALTHCARE SYSTEM.

The generic and biosimilar industries have saved the U.S. healthcare system trillions while diversifying the supply sources for critical medicines. But even with abbreviated approval pathways, developing generic and biosimilar products requires significant investments. The Program's unconstitutional conditions on innovator manufacturers threaten the benefits offered by generics and biosimilars by distorting the national market for them.

A. Generics And Biosimilars Reduce Costs While Diversifying Supply.

Four decades ago, Congress passed the Drug Price Competition and Patent Term Restoration Act—commonly known as the Hatch-Waxman Act—creating today's generic drug industry. Pub. L. No. 98-417, 98 Stat. 1585 (1984). The Hatch-Waxman Act shortens the pathway for FDA approval of generic drugs by permitting generic manufacturers to file an application "specifying that the generic has the 'same active ingredients as,' and is 'biologically equivalent' to, the already-approved brand-name drug." *FTC* v. *Actavis, Inc.*, 570 U.S. 136, 142 (2013) (citation omitted). By "allowing the generic to piggyback on the pioneer's approval efforts," the Hatch-Waxman Act "speed[s] the introduction of low-cost generic drugs to market." *Id.* (citation omitted).

This 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 in turn led the "average prescription price of a generic drug [to] fall[]." Cong. Budget Off., *How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* xiii (July 1998), https://perma.cc/KR6F-WQZB. Over the past decade, generic drugs have saved patients and the healthcare system $3.4 trillion, including $467 billion in 2024 alone. Ass'n for Accessible Meds., *2025 U.S. Generic & Biosimilar Medicines Savings Report* 10 (Sept. 2025), https://perma.cc/7UDL-HCMC (*Savings Report*). On average, the price of a generic is 60% lower than that of the reference innovator drug.

FDA, *Generic Competition & Drug Prices: New Evidence Linking Greater Generic Competition & Lower Generic Drug Prices* 8 (Dec. 2019), https://perma.cc/9Z9R-2VXW.

Given the Hatch-Waxman Act's success, Congress sought to replicate it for biologics—complex medicines derived from living organisms that "often represent the cutting-edge of biomedical research." FDA, *What Are "Biologics" Questions and Answers* (Feb. 6, 2018), https://perma.cc/8Q97-R7K6 (*Biologics Questions and Answers*). In 2010, Congress enacted the Biologics Price Competition and Innovation Act (BPCIA), which introduced an abbreviated pathway for biosimilars that are "highly similar" to and have "no clinically meaningful differences" from existing FDA-approved biologic products. *See id.* § 262(i)(2), (k).

Biosimilars, like generics, offer significant cost savings through price competition. *Savings Report*, *supra*, at 12, 19. The average sales price of a biosimilar is 40% lower than the branded biologic's price. *Id.* at 38. Biosimilars have saved the U.S. healthcare system nearly $56 billion since the first biosimilar entry in 2015. *Id.* at 34.

In addition to lowering costs, generics and biosimilars also offer help diversify supply. Without generic or biosimilar manufacturers, the innovator medicine's manufacturer would be the only source, leaving supplies susceptible to shortages due to "manufacturing and quality problems, delays, [or] discontinuations." FDA, *Drug Shortages* (Oct. 23, 2025), https://perma.cc/L34Y-7GVT. Tice BCG®—a biologic used to treat bladder cancer that is marketed by a single company—is a prime example. The

biologic has faced ongoing shortages since January 2019, forcing the manufacturer to "allocat[e] the drug to distributors based on past use." Laurie McGinley, *Low Prices of Some Lifesaving Drugs Make Them Impossible to Get*, Wash. Post (June 18, 2019), https://perma.cc/PSR7-3LAF; FDA, *CBER-Regulated Products: Current Shortages* (July 11, 2025), https://perma.cc/9PM7-KD4K (listing BCG Live as ongoing shortage). That has left patients to "scour[] chat rooms looking for help" and required "[m]edical groups [to] develop[] guidelines for using the reduced supply" and "giv[e] top priority to new patients." McGinley, *supra*; *see also* Merck, *Addressing the Global Shortage of TICE BCG* (May 30, 2025), https://perma.cc/R7PB-2A8E (stating that it takes three months to produce one batch of the medication).

