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

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I. VENUE IS IMPROPER. 4

A. Defendants explicitly preserved their venue objection. 4

Defendants objected to venue in their first dispositive motion, on the same theory that they object to venue now—that is, that the naming of the Dayton Area Chamber of Commerce as a plaintiff cannot form the only basis for venue in this Court, because the Dayton Area Chamber lacks associational standing. To the extent Defendants have made any "new" argument at all, it would be a new argument about subject-matter jurisdiction, not venue. And arguments relating to a lack of subject-matter jurisdiction "can never be forfeited or waived." *Arbaugh v. Y&H Corp.*, 546 U.S. 500, 501 (2006) (citation omitted).

B. The Dayton Area Chamber of Commerce lacks associational standing because this lawsuit is not germane to the organization's purpose. 6

Plaintiffs now concede that the Dayton Area Chamber of Commerce's "purpose is to improve *its region's* business climate." Pls.' Combined Opp'n & Reply at 17, ECF No. 90 (emphasis added). This lawsuit is not "germane" to that geographically limited purpose, given the absence of any meaningful connection between the Dayton area and the small number of pharmaceutical giants that are participating in the Negotiation Program. Accordingly, the Dayton Area Chamber lacks associational standing.

C. Without the Dayton Area Chamber of Commerce, this lawsuit cannot proceed in this Court. 9

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 Court, 28 U.S.C. § 1391(e)(1), and this suit should be dismissed, Fed. R. Civ. P. 12(b)(3). *See, e.g.*, *Nat'l Infusion Ctr. Ass'n v. Becerra*, No. 1:23-cv-707, 2024 WL 561860 (W.D. Tex. Feb. 12, 2024).

II. ALL PLAINTIFFS LACK ASSOCIATIONAL STANDING BECAUSE THE RELIEF REQUESTED REQUIRES THE PARTICIPATION OF THEIR INDIVIDUAL MEMBERS. 11

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 & Surgeons v. FDA*, 13 F.4th 531, 537 (6th Cir. 2021) (quoting *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977)). Here, it does, because of the multiplicity of other pending lawsuits brought by drug manufacturers who also seem to be 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 undermined by finding associational standing in these circumstances. And Plaintiffs' latest remedial concession—that their members who brought their own separate lawsuits would not be entitled to relief here, even if Plaintiffs were to prevail—only underscores the bizarre arrangement that Plaintiffs ask this Court to endorse.

III. THE COURT LACKS SUBJECT-MATTER JURISDICTION OVER PLAINTIFFS' CLAIMS CHALLENGING THE IRA'S EXCISE TAX. 13

A. Because Plaintiffs failed to sue Treasury and the IRS, Plaintiffs' excise-tax claims are not redressable in this suit. 13

Plaintiffs' excise-tax claims are not redressable in this suit, which Plaintiffs filed against HHS and CMS but *not* Treasury and the IRS—the only agencies empowered to enforce § 5000D of the Internal Revenue Code. Plaintiffs assert that Defendants HHS and CMS have a supporting role to play in connection with the excise tax, but they offer no basis to conclude that enjoining HHS and CMS would redress any alleged tax-related harm.

B. The AIA and DJA preclude review of Plaintiffs' excise-tax challenges......... 18

Plaintiffs do not dispute that, on its face, the Anti-Injunction Act (AIA), 26 U.S.C. § 7421(a), applies here, requiring Plaintiffs' members to pay the tax and then press their constitutional claims in a refund suit—which they can do by paying the tax on a single sale of a single drug. Accordingly, and because this case does not fit within either of the two narrow exceptions to the AIA, this Court lacks jurisdiction over Plaintiffs' tax claims.

IV. ALL OF PLAINTIFFS' CLAIMS LACK MERIT. 24

A. Plaintiffs' separation-of-powers claim (Count 1) is foreclosed by precedent. 24

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, and Plaintiffs' arguments therefore fail under established precedent.

B. Plaintiffs' due process claim (Count 2) fails because the IRA does not impinge on manufacturers' property interests. 28

This Court has already rejected Plaintiffs' due process claim "as a matter of law," *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 because, among other reasons, "[p]articipation in the Medicare program is wholly voluntary," *Baptist Hosp. E. v. Sec'y of Health & Hum. Servs.*, 802 F.2d 860, 869 (6th Cir. 1986), which means that Plaintiffs are not suffering any deprivation that triggers Fifth Amendment scrutiny. Even aside from that, Plaintiffs also cannot make a showing that the statute they challenge imperils any protected property interest, given the clear Sixth Circuit precedent establishing that "those who opt to participate in Medicare are not assured of revenues." *Livingston Care Ctr., Inc. v. United States*, 934 F.2d 719, 721 (6th Cir. 1991).

1. There is no deprivation because the Negotiation Program is voluntary. 28

a. The Negotiation Program is not "coercive." 29

b. Plaintiffs' other objections lack merit. 36

2. Plaintiffs also have no protected property interest at stake. 41

C. Plaintiffs' First Amendment claim (Count 5) is meritless because the Negotiation Program does not compel manufacturers to speak. 45

Plaintiffs' First Amendment claim remains premised on the novel idea that by using statutory terms of art like "negotiation," "agreement," and "maximum fair price," Congress has compelled Plaintiffs to endorse the government's message. Even ignoring the explicit text in the agreement that forecloses Plaintiffs' misinterpretation, Plaintiffs' response brief makes clear that their understanding of the First Amendment—as prohibiting the use of words like "negotiate" or "agreement" in voluntary agreements with the government—would revolutionize the law of federal procurement. In fact, the agreements at issue are merely elements of "ordinary price regulation [which] 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)). Plaintiffs also remain free "to opt out" of the Program altogether. *Chamber I*, 2023 WL 6378423, at *11.

D. Even if the Court were to reach the merits of Plaintiffs' excise-tax claims, the tax is constitutional. 49

1. The excise tax does not violate the Eighth Amendment (Count 3). 50

The excise tax does not violate the Excessive Fines Clause because it is neither a "fine" nor an "excessive" one. U.S. Const. amend. VIII. Plaintiffs have not cited a case in which a tax was deemed to be "punishment for some offense"—that is, a "fine"—under the Excessive Fines Clause. Similarly, Plaintiffs do not identify any tax—like the one here, which lacks any connection to criminal conduct or criminal proceedings—that was held to be "punishment for some offense" under any provision of the Constitution. Even if the excise tax were nonetheless deemed a "fine," it would not be a "grossly disproportional" one. *United States v. Bajakajian*, 524 U.S. 321, 336 (1998).

2. The excise tax is authorized by Congress's enumerated powers (Count 4). 55

Under the Taxing and Spending Clause, 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. Plaintiffs insist that "[t]he distinction between doing something and doing nothing would not have been lost on the Framers," Pls.' Opp'n at 66 (quoting *NFIB*, 567 U.S. at 555)—but the excise tax applies only to manufacturers that are "doing something," by selling selected drugs to Medicare beneficiaries in interstate commerce.

CONCLUSION 59

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INTRODUCTION

Both Defendants' dispositive motion and this Court's prior opinion were based on the "clear" precedent "established in the Sixth Circuit and beyond," holding that "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*). Congress thus has broad latitude to set conditions on Medicare participation. That principle is just as fatal to Plaintiffs' core constitutional theories now as it was last September.

But the Court need not reach the merits at all. Plaintiffs now concede that the Dayton Area Chamber of Commerce's "purpose is to improve *its region's* business climate." Pls.' Combined Opp'n & Reply at 17, ECF No. 90 ("Pls.' Opp'n") (emphasis added). This lawsuit is not "germane" to that geographically limited purpose, given the absence of any meaningful connection between the Dayton area and the small number of pharmaceutical giants that are participating in the Negotiation Program. *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)). That (non-waivable) jurisdictional defect means that the Dayton Area Chamber lacks associational standing and thus cannot be the basis for venue in this Court. This Court need go no further than that to dismiss this case.

Other threshold problems abound. As for associational standing, Plaintiffs' amended complaint seeks association-wide relief, even while some—or maybe all—of Plaintiffs' unidentified members affected by the Negotiation Program have already sued in other federal districts. Given the possibility that this duplicative litigation could end in a morass of competing judgments, Plaintiffs' atypical association suit is one in which "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). The Court can dismiss on that ground without prejudice to individual members litigating their own claims separately—as many of them already are.

Even if the rest of the case could proceed, Plaintiffs' claims challenging the constitutionality of the § 5000D tax (Counts 3 and 4) are jurisdictionally barred for two independent reasons. First, the excise-tax claims are not redressable in this suit, which Plaintiffs filed against HHS and CMS but *not* Treasury and the IRS—the only agencies empowered to enforce § 5000D of the Internal Revenue Code. Plaintiffs assert that HHS and CMS have a supporting role to play in connection with the excise tax, but they offer no basis to conclude that enjoining HHS and CMS would provide Plaintiffs redress of any alleged tax-related harm. Second, Plaintiffs' preemptive challenge to the excise tax is barred by the Anti-Injunction Act (AIA), 26 U.S.C. § 7421(a). Plaintiffs do not dispute that, on its face, the AIA applies here, requiring Plaintiffs' members to pay the tax and then press their constitutional claims in a refund suit—which they can do by paying the tax on a single sale of a single drug. Plaintiffs nonetheless ask the Court to excuse them from having to comply with that requirement. Because this case does not fit within either of the two narrow exceptions to the AIA, the Court should reject that invitation.

If the Court were to reach the merits, Plaintiffs would fare no better. They start with their nondelegation claim—a claim of the sort that has not prevailed at the Supreme Court since 1935. These Plaintiffs are hardly the first to *assert* that a statute "offers no 'meaningful definitions' and has 'standardless' principles." *Consumers' Rsch. v. FCC*, 67 F.4th 773, 790 (6th Cir. 2023). But Plaintiffs' imagined version of the IRA bears only a passing resemblance to the real one—as confirmed by a series of statutory constraints that are ignored in Plaintiffs' brief. Regardless, given the far broader delegations that have been upheld by the Supreme Court and the Sixth Circuit, there is no principled basis to treat this statute as a once-in-a-century aberration.

As for Plaintiffs' due process theory, this Court has already rejected it "as a matter of law." *Chamber I*, 2023 WL 6378423, at *11. That is because, among other reasons, "[p]articipation in the Medicare program is wholly voluntary," *Baptist Hosp. E. v. Sec'y of Health & Hum. Servs.,* 802 F.2d 860, 869 (6th Cir. 1986), which means that Plaintiffs are not suffering any deprivation that triggers Fifth Amendment scrutiny. Plaintiffs likewise cannot make the threshold showing of any protected property interest, given the clear Sixth Circuit precedent establishing that "those

who opt to participate in Medicare are not assured of revenues." *Livingston Care Ctr., Inc. v. United States*, 934 F.2d 719, 721 (6th Cir. 1991). Ultimately, the Negotiation Program "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." *Chamber I*, 2023 WL 6378423, at *11. This Court got it exactly right in its prior opinion.

Plaintiffs' First Amendment claim remains premised on the novel idea that by using statutory terms of art like "negotiation," "agreement," and "maximum fair price," Congress has compelled Plaintiffs to endorse the government's message. Even ignoring the explicit text in the agreement that forecloses Plaintiffs' misinterpretation, Plaintiffs' response brief makes clear that their understanding of the First Amendment—as prohibiting the use of innocuous words like "negotiate" or "agreement" in voluntary agreements with the government—would revolutionize the law of federal procurement. There is no basis in the First Amendment for that bizarre result—especially where, as here, Plaintiffs remain free "to opt out" of the Program altogether. *Id.*

If the Court reaches the merits of Plaintiffs' tax claims, those claims fail too. Their Eighth Amendment claim fails because the excise tax is neither a "fine" nor an "excessive" one. Plaintiffs still do not identify a single case in which a tax was held to be a "fine" under the Excessive Fines Clause. Even if the IRA's excise tax were the first to fit that bill, it would not be an unconstitutionally excessive fine given that it is proportional to the harm to the fisc—a point to which Plaintiffs do not respond. And as for Congress's enumerated powers, the IRA's excise tax is an "excise" or a "tax" within the meaning of the Taxing and Spending Clause. But even if it were instead conceived of as a regulation or a penalty, it would still fall within the heartland of Congress's Commerce Clause authority. After all, the sale of prescription drugs to Medicare beneficiaries—whether those sales occur at prices set by manufacturers alone or at negotiated prices—is classic commercial activity, not inactivity beyond Congress's reach.

Ultimately, nothing in the Constitution compels Medicare to continue paying more for the same prescription drugs than any comparable buyer, foreign or domestic. Either at the threshold or on the merits, all of Plaintiffs' claims should be rejected.

ARGUMENT

I. VENUE IS IMPROPER.

It is undisputed that the only possible basis for venue in this Court is that one of the four Plaintiffs—the Dayton Area Chamber of Commerce—"resides" here within the meaning of 28 U.S.C. § 1391(e)(1)(C). But because the Dayton Area Chamber lacks standing, it should be dismissed for lack of subject-matter jurisdiction under Rule 12(b)(1), and this entire lawsuit should be dismissed for lack of venue under Rule 12(b)(3).

A. Defendants explicitly preserved their venue objection.

Before addressing the substance of the venue issue, Defendants must explain why that argument has been preserved, as Plaintiffs assert that the government inadvertently waived it by "electing not to raise it in its prior motion to dismiss." Pls.' Opp'n at 8. That argument is meritless.

The core premise of Plaintiffs' waiver theory is incorrect: Defendants *did* object to venue in their prior motion to dismiss—and on the same theory, about the residence of the Dayton Area Chamber of Commerce being insufficient to establish venue, due to its inability to show standing. After arguing that the Dayton Area Chamber (and all other Plaintiffs) lacked standing (including associational standing), Defendants explained that, "if the Dayton Area Chamber were dismissed for lack of jurisdiction, venue would not be proper in this District, and dismissal of this lawsuit would then also be required on that basis, under Federal Rule of Civil Procedure 12(b)(3)." Defs.' Mot. to Dismiss at 15, ECF No. 33. Then, "to the extent necessary, Defendants also move[d] to dismiss for lack of venue under Rule 12(b)(3)." *Id*. So all of Plaintiffs' theories about how Rule 12(g)(2) might apply here—even after they amended their complaint—are beside the point. Rule 12(g)(2), on its face, applies only to a defendant's second Rule 12 motion that includes a "defense or objection" that was "omitted from its earlier motion." And here, Defendants' venue defense was not "omitted" from the earlier motion at all. That should end the matter.

To be sure, after Plaintiffs amended their complaint, some of Defendants' threshold arguments took on more (or less) importance—a routine consequence of an amended pleading. As a result, Defendants have now included an expanded jurisdictional argument about why, even if

some Plaintiffs could show standing, the Dayton Area Chamber still cannot—*i.e.*, because of the germaneness requirement for associational standing. But assuming that were a "new" argument at all—even though Defendants have always argued that the Dayton Area Chamber lacked associational standing—it would be a new argument *about subject-matter jurisdiction*, not venue. *See, e.g.*, *United Food & Com. Workers Union Loc. 751 v. Brown Grp., Inc.*, 517 U.S. 544, 555-56 (1996) (discussing germaneness requirement as a matter of Article III's requirements for subject-matter jurisdiction). So Plaintiffs' waiver argument boils down to the notion that Defendants had to list all reasons why the Dayton Area Chamber lacked standing in all of their motions, on penalty of waiver. But that is not how subject-matter jurisdiction works—an argument relating to a lack of subject-matter jurisdiction "can never be forfeited or waived." *Arbaugh v. Y&H Corp.*, 546 U.S. 500, 501 (2006) (citation omitted).

Were there any doubt as to Defendants' preservation of this issue, it is dispelled by Plaintiffs' own filings. In the Rule 26(f) report, Defendants stated explicitly that they "intend[ed] to challenge both venue and subject-matter jurisdiction." ECF No. 58 at 2. Defendants thus proposed that the parties first brief a second motion to dismiss and only brief summary judgment later, if necessary—among other reasons, to avoid waiver concerns about Defendants' venue objection. *See id.* at 8 (citing Fed. R. Civ. P. 12(h)(1)). Plaintiffs responded by arguing that "[i]f Defendants wish to make non-merits arguments, like those addressing jurisdiction or venue, nothing would prevent them from incorporating those arguments into a cross-motion for summary judgment." *Id.* at 3. Plaintiffs also emphasized that "[w]aiver must be knowing, intelligent, and voluntary." *Id.* at 6 (citation omitted). The Court's order sided with Plaintiffs on the order-of-operations question, but in doing so also made an explicit finding about waiver: "Although Defendants intend to raise threshold arguments on both subject-matter jurisdiction and venue, the Court finds that these arguments have not been waived. Defendants may raise these arguments in their motion for summary judgment." Prelim. Pretrial Conference Order at 1, ECF No. 59 (citation omitted); *see also* Rule 26(f) Report at 6 (Plaintiffs: "But obviously, if the Court grants Plaintiffs' request to proceed to cross-motions for summary judgment and Defendants do so, they will not

have waived their venue objections."). Plaintiffs' belated efforts to unravel that finding should be rejected.

