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# Constitutional Challenges to the Medicare Drug Price Negotiation Program

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SUMMARY

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# Constitutional Challenges to the Medicare Drug Price Negotiation Program

Congress created the Medicare Drug Pricing 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.

In summer 2023, several drug manufacturers and trade associations representing manufacturers challenged the law before federal district courts across the country. The plaintiffs argue that the law is unconstitutional under the First, Fifth, and Eighth Amendments, and they also allege violations of the Nondelegation Doctrine and the Spending Clause. This report explains and contextualizes the plaintiffs' constitutional claims by analyzing relevant U.S. Supreme Court jurisprudence.

The plaintiffs argue 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 argue that the IRA violates the Fifth Amendment, both the Due Process Clause and the Takings Clause. First, the plaintiffs claim 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 allege that the law constitutes a taking of both tangible (drugs) and intangible (patents) property. Some of the plaintiffs claim that the program amounts to a per se taking, while others argue that it constitutes a regulatory taking.

A few of the plaintiffs argue 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 argue that the IRA violates the Nondelegation Doctrine by ceding too much power to the Secretary of HHS to set drug prices. Finally, several plaintiffs argue 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 allege 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.

The report concludes by identifying relevant considerations for the 118th Congress as the litigation proceeds. At least one drug manufacturer has filed a preliminary injunction, seeking to halt CMS's implementation of the program until the litigation is resolved. Some stakeholders predict that the litigation could reach the U.S. Supreme Court.

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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. 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, 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.[2] Taken together, the cases bring a variety of facial constitutional challenges against the IRA, including under the First, Fifth, and Eighth Amendments; the Nondelegation Doctrine; and the Spending Clause.[3] At least two of the plaintiffs also argue that the CMS guidance implementing the program violates the Administrative Procedure Act.[4]

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.[5] 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).[6] 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."[7] As described in previous CRS reports, CMS began implementing the Medicare Drug Price Negotiation Program by issuing

[1] Inflation Reduction Act of 2022, P.L. 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 *et seq*.

[2] Complaint, Merck & Co. v. Becerra, No. 23-1616 (D.D.C. Jun. 6, 2023), ECF No. 1 [hereinafter Merck Compl.]. Complaint, U.S. Chamber of Commerce, et al. v. Becerra, No. 23-0156 (S.D. Ohio, Jun. 9, 2023) ECF No. 1 [hereinafter Chamber of Com. Compl.]; Complaint, Bristol Myers Squibb Company v. Becerra, No. 23-3335 (D.N.J. Jun. 16, 2023), ECF No. 1 [hereinafter Bristol Myers Compl.]; Complaint, Pharmaceutical Research and Manufacturers of America (PhRMA) et al. v. Becerra, No. 23-0707 (W.D. Tex. Jun. 21, 2023), ECF No. 1 [hereinafter PhRMA Compl.]; Complaint, Janssen Pharmaceuticals Inc. v. Becerra, No 23-3818 (D.N.J. July 18, 2023), ECF No. 1 [hereinafter Janssen Compl.]; Complaint, Astellas Pharma U.S., Inc. v. Becerra, No. 23-4578 (N.D. Ill. July 14, 2023), ECF No. 1 [hereinafter Astellas Compl.]; Complaint, Boehringer Ingelheim Pharmaceuticals, Inc., v. Becerra, No. 23-01103 (D. Conn. Aug. 18, 2023), ECF No. 1 [hereinafter Boehringer Compl.]; Complaint, AstraZeneca Pharmaceuticals LP v. Becerra, No. 23-0931 (D. Del. Aug. 25, 2023), ECF No. 1 [hereinafter AstraZeneca Compl.].

[3] Complaints *supra* note 2.

[4] AstraZeneca Compl. at 7; Boehringer Compl. at 8. This Report only addresses the plaintiffs' constitutional challenges.

[5] 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).

[6] 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, the drug must be a covered Part B or Part D drug and (1) 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 § 351 of the Public Health Service Act (42 U.S.C. §§ 201 et seq.) and be marketed under the license; to have been marketed for at least 11 years from the date of initial licensure; and (3) not to be the reference product for any other licensed and marketed biosimilar. *Id.* § 1320f-1(e)(1)(B)(i)-(iii).

[7] 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 through notice-and-comment rulemaking." CMS REVISED GUIDANCE, *infra* note 8, at 2.