With the entry of generics and biosimilars, the number of sources for a medicine increases, reducing the risk of shortages and ensuring that patients receive the medications they need. *See* FDA, *Generic Drugs Can Help Promote Health Equity*, https://perma.cc/495Y-TL85. Generics and biosimilars are thus essential to maintaining a diverse, robust, low-cost supply chain for medicines on which all Americans rely.

B. The Development Of Generics And Biosimilars Requires Substantial Investment And Therefore Depends On Market Incentives To Succeed.

The benefits from generic and biosimilar competition depend on manufacturers' willingness to invest substantial time and money to bring these products to market. That is no easy (or cheap) feat. For

example, in 2020 alone, Teva "invested nearly $1 billion in R&D activities and had more than 1,160 generic products in its development pipeline." Teva, *Generic Medicines and R&D* (Nov. 11, 2021), https://perma.cc/USE3-QJFM.

Developing biosimilars requires particularly substantial investment. "[M]ost biologics are complex mixtures that are not easily identified or characterized," making their development time- and capital-intensive. *Biologics Questions and Answers*, *supra*; *see also* FDA, *Review and Approval* (Dec. 13, 2022), https://perma.cc/ZL78-2XZ7. Even under the BPCIA's abbreviated pathway, "biosimilar drugs must still be put through some clinical trials," adding to the manufacturer's expenses. Cong. Budget Off., *Research and Development in the Pharmaceutical Industry* 22 (Apr. 2021), https://perma.cc/W43X-4YJC. A typical biosimilar costs $100 million to $300 million and takes six to nine years to develop. Miriam Fontanillo, et al., McKinsey & Co., *Three Imperatives for R&D in Biosimilars* (Aug. 19, 2022), https://perma.cc/NSC3-B24S. Even after this investment, the chances of obtaining FDA approval and reaching the market "remains low." *Id.*

Nor does a manufacturer realize its investment immediately after securing FDA approval. To incentivize continued investment in and development of innovator products, Congress granted innovator manufacturers set exclusivity periods: seven years for drugs and twelve years for biologics. 21 U.S.C. § 355(c)(3)(E)(ii), (j)(5)(F)(ii); 42 U.S.C. § 262(k)(7). As a result, by the time a generic or biosimilar launches, the innovator drug will have secured substantial market share, requiring the generic or

biosimilar to slash prices to compete. Patent-infringement litigation is also common and can further drive up costs and delay generic and biosimilar launches. *See, e.g.*, *Sandoz Inc.* v. *Amgen Inc.*, 582 U.S. 1, 7-11 (2017) (describing BPCIA's framework for infringement litigation); *see also* Stephanie E. O'Byrne, *IPRs and ANDA Litigation: All a Matter of Timing*, Fed. Lawyer 55 (Jan. 2015), https://perma.cc/YNU5-LBLF (average generic patent litigation costs up to $4.5 million).

Generics and biosimilar manufacturers can undertake these significant investments only if they reliably expect a sufficient return. A generic or biosimilar manufacturer's ability to undercut the innovator product's price is thus crucial to the continued development and success of these products. *See* Dana Goldman et al., *Mitigating the Inflation Reduction Act's Adverse Impacts on the Prescription Drug Market*, USC Schaeffer 5 (Apr. 2023), https://perma.cc/JG3V-J8RL (explaining that "generic drugs require a sufficiently discounted price * * * to attract a large portion of market share away from the branded market," and that generic manufacturers may not enter if they face lower revenues). Manufacturers must be able to set prices consistent with market opportunity and to make plans based on expected market prices and competition several years down the line. The Program's threats to this model fundamentally undermine the premises on which successful generic and biosimilar competition is based—and our healthcare system as a whole.

II. THE IRA, AS IMPLEMENTED BY CMS, WILL STIFLE GENERIC AND BIOSIMILAR COMPETITION THROUGH MARKET-DISTORTING COERCION.

The IRA eviscerates the market incentives on which the Hatch-Waxman Act and BPCIA rely. The federal government was historically prohibited from "interfer[ing]" in private price negotiations between drug manufacturers, pharmacies, and insurance plan sponsors. *See* 42 U.S.C. § 1395w-111(i) (2003). But under the IRA, CMS can now dictate pricing for certain high-Medicare-spend medicines before generics or biosimilars have a chance to enter the market—and in some instances, even when biosimilar or generic competition already exists. When a branded product is price-capped, the generic or biosimilar manufacturer has little or no room to undercut it without being forced to sell at a loss. And the limited mechanisms available in the IRA to protect generic and biosimilar competition are facially inadequate to guard against these risks; indeed, the uncertainty they foster exacerbates the market disruption.

