UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

DAYTON AREA CHAMBER OF COMMERCE *et al.*, Plaintiffs, v. XAVIER BECERRA *et al.*, Defendants.	Civil Action No. 3:23-cv-00156-MJN-PBS Judge Michael J. Newman Magistrate Judge Peter B. Silvain, Jr.

DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, CROSS-MOTION FOR SUMMARY JUDGMENT

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For the reasons stated in the accompanying combined memorandum of law, Defendants move to dismiss Plaintiffs' amended complaint, in its entirety, for lack of venue under Federal Rule of Civil Procedure 12(b)(3) and for lack of subject-matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1). In the alternative, at a minimum, Plaintiffs' pre-enforcement challenges to the excise tax (Counts 3 and 4) should be dismissed for lack of subject-matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1).

If the Court reaches the merits, the Court should deny Plaintiffs' motion for summary judgment, grant Defendants' cross-motion for summary judgment, and enter judgment for Defendants on all remaining claims under Federal Rule of Civil Procedure 56.

Dated: December 15, 2023

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DEFENDANTS' COMBINED MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, CROSS-MOTION FOR SUMMARY JUDGMENT

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ARGUMENT 10

I. VENUE IS IMPROPER. 11

A. The Dayton Area Chamber of Commerce lacks associational standing because this lawsuit is not germane to the organization's purpose. 12

The "second associational-standing requirement asks whether the interests that an association's suit seeks to vindicate are 'germane' to its purpose." *Ass'n of Am. Physicians & Surgeons v. FDA*, 13 F.4th 531, 542 (6th Cir. 2021) (quoting *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977)). Here, the purpose of the organization is to improve the business climate in a 14-county area surrounding Dayton, Ohio. FAC ¶ 28. That purpose has no meaningful connection to this lawsuit, so the Dayton Area Chamber should be dismissed for lack of associational standing. *See* Fed. R. Civ. P. 12(b)(1).

B. Without the Dayton Area Chamber of Commerce, this lawsuit cannot proceed in this forum. 15

Plaintiffs' theory of venue depends entirely on the Dayton Area Chamber's residence. *See* FAC ¶ 26. But a plaintiff who lacks standing cannot create venue where it would not otherwise exist. *See, e.g.*, *Miller v. Albright*, 523 U.S. 420, 426-27 (1998) (op. of Stevens, J.). Accordingly, because the Court lacks subject-matter jurisdiction over the Dayton Area Chamber, there is no basis for venue in this District, 28 U.S.C. § 1391(e)(1), and this suit should be dismissed, Fed. R. Civ. P. 12(b)(3).

II. ALL PLAINTIFFS LACK ASSOCIATIONAL STANDING BECAUSE THE RELIEF REQUESTED REQUIRES THE PARTICIPATION OF THEIR INDIVIDUAL MEMBERS. 17

The third requirement for associational standing asks whether "the relief requested requires the participation of individual members in the lawsuit." *Ass'n of Am. Physicians*, 13 F.4th at 537 (quoting *Hunt*, 432 U.S. at 343). Here, it does, because of the multiplicity of other pending lawsuits brought by drug manufacturers who are also members of at least one of the plaintiff associations. After all, "the third prong of the associational standing test" is designed to promote "administrative convenience and efficiency," *United Food & Com. Workers Union Loc. 751 v. Brown Grp., Inc.*, 517 U.S. 544, 557 (1996)—goals that would be severely undermined by finding associational standing in these unusual circumstances, in which there is a real risk that individual members might seek to benefit from competing judgments.

III. THE COURT LACKS SUBJECT-MATTER JURISDICTION OVER PLAINTIFFS' CLAIMS CHALLENGING THE IRA'S EXCISE TAX. 20

A. Plaintiffs' excise-tax claims are not redressable in this suit. 21

Only the Department of the Treasury and the Internal Revenue Service have authority to administer § 5000D of the Internal Revenue Code. Because Plaintiffs have not sued either agency, the relief Plaintiffs request cannot redress their injuries. *See, e.g.*, *Haaland v. Brackeen*, 599 U.S. 255, 292-93 (2023).

B. The Anti-Injunction Act and the tax exception to the Declaratory Judgment Act prohibit this Court from adjudicating Plaintiffs' excise-tax claims. 24

1. The AIA deprives this Court of jurisdiction over the excise-tax claims 24

Under the Anti-Injunction Act (AIA), "no court has jurisdiction over a suit" like this one "to preemptively challenge a tax." *RYO Mach., LLC v. Dep't of Treasury*, 696 F.3d 467, 470 (6th Cir. 2012). For AIA purposes, a "tax" is any exaction—like the excise tax—that Congress has "label[ed]" as such. *NFIB v. Sebelius*, 567 U.S. 519, 544, 564 (2012); *see also* 26 U.S.C. § 5000D (labeling excise tax as a "tax").

2. The DJA tax exception bars declaratory relief regarding the excise tax. 31

"Although Congress has empowered federal courts to issue declaratory judgments, it has prohibited them from doing so in lawsuits 'with respect to Federal taxes.'" *Jarrett v. United States*, 79 F.4th 675, 683 (6th Cir. 2023) (quoting 28 U.S.C. § 2201(a)). So Plaintiffs cannot obtain a declaratory judgment regarding the constitutionality of the excise tax.

IV. ALL OF PLAINTIFFS' CLAIMS LACK MERIT. 31

A. Plaintiffs' separation-of-powers claim (Count 1) is foreclosed by precedent.. 32

Delegations by Congress to the Executive Branch are constitutional "[s]o long as Congress shall lay down by legislative act an intelligible principle to which the person or body authorized to exercise the delegated authority is directed to conform." *Consumers' Rsch. v. FCC*, 67 F.4th 773, 787 (6th Cir. 2023) (alterations omitted) (quoting *Mistretta v. United States*, 488 U.S. 361, 372 (1989); *J.W. Hampton, Jr. & Co. v. United States*, 276 U.S. 394, 409 (1928)), *reh'g en banc denied*, No. 21-3886, 2023 WL 3807406 (6th Cir. May 30, 2023). Congress used far more detail here than in dozens of statutes that have been upheld in the face of nondelegation challenges over the past century.

B. Plaintiffs' due process claim (Count 2) fails because the Negotiation Program is voluntary. 39

As this Court explained in denying Plaintiffs' motion for a preliminary injunction, "[t]he law established in the Sixth Circuit and beyond is clear: participation in Medicare, no matter how vital it may be to a business model, is a completely voluntary choice," and therefore does not deprive manufacturers of protected property interests. *Dayton Area Chamber of Com. v. Becerra*, No. 3:23-cv-156, — F. Supp. 3d. —, 2023 WL 6378423, at *11 (S.D. Ohio Sept. 29, 2023) (*Chamber I*). Plaintiffs' efforts to overcome that holding are unavailing, and their due process claim therefore fails "as a matter of law." *Id.*

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C. Plaintiffs' First Amendment claim (Count 5) is meritless because the Negotiation Program does not compel manufacturers to speak.................... 56

Because the Negotiation Program is voluntary, it does not compel any speech at all because no manufacturer is required to sign an agreement. *See Chamber I*, 2023 WL 6378423, at *11. In any event, reaching an agreement with CMS is not speech or expressive conduct. And any "speech" that may ordinarily be implicated in the

execution of a commercial contract "is plainly incidental to the . . . regulation of conduct" that the contract governs. *Rumsfeld v. Forum for Acad. & Institutional Rts., Inc.* (*FAIR*), 547 U.S. 47, 62 (2006). After all, "ordinary price regulation does not implicate constitutionally protected speech" at all. *Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 292 (D.C. Cir. 2019) (citing *Expressions Hair Design v. Schneiderman*, 581 U.S. 37, 47 (2017)).

D. Even if the Court had jurisdiction over Plaintiffs' excise tax claims, the excise tax is constitutional. 61

1. The excise tax does not violate the Eighth Amendment (Count 3)..... 61

The Eighth Amendment provides that "[e]xcessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted." U.S. Const. amend. VIII. "The purpose of the Eighth Amendment"—both the Excessive Fines Clause and the Cruel and Unusual Punishments Clause—"was to limit the government's power to punish." *Austin v. United States*, 509 U.S. 602, 609 (1993). The threshold question in any Excessive Fines Clause case then is whether the challenged exaction constitutes "punishment for an offense"—*i.e.*, whether the exaction is a "fine" covered by the Eighth Amendment. *United States v. Alt*, 83 F.3d 779, 784 (6th Cir. 1996). Here, the excise tax is not a "fine" covered by the Eighth Amendment because it is not "punishment for some offense." *United States v. Bajakajian*, 524 U.S. 321, 327 (1998). And even if it were a fine, it would not be a "grossly disproportional" one. *Id.* at 336.

2. The excise tax is authorized by Congress's enumerated powers (Count 4). 70

Under the Taxing and Spending Clause, Congress has the power to "lay and collect Taxes, Duties, Imposts and Excises" in order to "provide for the common Defence and general Welfare of the United States." U.S. Const. art. I, § 8, cl. 1. The excise tax is a lawful exercise of that authority, because "taxes that seek to influence conduct are nothing new." *NFIB*, 567 U.S. at 567. The excise tax "does not cease to be valid merely because it regulates, discourages, or even definitely deters the activities taxed." *United States v. Sanchez*, 340 U.S. 42, 44 (1950). In the alternative, the excise tax—if it were to be conceived as a regulation or a penalty, rather than a tax—is also authorized by the Commerce Clause. "[I]t is now well established that Congress has broad authority under the [Commerce] Clause." *NFIB*, 567 U.S. at 549. That authority extends to the sale of prescription drugs to Medicare beneficiaries in interstate commerce.

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INTRODUCTION

As this Court explained in denying Plaintiffs' motion for a preliminary injunction, "[t]he law established in the Sixth Circuit and beyond is clear: participation in Medicare, no matter how vital it may be to a business model, is a completely voluntary choice." *Dayton Area Chamber of Com. v. Becerra*, No. 3:23-cv-156, — F. Supp. 3d. —, 2023 WL 6378423, at *11 (S.D. Ohio Sept. 29, 2023) (*Chamber I*). That is among the reasons why Plaintiffs' claims would ultimately fail on the merits. Before the Court reaches the merits, however, Plaintiffs must carry their burden to establish jurisdiction and venue. They have not done so (and cannot do so), for several reasons.

First, this is an improper venue. This case has no relevant connection to the Southern District of Ohio, other than that one of the four Plaintiffs—the Dayton Area Chamber of Commerce—"resides" here. 28 U.S.C. § 1391(e)(1)(C). But that theory of venue doesn't work because the Dayton Area Chamber lacks associational standing. In particular, the Dayton Area Chamber fails to plausibly allege that "the interests at stake" in this litigation "are germane to the organization's purpose." *Waskul v. Washtenaw Cnty. Cmty. Mental Health*, 900 F.3d 250, 254-55 (6th Cir. 2018). That purpose is, in Plaintiffs' words, "improv[ing] the region's business climate" in the "14-county area surrounding Dayton, Ohio," First Am. Compl. ¶ 28, ECF No. 57 ("FAC")—but this lawsuit has nothing to do with improving the business climate in or around Dayton, Ohio. That is especially obvious because the only members of the association that Plaintiffs have identified are Pharmacyclics and AbbVie—drug companies based in California and Illinois. Because the Dayton Area Chamber must be dismissed for lack of standing, there is no basis for venue in this District, and the entire case should be dismissed under Rule 12(b)(3).

Second, even if this were an appropriate venue, *all* Plaintiffs lack associational standing because participation of their individual members would be necessary for this Court to issue equitable and orderly relief. Because all drug companies currently affected by the challenged statute already purport to be accounted for in separate lawsuits, allowing this association suit to proceed risks a practical morass of overlapping judgments and gives manufacturers multiple bites at the apple, in violation of equitable and prudential limits on justiciability.

Third, the Court lacks subject-matter jurisdiction over Plaintiffs' challenges to the excise tax (Counts 3 and 4), for two independent reasons. First, these claims are not redressable because no defendant in this lawsuit is empowered to enforce the tax that Plaintiffs seek to enjoin and have declared unconstitutional. Second, these claims are barred by the Anti-Injunction Act (AIA), 26 U.S.C. § 7421(a), which prohibits any "suit for the purpose of restraining the assessment or collection of any tax," and the tax exception to the Declaratory Judgment Act (DJA), 28 U.S.C. § 2201(a), which prohibits issuance of a declaratory judgment "with respect to Federal taxes." For both AIA and DJA purposes, a "tax" is an exaction that Congress has labeled as such, and Congress has unambiguously described the § 5000D excise tax as a "tax." Because Counts 3 and 4 ask this Court to preemptively enjoin, and declare the constitutionality of, that tax, *see* FAC ¶¶ 227, 246, 267, those counts must be dismissed for lack of subject-matter jurisdiction.

Should the Court reach the merits of any or all of Plaintiffs' claims, they would fare no better. In Count 1, Plaintiffs ask this Court to strike down an Act of Congress for lack of an "intelligible principle," in violation of the nondelegation doctrine—an argument that has not prevailed at the Supreme Court since 1935, despite repeated efforts. There is nothing about the IRA that warrants a departure from that unbroken line of precedent—in fact, Congress provided far more guidance to the agency here than in the many statutes that have been upheld by the Supreme Court and the Sixth Circuit.

As for Plaintiffs' Fifth Amendment claim, this Court has already rejected it—and for exactly the right reasons. Ultimately, Plaintiffs' due process theory fails "as a matter of law" because manufacturers are "not legally compelled to participate in the [Negotiation] Program." *Chamber I*, 2023 WL 6378423, at *11. And even taken on its own terms, Plaintiffs' arguments (still) rest primarily on one Sixth Circuit case dealing with price controls imposed on public utilities, *Michigan Bell Telephone Company v. Engler*, 257 F.3d 587 (6th Cir. 2001)—but the Supreme Court rejected the central rule of that case in a subsequent decision that Plaintiffs (still) do not cite. *See Verizon Commc'ns, Inc. v. FCC*, 535 U.S. 467 (2002).

Plaintiffs' First Amendment claim also fails. Neither the agreements that manufacturers have now signed with CMS, nor any other component of the Negotiation Program, compels manufacturers to endorse any message. Those agreements do not require manufacturers to engage in any expressive conduct at all, much less compel them to speak. They are purely commercial arrangements that pertain solely to the price at which manufacturers may choose to sell selected drugs to Medicare beneficiaries, using statutory language that ensures the signatories share a common understanding of the agreements' terms. Plaintiffs' unfounded fears about how those agreements might be incorrectly perceived by the public do not justify abrogating decades of First Amendment case law in favor of a new—and limitless—presumption of First Amendment expression in every commercial act.

Finally, even if the Court had jurisdiction to consider them, Plaintiffs' two excise-tax claims would also fail on the merits. The tax does not violate the Eighth Amendment because it is neither a fine nor excessive. Neither the Supreme Court nor, to Defendants' knowledge, any other court has ever held that a tax—let alone one, like this excise tax, lacking any connection to a criminal offense—was a fine for Excessive Fines Clause purposes. Even if the excise tax were deemed a fine, it would not be a grossly disproportionate one, as the excise tax is proportional to the harm to the public fisc and within the range of other constitutionally permissible exactions. And the tax is authorized by Congress's enumerated powers under both the Taxing and Spending Clause and the Commerce Clause. After all, the sale of prescription drugs to Medicare beneficiaries across the country doesn't just have a substantial effect on interstate commerce—it *is* interstate commerce.

Ultimately, in creating the Negotiation Program, Congress exercised its constitutional prerogative to ensure that federal funds are spent according to its view of the "general Welfare." U.S. Const., art. I, § 8, cl. 1. Plaintiffs' objections to that program are nothing more than "a dispute with the policy choices" made by Congress, masquerading as constitutional theory. *Franklin Mem'l Hosp. v. Harvey*, 575 F.3d 121, 130 (1st Cir. 2009). Rather than arguing against established precedent, the "better course of action is to seek redress through the . . . political process." *Id.*

BACKGROUND

I. Medicare and the IRA's Drug Negotiation Program

A. Medicare is a federal program that pays for covered health-care services of qualified beneficiaries as well as for prescription drugs. *See generally* 42 U.S.C. §§ 1395 *et seq.* The Medicare statute is divided into five "Parts," which set forth the terms by which Medicare will pay for benefits. *See Ne. Hosp. Corp. v. Sebelius*, 657 F.3d 1, 2 (D.C. Cir. 2011).

"Traditional Medicare comprises Part A, which covers medical services furnished by hospitals and other institutional care providers, and Part B, which covers outpatient care like physician and laboratory services," as well as the cost of drugs administered as part of that care. *Cares Cmty. Health v. HHS*, 944 F.3d 950, 953 (D.C. Cir. 2019) (citation omitted). In 2003, Congress added Medicare Part D, which provides "a voluntary prescription drug benefit program that subsidizes the cost of prescription drugs and prescription drug insurance premiums for Medicare enrollees." *United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 749 (3d Cir. 2017); *see* 42 U.S.C. §§ 1395w-101 *et seq*. Prior to the Inflation Reduction Act (IRA), Congress had not granted the Secretary of Health and Human Services (HHS) authority to negotiate directly with drug manufacturers for the costs of covered medications under Medicare. To the contrary, Congress barred the Secretary from negotiating drug prices under Part D or otherwise interfering in the commercial arrangements between manufacturers and the private insurance plans that, in turn, enter into agreements with Medicare to provide benefits. *See* 42 U.S.C. § 1395w-111(i).

Although this model was relatively economical at first, it has led to rapidly rising costs to Medicare in recent years. Medicare Part D spending has doubled over the last decade, and it "is projected to increase faster than any other category of health spending." S. Rep. No. 116-120, at 4 (2019); *see also* Cong. Budget Office, *Prescription Drugs: Spending, Use, and Prices* 16 (Jan. 2022), https://perma.cc/9WPC-VLFC. Much of that increase is attributable to a "relatively small number of drugs [which] are responsible for a disproportionately large share of Medicare costs." H.R. Rep. No. 116-324, pt. II, at 37 (2019). Congressional reports have found that generic

competitors face many legal and practical obstacles to market entry, sometimes leaving only a single manufacturer of a particular drug on the market for extended periods of time. *See* Staff of H. Comm on Oversight and Reform, *Drug Pricing Investigation: AbbVie – Humira and Imbruvica* 36 (May 2021), https://perma.cc/9L42-VRBK. And the payment formula for drugs covered under Part B permits a manufacturer of a drug without generic competition to "effectively set[] its own Medicare payment rate." Medicare Payment Advisory Comm'n, *Report to the Congress: Medicare and the Health Care Delivery System* 84 (June 2020), https://perma.cc/5X4R-KCHC. The result has been a shift of financial burden to the Medicare program, which undermines the program's premise of using market competition to reduce prices for beneficiaries and taxpayers. *Id.* at 120. Because of how cost-sharing and premiums function under the Part D program, high drug costs also increase out-of-pocket payments by Medicare beneficiaries.

B. The IRA seeks to address these concerns. Inflation Reduction Act of 2022, Pub. L. No. 117-169, §§ 11001-11003, 136 Stat. 1818 (codified at 42 U.S.C. §§ 1320f–1320f-7 and 26 U.S.C. § 5000D). As relevant here, the IRA requires the Secretary, acting through the Centers for Medicare & Medicaid Services (CMS), to establish the Negotiation Program, through which he will negotiate the prices Medicare pays for certain covered drugs: those that have the highest Medicare Parts B and D expenditures and no generic or biosimilar competitors, and that have been marketable for at least 7 years (*i.e.*, drugs that have long enjoyed little market competition). *See* 42 U.S.C. §§ 1320f *et seq.* The Negotiation Program applies only to the prices Medicare pays for drugs that it covers; the statute regulates neither the prices manufacturers may charge for drugs generally nor the conduct of manufacturers that do not participate in Medicare or Medicaid. *See, e.g.*, *id.* § 1320f-1(b), (d).

To carry out the Negotiation Program, the statute requires CMS to first identify a set of negotiation-eligible drugs; the agency is then to select up to 10 such drugs for negotiation for price applicability year 2026, up to 15 drugs for price applicability years 2027 and 2028, and up to 20 drugs for price applicability year 2029 and for subsequent years. *Id.* § 1320f-1(a)-(b). After selecting the drugs, CMS is directed to negotiate with the manufacturer of each selected drug in

an effort to reach agreement on a "maximum fair price" for that drug. *Id.* § 1320f-3. Congress required CMS to consider numerous categories of information when formulating offers during the course of those negotiations, including (1) "[r]esearch and development costs of the manufacturer for the drug and the extent to which the manufacturer has recouped" those costs, (2) current "costs of production and distribution," (3) prior "Federal financial support for . . . discovery and development with respect to the drug," and (4) evidence about alternative treatments. *Id.* § 1320f-3(e). In hopes of achieving meaningful savings to the American people, Congress imposed a "ceiling for [the] maximum fair price," which it tied to specified pricing data for the subject drugs. *Id.* § 1320f-3(c). But Congress also directed CMS to "aim[] to achieve the lowest maximum fair price" that it can persuade manufacturers to accept. *Id.* § 1320f-3(b)(1).

CMS will sign agreements to negotiate prices for selected drugs with willing manufacturers. *Id.* § 1320f-2. If those negotiations prove successful, a manufacturer will then sign an addendum agreement to provide Medicare beneficiaries access to the drug at the negotiated price. *Id.* A manufacturer that does not wish to sign such an agreement—or to otherwise participate in the Negotiation Program—has several options. It can continue selling its drugs to be dispensed or furnished to Medicare beneficiaries at non-negotiated prices and pay an excise tax on those sales. 26 U.S.C. § 5000D. It can continue selling its other drugs to Medicare but transfer its interest in the selected drug to another entity, which can then make its own choices about negotiations. *See* CMS, *Medicare Drug Price Negotiation Program: Revised Guidance* at 131-32 (June 30, 2023), https://perma.cc/K6QB-C3MM (Revised Guidance). Or it can withdraw from the Medicare and Medicaid programs—in which case it will incur no excise tax and no other liability. *See id.* at 33-34, 120-21, 129-31; *see also* Pub. L. No. 117-169, § 11003 (enacting 26 U.S.C. § 5000D(c)(1)).

These conditions parallel those Congress has long attached to other government health care programs. For example, Congress has long required that any drug manufacturer wishing to participate in Medicaid enter into agreements with the Secretary of Veterans Affairs—agreements that give the VA, the Department of Defense, the Public Health Service, and the Coast Guard the

option to purchase drugs at negotiated prices at or below statutory ceilings. *See* 38 U.S.C. § 8126(a)-(h). Like those statutory provisions, the Negotiation Program thus gives manufacturers a choice: they can sell their products at prices the government is willing to pay, or they can take their business elsewhere.

