IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ABBVIE INC., *Plaintiff*, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, *Defendants*.	**Case No. 1:26-cv-00431 (CJN)** **ORAL ARGUMENT REQUESTED**

PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

Plaintiff AbbVie Inc. respectfully moves this Court, pursuant to Rule 56 of the Federal Rules of Civil Procedure, for an order granting summary judgment in its favor on the grounds that no genuine issue as to any material fact exists and Plaintiff is entitled to judgment as a matter of law. In support of this motion, the Court is respectfully referred to Plaintiff's Memorandum of Law and to the declarations of Mitchell F. Brin, MD, and Dalia A. Mahmoud and the exhibits attached thereto. A proposed order is also attached.

Date: April 28, 2026

Respectfully submitted,

/s/ Kannon K. Shanmugam
Kannon K. Shanmugam (D.C. Bar 474304)
DAVIS POLK & WARDWELL LLP
1050 17th Street, N.W.
Washington, DC 20036
(202) 962-7000
kshanmugam@davispolk.com

S. Conrad Scott (D.C. Bar 1685829)*
Joshua A. Altman*
PAUL, WEISS, RIFKIND,
WHARTON & GARRISON LLP
1285 Avenue of the Americas
New York, NY 10019
(212) 373-3000

Eleanor K. Ritter (D.C. Bar 90041795)*
J. Corey Schiff (D.C. Bar 90033134)*
PAUL, WEISS, RIFKIND,
WHARTON & GARRISON LLP
2001 K Street, N.W.
Washington, DC 20006
(202) 223-7300

*Admitted *pro hac vice*

Counsel for Plaintiff AbbVie Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ABBVIE INC., *Plaintiff*, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, *Defendants*.	**Case No. 1:26-cv-00431 (CJN)** **ORAL ARGUMENT REQUESTED**

MEMORANDUM OF LAW IN SUPPORT OF
PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

Kannon K. Shanmugam (D.C. Bar 474304)
DAVIS POLK & WARDWELL LLP
1050 17th Street, N.W.
Washington, DC 20036
(202) 962-7000
kshanmugam@davispolk.com

S. Conrad Scott (D.C. Bar 1685829)*
Joshua A. Altman*
PAUL, WEISS, RIFKIND,
WHARTON & GARRISON LLP
1285 Avenue of the Americas
New York, NY 10019
(212) 373-3000

Eleanor K. Ritter (D.C. Bar 90041795)*
J. Corey Schiff (D.C. Bar 90033134)*
PAUL, WEISS, RIFKIND,
WHARTON & GARRISON LLP
2001 K Street, N.W.
Washington, DC 20006
(202) 223-7300

*Admitted *pro hac vice*

Counsel for Plaintiff AbbVie Inc.

TABLE OF CONTENTS

INTRODUCTION 1

BACKGROUND 3

A. AbbVie's BOTOX Is An Innovative, Plasma-Derived Biological Product That Is Used To Treat Serious Medical Conditions 3

B. Congress Enacts The IRA And Imposes Novel Price Controls On Selected Drugs 7

C. BOTOX Is Selected For The Drug Price Negotiation Program 13

LEGAL STANDARD 14

ARGUMENT 14

I. This Court Has Jurisdiction To Review Defendants' Unlawful Selection Of BOTOX 15

A. AbbVie Has Article III Standing To Challenge BOTOX's Selection 15

B. The IRA's Judicial-Review Bar Is Inapplicable 15

1. This Court Has Jurisdiction To Review The Merits Of AbbVie's Claims That The Selection Of BOTOX Exceeded Defendants' Statutory Authority 16

2. This Court Has Jurisdiction To Review AbbVie's Constitutional Claims 21

II. Defendants Exceeded Their Statutory Authority By Selecting BOTOX For Price Controls 22

A. Through The IRA, Congress Excluded Plasma-Derived Biological Products From Selection For Price Controls 23

B. Under The IRA's Plain Text, BOTOX Is A "Plasma-Derived Product" That Is Ineligible For Price Controls 23

1. BOTOX Is A "Biological Product" Within The Meaning Of The IRA 24

2. BOTOX Is "Derived From Human Whole Blood Or Plasma" 26

C. Alternatively, Defendants' Selection Of BOTOX Was *Ultra Vires* 31

III. The Drug Price Negotiation Program Violates AbbVie's Constitutional Rights 33

A. The IRA Effects An Unconstitutional Taking Of AbbVie's Property 33

B. The IRA Deprives AbbVie Of Property Without Due Process 34

C. The IRA Unconstitutionally Compels Speech 36

D. AbbVie's Participation In The Drug Price Negotiation Program Is Involuntary . 38

E. The IRA Is Unconstitutional Even If The Drug Price Negotiation Program Is Voluntary 42

CONCLUSION 44

TABLE OF AUTHORITIES

Page

CASES

303 Creative LLC v. *Elenis*, 600 U.S. 570 (2023) 36, 37

Agency for International Development v. *Alliance for Open Society International, Inc.*, 570 U.S. 205 (2013) 44

Aid Association for Lutherans v. *USPS*, 321 F.3d 1166 (D.C. Cir. 2003) 32

American Hospital Association v. *Azar*, 964 F.3d 1230 (D.C. Cir. 2020) 17, 18, 19, 20, 21

**Amgen, Inc.* v. *Smith*, 357 F.3d 103 (D.C. Cir. 2004) 17, 18, 19

Ardelyx, Inc. v. *Becerra*, 757 F. Supp. 3d 37 (D.D.C. 2024) 19

Arkansas Writers' Project, Inc. v. *Ragland*, 481 U.S. 221 (1987) 42

Boehringer Ingelheim Pharmaceuticals, Inc. v. *Department of Health & Human Services*, 150 F.4th 76 (2d Cir. 2025) 38

Bowen v. *Michigan Academy of Family Physicians*, 476 U.S. 667 (1986) 17, 21

Bowles v. *Willingham*, 321 U.S. 503 (1944) 36

**Bristol Myers Squibb Co.* v. *Secretary*, 155 F.4th 245 (3d Cir. 2025) .... *passim*

Capital Area Immigrants' Rights Coalition v. *Trump*, 471 F. Supp. 3d 25 (D.D.C. 2020) 14

Cedar Point Nursery v. *Hassid*, 594 U.S. 139 (2021) 34, 35

Citizens United v. *Federal Election Commission*, 558 U.S. 310 (2010) 36

**COMSAT Corp.* v. *FCC*, 114 F.3d 223 (D.C. Cir. 1997) .... *passim*

Concrete Pipe & Products of California, Inc. v. *Construction Laborers Pension Trust for Southern California*, 508 U.S. 602 (1993) 35

DCH Regional Medical Center v. *Azar*, 925 F.3d 503 (D.C. Cir. 2019) 18, 19

Diamond Alternative Energy, LLC v. *EPA*, 606 U.S. 100 (2025) 15

Dolan v. *City of Tigard*, 512 U.S. 374 (1994) 43

Duncan v. *Walker*, 533 U.S. 167 (2001) 41

Environmental Defense v. *Duke Energy Corp.*, 549 U.S. 561 (2007) 29

Page

Cases—continued:

FDA v. *Wages & White Lion Investments, L.L.C.*, 604 U.S. 542 (2025) 28

Federal Express Corp. v. *Department of Commerce*, 39 F.4th 756 (D.C. Cir. 2022) 31

Feliciano v. *Department of Transportation*, 605 U.S. 38 (2025) 20, 27

Fischer v. *United States*, 602 U.S. 480 (2024) 27

Free Speech Coalition, Inc. v. *Paxton*, 606 U.S. 461 (2025) 38

Fresno Community Hospital & Medical Center v. *Cochran*, 987 F.3d 158 (D.C. Cir. 2021) 19

Honda Motor Co. v. *Oberg*, 512 U.S. 415 (1994) 36

Horne v. *Department of Agriculture*, 576 U.S. 351 (2015) 34, 36

Hurley v. *Irish-American Gay, Lesbian & Bisexual Group of Boston*, 515 U.S. 557 (1995) 36, 37

Illinois Tool Works Inc. v. *Independent Ink, Inc.*, 547 U.S. 28 (2006) 41

Ipsen Pharmaceuticals, Inc. v. *Becerra*, 108 F.4th 836 (D.C. Cir. 2024) 24

Jefferson Parish Hospital District No. 2 v. *Hyde*, 466 U.S. 2 (1984) 41

Johanns v. *Livestock Marketing Association*, 544 U.S. 550 (2005) 15

Knapp Medical Center v. *Hargan*, 875 F.3d 1125 (D.C. Cir. 2017) 19

Koontz v. *St. Johns River Water Management District*, 570 U.S. 595 (2013) 43

Kucana v. *Holder*, 558 U.S. 233 (2010) 21

Lamie v. *United States Trustee*, 540 U.S. 526 (2004) 28

Leedom v. *Kyne*, 358 U.S. 184 (1958) 31, 32

Loper Bright Enterprises v. *Raimondo*, 603 U.S. 369 (2024) 24

Loretto v. *Teleprompter Manhattan CATV Corp.*, 458 U.S. 419 (1982) 34

Mathews v. *Eldridge*, 424 U.S. 319 (1976) 35

McDonnell v. *United States*, 579 U.S. 550 (2016) 40

Mora v. *Mejias*, 223 F.2d 814 (1st Cir. 1955) 41

Page

Cases—continued:

National Association of Manufacturers v. *SEC*, 800 F.3d 518 (D.C. Cir. 2015) 37

National Association of Postal Supervisors v. *USPS*, 26 F.4th 960 (D.C. Cir. 2022)........ 2, 23, 32

National Infusion Center Association v. *Becerra*, 116 F.4th 488 (5th Cir. 2024)...... 11, 15, 35, 36

Newman v. *Moore*, 151 F.4th 472 (D.C. Cir. 2025) 22

Nicopure Labs, LLC v. *FDA*, 944 F.3d 267 (D.C. Cir. 2019) 28, 29

Nollan v. *California Coastal Commission*, 483 U.S. 825 (1987) 43

Nuclear Regulatory Commission v. *Texas*, 605 U.S. 665 (2025) 31, 32, 33

Nyunt v. *Chairman, Broadcasting Board of Governors*, 589 F.3d 445 (D.C. Cir. 2009) 31, 32

Old Dearborn Distributing Co. v. *Seagram-Distillers Corp.*, 299 U.S. 183 (1936) 35

Perry v. *Sindermann*, 408 U.S. 593 (1972) 42

Ralls Corp. v. *Committee on Foreign Investment in the United States*,
758 F.3d 296 (D.C. Cir. 2014) 22

Sanofi Aventis U.S. LLC v. *United States Department of Health & Human Services*,
58 F.4th 696 (3d Cir. 2023) 41

Sheetz v. *County of El Dorado*, 601 U.S. 267 (2024) 43

Sky Television, LLC v. *FCC*, 589 Fed. Appx. 541 (D.C. Cir. 2014) 19

Sottera, Inc. v. *FDA*, 627 F.3d 891 (D.C. Cir. 2010)... 28

**Southwest Airlines* v. *TSA*, 554 F.3d 1065 (D.C. Cir. 2009) 17, 18, 19, 20

Sturm, Ruger & Co. v. *Chao*, 300 F.3d 867 (D.C. Cir. 2002) 33

Thunder Basin Coal Co. v. *Reich*, 510 U.S. 200 (1994)... 33

Turner Broadcasting System, Inc. v. *FCC*, 512 U.S. 622 (1994) 38

United States v. *American Library Association, Inc.*, 539 U.S. 194 (2003)............................... 43

United States v. *Butler*, 297 U.S. 1 (1936) 42

Utility Air Regulatory Group v. *EPA*, 573 U.S. 302 (2014) 40

Page

Cases—continued:

Valancourt Books, LLC v. *Garland*, 82 F.4th 1222 (D.C. Cir. 2023) 42

Vanda Pharmaceuticals, Inc. v. *FDA*, 123 F.4th 513 (D.C. Cir. 2024) 24

Webster v. *Doe*, 486 U.S. 592 (1988) 21

West Virginia v. *EPA*, 597 U.S. 697 (2022) 2

Williams v. *Taylor*, 529 U.S. 362 (2000) 27

Yakus v. *United States*, 321 U.S. 414 (1944) 36

CONSTITUTIONS, STATUTES, AND REGULATIONS

U.S. Const. amend. I 2, 14, 15, 16, 43

U.S. Const. amend. V 2, 14, 15, 16, 34, 43

Administrative Procedure Act,
5 U.S.C. § 706(2)(C) 2, 14, 23, 31

Family Smoking Prevention and Tobacco Control Act of 2009,
21 U.S.C. § 321(rr)(1) 28, 29

Public Health Service Act 26

42 U.S.C. § 262 .... 24, 25, 26

42 U.S.C. § 262(a) 24, 25, 29, 30

42 U.S.C. § 262(a)(1) 25

42 U.S.C. § 262(a)(2)(C) 25

21 U.S.C. § 331(a) 29, 30

21 U.S.C. § 351 .... 29, 30

21 U.S.C. § 352 .... 29, 30

21 U.S.C. § 355 24

21 U.S.C. § 356a 7, 29, 30

26 U.S.C. § 5000D(a) .... *passim*

Page

Statutes—continued:

26 U.S.C. § 5000D(b) 42

26 U.S.C. § 5000D(b)(1) 39, 40

26 U.S.C. § 5000D(b)(2) 37, 39

26 U.S.C. § 5000D(c) 10, 39

26 U.S.C. § 5000D(d) 10

42 U.S.C. § 1320a-7 15

42 U.S.C. § 1320f 9

42 U.S.C. § 1320f(a) 9

42 U.S.C. § 1320f(b)(3) 9, 39, 40

42 U.S.C. § 1320f(c)(5) 25

42 U.S.C. § 1320f-1(a) 9, 39, 40

42 U.S.C. § 1320f-1(a)(4) 21

42 U.S.C. § 1320f-1(b) 17, 20, 21, 23

42 U.S.C. § 1320f-1(b)(1) 25

42 U.S.C. § 1320f-1(c) 39

42 U.S.C. § 1320f-1(d) 12, 20, 25

42 U.S.C. § 1320f-1(d)(1) 22, 23

42 U.S.C. § 1320f-1(e) 12, 17, 20

42 U.S.C. § 1320f-1(e)(1) 21, 22, 23

42 U.S.C. § 1320f-1(e)(1)(A) 12

42 U.S.C. § 1320f-1(e)(1)(B) 12

42 U.S.C. § 1320f-1(e)(1)(B)(i) 24

Page

Statutes—continued:

42 U.S.C. § 1320f-1(e)(3) ... 23

42 U.S.C. § 1320f-1(e)(3)(A) ... 12

42 U.S.C. § 1320f-1(e)(3)(B) ... 12, 25

42 U.S.C. § 1320f-1(e)(3)(C) ... *passim*

42 U.S.C. § 1320f-1(f)(4)(B)(i) ... 26

42 U.S.C. § 1320f-1(f)(4)(B)(i)(I)(aa) ... 26

42 U.S.C. § 1320f-2(a) ... 37, 39, 40

42 U.S.C. § 1320f-2(a)(1) ... *passim*

42 U.S.C. § 1320f-2(a)(3) ... 34, 35

42 U.S.C. § 1320f-3(b)(1) ... 11, 35, 38

42 U.S.C. § 1320f-3(b)(2)(B) ... 10, 35

42 U.S.C. § 1320f-3(b)(2)(C) ... 10, 35

42 U.S.C. § 1320f-3(b)(2)(D) ... 10, 35

42 U.S.C. § 1320f-3(b)(2)(E) ... 10, 39

42 U.S.C. § 1320f-3(b)(2)(F)(i) ... 11

42 U.S.C. § 1320f-3(c) ... 11, 15

42 U.S.C. § 1320f-3(c)(3)(A) ... 11

42 U.S.C. § 1320f-3(c)(3)(C) ... 11

42 U.S.C. § 1320f-3(c)(5) ... 11

42 U.S.C. § 1320f-3(d) ... 11

42 U.S.C. § 1320f-4(a) ... 12

42 U.S.C. § 1320f-4(a)(2) ... 35

42 U.S.C. § 1320f-6(a) ... 12, 42

Page

Statutes—continued:

42 U.S.C. § 1320f-6(c) ... 12

42 U.S.C. § 1320f-7 ... *passim*

42 U.S.C. § 1320f-7(2) ... 16, 17, 20

42 U.S.C. § 1395j ... 7

42 U.S.C. § 1395w-3a ... 8

42 U.S.C. § 1395w-6 ... 7

42 U.S.C. § 1395w-101 ... 7, 8, 26

42 U.S.C. § 1395w-102(e)(1) ... 26

42 U.S.C. § 1395w-111(d)(2) ... 8

42 U.S.C. § 1395w-111(d)(2)(i) ... 8

42 U.S.C. § 1395w-111(i)(1) ... 9

42 U.S.C. § 1395w-111(i)(3) ... 9

42 U.S.C. § 1395w-114c(b)(4)(B)(i) ... 40

42 U.S.C. § 1395w-114c(b)(4)(B)(ii) ... 39

42 U.S.C. § 1395w-115(b)(3) ... 25

42 U.S.C. § 1395w-153(a) ... 8

42 U.S.C. § 1395w-154 ... 7

42 U.S.C. § 1396-1 ... 8

42 U.S.C. § 1396d(a)(12) ... 8

42 U.S.C. § 1396r-8 ... 26

42 U.S.C. § 1396r-8(a) ... 8

42 U.S.C. § 1396r-8(a)(1) ... 8

42 U.S.C. § 1396r-8(b)(4)(B)(ii) ... 39

Page

Statutes—continued:

42 U.S.C. § 1396r-8(c) ... 8

42 U.S.C. § 1396r-8(c)(1)(C)(i) ... 9

42 U.S.C. § 1396r-8(k)(1) ... 9

42 U.S.C. § 1396r-8(k)(1)(A) ... 26

42 U.S.C. § 1396r-8(k)(2)(A) ... 26

42 U.S.C. § 1396r-8(k)(2)(B) ... 26

47 U.S.C. § 159(b)(3) ... 18

21 C.F.R. § 601.2 ... 25

21 C.F.R. § 601.12 ... 29

21 C.F.R. § 601.12(b) ... 6, 7

Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act, 81 Fed. Reg. 28974 (May 10, 2016) ... 29

Delegation of Authorities, 88 Fed. Reg. 1390 (Jan. 5, 2023) ... 9

MISCELLANEOUS

149 Cong. Rec. 31043 (Nov. 23, 2003) (Sen. Grassley) ... 9

149 Cong. Rec. 31051 (Nov. 23, 2003) (Sen. Frist) ... 9

149 Cong. Rec. 31160 (Nov. 23, 2003) (Sen. Santorum) ... 9

American Heritage Dictionary of the English Language (5th ed. 2018) ... 27

CMS, Department of Health and Human Services, Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2028 (2026) ... 5

CMS, Medicare Drug Price Negotiation Program Agreement, <tinyurl.com/ManufacturerAgreementTemplate> ... 10, 11, 37, 39, 44

Page

Miscellaneous—continued:

CMS, Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027 (2024) 13, 30

CMS, 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 (2025) 10, 13, 30, 40

CMS, Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026 (2024) 11

CMS, Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026 (2023) 13, 30

CMS, Table 4: National Health Expenditures by Source of Funds and Type of Expenditure: Calendar Years 2017-2024, <tinyurl.com/NHE-Tables> 8, 41

Congressional Budget Office, How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act (2023), <tinyurl.com/IRA-CBO-Estimate> 11

Medicaid.gov, Medicaid Drug Rebate Program (Feb. 6, 2026), <tinyurl.com/MedicaidMDRP> . 8

Merriam-Webster's Medical Dictionary (2016) 27

Molly F. Sherlock et al., Congressional Research Service, R47202, Tax Provisions in the Inflation Reduction Act of 2022 (H.R. 5376) (Aug. 10, 2022) 10

The New Oxford Dictionary of English (2001 ed.) 27

USA.gov, Centers for Medicare and Medicaid Services (CMS), <tinyurl.com/CMS-Data> 7

INTRODUCTION

Some medicines used to treat serious diseases are derived from whole blood or plasma obtained from human donors. As a result of both fluctuations in donor availability and the complex manufacturing processes required to make such medicines, those products are vulnerable to supply-chain disruptions. When Congress enacted the Inflation Reduction Act of 2022 (IRA), which authorized the Centers for Medicare & Medicaid Services (CMS) to impose price controls on certain drugs covered by Medicare, Congress sensibly exempted plasma-derived medicines. By excluding from the definition of a "qualifying single source drug" any "biological product that is derived from human whole blood or plasma," Congress ensured that no such products could be selected for "negotiation"—that is, price controls—under the IRA's Medicare Drug Price Negotiation Program (the Program). *See* 42 U.S.C. § 1320f-1(e)(3)(C).

Defendants CMS and the Department of Health and Human Services (HHS) contravened that clear statutory prohibition when, on January 27, 2026, they selected Plaintiff AbbVie Inc.'s BOTOX® for "negotiation" under the Program. BOTOX is a biological product that FDA has licensed to treat numerous medical conditions, including chronic migraine, movement disorders, bladder conditions, and involuntary eye dysfunctions. *See* Decl. of Mitchell F. Brin, MD, Ex. 4 § 1. BOTOX is derived in part from a powerful neurotoxin, onabotulinumtoxinA (onabotA), which is produced from fermentation of *Clostridium botulinum* bacteria. Brin Decl., Ex. 4 § 11. BOTOX is also derived from human plasma: since it was first licensed in 1989, BOTOX has always contained human serum albumin (HSA), a plasma protein that stabilizes onabotA, prevents it from adhering to the sides of the vials in which BOTOX is distributed, and facilitates the product's therapeutic effect. Brin Decl. ¶¶ 12, 14, 16. BOTOX is therefore a "[p]lasma-derived product" categorically ineligible for IRA price controls. *See* 42 U.S.C. § 1320f-1(e)(3)(C).

Federal agencies possess only the power Congress has granted them by statute. *See West Virginia* v. *EPA*, 597 U.S. 697, 723 (2022). By selecting BOTOX for price controls, Defendants acted "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C). This Court should "hold unlawful and set aside" that selection, *id*., or, alternatively, enjoin Defendants from implementing or enforcing that *ultra vires* action, *see National Association of Postal Supervisors* v. *USPS*, 26 F.4th 960, 966 (D.C. Cir. 2022).

While Defendants' disregard of the IRA's plasma-derived-products exclusion is reason enough to set aside their selection of BOTOX, that selection also violates AbbVie's rights under the First and Fifth Amendments. When Congress enacted the IRA, it authorized CMS to impose price controls with minimal input from affected parties or oversight by the courts. Defendants' selection of BOTOX sets in motion a sham "negotiation" process in which CMS unilaterally dictates the product's "maximum fair price" (capped at a fraction of its market price). As a result of that selection, AbbVie faces a Hobson's choice among selling the drug to Medicare beneficiaries and providers at the government-fixed "maximum fair price," paying ruinous excise taxes and penalties, or withdrawing not just BOTOX but all its products from Medicare and Medicaid. *See* pp. 9-12, 39-42, *infra*. Adding insult to injury, AbbVie must also sign a purported "agreement" that declares that the government-fixed price is the "maximum fair price" for BOTOX that resulted from "negotiations"—both of which are false. *See* pp. 9-12, 36-38, *infra*. Selection of BOTOX not only violates the IRA, but will inevitably deprive AbbVie of its constitutional rights.

Defendants' action is unlawful, and there is no genuine dispute as to any material fact. AbbVie therefore respectfully requests that the Court grant summary judgment on its APA claim (or, alternatively, on its *ultra vires* or constitutional claims) and hold unlawful and set aside Defendants' selection of BOTOX.

BACKGROUND

A. AbbVie's BOTOX Is An Innovative, Plasma-Derived Biological Product That Is Used To Treat Serious Medical Conditions

1. BOTOX is an innovative biological product used to treat a number of serious medical conditions. As a locally administered, targeted therapy, BOTOX delivers treatment directly to the affected muscles and nerves underlying the disease, enabling health-care professionals to tailor therapy to each patient's anatomy and disease course. This non-systemic profile is a defining attribute of BOTOX. BOTOX is the only FDA-licensed biological product that provides localized treatment of chronic migraine, bladder disorders, involuntary eye dysfunctions, and hyperhidrosis. Brin Decl. ¶ 5.

BOTOX was first licensed by FDA for the treatment of strabismus and blepharospasm, two eye disorders caused by muscle dysfunction. Brin Decl. ¶ 6; *see also* Brin Decl., Ex. 3.[1] These conditions had previously been treated either with surgeries, which were often unsuccessful or resulted in complications, or with other medications that were generally ineffective and sometimes caused intolerable side effects. Brin Decl., Ex. 2 at S24. BOTOX, which permits targeted treatment of specific muscles, proved to be an effective alternative to surgery and significantly reduced the risk of intolerable side effects linked to oral medicines. Brin Decl., Ex. 2 at S24, S26. Over the years, FDA has licensed BOTOX for multiple other indications:

[1] BOTOX was initially licensed by FDA in 1989 under the name Oculinum. Allergan, Inc. acquired Oculinum in 1991 and renamed it BOTOX a year later. *See* Brin Decl. ¶ 11.