The result is less innovation, less competition, and a weaker supply chain because of the risk that generic and biosimilar manufacturers will not introduce medicines on which they cannot earn a profit.

A. Government-Imposed Prices For Innovator Products Will Directly Impact The Generic And Biosimilar Markets.

The IRA directs CMS to select top-Medicare-spend drugs for price negotiations. 42 U.S.C. § 1320f-1(a). On its face, the IRA purports to protect generics and biosimilars by providing that CMS may not select an

innovator product for which generic or biosimilar competition exists: CMS may select a drug for negotiations only if there is no approved and "marketed" generic version of the drug and seven or more years have elapsed since FDA's approval. *Id.* § 1320f-1(e)(1)(A). And CMS may select a biologic if there is no licensed and "marketed" biosimilar and at least eleven years have elapsed since the date of its licensure. *Id.* § 1320f-1(e)(1)(B).

In practice, however, those protections are not as robust as they appear. Although the IRA formally excludes products that already face generic and biosimilar competition from the Program, the statute creates a race between CMS and follow-on competitors that the generic and biosimilar industries will almost inevitably lose.

Newly licensed drugs are entitled to 7.5 years of regulatory exclusivity, during which time FDA cannot approve a generic. 21 U.S.C. § 355(c)(3)(E)(ii), (j)(5)(F)(ii).[2] In reality, that exclusivity period is often far longer—up to 12 years or beyond. *See* Aaron S. Kesselheim et. al, *Determinants of Market Exclusivity for Prescription Drugs in the United States* at 1 (Sept. 11, 2017), https://perma.cc/8EU2-8MWM (stating average exclusivity period for new drugs is over 12 years and over 14.5 years for top-selling drugs). But the Program authorizes CMS to

[2] FDA cannot even accept the filing of a generic application for review until four years after the approval of the new-chemical entity, and even then only if the generic manufacturer certifies that its product does not infringe a valid patent, which is typically a prelude to patent litigation and an automatic stay of the generic's FDA application. 21 U.S.C. § 355(c)(3)(E)(ii), (j)(5)(F)(ii).

select drugs for price controls at year seven—a minimum of six months before any generic can even obtain FDA approval. 42 U.S.C. § 1320f-1(e)(1)(A). The same disconnect holds true for biosimilars; biologics receive 12 years of regulatory exclusivity, but CMS can select a biologic for price controls after 11 years. *Id.* §§ 262(k)(7), 1320f-1(e)(1)(B). Generics and biosimilars therefore have no chance to obtain FDA approval, let alone get onto the market, before the highest-value innovator products are selected for price controls.

The below timeline illustrates the problem:

- **Year 0**: Innovator drug or biologic approved by FDA
- **Year 7**: CMS can select innovator drug for price-control program
- **Year 7.5**: Earliest generic drug can obtain FDA approval for reference drugs with a novel active ingredient
- **Year 11**: CMS can select biologic for price-control program
- **Year 12**: Earliest biosimilar can obtain FDA approval

The IRA thus stacks the deck against genuine competition from generic and biosimilar manufacturers. The government bars these products from entering the market during a period of government-conferred exclusivity to innovator manufacturers. During this period, the innovator manufacturer can set prices high enough to recoup its research and development costs. Cong. Rsch. Serv., No. R46679, *The Role of Patents and Regulatory Exclusivities in Drug Pricing* at 4-5 (Jan. 30, 2024), https://perma.cc/4SAS-

JUT6. And that provides generic and biosimilar manufacturers an opening to capture market share by undercutting the innovator on price. *See supra* pp. 10-11. But the IRA permits CMS to select innovator products for the Program *before* their exclusivity periods expire, meaning that by the time generics and biosimilars are able to enter the market, the government has already imposed artificially low prices. Generic and biosimilar manufacturers therefore never have the chance to compete on the free market.