II. CMS's Implementation of the Negotiation Program

Although the IRA provides a wealth of criteria and detail regarding the selection of drugs, the negotiation process, and the requirements of any agreement, Congress also recognized that implementing a new program of such complexity would require numerous operational decisions within the new statutory framework. Accordingly, Congress directed CMS to implement the Negotiation Program through "program instruction or other forms of program guidance" through 2028. Pub. L. No. 117-169, § 11001(c). Following that statutory mandate, CMS issued initial guidance on March 15, 2023, explaining how it intended to implement certain aspects of the statute and soliciting public input. *See* CMS, *Medicare Drug Price Negotiation Program: Initial Memorandum* (Mar. 15, 2023), https://perma.cc/8X4K-CVD8. After considering more than 7,500 public comments "representing a wide range of views," CMS published Revised Guidance on June 30, 2023. Revised Guidance at 1-2.

The Revised Guidance describes several aspects of the Negotiation Program for initial price applicability year 2026, including information about (1) the methodologies by which CMS selected drugs for negotiation; (2) the negotiation process, including the types of data that CMS will consider, the procedures for exchanges of offers and counteroffers, and the public explanations CMS will provide for negotiated prices; and (3) the procedures for manufacturers to follow if they decide at any point not to participate. *Id.* at 2-8. On that last point, the Revised Guidance expressly provides that if a manufacturer "decides not to participate in the Negotiation Program," CMS will "facilitate an expeditious termination of" the manufacturer's Medicare agreements before the manufacturer would incur liability for any excise tax, so long as the manufacturer notifies CMS of its desire to withdraw at least 30 days in advance of when that tax would otherwise begin to accrue. *Id.* at 33-34. The Revised Guidance also notes that manufacturers that wish to remain in the

Medicare and Medicaid programs but that do not wish to negotiate can divest their interest in the selected drug(s). *Id.* at 131-32.

III. The Treasury Department's Excise-Tax Notice

The Treasury Department and the IRS issued a separate notice outlining how they interpret the IRA's excise-tax provision. *See* IRS Notice No. 2023-52, 2023-35 I.R.B. 650 (Aug. 4, 2023), https://perma.cc/B9JZ-ZG7P (IRS Notice). As that notice explains, Treasury intends to propose regulations specifying that the tax provided for in 26 U.S.C. § 5000D would be imposed on the manufacturer's "sales of designated drugs dispensed, furnished, or administered to individuals *under the terms of Medicare*"—*i.e.*, only those drugs dispensed, furnished, or administered to Medicare beneficiaries. *Id.* at 3 (emphasis added). Further, the notice provides that, consistent with Treasury's pre-existing regulations applicable to certain other excise taxes, "[w]hen no separate charge is made as to the § 5000D tax on the invoice or records pertaining to the sale of a designated drug, it will be presumed that the amount charged for the designated drug includes the proper amount of § 5000D tax and the price of the designated drug." *Id.*

The Treasury Department's notice confirms that, "if a manufacturer charges a purchaser $100 for a designated drug during the first 90 days in a statutory period and does not make a separate charge for the § 5000D tax, $65 is allocated to the § 5000D tax and $35 is allocated to the price of the designated drug." *Id.* at 4. Under this same rule, after 271 days, $95 is allocated to the § 5000D tax and $5 is allocated to the price of the designated drug. Thus, the maximum ratio of the tax to the total amount the manufacturer charges for a drug is 95% (not 1900% of "the drug's total sales revenue," as Plaintiffs claim, *see* FAC ¶ 119).[1] This interpretation is effective immediately; as the notice explains, "[u]ntil the Treasury Department and the IRS issue further guidance, taxpayers may rely on" the interpretation the agency has articulated. IRS Notice at 5.[2]

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[1] This result flows from the statutory formula for the tax amount specified in 26 U.S.C. § 5000D(a), (d).

[2] Treasury has also proposed regulations regarding "how taxpayers will report liability for the excise tax imposed on manufacturers, producers, or importers of certain designated drugs." *Excise Tax on Designated Drugs; Procedural Requirements*, 88 Fed. Reg. 67,690, 67,691 (Oct. 3, 2023) (proposing to, among other things, amend the "Excise Tax Procedural Regulations" applicable to other excise taxes enforced by the IRS).

IV. Status of Negotiation Process

The primary manufacturers of all ten selected drugs for the first negotiation cycle have now executed agreements to negotiate. *See Manufacturer Agreements for Selected Drugs for Initial Price Applicability Year 2026* (Oct. 3, 2023), https://perma.cc/7R6M-ENEP (Manufacturer Agreements). Under the schedule set by Congress, negotiations are to conclude by August 1, 2024. 42 U.S.C. §§ 1320f(b), (d), 1320f-2(a), 1320f-3(b); *see generally* Revised Guidance at 91-92 (statutory timetable). Any agreed-upon prices for the selected drugs will take effect on January 1, 2026, about two years from now. 42 U.S.C. §§ 1320f(b), 1320f-2(a); Revised Guidance at 92.

V. Litigation Background

Prior to the deadline to execute negotiation agreements with CMS, drug manufacturers and interest groups filed suits across the country challenging the constitutionality of the Negotiation Program.[3] Plaintiffs in this case alone, however, sought a preliminary injunction "to prevent the implementation of [the] Program." *Chamber I*, 2023 WL 6378423, at *1. In particular, Plaintiffs argued that they were likely to succeed on their argument that the Negotiation Program violated the Due Process Clause. *Id.* at *11. In denying Plaintiffs' motion, the Court explained that Plaintiffs' arguments failed "as a matter of law" because manufacturers were "not legally compelled to participate in the [Negotiation] Program." *Id.* As a result, the Negotiation "Program's eventual 'maximum fair price' cannot be considered confiscatory because pharmaceutical manufacturers who do not wish to participate in the Program have the ability—practical or not—to opt out." *Id.* (citation omitted). Plaintiffs did not appeal that decision. In the same order, the Court also "denie[d], at this early juncture in the litigation and without prejudice to renew, Defendants' motion to dismiss," *id.* at *9, and granted Plaintiffs leave to amend.

[3] *Bristol Myers Squibb Co. v. Becerra*, No. 3:23-cv-3335 (D.N.J. filed June 16, 2023); *Janssen Pharms, Inc. v. Becerra*, No. 3:23-cv-3818 (D.N.J. filed July 18, 2023); *Boehringer Ingelheim Pharms., Inc. v. HHS*, No. 3:23-cv-1103 (D. Conn. filed Aug. 18, 2023); *Nat'l Infusion Ctr. Ass'n v. Becerra*, No. 1:23-cv-707 (W.D. Tex. filed June 21, 2023); *Merck & Co. v. Becerra*, No. 1:23-cv-1615 (D.D.C. filed June 6, 2023); *Novartis Pharms. Corp. v. Becerra*, No. 3:23-cv-14221 (D.N.J. filed Sept. 1, 2023); *Novo Nordisk Inc. v. Becerra*, No. 3:23-cv-20814 (D.N.J. filed Sept. 29, 2023); *AstraZeneca Pharms. LP v. Becerra*, No. 1:23-cv-931 (D. Del. filed Aug. 25, 2023). Another case was filed but voluntarily dismissed. *See Astellas Pharma US, Inc. v. HHS*, No. 1:23-cv-4578 (N.D. Ill. filed July 14, 2023).

The amended complaint (like the original complaint) includes four Plaintiffs, all of which are advocacy organizations: the Dayton Area Chamber of Commerce, the Ohio Chamber of Commerce, the Michigan Chamber of Commerce, and the Chamber of Commerce of the United States. Plaintiffs name two (and only two) of their members with interests that are allegedly affected by the Negotiation Program: (1) Pharmacyclics, a California company that is the primary manufacturer of one of the 10 drugs selected for negotiation (the cancer drug Imbruvica); and (2) AbbVie, an Illinois company that is *not* the primary manufacturer of any such drug, but which is the controlling shareholder in Pharmacyclics. *See* FAC ¶¶ 37, 42. Plaintiffs bring the same five claims as they did in their original complaint: (1) a "separation of powers" claim under the nondelegation doctrine, *see id.* ¶¶ 157-81; (2) the due process claim that this Court already concluded was unlikely to succeed on the merits, *see id.* ¶¶ 182-212; (3) a claim arguing that the IRA's excise tax violates the Eighth Amendment, *see id.* ¶¶ 213-27; (4) a claim arguing that the excise tax is beyond the reach of Congress's enumerated powers, *see id.* ¶¶ 228-46; and (5) a compelled-speech claim under the First Amendment, *see id.* ¶¶ 247-59.

Plaintiffs moved for summary judgment. ECF No. 64 ("Pls.' Br."). Defendants now oppose Plaintiffs' motion and also move to dismiss or, in the alternative, for summary judgment.

ARGUMENT

Plaintiffs' original complaint alleged that Congress violated the Constitution for five very different reasons. When this Court denied Plaintiffs' preliminary-injunction motion, it also gave Plaintiffs a chance to amend. But Plaintiffs' amended complaint suffers from most of the same problems as the original, as explained in Defendants' prior motion—and also a few new ones.

First, this is an improper venue. Plaintiffs' only theory of venue rests entirely on the implausible premise—contradicted by Plaintiffs' own words in the amended complaint—that this lawsuit is germane to the purposes of the Dayton Area Chamber of Commerce, the only Plaintiff that resides in this District. It is not, so the Dayton Area Chamber should be dismissed for lack of subject-matter jurisdiction, and the entire case should then be dismissed for lack of venue.

Second, *all* Plaintiffs lack associational standing for the additional reason that the relief requested requires the participation of Plaintiffs' (still largely unidentified) individual members. Allowing this lawsuit to proceed—alongside separate lawsuits, brought around the country by virtually every other primary manufacturer of a selected drug—risks a practical morass of contradictory and inconsistent judgments. That result is anathema to the practical concerns of efficiency and administrability that the doctrine of associational standing is designed to address.

Third, at a minimum, both of Plaintiffs' claims challenging the IRA's excise tax should be dismissed for lack of subject-matter jurisdiction—either because Plaintiffs have failed to sue any agency that is actually responsible for enforcing the tax, or because the Anti-Injunction Act and the tax exception to the Declaratory Judgment Act bar these preemptive challenges.

For those reasons, the Court should not reach the merits of any of Plaintiffs' claims. If it does, however, it should reject all of those claims as meritless. Plaintiffs' nondelegation claim is foreclosed by nearly a century of precedents from the Supreme Court and the Sixth Circuit, which have concluded that far broader delegations had a sufficiently "intelligible principle" to pass constitutional muster. Plaintiffs' due process claim fails, among other reasons, because "participation in Medicare, no matter how vital it may be to a business model, is a completely voluntary choice," such that "the consequences of that participation cannot be considered a constitutional violation." *Chamber I*, 2023 WL 6378423, at *11. Plaintiffs' First Amendment claim ignores that entering into a voluntary agreement with the government is neither speech nor expressive conduct. And the excise tax is both consistent with the Eighth Amendment's Excessive Fines Clause and also authorized by at least two of Congress's expressly enumerated powers.

In short, nothing in the United States Constitution enshrines the pharmaceutical industry's policy preferences about government purchases of prescription drugs. This suit is meritless.

I. VENUE IS IMPROPER.

Plaintiffs' only theory of venue rests entirely on the unstated assumption that the Dayton Area Chamber of Commerce is an appropriate plaintiff. That assumption is wrong, because the Dayton Area Chamber cannot satisfy the "germaneness" requirement for associational standing.

After all, although this lawsuit plainly advances the interests of global pharmaceutical giants—located in places like Denmark, Switzerland, and California—it has no meaningful connection to the Dayton area. The Dayton Area Chamber should thus be dismissed for lack of associational standing, and then this entire lawsuit should be dismissed for lack of venue.

A. The Dayton Area Chamber of Commerce lacks associational standing because this lawsuit is not germane to the organization's purpose.

Because Plaintiffs are membership associations—rather than manufacturers who could be directly affected by the statute—they must satisfy additional requirements for associational standing, beyond the more basic standing requirements of injury-in-fact, causation, and redressability. *See Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560-61 (1992). In particular, "[a]n association has standing to bring suit on behalf of its members" only "when (1) its members would otherwise have standing to sue in their own right, (2) the interests at stake are germane to the organization's purpose, and (3) neither the claim requested nor the relief requested requires the participation of individual members in the lawsuit." *Waskul v. Washtenaw Cnty. Cmty. Mental Health*, 900 F.3d 250, 254-55 (6th Cir. 2018) (citing *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977)). With respect to that second requirement—germaneness—the Dayton Area Chamber of Commerce has not carried (and cannot carry) its burden.

To "assur[e] adversarial vigor," *United Food & Com. Workers Union Loc. 751 v. Brown Grp., Inc.*, 517 U.S. 544, 556 (1996), the "second associational-standing requirement asks whether the interests that an association's suit seeks to vindicate are 'germane' to its purpose." *Ass'n of Am. Physicians & Surgeons v. FDA*, 13 F.4th 531, 542 (6th Cir. 2021) (quoting *Hunt*, 432 U.S. at 343). Under this requirement, "Plaintiff's mere interest in the subject does not confer associational standing upon it." *Hillspring Health Care Ctr., LLC v. Dungey*, No. 1:17-cv-35, 2018 WL 287954, at *6 n.12 (S.D. Ohio Jan. 4, 2018). Instead, "[t]he germaneness requirement mandates pertinence between litigation subject and organizational purpose." *Ctr. for Sustainable Econ. v. Jewell*, 779 F.3d 588, 597 (D.C. Cir. 2015) (citation omitted). In doing so, "prong two guarantees that the grievances expressed in a suit apply to a critical mass of association members." *Humane Soc. of*

the U.S. v. Hodel, 840 F.2d 45, 58 n.21 (D.C. Cir. 1988). Ultimately, "the 'germaneness' requirement of *Hunt* should be read in accordance with the modest yet important goal of preventing litigious organizations from forcing the federal courts to resolve numerous issues as to which the organizations themselves enjoy little expertise and about which few of their members demonstrably care." *Bldg. & Constr. Trades Council of Buffalo v. Downtown Dev., Inc.*, 448 F.3d 138, 149 (2d Cir. 2006) (citation omitted).

The Dayton Area Chamber of Commerce cannot satisfy this requirement because there is insufficient "pertinence between litigation subject and organizational purpose," *Jewell*, 779 F.3d at 597—in particular, this suit has no meaningful connection to the organization's purpose of improving the business climate in Dayton. In Plaintiffs' words, the "Dayton Area Chamber of Commerce brings together more than 2,200 businesses and organizations in a 14-county area surrounding Dayton, Ohio." FAC ¶ 28. It "strives to improve *the region's* business climate and overall standard of living through public policy advocacy," and "is widely recognized for its innovative programs and outstanding contribution to positive change *in the region*." *Id.* (emphases added). Its website says much of the same, describing the organization's "vision" as "[t]o position *the Dayton region* as the world's greatest place to live, work and grow business," and its "mission" as "[t]o strengthen, promote and advocate for our member businesses and *the region's* economy." *About Us*, DaytonChamber.org, https://perma.cc/TX7M-8AX3 (emphases added).

None of those goals have any connection to this lawsuit, which challenges federal legislation affecting a handful of pharmaceutical giants around the globe, none of which has any apparent connection to the Dayton area. This is confirmed by the fact that the only two members of the Dayton Area Chamber that Plaintiffs have identified as actually being affected by the Negotiation Program—Pharmacyclics (which is the primary manufacturer of a selected drug), and AbbVie (which is not)—have no significant ties to the region. Pharmacyclics is "based in the Bay Area, California," https://perma.cc/LTR5-TQ7Z, and AbbVie is headquartered in North Chicago (with other offices in California, Massachusetts, and the District of Columbia), *see Locations: United States*, AbbVie, https://perma.cc/DX6J-BNRX.

Under these circumstances, there is no "guarantee[] that the grievances expressed in" this lawsuit "apply to a critical mass of association members." *Hodel*, 840 F.2d at 58 n.21. Far from it: there is apparently only *one* member with any cognizable interest at all—a California company with no connection to the Dayton area. And, tellingly, Pharmacyclics joined the Dayton Area Chamber only *after* Defendants' first motion to dismiss was filed, in what Plaintiffs have never disputed was a transparent effort to defuse Defendants' shareholder-standing arguments. Even if that maneuver works to resolve Plaintiffs' problem on the *first* associational-standing requirement (*i.e.*, naming a member that would otherwise have had standing if it sued on its own), it underscores Plaintiffs' problem on the *second* requirement (germaneness). Ultimately, all of this unnecessary complexity confirms that the Dayton Area Chamber is not the government's "natural adversary" on the subject of Medicare price negotiation. *Brown*, 517 U.S. at 556.

Federal courts, including the Supreme Court and the Sixth Circuit, have applied the germaneness test through a lens of geographic specificity. *See, e.g.*, *Pennell v. City of San Jose*, 485 U.S. 1, 7 n.3 (1988) (germaneness requirement satisfied because "[t]he Association was organized for the purpose of representing the interests of the owners and lessors of real property *in San Jose*" (emphasis added)); *Neighborhood Action Coal. v. City of Canton*, 882 F.2d 1012, 1017 (6th Cir. 1989) (same, because "[t]he NAC was organized for the purpose of fostering open housing *in the City of Canton*" (emphasis added)); *In re Cincinnati Policing*, 209 F.R.D. 395, 398 (S.D. Ohio 2002) (same, because "[t]he CBUF was founded to combat racial subordination *in Hamilton County, Ohio*" (emphasis added)). This Court should take the same approach. After all, there are local business communities in every federal district. If Plaintiffs' transparent efforts to manipulate venue were permissible, a corporation could always ensure that its claims were litigated in any venue of its choosing, merely by (nominally) joining some local organization—in derogation of Congress's contrary choices in the federal venue statutes.

B. Without the Dayton Area Chamber of Commerce, this lawsuit cannot proceed in this forum.

Once the Dayton Area Chamber is dismissed for lack of standing, the rest follows as a matter of course. Rule 12(b)(3) calls for dismissal of an action if venue is "improper." *Atl. Marine Const. Co. v. U.S. Dist. Ct. for W. Dist. of Texas*, 571 U.S. 49, 55 (2013). And where, as here, the case is brought against "an agency of the United States," venue is proper only in a "judicial district in which (A) a defendant in the action resides, (B) a substantial part of the events or omissions giving rise to the claim occurred, or a substantial part of property that is the subject of the action is situated, or (C) the plaintiff resides if no real property is involved in the action." 28 U.S.C. § 1391(e)(1). "On a motion to dismiss for improper venue, the plaintiff bears the burden of proving that venue is proper." *Smith v. Swaffer*, 566 F. Supp. 3d 791, 802 (N.D. Ohio 2021); *accord* 14D Charles Alan Wright & Arthur R. Miller, Federal Practice & Procedure § 3826 (4th ed.).

Plaintiffs' theory of venue depends entirely on the Dayton Area Chamber's residence. *See* FAC ¶ 26.[4] Accordingly, because the Court lacks subject-matter jurisdiction over the Dayton Area Chamber, there is no basis for venue in this district: no defendant resides here, *see* 28 U.S.C. § 1391(e)(1)(A); none of the "events or omissions giving rise to the claim occurred" here, *id.* § 1391(e)(1)(B); and no (proper) plaintiff resides here, *see id.* § 1391(e)(1)(C).

A plaintiff who lacks standing cannot create venue where it would not otherwise exist. *See Miller v. Albright*, 523 U.S. 420, 426-27 (1998) ("[T]he District Court concluded that Mr. Miller did not have standing and dismissed him as a party. Because venue in Texas was therefore improper, *see* 28 U.S.C. § 1391(e), the court transferred the case to the District Court for the District of Columbia, the site of the Secretary's residence.") (op. of Stevens, J.); *Mich. Ass'n of Pub. Sch. Acads. v. U.S. Dep't of Educ.*, No. 1:22-cv-712, — F. Supp. 3d —, 2023 WL 8533456,

[4] The legal residence of the Ohio Chamber of Commerce is unstated in the pleadings, but ultimately irrelevant—again, neither Pharmacyclics nor AbbVie is based in Ohio, nor is any other primary manufacturer of a selected drug. In any event, although the caption of the amended complaint lists an address in Dayton, that appears to be an error—the website of the Ohio Chamber of Commerce lists the same street address (34 S. Third Street, Suite 100), but in Columbus, not Dayton. *Compare* FAC at 1, *with* https://ohiochamber.com/contact-us/ (last visited Dec. 15, 2023). So even if Plaintiffs sought to pivot to a theory of venue based on the residence of the Ohio Chamber, this lawsuit would have had to be filed in the Eastern Division, not in the Western Division. *See* Local Rule 82.1.

at *5 (W.D. Mich. Dec. 6, 2023) (after concluding that the venue-creating plaintiff "lacks standing," holding that "the Western District of Michigan is no longer" an appropriate venue); *Inst. of Certified Pracs., Inc. v. Bentsen*, 874 F. Supp. 1370, 1372 (N.D. Ga. 1994) ("Having found that the Institute lacks standing to bring this action and has failed to state a claim upon which relief can be granted, plaintiff cannot manufacture venue by adding the Institute as a party."); *A.J. Taft Coal Co. v. Barnhart*, 291 F. Supp. 2d 1290, 1304 (N.D. Ala. 2003) ("Venue is proper in this court because at least one Alabama plaintiff had standing."); *see also* 14D Charles Alan Wright & Arthur R. Miller, Federal Practice & Procedure § 3815 (4th ed.) ("[V]enue cannot be based on the joinder of a plaintiff" that has been added "for the purpose of creating venue in the district."). If that were not the rule, then the U.S. Chamber of Commerce could have enlisted any citizen of Dayton with policy objections to the IRA to serve as a nominal plaintiff, solely to create venue in this District—a result that would encourage forum shopping and undermine both the federal venue statute and Article III of the Constitution. Accordingly, the entire case should be dismissed for lack of venue.

On the subject of venue, one additional point warrants mention. Separate from Rule 12(b)(3), 28 U.S.C. § 1406 provides that, in the case of improper venue, the district court "shall dismiss, or if it be in the interest of justice, transfer such case to any district or division in which it could have been brought." 28 U.S.C. § 1406(a). As between those options, "[t]he decision of whether to dismiss or transfer is within the district court's sound discretion." *First of Mich. Corp. v. Bramlet*, 141 F.3d 260, 262 (6th Cir. 1998). But here, "the interest[s] of justice" favor dismissal, rather than transfer—even assuming that there is some other district in which this suit "could have been brought." 28 U.S.C. § 1406(a).[5]

Plaintiffs include the U.S. Chamber of Commerce—a sophisticated litigant, which presumably selected this venue intentionally, with awareness of the downside risk: that Plaintiffs' only claim to venue would turn on whether the Dayton Area Chamber was an appropriate plaintiff.

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[5] As discussed below, *all* Plaintiffs lack associational standing, *see infra*, Part II, but the Court need not decide that issue, given the straightforward venue defect that is immediately revealed by the dismissal of the Dayton Area Chamber on germaneness grounds. As to the other three plaintiffs, the Court can dismiss on venue grounds without reaching standing, because "a federal court has leeway to choose among threshold grounds for denying audience to a case on the merits." *Sinochem Int'l Co. v. Malaysia Int'l Shipping Corp.*, 549 U.S. 422, 431 (2007).