<table>
<tr><th>BOTOX Indications[2]</th><th>Licensure Date</th><th colspan="2">Description</th></tr>
<tr><td>Blepharospasm</td><td>1989</td><td colspan="2">Involuntary, repeated blinking, or spasm of eyelid muscles resulting in uncontrollable blinking or eyelid closure</td></tr>
<tr><td>Strabismus</td><td>1989</td><td colspan="2">Eye misalignment due to poor control of eye muscles resulting in double vision, reduced depth perception, eye strain, and potential vision loss</td></tr>
<tr><td>Cervical dystonia</td><td>2000</td><td colspan="2">Painful neurological condition due to involuntary neck muscle contractions, causing the head to twist, turn, or tilt uncontrollably in various directions</td></tr>
<tr><td>Hyperhidrosis</td><td>2004</td><td colspan="2">Skin disorder resulting in excessive sweating due to overactive sweat glands</td></tr>
<tr><td rowspan="4">Spasticity</td><td>2010</td><td>Adult Upper Limb</td><td rowspan="4">Debilitating neurological condition causing muscle stiffness and impaired movement that can interfere with movement and function, often seen after stroke, spinal cord injury, multiple sclerosis, traumatic brain injury, or cerebral palsy</td></tr>
<tr><td>2016</td><td>Adult Lower Limb</td></tr>
<tr><td>2019</td><td>Pediatric Upper Limb</td></tr>
<tr><td>2019</td><td>Pediatric Lower Limb</td></tr>
<tr><td>Chronic migraine</td><td>2010</td><td colspan="2">Headaches on 15 or more days per month, often severely impacting daily life due to pain and other symptoms</td></tr>
<tr><td rowspan="2">Neurogenic detrusor overactivity</td><td>2011</td><td>Adult</td><td rowspan="2">Uncontrolled contraction of bladder muscles causing frequent, urgent urination or leakage, resulting from nerve damage from neurological conditions</td></tr>
<tr><td>2021</td><td>Pediatric</td></tr>
<tr><td>Overactive bladder</td><td>2013</td><td colspan="2">Uncontrolled contraction of bladder muscles causing frequent, urgent urination or leakage, without underlying neurological cause or infection</td></tr>
</table>

[2] This table does not include the numerous other uses for which BOTOX has been investigated, nor does it reflect AbbVie's ongoing investment in exploring new uses for the drug.

While administering BOTOX to treat overactive facial muscles, researchers discovered that BOTOX decreased wrinkles near the injection site. Brin Decl. ¶ 7. FDA has since licensed BOTOX Cosmetic® for four cosmetic indications. *Id.* Medicare and Medicaid do not cover BOTOX's cosmetic uses, so BOTOX Cosmetic is not subject to price controls or at issue in this action.[3]

AbbVie has continued to investigate whether BOTOX can be used to treat other severe, difficult-to-treat medical conditions. Brin Decl. ¶ 5. AbbVie has made—and continues to make—significant investments in discovering new uses and optimizing manufacturing processes for BOTOX and related products, including a recently completed, $69 million expansion of research and development facilities. *See* Declaration of Dalia A. Mahmoud ¶ 33.

2. Since it was first licensed, BOTOX has always consisted of three ingredients: onabotulinumtoxinA (onabotA), human serum albumin (HSA), and sodium chloride (salt), each of which is critical to BOTOX's medicinal effect. Brin Decl. ¶ 12; *see* Brin Decl., Ex. 8 § 1. OnabotA is cultured from *Clostridium botulinum* bacteria. Brin Decl. ¶ 13. OnabotA, which FDA identifies as BOTOX's active ingredient, *see* Brin Decl., Ex. 4 at 1, suppresses the release of acetylcholine, a neurotransmitter nerve cells use to communicate with muscles and sweat glands, *see* Brin Decl., Ex. 4 § 12.1. Sodium chloride is used to produce an isotonic solution with the same osmotic balance as fluids in the human body, to protect cells from damage, and to minimize patient discomfort. Brin Decl. ¶ 15. HSA is a protein extracted from human blood plasma. Brin

[3] Although Defendants have selected BOTOX Cosmetic alongside BOTOX for price "negotiation," that reflects only that both products were approved under the same biologics license application and, as CMS itself has noted, does not indicate that BOTOX Cosmetic is now covered or reimbursed under Medicare. *See* CMS, Department of Health and Human Services, Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2028, at 1 n.* (2026).

Decl. ¶ 14. Since it was first licensed, BOTOX has always been formulated with HSA to protect onabotA from environmental factors that can affect BOTOX's quality, stability, and performance. Brin Decl. ¶ 16. For example, as the scientific community has long understood, HSA protects against the breakdown of onabotA into other compounds, minimizes protein "clumping" that could reduce efficacy or trigger immune responses, and prevents onabotA from sticking to surfaces or syringes (resulting in inconsistency in the delivered dose). *Id*.

In addition, HSA plays an important role in achieving BOTOX's therapeutic effects. Peer-reviewed studies report that the concentration of HSA affects toxin activity and enables the effective administration of lower dosages of toxin products. *See*, *e.g.*, Brin Decl., Ex. 6 at 440. Building on those observations and using modern analytical tools, AbbVie recently conducted additional studies regarding how HSA affects onabotA and the therapeutic effect of BOTOX. Brin Decl. ¶ 18. Those studies demonstrate that HSA's presence leads to greater binding between onabotA and the targeted nerve cell receptors, resulting in greater toxin peak effect, duration, and overall effect. Brin Decl. ¶ 19. They also demonstrate that, in the presence of HSA, onabotA persists longer near the injection site, increasing receptor binding. *Id*.

While each ingredient in BOTOX plays an important role, these ingredients are not present in equal amounts. Each vial of BOTOX contains approximately 100,000 times more HSA by mass than onabotA. Brin Decl. ¶ 14.

3. BOTOX is a biological product licensed and marketed in three strengths under a biologics license application (BLA 103000) held by AbbVie. Brin Decl., Ex. 7 § I.B; *see* Brin Decl., Ex. 1. FDA has licensed BOTOX only in its finished dosage forms, which have always included HSA, and AbbVie's ability to market BOTOX under this license depends on the presence of HSA. *See* Brin Decl. ¶ 12; 21 C.F.R. § 601.12(b). BOTOX's FDA-approved label reflects the

presence of HSA in the licensed formulation of the medicine. *See* Brin Decl., Ex. 4 § 5.14. Indeed, the FDA-approved product labeling for BOTOX expressly states that the "product contains albumin, a derivative of human blood." *Id*.

4. HSA is sourced from human plasma donations, which leaves AbbVie vulnerable to shocks in plasma supply. *See* Mahmoud Decl. ¶ 11; Brin Decl., Ex. 9 ¶¶ 8, 10, 13. The presence of HSA in BOTOX also presents special manufacturing challenges. *See* Brin Decl. ¶¶ 22-24. Separating and purifying specific proteins (such as HSA) from human plasma requires plasma fractionation, a complex, multi-step process. Brin Decl. ¶ 14. As explained in exhibits to the accompanying declaration of Dr. Mitchell Brin, slight variations in this process can alter the properties of HSA in ways that can affect products containing this protein. *See* Brin Decl., Ex. 9 ¶¶ 8, 9, 19. To minimize those risks, AbbVie procures HSA from two different qualified suppliers. Brin Decl. ¶ 21. Even minor changes in either supplier's HSA extraction processes or handling protocols—like changes in the fractionation process—can require costly changes to AbbVie's process for manufacturing BOTOX. *See* Brin Decl. ¶¶ 22-24. Those changes can take years to develop and require FDA pre-approval to implement. *Id*.; 21 U.S.C. § 356a; 21 C.F.R. § 601.12(b).

B. Congress Enacts The IRA And Imposes Novel Price Controls On Selected Drugs

1. Two federal health-care programs, Medicare and Medicaid, provide health coverage to more than 100 million eligible Americans. *See* USA.gov, Centers for Medicare and Medicaid Services (CMS), <tinyurl.com/CMS-Data>. Medicare offers prescription drug coverage through Medicare Parts B and D, which cover provider-administered drugs and self-administered prescription drugs, respectively, primarily for those 65 and older. *See generally* 42 U.S.C. §§ 1395j to 1395w-6 (Part B); 42 U.S.C. §§ 1395w-101 to 1395w-154 (Part D). For a drug to be

covered under Medicare Part B, its manufacturer must enter into a rebate agreement with each approved state Medicaid plan. *See* 42 U.S.C. § 1396r-8(a)(1). Congress also requires that manufacturers enter into separate agreements for their drugs to be covered under Medicare Part D. 42 U.S.C. § 1395w-153(a). Medicaid pays for medical assistance for individuals and families with low incomes and relatively few assets. *See* 42 U.S.C. § 1396-1. Although pharmacy coverage is an optional benefit, all states currently provide coverage for outpatient prescription drugs to enrollees within their state Medicaid programs. *See* 42 U.S.C. §§ 1396d(a)(12), 1396r-8(a); *see also* Medicaid.gov, Medicaid Drug Rebate Program (Feb. 6, 2026) <tinyurl.com/Medicaid-MDRP>. In 2024, Medicare and Medicaid together accounted for nearly 40% of domestic health-care consumption expenditures and more than 45% of prescription-drug spending; Medicare and Medicaid spending on retail outlet prescription drugs totaled approximately $217 billion. CMS, Table 4: National Health Expenditures by Source of Funds and Type of Expenditure: Calendar Years 2017-2024, <tinyurl.com/NHE-Tables>.

2. Before enactment of the IRA, Congress mandated a market-based approach to Medicare pricing for prescription drugs, with prices for drugs covered by Medicare Part B determined by a formula based on a drug's average sales price, 42 U.S.C. § 1395w-3a, and prices for drugs covered by Part D negotiated by manufacturers and private plan sponsors or their pharmacy benefit managers, 42 U.S.C. § 1395w-111(d)(2), (i). It likewise adopted a framework for Medicaid under which manufacturers must pay rebates calculated by reference to certain market-based indicators, such as the "average manufacturer price," that ensure Medicaid receives the "best price" among purchasers. *See* 42 U.S.C. § 1396r-8(c).[4] When Congress established the

[4] The "average manufacturer price" is the average price paid to the manufacturer for the drug in the United States by wholesalers for distribution to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer, net of certain

Part D benefit, it prohibited CMS from "interfer[ing] with the negotiations between drug manufacturers and pharmacies and [private plan] sponsors" or "institut[ing] a price structure for the reimbursement of covered part D drugs." 42 U.S.C. § 1395w-111(i)(1), (3). It imposed that "fundamental protection" to prevent the federal government—a health-care purchaser with considerable market power—from "dictat[ing]" prescription-drug prices. 149 Cong. Rec. 31043-31044 (Nov. 23, 2003) (Sen. Grassley); *see id*. at 31051 (Sen. Frist); *id*. at 31160 (Sen. Santorum).

3. The IRA's Medicare Drug Price Negotiation Program (the Program) attempts to revise that framework. *See* 42 U.S.C. §§ 1320f to 1320f-7. In relevant part, the IRA charges the Secretary of Health and Human Services, acting through CMS, with "negotiating" prices—i.e., setting the prices to be paid by Medicare—on certain drugs and biological products. *See* 42 U.S.C. § 1320f(a).[5] Under the IRA, CMS must "select" between 10 and 20 new drugs each year for "negotiation," with eligible drugs chosen based in part on their contribution to Medicare drug spending. 42 U.S.C. § 1320f-1(a), (b). This selection must be made by February 1 twenty-three months before the new, government-mandated price will take effect (the initial price applicability year, or IPAY). 42 U.S.C. §§ 1320f(b)(3), 1320f-1(a).

Once CMS publishes the list of selected drugs, manufacturers of selected drugs have until February 28 to "enter into agreements" with CMS, under which manufacturers must accede to (among other things) "negotiate to determine" a "maximum fair price." 42 U.S.C. § 1320f-2(a)(1). According to CMS's form agreement, each affected manufacturer must express that it "agree[s]"

---

discounts. 42 U.S.C. § 1396r-8(k)(1). The "best price" is the lowest price at which a drug manufacturer made the drug available to a "wholesaler, retailer, provider, health maintenance organization, nonprofit, or governmental entity" in the United States during a rebate period. 42 U.S.C. § 1396r-8(c)(1)(C)(i).

[5] Although the IRA grants these powers to the HHS Secretary, the Secretary has delegated them to CMS. *See* Delegation of Authorities, 88 Fed. Reg. 1390 (Jan. 5, 2023).

that it will "negotiate to determine" and ultimately "agree to" a "maximum fair price." CMS, Medicare Drug Price Negotiation Program Agreement 2, <tinyurl.com/ManufacturerAgreementTemplate> (Template Program Agreement). The Template Program Agreement disclaims that "[u]se of the term 'maximum fair price' and other statutory terms throughout this Agreement reflects the parties' intention that such terms be given the meaning specified in the statute and does not reflect any party's views regarding the colloquial meaning of those terms." *Id.* at 4. If a manufacturer refuses to sign the Template Program Agreement by February 28, the manufacturer must, by statute, pay an escalating daily excise tax that starts at 186% and increases to 1,900% of the selected drug's daily sales. 26 U.S.C. § 5000D(a), (d).[6] A manufacturer that does not agree to "negotiate" may avoid this tax only by withdrawing *all* of its products—not just the selected drug—from both Medicare and Medicaid. 26 U.S.C. § 5000D(c); IPAY 2028 Guidance 257-259 & n.148.[7]

Following execution of this involuntary "agreement," the manufacturer must engage in a "negotiation" in which it must accept whatever price CMS unilaterally sets. By June 1 of the selection year, CMS must disclose to the manufacturer its "initial offer" along with a "concise justification." 42 U.S.C. § 1320f-3(b)(2)(B). Within 30 days of receiving CMS's opening offer, the manufacturer must either accept that offer or make a "counteroffer." 42 U.S.C. § 1320f-3(b)(2)(C). CMS must "respond in writing" to the counteroffer, but the statute does not require any further negotiation with the manufacturer. *See* 42 U.S.C. § 1320f-3(b)(2)(D). The

[6] *See* Molly F. Sherlock et al., Congressional Research Service, R47202, Tax Provisions in the Inflation Reduction Act of 2022 (H.R. 5376), at 4 (Aug. 10, 2022).