Initial Guidance on March 15, 2023.[8] 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).[9] In accordance with the statute, on August 29, 2023, CMS selected the first 10 drugs for price negotiation.[10] The MFP negotiations are to conclude by August 1, 2024, and the MFP is to take effect in 2026.[11]

This report explains and contextualizes the plaintiffs' constitutional claims, relying on relevant Supreme Court jurisprudence.[12]

# First Amendment Claim

The First Amendment states, in relevant part, that "Congress shall make no law . . . abridging the freedom of speech."[13] 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 otherwise express a viewpoint that the speaker does not agree with or wish to communicate.[14] At least six plaintiffs have claimed that the IRA violates the First Amendment prohibition against compelled speech.[15]

Under the IRA, the manufacturers of selected drugs are required to enter into agreements with HHS to negotiate, and potentially renegotiate, what the statute calls the "maximum fair price" (MFP) of the drug.[16] If the manufacturers of selected drugs fail to sign an agreement with CMS by October 1, 2023, the manufacturers will be subject to an excise tax, which is described in

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[8] CENTERS FOR MEDICARE AND MEDICAID, 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 [hereinafter CMS INITIAL GUIDANCE].

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 Medicare Prescription Drug Price Negotiation 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).

[9] CENTERS FOR MEDICARE AND MEDICAID, MEDICARE DRUG PRICE NEGOTIATION PROGRAM: REVISED GUIDANCE, IMPLEMENTATION OF SECTIONS 1191–98 OF THE SOCIAL SECURITY ACT FOR INITIAL PRICE APPLICABILITY YEAR 2026, (JUN. 30, 2023), https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf [hereinafter CMS REVISED GUIDANCE].

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

[11] CMS REVISED GUIDANCE at 117; 42 U.S.C. § 1320f(d)(1).

[12] At the time of this writing, HHS has not had the opportunity to address all of the plaintiffs' claims—the report does not address the validity of the claims being made or any arguments or defenses with which the government may respond.

[13] U.S. CONST. amend. I. *See also* CONG. RESEARCH SERV., Amdt 1.7.1 *Historical Background on Free Speech Clause*, https://constitution.congress.gov/browse/essay/amdt1-7-1/ALDE_00013537/ (last accessed Sept. 1, 2023).

[14] *See, e.g.*, 303 Creative LLC v. Elenis, 143 S. Ct. 2298, 2312 (2023); Nat'l Inst. of Family & Life Advocates v. Becerra, 138 S. Ct. 2361, 2371 (2018).

[15] 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.

[16] *See* 42 U.S.C. 1192f-3(c).

further detail below.[17] One plaintiff claims that signing such agreements amounts to "forced messaging that promotes the (false) impression that manufacturers . . . agree with prices imposed by HHS decree."[18] Similarly, another plaintiff alleges 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."[19] The manufacturer claims the government cannot justify this "compelled-speech regime" because it lacks a "legitimate reason" to force manufacturers to convey these "misleading" messages.[20] The plaintiffs further argue that Congress could regulate drug prices "without burdening a speaker with unwanted speech," and that "[p]rice controls do not require speech controls."[21] It further claims that the government lacks a "legitimate reason" to force manufacturers to convey misleading messages.[22]

In evaluating First Amendment challenges, one critical threshold question a court would consider is whether the government is regulating expressive activity, which is protected by the First Amendment, or only nonexpressive conduct, which is not protected. The Supreme Court has observed that "the First Amendment directs that the government may not suppress speech as easily as it may suppress conduct."[23] 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.[24] "[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 a means of language, either spoken, written, or printed."[25]

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.[26] The Court observed that a "typical price regulation"[27] might not implicate the First Amendment if it would only regulate conduct.[28] However, if a law regulates "the communication of prices rather than prices themselves," it regulates "speech," thus triggering First Amendment scrutiny.[29] The *Expressions* Court reasoned that the state law regulated speech because rather than

[17] For more information about the excise tax and other penalties to which manufacturers will be subject under the IRA, *see infra* p. 9.

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

[19] Bristol Myers Compl. at 20.

[20] *Id.*

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

[22] *Id.*

[23] 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 512 (1996) (plurality opinion).

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

[25] *Id.*

[26] 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.*

[27] *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.*

[28] *See, e.g.*, 44 Liquormart, Inc. v. Rhodes Island, 517 U.S. 484 (1996) (plurality opinion).

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

dictating the price of goods, it instead prohibited the vendors' means of communicating its prices to customers.[30]

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.[31] 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.[32] 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."[33] The Court observed that "[t]he expressive component of a law school's actions is not created by the conduct itself but by the speech that accompanies it."[34] 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.[35]

Assuming that 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.[36] 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.[37] 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 "substantial" governmental interest that is "directly advance[d]" by the law.[38]

*Central Hudson*, however, is not the only standard that could apply to messaging concerning price regulations. Government actions compelling speech are usually subject to strict scrutiny—a rigorous standard that laws rarely satisfy,[39] but the Supreme Court has sometimes applied a standard of review even less stringent than intermediate scrutiny to commercial disclosure requirements.[40]

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[30] *Id.*

[31] *FAIR*, 547 U.S. at 48. 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.

