ORAL ARGUMENT NOT YET SCHEDULED

No. 25-5425

IN THE

United States Court of Appeals for the District of Columbia Circuit

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

v.

ROBERT F. KENNEDY, JR., in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, and MEHMET OZ, in his official capacity as ADMINISTRATOR OF THE CENTERS FOR MEDICARE & MEDICAID SERVICES,
Defendants-Appellees.

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

JOINT APPENDIX

SEAN MAROTTA
DANIELLE DESAULNIERS STEMPEL
DANA A. RAPHAEL
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Counsel for Plaintiffs-Appellants

January 9, 2026

TABLE OF CONTENTS

U.S. District Court
District of Columbia (Washington, DC)
CIVIL DOCKET FOR CASE #: 1:25-cv-00113-SLS

TEVA PHARMACEUTICALS USA, INC. et al v. BECERRA et al
Assigned to: Judge Sparkle L. Sooknanan
Case in other court: USCA, 25-05425
Cause: 05:702 Administrative Procedure Act

Date Filed: 01/15/2025
Date Terminated: 11/21/2025
Jury Demand: None
Nature of Suit: 899 Administrative Procedure Act/Review or Appeal of Agency Decision
Jurisdiction: U.S. Government Defendant

Plaintiff

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Plaintiff

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V.

Defendant

XAVIER BECERRA
in his official capacity as Secretary of Health and Human Services
TERMINATED: 02/10/2025

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TERMINATED: 02/10/2025

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Defendant

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#	Docket Text	Date Filed
1	COMPLAINT against All Defendants XAVIER BECERRA, CHIQUITA BROOKS-LASURE (Filing fee $ 405 receipt number ADCDC-11409459) filed by TEVA PHARMACEUTICALS USA, INC., TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC. (Attachments: # 1 Civil Cover Sheet, # 2 Summons, # 3 Summons, # 4 Summons, # 5 Summons)(Marotta, Sean) (Entered: 01/15/2025)	01/15/2025
2	LCvR 26.1 CERTIFICATE OF DISCLOSURE of Corporate Affiliations and Financial Interests by TEVA PHARMACEUTICALS USA, INC., TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC (Marotta, Sean) (Entered: 01/15/2025)	01/15/2025
3	NOTICE of Appearance by Jacob Tyler Young on behalf of TEVA PHARMACEUTICALS USA, INC., TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC (Young, Jacob) (Entered: 01/15/2025)	01/15/2025
4	SUMMONS (4) Issued Electronically as to XAVIER BECERRA, CHIQUITA BROOKS-LASURE, U.S. Attorney and U.S. Attorney General (Attachment: # 1 Notice and Consent)(zsl) (Entered: 01/16/2025)	01/16/2025
	Case Assigned to Judge Sparkle L. Sooknanan. (zsl) (Entered: 01/16/2025)	01/16/2025
5	RETURN OF SERVICE/AFFIDAVIT of Summons and Complaint Executed as to the United States Attorney. Date of Service Upon United States Attorney on 1/17/2025. Answer due for ALL FEDERAL DEFENDANTS by 3/18/2025. (Marotta, Sean) (Entered: 01/23/2025)	01/23/2025
6	NOTICE of Appearance by Stephen M. Pezzi on behalf of All Defendants (Pezzi, Stephen) (Entered: 02/04/2025)	02/04/2025
7	NOTICE of Appearance by Christine L. Coogle on behalf of All Defendants (Coogle, Christine) (Entered: 02/05/2025)	02/05/2025
8	NOTICE of Appearance by Cassandra Snyder on behalf of All Defendants (Snyder, Cassandra) (Entered: 02/07/2025)	02/07/2025
9	AMENDED COMPLAINT against All Defendants filed by TEVA PHARMACEUTICALS USA, INC., TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC, TEVA NEUROSCIENCE, INC..(Marotta, Sean) (Entered: 02/10/2025)	02/10/2025
10	LCvR 26.1 CERTIFICATE OF DISCLOSURE of Corporate Affiliations and Financial Interests Supplement by TEVA PHARMACEUTICALS USA, INC., TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC, TEVA NEUROSCIENCE, INC. (Marotta, Sean) (Entered: 02/10/2025)	02/10/2025
11	Joint MOTION for Briefing Schedule and to Vacate the Answer Deadline by TEVA PHARMACEUTICALS USA, INC., TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC, TEVA NEUROSCIENCE, INC.. (Attachments: # 1 Text of Proposed Order) (Marotta, Sean). Added MOTION to Vacate on 2/21/2025 (zjm). (Entered: 02/21/2025)	02/21/2025
12	NOTICE of Appearance by Danielle Desaulniers Stempel on behalf of All Plaintiffs (Stempel, Danielle) (Entered: 02/26/2025)	02/26/2025
13	NOTICE of Appearance by Dana A. Raphael on behalf of All Plaintiffs (Raphael, Dana) (Entered: 02/26/2025)	02/26/2025
14	MOTION for Summary Judgment by TEVA PHARMACEUTICALS USA, INC., TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC, TEVA NEUROSCIENCE, INC.. (Attachments: # 1 Memorandum in Support, # 2 Declaration of Dell Faulkingham, # 3 Declaration of Carrie Groff, # 4 Proposed Order)(Marotta, Sean) (Entered: 02/26/2025)	02/26/2025
	MINUTE ORDER granting in part the Parties' 11 Joint Motion to Vacate the Answer Deadline and Set Summary Judgment Briefing Schedule. The Defendants' deadline to answer or otherwise respond to the Complaint is vacated. The Parties shall appear for a scheduling conference by VTC on March 4, 2025, at 2:00 p.m regarding the proposed briefing schedule. Video information will be emailed to the Parties. Signed by Judge Sparkle L. Sooknanan on 2/27/2025. (lcah) (Entered: 02/27/2025)	02/27/2025
	MINUTE ORDER striking the Plaintiffs' 14 Motion for Summary Judgment. The Court has not adopted a briefing schedule in this case. The Parties shall appear for a scheduling conference by VTC on March 4, 2025, at 2:00 p.m regarding the proposed briefing schedule. At that conference, the Parties should be prepared to discuss the submission of the administrative record. Signed by Judge Sparkle L. Sooknanan on 2/27/2025. (lcah) (Entered: 02/27/2025)	02/27/2025
	Minute Entry for proceedings held before Judge Sparkle L. Sooknanan: Status Conference held on 3/4/2025 virtually. A Briefing schedule will be issued. (Court Reporter Elizabeth Davila) (zglw) (Entered: 03/04/2025)	03/04/2025
	MINUTE ORDER: Upon consideration of the Parties' 11 Joint Motion for Briefing Schedule, the Court adopts the following schedule. The Plaintiffs' Motion for Summary Judgment is due by March 7, 2025. The Defendants' Combined Response to the Plaintiffs' Motion for Summary Judgment and Cross-Motion for Summary Judgment is due by April 12, 2025. The Plaintiffs' Response to the Defendants' Cross-Motion for Summary Judgment and Reply in Support of its Motion for Summary Judgment is due by May 7, 2025. The Defendants' Reply in support of their Cross-Motion for Summary Judgment is due by May 30, 2025. The Court further orders the Parties to abide by the page limits listed in the Joint Motion for Briefing Schedule. Signed by Judge Sparkle L. Sooknanan on 3/5/2025. (lcah) (Entered: 03/05/2025)	03/05/2025
15	MOTION for Summary Judgment by TEVA PHARMACEUTICALS USA, INC., TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC, TEVA NEUROSCIENCE, INC.. (Attachments: # 1 Brief in Support, # 2 Declaration of Dell Faulkingham, # 3 Declaration of Carrie Groff, # 4 Proposed Order)(Marotta, Sean) (Entered: 03/07/2025)	03/07/2025
16	MOTION for Leave to File Amicus Brief by Bausch Health Companies Inc., ELI LILLY AND COMPANY, JOHNSON & JOHNSON, PFIZER INC., SANOFI-AVENTIS U.S. LLC, BIOTECHNOLOGY INNOVATION ORGANIZATION. (Attachments: # 1 Proposed Amicus Brief, # 2 Text of Proposed Order)(Silverman, Andrew) (Entered: 03/14/2025)	03/14/2025

#	Docket Text	Date Filed
17	MOTION for Leave to File Brief of Amicus Curiae by ASSOCIATION FOR ACCESSIBLE MEDICINES. (Attachments: # 1 Proposed Brief of Amicus Curiae, # 2 Text of Proposed Order)(Burgess, Brian) (Entered: 03/14/2025)	03/14/2025
18	MOTION for Leave to Appear Pro Hac Vice :Attorney Name- Alyssa M. Caridis, Filing fee $ 100, receipt number ADCDC-11544524. Fee Status: Fee Paid. by Bausch Health Companies Inc., ELI LILLY AND COMPANY, JOHNSON & JOHNSON, PFIZER INC., SANOFI-AVENTIS U.S. LLC, BIOTECHNOLOGY INNOVATION ORGANIZATION. (Attachments: # 1 Declaration of Alyssa M. Caridis, # 2 Certificate of Good Standing, # 3 Text of Proposed Order)(Silverman, Andrew) (Entered: 03/14/2025)	03/14/2025
19	MOTION for Leave to Appear Pro Hac Vice :Attorney Name- Cesar A. Lopez-Morales, Filing fee $ 100, receipt number ADCDC-11544526. Fee Status: Fee Paid. by Bausch Health Companies Inc., ELI LILLY AND COMPANY, JOHNSON & JOHNSON, PFIZER INC., SANOFI-AVENTIS U.S. LLC, BIOTECHNOLOGY INNOVATION ORGANIZATION. (Attachments: # 1 Declaration of Cesar A. Lopez-Morales, # 2 Certificate of Good Standing, # 3 Text of Proposed Order)(Silverman, Andrew) (Entered: 03/14/2025)	03/14/2025
20	MOTION for Leave to Appear Pro Hac Vice :Attorney Name- Emily Minton Mattson, Filing fee $ 100, receipt number ADCDC-11544528. Fee Status: Fee Paid. by Bausch Health Companies Inc., ELI LILLY AND COMPANY, JOHNSON & JOHNSON, PFIZER INC., SANOFI-AVENTIS U.S. LLC, BIOTECHNOLOGY INNOVATION ORGANIZATION. (Attachments: # 1 Declaration of Emily Minton Mattson, # 2 Certificate of Good Standing, # 3 Text of Proposed Order)(Silverman, Andrew) (Entered: 03/14/2025)	03/14/2025
21	MOTION for Leave to Appear Pro Hac Vice :Attorney Name- Clement S. Roberts, Filing fee $ 100, receipt number ADCDC-11544529. Fee Status: Fee Paid. by Bausch Health Companies Inc., ELI LILLY AND COMPANY, JOHNSON & JOHNSON, PFIZER INC., SANOFI-AVENTIS U.S. LLC, BIOTECHNOLOGY INNOVATION ORGANIZATION. (Attachments: # 1 Declaration of Clement S. Roberts, # 2 Certificate of Good Standing, # 3 Text of Proposed Order)(Silverman, Andrew) (Entered: 03/14/2025)	03/14/2025
22	MOTION for Leave to Appear Pro Hac Vice :Attorney Name- Irena Royzman, Filing fee $ 100, receipt number ADCDC-11544530. Fee Status: Fee Paid. by Bausch Health Companies Inc., ELI LILLY AND COMPANY, JOHNSON & JOHNSON, PFIZER INC., SANOFI-AVENTIS U.S. LLC, BIOTECHNOLOGY INNOVATION ORGANIZATION. (Attachments: # 1 Declaration of Irena Royzman, # 2 Certificate of Good Standing, # 3 Text of Proposed Order)(Silverman, Andrew) (Entered: 03/14/2025)	03/14/2025
23	Unopposed MOTION for Extension of Time to File Summary Judgment Briefing by DOROTHY A. FINK, STEPHANIE CARLTON. (Attachments: # 1 Text of Proposed Order)(Snyder, Cassandra) (Entered: 03/20/2025)	03/20/2025
	MINUTE ORDER granting the Defendants' 23 Unopposed Motion for an Extension of Time to File Summary Judgment Briefing. The Court ORDERS the Parties to comply with the following schedule: The Defendants shall file their combined opposition to the Plaintiffs' motion for summary judgment and cross-motion for summary judgment by April 29, 2025. The Plaintiffs shall file their combined opposition to the Defendants' cross-motion and reply in support of the Plaintiffs' motion by May 19, 2025. The Defendants shall file their reply in support of their cross-motion for summary judgment by June 6, 2025. Signed by Judge Sparkle L. Sooknanan on 3/22/2025. (lcah) (Entered: 03/22/2025)	03/22/2025
	MINUTE ORDER granting 18 Motion for Leave to Appear Pro Hac Vice. Counsel should register for e-filing via PACER and file a notice of appearance pursuant to Local Civ. R. 83.6(a). Click for Instructions. Signed by Judge Sparkle L. Sooknanan on 3/22/2025. (lcah) (Entered: 03/22/2025)	03/22/2025
	MINUTE ORDER granting 19 Motion for Leave to Appear Pro Hac Vice. Counsel should register for e-filing via PACER and file a notice of appearance pursuant to Local Civ. R. 83.6(a). Click for Instructions. Signed by Judge Sparkle L. Sooknanan on 3/22/2025. (lcah) (Entered: 03/22/2025)	03/22/2025
	MINUTE ORDER granting 20 Motion for Leave to Appear Pro Hac Vice. Counsel should register for e-filing via PACER and file a notice of appearance pursuant to Local Civ. R. 83.6(a). Click for Instructions. Signed by Judge Sparkle L. Sooknanan on 3/22/2025. (lcah) (Entered: 03/22/2025)	03/22/2025
	MINUTE ORDER granting 21 Motion for Leave to Appear Pro Hac Vice. Counsel should register for e-filing via PACER and file a notice of appearance pursuant to Local Civ. R. 83.6(a). Click for Instructions. Signed by Judge Sparkle L. Sooknanan on 3/22/2025. (lcah) (Entered: 03/22/2025)	03/22/2025
	MINUTE ORDER granting 22 Motion for Leave to Appear Pro Hac Vice. Counsel should register for e-filing via PACER and file a notice of appearance pursuant to Local Civ. R. 83.6(a). Click for Instructions. Signed by Judge Sparkle L. Sooknanan on 3/22/2025. (lcah) (Entered: 03/22/2025)	03/22/2025
24	NOTICE of Appearance by Irena Royzman on behalf of Bausch Health Companies Inc., ELI LILLY AND COMPANY, JOHNSON & JOHNSON, PFIZER INC., SANOFI-AVENTIS U.S. LLC, BIOTECHNOLOGY INNOVATION ORGANIZATION (Royzman, Irena) (Entered: 03/25/2025)	03/25/2025
25	NOTICE of Appearance by Clement S. Roberts on behalf of Bausch Health Companies Inc., ELI LILLY AND COMPANY, JOHNSON & JOHNSON, PFIZER INC., SANOFI-AVENTIS U.S. LLC, BIOTECHNOLOGY INNOVATION ORGANIZATION (Roberts, Clement) (Entered: 03/25/2025)	03/25/2025
26	NOTICE of Appearance by Alyssa Caridis on behalf of Bausch Health Companies Inc., ELI LILLY AND COMPANY, JOHNSON & JOHNSON, PFIZER INC., SANOFI-AVENTIS U.S. LLC, BIOTECHNOLOGY INNOVATION ORGANIZATION (Caridis, Alyssa) (Entered: 03/25/2025)	03/25/2025