[7] CMS, 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 257-259 & n.148 (2025) (IPAY 2028 Guidance).

"negotiation" window automatically closes on November 1. 42 U.S.C. § 1320f-3(b)(2)(E). In making its final offer, CMS must "aim[] to achieve the lowest maximum fair price for each selected drug," 42 U.S.C. § 1320f-3(b)(1), and must set the "maximum fair price" at or below certain "[c]eiling" prices, 42 U.S.C. § 1320f-3(c). That ceiling provision requires prices to be set at reductions to private-market wholesale prices of at least 25% for "[s]hort-monopoly drugs" and up to 60% for certain "[l]ong-monopoly drugs." 42 U.S.C. § 1320f-3(b)(2)(F)(i), (c)(3)(A), (c)(3)(C), (c)(5). While the IRA caps how high the "maximum fair price" can be, it imposes "no limit to how low HHS's offer can be." *National Infusion Center Association* v. *Becerra*, 116 F.4th 488, 495 (5th Cir. 2024).[8] The "maximum fair price" established for drugs selected for the first two years of the Program is on average 62% lower than those drugs' list prices—and 73% below list price for "long-monopoly drugs."[9] If a manufacturer declines CMS's "offer" or walks away from the process, it becomes subject to the daily excise taxes described above. *See* 26 U.S.C. § 5000D(a). Given the magnitude of those taxes, no manufacturer has elected to pay them instead of "negotiating." Indeed, when scoring a version of the IRA, the Congressional Budget Office projected that these taxes would raise no revenue because no manufacturer would pay them.[10]

Once a manufacturer accedes to CMS's "offer," it must sign an addendum to the Template Program Agreement representing that the parties "have engaged in negotiation" and "now agree to" CMS's offered price. Template Program Agreement 7. CMS must publish the price it has set

---

[8] The IRA sets a "[t]emporary floor" to the "maximum fair price" only for certain "small biotech drugs." 42 U.S.C. § 1320f-3(d). That narrow exception is inapplicable here.

[9] *See* CMS, Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026, at 2 (2024); Centers for Medicare & Medicaid Services, Department of Health and Human Services, Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2027, at 2 (2025).

[10] Congressional Budget Office, How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act 9-10 (2023), <tinyurl.com/IRA-CBO-Estimate>.

by November 30, but need not explain its decision until March 1 of the following year. 42 U.S.C. § 1320f-4(a). After a price has been set, beginning in the initial price applicability year, the manufacturer must "provide access to such price" for the "selected drug" to Medicare beneficiaries and providers who administer the drug to such beneficiaries. 42 U.S.C. § 1320f-2(a)(1). If the manufacturer does not, it faces civil monetary penalties of 10 times the difference between the price the manufacturer charges and the "maximum fair price." 42 U.S.C. § 1320f-6(a). In addition, a manufacturer that violates any term of its "agreement" with CMS will be subject to a civil penalty of $1 million per day. *See* 42 U.S.C. § 1320f-6(c).

The IRA bars both administrative and judicial review of specific aspects of the price-control process. *See* 42 U.S.C. § 1320f-7.

4. When Congress created this price-control scheme, it also specified criteria for determining which drugs would be eligible for selection. To be "negotiation-eligible" and thus subject to selection under the Program, a drug must be a "qualifying single source drug." 42 U.S.C. § 1320f-1(d), (e). "[Q]ualifying single source drug[s]" include (1) drug products "approved" and "marketed" under new drug applications that have been approved for at least seven years and are not the listed drugs for marketed generic drugs; and (2) biological products "licensed" and "marketed" under biologics license applications, which have been licensed for at least 11 years and are not reference products for marketed biosimilar products. 42 U.S.C. § 1320f-1(e)(1)(A), (B). Paragraph (3) makes clear, however, that a "qualifying single source drug" cannot be a "[c]ertain orphan drug[]," "[l]ow spend Medicare drug[]," or—relevant here—"[p]lasma-derived product[]," defined as "[a] biological product that is derived from human whole blood or plasma." 42 U.S.C. § 1320f-1(e)(3)(A) to (C).

5. In guidance promulgated every year since the IRA's enactment—including guidance specifically applicable to IPAY 2028—CMS has stated that, in applying the plasma-derived products exclusion, it will consider whether "a plasma-derived product is a licensed biological product that is derived from human whole blood or plasma, as indicated on the approved product labeling." IPAY 2028 Guidance 173.[11] CMS has further stated that it will "verify if [a] product is derived from human whole blood or plasma" by referring to the "product information available on the FDA Approved Blood Products website" and "databases such as FDALabel and the FDA Online Label Repository," and CMS "will consult with FDA, as appropriate." *Id.*; *see* IPAY 2027 Guidance 173-174; *see also* IPAY 2026 Guidance 104 (citing the FDA Online Label Repository but not FDALabel).

C. BOTOX Is Selected For The Drug Price Negotiation Program

Based on projections suggesting that, if not for the plasma-derived-products exclusion, Defendants might attempt to select BOTOX, AbbVie sought to engage with CMS to explain why the plain text of that exclusion precluded CMS from selecting BOTOX. *See* Mahmoud Decl. ¶¶ 16-22 & Exs. 1 & 2. CMS never substantively responded to AbbVie regarding the scope of the plasma-derived-products exclusion. *See* Mahmoud Decl. ¶ 22. Instead, on January 27, 2026, Defendants selected BOTOX and BOTOX Cosmetic for IPAY 2028. *See* Mahmoud Decl. ¶ 23 & Ex. 3. Defendants justified neither their failure to apply the statute's plasma-derived-products exclusion to BOTOX nor their deviation from years of CMS guidance about the exclusion.

[11] *See also* CMS, Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027, at 173-174 (2024) (IPAY 2027 Guidance); CMS, Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, at 104 (2023) (IPAY 2026 Guidance).

Mahmoud Decl. ¶ 23. On February 11, 2026, AbbVie filed this lawsuit challenging, under section 706(2)(C) of the Administrative Procedure Act (APA) or, alternatively, as *ultra vires*, the selection of BOTOX as exceeding Defendants' statutory authority, and further claiming that the selection violates AbbVie's rights under the First and Fifth Amendments to the U.S. Constitution. Compl., Dkt. 1.

LEGAL STANDARD

Summary judgment is appropriate when "the pleadings, the discovery and disclosure materials on file, and any affidavits [or declarations] show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." *Capital Area Immigrants' Rights Coalition* v. *Trump*, 471 F. Supp. 3d 25, 36 (D.D.C. 2020) (internal quotation marks and citation omitted). In "a case involving review of a final agency action under the Administrative Procedure Act," summary judgment "serves as the mechanism for deciding, as a matter of law, whether the agency action is . . . consistent with the APA standard of review." *Id.* at 36 (internal quotation marks and citations omitted). Under that standard, a reviewing court "shall . . . hold unlawful and set aside agency action" that is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C).

ARGUMENT

When Congress enacted the Medicare Drug Price Negotiation Program (the Program) as part of the IRA, it expressly prohibited CMS from selecting and "negotiating" a "maximum fair price" for—that is, imposing price controls on—any "biological product that is derived from human whole blood or plasma." 42 U.S.C. § 1320f-1(e)(3)(C). Notwithstanding that express prohibition, and in contravention of three consecutive years of agency guidance, Defendants selected BOTOX, a medicine derived from human plasma, for price controls. This Court should invalidate and set aside Defendants' selection of BOTOX as exceeding their statutory authority or,

alternatively, as *ultra vires*. Moreover, Defendants' decision to subject AbbVie to the IRA's crushing price controls, all while forcing AbbVie to declare its support for these sham negotiations, violates not only the IRA, but also the First and Fifth Amendments.

I. This Court Has Jurisdiction To Review Defendants' Unlawful Selection Of BOTOX

A. AbbVie Has Article III Standing To Challenge BOTOX's Selection

AbbVie has Article III standing to bring these claims. As the holder of the approved Biologics License Application for BOTOX, AbbVie has the exclusive right to market BOTOX. *See* Brin Decl. ¶¶ 9, 11. Selection inevitably "will lower the price" for BOTOX, *National Infusion Center Association* v. *Becerra*, 116 F.4th 488, 501 (5th Cir. 2024) (*NICA*), because the IRA requires CMS to set the "maximum fair price" at a substantial discount to the price for the drug on the private wholesale market, *see* 42 U.S.C. § 1320f-3(c); Mahmoud Decl. ¶¶ 30-31. This "lower price will lead to lower revenue" for AbbVie. *NICA*, 116 F.4th at 501. Furthermore, selection of BOTOX will compel AbbVie to participate in the IRA's sham "negotiation" process, in which AbbVie will be forced to express messages with which it disagrees, *see* pp. 36-38, *infra*, which is classic First Amendment injury. *See Johanns* v. *Livestock Marketing Association*, 544 U.S. 550, 557, 565 n.8 (2005); *id.* at 568 (Thomas, J., concurring). Because AbbVie is the "object of the action" under review, will suffer both pocketbook and expressive injuries, and would have those injuries redressed by a favorable ruling, there is "little question" that it has standing to challenge BOTOX's selection. *Diamond Alternative Energy, LLC* v. *EPA*, 606 U.S. 100, 112, 114 (2025).

B. The IRA's Judicial-Review Bar Is Inapplicable

Defendants will presumably argue that this Court lacks jurisdiction to consider whether their actions violated both the IRA and the Constitution. That argument is meritless. The IRA's judicial-review bar does not prevent this Court from setting aside the selection of BOTOX as a

flagrant violation of the statute's plasma-derived-products exclusion. The IRA's limitation on judicial review, 42 U.S.C. § 1320f-7, restricts review of actions taken "under" specific statutory provisions. Specifically, the IRA provides that "[t]here shall be no administrative or judicial review" of several actions under the Program, including "[t]he selection of drugs under [42 U.S.C. § 1320f-1(b)], the determination of negotiation-eligible drugs under [42 U.S.C. § 1320f-1(d)], and the determination of qualifying single source drugs under [42 U.S.C. § 1320f-1(e)]." 42 U.S.C. § 1320f-7(2). Under a long line of D.C. Circuit decisions, that limitation does not bar review of claims that Defendants violated those provisions; it simply makes the jurisdictional and merits analyses coextensive. Because the selection of BOTOX contravenes the statute's plasma-derived-products exclusion, Defendants exceeded their statutory authority and did not act "under" those provisions. Moreover, the IRA's judicial-review bar falls far short of the high standard required to preclude AbbVie's claims that the selection of BOTOX inflicts an uncompensated taking and a deprivation of property without due process of law, in violation of the Fifth Amendment, and compels AbbVie to express messages with which it disagrees, in violation of the First Amendment.

1. This Court Has Jurisdiction To Review The Merits Of AbbVie's Claims That The Selection Of BOTOX Exceeded Defendants' Statutory Authority

The IRA's judicial-review bar does not prevent this Court from reviewing the merits of AbbVie's claims that Defendants exceeded their statutory authority, because this Court must consider the merits of those claims to decide whether the judicial-review bar applies in the first place. Section 1320f-7 does not prohibit all review of the "selection of drugs" or "determination of negotiation-eligible" or "qualifying single source drugs." Instead, that provision bars review only of the "selection" or "determination" of drugs "under" the specific statutory provisions that authorize CMS to select drugs for negotiation and that prescribe how CMS must exercise that authority. 42 U.S.C. § 1320f-7(2). Under longstanding D.C. Circuit precedent, that judicial-

review bar is inapplicable unless the court finds that Defendants' selection of BOTOX complied with—and thus was made "under"—42 U.S.C. § 1320f-1(b), (d), and (e).[12] Because AbbVie's statutory claim challenges Defendants' authority under those provisions to select BOTOX, the judicial-review bar "merges consideration of the legality of [Defendants'] action with consideration of the court's jurisdiction." *American Hospital Association* v. *Azar*, 964 F.3d 1230, 1238 (D.C. Cir. 2020).

a. "There is a 'strong presumption that Congress intends judicial review of administrative action,'" and "[t]he presumption is particularly strong that Congress intends judicial review of agency action taken in excess of delegated authority." *Amgen, Inc.* v. *Smith*, 357 F.3d 103, 111 (D.C. Cir. 2004) (quoting *Bowen* v. *Michigan Academy of Family Physicians*, 476 U.S. 667, 670 (1986)). Applying those principles, the D.C. Circuit has repeatedly read similarly worded judicial-review provisions as allowing courts to review claims that agencies exceeded their statutory authority. *See American Hospital Association*, 964 F.3d at 1238 (discussing *Amgen*, 357 F.3d at 113-114; *COMSAT Corp.* v. *FCC*, 114 F.3d 223, 227 (D.C. Cir. 1997); *Southwest Airlines* v. *TSA*, 554 F.3d 1065, 1071 (D.C. Cir. 2009)). Particularly when a statute prohibits judicial review of agency action "pursuant to," "under," or "described in" a specific statutory provision, the judicial-review bar applies only to the extent that the agency's action complied with that provision. *See*, *e.g.*, *Southwest Airlines*, 554 F.3d at 1071; *Amgen*, 357 F.3d at 113-114; *COMSAT*, 114 F.3d at 227. By that logic, "[t]he same agency error [will]

[12] A claim under the APA that an agency exceeded its statutory authority is distinct from a claim that an agency or official acted *ultra vires*. *Nuclear Regulatory Commission* v. *Texas*, 605 U.S. 665, 680 (2025). Although AbbVie's primary argument is that the selection of BOTOX is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right" and thus violates the APA, AbbVie, in the alternative, also challenges the selection of BOTOX as *ultra vires*.

simultaneously ma[ke] the jurisdictional bar 'inapplicable' and compel[] setting aside the challenged agency action." *DCH Regional Medical Center* v. *Azar*, 925 F.3d 503, 510 (D.C. Cir. 2019); *accord American Hospital Association*, 964 F.3d at 1238. Where jurisdiction and the merits are coextensive, the court may "simply skip to the merits." *American Hospital Association*, 964 F.3d at 1238.