Accordingly, before reaching the merits, the Court must consider whether the Dayton Area Chamber of Commerce has carried its burden to show standing—and thus, whether all Plaintiffs have carried their burden to establish venue.

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

On the germaneness question, Plaintiffs concede that the Dayton Area Chamber's "purpose is to improve *its region's* business climate." Pls.' Opp'n at 17 (emphasis added). In other words, even according to Plaintiffs, this is a regional organization, designed to advance regional interests. *See also* Defs.' Mot. for Summ. J. at 13, ECF No. 71 ("Defs.' Br.") (citing First Am. Compl. ¶ 28, ECF No. 57 ("FAC")). That concession is fatal to the associational standing of the Dayton Area Chamber, because this lawsuit is not about improving the business climate in the Dayton region.

Despite its concededly regional focus, the Dayton Area Chamber seeks relief that would benefit (at most) a single-digit number of major pharmaceutical manufacturers, located in places like Europe and Northern California, none of which have any apparent presence in or around Dayton. So, recognizing that some sort of Dayton connection to this lawsuit is needed, Plaintiffs now fall back on vague references to "other effects on the industry as a whole," Pls.' Opp'n at 15—but they never explain how (if at all) those unspecified "other effects" will be felt in Dayton. Plaintiffs likewise gesture at "effects on other enterprises in the supply chain, such as suppliers of raw materials, distributors, equipment makers, and builders of laboratories; on participants in the broader healthcare system, all the way from healthcare providers to insurers to employers." *Id.* Plaintiffs call those effects "inevitable" but don't explain why, or even specify what indirect "effects" they have in mind. And Plaintiffs include no citation to the amended complaint (or the summary-judgment record) that would support their speculation about tenuous and unidentified downstream consequences for other unnamed businesses—businesses that aren't even subject to the Negotiation Program, some small and unidentified percentage of which *might* be located in

Dayton. All of this vague speculation about extra-record facts confirms that "[t]he connection between [this] suit" and "an organization committed to" improving the Dayton business community is "too attenuated" to satisfy the germaneness requirement. *Child. Health Def. v. FDA*, No. 21-6203, 2022 WL 2704554, at *3 (6th Cir. July 12, 2022), *cert. denied*, 143 S. Ct. 784 (2023).

Even if this sort of speculation were permissible, Plaintiffs still do not attempt to identify any interest in this litigation that has anything to do with the Dayton area specifically. Instead, they consistently describe the litigation in global terms, as "a challenge to government overreach that threatens to hamper economic prosperity and create an unfavorable environment for business, *including* in the Dayton area." Pls.' Opp'n at 16 (emphasis added). In other words, on Plaintiffs' view, because the effects of the Negotiation Program will be felt "around the globe," that is sufficient—because Dayton is on "the globe." *Id.* at 17 (quoting Defs.' Br. at 13). But Plaintiffs cite no authority for that global interpretation of the germaneness requirement, which is impossible to square with Plaintiffs' descriptions of the Dayton Area Chamber—not to mention its name—as a regional entity focused on regional interests. It is also impossible to square Plaintiffs' position with the Supreme Court's statements that the germaneness requirement is a jurisdictional principle "rooted in Article III," *Ass'n of Am. Physicians & Surgeons*, 13 F.4th at 542 (citing *Brown*, 517 U.S. at 555-56), in that it "ensures a modicum of concrete adverseness by reconciling membership concerns and litigation topics by preventing associations from being merely law firms with standing," *Humane Soc. of the U.S. v. Hodel*, 840 F.2d 45, 58 (D.C. Cir. 1988). Those separation-of-powers concerns are squarely implicated by this lawsuit.

Plaintiffs also rely on an op-ed co-authored by the president of the Dayton Area Chamber during this litigation, *about* this litigation, to demonstrate that the Dayton Area Chamber is interested in this matter. *See* Pls.' Opp'n at 14 (quoting op-ed asserting that this lawsuit was filed because the IRA "jeopardizes free enterprise across business as a whole"). But it is well established that an organization'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). Plaintiffs' contrary argument is circular: if the fact that an

organization was sufficiently interested to file a lawsuit were enough to show germaneness, there would be no germaneness requirement at all—just a meaningless truism, automatically satisfied in all cases. Other than the filing of this lawsuit (and public-relations work associated with this lawsuit), there is nothing in the record to suggest *any* interest by the Dayton Area Chamber in how much the government or Medicare beneficiaries pay for high-cost prescription drugs. *Cf. Ne. Ohio Coal. for Homeless & Serv. Emps. Int'l Union, Loc. 1199 v. Blackwell*, 467 F.3d 999, 1010 (6th Cir. 2006) ("The scanty information about the plaintiff organizations in the complaint also raises substantial questions about whether the interests at stake here are germane to the organizations' purposes, which clearly are not primarily related to election or voters' rights issues.").

Plaintiffs also assert that winning this lawsuit "will advance its members' interests." Pls.' Opp'n at 14. But that argument conflates the first requirement for associational standing (identifying a member with standing) with the second (germaneness). In any event, tellingly, there is apparently only *one* member of the Dayton Area Chamber that has a concrete stake in the outcome: Pharmacyclics. And as this Court is aware from earlier stages of this litigation, Pharmacyclics—which is based in California (and is owned by AbbVie, based in Illinois)—joined the Dayton Area Chamber only *after* the lawsuit was filed, and only *after* Defendants pointed out that the Dayton Area Chamber had failed to identify a member with standing. *See Chamber I*, 2023 WL 6378423, at *7; Defs.' First MTD Reply at 1-2, 12-13, ECF No. 52. So, of the only two members that Plaintiffs have actually identified, neither has any meaningful connection to Dayton—another point that Plaintiffs do not dispute. *See* Defs.' Br. at 13-14. It thus hurts, not helps, Plaintiffs' germaneness argument to consider the interests of their members, which only further confirm the tenuous connection between this lawsuit and Dayton.[1]

[1] On similar grounds, Plaintiffs dismiss (portions of) the D.C. Circuit's germaneness analysis in *Hodel* as dicta. *See* Pls.' Opp'n at 16 (citing *Hodel*, 840 F.2d at 58 n.21) (explaining that the germaneness requirement "guarantees that the grievances expressed in a suit apply to a critical mass of association members"). But little turns on whether the "critical mass" language in *Hodel* was holding or dicta, given that this Court is not bound by either from the D.C. Circuit. To use the Supreme Court's phrasing, the Dayton Area Chamber is not the government's "natural adversary" on the subject of the constitutionality of the Negotiation Program, *Brown*, 517 U.S. at 556—particularly in light of the (now undisputed) fact that there is not a single primary manufacturer of a selected drug located in or around Dayton.

Finally, Plaintiffs describe the government's venue argument as "offensive," and interpret it as a "suggestion that the Dayton Area Chamber should not concern itself with major federal legislation that upends a critical industry." Pls.' Opp'n at 17. But the government's venue argument is based on *Plaintiffs'* descriptions of the purpose of the Dayton Area Chamber, including in the amended complaint and their summary-judgment briefing, all of which are consistent with statements on the organization's website. *See* Defs.' Br. at 13 (citing FAC ¶ 28; *About Us*, DaytonChamber.org, https://perma.cc/TX7M-8AX3). If the venue-creating plaintiff in this case were a different sort of entity that resides in Dayton—for example, a trade association dedicated to advancing the interests of the pharmaceutical industry—the germaneness analysis would be very different. But because the Dayton Area Chamber is—in its own words—an organization whose "purpose is to improve *its region's* business climate," Pls.' Opp'n at 17 (emphasis added), it has failed to carry its burden to satisfy the germaneness requirement for associational standing, to bring this lawsuit that is unrelated to the Dayton business community.

C. Without the Dayton Area Chamber of Commerce, this lawsuit cannot proceed in this Court.

For the reasons already explained in Defendants' motion, "once the Dayton Area Chamber is dismissed for lack of standing, the rest follows as a matter of course," and venue is improper. Defs.' Br. at 15. To the extent that Plaintiffs respond at all to this point, it is only to say—in one sentence, with no explanation—that even "if the Dayton Area Chamber alone were dismissed for lack of standing, this suit could still proceed here because other Plaintiffs have standing." Pls.' Opp'n at 12. That is incorrect, for all the reasons (and all the authority) in Defendants' prior brief—none of which Plaintiffs address. *See* Defs.' Br. at 15-16 (citing four cases and the leading treatise on the Federal Rules of Civil Procedure). When a court lacks jurisdiction over the only venue-creating plaintiff, venue is improper. Were it otherwise, anyone could sue in any district, by finding a single concerned citizen with policy objections to sign on as a local co-plaintiff.[2]

[2] Plaintiffs' citation (at 12) to *Biden v. Nebraska*, 143 S. Ct. 2355, 2365 (2023), misses the mark—that case is about standing, not venue. To maintain this suit *in this Court*, Plaintiffs must establish both standing *and* venue.

Another court reached that same conclusion earlier this week, in the only other challenge to the Negotiation Program brought by association plaintiffs (rather than by individual drug manufacturers). In that case, the government argued, like here, that the only plaintiff that supported venue was beyond the subject-matter jurisdiction of the court. The U.S. District Court for the Western District of Texas agreed—so, upon dismissal of the venue-creating plaintiff for lack of jurisdiction, the court dismissed the entire case for lack of venue. *See Nat'l Infusion Ctr. Ass'n v. Becerra*, No. 1:23-cv-707, — F. Supp. 3d. —, 2024 WL 561860 (W.D. Tex. Feb. 12, 2024) ("[T]he Court dismisses Plaintiff NICA for lack of subject matter jurisdiction under Fed. Rule of Civ. P. 12(b)(1) and dismisses the case for lack of venue under Fed. Rule of Civ. P. 12(b)(3)."). That same result is warranted in this case.

Finally, Plaintiffs retreat to the argument that, if the Court were to hold "that the Dayton Area Chamber cannot support venue, the proper remedy would be transfer to the Eastern Division of this District, not dismissal." Pls.' Opp'n at 17. But that argument is predicated on the legal residence of the Ohio Chamber of Commerce—which remains unknown to Defendants and the Court, even at this advanced stage of the litigation. Despite Defendants calling the matter to their attention, Defs.' Br. at 15 n.4, Plaintiffs do not dispute that the address for the Ohio Chamber in the amended complaint is inaccurate, as it mistakenly lists a Dayton address. And although Plaintiffs seem to *imply* that the Ohio Chamber resides in the Eastern Division of this District, *see* Pls.' Opp'n at 18, they do not say so, and Defendants have no meaningful ability to respond to that backup theory without any information about the Ohio Chamber's "principal place of business," 28 U.S.C. § 1391(c)(2). That is reason enough for this Court to exercise its discretion to dismiss under Rule 12(b)(3), rather than to transfer under 28 U.S.C. § 1406(a). But, in all events, dismissal or transfer are the only available options that are consistent with the federal venue statutes.

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 for associational standing, which independently justifies dismissal. Under that requirement, the 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. In particular, the pendency of multiple suits by individual drug manufacturers, including Plaintiffs' members, *see* Defs.' Br. at 9 n.3, 17-20, makes an association suit unworkable.

Defendants have little quarrel with Plaintiffs' central argument in opposition: that "the general rule is that individual participation of members 'is not normally necessary when an association seeks prospective or injunctive relief for its members' but may be required when the association is seeking damages." *Chamber I*, 2023 WL 6378423, at *8 (quoting *Brown*, 517 U.S. at 546). But that "general rule" is a very poor fit for this very atypical association suit—which stands to benefit a handful of drug manufacturers, virtually all of which have already filed their own separate lawsuits, and which collectively make up only a minuscule percentage of Plaintiffs' overall membership. Plaintiffs have cited no authority indicating otherwise.

As Defendants anticipated, *see* Defs.' Br. at 20, Plaintiffs again seek to mitigate this unusual problem with an unusual concession: that "any members who have filed separate suits will be bound by judgments in those suits," Pls.' Opp'n at 8, and thus are not entitled to relief here, even if Plaintiffs were to prevail. To be clear, Defendants *agree* that manufacturers should not be permitted to litigate the same claims in two different courts simultaneously (*i.e.*, both in their own lawsuit and through an association by proxy). It is not at all clear, however, what Plaintiffs' member manufacturers think about that. Regardless, the fact that Plaintiffs have been forced to carve out a significant (yet still unspecified) portion of their own membership from the requested relief that appears in their amended complaint, *see* FAC ¶¶ 265-67—by means of a strategic concession in an opposition brief—lays bare the curious arrangement that Plaintiffs ask this Court to endorse. Given the Supreme Court's understanding of "the third prong of the associational

standing test" as being designed to promote "administrative convenience and efficiency," *Brown*, 517 U.S. at 557—goals that would be severely undermined by allowing this suit to proceed—the appropriate course is dismissal. That would still leave individual manufacturers free to litigate their own claims, but without risking a morass of conflicting judgments, or collateral litigation over the preclusive effect of different orders issued by different courts on the same claims.

In response, Plaintiffs protest that "forcing Plaintiffs' members to file even more standalone suits would not enhance convenience or efficiency for anyone." Pls.' Opp'n at 7. But it is not even clear that the government would see additional suits—other than Pharmacyclics, virtually every other affected manufacturer has *already* sued, which is why this case is such a bizarre candidate for the associational-standing doctrine in the first place.[3] And a few additional lawsuits would in any event be far less problematic than the risk of conflicting remedies.

Finally, Plaintiffs claim that "[t]he government . . . does not dispute that the other suits largely entail different sets of claims, so even if all the cases proceed to judgment, the judgments would not necessarily rest on the same grounds." Pls.' Opp'n at 8. That is incorrect. Except for Plaintiffs' enumerated-powers claim challenging the IRA's excise tax, *all* of Plaintiffs' claims also appear in other lawsuits filed by individual manufacturers.[4] Regardless, conflicting judgments are inherently problematic, whatever the supporting reasons may be. *Cf. Carver v. Knox Cty.*, 887 F.2d 1287, 1291, 1293 (6th Cir. 1989) (noting the "intolerable situation" of a State being subjected to "competing and conflicting orders").

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[3] Despite Defendants having repeatedly raised this issue (both before and after Plaintiffs amended their complaint), *see* ECF Nos. 33, 52, 71, Plaintiffs have still not identified which of the primary manufacturers of selected drugs (other than Pharmacyclics) are members of one or more of the plaintiff associations. That uncertainty is another problem with Plaintiffs' approach; on Plaintiffs' view, this Court would need to limit any relief to an *unidentified* subset of Plaintiffs' *unidentified* members.

[4] Of the eight other lawsuits challenging the Negotiation Program, *see* Defs.' Br. at 9 n.3, six of them include a First Amendment claim (*Merck*, *Bristol Myers Squibb*, *Janssen*, *Boehringer Ingelheim*, *Novartis*, and *Novo Nordisk*); three of them include an Eighth Amendment claim (*Boehringer Ingelheim*, *Novartis*, and *NICA*); two of them include a nondelegation claim (*Novo Nordisk* and *NICA*); and all eight of them include a Fifth Amendment claim (some proceeding under the Takings Clause, some under the Due Process Clause, and some under both). *NICA* was dismissed without prejudice, on venue grounds, earlier this week. *See* 2024 WL 561860.

In sum, based on Plaintiffs' remedial concession, Pls.' Opp'n at 8, at a minimum, any relief would have to be limited to Plaintiffs' members that (1) are primary manufacturers of selected drugs, and (2) have not brought separate litigation challenging the Negotiation Program. But rather than carving up Plaintiffs' own request for relief in that unusual fashion, the simpler and more appropriate course is to dismiss this lawsuit for lack of associational standing, leaving Plaintiffs' individual members free to litigate their own claims in the normal course.

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

Plaintiffs continue to fail to overcome two, independent jurisdictional bars that prevent the Court from reaching the merits of their excise-tax claims: redressability and the Anti-Injunction Act. As to the former, Plaintiffs do not explain how the Court can redress their alleged tax-related injuries by enjoining *only* HHS and CMS—but not Treasury and the IRS—from enforcing § 5000D of the Internal Revenue Code. Plaintiffs' redressability problem is particularly pronounced here where enjoining HHS and CMS would likely exacerbate—not alleviate—a manufacturer's tax liability. As to the latter, Plaintiffs do not dispute that the AIA, on its face, precludes their tax claims. And Plaintiffs' attempt to contort and broaden the two narrow exceptions to that bar on preemptive challenges to tax provisions should be rejected.

A. Because Plaintiffs failed to sue Treasury and the IRS, Plaintiffs' excise-tax claims are not redressable in this suit.