[32] *FAIR*, 547 U.S. at 64.

[33] *Id.* at 64. 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."

[34] *FAIR*, 547 U.S. at 66.

[35] *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).

[36] See generally CRS Report R45700, *Assessing Commercial Disclosure Requirements under the First Amendment*, by Valerie C. Brannon (Apr. 23, 2019).

[37] Cent. Hudson Elec. Corp. v. Pub. Serv. Comm'n, 477 U.S. 557, 561 (1980).

[38] *Id.* at 566.

[39] Nat'l Inst. of Family & Life Advocates v. Becerra, 138 S. Ct. 2361, 2371 (2018).

[40] *Id.* at 2372; *e.g.*, Zauderer v. Off. of Disciplinary Couns., 471 U.S. 626, 651 (1985).

Thus, a court analyzing the plaintiffs' First Amendment arguments in the Medicare Drug Price Negotiation Program litigation may have to address several threshold questions, including whether the act of signing a contract that describes a drug price as "fair" is an inherently expressive activity that warrants First Amendment protection, or whether such action is merely nonexpressive conduct. Assuming that a court were to find the signing of the negotiation contract an expressive activity, it would then likely consider which standard of constitutional scrutiny to apply. Determining the level of scrutiny to be applied would likely require a court to determine the type of speech the IRA regulates (e.g., commercial or noncommercial speech) and how the law operates (e.g., whether it burdens or compels speech).

# 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."[41] 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.[42] 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.[43] All of the plaintiffs argue that the IRA violates some provision of the Fifth Amendment, with some claiming Due Process Clause violations,[44] and others claiming Takings Clause violations.[45] Each of these claims is explored in further detail below.

## Due Process Clause

The plaintiffs argue that the IRA violates the Fifth Amendment's Due Process Clause by depriving drug manufacturers of their property without the requisite procedural safeguards.[46] The alleged property at issue is drug manufacturers' "investment-backed patent rights and common-law right to sell their products at market prices free from arbitrary and inadequately disclosed governmental constraints."[47] The plaintiffs insist that the IRA does not comply with the core principles of procedural due process—notice and "the opportunity to be heard"[48]—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.[49] They further argue 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

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

[42] *See* CONG. RESEARCH SERV., Amdt 5.5.1 *Overview of Due Process*, https://constitution.congress.gov/browse/essay/amdt5-5-1/ALDE_00013721/ (last accessed August 23, 2023).

[43] *See* CONG. RESEARCH SERV., Amdt 5.9.1 *Overview of Takings Clause*, https://constitution.congress.gov/browse/essay/amdt5-9-6/ALDE_00013285/#ALDF_00022171 (last accessed August 23, 2023).

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

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

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

[47] PhRMA Compl. at 43.

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

[49] PhRMA Compl. at 47.

2026."[50] The plaintiffs also claim 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."[51]

The Supreme Court established the basic framework for considering procedural due process claims in *Mathews v. Eldridge*.[52] The *Mathews* factors address the amount of process required before the government may impair a protected property or liberty interest.[53] This fact-dependent analysis weighs (1) the private interest affected by the government's action; (2) the "risk of 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.[54]

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.[55] The Court cautioned that "[d]ue process is flexible and calls for such procedural protections as the particular situation demands."[56] The Court reviewed the "elaborate" procedures for terminating benefits under the Social Security Act, the various safeguards that the SSA put in place to avoid a mistaken deprivation of benefits, and considered how to balance the high cost of additional safeguards with the need to conserve "scarce fiscal and administrative resources."[57]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.[58]

When considering the plaintiffs' Due Process claim in the Medicare Drug Price Negotiation Program litigation, a court could use the *Mathews* factors to weigh the interests of the drug manufacturers against those of the government and could consider the manufacturers' risk of being deprived of their property. As part of this inquiry, a court could also analyze the language of the IRA to determine whether it contains sufficient procedural safeguards to protect drug manufacturers' property. Such an inquiry might also address whether CMS, in its implementation of the law, provided sufficient procedural safeguards.

## Takings Clause

Other plaintiffs have 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

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

[51] *Id.* at 4;1 *see also* PhRMA Compl. at 43; Astellas Compl. at 4. For more information about the Medicare Drug Pricing 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.

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

[53] 424 U.S. 319, 334–35.

[54] *Id*. at 335.

[55] *Id.* at 323.

[56] *Id.* at 324 (*quoting* Morrisey v. Brewer, 408 U.S. 471, 481 (1972) (internal quotations omitted)).

[57] *Id.* at 339, 345.

