UNITED STATES DISTRICT COURT
FOR THE 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-TMR-PBS Judge Thomas M. Rose Magistrate Judge Peter B. Silvain, Jr.

DEFENDANTS' OPPOSITION TO
PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

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INTRODUCTION

For more than 30 years, Congress has imposed limits on how much federal agencies pay for prescription drugs. Manufacturers who wish to sell their drugs to the Department of Defense and the Department of Veterans Affairs do so at statutorily defined ceiling prices, and both agencies have authority to negotiate prices further below those ceilings. *See* 38 U.S.C. § 8126(a)-(h). Building on this model in last August's Inflation Reduction Act (IRA), Pub. L. No. 117-169, Congress granted the Secretary of Health and Human Services similar authority to negotiate how much Medicare will pay for some of the costliest, single-source, brand-name prescription drugs. *See* 42 U.S.C. § 1320f(a) (establishing the "Negotiation Program"). In this way, Congress sought to reduce government spending on pharmaceutical products that lack generic (or biosimilar) competition and account for a disproportionate share of Medicare's expense. 42 U.S.C. § 1320f-1(b), (d), (e). But, as with Medicare generally, Congress made participation in the Negotiation Program voluntary. Manufacturers that do not wish to make their drugs available at negotiated prices can avoid doing so by, for example, withdrawing from Medicare and Medicaid or by divesting their interests in the relevant drugs before 2026, when the negotiated prices would first take effect. The choice is theirs.

Not surprisingly, drug manufacturers lobbied hard against legislative efforts to seat the Secretary at the negotiating table. And now that their lobbying failed, manufacturers and interest groups have run to court, filing multiple suits around the country challenging the statute on its face. At the forefront of that effort, Plaintiffs in this case (but no other) have moved for a preliminary injunction, seeking to stop the Negotiation Program before any negotiations even start. *See* Pls.' Mot., ECF No. 29; Pls.' Br., ECF No. 29-1 (Pls.' Br.). But their motion fails at every step.

As a threshold matter, for the reasons explained in Defendants' concurrently filed motion to dismiss, Plaintiffs have not demonstrated Article III standing to pursue any of their claims; that is reason alone to deny their motion and dismiss the entire case. *See* Defs.' Mot., ECF No. 33 (MTD). But if the Court reaches the merits, Plaintiffs fare no better. Because Plaintiffs challenge the Negotiation Program on its face, they bear a significant burden of demonstrating that the program is "unconstitutional in all its applications." *Warshak v. United States*, 532 F.3d 521, 529 (6th Cir. 2008)

(en banc). Here, however, Plaintiffs' entire argument rests on one Sixth Circuit case dealing with price controls imposed on public utilities, *Michigan Bell Tel. Co. v. Engler*, 257 F.3d 587 (6th Cir. 2001)—and the Supreme Court rejected the central rule of that case in a subsequent decision the Plaintiffs do not even cite. *See Verizon Commc'ns, Inc. v. FCC*, 535 U.S. 467 (2002). So even by its own terms, Plaintiffs' argument is untenable. And established precedent forecloses Plaintiffs' efforts to analogize the Negotiation Program to utility regulation in any event.

Unlike regulated utilities that are required by law to provide services to the public, manufacturers are not obligated to participate in the Negotiation Program. Rather, Congress has merely sought to limit how much it pays for high-cost pharmaceuticals by "expressly connect[ing]" the Negotiation Program to "manufacturer[s'] *voluntary* participation" in Medicare and Medicaid. Centers for Medicare & Medicaid Services, Medicare Drug Price Negotiation Program: Revised Guidance, at 120 (June 30, 2023), https://perma.cc/K6QB-C3MM (emphasis added) (Revised Guidance); *see also* Pub. L. No. 117-169, § 11003 (enacting 26 U.S.C. § 5000D(c)). Courts of appeals—including the Sixth Circuit—have repeatedly confirmed that imposing voluntary conditions on federal health-care spending is Congress's prerogative and does not implicate property interests protected by the Fifth Amendment. Because "participation in the Medicare program is a voluntary undertaking," *Livingston Care Ctr. v. United States*, 934 F.2d 719, 720 (6th Cir. 1991), Plaintiffs cannot succeed on the only claim on which they seek preliminary relief.