#	Docket Text	Date Filed
27	NOTICE of Appearance by Cesar Lopez-Morales on behalf of Bausch Health Companies Inc., ELI LILLY AND COMPANY, JOHNSON & JOHNSON, PFIZER INC., SANOFI-AVENTIS U.S. LLC, BIOTECHNOLOGY INNOVATION ORGANIZATION (Lopez-Morales, Cesar) (Entered: 03/25/2025)	03/25/2025
28	NOTICE of Appearance by Emily Minton Mattson on behalf of Bausch Health Companies Inc., ELI LILLY AND COMPANY, JOHNSON & JOHNSON, PFIZER INC., SANOFI-AVENTIS U.S. LLC, BIOTECHNOLOGY INNOVATION ORGANIZATION (Minton Mattson, Emily) (Entered: 03/25/2025)	03/25/2025
29	Memorandum in opposition to re 15 MOTION for Summary Judgment (Defendants' Combined Memorandum of Law) filed by STEPHANIE CARLTON, DOROTHY A. FINK. (Pezzi, Stephen) (Entered: 04/29/2025)	04/29/2025
30	Cross MOTION for Summary Judgment by STEPHANIE CARLTON, DOROTHY A. FINK. (Attachments: # 1 Memorandum in Support, # 2 Text of Proposed Order)(Pezzi, Stephen) (Entered: 04/29/2025)	04/29/2025
31	NOTICE of Appearance by Nandan M. Joshi on behalf of PUBLIC CITIZEN, FAMILIES USA, DOCTORS FOR AMERICA, PROTECT OUR CARE (Joshi, Nandan) (Entered: 05/01/2025)	05/01/2025
32	Unopposed MOTION for Leave to File Amicus Briefin support of Defendants by DOCTORS FOR AMERICA, FAMILIES USA, PROTECT OUR CARE, PUBLIC CITIZEN. (Attachments: # 1 Exhibit Proposed amicus brief)(Joshi, Nandan) (Entered: 05/01/2025)	05/01/2025
33	NOTICE of Appearance by Joseph J. Wardenski on behalf of Richard G. Frank, FIONA M. SCOTT MORTON, AARON S. KESSELHEIM, GERARD F. ANDERSON, RENA M. CONTI, DAVID M. CUTLER, JACK HOADLEY (Wardenski, Joseph) (Entered: 05/05/2025)	05/05/2025
34	Consent MOTION for Leave to File Amicus Brief by GERARD F. ANDERSON, RENA M. CONTI, DAVID M. CUTLER, Richard G. Frank, JACK HOADLEY, AARON S. KESSELHEIM, FIONA M. SCOTT MORTON. (Attachments: # 1 Proposed Amicus Brief) (Wardenski, Joseph) (Entered: 05/05/2025)	05/05/2025
35	REPLY to opposition to motion re 15 Motion for Summary Judgment, filed by TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC, TEVA NEUROSCIENCE, INC., TEVA PHARMACEUTICALS USA, INC.. (Marotta, Sean) (Entered: 05/19/2025)	05/19/2025
36	Memorandum in opposition to re 30 Cross MOTION for Summary Judgment filed by TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC, TEVA NEUROSCIENCE, INC., TEVA PHARMACEUTICALS USA, INC.. (Attachments: # 1 Proposed Order) (Marotta, Sean) (Entered: 05/19/2025)	05/19/2025
37	Unopposed MOTION for Extension of Time to File Response/Reply as to 30 Cross MOTION for Summary Judgment by STEPHANIE CARLTON, DOROTHY A. FINK. (Attachments: # 1 Text of Proposed Order)(Pezzi, Stephen) (Entered: 05/27/2025)	05/27/2025
	MINUTE ORDER granting the Defendants' 37 Unopposed Motion for Extension of Time to File Response/Reply. The Defendants' Reply is due by June 12, 2025. Signed by Judge Sparkle L. Sooknanan on 5/28/2025. (lcah) (Entered: 05/28/2025)	05/28/2025
38	REPLY to opposition to motion re 30 Motion for Summary Judgment filed by STEPHANIE CARLTON, DOROTHY A. FINK. (Pezzi, Stephen) (Entered: 06/12/2025)	06/12/2025
39	NOTICE OF SUPPLEMENTAL AUTHORITY by STEPHANIE CARLTON, DOROTHY A. FINK (Attachments: # 1 Ex. 1 - NRC v. Texas (U.S. June 18, 2025))(Pezzi, Stephen) (Entered: 06/25/2025)	06/25/2025
40	RESPONSE re 39 NOTICE OF SUPPLEMENTAL AUTHORITY RESPONSE TO NOTICE OF SUPPLEMENTAL AUTHORITY by TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC, TEVA NEUROSCIENCE, INC., TEVA PHARMACEUTICALS USA, INC. (Marotta, Sean) Modified on 6/26/2025 to correct event (zjm). (Entered: 06/26/2025)	06/26/2025
	MINUTE ORDER granting the 16 Motion for Leave to File Amicus Brief, 17 Motion for Leave to Participate as Amicus Curiae, 32 Motion for Leave to File Brief of Amici Curiae, and 34 Motion for Leave to File Brief as Amici Curiae. The Court will treat the motions' attachments, ECF Nos. 16-1, 17-1, 32-1, 34-1, as the amicus briefs. Signed by Judge Sparkle L. Sooknanan on 8/12/2025. (lcdl) (Entered: 08/12/2025)	08/12/2025
41	NOTICE OF SUPPLEMENTAL AUTHORITY by STEPHANIE CARLTON, DOROTHY A. FINK (Attachments: # 1 Exhibit A - BI Decision, # 2 Exhibit B - NICA Decision)(Snyder, Cassandra) (Entered: 08/13/2025)	08/13/2025
42	RESPONSE re 41 NOTICE OF SUPPLEMENTAL AUTHORITY filed by TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC, TEVA NEUROSCIENCE, INC., TEVA PHARMACEUTICALS USA, INC.. (Marotta, Sean) (Entered: 08/14/2025)	08/14/2025
43	NOTICE OF WITHDRAWAL OF APPEARANCE as to STEPHANIE CARLTON, DOROTHY A. FINK. Attorney Cassandra Snyder terminated. (Snyder, Cassandra) (Entered: 09/05/2025)	09/05/2025
44	NOTICE OF SUPPLEMENTAL AUTHORITY by STEPHANIE CARLTON, DOROTHY A. FINK (Attachments: # 1 Ex. 1 - Novo Nordisk Inc. v. HHS, 154 F.4th 105 (3d Cir. 2025))(Pezzi, Stephen) (Entered: 11/13/2025)	11/13/2025
45	RESPONSE re 44 NOTICE OF SUPPLEMENTAL AUTHORITY filed by TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC, TEVA NEUROSCIENCE, INC., TEVA PHARMACEUTICALS USA, INC.. (Marotta, Sean) (Entered: 11/14/2025)	11/14/2025

#	Docket Text	Date Filed
46	MEMORANDUM OPINION re the Plaintiff's 15 Motion for Summary Judgment and the Defendants' 30 Cross-Motion for Summary Judgment. See the attached document for details. Signed by Judge Sparkle L. Sooknanan on 11/20/2025. (lcak) (Entered: 11/20/2025)	11/20/2025
47	ORDER denying the Plaintiff's 15 Motion for Summary Judgment and granting the Defendants' 30 Cross-Motion for Summary Judgment. See the 46 Memorandum Opinion for details. The Court directs the Clerk of the Court to terminate this case from the active docket. Signed by Judge Sparkle L. Sooknanan on 11/20/2025. (lcak) (Entered: 11/20/2025)	11/20/2025
48	NOTICE OF APPEAL TO DC CIRCUIT COURT as to 47 Order on Motion for Summary Judgment,,, by TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC, TEVA NEUROSCIENCE, INC., TEVA PHARMACEUTICALS USA, INC.. Filing fee $ 605, receipt number ADCDC-12093071. Fee Status: Fee Paid. Parties have been notified. (Marotta, Sean) (Entered: 11/20/2025)	11/20/2025
49	Transmission of the Notice of Appeal, Order Appealed (Memorandum Opinion), and Docket Sheet to US Court of Appeals. The Court of Appeals fee was paid re 48 Notice of Appeal to DC Circuit Court,. (mg) (Entered: 11/21/2025)	11/21/2025
	USCA Case Number 25-5425 for 48 Notice of Appeal to DC Circuit Court, filed by TEVA NEUROSCIENCE, INC., TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC, TEVA PHARMACEUTICALS USA, INC.. (zjm) (Entered: 12/03/2025)	12/01/2025

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,

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

Dated: January 15, 2025

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 LLC,
145 Brandywine Parkway,
West Chester, Pennsylvania 19380;

and

TEVA NEUROSCIENCE, INC.,
400 Interpace Parkway, Bldg A
Parsippany, New Jersey 07054;

Plaintiffs,

v.

DOROTHY A. FINK, in her official capacity as ACTING SECRETARY OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue, S.W.,
Washington, D.C. 20201;

and

STEPHANIE CARLTON, in her official capacity as ACTING ADMINISTRATOR OF THE CENTERS FOR MEDICARE & MEDICAID SERVICES,
7500 Security Boulevard,
Baltimore, Maryland 21244,

Defendants.

No. 1:25-cv-00113-SLS

AMENDED COMPLAINT

Teva Pharmaceuticals USA, Inc.; Teva Branded Pharmaceutical Products R&D LLC; and Teva Neuroscience, 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 rewrites 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 rewriting 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 Parkway #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, Rivaroxiban, Linaclotide, Rifaximin, and Apremilast.

22. Plaintiff Teva Branded Pharmaceutical Products R&D LLC is a limited liability company organized in Delaware with its principal place of business at 145 Brandywine Parkway, West Chester, Pennsylvania 19380. Teva Branded Pharmaceutical Products R&D LLC is the application holder for AUSTEDO BID, NDA Nos. 208082 and 209885.

23. Plaintiff Teva Neuroscience, Inc. is a corporation organized in Delaware with its principal place of business at 400 Interpace Parkway, Building A, Parsippany, New Jersey 07054. Teva Neuroscience, Inc. is the application holder for AUSTEDO XR, NDA No. 216345.

24. Defendant Dorothy Fink is the Acting Secretary of the U.S. Department of Health and Human Services (HHS). Defendant Fink maintains an office at 200 Independence Avenue, S.W., Washington, D.C. 20201. She is sued in her official capacity only.

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

JURISDICTION AND VENUE

26. 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, 2202, 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.

27. 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

28. 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.

29. 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]

[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.

30. 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 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

31. 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.

32. 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

[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).

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 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)).

33. 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).

34. 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.

35. 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]

36. 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).

37. 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

[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).

/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.*

38. 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.

39. 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.

40. 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).

41. 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.

42. 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.

43. 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.

44. 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.

45. 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.*

46. 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://tinyurl.com/4bkh5xwt (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.

47. 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 lifesaving innovation and keeping drug prices as low as possible—until the IRA.

C. The IRA Becomes Law

48. 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

49. 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).

50. 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"). *Id.* § 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–1(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.*

51. To be eligible for selection and negotiation, a drug must be a Qualifying Single Source Drug. *Id.* § 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–1(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"

52. A manufacturer whose product is selected must agree to participate in what the IRA calls "the negotiation period." *Id.* § 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).

53. 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 id.* §§ 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).

54. The IRA also limits the bases for manufacturers' nominal counteroffers to myopic "factors" specified by statute. *Id.* § 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.

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

56. Once CMS has imposed a "maximum fair price," a manufacturer must provide various Medicare participants "access to such price." *Id.* § 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).

57. 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." *Id.* §§ 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

58. A manufacturer's agreement to participate in "negotiations" and to acquiesce to CMS's "maximum fair price" are compelled by a punitive, escalating "tax." *Id.* §§ 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.

59. The IRA provides for the "[s]uspension" of the penalty, but only if a manufacturer destroys itself. *Id.* § 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.

60. 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*, at 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.

61. 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

62. Congress directed that CMS implement the DPNP for IPAY 2026, 2027, and 2028 through "program instruction or other forms of program guidance." *Id.* § 1320f–1 note.

63. 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).

64. 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.

65. 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.

66. 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.

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

68. *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.

69. 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–1(b)(1)(A)-(B). CMS's definition also changes the selection clock for a newer drug that shares an active moiety with an earlier-approved drug because its eligibility for selection will

[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.

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.

70. *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." *Id.* § 1320f–1(e)(1)(A), (B). Both of these requirements are 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.

71. 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.

72. 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

73. 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.

74. 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).

75. 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.

76. 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.

77. 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.

78. *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, *id.* § 1320f–1(e)(1)(A)(ii), and biologics cannot be selected until they have been approved for eleven years, *id.* § 1320f–1(e)(1)(B)(ii).

79. 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.

80. 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.*, *id.* § 1320f–1(e)(1)(A)(iii), (B)(iii).

81. If generic or biosimilar competition begins before a drug or biologic is selected, it is simply not eligible for the program. 2027 Final Guidance 278-280. 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.*

82. 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").

83. Under CMS's "bona fide marketing" standard, by contrast, a generic or biosimilar is likely to take many months to reach whatever level of sales CMS will ultimately deem bona fide. A time lag is certain based on CMS's selected methodology, which relies on the evaluation of time-lagged utilization data. For generics launched shortly before April 1 of the branded drug's IPAY, the inherent delay in utilization data will be the difference between an additional *year* of

the branded drug's being subject to an IRA price control, even if the generic or biosimilar's first sale occurred before April 1. 2027 Final Guidance 278-280.

84. 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 170-171, 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. Nor will CMS have PDE data from March. *Id*. The inherent time lags in this data will result in generics launched shortly before the branded drug's IPAY being insufficient, under CMS's definition, to remove the

branded drug from selection, with the result that the generic is forced to compete against a price-controlled branded drug for an additional year.

85. 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

86. 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

87. 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.

88. 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.

89. 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.

90. 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.

91. 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, 814-815 (2019), *available at* https://pmc.ncbi.nlm.nih.gov/articles/PMC10398273/; Anisha M. Patel et al., *Healthcare Utilization and Direct Medical Costs of Huntington's Disease Among Medicaid Beneficiaries in the United States*, 26 J. of Med. Econ. 811, 813-815 (2023), *available at* https://www.tandfonline.com/doi/epdf/10.1080/13696998.2023.2222561.