[58] *Id.* at 349. The Court further observed: "The judicial model of an evidentiary hearing is neither a required, or 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 (*quoting* Joint Anti-Fascist Refugee Comm. v. McGrath, 341 U.S. 123, 171–72 (1951) (internal quotations omitted)).

biological products) and intellectual property (patents) without just compensation.[59] One plaintiff claims that "the singular purpose of this scheme [in the IRA] is for Medicare to obtain prescription drugs *without* paying fair market value."[60] Another alleges 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.'"[61]

As with the Due Process Clause allegations made by other plaintiffs, the manufacturers argue that their drugs and patents are property, and that the government is "forcing [them] to provide third parties with 'access' to [their] products at steeply discounted prices."[62] The manufacturers state that such a "compelled transfer of title effects a classic, *per se* taking."[63] The plaintiffs further allege 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."[64]

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.[65] To determine whether a taking has occurred, a party must demonstrate that the claimed property at issue is protected by the Takings Clause, and that it was "taken" by the government.[66] To show that the taking was unconstitutional, the party must prove either that (1) the taking was not for public use,[67] or (2) the party has not received just compensation.[68]

The Takings Clause applies only to "private property" interests protected under the Fifth Amendment.[69] Personal property (such as pills or vials of a drug) is protected,[70] but the Supreme Court has never directly held that patents are property protected by the Takings Clause.[71] Assuming that the property (whether drugs, patents, or both) is protected, a court would next analyze whether it has been "taken" under two doctrinal frameworks: per se takings or regulatory takings.

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

[60] Merck Compl. at 2.

[61] Janssen Compl. at 6.

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

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

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

[65] 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*, https://constitution.congress.gov/browse/essay/amdt5-9-2/ALDE_00013281/ (last accessed July 10, 2023).

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

[67] Kelo v. New London, 545 U.S. 469, 483 (2005) ("For more than a century, our public use jurisprudence has wisely eschewed rigid formulas and intrusive scrutiny in favor of affording legislatures broad latitude in determining what public needs justify the use of the takings power.")

[68] *Id.*

[69] *See Ruckelshaus*, 467 U.S. at 1001. For more information, *see* CONG. RESEARCH SERV., Amdt 5.9.3 *Property Interests Subject to Takins Clause*, https://constitution.congress.gov/browse/essay/amdt5-9-3/ALDE_00013282/ (last accessed August 17, 2023).

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

[71] 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)).

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.[72] 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 exterior of their buildings constituted a per se taking for purposes of the Takings Clause, because the law authorized a permanent, if only minimal, physical occupation of the property.[73] 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,[74] or when an owner was deprived of all his property's economic use or value.[75]

When the per se framework does not apply, 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."[76] Although the Court has avoided a "set formula to determine where regulation ends and a taking begins,"[77] and has stated that regulatory takings cases require "essentially ad hoc, factual inquiries,"[78] the Court has established some general principles for determining when regulatory takings occur.

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) "the economic impact of the regulation"; (2) whether the regulation interfered with "distinct investment-backed expectations"; and (3) the character of the government's action.[79] 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."[80]

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).[81] 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.[82] The Court highlighted that

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[72] *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)).

[73] *Id.*

[74] Horne v. Dep't of Agric., 576 U.S. 351, 361 (2015).

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

[76] Pa. Coal Co. v. Mahon, 260 U.S. 393, 415 (1922). *See also* CONG. RESEARCH SERV., *Early Jurisprudence on Regulatory Takings*, https://constitution.congress.gov/browse/essay/amdt5-9-5/ALDE_00013284/ (last accessed July 10, 2023).

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

[78] *Id.*

[79] *Id.* at 124. For more information about the *Penn Central* analysis and how it is used to evaluate regulatory takings, *see* CONG. RESEARCH SERV., *Regulatory Takings and Penn Central Framework*, https://constitution.congress.gov/browse/essay/amdt5-9-6/ALDE_00013285/#ALDF_00022171 (last accessed July 13, 2023).

[80] *Id.* (citation omitted).

[81] Ruckelshaus v. Monsanto, 467 U.S. 986, 990 (1983).

[82] *Ruckelshaus*, 467 U.S. at 1005. The Court found a taking of data submitted during some time periods, based (continued...)

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.[83] 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.[84] For these reasons, the Court held the manufacturer did not have a "reasonable investment-backed expectation," and that no regulatory taking occurred.[85]

In considering whether the Medicare Drug Price Negotiation Program constitutes an unconstitutional taking for purposes of the Fifth Amendment, a court would likely need to resolve several questions. As a threshold matter, a court would likely need to address whether drug patents are a form of property protected by the Takings Clause. If so, a court could consider whether the patents or drugs themselves were "taken" by the government. Such an inquiry might assess whether the IRA's processes of selecting drugs for negotiation and determining the MFP of those drugs constitutes a per se taking, or a regulation that goes so far that it should be considered a taking under the *Penn Central* framework. It is unclear whether the plaintiffs could demonstrate a per se taking with the present facts. If a court were to use the *Penn Central* framework to evaluate whether a regulatory taking occurred, the court would likely look at the potential economic impact of the IRA on manufacturers, how it is being implemented, and whether the manufacturers had a "reasonable investment-backed expectation" that they would be able to freely market their products without negotiating Medicare prices with the government.