See FAC ¶ 26. And this Court already gave Plaintiffs a second chance to plead their case, granting leave to file an amended complaint. There is no reason for this Court to rescue these Plaintiffs from the consequences of their own strategic litigation decisions. *See* 14D Charles Alan Wright & Arthur R. Miller, Federal Practice & Procedure § 3827 (4th ed.) ("[D]istrict courts often dismiss rather than transfer under Section 1406(a) if the plaintiff's attorney reasonably could have foreseen that the forum in which the suit was filed was improper and that similar conduct should be discouraged."). In addition, dismissal will cause minimal (if any) prejudice: if they can overcome their jurisdictional problems, Plaintiffs (or some subset of them) can refile in another district where there is no venue problem. *See* Fed. R. Civ. P. 41(b) (venue dismissal is not "an adjudication on the merits" and thus would not have any preclusive effect).

For these reasons, the Dayton Area Chamber should be dismissed for lack of subject-matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1), and this entire lawsuit should then be dismissed for lack of venue under Federal Rule of Civil Procedure 12(b)(3).

II. ALL PLAINTIFFS LACK ASSOCIATIONAL STANDING BECAUSE THE RELIEF REQUESTED REQUIRES THE PARTICIPATION OF THEIR INDIVIDUAL MEMBERS.

Even if this were a proper venue, *all* Plaintiffs fail to meet the third requirement of the associational standing test, which independently justifies dismissal of this suit. Under that third requirement, a court must decide whether "the relief requested requires the participation of individual members in the lawsuit." *Ass'n of Am. Physicians*, 13 F.4th at 537 (quoting *Hunt*, 432 U.S. at 343). Here, it does. After all, "the third prong of the associational standing test" is designed to promote "administrative convenience and efficiency," *Brown*, 517 U.S. at 557—goals that would be severely undermined by finding associational standing in these unusual circumstances. In particular, the pendency of multiple suits by individual drug manufacturers, including Plaintiffs' members, makes this association suit unworkable.

As the Sixth Circuit has noted in the context of associational standing, "a valid Article III remedy must 'operate with respect to specific parties,' not with respect to a law or regulation 'in

the abstract.'" *Ass'n of Am. Physicians*, 13 F.4th at 540 (quoting *California v. Texas*, 141 S. Ct. 2104, 2115 (2021)); *see also United States v. Texas*, 599 U.S. 670, 693 (2023) (Gorsuch, J., concurring) ("Traditionally, when a federal court finds a remedy merited, it provides party-specific relief, directing the defendant to take or not take some action relative to the plaintiff."). Related principles of equity and Article III provide that the court must be able to bind the parties before it—and only them—to a judgment. *See, e.g.*, *Haaland v. Brackeen*, 599 U.S. 255, 292-93 (2023) (no standing where the necessary relief would have to run against non-parties); *Taylor v. Sturgell*, 553 U.S. 880, 898 (2008) ("[O]ur decisions emphasize the fundamental nature of the general rule that a litigant is not bound by a judgment to which she was not a party."). *Cf. Arizona v. Biden*, 40 F.4th 375, 395, 398 (6th Cir. 2022) (Sutton, C.J., concurring) (explaining why "nationwide (or universal) injunctions (or remedies) that bar the federal government from enforcing a law or regulation anywhere and against anyone" should be "eliminated root and branch"). When it comes to suits by associations, the ordered relief, though formally running to the association, benefits the individual members who would otherwise be able to show injury. *Ass'n of Am. Physicians*, 13 F.4th at 540 ("[R]elief in an associational-standing case must benefit (and ameliorate an injury to) the association's members."). In the typical associational-standing case, then, the Sixth Circuit has assumed that such remedies satisfy Article III and related equitable requirements. *See id.*

But that assumption is untenable where a plaintiff association's members also bring their own lawsuits seeking to advance the same interests and to obtain the same remedy. That is the case here: virtually all affected manufacturers have already brought their own suits, effectively seeking the same relief as these Plaintiff associations—and Plaintiffs have never disputed that some or all of those manufacturers are also members of (at least) the U.S. Chamber of Commerce. *See, e.g.*, *Merck v. Becerra*, No. 1:23-cv-01615 (D.D.C. filed June 6, 2023); Allison Dembeck, *In Her Own Words*, U.S. Chamber of Com. (Jan. 27, 2023), https://perma.cc/MAS8-W8B4 (describing Merck as a member). By filing their own lawsuits, those manufacturers have demonstrated an intent to be bound by those courts' judgments, win or lose—not this Court's. And those choices undermine this Court's ability to render a judgment that provides association-wide

relief. *Cf., e.g.*, *Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg'l Plan. Agency*, 322 F.3d 1064, 1084 (9th Cir. 2003) ("If the individual members of the Association were not bound by the result of the former litigation, the organization would be free to attack the judgment ad infinitum by arranging for successive actions by different sets of individual member plaintiffs.").

If Plaintiffs here and individual member manufacturers continued with simultaneous lawsuits, different courts might reach different conclusions on the merits of the same claims. If such a conflict arose, drug manufacturers that are also members of one of the association Plaintiffs here might seek to follow the more favorable ruling, while refusing to accept the more adverse judgment. The parties might then have to litigate complex questions of preclusion. *See, e.g.*, *Taylor*, 553 U.S. at 894 (discussing circumstances in which "a nonparty may be bound by a judgment because she was 'adequately represented,'" as occurs in "class actions"). *Cf. Ass'n of Am. Physicians*, 13 F.4th at 541 ("If members may rely on the injunction if an organization wins, should they be bound by the judgment if it loses?"). That sort of remedial morass is inimical to the equitable concerns of "administrative convenience and efficiency" that the associational-standing doctrine seeks to promote. *Brown*, 517 U.S. at 557. And it could be the case that the government, even having prevailed over a manufacturer in a lawsuit filed by that manufacturer, would never see the benefit of that victory. *See Dep't of Homeland Sec. v. New York*, 140 S. Ct. 599, 601 (2020) (Gorsuch, J., concurring) (lamenting the "gamesmanship and chaos" as well as the "asymmetric" effects of injunctions benefitting non-parties, in which "the government's hope of implementing any new policy could face the long odds of a straight sweep, parlaying a 94-to-0 win in the district courts into a 12-to-0 victory in the courts of appeal").

As one illustration of the bizarre features of the current litigation landscape, Plaintiffs filed a declaration that relies on the fact that CMS selected several widely used drugs like Eliquis, Xarelto, Jardiance, Januvia, Farxiga, Fiasp/Novolog, and Entresto. Third Decl. of Michael C. Staff ¶ 16, ECF No. 64-1. But *all* of those drugs are already the subject of other pending litigation—Eliquis in *Bristol Myers Squibb*, Xarelto in *Janssen*, Jardiance in *Boehringer Ingelheim*, Januvia in *Merck*, Farxiga in *AstraZeneca*, Fiasp/NovoLog in *Novo Nordisk*, and Entresto in *Novartis*.

Recognizing that it would be untenable for manufacturers to be litigating by proxy the same issues in two different courts simultaneously, Plaintiffs previously expressed their view that "any of Plaintiffs' members who have brought separate suits will be bound by any judgments in those suits that apply to particular plaintiffs." ECF No. 50 at 18. In other words, Plaintiffs here are apparently willing to throw overboard their own members who have brought their own lawsuits, when it comes to obtaining association-wide relief. But what do the actual manufacturers think about that? The Court has no way to know. So, Plaintiffs' proposed "solution" doesn't solve anything at all—the risk of complicated follow-on litigation over preclusion and remedies remains unacceptably high (both in this Court and in at least five other courts). And more fundamentally, if Plaintiffs' members are not going to be bound by a judgment for or against the association, there is no reason for an association suit in the first place.

This problem has only gotten worse since the Court last considered the issue. Now, after the latest new lawsuit (filed by Novo Nordisk, on the same day this Court denied Plaintiffs' preliminary-injunction motion), *see Novo Nordisk Inc. v. Becerra*, No. 3:23-cv-20814 (D.N.J. filed Sept. 29, 2023), *all* primary manufacturers of selected drugs (or their corporate affiliates) purport to be accounted for in other pending lawsuits. So, given Plaintiffs' prior concession, it is not even clear that Plaintiffs are requesting relief for *anyone* other than Pharmacyclics. There is thus no reason to allow this association suit to proceed—nothing is stopping Pharmacyclics from suing in its own name (that is, other than its apparent desire to litigate in an otherwise impermissible venue).

Under these extraordinary circumstances, an association suit is impractical and inequitable. Because "the relief requested requires the participation of individual members in the lawsuit," *Ass'n of Am. Physicians*, 13 F.4th at 537 (quoting *Hunt*, 432 U.S. at 343), this case should be dismissed for lack of associational standing.

III. THE COURT LACKS SUBJECT-MATTER JURISDICTION OVER PLAINTIFFS' CLAIMS CHALLENGING THE IRA'S EXCISE TAX.

At a minimum, Plaintiffs' claims challenging the constitutionality of the excise tax (Counts 3 and 4) should be dismissed for lack of jurisdiction. Two independent jurisdictional barriers

require dismissal. First, these claims are not redressable because Plaintiffs have not sued the Department of the Treasury or the Internal Revenue Service (IRS)—the only agencies empowered to enforce the tax that Plaintiffs seek to enjoin and have declared unconstitutional. Second, these claims are barred by the Anti-Injunction Act (AIA), 26 U.S.C. § 7421(a), and the tax exception to the Declaratory Judgment Act (DJA), 28 U.S.C. § 2201(a). The AIA requires litigants to pay a tax before challenging its assessment or collection by prohibiting (with statutory exceptions not relevant here) any "suit for the purpose of restraining the assessment or collection of any tax." 26 U.S.C. § 7421(a). The DJA serves a similar purpose by excluding from its scope (again with exceptions not relevant here) any case "with respect to Federal taxes." 28 U.S.C. § 2201(a). Accordingly, Counts 3 and 4—which seek injunctive and declaratory relief before any tax is assessed or collected—must be dismissed.

A. Plaintiffs' excise-tax claims are not redressable in this suit.

Plaintiffs lack Article III standing to press their constitutional challenges to the excise tax. To show Article III standing, a plaintiff "bears the burden of establishing" that it has "suffered an injury in fact . . . that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016). "To determine whether an injury is redressable, a court will consider the relationship between 'the judicial relief requested' and the 'injury' suffered." *California*, 141 S. Ct. at 2115. "Relief that does not remedy the injury suffered cannot bootstrap a plaintiff into federal court; that is the very essence of the redressability requirement." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 107 (1998). Redressability must be established "for each claim that [plaintiffs] press and for each form of relief that they seek." *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2208 (2021); *see also id.* ("[S]tanding is not dispensed in gross.").

Plaintiffs' excise-tax claims cannot be redressed in this suit against HHS and CMS. *See Brackeen*, 599 U.S. at 292. Plaintiffs seek two remedies with respect to the § 5000D tax: injunctive and declaratory relief. *See* FAC ¶ 262 ("Declare that the IRA's 'excise tax' violates the Excessive Fines Clause"); *id.* ¶ 263 ("Declare that the IRA's 'excise tax' exceeds Congress's enumerated powers"); *id.* ¶ 267 ("Enjoin HHS from enforcing the IRA's 'excise tax'"). Even if such relief

were available, *but see infra*, Part III.B, neither remedy would provide Plaintiffs with any redress, and therefore Plaintiffs lack standing to pursue them.

Take the requested injunctive relief first. Plaintiffs request that the Court "[e]njoin HHS from enforcing the IRA's 'excise tax.'" FAC ¶ 267. But HHS does not administer the tax provisions of the IRA, which are codified in the Internal Revenue Code. *See* 26 U.S.C. § 5000D. Rather, the Department of the Treasury, of which the IRS is a part, is charged with enforcing § 5000D and interpreting its provisions. *Compare* 26 U.S.C. § 5000D(h) ("The Secretary shall prescribe such regulations and other guidance as may be necessary to carry out this section."), *with id.* § 5000D(b)(1)(B) (referring separately to "the Secretary of Health and Human Services"), *and id.* § 5000D(c)(1)(A)(i) (same); *see also* 26 U.S.C. § 7701(a)(11)(B) ("When used in this title, where not otherwise distinctly expressed or manifestly incompatible with the intent thereof . . . [t]he term 'Secretary' means the Secretary of the Treasury or his delegate."). Under this authority, the Treasury Department has issued a notice explaining how it interprets the IRA's excise-tax provision. *See* IRS Notice. The IRS Notice explains that the "Treasury Department and the IRS"—not HHS or CMS—"intend" to issue "forthcoming proposed regulations" regarding the scope of taxable sales, *see* IRS Notice § 3.01, and the applicable tax percentage, *see id.* § 3.02 (consistent with Treasury's pre-existing regulations applicable to certain other excise taxes, "[w]hen no separate charge is made as to the § 5000D tax on the invoice or records pertaining to the sale of a designated drug, it will be presumed that the amount charged for the designated drug includes the proper amount of § 5000D tax and the price of the designated drug").

Accordingly, the injunction Plaintiffs request cannot redress any tax-based injuries in this suit. Plaintiffs cannot enjoin the Defendants from enforcing § 5000D because they are not the agencies that would assess or collect any tax. And even though Treasury and IRS are of course federal agencies, the Court cannot enter judgment against them because they are "not parties to the suit" and they would not be "obliged to honor an incidental legal determination the suit produced." *Lujan*, 504 U.S. at 569 (plurality opinion); *see also id.* at 570-71 ("The short of the matter is that redress of the only injury in fact respondents complain of requires action . . . by the individual

funding agencies; and any relief the District Court could have provided in this suit against the Secretary was not likely to produce that action.”).

The Supreme Court recently reaffirmed that a plaintiff lacks Article III standing to secure an injunction if it fails to sue the entities allegedly responsible for the plaintiff's purported injuries. *See Brackeen*, 599 U.S. at 292. In *Brackeen*, the Court held that the “individual petitioners [had] not shown that [their] injury is ‘likely’ to be ‘redressed by judicial relief’” because they sought “an injunction preventing the federal parties from enforcing ICWA and a declaratory judgment that the challenged provisions are unconstitutional,” “[y]et enjoining the federal parties would not remedy the alleged injury, because state courts apply the placement preferences, and state agencies carry out the court-ordered placements.” *Id.* Similarly, here, whatever injury Plaintiffs might one day suffer “at the hands” of Treasury and the IRS “is insufficient by itself to establish a case or controversy in the context of this suit, for [neither Treasury nor the IRS] is a defendant.” *See Simon v. E. Ky. Welfare Rts. Org.*, 426 U.S. 26, 41 (1976).

Plaintiffs' “request for a declaratory judgment suffers from the same flaw.” *Brackeen*, 599 U.S. at 293. “[J]ust like suits for every other type of remedy, declaratory-judgment actions must satisfy Article III's case-or-controversy requirement.” *California*, 141 S. Ct. at 2115. Declaratory relief “conclusively resolves ‘the legal rights o*f the parties*.’” *Brackeen*, 599 U.S. at 293 (quoting *Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 571 U.S. 191, 200 (2014)); *see also Md. Cas. Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941) (“[T]he question in each case is whether the facts alleged . . . show that there is a substantial controversy, *between parties having adverse legal interests* . . . to warrant the issuance of a declaratory judgment.”) (emphasis added). “But again, [Treasury and IRS] are nonparties who would not be bound by the judgment.” *Brackeen*, 599 U.S. at 293. Thus, the constitutional challenges to the excise tax “would not be settled between [Plaintiffs] and the officials who matter—which would leave the declaratory judgment powerless to remedy the alleged harm.” *Id.* And “[w]ithout preclusive effect, a declaratory judgment is little more than an advisory opinion.” *Id.*; *see also California*, 141 S. Ct. at 2115

("Remedies . . . operate with respect to specific parties. In the absence of any specific party, they do not simply operate on legal rules in the abstract.") (cleaned up).

The mere possibility that a court's "legal reasoning may inspire or shame others into acting differently" is immaterial; rather, courts "measure redressability by asking whether a court's judgment will remedy the plaintiff's harms." *United States v. Texas*, 143 S. Ct. 1964, 1979 (2023) (Gorsuch, J., concurring). After all, "[i]t is a federal court's judgment, not its opinion, that remedies an injury; thus it is the judgment, not the opinion, that demonstrates redressability." *Brackeen*, 599 U.S. at 294. Because Plaintiffs "can hope for nothing more than an opinion" in this suit against HHS and CMS, "they cannot satisfy Article III" as to Counts 3 and 4. *See id.*

B. The Anti-Injunction Act and the tax exception to the Declaratory Judgment Act prohibit this Court from adjudicating Plaintiffs' excise-tax claims.

Plaintiffs' excise-tax claims are also independently barred by the AIA and the tax exception to the DJA. Under the AIA, "no court has jurisdiction over a suit" like this one "to preemptively challenge a tax." *RYO Mach., LLC v. Dep't of Treasury*, 696 F.3d 467, 470 (6th Cir. 2012). And, for AIA purposes, a "tax" is any exaction—like the excise tax—that Congress has "label[ed]" as such. *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 544, 564 (2012) (*NFIB*); *see also* 26 U.S.C. § 5000D (labeling excise tax as a "tax"). This Court is similarly prohibited from granting the declaratory relief that Plaintiffs seek. "Although Congress has empowered federal courts to issue declaratory judgments, it has prohibited them from doing so in lawsuits 'with respect to Federal taxes.'" *Jarrett v. United States*, 79 F.4th 675, 683 (6th Cir. 2023) (quoting 28 U.S.C. § 2201(a)). Because Counts 3 and 4 ask the Court to preemptively enjoin, and declare the constitutionality of, the § 5000D tax, these counts must be dismissed.

1. The AIA deprives this Court of jurisdiction over the excise-tax claims.

As Plaintiffs acknowledge, *see* Pls.' Br. at 39, "Congress has deprived 'any court' of the power to 'restrain[ ] the assessment or collection of any tax' for 'any person.'" *Jarrett*, 79 F.4th at 683 (quoting 26 U.S.C. § 7421(a)). "The [AIA] apparently has no recorded legislative history, but its language could scarcely be more explicit—'no suit for the purpose of restraining the

assessment or collection of any tax shall be maintained in any court . . . .'" *Bob Jones Univ. v. Simon*, 416 U.S. 725, 736 (1974). Accordingly, the "AIA has been interpreted broadly to encompass almost all premature interference with the assessment or collection of any federal tax." *RYO Mach.*, 696 F.3d at 471. "Because of the [AIA], taxes can ordinarily be challenged only after they are paid, by suing for a refund." *NFIB*, 567 U.S. at 543.

The AIA's jurisdictional bar applies with equal force to constitutional challenges to a tax—like those presented in Counts 3 and 4. The Supreme Court has made "it unmistakably clear that the constitutional nature of a taxpayer's claim . . . is of no consequence under the [AIA]." *Alexander v. Ams. United Inc.*, 416 U.S. 752, 759 (1974). "[N]otwithstanding that plaintiffs have couched their tax collection claim in constitutional terms," "plaintiffs seek to restrain the Government's collection of taxes, which is precisely what the [AIA] prohibits." *We the People Found., Inc. v. United States*, 485 F.3d 140, 143 (D.C. Cir. 2007); *see also Franklin v. United States*, No. 3:20-cv-1303, 2021 WL 4458377, at *7 (N.D. Tex. Sept. 29, 2021) ("Merely couching an argument against the validity of a tax assessment in constitutional terms will not allow a court to entertain the claim in contravention of the AIA."), *aff'd*, 49 F.4th 429 (5th Cir. 2022). Likewise, the AIA is applicable when entities—like the associational plaintiffs here—seek to enjoin a tax on behalf of others. "Section 7421(a) does not bar merely a taxpayer's attempt to enjoin the collection of his own taxes." *Am. United*, 416 U.S. at 760. "Rather, it declares in sweeping terms that 'no suit for the purpose of restraining the assessment or collection of any tax shall be maintained in any court by any person, *whether or not such person is the person against whom such tax was assessed*.'" *Id.* (quoting 26 U.S.C. § 7421(a)) (emphasis added). "Thus a suit to enjoin the assessment or collection of anyone's taxes triggers the literal terms of" the AIA. *Id.*

a. To determine whether the AIA applies, courts ask whether the exaction at issue is a "tax," and whether the purpose of the claim is to "restrain[] the assessment or collection" of that tax. Because both are true here, Counts 3 and 4 are barred by the AIA.

First, the § 5000D excise tax is a "tax" for AIA purposes because Congress "label[ed]" it as such. *See NFIB*, 567 U.S. at 564. The AIA and the IRA's excise tax are "creatures of Congress's

own creation" and, therefore, "[h]ow they relate to each other is up to Congress, and the best evidence of Congress's intent is the statutory text." *Id.* at 544. Accordingly, "even where [a] label was inaccurate" for constitutional purposes, the Supreme Court has "applied the [AIA]" to bar preemptive challenges "to statutorily described 'taxes.'" *Id.*; *id.* at 564 ("It is up to Congress whether to apply the [AIA] to any particular statute, so it makes sense to be guided by Congress's choice of label on that question."). Simply put, "the [AIA's] reach depends on statutory labels." *In re Juntoff*, 76 F.4th 480, 485 (6th Cir. 2023); *see also Optimal Wireless LLC v. IRS*, 77 F.4th 1069, 1074 (D.C. Cir. 2023) (looking to statutory references to determine whether an exaction is a tax for the purposes of the AIA); *Matter of Westmoreland Coal Co.*, 968 F.3d 526, 534 (5th Cir. 2020) ("With the AIA, form—specifically, the label Congress uses—does matter over substance."). That is, the AIA "draws no distinction between regulatory and revenue-raising tax rules"; rather, if the exaction is labeled a tax by Congress, it is a tax for AIA purposes. *See CIC Servs., LLC v. IRS*, 593 U.S. 209, 226 (2021).

Notably, Plaintiffs do not contest that Congress labeled the excise tax a "tax." Pls.' Br. at 39. Nor could they. Section 5000D refers to a "tax" nearly a half dozen times. *See* 26 U.S.C. § 5000D(a) ("There is hereby imposed on the sale by the manufacturer . . . of any designated drug . . . a tax . . . ."); *id.* § 5000D(a)(1) (referring to "such tax"); *id.* § 5000D(a)(2) (same); *id.* § 5000D(c) ("Suspension of Tax"). The final of these references makes plain that Congress meant to label the exaction described in § 5000D as a tax: "In the case of a sale which was timed for the purpose *of avoiding the tax imposed by this section*, the Secretary may treat such sale as occurring during a day described in [subsection defining periods to which the tax applies]." *Id.* § 5000D(f)(2). Further, Congress codified § 5000D in Title 26—*i.e.*, the Internal Revenue Code—separate from the rest of the drug-negotiation provisions of the IRA. *See* Pub. L. No. 117-169, § 11003 ("Subtitle D of the Internal Revenue Code of 1986 is amended by adding at the end the following . . ."). For AIA purposes, the statutory text is clear: Section 5000D imposes a "tax."