The IRA's market-distorting effect will be dramatic. During the putative "price negotiations," CMS sets a "maximum fair price" for the selected drug. 42 U.S.C. § 1320f-2(a)(1). The selected drug must be made available to Medicare beneficiaries at the government-mandated price beginning the first day of the initial price applicability year (IPAY), which is roughly two years after the selection date. *Id.* And the price caps CMS dictates will inevitably be far lower than market value; that is, after all, the Program's point. *See id.* § 1320f-3(c). Indeed, CMS capped the prices of the first ten Program drugs at an average of 63% off the list price. CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026*, at 2 (Aug. 2024), https://perma.cc/2G25-LL63. The second group of drugs are subject to an average price cap of 62%, with the highest cap topping out at a staggering 85%. CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2027*, at 2 (Nov. 2025), https://perma.cc/6YZB-AMDL (IPAY 2027 Results).

Generic and biosimilar manufacturers have no opportunity to participate in the Program's "negotiations," yet these government-mandated prices effectively bind them, too. When CMS orders the branded manufacturer to charge prices at that level or lower, there is no practical room for competition. As a result, the Program threatens to "erode the value proposition for a potential" generic or "biosimilar entrant": Once CMS mandates "a significantly lower price for a given product," generics or "biosimilars in the pipeline may then carry a lower value proposition than initially expected, while others may exit the market or never launch." Becky Davidson et al., Avalere, *How Will the IRA Impact the Future of Biosimilars?* (Aug. 17, 2023), https://perma.cc/Y88M-BJUW; *see also* Goldman, *supra*, at 5 ("[T]he decrease in brand prices due to negotiations could reduce the prices that any generic firm can charge, disincentivizing generics from * * * entering the market.").

In fact, the IRA not only undermines the market for generic and biosimilar entrants by pushing down prices, it also directly compromises their ability to compete with selected drugs. A new Medicare Part D discount program requires manufacturers of certain "applicable drugs"—including innovator products, generics, and biosimilars dispensed to Medicare enrollees—to agree to a 10-to-20% discount. *See* Inflation Reduction Act of 2022, Pub. L. 117-169, § 11201, 136 Stat. 1818, 1877 (codified as §§ 1860D-14C, 1860D-43 of the Social Security Act (42 U.S.C. §§ 1395w-114c, 1395w-153)). Drugs "selected" for the Program and subject to its mandated price caps are exempt from this additional discount. *See* 42 U.S.C. § 1395w-114c(g)(2). But generics and

biosimilars cannot be "selected" for Program participation; only innovator products are eligible. *See id.* § 1320f-1(c), (e). Generics and biosimilars are thus disadvantaged twice over: the government-mandated price cap for the innovator product drives down what the generic or biosimilar manufacturer can plausibly charge, but generics and biosimilars also remain subject to the additional Medicaid Part D discount. The inevitable result will be to discourage investment in generic and biosimilar competition, which harms patients who lose access to alternative, cheaper supplies of critical medicines.

B. The IRA Fails To Protect Generics and Biosimilars From Market Disruption Caused By Government-Coerced Price Erosion.

In seeming recognition of the threats the IRA poses to generics and biosimilars, the statute includes certain limited concessions supposedly designed to protect those products. But the exemptions are facially inadequate and only underscore the flaws inherent in the IRA's coercive price-control regime.

1. As implemented by CMS, the IRA lifts its price mandates only after the generic or biosimilar market is affected.

Under the IRA, only "qualifying single source drugs"—that is, innovator drugs and biologics that do not face generic or biosimilar competition—are "negotiation-eligible." 42 U.S.C. § 1320f-1(d), (e)(1). CMS nonetheless enforces its price mandates even in the face of date-certain generic or biosimilar market entry.

As noted, a drug or biologic is ineligible for selection if a generic is "approved and marketed" or a biosimilar is "licensed and marketed." *Id.* § 1320f-1(e)(1)(A)-(B). Although statutory interpretation is "exclusively a judicial function," *Loper Bright Enters.* v. *Raimondo*, 603 U.S. 369, 387 (2024) (citation omitted), CMS's Guidance has rewritten the statute to add a "bona fide marketing" requirement. Under the Guidance, the agency will only deselect an innovator product if it determines that a generic or biosimilar provides "meaningful competition" based on an arbitrary (and atextual) "holistic" review. CMS, *Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026* 72-75 (June 30, 2023), https://perma.cc/BP7R-MMVM (2026 Guidance).[3]