If a court were to find that a taking of drugs occurred, the next question could be whether the taking was for public use and whether the manufacturers received just compensation for their drugs and other property. Such an inquiry might require the court to look more closely at the MFP and how it was calculated by CMS. As this is a fact-specific analysis, it may be difficult for a court to make this evaluation before the actual MFP is established by CMS.

# 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."[86] Some plaintiffs claim 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.[87] 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.[88] The tax is calculated based on a percentage of the sales during the noncompliance period, starting with 65% for the first 90 days

primarily on whether the manufacturer had a "'reasonable investment-backed expectation' that EPA would maintain those data in strictest confidence." *Id.* at 1110.

[83] *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.

[84] *Id.* at 1005.

[85] *Ruckelshaus*, 467 U.S. at 1006.

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

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

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

of noncompliance, and reaching up to 95% after 270 days.[89] In addition, separate provisions impose civil money penalties on manufacturers that fail to sell their drug at or below the MFP;[90] violate the terms of the pricing agreement;[91] or provide false information to the Secretary.[92]

The plaintiffs are particularly concerned with the impact of the excise tax, which one characterizes as a "massive penalty."[93] Another plaintiff asserts that "Congress well understood that, in practice, the threat of this ruinous excise tax would force manufacturers to accept whatever price HHS demands."[94] The parties point 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.[95] Manufacturers argue 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.[96] Another plaintiff argues 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.[97]

The Supreme Court has found that the purpose of the Excessive Fines Clause is "to limit the government's power to punish,"[98] and has applied the clause to situations in which fines are both imposed by and paid to the government.[99] Although historically applied only to criminal cases, the prohibition on excessive fines can also apply in civil cases.[100] The Court has made clear that

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[89] 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.

[90] 42 U.S.C. § 1320f-6(a). The CMP 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).

[91] The penalty is $1,000,000 for each day of a violation. 42 U.S.C. § 1320f-6(c).

[92] The penalty is $1,000,000 for each item of false information. 42 U.S.C. § 1320f-6(d).

[93] Boehringer Compl. at 39.

[94] PhRMA Compl. at 25.

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

[96] PhRMA Compl. at 25. "The

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

[98] *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).

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

[100] *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." 492 U.S. 257, 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 recently denied a 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 noted "taking up this case would have been well worth our time." *Id.* at 553 (Gorsuch, J., dissenting).

the threshold question "is not … whether [the action] … is civil or criminal, but rather whether it is punishment."[101] 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."[102]

If a fine can properly be characterized as punishment so as to fall within the purview of the Excessive Fines Clause, the Court has next analyzed whether the fine is excessive.[103] In 1998, the Court decided *United States v. Bajakajian*, which addressed whether a civil forfeiture of cash constituted a punishment, and whether the punishment was considered "excessive" for purposes of the Eighth Amendment.[104] The case was brought by a family attempting to smuggle cash onto an international flight in violation of federal law; the government sought full forfeiture of the money.[105] 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.[106] 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.[107] 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 transfer of money, not the transfer itself.[108] Additionally, "the money was the proceeds of legal activity," and the family did not fit the "class of persons for whom the statute was principally designed" (i.e., tax evaders and money launderers).[109]

A court reviewing the plaintiffs' Eighth Amendment claim would likely need to decide whether the IRA's excise tax constitutes a punishment. To do this, a court might ask what Congress intended by enacting the tax, and whether the tax was designed to "punish" manufacturers of selected drugs who did not wish to participate in the program, or who did not comply with its requirements. Because the IRA was enacted as a budget reconciliation measure, the bill

[101] *Austin*, 509 U.S. at 610.

[102] *Austin*, 509 U.S. 619. It is unclear whether the Court would consider a civil tax imposed by the Internal Revenue Code to be a "fine" for purposes 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.

[103] *Bajakajian*, 524 U.S. at 334.

[104] *Id.* at 328, 334.

[105] *Id.* at 325.

[106] *Id.* Justice Kennedy authored a strongly worded dissent that was joined by Chief Justice Roberts, Justice O'Connor, and Justice Scalia. Justice Kennedy argued, "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. At issue is a fine Congress fixed in the amount of the currency respondent sought to smuggle . . . without reporting. If a fine calibrated with this accuracy fails the Court's test, its decision portends serious disruption of a vast range of statutory fines." *Id*. at 344 (Kennedy, J., dissenting).

[107] *Id.* at 336–37.

[108] *Id.* at 337, 339.