Plaintiffs do not dispute that (setting aside the AIA) it would have been proper to have sued Treasury and the IRS in connection with their challenge to the enforcement of § 5000D. Similarly, Plaintiffs do not dispute that Treasury and the IRS are the *only* agencies empowered to assess and collect the excise tax. Plaintiffs nonetheless say that their failure to bring a tax challenge against the agencies that administer the tax code is of no moment because HHS and CMS also play some role in connection with the tax. But that assertion answers a different question from the one that matters, which is whether enjoining HHS and CMS—but *not* Treasury and the IRS—would redress Plaintiffs' tax-related injuries. Because it would not do so, Plaintiffs lack standing to press Counts 3 and 4. *See Haaland v. Brackeen*, 599 U.S. 255, 292 (2023).

1. Section 5000D of the Internal Revenue Code establishes that the excise tax accrues for manufacturers, producers, and importers of designated drugs that choose not to sign a negotiation agreement or to agree to a maximum fair price—without any action by HHS or CMS. 26 U.S.C. § 5000D. The excise tax is "imposed on the sale by the manufacturer, producer, or importer of any designated drug during a day described in subsection (b)." *Id.* § 5000D(a). Subsection (b) then defines the periods during which the tax is imposed. *Id.* § 5000D(b).

Treasury and the IRS are responsible for enforcing § 5000D and issuing implementing regulations regarding the excise tax. The Secretary of the Treasury and, by delegation, the IRS Commissioner, are "authorized and required to make . . . assessments of all taxes" imposed by Title 26, including § 5000D, 26 U.S.C. § 6201(a), and "shall collect the taxes imposed by the internal revenue laws," *id.* § 6301. *See also id.* § 7803(a)(2) ("The Commissioner shall have such duties and powers as the Secretary may prescribe, including the power to . . . administer . . . the execution and application of the internal revenue laws[.]"). Treasury is also responsible for issuing tax-related regulations and guidance. *See id.* § 5000D(h) ("The Secretary shall prescribe such regulations and other guidance as may be necessary to carry out this section."); *id.* § 7805(a) ("[T]he Secretary shall prescribe all needful rules and regulations for the enforcement of this title."); *see also id.* § 7701(a)(11)(B) ("The term 'Secretary' means the Secretary of the Treasury or his delegate."). Pursuant to this authority, the Treasury Department has issued a notice explaining how it interprets the excise-tax provision. *See* IRS Notice No. 2023-52, 2023-35 I.R.B. 650 (Aug. 4, 2023), https://perma.cc/B9JZ-ZG7P (addressing interpretation of 26 U.S.C. § 5000D) ("IRS Notice"). Treasury has also proposed regulations regarding a taxpayer's obligations to self-report its excise-tax liability. *Excise Tax on Designated Drugs; Procedural Requirements*, 88 Fed. Reg. 67,690, 67,690 (Oct. 3, 2023) (proposing "how taxpayers will report liability for the excise tax imposed on manufacturers, producers, or importers of certain designated drugs").

To be sure, as Plaintiffs observe, HHS may indeed play a role in assisting Treasury. But that role is not what Plaintiffs take it to be. For example, for initial price applicability year 2026, the tax is imposed beginning on October 2, 2023, and "*ending* on the earlier of" "the first date on

which the manufacturer of such designated drug has in place [a negotiation agreement]" or "the date that the Secretary of Health and Human Services" determines the standards for deselection found in 42 U.S.C. § 1320f-1(c) have been satisfied. 26 U.S.C. § 5000D(b)(1) (emphasis added); *see also* 42 U.S.C. § 1320f-1(c) (describing standards for deselection from eligibility for negotiation). The tax is also imposed, for initial price applicability year 2026, beginning on August 2, 2024, and "*ending* on the earlier of" "the first date on which the manufacturer of such designated drug and the Secretary of Health and Human Services have agreed to a maximum fair price" or "the date that the Secretary of Health and Human Services" determines the standards for deselection have been satisfied. 26 U.S.C. § 5000D(b)(2) (emphasis added). For each of these periods, *see id.* § 5000D(b)(1), (2), the HHS Secretary may play a role, but that role is to make determinations that would stop—not start—accrual of the excise tax.[5]

As § 5000D(b) itself makes plain, these "determination[s]" by the HHS Secretary are not "indispensable" to the administration of the excise tax and HHS is not "responsible for the statutory and regulatory machinery that *leads to* [the tax's] imposition." Pls.' Opp'n at 19-20 (emphasis added). Instead, because the HHS Secretary's "determination[s]" referenced in § 5000D mark the end of a period in which the tax is imposed, enjoining HHS and CMS—and *only* HHS and CMS—would, if anything, risk further tax liability for Plaintiffs and their members.

Plaintiffs also point to the fact that HHS is empowered to "carry out" various "administrative duties," including the sharing of "such information as is necessary to determine the tax imposed by [§] 5000D." 42 U.S.C. §§ 1320f(a)(4), 1320f-5(a)(6). However, "[f]or

[5] The excise tax may also be imposed during the period in which information required to be submitted to the HHS Secretary is "overdue." 26 U.S.C. § 5000D(b)(4). The IRA elsewhere requires manufacturers of selected drugs to submit certain negotiation-related information to HHS. 42 U.S.C. § 1320f-2(a)(4). That information is generally due on "March 1 of the year of the selected drug publication date," *id.* § 1320f-3(b)(2)(A), but for initial price applicability year 2026, the deadline was October 2, 2023, *id.* § 1320f(d)(5)(A). Because all manufacturers of the first ten selected drugs have submitted such information, no tax is anticipated to accrue on the basis that a manufacturer has failed to submit the required information (at least during the first negotiation cycle). Accordingly, while Plaintiffs' tax claims do not appear to target § 5000D(b)(4), *see, e.g.*, FAC ¶ 221 (alleging that the tax "punishes manufacturers that refuse to 'agree' to 'negotiate' or to 'agree' to the 'maximum fair price'"—allegations that pertain only to § 5000D(b)(1) and (b)(2)), any claim that did pertain to manufacturers' information-sharing requirements would be moot.

purposes of the preceding sentence, such information" includes "the date on which the Secretary receives notification of any termination of an agreement under the Medicare coverage gap discount program," "the date on which the Secretary receives notification of any termination of an agreement under the manufacturer discount program," and "the date on which the Secretary receives notification of any termination of a rebate agreement described in section 1396r-8(b)." *Id.* § 1320f-5(a)(6)(A)-(C). In other words, the HHS Secretary is authorized to provide Treasury with information that would *terminate* tax liability; sharing this information does not "*lead[] to* [the tax's] imposition." Pls.' Opp'n at 19 (emphasis added). Accordingly, the information-sharing activities described in § 1320f-5(a)(6) are not "necessary precursors" to the imposition of that tax, *see id.* at 21, but rather acts that could prevent further tax assessment.

Plaintiffs' reliance on the Revised Guidance fares no better. *See Medicare Drug Price Negotiation Program: Revised Guidance* (June 30, 2023), https://perma.cc/K6QB-C3MM ("Revised Guidance"). First, while the Revised Guidance states that CMS may "refer[] to IRS" the fact that a given manufacturer has not entered into a negotiation agreement or agreed to a maximum fair price, *see* Pls.' Opp'n at 20 (citing Revised Guidance at 91-92), those facts are already publicly available, including to the IRS, *see Manufacturer Agreements for Selected Drugs for Initial Price Applicability Year 2026* (Oct. 3, 2023), https://perma.cc/7R6M-ENEP. Whatever administrative convenience might flow from alerting the IRS of those publicly available facts, the IRS's authority to impose the excise tax does not depend on CMS's notifications. Second, that CMS intends to issue "reminder letters" to manufacturers in connection with statutory deadlines that, if missed, would trigger tax liability, *see* Pls.' Opp'n at 20, does not make CMS responsible for assessing or collecting that tax.

In sum, a manufacturer, producer, or importer that makes sales of a designated drug to Medicare during a period set forth in § 5000D(b) would be responsible for self-reporting and paying the tax, and potentially subject to examination with respect to the accuracy of its return—regardless of whether Defendants share any information with the IRS, regardless of any referral from Defendants to the IRS, and regardless of any notification or corrective action letter from

Defendants to such manufacturer, producer, or importer. Accordingly, the injunction Plaintiffs seek would not redress their alleged tax-related injuries.

2. The two Sixth Circuit decisions on which Plaintiffs rely do not establish otherwise. *See* Pls.' Opp'n at 19 (citing *Durham v. Martin*, 905 F.3d 432 (6th Cir. 2018), and *Lavin v. Husted*, 689 F.3d 543 (6th Cir. 2012)).

First, in *Durham v. Martin*, the Sixth Circuit held that a Tennessee legislator who had been expelled by the state legislature and was then denied various state benefits could sue the administrators who ultimately issued the denial. 905 F.3d at 433. Even if the legislature's expulsion was "the ultimate reason" why the legislator "lost his benefits" and even though "the administrators were not responsible for [the legislator's] expulsion," they did "possess authority to enforce the complained-of provision" such that the legislator's claim was redressable in a suit against the administrators. *Id.* at 434-35 (quoting *Kitchen v. Herbert*, 755 F.3d 1193, 1201 (10th Cir. 2014)). Here, of course, Defendants do *not* have authority to enforce the complained-of excise-tax provisions; that power rests with Treasury and the IRS—both absent from this suit.

Second, in *Lavin v. Husted*, the Sixth Circuit addressed whether Medicaid providers who were barred by state election law from making certain campaign contributions could challenge the contribution restrictions by suing the Ohio Secretary of State, who investigated and reported election law violations to the state Attorney General, rather than suing the Attorney General himself, who brought criminal charges for violations of state election law. 689 F.3d at 546. The court held that the plaintiffs could sue the Secretary of State because he was the "chief election officer" and "must," by state statute, "investigate the administration of election laws . . . and report violations of election laws to the attorney general or prosecuting attorney, or both, for prosecution." *Id.* at 546 (quoting Ohio Rev. Code §§ 3501.04, 3501.05(N)(1)). The Secretary was also statutorily authorized to "'issue subpoenas, summon witnesses, [and] compel the production of . . . evidence . . . [in] any matters relating to the administration and enforcement of the election laws." *Id.* (quoting Ohio Rev. Code § 3501.05(DD)). Given the Secretary's statutory obligation to investigate and report election law violations, as well as the Secretary's power to issue

compulsory process in election law matters, the Sixth Circuit held that an injunction preventing the Secretary "from doing any of these things in connection" with the challenged election law would provide redress to Plaintiffs. *Id.*

Not so here, where HHS and CMS have neither the statutory obligation to investigate possible tax liability nor the legal authority to issue legal process in connection with a possible tax assessment. Rather, the statutory role of Defendants in connection with the subsections of § 5000D relevant here is to make "determination[s]" that would *end* a taxpayer's liability and, pursuant to the Revised Guidance, to alert both the IRS and Plaintiffs' members of potential liability. That is a far cry from being statutorily required to perform an investigation of possible tax liability or statutorily empowered to participate directly in the tax assessment and collection process.

Because Plaintiffs failed to sue Treasury and the IRS—the only agencies empowered to collect the tax—in connection with their excise-tax claims, Plaintiffs "have not shown that [their] injury is 'likely' to be 'redressed by judicial relief'" in this suit. *See Brackeen*, 599 U.S. at 292.

B. The AIA and DJA preclude review of Plaintiffs' excise-tax challenges.

Plaintiffs do not contest that the AIA, on its face, applies to bar Plaintiffs' excise-tax claims. *See generally* Pls.' Opp'n at 22-28. That concession is unsurprising given that Congress labeled the excise tax a "tax" and the purpose of Plaintiffs' excise-tax claims is to "restrain[] the assessment or collection" of that tax. 26 U.S.C. § 7421(a); *see also* 26 U.S.C. § 5000D (labeling excise tax a "tax"). That is all that matters for AIA purposes. *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 544, 564 (2012) (*NFIB*) (the AIA precludes a preemptive challenge to any exaction that Congress has "label[ed]" as a "tax"). *See generally* Defs.' Br. at 24-26.

Plaintiffs nonetheless assert that this would be a "peculiar case for the application of the AIA." Pls.' Opp'n at 23. In support, Plaintiffs invite the Court to skip ahead to the merits, devoting the first two-and-a-half pages of their AIA argument to discussion of the tax rate and how much revenue the tax is likely to generate. *See id.* at 22-25. Putting aside that Plaintiffs mischaracterize the nature and scope of the tax, *see* Defs.' Br. at 8, 67, the reach of the AIA does not depend on these features, and Plaintiffs do not point to a single case suggesting otherwise. *See* Pls.' Opp'n

at 23-25.[6] Rather, the AIA "prohibit[s] a taxpayer from bringing . . . a 'preemptive[]' suit to foreclose tax liability[,] . . . [a]nd it does so *always*." *CIC Servs., LLC v. IRS*, 593 U.S. 209, 224 (2021) (emphasis added). "That is just as true when the tax in question is a so-called regulatory tax—that is, a tax designed mainly to influence private conduct, rather than to raise revenue." *Id.* Therefore, even if Plaintiffs could establish that the excise tax would not generate significant revenue—a prediction in some tension with their assertion that the tax would have an "unsustainable" and "'unbearable' impact" on a manufacturer's bottom line, Pls.' Opp'n at 26—the AIA would still "bar[] pre-enforcement review." *See CIC Servs.*, 593 U.S. at 224.

The Court should therefore reject Plaintiffs' attempt to evade the AIA, which effectively boils down to a policy disagreement with Congress: In Plaintiffs' eyes, large corporate taxpayers that are engaged in sizeable or frequent transactions that may trigger substantial tax liability should not have to wait to challenge the constitutionality of a tax until after paying it. *See* Pls.' Opp'n at 25-28. Whatever the costs and benefits of Plaintiffs' alternative approach, Congress chose a different path wherein Plaintiffs' "sole recourse is to pay the tax and seek a refund." *CIC Servs.*, 593 U.S. at 224. And—save the two limited, judicially created exceptions that, as discussed below, are inapplicable here—that is "always" the case, "whatever the taxpayer's subjective reason for contesting the tax at issue." *Id.* Plaintiffs and their members are simply no differently situated from the many individual and corporate taxpayers who would prefer to have a tax preemptively enjoined before paying it—precisely what the Anti-Injunction Act precludes.

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[6] In this discussion of the tax rate, Plaintiffs cite two cases in which the AIA was held not to apply. *See* Pls.' Opp'n at 23 (citing *Z St. v. Koskinen*, 791 F.3d 24, 30 (D.C. Cir. 2015), and *NorCal Tea Party Patriots v. IRS*, No. 1:13-cv-341, 2014 WL 3547369, at *11 (S.D. Ohio July 17, 2014)). Neither of these cases bears any resemblance to this one. Most fundamentally, neither case involved a request to enjoin the assessment or collection of a tax—unlike here, where Plaintiffs do not dispute that they are directly challenging the constitutionality of, and seeking to have enjoined, an exaction that Congress has labeled a "tax." In *Z Street*, the plaintiff sought an injunction "prohibiting the IRS from delaying consideration" of its application for non-profit status. 791 F.3d at 31. It specifically did not seek a favorable adjudication of its application. *See id.* at 30. Likewise, in *NorCal*, the plaintiffs sought only to prohibit the IRS from delaying their applications or engaging in viewpoint discrimination while evaluating the application. *See* 2014 WL 3547369 at *11 (following district court decision in *Z Street*). Thus, in each of those cases, a decision in the plaintiff's favor would not have prevented the imposition of a tax. Here, of course, Plaintiffs *are* asking the Court to issue an order preventing assessment or collection of the excise tax.

Given that the AIA applies as a statutory matter, Plaintiffs try—but fail—to fit this case into the two judicially created exceptions to the AIA. Neither of these "two narrow exceptions" applies here. *RYO Mach., LLC v. Dep't of Treasury*, 696 F.3d 467, 470-71 (6th Cir. 2012).

The *Williams Packing* exception does not apply because Plaintiffs have failed "to carry the 'double burden' of showing that" a refund suit would be inadequate and that "it is clear that under no circumstances could the Government ultimately prevail" on the merits. *Vuin v. Burton*, 327 F.2d 967, 970 (6th Cir. 1964) (quoting *Botta v. Scanlon*, 314 F.2d 392, 394 (2d Cir. 1963), and *Enochs v. Williams Packing & Navigation Co., Inc.*, 370 U.S. 1, 7 (1962)). As to whether there is an adequate remedy at law, Plaintiffs' members have multiple avenues to press their constitutional challenges in court. A manufacturer could file a refund suit in federal district court or in the Court of Federal Claims after the tax is imposed on just a single sale of a single drug. *See* 26 U.S.C. § 7422; 28 U.S.C. §§ 1346(a)(1), 1491.[7] Or, if the IRS takes any collection action in connection with unpaid excise tax amounts, the manufacturer could raise its constitutional challenge during a collection due process ("CDP") hearing and, if unsuccessful, petition the Tax Court for review, *see* 26 U.S.C. § 6330(d)(1).[8] "The issue here is when—not if—[Plaintiffs' members] may challenge" the excise tax. *Fla. Bankers Ass'n v. U.S. Dep't of the Treasury*, 799 F.3d 1065, 1067 (D.C. Cir. 2015).[9]

Plaintiffs raise a host of arguments as to why this judicial review would be inadequate, but none is persuasive. As a threshold matter, they again question the IRS's interpretation of the excise

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[7] To do so, a manufacturer would file a return at the end of the quarter that accurately reported its various sales, pay the tax owed on at least one of those sales, file an administrative claim for a refund, and then—if the IRS denies that claim or if six months elapse without a decision—file a refund suit. 26 U.S.C. §§ 6511, 6532(a)(1), 7422(a). As discussed further below, *see infra* at 21-22, a manufacturer would only have to pay the excise tax on a single sale to bring a refund suit.

