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SUMMARY

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Constitutional Challenges to the Medicare Drug Price Negotiation Program

Congress created the Medicare Drug Price Negotiation Program (the program) through the budget reconciliation measure known as the Inflation Reduction Act (IRA; P.L. 117-169), which became law on August 16, 2022. The program allows Medicare to negotiate the prices of certain Medicare drugs directly with drug manufacturers for the first time. The Centers for Medicare and Medicaid Services (CMS), the division of the U.S. Department of Health and Human Services (HHS) tasked with administering the program, has issued guidance to explain the program's initial implementation. On August 29, 2023, CMS selected the first 10 Medicare Part D drugs that will be subject to negotiated prices in 2026. The agency announced the negotiated prices for those drugs on August 14, 2024.

In summer 2023, several drug manufacturers and trade associations representing manufacturers challenged the law before federal district courts across the country. The plaintiffs made various arguments in different lawsuits, including that the law is unconstitutional under the First, Fifth, and Eighth Amendments. They also alleged violations of the Nondelegation Doctrine, the Spending Clause, and the Administrative Procedure Act.

The plaintiffs argued that the IRA violates the First Amendment because it forces manufacturers to sign a pricing agreement with the Secretary of HHS that characterizes the negotiated price of the drug as "fair," which amounts to compelled speech. The plaintiffs also argued that the IRA violates the Fifth Amendment, both the Due Process Clause and the Takings Clause. First, the plaintiffs claimed that the IRA violates the Due Process Clause because it lacks the requisite procedural safeguards, including notice, the opportunity to be heard, and the potential for judicial review. Second, the plaintiffs alleged that the law constitutes a taking of both tangible property (drugs) and intangible property (patents). Some of the plaintiffs claimed that the program amounts to a per se taking, while others argue that it constitutes a regulatory taking.

A few of the plaintiffs argued that the IRA violates the Eighth Amendment Excessive Fines Clause because the excise tax to which manufacturers of selected drugs that do not comply with the statute will be subjected is really a punishment disguised as a tax. The trade association plaintiffs argued that the IRA violates the Nondelegation Doctrine by ceding too much power to the Secretary of HHS to set drug prices. Finally, several plaintiffs argued that the IRA cannot be justified on the basis of Congress's Spending Clause power because the IRA does not condition the receipt of federal funding on a manufacturer's participation in the program. The plaintiffs further alleged that even if the IRA could be said to impose such a condition, the statute does not provide adequate notice of the condition, the condition is not related to the purpose of the spending and is unconstitutionally coercive, and compliance with the condition would violate manufacturers' other rights under the Constitution.

Of the 10 cases initially filed, one was voluntarily dismissed, two remain pending in federal district court, and seven have been decided at the federal district court level. Some of the decisions issued so far were appealed and, to date, one appeal has been decided; the appellate court remanded the case to the district court. Thus, there are three cases pending in federal district courts at the time of this writing. Of the district court cases decided so far, two did not reach the merits of the constitutional claims because they were dismissed for procedural reasons. As discussed in this report, the other decisions reached the merits of some of the plaintiffs' constitutional challenges, but none of the plaintiffs' constitutional claims have been successful to date. Six of the decisions issued were appealed to the U.S. Courts of Appeals for the Second, Third, Fifth, and Sixth Circuits, and the cases before the Second, Third, and Sixth Circuits remain pending. Thus far, attempts to enjoin CMS's implementation of the program have been unsuccessful. Some stakeholders predict that the litigation could eventually reach the U.S. Supreme Court.

This report explains and contextualizes the plaintiffs' constitutional claims by analyzing relevant U.S. Supreme Court jurisprudence, and it discusses the federal district courts' resolution of the claims thus far. The Administrative Procedure Act claims are outside the scope of this report but are discussed in other CRS products. The report concludes by identifying relevant considerations for the 118th Congress as the litigation proceeds.

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Congress created the Medicare Drug Price Negotiation Program (the program) in a budget reconciliation measure known as the Inflation Reduction Act (IRA), which became law on August 16, 2022.[1] Beginning in June 2023, several pharmaceutical manufacturers and trade associations filed lawsuits in various federal district courts alleging that the program was unconstitutional and violated the Administrative Procedure Act (APA).[2] These cases, brought against the U.S. Department of Health and Human Services (HHS) and the Centers for Medicare and Medicaid Services (CMS), were filed in D.C. District Court, the U.S. District Court for the Southern District of Ohio, the New Jersey District Court, the U.S. District Court for the Western District of Texas, the U.S. District Court for the Northern District of Illinois, the U.S. District Court for the District of Connecticut, and the U.S. District Court for the District of Delaware.[3] Taken together, the cases brought a variety of facial constitutional challenges against the IRA, including under the First, Fifth, and Eighth Amendments; the Nondelegation Doctrine; and the Spending Clause.[4] Additionally, at least two of the plaintiffs also argued that the CMS Guidance implementing the program violates the APA.[5]

The IRA authorizes the Secretary of HHS, via CMS, to negotiate the prices of certain qualifying, single-source drugs directly with manufacturers for the first time.[6] The program will apply to certain single-source prescription drugs and biological products covered by Medicare Part B (physician-administered drugs) and Medicare Part D (retail prescription drugs).[7] The IRA instructs CMS to implement the first three years of the program (price years 2026–2028) through "program instruction or other forms of program guidance."[8] As described in previous CRS

[1] Inflation Reduction Act of 2022, Pub. L. No. 117-169, 136 Stat 1818. The IRA is codified in multiple titles of the *U.S. Code*. The relevant sections of the Medicare Drug Price Negotiation Program are found at 42 U.S.C. §§ 1320f-1–1320f-7.

[2] Administrative Procedure Act, 609 Stat. 237 (1946) (codified at 5 U.S.C. §§ 551–559).

[3] Complaint, Merck & Co. v. Becerra (Merck Compl.), No. 23-1616 (D.D.C. June 6, 2023), ECF No. 1. Complaint, U.S. Chamber of Com. et al. v. Becerra (Chamber of Com. Compl.), No. 23-0156 (S.D. Ohio June 9, 2023), ECF No. 1; Complaint, Bristol Myers Squibb Company v. Becerra (Bristol Myers Compl.), No. 23-3335 (D.N.J. June 16, 2023), ECF No. 1; Complaint, Nat'l Infusion Center et al. v. Becerra (PhRMA Compl.), No. 23-0707 (W.D. Tex. June 21, 2023), ECF No. 1; Complaint, Janssen Pharms. v. Becerra (Janssen Compl.), No 23-3818 (D.N.J. July 18, 2023), ECF No. 1; Complaint, Astellas Pharms. v. Becerra (Astellas Compl.), No. 23-4578 (N.D. Ill. July 14, 2023), ECF No. 1; Complaint, Boehringer Ingelheim Pharms. v. Becerra (Boehringer Compl.), No. 23-01103 (D. Conn. Aug. 18, 2023), ECF No. 1; Complaint, AstraZeneca Pharms. v. Becerra (AstraZeneca Compl.), No. 23-0931 (D. Del. Aug. 25, 2023), ECF No. 1.

[4] Complaints, *supra* note 3.

[5] AstraZeneca Compl. at 7; Boehringer Compl. at 8. This report addresses only the plaintiffs' constitutional challenges. For more information about the APA challenges, *see* CRS Legal Sidebar LSB11112, *Administrative Procedure Act Challenges to CMS's Implementation of the Medicare Drug Price Negotiation Program*, by Hannah-Alise Rogers (2024).

[6] Inflation Reduction Act of 2022, Pub. L. No. 117-169, §§ 11001-02, 136 Stat. 1818 (codified at 42 U.S.C. §§ 1320f-1 –1320f-7).

[7] The statute's definition of "qualifying single source drug" distinguishes between drug products and biological products. 42 U.S.C. § 1320f-1(e)(1)(A)–(B). For a drug product to be a qualifying single-source drug, (1) the drug must be a covered Part B or Part D drug, be approved by the U.S. Food and Drug Administration (FDA), and be marketed pursuant to such approval; (2) at least seven years must have passed since the initial approval; and (3) the drug cannot be the listed drug for any approved and marketed generic drug. *Id*. § 1320f-1(e)(1)(A)(i)-(iii). For a biological product to be a qualifying single-source drug, the statute requires the covered Part B or Part D biological product (1) to be licensed under Section 351 of the Public Health Service Act (42 U.S.C. §§ 201–239*l*-3) and be marketed under the license; (2) to have been marketed for at least 11 years from the date of initial licensure; and (3) to not be the reference product for any other licensed and marketed biosimilar. *Id.* § 1320f-1(e)(1)(B)(i)-(iii).

[8] The statute directs CMS to carry out the first three years of the program (price years 2026–2028) "by program instruction or other forms of program guidance." 42 U.S.C. § 1320f note. In its Revised Guidance, CMS states that it "will develop its policies for 2029 and all subsequent initial price applicability years of the Negotiation Program (continued...)

reports, CMS began implementing the Medicare Drug Price Negotiation Program by issuing Initial Guidance for price applicability year 2026 on March 15, 2023.[9] CMS subsequently issued Revised Guidance on June 30, 2023, to address stakeholder concerns regarding the selection of negotiation-eligible drugs and the factors to be considered when evaluating maximum fair prices (MFPs).[10] In accordance with the statute, on August 29, 2023, CMS selected the first 10 drugs for price negotiation.[11] On May 4, 2024, CMS issued more guidance for price applicability year 2027.[12]

On August 14, 2024, CMS announced the negotiated prices for the first 10 selected drugs, which represented between a 38% and 79% discount from the drugs' list prices.[13] The MFPs are scheduled to take effect on January 1, 2026.[14] As discussed in the CMS Guidance for price applicability year 2027, CMS will select 15 more drugs for negotiation on February 1, 2025, and those prices will take effect on January 1, 2027.[15]

through notice-and-comment rulemaking." 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 2 (June 30, 2023), https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf [hereinafter CMS REVISED GUIDANCE].

[9] CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS), MEDICARE DRUG PRICE NEGOTIATION PROGRAM: INITIAL MEMORANDUM, IMPLEMENTATION OF SECTIONS 1191–1198 OF THE SOCIAL SECURITY ACT FOR INITIAL PRICE APPLICABILITY YEAR 2026, AND SOLICITATION OF COMMENTS (Mar. 15, 2023), https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf.

For a description of the Medicare Drug Price Negotiation Program, the CMS Guidance, and the statute's limitations on judicial review, *see* CRS Report R47555, *Implementation of the Medicare Drug Price Negotiation Program: Centers for Medicare and Medicaid Guidance and Legal Considerations*, by Hannah-Alise Rogers (2023). For a complete summary of the IRA's changes to Medicare, Medicaid, and private insurance, *see* CRS Report R47396, *Health Care Provisions of the Budget Reconciliation Measure P.L. 117-169*, coordinated by Katherine M. Kehres (2022). For a brief overview of the IRA's changes to the Medicare Program, including an overview of the program and other changes to Medicare Parts B and D, see CRS In Focus IF12203, *Selected Health Provisions of the Inflation Reduction Act*, by Suzanne M. Kirchhoff (2022) (for follow up, congressional offices may contact Laura Wreschnig at CRS).

[10] CMS REVISED GUIDANCE, *supra* note 8.

[11] U.S. DEPT. OF HEALTH & HUMAN SERVS., *HHS Selects the First Drugs for Medicare Drug Price Negotiation*, Press Release (Aug. 29, 2023), https://www.hhs.gov/about/news/2023/08/29/hhs-selects-the-first-drugs-for-medicare-drug-price-negotiation.html.

[12] CMS, MEDICARE DRUG PRICE NEGOTIATION PROGRAM: DRAFT GUIDANCE, IMPLEMENTATION OF SECTIONS 1192–98 OF THE SOCIAL SECURITY ACT FOR INITIAL PRICE APPLICABILITY YEAR 2027 AND MANUFACTURER EFFECTUATION OF THE MAXIMUM FAIR PRICE (MFP) IN 2026 AND 2027, at 10 (May 3, 2024), https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf [hereinafter CMS 2027 GUIDANCE].

[13] CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026* (Aug. 14, 2024), https://www.cms.gov/newsroom/fact-sheets/medicare-drug-price-negotiation-program-negotiated-prices-initial-price-applicability-year-2026.

[14] CMS REVISED GUIDANCE, *supra* note 8, at 117; 42 U.S.C. § 1320f(d)(1).

[15] CMS 2027 GUIDANCE, *supra* note 12, at 6.