The remainder of the preliminary-injunction factors likewise cut against Plaintiffs' motion. Even setting aside Plaintiffs' threshold failure to adequately plead an Article III injury, Plaintiffs cannot show irreparable harm absent an injunction, not least because this case can be fully litigated to final judgment well before 2026, when any negotiated prices would first take effect. And the public's interests would be gravely disserved by acceding to Plaintiffs' premature efforts to take down the entirety of the Negotiation Program—which achieves a longstanding goal of controlling skyrocketing Medicare spending and making drugs more affordable for seniors—before that program even begins.

BACKGROUND

I. Medicare and the IRA's Drug Negotiation Program

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

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

Although this model was relatively economical at first, it has led to rapidly rising costs to Medicare in recent years. Medicare Part D spending has doubled over the last decade, and it "is projected to increase faster than any other category of health spending." S. REP. NO. 116-120, at 4 (2019); *see also* Cong. Budget Office (CBO), *Prescription Drugs: Spending, Use, and Prices* 16 (Jan. 2022), https://perma.cc/9WPC-VLFC. Much of that increase is attributable to a "relatively small number of drugs [which] are responsible for a disproportionately large share of Medicare costs." H.R. Rep. No. 116-324, pt. II, at 37 (2019). Congressional reports have found that generic competitors face many legal and practical obstacles to market entry, sometimes leaving only a single manufacturer of a particular drug on the market for extended periods of time. *See* Staff of H. Comm on Oversight and

Reform, Drug Pricing Investigation: AbbVie – Humira and Imbruvica 36 (May 2021). And the payment formula for drugs covered under Part B permits a manufacturer of a drug without generic competition to "effectively set[] its own Medicare payment rate." Medicare Payment Advisory Comm'n, *Report to the Congress: Medicare and the Health Care Delivery System* 84 (June 2020), https://perma.cc/5X4R-KCHC. The result has been a shift of financial burden to the Medicare program, which undermines the program's premise of leveraging market competition to reduce prices for beneficiaries and taxpayers. *Id.* at 120.

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

To carry out the Negotiation Program, the statute requires CMS to first identify a set of negotiation-eligible drugs; the agency is then to select up to 10 such drugs for negotiation for price applicability year 2026, up to 15 drugs for price applicability years 2027 and 2028, and up to 20 for price applicability year 2029 and for subsequent years. *Id.* § 1320f-1(a)-(b). After selecting the drugs, CMS is directed to negotiate with the manufacturer of each selected drug in an effort to reach agreement on a "maximum fair price" for that drug. *Id.* § 1320f-3. In formulating offers during the course of those negotiations, the statute requires CMS to consider numerous categories of information, including (1) "[r]esearch and development costs of the manufacturer for the drug and the extent to which the manufacturer has recouped" those costs, (2) current "costs of production and distribution," (3) prior "Federal financial support for . . . discovery and development with respect to

the drug," and (4) evidence about alternative treatments. *Id.* § 1320f-3(e). In hopes of achieving meaningful savings to the American people, Congress also imposed a "ceiling for [the] maximum fair price," which it tied to specified pricing data for the subject drugs. *Id.* § 1320f-3(c). Congress did not impose a floor, but directed CMS to "aim[] to achieve the lowest maximum fair price" that manufacturers will accept. *Id.* § 1320f-3(b)(1).

CMS will sign an agreement with willing manufacturers to negotiate prices for selected drugs. *Id.* § 1320f-2. If those negotiations prove successful, the manufacturer will then sign a final agreement to provide Medicare beneficiaries access to the drug at the negotiated price. *Id.* A manufacturer that does not wish to sign such an agreement—or to otherwise participate in the Negotiation Program—has several options. It can continue selling its drugs to Medicare beneficiaries at non-negotiated prices and pay an excise tax (which is calculated as a percentage of the sales of designated drugs dispensed, furnished, or administered to individuals under the terms of Medicare). 26 U.S.C. § 5000D(a)-(d); IRS Notice No. 2023-52 (Aug. 4, 2023), https://perma.cc/B9JZ-ZG7P. It can continue selling its other drugs to Medicare but transfer its interest in the selected drug to another entity, which can then make its own choices about negotiations. *See* Revised Guidance at 131-32. Or it can withdraw from the Medicare and Medicaid programs—in which case it will incur no excise tax and no other liability. *See id.* at 33-34, 131-32; 26 U.S.C. § 5000D(c)(1).