[8] For example, if a manufacturer filed an accurate return, reported its sales and the tax owed, but paid only a portion of the tax owed and the IRS later took some collection action (*e.g.*, issued notice that it intended to levy), the manufacturer could then contest the constitutionality of the excise tax in a CDP hearing before an impartial officer in the IRS Independent Office of Appeals. *See* 26 U.S.C. § 6330(c)(2)(B) (if taxpayer had not yet had an opportunity to do so, it may "raise . . . challenges to the existence or amount of the underlying tax liability" at a CDP hearing); *id.* § 6330(b)(1) (describing CDP hearing); *see also id.* § 7803(e)(3) (describing function of IRS Appeals). If unsuccessful before IRS Appeals, the manufacturer could then file suit in Tax Court.

[9] Accordingly, because the AIA dictates the timing rather than the availability of judicial review, the AIA does not "render[] judicial review of constitutional claims practically impossible." Pls.' Opp'n at 28.

tax's rate and reach. *See* Pls.' Opp'n at 23-25 & n.10 (citing IRS Notice). The Notice makes clear that the IRS interprets the tax to apply only to a 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. IRS Notice at 3. The Notice also explains that, after 271 days, the maximum ratio of the tax to the total amount the manufacturer charges for a drug is 95% (not 1900%, as Plaintiffs claim). *Id.* at 4. Plaintiffs suggest that they cannot rely on the IRS's interpretation of the excise tax, referring to the Notice as "non-binding." Pls' Opp'n at 25 n.10. But that fear is belied by the Notice itself, which specifically states that "taxpayers may rely on" it now. IRS Notice at 5. And, of course, Plaintiffs have not actually sought relief against the IRS's interpretation, which operates to their benefit and the benefit of their members.

Next, Plaintiffs question—without explanation—whether the excise tax is actually "divisible." *See* Pls.' Opp'n at 25. But it is, as Defendants have already explained. *See* Defs.' Br. at 28. The tax is divisible because it is imposed on each "sale" of a designated drug, 26 U.S.C. § 5000D(a), and a taxpayer who wishes to challenge such a tax need only pay "the excise tax on a single transaction" before bringing a refund suit, *Rocovich v. United States*, 933 F.2d 991, 995 (Fed. Cir. 1991); *see also Flora v. United States*, 362 U.S. 145, 171-75 nn. 37, 38 (1960).[10] And "[w]hen a refund suit is pending on a divisible assessment, the [IRS] will exercise forbearance with respect to collection provided that the interests of the government are adequately protected and the revenue is not in jeopardy." IRS Policy Statement 5-16, IRM 1.2.1.6.4(6). Without any basis, Plaintiffs speculate that the IRS might act in contravention of its own policy statement. *See* Pls.' Opp'n at 25-26. That fear is unfounded and, in any event, if the IRS did take steps to collect the excise tax during the pendency of a refund suit, the taxpayer could challenge, during a CDP hearing, the propriety of that collection effort in light of the policy statement. *See* 26 U.S.C.

[10] Again, it is not clear why Plaintiffs object to Defendants' assertion that the excise tax is divisible such that a manufacturer need not wait to pay the tax on all of its transactions before bringing a refund suit—an interpretation that is not only based in precedent, but that will facilitate quicker judicial review for manufacturers than if the tax were not divisible.

§ 6330(c)(2) (a taxpayer "may raise at the [CDP] hearing any relevant issue relating to the unpaid tax or the proposed levy," including a challenge to whether a collection action is appropriate or alternatives to collection are available).

Finally, Plaintiffs argue that even if the tax is divisible, and even if they could thus bring a refund suit after paying the tax on just a single sale, and even if the IRS would not seek to collect any further tax payments during the pendency of that refund suit, they still need a preemptive injunction now because they would not know whether future sales ultimately would be subject to the excise tax. *See* Pls.' Opp'n at 26. But that is just another way of saying they would like to challenge the constitutionality of the excise tax before paying it—exactly what the AIA forbids. *RYO Mach.*, 696 F.3d at 471 ("The AIA has been interpreted broadly to encompass almost all premature interference with the assessment or collection of any federal tax."). And Plaintiffs' members are not unique in this regard; corporate taxpayers often must engage in large transactions without fully knowing the tax consequences, setting aside reserves to pay any amount of tax that is ultimately due. If anything, Plaintiffs' members are better positioned than most, because the excise tax is divisible such that they will not have to pay the excise tax on more than a single transaction before they can press their constitutional challenge. At that point, if they prevail—which Plaintiffs (wrongly) believe they are certain to do, *see* Pls.' Opp'n at 26—no further excise tax would be assessed or collected.[11]

Even if these opportunities for judicial review were inadequate, the *Williams Packing* exception does not apply here because Plaintiffs cannot show that, "under the most liberal view of

[11] Plaintiffs also argue that the divisibility of the excise tax is of no help to their members. They claim that a "manufacturer could not simply stop selling its drugs after a single transaction," because of the "unworkability of running a production line to make a single unit" and because doing so "would deprive millions of patients of vitally needed treatments and cause irreparable harm to the manufacturer's goodwill." Pls.' Opp'n at 26. Defendants are not asserting that manufacturers should stop selling their drugs after a single transaction; Defendants have merely explained that, because the excise tax is divisible, manufacturers need not *pay* tax on more than a single transaction before bringing a refund suit. And presumably manufacturers would not need to redesign their production lines because they will either continue selling to Medicare beneficiaries at a negotiated price or, if they choose to leave Medicare, they will continue selling to patients covered by private insurance. And any loss of goodwill due to choices of the manufacturer to pull its products from either the public or private payer markets is a result of the manufacturer's voluntary choices.

the law and the facts," "it is clear that under no circumstances could the Government ultimately prevail" on the merits. *Williams Packing*, 370 U.S. at 7. As set forth below, *see infra* Section IV.D.1, the excise tax is neither a "fine" nor an "excessive" one. At the very least, Plaintiffs have not established a "certainty of success on the merits," *Bob Jones Univ. v. Simon*, 416 U.S. 725, 737 (1974)—a high bar, and one that is clearly not met here, where Plaintiffs have failed to identify a single court decision finding a tax to constitute a "fine" for Excessive Fines Clause purposes or to be an "excessive" fine in violation of the Eighth Amendment, and where the excise tax is squarely authorized by the powers granted to Congress under both the Taxing and Spending Clause and the Commerce Clause. *See infra* Section IV.D.

The *South Carolina v. Regan* exception does not apply either because, as explained, a refund suit remains legally available to Plaintiffs. As the Sixth Circuit has made clear, "[*South Carolina v. Regan*] holds only that [the AIA] does not apply when Congress has failed to provide 'an alternative remedy.'" *Jarrett v. United States*, 79 F.4th 675, 684 (6th Cir. 2023) (quoting *South Carolina v. Regan*, 465 U.S. 367, 381 (1984)). "But in this instance"—like in *South Carolina*—"Congress has provided a remedial process (refund suits)." *Id.* Here, as in a recent Second Circuit case—where the court held that the plaintiff was required to pay a $61 million tax penalty and then seek a refund before pressing his Eighth Amendment Excessive Fines Clause claim—Plaintiffs have "an adequate remedy; [they] simply [don't] like it." *Larson v. United States*, 888 F.3d 578, 589 (2d Cir. 2018). Plaintiffs nonetheless urge this Court to broaden this exception to account for other considerations, including the practical feasibility of paying a particular tax and then seeking a refund of the tax paid. *See* Pls.' Opp'n at 27. They point to no case in which a court has similarly expanded the reach of this "very narrow" exception. *See RYO Mach.*, 696 F.3d at 472. This Court should not do so here, particularly given that, as explained, Plaintiffs misstate the size and scope of the excise tax, and therefore mischaracterize the burden Plaintiffs' members confront in pursuing Congress's chosen path of a refund suit—a path all taxpayers must pursue despite their desire to preemptively challenge taxes before paying them.

Because the AIA applies, and because the "federal tax exception to the [DJA] is at least as broad as the [AIA]," *Bob Jones Univ.*, 416 U.S. at 732 n.7, the Court must dismiss Counts 3 and 4.

IV. ALL OF PLAINTIFFS' CLAIMS LACK MERIT.

If the Court reaches the merits, it should enter summary judgment for Defendants on any remaining claims, because nothing in the Constitution requires the government to continue overpaying for prescription drugs.

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

Plaintiffs' lead merits argument is still that this Court should hold that, in creating the Negotiation Program, Congress violated the nondelegation doctrine for lack of an "intelligible principle," Pls.' Opp'n at 29—a conclusion that the Supreme Court has reached only twice, both times in 1935, and repeatedly rejected since then. In Plaintiffs' words, "Plaintiffs' position is that the IRA's unconstitutional delegation is inconsistent with *both* precedent *and* the original understanding of the Constitution," *id.*—as if this Court is supposed to disentangle the two, or to do something other than apply binding precedent from the Supreme Court and the Sixth Circuit.

To be clear, Plaintiffs are quite wrong to say that "the government does not dispute that the IRA's delegation to HHS would fail under the original understanding of the nondelegation doctrine." *Id.* at 30 (emphasis omitted). "In fact, the Constitution at the Founding contained no discernable, legalized prohibition on delegations of legislative power, at least so long as the exercise of that power remained subject to congressional oversight and control." Julian Davis Mortenson & Nicholas Bagley, *Delegation at the Founding*, 121 COLUM. L. REV. 277, 280 (2021).[12] But more importantly, it is not this Court's job to craft and apply the nondelegation doctrine from scratch—because the Supreme Court and the Sixth Circuit have already done so. This Court need only compare the delegations at issue here to those that have been upheld by the

[12] *See also, e.g.*, *Delegation at the Founding*, 121 COLUM. L. REV. at 282 ("Our conclusion is straightforward. The nondelegation doctrine has nothing to do with the Constitution as it was originally understood. You can be an originalist or you can be committed to the nondelegation doctrine. But you can't be both."); Cass R. Sunstein, *Nondelegation Canons*, 67 U. CHI. L. REV. 315, 322 (2000) ("[I]t is more accurate, speaking purely descriptively, to see 1935 as the real anomaly. We might say that the [nondelegation] doctrine has had one good year, and 211 bad ones (and counting).").

Supreme Court and the Sixth Circuit. *See* Defs.' Br. at 32-34 (collecting cases). That extensive, binding precedent forecloses Plaintiffs' nondelegation claim.

In response to this flood of precedent, Plaintiffs note that "only two of the government's nondelegation cases involved administrative price-control regimes." Pls.' Opp'n at 30 (citing *Fed. Power Comm'n v. Hope Nat. Gas Co.*, 320 U.S. 591, 600 (1944); *Yakus v. United States*, 321 U.S. 414, 420 (1944)). But the Negotiation Program is not a price-control regime—among other reasons, because participation is voluntary, and the Program says nothing about the prices that Plaintiffs may charge when selling drugs to any buyer *other* than the federal government. *See infra* Section IV.B. And even if it were, Plaintiffs don't offer any authority (or even a theory) as to why the intelligible-principle test would apply more strictly to price-control statutes—which is unsurprising, because the Sixth Circuit "appl[ies] one universal intelligible-principle test regardless of the type of statute at issue." *Consumers' Rsch.*, 67 F.4th at 788.

In all events, Defendants would have no trouble defending the IRA based on *Yakus* and *Hope* alone. *Yakus* upheld a delegation to the Price Administrator to set commodity prices that would be "fair and equitable" and would "effectuate the purposes of" the Emergency Price Control Act of 1942. 321 U.S. at 420. And *Hope* upheld a delegation to the Federal Power Commission to determine "just and reasonable" rates for sales of natural gas. 320 U.S. at 600. If those extraordinarily open-ended delegations were permissible, this more circumscribed delegation has to be. *See* Defs.' Br. at 34-35 (identifying statutory constraints).

Plaintiffs note that in *Yakus*, the statute also provided that, "so far as practicable," the Price Administrator "shall ascertain and give due consideration to the prices prevailing between October 1 and October 15, 1941." 321 U.S. at 420-21. But again, that criterion constrained the Executive Branch much less than Congress did in the IRA, which (1) contains no comparable mechanism for the agency to ignore Congress's criteria if the agency considers them not "practicable," *id.* at 421; (2) includes two mathematical formulae to calculate a "ceiling" price, 42 U.S.C. § 1320f-3(c); and (3) lists *ten* specific criteria that the agency *must* consider, *id.* § 1320f-3(e)(1), (2), rather than *one*

that it *may*. So, even if the Court were to ignore every case other than *Yakus* and *Hope*—and there is no principled basis to do so—Plaintiffs' nondelegation claim still fails.

Unable to square their nondelegation theory with precedent, Plaintiffs resort to misrepresenting the text of the statute. They lament "the lack of *any* price-setting standard," and assert that, under the IRA, "the 'maximum fair price' is whatever HHS says it is." Pls.' Opp'n at 36, 37 (citation omitted). But that just isn't true. Plaintiffs' caricature ignores several detailed statutory provisions guiding the agency's exercise of discretion, which are quoted in full on pages 34 and 35 of Defendants' opening brief. *See* 42 U.S.C. §§ 1320f-3(b)(1), (c), (e)(1), (e)(2).[13]

As for the relevance of Congress's decision to preclude review over certain agency determinations, Plaintiffs now try a softer version of their argument. Conceding that "Congress generally has the power to restrict the jurisdiction of the lower federal courts," Pls.' Opp'n at 34 (citing Defs.' Br. at 37-38 (collecting cases)), Plaintiffs now clarify that they "have never argued that the preclusion of review *by itself* 'creates a nondelegation problem,'" *id.* (quoting Defs.' Br. at 36-37). Instead, Plaintiffs now insist that "[t]he problem with the IRA is its unique combination of a vast delegation of power to an administrative agency with a dearth of safeguards such as statutory standards, judicial review, and notice-and-comment requirements." *Id.* Even accepting uncritically Plaintiffs' distortion of the statute, however, their gerrymandered legal theory still lacks a citation to a single case finding a nondelegation violation on any similar basis.[14] And it is difficult to understand why Plaintiffs think Congress had to vest more power in *courts* to avoid a

[13] Defendants previously explained that the statute directs CMS 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." Defs.' Br. at 34 (quoting 42 U.S.C. § 1320f-3(b)(1)). Although that quotation was accurate, Plaintiffs accuse Defendants of an "attempt to amend that statutory instruction on the fly," because the statute's text "does not include the caveat 'for which it is able to persuade manufacturers to sign an agreement.'" Pls.' Opp'n at 37 (quoting Defs.' Br. at 34). Defendants never suggested otherwise. Plaintiffs misunderstood the point—if manufacturers refuse to sign an agreement, there can be no "maximum fair price" at all. So it is necessarily the case that CMS's efforts to "achieve the lowest maximum fair price," 42 U.S.C. § 1320f-3(b)(1), will account for the possibility that the manufacturer could always walk away from the negotiation.

[14] Plaintiffs do cite various cases in which a court *rejected* a nondelegation challenge and, while doing so, also pointed out that the statute contemplated some form of judicial review. *See* Pls.' Opp'n at 32-34. But Plaintiffs still do not cite any case concluding that "*preclusion* of review creates a nondelegation problem, and Defendants are [still] aware of no such case." Defs.' Br. at 36-37.

finding that it surrendered too much of its own power. The Constitution's vesting of legislative power in Congress does not also require a flood of lawsuits challenging the agency's offer price, with the final say about the "maximum fair price" of complex pharmaceuticals to be made by federal judges. Ultimately, it is thus Plaintiffs' proposal that would "undermine accountability," Pls.' Opp'n at 35—after all, unlike the federal courts, the Secretary of Health and Human Services is directly accountable to an elected President.

Finally, to the extent there is anything "unique," *id.* at 34, about the IRA that is relevant to the nondelegation inquiry, Defendants have already explained why the intelligible-principle test should (if anything) be *relaxed* "in the context of a delegation governing the negotiation of individual contracts," given that this is "a traditional Executive Branch function." Defs.' Br. at 36; *cf. Loving v. United States*, 517 U.S. 748, 772 (1996) ("[T]he question to be asked is not whether there was any explicit principle telling the President how to" exercise his statutory discretion, "but whether any such guidance was needed, given the nature of the delegation and the officer who is to exercise the delegated authority."). In this context, the Supreme Court has emphasized "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." *Perkins v. Lukens Steel Co.*, 310 U.S. 113, 127 (1940). Plaintiffs offered no response.