Table 1. Medicare Drug Price Negotiation Program Challenges

Case Name	District Court	Case Number	District Court Decision	Appeal
Merck & Co., Inc. v. Becerra	District of Columbia	1:23-CV-01615	Not yet issued	N/A
Dayton Area Chamber of Commerce v. Becerra	Southern District of Ohio	3:23-CV-00156	2024 WL 3741510 (Aug. 8, 2024)[a]	Sixth Circuit
Bristol Myers Squibb Co. v. Becerra	New Jersey	3:23-CV-03335	2024 WL 1855054 (Apr. 29, 2024)[b]	Third Circuit
Janssen Pharms., Inc. v. Becerra	New Jersey	3:23-CV-03818	2024 WL 1855054 (Apr. 29, 2024)[c]	Third Circuit
National Infusion Center Assoc. et al. v. Becerra	Western District of Texas	1:23-CV-00707	2024 WL 561860 (Feb. 12, 2024)[d]	Fifth Circuit 2024 WL 4247856 (Sept. 20, 2024) (remanded back to district court)
Boehringer Ingelheim Pharms., Inc. v. Becerra	Connecticut	3:23-CV-01103	2024 WL 3292657 (July 3, 2024)[e]	Second Circuit
AstraZeneca Pharms. LP v. Becerra	Delaware	1:23-CV-00931	2024 WL 895036 (Mar. 1, 2024)[f]	Third Circuit
Novartis Pharms. Corp. v. Becerra	New Jersey	3:23-CV-14221	Not yet issued	N/A
Novo Nordisk, Inc. v. Becerra	New Jersey	3:23-CV-20814	2024 WL 3594413 (July 31, 2024)[g]	Third Circuit
Astellas Pharms. v. Becerra	Northern District of Illinois	1:23-CV-04578	Voluntarily dismissed	N/A

Notes:

a. https://scholar.google.com/scholar_case?case=14957151993020792367.

b. https://scholar.google.com/scholar_case?case=13600377549457583072.

c. https://scholar.google.com/scholar_case?case=13600377549457583072.

d. https://litigationtracker.law.georgetown.edu/wp-content/uploads/2023/06/PhRMA_2024.02.12_ORDER-GRANTING-DEFENDANTS-MOTION-TO-DISMISS.pdf.

e. https://scholar.google.com/scholar_case?case=10927106288045023 67.

f. https://scholar.google.com/scholar_case?case=16050526634522480155.

g. https://scholar.google.com/scholar_case?case=6163817055414354501.

As outlined in **Table 1**, the 10 originally filed cases are now at different stages of litigation. One case (*Astellas Pharmaceuticals v. Becerra*) was voluntarily dismissed after the manufacturer's drug was not selected for price negotiation for price year 2026.[16] Two other cases (*Merck & Company v. Becerra* and *Novartis Pharmaceuticals Corporation v. Becerra*) have not yet been decided by district courts.[17] Seven other cases were decided at the district court level.[18] The

[16] Notice of Voluntary Dismissal, Astellas Pharms. v. Becerra, No. 23-4578 (N.D. Ill. Sept. 6, 2023), ECF No. 23.

[17] Merck & Co., Inc. v. Becerra, No. 23-1616 (D.D.C.); Novartis Pharms. Corp. v. Becerra, No. 23-4221 (D.N.J.).

[18] *See* Dayton Area Chamber of Com. v. Becerra, 696 F. Supp. 3d 440 (S.D. Ohio Sept. 29, 2023); Nat'l Infusion Ctr. Ass'n v. Becerra, No. 23-CV-707, 2024 WL 561860 (W.D. Tex. Feb. 12, 2024); AstraZeneca Pharms. v. Becerra, No. (continued...)

decisions were all appealed to the United States Courts of Appeals for the Second, Third, Fifth, and Sixth Circuits.[19] To date, the only appeal that has been decided is *National Infusion Center v. Becerra*; the Fifth Circuit issued its decision in that case on September 20, 2024.[20] This report explains and contextualizes the plaintiffs' constitutional claims, and it examines relevant Supreme Court jurisprudence related to those claims. The report has been updated to discuss the substantive district court decisions addressing the constitutional issues.[21] It concludes with selected considerations for Congress.

First Amendment Claim

The First Amendment states, in relevant part, that "Congress shall make no law . . . abridging the freedom of speech."[22] Among other free speech protections, the U.S. Supreme Court has recognized that Free Speech Clause concerns arise when a person or entity is compelled to say or

23-931, 2024 WL 895036 (D. Del. Mar. 1, 2024); Bristol Myers Squibb Co. v. Becerra, No. 23-3335, 2024 WL 1855054 (D.N.J. Apr. 29, 2024); Janssen Pharms. v. Becerra, No. 23-02818, 2024 WL 1855054 (D.N.J. Apr. 29, 2024); Boehringer Ingelheim Pharms. v. HHS, No. 23-CV-01103, 2024 WL 3292657 (D. Conn. July 3, 2024); Novo Nordisk v. Becerra, No. 23-20814, 2024 WL 3594413 (D.N.J. July 31, 2024).

In the *Bristol Myers Squibb* and *Janssen* cases, the U.S. District Court for the District of New Jersey decided both cases in the same opinion, but the cases were not consolidated and each have their own docket number. As such, citations in this report to these two cases will hereinafter be short-cited as "*Bristol Myers Squibb/Janssen*."

[19] On March 14, 2024, the National Infusion Center Association appealed the district court's summary judgment ruling in its case to the U.S. Court of Appeals for the Fifth Circuit. Case Docket, Nat'l Infusion Ctr. Ass'n v. Becerra, No. 24-50180 (5th Cir. Mar. 14, 2024), ECF No. 1. On May 2, 2024, AstraZeneca appealed the district court's summary judgment ruling to the U.S. Court of Appeals for the Third Circuit. Notice, AstraZeneca Pharms. v. Becerra, No. 24-1819 (3d Cir. May 2, 2024), ECF No. 1.

On May 6, 2024, Bristol Myers Squibb and Janssen appealed the district court's summary judgment rulings in their cases to the U.S. Court of Appeals for the Third Circuit. Notice, Bristol Myers Squibb Co. v. Sec'y U.S. Dept. of HHS, No. 24-1820 (3d Cir. May 6, 2024), ECF No. 1; Notice, Janssen Pharms. v. Becerra, No. 24-1821 (3d Cir. May 6, 2024), ECF No. 1. The Third Circuit consolidated the appeals. Order, Bristol Myers Squibb Co. & Janssen Pharms. v. Sec'y U.S. Dept. of HHS et al., Nos. 24-1820, 24-1821 (3d Cir. May 6, 2024), ECF No. 4.

On July 26, 2024, Boehringer Ingelheim appealed the ruling in its case to the U.S. Court of Appeals for the Second Circuit. Civil Appeal, Boehringer Ingelheim Pharms. v. Becerra, No. 24-2092, (2d Cir. July 26, 2024), ECF No. 7. On August 19, 2024, Novo Nordisk appealed the district court's ruling on summary judgment to the U.S. Court of Appeals for the Third Circuit. Notice, Novo Nordisk v. Becerra, No. 24-2510 (3d Cir. Aug. 19, 2024), ECF No. 1.

On October 4, 2024, the Chamber of Commerce appealed the ruling in its case to the U.S. Court of Appeals for the Sixth Circuit. Notice of Appeal, Dayton Area Chamber of Com. v. Becerra, No. 23-156 (S.D. Ohio Oct. 4, 2024), ECF No. 105.

[20] On September 20, 2024, a divided Fifth Circuit panel reversed and remanded the *National Infusion Center* case to the district court, finding that the plaintiffs had standing to bring their claims and that those claims did not "arise under" the Medicare Act. *Nat'l Infusion Ctr. Ass'n*, No. 24-50180, 2024 WL 4247856 (5th Cir. Sept. 20, 2024), at *1. Because this ruling did not reach the merits of the plaintiffs' constitutional claims, it is not discussed here.

[21] Thus far, all of the district courts' decisions in the cases discussed herein were decided on the parties' summary judgment motions. In accordance with the Federal Rules of Civil Procedure, a court may grant a motion for summary judgment when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a).

Of the district court decisions issued thus far, two decisions did not address the merits of the plaintiffs' constitutional claims, because they were dismissed on procedural grounds. *See* Nat'l Infusion Ctr. Ass'n v. Becerra, No. 23-CV-707, 2024 WL 561860 (W.D. Tex. Feb. 12, 2024), *rev'd* 2024 WL 4247856 (5th Cir. Sept. 20, 2024); Dayton Area Chamber of Com. v. Becerra, 696 F. Supp. 3d 440 (S.D. Ohio Sept. 29, 2023). Because these decisions did not address the merits of the constitutional claims, they are not discussed here.

[22] U.S. CONST. amend. I. *See also* CONG. RESEARCH SERV., *Amdt 1.7.1 Historical Background on Free Speech Clause*, Constitution Annotated, https://constitution.congress.gov/browse/essay/amdt1-7-1/ALDE_00013537/ (last accessed Sept. 17, 2024).

otherwise express a viewpoint that the speaker does not agree with or wish to communicate.[23] At least six plaintiffs have claimed that the IRA violates the First Amendment prohibition against compelled speech.[24]

Under the IRA, the manufacturers of selected drugs are required to enter into agreements with HHS to negotiate, and potentially renegotiate, the MFPs of the drugs.[25] If the manufacturers of selected drugs had failed to sign an agreement with CMS by October 1, 2023, the manufacturers would have been subject to an excise tax, which is described in further detail below.[26] One plaintiff claimed that signing such agreements amounted to "forced messaging that promotes the (false) impression that manufacturers . . . agree with prices imposed by HHS decree."[27] Similarly, another plaintiff alleged that the IRA compels manufacturers to "become a spokesperson for promoting the Government's value judgments" by requiring manufacturers to "endorse and express the viewpoint that they 'agree' to HHS-dictated prices, and that those prices are fair."[28] The manufacturer claimed the government could not justify this "compelled-speech regime" because it lacked a "legitimate reason" to force manufacturers to convey these "misleading" messages.[29] The plaintiffs further argued that Congress could regulate drug prices "without burdening a speaker with unwanted speech" and that "[p]rice controls do not require speech controls."[30] It further claimed that the government lacked a "legitimate reason" to force manufacturers to convey misleading messages.[31]

In evaluating First Amendment challenges, one critical threshold question is whether the government is regulating expressive activity, which is protected by the First Amendment, or only nonexpressive conduct, which is not protected.[32] The Supreme Court has observed that "the First

[23] *See, e.g.*, 303 Creative LLC v. Elenis, 600 U.S. 570, 586–87 (2023); Nat'l Inst. of Family & Life Advocates v. Becerra, 585 U.S. 755, 766–67 (2018).

[24] Merck Compl. at 3; Chamber of Com. Compl. at 8; Bristol Myers Compl. at 20; Janssen Compl. at 6; Astellas Compl. at 4; Boehringer Compl. at 6.

[25] *See* 42 U.S.C. § 1192f-3(c).

[26] For more information about the excise tax and other penalties to which manufacturers will be subject under the IRA, *see infra* "Eighth Amendment Claim."

[27] Merck Compl. at 17; *see also* Astellas Compl. at 32; Janssen Compl. at 6; Boehringer Compl. at 7.

[28] Bristol Myers Compl. at 20.

[29] *Id.*

[30] Chamber of Com. Compl. at 54.

[31] *Id.*

[32] Determining whether an activity is sufficiently expressive so as to trigger the First Amendment can involve analyzing various factors. For example, in *Rumsfeld v. Forum for Academic and Institutional Rights (FAIR)*, several law schools argued that the Solomon Amendment, which conditioned the receipt of federal funding on the schools' willingness to allow military recruiters equal access to their campuses, violated the First Amendment. *FAIR*, 547 U.S. 47, 48 (2006). The case arose when a group of law schools restricted campus access to military recruiters because of the military's policy on homosexuals. *Id.* at 51. In response, Congress enacted the Solomon Amendment. *Id.* The law schools sued, arguing that the "forced inclusion and equal treatment of military recruiters violated the law schools' First Amendment freedoms of speech and association." *Id.* at 53. The Court found that "accommodating the military's message does not affect the law schools' speech," because the schools were not actually speaking by hosting on-campus interviews. *Id.* at 64.

The Court also did not find the law school's conduct of hosting military recruiters "inherently expressive," because giving the recruiters access to its campus did not "interfere with any message of the school." *Id.* The Court observed, "[l]aw schools remain free under the statute to express whatever views they may have on the . . . policy [with which they disagree] all the while retaining eligibility for federal funds." *Id.* at 60. Because explanatory speech was necessary to express the conduct, the Court said this was "strong evidence" that the conduct was not so expressive as to warrant First Amendment protection. *Id.*; *see also* United States v. O'Brien, 391 U.S. 367, 376 (1968) (finding that even if a law regulating conduct contains a "communicative element," more is needed in order to "bring into play" the First Amendment).

Amendment directs that [the] government may not suppress speech as easily as it may suppress conduct."[33] The Court has also said that the government can prohibit an agreement to engage in unlawful conduct "brought about through speaking or writing" without violating the First Amendment.[34] "[I]t has never been deemed an abridgement of freedom of speech," the Court has stated, "to make a course of conduct illegal merely because the conduct was in part initiated, evidenced, or carried out by means of language," either spoken, written, or printed.[35]

With respect to pricing regulations specifically, in *Expressions Hair Design v. Schneiderman*, the Court analyzed whether a state law banning surcharges on credit card purchases violated the First Amendment.[36] The Court observed that a "typical price regulation"[37] might not implicate the First Amendment if it would only regulate conduct.[38] However, if a law regulates "the communication of prices rather than prices themselves," it regulates "speech," thus triggering First Amendment scrutiny.[39] The *Expressions* Court reasoned that the state law regulated speech because rather than dictating the price of goods, it instead prohibited the vendors' means of communicating its prices to customers.[40]

To date, four of the decisions issued by federal district courts have substantively analyzed whether the IRA violates the First Amendment, but thus far, none of the plaintiffs' First Amendment claims have been successful.[41] All the courts that considered this issue held that the Medicare Drug Price Negotiation Program regulates non-expressive conduct, rather than speech, and that "[a]ny effect on [p]laintiffs' speech . . . is merely incidental."[42] Because the courts found that the IRA regulates conduct, rather than speech, the courts did not address whether the statute survived First Amendment scrutiny.[43]

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[33] 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 512 (1996) (plurality opinion).