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

93. On January 17, 2025, HHS announced that AUSTEDO and AUSTEDO XR were selected for inclusion in the DPNP for "negotiations" in 2025, leading to a price control in IPAY 2027. *HHS Announces 15 Additional Drugs Selected for Medicare Drug Price Negotiations in Continued Effort to Lower Prescription Drug Costs for Seniors* (Jan. 17, 2025), https://www.cms.gov/newsroom/press-releases/hhs-announces-15-additional-drugs-selected-medicare-drug-price-negotiations-continued-effort-lower (2025 Drug Selections). 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), *available at* https://www.jmcp.org/doi/10.18553/jmcp.2024.24167. AUSTEDO XR was eligible for selection only because of CMS's definition of a Qualifying Single Source Drug, even though it has been approved for well under seven years, because it shares an active moiety with AUSTEDO and Teva holds both NDAs.

94. Because AUSTEDO and AUSTEDO XR were 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

95. 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.

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

97. 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.

98. 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)

99. 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 was selected for inclusion in the DPNP for "negotiation" in 2025, leading to an IPAY in 2027. 2025 Drug Selections, *supra*.

100. 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.

101. 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.

102. 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 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).

103. 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.

104. 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. And in those eight months, Teva will be selling only the capsule version of XTANDI, not the tablet form which dominates the market, further reducing the likelihood that CMS will deem the bona fide marketing standard satisfied.

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, causing Teva to suffer financial harm.

OFEV (Nintedanib)

105. 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 was selected for inclusion in the DPNP for "negotiation" in 2025, leading to an IPAY in 2027. 2025 Drug Selections, *supra*.

106. 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]

107. Teva plans to launch a generic form of Nintedanib that will compete with OFEV starting as early as September 26, 2026, and no later than March 26, 2027. 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).

108. 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

[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).

less certain that CMS will conclude that Teva has done so. A launch on September 26, 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 26, 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, causing Teva to suffer financial harm.

XARELTO (Rivaroxiban)

109. 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, 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. *HHS Selects the First Drugs for Medicare Drug Price Negotiation* (Aug. 29, 2023), https://tinyurl.com/2nmu8snk. CMS has imposed a price control amounting to a 62 percent discount on branded XARELTO. IPAY 2026 Results, *supra*, at 2.

110. 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.

111. Teva filed its ANDA for a generic version of XARELTO 10, 15, and 20 mg tablets on August 30, 2018. That ANDA 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 ANDA. The lawsuit against Teva with respect to the 10, 15, and 20 mg ANDAs was dismissed pursuant to a settlement on April 8, 2020.

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

113. CMS's imposition of the "bona fide marketing" standard will harm Teva by making it impossible to stop an IRA price control from applying to XARELTO in 2028. A launch on March 15, 2027 will give only *two weeks* between generic entry and the critical April 1 date by which CMS will determine whether a generic is "bona fide marketed" such that the branded drug will no longer be price controlled in 2028. The two data sources that CMS looks to in making its "bona fide marketing" determination—PDE data and AMP data—will not contain any data for the month of March. As a result, under CMS's definition, generic launch in March cannot remove a branded product from the DPNP for the following price year, with the result that Teva will be forced to compete against three price-controlled versions of XARELTO not just for 2027, but also throughout all of 2028, causing Teva to suffer financial harm.

LINZESS (Linaclotide)

114. LINZESS (Linaclotide), a branded drug that treats irritable-bowel syndrome, has been approved under NDA No. 202811 since August 2012. LINZESS was selected for inclusion in the DPNP for "negotiation" in 2025, leading to an IPAY in 2027. 2025 Drug Selections, *supra*.

115. 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.

116. 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).

117. CMS's imposition of the bona fide marketing standard will harm Teva by making it impossible for Teva and other generics to stop an IRA price control from applying to LINZESS in 2030. 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. Because no PDE or AMP data will be available for March, the generics will not be able to demonstrate bona fide marketing under CMS's definition, with the result that Teva will be forced to compete against a price-controlled version of LINZESS throughout all of 2030.

XIFAXAN (Rifaximin)

118. XIFAXAN (Rifaximin) is a branded drug that treats irritable bowel syndrome with diarrhea and hepatic encephalopathy. XIFAXAN has been approved under NDA No. 22554 (550 mg) since March 2010, and NDA No. 21361 (200 mg) since May 2004. XIFAXAN was selected for inclusion in the DPNP for "negotiation" in 2025, leading to an IPAY in 2027. 2025 Drug Selections, *supra*.

119. Teva filed its ANDA for a generic version of the 550 mg strength of XIFAXAN on December 17, 2015. 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 March 23, 2016, as a result of filing its ANDA. The lawsuit was dismissed against Teva pursuant to a settlement on September 17, 2018.

120. Pursuant to the terms of the settlement, Teva plans to launch a generic form of the 550 mg strength Rifaximin that will compete with XIFAXAN starting on January 1, 2028. Teva's generic will be the sole generic to launch on that date; FDA has confirmed that Teva has retained its 180-Day exclusivity as the first company to file a Paragraph IV challenge to XIFAXAN. 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).

121. CMS's "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 XIFAXAN in 2027, and less certain that CMS will conclude that generic manufacturers have done so. A launch before March 31, 2028, will give Teva very limited time to satisfy CMS's standard for price-applicability year 2028. In Teva's experience, there will be insufficient time to generate the utilization levels required by CMS's subjective "bona fide marketing" standard. That is particularly true because Teva's generic will compete only against the 550 mg strength, further reducing the likelihood that CMS will determine that the bona fide marketing standard has been satisfied. But if Teva does not meet that standard by March 31, 2028, Teva will be forced to compete against a price-controlled version of XIFAXAN not just in 2028, but also throughout all of 2029.

OTEZLA (Apremilast)

122. OTEZLA (Apremilast) is a branded drug that treats psoriatic arthritis and plaque psoriasis. OTEZLA has been approved under NDA Nos. 205437 and 206058 since March 2014 and September 2014, respectively. OTEZLA comes in a titration pack, containing combinations of 10 mg, 20, mg, and 30 mg strength tablets, as well as bottles of the 20 mg and 30 mg tablets. All approved indications for OTEZLA provide for the patient to start treatment with the appropriate titration pack and be followed by maintenance dosing using the 20 mg or 30 mg strength tablets. OTEZLA was selected for inclusion in the DPNP for "negotiation" in 2025, leading to an IPAY in 2027. 2025 Drug Selections, *supra*.

123. Teva filed its ANDA for a generic version of the 20 mg and 30 mg strengths of OTEZLA on March 21, 2018. 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 June 28, 2018, as a result of filing its ANDA. The lawsuit was dismissed against Teva pursuant to a settlement on January 26, 2021.

124. Pursuant to the terms of the settlement, Teva plans to launch a generic form of the 20 mg and 30 mg strengths of Apremilast that will compete with OTEZLA starting in August 2028. Teva's generic is expected to be among the first generic forms of Apremilast 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).

125. CMS's "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 OTEZLA in 2027, and less certain that CMS will conclude that generic manufacturers have done so. A launch in August 2028 will give Teva a limited amount of time to satisfy CMS's standard for price-

applicability year 2029, such that it will be removed from the IRA list by plan year 2029. In Teva's experience this is an insufficient amount of time to generate the utilization levels required by CMS's subjective "bona fide marketing" standard. That is particularly true because Teva's generic will not compete against the titration packs of OTEZLA, which provide the starting doses for all indications, further reducing the likelihood that CMS will determine the bona fide marketing standard to be satisfied. But if Teva does not meet the bona fide marketing standard by March 31, 2029, Teva will be forced to compete against a price-controlled version of OTEZLA not just in 2028, but also throughout all of 2029, causing Teva to suffer financial harm.

126. 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.

127. Given Teva's broad exposure to the innovator-drug and generic-and-biosimilar markets, Teva is 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.

128. 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).

129. 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).

130. CMS violated all of these maxims here.

Qualifying Single Source Drug

131. 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.

132. 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 167-168. 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.

133. 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.

134. 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).

135. 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.

136. 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.

137. 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. *Id.* § 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).

138. 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)).

139. 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.").

140. 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 an 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.

141. 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 id.* § 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."

142. 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 id.* § 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).

143. 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.

144. 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.

145. 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

146. 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.

147. 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.* § 1320–1(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).

148. 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." *Id.* § 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.

149. CMS "will consider a generic drug . . . to be marketed" 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 101-102; 2027 Final Guidance at 170-171. And that inquiry will occur over a "12-month period." *Id.*

150. 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.

151. 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.

152. 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.

153. 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.

154. 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.

155. 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.

156. 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.

157. 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.

158. 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.

159. 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.

160. 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).

161. 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.

162. 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).

163. 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. This is not a hypothetical scenario. Teva's generic Rivaroxiban, Enzalutimide, Rifaximin, and Apremilast products will all launch with fewer presentations than the brand drugs against which they will compete. 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.

164. 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.

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

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

167. 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).

168. 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).

169. 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.

170. 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.

171. 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.

172. 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).

173. 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. *Id.* § 5000D(c).

174. 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.

175. 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.

176. 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).

177. 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, Nintedanib, Rivaroxaban, Linaclotide, Rifaximin, and Apremilast, as well as protected property interests in its license agreements with the manufacturers of the reference listed drugs XTANDI, OFEV, XARELTO, LINZESS, XIFAXAN, and OTEZLA. 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 had no chance to be heard before CMS selected it for "negotiation" in 2025. And Teva

will have no chance to be heard at all as to Enzalutamide, Nintedanib, Rivaroxaban, Linaclotide, Rifaximin, and Apremilast.

178. 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, Nintedanib, Linaclotide, Rifaximin, and Apremilast. 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.

179. 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)

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

181. 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).

182. 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).

183. 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.

184. 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.

185. 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.

186. 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)

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

188. 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).

189. 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).

190. 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.

191. 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.

192. 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.

193. 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)

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

195. 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.

196. 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).

197. 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.

198. 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.

199. Because AUSTEDO and AUSTEDO XR were selected for the DPNP, the IRA strips 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, is unchecked by any administrative or judicial review. 42 U.S.C. § 1320f–7.

200. 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.

201. When XTANDI, OFEV, XARELTO, LINZESS, XIFAXAN, and OTEZLA are subject to IRA price controls, Teva will be deprived of its property interests in its competing generic products: Enzalutamide, Nintedanib, Rivaroxaban, Linaclotide, Rifaximin, and Apremilast. 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.

202. 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, Nintedanib, Rivaroxaban, Linaclotide, Rifaximin, and Apremilast 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, Linaclotide, Rifaximin, and Apremilast 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.

203. 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.

204. 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,

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Dated: February 10, 2025

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TEVA PHARMACEUTICALS USA, INC., *et al.*, *Plaintiffs*, v. ROBERT F. KENNEDY JR., in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, *et al.*, *Defendants*.	Civil Action No. 25-113 (SLS)

JOINT MOTION TO VACATE THE ANSWER DEADLINE
AND SET SUMMARY JUDGMENT BRIEFING SCHEDULE

The parties jointly move to vacate Defendants' deadline to answer Plaintiffs' complaint and to set a briefing schedule for motions for summary judgment.

1. Teva Pharmaceuticals USA, Inc.; Teva Branded Pharmaceutical Products R&D, LLC; and Teva Neuroscience, Inc. (collectively, Teva) brought this lawsuit challenging certain aspects of the drug-pricing provisions of the Inflation Reduction Act of 2022 and related guidance issued by the Centers for Medicare & Medicaid Services (CMS).

2. Teva filed its complaint on January 15, 2025. ECF No. 1. Teva then filed an amended complaint on February 10, 2025. ECF No. 9. Defendants' deadline to answer Teva's First Amended Complaint is March 18, 2025. *See* ECF No. 5; Fed. R. Civ. P. 15(a)(3).

3. The parties have conferred regarding the most efficient approach to this litigation. The parties agree that none of Teva's claims will require discovery, witness testimony, or trial, and should instead be resolved on dispositive motions. The parties further agree that Defendants will not submit an administrative record in this matter. To the extent the parties intend to reference any administrative documents not already publicly available, they will submit them to the Court

by attaching them as exhibits to their briefs. The parties reserve the right to object to any documents submitted in this way.

4. The parties have agreed to the briefing schedule and page limitations set forth below and respectfully request that the Court adopt the schedule and page limitations by order.

a. Teva will file a motion for summary judgment, not to exceed 45 pages, by February 26, 2025;

b. Defendants will file a combined response to Teva's motion and cross-motion for summary judgment, not to exceed 55 pages, by April 3, 2025;

c. Teva will file a combined response to Defendants' cross-motion and any reply in support of its motion, not to exceed 50 pages, by April 28, 2025; and

d. Defendants will file any reply in support of their cross-motion, not to exceed 35 pages, by May 21, 2025.

5. Because this case involves the facial constitutionality of a federal statute and related claims under the Administrative Procedure Act, the parties further respectfully request that the Court dispense with Local Civil Rule 7(h)(1)'s requirement that motions for summary judgment be accompanied by separate statements of material facts. The parties do not believe those statements would serve a useful purpose in this matter.

6. For essentially the same reasons, the parties respectfully request that the Court also dispense with Defendants' obligation to file an answer to the complaint.

7. Teva respectfully requests the Court's decision on the parties' cross-motions for summary judgment by **June 30, 2025**. CMS has selected Teva's innovator products AUSTEDO and AUSTEDO XR for inclusion in the Drug Price Negotiation Program beginning this year. By

June 30, 2025, Teva must provide CMS with its counter-offer as part of the process of determining the statutory Maximum Fair Prices that will apply to AUSTEDO and AUSTEDO XR. A decision from this Court by June 30, 2025, would provide helpful guidance that would inform Teva's approach to doing so. If the Court invalidates CMS's guidance regarding the definition of Qualifying Single Source Drug, Teva's AUSTEDO XR will no longer be subject to the negotiation process because its New Drug Application is fewer than seven years old. Even assuming that Teva's AUSTEDO remains selected for negotiation, Teva's counter-offer will be completely different if it is proposing a price for AUSTEDO alone rather than AUSTEDO and AUSTEDO XR. Moreover, if the Court invalidates CMS's "bona fide marketing" standard, that will inform Teva's ongoing evaluation of whether to continue its investment and preparation for generic launches that will compete with branded drugs selected for negotiation. Defendants do not join in this request. Defendants take no position on when the Court should issue any decision, do not believe that expedited decision is warranted, and defer to the Court about how best to manage its docket.