In sum, "[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 v. United States*, 488 U.S. 361, 372 (1989)). Plaintiffs are not shy about their disagreement with that precedent, but it is binding. That is enough to dispose of Plaintiffs' nondelegation claim.

B. Plaintiffs' due process claim (Count 2) fails because the IRA does not impinge on manufacturers' property interests.

Plaintiffs' response likewise does not—and cannot—rescue the due process theory that this Court previously rejected. For all their eagerness to impugn the procedures of the Negotiation Program, Plaintiffs continue to ignore that the threshold "inquiry in every due process challenge is whether the plaintiff has been [1] deprived of [2] a protected interest in property or liberty." *Am. Mfrs. Mut. Ins. Co. v. Sullivan*, 526 U.S. 40, 59 (1999) (citing *Mathews v. Eldridge*, 424 U.S. 319, 332 (1976)). "Only after finding the deprivation of a protected interest do [courts] look to see if the [challenged] procedures comport with due process." *Id.* And here, there is no occasion for the Court to get that far.

1. There is no deprivation because the Negotiation Program is voluntary.

As this Court correctly recognized, Plaintiffs' due process theory runs aground at the first step of the analysis. *Chamber I*, 2023 WL 6378423, at *11. Much as the drafters of the IRA may have wanted pharmaceutical manufacturers to negotiate discounts for their high-price drugs, the statute does "not legally compel[]" them to do so. *Id.* Both the IRA's text and CMS's implementing guidance give manufacturers multiple options "to opt out" of the Negotiation Program—before, during, and after negotiations—either by divesting their interest in the selected drug or by withdrawing from Medicare and Medicaid. *Id.*; *see also* Defs.' Br. at 42-45 (detailing the exit options). Drug manufacturers' participation in the Program is thus "completely voluntary." *Chamber I*, 2023 WL 6378423, at *11. And it is well established that "where a property owner voluntarily participates in a regulated program, there can be no unconstitutional" deprivation. *Franklin Mem'l Hosp. v. Harvey*, 575 F.3d 121, 129 (1st Cir. 2009); *see also Baker Cnty. Med. Servs., Inc. v. U.S. Att'y Gen.*, 763 F.3d 1274, 1276, 1279-80 (11th Cir. 2014) (collecting cases for the same proposition).

Plaintiffs protest that all the cases Defendants cite that rejected Fifth Amendment challenges to Medicare conditions concerned "distinct claims by differently situated plaintiffs." Pls.' Opp'n at 41. This, of course, is true of most precedent—though notably *not* of this Court's

prior decision, which Plaintiffs outright ignore. And neither Plaintiffs' repeated invocation of *NFIB* nor their other complaints about the IRA would justify this Court reversing its prior conclusion or departing from the "clear" "law established in the Sixth Circuit and beyond" that is applicable here. *Chamber I*, 2023 WL 6378423, at *11; *see, e.g.*, *Baptist Hosp. E. v. Sec'y of Health & Hum. Servs.*, 802 F.2d 860, 869 (6th Cir. 1986) (rejecting due process challenge to Medicare reimbursement rates on the ground that "participation in the Medicare program is wholly voluntary"); *Livingston Care Ctr., Inc. v. United States*, 934 F.2d 719, 720 (6th Cir. 1991) (applying same rule); *Garelick v. Sullivan*, 987 F.2d 913, 917 (2d Cir. 1993) ("All court decisions of which we are aware that have considered takings challenges by physicians to Medicare price regulations have rejected them in the recognition that participation in Medicare is voluntary.").

a. The Negotiation Program is not "coercive."

This Court already rejected Plaintiffs' reliance on *NFIB* for the contention that the Negotiation Program is "coercive" when it denied Plaintiffs' motion for a preliminary injunction. *See* Pls.' Reply in Supp. of Mot. for Prelim. Inj. at 12-14, ECF No. 49 (arguing that the Negotiation Program was "coercive" in violation of *NFIB*). And rightly so. Plaintiffs' reading of that decision doubles down on the legal errors Defendants previously identified—and places the decision so far outside its context that it would radically rework federal spending law.

***First*,** contrary to Plaintiffs' claims, *NFIB* does not provide a generally applicable framework for analyzing whether a condition on a government program is voluntary. *See* Pls.' Opp'n at 43. Rather, federalism was the animating concern of the *NFIB* "coercion" inquiry. 567 U.S. at 577 (plurality op.) (explaining the need to protect "the status of the States as independent sovereigns in our federal system"). That inquiry is derived exclusively from cases addressing how principles of federalism limit Congress's authority to attach funding conditions on grants to States. *See id.* at 579-81 (discussing, *inter alia*, *South Dakota v. Dole*, 483 U.S. 203 (1987)). In analyzing whether the condition at issue was coercive, the lead opinion did not cite to or discuss any other type of Spending Clause or unconstitutional-conditions case. *Contra* Pls.' Opp'n at 43-44.

The Supreme Court has not relied on *NFIB*'s "coercion" test when dealing with the broader doctrine of unconstitutional conditions in suits by private parties. For example, the very next term after deciding *NFIB*, the Court decided *Koontz v. St. Johns Water Management District*, explaining that the unconstitutional conditions doctrine "vindicates the Constitution's enumerated rights by preventing the government from coercing people into giving them up." 570 U.S. 595, 604 (2013). It also decided *Agency for International Development v. Alliance for Open Society International, Inc.*, which likewise analyzed unconstitutional conditions in the context of the government seeking "to leverage funding to regulate speech outside the contours of the program" at issue. 570 U.S. 205, 214-15 (2013). In neither of those decisions involving funding to private parties did the Court so much as cite *NFIB*, much less employ its analysis. *See Koontz*, 570 U.S. at 604; *Agency for Int'l Dev.*, 570 U.S. at 214. Similarly, the decision from last term in *Cummings v. Premier Rehab Keller, PLLC*—which, as Plaintiffs note, discussed the "voluntar[iness]" of Spending Clause legislation in the context of identifying remedies available to private parties—also did not cite *NFIB*. 596 U.S. 212, 219 (2022).

Plainly, the Supreme Court has not treated *NFIB* as establishing a generally applicable standard for voluntariness. *Contra* Pls.' Opp'n at 43-44. The mere fact that *NFIB* uses a general term like "coercion," which can also be used in other contexts, does not mean that the decision established a universally applicable principle of Spending Clause law. *See, e.g.*, *Turkiye Halk Bankasi A.S. v. United States*, 598 U.S. 264, 278 (2023) ("This Court has often admonished that 'general language in judicial opinions' should be read 'as referring in context to circumstances similar to the circumstances then before the Court and not referring to quite different circumstances that the Court was not then considering.'" (quoting *Illinois v. Lidster*, 540 U.S. 419, 424 (2004))).[15] Plaintiffs fail to acknowledge the authority Defendants cited recognizing that *NFIB* is limited to

[15] Plaintiffs' error is encapsulated in their citation to *Doe v. University of Sciences*, 961 F.3d 203, 213 (3d Cir. 2020), which Plaintiffs claim "appl[ied] [the] concept of" *NFIB* to private parties. Pls. Opp'n at 43. But that case involved a contractual dispute between two private parties, not a challenge to a condition on federal funding. *See Doe*, 961 F.3d at 212. And although the court observed in passing that the loss of federal funds could be "ruinous" for private parties, it never analyzed whether the withdrawal of such funds would be impermissible (which the "coercion" inquiry would demand). *Id.* at 213.

the unique context of federalism. *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.").

Second, Plaintiffs' suggestion that *NFIB*'s "coercion" inquiry can reach the federal government's purchases of goods or services is a radical concept that does not track *NFIB*'s language or logic and is unsupported by other precedent.

The animating principle of *NFIB*—which Plaintiffs disregard in their response—was that the government should not be able to use its Spending Clause powers to end-run restrictions on its ability to *regulate*. 567 U.S. at 580-81. But the Supreme Court has "long held the view that there is a crucial difference, with respect to constitutional analysis, between the government exercising 'the power to regulate or license, as lawmaker,' and the government acting 'as proprietor.'" *Engquist v. Oregon Dep't of Agric.*, 553 U.S. 591, 598 (2008) (quoting *Cafeteria & Restaurant Workers v. McElroy*, 367 U.S. 886, 896 (1961)). When the government acts in the latter capacity, constitutional review "must rest on different principles than review of . . . restraints imposed by the government as sovereign." *Id.* at 599 (quoting *Waters v. Churchill*, 511 U.S. at 674 (1994)); *see also Waters*, 511 U.S. at 671 ("[T]he government as employer . . . has far broader powers than does the government as sovereign.").

For this reason, courts do not superintend government contracting decisions to ensure that the compensation contractors agree to accept reflects "fair market value" for their products. As the Supreme Court has confirmed across a range of different constitutional contexts, "[w]here the government is acting as a proprietor, managing its internal operations, rather than acting as lawmaker with the power to regulate or license, its action will *not* be subjected to the heightened review to which its actions as a lawmaker may be subject." *Int'l Soc'y for Krishna Consciousness,*

Inc. v. Lee, 505 U.S. 672, 678 (1992) (emphasis added); *see also Waters*, 511 U.S. at 675 (the "government's interest in achieving its goals as effectively and efficiently as possible is elevated from a relatively subordinate interest when it acts as sovereign to a significant one when it acts as employer"); *Ridley v. Mass. Bay Transp. Auth.*, 390 F.3d 65, 79 (1st Cir. 2004) ("[A] lower level of scrutiny usually applies when the government acts as proprietor."). Of course, "the Government unquestionably is the proprietor of its own funds, [so] when it acts to ensure the most effective use of those funds, it is acting in a proprietary capacity." *Bldg. & Const. Trades Dep't, AFL-CIO v. Allbaugh*, 295 F.3d 28, 35 (D.C. Cir. 2002).

The same principle animates the cases Defendants cited in their opening brief dealing with the difference between states acting as regulators as opposed to purchasers. *See Chamber of Com. of U.S. v. Brown*, 554 U.S. 60, 70-71 (2008) (distinguishing between government acting "as a regulator rather than a market participant"); *see also Bldg. & Const. Trades Council of Metro. Dist. v. Associated Builders & Contractors of Mass./R.I., Inc.*, 507 U.S. 218, 229 (1993) (discussing the "conceptual distinction between regulator and purchaser"); *Associated Builders & Contractors Inc. N.J. Chapter v. City of Jersey City*, 836 F.3d 412, 417-18 (3d Cir. 2016). In seeking to distinguish those decisions, Pls.' Opp'n at 45, Plaintiffs miss the underlying point that governments, whether state or federal, are subject to different constitutional constraints when they act as market participants. *See, e.g.*, *Allbaugh,* 295 F.3d at 36 ("A condition that the Government imposes in awarding a contract or in funding a project is regulatory only when . . . it 'addresse[s] employer conduct unrelated to the employer's performance of contractual obligations to the [Government].'" (quoting *Bldg. & Const. Trades Council*, 507 U.S. at 228-29)).

Contrary to Plaintiffs' claims, these distinctions do not vanish merely because the government can also regulate the relevant market (in often-unrelated ways). Pls.' Opp'n at 44-45. As the cases Defendants previously cited make clear, "the Supreme Court has approved applying the market participant exception even when a State's regulations are trained on the specific market in which it participates." *Brooks v. Vassar*, 462 F.3d 341, 358 (4th Cir. 2006); *see Hughes v. Alexandria Scrap Corp.*, 426 U.S. 794, 797 (1976) (the State of Maryland not only participated in

the automobile scrap market but also regulated it); *see also Chance Mgmt., Inc. v. South Dakota*, 97 F.3d 1107, 1113 (8th Cir. 1996) (finding that, despite South Dakota's heavy regulation of the state lottery and all other forms of gambling, the State's pervasive involvement in running the lottery was not "regulation of 'the market,'" but rather was no more than "administering its own business"). A State can impose taxes or restrictions to "regulate[] the market," and that "is not sufficient to preclude its status as a market participant." *Brooks*, 462 F.3d at 358.

So too here. As Defendants detailed in their opening brief, Congress designed the Negotiation Program to achieve "[e]fficient and equitable procurement" of high-cost prescription drugs. Defs.' Br. at 48. These steps to limit government outlays on selected drugs are a valid exercise of Congress's power to control federal spending—and reflect Congress's view that the "general Welfare" is best served by reducing expenditures on certain high-cost pharmaceuticals. U.S. Const. art. I, § 8, cl. 1; *cf. Sabri v. United States*, 541 U.S. 600, 608 (2004) ("The power to keep a watchful eye on expenditures . . . is bound up with congressional authority to spend in the first place."). And the mere fact that antitrust laws may restrict private entities from enacting similar pricing controls does not mean that the imposition of such controls is *regulation* in a constitutional sense. *Contra* Pls.' Opp'n at 44-45.

Simply put, *NFIB*'s "coercion" test has no place in the procurement (rather than regulatory) context of the Negotiation Program—and Plaintiffs offer no reasoned basis to apply it here.

Third, and finally, Plaintiffs' *NFIB* argument proves too much. According to Plaintiffs, what makes the Negotiation Program "coercive" is the fact that the most straightforward "way for a manufacturer of a selected drug to escape the" Program's requirements is to forgo Medicare and Medicaid participation generally—which, Plaintiffs claim, imperils "independent" payments for their other drugs. Pls.' Opp'n at 46 (quoting *NFIB*, 567 U.S. at 580). But the same could be said about numerous conditions on Medicare and Medicaid participation that have long been understood as voluntary, not coercive.

For example, Congress has long required drug manufacturers wishing to participate in Medicaid to enter into agreements with the Secretary of Veterans Affairs, to make their covered

drugs available for procurement by the Department of Veterans Affairs and other agencies at or below statutory ceiling prices. *See* 38 U.S.C. § 8126(a)-(h). Similarly, Congress routinely requires that parties accepting Medicare and Medicaid funding observe 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 requirements under 42 U.S.C. § 1396r-8(a)(1), which conditions participation in the Medicaid Drug Rebate Program on participation in the 340B program, through which participating drug manufacturers must give 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"). Plaintiffs' argument would, perforce, declare all those programs coercive—something no court has previously found. *See, e.g.*, *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).

Even more fundamentally, hospitals, nursing homes, and other entities are not eligible for Medicare reimbursement for any one service unless they sign a participation agreement acknowledging their acceptance of the prescribed rates for all their services that are reimbursable by Medicare. 42 U.S.C. § 1395cc; *see also id.* § 1395a(b). These participation agreements require the provider to comply with a series of conditions on participation. *See, e.g.*, 42 U.S.C. §§ 1395cc(b)(2)(B), 1395x(e)(9); 42 C.F.R. §§ 482.1-482.104 (part 482, providing "[c]onditions of [p]articipation for [h]ospitals"). These include numerous requirements concerning hospital "[a]dministration" and operation, 42 C.F.R. §§ 482.11-482.15; basic hospital functions, such as staffing and various types of diagnostic and care procedures, *id.* §§ 482.22-482.23, 482.26; and various aspects of "pharmaceutical services," *id.* § 482.25. Many of these conditions are not limited to providers' interactions with Medicare beneficiaries, but instead apply to the providers generally. *See, e.g.*, *id.* § 482.12 (requiring hospitals to have "effective governing body"); *id.* § 482.21 (requiring hospitals to "maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program"); *see generally id.* § 482.22-482.45

(requiring numerous hospital functions); *see also Cummings*, 596 U.S. at 216-18 (noting that Congress prohibits "discriminat[ion] . . . on certain protected grounds" "by healthcare entities" receiving federal funds). And the consequence of declining to accept *any* condition—including any new condition that CMS determines is necessary—is potential loss of reimbursement for all services, even unrelated ones. All such conditions would be "coercive" under Plaintiffs' logic. Pls.' Opp'n at 46.

Nor would the problems stop there. As the Supreme Court has noted, "[p]ursuant to its authority to 'fix the terms on which it shall disburse federal money,' . . . Congress has enacted four statutes prohibiting recipients of federal financial assistance from discriminating based on certain protected grounds." *Cummings*, 596 U.S. at 217-18 (citation omitted).[16] Congress has separately authorized the President to prescribe policies that he deems necessary to promote economy or efficiency in federal procurement. 40 U.S.C. §§ 101 *et seq*. Under Plaintiffs' construction, these conditions too are potentially constitutionally vulnerable under the *NFIB* "coercion" framework—and entities ranging from educational institutions to defense contractors can claim a constitutional right to take government money while refusing to comply with the accompanying obligations.