[34] Giboney v. Empire Storage & Ice Co., 336 U.S. 490, 502 (1949); *see also* Brown v. Hartlage, 456 U.S. 45 (1982).

[35] Hartlage, 456 U.S. at 51 (quoting Appeal at 36–37, Hartlage v. Brown, 618 S.W.2d 603 (Ky. Ct. App. 1980)).

[36] Expressions Hair Design v. Schneiderman, 581 U.S. 37, 42 (2017). The New York law stated that "[n]o seller in any sales transaction may impose a surcharge on a holder who elects to use a credit card in lieu of payment by cash . . . ." *Id.*

[37] *Id.* at 47. The Court gave an example of a "typical price regulation" as one that would "regulate the amount that a store could collect" from a buyer. In such an example, the Court said, the regulation would regulate the seller's conduct, because by communicating prices to buyers, "the law—by determining the amount charged—would indirectly dictate the content of [the] speech." In that example, the Court said that the law would only "incidental[ly]" affect speech, because its "primary effect" would be on the seller's conduct. *Id.*

[38] *See, e.g., 44 Liquormart*, 517 U.S. 484.

[39] *Expressions Hair Design*, 581 U.S. at 48.

[40] *Id.*

[41] *See Bristol Myers Squibb/Janssen*, 2024 WL 1855054, at *10; *Boehringer Ingelheim Pharms*., 2024 WL 3292657, at *16; *Novo Nordisk*, 2024 WL 3594413, at *5.

[42] *Bristol Myers Squibb/Janssen*, 2024 WL 1855054, at *10; see also *Boehringer Ingelheim Pharms*., 2024 WL 3292657, at *16; *Novo Nordisk*, 2024 WL 3594413, at *5.

[43] *See, e.g.*, *Bristol Myers Squibb/Janssen*, 2024 WL 1855054, at *12.

If a regulation interferes with an expressive activity that triggers First Amendment protection, the next threshold inquiry a court would consider is the appropriate level of constitutional scrutiny to be applied. The First Amendment's protections do not apply with uniformity: Different types of regulations will trigger different levels of scrutiny, depending on the type of speech being regulated and how the regulation operates. *See generally*, CRS Report R45700, *Assessing Commercial Disclosure Requirements under the First Amendment*, by Valerie C. Brannon (2019). For example, commercial speech—defined as speech that relates "solely to the economic interests of the speaker and its audience"—is typically afforded intermediate scrutiny under the *Central Hudson* test. Cent. Hudson Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 561 (1980). As the name suggests, "intermediate" scrutiny is a medium level of constitutional scrutiny. The *Central Hudson* test requires the government to show that the regulation relates to a (continued...)

In *Bristol Myers Squibb* and *Janssen*, for example, the court distinguished *Expressions Hair Design*, reasoning that the pricing law at issue in that case, which the Supreme Court said was not a "typical price regulation," was distinct from the IRA, because it regulated the way in which merchants communicated the price of goods, rather than the amount they charged.[44] The court found that the purpose of the Medicare Drug Price Negotiation Program is to set MFPs for certain Medicare drugs, and it characterized the agreements and negotiations as "incidental mechanisms the government is using to set those prices."[45]

Several manufacturers also took issue with the IRA's terminology (e.g., words like "negotiate" and "maximum fair price"), arguing that signing an agreement that uses those terms also signals their agreement with the price.[46] The *Bristol Myers Squibb* and *Janssen* court, however, was unpersuaded by the manufacturers' arguments that signing such "ordinary commercial contracts" would constitute expressive conduct.[47] The court instead looked closely at the language used in the IRA, finding that statutory terms like "maximum fair price" were "terms of art" that have statutory definitions.[48] The court emphasized that nothing in the statute keeps the manufacturers from criticizing the MFP, and thus the court "decline[d] . . . to interpret the [p]rogram's terms beyond the scope of their statutory meaning."[49] Similarly, in *Boehringer Ingelheim*, the court clarified that the IRA does not compel speech simply because an "uninformed observer might read [its] terms out of context," reasoning that such a "speculative and incidental" burden to speech would not implicate the First Amendment.[50]

Further, the courts also found that the agreements could not compel speech in violation of the First Amendment because a drug manufacturer's participation in the Medicare Drug Price Negotiation Program is voluntary, and thus "the [a]greement[s] [do] not 'compel' [the manufacturers] to do anything."[51] In *Boehringer Ingelheim*, the court analyzed whether the Medicare program was voluntary or compulsory, given the government's significant presence in the pharmaceutical market as a purchaser of drugs.[52] While the manufacturer argued that signing the price agreement with HHS conveyed a public message that it "voluntarily agreed to participate in the [p]rogram,"[53] the court said that the company could have withdrawn from participation in Medicare before the requisite deadline to sign the contract.[54]

"substantial" governmental interest that is "directly advance[d]" by the law. *Id*. at 566. *Central Hudson*, however, is not the only standard that could apply. Government actions compelling speech are usually subject to strict scrutiny—a rigorous standard that laws rarely satisfy, Nat'l Inst. of Family & Life Advocates v. Becerra, 585 U.S. 755, 766–67 (2018), but the Supreme Court has sometimes applied a standard of review even less stringent than intermediate scrutiny to commercial disclosure requirements. *Id.* at 767–69; *e.g.*, Zauderer v. Off. of Disciplinary Couns., 471 U.S. 626, 651 (1985).

[44] *Bristol Myers Squibb/Janssen*., 2024 WL 1855054, at *11 (citing *Expressions Hair Design*, 581 U.S. 37, 47).

[45] *Id.*

[46] *Id.*; *see also Boehringer Ingelheim Pharms*., 2024 WL 3292657, at *15.

[47] *Bristol Myers Squibb/Janssen*, 2024 WL 1855054, at *11.

[48] *Id.*

[49] *Id.* at *12.

[50] *Boehringer Ingelheim Pharms*., 2024 WL 3292657, at *16 (citing Ark. Times LP v. Waldrip, 37 F.4th 1386, 1390, 1394 (8th Cir. 2022)).

[51] *Id.; see also Bristol Myers Squibb/Janssen*, 2024 WL 1855054, at *9 ("A threshold issue for their Compelled Speech claim is whether Plaintiffs are compelled to participate in the Program.").

[52] *Boehringer Ingelheim Pharms*., 2024 WL 3292657, at *12.

[53] *Id.* at *15.

[54] *Id.* at *16.

Fifth Amendment Claims

The Fifth Amendment provides, "No person shall be . . . deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation."[55] The first clause quoted above, known as the Due Process Clause, requires that the government provide sufficient ("due") procedures before it deprives a person of life, liberty, or property.[56] The second clause, known as the Takings Clause, allows the government to seize a person's property for a public use, but only if the government pays fair compensation for the taking.[57] All of the plaintiffs argue that the IRA violates some provision of the Fifth Amendment, with some claiming Due Process Clause violations[58] and others claiming Takings Clause violations.[59] Each of these claims, and the district courts' rejection of the claims, is explored in further detail below.

Due Process Clause Claim

Several plaintiffs argued that the IRA violated the Fifth Amendment's Due Process Clause by depriving drug manufacturers of their property without the requisite procedural safeguards.[60] The plaintiffs alleged various property rights, including "investment-backed patent rights and [a] common-law right to sell their products at market prices free from arbitrary and inadequately disclosed governmental constraints."[61] The plaintiffs insisted that the IRA does not comply with the core principles of procedural due process—notice and "the opportunity to be heard"[62]—because they were not given sufficient notice of the IRA's "fundamental change[s] to the legal landscape," which affected investments they made before the IRA was passed.[63] They further argued that because some aspects of CMS's guidance implementing the program were finalized without stakeholder input, there is "no guarantee that they will have an opportunity to be heard on the key decisions that HHS will make over the next three years before the first [MFP] takes effect in 2026."[64] The plaintiffs also claimed that the law runs afoul of the Due Process Clause because "the IRA expressly deprives manufacturers of any judicial review of HHS's key decisions."[65]

The Supreme Court has established that "[t]he first inquiry in every due process challenge is whether the plaintiff has been deprived of a protected interest in 'property' or 'liberty.'"[66] Assuming the plaintiff can demonstrate such a deprivation, the plaintiff's interests must then be

[55] U.S. CONST. amend. V.

[56] *See* CONG. RESEARCH SERV., *Amdt 5.5.1 Overview of Due Process*, Constitution Annotated, https://constitution.congress.gov/browse/essay/amdt5-5-1/ALDE_00013721/ (last accessed Sept. 17, 2024).

[57] *See* CONG. RESEARCH SERV., *Amdt 5.9.1 Overview of Takings Clause*, Constitution Annotated, https://constitution.congress.gov/browse/essay/amdt5-9-1/ALDE_00013280/ (last accessed Sept. 17, 2024).

[58] Chamber of Com. Compl. at 40; PhRMA Compl. at 6.

[59] Merck Compl. at 15; Bristol Myers Compl. at 26.

[60] PhRMA Compl. at 43; Chamber of Com. Compl. at 40; AstraZeneca Compl. at 30.

[61] PhRMA Compl. at 43.

[62] *See* Mathews v. Eldridge, 424 U.S. 319, 333 (1976); Armstrong v. Manzo, 380 U.S. 545, 552 (1965).

[63] PhRMA Compl. at 47.

[64] Chamber of Com. Compl. at 40; *see also* AstraZeneca Compl. at 30.

[65] Chamber of Com. Compl. at 40; *see also* PhRMA Compl. at 43; Astellas Compl. at 4. For more information about the Program's limitations on judicial review, *see* CRS Report R47555, *Implementation of the Medicare Drug Price Negotiation Program: Centers for Medicare and Medicaid Guidance and Legal Considerations*, by Hannah-Alise Rogers (2023).

[66] Am. Mfrs. Mut. Ins. Co. v. Sullivan, 526 U.S. 40, 59 (1999).

weighed against the government's interests.[67] The Supreme Court created the basic framework for considering procedural due process claims in *Mathews v. Eldridge*.[68] The *Mathews* factors address the amount of process required before the government may impair a protected property or liberty interest.[69] This fact-dependent analysis weighs (1) the private interest affected by the government's action; (2) "the risk of an erroneous deprivation" of an interest given the current procedures and the value of additional "procedural safeguards"; and (3) the government's interest, including the "function involved" and any burden that additional procedures would entail.[70]

To date, three district courts have considered and rejected the manufacturers' arguments that the IRA violates the Due Process Clause.[71] All three courts began their analyses of these claims by discussing the manufacturers' constitutionally protected interests.[72] The companies claimed a variety of protected property interests, including property interests in the selected drugs they manufacture and the data they collect on those drugs; the right to sell their products to Medicare for fair market value; and the right to continue to sell their products to Medicare.[73] The courts largely agreed with the government's position that the IRA does not infringe on any of the plaintiffs' rights, whether or not they are constitutionally protected.[74] Because the manufacturers did not sufficiently demonstrate any violation of a constitutionally protected property interest, the courts did not undertake a balancing of the interests or consider the sufficiency of the administrative process.[75]

[67] *See, e.g.*, Mathews v. Eldridge, 424 U.S. 319 (1976).

[68] Chamber of Com. Compl. at 44; *see also* PhRMA Compl. at 50–52; *see also* Mathews v. Eldridge, 424 U.S. 319 (1976).

[69] 424 U.S. 319, 334–35.

[70] *Id*. at 335. For example, in *Mathews*, a plaintiff sued the Social Security Administration (SSA) after termination of his disability benefits, and the Court addressed whether the Fifth Amendment required that he be given a hearing prior to the termination. *Id.* at 323. The Court cautioned that "[d]ue process is flexible and calls for such procedural protections as the particular situation demands." *Id.* at 334 (quoting Morrissey v. Brewer, 408 U.S. 471, 481 (1972)). The Court reviewed the "elaborate" procedures for terminating benefits under the Social Security Act and the various safeguards the SSA put in place to avoid a mistaken deprivation of benefits, and it considered how to balance the high cost of additional safeguards with the need to conserve "scarce fiscal and administrative resources." *Id.* at 348. After weighing the three factors, the Court's majority held that an evidentiary hearing was not required prior to the benefit determination, and that the agency's administrative procedures were sufficient to meet the minimum standard required by the Fifth Amendment. *Id.* at 349. The Court further observed: "The judicial model of an evidentiary hearing is neither a required, nor even the most effective, method of decision-making in all circumstances. The essence of due process is the requirement that 'a person in jeopardy of serious loss [be given] notice of the case against him and opportunity to meet it.'" *Id.* at 348 (alteration in original) (quoting Joint Anti-Fascist Refugee Comm. v. McGrath, 341 U.S. 123, 171–72 (1951)).

[71] *Boehringer Ingelheim Pharms*., 2024 WL 3292657, at *19; Novo Nordisk v. Becerra, No. 23-20814, 2024 WL 3594413, at *5 (D.N.J. July 31, 2024); AstraZeneca Pharms., 2024 WL 895036, at *13 (D. Del. Mar. 1, 2024).

[72] *Boehringer Ingelheim Pharms*., 2024 WL 3292657, at *7; *Novo Nordisk*, 2024 WL 3594413, at *5; *AstraZeneca Pharms.*, 2024 WL 895036, at *14.