Second, the purpose of Counts 3 and 4 is to "restrain" the "assessment or collection" of the § 5000D tax. In considering a claim's purpose, courts must "inquire not into a taxpayer's

subjective motive, but into the action's objective aim—essentially, the relief the suit requests." *CIC Servs.*, 141 S. Ct. at 1589. The relief requested in both counts is to restrain the assessment or collection of the excise tax. *See* FAC ¶ 227 (Count 3: Because the "excise tax" "violates the Excessive Fines Clause," it "must be enjoined"); *id.* ¶ 246 (Count 4: "Because the IRA's 'excise tax' is not authorized by any enumerated power of Congress, it must be enjoined."); *see also id.* ¶ 267 (Prayer for Relief: "Enjoin HHS from enforcing the IRA's 'excise tax'"). And Plaintiffs' legal claims squarely target the tax. Plaintiffs dedicate over 60 paragraphs of their amended complaint to allegations about the constitutionality of the excise tax. *See id.* ¶¶ 16, 111-42, 213-46. *Compare CIC Servs.*, 141 S. Ct. at 1590 ("The complaint contests the legality of Notice 2016-66, not of the statutory tax penalty that serves as one way to enforce it. CIC alleges that the Notice is procedurally and substantively flawed; it brings no legal claim against the separate statutory tax."). "These allegations leave little doubt that a primary purpose of" Counts 3 and 4 "is to prevent the Service from assessing and collecting" the excise tax. *Bob Jones Univ.*, 416 U.S. at 738. Whether and how much revenue the excise tax will ultimately generate has no bearing on the threshold AIA analysis, *contra* Pls.' Br. at 40-41; what matters for AIA purposes is that Counts 3 and 4 seek to prevent the assessment or collection of the excise tax, *see CIC Servs.*, 141 S. Ct. at 1593-94. Accordingly, the two claims "directly challenging the excise tax" are "plainly prevented by the AIA." *RYO Mach.*, 696 F.3d at 471.

b. Plaintiffs attempt to evade this jurisdictional bar by invoking "two narrow exceptions to the AIA." *RYO Mach.*, 696 F.3d at 470-71; *see* Pls.' Br. at 40 (asserting exceptions apply). Neither the *Williams Packing* nor the *South Carolina* exception applies.

The "stringent" *Williams Packing* exception requires "proof of the presence of two factors" to avoid "the literal terms of" the AIA: "first, irreparable injury, the essential prerequisite for injunctive relief in any case; and second, certainty of success on the merits." *Bob Jones Univ.*, 416 U.S. at 737 (discussing *Enochs v. Williams Packing & Navig. Co.*, 370 U.S. 1, 6 (1962)). "Unless both conditions are met, a suit for preventive injunctive relief must be dismissed." *Am. United*, 416 U.S. at 758. Plaintiffs do not satisfy either requirement.

First, because a refund suit provides an adequate remedy here, Plaintiffs cannot establish that they would suffer irreparable harm absent preemptive injunctive relief. *See Gaetano v. United States*, 942 F.3d 727, 734 (6th Cir. 2019) ("The tripping point" for plaintiffs "is that they have not shown an inadequate remedy at law."). Like *Bob Jones University*, "[t]his is not a case in which an aggrieved [taxpayer] has no access at all to judicial review." 416 U.S. at 746. A manufacturer who wished to challenge the excise tax could pay it, seek a refund from the IRS, then sue for a refund in district court or the Court of Federal Claims. *See* 26 U.S.C. § 7422; 28 U.S.C. §§ 1346(a)(1), 1491. Nor would following the procedure Congress required pose the outrageous burden Plaintiffs assert. The excise tax is imposed on each "sale" of a designated drug. *See* 26 U.S.C. § 5000D(a). It is therefore a "divisible tax," meaning "one that represents the aggregate of taxes due on multiple transactions (*e.g.*, sales of items subject to excise taxes)." *Rocovich v. United States*, 933 F.2d 991, 995 (Fed. Cir. 1991). A taxpayer who wishes to challenge a divisible tax need only pay "the excise tax on a single transaction [to] satisfy" the rule that it must fully pay the tax before seeking a refund. *Id.*; *see also Flora v. United States*, 362 U.S. 145, 171-75 nn. 37, 38 (1960). And while a refund suit is pending, the IRS typically does not collect the balance of any divisible tax that would otherwise be due, except when unusual circumstances warrant. IRS Policy Statement 5-16, IRM § 1.2.1.6.4(6) ("When a refund suit is pending on a divisible assessment, the Service will exercise forbearance with respect to collection provided that the interests of the government are adequately protected and the revenue is not in jeopardy."). Thus, Plaintiffs cannot show irreparable harm exists from following the path that Congress created.

Plaintiffs nonetheless maintain—without any factual support—that they would "suffer ruinous harm" if they had to first pay the tax and then sue for a refund. Pls.' Br. at 40. The Court has already ruled that Plaintiffs are not likely to suffer irreparable injury absent immediate judicial relief—notwithstanding Plaintiffs' assertion that the excise tax would cause them "literally unbearable" harm. *See Chamber I*, 2023 WL 6378423, at *13 (quoting Declaration of Michael C. Staff, ¶ 16, ECF No. 29-5); *see also RYO Mach.*, 696 F.3d at 473 (*Williams Packing* exception only applies if companies would suffer "irreparable harm" prior to bringing refund suit). Plaintiffs

offer no basis for the Court to revisit its earlier order. That order is also consistent with the Supreme Court's observation that "the degree of harm is not a factor" in determining whether the AIA applies. *Bob Jones Univ.*, 416 U.S. at 745. What matters is whether a refund suit is available. *Id.* at 746. And here Plaintiffs have "an adequate remedy; [they] simply [don't] like it." *Larson v. United States*, 888 F.3d 578, 589 (2d Cir. 2018) (requiring Larson to make $61 million penalty payment and seek refund before pressing Eighth Amendment Excessive Fines Clause claim).

Second, in any event, even a showing of irreparable harm would be insufficient to set the AIA aside. *See Williams Packing*, 370 U.S. at 6 ("a suit may not be entertained merely because collection would cause an irreparable injury"). Plaintiffs also would have to show that, "under the most liberal view of the law and the facts," "it is clear that under no circumstances could the Government ultimately prevail" on its defense of the merits. *Id.* at 7. A plaintiff can satisfy this second prong only if it establishes "certainty of success on the merits." *Bob Jones Univ.*, 416 U.S. at 737. That is, the government's authority to tax must be "so utterly without merit that it is apparent that under the most liberal view of the law and the facts," the government's defense cannot prevail. *Licavoli v. Nixon*, 312 F.2d 200, 203 (6th Cir. 1963). This high bar is rarely met. *See, e.g.*, *Williams Packing*, 370 U.S. at 8 (burden not met because government's defense of tax "was not without foundation"); *Gaetano*, 942 F.3d at 734 (neither prong satisfied); *RYO Mach.*, 696 F.3d at 473 (government's "interpretation of the Code is plausible on its face"); *Dickens v. United States*, 671 F.2d 969, 972 (6th Cir. 1982) ("we cannot conclude that the plaintiffs have satisfied the first condition, i.e. certainty of success on the merits"); *Vuin v. Burton*, 327 F.2d 967, 970 (6th Cir. 1964) (taxpayer failed "to carry the 'double burden' of showing that he has no adequate remedy at law, and that 'it is clear that under no circumstances could the Government ultimately prevail.'") (citations omitted). And, for the reasons set forth below, *see infra*, Part IV.D.1, it is plainly not met here either given that no court, to Defendants' knowledge, has ever held that a tax—let alone one, like the excise tax, lacking any connection to criminal conduct or a criminal proceeding—was a fine for Excessive Fines Clause purposes.

The *South Carolina* exception similarly offers no safe harbor. *See South Carolina v. Regan*, 465 U.S. 367 (1984). That exception is a "very narrow" one that applies only when "Congress has not 'provided an alternative avenue for an aggrieved party to litigate its claims,'" necessitating the party harmed by the tax to find a third party to assert the legal issues. *RYO Mach.*, 696 F.3d at 472; *see also Jarrett*, 79 F.4th at 684. Here, "Congress has provided a remedial process (refund suits)" in which Plaintiffs' members can press the same constitutional arguments that Plaintiffs raise now. *See Jarrett*, 79 F.4th at 684.[6] This case is therefore a far cry from "the unique factual pattern" in *South Carolina*. *RYO Mach.*, 696 F.3d at 472 (quoting *Am. Soc. of Ass'n Execs. v. Bentsen*, 848 F. Supp. 245, 250 (D.D.C. 1994)). In *South Carolina*, the state challenged a change in the tax code that stripped certain state-issued bonds of their tax-exempt status. "Because bondholders, not the issuing state or municipality, pay taxes on taxable debt securities, South Carolina could not bring a refund action itself." *Franklin*, 2021 WL 4458377, at *7. Not so here, where Plaintiffs' members may raise the same constitutional challenges by "paying the excise tax" and "then suing for a refund." *RYO Mach.*, 696 F.3d at 472. Plaintiffs nonetheless claim that no manufacturer "could afford to" pursue the path Congress has required. Pls.' Br. at 40. Again, Plaintiffs offer no factual support for that assertion, which, as discussed above, runs contrary to the Court's prior ruling, and ignores the divisible nature of the excise tax. And Plaintiffs offer no legal basis to expand the *South Carolina* exception to excuse a plaintiff from pursuing a refund suit that is legally available, but allegedly practically challenging. The Court should not break new ground here.

Because Counts 3 and 4 seek to enjoin the assessment and collection of the excise tax, and because neither of the two narrow exceptions to the AIA applies, the Court's "exercise of jurisdiction [is] barred by the [AIA]." *See RYO Mach.*, 696 F.3d at 470.

[6] For good reason, Plaintiffs have not argued that *they*, unlike their taxpayer members, do not have an adequate remedy to later bring a refund suit. The Supreme Court closed that loophole before it opened: "[T]axpayers [cannot] evade the [AIA] by forming organizations to litigate their tax claims." *South Carolina*, 465 U.S. at 381 n.19; *see also id.* ("Because taxpayers have alternative remedies, it would elevate form over substance to treat such organizations as if they did not possess alternative remedies. Accordingly, such organizations could not successfully argue that the Act does not apply because *they* are without alternative remedies.") (emphasis added).

2. The DJA tax exception bars declaratory relief regarding the excise tax.

Plaintiffs' "attempt to obtain declaratory relief is also deficient." *Dickens*, 671 F.2d at 972 ("Since we have already found the [AIA] applicable we also find that declaratory relief is equally unavailable."). "Although Congress has empowered federal courts to issue declaratory judgments, it has prohibited them from doing so in lawsuits 'with respect to Federal taxes.'" *Jarrett*, 79 F.4th at 683 (quoting 28 U.S.C. § 2201(a)) (describing "ban on declaratory judgments in tax cases"). "[T]he federal tax exception to the [DJA] is at least as broad as the [AIA]." *Bob Jones Univ.*, 416 U.S. at 733 n.7; *see also Ams. United Inc.*, 416 U.S. at 759 n.10 (same). Accordingly, courts regularly hold that they lack jurisdiction to issue declaratory relief regarding challenged tax provisions. *See, e.g.*, *Rivero v. Fid. Invs., Inc.*, 1 F.4th 340, 344 (5th Cir. 2021) ("the DJA's federal-tax exception imposes a jurisdictional condition that was not met [and therefore] the district court properly dismissed Rivero's complaint"); *Ecclesiastical Ord. of the ISM of AM, Inc. v. IRS*, 725 F.2d 398, 402 (6th Cir. 1984) ("the district court correctly dismissed the action for lack of jurisdiction under the [AIA], as well as under the [DJA]").

Accordingly, for the same reasons that the AIA bars the Court from enjoining assessment or collection of the excise tax, the DJA bars the Court from issuing a declaratory judgment as to the tax's constitutionality.[7]

IV. ALL OF PLAINTIFFS' CLAIMS LACK MERIT.

This entire lawsuit should be dismissed for either lack of venue or lack of associational standing. At a minimum, Plaintiffs' claims challenging the IRA's excise tax (Counts 3 and 4) should be dismissed for lack of subject-matter jurisdiction. If the Court reaches the merits, however, summary judgment should be entered for Defendants on any remaining claims. That is because, in short, nothing in the Constitution requires the government to continue overpaying for prescription drugs. All of Plaintiffs' claims lack merit.

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[7] The Court may dismiss Counts 3 and 4 either under the AIA and DJA or for lack of redressability, *see Sinochem*, 549 U.S. at 431, just as the Sixth Circuit has dismissed a similar tax challenge on AIA grounds without addressing standing, *see RYO Mach.*, 696 F.3d at 473 n.3. Here, if the Court reaches these issues, dismissal of Counts 3 and 4 on AIA and DJA grounds (rather than lack of redressability) would be more efficient, because Plaintiffs cannot overcome the AIA and DJA by filing a new or revised complaint against the proper defendants.

A. Plaintiffs' separation-of-powers claim (Count 1) is foreclosed by precedent.

Plaintiffs assert that the statutory provisions creating the Negotiation Program violate the nondelegation doctrine for lack of an "intelligible principle," Pls.' Br. at 49—an argument that has not prevailed at the Supreme Court in nearly a century. Plaintiffs urge this Court to reconstruct that doctrine from first principles, applying their own gloss on "the original understanding of the Constitution's separation of powers." *Id.* at 54. Plaintiffs are free to preserve those arguments for further review, but the Supreme Court and the Sixth Circuit's understanding of those principles is binding here. And under those precedents, this claim fails.

1. Under what Plaintiffs concede are "the Supreme Court's modern precedents," FAC ¶ 164, delegations by Congress to the Executive Branch are constitutional "[s]o long as Congress shall lay down by legislative act an intelligible principle to which the person or body authorized to exercise the delegated authority is directed to conform." *Consumers' Rsch. v. FCC*, 67 F.4th 773, 787 (6th Cir. 2023) (alterations omitted) (quoting *Mistretta v. United States*, 488 U.S. 361, 372 (1989); *J.W. Hampton, Jr. & Co. v. United States*, 276 U.S. 394, 409 (1928)), *reh'g en banc denied*, No. 21-3886, 2023 WL 3807406 (6th Cir. May 30, 2023). Under this standard, it is "constitutionally sufficient if Congress clearly delineates the general policy, the public agency which is to apply it, and the boundaries of th[e] delegated authority." *Am. Power & Light Co. v. SEC*, 329 U.S. 90, 105 (1946).

"Those standards . . . are not demanding." *Gundy v. United States*, 139 S. Ct. 2116, 2129 (2019) (plurality op.). Although Congress has delegated authority "from the beginning of the government," *Big Time Vapes, Inc. v. FDA*, 963 F.3d 436, 442 (5th Cir. 2020) (quoting *United States v. Grimaud*, 220 U.S. 506, 517 (1911)), "[o]n only two occasions—both in 1935 as part of its resistance to New Deal legislation—has the Court found a violation of the nondelegation doctrine," *Allstates Refractory Contractors, LLC v. Su*, 79 F.4th 755, 762 (6th Cir. 2023). One of those statutory provisions "provided literally no guidance for the exercise of discretion," and the other "conferred authority to regulate the entire economy on the basis of no more precise a standard than stimulating the economy by assuring 'fair competition.'" *Whitman v. Am. Trucking Ass'ns*,

531 U.S. 457, 474 (2001) (citing *Panama Refin. Co. v. Ryan*, 293 U.S. 388 (1935); *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495 (1935)). By contrast, in the almost 90 years since, the Supreme Court has consistently upheld "Congress' ability to delegate power under broad standards," *Mistretta*, 488 U.S. at 373, and "ha[s] 'almost never felt qualified to second-guess Congress regarding the permissible degree of policy judgment that can be left to those executing or applying the law,'" *Am. Trucking*, 531 U.S. at 474-75 (quoting *Mistretta*, 488 U.S. at 416 (Scalia, J., dissenting)).

Applying those principles, the Supreme Court has upheld nearly every delegation it has confronted, including delegations

- to the FCC to regulate broadcast licensing as "public interest, convenience, or necessity" requires, *Nat'l Broad. Co. v. United States*, 319 U.S. 190, 225-26 (1943);

- to the Federal Power Commission to determine "just and reasonable" rates for wholesale sales of natural gas, *Fed. Power Comm'n v. Hope Nat. Gas Co.*, 320 U.S. 591, 600 (1944);

- to the Price Administrator to fix commodity prices that would be "fair and equitable" and would "effectuate the purposes of th[e] [Emergency Price Control Act of 1942]," *Yakus v. United States*, 321 U.S. 414, 420 (1944) (citation omitted); *see id.* at 425-27;

- to the Securities and Exchange Commission to prevent unfair or inequitable distribution of voting power among security holders, *Am. Power & Light*, 329 U.S. at 104-05;

- to the Secretary of War to determine and recover "excessive profits" from military contractors, *Lichter v. United States*, 334 U.S. 742, 785-86 (1948) (citation omitted);

- to the Federal Home Loan Administration to make "rules and regulations . . . for the reorganization, consolidation, merger, or liquidation of [savings-and-loan] associations," *Fahey v. Mallonee*, 332 U.S. 245, 247, 249-50 (1947) (citation omitted);

- to the Sentencing Commission to promulgate (then-binding) sentencing guidelines establishing the permissible sentences for federal crimes, *Mistretta*, 488 U.S. at 374-77;

- to the Attorney General to designate controlled substances on a temporary basis, *Touby v. United States*, 500 U.S. 160, 165-67 (1991);

- to the President to identify aggravating factors used to impose the death penalty in courts martial, *Loving v. United States*, 517 U.S. 748, 771-74 (1996); and

- to the Environmental Protection Agency to set nationwide air-quality standards limiting pollution to the level required "to protect the public health," *Am. Trucking*, 531 U.S. at 472 (quoting 42 U.S.C. § 7409(b)(1)); *see id.* at 472-76.

As the Sixth Circuit summarized this precedent recently, "[t]he intelligible-principle test has long recognized '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.'" *Consumers' Rsch.*, 67 F.4th at 787 (quoting *Mistretta*, 488 U.S. at 472). Ultimately, "[t]he Constitution . . . allows 'Congress to obtain the assistance of its coordinate Branches,' . . . and to 'confer substantial discretion on executive agencies to implement and enforce the laws.'" *Id.* (quoting *Gundy*, 139 S. Ct. at 2123 (plurality op.)).

2. The provisions challenged here fit comfortably within these precedents. At the outset, Congress itself "made virtually every legislative determination" in creating the Negotiation Program, "which has the effect of constricting the [agency's] discretion to a narrow and defined category." *United States v. Ambert*, 561 F.3d 1202, 1214 (11th Cir. 2009). Congress defined the critical terms. *See* 42 U.S.C. § 1320f(b), (c). Congress established detailed criteria for the selection of negotiation-eligible drugs and selected drugs. *See id.* § 1320f-1. Congress established multiple mathematical formulae for calculating ceiling prices. *See* 42 U.S.C. § 1320f-3(c). Congress specified the procedures for negotiation, down to specific timing deadlines that vary across different price applicability years. *See id.* § 1320f-3. And Congress established detailed parameters for CMS's agreements with participating manufacturers. *See id.* § 1320f-2.

Having resolved these minutiae (and many more) itself, Congress then (1) delegated to CMS the task of representing the government in negotiations, *id.* § 1320f-3(a), (2) directed it to "aim[] to achieve the lowest maximum fair price for each selected drug" for which it is able to persuade manufacturers to sign an agreement, *id.* § 1320f-3(b)(1), and (3) specified detailed criteria that CMS "shall consider" in "determining the offers and counteroffers" during the

negotiation, up to the congressionally specified ceiling price, using data "submitted by the manufacturer":

> (A) Research and development costs of the manufacturer for the drug and the extent to which the manufacturer has recouped research and development costs.
>
> (B) Current unit costs of production and distribution of the drug.
>
> (C) Prior Federal financial support for novel therapeutic discovery and development with respect to the drug.
>
> (D) Data on pending and approved patent applications, exclusivities recognized by the Food and Drug Administration, and applications and approvals under [the Food Drug and Cosmetic Act].
>
> (E) Market data and revenue and sales volume data for the drug in the United States.

Id. § 1320f-3(e)(1). Congress also mandated consideration of "evidence" about "therapeutic alternatives to such drug":

> (A) The extent to which such drug represents a therapeutic advance as compared to existing therapeutic alternatives and the costs of such existing therapeutic alternatives.
>
> (B) Prescribing information approved by the [FDA] for such drug and therapeutic alternatives to such drug.
>
> (C) Comparative effectiveness of such drug and therapeutic alternatives to such drug, taking into consideration the effects of such drug and therapeutic alternatives to such drug on specific populations, such as individuals with disabilities, the elderly, the terminally ill, children, and other patient populations.
>
> (D) The extent to which such drug and therapeutic alternatives to such drug address unmet medical needs for a condition for which treatment or diagnosis is not addressed adequately by available therapy.

Id. § 1320f-3(e)(2).[8] Under settled precedent, that was more than enough to satisfy the intelligible-principle test. Congress used far more detail here than in dozens of statutes that have been upheld in the face of nondelegation challenges in the past century. *See, e.g.*, *Am. Trucking*, 531 U.S. at

[8] Congress also specified that, "[i]n using evidence described in subparagraph (C), the Secretary shall not use evidence from comparative clinical effectiveness research in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill." 42 U.S.C. § 1320f-3(e)(2)(D).

472 ("protect the public health"); *Nat'l Broad.*, 319 U.S. at 225-26 ("public interest, convenience, or necessity"). Especially in the context of a delegation governing the negotiation of individual contracts—a traditional Executive Branch function—no further detail was necessary. *See, e.g.*, *Perkins v. Lukens Steel Co.*, 310 U.S. 113, 127 (1940) (recognizing "the traditional principle of [Congress] leaving purchases necessary to the operation of our Government to administration by the executive branch of Government, with adequate range of discretion free from vexatious and dilatory restraints at the suits of prospective or potential sellers").

Plaintiffs seem most concerned with the lack of a specific and binding formula for CMS to use in calculating an offer price (other than the statutory ceiling price). *See* Pls.' Br. at 53 (disparaging the factors that Congress directed CMS to consider as "window-dressing"). It is difficult to imagine how Congress could have perfected such a formula, given the wide variety of drugs that will be covered by the Negotiation Program. In any event, as the Sixth Circuit explained earlier this year, no precedent "stand[s] for the proposition that delegations lacking some sort of Congressional formula lack sufficient guidance." *Consumers' Rsch.*, 67 F.4th at 790. At bottom, the level of specificity that Plaintiffs demand bears no resemblance to the Supreme Court's or the Sixth Circuit's approach to these issues. *See, e.g.*, *Allstates*, 79 F.4th at 766 ("Congress has indeed laid out the general policy (a safe working environment), the agency to apply it (OSHA), and the boundaries of that authority (necessary standards to mitigate significant risks of harm).").