The Supreme Court recently made clear that it does not share Plaintiffs' maximalist reading of *NFIB*. As Defendants observed in their opening brief, Defs.' Br. at 47, the Court granted a stay of an injunction against a COVID-19 vaccine mandate that CMS had imposed for workers at federally funded healthcare facilities. *Biden v. Missouri*, 595 U.S. 87, 94 (2022). In doing so, the Court observed "the longstanding practice" of Congress and CMS, under which "healthcare facilities that wish to participate in Medicare and Medicaid have always been obligated to satisfy a host of conditions that address the safe and effective provision of healthcare"—conditions that

[16] These include (1) Title VI of the Civil Rights Act of 1964, which forbids race, color, and national origin discrimination in federally funded programs or activities, 42 U.S.C. § 2000d; (2) Title IX of the Education Amendments of 1972, which prohibits sex-based discrimination by federally funded education programs or activities, 20 U.S.C. § 1681; (3) the Rehabilitation Act, which bars funding recipients from discriminating because of disability, 29 U.S.C. § 794; and (4) the Affordable Care Act, which outlaws discrimination on any of the preceding grounds, in addition to age, by federally funded health programs or activities, 42 U.S.C. § 18116. *See Cummings*, 596 U.S. at 218 (describing these restrictions).

function as a single package. *Id.* Notably, the Court did this even in the face of the challengers raising an *NFIB* "coercion" argument like the one Plaintiffs present here, in which they asserted that the condition improperly sought to leverage other federal funds. *See Becerra v. Louisiana*, Nos. 21A240, 21A241, Resp. to Stay App. at 27, 2021 WL 8939385 (Dec. 30, 2021) (arguing that the vaccination "condition was impermissibly coercive because the consequence of opting out would be the loss of *all* Medicare and Medicaid funds" (citing *NFIB*, 567 U.S. at 580-81)); *Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination*, 86 Fed. Reg. 61,555, 61,574 (Nov. 5, 2021) (noting that "providers and suppliers that are cited for noncompliance may be subject to . . . termination of the Medicare/Medicaid provider agreement").

Plaintiffs miss this failed invocation of the *NFIB* "coercion" argument in *Missouri*. Pls.' Opp'n at 45. But that itself demonstrates that the argument did not have any purchase. Indeed, not even the dissents questioned Congress's authority to condition federal funds on an entity satisfying *all* applicable rules. *See generally Missouri*, 595 U.S. at 98-104 (Thomas, J., dissenting); *id.* at 105-06 (Alito, J., dissenting).

In short, there is no indication that, in deciding *NFIB*, the Supreme Court was transforming a federalism-specific "coercion" limitation into an omnibus framework governing how the federal government spends funds to purchase goods or services from the private sector. No court, to Defendants' knowledge, has embraced such a reading. This Court properly rejected it. And Plaintiffs offer no reason to change course.

b. Plaintiffs' other objections lack merit.

Rejecting Plaintiffs' inapposite invocation of *NFIB* disposes of the heart of Plaintiffs' arguments. Plaintiffs still quibble—in rather cursory form—with the supposed practical difficulty that manufacturers would face either in divesting interest in their drugs or withdrawing wholesale from Medicare and Medicaid. Pls.' Opp'n at 48-50. But Plaintiffs still do not assert that any of their members actually wish to exercise these options, making their objections academic. And regardless, those objections collapse upon examination.

First, contrary to Plaintiffs' repeated suggestions, the *financial* feasibility of divesting a drug or exiting Medicare and Medicaid has no bearing on whether the Negotiation Program is *legally* voluntary. *See* Pls.' Opp'n at 48-49. Decades of precedent Defendants have cited throughout this case makes clear that economic or other practical "hardship is not equivalent to legal compulsion for purposes of" a Fifth Amendment analysis, including in the Medicare context. *Garelick*, 987 F.2d at 917; *see also St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 875 (7th Cir. 1983) (the "fact that practicalities may in some cases dictate participation does not make participation involuntary"). 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 of Health Care Facilities, Inc. v. Minn. Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984). Indeed, that is binding law in the Sixth Circuit. *See Livingston Care Ctr., Inc.*, 934 F.2d at 720 (explaining that "participation in the Medicare program is a voluntary undertaking" in the context of a nursing home's wrongful-termination claim).

Plaintiffs offer no acknowledgement of this established rule—much less provide a reason for this Court to depart from that precedent. *See* Pls.' Opp'n at 48-50. That is fatal. Plaintiffs may be dissatisfied with what they fear to be the financial consequences of a manufacturer divesting its interest in a selected drug or withdrawing all its drugs from Medicare and Medicaid. But, as this Court correctly recognized in its prior decision, what matters is that they legally have that choice—"practical or not." *Chamber I*, 2023 WL 6378423, at *11 (discussing cases); *see also Baker Cnty.*, 763 F.3d at 1280.

Second, Plaintiffs cannot escape this precedent—nor transform the supposed cost of withdrawing from Medicare and Medicaid into a legal problem—merely by mentioning the phrase "unconstitutional conditions doctrine." Pls.' Opp'n at 46-47. As Defendants explained in their opening brief, Defs.' Br. at 50-52, that doctrine comes into play only when a plaintiff can show that the government seeks waiver of a concrete constitutional right (such as a vested property interest) in exchange for a separate discretionary benefit. *See, e.g.*, *Koontz*, 570 U.S. at 612

(explaining that the "predicate for any unconstitutional conditions claim is that the" plaintiff have a protected constitutional right such that the "government could not have constitutionally ordered the person asserting the claim to do what it attempted to pressure that person into doing."); *R.S.W.W., Inc. v. Keego Harbor*, 397 F.3d 427, 434 (6th Cir. 2005) (holding that plaintiff stated a plausible unconstitutional-conditions claim when it alleged that "Defendants withheld certain administrative approvals from it unless it agreed to close" earlier than the regulations governing its liquor license permitted). Plaintiffs do not dispute that standard. *See* Pls.' Opp'n at 46-47. Yet, challenged to articulate what the IRA supposedly asks them to trade *in exchange* for the benefit of continued Medicare reimbursement, Plaintiffs point only to their supposed interest in having Medicare reimburse their drugs. *Id.*

Thus, as Defendants previously observed, Plaintiffs' unconstitutional-conditions theory is completely circular—and fails to identify anything other than financial hardship as the relevant interest at stake. Defs.' Br. at 51-52. But a government spending or procurement program does not come to violate the unconstitutional-conditions doctrine—and thus become involuntary—merely because the offer the government puts on the table isn't as lucrative as Plaintiffs wanted. Were it otherwise, a plaintiff could always challenge their Medicare reimbursement rate as unconstitutional, contrary to well-established law. *See, e.g.*, *Baptist Hosp.*, 802 F.2d at 869 (rejecting due process challenge to Medicare reimbursement rates on voluntariness grounds); *Garelick*, 987 F.2d at 917 (noting that courts have uniformly rejected Fifth Amendment challenges "to Medicare price regulations . . . in the recognition that participation in Medicare is voluntary").

Third, and finally, Plaintiffs cannot overcome the voluntariness of the Negotiation Program by complaining about the expedited pathways that CMS has provided for unwilling manufacturers to withdraw. *See* Pls.' Opp'n at 49-50.

As Defendants explained in their opening brief, CMS's Revised Guidance provides that manufacturers who wish to avoid the Negotiation Program by withdrawing from Medicare and Medicaid need only notify CMS of that intent "30 days in advance of the date that excise tax liability otherwise may begin to accrue." Revised Guidance at 33-34; *see also* Defs.' Br. at 43-44

(laying out this option). This timeline derives from CMS's pre-existing statutory authority in the Social Security Act (SSA) to terminate agreements with manufacturers. *See id.* at 130 (explaining how CMS intends to exercise its authority); *see generally* 42 U.S.C. §§ 1395w-114a(b)(4)(B)(i), 1395w-114c(b)(4)(B)(i) (providing for "good cause" termination). Plaintiffs make a passing objection that these options were "issued in response to litigation." Pls.' Opp'n at 49. But the rush of drug manufacturers to challenge the IRA even before CMS had finalized its guidance—which those manufacturers knew was forthcoming—can hardly be laid at the feet of the agency. And Plaintiffs do not deny that the Revised Guidance, which CMS promulgated pursuant to Congress's direction to "implement" the Negotiation Program, forms an authoritative statement of how the agency will conduct the program's first round of negotiations—and so, unlike some *post hoc* rationale, can be relied upon by manufacturers planning their business affairs.

Meanwhile, because the withdrawal procedures are favorable to manufacturers—and because Plaintiffs have still not indicated that any of their members wish to take advantage of them—there is neither any need nor any constitutional justification for this Court to consider Plaintiffs' complaints about how CMS's procedures align with its statutory authority. *See Bond v. United States*, 564 U.S. 211, 225 (2011) (plaintiffs "have 'no standing to complain simply that their Government is violating the law'" (*quoting Allen v. Wright*, 468 U.S. 737, 755 (1984)). But even if they were properly presented, Plaintiffs' arguments would fail.

As Plaintiffs themselves observe, the statutory language on which CMS relied states that the "Secretary may provide for termination of an agreement under this section for a knowing and willful violation of the requirements of the agreement or *other good cause shown*." 42 U.S.C. § 1395w-114a(b)(4)(B)(i) (emphasis added). Plaintiffs ask this Court to read "other good cause shown" as somehow synonymous with a "knowing and willful violation." Pls.' Opp'n at 50 (emphasis omitted). Notably, Plaintiffs do not volunteer what type of circumstances would be covered by their interpretation—likely because any example would emphasize that their construction would reduce the "good cause" clause to a nullity. Yet "one of the most basic interpretive canons, [is] that '[a] statute should be construed so that effect is given to all its

provisions, so that no part will be inoperative or superfluous, void or insignificant." *Corley v. United States*, 556 U.S. 303, 314 (2009) (quoting *Hibbs v. Winn*, 542 U.S. 88, 101 (2004)). And it is hard to see how a manufacturer indicating that it wishes to withdraw from an agreement early—which would be inconsistent with (and thus a potential violation of) the agreement's terms—would not constitute "good cause shown," particularly when Plaintiffs themselves claim that the absence of a speedy exit option would raise serious constitutional questions. *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" (citation omitted)).

Further, Plaintiffs still fail to rebut the fact that—even under the more extended withdrawal timeline that Plaintiffs concede exists absent CMS's guidance—manufacturers can *still* notice their withdrawal from Medicare and Medicaid and have that withdrawal take effect before any negotiated prices become operative. *See* Defs.' Br. at 44-45. After all, the IRA creates a *28-month* delay between when the first drugs are selected for negotiation and when any negotiated prices would take effect. During that period, a manufacturer can indicate that it intends to withdraw from Medicare—and have that withdrawal take effect before it would ever have to sell its drugs at the negotiated prices. 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 "[i]f 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"). Indeed, manufacturers could exercise this option to notice their termination before, during, or after they negotiate with CMS—and as late as January 2025. *Id.* This option fully resolves Plaintiffs' stated concerns because it is only the sale of drugs at negotiated prices—not any other aspect of participation in the Negotiation Program—that Plaintiffs (wrongly) claim impinges on the manufacturers' property interests. *See* Pls.' Opp'n at 39-40, 46-47 (arguing that it is the setting of the price that injures manufacturers).

Confining their response to a footnote, Plaintiffs profess surprise that the IRA would allow manufacturers to withdraw from Medicare after negotiating a price, characterizing such conduct

as "gamesmanship." Pls.' Opp'n at 50 n.20 (citation omitted). But giving manufacturers the ability to change their mind is part of the flexibility that Congress provided—and it emphasizes the lack of any legal compulsion that those manufacturers face. Plaintiffs' continued efforts to mischaracterize this flexibility only highlights the degree to which the statutory timelines for withdrawal are fatal to their legal theory. Indeed, as Defendants previously noted, the Supreme Court has found that being able to withdraw from a price-capped market with "6 or 12 months notice" is sufficient to defeat a Fifth Amendment claim. *Yee v. City of Escondido*, 503 U.S. 519, 527-28 (1992). And manufacturers have no less flexibility here.

In short, none of Plaintiffs' arguments show that the law "established in the Sixth Circuit and beyond" is inapplicable to the Negotiation Program or undermine this Court's conclusion that the Program is "completely voluntary." *Chamber I*, 2023 WL 6378423, at *11. And because it is voluntary, it cannot give rise to a deprivation that would violate the Due Process Clause.

2. Plaintiffs also have no protected property interest at stake.

Even setting aside the voluntary nature of the Negotiation Program—and the binding Sixth Circuit precedent rejecting due process challenges to Medicare reimbursement rates, *Baptist Hosp.*, 802 F.2d at 869—Plaintiffs' response also fails to establish the second threshold requirement for a due process inquiry: namely, the existence of a protected property interest that is ostensibly impaired.

a. As a starting point, although Plaintiffs continue to point to "manufacturers' prescription drugs" as "the underlying property" interest, they cannot show that the Negotiation Program imperils that interest. *See* Pls.' Opp'n at 46-47. The reason is obvious. While the Negotiation Program regulates how much Medicare will reimburse participating manufacturers, no provision of the IRA requires participating manufacturers to surrender their drugs. *See, e.g.*, 42 U.S.C. § 1320f-2(a)(1), (3) (agreements only regulate the price at which drugs are sold, not whether sales are made); 42 U.S.C. § 1320f-6(a) (penalties apply for failure to "provide access to a *price*" (emphasis added)). All uses of the word "access" in the IRA describe manufacturers providing "access to . . . [a] price" that they may choose to negotiate with CMS. *See id.* §§ 1320f-2(a), (d),

1320f-6(a). Not a single provision uses the phrase "access to drugs" or its equivalent. *See generally id.* Plaintiffs cite no provision of the IRA or the Medicare statute generally that would force manufacturers to sell or otherwise transfer ownership of drugs against their will.

Unable to evade this reality, Plaintiffs once again attempt to assert a property interest over manufacturers' rate of Medicare reimbursement. Pls.' Opp'n at 46-47 (asserting "right . . . to fix the price" (citation omitted)). Plaintiffs endeavor to bolster this claim by arguing that they have built their business model around the pre-IRA Medicare reimbursement model, and therefore "have a 'legitimate claim of entitlement'" to their existing payment rates. *Id.* at 47-48 (quoting *Perry v. Sindermann*, 408 U.S. 593, 602-03 (1972)). But here again Plaintiffs are battling against insurmountable precedent.

As this Court correctly recognized, manufacturers have "no constitutional right (or requirement) to engage in business with the government." *Chamber I*, 2023 WL 6378423, at *11. That does not change merely because manufacturers have built a business on a particular type of past practice. *Contra* Pls.' Opp'n at 47-48. Continued "participation in the federal Medicare reimbursement program is not a property interest." *Shah v. Azar*, 920 F.3d 987, 998 (5th Cir. 2019). And, regardless of their past dealings with Medicare, "providers do not have a property interest in a particular reimbursement rate." *Managed Pharmacy Care v. Sebelius*, 716 F.3d 1235, 1252 (9th Cir. 2013); *see also 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"). Consistent with this reasoning, 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.

Plaintiffs simply ignore these holdings. *See* Pls.' Opp'n at 46-47. And they fail to cite a *single* case that found a provider or other entity to have a property interest in future rates of Medicare reimbursement. *See id.* The key case they quote in support of their claim of a property interest in "high prices," *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1374 (Fed. Cir. 2007), concerned preemption of federal patent laws over a District of Columbia act—

not the existence of property rights. As the court in that case explained, the legislation at issue was "a clear attempt to restrain [pharmaceutical companies'] excessive prices, in effect diminishing the reward to patentees in order to provide greater benefit to District drug consumers[;] [t]his may be a worthy undertaking on the part of the District government, but it is contrary to the goals established by Congress in the patent laws." *Id.* Here, of course, there is no question of preemption: it is Congress itself that determined that reducing Medicare outlays on high-cost pharmaceuticals is "a worthy undertaking." *Id.* And the binding precedent from the Sixth Circuit, which Plaintiffs disregard, makes clear that Congress's choice to pursue that policy in the IRA did not imperil manufacturers' cognizable property rights. *See Livingston Care Ctr.*, 934 F.2d at 721 (explaining that nursing homes "who choose to participate in [Medicare] . . . do so with no guarantee of solvency").