[73] *AstraZeneca Pharms.*, 2024 WL 895036, at *14. The *AstraZeneca* court also acknowledged that the drugmaker claimed a protected interest in the patent rights for its products, but the court found that the company "never identifie[d] a patent or exlain[ed] how the IRA affects or could affect a patent right." *Id.* Because AstraZeneca's arguments about its protected patent rights were tied to its arguments about its right to sell its drug above the MFP, the court found that "the property interest encompassed by AstraZeneca's alleged 'patent rights' is at bottom the ability to sell products to Medicare beneficiaries at prices above what the IRA requires." *Id.*

[74] *Boehringer Ingelheim Pharms*., 2024 WL 3292657, at *7; *Novo Nordisk*, 2024 WL 3594413, at *5; *AstraZeneca Pharms.*, 2024 WL 895036, at *14.

[75] *See Novo Nordisk*, 2024 WL 3594413, at *6.

The government did not dispute that the manufacturers had a constitutionally protected property interest in their selected drugs.[76] So far, though, the courts have all agreed with the government's argument that the IRA did not infringe upon these interests because participation in the Medicare program is voluntary.[77] In *Novo Nordisk*, the court found that because the program is voluntary, the companies "are not forced to make any sales to Medicare in the first place."[78] Further, in *Boehringer Ingelheim*, the court thoroughly analyzed the options for drug companies that did not wish to comply with the terms of the IRA, concluding that manufacturers could choose to withdraw from participation in the Medicare program "without penalty" before the MFP became effective.[79] The court did, however, reject the government's argument that a drug company could simply divest its interest in its selected drug (Jardiance) if it did not wish to participate in the program, highlighting that the Supreme Court has held that the divestment of a property interest does not prevent a violation of the Fifth Amendment.[80]

Reviewing courts also rejected the companies' arguments that the IRA infringed upon their due process rights to sell drugs to Medicare at fair market value. As the court put it in the *AstraZeneca* case, "[n]o one . . . is entitled to sell the [g]overnment drugs at prices the [g]overnment won't agree to pay," citing to the Supreme Court's finding that "the [g]overnment enjoys the unrestricted power to . . . fix the terms and conditions upon which it will make needed purchases."[81] The court characterized the IRA as "simply establish[ing] [the] maximum prices the [g]overnment will pay for selected drugs" and found that the law did not require AstraZeneca to

[76] *Boehringer Ingelheim Pharms*., 2024 WL 3292657, at *8; *Novo Nordisk*, 2024 WL 3594413, at *6; *AstraZeneca Pharms.*, 2024 WL 895036, at *13.

[77] *Novo Nordisk*, 2024 WL 3594413, at *6; *Boehringer Ingelheim Pharms*., 2024 WL 3292657, at *10; *AstraZeneca Pharms.*, 2024 WL 895036, at *15.

[78] *Novo Nordisk*, 2024 WL 3594413, at *6.

[79] *Boehringer Ingelheim Pharms*., 2024 WL 3292657, at *8. The court discussed CMS's "accelerated path" for a drug manufacturer to terminate its agreement with the agency (i.e., terminating a manufacturer agreement within 30 days of a notice of intention to withdraw), finding that this administrative mechanism was a permissible interpretation of the Medicare Act's statutory language. *Id.* at *9 (citing 42 U.S.C. §§ 1395w-114a(b)(4)(B)(i), 1395w-114c(b)(4)(B)(i)). Even if the manufacturer is required to comply with the IRA's directives during the 30 days during which CMS is processing its withdrawal, the court found that this did not run afoul of the Due Process Clause, because "mere participation in the [Medicare Drug Price Negotiation Program] . . . does not constitute a deprivation of property." *Id.* at *10.

[80] *Id.* at *11 (citing Horne v. Dept. of Agric., 576 U.S. 350 (2015)). The court did not address the parties' final arguments about whether Boehringer Ingelheim could stop selling Jardiance to Medicare altogether. *Boehringer Ingelheim Pharms*., 2024 WL 3292657, at *11 ("I need not decide whether manufacturers can evade the Program (or its penalties) by refusing to sell the [s]elected [d]rug to Medicare beneficiaries. Even if they cannot . . . that does not deprive manufacturers of their property, because they have the option to withdraw from Medicare and Medicaid.").

[81] *Id.* at *15 (quoting Perkins v. Lukens Steel Co., 310 U.S. 113, 127 (1940)).

sell its products to Medicare.[82] On the contrary, the court held that the IRA presented "a potential economic opportunity" to AstraZeneca that the company "is free to accept or reject."[83]

Takings Clause Claim

Some plaintiffs also raised distinct Fifth Amendment claims under the Takings Clause, alleging that the implementation of the IRA constitutes a taking of both tangible property (drugs and biological products) and intellectual property (patents) without just compensation, as well as a per se taking.[84] One plaintiff claimed that "the singular purpose of this scheme [in the IRA] is for Medicare to obtain prescription drugs *without* paying fair market value."[85] Another alleged that the program "is akin to the Government taking your car on terms that you would never voluntarily accept and threatening to also take your house if you do not 'agree' that the taking was 'fair.'"[86]

As with the Due Process Clause allegations discussed above, the manufacturers argued that their drugs, data, and patents are property and that the government is "forcing [them] to provide third parties with 'access' to [their] products at steeply discounted prices."[87] A few of the manufacturers stated that such a "compelled transfer of title effects a classic, *per se* taking."[88] The plaintiffs further alleged that the program's pricing mechanism is not "just compensation" because it is not sufficiently connected to fair market value and, in fact, the statute requires the price to be set "significantly below the drug's market value."[89]

The Supreme Court has clarified that the Takings Clause "does not prohibit the taking of private property, but instead places a condition on the exercise of that power" by requiring the government to fairly compensate someone whose property rights are taken.[90] To determine whether a taking has occurred, a party must demonstrate that the claimed property interest at issue is protected by the Takings Clause.[91]

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[82] *Id.* The court also disagreed with AstraZeneca's reference to the Third Circuit's decision in Sanofi-Aventis LLC v. HHS, 58 F.4th 696 (3d Cir. 2023), *judgment entered*, No. 21-3167, 2023 WL 1325507 (3d Cir., Jan. 30, 2023), in support of its argument that participation in the Medicare program was involuntary. *AstraZeneca Pharms.*, 2024 WL 895036, at *15. The *Sanofi-Aventis* case arose from a disputed provision of the 340B statute, and as part of its decision in that case, the Third Circuit said, in dicta, that "the federal government dominates healthcare and uses [its] market power to get drug makers to subsidize healthcare." *Id.* (first and third alterations in original) (quoting AstraZeneca's Brief in Opposition to Defendants' Cross-Motion for Summary Judgment and Reply in Support of Plaintiffs' Motion for Summary Judgment at 48, No. 23-CV-931 (filed Dec. 1, 2023, D. Del. 2023) (ECF No. 58)). The *AstraZeneca* court acknowledged that because the federal government is the largest payer of prescription drugs, manufacturers have a "powerful incentive" to participate in 340B. *Id.* The court stated, however, that "it does not follow, and the court did not say or imply in *Sanofi*[*-Aventis*], that the 340B Program *or any other law* requires a drug manufacturer to participate in the 340B Program or any other Medicare Program." *Id.*

[83] *AstraZeneca Pharms.*, 2024 WL 895036, at *16.

[84] Merck Compl. at 15; Bristol Myers Compl. at 26; Astellas Compl. at 4; Janssen Compl. at 27; Boehringer Compl. at 34.

[85] Merck Compl. at 2.

[86] Janssen Compl. at 6.

[87] Merck Compl. at 16; *see also* Boehringer Compl. at 35.

[88] Merck Compl. at 16; *see also* Boehringer Compl. at 36.

[89] Bristol Myers Compl. at 18; Astellas Compl. at 28.

[90] Lingle v. Chevron U.S.A. Inc., 544 U.S. 528, 536 (2005) (quoting First English Evangelical Lutheran Church v. Cnty. of L.A., 482, U.S. 304, 314 (1987)); *see also* CONG. RESEARCH SERV., *Amdt 5.9.2 Public Use and Takings Clause*, Constitution Annotated, https://constitution.congress.gov/browse/essay/amdt5-9-2/ALDE_00013281/ (last accessed Sept. 17, 2024).

[91] *See, e.g.*, Ruckelshaus v. Monsanto Co., 467 U.S. 986, 1000-01 (1984).

The Takings Clause applies only to "private property" interests protected under the Fifth Amendment.[92] Personal property (such as pills or vials of a drug) is protected,[93] but the Supreme Court has never directly held that patents are property protected by the Takings Clause.[94]

Historically, the Court has recognized certain physical invasions of property under a per se rule: an appropriation of property, even if minor, is a taking that requires compensation.[95] For example, in *Loretto v. Teleprompter Manhattan CATV Corp*., the Court held that a law requiring landlords to permit cable companies to install equipment on the exteriors of their buildings constituted a per se taking for the purposes of the Takings Clause, because the law authorized a permanent, if only minimal, physical occupation of the property.[96] Other instances in which the Court has recognized a per se taking are when the government took title to a share of a farm's agricultural crop[97] and when an owner was deprived of all his property's economic use or value.[98]

When a physical invasion has not occurred, the Court has still recognized a "regulatory taking" when a government action significantly affects property rights, holding that if the regulation "goes too far[,] it will be recognized as a taking."[99] Although the Court has avoided a "set formula to determine where regulation ends and a taking begins"[100] and has stated that regulatory takings cases require "essentially ad hoc, factual inquiries,"[101] the Court has established some general principles for determining when regulatory takings occur.[102]

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[92] *See Ruckelshaus*, 467 U.S. at 1001. For more information, *see* CONG. RESEARCH SERV., *Amdt 5.9.3 Property Interests Subject to Takings Clause*, Constitution Annotated, https://constitution.congress.gov/browse/essay/amdt5-9-3/ALDE_00013282/ (last accessed Sept. 17, 2024).

[93] *See* Horne v. Dept. of Agric., 576 U.S. 350 (2015).

[94] In *Horne*, the Court reiterated its previous observation that "[a patent] confers upon the patentee an exclusive property in the patented invention which cannot be appropriated or used by the government itself, without just compensation, any more than it can appropriate or use without compensation land which has been patented to a private purchaser." 576 U.S. 359–60 (alteration in original) (quoting James v. Campbell, 104 U.S. 356, 358 (1882)).

[95] *See, e.g.*, Loretto v. Teleprompter Manhattan CATV Corp., 458 U.S. 419, 434–35 (1982) ("In short, when the 'character of the governmental action' is a permanent physical occupation of property, our cases uniformly have found a taking to the extent of the occupation, without regard to whether the action achieves an important public benefit or has only minimal economic impact on the owner." (quoting Penn Cent. Transp. v. City of New York, 438 U.S. 104, 121 (1978)).

[96] *Id.*

[97] Horne v. Dep't of Agric., 576 U.S. 350, 361 (2015).

[98] *See* Agins v. City of Tiburon, 477 U.S. 255, 260 (1980); Lucas v. S.C. Coastal Council, 505 U.S. 1003 (1992).

[99] Pa. Coal Co. v. Mahon, 260 U.S. 393, 415 (1922). *See also* CONG. RESEARCH SERV., *Amdt 5.9.5 Early Jurisprudence on Regulatory Takings*, Constitution Annotated, https://constitution.congress.gov/browse/essay/amdt5-9-5/ALDE_00013284/ (last accessed Sept. 17, 2024).

[100] *Penn Cent. Transp. Co.*, 438 U.S. at 124.

[101] *Id.*

[102] For example, in *Penn Central Transportation Co. v. City of New York*, the Court analyzed whether a government regulation amounted to a taking. Factors considered by the Court included (1) "[t]he economic impact of the regulation"; (2) whether the regulation interfered with "distinct investment-backed expectations"; and (3) the character of the government's action. *Id.* at 124. For more information about the *Penn Central* analysis and how it is used to evaluate regulatory takings, *see* CONG. RESEARCH SERV., *Amdt 5.9.6 Regulatory Takings and Penn Central Framework*, Constitution Annotated, https://constitution.congress.gov/browse/essay/amdt5-9-6/ALDE_00013285/ (last accessed Sept. 17, 2024). Regarding the third factor, the Court explained that a taking "may more readily be found when the interference with property can be characterized as a physical invasion by a government than when interference arises from some public program adjusting the benefits and burdens of economic life to promote the common good." *Penn Cent. Transp. Co*., 438 U.S. at 124 (citation omitted).

The Court applied the *Penn Central* framework in *Ruckelshaus v. Monsanto*, which concerned public disclosure of trade secrets that were submitted by a pesticide manufacturer to the Environmental Protection Agency (EPA). (continued...)