8. A proposed order is attached.

Dated: February 21, 2025

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TEVA PHARMACEUTICALS USA, INC., *et al.*, *Plaintiffs*, v. ROBERT F. KENNEDY, JR., in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, *et al.*, *Defendants*.	No. 1:25-cv-00113-SLS

DECLARATION OF DELL FAULKINGHAM

I, Dell Faulkingham, declare as follows:

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

2. I am the Senior Vice President, U.S. Innovative Medicines at Teva. Teva is a wholly owned, indirect subsidiary of Teva Pharmaceuticals Industries, Ltd., a global pharmaceutical company headquartered in Israel. Teva is an industry leader in the development, manufacture, and marketing of innovator, generic, and biosimilar pharmaceutical products in the United States.

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

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

TEVA'S INVESTMENTS IN ITS MEDICINE PORTFOLIO

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

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

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

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

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

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

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

8. That cycle relies on Teva's ability to market its innovator products at market prices during statutory-exclusivity periods. Federal law provides sponsors of innovator drugs with various statutory-exclusivity periods, during which they may market their products free from competition by generic versions of those products. Innovator manufacturers make most of their revenue on their products during those exclusivity periods because they sell a higher volume of their product at market prices when no generic version is available.

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

TEVA'S AFFECTED INNOVATOR PRODUCTS

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

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

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

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

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

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

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

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

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

THE DRUG PRICE NEGOTIATION PROGRAM HARMS TEVA

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

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

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

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

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

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

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

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

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

CMS'S GUIDANCE FURTHER HARMS TEVA

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

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

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

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

Dell Faulkingham

February 21, 2025

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TEVA PHARMACEUTICALS USA, INC., *et al.*, *Plaintiffs*, v. ROBERT F. KENNEDY, JR., in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, *et al.*, *Defendants*.	No. 1:25-cv-00113-SLS

DECLARATION OF CARRIE GROFF

I, Carrie Groff, declare as follows:

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

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

3. In my capacity as Vice President of Portfolio and New Product Launch, I lead Teva's U.S. generic product portfolio and launch teams, which includes responsibility for selecting new generic products for development, and overseeing Teva's generic product-development strategy from the time Teva chooses to develop a given product through the time Teva launches that product into the market. My team and I value new product opportunities, coordinate with

Teva's regulatory affairs personnel to ensure that our strategies align, and make decisions about which products to prioritize based on the company's goals, projections, manufacturing capacity, and pertinent regulatory developments. My responsibilities for Teva's generic products include timeline alignment taking into consideration product approval, operational readiness, and legal status. My team also coordinates internal decision-making regarding inventory preparation activities.

TEVA'S INVESTMENTS IN ITS GENERIC PORTFOLIO

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

THE DRUG PRICE NEGOTIATION PROGRAM

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

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

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

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

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

TEVA'S AFFECTED GENERIC PRODUCTS

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

XTANDI (Enzalutamide)

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

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

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

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

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

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

OFEV (Nintedanib)

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

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

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

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

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

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

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

XARELTO (Rivaroxaban)

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

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

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

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

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

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

LINZESS (Linaclotide)

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

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

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

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

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

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

XIFAXAN (Rifaximin)

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

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

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

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

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

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

OTEZLA (Apremilast)

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

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

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

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

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

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

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

THE DRUG PRICE NEGOTIATION PROGRAM HARMS TEVA

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

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

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

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

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

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

CMS'S GUIDANCE FURTHER HARMS TEVA

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

Qualifying Single Source Drug

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

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

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

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

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

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

"Bona Fide" Marketed

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Carrie Groff

February 20 2025

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TEVA PHARMACEUTICALS USA, INC.,

Plaintiff,

v.

ROBERT F. KENNEDY, *et al.*,[1]

Defendants.

Civil Action No. 25-113 (SLS)
Judge Sparkle L. Sooknanan

MEMORANDUM OPINION

This case is one of several challenges to the validity of the 2022 Inflation Reduction Act's Drug Price Negotiation Program, which establishes a methodology to determine the price at which Medicare will reimburse payments for drug costs incurred by Medicare beneficiaries.[2] The goal of the Drug Price Negotiation Program is to set the lowest maximum fair price that Medicare will pay manufacturers for drugs selected for the Program. Teva Pharmaceuticals USA (Teva) is a large pharmaceutical manufacturer that sells over 3,600 medicines to over 200 million people. Teva brought this lawsuit against various officers and employees of the U.S. Department of Health and Human Services (HHS) and the Centers for Medicare & Medicaid Services (CMS) who implement the Drug Price Negotiation Program. Teva alleges that CMS's guidance governing selections for

[1] The current Secretary is substituted for his predecessor pursuant to Federal Rule of Civil Procedure 25(d).

[2] *See AstraZeneca Pharms. LP v. Sec'y U.S. Dep't of Health & Hum. Servs.*, 137 F.4th 116 (3d Cir. 2025); *Boehringer Ingelheim Pharms., Inc. v. U.S. Dep't of Health & Hum. Servs.*, 150 F.4th 76 (2d Cir. 2025); *Nat'l Infusion Ctr. Ass'n v. Kennedy*, No. 23-cv-707, 2025 WL 2380454 (W.D. Tex. Aug. 7, 2025); *Bristol Myers Squibb Co. v. Sec'y U.S. Dep't of Health & Hum. Servs.*, 155 F.4th 245 (3d Cir. 2025); *Novo Nordisk Inc. v. Sec'y U.S. Dep't of Health & Hum. Servs.*, 154 F.4th 105 (3d Cir. 2025).

the Drug Price Negotiation Program is contrary to law and that the Program itself violates the Fifth Amendment's Due Process Clause. Before the Court are competing motions for summary judgment from Teva and the Defendants. Because Teva's claims either fail on the merits or are unripe, the Court denies its motion and grants the Defendants' cross-motion.

BACKGROUND

A. Statutory Background

1. Medicare Part D and the IRA

Medicare is a federally funded health insurance program that pays for covered healthcare items and services, including prescription drugs, for individuals who are 65 or older and some individuals with disabilities. *See* 42 U.S.C. §§ 426, 426a, 426-1, 1395 *et seq.* The Medicare statute "is divided into five 'Parts,'" which set forth the terms by which Medicare will pay for benefits. *Ne. Hosp. Corp. v. Sebelius*, 657 F.3d 1, 2 (D.C. Cir. 2011). Two Parts are at issue here. Part B is a supplemental insurance program that, in part, covers certain drugs administered as part of a physician's service or furnished for use with certain durable medical equipment. *See* 42 U.S.C. §§ 1395j–1395w-6; 42 C.F.R. § 410.28. Meanwhile, Part D establishes a prescription drug coverage program for beneficiaries. *See* 42 U.S.C. § 1395w-101 *et seq.*

"Part D-eligible individuals can access prescription-drug coverage by joining a Part D plan. . . . offered by private insurers," known as plan sponsors, "which must comply with Medicare requirements" and must bid to be accepted into the Part D program. *Pharm. Care Mgmt. Ass'n v. Mulready*, 78 F.4th 1183, 1188 (10th Cir. 2023); *see* 42 U.S.C. § 1395w-111. CMS reimburses plan sponsors for Part D expenditures pursuant to certain contractual arrangements and regulations. *See* 42 U.S.C. § 1395w-112; 42 C.F.R. § 423.301 *et seq.*

Prior to 2022, Part D barred CMS from "interfer[ing] with the negotiations between drug manufacturers" and plan sponsors. 42 U.S.C. § 1395w-111(i). At that time, Medicare Part D was

"projected to increase faster than any other category of health spending[,]" S. Rep. No. 116-120, at 4 (2019), with recent increases "in large part driven" by a "rise in spending for specialty drugs" that face "little or no competition" and "a relatively small number of drugs [being] responsible for a disproportionately large share of Medicare costs," H.R. Rep. No. 116-324, pt. 2, at 37–38 (2019). Congress sought to address these issues by passing drug negotiation provisions in the Inflation Reduction Act of 2022 (IRA). *See* 42 U.S.C. §§ 1320f–1320f-7; 26 U.S.C. § 5000D.

2. The Drug Price Negotiation Program

In relevant part, the IRA directs CMS to "establish a Drug Price Negotiation Program" to "negotiate and, if applicable, renegotiate maximum fair prices for such selected drugs." 42 U.S.C. § 1320f(a)(3). The Program "aims to achieve the lowest maximum fair price for each selected drug[,]" *id.* § 1320f-3(b)(1), to be paid by "eligible individuals" under Medicare Parts B and D, *id.* §§ 1320f(c)(2), 1320f-2(a)(1)–(3), 1320f-3(a). The IRA does not "pursue[] its stated purpose at all costs," *Stanley v. City of Sanford*, 145 S. Ct. 2058, 2067 (2025) (citation omitted), and imposes a "[c]eiling for maximum fair price" paid, 42 U.S.C. § 1320f-3(c). But if a manufacturer declines to participate in negotiations, it must terminate its participation in Medicare and Medicaid or otherwise face an excise tax on all sales of the selected drug. *See* 26 U.S.C. § 5000D.

The Program operates in cycles based on price applicability periods. 42 U.S.C. § 1320f(b)(2). Each "price applicability period" begins on January 1 of the "first initial price applicability year" and ends "with the last year during which the drug is a selected drug" subject to the negotiated maximum fair price. *Id.* § 1320f(b)(1)–(2). Each initial price applicability year is a calendar year. *Id.* § 1320f(b)(1).

3. Drug Selection

The IRA directs CMS to begin the drug selection process by identifying "negotiation-eligible drugs" from "qualifying single source drugs" defined by the statute. 42 U.S.C. § 1320f-1(a), (d)–(e). To be a "qualifying single source drug," a drug must be covered by Part D or eligible for reimbursement under Part B and the three following conditions must be met:

> (i) [the drug] is approved [by the United States Food and Drug Administration (FDA)] under section 355(c) of Title 21 and is marketed pursuant to such approval;
>
> (ii) . . . at least 7 years [has] elapsed since the date of such approval; and
>
> (iii) [the drug] is not the listed [brand-name] drug for any [generic] drug that is approved and marketed under [an abbreviated new drug application by the FDA].

Id. § 1320f-1(e)(1)(A).[3] The Act requires CMS to identify "negotiation-eligible drug[s]" from among these qualifying drugs. *Id.* § 1320f-1(d)(1). For the 2026 and 2027 price periods, the negotiation-eligible drugs are the 50 qualifying single source drugs with the highest total Medicare Part D expenditures over a specified 12-month period. *Id.* § 1320f-1(d)(1)(A). For subsequent price periods, the negotiation-eligible drugs are the 50 qualifying single source drugs with the highest Medicare Part B expenditures and the 50 qualifying single source drugs with the highest Part D expenditures over a specified 12-month period. *Id.* § 1320f-1(d)(1). Certain drugs, not at issue here, are excluded from serving as either a qualifying single source drug or negotiation-eligible drug. *Id.* § 1320f-1(d)(2), (e)(3).

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[3] The IRA also includes certain biological products approved under a Biologics License Application (BLA) as qualifying single source drugs. 42 U.S.C. § 1320f-1(e)(1)(A). Teva's Complaint does not allege that any of its drugs or ongoing projects impacted by the IRA are for a biological product approved under a BLA as opposed to a drug approved under a New Drug Application (NDA). Accordingly, Teva lacks standing to challenge those provisions and they are not discussed substantially here. Nevertheless, the challenged portions of the statutory scheme operate similarly with respect to both drugs and biologics. *See, e.g.*, Am. Compl. ¶ 68 n.4.

The Act requires CMS to rank the negotiation-eligible drugs according to total expenditures and to "select and publish" a list of the highest-ranking drugs no later than a publication date specified in the Act for each price period. 42 U.S.C. § 1320f-1(a). Each drug selected and included on the list constitutes a "selected drug" and "shall be subject to the negotiation process" under the statute. *Id.* § 1320f-1(a), (c).

The Act mandates that CMS base its total expenditure determinations using "data that is aggregated across dosage forms and strengths of the drug." 42 U.S.C. § 1320f-1(d)(3)(B); *see also id.* § 1320f-5(a)(2). The number of drugs to be selected varies by year. CMS must select 10 drugs for the 2026 price period, 15 drugs for the 2027 and 2028 price periods, and 20 drugs for all subsequent price periods. *Id.* § 1320f-1(a)–(b). If the number of negotiation-eligible drugs for any price period is fewer than the specified number of selected drugs for that period, CMS must select "all" negotiation-eligible drugs for negotiation. *Id.* § 1320f-1(a).

4. Statutory Bar of Review

CMS alone selects the individual drugs covered by the Program. The IRA provides that "[t]here shall be no administrative or judicial review of . . . [t]he selection of drugs under section 1320f-1(b) of this title, the determination of negotiation-eligible drugs under section 1320f-1(d) of this title, and the determination of qualifying single source drugs under section 1320f-1(e) of this title." 42 U.S.C. § 1320f-7(2).

5. Negotiations and Agreements

The negotiation process begins with the manufacturer's submission of pricing and other related data to CMS on a date prescribed by the statute. 42 U.S.C. §§ 1320f-2(a)(4), 1320f-3(b)(2)(A). CMS is then required—again by a date set by the statute for each price period—to make "a written initial offer that contains [its] proposal for the maximum fair price of the drug and

a concise justification" of the proposal. *Id.* § 1320f-3(b)(2)(B). "Not later than 30 days after" receiving the initial offer, the manufacturer must either "accept such offer or propose a counteroffer." *Id.* § 1320f-3(b)(2)(C)(i). The Act requires CMS to "respond in writing to such counteroffer." *Id.* § 1320f-3(b)(2)(D). The Act lays out factors that CMS shall consider in assessing offers and counteroffers in these negotiations. *Id.* § 1320f-3(e). For each price period, the Act specifies a deadline when the negotiations between CMS and the manufacturers of the selected drugs "shall end." *Id.* § 1320f-3(b)(2)(E).

If CMS and a manufacturer agree on a maximum fair price by that deadline, the IRA instructs CMS to "enter into agreements with manufacturers of selected drugs" to provide "access to such price" to "eligible" Medicare beneficiaries and their eligible "hospitals, physicians, and other providers of services and suppliers" beginning on January 1 of the initial price applicability year. 42 U.S.C. § 1320f-2(a)(1)–(3). And the agreed upon price may also factor into price determinations for drugs under the 340B Drug Pricing Program, *id.* § 1320f-2(d), and state Medicaid Programs, *id.* § 1396r-8(c)(1)(C)(i)(V). If the parties have not agreed on a price and entered into an agreement by the relevant deadlines, the manufacturer is deemed to be noncompliant and subject to the excise tax penalties under 26 U.S.C. § 5000D.

If a maximum fair price is established for a selected drug, the drug remains for sale to Medicare beneficiaries at the negotiated price. 42 U.S.C. § 1320f(b)(2). In some circumstances, a drug can be eligible for re-negotiation. *Id.* § 1320f-3(f). A drug can also be removed from the Program the following year if a generic version of the drug is "approved" and "marketed" for at least 9 months. *Id.* § 1320f-1(c)(1).