Regardless of how well Plaintiffs liked Medicare prior to the IRA—and regardless of how lucrative or "entic[ing]" it was for their members, Pls.' Opp'n at 38—they have no constitutional right to dictate the government's expenditures. *See generally 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."). Congress has expressly reserved the right to change Medicare's terms, making clear that manufacturers can have no expectation that their current reimbursements would continue. *See* 42 U.S.C. § 1304 (providing that the "right to alter, amend, or repeal any provision of this chapter is hereby reserved to the Congress"). Just as a defense contractor cannot assert a property interest in the Pentagon continuing to buy aircraft carriers just because it once did so, so too Plaintiffs cannot claim that manufacturers have a right to dictate Medicare expenditures for future years because they have previously found the program profitable. *See, e.g.*, *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").

b. The absence of a protected property interest at stake here also defeats Plaintiffs' continued efforts to rely on the Sixth Circuit's utility rate-setting decision in *Michigan Bell*

Telephone Company v. Engler, 257 F.3d 587 (6th Cir. 2001). As courts have repeatedly explained—and as Defendants detailed in their opening brief—utilities "generally are compelled" by statute "to employ *their property* to provide services to the public. *Garelick*, 987 F.2d at 916 (emphasis added); *see also Minn. Ass'n of Health Care Facilities*, 742 F.2d at 446 (same). It is this imposition on a cognizable property interest that triggers a Fifth Amendment inquiry. *See Duquesne Light Co. v. Barasch*, 488 U.S. 299, 307 (1989) (noting that as "public utilities . . . [plaintiffs'] assets are employed in the public interest"). Thus, the court in *Michigan Bell* did not question whether regulation of the telephone providers' rate-setting for all customers affected their cognizable property interests. *See generally* 257 F.3d at 590-91. Here, however, the opposite is true: for all the reasons discussed above, the IRA does *not* implicate or imperil any property rights.

Of course, as Defendants previously explained, the reasoning of *Michigan Bell* is a particularly unstable platform for Plaintiffs' claims because that reasoning does not survive the Supreme Court's subsequent decision in *Verizon Communications, Inc. v. FCC*, 535 U.S. 467 (2002). *See* Defs.' Br. at 55-56. Try as they might to distinguish the claims at issue in the two cases, Plaintiffs cannot avoid the reality that *Verizon* rejected the exact legal standard that *Michigan Bell* employed. *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"). The Court ultimately need not wade into that thicket, however. Because "cases concerning public utilities are inapposite" in the Medicare context, *Minn. Ass'n of Health Care Facilities*, 742 F.2d at 446, this Court was correct to find that Plaintiffs' invocation of *Michigan Bell* fails "as a matter of law," *Chamber I*, 2023 WL 6378423 * 11.

* * *

Throughout their briefing in this case, Plaintiffs have failed to cite *a single* case finding conditions on Medicare participation to violate the Due Process Clause. That is not surprising. As

this Court correctly held, the "clear" law in this Circuit and beyond dictates that the Negotiation Program "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.*

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

Plaintiffs' First Amendment arguments likewise repeat the same conceptual errors that animated their opening brief. In particular, Plaintiffs continue to assert that signing agreements with CMS is a form of expression that they are "compelled" to undertake. Pls.' Opp'n at 52. It is not.

1. As a starting point, Plaintiffs' assertions that the IRA's agreements "force[] manufacturers to declare" a message fails to overcome the reality that the agreements are purely commercial arrangements. *Id*. As Defendants detailed in their opening brief, these agreements exist solely to memorialize manufacturers' voluntary undertaking of a commitment to participate in the Negotiation Program—and, ultimately, to charge Medicare beneficiaries no more than the negotiated prices. *See* Revised Guidance at 118-20. Healthcare providers and other entities execute similar agreements to memorialize their acceptance of the terms for participation across a range of federal healthcare programs. *See, e.g.*, 42 U.S.C. §§ 1395cc, 1396r-8(b)-(c), 1395w-102(b)(1). For example, the Medicare Participating Physician or Supplier Agreement uses the word "agreement" 29 times to indicate that the parties are entering a commercial arrangement and share a common understanding of their obligations. *See* CMS, Medicare Participating Physician or Supplier Agreement (CMS-460), https://perma.cc/U69K-MTJR.

Contrary to Plaintiffs' insistence, such agreements are "not directed at the communication of information" at all, and any conduct restriction "is imposed 'for reasons unrelated to the communication of ideas.'" *Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 291 (D.C. Cir. 2019) (quoting *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 569 (2001)). Any speech implicated by the execution of the agreement "is plainly incidental to the . . . regulation of conduct" that the agreements govern: namely, the establishment of future prices that the government will pay for

drugs. *Rumsfeld v. Forum for Acad. & Institutional Rts., Inc. (FAIR)*, 547 U.S. 47, 62 (2006); *see also Expressions Hair Design v. Schneiderman*, 581 U.S. 37, 47 (2017) (a "law's effect on speech [that is] only incidental to its primary effect on conduct" does not draw First Amendment scrutiny). Put another way, the only thing these agreements regulate are the actual *prices*, and the words used in the agreements are merely a means by which the regulation is given effect. These types of commercial arrangements in the service of "ordinary price regulation do[] not implicate constitutionally protected speech." *Nicopure*, 944 F.3d at 292 (citing *Expressions Hair Design*, 581 U.S. at 47); *see also Sorrell v. IMS Health Inc.*, 564 U.S. 552, 567 (2011) ("[T]he First Amendment does not prevent restrictions directed at commerce or conduct from imposing incidental burdens on speech); *Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence*, 731 F.3d 71, 77 (1st Cir. 2013) ("[P]rice regulations and other forms of direct economic regulation do not implicate First Amendment concerns.").

Notably, Plaintiffs do not even acknowledge that the agreements they protest have *any* commercial purpose. *See generally* Pls.' Opp'n at 53-54. Instead, they continue to argue that Congress's use of terms like "negotiation[]" "agreement" and "maximum fair price"—which Congress employed as statutory terms of art—compels manufacturers to endorse colloquial understandings of the words and phrases. *Id.* at 53. Of course, CMS's agreement includes an explicit disclaimer to the contrary—precisely to avoid the kind of misunderstanding Plaintiffs seem intent on creating. *See* CMS, Medicare Drug Price Negotiation Program Agreement ("Template Agreement"), https://perma.cc/6VG4-KKF6. Contrary to Plaintiffs' suggestion, the point of that disclaimer is not to "save" a "compelled-speech requirement" by disclaiming the otherwise expressive content of the agreement. Pls.' Opp'n at 54. Rather, the point is to highlight the obvious fact that the terms of the agreement are used solely as statutory terms of art, not as forms of colloquial expression about what is "fair."

It is this absence of expressive content in the agreement that distinguishes the IRA from the precedent Plaintiffs cite in their response. *See, e.g.*, *Expressions Hair Design*, 581 U.S. at 47 (First Amendment implicated by a law that did not regulate "the amount [merchants] are allowed

to collect from a cash or credit card payer" but instead directly targeted "how sellers may *communicate* their prices" (emphasis added)); *Nat'l Ass'n of Mfrs. v. SEC*, 800 F.3d 518, 530 (D.C. Cir. 2015) (label the government was requiring plaintiffs to affix to their products "was hardly factual and non-ideological" but rather was "a metaphor that conveys moral responsibility" and "requires an issuer to tell consumers that its products are ethically tainted" (citations omitted)); *Thompson v. Marietta Educ. Ass'n*, 972 F.3d 809, 812-13 (6th Cir. 2020) (rejecting First Amendment challenge to law that gave unions authority to be "the exclusive bargaining representative for all public employees" and thereby to "speak on [plaintiff's] behalf during collective-bargaining sessions"). Indeed, Plaintiffs identify *no* case in which a court found that the words of a contract are expressive merely because they were written and *could* be incorrectly understood as conveying a message. *See* Pls.' Opp'n at 53-55. That is not surprising. As the Supreme Court has emphasized, "'it has never been deemed an abridgment of freedom of speech or press to'" regulate conduct "'merely because the conduct was in part initiated, evidenced, or carried out by means of language, either spoken, written, or printed.'" *Expressions Hair Design*, 581 U.S. at 47 (quoting *FAIR*, 547 U.S. at 62).

Ultimately, Plaintiffs' argument that the commercial agreements between them and CMS convey a "message" is nothing more than an unsupported assertion that all contracts are necessarily expressive speech. By that logic, the Department of Defense would have to scrub every one of its contracts to ensure that they never use terms like "agree," "fair," or other terms that Plaintiffs view as potentially expressive. *Cf.* Cong. Resch. Serv., *Defense Primer: Dep't of Defense Contractors* (Jan. 17, 2023), https://crsreports.congress.gov/product/pdf/IF/IF10600 (noting that in fiscal year 2021, "DOD obligated more money on federal contracts ($397 billion in current dollars) than the contract spending of all other government agencies combined"). That cannot be correct. As the D.C. Circuit has observed, "the Supreme Court has long rejected the 'view that an apparently limitless variety of conduct can be labeled speech'" even when "the person engaging in the conduct intends thereby to express an idea." *Nicopure*, 944 F.3d at 291 (quoting *United States v. O'Brien*, 391 U.S. 367, 376 (1968), citing *Barnes v. Glen Theatre, Inc.*, 501 U.S. 560, 570 (1991)). And

Plaintiffs' "extraordinary argument, if accepted, would extend First Amendment protection to every commercial transaction"—contrary to current law. *Id.*

2. Plaintiffs' First Amendment concerns are all the more inapt given that participation in the Negotiation Program is a voluntary undertaking. *See supra* Section IV.B.1. If manufacturers are truly concerned that their signing of an agreement to negotiate will be—incorrectly—perceived as their adoption of the government's message, they can decline to participate in the program. In this way too, there is no compulsion for manufacturers to say—or to be perceived as saying—anything at all.

Contrary to Plaintiffs' claims, viewing the Negotiation Program this way does not raise the specter of it being an unconstitutional condition. *See* Pls.' Opp'n at 55. Even if the negotiation agreements raised First Amendment questions—which they do not, for all the reasons above—Congress is free to attach "conditions that define the limits of the government spending program." *Agency for Int'l Dev.*, 570 U.S. at 214. Here, of course, the program that Plaintiffs protest is the *negotiation* of prices. *See* 42 U.S.C. § 1320f-3(a). So, signing something termed an "agreement" after the completion of that negotiation—and promising to give Medicare beneficiaries the benefit of the agreed-upon price—is nothing more than "the activit[y] Congress wants to subsidize." *Agency for Int'l Dev.*, 570 U.S. at 214-15; *see also United States v. Am. Libr. Ass'n, Inc.*, 539 U.S. 194, 211 (2003) ("Within broad limits, 'when the Government appropriates public funds to establish a program it is entitled to define the limits of that program.'" (quoting *Rust v. Sullivan,* 500 U.S. 173, 194 (1991)).

Indeed, no portion of the agreement that Plaintiffs protest (nor the IRA generally) purports to "regulate speech outside the contours of the [Negotiation] [P]rogram" or places restrictions on the manufacturers themselves. *Agency for Int'l Dev.*, 570 U.S. at 214-15; *see also Rust*, 500 U.S. at 197 (explaining that the Court's "'unconstitutional conditions' cases involve situations in which the Government has placed a condition on the *recipient* of the subsidy . . . thus effectively prohibiting the recipient from engaging in the protected conduct outside the scope of the federally funded program"). Plaintiffs do not deny that they are free to continue saying anything they want

about the IRA, CMS, or the Negotiation Program—both in the course of negotiations and in public. So even if Plaintiffs were correct that the agreements are expressive (which, again, they are not) or create a "façade of consent" to the IRA, Plaintiffs would *still* be unable to establish that they attach an improper condition on government funds. Pls.' Opp'n at 56.

In the end, Plaintiffs' objection to the agreements boils down to the claim that they dislike the Negotiation Program and do not want to be *perceived* as supporting it. *See id.* 55-56. Put another way, Plaintiffs want to receive government money without the fear that some members of the public may conclude (plainly incorrectly) that Plaintiffs like how the government has made the money available. As a business model, this aspiration may be understandable. But "Congress is not required by the First Amendment to subsidize" Plaintiffs' preferred messaging. *Regan v. Tax'n With Representation of Wash.*, 461 U.S. 540, 546 (1983); *see also Am. Libr. Ass'n*, 539 U.S. at 212 ("'A refusal to fund protected activity, without more, cannot be equated with the imposition of a "penalty" on that activity.'" (quoting *Rust*, 500 U.S. at 193)); *see 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)). If manufacturers fear that their publicity campaign against the IRA is insufficient, and fear that participating in the Negotiation Program puts them in conflict with their firmly held principles, they are free to withdraw from the program. *See Chamber I*, 2023 WL 6378423, at *11. The IRA does not compel unwilling manufacturers to take—or be perceived as taking—the government's funds.

D. Even if the Court were to reach the merits of Plaintiffs' excise-tax claims, the tax is constitutional.

As discussed above, the Court should not reach the merits of Plaintiffs' two excise-tax claims because those claims are not redressable in this suit and because the AIA precludes a court from preemptively enjoining the assessment or collection of a tax. *See supra* Section III. If the Court nonetheless reaches the merits, Plaintiffs' tax claims still fail because the excise tax is not an "excessive fine" in violation of the Eighth Amendment, and because the tax is authorized by Congress's powers under the Taxing and Spending Clause and the Commerce Clause.

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

The excise tax does not run afoul of the Excessive Fines Clause of the Eighth Amendment because it is neither a "fine" nor an "excessive" one. *See* Defs.' Br. at 61-70. In response to Defendants' brief, Plaintiffs mostly rehash arguments they have already made. *See* Pls.' Opp'n at 57-62. Most noteworthy, however, is what Plaintiffs do not say and what cases they are not able to muster: Plaintiffs have still not cited a *single* case in which a tax was deemed to be "punishment for some offense"—that is, a "fine"—under the Excessive Fines Clause. Similarly, Plaintiffs do not identify any tax other than those with a connection to criminal conduct or criminal proceedings that was held to be "punishment for some offense" under *any* provision of the Constitution. Those omissions tell the Court all it needs to know: this Court would be breaking new ground if it were to hold that the IRA's excise tax—which has no connection to any criminal conduct or criminal proceedings, and which does not turn on any particular level of culpability—is an excessive fine in violation of the Eighth Amendment.

a. The only cases that Plaintiffs cite in which a tax was held to be punishment remain the two Double Jeopardy Clause cases cited in their opening brief: *Department of Revenue of Montana v. Kurth Ranch*, 511 U.S. 767 (1994), and *Dye v. Frank*, 355 F.3d 1102 (7th Cir. 2004). As discussed at length in Defendants' opening brief, *see* Defs.' Br. at 65-68, those decisions rested on features of the taxes in those two cases—state drug taxes imposed on criminal activity—that are wholly absent here. Plaintiffs do not even attempt to argue otherwise. Pls.' Opp'n at 59-60.[17] It is thus undisputed that Plaintiffs have not identified any tax like the one here, which is not predicated on the commission of a crime, that was held to be punishment.

[17] The only basis on which Plaintiffs try to distinguish *Kurth Ranch* is on the tax rate. That effort is flawed twice over. First, the Court's holding in *Kurth Ranch* did not turn on the tax rate. *See* 511 U.S. at 781 (the tax's high rate and deterrent purpose did "not necessarily render the tax punitive"; instead, "unusual features" and "anomalies" made the "exceptional" Montana tax punishment). Plaintiffs understandably do not assert that these "unusual features" are present here. Second, as to the tax rate, Plaintiffs are wrong on the facts, as Defendants have previously explained. *See* Defs.' Br. at 67. To repeat the point, the tax assessment in *Kurth Ranch* led to a $400 tax on every $100 the drug dealer charged for the drug; here, a manufacturer's excise tax obligations may be satisfied—assuming a manufacturer does not separately invoice the tax and assuming 271 days have passed such that the highest tax rate applies—by paying $95 in tax on every $100 the manufacturer charges for the drug.

Plaintiffs nonetheless fault Defendants for "spill[ing] a great deal of ink" on these two Double Jeopardy Clause cases. Pls.' Opp'n at 59. Plaintiffs have it backwards: Defendants analyzed those cases in detail because they were the only cases that Plaintiffs cited in their opening brief that involved a tax that was deemed to be punishment. And even Plaintiffs concede, in the same paragraph in which they criticize Defendants for correctly distinguishing *Kurth Ranch* and *Dye*, that these cases are relevant to the threshold question of whether the excise tax is a fine (*i.e.*, "punishment for some offense"): "[T]he [Excessive Fines and Double Jeopardy Clauses] involve overlapping questions about what constitutes 'punishment' (which is why Plaintiffs cited case law on both clauses in their opening brief)[.]" *Id.* at 59-60.

Kurth Ranch is relevant for another reason that Plaintiffs ignore: it demonstrates that the deterrent-in-part test on which Plaintiffs rely has never been applied by the Supreme Court in the tax context and, indeed, was squarely rejected in that case. *See* Defs.' Br. at 65-66. Plaintiffs do not even attempt to rebut this point. The only argument that Plaintiffs press as to *Kurth Ranch* is that it was a Double Jeopardy Clause case. That much is undisputed. But, just as Plaintiffs acknowledge that the Double Jeopardy Clause and Excessive Fines Clause cases previously treated the punishment determination as the "same under both doctrines," *see* Pls.' Opp'n at 60 n.23 (quoting *United States v. Alt*, 83 F.3d 779, 784 (6th Cir. 1996)), Defendants explained in their opening brief that the Court's rejection of the deterrent-in-part test for tax cases occurred *before* any distinction was recognized between the two clauses for purposes of determining whether an exaction constituted "punishment," *see* Defs.' Br. at 65-66. In other words, at the time *Kurth Ranch* was decided, an exaction was deemed "punishment for some offense" under either clause if it served in part to deter conduct, and *Kurth Ranch* rejected that test for taxes. *See Kurth Ranch*, 511 U.S. at 780 ("neither a high rate of taxation nor an obvious deterrent purpose automatically marks [a] tax as a form of punishment"). As other courts have recognized, *Kurth Ranch* "announc[ed] that the 'no deterrent purpose' rule of *Halper* [a Double Jeopardy Clause case] and *Austin* [an Excessive Fines Clause case] does not apply in all situations." *Artway v. Att'y Gen. of N.J.*, 81 F.3d 1235, 1258 (3d Cir. 1996). And, indeed, Plaintiffs do not identify any case in which

a court has held that a tax, on account of its having a partly deterrent purpose, constituted "punishment for some offense," either under the Excessive Fines Clause or under any other provision of the Constitution.