Like other market systems, the Negotiation Program thus gives a manufacturer a choice: it can sell its wares at prices a buyer is willing to pay, or it can take its business elsewhere.

II. CMS's Implementation of the Negotiation Program

Although the IRA provides a wealth of criteria and detail regarding the selection of drugs, the negotiation process, and the requirements of any agreement, Congress also recognized that implementing a new program of such complexity would require a plethora of operational and policy decisions within the new statutory framework. Accordingly, Congress directed CMS to implement the Negotiation Program through "program instruction or other forms of program guidance" through 2028. Pub. L. No. 117-169, § 11001(c). Following that statutory mandate, CMS issued initial guidance on March 15, 2023, explaining how it intended to implement certain aspects of the statute and

soliciting public input. *See* CMS, Initial Guidance (Mar. 15, 2023), https://perma.cc/8X4K-CVD8. After considering more than 7,500 public comments "representing a wide range of views," CMS published Revised Guidance on June 30, 2023. Revised Guidance at 1–2.

The Revised Guidance describes several aspects of the Negotiation Program for initial price applicability year 2026, including (1) the methodologies by which CMS will identify drugs that are selected for negotiation; (2) the negotiation process, including the types of data that CMS will consider, the procedures for exchange of offers and counteroffers, and the public explanations CMS will provide for negotiated prices; and (3) the procedures for manufacturers to follow if they decide at any point not to participate. *Id.* at 2-8. On that last point, the Revised Guidance expressly provides that if a manufacturer "decides not to participate in the Negotiation Program," CMS will "facilitate an expeditious termination of" the manufacturer's Medicare agreements before the manufacturer would incur liability for any excise tax, so long as the manufacturer notifies CMS of its desire to withdraw at least 30 days in advance of when that tax would otherwise begin to accrue. *Id.* at 33–34. The Revised Guidance also notes that manufacturers who wish to remain in the Medicare and Medicaid programs but who do not wish to negotiate can divest their interest in the selected drug(s). *Id.* at 131-32.

As required by Congress, CMS will publish the list of drugs selected for negotiation for initial price applicability year 2026 by September 1, 2023. *See id.* at 91. Manufacturers of the selected drugs shall choose whether to enter into agreements to negotiate by October 1, 2023; negotiations will conclude by August 1, 2024. *Id.* at 91–92; *see* 42 U.S.C. §§ 1320f(b), (d), 1320f-2(a), 1320f-3(b). Any agreed-upon prices for the selected drugs will first take effect on January 1, 2026—about two-and-a-half years from now. 42 U.S.C. §§ 1320f(b), 1320f-2(a); Revised Guidance at 92.

ARGUMENT

A preliminary injunction is an "extraordinary and drastic remedy" that "may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Fowler v. Benson*, 924 F.3d 247, 256 (6th Cir. 2019) (quotation omitted). "A plaintiff seeking a preliminary injunction must establish [1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, *and* [4] that an injunction

is in the public interest." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008) (emphasis added). Where, as here, the federal government is the defendant, the third and fourth factors merge into a consideration of the public interest. *Nken v. Holder*, 556 U.S. 418, 435 (2009). But, as the Sixth Circuit has recently explained, "where there is no likelihood of *either* success on the merits or irreparable harm, an injunction is unwarranted—regardless of the showing on the other factors." *Union Home Mortg. Corp. v. Cromer*, 31 F.4th 356, 366 (6th Cir. 2022); *see also Winter*, 555 U.S. at 20.

Defendants' motion to dismiss (which the Court should consider first) explains why Plaintiffs have failed properly to invoke this Court's jurisdiction. Those defects are sufficient to deny Plaintiffs' request for a preliminary injunction outright. *See, e.g.*, *Munaf v. Geren*, 553 U.S. 674, 691 (2008) (jurisdiction is a necessary part of the preliminary-injunction inquiry). But even beyond those defects, Plaintiffs fail to establish any of the injunction factors.