6. Penalties and Excise Tax

Any manufacturer that has made an agreement under the Program but fails to make the selected drug available to Medicare beneficiaries at the negotiated price is subject to civil penalties. 42 U.S.C. § 1320f-6. Each time such a manufacturer distributes a selected drug at a price above the drug's maximum fair price, it "shall be subject to a civil monetary penalty equal to ten times the . . . difference between the price for such drug . . . and the maximum fair price." *Id.* § 1320f-6(a). Additionally, any such manufacturer that fails to submit required information to CMS or otherwise fails to comply with the Negotiation Program's requirements must pay a penalty of $1,000,000 for each day of the violation. *Id.* §§ 1320f-6(c), 1320f-2(a)(4)–(5).

As discussed earlier, the IRA also imposes an excise tax on all manufacturers who do not sign a maximum fair price agreement but continue to participate in Medicare or Medicaid. 26 U.S.C. § 5000D. The tax is assessed daily for "noncompliance periods," which begin when the deadline to sign the Manufacturer Agreement or to agree to a maximum fair price has passed and end when the manufacturer reaches an agreement with CMS or withdraws from the Program. *Id.* § 5000D(b)–(c). The tax is imposed on any sale of the selected drug when "manufactured or produced in the United States or entered into the United States for consumption, use, or warehousing." *Id.* § 5000D(e)(1). If the manufacturer provides notice of withdrawal of its products from Medicare and Medicaid, the excise tax is suspended. *Id.* § 5000D(c)(1)(A), (c)(2)(B).[4]

[4] The Third Circuit has explained the process of withdrawing from the Program:

> We have held that the Act provides an escape hatch for a company that declines to participate in the Program. A manufacturer can cause the excise tax to be "[s]uspen[ded]" by terminating its extant Medicare and Medicaid agreements under the Medicare Coverage Gap Discount Program, the Manufacturer Discount Program, and the Medicaid Drug Rebate Program. 26 U.S.C. § 5000D(c).

B. Regulatory Background

Congress directed CMS to implement the Program through "instruction or other forms of program guidance." Inflation Reduction Act of 2022, Pub. L. No. 117–169, §§ 11001–02, 136 Stat. 1818, 1833, 1862, (to be codified at 42 U.S.C. §§ 1320f note, 1320f-1 note). Following public comment and revisions, CMS has issued final guidance implementing the Negotiation Program for the 2026 and 2027 initial price applicability years. *See* Ctrs. for Medicare & Medicaid Servs., 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) (2026 Guidance), https://perma.cc/J2VZ-F5BZ; Ctrs. for Medicare & Medicaid Servs., 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 (Oct. 2, 2024) (2027 Guidance), https://perma.cc/TK33-JX9S. Teva challenges two provisions in the 2026 and 2027 Guidance. Am. Compl. ¶ 67, ECF No. 9.

1. Qualifying Single Source Drug

The first challenged provision implements "the requirement in [42 U.S.C. § 1320f-1(d)(3)(B)] to use data aggregated across dosage forms and strengths of the drug, including new formulations of the drug," when identifying a qualifying single source drug. 2026 Guidance § 30.1,

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> CMS may terminate a manufacturer's extant Medicare agreements under the Coverage Gap Discount and Manufacturer Discount Programs for "good cause" effective upon 30 days' notice. 42 U.S.C. §§ 1395w-114a(b)(4)(B)(i), 1395w-114c(b)(4)(B)(i). Relying on that authority, CMS promised to offer manufacturers a 30-day exit from the Coverage Gap Discount and Manufacturer Discount Programs upon request, which it said would enable a manufacturer to avoid excise tax liability. 2023 Revised Guidance at 33–34, 120–21. We have held that CMS has statutory authority to do so.

Novo Nordisk, 154 F.4th at 110 (citations omitted).

at 100; 2027 Guidance § 30.1, at 169. Under this provision, CMS "will identify a potential qualifying single source drug using . . . all dosage forms and strengths of the drug with the same active moiety and the same holder of a New Drug Application (NDA), inclusive of products that are marketed pursuant to different NDAs." 2026 Guidance § 30.1, at 99; 2027 Guidance § 30.1, at 167. CMS deemed this approach "appropriate" based on its finding "that existing NDA / BLA holders have obtained approval for new dosage forms or different routes of administration of the same active moiety / active ingredient under different NDAs or BLAs." 2027 Guidance § 30.1, at 169; *see also* 2026 Guidance § 30.1, at 100.

2. Bona Fide Marketing

The second challenged provision explains how CMS will determine if an approved generic drug "is marketed" under 42 U.S.C. § 1320f-1(e)(1)(A)(iii)—thereby, excluding any brand-name counterpart from being designated a "qualifying single source drug." Under this Provision, an approved generic drug will be considered "marketed when the totality of the circumstances . . . reveals that the manufacturer of that drug . . . is engaging in bona fide marketing of that drug." 2026 Guidance § 30.1, at 102; *see also* 2027 Guidance § 30.1, at 170. In this inquiry, CMS considers Prescription Drug Event (PDE) and Average Manufacturer Price (AMP) data, which covered manufacturers are required to submit to CMS. 2026 Guidance § 30.1, at 101–02; 2027 Guidance § 30.1, at 170–71; *see also* 2026 Guidance at 73 n. 23; 2027 Guidance at 205 n.103. The "use of [PDE and AMP] data is not exhaustive," and "[t]he determination whether a generic drug or biosimilar is marketed on a bona fide basis [is] a holistic inquiry . . . that will not necessarily turn on any one source of data." 2027 Guidance § 30.1, at 171; *see also* 2026 Guidance § 70, at 169. "Additional relevant factors may include whether the generic drug or biosimilar is regularly

and consistently available for purchase" and "whether any licenses or other agreements" may "limit the availability or distribution of the selected drug." 2027 Guidance § 30.1, at 171.

C. Factual and Procedural Background

Teva is a large pharmaceutical manufacturer offering over 3,600 medicines to over 200 million people. Am. Compl. ¶ 86. On January 15, 2025, Teva filed this action challenging certain aspects of the drug-pricing provisions of the IRA as well as the above-mentioned guidance issued by CMS. *See* Compl., ECF No. 1. Two days later, CMS selected Austedo, a drug manufactured by Teva to treat involuntary muscle movements, for the IRA's Drug Price Negotiation Program during the 2027 initial price applicability year. Am. Compl. ¶¶ 87, 93. Teva also produces an extended-release formulation of Austedo, known as Austedo XR, that was selected alongside Austedo and approved by the FDA under a different NDA than Austedo. Am. Compl. ¶ 89. On February 10, 2025, Teva filed an Amended Complaint as a matter of right, which reflected these new developments. *See* Am. Compl., ECF No. 9.

In the Amended Complaint, Teva alleges that Austedo XR would not have been selected for negotiation absent CMS Guidance that treats both Auestdo and Austedo XR as a single source qualifying drug "because [they] share[] an active moiety . . . and Teva holds both NDAs." Am. Compl. ¶ 93. And Teva also plans to bring to market a variety of generic drugs and alleges its ability to price these drugs is harmed by CMS's bona fide marketing requirement as well. Am. Compl. ¶¶ 95–127.

The Amended Complaint brings three claims. Counts I and II allege that CMS's Guidance violates the Administrative Procedure Act (APA), 5 U.S.C. § 706(2)(A). Am. Compl. ¶¶ 180–93. On these APA claims, Teva seeks a declaration that CMS's Guidance defining a qualifying single source drug and setting a standard for "bona fide marketing" is unlawful and should be vacated.

Am. Compl. ¶¶ A–C. Count III alleges that the IRA's price control scheme and CMS's Guidance implementing it are unconstitutional under the Fifth Amendment right to due process. Am. Compl. ¶ 204. On the due process claim, Teva asks the Court to declare the drug-pricing provisions of the IRA unlawful and enjoin the Defendants from applying the Program in the future. Am. Compl. ¶¶ D–E.

Following the filing of the Amended Complaint, the parties agreed "that none of Teva's claims will require discovery, witness testimony, or trial, and should instead be resolved on dispositive motions." Joint Mot. ¶ 3, ECF No. 11. In March 2025, Teva filed a Motion for Summary Judgement. Pl.'s Mot. Summ. J. (Pl.'s Mot.), ECF No. 15. In April 2025, the Defendants filed a Cross-Motion for Summary Judgment. Defs.' Cross-Motion for Summ. J. (Defs.' Cross-Mot.), ECF No. 30. These motions are fully briefed and ripe for review. *See* Defs.' Opp'n Mot. Summ. J., ECF No. 29; Pl.'s Reply Supp. Mot. Summ. J., ECF No. 35; Pl.'s Opp'n Cross-Mot. Summ. J. (Pl.'s Opp'n), ECF No. 36; Defs.' Reply Supp. Cross-Mot. Summ. J. (Defs.' Reply), ECF No. 38.

LEGAL STANDARD

A court "shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "The burden is on the movant to make the initial showing of the absence of any genuine issues of material fact." *Ehrman v. United States*, 429 F. Supp. 2d 61, 66 (D.D.C. 2006) (citations omitted). "The evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in [its] favor." *Est. of Parsons v. Palestinian Auth.*, 651 F.3d 118, 123 (D.C. Cir. 2011) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986)). When "both parties file cross-motions for summary judgment, each must carry its own burden under the applicable legal standard." *Ehrman*, 429 F. Supp. 2d. at 67 (citations omitted).

DISCUSSION

Teva raises three claims: (1) an APA challenge asserting that CMS's Guidance defining a qualifying single source drug is contrary to the IRA, Am. Compl. ¶¶ 180–86; (2) an APA challenge asserting that CMS's Guidance establishing a bona fide marketing requirement is contrary to the IRA, Am. Compl. ¶¶ 187–93; and (3) a Fifth Amendment challenge to the IRA's Drug Negotiation Program, Am. Compl. ¶¶ 194–204. In response, the Defendants argue that the IRA's bar on judicial review, 42 U.S.C. § 1320f-7, forecloses Teva's APA claims, Defs.' Cross-Mot. 9–14, and that all claims nevertheless fail on the merits, Defs.' Cross-Mot. 14–37. Both parties move for summary judgment. *See* Pl.'s Mot.; Defs.' Cross-Mot.

Because Teva's APA claims are facial challenges to policies and not as-applied challenges to drug determinations, they are not barred by the IRA's bar on judicial review in 42 U.S.C. § 1320f-7. But regardless, Teva's claims either fail on the merits or are unripe. CMS's definition of a qualifying single source drug is not arbitrary, capricious, or otherwise contrary to law because it complies with the IRA.[5] And Teva's challenge to the bona fide marketing standard cannot proceed because it is unripe. Finally, the IRA does not impair or deprive Teva of a protected property interest cognizable under the Due Process Clause. The Court thus denies the Plaintiff's Motion for Summary Judgment and grants the Defendants' Cross-Motion for Summary Judgment.

A. IRA Bar on Judicial Review

Because Teva's APA claims seek vacatur of the 2026 and 2027 CMS Guidance and not reversal of a past drug determination, the IRA does not bar this suit. *See* 42 U.S.C. § 1320f-7. In

[5] Teva's Motion and Complaint ask that CMS's guidance be declared "arbitrary, capricious, and contrary to law." Proposed Order , ECF No. 15-4; *see also* Am. Compl. ¶¶ A–B. But Teva's briefing focuses only on how CMS's Guidance is contrary to the statutory provision of the IRA. *See, e.g.*, Pl.'s Mot. 21–37; Pl.'s Opp'n 17–37. So the Court's examination of Teva's arbitrary and capricious claim focuses only on whether the Guidance is consistent with the IRA.

statutory interpretation, there is a "strong presumption favoring judicial review of administrative action." *Salinas v. United States R.R. Ret. Bd.*, 592 U.S. 188, 197 (2021) (quotation omitted). "This default rule is well-settled, and Congress is presumed to legislate with it in mind." *Id.* (cleaned up). The "presumption dictates" that "even when . . . the statute expressly prohibits judicial review . . . such provisions must be read narrowly." *El Paso Nat. Gas Co. v. United States*, 632 F.3d 1272, 1276 (D.C. Cir. 2011) (citation omitted). "Whether and to what extent a particular statute precludes judicial review is determined not only from its express language, but also from the structure of the statutory scheme, its objectives, its legislative history, and the nature of the administrative action involved." *Am. Clinical Lab'y Ass'n v. Azar*, 931 F.3d 1195, 1204 (D.C. Cir. 2019) (*Azar*) (quoting *Block v. Cmty. Nutrition Inst.*, 467 U.S. 340, 345 (1984)). "When a statute is reasonably susceptible to divergent interpretation, [the Court] adopts the reading" that favors "judicial review," *Kucana v. Holder*, 558 U.S. 233, 251 (2010) (cleaned up), and bars suit only when the agency meets its "heavy burden" of showing that "Congress prohibited all judicial review," *Mach Mining, LLC v. EEOC*, 575 U.S. 480, 486 (2015) (cleaned up).

1. Permissibility of Facial Policy Challenges

Here, the IRA provides that there "shall be no administrative or judicial review" of CMS's "determination of qualifying single source drugs," its determination of "negotiation-eligible drugs," and its "selection of drugs" for negotiation. 42 U.S.C. § 1320f-7(2). Teva asserts that this provision does not bar its APA challenge because it is not an as-applied action to vacate any selections but rather a facial challenge to set aside CMS's guidance. Pl.'s Opp'n 7. The Court agrees. Indeed, it is well-established that a statutory provision barring review of an individual determination "leaves [regulated parties] free to challenge the general rules" or policies "leading

to" those determinations. *ParkView Med. Assocs., L.P. v. Shalala*, 158 F.3d 146, 148 (D.C. Cir. 1998).

For instance, in *McNary v. Haitian Refugee Ctr.*, the Supreme Court interpreted a similar provision precluding "judicial review of a determination respecting an application." 498 U.S. 479, 491 (1991) (emphasis omitted). There, the court explained that "the reference to 'a determination' describes a single act rather than a group of decisions or a practice or procedure employed in making decisions." *Id.* at 492. So, although the review of a determination on an individual application is barred, the court held that a challenge to the "practices and policies used by the agency in" making the determination may proceed. *Id.*

Similarly, in *ParkView*, a statute precluded review of "[t]he decision of the Secretary" on certain Medicare reimbursement classifications. 158 F.3d at 148 (citation omitted). A plaintiff who was denied reclassification challenged the regulation that defined the time periods the agency considers when making this determination. *Id.* at 149. The D.C. Circuit reasoned that although it could not review the "denial[s] itself," the suit could still proceed because the "bar leaves [regulated parties] free to challenge the *general rules leading to* denial" of reclassification. *Id.* at 148 (emphasis added).