3. Plaintiffs also insist that the alleged "lack of intelligible legal standards is compounded by the foreclosure of administrative and judicial review" over some of CMS's decisions in carrying out the Negotiation Program. Pls.' Br. at 53 (citing 42 U.S.C. § 1320f-7). As a threshold matter, preclusion of review has no obvious logical connection to the operative question under the nondelegation doctrine: whether Congress provided an intelligible principle to guide agency discretion. And although Plaintiffs cite out-of-circuit dicta (at 53) for the theory that the *availability* of "judicial review is a factor weighing in favor of *upholding* a statute against a nondelegation challenge," *United States v. Garfinkel*, 29 F.3d 451, 458-59 (8th Cir. 1994) (emphasis added), they cite nothing for the idea that *preclusion* of review creates a nondelegation

problem, and Defendants are aware of no such case. At least one holds the opposite. *See United States v. Bozarov*, 974 F.2d 1037, 1045 (9th Cir. 1992) ("[T]he EAA's preclusion of judicial review does not violate the nondelegation doctrine."). That is unsurprising: the nondelegation doctrine is about the nature of the power that Congress has delegated to the Executive Branch, on the front end—not whether the exercise of that power is subject to otherwise-unrelated constraints, on the back end.

Indeed, Plaintiffs' theory that preclusion of review creates a delegation problem is inconsistent with (yet another) line of settled precedent—which holds that, at least within outer bounds not relevant here,[9] Congress's "control over the jurisdiction of the federal courts is plenary." *Patchak v. Zinke*, 138 S. Ct. 897, 906 (2018) (citation omitted). Because Congress alone "possess[es] the sole power of creating the tribunals (inferior to the Supreme Court)," it also has the exclusive power "of withholding jurisdiction from them in the exact degrees and character which to Congress may seem proper for the public good." *Palmore v. United States*, 411 U.S. 389, 400-01 (1973) (quoting *Cary v. Curtis*, 44 U.S. 236, 245 (1845)); *accord Kontrick v. Ryan*, 540 U.S. 443, 452 (2004) ("Only Congress may determine a lower federal court's subject-matter jurisdiction." (citing U.S. Const. art. III, § 1)). Ultimately, when Congress limits federal jurisdiction, "it exercises a valid legislative power no less than when it lays taxes, coins money, declares war, or invokes any other power that the Constitution grants it." *Patchak*, 138 S. Ct. at 906. And "what the Congress gives, the Congress may take away." *Knapp Med. Ctr. v. Hargan*, 875 F.3d 1125, 1128 (D.C. Cir. 2017).

Plaintiffs call congressional preclusion of judicial review over certain agency determinations "significant and unusual." Pls.' Br. at 53 (quoting *Free Enter. Fund v. Public Co. Acct. Oversight Bd.*, 561 U.S. 477, 506 (2010)).[10] In fact, it is neither. Even the Administrative

[9] For example, the Supreme Court has suggested that it would raise a "serious constitutional question" if a preclusion provision were read "to deny a judicial forum for constitutional claims." *Bowen v. Mich. Acad. of Fam. Physicians*, 476 U.S. 667, 681 n.12 (1986). The government has not argued here (or in any of the other cases challenging the Negotiation Program) that 42 U.S.C. § 1320f-7 forecloses judicial review of constitutional claims.

[10] Plaintiffs rely heavily on *Free Enterprise Fund* and *Seila Law LLC v. CFPB*, 140 S. Ct. 2183, 2202 (2020), but those cases are about the Appointments Clause and the related Article II limitations on Congress's ability to restrict

Procedure Act (APA) itself—which creates the fundamental framework for judicial review of agency action—has an explicit textual exception for the common situations in which other "statutes preclude judicial review," or when "agency action is committed to agency discretion by law." 5 U.S.C. § 701(a). Courts have applied these sorts of preclusion provisions for decades, without ever suggesting that they create (or contribute to) a nondelegation problem. *See, e.g.*, *Webster v. Doe*, 486 U.S. 592 (1988) (no judicial review of certain agency actions under the APA); *Heckler v. Chaney*, 470 U.S. 821 (1985) (same); *S. Ry. Co. v. Seaboard Allied Milling Corp.*, 442 U.S. 444, 454 (1979) (same, under the Interstate Commerce Act); *Briscoe v. Bell*, 432 U.S. 404 (1977) (same, under the Voting Rights Act); *Schilling v. Rogers*, 363 U.S. 666 (1960) (same, under the Trading with the Enemy Act); *Arizona*, 40 F.4th at 389 (same, under the APA).

Even focusing on Medicare alone, Congress has enacted dozens of similar provisions, *see, e.g.*, 42 U.S.C. §§ 1395 *et seq.* (using the phrase "no administrative or judicial review" dozens of times), which courts have applied with little controversy. *See, e.g.*, *United States v. Erika, Inc.*, 456 U.S. 201, 208 (1982); *Yale New Haven Hosp. v. Becerra*, 56 F.4th 9, 13 (2d Cir. 2022); *DCH Reg'l Med. Ctr. v. Azar*, 925 F.3d 503, 506 (D.C. Cir. 2019); *Knapp*, 875 F.3d at 1129; *Paladin Cmty. Mental Health Ctr. v. Sebelius*, 684 F.3d 527, 532 (5th Cir. 2012). Plaintiffs emphasize "historical precedent" as a factor in the nondelegation analysis, Pls.' Br. at 48 (quoting *Free Enter. Fund*, 561 U.S. at 505), but, if anything, all this history helps the government.[11]

This statute raises no nondelegation problem.

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the President's removal power. Plaintiffs do not bring any appointment or removal claims in this case, so those cases have little relevance.

[11] To the extent that Plaintiffs make distinct arguments about the preclusion of *administrative* (rather than judicial) review, or the Negotiation Program's (temporary) exemption from notice-and-comment rulemaking requirements, Pub. L. No. 117-169, § 11001(c)—which is not entirely clear from their brief—those arguments ultimately collapse into Plaintiffs' due process claim. After all, HHS and CMS are creatures of Congress in their entirety, so Congress can structure their internal administrative procedures how it wishes, subject only to constitutional constraints. And here, the relevant constitutional constraint on the procedural protections included within the Negotiation Program come from the Due Process Clause, as Plaintiffs themselves argue. For the reasons below, Plaintiffs' due process claim is meritless. *See infra*, Part IV.B. But that same issue need not be considered again in the context of Plaintiffs' nondelegation claim. *See, e.g.*, *United States v. Horn*, 679 F.3d 397, 406 (6th Cir. 2012) ("the absence of a statutorily mandated notice-and-comment procedure for policy statements does not raise serious separation-of-powers concerns").

B. Plaintiffs' due process claim (Count 2) fails because the Negotiation Program is voluntary.

Plaintiffs' Fifth Amendment claim follows a familiar playbook. Hospitals, nursing homes, and other providers have, for decades, raised similar arguments against other limits on Medicare reimbursements—and courts have, for decades, rejected such claims. *See, e.g.*, *Baker Cnty. Med. Servs., Inc. v. U.S. Att'y Gen.*, 763 F.3d 1274, 1276, 1279-80 (11th Cir. 2014) (collecting cases); *Garelick v. Sullivan*, 987 F.2d 913, 916 (2d Cir. 1993). As this Court correctly observed in denying Plaintiffs' motion for a preliminary injunction, the "law established in the Sixth Circuit and beyond is clear:" because "participation in Medicare, no matter how vital it may be to a business model, is a completely voluntary choice," "the consequences of that participation cannot be considered a constitutional violation." *Chamber I*, 2023 WL 6378423, at *11 (citations omitted). And this principle, the Court correctly recognized, applies equally to the Negotiation Program. *Id.*

Contrary to Plaintiffs' contentions, neither the IRA nor any other part of Medicare "legally compel[s]" manufacturers to negotiate with CMS or to sell their drugs to Medicare beneficiaries. *Id.* "[P]harmaceutical manufacturers who do not wish to participate in the [Negotiation] Program have the ability . . . to opt out" in several different ways. *Id.* Like other Medicare reimbursement limits, the voluntary Negotiation Program thus reflects a valid exercise of Congress's constitutional authority to control the government's spending as a market participant. Imposing such controls implicates no due process concerns under any standard—much less under the demanding standard of a facial challenge, which requires Plaintiffs to "'establish[] that no set of circumstances exists under which the Act would be valid,' *i.e.*, that the law is unconstitutional in all of its applications." *Wash. State Grange v. Wash. State Republican Party*, 552 U.S. 442, 449 (2008) (quoting *United States v. Salerno*, 481 U.S. 739, 745 (1987)).

1. The Negotiation Program Does Not Compel Participation

Plaintiffs' due process challenge seeks to analogize the Negotiation Program to price-setting statutes for utilities that "lack[] adequate safeguards against confiscatory pricing." Pls.' Br. at 21; *see id.* at 21-23. As the Supreme Court has made clear, however, the "Constitution[al]

protect[ion] [of] utilities from . . . confiscatory" rates derives from "the Takings Clause of the Fifth Amendment," which prohibits the taking of private property for public use without just compensation. *Duquesne Light Co. v. Barasch*, 488 U.S. 299, 307 (1989). And it is well established that a "property owner must be *legally compelled* to engage in price-regulated activity for regulations to" impair a property interest that the Fifth Amendment protects. *Garelick*, 987 F.2d at 916 (emphasis added); *see, e.g., Bowles v. Willingham*, 321 U.S. 503, 517-18 (1944) (rent controls are not prohibited takings because statute did not require landlords to offer apartments for rent). Utilities—like the phone companies in *Michigan Bell*, 257 F.3d at 591—"generally are compelled" by statute "to employ their property to provide services to the public, [so] the Fifth Amendment requires regulators to provide utilities with reasonable compensation for their services," *Garelick*, 987 F.2d at 916. By contrast, if an entity "voluntarily participates in a price-regulated program or activity, there is no legal compulsion to provide service and thus there can be no" deprivation of property at all. *Id.* (citing cases); *see, e.g.*, *Harvey*, 575 F.3d at 129 ("Of course, where a property owner voluntarily participates in a regulated program, there can be no unconstitutional taking."). That is the case with limits on Medicare spending, like those Congress sought to achieve with the Negotiation Program. *See Chamber I*, 2023 WL 6378423, at *11.

As courts have repeatedly explained, "participation in the Medicare program is a voluntary undertaking." *Livingston Care Ctr., Inc. v. United States*, 934 F.2d 719, 720 (6th Cir. 1991); *see Baptist Hosp. E. v. Sec'y of Health & Hum. Servs.*, 802 F.2d 860, 869-70 (6th Cir. 1986) (same); *see also Baker Cnty.*, 763 F.3d at 1279-80 (surveying cases); *Garelick*, 987 F.2d at 917 (same); *see generally Chamber I*, 2023 WL 6378423, at *11 (discussing this precedent). Unlike public utilities, which "generally are compelled" by statute "to employ their property to provide services to the public," no statutory provision *requires* entities to participate in Medicare or to sell their property. *Garelick*, 987 F.2d at 916. So, whether confronting regulations limiting physician fees, nursing-home payments, or hospital reimbursements, courts have been unequivocal: entities are not required to serve Medicare beneficiaries, and thus the government deprives them of no property interest for purposes of the Fifth Amendment when it imposes caps on the amount the government

will reimburse. *Baptist Hosp.*, 802 F.2d at 869-70; *see also Se. Ark. Hospice, Inc. v. Burwell*, 815 F.3d 448, 450 (8th Cir. 2016) (no taking because plaintiff "voluntarily chose to participate in the Medicare hospice program"); *Baker Cnty.*, 763 F.3d at 1279-80 (rejecting hospital's "challenge [to] its rate of compensation in a regulated industry for an obligation it voluntarily undertook . . . when it opted into Medicare"); *Franklin Mem'l Hosp.*, 575 F.3d at 129-30; *Garelick*, 987 F.2d at 916-19; *Burditt v. HHS*, 934 F.2d 1362, 1376 (5th Cir. 1991); *Whitney v. Heckler*, 780 F.2d 963, 972 (11th Cir. 1986) ("[A]ppellants are not required to treat Medicare patients, and the temporary freeze is therefore not a taking within the meaning of the Fifth Amendment."). If a provider dislikes the conditions offered by the government, it can simply withdraw from the program. *Baptist Hosp.*, 802 F.2d at 869-70. There is no legal compulsion to participate.

This uniform recognition that Medicare reimbursement caps do not implicate the Fifth Amendment is unsurprising. Congress enacted Medicare, and imposed conditions on participation, pursuant to its Spending Clause powers. "Unlike ordinary legislation, which imposes congressional policy on regulated parties involuntarily, Spending Clause legislation operates based on consent: in return for federal funds, the [recipients] agree to comply with federally imposed conditions." *Cummings v. Premier Rehab Keller, PLLC*, 596 U.S. 212, 219 (2022) (citation omitted). And, as with any voluntary undertaking, "if a party objects to a condition on the receipt of federal funding, its recourse is to decline the funds." *Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc.*, 570 U.S. 205, 214 (2013).

The Negotiation Program is no different. *See Chamber I*, 2023 WL 6378423, at *11. The IRA regulates neither the prices manufacturers may charge for drugs generally nor the conduct of manufacturers that elect not to participate in Medicare and Medicaid. *See, e.g.*, 42 U.S.C. § 1320f-1(b), (d). Rather, Congress established the Negotiation Program in an effort to reduce how much Medicare pays for selected drugs provided to Medicare beneficiaries. *See id.* § 1320f-2(a)(2). As CMS noted, "the IRA expressly connects a . . . [m]anufacturer's financial responsibilities under the voluntary Negotiation Program to that manufacturer's voluntary participation" in Medicare and Medicaid. Revised Guidance at 120; *see also* 26 U.S.C. § 5000D(c)(1) (providing that tax

consequences are only applicable if the manufacturer continues to participate in Medicare and Medicaid). Drug manufacturers that do not wish to make their drugs available to Medicare beneficiaries at negotiated prices can avoid doing so by withdrawing from the Medicare and Medicaid markets. *See Chamber I*, 2023 WL 6378423, at *11; *see also* Revised Guidance at 33-34, 120-21, 129-31.[12] Alternatively, a manufacturer can divest its interest in the selected drug to a subsidiary or a separate entity—or otherwise stop selling it to Medicare beneficiaries, either permanently or temporarily, which would expose it to no penalty or tax. *Id.* at 131-32.

Thus, contrary to Plaintiffs' claims, manufacturers "are not legally compelled to participate in the Program" or forced to make sales they don't want to make. *Chamber I*, 2023 WL 6378423, at *11. Unlike laws requiring utilities to serve the public, the IRA does not "compel[] [manufacturers] to employ their property to provide [drugs] to" Medicare beneficiaries—at any price. *Garelick*, 987 F.2d at 916. Rather, a manufacturer of a selected drug is *only* required to provide "access" to negotiated prices if it *chooses* to participate in Medicare and make its drugs available for Medicare coverage. As courts have explained in rejecting Fifth Amendment challenges to other Medicare conditions, "[i]f any provider fears that its participation [in the program] will drive it to insolvency, it may withdraw from participation." *Baptist Hosp.*, 802 F.2d at 869-70. That choice is the manufacturer's to make.

2. Manufacturers Have Adequate Opportunity to Withdraw from the Program

Attempting to evade this well-settled precedent, Plaintiffs assert that the IRA makes it legally impossible for manufacturers to withdraw from the Negotiation Program "for [a] lengthy period," during which they would be subject to a sizeable tax or a penalty. Pls.' Br. at 28-30. This argument fails. As an initial matter, Plaintiffs have not indicated that any of their members wish to withdraw from the Negotiation Program or from Medicare generally; to the contrary, the only named member that is the primary manufacturer of a selected drug, Pharmacyclics, has already

[12] Recognizing the viability of this option, some manufacturers previously stated that they might do so. *See* Zachary Brennan, *IRA side effect: Pharma companies will increasingly skip Medicare altogether, Lilly CEO says*, Endpoint News (June 14, 2023), https://perma.cc/ZWJ4-6EXF.

signed an agreement to negotiate. *See Manufacturer Agreements* at 1. So Plaintiffs' complaints about the process for withdrawal are purely academic. But regardless, these arguments fail because Plaintiffs misunderstand the IRA's terms.

Section 11003 of the IRA provides that manufacturers will incur no tax if they cease participating in Medicare and Medicaid prior to the statutory deadline to enter into an agreement to negotiate—or, if they have initially agreed to negotiate (as the primary manufacturers of all 10 selected drugs now have), prior to the statutory deadline to enter into a pricing agreement with CMS. *See* 26 U.S.C. § 5000D(b)(1)-(2) (defining periods when tax would take effect); *id.* § 5000D(c)(1)(A)(i)-(ii) (providing that the excise tax will be suspended "beginning on the first date on which" "none of the drugs of the manufacturer" are covered by Medicare).[13] The Social Security Act (SSA) provides that the relevant Medicare-participation agreements can be terminated by CMS in 30 days for "good cause." 42 U.S.C. §§ 1395w-114a(b)(4)(B)(i), 1395w-114c(b)(4)(B)(i). Relying on these provisions, CMS's Revised Guidance explains that if a "[m]anufacturer determines . . . that it is unwilling to continue its participation in the Negotiation Program and provides a termination notice," CMS will treat that determination as providing "good cause to terminate the . . . Manufacturer's agreement(s) . . . and thus facilitate an expedited" termination in 30 days. Revised Guidance at 130. As a result, "any manufacturer that declines to enter an Agreement for the Negotiation Program may avoid incurring excise tax liability by submitting the notice and termination requests . . . 30 days in advance of the date that excise tax liability otherwise may begin to accrue." *Id.* at 33-34.

That timeline provides manufacturers flexibility to "opt out" of the Negotiation Program. *Chamber I*, 2023 WL 6378423, at *11. Manufacturers of the first 10 selected drugs had 34 days to decide whether they wanted to negotiate with CMS before any tax liability (for selling the drug without signing an agreement to negotiate) could be triggered. *See* 42 U.S.C. § 1320f(d)(1)

[13] Section 5000D(c) also conditions suspension of the tax on a manufacturer giving notice of termination of its drug rebate agreement under Medicaid. 26 U.S.C. § 5000D(c)(2).

(requiring first list of drugs for negotiation to be published by September 1, 2023)[14]; 26 U.S.C. § 5000D(b)(1) (tax triggered on October 2, 2023, absent agreement to negotiate). Manufacturers will know how those negotiations are going far in advance of August 2, 2024, when they could first be exposed to tax liability if they have not signed a price agreement. *See* 26 U.S.C. § 5000D(b)(2). And if a manufacturer signs such an agreement before the statutory deadline, there are still *at least 17 months* before January 1, 2026, when any negotiated prices would first take effect—and any civil penalty (but no tax) could even possibly be triggered. 42 U.S.C. § 1320f-6(a) (providing for civil monetary penalties for failing to honor agreement). During this period, a manufacturer can ask CMS to terminate its participation in Medicare and Medicaid, or can divest its interest in the selected drug. Revised Guidance at 129-32. In this way, a "manufacturer that has entered into an Agreement [] retain[s] the ability to promptly withdraw from the program prior to the imposition of civil monetary penalties or excise tax liability." *Id.* at 34.

Plaintiffs quibble with these exit options, arguing that CMS's use of its own "good cause" authority to provide for the 30-day termination option impermissibly rewrites the statutory language. Pls.' Br. at 29-30. But Plaintiffs themselves contend that the absence of an adequate opportunity to withdraw from the Negotiation Program would be unconstitutional—so they can hardly claim that CMS lacks "good cause" to facilitate their exit from the program. *See, e.g.*, *United States ex rel. Polansky v. Exec. Health Res., Inc.*, 599 U.S. 419, 429 n.2 (2023) ("good cause" is "a uniquely flexible and capacious concept, meaning simply a legally sufficient reason"); *see generally* 42 U.S.C. §§ 1395w-114a(b)(4)(B)(i), 1395w-114c(b)(4)(B)(i) (providing for "good cause" termination). That may explain why Plaintiffs have not actually sought relief against CMS's interpretation—which operates to their benefit, and which they would therefore lack standing to challenge in any event.

Further, even putting aside CMS's Revised Guidance, Plaintiffs overlook the 28-month period between a manufacturer's drug(s) being selected for negotiation and the January 2026

[14] In fact, the list was published early, on August 29, 2023.

effective date for any negotiated prices. Even by Plaintiffs' logic, this delay gives a manufacturer ample time to notice its termination of the relevant Medicare agreements (something it could do even while otherwise engaged in negotiations) and have that termination take effect. *See* Pls.' Br. at 27, 29 (claiming that notice must be given at least 11 months in advance); 42 U.S.C. § 1395w-114a(b)(4)(B)(ii) (providing that a "manufacturer may terminate an agreement under this section for any reason" and that "if the termination occurs before January 30 of a plan year" it shall become effective "as of the day after the end of the plan year"). Notably, the Supreme Court has found no impingement of a property right where a property owner could leave a price-capped market with "6 or 12 *months* notice." *Yee v. City of Escondido*, 503 U.S. 519, 527-28 (1992) (emphasis added). So the statutory exit mechanisms would pass muster even without CMS's Revised Guidance.

In short, Plaintiffs are wrong to claim that the option to avoid participation in the Negotiation Program is illusory or that Congress did not give manufacturers a genuine choice about whether to sell their drugs at negotiated prices. Pls.' Br. at 27. The ability "to opt out" of the Negotiation Program is real. *Chamber I*, 2023 WL 6378423, at *11.

3. The Negotiation Program Is Not "Coercive"

Unable to show that any manufacturer is *legally* compelled to participate in the Negotiation Program, Plaintiffs seek to analogize the IRA to the Medicaid expansion considered by the Supreme Court in *NFIB*, 567 U.S. at 519, contending that the Negotiation Program is impermissibly "coercive" because the options for avoiding it are economically infeasible. Pls.' Br. at 21, 33-35. This argument reflects a basic misunderstanding of *NFIB*.

a. Both before and after *NFIB*, courts have uniformly rejected the idea that the lucrative nature of Medicare and Medicaid coerces private parties to accept any conditions. *See, e.g.*, *Baker Cnty.*, 763 F.3d at 1280 ("Although the Hospital contends that opting out of Medicare would amount to a grave financial setback, 'economic hardship is not equivalent to legal compulsion . . . .'" (quoting *Garelick*, 987 F.2d at 917)); *Sanofi-Aventis U.S., LLC v. HHS*, 570 F. Supp. 3d 129, 209-10 (D.N.J. 2021), *rev'd in part on other grounds*, 58 F.4th 696 (3d Cir. 2023); *see also Minn. Ass'n of Health Care Facilities, Inc. v. Minn. Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th

Cir. 1984) (holding that a "strong financial inducement to participate" in a regulated program does not make such participation involuntary); *St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 875 (7th Cir. 1983). For good reason. The *NFIB* "coercion" framework addresses—and is derived exclusively from cases analyzing—how *federalism* principles inform what conditions Congress may attach to money it grants *to states*. *See* 567 U.S. at 579-81 (discussing, *inter alia*, *South Dakota v. Dole*, 483 U.S. 203 (1987)). As the lead opinion in *NFIB* emphasizes, those principles protect "the status of the States as independent sovereigns in our federal system." *Id.* at 577.