I. Plaintiffs Are Unlikely to Succeed on the Merits

First and foremost, Plaintiffs cannot succeed on the merits of their Due Process Clause challenge—the only claim on which they seek preliminary relief.[1] That challenge begins and ends with Plaintiffs' attempt to analogize the Negotiation Program to a utility rate cap that the Sixth Circuit, in 2001, found to be "confiscatory" in violation of the Fourteenth Amendment. *Michigan Bell*, 257 F.3d at 592–93; Pls.' Br. at 1-2. But a long line of precedent unmentioned in Plaintiffs' motion—including from the Sixth Circuit—forecloses treating conditions on the "wholly voluntary" Medicare program as akin to utility regulation. *Baptist Hosp. E. v. HHS*, 802 F.2d 860, 869 (6th Cir. 1986). Creating the Negotiation Program is well within Congress's power to control federal spending, does not in any way compel manufacturers, and raises no "Fifth Amendment due process" concerns under any standard, *id.*—much less under the demanding standard of a facial challenge, which requires Plaintiffs to demonstrate that the program is "unconstitutional in all its applications," *Warshak*, 532 F.3d at 529.

[1] Because of this choice by Plaintiffs, the Court need not (and should not) address the merits of any of Plaintiffs' other claims. *See, e.g.*, *Heid v. Mohr*, No. 19-3259, 2020 WL 13561751, at *5 (6th Cir. Mar. 30, 2020) (affirming denial of preliminary-injunction motion on claim-by-claim basis, considering only those claims as to which plaintiff argued it had a likelihood of success on the merits).

A. The Negotiation Program is not confiscatory because participation is voluntary.

For decades, courts analyzing price regulation under Medicare have uniformly rejected the same analogy to utility-rate regulation that Plaintiffs attempt to draw here. *See, e.g.*, *Garelick v. Sullivan*, 987 F.2d 913, 916 (2d Cir. 1993); *see also Minn. Ass'n of Health Care Facilities, Inc. v. Minn. Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984) ("Cases concerning public utilities are inapposite" to voluntary programs like Medicaid and Medicare). For good reason.

1. Although Plaintiffs (at times) present their claims through the lens of the Due Process Clause of the Fifth Amendment, the Supreme Court has made clear that the "Constitution[al] protect[ion] [of] utilities from . . . confiscatory" rates derives from "the Takings Clause of the Fifth Amendment," which prohibits the taking of private property for public use without just compensation. *Duquesne Light Co. v. Barasch*, 488 U.S. 299, 299 (1989); *see Michigan Bell*, 257 F.3d at 593 (citing *Duquesne Light* as the operative standard). And it is well-established that a "property owner must be *legally compelled* to engage in price-regulated activity for regulations to" impair a property interest that the Fifth Amendment protects. *Garelick*, 987 F.2d at 916 (emphasis added); *see, e.g., Bowles v. Willingham*, 321 U.S. 503, 517–18 (1944) (rent controls do not constitute prohibited taking because statute did not require landlords to offer their apartments for rent). Utilities—like the phone companies in *Michigan Bell*, 257 F.3d at 591—"generally are compelled" by statute "to employ their property to provide services to the public, [so] the Fifth Amendment requires regulators to provide utilities with reasonable compensation for their services," *Garelick*, 987 F.2d at 916. By contrast, where an entity "voluntarily participates in a price-regulated program or activity, there is no legal compulsion to provide service and thus there can be no" deprivation of property at all. *Id.* (citing cases); *see, e.g.*, *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1007 (1984) (a "voluntary submission of data . . . in exchange for the economic advantages of" a program "can hardly be called a taking"); *Franklin Mem'l Hosp. v. Harvey*, 575 F.3d 121, 129 (1st Cir. 2009) ("Of course, where a property owner voluntarily participates in a regulated program, there can be no unconstitutional taking."). And that is the case with Medicare.