To make matters worse, the Program mandates a highly reticulated deselection timeframe: If a generic is "approved and marketed" before the end of the "negotiation" period, the innovator is never subject to a price cap. But if the generic is marketed even one day later, the price cap remains in effect for at least one full calendar year. *See* 42 U.S.C. § 1320f-1(c)(1). After that, the relevant cutoff is March 31 each year: If the generic is approved and marketed by March 31, the price cap sunsets at the end of that calendar year. But if the generic is

[3] CMS's IPAY 2027 and IPAY 2028 Guidance include the same "bona fide" marketing requirement. CMS, *Medicare Drug Price Negotiation Program: Final Guidance for IPAY 2027*, at 278-280 (Oct. 2, 2024), https://perma.cc/AJ33-F9U4; CMS, *Medicare Drug Price Negotiation Program: Final Guidance for IPAY 2028*, at 317 (Sept. 30, 2025), https://perma.cc/78BF-LL9C.

marketed *after* March 31, the earliest the price cap can sunset is the end of the *next* calendar year. Missing the cutoff thus means the innovator drug is subject to the price cap for significantly longer. The same holds true for biosimilars. *See id.*

The following table summarizes this regime for IPAY 2026:

Selected IPAY 2026 Drugs and Biologics	
Date by which generic or biosimilar is marketed	**Effect on price cap**
November 1, 2024	No price cap goes into effect
November 2, 2024 through March 31, 2026	Price cap effective January 1, 2026 through December 31, 2026
April 1, 2026 through March 31, 2027	Price cap effective January 1, 2026 through December 31, 2027
. . . and so on	

See 42 U.S.C. § 1320f-1(c)(1); 2026 Guidance 279-280.

Putting all this together, the innovator manufacturer must comply with the government-mandated price unless a generic or biosimilar is approved and marketed *before or during the negotiation period*. 2026 Guidance 71. Because CMS can select a drug or biologic for negotiation *before* the earliest generic or biosimilar is eligible for FDA-approval, *supra* pp. 11-12, beating the negotiation deadline will often

prove impossible. Even for those generics or biosimilars that do launch in time, they now face another hurdle: the manufacturer must engage in sufficient marketing to satisfy CMS's "holistic" inquiry before the deadline. 2026 Guidance 101-102. And if a generic or biosimilar launches *after* the negotiation period closes, the innovator will remain subject to the price cap for at least one full calendar year and potentially much longer, depending on when CMS determines the "bona fide" marketing requirement is met. *Id.* at 102.

Rather than allowing generic and biosimilar manufacturers to set market-competitive prices, the IRA pulls the rug out from under them. Even if CMS deselects the reference innovator drug in a later year, the damage will have been done: the government-mandated price will have already set buyers' expectations and retooled the market to the government's advantage, depriving generics and biosimilars of the market conditions on which their development was premised. *See, e.g.*, *Polymer Techs., Inc.* v. *Bridwell*, 103 F.3d 970, 976 (Fed. Cir. 1996) ("[r]equiring purchasers to pay higher prices after years of paying lower prices * * * is not a reliable business option").

Two examples demonstrate these problems. First is Stelara®, a biologic that was selected for the Program's price controls effective January 1, 2026. CMS selected the innovator biologic even after several manufacturers had submitted biosimilar applications to FDA and two manufacturers had publicly announced settlements with specific 2025 market entry dates. *See* Alvotech, *Alvotech and Teva Secure U.S. License Date for AVT04, a Proposed Biosimilar to Stelara* (June 12, 2023), https://perma.cc/7LTS-

WUYW. Those biosimilars in fact launched in early 2025. *E.g.*, BusinessWire, *Samsung Biopeis Announces US Launch of PYZCHIVA, Biosimliar to Stelara* (Feb. 24, 2025), https://perma.cc/6K3M-L7K4. And even though CMS ultimately removed Stelara® from the agency's price-control list beginning in 2027, CMS will still apply a 66% price discount to Stelara® from January 1, 2026, to December 31, 2026—forcing the biosimilars to compete with the price-controlled biologic during the critical early-launch period. *See Negotiated Prices for Initial Price Applicability Year 2026*, *supra*.

Teva's generic Nintedanib provides another example of this perverse system. CMS selected the referenced innovator drug, Ofev®, for a price cap beginning January 1, 2027. IPAY 2027 Results at 2. Ofev® treats idiopathic pulmonary fibrosis, a progressive and fatal lung disease. Teva's generic will launch when the last patent covering Ofev® expires on April 2, 2026. Appellant's Opening Br. at Add.4, *Teva Pharmaceuticals USA, Inc.* v. *Kennedy*, No. 25-5425 (D.C. Cir. Jan. 9, 2026).