These federalism principles are inapposite in evaluating whether Congress has overstepped its enumerated powers in dealing with private corporations like Plaintiffs' members. *See, e.g.*, *Northport Health Servs. of Ark., LLC v. HHS*, 14 F.4th 856, 869 n.5 (8th Cir. 2021) (explaining that *NFIB* "coercion" inquiry "describe[s] the federal government's limited constitutional authority under the Spending Clause to regulate the states, not a federal agency's ability to regulate [private] facilities' use of federal funding"), *cert. denied*, 143 S. Ct. 294 (2022); *see also Northport Health Servs. of Ark., LLC 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."), *aff'd* 14 F.4th 856 (8th Cir. 2021). After all, pharmaceutical manufacturers are not states; they have no equivalent Tenth Amendment interest in being free of direct congressional regulation. *See, e.g.*, *Sabri v. United States*, 541 U.S. 600, 608 (2004) (drawing distinction between congressional "authority to bring federal power to bear directly on individuals who convert public spending into unearned private gain," and Congress "bringing federal economic might to bear on a State's own choices of public policy"); *see generally Murphy v. NCAA*, 138 S. Ct. 1461, 1476 (2018) ("The Constitution . . . 'confers upon Congress the power to regulate individuals, not States.'" (quoting *New York v. United States,* 505 U.S. 144, 166 (1992))).

b. In any event, inquiring whether Congress has improperly used federal spending to regulate—which is what the *NFIB* "coercion" inquiry analyzes—does not make sense when, rather than using grant conditions to "encourag[e]" states, Congress has merely set terms for how the federal government will pay for goods in the market. 567 U.S. at 580-81 (quoting *New York*, 505

U.S. at 175). Such terms do not seek to end-run limits on Congress's regulatory powers—and any "pressure" Congress may exert in this way is no different from the leverage of any well-funded market participant, which is of no constitutional import. *Id.* (discussing "coercion" as a limit on Congress's ability to achieve through spending what it cannot achieve directly through regulation); *cf. Ray Baillie Trash Hauling, Inc. v. Kleppe*, 477 F.2d 696, 709 (5th Cir. 1973) (noting that it "has long been recognized that the government, like private individuals and businesses, has the power 'to determine those with whom it will deal, and to fix the terms and conditions upon which it will make needed purchases'" absent statutory prohibition (quoting *Perkins*, 310 U.S. at 127)).

Indeed, courts—including the Supreme Court—have long distinguished, for constitutional purposes, between government acting "as a regulator rather than a market participant" vindicating a "legitimate proprietary interest." *Chamber of Com. of U.S. v. Brown*, 554 U.S. 60, 70 (2008); *see also Bldg. & Const. Trades Council of Metro. Dist. v. Associated Builders & Contractors of Mass./R.I.*, 507 U.S. 218, 229 (1993) (*Bos. Harbor*) (discussing the "conceptual distinction between regulator and purchaser"); *Reeves, Inc. v. Stake*, 447 U.S. 429, 436 (1980) (noting the difference "between States as market participants and States as market regulators"). This distinction reflects the "principle that a government, just like any other party participating in an economic market, is free to engage in the efficient procurement and sale of goods and services." *Associated Builders & Contractors Inc. v. City of Jersey City*, 836 F.3d 412, 417-18 (3d Cir. 2016) (citing *Chamber of Com.*, 554 U.S. at 70; *Bos. Harbor*, 507 U.S. at 228-30; *Reeves*, 447 U.S. at 437-40); *see also Brooks v. Vassar*, 462 F.3d 341, 358 (4th Cir. 2006) (government can be a market participant even when it regulates "the specific market in which it participates"). Observing this distinction, last year the Supreme Court upheld a COVID-19 vaccination requirement for workers in facilities funded by Medicare or Medicaid, emphasizing that "healthcare facilities that wish to participate in Medicare and Medicaid have always been obligated to satisfy a host of conditions"—despite the challengers arguing that those conditions were coercive under *NFIB*. *Biden v. Missouri*, 595 U.S. 87, 94 (2022).

Economical and equitable procurement in the market is exactly what Congress sought with the Negotiation Program. Recognizing that American taxpayers spend far too much on high-cost prescription drugs—more than people in any comparable country, for the same drugs—Congress has taken steps to limit how much the government will pay for selected drugs going forward. These steps to limit government spending on selected drugs reflect a valid exercise of Congress's power to "control" federal "spen[ding] according to its view [that] the 'general Welfare'" is best served by reducing taxpayer expenditure on high-cost pharmaceuticals. *NFIB*, 567 U.S. at 579-80; *cf. Sabri*, 541 U.S. at 608 ("The power to keep a watchful eye on expenditures . . . is bound up with congressional authority to spend in the first place."). Such spending conditions are "justified on that basis"—and give rise to no *NFIB*-style "coercion" concerns. 567 U.S. at 579-80.

c. For similar reasons, the Negotiation Program would not be "coercive" under *NFIB* even if that test were applicable. Pls.' Br. at 33-34. As the lead opinion in *NFIB* explained, the Spending Clause permits Congress to place "restrictions on the use of [] funds, because that is the means by which Congress ensures that the funds are spent according to its view of the 'general Welfare.'" 567 U.S. at 580. But "[c]onditions that do not . . . govern the use of the funds . . . cannot be justified on that basis." *Id.* Particularly when "such conditions take the form of threats to terminate other significant independent grants," their coerciveness must be evaluated—a test Congress failed in *NFIB* because it threatened to revoke *all* of a state's traditional federal Medicaid funding unless the state agreed to create a "new health care program." *Id.* at 580-81, 584; *see also Miss. Comm'n on Env't Quality v. EPA*, 790 F.3d 138, 179 (D.C. Cir. 2015) (discussing this framework).

Unlike the challenged statutory provisions in *NFIB*, however, the Negotiation Program directly "govern[s] the use of" Medicare funds for the selected drugs. *See generally Miss. Comm'n*, 790 F.3d at 179 ("[A]s described in *NFIB*, the [coerciveness] inquiry . . . was triggered by the fact that the Congress had imposed a condition that did not restrict how the . . . funds at issue were to be used."). As noted above, the conditions Congress established in the Negotiation Program merely reflect limits on how much the government is willing to spend on the drugs selected for negotiation. If a manufacturer does not wish to comply with those limits, it can avoid

them by not selling the selected drug to Medicare beneficiaries during the relevant period (including by divesting its interest in the drug). *See* Revised Guidance at 131-32.

Notably, manufacturers *also* have the option of leaving Medicare and Medicaid entirely. For some manufacturers—particularly those that sell only one drug, like Pharmacyclics[15]—that may be a more straightforward option. But contrary to Plaintiffs' characterization, the availability of this second choice does not mean that Congress has offered manufacturers anything improper. Pls.' Br. at 33-35. Congress routinely conditions Medicare and Medicaid funding on parties observing conditions that reach beyond the specific products or services that Medicare reimburses. *See, e.g.*, *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113-16 (2011) (describing the 340B program under 42 U.S.C. §§ 1396r-8(a)(1), which requires participating drug manufacturers to give steep discounts to various categories of private purchasers); *see also Baker Cnty.*, 763 F.3d at 1277-78 (noting that, "[a]s a condition of participating in and receiving payments from Medicare, a hospital must also opt into EMTALA," which generally "requires participating hospitals to provide care to anyone who visits an emergency room"). Similarly, Congress has long required drug manufacturers wishing to participate in Medicaid to enter into agreements with the VA Secretary, which make their covered drugs available for procurement by the VA and other agencies at or below statutory ceiling prices. *See* 38 U.S.C. § 8126(a)-(h). These arrangements have never been found to trigger coercion concerns, and for good reason: suggesting that Medicare and Medicaid conditions can be coercive would be contrary to decades of precedent holding that acceptance of such conditions is fully voluntary. *See, e.g.*, *Baker Cnty.*, 763 F.3d at 1278-79. Plaintiffs provide no basis to believe that *NFIB* upset that settled law.

* * *

Ultimately, Plaintiffs' "coercion" claim boils down to their assertion that the Medicare and Medicaid market is just too lucrative, and that abandoning this market, in their words, "would be

[15] *See* FDA, Orange Book: Approved Drug Product with Therapeutic Equivalence Evaluations, www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm (click "search by applicant"; search "Pharmacyclics LLC"); FDA, Purple Book Database of Licensed Biological Products, https://purplebooksearch.fda.gov (click "advanced search"; click "additional search filters" button; click "filter by applicant"; search "Pharmacyclics LLC").

economic suicide—not a 'real option.'" Pls.' Br. at 34 (quoting *NFIB*, 567 U.S. at 582). But as this Court correctly recognized in denying Plaintiffs' preliminary-injunction motion, it makes no difference legally whether withdrawing from Medicare is "practical or not." *Chamber I*, 2023 WL 6378423, at *11. "[P]articipation in Medicare, no matter how vital it may be to a business model, is a completely voluntary choice." *Id.* (discussing cases). Even where "business realities" create "strong financial inducement to participate"—such as, for example, when Medicaid provides the vast majority of a nursing home's revenue—courts have emphasized that the decision to participate in the program "is nonetheless voluntary." *Minn. Ass'n*, 742 F.2d at 446. By telling manufacturers that Medicare might not continue paying them at current levels for their products, Congress has left them free to choose whether to continue selling the drug to Medicare on new terms. That is not coercion: it is an offer made by a buyer to a seller who can then either agree or forgo the sale.

4. The Negotiation Program Is a Proper Condition on Medicare and Medicaid Participation

In another attempt to avoid this Court's prior conclusion that the Negotiation Program is "completely voluntary" and thus raises no due process concerns, *Chamber I*, 2023 WL 6378423, at *11, Plaintiffs assert that making the program a condition of Medicare and Medicaid participation violates the unconstitutional-conditions doctrine. Pls.' Br. at 30-32. But, like Plaintiffs' other objections, this one collapses upon examination.

The unconstitutional-conditions doctrine "vindicates the Constitution's enumerated rights by preventing the government from coercing people into giving them up." *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013). At a minimum, then, the "predicate for any unconstitutional conditions claim" is the existence of a protected constitutional right that the government's offer would infringe. *Id.* at 612; *see also Rumsfeld v. Forum for Acad. & Institutional Rts., Inc.* (*FAIR*), 547 U.S. 47, 59-60 (2006) ("It is clear that a funding condition cannot be unconstitutional if it could be constitutionally imposed directly."); *R.S.W.W., Inc. v. City of Keego Harbor*, 397 F.3d 427, 434 (6th Cir. 2005) (explaining that while the unconstitutional conditions "doctrine should equally apply to prohibit the government from conditioning benefits

on a citizen's agreement to surrender due process rights," the plaintiff must first establish the existence of such a right). And when it comes to an assertion that the government has improperly conditioned a benefit on an entity's surrender of its due process rights, Plaintiffs must first establish the existence of a "liberty or property interest" that the Due Process Clause would protect. *Keego Harbor*, 397 F.3d at 434; *see also Vance v. Barrett*, 345 F.3d 1083, 1090 (9th Cir. 2003) (same). That is, a Plaintiff must demonstrate that the government is seeking to leverage a discretionary benefit against a *separate* vested property interest. *See, e.g.*, *Keego Harbor*, 397 F.3d at 434 (finding that Plaintiffs had stated a plausible unconstitutional-conditions claim when they alleged that "Defendants withheld certain administrative approvals from it unless it agreed to close" earlier than the regulations governing its liquor license permitted).

Here, however, Plaintiffs can identify no distinction between the benefit and the right that is supposedly being leveraged. As Plaintiffs themselves explain, the "valuable benefit" they seek is continued "Medicare participation" and making sales of their members' drugs to Medicare beneficiaries. Pls.' Br. at 32. Plaintiffs appear to recognize that this is not a benefit the government is required to provide—and rightly so. *Id.* As this Court correctly recognized—and as detailed further in the next section, *see infra*, Part IV.B.5—Plaintiffs have no vested right to conduct business with the government at all, and no vested property right to continue participating in Medicare. *Chamber I*, 2023 WL 6378423, at *11; *see, e.g.*, *Shah v. Azar*, 920 F.3d 987, 998 (5th Cir. 2019) ("[P]articipation in the federal Medicare reimbursement program is not a property interest."). What then is the vested property interest that Plaintiffs claim Congress is leveraging in exchange for that benefit? In Plaintiffs' telling, it is the *procedural* right to ensure that the government fairly sets the price for *those very sales to Medicare*, to ensure that they are not unfairly low. *See* Pls.' Br. at 32; *see id.* at 20, 22 (arguing that the IRA will lead to "confiscatory" prices). This argument is completely circular. Plaintiffs are not claiming that there are free-standing commercial sales that the government is seeking to regulate in exchange for some benefit. *See id.* at 20-22. Rather, the lack of process they claim as a violation of their rights concerns the *very same Medicare sales* that Plaintiffs are seeking as a benefit.

Not surprisingly, Plaintiffs identify no case that bootstrapped an unconstitutional-conditions theory in this manner. Plaintiffs' argument amounts to nothing more than the idea that the government denies them a constitutional right by not structuring the benefit in the way that Plaintiffs like. But to state this theory is to refute it. The Supreme Court has "never held that the [government] must grant a benefit . . . to a person who wishes to exercise a constitutional right." *Regan v. Tax'n with Representation of Washington*, 461 U.S. 540, 545 (1983); *see also J.H. Rutter Rex Mfg. Co. v. United States*, 706 F.2d 702, 712 (5th Cir. 1983) (rejecting government contractor's claim for "Fifth Amendment property entitlement to participate in the awarding of government contracts"). Just as a government contractor cannot claim that the denial of a contract improperly infringed on his procedural rights to negotiate that contract, so too the government cannot be said to violate the unconstitutional-conditions doctrine by offering allegedly inadequate procedures for negotiating the price that the government will pay for manufacturers' drugs.

* * *

In the end, Plaintiffs cannot establish that the Negotiation Program is anything other than "completely voluntary." *Chamber I*, 2023 WL 6378423, at *11. And because it is voluntary, the Program "simply does not involve a forced taking of property by the state." *Minn. Ass'n*, 742 F.2d at 446. Plaintiffs may be dissatisfied with how the Negotiation Program differs from other voluntary conditions they are used to seeing in the Medicare statute. But their dissatisfaction does not establish a constitutional claim.

5. Plaintiffs' Due Process Challenge Is Meritless, Even On Its Own Terms

Even setting aside this Court's prior holding—along with the well-settled precedent rejecting Fifth Amendment challenges to Medicare reimbursement caps—Plaintiffs' due process claim also fails for additional reasons. Plaintiffs assert that the IRA does not afford constitutionally adequate procedures to ensure that the rates at which the government will reimburse manufacturers for the selected drugs will not be "confiscatory." Pls.' Br. at 20, 22. This argument fails.

a. The Due Process Clause protects against the deprivation "of life, liberty, or property, without due process of law." U.S. Const. amend. V. The threshold "inquiry in every due process

challenge is whether the plaintiff has been deprived of a protected interest." *Am. Mfrs. Mut. Ins. Co. v. Sullivan*, 526 U.S. 40, 59 (1999). A protected property interest arises where an individual has "a legitimate claim of entitlement" to a particular benefit, not merely a "unilateral expectation" or "abstract need or desire" for it. *Bd. of Regents of State Colls. v. Roth*, 408 U.S. 564, 577 (1972). These property interests are "not created by the Constitution, they are created and their dimensions are defined by existing rules or understandings that stem from an independent source such as state law." *Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 538 (1985). As a result, "a party cannot possess a property interest in the receipt of a benefit when the state's decision to award or withhold the benefit is wholly discretionary." *Med Corp., Inc. v. City of Lima,* 296 F.3d 404, 409 (6th Cir. 2002). Rather, "to establish a constitutionally protected property interest," Plaintiffs "'must point to some policy, law, or mutually explicit understanding that both confers the benefits and limits the discretion of the [government] to rescind'" it. *Keego Harbor*, 397 F.3d at 435 (quoting *Med Corp.*, 296 F.3d at 410).

Here, Plaintiffs assert that manufacturers have protected property interests in "intellectual property," the investments they have made in their drugs, and the ability to "sell their products at market-based prices." Pls.' Br. at 25. But pharmaceutical manufacturers have no inherent entitlement—and therefore no property interest—in the privilege of selling their drugs *to Medicare*, at *any* price. *Contra* Pls.' Br. at 25 (alleging "promise of future sales"). As this Court correctly recognized in denying Plaintiffs' motion for a preliminary injunction, no one is entitled to conduct business with the government in the first instance. *Chamber I*, 2023 WL 6378423, at *11; *see also Coyne-Delany Co. v. Cap. Dev. Bd.*, 616 F.2d 341, 342 (7th Cir. 1980) ("[N]o one has a 'right' to sell to the government that which the government does not wish to buy."); *Perkins*, 310 U.S. at 127 (government has authority to "determine those with whom it will deal"); *J.H. Rutter*, 706 F.2d at 712 (rejecting government contractor's claim for "Fifth Amendment property entitlement to participate in the awarding of government contracts"). By extension, as Courts have repeatedly emphasized, no one has a property interest in future Medicare sales. *See, e.g.*, *Shah*, 920 F.3d at 998 ("[P]articipation in the federal Medicare reimbursement program is not a property

interest."); *Managed Pharmacy Care v. Sebelius*, 716 F.3d 1235, 1252 (9th Cir. 2013) ("[P]roviders do not have a property interest in a particular reimbursement rate."); *Painter v. Shalala*, 97 F.3d 1351, 1358 (10th Cir. 1996) (holding that a physician has no property interest in "having his [Medicare] reimbursement payments calculated in a specific manner").

Indeed, crediting Plaintiffs' claim that drug manufacturers have a protected property interest in Medicare sales would mean that manufacturers have a *constitutional* right to dictate the government's expenditures. But it is settled that "Congress may attach appropriate conditions to federal taxing and spending programs to preserve its control over the use of federal funds." *NFIB*, 567 U.S. at 579; *see Sabri*, 541 U.S. at 608. Not surprisingly then, the Sixth Circuit has explicitly rejected the core premise of Plaintiffs' theory, noting that "those who opt to participate in Medicare are not assured of revenues." *Livingston Care Ctr.*, 934 F.2d at 721. Just as a defense contractor could not build an aircraft carrier and force an unwilling Pentagon to buy it (at any price), so too manufacturers cannot force their drugs onto the government at unilaterally dictated rates.

In the absence of a protected property interest in future Medicare sales, Plaintiffs' due process claim collapses. *See Keego Harbor*, 397 F.3d at 434 ("In order to assert a valid due process claim . . . a plaintiff must establish that the interest asserted is a liberty or property interest."). For that reason, there is no need for the Court to address what Plaintiffs describe as the "general due-process balancing test . . . set forth in *Mathews v. Eldridge*, 424 U.S. 319 (1976)." Pls.' Br. at 25-27. Simply put, the IRA cannot deprive Plaintiffs of due process of law in setting the price of Medicare sales when Plaintiffs have no protected property interest in those sales to begin with. *See, e.g.*, *Roth,* 408 U.S. at 578 (untenured professor, whose appointment was for only one year, did not possess a protected property interest in his continued employment after the term of his appointment expired, and university was therefore not required "to give him a hearing when they declined to renew his contract of employment"); *Med Corp.*, 296 F.3d at 411 (absence of "property interest in receiving 911 calls" meant that plaintiff lacked due process claim related to their removal from the dispatch list).

b. Separately, Plaintiffs' attempts to bring a facial challenge to the IRA by analogizing the Negotiation Program to the Sixth Circuit's 2001 decision in *Michigan Bell* remains irreconcilable with the Supreme Court's 2002 decision in *Verizon*.

The Court in *Verizon* confronted a challenge by telephone carriers to an FCC rule that "require[d] state utility commissions to set the rates charged by the" companies for certain property "on a forward-looking basis untied to the[ir] investment." 535 U.S. at 475. Petitioners claimed that "a methodology so divorced from investment actually made will lead to a taking of property." *Id.* at 523. The Court summarily rejected this contention. As the Court noted, the carriers' claim was "not . . . usual" because they did not "argue that any particular, actual [] rate is 'so unjust as to be confiscatory,' that is, [] threatening [their] 'financial integrity,'" but instead challenged the methodology on its face. *Id.* at 523-24 (quoting *Duquesne Light*, 488 U.S. at 307, 312). The Court explained that it had "never considered a taking challenge on a ratesetting methodology without being presented with specific rate orders alleged to be confiscatory." *Id.* at 524 (citing *Duquesne Light*, 488 U.S. at 303-04). And "the general rule is that any question about the constitutionality of ratesetting is raised by rates, not methods." *Id.* at 525.

So too here. Plaintiffs are not challenging any particular price—nor could they, given that CMS has not yet negotiated a price agreement with any manufacturer. Rather, Plaintiffs are challenging the methodology by which that price *will* be negotiated, as well as certain limitations on administrative and judicial review. As in *Verizon*, Plaintiffs are thus not arguing that any "particular, actual" price threatens manufacturers' "financial integrity," but rather merely raise the specter that some future price *might* do so. 535 U.S. at 524. Yet that is exactly the kind of challenge that raises no "question" of "constitutionality," per the Supreme Court. *Id*. at 523-25.

Notably, Plaintiffs do not even cite *Verizon* in their papers, despite Defendants previously bringing the decision to their attention during preliminary-injunction briefing. *See generally* Defs.' Opp'n to Pls.' Mot. for a Prelim. Inj., ECF No. 34. But Plaintiffs' assertion that the IRA does not afford adequate *methodology* to protect against confiscatory rates cannot survive *Verizon*'s reasoning. *Compare Michigan Bell*, 257 F.3d at 594 (holding that methodology "does

not guarantee a constitutionally adequate rate of return . . . because it merely permits [] service providers to cover costs, and does not ensure a fair and reasonable rate of return on investment"), *with Verizon*, 535 U.S. at 523-25 (rejecting argument that "a methodology [] divorced from investment actually made will lead to a taking of property").[16] Thus, even if Plaintiffs had alleged that the IRA threatens their "financial integrity"—which *Verizon* sets as the standard, but which Plaintiffs do not meet given that (unlike utilities) they are not required to sell the fruit of their investments—this claim would still fail.

Simply put, Plaintiffs cannot satisfy the standard for a facial challenge—which is "the most difficult challenge to mount successfully, since the challenger must establish that no set of circumstances exists under which" the Negotiation Program could be constitutionally applied. *Salerno*, 481 U.S. at 745; *see also Warshak v. United States*, 532 F.3d 521, 529 (6th Cir. 2008) (court should be "reluctan[t] to grant relief in the face of facial, as opposed to as-applied, attacks on statutes") (en banc). Plaintiffs do not yet know whether any of their members will agree to prices that are so low as to threaten their "financial integrity." *Verizon*, 535 U.S. at 524 (quotations omitted). Further—as this Court and the Sixth Circuit have emphasized—manufacturers can always avoid any supposed deprivation by withdrawing from Medicare and Medicaid altogether. *Baptist Hosp.*, 802 F.2d at 869-70. Any of these "conceivable set[s] of circumstances" defeat Plaintiffs' facial due process challenge. *Salerno*, 481 U.S. at 745.