[109] *Id.* at 338.

progressed through Congress outside of the formal committee process, resulting in a more limited legislative history. It is not clear how a court would proceed in light of this limitation.[110]

If a court reviewing the plaintiffs' claims were to find that the excise tax constitutes a punishment for purposes of the Eighth Amendment, it might next assess whether the tax is excessive. If the court were to look to Justice Thomas' decision in *Bajakajian*, it would ask whether the excise tax is grossly disproportionate to the conduct it was designed to prevent—in other words, whether the IRA's excise tax is disproportionate to drug manufacturers' actions of charging Medicare higher prices. It might be difficult for a court to undertake this balancing test without additional facts, such as the amount of the negotiated MFP.

# 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."[111] In interpreting these words, the Supreme Court has created what is known as the Nondelegation Doctrine, which is the principle that "Congress cannot transfer … powers which are strictly and exclusively legislative" to another branch of government.[112] 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.[113] The trade association plaintiffs argue that the IRA runs afoul of the Nondelegation Doctrine because "Congress delegated unfettered discretion to HHS to set prices however it wishes."[114] Similarly, a manufacturer argues, "Congress has impermissibly delegated sweeping authority to implement price controls without providing a clear standard to guide the agency's discretion …."[115] The trade association plaintiffs contrast the Medicare Drug Price Negotiation Program with other price-setting programs, such as the regulation of natural gas companies,

[110] In debating legislative language similar to the IRA, Rep. Shalala argued that Americans "pay more for our prescription drugs than any other country on Earth," but that many Americans "can't afford to benefit" from the scientific advances that have led to the development of lifesaving medications. 165 CONG. REC. H10034 (Dec. 11, 2019) (statement of Rep. Donna Shalala). On the other hand, Rep. Burgess argued that the bill "claims to negotiate drug prices, but with a 95 percent excise tax for manufacturers who fail to reach a price agreement with the government, it is more akin to a hostage taking and then shooting the hostage." *Id.* at H10036 (statement of Rep. Michael Burgess). It is unclear whether and to what extent a court might find the legislative history of predecessor bills persuasive in considering whether the excise tax is designed as a punishment.

[111] U.S. CONST. art. I, § 1.

[112] Gundy v. United States, 139 S. Ct. 2116, 2123 (2019). *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, available at https://constitution.congress.gov/browse/essay/artI-S1-5-1/ALDE_00000014/#ALDF_00016513 (last accessed July 26, 2023). 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, available at https://constitution.congress.gov/browse/essay/artI-S1-5-2/ALDE_00000009/ (last accessed July 26, 2023).

[113] *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 judgements 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. U.S., 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.").

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

[115] Boehringer Compl. at 6.

which the plaintiffs argue are implemented with satisfactory procedural safeguards, including notice-and-comment rulemaking and the opportunity for judicial review.[116]

The plaintiffs specifically argue that the IRA's delegation of authority to the Secretary lacks an intelligible principle.[117] As an example, they point to the factors the Secretary is to consider in developing the MFP, which they purport "provide[] no guidance whatsoever about how the agency should weigh those factors."[118] They argue the program is further unlawful because it establishes only a ceiling price which the MFP cannot exceed, while simultaneously directing HHS to "achieve the lowest [MFP] for each selected drug."[119] The plaintiffs describe 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.[120]

Although Congress may not simply 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."[121] As a result, the Court has generally used the rather lenient intelligible principle test to uphold delegations.[122] In fact, 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*.[123]

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.[124] 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

[116] *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).

[117] *Id.* at 30.

[118] *Id.*

[119] Chamber of Com, Compl. at 43.

[120] *Id*. at 36.

[121] Gundy v. United States, 139 S. Ct. 2116, 2123 (2019) (plurality opinion) (Gorsuch, J., dissenting) (cleaned up)).

[122] 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. *Gundy* 139 S. Ct. at 2131 (2019). 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 2139.

[123] A.L.A. Schechter Poultry Corp. v. United States, 295 U.S. 495 (1935) and Panama Refining 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, available at https://constitution.congress.gov/browse/essay/artI-S1-5-3/ALDE_00001317/ (last accessed July 26, 2023).

[124] *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 530.

dealt with as he pleased."[125] 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.[126]

A court evaluating the plaintiffs' Nondelegation Doctrine challenge in the Medicare Drug Price Negotiation Program litigation would likely turn to the intelligible principle test to determine whether Congress provided CMS with enough legislative direction to implement the program in accordance with its vision. In doing so, a court might look at 42 U.S.C. § 1320f-3, the section of the statute outlining the process for CMS to develop an initial offer for the MFP. The statute calls for CMS to "develop and use a consistent methodology and process" for the price negotiation, in order to "achieve the lowest maximum fair prices for each selected drug."[127] It goes on to list various factors that the Secretary "shall consider" when developing an initial offer.[128] The statute does not dictate how much weight the Secretary should give each factor or otherwise rank their importance. A court reviewing the plaintiffs' Nondelegation Doctrine challenge could evaluate whether these provisions contain enough of an intelligible principle with sufficient "standard[s] or rule[s]" to guide CMS through the negotiation process. The plaintiffs would have the burden of showing why the standards in the IRA differ from other delegations previously upheld by the Court.