But CMS's "negotiated" 50% discount on Ofev® will *still* go into effect on January 1, 2027—eight months after Teva's generic enters the market. *See* IPAY 2027 Results. Teva's generic launching in April 2026 means it will necessarily miss the crucial November 2025 cutoff to knock Ofev® out of the Program. The earliest CMS could withdraw the price cap on Ofev® is December 31, 2027, forcing Teva's generic to compete with an artificially low-priced branded drug for at least a full year. That kind of "competition" is untenable for generics manufacturers.

2. The biosimilar delay provision is too limited and opaque to meaningfully protect competition.

The IRA nominally acknowledges the perverse effects of subjecting a biologic for price controls if biosimilar competition is imminent. But even setting aside that there is no parallel exception for generic drugs, the IRA's exception for biologics does not provide a sufficient safe-harbor from the IRA's price-control regime.

Section 11002 provides a "[s]pecial rule to delay selection and negotiation of biologics for biosimilar market entry," known as the "biosimilar-delay provision." 42 U.S.C. § 1320f-1(f). Under that rule, a biosimilar manufacturer can request that CMS delay the selection of a brand-name biologic if the biologic will have been licensed for fewer than 16 years by the time the government-mandated price would take effect, provided CMS determines there is a "high likelihood" that the biosimilar will be licensed and marketed by then. *See* 2026 Guidance 109-112. This requires a biosimilar manufacturer to compile and submit substantial documentation to show CMS that (1) the reference drug's patents are unlikely to prevent the biosimilar from being marketed and (2) the biosimilar will be operationally ready to market within two years of when the reference product would otherwise be selected into the Program. 42 U.S.C. § 1320f-1(f)(1)(B)(ii).

In practice, however, the relief supposedly afforded by the biosimilar-delay provision is highly unreliable and simply serves to impose additional costs on biosimilar manufacturers. Biosimilar manufacturers can only guess as to what drugs CMS might

select in any given program year. But they must submit any delay request to CMS *before* the reference biologic is selected, forcing them to prepare a burdensome request merely to hedge against the possibility that the reference product will be selected. *Id.* § 1320f-1(f)(1)(B)(i)(I). And if relevant developments postdate the biologic's initial selection—for example, if a patent settlement and licensed entry date allows a biosimilar to enter the market after negotiations close, but before price controls become effective—the biosimilar manufacturer is simply out of luck.

The biosimilar-delay provision also provides no meaningful recourse for biosimilar manufacturers if CMS rejects their request. Delay requests are not public, and as with much of the Program, CMS conducts its review behind closed doors. CMS notifies the requestor if a delay has been granted or denied only after it announces what drugs it has selected for the Program. CMS is not required to provide any explanation or justification. *See* 2026 Guidance 108-110. Nor is judicial review available. *See* 42 U.S.C. § 1320f-7(2). The biosimilar-delay provision therefore provides no meaningful assurance that CMS's secretive review will respect the expectation interests of manufacturers who invest years of research and development into bringing biosimilars to market.

III. THE IRA'S MARKET-DISTORTING EFFECT BELIES THE GOVERNMENT'S CONTENTION THAT IT IS MERELY AN ORDINARY MARKET PARTICIPANT.

The IRA's significant market-distorting effects make clear that the government is not an ordinary

market participant. To make matters worse, the IRA's onerous penalties and CMS's heavy-handed role in the Program confirms it is nowhere close to voluntary: Drug manufacturers have no real choice over whether to participate.

The IRA compels manufacturers' participation in the Program through several highly coercive mechanisms. Manufacturers that refuse to participate in CMS's sham negotiations face a crippling, punitive tax beginning at 185% of the drug's price and escalating to 1,900%. *See* 42 U.S.C. §§ 1320f-2, 1320f-6(a); 26 U.S.C. § 5000D; Cong. Rsch. Serv., No. R47202, *Tax Provisions in the IRA of 2022 (H.R. 5376)*, at 4 tbl. 2 (Aug. 10, 2022), https://perma.cc/5TWK-RULD. A manufacturer that declines to offer its selected drug at CMS's "maximum fair price" is subject to civil monetary penalties of ten times the difference between the price charged and the CMS-mandated price. 42 U.S.C. § 1320f-6(a). A manufacturer that wishes to avoid CMS's price-control regime entirely must withdraw *all* of its drugs from Medicare *and* Medicaid. 26 U.S.C. § 5000D(c); 42 U.S.C. § 1396r-8(a)(1).