Multiple D.C. Circuit decisions illustrate this "merged" inquiry. In *COMSAT*, a common carrier challenged the FCC's imposition of a new fee schedule as exceeding the agency's authority under section 9 of the Communications Act of 1934. 114 F.3d at 225-226. The FCC argued that the D.C. Circuit lacked jurisdiction because the Communications Act provided that "[i]ncreases or decreases in fees made by amendments pursuant to this paragraph shall not be subject to judicial review." *Id.* at 227 (quoting 47 U.S.C. § 159(b)(3)). The D.C. Circuit rejected that argument, concluding that the Act barred judicial review only "where the Commission has acted within the scope of its authority under section 9," not where "the Commission has acted outside the scope of its statutory mandate." *Id.* The Act thus "merge[d] consideration of the legality of the Commission's action with consideration of [the] court's jurisdiction." *Id.*

Likewise, in *Amgen*, the D.C. Circuit construed a provision of the Medicare statute barring "administrative or judicial review" of the "development of the [prospective payment] classification system under paragraph (2), including . . . other adjustments" to apply only to "those 'other adjustments' that the Medicare Act authorizes the Secretary to make," and not "those for which such authority is lacking." 357 F.3d at 111-112, 113. And similarly, in *Southwest Airlines*, the D.C. Circuit concluded that a provision barring review of "[d]eterminations . . . under" a certain statutory provision did not preclude review of whether a determination complied with that provision. 554 F.3d at 1067-1069. As the court explained, the "jurisdiction-stripping provision

[did] not apply" because the court's "conclusion rest[ed] not on a review of a 'determination . . . under' the subparagraph covered by the [no-review] provision, but rather resolve[d] the question whether TSA has made the kind of determination required by the statute." *Id.* at 1071.[13]

That merged consideration of jurisdiction and the merits prevents the government from insulating unlawful action from judicial review: "Otherwise, agencies could characterize reviewable or unauthorized action as falling within the scope of no-review provisions whose application to such action Congress did not intend." *Amgen*, 357 F.3d at 113. As the *COMSAT* court explained, it would be "preposterous" if "any Commission action purportedly taken pursuant to section 9" was "shield[ed] from judicial review," as such an interpretation would permit, for example, the FCC to "impose a tax . . . on an individual for eating ice cream, so long as the FCC claimed to be acting under section 9." 114 F.3d at 227. The D.C. Circuit refused to accept such a "bald assertion of power" by the agency. *Id.* (citation omitted).

b. The IRA's judicial-review bar is indistinguishable from other statutory provisions the D.C. Circuit has read as requiring courts to consider the merits to decide whether a limitation on jurisdiction applies. The IRA's judicial-review bar states that "[t]here shall be no administrative or judicial review of," among other things, the "selection of drugs under section 1320f-1(b)," "the determination of negotiation-eligible drugs under section 1320f-1(d)," and the "determination of qualifying single source drugs under section 1320f-1(e) of this title." 42 U.S.C. § 1320f-7(2). Like the provisions in *COMSAT* and *Southwest Airlines*, the IRA insulates from review only the

[13] The D.C. Circuit has continued to apply that "merged" inquiry in numerous cases since *COMSAT*, *Amgen*, and *Southwest Airlines* were decided. *See*, *e.g.*, *Fresno Community Hospital & Medical Center* v. *Cochran*, 987 F.3d 158, 161 (D.C. Cir. 2021); *American Hospital Association*, 964 F.3d at 1238; *DCH Regional Medical Center*, 925 F.3d at 510; *Knapp Medical Center* v. *Hargan*, 875 F.3d 1125, 1128 (D.C. Cir. 2017); *Sky Television, LLC* v. *FCC*, 589 Fed. Appx. 541, 542-543 (D.C. Cir. 2014); *accord Ardelyx, Inc.* v. *Becerra*, 757 F. Supp. 3d 37, 47-51 (D.D.C. 2024).

"selection" or "determination" made "under" these statutory provisions. *Id*. By cross-referencing section 1320f-1(b), (d), and (e), the IRA expressly limits the judicial-review bar to apply only to challenges to agency actions authorized by those provisions, and not to actions "outside the scope of" the "statutory mandate." *See COMSAT*, 114 F.3d at 225-226. Indeed, if section 1320f-7(2) were read simply to preclude any review of "selection of drugs," "determination of negotiation-eligible drugs," or "determination of qualifying single source drugs," that provision's use of the limiting phrases "under section 1320f-1(b)," "under section 1320f-1(d)," and "under section 1320f-1(e)" would be unnecessary. The IRA should not be interpreted as if Congress was "wasting its breath with superfluous language." *Feliciano* v. *Department of Transportation*, 605 U.S. 38, 53 (2025).

Section 1320f-7(2) does not prevent this Court from reviewing AbbVie's claims that Defendants exceeded their statutory authority. Those claims allege that, by selecting BOTOX for price controls, Defendants exceeded their authority under section 1320f-1(e), which excludes from the definition of "qualifying single source drug" any "biological product that is derived from human whole blood or plasma." 42 U.S.C. § 1320f-1(e)(3)(C). The determination that BOTOX is a qualifying single source drug thus was *not* made "under section 1320f-1(e)." Because section 1320f-1(d) provides that only qualifying single source drugs can be "negotiation-eligible drugs," the determination that BOTOX was negotiation-eligible was *not* made under that provision. And because section 1320f-1(b) limits selection to "negotiation-eligible drugs," the selection of BOTOX was *not* made "under section 1320f-1(b)." Because Defendants' selection of BOTOX—a plasma-derived product—violated each of these provisions, that selection "fails to qualify as the kind of action for which review is barred." *American Hospital Association*, 964 F.3d at 1238.

Indeed, stretching section 1320f-7 to bar review of AbbVie's statutory claims would eviscerate any meaningful limits on CMS's authority under the Program. For example, the agency could purport to select every drug covered by Medicare, even though the statute allows it to select no more than 20 per year. *See* 42 U.S.C. § 1320f-1(a)(4). It could purport to select products with marketed generics, or even generics themselves, even though the IRA authorizes the selection of only certain brand-name drugs without marketed generics or biosimilars. *See* 42 U.S.C. § 1320f-1(e)(1). Defendants could attempt to ignore even the minimal procedures the IRA requires them to follow when selecting drugs and imposing price controls. And neither this nor any other Court could stop them. Rather than "countenance" that "preposterous position," *COMSAT*, 114 F.3d at 227, this Court should proceed to the merits of AbbVie's claims.

c. Even if there were "substantial doubt" about the scope of the IRA's judicial-review bar, "the general presumption favoring judicial review of administrative action is controlling" and dictates merits review of AbbVie's claims that BOTOX is exempt from selection. *Bowen*, 476 U.S. at 672 n.3 (citation omitted); *see also Kucana* v. *Holder*, 558 U.S. 233, 251 (2010) (noting that "[w]hen a statute is reasonably susceptible to divergent interpretation, we adopt the reading that accords with traditional understandings and basic principles: that executive determinations generally are subject to judicial review" (internal quotation marks and citation omitted)).

2. This Court Has Jurisdiction To Review AbbVie's Constitutional Claims

The IRA's judicial-review bar does not deprive this Court of jurisdiction to review AbbVie's constitutional claims. "[W]here Congress intends to preclude judicial review of constitutional claims its intent to do so must be clear." *Webster* v. *Doe*, 486 U.S. 592, 603 (1988). Courts "require [a] heightened showing in part to avoid the serious constitutional question that would arise if a federal statute were construed to deny any judicial forum for a colorable constitutional claim." *Id*. (internal quotation marks and citation omitted). This "rigorous clear-

and-convincing standard applies to both facial and as-applied constitutional claims." *Ralls Corp.* v. *Committee on Foreign Investment in the United States*, 758 F.3d 296, 308 (D.C. Cir. 2014) (internal quotation marks and citation omitted).

Nothing in the IRA suggests any intent to preclude the sorts of constitutional challenges asserted in AbbVie's complaint. There is "no affirmative statement in the text" of 42 U.S.C. § 1320f-7 "addressing judicial review of constitutional claims," and its "broadly worded statutory bar" does not make that showing either. *Ralls Corp.*, 758 F.3d at 309. The IRA precludes "administrative or judicial review" of specific actions taken by CMS, but the D.C. Circuit has deemed similarly worded judicial-review bars not to preclude constitutional challenges. *See*, *e.g.*, *id*. at 311 (holding that a statute barring "judicial review" of "actions of the President under" a particular statutory provision "does not . . . refer to the reviewability of a constitutional claim challenging the process preceding such presidential action"). The IRA is also devoid of "clear and convincing evidence of Congress's intent to channel review of as-applied challenges" to another forum "and away from federal courts." *Newman* v. *Moore*, 151 F.4th 472, 480 (D.C. Cir. 2025). Congress has not precluded constitutional challenges in this context, so the Court can review AbbVie's constitutional claims.

II. Defendants Exceeded Their Statutory Authority By Selecting BOTOX For Price Controls

By excluding from the definition of a "qualifying single source drug" any "biological product that is derived from human whole blood or plasma," Congress made clear that plasma-derived products cannot be selected for "negotiation." *See* 42 U.S.C. § 1320f-1(d)(1), (e)(1), (e)(3)(C). BOTOX, which contains human serum albumin (HSA), is a "biological product . . . derived from human . . . plasma" and is therefore ineligible for IRA price controls. Because Defendants' selection of BOTOX violated this express statutory prohibition, that selection should

be "set aside" as "in excess of statutory jurisdiction, authority, or limitations," 5 U.S.C. § 706(2)(C), or, alternatively, as *ultra vires*, *see National Association of Postal Supervisors* v. *USPS*, 26 F.4th 960, 966 (D.C. Cir. 2022).

A. Through The IRA, Congress Excluded Plasma-Derived Biological Products From Selection For Price Controls

When it enacted the IRA, Congress unambiguously prohibited CMS from selecting plasma-derived biological products like BOTOX for price controls. CMS may select a product for price controls only if that product is a "negotiation-eligible drug[]" and meets certain other criteria. 42 U.S.C. § 1320f-1(b). To be a "negotiation-eligible drug," a product must be, among other things, a "qualifying single source drug." 42 U.S.C. § 1320f-1(d)(1). And to be a "qualifying single source drug," a product must be (to simplify) a small-molecule drug that has been approved for at least seven years and which is not the listed drug for a marketed generic, or a biological product that has been licensed for at least 11 years and which is not the reference product for a marketed biosimilar. 42 U.S.C. § 1320f-1(e)(1).

In a section of the statute labeled "[e]xclusions," Congress also carefully articulated certain categories of drugs and biological products that cannot be considered "qualifying single source drugs" and thus are excluded from selection. 42 U.S.C. § 1320f-1(e)(3). These include "[c]ertain orphan drugs," "[l]ow spend medicare drugs," and, as relevant here, "[p]lasma-derived products." *Id*. Specifically, the IRA states that "the term 'qualifying single source drug' does not include "[a] biological product that is derived from human whole blood or plasma." 42 U.S.C. § 1320f-1(e)(3)(C).

B. Under The IRA's Plain Text, BOTOX Is A 'Plasma-Derived Product' That Is Ineligible For Price Controls

The express exclusion of plasma-derived biological products from the IRA's definition of "qualifying single source drug" precludes Defendants from selecting BOTOX for price controls

under the IRA. "Where the question is whether the agency action was consistent with statutory authorization," a court's task "is to determine whether the agency acted consistently with the 'best reading' of the statute." *Vanda Pharmaceuticals, Inc.* v. *FDA*, 123 F.4th 513, 521 (D.C. Cir. 2024) (quoting *Loper Bright Enterprises* v. *Raimondo*, 603 U.S. 369, 395 (2024)). Under the plain language of the IRA's plasma-derived-products exclusion, BOTOX is both a "biological product" and "derived from human . . . plasma." *See* 42 U.S.C. § 1320f-1(e)(3)(C).

1. BOTOX Is A 'Biological Product' Within The Meaning Of The IRA

The IRA does not define the term "biological product," but uses it to refer to a whole product in its finished, licensed form—and not, as the government may argue, solely to the active ingredient identified in the product labeling. That conclusion follows from multiple provisions of section 1320f-1 (the same section that contains the plasma-derived-products exclusion) and from the relevant statutory and regulatory context.

a. The IRA defines the term "qualifying single source drug" to include "[a] biological product" that is "licensed" and "marketed under [42 U.S.C.] § 262(a)"—that is, as the whole, finished product. 42 U.S.C. § 1320f-1(e)(1)(B)(i). When initially determining whether to classify a product as a drug requiring approval of a new drug application under 21 U.S.C. § 355 or as a biological product requiring approval of a biologics license application under 42 U.S.C. § 262, "FDA analyzes the product's 'active ingredient.' " *Ipsen Pharmaceuticals, Inc.* v. *Becerra*, 108 F.4th 836, 838 (D.C. Cir. 2024). As noted, FDA identifies "onabotulinumtoxinA" as BOTOX's active ingredient. *See* Brin Decl., Ex. 4 at 1.