And in *Grace v. Barr*, the D.C. Circuit held that an immigration statute barring review of "the determination made" by the agency barred only "direct review of individual aliens' credible-fear determinations"—*i.e.*, as-applied challenges—but not "facial challenges to the written policies that govern those determinations." 965 F.3d 883, 892–93 (D.C. Cir. 2020) (cleaned up).

The Defendants attempt to distinguish these cases by arguing: (1) that the D.C. Circuit has carved out exceptions to this general rule which are applicable here, and (2) that the language of

42 U.S.C. § 1320f-7(2) should lead to a different result. Defs.' Reply 2–15. Neither argument carries the day.

2. Applicability of Exceptions

The Defendants cite a line of interrelated cases to argue that the D.C. Circuit has "limited" the presumption that a plaintiff can challenge general rules and procedures in contexts similar to this one. Defs.' Reply 10 (citation omitted). But these cases are inapposite.

First, the Defendants rely on the D.C. Circuit's decision in *Texas All. for Home Care Servs. v. Sebelius*, 681 F.3d 402 (D.C. Cir. 2012) (*Texas Alliance*). Defs.' Reply at 7. There, the plaintiff challenged a CMS regulation governing the award of Medicare contracts, arguing that it violated the APA by failing to "specify[]" the "applicable financial standards" used to review submissions. *Id.* at 408. The court held that the action was barred by the statute's jurisdiction-stripping provision precluding "administrative or judicial review" of "the awarding of contracts." *Id.* at 408–09 (quoting 42 U.S.C. § 1395w-3(b)(11)). Because satisfying the agency's financial standards was a necessary condition to awarding a contract, the court reasoned that a challenge to the agency's "formulation and application of financial standards" was necessarily a challenge to the "the awarding of contracts" themselves. *Id.* at 410. Importantly, there, the plaintiff did not challenge "the general rules leading to denial" of contracts but instead the denial of contracts without general rules. *ParkView*, 158 F.3d at 148. Without such a policy, the action amounted to nothing more than a challenge to "the awarding of [the] contracts" themselves. *Texas Alliance*, 681 F.3d at 410. But here, Teva's challenge is not rooted in the lack of guidance defining a qualifying single source drug, but in the guidance terms themselves *See* Pl.'s Opp'n 7.

Second, the Defendants rely on decisions barring challenges to the use or treatment of "data underlying" an unreviewable agency action. *Fla. Health Scis. Ctr., Inc. v. Sec'y of Health & Hum.*

Servs., 830 F.3d 515, 517 (D.C. Cir. 2016) (*Fla. Health*); *see also* Defs.' Reply at 7–8, 10 (citing also *DCH Reg'l Med. Ctr. v. Azar*, 925 F.3d 503 (D.C. Cir. 2019) (*DCH*); *Mercy Hosp., Inc. v. Azar*, 891 F.3d 1062 (D.C. Cir. 2018); *Palisades Gen. Hosp. Inc. v. Leavitt*, 426 F.3d 400 (D.C. Cir. 2005)). In these cases, the D.C. Circuit held that the presumption that plaintiffs are "free to challenge the general rules leading to" an unreviewable action is "inapplicable . . . where the [] challenge is no more than an attempt to undo an individual decision." *DCH*, 925 F.3d at 508 (cleaned up); *see also Fla. Health*, 830 F.3d at 522–23. And those plaintiffs sought to "reverse" an agency "determination" by challenging the data or calculations used to reach it. *Fla. Health*, 830 F.3d at 521 (prohibiting APA challenge to set aside calculation of "estimate" that is itself unreviewable on the ground that the calculation used obsolete data); *see also DCH*, 925 F.3d at 505–75 (barring APA action to vacate and recalculate payments by challenging calculation method for unreviewable estimates); *Mercy Hosp.*, 891 F.3d at 1065 (prohibiting challenge to reimbursement calculation due to an adjustment error because the adjustment applied to an unreviewable reimbursement rate); *Palisades Gen. Hosp.*, 426 F.3d at 401, 404–405 (barring action seeking reimbursement adjustment by challenging data underlying an unreviewable reimbursement classification decision). The D.C. Circuit has stressed that this exception to the general rule applies more so in challenges to "estimate[s] used to make [a] decision" than to "adjudicatory decision[s]," like in *McNary* or *Parkview*. *DCH*, 925 F.3d at 508 (citations omitted).

Unlike in these cases, the challenged guidance here relates to "adjudicatory decision[s]" for selection of drugs. *DCH*, 925 F.3d at 508. And "the practical effect" of Teva's challenge would not be to "reverse" the selection of its drug Austedo for the 2027 price applicability year. *Id.* (citations omitted). These selections have already been made, and the statutory deadlines for them

have passed. Am. Compl. ¶ 93; 42 U.S.C. § 1320f-1(a). Rather, Teva only seeks forward-looking vacatur of the challenged guidance. Am. Compl. ¶ C.

Third, the Defendants point to *Knapp Med. Ctr. v. Hargan*, which extended the rationale underlying the above-mentioned cases in a challenge to an agency exemption approval. 875 F.3d 1125, 1126–27 (D.C. Cir. 2017). The statute at issue barred review of the "process" to determine such exemptions. *Id.* at 1129 (citation omitted). And the plaintiff made a reverse *McNary* argument—namely, that by only barring review of the "process" of determining exemptions, Congress permitted review of "any determination made under such process." *Id.* (citation omitted). The court rejected this argument, reasoning that there is no "categorical distinction between inputs and outputs." *Id.* at 1131 (quoting *Fla. Health*, 830 F.3d at 519). Since the exemption determination (output) could not be challenged without casting doubt on the unreviewable process (input), the court held that the challenge was barred as they were "inextricably intertwined." *Id.* (quoting *Fla. Health*, 830 F.3d at 519).

In *Azar*, the court further expounded on the "inextricably intertwined" standard while permitting a challenge to the data selection process underlying unreviewable payment determinations. 931 F.3d at 1206–07. Even though "the results of that data collection process [were] used to establish [unreviewable] payment amounts," the court held that the two were not "inextricably intertwined" because the payment statute cross-referenced another provision (not subject to the statutory bar) to determine data collection. *Id.* 1205–07. In allowing the suit to proceed, the court rejected the government's argument that it was non-sensical "for Congress to have barred review only of 'basic math' while 'permitting review of every discretionary step that preceded that math.'" *Id.* at 1207 (citation omitted).

Here, Teva's definitional challenge is not inextricably intertwined with "the determination of qualifying single source drugs under section 1320f-1(e) of this title." 42 U.S.C. § 1320f-7(2). Like in *Azar*, the challenge is instead based on that provision's cross-reference, *id.* § 1320f-1(e)(1), to the Medicare statute's definition of a Part D Drug, *id.* § 1395w-102(e), which is not covered by the IRA's jurisdiction stripping provision, *id.* § 1320f-7(2). *See Azar*, 931 F.3d at 1206–07. Accordingly, this case presents no reason to deviate from the usual rule that challenges to "practices and policies" are not barred. *McNary*, 498 U.S. at 492.

3. 42 U.S.C. § 1320f-7(2)

Next, the Defendants attempt to distinguish *McNary* and *Grace* on grammatical grounds. They point out that the term "determination" in those cases was singular. *See McNary*, 498 U.S. at 492; *Grace*, 965 F.3d at 893. And they note that the statute at issue here bars review of the "*determination*" (singular) of "qualifying single source *drugs*" (plural). Defs.' Reply at 6 (citing 42 U.S.C. § 1320f-7(2)) (emphasis added). The Defendants posit that the use of the plural "drugs" suggests that Congress was not referring to individual decisions but expanding the provision to cover policies. *Id.* But this argument collapses when looking at the "structure of the statutory scheme." *Azar*, 931 F.3d at 1204 (citation omitted).

The IRA does not establish a procedure requiring CMS to make individual case-by-case decisions on each qualifying single source drug. *See* 42 U.S.C. § 1320f-1(e). Rather, the IRA mandates only that CMS release "a list" of "drugs" by specified deadlines. *Id.* § 1320f-1(a)–(d). Indeed, manufacturers are unaware whether any individual drug "might be selected" for inclusion on that list of "drugs" until publication. 2027 Guidance, at 26. Accordingly, the only individual "determination" that CMS is required to make is with respect to a list of "drugs." 42 U.S.C. § 1320f-7(2). Thus, the provision at issue here is no different than that in *McNary* and *Grace*—it

applies to a singular "determination," *i.e.*, what "drugs" are included in the list. *Id.* And that determination is not what Teva is challenging.

"When judicial interpretations have settled the meaning of an existing statutory provision, repetition of the same language in a new statute is presumed to incorporate that interpretation." *Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 330 (2015) (cleaned up). And since *McNary*, the term "determination" in a jurisdiction stripping statute is understood to only shield review of individual decisions but not policies or guidance. 498 U.S. at 492. By using the term "determination" in § 1320f-7(2), the Court presumes Congress intended that same construction to apply.[6] Because the "statute is reasonably susceptible to this interpretation," Teva's APA challenges may proceed. *Azar*, 931 F.3d at 1208 (quotation omitted).[7]

B. Definition of a Qualifying Single Source Drug

Having concluded that Teva's claims may proceed, the Court now addresses them on the merits. Teva first challenges the CMS Guidance "identify[ing] a potential qualifying single source

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[6] In *Novo Nordisk*, the Third Circuit recently interpreted the term "determination" differently. 154 F.4th at 111–12. But *Novo Nordisk* relied on in-circuit precedent for the proposition that "when a statute prohibits review of a particular 'determination,' the bar extends to the ultimate decision *and* 'the process by which [the agency] reaches this decision.'" *Id.* (alteration in original) (quoting *Bakran v. Sec'y*, 894 F.3d 557, 563 (3d Cir. 2018)). *Bakran*, the controlling case there, interpreted the Immigration and Nationality Act (INA) and the Adam Walsh Child Protection and Safety Act (AWA) to bar challenges to certain evidentiary standards underlying unreviewable agency determinations. 894 F.3d at 563–64. But the D.C. Circuit has taken a different approach. In *Castaneira v. Noem*, it permitted a challenge to those evidentiary standards to proceed—interpreting the same provisions of the INA and AWA differently and expressly disclaiming *Bakran*'s rationale as inconsistent with both "*McNary* and [D.C.] [C]ircuit precedent." 138 F.4th 540, 550 (D.C. Cir. 2025) (citing *Bakran*, 894 F.3d at 563). It is well settled in this Circuit that when "determinations are unreviewable, 'general collateral challenges' to the agency's practices and policies still fall within judicial purview." *Id.* (quoting *McNary*, 498 U.S. at 492); *see also Grace*, 965 F.3d at 915 (Henderson, J., dissenting) (noting the D.C. Circuit's approach cannot be squared with *Bakran*). This Court is thus unpersuaded by *Novo Nordisk*'s reading of the term "determination" in § 1320f-7.

[7] Since the IRA does not bar this suit, the Court does not address Teva's alternative *ultra vires* argument. Pl.'s Opp'n at 15–17.

drug using . . . all dosage forms and strengths of the drug with the same active moiety and the same holder of a New Drug Application (NDA), inclusive of products that are marketed pursuant to different NDAs." 2026 Guidance § 30.1, at 99; 2027 Guidance § 30.1, at 167. Teva asks this Court to set aside this Guidance, arguing that it is contrary to the definition of qualifying single source drug in the IRA, 42 U.S.C. § 1320f-1(e)(1). Pl.'s Mot. at 21–23. Relying on a series of cross-references in the statutory scheme, Teva posits that CMS should be prohibited from considering drugs under different NDAs when identifying qualifying single source drugs because "a drug" under the IRA must be "approved or licensed by FDA under a distinct NDA." Pl.'s Mot. at 22–23.

The IRA term "qualifying single source drug" is defined according to a ladder of cross-references:

- The IRA defines the term "qualifying single source drug" as a "covered part D drug" (as "defined in" the Medicare statute) that meets certain enumerated criteria. 42 U.S.C. § 1320f-1(e)(1).
- The Medicare statute defines a "covered part D drug" as "a drug that may be dispensed only upon a prescription" and constitutes a covered outpatient drug under the Medicaid Drug Rebate Program. *Id.* § 1395w-102(e)(1).
- The Medicaid Drug Rebate Program defines a "covered outpatient drug" as a "a drug which may be dispensed only upon a prescription" and "which is approved for safety and effectiveness as a prescription drug under [21 U.S.C. § 355] of the Federal Food, Drug, and Cosmetic Act." *Id.* § 1396r-8(k)(2).[8]

[8] In relevant part, the statute cites Section 505 of the Federal Food, Drug, and Cosmetic Act which is now codified in 21 U.S.C. § 355.

- And § 355 governs the FDA's approval of the New Drug Applications (NDAs) for a prescription drug. 21 U.S.C. § 355.

Taken together, Teva interprets these provisions to mean that "a drug" in the IRA can only be a prescription product that is "approved or licensed by FDA under a distinct NDA." Pl.'s Mot. 22–23.

The Court agrees with Teva that under these statutory provisions, a drug in the Program must be approved or licensed by an NDA. But Teva's next conclusion that a drug must be approved or licensed by a single, "distinct" approval does not necessarily follow. *See* Pl.'s Mot. 23. "In determining the meaning of any Act of Congress, unless the context indicates otherwise—words importing the singular include and apply to several persons, parties, or things." 1 U.S.C. § 1. And "[i]t is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." *West Virginia v. EPA*, 597 U.S. 697, 721 (2022) (citation omitted). Considering the entire statutory scheme, several IRA provisions cut against Teva's argument.

First, when negotiating maximum fair price, the statute instructs CMS to consider the "*applications* and *approvals* under section 355(c) of title 21 . . . for *the drug*." 42 U.S.C. § 1320f-3(e)(1)(D) (emphasis added). In relevant part, 21 U.S.C. § 355(c) is the operative provision governing approval of an NDA, and the IRA's negotiation provision seems to clearly recognize that a single "drug" can have multiple corresponding "approvals" and "applications." *Id.* Teva resists this conclusion by arguing that this cross-reference only encompasses § 355(c)(5), a subsection of that provision dealing only with "approval of [] supplemental application[s]" to an existing NDA. Pl.'s Opp'n 19 (quoting 21 U.S.C. § 355(c)(5)). But Teva proffers no explanation for why the statute references all of § 355(c)—whose other provisions govern the timeline for

approving an NDA, 21 U.S.C. § 355(c)(1), the submissions required to grant that approval, *id.* § 355(c)(2), the approval of an NDA, *id.* § 355(c)(3), and the means to demonstrate safety and effectiveness of certain drugs for an NDA approval, *id.* § 355(c)(4)—if Congress only intended to refer to a minor subsection governing supplemental applications for an already-approved NDA, *id.* § 355(c)(5). Beyond the initial implausibility of Teva's reading, the statutory framework also renders it untenable.