No ordinary market participant, even one with a dominant share, carries anywhere close to this power. No other buyer could impose "unavoidable, enterprise-crippling tax liabilities" or fines "if [a manufacturer] refused to sell drugs" on the buyer's terms. *Bristol Myers Squibb*, 155 F.4th at 269 (Hardiman, J., dissenting). And where the government exercises powers "tantamount to regulation," it is not entitled to market-participant treatment. *Cardinal Towing & Auto Repair, Inc.* v. *City of Bedford*,

180 F.3d 686, 691 (5th Cir. 1999); *see Engquist* v. *Oregon Dep't of Agric.*, 553 U.S. 591, 598 (2008); *South-Central Timber Dev., Inc.* v. *Wunnicke*, 467 U.S. 82, 97 & n.10 (1984) (plurality op.).

Nor could any other buyer condition manufacturers' access to Medicare and Medicaid on their participation in the Program—a blatant example of tying. Medicare is "the largest federal program after Social Security" and "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 a substantial proportion of the American population, with over 75 million individuals enrolled in the program. Medicaid.gov, *March 2024 Medicaid & CHIP Enrollment Data Highlights* (updated Nov. 28, 2025), https://perma.cc/4PJ5-XU6Z. "Through Medicare and Medicaid, [the government] pays for almost half the annual nationwide spending on prescription drugs." *Sanofi*, 58 F.4th at 699. Choosing between acceding to price controls, incurring crippling penalties, and withdrawing from Medicare and Medicaid—which constitute nearly half the prescription drug market—is as voluntary as giving your wallet to a mugger who has jabbed his pistol between your ribs.

Congress plainly designed the IRA, with its all-or-nothing structure, to put forward an "offer" drug manufacturers cannot refuse. Medicare and Medicaid serve highly vulnerable communities, including the elderly, individuals with disabilities, and the indigent. Congress could not have contemplated any

genuine risk that these populations would lose access to critical medicines.

The argument that companies could avoid the mandate to exit Medicare and Medicaid by divesting their interest in a selected drug only underscores the fiction that the government is operating like a market participant. *See Bristol Myers Squibb*, 155 F.4th at 273 (Hardiman, J., dissenting). No mere market participant could require, on the pain of substantial financial penalties, that a company divest its interest in its hard-won asset. Moreover, the theoretical buyer of the selected drug post-divestment would still be subject to the Program. So it, too, would be obligated to sell the selected drug at an artificially low, mandated price. *See* 2026 Guidance 131-132. The collateral damage on the generic and biosimilar marketplace would therefore be unchanged, with the suppressed prices—compounded by mandatory discounts—undermining incentives for the development of generic and biosimilar alternatives. *See supra* pp. 10-14, 14-20. All divestment would achieve is changing the brand manufacturer's name.

In addition, voluntary transactions do not ordinarily fundamentally reorder entire marketplaces or eliminate effective competition. The government acts here as a regulator whose mandates appropriate private industry for its own use, with the perverse effect that a law ostensibly intended to lower drug prices will undermine the ability of generic and biosimilar manufacturers to drive down costs through competition. The Court should reject the Government's constitutional defenses premised on the fiction that coercive pricing mandates are tantamount to voluntary commercial terms.

As the Third Circuit has recognized, the government "uses [its] market power to get drug makers to subsidize healthcare." *Sanofi*, 58 F.4th at 699. The government goes even further here. Its mandate that manufacturers provide selected drugs at artificially low prices will distort the healthcare market and deprive millions of people of life-saving treatments. This Court should not sustain the government's unprecedented market intrusion.

CONCLUSION

For the foregoing reasons and those in the petition, the petition should be granted.

Respectfully submitted,

SEAN MAROTTA
Counsel of Record
DANIELLE DESAULNIERS STEMPEL
KATHERINE T. MCKAY
HOGAN LOVELLS US LLP
555 Thirteenth Street, N.W.
Washington, D.C. 20004
(202) 637-5600
sean.marotta@hoganlovells.com

Counsel for Amicus Curiae

JANUARY 2026