FDA does not license active ingredients in isolation, however, nor does AbbVie market active ingredients by themselves. Instead, the "biological product" that is "licensed" and "marketed" under section 262 is the whole, finished product. Specifically, once FDA decides to regulate a pharmaceutical product pursuant to the 42 U.S.C. § 262 "biological product" statutory

pathway, FDA reviews and licenses the entire finished product, including all of its components, as a single "biological product." When submitting a biologics license application, a manufacturer must identify a specific finished dosage form for its proposed product, with a defined formulation (including *all* ingredients) and specific manufacturing process at a specified facility and location, and the manufacturer must comply with specific labeling requirements. *See* 42 U.S.C. § 262(a)(2)(C); 21 C.F.R. § 601.2. It is these finished dosage forms that FDA licenses and AbbVie markets under section 262 and which are ultimately "package[d]" and "introduce[d] . . . into interstate commerce." *See* 42 U.S.C. § 262(a)(1).

Multiple other provisions of section 1320f-1 turn on what the government spends on "biological products" and thus confirm that the "biological product" is the whole, finished product that is licensed and marketed. For example, to select drugs for price controls, CMS must first rank "negotiation-eligible drugs" according to the "total expenditures" for each such drug. 42 U.S.C. § 1320f-1(b)(1), (d); *see* 42 U.S.C. § 1320f(c)(5) (defining "total expenditures" by reference to 42 U.S.C. § 1395w-115(b)(3)). Similarly, another exclusion from the definition of "qualifying single source drug," the carve-out for "low spend Medicare drugs," excludes any "biological product" for which "total expenditures" are less than $200 million, adjusted for inflation. 42 U.S.C. § 1320f-1(e)(3)(B). Because the government pays for whole products—not active ingredients alone—the statute's use of "biological product" necessarily refers to the whole product, not just its active ingredient.

Section 1320f-1(f)(4) further confirms that the IRA refers to a "biological product" in the sense of a whole product. Subparagraph (f)(4)(B) sets forth the methodology for calculating the rebate that a manufacturer must pay when the Secretary delays selection of "a biological product that is a covered part D drug." 42 U.S.C. § 1320f-1(f)(4)(B)(i). A biological product cannot be a

"covered part D drug" unless "biological product" refers to the whole finished product, as Part D provides coverage for finished drugs, not active ingredients. *See* 42 U.S.C. §§ 1395w-102(e)(1), 1396r-8(k)(2)(A)-(B) (referring to approved prescription drugs and licensed biological products). Moreover, section 1320f-1(f)(4)(B) provides that the rebate must be calculated based on the product's "average manufacturer price," as "reported" under 42 U.S.C. § 1396r-8. 42 U.S.C. § 1320f-1(f)(4)(B)(i)(I)(aa). Because the "average manufacturer price" depends on what the manufacturer receives for certain wholesale and direct sales—i.e., sales of whole products, not active ingredients alone—that provision confirms that a "biological product" refers to the whole, finished drug, inclusive of both active and inactive ingredients. *See* 42 U.S.C. § 1396r-8(k)(1)(A).

b. Applying that definition, BOTOX constitutes a "biological product" in its whole, finished form. BOTOX is licensed in three strengths under a biologics license application (BLA 103000), which is held by AbbVie. Brin Decl., Ex. 7 § I.B; Brin Decl., Ex. 1. FDA initially approved that BLA in 1989—and has approved every subsequent supplemental application for BOTOX under 42 U.S.C. § 262, a provision of the Public Health Service Act (PHSA) regulating biological products. *See* Brin Decl. ¶ 6. While the number and scope of BOTOX's FDA-approved indications have evolved since its initial licensure in 1989, BOTOX has always been licensed as a biological product under the same BLA and with onabotA, HSA, and sodium chloride as its three ingredients. Brin Decl. ¶¶ 6, 12.

2. BOTOX Is 'Derived From Human Whole Blood Or Plasma'

In its whole, finished form as a licensed biological product, BOTOX is "derived from human whole blood or plasma." 42 U.S.C. § 1320f-1(e)(3)(C).

a. Because the IRA does not define when products are "derived from . . . plasma" and that phrase carries no "long-encrusted connotations," the statutory language must be given its ordinary meaning. *See Feliciano* v. *Department of Transportation*, 605 U.S. 38, 45 (2025). A

product is "derived from" a source when it is "obtain[ed]" from that source, *see* The New Oxford Dictionary of English 497 (2001 ed.); The American Heritage Dictionary of the English Language 489 (5th ed. 2018), or "made up or marked by derived elements," Derivative, Merriam-Webster's Medical Dictionary 199 (2016). The plasma-derived-products exclusion thus applies when a biological product is "derived from"—*i.e.*, "obtain[ed]" from, "made up of or marked by"—"human whole blood or plasma." Put differently, the plasma-derived-products exclusion applies when a biological product includes a component that is derived from human whole blood or plasma, regardless of whether the product consists solely of material obtained from blood or plasma.

First, reading the exclusion to include products that contain ingredients derived from plasma "give[s] effect . . . to every clause and word of [the] statute." *Fischer* v. *United States*, 602 U.S. 480, 486 (2024) (internal quotation marks omitted) (quoting *Williams* v. *Taylor*, 529 U.S. 362, 404 (2000)). Otherwise, the plasma-derived-products exclusion would apply only to biological products derived exclusively from human blood or plasma. Under that reading, a biological product containing a single ingredient not derived from whole blood or plasma (such as an inert stabilizer, preservative, or pH buffer) would never fall within the exclusion, no matter what the proportion or function of the whole blood or plasma component may be. Such an interpretation would render meaningless Congress's use of the term "biological product," which, as explained, encompasses a whole, finished product, inclusive of all ingredients.

Second, and relatedly, a contrary interpretation would require the Court to "read an absent word into the statute." *Lamie* v. *United States Trustee*, 540 U.S. 526, 538 (2004). The exclusion's text includes no requirement that a biological product be "wholly" or "directly" derived from whole blood or plasma, and there is no reason to rewrite the exclusion to impose such a limitation.

"With a plain, nonabsurd meaning in view," the Court "need not proceed in [such a] way." *Id.* The exclusion's plain meaning suffices.

Finally, other statutes use the term "derived from" in similar contexts to refer to a product obtained from another source, whether directly or by means of a component that is derived from that source. For example, the Family Smoking Prevention and Tobacco Control Act of 2009 (TCA), which amended the Federal Food, Drug, and Cosmetic Act (FDCA), defined "tobacco product" as "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product." 21 U.S.C. § 321(rr)(1) (2009). Applying that definition, the D.C. Circuit held that an e-cigarette satisfied that definition of "tobacco product" because one of its components was a "plastic cartridge" containing a "liquid nicotine mixture," which was, in part, "derived from tobacco." *Sottera, Inc.* v. *FDA*, 627 F.3d 891, 893, 897-898 (D.C. Cir. 2010); *see also FDA* v. *Wages & White Lion Investments, L.L.C.*, 604 U.S. 542, 555 (2025) (discussing a 2016 FDA rule deeming all e-cigarette and e-liquid products "tobacco products"). Such e-cigarette products were "derived from tobacco" even though, as the D.C. Circuit observed, they contain "myriad potentially hazardous substances not limited to those derived from tobacco," *Nicopure Labs, LLC* v. *FDA*, 944 F.3d 267, 293 (D.C. Cir. 2019), and do not themselves consist solely of tobacco or an extract thereof. Indeed, the FDA rule that first deemed e-cigarettes to be "tobacco products" provided that " 'covered tobacco products' include not only those that contain tobacco or nicotine, but also those that *contain any tobacco derivative*." Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act, 81 Fed. Reg. 28974, 28976 (May 10, 2016) (emphasis added).

Statutory context confirms that the phrase "derived from" should be read the same way in the IRA as in the TCA. Each provision involves FDA-regulated products, and both the TCA and the IRA use "derived from" to classify whether a product is subject to an agency's regulatory jurisdiction. The related context across these statutes provides strong reason to think that the term "derived from" "has the same meaning [in each,] despite contextual variations in the two admittedly different statutory schemes." *Environmental Defense* v. *Duke Energy Corp.*, 549 U.S. 561, 582 (2007) (Thomas, J., concurring in part).

b. BOTOX is subject to the plasma-derived-products exclusion because it includes a component derived from human whole blood or plasma. It contains HSA, a protein that is present in human blood plasma and extracted from plasma collected from human donors. Brin Decl. ¶ 14. HSA makes up much of the finished BOTOX product: approximately 100,000 times the content of onabotA per dose of BOTOX. *Id.* Indeed, there is no "BOTOX" without HSA. FDA has licensed BOTOX only in finished forms that have always included HSA. Brin Decl. ¶ 12. And BOTOX's FDA-approved product labeling states that the "product contains albumin, a derivative of human blood." Brin Decl., Ex. 4 § 5.14. Were AbbVie to distribute as "BOTOX" a preparation that omitted HSA, that product would not conform to BOTOX's approved BLA, and AbbVie would be barred from manufacturing and distributing it without changing the label and obtaining FDA licensure. *See* 21 U.S.C. §§ 331(a), 351-352, 356a; 42 U.S.C. § 262(a); 21 C.F.R. § 601.12. Because HSA, a plasma-derived protein, is a necessary component of FDA-licensed BOTOX, BOTOX is plasma-derived and ineligible for selection.

c. Although the IRA's plain text is reason enough to conclude that BOTOX is "derived from . . . plasma," 42 U.S.C. § 1320f-1(e)(3)(C), that conclusion also comports with CMS's public guidance interpreting the IRA. When it first imposed price controls under the IRA,

CMS issued guidance interpreting the plasma-derived-products exclusion to refer to a "licensed biological product that is derived from human whole blood or plasma, *as indicated on the approved product labeling*."[14] CMS reiterated this policy in the guidance for both IPAY 2027 and IPAY 2028.[15] The IPAY 2028 Guidance further states that CMS will, in consultation with FDA "as appropriate," "verify if [a] product is derived from human whole blood or plasma" by referring to the "product information available on the FDA Approved Blood Products website" and "databases such as FDALabel and the FDA Online Label Repository." IPAY 2028 Guidance 173; *accord* IPAY 2027 Guidance 173-174; IPAY 2026 Guidance 104.

BOTOX qualifies as a plasma-derived product under that guidance. Its "approved product labeling" states that the "product contains albumin, a derivative of human blood." Brin Decl., Ex. 4 § 5.14. And that information is confirmed by each of the FDA label databases to which CMS's guidance refers, namely, FDALabel and the FDA Online Label Repository. *See* Brin Decl., Ex. 7 § II.B. While CMS's guidance and practice cannot supersede the IRA's text, BOTOX qualifies as a plasma-derived product even under CMS's stated construction of the plasma-derived-products exclusion.

---

[14] CMS, Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, at 104 (2023) (IPAY 2026 Guidance) (emphasis added).

[15] CMS, Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027, at 173 (IPAY 2027 Guidance); CMS, 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 173 (2025) (IPAY 2028 Guidance).

* * * * *

The plain language of the plasma-derived-products exclusion makes clear that a biological product is categorically ineligible for selection under the Program if it contains material that itself is derived from human whole blood or plasma. BOTOX meets that statutory criterion because it is a biological product licensed under a BLA and it contains HSA, which is indisputably plasma-derived. Because Defendants disregarded the IRA's statutory command, their selection of BOTOX was "in excess of statutory jurisdiction, authority, or limitations," and should be held unlawful and set aside. 5 U.S.C. § 706(2)(C).

C. Alternatively, Defendants' Selection Of BOTOX Was *Ultra Vires*

If the Court concludes that the IRA's judicial-review bar precludes AbbVie's statutory-authority claim under the APA, it should nevertheless enjoin Defendants from implementing the selection of BOTOX on the alternative ground that the selection was *ultra vires*.

"Judicial review for *ultra vires* agency action rests on the longstanding principle that if an agency action is unauthorized by the statute under which [the agency] assumes to act, the agency has violated the law and the courts generally have jurisdiction to grant relief." *Federal Express Corp.* v. *Department of Commerce*, 39 F.4th 756, 763 (D.C. Cir. 2022) (internal quotation marks and citation omitted); *see Leedom* v. *Kyne*, 358 U.S. 184, 188 (1958). *Ultra vires* review is available when an agency "has taken action entirely in excess of its delegated powers and contrary to a specific prohibition in a statute" and where the statutory scheme does not provide "a meaningful and adequate opportunity for judicial review" or "foreclose[] all other forms of judicial review." *Nuclear Regulatory Commission* v. *Texas*, 605 U.S. 665, 681 (2025) (*NRC*) (internal quotation marks and citations omitted). Courts may review *ultra vires* action even when a statute implicitly precludes review. *See Nyunt* v. *Chairman, Broadcasting Board of Governors*, 589 F.3d 445, 449 (D.C. Cir. 2009) (Kavanaugh, J.).