In examining a statutory scheme, it is well established that "identical words and phrases within the same statute should normally be given the same meaning." *Monsalvo v. Bondi*, 604 U.S. 712, 726 (2025) (quotation omitted). And the IRA references "§ 355(c)" in various provisions. *See* 42 U.S.C. § 1320f-1(e)(1)(A)(i); *id.* § 1320f-3(c)(4)(A), (c)(5)(A), (e)(1)(D). In relevant part, the definition of a qualifying single source drug also requires the drug to be "approved under section 355(c) of title 21." *Id.* § 1320f-1(e)(1)(A)(i). But should the Court adopt Teva's construction in this section, it would yield the "absurd result" that only drugs that needed further supplementation under 21 U.S. § 355(c)(5) would be eligible for selection. *United States v. Neely*, 124 F.4th 937, 944 (D.C. Cir. 2024).

And Teva cannot have its cake and eat it too. Teva argues that the Medicaid statute's cross-reference to § 355, the last step in its ladder of cross-references, should be read broadly to cover any NDA. Pl.'s Mot. at 22–23 (citing 42 U.S.C. § 1396r-8(k)(2)). But it then argues that the IRA's cross-reference to the operative provision of § 355, subsection c, should be narrowly construed to apply only to supplemental applications. Pl.'s Opp'n at 19; *See* 42 U.S.C. § 1320f-1(e)(1). Such a reading "defies rationality" and the Court does not adopt it here. *Neely*, 124 F.4th at 944 (quotation omitted). Reading the negotiation provision and the definition of a qualifying single source drug

in harmony, the only reasonable construction is that a "drug" under the IRA can have multiple "applications" and "approvals." 42 U.S.C. § 1320f-3(e)(1)(D).

Second, the IRA instructs CMS to "use data that is aggregated across dosage forms and strengths of the drug, including *new formulations* of the drug, *such as an extended release formulation*, and not based on the specific formulation or package size or package type of *the drug*" when "determining whether a qualifying single source drug" has expenditures sufficient to be eligible for negotiations. *Id.* § 1320f-1(d)(3)(B) (emphases added); *see also id.* § 1320f-5(a)(2). CMS implements this provision by considering new drug formulations in other NDAs when identifying and reviewing qualifying single source drugs. 2026 Guidance § 30.1, at 100; 2027 Guidance § 30.1, at 169. Teva contends that this expenditure provision is consistent with its proposed drug definition. Pl.'s Mot. at 28. It unconvincingly argues that this subsection, too, should be limited to supplemental applications and the formulations therein. *Id.* The Court rejects Teva's proposed construction because it would render the entire expenditure provision "surplusage." *Nielsen v. Preap*, 586 U.S. 392, 414 (2019).

Indeed, Teva's drug Austedo is a telling example of how the expenditure provision operates. Currently, under 42 U.S.C. § 1320f-1(d)(3)(B), CMS calculates the expenditures for Austedo by considering both the expenditures for (1) the original-form Austedo under NDA 208082 and (2) the extended-release formulation Auestedo XR under NDA 216354. Am. Compl. ¶¶ 88–89, 93–94. But if CMS could consider only one NDA, there would be no need to look at Austedo's extended-release or indeed any other "formulations." 42 U.S.C. § 1320f-1(d)(3)(B). This is because all sales of a drug under a supplemental formulation are included in the sales of the drug in the original NDA. *See* 21 U.S.C. § 355(b)(4)(A) (noting a supplemental application cannot be used to approve a different drug than the original drug in the NDA). Accordingly, if all

qualifying single source drugs had only a single NDA, the calculation would be easy—one would identify drugs only by their NDA and look at the corresponding expenditures alone. *See* 42 U.S.C. § 1320f-1(d)(1). The IRA's other provisions governing the selection process would already account for different formulations because any drug, under Teva's proposed definition, would automatically encompass these supplemental formulations. *See id.* § 1320f-1(e)(1). So the statute's instruction to additionally look at "new formulations of the drug" to determine the expenditure level would have no operative effect. *Id.* § 1320f-1(d)(3)(B). Because the statutory definition ought not needlessly "be given an interpretation that" results in the expenditure provision "to have no consequence," the Court declines to adopt Teva's definition of a "drug" for this reason as well. *Nielsen*, 586 U.S. at 414.

Third, if the Court were to adopt Teva's definition of a qualifying single source drug, the "statutory outcome [would be] absurd . . . by rendering [the] statute nonsensical." *Neely*, 124 F.4th at 944 (citation omitted). For instance, Teva alleges that the capsule-version and tablet-version of the selected drug XTANDI should be different drugs under its construction because they are approved under distinct NDAs. Am. Compl. ¶¶ 99–100. In this situation, XTANDI's manufacturer could avoid selection by simply balancing its sales of capsules and tablets such that neither reaches the selection threshold—even though both drugs are materially identical in their active effect. *See* 42 U.S.C. § 1320f-1(d)(1). Furthermore, the manufacturer could extend its seven-year grace period from selection in the Program, *id.* § 1320f-1(e)(1)(A)(ii), and continue to manipulate its sales to avoid the eligibility threshold, *id.* § 1320f-1(d)(1), by introducing inconsequential changes to the drug in new NDAs and shifting patients to that new version, an existing strategy known as "product hopping," H.R. Rep. No. 116-695, at 3 (2020). The statutory text gives us no reason to conclude that Congress enacted such a "self-defeating statute." *Pugin v. Garland*, 599 U.S. 600, 607 (2023)

(citation omitted). The better reading is that the IRA permits CMS to look at the active moiety under multiple NDAs when identifying a qualifying single source drug.

Since the IRA's statutory scheme demonstrates that a drug can have multiple approvals, the Court declines to set aside CMS's definition of a qualifying single source drug for including a drug approved under multiple applications.

C. Bona Fide Marketing

Teva's other APA claim challenges CMS's interpretation of the term "marketed" in the IRA, which impacts a drug's eligibility for inclusion in the Program and its ability to exit the Program in price applicability years after an agreement is reached. 42 U.S.C. § 1320f-1(c), (e)(1)(A)(iii). Under CMS Guidance, a drug will be considered "marketed when the totality of the circumstances . . . reveals that the manufacturer of that drug . . . is engaging in bona fide marketing of that drug." 2026 Guidance § 30.1, at 102; *see also* 2027 Guidance § 30.1, at 170. Teva argues that this interpretation is contrary to the plain meaning of "marketed" in the statute which is a "yes-or-no determination." Pl.'s Mot. 13. Teva instead argues that a drug "is marketed when its manufacturer launches it in the commercial marketplace." *Id.* The Defendants disagree and suggest that such a reading would permit "a generic drug or biosimilar manufacturer [to] launch into the market a token or de minimis amount of a generic drug . . . and [then] claim that the [maximum fair price] should no longer apply." Defs.' Cross-Mot. 23 (quoting 2026 Guidance, at 72). The Court need not resolve this disagreement because Teva's challenge to the bona fide marketing standard is unripe.

"A claim is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." *Nat'l Treasury Emps. Union v. Vought*, 149 F.4th 762, 786 (D.C. Cir. 2025) (quoting *Texas v. United States*, 523 U.S. 296, 300 (1998)). Courts

apply a two-part ripeness test that evaluates (1) "the fitness of the issues for judicial decision" and (2) "the hardship to the parties" of withholding review. *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967). "The paradigmatic unripe case is one that challenges a preliminary agency policy that has not been—and may never be—enforced against the named plaintiff." *Indus. Energy Consumers of Am. v. FERC*, 125 F.4th 1156, 1163 (D.C. Cir. 2025) (Henderson, J., concurring) (citing *AT&T Corp. v. Iowa Utils. Bd.*, 525 U.S. 366, 386 (1999)).

Teva's lawsuit challenges only CMS's Guidance for the 2026 and 2027 price applicability years. Am. Comp. ¶¶ 63–72, 184, 195. That Guidance governs selections for those years alone and "[d]iscussion of [maximum fair price] effectuation for 2028 and subsequent years is out of scope for th[e] final guidance." 2027 Guidance, at 41. Based on the current record, Teva will not suffer a ripe injury from the application of the 2026 and 2027 Guidance to its selected drug or its generic drugs awaiting approval.

1. Selected Drug

Teva's only drug currently selected for negotiation is Austedo/Austedo XR. Am. Compl. ¶93. But Teva does not allege that any generic drug exists on the market or will imminently enter the market by the end of the negotiation period such that it could potentially be subject to a maximum fair price for 2027. *See* 42 U.S.C. § 1320f-1(c)(2). Absent some "specific facts" that a generic drug has or will enter the market while the 2026 or 2027 Guidance is in effect and that such a generic would not satisfy the bona fide marketing requirement by a relevant deadline, Teva lacks any Article III injury. *AstraZeneca Pharms. LP v. Sec'y U.S. Dep't of Health & Hum. Servs.*, 137 F.4th 116, 125 (3d Cir. 2025) (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992)).[9]

[9] *See also Trump v. New York*, 592 U.S. 125, 131 (2020) (noting standing and ripeness are "[t]wo related doctrines of justiciability—each originating in the case-or-controversy requirement of Article III").

And as the Third Circuit recently noted, any other purported injuries to the manufacturer from "broad-based market effects stemming from regulatory uncertainty are quintessentially conjectural" and thus, inactionable. *Id.* at 124 (quoting *New Eng. Power Generators Ass'n v. FERC*, 707 F.3d 364, 369 (D.C. Cir. 2013)) (holding challenge to the bona fide marketing requirement by manufacturer of selected drug Farxiga was non-justiciable). Thus, Teva does not allege that any of its purported harm from the bona fide marketing requirement arises from the selection of Austedo. Am. Compl. ¶¶ 86–94; Pl.'s Opp'n at 34–35.

2. Generic Drugs Awaiting Approval

Teva also points to six other selected drugs for which it hopes to launch a generic counterpart and alleges that the price for these future generics would be negatively affected by competition with drugs subject to the bona fide marketing requirement: (1) XTANDI (aiming to launch on or before March 31, 2028), (2) OFEV (aiming to launch in October 2026), (3) XARELTO (aiming to launch on March 15, 2027), (4) LINZESS (aiming to launch on March 31, 2029), (5) XIFAXAN (aiming to launch on January 1, 2028), and (6) OTEZLA (aiming to launch in August 2028). Am. Compl. ¶¶ 99–127; Groff Decl., ¶¶ 21–31, ECF No. 15-3.

The problem is that Teva does not suggest that its (or anyone else's) counterpart generics for these drugs have been "approved" by the FDA, *id.*—a pre-requisite for CMS to even make a "marketed" determination to disqualify a drug already selected for the 2026 or 2027 drug applicability years, 42 U.S.C. § 1320f-1(e)(1)(A)(iii), (c). Even if the Court assumed future approval of these drugs, it is unknown whether the approval or launch would be early enough for the 2026 or 2027 Guidance to apply or have an impact. Based on Teva's aspirational launch dates for its own drugs, only two in-progress generic drugs, XTANDI and OFEV, could possibly be launched early enough to affect prices for the 2027 price applicability year, *i.e.*, by March 31,

2026.[10] For its generic to XTANDI, Teva provides no specifics for its proposed launch date and alleges only that it will launch on or before March 31, 2028, *i.e.*, a speculative launch either before or after relevant deadlines. Am. Compl. ¶ 102. For its generic OFEV, Teva concedes that it faces a potential "barrier" to approval: because a corresponding drug has an exclusivity period that may run up until March 6, 2027—long after any relevant deadline for the 2027 price applicability year under § 1320f-1(c). *Id.* ¶ 106. Accordingly, with respect to bona fide marketing, Teva's purported injury from the 2026 or 2027 Guidance depends only on "contingent future events that may not occur as anticipated, or indeed may not occur at all." *Trump v. New York*, 592 U.S. 125, 131 (2020) (cleaned up).

Further, Teva's lawsuit does not extend to CMS's guidance beyond the 2027 price applicability year. Am. Compl. ¶¶ 63–72, 184, 195. And claims arising from purported injuries for later price applicability years would be "unripe" and "not fit for review" because "agency consideration remain[s] ongoing." *Nat'l Treasury Emps. Union*, 149 F.4th at 785–86. Already, CMS's Guidance for the 2028 Price Applicability Year has made modifications to the bona fide marketing provisions. *See* Ctrs. for Medicare & Medicaid Servs., Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028, at 3, 6 (Sep. 30, 2025), https://perma.cc/Y5W8-EGS7. And "CMS will develop its policies for 2029 and all subsequent initial price applicability years of the Negotiation

[10] *See* 42 U.S.C. § 1320f-1(c)(1) (noting the approved-and-marketed determination disqualifies a drug the "subsequent year beginning before the first year that begins at least 9 months after the date on which the Secretary determines" the drug is marketed); *see also id.* § 1320f-1(c)(2) (disqualifying a drug for the 2027 price applicability year if the approved-and-marketed determination is made by the end of the negotiation period for that year); *id.* §§ 1320f(3)–(4) (the negotiation period for the 2027 price applicability year ends on November 1, 2025, and the deadline for that year's drug selection has already passed).

Program through notice-and-comment rulemaking"—which could result in further modifications. 2026 Guidance, at 2. Accordingly, pre-mature "judicial intervention would inappropriately interfere with further administrative action" and, even assuming that Teva's APA claim is meritorious, "immediate judicial review would deny the [agency] 'an opportunity to correct its own mistakes.'" *Id.* at 786 (first quoting *Ohio Forestry Ass'n v. Sierra Club*, 523 U.S. 726, 733 (1998), and then quoting *FTC v. Standard Oil Co.*, 449 U.S. 232, 242 (1980)). Teva's purported injury depends heavily on (1) the Guidance in place when a generic to a selected drug is launched into the market, and (2) whether that Guidance causes Teva's launched generic drug to compete with a drug subject to a maximum fair price earlier than it would under Teva's proposed methodology. At this point, the Court cannot answer these questions.

Furthermore, Teva suffers no "hardship from postponing review" because it "may 'protect all of [its] rights and claims by returning to court when the controversy ripens.'" *Nat'l Treasury Emps. Union*, 149 F.4th at 786 (quoting *Atl. States Legal Found. v. EPA*, 325 F.3d 281, 285 (D.C. Cir. 2003)). For instance, assuming one of Teva's generics is approved early enough that it may be considered "marketed" under 42 U.S.C. § 1320f-1(c)(1), nothing prohibits Teva from bringing suit then if the corresponding selected drug is still subject to a maximum fair price. The statute itself leaves a minimum of nine months before a "marketed" determination has any effect on the inclusion of a drug for 2027, *id.* § 1320f-1(c)(1), leaving plenty of time to file an action. At that time, adjudication would be less premature because it would be possible to tell if CMS's bona fide marketing requirement actually causes "an unreasonable delay" as to the marketed determination when compared to Teva's proposed approach. *Nat'l Treasury Emps. Union*, 149 F.4th at 786. And courts "routinely consider shifting 'post-guidance events' to determine whether" a challenge to "informal guidance" is ripe for review. *Id.* at 786 n.7 (citation omitted).