C. Plaintiffs' First Amendment claim (Count 5) is meritless because the Negotiation Program does not compel manufacturers to speak.

Plaintiffs' First Amendment claim rests entirely on their unsupported assertions that manufacturers are "compelled" to sign agreements with CMS and that entry into these agreements constitutes "speech" protected by the First Amendment. Pls.' Br. at 45. Neither is true.

1. Reaching an agreement with CMS is not speech, nor is it expressive conduct. And any "speech" that may ordinarily be implicated in the execution of a commercial contract "is plainly

[16] In subsequent proceedings in *Michigan Bell,* the Sixth Circuit had no occasion to address *Verizon* in light of petitioners' voluntary motion to dismiss the appeal, which mooted the case. *Michigan Bell Tel. Co. v. Engler*, 72 F. App'x 380, 386 (6th Cir. 2003) (dismissing appeal). As the Sixth Circuit previewed, however, "future litigants may argue about the effect of *Verizon Communication* on th[e] decision." *Id.* Those future litigants are here.

incidental to the . . . regulation of conduct" that the contract governs. *Id.* at 62. The regulation of conduct "has never been deemed an abridgment of freedom of speech . . . merely because the conduct was in part initiated, evidenced, or carried out by means of language, either spoken, written, or printed." *Id.* (quoting *Giboney v. Empire Storage & Ice Co.*, 336 U.S. 490, 502 (1949)). Medicare routinely uses agreements that health care providers or other entities sign to memorialize their voluntary acceptance of the terms for participation in various programs; those agreements do not signify providers' endorsement of, for example, the general fairness of the Medicare rate-setting process. *See, e.g.*, 42 U.S.C. §§ 1395cc, 1396r-8(b), (c). These agreements—memorializing manufacturers' acceptance of the terms for participation in the Negotiation Program—are no different.

A manufacturer that chooses to sign an agreement with CMS undertakes a voluntary obligation to negotiate prices and, ultimately, to provide Medicare beneficiaries with access to the negotiated prices for the selected drugs that the manufacturer sells. *See* Revised Guidance at 118-20; *see also* CMS, Medicare Drug Price Negotiation Program Agreement ("Template Agreement"), https://perma.cc/6VG4-KKF6. This does not implicate the First Amendment any more than "typical price regulation," which "would simply regulate the amount [of money] that a [manufacturer] could collect." *Expressions Hair Design v. Schneiderman*, 581 U.S. 37, 47 (2017). As Plaintiffs appear to recognize, *see* Pls.' Br. at 45-46, such "ordinary price regulation does not implicate constitutionally protected speech," *Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 292 (D.C. Cir. 2019) (citing *Expressions Hair Design*, 581 U.S. at 47); *see also Campbell v. Robb*, 162 F. App'x 460, 468 (6th Cir. 2006) (recognizing "the general principle that government retains its full power to regulate commercial transactions directly, despite elements of speech and association inherent in such transactions"). In the same way, because the request that a participating manufacturer sign an agreement "is imposed 'for reasons unrelated to the communication of ideas,'" that offer does "not implicate the First Amendment." *Nicopure*, 944 F.3d at 291 (quoting *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 569 (2001)); *see also Expressions Hair Design*, 581

U.S. at 47 (where a "law's effect on speech would be only incidental to its primary effect on conduct," the law is not a regulation of speech subject to First Amendment scrutiny).

A manufacturer's decision to sign the negotiation agreement "is not inherently expressive," *FAIR*, 547 U.S. at 64, which is "underscored by [the agreement's] bearing only on product price," *Nicopure*, 944 F.3d at 292. The terms of the agreement explicitly state what is already apparent: a manufacturer's signature constitutes neither an "endorsement of CMS' views" nor a representation of the manufacturers' views concerning the fairness of prices. *See* Template Agreement at 4 (explaining that, by "signing this Agreement, the Manufacturer does not make any statement regarding or endorsement of CMS' views").[17] Lest there be any doubt, the agreement affirms that the use "of the term 'maximum fair price' and other statutory terms throughout this Agreement reflects the parties' intention that such terms be given the meaning specified in the statute and does not reflect any party's views regarding the colloquial meaning of those terms." *Id.* In other words, the agreement uses statutory terms merely as a way of ensuring that the signatories share the same understanding of their respective obligations.

This is nothing like the regulations challenged in the cases that Plaintiffs cite. *See, e.g.*, *Janus v. Am. Fed'n of State, Cnty., & Mun. Emps.*, 138 S. Ct. 2448, 2464 (2018) (holding that requiring public employees to pay union fees violated their free speech rights); *Thompson v. Marietta Educ. Ass'n*, 972 F.3d 809, 813 (6th Cir. 2020) (addressing "compelled speech" challenge to Ohio's system of exclusive public-sector union representation); *Video Software Dealers Ass'n v. Schwarzenegger*, 556 F.3d 950, 966-67 (9th Cir. 2009) (holding, in relevant part, that state law's labeling requirement for "violent video games" was unconstitutional compelled speech); Pls.' Br. at 45-47. The agreement to negotiate does not require manufacturers "to utter or distribute speech bearing a particular message," *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 642 (1994), or to

[17] There is no merit to Plaintiffs' claim that the "disclaimer only underscores" their view that the contract suggests an endorsement of CMS's views. Pls.' Br. at 46 n.17. The government, no less than a commercial party, is free to emphasize an already obvious point. Contracts do this routinely. Plaintiffs cite no canon of construction supporting their reading of such emphasis as a negation.

say anything about any agreed-upon prices. Nor does the agreement restrict manufacturers' ability to say whatever they wish about the Negotiation Program or to criticize CMS or the IRA.

A manufacturer may, of course, have numerous reasons for signing or not signing an agreement with CMS, and some of those reasons may pertain to views that it holds or wants to communicate to others. But a manufacturer's views regarding the IRA or negotiated prices "do[] not convert all regulation that affects access to [selected drugs] into speech restrictions subject to First Amendment scrutiny." *Nicopure*, 944 F.3d at 291. *Cf. City of Dallas v. Stanglin*, 490 U.S. 19, 25 (1989) ("It is possible to find some kernel of expression in almost every activity a person undertakes—for example, walking down the street or meeting one's friends at a shopping mall—but such a kernel is not sufficient to bring the activity within the protection of the First Amendment."). Signing an agreement to negotiate "is simply not the same as forcing a student to pledge allegiance to the flag . . . or forcing a Jehovah's Witness to display a particular motto on his license plate . . . and it trivializes the freedom protected in [those circumstances] to suggest that it is." *FAIR*, 547 U.S. at 48 (citing *W. Va. Bd. of Educ. v. Barnette,* 319 U.S. 624 (1943), and *Wooley v. Maynard,* 430 U.S. 705 (1977)).

2. Moreover, because the Negotiation Program is voluntary, it does not compel any manufacturer to sign an agreement—or to do anything at all. For the reasons explained above, Plaintiffs' assertion that the manufacturer of a selected drug is "forced" to sign an agreement to negotiate, Pls.' Br. at 46, overlooks the various options the manufacturer has to exit or otherwise avoid the Negotiation Program, *see supra*, Part IV.B.2; *see also Chamber I*, 2023 WL 6378423, at *11. The First Amendment does not prohibit the government from giving a company the option to sign an agreement governing the terms of a program in which the company chooses to participate. *See, e.g.*, *FAIR*, 547 U.S. at 59 (noting that "Congress is free to attach reasonable and unambiguous conditions to federal" funds without triggering First Amendment scrutiny (quoting *Grove City College v. Bell*, 465 U.S. 555, 575-76 (1984)). Just as manufacturers are not forced to sell drugs to Medicare, manufacturers are not forced to sign agreements to negotiate the prices of those drugs. So even if Plaintiffs' "speech" were at issue here, that speech is not "compelled."

3. Plaintiffs alternatively cast their First Amendment challenge as a claim that the invitation to sign a negotiation agreement violates the "unconstitutional conditions doctrine," Pls.' Br. at 47-48—but this argument likewise fails at the threshold because, as explained above, the IRA does not require manufacturers to engage in speech under the First Amendment. In any event, the Supreme Court has long upheld conditions on speech that pertain to the nature of a government program. As the Court has explained, if a program arises under the Spending Clause, Congress is free to attach "conditions that define the limits of the government spending program—those that specify the activities Congress wants to subsidize." *Agency for Int'l Dev.*, 570 U.S. at 214; *see, e.g.*, *United States v. Am. Lib. Ass'n*, 539 U.S. 194, 212 (2003) (plurality opinion) (rejecting a claim by public libraries that conditioning funds for Internet access on the libraries' installing filtering software violated their First Amendment rights, explaining that "[t]o the extent that libraries wish to offer unfiltered access, they are free to do so without federal assistance"); *Regan*, 461 U.S. at 546 (dismissing "the notion that First Amendment rights are somehow not fully realized unless they are subsidized by the State" (citation omitted)). Conditions implicating speech may be suspect only where those conditions "seek to leverage funding to regulate speech outside the contours of the program itself." *Agency for Int'l Dev.*, 570 U.S. at 214-15.

Here, the supposed condition about which Plaintiffs complain is the signing of an agreement to negotiate and, ultimately, a pricing agreement. But those voluntary agreements are the core mechanisms by which negotiations will proceed, and the source of the enforceable obligation for manufacturers to provide selected drugs at negotiated prices. *See* Revised Guidance at 118-20. In this way, these agreements "define the [Negotiation] program and" do not "reach outside it." *Agency for Int'l Dev.*, 570 U.S. at 217. And because these agreements are simply "designed to ensure that the limits of the federal program are observed"—and that Medicare funds are "spent for the purposes for which they were authorized"—the opportunity to sign an agreement to participate in the Negotiation Program does not impose unconstitutional conditions on the use of federal funds. *Rust v. Sullivan*, 500 U.S. 173, 193, 196 (1991).

D. Even if the Court had jurisdiction over Plaintiffs' excise tax claims, the excise tax is constitutional.

The excise tax is likewise constitutional. Because it is neither a fine nor excessive, it is not an excessive fine that violates the Eighth Amendment. And the tax is authorized by Congress's enumerated powers under both the Taxing and Spending Clause and the Commerce Clause.

1. The excise tax does not violate the Eighth Amendment (Count 3).

The Eighth Amendment provides that "[e]xcessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted." U.S. Const. amend. VIII. "Taken together, these Clauses place 'parallel limitations' on 'the power of those entrusted with the criminal-law function of government.'" *Timbs v. Indiana*, 139 S. Ct. 682, 687 (2019) (quoting *Browning-Ferris Indus. of Vt., Inc. v. Kelco Disposal, Inc.*, 492 U.S. 257, 263 (1989)). "The purpose of the Eighth Amendment"—both the Excessive Fines Clause and the Cruel and Unusual Punishments Clause—"was to limit the government's power to punish." *Austin v. United States*, 509 U.S. 602, 609 (1993); *see also Moser v. United States*, No. 97-6302, 1998 WL 833714, *1 (6th Cir. Nov. 20, 1998) (same). The threshold question in any Excessive Fines Clause case then is whether the challenged exaction constitutes "punishment for an offense"—*i.e.*, whether the exaction is a "fine" covered by the Eighth Amendment. *United States v. Alt*, 83 F.3d 779, 784 (6th Cir. 1996); *see also United States v. Bajakajian*, 524 U.S. 321, 328 (1998) ("Forfeitures—payments in kind—are thus 'fines' if they constitute punishment for an offense."). Only if the exaction is deemed punishment does a court consider whether the fine "is unconstitutionally excessive." *Dewees v. United States*, 272 F. Supp. 3d 96, 100 (D.D.C. 2017), *aff'd*, 767 F. App'x 4 (D.C. Cir. 2019).

The IRA's excise tax does not violate the Eighth Amendment's Excessive Fines Clause because it is neither a "fine" nor "excessive." The excise tax is not a "fine" covered by the Eighth Amendment because it is not "punishment for some offense." *Bajakajian*, 524 U.S. at 327. The excise tax has no connection to a criminal offense or criminal proceedings—unlike the exactions at issue in the Excessive Fines Clause precedents that Plaintiffs cite. The excise tax also lacks the

"unusual features" of the drug taxes in *Kurth Ranch* and *Dye* that led the Supreme Court and the Seventh Circuit, respectively, to conclude that those taxes constituted punishment for purposes of the Double Jeopardy Clause. Even if the tax were a fine, the proportionality test—which itself looks to the "gravity of the offense," a factor that has no bearing here given the lack of any offense—demonstrates that the excise tax is not grossly disproportionate to the harm to the fisc and is within the range of other constitutional exactions.

a. "[A]t the time the Constitution was adopted, 'the word "fine" was understood to mean a payment to a sovereign as punishment for some offense.'" *Id.* (quoting *Browning-Ferris*, 492 U.S. at 265). "Then, as now," fines were typically imposed as punishments in criminal prosecutions. *Browning-Ferris Indus.*, 492 U.S. at 265. While the Supreme Court has found certain civil penalties and forfeitures to constitute "punishment" within the scope of the Excessive Fines Clause, it has only done so in cases where the penalty or forfeiture either constituted a sanction for criminal conduct after a conviction, *see Bajakajian*, 524 U.S. at 325 (federal statute that provides that a person convicted of willfully violating reporting requirement shall forfeit to the government any property "involved in such offense"), or was assessed against property used in the commission of a crime for which the owner had already been convicted, *see Austin*, 509 U.S. at 622 (federal statute that makes property used to facilitate drug crimes subject to civil *in rem* forfeiture). The Court has never characterized an exaction with no connection to either criminal activity or a criminal proceeding as "punishment for some offense," let alone punishment that violates the Excessive Fines Clause.

Plaintiffs do not cite any such case—from the Sixth Circuit or elsewhere. *See* Pls.' Br. at 37-38. Instead, all three of the Excessive Fines Clause cases cited by Plaintiff in which the forfeiture or penalty was held to be "punishment" involved criminal conduct or criminal proceedings. None of those cases involve taxes or otherwise bear any resemblance to this case.

Take *Austin* first. After Austin pleaded guilty to possession of cocaine with intent to distribute, the government filed an *in rem* action, seeking forfeiture of his mobile home and auto shop pursuant to provisions that made property used in furtherance of certain crimes subject to

civil forfeiture. *Id.* at 604-05 (citing 21 U.S.C. § 881(a)(4), (7)). Both history and modern practice demonstrated that these provisions constituted punishment. The Court concluded that, "at the time the Eighth Amendment was ratified," forfeiture was understood "as imposing punishment." *Id.* at 611-18. And three features of these provisions demonstrated that they remained "punishment today": (1) the "inclusion of innocent-owner defenses," which reveals a "congressional intent to punish only those involved in drug trafficking"; (2) "Congress [having] chosen to tie forfeiture directly to the commission of drug offenses"; and (3) a legislative history that indicates "Congress recognized 'that the traditional criminal sanctions of fine and imprisonment are inadequate to deter or punish the enormously profitable trade in dangerous drugs.'" *Id.* at 619-20 (citation omitted). Taken together, these forfeiture provisions constituted "punishment for some offense" "subject to the limitations of the Eighth Amendment's Excessive Fines Clause." *Id.* at 622 (citation omitted).

Bajakajian is equally unhelpful to Plaintiffs. That case involved a criminal forfeiture. After Bajakajian tried to leave the country without reporting that he was transporting over $350,000 in cash, he was charged with three counts. *Bajakajian*, 524 U.S. at 325. The third sought forfeiture of the unreported funds pursuant to 18 U.S.C. § 982(a)(1), which provides that, "in imposing sentence on a person convicted of [failing to report that he was transporting more than $10,000 outside the United States]," the court "shall order that the person forfeit to the United States any property . . . involved in such offense, or any property traceable to such property." *Id.* The Court held that this forfeiture was "punishment" under the Excessive Fines Clause. *Id.* at 328-34. Again, the Court looked to history, concluding that such forfeitures "have historically been treated as punitive, being part of the punishment imposed for felonies and treason in the Middle Ages and at common law." *Id.* at 332. The modern version remained "punishment": the forfeiture is "imposed at the culmination of a criminal proceeding and requires conviction of an underlying felony, and it cannot be imposed upon an innocent owner of unreported currency, but only upon a person who has himself been convicted of a [criminal] reporting violation." *Id.* at 328.

None of the features of the *in rem* civil forfeiture in *Austin* or the criminal forfeiture in *Bajakajian* is present here. *See United States v. Toth*, 33 F.4th 1, 16 (1st Cir. 2022) ("[U]nlike

[the] forfeitures held to constitute 'punishment' in both *Austin* and *Bajakajian*, this civil penalty"—"imposed following an administrative tax audit"—"is not tied to any criminal sanction."), *cert. denied*, 143 S. Ct. 552 (2023). Unlike civil or criminal forfeiture, "taxes historically have not been viewed as punishment." *United States v. Beaty*, 147 F.3d 522, 525 (6th Cir. 1998). The other three *Austin* factors are similarly absent. First, § 5000D does not contain an innocent-taxpayer exception and imposition of the tax does not depend on any particular level of culpability. *See generally* 26 U.S.C. § 5000D. Second, the excise tax is not tied to the commission of any crime; rather, tax liability is triggered by the lawful choices of the taxpayer in connection with the Negotiation Program. *See id.* § 5000D(a), (b), (e)(1). Third, Congress did not indicate that the tax is meant to supplement "traditional criminal sanctions of fine and imprisonment" to adequately "deter or punish" illegal activity. *See Austin*, 509 U.S. at 620. And, unlike the criminal forfeiture in *Bajakajian*, the excise tax is not "imposed at the culmination of a criminal proceeding," does not "require[] [a] conviction of an underlying felony," and does not distinguish in its rate or scope between different levels of culpability. *See Bajakajian*, 524 U.S. at 328.

Finding no support in *Austin* or *Bajakajian*, Plaintiffs turn to dicta in an unpublished district court decision that was affirmed, in an unpublished Sixth Circuit decision, on alternative grounds. *See* Pls.' Br. at 38 (citing *Stevens v. City of Columbus*, No. 2:20-cv-01230, 2021 WL 3562918, at *4 (S.D. Ohio Aug. 12, 2021), *aff'd*, No. 21-3755, 2022 WL 2966396 (6th Cir. July 27, 2022)). In that case, two homeowners were "directed to comply with [a code violation] notice within 30 days or face monetary fines or punishment of sixty days imprisonment." *Stevens*, 2021 WL 3562918, at *1. Because no fine had been levied, the claim was not ripe. *Id.* In dicta, the court explained that, if the claim had been ripe, it would have likely found the potential fine was a "fine" for Eighth Amendment purposes, but not an excessive one. *Id.* at *3-4. That was in part because "the applicable regulations subject[ed] non-compliant homeowners to civil penalties of $100 per day, as well as criminal penalties carrying a maximum 60-day jail sentence." *Id.* at *4. The Sixth Circuit declined to address the merits, affirming on ripeness grounds. *Stevens v. City of Columbus*, No. 21-3755, 2022 WL 2966396, at *12 (6th Cir. July 27, 2022). *Stevens* is thus unhelpful to

Plaintiffs twice over: (1) because the "punishment" analysis is confined to dicta, and (2) because the conduct triggering the excise tax here does not subject taxpayers to any criminal punishment.

b. Having identified no case in which an exaction untethered from criminal conduct or criminal proceedings was deemed "punishment for some offense" under the Excessive Fines Clause, Plaintiffs turn to two Double Jeopardy Clause cases. *See* Pls.' Br. at 38 (citing *Dep't of Revenue of Montana v. Kurth Ranch*, 511 U.S. 767 (1994); *Dye v. Frank,* 355 F.3d 1102 (7th Cir. 2004)). Those are the *only* cases Plaintiffs identify in which a tax was held to be punishment; they do not cite *any* case (and Defendants are not aware of one) in which a tax was deemed to be "punishment for some offense" (*i.e.*, a "fine") under the Excessive Fines Clause. And both cases—involving drug taxes related to criminal offenses—reinforce why the tax here is *not* punishment.