To date, three district courts have reached the merits of the plaintiffs' takings claims, and all have found that the Medicare Drug Price Negotiation Program does not amount to a taking in violation of the Fifth Amendment.[103] In *Bristol Myers Squibb* and *Janssen*, the court first analyzed whether participation in the program amounts to a physical taking, distinguishing the Supreme Court's decision in *Horne v. Department of Agriculture*, where the Court held that the government's requirement that raisin growers set aside a portion of their yearly harvest without compensation was a taking.[104] Unlike in *Horne*, where "the only way for raisin growers to avoid the . . . requirement [to give up part of their crop] was to stop selling raisins altogether," in *Bristol Myers Squibb* and *Janssen*'s cases, the manufacturers could just stop selling their drugs to Medicare to avoid regulation.[105] The court found that the IRA is not requiring the manufacturers to set aside the selected drugs for the government's use, and neither does the program "require a manufacturer to physically transmit or transport drugs at the agreed price."[106] Thus, the court concluded it is not a taking.[107]

Similarly, the court in *Boehringer Ingelheim* said that the IRA's selection of drugs for price negotiation is not a taking because the company could withdraw from participation in Medicare before a taking of its property occurred.[108] The court reviewed caselaw from the Second Circuit (which has jurisdiction over cases appealed from the federal district court in Connecticut) and from sister circuits that analyzed the constitutionality of various Medicare payment limitations.[109] For example, the court pointed to *Garelick v. Sullivan*, wherein the Second Circuit held that no

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Ruckelshaus v. Monsanto, 467 U.S. 986, 990 (1983). The Court acknowledged that the manufacturer held a property interest in the data containing trade secrets, but it held that the EPA regulation requiring disclosure did not constitute a taking when a manufacturer did not have a "reasonable investment-backed expectation" that the data would remain confidential. *Id.* at 1005. The Court highlighted that the manufacturers voluntarily participated in a regulatory scheme that required their products to be registered with the federal government and that such participation allowed them to sell their products in the U.S. market. *Id.* The Court observed that "as long as [the manufacturer] is aware of the conditions under which the data are submitted, and the conditions are rationally related to a legitimate Government interest, a voluntary submission of data by an applicant in exchange for the economic advantages of a [product] registration can hardly be called a taking." *Id.* at 1007. The Court also found that the disclosure requirement was rationally related to the legitimate government interest of ensuring safety in the sales and use of pesticides.[102] For these reasons, the Court held that the manufacturer did not have a "reasonable investment-backed expectation" and that no regulatory taking occurred. *Ruckelshaus*, 467 U.S. at 1005.

[103] *Bristol Myers Squibb/Janssen*, 2024 WL 1855054, at *9; *Boehringer Ingelheim Pharms*., 2024 WL 3292657, at *10.

[104] *Bristol Myers Squibb/Janssen*, 2024 WL 1855054, at *4–5 (citing Horne v. Dept. of Agric., 576 U.S. 350, 354–56 (2015)). The *Boehringer Ingelheim* court also distinguished *Horne* on the basis that, in that case, the property owners did not have a choice of whether or not to turn over a portion of their raisin crop to the government. *Boehringer Ingelheim Pharms*., 2024 WL 3292657, at *14.

[105] *Bristol Myers Squibb/Janssen*, 2024 WL 1855054, at *6.

[106] *Id.* The court also distinguished the Supreme Court's per se taking rule in *Cedar Point Nursery v. Hassid*, 594 U.S. 139 (2021). *Bristol Myers Squibb/Janssen*, 2024 WL 1855054, at *6. In that case, a majority of the Court held that a state law regulation which gave certain labor groups a right to access an employer's property to solicit support for unionizing workers constituted a per se physical taking. *Cedar Point Nursey*, 594 U.S at 162. Bristol Myers Squibb and Janssen argued that, according to *Cedar Point*, a "per se taking occurs when the [g]overnment forces a property owner to transfer possession or title," and that the IRA's establishment of the MFP "forces the manufacturers to transfer the selected drugs to those third parties at a price demanded by the [g]overnment." *Bristol Myers Squibb/Janssen*, 2024 WL 1855054, at *6 (emphasis omitted) (quoting Memorandum of Law in Support of Defendants' Opposition to Plaintiff's Motion for Summary Judgment and Cross-Motion, Bristol Myers Squibb v. Becerra et al., Nos. 23-CV-03335, 3818 (filed Oct. 16, 2023, D.N.J.) (ECF No. 38-1)). The court distinguished *Cedar Point*, reasoning that the IRA does not require the company to "give or sell" its drugs to the government. *Id.* The court agreed with the government's argument that the IRA "does not authorize the government to requisition a manufacturer's drugs or other property . . . nor does [it] require a manufacturer to relinquish any drug it does not wish to sell." *Id.*

[107] *Id.*

[108] *Boehringer Ingelheim Pharms*., 2024 WL 3292657, at *10.

[109] *Id.* at *12.

taking had occurred after HHS lowered the Medicare Part B payment rate for certain anesthesia services.[110] Although the providers in *Garelick* claimed that the lowered payment rate resulted in a taking without just compensation, the court held that the providers voluntarily chose to participate in the Medicare program and were not required to treat Medicare patients.[111] The court rejected the argument that the providers' participation in Medicare was involuntary because to choose not to serve Medicare patients would be financially unfeasible.[112] The *Boehringer Ingelheim* court also reviewed similar caselaw from other circuits, noting that providers who disagree with a CMS payment condition may freely withdraw their Medicare participation and so avoid a taking.[113]

Eighth Amendment Claim

The Eighth Amendment provides that "[e]xcessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted."[114] At least three plaintiffs claimed that the IRA's excise taxes and penalties are in fact punishments designed to force manufacturers to comply with the statute's price negotiation scheme.[115] The IRA amended the Internal Revenue Code to create an excise tax on the sale of selected drugs if a manufacturer fails to execute a price negotiation agreement with the Secretary; fails to agree to an initial or renegotiated MFP; or does not submit requested information about the drug to the Secretary.[116] The tax is calculated based on a percentage of the sales during the noncompliance period, starting with 65% for the first 90 days of noncompliance, and reaching up to 95% after 270 days.[117] In addition, separate provisions impose civil money penalties on manufacturers that fail to sell their drug at or below the MFP;[118] violate the terms of the pricing agreement;[119] or provide false information to the Secretary.[120]

The plaintiffs are particularly concerned with the impact of the excise tax, which one characterized as a "massive penalty."[121] Another plaintiff asserted that "Congress well understood that, in practice, the threat of this ruinous excise tax would force manufacturers to accept whatever price HHS demands."[122] The parties pointed to the Joint Committee on Taxation's estimate of a similar iteration of the excise tax found in previous legislative proposals as raising "no revenue whatsoever," as well as a similar Congressional Budget Office projection.[123]

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[110] *Id.* (citing Garelick v. Sullivan, 987 F.2d 913, 915-17 (2d Cir. 1993).

[111] *Id.*

[112] *Id.*

[113] *Boehringer Ingelheim Pharms.*, 2024 WL 3292657, at *10.

[114] U.S. CONST. amend. VIII.

[115] Chamber of Com. Compl. at 47; PhRMA Compl. at 55; Boehringer Compl. at 39.

[116] Inflation Reduction Act of 2022, Pub. L. No. 117-169, § 11003, 136 Stat. 1818 (codified at 26 U.S.C. § 5000D).

[117] 26 U.S.C. § 5000D(d). For an example of how the excise tax would be calculated, *see* CRS Report R47396, *Health Care Provisions of the Budget Reconciliation Measure P.L. 117-169*, coordinated by Katherine M. Kehres (2023).

[118] 42 U.S.C. § 1320f-6(a). The civil monetary penalty is calculated by multiplying by 10 the difference between the MFP and the sale price. *Id.* For example, if a manufacturer sold 100 units of a selected drug at $10 per unit, the total sale would be $1,000. But if the MFP for that selected drug was $5, the manufacturer would be liable for $5,000 (10 times the number of units sold (100) and the difference between the sale price ($10) and the MFP ($5).

[119] The penalty is $1,000,000 for each day of a violation. *Id.* § 1320f-6(c).

[120] The penalty is $1,000,000 for each item of false information. *Id.* § 1320f-6(d).

[121] Boehringer Compl. at 39.

[122] PhRMA Compl. at 25.

[123] PhRMA Compl. at 25; Chamber of Com. Compl. at 28; Boehringer Compl. at 40. The estimate is based on the Build Back Better Act, H.R. 5376 (117th Cong. 2022), which proposed a similar excise tax.

Manufacturers argued that such projections demonstrate that Congress intended the excise tax as a punishment for noncompliant manufacturers, because noncompliance is so costly that no manufacturer would risk being subject to the tax.[124] Another plaintiff argued that "[r]egardless of its name, the IRA's 'excise tax' is a penalty," and that "no manufacturer could possibly afford to pay" the amounts owed for noncompliance.[125]

The Supreme Court has found that the purpose of the Excessive Fines Clause is to "limit the government's power to punish,"[126] and the Court has applied the clause to situations in which fines are both imposed by and paid to the government.[127] If a fine can properly be characterized as punishment so as to fall within the purview of the Excessive Fines Clause, the Court has also analyzed whether fines are excessive so as to run afoul of the Eighth Amendment.[128]

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[124] PhRMA Compl. at 25.

[125] Chamber of Com. Compl. at 48.

[126] *See, e.g.*, Austin v. United States, 509 U.S. 602, 607–09 (1993) ("Some provisions of the Bill of Rights are expressly limited to criminal cases. . . . The text of the Eighth Amendment includes no similar limitation. Nor does the history of the Eighth Amendment require such a limitation.") *Id.* at 607–08. *See also* United States v. Bajakajian, 524 U.S. 321 (1998) (holding that a punitive civil forfeiture violated the Excessive Fines Clause); *but see* Browning-Ferris Indus., 492 U.S. 257 (1989) (holding that the Eighth Amendment's prohibition on excessive fines did not apply to an award of punitive damages in a civil suit between private parties).

[127] *See* Browning-Ferris Indus. v. Kelco Disposal, Inc., 492 U.S. 257, 266–67 (1989).

Although historically applied only to criminal cases, the prohibition on excessive fines can also apply in civil cases. *See, e.g., Browning-Ferris*, where, in considering the legislative history behind the Excessive Fines Clause, the Court stated, "Congress did not discuss what was meant by the term 'fines,' or whether the prohibition had any application in the civil context." *Id.* at 264–65. The Court further observed: "Bail, fines, and punishment traditionally have been associated with the criminal process, and by subjecting the three to parallel limitations the text of the Amendment suggests an intention to limit the power of those entrusted with the criminal-law function of government." *Id*. at 263 (quoting Ingraham v. Wright, 430 U.S. 651, 644 (1977)); *but see* Austin, 509 U.S. at 608 (observing that "some provisions of the Bill of Rights are expressly limited to criminal cases. . . . The text of the Eighth Amendment includes no similar limitation. Nor does the history of the Eighth Amendment require such a limitation)." The Supreme Court denied a 2023 petition for certiorari in a case in which the Fourth Circuit decided that a civil tax penalty imposed by the IRS was not an excessive fine. *See* Toth v. United States, 143 S. Ct. 552 (2023). Justice Gorsuch filed a dissenting opinion in which he expressed that "taking up this case would have been well worth our time." *Id.* at 553 (Gorsuch, J., dissenting).

The Court has made clear that the threshold question "is not . . . whether [the action] . . . is civil or criminal, but rather whether it is punishment." *Austin*, 509 U.S. at 610. When analyzing whether a fine constitutes punishment, the Court has looked at the history of the action and whether it could be "properly considered punishment today." *Id.* at 619. It is unclear whether the Court would consider a civil tax imposed by the Internal Revenue Code to be a "fine" for the purpose of applying the Excessive Fines Clause. In 2016, the United States Bankruptcy Court for the Northern District of Texas observed, "The parties have not cited, nor has the Court located through its own research, a single case that holds that a tax penalty . . . . is a fine under the Excessive Fines Clause, let alone an excessive fine . . . . In sum, those courts that have been faced with the dilemma of how to apply an Excessive Fines Clause analysis to civil tax penalties have all arrived at largely the same answer—i.e., civil tax penalties . . . are not fines, and therefore the Excessive Fines Clause is not applicable to them." *In re Wyly*, 552 B.R. 338, 613 (Bankr. N.D. Tex. 2016). The Court has not addressed whether the reasoning from *Wyly* would extend to civil tax penalties in the Internal Revenue Code.

[128] For example, in 1998, the Court decided *United States v. Bajakajian*, which addressed whether a forfeiture of cash constituted a punishment and whether the punishment was considered "excessive" for the purposes of the Eighth Amendment. 524 U.S. at 328, 334 (1998). The case arose when the government sought forfeiture of the full amount of money that was smuggled onto an international flight in violation of federal law. *Id.* at 325. Justice Thomas, writing for a five-Justice majority, held that under the Eighth Amendment, a fine is unconstitutional when its amount is grossly disproportionate to the gravity of the conduct it was designed to discourage. *Id.* at 325. Observing that the amendment's text and history provided few insights as to the level of disproportionality required, the Court undertook a fact-specific inquiry to compare the amount of the forfeiture against the gravity of the offense for which the defendant had pleaded guilty. *Id.* at 336–37. The majority held that forfeiture of the entire amount would violate the Excessive Fines Clause, reasoning that the harm caused was minimal, as the crime underlying the forfeiture was a failure to report the transport (continued...)