# Spending Clause Arguments

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."[129] The pharmaceutical manufacturer plaintiffs argue that Congress's power under the Spending Clause cannot justify the IRA's regulatory scheme.[130] First, the plaintiffs assert 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.[131] Instead, one plaintiff alleges, the IRA "commands manufacturers to comply and levies monetary penalties for failure to do so."[132] Another plaintiff argues that the IRA "unconstitutionally conditions participation in Medicare" on its "relinquishment" of its constitutional rights.[133]

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[125] *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.

[126] *Id.* at 430. 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.

[127] 42 U.S.C. § 1320f-3(b)(1).

[128] 42 U.S.C. § 1320f-3(c)-(e). The factors are based both on data submitted by manufacturers—demonstrating facts such as research, development, and production costs, federal financial support the manufacturer received, and patent and regulatory exclusivity information—as well as evidence of alternative treatments, including therapeutic alternatives to the drug, as well as their cost and availability. *Id.* at (e)(1)-(2).

[129] U.S. CONST. art. I, § 8.

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

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

[132] 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.

[133] Boehringer Compl. at 42.

Another manufacturer further argues that even if Congress created a funding condition in the IRA, the statute does not provide "clear notice" of the condition.[134] 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.[135] Another manufacturer claims the statute is "unconstitutionally coercive because it leverages vast, unrelated benefits to induce distinct transactions that the Government wants."[136] Another manufacturer argues 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 head."[137]Additionally, the plaintiffs state 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.[138]

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.[139] First, Congress must articulate clear notice of the funding condition.[140] 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 state voluntarily and knowingly accepts the terms of the 'contract.'"[141] The Court

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[134] *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.") *Id*.

[135] 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, federal law requires them to 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. As 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.

[136] Merck Compl. at 23.

[137] Janssen Compl. at 4.

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

[139] 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)).

[140] *See generally*, CONG. RESEARCH SERVICE, *Art. I S.8.C1.2.1 Overview of Spending Clause*, Constitution Annotated, available at https://constitution.congress.gov/browse/essay/artI-S8-C1-2-1/ALDE_00013356/ (last accessed July 10, 2023); CRS Report R46827, *Funding Conditions: Constitutional Limits on Congress's Spending Power*, by Victoria L. Killion (July 1, 2021).

[141] 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.

(continued...)

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."[142]

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."[143] 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."[144] In *Dole*, 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."[145]

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.[146] In *NFIB v. Sebelius*, the 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 on the basis that such changes violated the anticoercion principle described in *Dole*.[147] 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, but *all* of it."[148] 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."[149]

Finally, 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."[150] Under this

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Congress created explicit funding conditions in other sections of the statute, which outlined "procedures and sanctions to ensure state compliance with its requirements." *Id.* at 12. In determining whether the Bill of Rights provisions constituted a condition, the Court likened the funding conditions to a contract, wherein the federal government is offering federal funds in exchange for the state's compliance with a condition on how the funds can be used or on the state's adoption of a particular policy. *Id.* at 17.

Although *Pennhurst* addresses funding conditions in the context of states, its reasoning has been applied to funding conditions that Congress places on private entities receiving federal funding as well. *See, e.g.,* Gonzaga Univ. v. Doe, 536 U.S. 273 (2002).

[142] *Pennhurst*, 451 U.S. at 17.

[143] 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, available at https://constitution.congress.gov/browse/essay/artI-S8-C1-2-1/ALDE_00013356/ (last accessed July 10, 2023); and CRS Report R46827, *Funding Conditions: Constitutional Limits on Congress's Spending Power*, by Victoria L. Killion (July 1, 2021).

[144] *Dole*, 483 U.S. 203, 207 (1987).

[145] *Id.* at 208. ("Indeed, the condition imposed by Congress is directly related to one of the main purposes for which highway funds are expended–safe interstate travel.") *Id.*

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

[147] National Federation of Independent Business (NFIB) v. Sebelius, 567 U.S. 519 (2012).

[148] *Id.* at 575, 581.

[149] *Id.* at 587.

[150] *Dole*, 483 U.S. 210. This principle has come to be known as the "unconstitutional conditions" doctrine. The Fifth (continued...)