In sum, the Court declines to address Teva's challenge to the bona fide marketing requirement because such a challenge is unripe.

D. Due Process

Finally, Teva asks the Court to declare the drug-pricing provisions of the IRA unlawful under the Fifth Amendment's Due Process Clause and enjoin the Defendants from applying it in the future. Am. Compl. ¶¶ D–E. The Court declines to do so because Teva has not demonstrated a deprivation of a property interest cognizable under the Fifth Amendment. Indeed, at least three other courts have rejected near identical due process challenges to the IRA. *See AstraZeneca*, 137 F.4th 116 (3d Cir. 2025); *Boehringer*, F.4th 76 (2d Cir. 2025); *Nat'l Infusion Ctr. Ass'n*, 2025 WL 2380454 (W.D. Tex. Aug. 7, 2025).

When reviewing a challenge under the Due Process Clause, the Court "first ask[s] whether there exists a liberty or property interest of which a person has been deprived, and if so [the Court] ask[s] whether the procedures followed by the State were constitutionally sufficient." *Swarthout v. Cooke*, 562 U.S. 216, 219 (2011). If a party lacks "a protected interest in 'property' or 'liberty'" at the threshold, then the claim fails. *Am. Mfrs. Mut. Ins. Co. v. Sullivan*, 526 U.S. 40, 59 (1999) (citation omitted). "To have a property interest in a benefit, a person clearly must have more than an abstract need or desire" and "more than a unilateral expectation of it. He must, instead, have a legitimate claim of entitlement to it." *Bd. of Regents of State Colls. v. Roth*, 408 U.S. 564, 577 (1972). For instance, "federal statute or state law" may be a source of a property interest. *AstraZeneca*, 137 F.4th at 125.

Teva argues that the IRA interferes with its protected property interest in its drug products and specifically its interest "to sell its products at a fair market value." Pl.'s Mot. 38. Teva argues

that its entitlement to this interest is derived from: (1) federal statute, (2) a course of dealing, (3) common law, and (4) patent. The Court disagrees.

1. Statutory Entitlement

Teva first argues that the Medicare statute's long-standing provision that prohibited a "price structure for the reimbursement of covered part D drugs" or interference with "negotiations" between manufacturers and Part D plan sponsors, 42 U.S.C. § 1395w-111(i), created a "statutory entitlement" to "set the prices for its products without government interference," Pl.'s Mot. 38–39 (citation omitted). And Teva posits that the IRA's amendment of that provision does not impair that property interest. *Id.* (citing 42 U.S.C. § 1395w-111(i)(3)).

For support, Teva relies on the Supreme Court's decision in *O'Bannon v. Town Ct. Nursing Ctr.*, 447 U.S. 773 (1980). Pl.'s Mot. 39. Teva points to language in the Court's opinion recognizing that the statute gave Medicaid recipients "the right to choose among a range of qualified providers[] without government interference" and "confer[red] an absolute right to be free from government interference with the choice to remain in a home that continues to be qualified." *O'Bannon*, 447 U.S. at 785 (emphasis omitted). Teva argues that it is similarly situated because Part D vested it with a right to "noninterference" in negotiations, which the IRA amendment did not remove. Pl.'s Mot. at 39–40.

But *O'Bannon* does not support Teva's proposition. There, elderly residents of a nursing home argued that they had a constitutionally protected property interest in continued residence that gave them the right to a hearing before a state or federal agency could revoke the home's certification to provide them with nursing care. *O'Bannon*, 447 U.S. at 775. And the Court could not have been clearer: "Whether viewed singly or in combination, the Medicaid provisions . . . do not confer a right to continued residence in the home of one's choice." *Id.* at 785. Even if

Medicaid's non-interference provision conferred a right to choose between qualifying homes, the Court recognized that this would not "limit the Government's right" to "decertify[]" the home and a beneficiary could not "demand a hearing to certify" an "unqualified home" where she wished to reside. *Id.* at 785. And that is exactly what happened here—by passing the IRA, Congress similarly exercised its "right" to remove or "decertify[]" selected drugs as no-longer eligible for non-interference. *Id.*; *see also* 42 U.S.C. § 1395w-111(i)(3). Indeed, Congress may "undo . . . statutory rights that it has created." *Omar v. McHugh*, 646 F.3d 13, 22-23 (D.C. Cir. 2011). Teva has no entitlement to constrain Congress' authority to oversee its expenditures. *See Sabri v. United States*, 541 U.S. 600, 608 (2004) ("The power to keep a watchful eye on expenditures and on the reliability of those who use public money is bound up with congressional authority to spend in the first place[.]"). Thus, the statute does not create a property interest.

2. Course of Dealing

Teva next argues that it has a "protected expectation in receiving the market rates that have long prevailed in Medicare Part D transactions" based on its "course of dealing," "conduct," and past "practice." Pl.'s Opp'n at 41 (citation omitted). But dealings with the Government only create a property interest if there is a "claim of entitlement" to renewal as well. *Roth*, 408 U.S. at 578 (government employment contract does not create entitlement to another renewed contract). The fact that the Government has reimbursed some of Teva's customers (Part D sponsors) for drug purchases in the past does not mean that the Government is obligated to continue paying for purchases of those drugs in the future. *See Perkins v. Lukens Steel Co.*, 310 U.S. 113, 127 (1940) ("Like private individuals and businesses, the Government enjoys the unrestricted power to produce its own supplies, to determine those with whom it will deal, and to fix the terms and conditions upon which it will make needed purchases."). Put simply, Teva's past sales of drugs

under Medicare Part D is not a course of dealing that leads to an entitlement of future sales under that program.

3. Common Law

Next, Teva argues that it has a "common-law right to offer access to its products at prices set by voluntary agreements, not government dictates, and to choose not to sell its product at prices it deems insufficient." Pl.'s Mot. 41 (citation omitted).[11] For support, Teva relies on *Bowles v. Willingham*, where the Supreme Court considered the due process implications of rent-fixing determinations under a wartime rent-control statute. 321 U.S. 503, 517–21 (1944); Pl.'s Opp'n at 44. In relying on *Bowles*, Teva fails to appreciate the "crucial difference, with respect to constitutional analysis, between the government exercising the power to regulate or license, as lawmaker, and the government acting as proprietor." *Engquist v. Or. Dep't of Agric.*, 553 U.S. 591, 598 (2008) (quotation omitted).

"Unlike ordinary legislation, which imposes congressional policy on regulated parties involuntarily, Spending Clause legislation operates based on consent: in return for federal funds, the recipients agree to comply with federally imposed conditions." *Cummings v. Premier Rehab Keller, PLLC*, 596 U.S. 212, 219 (2022) (cleaned up). Because "participation in the Medicare [and Medicaid spending] program is wholly voluntary," "any obligations" under the Drug Price Negotiation Program "are as freely accepted as the benefits." *Baptist Hosp. E. v. Sec'y of Health & Hum. Servs.*, 802 F.2d 860, 869–70 (6th Cir. 1986). Like any market transaction, "[i]t is a potential economic opportunity" with benefits and costs that the manufacturer can weigh. *AstraZeneca Pharms. LP v. Becerra*, 719 F. Supp. 3d 377, 397 (D. Del. 2024). But the "fact that

[11] Teva's briefing initially asserts an interest in voluntary transactions, Pl.'s Mot. 41, but later suggests "voluntariness" is "legally irrelevant" under the Due Process Clause, Pl.'s Opp'n 43.

practicalities may in some cases dictate participation does not make participation involuntary." *St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 875 (7th Cir. 1983) (per curiam).[12] As the Third Circuit recently noted in a case alleging different constitutional violations:

> The federal government, by virtue of its size, possesses a sizable market share in many of the markets it enters. In certain markets—for example, for military hardware that is unlawful for civilians to own—the government may be the only purchaser. Economic factors may have a strong influence on a company's choice to do business with the government, but a company that chooses to do so still acts voluntarily.

Bristol Myers Squibb Co. v. Sec'y U.S. Dep't of Health & Hum. Servs., 155 F.4th 245, 257 (3d Cir. 2025). Since it is voluntary, "participation in the federal Medicare reimbursement program is not a property interest" for purposes of the Due Process Clause. *Shah v. Azar*, 920 F.3d 987, 998 (5th Cir. 2019).

Teva also suggests a property owner has an interest to "decide the terms on which one will dispose of property" and "fix the price at which he will sell." *Old Dearborn Distribution Co. v. Seagram-Distillers Corp.*, 299 U.S. 183, 192 (1936); Pl.'s Mot. at 38–39. But even that interest is not implicated here—the statute expressly provides a mechanism for a manufacturer to submit an offer for a maximum fair price. 42 U.S.C. § 1320f-3(b)(2)(C). Indeed, "the Negotiation Program only sets prices for drugs that [the Government] pays for when it reimburses sponsors."

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[12] *See Cummings*, 596 U.S. at 220 (spending programs may expose a "recipient" to "penalties" so long as the "funding recipient is on notice that, by accepting federal funding, it exposes itself to liability of that nature" (cleaned up)); *Boehringer*, 150 F.4th at 90 ("[T]he choice to participate in a voluntary government program does not become involuntary simply because the alternatives to participation appear to entail worse, even substantially worse, economic outcomes."); *Livingston Care Ctr., Inc. v. United States*, 934 F.2d 719, 720 (6th Cir. 1991) ("[P]articipation in the Medicare program is a voluntary undertaking."); *Whitney v. Heckler*, 780 F.2d 963, 972 n.12 (11th Cir. 1986) ("[T]he fact that Medicare patients comprise a substantial percentage of [the plaintiffs'] practices does not render their participation 'involuntary.'"); *Minn. Ass'n of Health Care Facilities, Inc. v. Minn. Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984) ("Despite the strong financial inducement to participate in Medicaid, a nursing home's decision to do so is nonetheless voluntary.").

AstraZeneca, 137 F.4th at 126 (emphasis omitted). And like any buyer on the market, "no one has a right to sell to the government that which the government does not wish to buy." *Coyne-Delany Co. v. Cap. Dev. Bd.*, 616 F.2d 341, 342 (7th Cir. 1980) (quotation omitted); *see also Perkins*, 310 U.S. at 127 (the Government may "determine those with whom it will deal" and upon what "terms and conditions").

It makes no different that Part D is implemented through private intermediaries or even "agents." *Cf. Perkins*, 310 U.S. at 127. "[T]he Government may for the purpose of keeping its own house in order lay down guide posts by which its agents are to proceed in the procurement of supplies." *Id.* An Act that does "no more than instruct its agents who were selected and granted final authority to fix the terms and conditions under which the Government will permit goods to be sold to it" is not "an exercise by Congress of regulatory power over private business." *Id.* at 128–29. Teva "suffers no deprivation of its property interests by voluntarily submitting to a price-regulated government program." *Boehringer*, 150 F.4th at 94.

4. Patent and Exclusivity Interests

Finally, Teva argues that the IRA interferes with its protected property interest in its "drug products" because they are "entitled to a guaranteed exclusivity period" under patents, alongside associated approvals, settlements, and licenses. Pl.'s Mot. 40. And it "is correct that patent rights exist to permit greater profits during a product's exclusivity period to incentivize innovation." *AstraZeneca*, 137 F.4th at 125 (citing *Eldred v. Ashcroft*, 537 U.S. 186, 215–16 (2003)). But "the federal patent laws do not create any affirmative right to make, use, or sell anything." *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1372 (Fed. Cir. 2007) (quoting *Leatherman Tool Grp., Inc. v. Cooper Indus., Inc.*, 131 F.3d 1011, 1015 (Fed. Cir. 1997)). And

"where federal patent laws do not confer a right to sell at all, they do not confer a right to sell at a particular price." *AstraZeneca*, 137 F.4th at 125.

Furthermore, even if commonly an "exclusivity period yields 'economic rewards,' subject only to 'the dictates of the marketplace,'" Pl.'s Mot. 40 (quoting *Biotechnology Indus.*, 496 F.3d at 1372), "[f]air market value" is only the "price as would be fixed by negotiation and mutual agreement, after ample time to find a purchaser, as between a vendor who is willing (but not compelled) to sell and a purchaser who desires to buy but is not compelled to take the particular piece of property," *BFP v. Resol. Tr. Corp.*, 511 U.S. 531, 538 (1994) (cleaned up). Here, that would be the negotiated price. Teva's argument that a patent entitles it to instead sell goods at prices higher than a buyer would agree to pay fails to "resemble any traditional conception of property." *Town of Castle Rock, Colorado v. Gonzales*, 545 U.S. 748, 766 (2005).

In sum, there is "no protected property interest in selling goods to Medicare beneficiaries . . . at a price higher than what the government is willing to pay when it reimburses those costs." *AstraZeneca*, 137 F.4th at 125–26.

Accordingly, Teva's due process claim also fails.

CONCLUSION

For the foregoing reasons, the Court denies the Plaintiff's Motion for Summary Judgment, ECF No. 15, and grants the Defendants' Cross-Motion for Summary Judgment, ECF No. 30.

A separate order will issue.

SPARKLE L. SOOKNANAN
United States District Judge

Date: November 20, 2025

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TEVA PHARMACEUTICALS USA, INC.,

Plaintiff,

v.

ROBERT F. KENNEDY, *et al.*,[1]

Defendants.

Civil Action No. 25-113 (SLS)
Judge Sparkle L. Sooknanan

ORDER

For the reasons stated in the Court's Memorandum Opinion, ECF No. 46, the Court **GRANTS** the Defendants' Cross-Motion for Summary Judgment, ECF No. 30, and **DENIES** the Plaintiff's Motion for Summary Judgment, ECF No. 15. The Court directs the Clerk of the Court to terminate this case from the active docket.

SO ORDERED.

SPARKLE L. SOOKNANAN
United States District Judge

Date: November 20, 2025

[1] The current Secretary is substituted for his predecessor pursuant to Federal Rule of Civil Procedure 25(d).

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

Plaintiffs,

v.

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

Defendants.

No. 1:25-cv-00113-SLS

NOTICE OF APPEAL

Notice is hereby given that Plaintiffs Teva Pharmaceuticals USA, Inc.; Teva Branded Pharmaceutical Products R&D LLC; and Teva Neuroscience, Inc. appeal to the United States Court of Appeals for the District of Columbia Circuit from this Court's November 20, 2025 order (ECF No. 47) granting Defendants' motion for summary judgment and denying Plaintiffs' motion for summary judgment.

Respectfully submitted,

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November 20, 2025

CERTIFICATE OF SERVICE

I hereby certify that on November 20, 2025, I electronically filed the foregoing using the CM/ECF system, which will send notification of this filing to the attorneys of record.

/s/ Sean Marotta
Sean Marotta

CERTIFICATE OF SERVICE

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

/s/ Sean Marotta
Sean Marotta