Of the three plaintiffs who challenged the IRA on the basis that it violated the Eighth Amendment Excessive Fines Clause, to date only one of the courts has discussed it in detail: *Boehringer Ingelheim v. HHS*.[129] In that case, the court denied the manufacturer's motion for summary judgment, finding that the court lacked jurisdiction over the challenge under the Anti-Injunction Act (AIA).[130] With a few exceptions, the AIA states that a person may not bring a claim to restrain "the assessment or collection of any tax,"[131] and the Supreme Court has observed that the purpose of the law, in part, is to allow for the collection of taxes without court intervention.[132] One exception to the AIA's jurisdictional bar, known as the *Williams Packing* exception, says that a plaintiff may bring such a challenge if he can demonstrate an irreparable injury and a certainty of success on the merits.[133] The court found, however, that Boehringer Ingelheim could not meet either of the requirements for the exception to apply to give the court jurisdiction.[134]

First, the court considered whether the company would suffer an irreparable injury if it could not bring the claim.[135] The court was unpersuaded by the manufacturer's argument that it would be irreparably harmed by "the extraordinary magnitude of the tax," finding instead that the company could just as easily pay a portion of the tax up front and then file suit for a refund.[136] The court stated that it was unlikely that the company would even have to pay the entire amount of the tax before challenging it, because "the IRS would likely exercise forbearance" of the total amount during the adjudication of the refund suit.[137] The court reasoned that if the manufacturer prevailed in a refund suit, the IRS could not require payment, but if the manufacturer's suit failed, then "the IRS could constitutionally require it to pay the tax, which would mean the tax inflicted no actionable harm."[138]

Next, in determining whether the company was entitled to an exception to the AIA's jurisdictional bar, the court addressed the plaintiff's certainty of success on the merits of its claim.[139] The court found that because Boehringer Ingelheim's claim was "novel," it could not "meet this demanding standard."[140] The court observed that the plaintiff had not identified a "case in which a court has applied the Excessive Fines Clause to a monetary amount that was not connected to criminal conduct or a criminal proceeding."[141] In addition, the court was persuaded by the government's

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of money, not the transport itself. *Id.* at 337, 339. Four other justices dissented in *Bajakajian*, arguing, "For the first time in its history, the Court strikes down a fine as excessive under the Eighth Amendment. The decision is disturbing both for its specific holding and for the broader upheaval it foreshadows." *Id*. at 344 (Kennedy, J., dissenting).

[129] Boehringer Ingelheim Pharms. v. HHS, No. 23-CV-01103, 2024 WL 3292657 (D. Conn. July 3, 2024), *appeal docketed*, 24-2092 (2d Cir. Aug. 8, 2024). The other two cases, brought by PhRMA and the U.S. Chamber of Commerce, were dismissed on procedural grounds, and the courts did not reach the merits of the Eighth Amendment claims. *See* Nat'l Infusion Ctr. Ass'n v. Becerra, No. 23-CV-707, 2024 WL 561860 (W.D. Tex. Feb. 12, 2024), *rev'd* 2024 WL 4247856 (5th Cir. Sept. 20, 2024); Dayton Area Chamber of Com. v. Becerra, 696 F. Supp. 3d 440 (S.D. Ohio Sept. 29, 2023).

[130] *Boehringer Ingelheim Pharms*., 2024 WL 3292657, at *22; *see also* 26 U.S.C. § 7421.

[131] *Boehringer Ingelheim Pharms*., 2024 WL 3292657, at *21.

[132] *Id.* (citing Enochs v. Williams Packing & Nav. Co., 370 U.S. 1, 7 (1962)).

[133] *Id.* at *22 (quoting Bob Jones Univ. v. Simon, 416 U.S. 725, 737 (1974)).

[134] *Id.* at *23.

[135] *Id.* at *22.

[136] *Id.*

[137] *Id.*

[138] *Id.*

[139] *Boehringer Ingelheim Pharms.*, 2024 WL 3292657, at *23.

[140] *Id.*

[141] *Id.*

argument that the Excessive Fines Clause applied only to criminal cases, pointing to both the text and structure of the Constitution.[142]

The Nondelegation Doctrine Claim

Article I, Section I of the Constitution, known as the Vesting Clause, states, "All legislative Powers herein granted shall be vested in a Congress of the United States, which shall consist of a Senate and House of Representatives."[143] In interpreting these words, the Supreme Court has recognized what is known as the Nondelegation Doctrine, which is the principle that "Congress may not transfer . . . 'powers which are strictly and exclusively legislative'" to another branch of government.[144] Pursuant to Supreme Court precedent, all delegations to federal agencies must, therefore, be accompanied by an "intelligible principle" that both constrains and guides the agency in its implementation of the law.[145] The trade association plaintiffs argued that the IRA runs afoul of the Nondelegation Doctrine because "Congress delegated unfettered discretion to HHS to set prices however it wishes."[146] Similarly, a manufacturer argued, "Congress has impermissibly delegated sweeping authority to implement price controls without providing a clear standard to guide the agency's discretion . . . ."[147] The trade association plaintiffs contrasted the Medicare Drug Price Negotiation Program with other price-setting programs, such as the regulation of natural gas companies, which the plaintiffs argued are implemented with satisfactory procedural safeguards, including notice-and-comment rulemaking and the opportunity for judicial review.[148]

The plaintiffs specifically argued that the IRA's delegation of authority to the Secretary lacks an intelligible principle.[149] As an example, they pointed to the factors the Secretary is to consider in developing the MFP, which they purported "provide[] no guidance whatsoever about how the

[142] *Id.* Boehringer argued that at least two Supreme Court justices would have applied the Excessive Fines clause to a civil forfeiture, but in determining the manufacturer's certainty of success on the merits for purposes of the AIA's applicability, the court said that "the view of a minority of justices, expressed in dicta in a concurrence, does not demonstrate a certainty of success." *Id.* (citing Tyler v. Hennepin Cnty., 598 U.S. 631, 658–60 (2023) (Gorsuch, J., concurring)).

[143] U.S. CONST. art. I, § 1.

[144] Gundy v. United States, 588 U.S. 128, 135 (2019) (quoting Wayman v. Southard, 23 U.S. (10 Wheat.) 1, 42–43 (1825)). *See also* Mistretta v. United States, 488 U.S. 361, 371 (1989) ("The nondelegation doctrine is rooted in the principle of separation of powers that underlies our tripartite system of government."). For an overview of the Nondelegation Doctrine, *see* CONG. RESEARCH SERV., *Art. I, S.1.5.1 Overview of Nondelegation Doctrine*, Constitution Annotated, https://constitution.congress.gov/browse/essay/artI-S1-5-1/ALDE_00000014/ (last accessed Sept. 17, 2024). For more information on the Nondelegation Doctrine and its history, *see* CONG. RESEARCH SERV., *Art. I, S.1.5.2 Historical Background on Nondelegation Doctrine*, Constitution Annotated, https://constitution.congress.gov/browse/essay/artI-S1-5-2/ALDE_00000009/ (last accessed Sept. 17, 2024).

[145] *Mistretta*, 488 U.S. at 372 ("Applying this 'intelligible principle' test to congressional delegations, our jurisprudence has been driven by a practical understanding that in our increasingly complex society, replete with ever changing and more technical problems, Congress simply cannot do its job absent an ability to delegate power under broad general directives.") *Id.* In *Mistretta*, the Court further observed that "no statute can be entirely precise" and that, as a result, "some judgments involving policy considerations, must be left to the officers executing the law and to the judges applying it." *Id.* at 415. *See also* J.W. Hampton, Jr., & Co. v. United States, 276 U.S. 394, 409 (1928) ("If Congress shall lay down by legislative act an intelligible principle to which the person or body authorized [] is directed to conform, such legislative action is not a forbidden delegation of legislative power.").

[146] PhRMA Compl. at 31; *see also* Boehringer Compl. at 6.

[147] Boehringer Compl. at 6.

[148] *Id. referencing* 15 U.S.C. §§ 717c, 717r (regulation of natural gas companies); 16 U.S.C. §§ 824d, 824e (regulation of electric utilities); 39 U.S.C. § 3622 (regulation of mail products).

[149] *Id.* at 30.

agency should weigh those factors."[150] They argued the program is further unlawful because it establishes only a ceiling price that the MFP cannot exceed, while simultaneously directing HHS to "achieve the lowest [MFP] for each selected drug."[151] The plaintiffs described the program as "unique and unprecedented," claiming that "[d]espite the IRA's breathtaking delegation of power to HHS, the statute lacks both the requisite 'intelligible principle' and the constitutional safeguards necessary to ensure accountability, rationality, and fairness" in price setting.[152]

Although Congress may not give away its legislative powers, the Supreme Court has recognized that Congress needs "flexibility and practicality . . . to perform its functions" and that it "may confer substantial discretion on executive agencies to implement and enforce the laws."[153] As a result, the Court has generally used the rather lenient intelligible principle test to uphold delegations.[154] The Court has not held a statute unconstitutional on the basis that Congress impermissibly delegated authority to another branch of government since 1935, when it decided *A.L.A. Schechter Poultry Corp. v. U.S.* and *Panama Refining Co. v. Ryan*.[155]

The *Schechter Poultry* and *Panama Refining* cases arose in the context of the Great Depression when Congress delegated authority to the executive branch to regulate various economic activities, including allowing the President to prohibit the interstate transport of excess petroleum.[156] In finding a violation of the Nondelegation Doctrine, the *Panama Refining* Court observed, "Congress did not declare in what circumstances that transportation [of petroleum] should be forbidden . . . . Congress left the matter to the President without standard or rule, to be dealt with as he pleased."[157] For these reasons, the Court said, even though the President was acting on behalf of the public interest in hopes of spurring the economy and easing the impact of

[150] *Id.*

[151] Chamber of Com. Compl. at 43.

[152] *Id*. at 36.

[153] Gundy v. United States, 588 U.S. 128, 135–36 (2019) (Gorsuch, J., dissenting) (plurality opinion) (alteration omitted) (quoting Yakus v. United States, 321 U.S. 414, 425 (1944)).

[154] Although the Nondelegation Doctrine has generally been used to uphold congressional delegations under the intelligible principle test, Justices Gorsuch, Roberts, and Thomas have indicated that it may be time for the Court to revisit the doctrine. *Id.* At least when it comes to delegations that allow for a noncongressional entity to directly restrict an individual's liberty, these three Justices seem to call for a new Nondelegation Doctrine standard. *See id.* at 2134. Justice Gorsuch remarked, "[I]t's undeniable that the 'intelligible principle' remark [in *J.W. Hampton*] eventually began to take on a life of its own. We sometimes chide people for treating judicial opinions as if they were statutes, divorcing a passing comment from its context, ignoring all that came before and after, and treating an isolated phrase as if it were controlling. But that seems to be exactly what happened here." *Id.* at 163 (footnote omitted).

[155] A.L.A. Schechter Poultry Corp. v. United States, 295 U.S. 495 (1935) and Pan. Refin. Co. v. Ryan, 293 U.S. 388 (1935). For more information about the history of the Nondelegation Doctrine, *see* CONG. RESEARCH SERV., *Art. I, S.1.5.3 Origin of Intelligible Principle Standard*, Constitution Annotated, https://constitution.congress.gov/browse/essay/artI-S1-5-3/ALDE_00001317/ (last accessed Sept. 17, 2024). *A.L.A. Schechter Poultry Corp. Schechter*, 295 U.S. at 530–31.

[156] *Schechter*, 295 U.S. at 526; *Panama Refining*, 293 U.S. at 433. The Court distinguished *Schechter* from *Panama Refining* by observing that the issue in *Schechter* was whether Congress had given adequate definition to the "codes of fair competition" under the National Industry Recovery Act, such that the President could interpret that term. *Schechter*, 295 U.S. at 530–31. *Panama Refining*, on the other hand, concerned the "range of discretion given to the President" to prohibit the interstate and foreign commerce transportation of petroleum. *Id*. at 419. For these reasons, the Court said, even though the President was acting on behalf of the public interest in hopes of spurring the economy and easing the impact of the Great Depression, Congress violated the Nondelegation Doctrine by ceding its legislative function to the executive branch without sufficient guidance. *Id.* at 430.

[157] *Panama Refining*, 293 U.S. at 419. The Court also observed that "[t]he President was not required to ascertain and proclaim the conditions prevailing in the industry which made the prohibition [on transporting petroleum] necessary." *Id.* at 418.

the Great Depression, Congress violated the Nondelegation Doctrine by ceding its legislative function to the executive branch without sufficient guidance.[158]

Of the cases that brought Nondelegation Doctrine challenges against the IRA, the U.S. District Court for the District of New Jersey, in *Novo Nordisk, Inc. v. Becerra*, is the only court so far to reach the merits of the issue.[159] In that case, the court disagreed with the drug manufacturer's argument that the IRA lacked an "intelligible principle," and the court characterized this standard as "not demanding."[160] The court reviewed the wording of the IRA to determine whether Congress had crafted an intelligible principle in it, concluding that its text "provides significantly much more guidance than [the manufacturer] claim[s]" and "easily passes constitutional muster."[161] As an example, the court cited the directive that CMS consider certain factors when determining the MFP, observing, "The IRA conveys a specific, delineated task to CMS, and it explains the scope and parameters of the delegation throughout the statute."[162]

The court also pointed out that the Supreme Court has not found that a statute has violated the Nondelegation Doctrine since 1935, when the court decided *Panama Refining Co.* and *Schechter*, where Congress did not "'articulate *any* policy or standard'" in the statutes at issue.[163] The court compared the IRA to the facts of those cases and found that "it certainly cannot be said that Congress failed to articulate *any* intelligible principle in the IRA."[164] Moreover, the court said it would not "disturb nearly century-long precedent upholding very broad delegations to agencies to regulate 'in the public interest' and to 'set fair and equitable' prices" by finding that the IRA lacked an intelligible principle.[165]

Finally, the court was not persuaded by the manufacturer's argument that the IRA violates the Nondelegation Doctrine because some of CMS's decisions in implementing the program are not subject to judicial review.[166] The court agreed with the government's argument that the preclusion of judicial review "is not related to" the Nondelegation Doctrine.[167] Citing a couple of Supreme Court decisions, the court stated that "courts have consistently considered statutes that preclude

[158] The Court observed: "When, therefore, such an administrative agency is required as a condition precedent to an order, to make a finding of facts, the validity of the order must rest upon the needed finding. If it is lacking, the order is ineffective." *Id.* at 433.