"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.[151]

Congress may condition funds to both governmental (e.g., states or federal agencies) and nongovernmental (e.g., private businesses) recipients.[152] 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,[153] it has not ruled on whether the relatedness or anticoercion limitations—which are rooted in federalism concerns—also apply to conditions on funding to private entities, such as drug manufacturers.[154]

In the Medicare Drug Price Negotiation Program litigation, a court analyzing whether Congress exceeded its power under the Spending Clause would likely need to address the threshold question of whether Congress actually conditioned Medicare reimbursement on the manufacturer of a selected drug's participation in the program. In so doing, a court might look at whether the IRA creates an "unambiguous" condition on Medicare spending, and if drug manufacturers could be said to "voluntarily and knowingly" accept the terms of the IRA when choosing to participate in Medicare. If a court were to find that Congress conditioned Medicare reimbursement on participation in the program, it could look at whether the condition was related to the purpose of the reimbursement for the manufacturer's products and whether the manufacturers are being coerced into participation as a result of the IRA's excise tax and other noncompliance penalties. However, it is unclear whether a court would find all of these factors applicable to a drug manufacturer, which is a private entity, as much of the Spending Clause doctrine has been built around the relationship between Congress and the states.

# Concluding Considerations

A number of studies have shown that the United States spends more per capita on retail prescription drugs than other developed countries. For example, using 2019 data, the Organization for Economic Cooperation and Development (OECD) found that the average prescription drug spending per capita in the United States was more than double the average across other OECD countries.[155] The Congressional Budget Office (CBO) estimated that the

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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. Bagalusa City Sch. Bd., 403 F.3d 286 (5th Cir. 2005) (en banc).

[151] *See* discussion of First Amendment Claims, *supra* p. 2.

[152] *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.

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

[154] *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 (July 1, 2021).

[155] Pharmaceutical Expenditure, ORGANISATION FOR ECONOMIC COOPERATION AND DEVELOPMENT, https://www.oecd-ilibrary.org/sites/2493ee95-en/index.html?itemId=/content/component/2493ee95-en#indicator-d1e13542 (last accessed Sept. 5, 2023). The OECD data are for retail prescription drugs and over-the-counter products. *Id.*

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.[156]

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.[157] Some manufacturers have claimed that it will incentivize pharmaceutical companies to delay research for drugs used to treat smaller patient populations.[158] In a September 2022 cost estimate for the IRA, the CBO estimated that "the number of drugs that would be introduced to the U.S. market would be reduced by about [one] over the next 2023-2032 period," and "about [five] over the subsequent decade, and about [seven] over the decade after that."[159] 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, 10 drugs were selected for negotiation in price year 2026, 15 drugs will be selected for each of price years 2027 and 2028, and 20 drugs will be selected in 2029 and every year thereafter.[160] Additionally, for the first two years of the program, CMS will only select Part D drugs; Part B drugs will not become eligible for negotiation until price year 2028.[161]

Litigation over the program is ongoing, and 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[]."[162] At the time of this writing, several plaintiffs and the government have filed or expressed their intention to file motions for summary judgment, which could speed up judicial consideration.[163] Additionally, at least one plaintiff has filed a motion for a preliminary injunction, seeking to immediately halt CMS's implementation of the program altogether on the basis that the program violates due process under long-standing Sixth Circuit precedent.[164]

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[156] 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/.

[157] 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.

[158] 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/.

[159] 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.*

[160] 42 U.S.C. § 1320f-1(a)(1)-(4).

[161] 42 U.S.C. § 1320f-1(d)(1)(A).

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

[163] *See, e.g.*, Order, Merck & Co. v. Becerra, No. 23-1616 (D.D.C. Jun. 28, 2023), ECF No. 14.

[164] Memorandum in Support of Motion for Preliminary Injunction, U.S. Chamber of Commerce, et al. v. Becerra, No. 23-0156 (S.D. Ohio, Jun. 9, 2023) ECF No. 29.

While the litigation proceeds, CMS's Revised Guidance attempts to address several stakeholder concerns, some of which could affect the litigation.[165] For example, the guidance attempts 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.[166] The agency's Revised Guidance also responded to the more than 7,500 comments it received after the release of the Initial Guidance in March 2023.[167] Through the Revised Guidance, CMS also advises that it intends to create additional "patient-focused listening sessions" to enable both the public as well as drug companies "to engage with CMS during the negotiation process."[168]

The fate of the program may depend in part on how courts resolve the various claims made by the parties. Courts could decide to uphold the entire statute, uphold parts of it while striking down others, or declare the entire statute unconstitutional. Absent additional action from Congress, 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 beneficiaries.

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

[166] *Id.* at 46–50; *see also* Chamber of Com. Compl. at 37.

[167] CMS Released Revised Guidance for Historic Medicare Drug Price Negotiation Program (Jun. 30, 2023), https://www.cms.gov/newsroom/press-releases/cms-releases-revised-guidance-historic-medicare-drug-price-negotiation-program.

[168] *Id.*