APPEAL,CLOSED,TYPE−E

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

TEVA PHARMACEUTICALS USA, INC. et al v. BECERRA et al
Assigned to: Judge Sparkle L. Sooknanan
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

TEVA PHARMACEUTICALS USA, INC.

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Plaintiff

represented by

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC

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Sean Marotta
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Plaintiff

TEVA NEUROSCIENCE, INC.

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V.

Defendant

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

represented by **Christine L. Coogle**
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Defendant

CHIQUITA BROOKS−LASURE
in her official capacity as Administrator of the Centers for Medicare & Medicaid Services
TERMINATED: 02/10/2025

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Defendant

DOROTHY A. FINK
in her official capacity as Acting Secretary of Health and Human Services

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Defendant

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TERMINATED: 09/05/2025
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Movant

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Movant

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Movant

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Movant

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JACK HOADLEY represented by **Joseph J. Wardenski**
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Date Filed	#	Docket Text
01/15/2025	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)
01/16/2025		Case Assigned to Judge Sparkle L. Sooknanan. (zsl) (Entered: 01/16/2025)
01/16/2025	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)
01/23/2025	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)
02/04/2025	6	NOTICE of Appearance by Stephen M. Pezzi on behalf of All Defendants (Pezzi, Stephen) (Entered: 02/04/2025)
02/05/2025	7	NOTICE of Appearance by Christine L. Coogle on behalf of All Defendants (Coogle, Christine) (Entered: 02/05/2025)
02/07/2025	8	NOTICE of Appearance by Cassandra Snyder on behalf of All Defendants (Snyder, Cassandra) (Entered: 02/07/2025)
02/10/2025	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)
02/21/2025	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)
02/26/2025	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)
02/27/2025		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)
03/04/2025		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)
03/05/2025		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)
03/07/2025	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)
03/14/2025	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	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)
03/20/2025	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)
03/22/2025		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)
03/25/2025	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	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)
04/29/2025	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)
05/01/2025	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 Brief*in 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)
05/05/2025	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)
05/19/2025	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)
05/27/2025	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)
05/28/2025		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)
06/12/2025	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)
06/25/2025	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)
06/26/2025	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)
08/12/2025		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)
08/13/2025	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)
08/14/2025	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)
09/05/2025	43	NOTICE OF WITHDRAWAL OF APPEARANCE as to STEPHANIE CARLTON, DOROTHY A. FINK. Attorney Cassandra Snyder terminated. (Snyder, Cassandra) (Entered: 09/05/2025)
11/13/2025	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)
11/14/2025	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)
11/20/2025	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)

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,

/s/ Sean Marotta
Sean Marotta (D.C. Bar 1006494)
Danielle Desaulniers Stempel (D.C. Bar 1658137)
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Attorneys for Plaintiffs Teva Pharmaceuticals USA, Inc.; Teva Branded Pharmaceutical Products R&D LLC; and Teva Neuroscience, Inc.

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

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).

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]

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[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