[159] In the other cases where plaintiffs challenged the IRA under the Nondelegation Doctrine and/or argued that the IRA violated the separation of powers, the courts did not reach this issue because the cases were dismissed on procedural grounds. *See* Nat'l Infusion Ctr. Ass'n v. Becerra, No. 23-CV-707, 2024 WL 561860 (W.D. Tex. Feb. 12, 2024), *rev'd* 2024 WL 4247856 (5th Cir. Sept. 20, 2024); Dayton Area Chamber of Com. v. Becerra, 696 F. Supp. 3d 440 (S.D. Ohio Sept. 29, 2023).

Additionally, in its decision on the parties' motion for summary judgment, the court in *Boehringer Ingelheim* observed in a footnote, "The [company's] complaint also briefly suggests that the Program constitutes an unconstitutional delegation of Congress's authority, but the complaint does not allege this as a distinct claim and none of the parties raise this issue in their summary judgment briefing. As such, I do not address it." *Boehringer Ingelheim Pharms.*, 2024 WL 3292657, at *6 n.4.

[160] Novo Nordisk v. Becerra, No. 23-20814, 2024 WL 3594413, at *7–8 (D.N.J. July 31, 2024).

[161] *Id.* at *8.

[162] *Id.* (discussing 42 U.S.C. § 1320f-3(e)(1)–(2)).

[163] *Id.* (quoting Mistretta v. United States, 488 U.S. 361, 373 n.7 (1989); *see also A.L.A. Schechter Poultry Corp.*, 295 U.S. 495 (1935); Pan. Refin. Co. v. Ryan, 293 U.S. 388 (1935).

[164] *Novo Nordisk*, 2024 WL 3594413, at *8.

[165] *Id.*

[166] *Id.*

[167] *Id.*

judicial review and have not indicated that such preclusion violates the nondelegation doctrine."[168]

Spending Clause and Related Claims

Article I, Section 8, Clause 1 of the Constitution, known as the "Spending Clause," provides, "The Congress shall have Power To lay and collect Taxes, Duties, Imposts, and Excises, to pay Debts and provide for the common Defence and general Welfare of the United States."[169] The pharmaceutical manufacturer plaintiffs argued that Congress's power under the Spending Clause cannot justify the IRA's regulatory scheme.[170] First, the plaintiffs asserted that the IRA is not a valid spending condition, because it does not condition federal Medicare reimbursement on a manufacturer's compliance with the terms of the statute.[171] Instead, one plaintiff alleged, the IRA "commands manufacturers to comply and levies monetary penalties for failure to do so."[172] Another plaintiff argued that the IRA "unconstitutionally conditions participation in Medicare" on its "relinquishment" of its constitutional rights.[173]

Another manufacturer further alleged that even if Congress created a funding condition in the IRA, the statute does not provide "clear notice" of the condition.[174] According to one plaintiff, "there is no offer . . . to accept," and thus the "choice" to comply with the statute and participate in the Medicare program is "illusory," because due to the structure of the tax, manufacturers may gain relief only by completely extricating themselves from Medicare.[175] Another manufacturer claimed the statute is "unconstitutionally coercive because it leverages vast, unrelated benefits to induce distinct transactions that the Government wants."[176] Another plaintiff argued that because manufacturers can only "escape" the program by "withdrawing *all* . . . products from Medicare and Medicaid—not just the drug selected for the Program," this amounts to a "gun to the

[168] *Id.* (citing Heckler v. Chaney, 470 U.S. 821 (1985); United States v. Erika, Inc., 456 U.S. 201, 208 (1982); Yale New Haven Hosp. v. Becerra, 56 F.4th 9 (2d Cir. 2022)).

[169] U.S. CONST. art. I, § 8.

[170] Bristol Myers Compl. at 24; Merck Compl at 22; Janssen Compl. at 6; Boehringer Compl. at 42.

[171] Bristol Myers Compl. at 24–25; Merck Compl. at 21.

[172] Bristol Myers Compl. at 24; Merck Compl. at 21. The monetary penalties to which the manufacturers refer are the law's excise tax, which is based on a percentage of the selected drug's total revenue, not just its Medicare revenue. *See* 26 U.S.C. § 5000D.

[173] Boehringer Compl. at 42.

[174] *See* Bristol Myers Compl. at 24 ("Here, the IRA does not set forth conditions on Medicare or Medicaid reimbursement, or provide for exclusion from those benefit programs if a manufacturer does not cooperate. . . . [The IRA's] indirect, convoluted scheme does not 'unambiguously' condition a manufacturer's receipt of federal funding on its acceptance of the IRA's mandates.").

[175] Merck Compl. at 21; s*ee also* 26 U.S.C. § 5000D(b). The manufacturers point out that in order to withdraw from participation in these programs, they must, under federal law, give notice of their decision to terminate, and the IRA "delays [their] ability to terminate . . . for between 11 and 23 months." Merck Compl. at 24 (citing 42 U.S.C. § 1395w-114a(b)(4)(B)(ii)) (regarding the allowable duration of Medicare Coverage Gap Discount Program agreements and a manufacturer's right to terminate such an agreement).

In effect, the manufacturers argue that they would have had to withdraw from Medicare and Medicaid by January 2022, before the IRA was even enacted, to avoid the excise taxes. Bristol Myers Compl. at 24. One plaintiff summarizes the issue: "In short, once a manufacturer is sucked into the IRA's vortex of forced below-market sales, it has at its disposal no evidenced means of escape." Merck Compl. at 12. In its Revised Guidance, CMS has attempted to resolve this issue by allowing for an expedited termination of Medicare participation for manufacturers of selected drugs who do not wish to participate in negotiations. *See* CMS REVISED GUIDANCE at 120–21.

[176] Merck Compl. at 23.

head."[177]Additionally, the plaintiffs stated that the IRA unlawfully conditions receipt of their Medicare reimbursement payments on the "abandonment of their First and Fifth Amendment rights," in violation of the doctrine of unconstitutional conditions.[178]

The Supreme Court has interpreted the Spending Clause to allow Congress "wide latitude" in attaching conditions to federal funding while simultaneously recognizing four main constitutional restrictions on such conditions.[179] First, Congress must articulate clear notice of the funding condition.[180] Other limitations that the Court has placed on Congress's power under the Spending Clause include whether the condition is related to the underlying purpose of the spending; whether the condition is unconstitutionally coercive; and whether the condition can be characterized as an "unconstitutional condition."[181]

Although Congress may condition federal funding, "in some circumstances the financial inducement offered by Congress might be so coercive as to pass the point at which 'pressure turns into compulsion,'" in violation of federalism principles.[182] In *NFIB v. Sebelius*, the Supreme Court invalidated a section of the Patient Protection and Affordable Care Act (ACA) that withheld all federal Medicaid funding from states that did not expand their Medicaid programs in accordance with the law, at least in part, on the basis that such changes violated the anti-coercion principle described in *South Dakota v. Dole*.[183] A plurality of the Court characterized the ACA's changes to the Medicaid program as "dramatic[]," because if a state opted not to comply with the statute, it would "lose not merely 'a relatively small percentage' of its existing Medicaid funding,

[177] Janssen Compl. at 4.

[178] Bristol Myers Compl. at 25; Janssen Compl. at 6.

[179] South Dakota v. Dole, 483 U.S. 203, 206 (1987) ("Incident to this [spending] power, Congress may attach conditions on the receipt of federal funds, and has repeatedly employed the power 'to further broad policy objectives by conditioning receipt of federal moneys upon compliance by the recipient with federal statutory and administrative directives.'" (quoting Fullilove v. Klutznick, 448 U.S. 448, 474 (1980)).

[180] *See generally*, CONG. RESEARCH SERVICE, *Art. I S.8.C1.2.1 Overview of Spending Clause*, Constitution Annotated, https://constitution.congress.gov/browse/essay/artI-S8-C1-2-1/ALDE_00013356/ (last accessed Sept. 17, 2024); CRS Report R46827, *Funding Conditions: Constitutional Limits on Congress's Spending Power*, by Victoria L. Killion (2021). In *Pennhurst State School and Hospital v. Halderman*, for example, the Court observed, "The legitimacy of Congress' power to legislate under the spending power thus rests on whether the [s]tate voluntarily and knowingly accepts the terms of the 'contract.'" 451 U.S. 1, 13, 17 (1984). The federal statute at issue created "a federal-state grant program" wherein the federal government provided financial assistance to participating states to create programs to care for the developmentally disabled. *Id*. at 1. States' participation in the program was voluntary; to receive federal funding, states were required to comply with various provisions in the bill. *Id.* A resident of Pennhurst State School and Hospital, a facility that provided care to the developmentally disabled, brought a class action challenging the facility's "inhumane" conditions and asserting patients' rights under the Federal Constitution and the "bill of rights" provisions of the statute authorizing the grant program. *Id.* at 2. The Court held that Congress must impose funding conditions "unambiguously," so that States could "exercise their choice knowingly, cognizant of the consequences of their participation," and that there could be "no knowing acceptance if a State is unaware of the conditions." *Pennhurst*, 451 U.S. at 17.

[181] South Dakota v. Dole, 483 U.S. 203, 207–08 (1987). For more detailed information about the restrictions the Court has placed on Congress's ability to place conditions on the receipt of federal funding, *see* CONG. RESEARCH SERVICE, *Art. I S.8.C1.2.1 Overview of Spending Clause*, Constitution Annotated, https://constitution.congress.gov/browse/essay/artI-S8-C1-2-1/ALDE_00013356/ (last accessed Sept. 17, 2024); and CRS Report R46827, *Funding Conditions: Constitutional Limits on Congress's Spending Power*, by Victoria L. Killion (2021). In *South Dakota v. Dole*, the Court observed "that conditions on federal grants might be illegitimate if they are unrelated 'to the federal interest in particular . . . programs." 483 U.S. 203, 207 (1987) (quoting Massachusetts v. United States, 435 U.S. 444, 461 (1978) (plurality opinion). For example, the Court found that conditioning the receipt of federal highway funds on states adopting a minimum drinking age was sufficiently related to the federal interest in "safe interstate travel." *Id*. at 208.

[182] *Dole*, 483 U.S. at 211 (quoting Steward Machine Co. v. Davis, 310 U.S. 548, 590 (1937)).

[183] Nat'l Fed. of Indep. Bus. v. Sebelius, 567 U.S. 519 (2012).

but *all* of it."[184] The Court reasoned that the Medicaid expansion essentially created a "new program" and that "Congress is not free to . . . penalize States that choose not to participate in that new program by taking away their existing Medicaid funding."[185]

Congress may condition funds to both governmental recipients (e.g., states or federal agencies) and nongovernmental recipients (e.g., private businesses).[186] Whether each of the Spending Clause limits discussed above applies to conditions on private entities, however, is unsettled. Although the Supreme Court has applied the clear notice principle in a case involving a private funding recipient,[187] it has not ruled on whether the relatedness or anti-coercion limitations—which are rooted in federalism concerns—also apply to conditions on funding to private entities, such as drug manufacturers.[188]

Of the cases decided so far, three courts have reached the merits of the manufacturers' various Spending Clause-related challenges.[189] As part of its conclusion that participation in Medicare is voluntary, the *Boehringer Ingelheim* court discussed the plaintiff's arguments that the IRA was not a valid exercise of Congress's power under the Spending Clause.[190] In support of its claim, the drugmaker pointed to the Supreme Court's decision in *NFIB*, which held, in part, that Congress could not condition all of a state's Medicaid funding on its willingness to comply with various conditions in the ACA.[191] The court distinguished *NFIB*, though, observing that it concerned the anti-commandeering doctrine, which is based on the idea that the Constitution does not give Congress the power to require a state to govern in a certain way.[192] The doctrine was "designed to preserve 'our system of federalism' by preventing Congress from interfering with state governments by placing overly controlling conditions on federal dollars."[193] As result, the *Boehringer Ingelheim* court held that "[n]o similar limit" on Congress' power under the Spending Clause applied to the IRA, because it regulates private parties, rather than the states.[194] The court

[184] *Id.* at 581 (quoting *Dole*, 483 U.S. at 211). Chief Justice Roberts authored the opinion of the Court, and Justices Breyer and Kagan joined. *Id.* at 529.

[185] *Id.* at 587. In addition, the Court has held that Congress may not use its Spending Clause power to "induce the States to engage in activities that would themselves be unconstitutional." *Dole*, 483 U.S. at 210. This principle has come to be known as the "unconstitutional conditions" doctrine. The Fifth Circuit has described the doctrine as examining "the extent to which government benefits may be conditioned or distributed in ways that burden constitutional rights or principles." Pace v. Bogalusa City Sch. Bd., 403 F.3d 272, 286 (5th Cir. 2005) (en banc). Under this "independent constitutional bar" principle, for example, a condition that would require states to violate the First Amendment rights of their citizens would be an unconstitutional spending condition. *See supra* "First Amendment Claim."

[186] *See, e.g.*, *Dole*, 482 U.S. 203; Gonzaga Univ. v. Doe, 536 U.S. 273 (2002). The plaintiffs' complaints do not address whether the Court's limitations on constitutional conditions apply equally to private entities and the states.

[187] *Gonzaga Univ.*, 536 U.S. 273.