As courts—including the Sixth Circuit—have repeatedly explained, "participation in the Medicare program is a voluntary undertaking." *Livingston Care Ctr.*, 934 F.2d at 720; *see Baptist Hosp.*, 802 F.2d at 869–70 (same); *see also Baker Cnty. Med. Servs., Inc. v. U.S. Atty. Gen.*, 763 F.3d 1274, 1279–80 (11th Cir. 2014) (surveying cases); *Garelick*, 987 F.2d at 917 (same). "Unlike ordinary legislation, which 'imposes congressional policy' on regulated parties 'involuntarily,' Spending Clause legislation," like Medicare, "operates based on consent: 'in return for federal funds, the [recipients] agree to comply with federally imposed conditions.'" *Cummings v. Premier Rehab Keller, PLLC*, 142 S. Ct. 1562, 1570 (2022) (quoting *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 16, 17 (1981)). So whether confronting limits on physician fees, nursing-home payments, or hospital reimbursements, courts have been unequivocal—providers are not required to serve Medicare beneficiaries, and thus the government deprives them of no property interest for purposes of the Fifth Amendment when it imposes caps on the amount the government will reimburse. *Baptist Hosp.*, 802 F.2d at 869–70; *see also Se. Ark. Hospice, Inc. v. Burwell*, 815 F.3d 448, 450 (8th Cir. 2016) (no taking because plaintiff "voluntarily chose to participate in the Medicare hospice program"); *Baker Cty.*, 763 F.3d at 1279–80 (rejecting hospital's "challenge [to] its rate of compensation in a regulated industry for an obligation it voluntarily undertook . . . when it opted into Medicare"); *Franklin Mem'l*, 575 F.3d at 129–30; *Garelick*, 987 F.2d at 916–19; *Burditt v. HHS*, 934 F.2d 1362, 1376 (5th Cir. 1991); *Whitney v. Heckler*, 780 F.2d 963, 972 (11th Cir. 1986) ("[A]ppellants are not required to treat Medicare patients, and the temporary freeze is therefore not a taking within the meaning of the Fifth Amendment."). If a provider dislikes the conditions offered by the government, it can simply withdraw from the program. *Baptist Hosp.*, 802 F.2d at 869-70; *see generally Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc.*, 570 U.S. 205, 214 (2013) ("[I]f a party objects to a condition on . . . federal funding, its recourse is to decline the funds.").

The Negotiation Program is no different. The IRA regulates neither the prices manufacturers may charge for drugs generally nor the conduct of manufacturers that do not participate in Medicare or Medicaid. *See, e.g.*, 42 U.S.C. § 1320f-1(b), (d). Rather, Congress established the Negotiation Program in an effort to reduce how much Medicare pays for selected drugs provided to Medicare beneficiaries. *See id.* § 1320f-2(a)(2). As CMS noted, "the IRA expressly connects a [] [m]anufacturer's

financial responsibilities under the voluntary Negotiation Program to that manufacturer's voluntary participation" in Medicare and Medicaid. Revised Guidance at 120; *see also* 26 U.S.C. § 5000D(c)(1) (providing that tax consequences are only applicable if the manufacturer continues to participate in Medicare and Medicaid). Drug manufacturers that do not wish to make their drugs available to Medicare beneficiaries at negotiated prices can avoid doing so by withdrawing from the Medicare and Medicaid markets. *See* Revised Guidance at 120-21, 129-30.[2] Alternatively, manufacturers can remain in those markets, but divest their interest in the selected drugs. *Id.* at 131-32.

Like every other pricing structure in Medicare, the Negotiation Program thus does not compel manufacturers to surrender their property—at any price. As the Sixth Circuit explained in rejecting a similar "Fifth Amendment due process" challenge, "[i]f any provider fears that its participation will drive it to insolvency, it may withdraw from participation." *Baptist Hosp.*, 802 F.2d at 869-70.

2. In an apparent attempt to evade this well-settled precedent, Plaintiffs suggest that the IRA makes it impossible for manufacturers to withdraw from the Negotiation Program without incurring a sizeable tax or a penalty—thus creating compulsion to participate. Pls.' Br. at 8. But Plaintiffs are, again, mistaken.

Section 11003 of the IRA provides that manufacturers will incur no tax if they cease participating in Medicare and Medicaid prior to the statutory deadline to enter into an agreement to negotiate—or, if they have initially agreed to negotiate, prior to the statutory deadline to enter into a final pricing agreement with CMS. *See* 26 U.S.C. §§ 5000D(b)(1)-(2) (defining periods when tax would take effect); *id.* § 5000D(c)(1)(A)(i)-(ii) (providing that the excise tax will be suspended "beginning on the first date on which" "none of the drugs of the manufacturer" are covered by Medicare).[3] If manufacturers choose to withdraw from Medicare, the Social Security Act (SSA) provides that the relevant Medicare-participation agreements can be terminated by CMS within 30 days. *See* 42 U.S.C.