Defendants also distinguished two other decisions on which Plaintiffs relied in their opening brief: *Austin v. United States*, 509 U.S. 602 (1993), and *United States v. Bajakajian*, 524 U.S. 321 (1998). *See* Defs.' Br. at 62-64. Defendants did so because those were the only cases Plaintiffs cited—aside from an unpublished district court decision that Defendants also addressed, *see id.* at 64-65—in which a court held that the exaction at issue constituted a "fine" for purposes of the Excessive Fines Clause. As explained, however, the exactions in those cases—the *in rem* civil forfeiture in *Austin* and the criminal forfeiture in *Bajakajian*—bear no resemblance to the excise tax. *See id.* at 62-64. In response, Plaintiffs offer silence. The net result of the various points Plaintiffs have left unrebutted: to the parties' knowledge, no court has held that a tax—or even another exaction similar to the excise tax—was a "fine" under the Excessive Fines Clause.

Plaintiffs conclude their argument as to why the excise tax is a "fine" by asserting that "the government ignores" numerous decisions in which courts have held that "civil *penalties* are subject to scrutiny under the Excessive Fines Clause." Pls.' Opp'n at 60 (emphasis added). These cases have a few things in common. First, none of them were cited in Plaintiffs' opening brief. Second, none of them involved taxes. Third, *all* of them involved sanctions the legislature actually referred to as "fines," "penalties," or treble damages assessed in connection with a statutory penalty. *See Grashoff v. Adams*, 65 F.4th 910, 913 (7th Cir. 2023) (unemployment benefits "claimant who knowingly fails to disclose earnings on a weekly application must repay all benefits received for that week and is subject to a civil penalty of 25% of that forfeited amount"); *Pimentel v. City of Los Angeles*, 974 F.3d 917, 920 (9th Cir. 2020) ("civil fines for parking meter violations"); *WCI, Inc. v. Ohio Dep't of Pub. Safety*, 774 F. App'x 959, 960 (6th Cir. 2019) ("fine" for "nude dancing" "in contravention of Ohio law and liquor-controlled regulations"); *United States v. Aleff*, 772 F.3d 508, 512 (8th Cir. 2014) (analyzing False Claims Act liability provision, 31 U.S.C. § 3729(a)(1), which states any person who knowingly presents a false claim "is liable to the [government] for a

civil penalty" and treble damages); *United States v. Gurley*, 384 F.3d 316, 324 (6th Cir. 2004) (analyzing 42 U.S.C. § 9604(e)(5)(B), which states that a "court may assess a civil penalty not to exceed $25,000"). Fourth, all of these "fines" required a finding that the individual or entity penalized had engaged in culpable conduct. *See Grashoff*, 65 F.4th at 913 ("After an investigation, the Department [of Workforce Development] determined that [the claimant] *knowingly* violated the law and assessed a forfeiture and penalty[.]"); *Pimentel*, 974 F.3d at 923 ("[P]laintiffs are indeed *culpable* because there is no factual dispute that they violated Los Angeles Municipal Code § 88.13 for failing to pay for over-time use of a metered space."); *WCI, Inc.*, 774 F. App'x at 967 (analyzing fine imposed for violation of Ohio Admin. Code 4301:1-1-52(B)(2), which states that "no [liquor] permit holder . . . shall *knowingly or willfully* allow in and upon his licensed permit premises any persons to . . . [a]ppear in a state of nudity"); *Aleff*, 772 F.3d at 512 (analyzing 31 U.S.C. § 3729(a)(1)(A), which states that "any person who . . . *knowingly* presents . . . a false or fraudulent claim" is subject to a statutory penalty and treble damages);[18] *Gurley*, 384 F.3d at 325 (describing defendant's "wilful [sic] noncompliance" and noting that the district court considered the "*good or bad faith* of the defendant" "before arriving at its penalty"). Accordingly, none of these newly cited cases involve exactions similar to the excise tax, which is not a "fine" under the Eighth Amendment.

b. Even if Plaintiffs could establish that the excise tax is a "fine" for Excessive Fines Clause purposes, it is not an "excessive" one. As a threshold matter, the test for determining gross disproportionality confirms that the excise tax here is not punishment. *See* Defs.' Br. at 68-69. Plaintiffs mischaracterize this point. *See* Pls.' Opp'n at 61 (writing that Defendants "backtrack[]" after "briefly suggest[ing] that the enormous chasm between the amount of the exaction and the reprehensibility of the conduct it targets is a reason not to apply the Excessive Fines Clause at

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[18] Plaintiffs cite three other False Claims Act cases. *See* Pls.' Opp'n at 60 (citing *Yates v. Pinellas Hematology & Oncology, P.A.*, 21 F.4th 1288, 1308 (11th Cir. 2021); *U.S. ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 389 (4th Cir. 2015); *United States v. Mackby*, 261 F.3d 821, 830 (9th Cir. 2001)). All of them involve the same penalty and treble-damages provision, 31 U.S.C. § 3729(a)(1)(A), and all of them required a finding that the defendant "knowingly" presented a false claim, *id.*

all"). There has been no "backtracking." *Id.* Rather, Defendants argued—and still maintain—that the excessiveness test, which instructs a court to "compare the amount of the [fine] to the gravity of the defendant's offense," *Bajakajian*, 524 U.S. at 336-37, requires an "offense" in the first instance. And there is no "offense" here, as that term is used in the Excessive Fines Clause cases—a point on which the parties appear to agree, given that Plaintiffs repeatedly put the term "offense" in quotation marks. *See* Pls.' Opp'n at 26 (referring skeptically to the idea that there is any "'offense'" in "refusing to 'agree' to provide access" to a selected drug at a negotiated price); *id.* at 61 (alleging excise tax "would be grossly disproportionate relative to the 'offense' of declining to submit" to the Negotiation Program).

If the Court nonetheless were to apply the *Bajakajian* factors, Defendants would still prevail. In applying the test, "substantial deference" to Congress is required—a point Plaintiffs do not dispute. *Solem v. Helm*, 463 U.S. 277, 290 (1983); *see also Bajakajian*, 524 U.S. at 336 ("judgments about the appropriate punishment for an offense belong in the first instance to the legislature"). And that is a high bar given that, at this stage, before any excise tax has been assessed or collected, Plaintiffs are challenging whether assessment of the excise tax at a rate equal to—or, in Plaintiffs' eyes, *below*—the rate established by Congress would violate the Excessive Fines Clause. Plaintiffs do not identify a single case in which a civil penalty assessed within or below the range set forth by Congress was deemed excessive. Indeed, in the decisions involving civil fines and penalties that Plaintiffs cite for the first time in their latest brief, *see* Pls.' Opp'n at 60, none of the courts held that the fine or penalty was excessive in violation of the Eighth Amendment. And several of those courts concluded that the fine was not excessive on the basis that the penalty assessed was at or below the one authorized by statute. *See, e.g.*, *Yates*, 21 F.4th at 1315 ("As to the imposed statutory penalties, they are lower than the potential maximum penalties under the FCA and other statutes."); *Aleff*, 772 F.3d at 513 ("While the judgment is about 4.3 times the actual damages, it is within the [False Claim Act's] statutory limits."); *Gurley*, 384 F.3d at 325 ("With a statutory maximum of $25,000 per day in potential civil penalties, an

imposition of tens of millions of dollars could have been assessed in this case, but only a fraction of that amount was ultimately levied: $1,908,000.”).

Defendants analyzed the *Bajakajian* factors in their opening brief, *see* Defs.’ Br. at 69-70, and Plaintiffs do not dispute much of that analysis, *see* Pls.’ Opp’n at 61-62. For example, Plaintiffs do not contest that the first factor is not met given that 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). And, as to the second and third factors, Plaintiffs do not dispute that here, unlike in *Bajakajian*, a manufacturer that chooses to continue participating in Medicare, but declines to agree to a maximum fair price and sells that drug to Medicare beneficiaries at a higher price than the statutory ceiling, would impose significant costs on the public fisc generally and seniors specifically, and that the excise tax is not grossly disproportional to that harm. The one point that Plaintiffs do dispute is the tax rate, an argument they repeat throughout their brief, *see* Pls.’ Opp’n at 23-25, 61-62, and an argument to which Defendants have already responded, *see* Defs.’ Br. at 8 (“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)” (citing FAC ¶ 119)); *see also id.* at 67; *supra* at 50 n.17.[19]

Because the excise tax is neither a “fine” nor an “excessive” one, if the Court reaches the merits of Plaintiffs’ Eighth Amendment claim (Count 3), that claim should be rejected.

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

Finally, Plaintiffs insist that even if the Court sustains the excise tax under the Eighth Amendment, it should still hold that it exceeds all of Congress’s enumerated powers in the Constitution. That is an ambitious argument. The Constitution explicitly authorizes Congress

[19] Plaintiffs repeatedly refer to what “the government does not appear to dispute,” often in connection with the legal consequences of penalties that operate differently than the tax at issue here does. *See, e.g.*, Pls.’ Opp’n at 61 (the “government does not appear to dispute that a penalty of 1,900%, or even 185%, would be grossly disproportionate relative to the ‘offense’ of” declining to participate in the Negotiation Program). Defendants do not concede any of these points; rather, Defendants are simply not addressing legal issues beyond those presented by the § 5000D tax.

(1) to "lay and 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 IRA's excise tax.

a. The excise tax is first authorized by Congress's power to "lay and 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. In arguing to the contrary, Plaintiffs continue to rely on their confident prediction, based on the statute's legislative history, that this never-before-implemented excise tax "will raise *zero* revenue." Pls.' Opp'n at 63. Defendants have already explained why "Plaintiffs' descriptions of these legislative projections are . . . overstated," Defs.' Br. at 73 n.23—an explanation to which Plaintiffs do not meaningfully respond. But regardless, according to the Supreme Court, "[i]t is beyond serious question that a 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). To get around that binding precedent that is fatal to their theory, Plaintiffs dismiss it as "dicta" that "has been superseded by the test set forth in *NFIB*." Pls.' Opp'n at 63. That is wrong on multiple levels.

First, that statement in *Sanchez* was not dicta. Helpfully, the subsequent paragraph begins with an unusually explicit statement to that effect: "These principles are controlling here." *Sanchez*, 340 U.S. at 45. Whatever the line between holding and dicta, it is easy to categorize the "controlling" "principles" of a case as part of the holding.

Second, "[e]ven if this were dicta," as the Sixth Circuit has cautioned, "Supreme Court dicta is persuasive and cannot be ignored by lower courts for no good reason." *Cunningham v. Shoop*, 23 F.4th 636, 659 n.7 (6th Cir. 2022), *cert. denied*, 143 S. Ct. 37. There is no good reason to do so here.

Third, whether holding or dicta, the idea that *Sanchez* has been undermined by *NFIB* would be news to the majority in *NFIB*—which cites this very passage in *Sanchez*, supportively, for the

proposition that "we have upheld such obviously regulatory measures as taxes on selling marijuana and sawed-off shotguns." *NFIB*, 567 U.S. at 567 (citing *Sanchez*, 340 U.S. at 44-45). And it did so in the course of holding that the challenged provision of the Affordable Care Act *survived* as a valid exercise of the taxing power—even though (just as Plaintiffs argue here) it was motivated by factors other than purely raising revenue. As the Court put it in *NFIB*—just a few sentences after a citation to *Sanchez*—"[t]hat § 5000A seeks to shape decisions about whether to buy health insurance does not mean that it cannot be a valid exercise of the taxing power." *Id.* Much the same could be said about the tax at issue here.

Fourth, at times, Plaintiffs seek not to undermine *Sanchez*, but to distinguish it, on the grounds that (according to a footnote in the Solicitor General's brief) the tax at issue in *Sanchez* had produced $5,445.90 of revenue in the relevant fiscal year, which Plaintiffs estimate to be worth "about $70,000 in today's dollars." Pls.' Opp'n at 64. But to suggest that the tax at issue in *Sanchez* was constitutional because it generated a few thousand dollars of revenue—a rounding error in the federal budget—while the IRA's excise tax is unconstitutional because Plaintiffs *predict* it may generate *zero* revenue, would turn constitutional law into a bookkeeping exercise, better suited to accountants than lawyers. Nothing in *NFIB* requires that bizarre result.

Consider the arbitrary consequences of Plaintiffs' math-centered theory. Pharmacyclics's cancer drug, Imbruvica, costs (on average) more than $130,000 per patient, per year. *See* CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026* (Aug. 2023), https://perma.cc/PJ8V-Y6XY ("CMS Fact Sheet"). So if Pharmacyclics sells just a few months' worth of Imbruvica, for one patient, in a manner that triggers excise-tax liability, *see supra* at 21-22 (explaining how tax liability is assessed for a "divisible tax"), it will have exceeded the revenue generated by the tax upheld by the Supreme Court in *Sanchez*—and Plaintiffs' distinction falls apart. And of course, on its face, the IRA's excise tax could easily generate many multiples of that number—the year before its selection, approximately 20,000 Medicare beneficiaries used Imbruvica to treat their blood cancer. *See* CMS Fact Sheet. Indeed, Plaintiffs themselves use to their rhetorical benefit what they describe as the "unbearable" impact

of the excise tax, and the "crushing burden" they say it will impose, Pls.' Opp'n at 26-27—descriptors that only make sense in a world in which the excise tax is raising large amounts of revenue. Especially in a facial challenge like this one—in which Plaintiffs "must establish that no set of circumstances exists under which the Act would be valid," *United States v. Salerno*, 481 U.S. 739, 745 (1987)—that is more than enough to sustain the excise tax.

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

b. Even if the Court were to conclude that the "excise tax" is neither an "excise" nor a "tax" within the meaning of the Taxing and Spending Clause, Plaintiffs' enumerated-powers claim would still fail. That is because the excise tax is also independently justified under the Commerce Clause (with or without resort to the Necessary and Proper Clause).

Plaintiffs' only Commerce Clause argument is that "the IRA runs afoul of *NFIB*'s limiting principle" by regulating "inactivity" instead of "activity." Pls.' Opp'n at 66. Plaintiffs emphasize that "[t]he distinction between doing something and doing nothing would not have been lost on the Framers," *id.* (quoting *NFIB*, 567 U.S. at 555)—but the excise tax applies only to manufacturers that are "doing something," by selling selected drugs to Medicare beneficiaries in interstate commerce. In other words, as Defendants have explained, "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." Defs.' Br. at 74. The plain text of the Internal Revenue Code makes that impossible to seriously dispute. *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)).

Plaintiffs come close to acknowledging this reality, when describing Defendants' arguments as an assertion "that the 'excise tax' is *nominally* 'tied to sales of selected drugs,' and that 'sales are quintessential commercial activity.'" Pls.' Opp'n at 66 (quoting Defs.' Br. at 74-75) (emphasis added). Plaintiffs similarly state without explanation that the excise tax is "not a

genuine sales tax." *Id.* (emphasis added). But adding the word "nominally" or "genuine" before the dispositive feature of the challenged statute is rhetoric, not argument. And there is nothing nominal or ingenuine about the way that excise-tax liability is "imposed on the sale" of drugs in the manner specified by Congress in the text of the statute. 26 U.S.C. § 5000D(a). So the unique and dispositive feature of the Supreme Court's Commerce Clause analysis in *NFIB*—that is, "the distinction between doing something and doing nothing," 567 U.S. at 555—cuts sharply against Plaintiffs here.

To resist this conclusion, Plaintiffs insist that "the 'excise tax' is designed to *prevent*" sales of selected drugs at certain prices, and then "replace them with a new course of dealing with CMS." Pls.' Opp'n at 66. But even accepting that description of the excise tax's purpose, it proves Defendants' point—after all, the "course of dealing" Plaintiffs have in mind is still the *sale* of selected drugs. In other words, whether participating manufacturers sell selected drugs to Medicare at negotiated prices (thus avoiding excise-tax liability) or at prices unilaterally dictated by manufacturers alone (thus incurring excise-tax liability), it will always be the case that the excise tax is targeted at actual *sales* of actual drugs. No matter the price of those sales, that is classic commercial activity, which falls squarely within the scope of Congress's powers under the Commerce Clause.

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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