[188] *See* Northport Health Servs. v. HHS, 438 F. Supp. 3d 956, 970–71 (W.D. Ark. 2020) ("No part of the Court's decision in *NFIB* touched on the government's power to place conditions on private entities. In fact, Courts of Appeals have held time and time again that the participation of private entities in Medicare and Medicaid is always voluntary, and providers can avoid regulations to which they object by choosing not to participate in Medicare or Medicaid."), *aff'd on other grounds*, 14 F.4th 856 (8th Cir. 2021). For more information on the distinctions between private and governmental entities with respect to the constitutional limitations on Congress's power under the Spending Clause, *see* CRS Report R46827, *Funding Conditions: Constitutional Limits on Congress's Spending Power*, by Victoria L. Killion (2021).

[189] *Bristol Myers Squibb/Janssen*, 2024 WL 1855054, at *12; Janssen Pharms., 2024 WL 1855054, at *8; *Novo Nordisk*, 2024 WL 3594413, at *5; *Boehringer Ingelheim Pharms*., 2024 WL 3292657, at *15.

[190] *Boehringer Ingelheim Pharms*., 2024 WL 3292657, at *15.

[191] *Id.* (citing NFIB v. Sebelius, 567 U.S. 519, 582 (2012)).

[192] *Id.*

[193] *Id.* (quoting NFIB, 567 U.S. at 577–78).

[194] *Id.*

concluded, "[t]he federal government is free to use its economic power as a bulk purchaser of certain goods to negotiate better deals for those goods."[195]

In *Bristol Myers Squibb* and *Janssen*, the court addressed the manufacturers' unconstitutional conditions argument, agreeing with the government that the IRA did not violate the doctrine because none of the manufacturers' constitutionally protected rights were "in danger of being trampled" by voluntarily participating in the Medicare program.[196] The court held that the IRA does not run afoul of First Amendment free speech and it does not violate the Due Process Clause or constitute a taking under the Fifth Amendment.[197] The court declined to substantively analyze the manufacturers' claims, holding that, under these circumstances, "the unconstitutional [conditions] doctrine does not apply."[198]

Similarly, the *Novo Nordisk* court observed that it had "swiftly rejected" the "nearly identical" unconstitutional conditions doctrine claims before it in the *Bristol Myers Squibb* and *Janssen* decision, because the manufacturers did not show that the IRA violated their First or Fifth Amendment rights.[199] The court in *Novo Nordisk* "decline[d] to disturb its prior holdings and applie[d] its reasoning and conclusions to the present action."[200] The court held that because Medicare participation is voluntary and is not coerced, it "does not infringe on a manufacturer's constitutional rights."[201]

Concluding Considerations

Many factors influence domestic drug prices, and Congress has continued to express interest in addressing high prices in a number of potential ways.[202] The Congressional Budget Office (CBO) estimated that the Medicare Drug Price Negotiation Program would lower the federal budget deficit by $25 billion and that, by 2031, Part D prices would be 8% lower, and Part B prices 9% lower, as a result of the negotiations.[203] In the administration's most recent estimate, which was released after CMS announced the MFPs for the first 10 selected drugs, the agency stated that if the negotiated prices had been used by Medicare in 2023, they "would have saved an estimated

[195] *Id.*

[196] *Bristol Myers Squibb/Janssen*, 2024 WL 1855054, at *12 (quoting Oral Argument Transcript at 58:2–4, Janssen Pharms. v. Becerra et al., Nos. 23-CV-3818, 3335, 14221, 20184 (Argument held Mar. 7, 2024, D.N.J. 2024) (ECF No. 97).

[197] *Id.* at *12. Bristol Myers Squibb did not make an Eighth Amendment argument; however, in *Boehringer Ingelheim*, an Eighth Amendment violation was not found, as the court held that it lacked jurisdiction over the manufacturer's claim. *See supra* "Eighth Amendment Claim."

[198] *Bristol Myers Squibb/Janssen*, 2024 WL 1855054, at *12.

[199] *Novo Nordisk v. Becerra*, No. CV 23-20814, 2024 WL 3594413, at *5 (D.N.J. July 31, 2024) (citing *Bristol Myers Squibb/Janssen*, 2024 WL 1855054, at *12). *Novo Nordisk*, *Bristol Myers Squibb*, and *Janssen* were all decided by the same district court judge.

[200] *Id.*

[201] *Id.*

[202] *See generally*, CRS In Focus IF12272, *Selected Issues in Pharmaceutical Drug Pricing*, by Jim Hahn et al. (2023).

[203] How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act at 5, 19, CONGRESSIONAL BUDGET OFFICE (Feb. 2023), https://www.cbo.gov/system/files/2023-02/58850-IRA-Drug-Provs.pdf. *See also* Michael Erman et al., *Bristol Myers, Pfizer, AbbVie Drugs Likely to Face U.S. Price Negotiation*, REUTERS (Mar. 13, 2023), https://www.reuters.com/business/healthcare-pharmaceuticals/bristol-myers-pfizer-abbvie-drugs-likely-face-us-price-negotiation-2023-03-13/.

$6 billion in net covered prescription drug costs," representing "22% lower net spending in aggregate."[204]

Although the program may result in a deficit reduction, some stakeholders have contended that the IRA will negatively affect future drug research and development by stifling innovation.[205] Some manufacturers have claimed that it will incentivize pharmaceutical companies to delay research for drugs used to treat smaller patient populations.[206] In a September 2022 cost estimate for the IRA, CBO estimated that "the number of drugs that would be introduced to the U.S. market would be reduced by about [one] over the 2023-2032 period," and "about [five] over the subsequent decade, and about [seven] over the decade after that."[207] It may take years for the U.S. drug market to realize the full effects of the legislation, as more and more drugs will be subject to negotiation in the future. For example, CMS selected 10 drugs for negotiation in price year 2026; CMS will select 15 drugs for each of price years 2027 and 2028; and CMS will select 20 drugs in 2029 and each year thereafter.[208] Additionally, for the first two years of the program, CMS will select only Part D drugs; Part B drugs will not become eligible for negotiation until price year 2028.[209]

Many of the constitutional claims made in the cases so far turn on whether participation in the drug negotiation program, and the Medicare program as a whole, is voluntary. As discussed above, if the manufacturers choose to participate in Medicare, an effect of that choice may be that one or more of the manufacturers' drugs will be selected for price negotiation. If participation is not compulsory, then the manufacturers are not being compelled to sign negotiation agreements or sell their drugs to Medicare for a lower price. In the summary judgment briefs, the plaintiffs argued that if they were to stop selling drugs to Medicare, patients would be deprived of innovative medicines and the manufacturers would lose tremendous profits.[210] The courts have thus far been unpersuaded by such policy arguments, noting the voluminous cases finding

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[204] CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026* (Aug. 2024), https://www.cms.gov/files/document/fact-sheet-negotiated-prices-initial-price-applicability-year-2026.pdf.

[205] Daniel Gilbert, *As Drugmakers Slam Medicare Price Controls, Wall Street Shrugs*, WASH. POST (Aug. 29, 2023) https://www.washingtonpost.com/business/2023/08/29/medicare-drug-price-pharma-companies-stock/?utm_campaign=wp_the7&utm_medium=email&utm_source=newsletter&wpisrc=nl_the7. Robert Langreth & David Gura, *Biden Drug Pricing Law Threatens New Products, J&J's Duato Says*, BLOOMBERG LAW (Sept. 11, 2024), https://news.bloomberglaw.com/product/blaw/bloomberglawnews/exp/eyJpZCI6IjAwMDAwMTkxLWU1OTItZGM0MC1hM2Y3LWVkYjIzMzAzMDAwNCIsImN0eHQiOiJIUE5XIiwidXVpZCI6IndkQzJVN1J2emVkbFNoUUs3bGI3anc9PW5Ld2ZUVnA1RVJzNUVmRW4vTlc0clE9PSIsInRpbWUiOiIxNzI2MTM4MzU4MDcyIiwic2lnIjoiNVNXTkpYL0JOQTZFOHNaVjFoKzJ0VDI3RGlJPSIsInYiOiIxIn0=?source=newsletter&item=read-text&region=top%20stories%20digest&channel=pharma-and-life-sciences.

For more information on the pharmaceutical industry's responses to the program, see CRS Report R47872, *Medicare Drug Price Negotiation Under the Inflation Reduction Act: Industry Responses and Potential Effects*, by Kevin J. Hickey, Suzanne M. Kirchhoff, and Hannah-Alise Rogers (2023).

[206] Rachel Cohrs, *Genentech Weighs Slow-Walking Ovarian Cancer Therapy to Make More Money Under Drug Price Reform*, STAT+ (Aug. 10, 2023), https://www.statnews.com/2023/08/10/genentech-drug-price-cancer/.

[207] Summary Estimated Budgetary Effects of Public Law 117-169 at 15, CONGRESSIONAL BUDGET OFFICE (Sept. 7, 2022), https://www.cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf. CBO stated that "[t]he amounts in this estimate are in the middle of the distribution of possible outcomes, by CBO's assessment, and they are subject to uncertainty." *Id.*

[208] 42 U.S.C. § 1320f-1(a)(1)–(4).

[209] *Id.* § 1320f-1(d)(1)(A).

[210] *See, e.g.*, Combined Opposition to Defendants' Cross-Motion for Summary Judgment and Reply in Support of Plaintiff's Motion for Summary Judgment, Janssen Pharms. v. Becerra, No. 23-3818, ECF No. 71 (D.N.J. Nov. 24, 2023), at 2; *see also*, Combined Opposition to Defendants' Cross-Motion for Summary Judgment and Reply in Support of Plaintiff's Motion for Summary Judgment, Boehringer Ingelheim Pharms. v. HHS, No. 23-1103, ECF No. 92 (D. Conn. Jan 26, 2024), at 7.

Medicare participation voluntary, even while acknowledging that the government's purchases make up a significant share of the domestic prescription drug market.[211]

Litigation over the program is ongoing, and the next phase for many of the cases discussed here will be the appeals that are currently pending in several U.S. Courts of Appeals, which will also involve the plaintiffs' APA claims. Additional cases with similar or new allegations may follow. Some stakeholders have characterized the lawsuits as a "legal crusade" that is being "strategically designed to reach the U.S. Supreme Court," while some legal scholars have characterized the litigation as an "uphill climb[]."[212] While the initial attempt to enjoin the program's implementation was unsuccessful,[213] a future court decision could put implementation of the negotiated prices on hold or stop CMS from selecting more drugs for negotiation in future years. The fate of the program may depend in part on how courts resolve the various claims made by the parties. The outcome of the litigation may have a substantial impact on how effectively CMS will be able to carry out the program and uphold its stated goals of lowering prescription drug prices for Medicare and its beneficiaries.

While the litigation proceeds, CMS has attempted to address several stakeholder concerns in its Revised Guidance; some of the revisions could affect the litigation.[214] For example, the guidance attempted to clarify CMS's consideration of the negotiation factors for the establishment of the MFP, which drug manufacturers and others have claimed are overly broad and do not specify the weight the Secretary will assign to each factor.[215]

The agency's Revised Guidance responded to the more than 7,500 comments CMS received after the release of the Initial Guidance in March 2023.[216] Through the Revised Guidance, CMS advised that it intends to create additional "patient-focused listening sessions" to enable both the public and drug companies "to engage with CMS during the negotiation process."[217]

Similarly, in May 2024, CMS issued additional guidance for price applicability year 2027, which clarified how the MFPs for price year 2026 will be effectuated.[218] The May 2024 guidance also provided more information about other aspects of the program, including the implementation of the small biotech exception and how CMS will monitor the bona fide marketing requirement, which also faces a legal challenge under the APA.[219]

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[211] *See, e.g.*, *Bristol Myers Squibb/Janssen*, 2024 WL 1855054, at *7 ("As an initial matter, the parties have not identified any authority holding that participation in the Medicare system is involuntary."); *see also Boehringer Ingelheim Pharms.*, 2024 WL 3292657, at *12 (discussing caselaw finding Medicare provider participation voluntary).

[212] Ian Lopez, *Drugmakers Prep Medicare Pricing Suits for March to High Court*, BLOOMBERG LAW (Aug. 17, 2023).

[213] The U.S. Chamber of Commerce filed a motion for a preliminary injunction to halt implementation of the drug pricing program while the litigation challenging the program's constitutionality remained ongoing, but the court denied this motion in September 2023. Dayton Area Chamber of Com. v. Becerra, 696 F. Supp. 3d 440 (W.D. Ohio Sept. 29, 2023). The court denied the motion after finding that the plaintiffs had not demonstrated that they were likely to succeed on the merits of their claims and did not face an imminent threat of harm if an injunction were not granted. *Id.* at 455, 458.

[214] *See generally*, CMS REVISED GUIDANCE, *supra* note 8.

[215] *Id.* at 46–50; s*ee also* Chamber of Com. Compl. at 37.

[216] CMS, *CMS Releases Revised Guidance for Historic Medicare Drug Price Negotiation Program*, Press Release (June 29, 2023), https://www.cms.gov/newsroom/press-releases/cms-releases-revised-guidance-historic-medicare-drug-price-negotiation-program.

[217] *Id.*

[218] CMS 2027 GUIDANCE, *supra* note 12 at 110.

[219] *Id.* at 115. For more information on the challenge related to CMS's bona fide marketing requirement, *see* CRS Legal Sidebar LSB11112, *Administrative Procedure Act Challenges to CMS's Implementation of the Medicare Drug Price Negotiation Program*, by Hannah-Alise Rogers (2024).

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