As a preliminary matter, the analytical framework used by the Supreme Court in *Kurth Ranch* undermines a core premise of Plaintiffs' argument: that the excise tax is a "fine" if it "is retributive or deterrent" "even in part." Pls.' Br. at 37 (quoting *F.P. Dev., LLC v. Charter Twp. of Canton*, 16 F.4th 198, 208-09 (6th Cir. 2021) (a non-tax case applying test used by Supreme Court in non-tax cases)). The Court first adopted that test in *United States v. Halper*, 490 U.S. 435 (1989), a case involving a $130,000 civil penalty on the heels of a 65-count criminal conviction that resulted in the plaintiff serving two years in prison and paying a $5,000 fine. *Id.* at 437-38. Because that post-conviction civil fine could not "fairly be said *solely* to serve a remedial purpose, but rather can only be explained as *also* serving either retributive or deterrent purposes," the Court held it was "punishment" for Double Jeopardy purposes. *Id.* at 448 (emphasis added).[18]

The Supreme Court has never applied this deterrent-in-part test in the tax context, and, in *Kurth Ranch*, the Court rejected its application to a state drug tax. 511 U.S. at 776. *Kurth Ranch* involved a Double Jeopardy Clause challenge to a Montana tax on the possession of illegal drugs. The Court concluded that the *Halper* test was inapplicable. *Id.* While *Halper* held that certain

[18] The Court later abrogated *Halper* in *Hudson v. United States*, 522 U.S. 93, 102 (1997) (noting that "all civil penalties have some deterrent effect" and rejecting "*Halper*'s test for determining whether a particular sanction is 'punitive'" under the Double Jeopardy Clause).

civil *penalties* could constitute punishment under the Double Jeopardy Clause, "*Halper* did not . . . consider whether a *tax* may similarly be characterized as punitive." *Id.* at 778 (emphasis added). The Court then held that evidence of a deterrent purpose does not determine whether a tax is punishment: As the "Chief Justice points out, tax statutes serve a purpose quite different from civil penalties, and *Halper*'s method of determining whether the exaction was remedial or punitive 'simply does not work in the case of a tax statute.' Subjecting Montana's drug tax to *Halper*'s test for civil penalties is therefore inappropriate." *Id.* at 784 (citation omitted). Accordingly, unlike in the penalty and forfeiture context, "neither a high rate of taxation nor an obvious deterrent purpose automatically marks [a] tax as a form of punishment." *Id.* at 780. "Whereas fines, penalties, and forfeitures are readily characterized as sanctions," absent "[o]ther unusual features," "an exaction labeled as a tax" is not deemed punishment, even if it is accompanied by a "deterrent purpose." *Id.* at 779-81; *id.* at 780-81 ("[M]any taxes that are presumed valid, such as taxes on cigarettes and alcohol, are also both high and motivated to some extent by an interest in deterrence . . . ."); *contra* Pls.' Br. at 37 (arguing excise tax is punitive because it allegedly serves a deterrent purpose and is not "wholly remedial").[19]

The facts of *Kurth Ranch* are equally unhelpful to Plaintiffs. The marijuana tax there was deemed "punishment" only because of a host of "unusual features" and "anomalies" absent here. Concluding that the tax's high rate and admittedly deterrent purpose did "not necessarily render the tax punitive," the Court identified three additional, "unusual features" that led the Court to label the "exceptional" Montana tax as punishment. *Id.* at 781, 783. First, Montana's "so-called

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[19] In any event, the excise tax serves a remedial purpose in compensating the public fisc for losses incurred from a manufacturer failing to agree to a maximum fair price and continuing to sell its drugs to Medicare beneficiaries, potentially at much higher prices. Indeed, courts regularly recognize that tax *penalties*—which would appear to have a greater deterrent purpose than taxes themselves—have a remedial purpose. *See Helvering v. Mitchell*, 303 U.S. 391, 401 (1938) (describing "[t]he remedial character of sanctions imposing additions to a tax"); *Dewees*, 272 F. Supp. 3d at 100-01 (courts "have erected 'an insurmountable wall of tax cases' to support this proposition" that "tax penalties are remedial"). Plaintiffs nonetheless assert that the excise tax cannot be deemed to have a remedial purpose because they believe, based on CBO projections, that the tax will not raise revenue. As explained below, that argument overreads the legislative history. *See infra* at 72-73 & n.23. It also confuses purposes and effects. The excise tax can and does have a remedial purpose even if, by Plaintiffs' telling, a manufacturer would not engage in the conduct that would cause the harm that the excise tax is designed to remedy. *Cf. United States v. Sanchez*, 340 U.S. 42, 44 (1950) (tax remains valid "even [if it] definitely deters the activity taxed").

tax"[20] was "conditioned on the commission of a crime." *Id.* at 781. Second, it was "exacted only after the taxpayer has been arrested for the precise conduct that gives rise to the tax obligation in the first place" such that "[p]ersons who have been arrested for possessing marijuana constitute[d] the entire class of taxpayers subject to the Montana tax." *Id.* at 781-82. Third, the tax was "levied . . . on previously confiscated goods" that the "taxpayer neither own[ed] nor possess[ed] when the tax [was] imposed." *Id.* at 783. Because of this "concoction of anomalies," the Court held that the tax was "too far-removed in crucial respects from a standard tax assessment to escape characterization as punishment." *Id.*; *see also Beaty*, 147 F.3d at 525 (describing anomalous features of tax in *Kurth Ranch*); *Alt*, 83 F.3d at 781-82 (same).

The IRA's excise tax contains none of these characteristics. None of the "unusual features" that made the Montana tax "exceptional" is present here: the excise tax is not conditioned on the commission of a crime, it is not exacted after an arrest, and it is not levied on previously confiscated goods. *See Kurth Ranch*, 511 U.S. at 781-83. Indeed, the excise tax does not follow any determination that the taxpayer has engaged in any unlawful activity. *See generally* 26 U.S.C. § 5000D. Further, unlike the Montana tax assessment in *Kurth Ranch*, which required the taxpayer to pay a *multiple* of gross revenue (approximately 4x), 511 U.S. at 780 n.17, a manufacturer's excise tax obligations here may be satisfied by paying a *fraction* of gross revenue because the tax ranges from 65 to 95% of the amount charged for a designated drug, IRS Notice at 3; *see also* 26 U.S.C.§ 5000D(d).[21]

[20] Plaintiffs similarly refer to the § 5000D tax as the "so-called 'excise tax.'" Pls.' Br. at 3, 36-37. That characterization, as the Court's own description of the Montana marijuana tax demonstrates, does not alter the punishment analysis. What mattered for purposes of the Court's decision in *Kurth Ranch* was that the Montana tax was "labeled as a tax." 511 U.S. at 780; *contra* Pls.' Br. at 38. Given that label, the Court refused, unlike in *Halper* and *Austin*, to hold that the tax constituted punishment on the sole basis that the tax partly had a deterrent purpose.

[21] Plaintiffs maintain that the tax rate is "19 times a product's price." Pls.' Br. at 39. But the IRS has made clear, in a notice that "taxpayers may rely on" now, that—assuming a manufacturer does not separately invoice the tax and assuming 271 days have passed—a covered taxpayer would owe a $95 tax out of $100 charged for a drug by a manufacturer. *See* IRS Notice at 3, 5. In any event, because Plaintiffs bring a facial challenge—before any tax has been assessed or collected, in violation of the AIA—they must establish that the tax is unconstitutional in all applications. *City of Los Angeles v. Patel*, 576 U.S. 409, 418 (2015). Therefore, to the extent the parties have a dispute about the applicable rate of tax that would apply, Plaintiffs are entitled to relief only if the excise tax is unconstitutional applying IRS's interpretation of its scope and rate. *Crawford v. Dep't of the Treasury*, No. 3:15-cv-250, 2015 WL 5697552, at *16 (S.D. Ohio Sept. 29, 2015) (rejecting facial challenge to tax penalty not yet imposed because it "will be constitutional in at least some circumstances").

The Seventh Circuit's decision in *Dye* is similarly inapposite. Dye appealed the denial of a habeas corpus petition he filed after he was criminally charged for possessing cocaine subsequent to a civil action to collect unpaid controlled substances taxes on the same cocaine. 355 F.3d at 1103. After applying a seven-factor test, the court concluded that the Wisconsin drug tax was the "rare tax statute" that "is so punitive in either purpose or effect that it is subject to double jeopardy analysis at all." *Id.* at 1108. The court's holding rested on key facts missing here: "the tax is only applied to behavior that is already a crime," was "created in order to deter criminal conduct," and the amount of the tax was "approximately five times the market value of the drugs" ($400 tax assessment and penalty owed on a gram of cocaine that could be sold for "approximately $80"). *Id.* at 1104-05. Based on these facts, and the similarities between the Wisconsin drug tax and the Montana drug tax in *Kurth Ranch*, the court described the drug tax as "criminal punishment masquerading as a civil tax" such that criminal proceedings after the imposition of the tax risked punishing Dye more than "once for his misconduct." *Id.* at 1108. Again, none of these features are present here.

c. The test used to determine whether a "fine" is "excessive" under the Excessive Fines Clause only reinforces the conclusion that the excise tax here is not "punishment." A fine will not be deemed excessive if the "amount of the [fine] bear[s] *some* relationship to the gravity of the offense that it is designed to punish," an inquiry that requires a court to "compare the amount of the [fine] to the gravity of the defendant's offense." *Bajakajian*, 524 U.S. at 334, 336-37 (emphasis added); *see also id.* at 339 (assessing defendant's "level of culpability"). That question has no bearing here given the lack of any "offense" or any "design[] to punish." *See id.* at 334.

Plaintiffs nonetheless argue that it is "obvious" that the excise tax here is "grossly disproportionate" because the conduct for which tax liability applies "would not entail any reprehensible conduct at all." Pls.' Br. at 39. That is precisely the point: Because the tax is not triggered by the commission of *any* offense—reprehensible or otherwise—it is not "punishment for some offense" and therefore is not a "fine" under the Excessive Fines Clause. Embracing Plaintiffs' argument would lead to absurd results: *most* taxes would be unconstitutionally

disproportionate because they are assessed following innocuous conduct like working or shopping. That would stretch the Eighth Amendment, which merely "limit[s] the government's power to punish," beyond recognition. *Austin*, 509 U.S. at 609.

d. If the Court were to nonetheless reach the excessiveness inquiry, the excise tax would not be a "grossly disproportionate" fine. First, "strict proportionality" is not required; a fine is constitutional unless it is grossly disproportional to the offense. *Bajakajian*, 524 U.S. at 336 (adopting "the standard of gross disproportionality articulated in [the Court's] Cruel and Unusual Punishments Clause precedents"). Second, that inquiry requires "substantial deference" to Congress. *Solem v. Helm*, 463 U.S. 277, 290 (1983); *Bajakajian*, 524 U.S. at 336 ("judgments about the appropriate punishment for an offense belong in the first instance to the legislature"). Because "Congress is a representative body, its pronouncements regarding the appropriate range of fines for a crime represent the collective opinion of the American people as to what is and is not excessive." *United States v. 817 N.E. 29th Dr.*, 175 F.3d 1304, 1309 (11th Cir. 1999). "Given that excessiveness is a highly subjective judgment, the courts should be hesitant to substitute their opinion for that of the people." *Id.* There is accordingly a "strong presumption" that a fine "within the range of fines prescribed by Congress" "is constitutional." *Id.* That is especially true in the tax context, where "the appropriate level or rate of taxation is essentially a matter for legislative, and not judicial, resolution." *Commonwealth Edison Co. v. Montana*, 453 U.S. 609, 627 (1981).

Plaintiffs fail to overcome the "strong presumption" of constitutionality here, as the *Bajakajian* factors make clear. First, unlike in *Bajakajian*, where the plaintiff who failed to report the cash in his possession did "not fit into the class of persons for whom the statute was principally designed" because he was not a "money launderer, a drug trafficker, or a tax evader," 524 U.S. at 338, any "manufacturer" "of any designated drug" against whom the excise tax is assessed is, by definition, an entity for which that statute was designed. 26 U.S.C. § 5000D(a). Second, while the "[f]ailure to report" currency "caused no loss to the public fisc" in *Bajakajian*, 524 U.S. at 339 (government "deprived only of [] information"), here the fisc will likely incur significant losses, and seniors will likely face substantially higher costs, if a manufacturer that chooses to continue

participating in Medicare declines to agree to a maximum fair price and sells that drug to Medicare at a higher price than the statutory ceiling. Third, unlike in *Bajakajian*, where there was "no inherent proportionality" in requiring forfeiture of the full amount of the undisclosed cash, *see id.*, the excise tax is proportional to the harm to the fisc: the more that a manufacturer of a designated drug that has refused to fully participate in the Negotiation Program sells its drug to Medicare—presumably at a price higher than that which the manufacturer could have agreed to as a "maximum fair price"—the greater the loss to the public and the higher the tax liability. *See* 26 U.S.C.§ 5000D(b); IRS Notice at 3. Indeed, because the tax attaches only to sales of the drug that are reimbursed by Medicare, the tax necessarily only recoups a portion of the outlays that the Medicare program or Medicare beneficiaries have paid out for the drug. And, where the tax is not separately invoiced, the ratio of the tax to the amount charged by the manufacturer—between 65 and 95%—is within the range of constitutionally permissible exactions. *See, e.g.*, *United States v. Martin*, 95 F.3d 406, 407 (6th Cir. 1996) (marketing penalty of 75%); *Alt*, 83 F.3d at 783 (civil fraud penalty of 81%).[22]

Accordingly, even if Plaintiffs had sued the proper defendant, and even if the AIA and DJA did not preclude jurisdiction, Plaintiffs' Eighth Amendment claim would fail on the merits because the excise tax is neither a fine nor a grossly disproportionate one.

2. The excise tax is authorized by Congress's enumerated powers (Count 4).

Plaintiffs also argue that the excise tax "is not authorized by any enumerated power of Congress." Pls.' Br. at 41. In fact, the Constitution explicitly authorizes Congress (1) to "lay and

[22] Selected drugs, by definition, have been on the market without competition for a minimum of seven years. 42 U.S.C. §1320f-1(e). Outside experts project that each of the manufacturers of the selected drugs have recouped their fixed-cost investments in those drugs during this time period, long in advance of the drug's selection for negotiation. *See* Richard G. Frank and Caitlin Rowley, *Medicare Negotiations Won't Keep Big Pharma from Making a Fortune*, Bloomberg Law (Sept. 5, 2023); *see also* Kiu Tay-Teo et al., *Comparison of Sales Income and Research and Development Costs for FDA-Approved Cancer Drugs Sold by Originator Drug Companies*, 2019 JAMA Network Open 186875 (2019). And, once a manufacturer has recouped its fixed costs, its marginal cost of producing small-molecule drugs is generally "just pennies per pill." CBO, *Prescription Drugs: Spending, Uses, and Prices* 20 (2022). Some manufacturers accordingly may find it to be in their business interest to continue to make Medicare-reimbursable sales of their selected drugs and to pay a portion of that Medicare reimbursement back in the form of the excise tax on those sales. *Contra* Pls. Br. at 40-41 (arguing that no manufacturer could be expected to pay excise tax).

collect Taxes, Duties, Imposts and Excises, to pay the Debts and provide for the common Defence and general Welfare of the United States," U.S. Const. art. I, § 8, cl. 1; (2) to "regulate Commerce . . . among States," U.S. Const. art. I, § 8, cl. 3; and (3) "[t]o make all Laws which shall be necessary and proper for carrying into Execution the foregoing Powers," U.S. Const. art. I, § 8, cl. 18. Those powers are more than enough to authorize the excise tax.

a. Under the Taxing and Spending Clause, Congress has the power to "lay and collect Taxes, Duties, Imposts and Excises" in order to "provide for the common Defence and general Welfare of the United States." U.S. Const. art. I, § 8, cl. 1. The taxing power is "comprehensive." *Steward Mach. Co. v. Davis*, 301 U.S. 548, 581-82 (1937).

The Supreme Court has long "abandoned the view that bright-line distinctions exist between regulatory and revenue-raising taxes." *Bob Jones Univ.*, 416 U.S. at 743 n.17. And "taxes that seek to influence conduct are nothing new." *NFIB*, 567 U.S. at 567. After all, "[e]very tax is in some measure regulatory" in that "it interposes an economic impediment to the activity taxed as compared with others not taxed." *Sonzinsky v. United States*, 300 U.S. 506, 513 (1937). For that reason, a tax "does not cease to be valid merely because it regulates, discourages, or even definitely deters the activities taxed." *Sanchez*, 340 U.S. at 44. Indeed, "[f]rom the beginning of our government, the courts have sustained taxes although imposed with the collateral intent of effecting ulterior ends which, considered apart, were beyond the constitutional power of the lawmakers to realize by legislation directly addressed to their accomplishment." *Id.* at 45 (citation omitted); *accord NFIB*, 567 U.S. at 574 (upholding a provision requiring individuals to purchase health insurance or to pay a tax under the taxing power, despite concluding it was beyond the scope of the commerce power). The Supreme Court has "upheld such obviously regulatory measures as taxes on selling marijuana and sawed-off shotguns." *NFIB*, 567 U.S. at 567.

The IRA's excise tax—even ignoring the label—"looks like a tax in many respects." *Id.* at 563. For starters, "[t]he requirement to pay is found in the Internal Revenue Code and enforced by the IRS," *id.*—in fact, the excise tax at 26 U.S.C. § 5000D is a statutory neighbor to 26 U.S.C. § 5000A, the provision that was upheld as a tax in *NFIB*. In addition, much like in *NFIB*, the only

legal consequence for failing to enter into an agreement with CMS is excise-tax liability: "Neither the Act nor any other law attaches negative legal consequences to" that conduct, "beyond requiring a payment to the IRS." *Id.* at 568. Manufacturers of selected drugs simply face "a lawful choice to do or not do a certain act, so long as" they are "willing to pay a tax levied on that choice." *Id.* at 574. That is how taxes work—not punishments. *See supra*, Part IV.D.1. (And that is to say nothing of the fact that manufacturers can also avoid tax liability entirely by withdrawing from Medicare and Medicaid. *See supra*, Part IV.B.2.)

In addition, the excise tax "contains no scienter requirement." *Id.* at 566. So again, much like in *NFIB*, "the fact the exaction here is paid like a tax, to the agency that collects taxes—rather than, for example, exacted by [HHS] inspectors after ferreting out willful malfeasance—suggests that this exaction may be viewed as a tax." *Id.* at 566 n.9. That is enough.

Falling back on legislative history, Plaintiffs protest that the Congressional Budget Office (CBO) made budget projections on the assumption that "drug manufacturers will comply with the negotiation process," and thus will not actually incur excise-tax liability. CBO, No. 58850, *How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act* at 10 (Feb. 2023), https://perma.cc/K789-T667. On Plaintiffs' telling, therefore, because the excise tax "will raise no revenue," it should not be considered a "real tax" authorized by the Constitution. Pls.' Br. at 3.

Constitutional law does not work that way—especially on a facial challenge. "[T]he CBO does not and cannot authoritatively interpret federal statutes." *Ohio v. United States*, 154 F. Supp. 3d 621, 642 (S.D. Ohio 2016), *aff'd*, 849 F.3d 313 (6th Cir. 2017); *see also Sharp v. United States*, 580 F.3d 1234, 1239 (Fed. Cir. 2009) ("the CBO is not Congress, and its reading of the statute is not tantamount to congressional intent"). The constitutionality of a federal statute is not determined by CBO's predictions about how industry might react to a brand-new program. And even accepting that "the essential feature of any tax" is that it "produces at least some revenue for the Government," this excise tax provision is capable of raising significant revenue, on its face. *NFIB*, 567 U.S. at 564. Whether it *actually* will do so is currently unknown, CBO's assumptions

notwithstanding. That uncertainty is among the reasons why, despite older precedents in which the Supreme Court "policed these limits aggressively" in reviewing challenges to taxes, "[m]ore often and more recently" it has "declined to closely examine the regulatory motive *or effect* of revenue-raising measures." *Id.* at 572-73 (emphasis added). And ultimately, a tax "does not cease to be valid merely because it regulates, discourages, *or even definitely deters* the activities taxed." *Sanchez*, 340 U.S. at 44 (emphasis added); *see also, e.g.*, *United States v. Kahriger*, 345 U.S. 22, 28 (1953) ("Nor is the tax invalid because the revenue obtained is negligible."), *overruled on other grounds by Marchetti v. United States*, 390 U.S. 39, 54 (1968); *Sonzinsky*, 300 U.S. at 513-14 (upholding tax that only produced a total of about $5,000 per year in revenue, in part because "[i]nquiry into the hidden motives which may move Congress to exercise a power constitutionally conferred upon it is beyond the competency of courts").

In this facial challenge, Plaintiffs "must establish that no set of circumstances exists under which the Act would be valid." *Salerno*, 481 U.S. at 745. So even if plaintiffs could show that the excise tax would be unconstitutional in a world where it never raised a single dollar of revenue, that speculation about the statute's operation in one "conceivable set of circumstances" would be "insufficient to render it wholly invalid" on its face. *Id.* That well-settled principle is fatal to Plaintiffs' reliance on legislative history speculating about how manufacturers might behave.[23]

In sum, because the excise tax is a tax—or, at a minimum, it "may reasonably be characterized as a tax," *NFIB*, 567 U.S. at 574—it is within Congress's taxing power.

b. Plaintiffs rightly recognize (at 43) that even if the "excise tax" were neither an "excise" nor a "tax" within the meaning of the Taxing and Spending Clause, that would not end the inquiry—it would simply require the Court to ask whether the excise tax is authorized by some

[23] Plaintiffs' descriptions of these legislative projections are also overstated. For example, the cited statistic from the Joint Committee on Taxation includes no analysis or explanation, and was prepared in connection with different legislation back in 2021 (as is clearer from the full citation, which is truncated in Plaintiffs' brief). *See* Pls.' Br. at 14-15 (citing Jt. Comm. on Tax'n, No. JCX-46-21, *Estimated Budget Effects of the Revenue Provisions of Title XIII - Committee on Ways and Means, Of H.R. 5376, The "Build Back Better Act," As Passed by The House of Representatives*, at 8 (Nov. 19, 2021)). These projections also do not account for the Treasury Department's reading of the enacted version of the statute, which clarifies both the calculation of the excise tax and the application of that tax only to Medicare sales, rather than to all U.S. sales of selected drugs.

other enumerated power. *See, e.g.*, *NFIB*, 567 U.S. at 561. And here, the excise tax—if it were to be conceived as a regulation or a penalty, rather than a tax—is plainly authorized by the Commerce Clause (even without resort to the additional power granted by the Necessary and Proper Clause).

"[I]t is now well established that Congress has broad authority under the [Commerce] Clause." *Id.* at 549. The Supreme Court has "recognized, for example, that '[t]he power of Congress over interstate commerce is not confined to the regulation of commerce among the states,' but extends to activities that 'have a substantial effect on interstate commerce.'" *Id.* (quoting *United States v. Darby*, 312 U.S. 100, 118-19 (1941)). "Congress's power, moreover, is not limited to regulation of an activity that by itself substantially affects interstate commerce, but also extends to activities that do so only when aggregated with similar activities of others." *Id.* So, the only Commerce Clause question potentially raised by this case is this: Does the sale of prescription drugs to Medicare beneficiaries substantially affect interstate commerce? The question answers itself—after all, the sale of prescription drugs *is* commerce.

Plaintiffs have only one argument in response: a tortured analogy to the minimum-essential-coverage provision that was declared beyond the commerce power (but within the taxing power) in *NFIB*. *See* Pls.' Br. at 44. In *NFIB*, the Supreme Court reasoned that that provision did "not regulate existing commercial activity"; it instead "compel[led] individuals to *become* active in commerce by purchasing a product, on the ground that their failure to do so affects interstate commerce." 567 U.S. at 552. In the view of five Justices, "[c]onstruing the Commerce Clause to permit Congress to regulate individuals precisely *because* they are doing nothing would open a new and potentially vast domain to congressional authority." *Id.*

Plaintiffs' analogy fails. According to Plaintiffs, "[a]s with the private citizens who objected to purchasing health insurance in *NFIB*, it is the manufacturers' failure to engage in commercial activity that triggers the penalty." Pls.' Br. at 44 (emphasis and quotation marks omitted). But Plaintiffs' key factual premise is mistaken—IRA excise-tax liability is tied to *sales* of selected drugs in the absence of agreement to a negotiated price with CMS, not the *failure* to make such sales. *See* 26 U.S.C. § 5000D(a) ("There is hereby imposed *on the sale* by the

manufacturer, producer, or importer of any designated drug during a day described in subsection (b) a tax in an amount . . . ." (emphasis added)). So, even ignoring all other distinctions between the failure of an individual to buy health insurance and the failure of a drug company to sell drugs to Medicare beneficiaries, IRA excise-tax liability is assessed only on actual *sales* of selected drugs. Those sales are quintessential commercial activity, in the heartland of Congress's commerce power.

CONCLUSION

For these reasons, this case should be dismissed in its entirety, either for lack of venue under Rule 12(b)(3) or lack of subject-matter jurisdiction under Rule 12(b)(1). In the alternative, at a minimum, Plaintiffs' pre-enforcement challenges to the excise tax (Counts 3 and 4) should be dismissed for lack of subject-matter jurisdiction under Rule 12(b)(1). If the Court reaches the merits, the Court should deny Plaintiffs' motion for summary judgment, grant Defendants' cross-motion for summary judgment, and enter judgment for Defendants on all remaining claims.

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Respectfully submitted,

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