Even if the selection of BOTOX were not reviewable under the APA, this Court could still review and enjoin that selection as *ultra vires*. By selecting BOTOX, a biological product derived from human plasma, for price controls under the IRA, Defendants have patently exceeded their "delegated powers" and acted "contrary to a specific prohibition" in the IRA that is "clear and mandatory." *Nyunt*, 589 F.3d at 449 (quoting *Kyne*, 358 U.S. at 188); *see Aid Association for Lutherans* v. *USPS*, 321 F.3d 1166, 1175 (D.C. Cir. 2003) (determining that an agency acted *ultra vires* when it "ignore[d] [a] limitation" in a statute and "totally pervert[ed]" the statute's meaning). Defendants cannot evade judicial review by pointing to supposed ambiguity as to whether the IRA's plasma-derived products exclusion applies to any derivative of human plasma or only to products containing an active ingredient that is itself derived from human plasma. As explained, the statute dictates that BOTOX—which in its FDA-licensed form necessarily includes HSA—is a plasma derivative that is excluded from selection. *See* pp. 27-31, *supra*. And as noted, Defendants' apparent construction "requires adding text to the [IRA] that Congress pointedly omitted," *National Association of Postal Supervisors*, 26 F.4th at 977, which confirms that their selection of BOTOX was *ultra vires*, *see* p. 28, *supra*. Because the selection of BOTOX is "an attempted exercise of power that had been specifically withheld" under a "specific prohibition" in the IRA—the plasma-derived-products exclusion—"nonstatutory review [must be] available" to examine and set aside Defendants' action. *NRC*, 605 U.S. at 681.

Nothing in this case supports withholding *ultra vires* review. Review of Defendants' unlawful selection of BOTOX should be available through the APA, s*ee* pp. 16-21, *supra*, but if that is not the case, AbbVie lacks an alternative "meaningful and adequate opportunity for judicial review" outside of its *ultra vires* claim. *See NRC*, 605 U.S. at 681. This is not a circumstance where Congress has substituted district-court jurisdiction by providing a "statutory review

procedure" that begins with the agency and "ultimately ends in a court of appeals." *See Sturm, Ruger & Co.* v. *Chao*, 300 F.3d 867, 874 (D.C. Cir. 2002) (citing *Thunder Basin Coal Co.* v. *Reich*, 510 U.S. 200, 216 (1994)). Nor does the IRA expressly "foreclose[] all other forms of judicial review." *See NRC*, 605 U.S. at 681; *Nyunt*, 589 F.3d at 449 (*ultra vires* review available where limitation on judicial review is "implied," not "express"). Because the IRA's judicial-review bar applies only to discrete agency actions carried out "under"—that is, in compliance with—specific statutory authorities, *see* p. 16-17, *supra*, that bar does not expressly preclude review of claims that Defendants acted contrary to or in excess of those specific statutory authorities when they selected BOTOX for price controls.

Accordingly, if this Court does not set aside Defendants' selection of BOTOX as unlawful under the APA, it should do so on the alternative basis that the agency's action was *ultra vires*.

III. The Drug Price Negotiation Program Violates AbbVie's Constitutional Rights

By selecting BOTOX, Defendants have not only ignored the IRA's plain text but subjected AbbVie to a price-control scheme that violates several constitutional provisions. The IRA forces AbbVie to hand over BOTOX for whatever the government decides to pay following a sham "negotiation" lacking any of the essentials of due process. Even worse, the IRA forces AbbVie to declare falsely that this mandated price is "fair" and results from "negotiations." The government defends this novel scheme as the price AbbVie pays for providing its products to Medicare and Medicaid beneficiaries. But the IRA's structure and economic reality leave AbbVie no way to opt out of this scheme. Even if they did, the Constitution prohibits the government from withholding benefits to coerce individuals into ceding their constitutional rights.

A. The IRA Effects An Unconstitutional Taking Of AbbVie's Property

The IRA violates the Fifth Amendment's Takings Clause because it requisitions AbbVie's property—its doses of BOTOX—at a substantial discount to "just compensation." U.S. Const.

amend. V. The government effects a classic or *per se* taking when, as here, it forces an owner to transfer title or possession to "itself or someone else," *Cedar Point Nursery* v. *Hassid*, 594 U.S. 139, 149 (2021), such that the owner loses the "rights to possess, use and dispose of" the appropriated property, *Loretto* v. *Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 435 (1982) (internal quotation marks and citation omitted). That is so whether the property is personal or real. *See Horne* v. *Department of Agriculture*, 576 U.S. 351, 357-358 (2015).

The Program "imposes a clear physical taking" of private property. *Bristol Myers Squibb Co.* v. *Secretary*, 155 F.4th 245, 273 (3d Cir. 2025) (Hardiman, J., dissenting) (*BMS*). After CMS imposes a "maximum fair price" for BOTOX, AbbVie must "provide access to such price" to Medicare enrollees and dispensing providers. 42 U.S.C. § 1320f-2(a)(1), (3). That requirement "forc[es] [AbbVie] to turn over physical doses of [BOTOX]," *BMS*, 155 F.4th at 273 (Hardiman, J., dissenting), and denies AbbVie's fundamental right to exclude others from that property, *see Horne*, 576 U.S. at 361-362, 364 (concluding that forcing raisin growers to "surrender" a portion of their raisin crop to the government effected a "clear physical taking"); *Cedar Point*, 594 U.S. at 144, 149-150 (holding that requiring property owners to cede a "right of access" to union organizers vitiated the "fundamental" right to exclude (internal quotation marks and citation omitted)). Having taken AbbVie's property, "[t]he government must pay for what it takes." *Id.* at 148.

B. The IRA Deprives AbbVie Of Property Without Due Process

The Program is also unconstitutional because it will deprive AbbVie of property without due process of law. AbbVie has a protected property interest in BOTOX encompassing "the rights to possess, use and dispose of" the product as it sees fit, the "right to exclude" others, and the right "to fix the price at which [it] will sell." *Horne*, 576 U.S. at 361-362 (internal quotation marks and citation omitted); *Cedar Point*, 594 U.S. at 149-150; *Old Dearborn Distributing Co.* v.

Seagram-Distillers Corp., 299 U.S. 183, 192 (1936). The Program will violate the Due Process Clause by requiring it to "provide access to" the "maximum fair price" to third parties, *see* 42 U.S.C. § 1320f-2(a)(1), (3), without providing AbbVie "the opportunity to be heard at a meaningful time and in a meaningful manner," *Mathews* v. *Eldridge*, 424 U.S. 319, 333 (1976) (internal quotation marks and citation omitted), by a "neutral and detached" decisionmaker, *Concrete Pipe & Products of California*, *Inc.* v. *Construction Laborers Pension Trust for Southern California*, 508 U.S. 602, 618 (1993).

First, CMS is not a "neutral and detached" decisionmaker. *Concrete Pipe*, 508 U.S. at 618. To the contrary, the IRA *requires* CMS to be biased by directing it to pursue "the *lowest* maximum fair price for each selected drug." 42 U.S.C. § 1320f-3(b)(1) (emphasis added).

Second, the Program's sham "negotiation" precludes any meaningful opportunity for AbbVie to view and contest CMS's evidence. *See Mathews*, 424 U.S. at 333. CMS must only submit "a concise justification" for its initial offer, 42 U.S.C. § 1320f-3(b)(2)(B), based on a nebulous "consider[ation]" of factors that the IRA neglects to guide CMS on "how to weigh," *NICA*, 116 F.4th at 495. And while AbbVie may submit a "counteroffer," CMS need not consider it, but only "respond in writing." 42 U.S.C. § 1320f-3(b)(2)(C), (D). And while CMS must "publish" its "explanation for the maximum fair price," it must do so only *after* negotiations conclude, when the price is fixed. 42 U.S.C. § 1320f-4(a)(2). At no point must CMS explain why a product is eligible for selection, nor does the IRA provide any means for AbbVie to formally object to selection of its products.

The Program aggravates the constitutional injury by limiting judicial and administrative review of many of CMS's key decisions. *See* 42 U.S.C. § 1320f-7. When upholding wartime price-control schemes, the Supreme Court emphasized that those schemes permitted some

"judicial review" and thus satisfied this basic "demand[] of due process." *Yakus* v. *United States*, 321 U.S. 414, 444 (1944); *see Bowles* v. *Willingham*, 321 U.S. 503, 521 (1944). The IRA's "abrogation of a well-established common-law protection against arbitrary deprivations of property raises a presumption that its procedures violate the Due Process Clause." *See Honda Motor Co.* v. *Oberg*, 512 U.S. 415, 430 (1994). While the partiality of the decisionmaker and the lack of an opportunity for AbbVie to be heard would each be constitutionally suspect on its own—particularly in combination with the Program's limits on judicial review—the Program's combination of deficient procedures creates a "substantial," unacceptable risk that AbbVie will be "erroneous[ly] depriv[ed]" of its property rights. *NICA*, 116 F.4th at 503.

C. The IRA Unconstitutionally Compels Speech

Not content simply to force manufacturers like AbbVie to hand over their products at prescribed prices, the IRA also requires them to voice their support for the expropriation. AbbVie is entitled to the protections of the First Amendment. *See Citizens United* v. *Federal Election Commission*, 558 U.S. 310, 342 (2010). Those protections include the right not to be "compel[led] . . . to speak [the government's] own preferred messages," *303 Creative LLC* v. *Elenis*, 600 U.S. 570, 586 (2023), or to have to "affirm[] . . . a belief with which [it] disagrees," *Hurley* v. *Irish-American Gay, Lesbian & Bisexual Group of Boston*, 515 U.S. 557, 573 (1995).

The IRA requires AbbVie to convey multiple messages with which it disagrees. Following selection of BOTOX, AbbVie had to "enter into" an "agreement[]" to "negotiate to determine" a "maximum fair price" for that product. 42 U.S.C. § 1320f-2(a). The agreement that AbbVie signed forced AbbVie to state, among other things, that "CMS and the Manufacturer agree" that they "shall negotiate to determine" and "agree to[] a maximum fair price for the [s]elected [d]rug." Mahmoud Decl., Ex. 4 at 1-2 (AbbVie Program Agreement). If, following that "negotiation," AbbVie does not "agree to" the "maximum fair price" dictated by CMS, 42 U.S.C. § 1320f-2(a)(1),

it faces crippling excise taxes of up to 1,900% of daily sales, *see* 26 U.S.C. § 5000D(a), (b)(2); p. 10, *supra*. CMS will document any ultimate "agreement" via an addendum, which proclaims that, having previously entered an agreement "to negotiate to determine a price (referred to as 'maximum fair price' in the Social Security Act)," the parties "have engaged in negotiation" and "now agree to" a specific price that is "binding." CMS, Medicare Drug Price Negotiation Program Agreement 7-9, <tinyurl.com/ManufacturerAgreementTemplate> (Template Program Agreement).

Absent compulsion, AbbVie would "disagree[]" with each of those government-"preferred" messages. *Hurley*, 515 U.S. at 573; *303 Creative*, 600 U.S. at 586. The Program, in which AbbVie is compelled to participate and which results in a price unilaterally dictated by the government, is not a "[n]egotiation." AbbVie Program Agreement 1; *see* Template Program Agreement 7; Mahmoud Decl. ¶ 29. Nor has AbbVie "agree[d]," AbbVie Program Agreement 2, to any aspect of the Program, in which it participates under compulsion, *see* Mahmoud Decl. ¶ 29. And AbbVie rejects that the government-determined, below-market price is the "maximum fair price"—a term that implies that AbbVie has historically overcharged Medicare payors and continues to do so in the private market. *See* AbbVie Program Agreement 2. "[R]equiring [AbbVie] to publicly condemn itself" in this manner is "constitutionally offensive." *National Association of Manufacturers* v. *SEC*, 800 F.3d 518, 530 (D.C. Cir. 2015) (internal quotation marks and citation omitted).

This compelled speech is particularly egregious given its "intentional and overwhelmingly apparent" use as a "political" tool. *BMS*, 155 F.4th at 285 (Hardiman, J., dissenting) (internal quotation marks and citation omitted). Had the government simply announced that it was imposing price controls for the drugs on which millions of Medicare beneficiaries rely, it would have faced

political consequences, especially if beneficiaries lost access to critical medicines. By misrepresenting that these price controls result from “agreement” and “negotiation,” however, the government attempted to shift responsibility to manufacturers, which can “disclaim” those falsehoods “only at the price of evident hypocrisy.” *Id.* at 286 n.14 (internal quotation marks and citation omitted).

Because the IRA “compel[s] [AbbVie] to utter or distribute speech bearing a particular message,” it is subject to “the most exacting scrutiny.” *Turner Broadcasting System, Inc.* v. *FCC*, 512 U.S. 622, 642 (1994). The IRA cannot withstand that scrutiny unless it is the “least restrictive means of achieving a compelling state interest.” *Free Speech Coalition, Inc.* v. *Paxton*, 606 U.S. 461, 471 (2025) (internal quotation marks and citation omitted). The government has no legitimate interest in compelling regulated entities to promote its favored viewpoint. Nor is that compelled speech narrowly tailored to achieving the IRA’s stated interest of reducing drug costs, *see* 42 U.S.C. § 1320f-3(b)(1), given that the government could simply dictate drug prices without the misleading façade of purportedly voluntary manufacturer participation, *see BMS*, 155 F.4th at 285-286 (Hardiman, J., dissenting). As such, the Program violates AbbVie’s First Amendment rights.

D. AbbVie’s Participation In The Drug Price Negotiation Program Is Involuntary

The government has defended the IRA’s price-control scheme on the ground that participation is voluntary: if manufacturers do not wish to accept the “maximum fair price,” they can withdraw their drugs from Medicare and Medicaid. *See*, *e.g.*, *Boehringer Ingelheim Pharmaceuticals, Inc.* v. *Department of Health & Human Services*, 150 F.4th 76, 88-91 (2d Cir. 2025); *BMS*, 155 F.4th at 256-257. But that purported option is legally and economically illusory.

1. A manufacturer has as little as one month between when CMS publishes the drugs selected for “negotiation” and the February 28 deadline to sign the Template Program Agreement. *See* 42 U.S.C. §§ 1320f(b)(3), 1320f-1(a), 1320f-2(a). The manufacturer must then accept CMS’s

imposed price by November 1 of that year. *See* 42 U.S.C. § 1320f-3(b)(2)(E). If a manufacturer refuses to participate or ultimately declines to sell its product at CMS's mandated price, it must pay crippling excise taxes of up to 1,900% on all sales of the selected drug until either the manufacturer acquiesces to CMS's set price or a specified time period elapses following marketing of a biosimilar. 26 U.S.C. § 5000D(a), (b)(1)-(2); 42 U.S.C. § 1320f-1(c). As set forth in the Mahmoud Declaration, AbbVie would have faced enormous tax liability had it opted out of the "negotiation." *See* Mahmoud Decl. ¶ 24.

2. The IRA purports to give a manufacturer that wishes neither to accept the "maximum fair price" nor pay those ruinous excise taxes a third option: it may withdraw all its drugs from Medicare and Medicaid. *See* 26 U.S.C. § 5000D(c). Manufacturers cannot, however, withdraw their products from Medicare and Medicaid in time to comply with the IRA's requirements. Medicaid imposes a 60-day delay between when a manufacturer files notice of its withdrawal and when withdrawal is effective, and Medicare similarly imposes either an 11- or 23-month delay depending on whether the manufacturer gives notice before or after January 30. 42 U.S.C. §§ 1396r-8(b)(4)(B)(ii), 1395w-114c(b)(4)(B)(ii). Those statutory waiting periods ensure that manufacturers remain enrolled in federal programs—and thus subject to the excise taxes—long after the March and November penalty dates. *See* 42 U.S.C. §§ 1320f-2(a), 1320f-3(b)(2)(E). As a result, a manufacturer can avoid the "enterprise-crippling" excise taxes only through compliance, rendering any participation involuntary. *See BMS*, 155 F.4th at 269-270 (Hardiman, J., dissenting).

Apparently recognizing that these waiting periods refute the notion that participation in the Program is voluntary, CMS attempted to rewrite the IRA through guidance. By law, CMS may unilaterally terminate its Medicare agreements with manufacturers on 30 days' notice based upon

"a knowing and willful violation of the requirements of the agreement or other good cause shown." 42 U.S.C. § 1395w-114c(b)(4)(B)(i). Relying on that authority, CMS has stated that if a manufacturer seeks to terminate its Medicare and Medicaid agreements to avoid Program participation, it will "automatically" treat that request as "constitut[ing] good cause" and grant it in 30 days. *See* IPAY 2028 Guidance 200-201. Even if CMS's position were legally valid, it would not render participation in the Program even formally voluntary.[16]

In any event, statutory text and structure foreclose CMS's efforts to "rewrite clear statutory terms to suit its own sense of how the statute should operate." *Utility Air Regulatory Group* v. *EPA*, 573 U.S. 302, 328 (2014). The "other good cause shown" requirement must be read in conjunction with "knowing and willful violations of the requirements of the agreement," *see McDonnell* v. *United States*, 579 U.S. 550, 568-569 (2016), as "refer[ring] to other forms of misconduct," not simply "whatever CMS wishes it to mean," *BMS*, 155 F.4th at 278 (Hardiman, J., dissenting). CMS's guidance "would render the voluntary termination provisions 'insignificant, if not wholly superfluous,' " thus "negat[ing] the option Congress enacted." *Id*. (quoting *Duncan* v. *Walker*, 533 U.S. 167, 174 (2001)). At bottom, CMS cannot rewrite the IRA to create a pathway for avoiding compliance that Congress never intended.

3. Withdrawing all drugs from federal government programs is not only legally illusory, but practically impossible. Simply put, "[t]he federal government dominates the

[16] For example, Defendants selected BOTOX for negotiation on January 27, 2026. *See* Mahmoud Decl., Ex. 3 at 1. The deadline for a manufacturer to "agree" to negotiate is February 28, with excise taxes beginning on March 1 if the manufacturer does not agree. 42 U.S.C. § 1320f-2(a); 26 U.S.C. § 5000D(b)(1). Accordingly, to accommodate the minimum 30-day withdrawal process, AbbVie would have needed to state its intent to withdraw all its drugs from Medicare and Medicaid two days after selection, on January 29, 2026. Moreover, had Defendants waited until the February 1 statutory deadline to select BOTOX, *see* 42 U.S.C. §§ 1320f(b)(3), 1320f-1(a), AbbVie could not have avoided incurring at least two days of excise taxes.

healthcare market." *Sanofi Aventis U.S. LLC* v. *United States Department of Health & Human Services*, 58 F.4th 696, 699 (3d Cir. 2023). "Through Medicare and Medicaid, [the federal government] pays for almost half the annual nationwide spending on prescription drugs," *id.*, spending $217 billion on retail outlet sales in 2024, CMS, Table 4: National Health Expenditures by Source of Funds and Type of Expenditure: Calendar Years 2017-2024, <tinyurl.com/NHE-Tables>. As detailed in the accompanying Mahmoud Declaration, Medicare and Medicaid account for a significant percentage of AbbVie's gross sales. Mahmoud Decl. ¶ 26. Those resources are essential to AbbVie's mission to discover and deliver innovative medicines and solutions that enhance people's lives. *Id.* Forcing AbbVie to withdraw all of its products from Medicare and Medicaid would also leave millions of Medicare and Medicaid patients without coverage for drugs they rely upon to treat serious, often life-threatening conditions, and upend AbbVie's relationships with providers. *See* Mahmoud Decl. ¶¶ 8, 26; *see also Mora* v. *Mejias*, 223 F.2d 814, 817 (1st Cir. 1955) ("wholly unrealistic" to believe that Puerto Rican rice importers could "withdraw[] from th[at] business" when they "suppl[ied] Puerto Rico with the most important staple in the diet of the people"); *cf. Jefferson Parish Hospital District No. 2* v. *Hyde*, 466 U.S. 2, 13-14 (1984) ("condemn[ing]" arrangements where an industry participant uses its "market power" to "force" another "to do something that [it] would not do in a competitive market"), *abrogated on other grounds by Illinois Tool Works Inc.* v. *Independent Ink, Inc.*, 547 U.S. 28 (2006). Economically, reputationally, and ethically, AbbVie cannot realistically withdraw all its products from government programs.

Nor can AbbVie simply pay a tax instead of accepting the government's price. To begin, the government cannot avoid the constitutional problems with the Program by exercising its coercive power through taxation rather than other means. *See Valancourt Books, LLC* v. *Garland*,

82 F.4th 1222, 1234-1235 (D.C. Cir. 2023); *cf. Arkansas Writers' Project, Inc.* v. *Ragland*, 481 U.S. 221, 230 (1987) (holding that a state's content-based sales-tax scheme violated the First Amendment). Regardless, as explained in the accompanying Mahmoud Declaration, AbbVie could hardly afford the "ruinous" taxes it faces if it does not comply with CMS's demands, *BMS*, 155 F.4th at 273 (Hardiman, J., dissenting); *see* 26 U.S.C. § 5000D(a)-(b); Mahmoud Decl. ¶ 24. Moreover, should AbbVie, having signed the AbbVie Program Agreement, ultimately decline to "provide access" to the selected drugs at the price CMS imposes, it would be subject to fines equal to 10 times the difference between the price it charges and the "maximum fair price." 42 U.S.C. § 1320f-6(a). The "threat of excise taxes and civil penalties looms like a sword of Damocles, creating a de facto mandate to participate." *BMS*, 155 F.4th at 273 (Hardiman, J., dissenting). AbbVie must choose between potentially "crippling" options: lose a significant percentage of its sales or pay billions in taxes. Mahmoud Decl. ¶ 24. The only "choice" the Program presents is that "between the rock and the whirlpool," *United States* v. *Butler*, 297 U.S. 1, 72 (1936)—no choice at all.

E. The IRA Is Unconstitutional Even If The Drug Price Negotiation Program Is Voluntary

Even if participation in the Program were in some sense "voluntary," that would not render the Program constitutional. The government "may not deny a benefit to a person on a basis that infringes his constitutionally protected interests," *Perry* v. *Sindermann*, 408 U.S. 593, 597 (1972), even where the individual "has no entitlement to that benefit," *United States* v. *American Library Association, Inc.*, 539 U.S. 194, 210 (2003) (plurality opinion) (internal quotation marks and citation omitted); *see also Koontz* v. *St. Johns River Water Management District*, 570 U.S. 595, 608 (2013) (collecting cases). The resulting "unconstitutional conditions doctrine forbids burdening the Constitution's enumerated rights by coercively withholding benefits from those who

exercise them." *Koontz*, 570 U.S. at 606. The IRA's conditions impermissibly burden AbbVie's rights under both the Takings Clause and First Amendment.

1. "Extortionate demands for property" can "impermissibly burden the right not to have property taken without just compensation." *Koontz*, 570 U.S. at 607. To prevent the government from forcing a property owner to surrender excessive property rights in order to exercise others, any imposed property condition must "have an essential nexus" to the government's interest and be "rough[ly] proportional[]" to the harm the government seeks to remedy. *Sheetz* v. *County of El Dorado*, 601 U.S. 267, 275-276 (2024) (internal quotation marks omitted); *see Nollan* v. *California Coastal Commission*, 483 U.S. 825, 837 (1987); *Dolan* v. *City of Tigard*, 512 U.S. 374, 391 (1994). Even assuming that the government satisfies the nexus requirement, the Program imposes an egregiously disproportionate condition on AbbVie. If it wishes to exercise its constitutional right not to sell BOTOX to Program beneficiaries and providers at below-market prices, AbbVie must withdraw *all* its products from Medicare and Medicaid. That tactic smacks of the type of "out-and-out . . . extortion," *Sheetz*, 601 U.S. at 275 (internal quotation marks and citation omitted), that the unconstitutional-conditions doctrine exists to prevent.

2. The Program also places unconstitutional conditions on AbbVie's exercise of its First Amendment rights. The government may not condition benefits on recipients' "profess[ing] a specific belief." *Agency for International Development* v. *Alliance for Open Society International, Inc.*, 570 U.S. 205, 218-219 (2013). The Supreme Court has distinguished conditions that permissibly "specify the activities Congress wants to subsidize" from those that unconstitutionally "seek to leverage funding to regulate speech outside the contours of the program itself." *Id.* at 214-215. When the government "demand[s] that funding recipients adopt—as their

own—the Government's view on an issue of public concern, the condition *by its very nature* affects protected conduct *outside the scope* of the federally funded program" and thus "falls on the unconstitutional side of the line." *Id*. at 217-218 (internal quotation marks and citation omitted; emphasis added). So too, here. To receive Medicare and Medicaid reimbursement for any of its drugs, AbbVie must misstate that it has "agree[d]" to participate, "negotiate[d]" with CMS, and arrived at a "maximum fair price" for BOTOX. AbbVie Program Agreement 2; *accord* Template Program Agreement 7. Those expressions "convey the Government's message about a subject of great political significance and debate: whether the Program is a voluntary negotiation or a forced sale at prices set by CMS." *BMS*, 155 F.4th at 286 (Hardiman, J., dissenting). Congress may choose how to spend Medicare dollars, but it cannot require AbbVie "to pledge allegiance" to the government's chosen policy as a condition of receiving them. *Agency for International Development*, 570 U.S. at 220.

CONCLUSION

For the foregoing reasons, the Court should grant AbbVie summary judgment.

Date: April 28, 2026

Respectfully submitted,

/s/ Kannon K. Shanmugam__
Kannon K. Shanmugam (D.C. Bar 474304)
DAVIS POLK & WARDWELL LLP
1050 17th Street, N.W.
Washington, DC 20036
(202) 962-7000
kshanmugam@davispolk.com

S. Conrad Scott (D.C. Bar 1685829)*
Joshua A. Altman*
PAUL, WEISS, RIFKIND,
WHARTON & GARRISON LLP
1285 Avenue of the Americas
New York, NY 10019
(212) 373-3000

Eleanor K. Ritter (D.C. Bar 90041795)*
J. Corey Schiff (D.C. Bar 90033134)*
PAUL, WEISS, RIFKIND,
WHARTON & GARRISON LLP
2001 K Street, N.W.
Washington, DC 20006
(202) 223-7300

*Admitted *pro hac vice*

Counsel for Plaintiff AbbVie Inc.