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

[3] Section 5000D(c) also conditions suspension of the tax on a manufacturer giving notice of termination of its drug rebate agreement under *Medicaid*. 26 U.S.C. § 5000D(c)(2). But, unlike with the Medicare agreements, that notice itself is sufficient. *Id.*

§§ 1395w-114a(b)(4)(B)(i), 1395w-114c(b)(4)(B)(i). Relying on these provisions, CMS's Revised Guidance explains that if a "Manufacturer determines . . . that it is unwilling to continue its participation in the Negotiation Program and provides a termination notice," CMS will treat that determination as providing "good cause to terminate the [] Manufacturer's agreement(s) . . . and thus facilitate an expedited" termination within 30 days. Revised Guidance at 130. "As a result of these procedures," CMS detailed, "any manufacturer that declines to enter an Agreement for the Negotiation Program may avoid incurring excise tax liability by submitting the notice and termination requests . . . 30 days in advance of the date that excise tax liability otherwise may begin to accrue." *Id.* at 33-34.

That timeline provides manufacturers plenty of flexibility. Under the IRA's schedule, a manufacturer will know whether its drug is selected for the first set of negotiations at least thirty days before any tax liability (for not signing a negotiation agreement and then selling the drug) would trigger. *See* 42 U.S.C. § 1320f(d)(1) (first list of drugs for negotiation published by September 1, 2023); 26 U.S.C. § 5000D(b)(1) (tax triggered on October 2, 2023, absent manufacturer signing agreement to negotiate). The manufacturer will know how those negotiations are going far in advance of August 2, 2024, when it would be exposed to tax liability if it has not signed a final price agreement. *See* 26 U.S.C. § 5000D(b)(2). And if a manufacturer signs a final price agreement before the statutory deadline, there is still *at least 16 months* before January 1, 2026, when that manufacturer would first be required to start providing access to any drug at negotiated prices—or face civil penalties (but no tax) for failing to do so. 42 U.S.C. § 1320f-6(a) (providing for civil monetary penalties for failing to honor agreement). During this period, that manufacturer can (with 30 days' notice) withdraw from Medicare and Medicaid or divest its interest in a drug. Revised Guidance at 129-32.[4] In this way, "any manufacturer that has entered into an Agreement [] retain[s] the ability to promptly withdraw from the program prior to the imposition of civil monetary penalties or excise tax liability." *Id.* at 34.

[4] The manufacturer could also stop selling the drug—either permanently, or temporarily while it pursued any of the above options—which would result in an excise tax liability of zero.

Given these multiple options to withdraw from the Negotiation Program without incurring any tax or penalty, manufacturers are hardly "trapped" or required to agree to any particular price concession. Pls.' Br. at 8. To the extent Plaintiffs are dissatisfied with having to give even the minimal 30-days' notice, they cite no authority establishing that such a requirement is in any way atypical or improper, let alone unconstitutional.[5] Nor could they. The Supreme Court has found no taking when a property owner could choose to leave a price-capped market with "6 or 12 *months* notice." *Yee v. City of Escondido*, 503 U.S. 519, 527–28 (1992) (emphasis added). Manufacturers have far more flexibility here. No compulsion exists.

Nor does compulsion arise from the otherwise lucrative nature of the Medicare market or the economic consequences that manufacturers might suffer if they withdrew. *Contra* Pls.' Br. at 8. Indeed, like with Plaintiffs' failed analogy to utility rates, courts have uniformly rejected similar arguments. *See, e.g.*, *Minn. Ass'n*, 742 F.2d at 446 ("Despite the strong financial inducement to participate in Medicaid, a nursing home's decision to do so is nonetheless voluntary."); *see also Baker Cnty.*, 763 F.3d at 1280. As those courts have emphasized, "economic hardship is not equivalent to legal compulsion for purposes of takings analysis." *Garelick*, 987 F.2d at 917. The "fact that practicalities may in some cases dictate participation does not make participation involuntary." *St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 875 (7th Cir. 1983). Structuring their business to depend on government dollars does not vest manufacturers with a constitutional right to taxpayer funds.

In short, Plaintiffs cannot establish that the voluntary Negotiation Program is at all similar to the kind of compulsory utility rate caps that the Sixth Circuit considered in *Michigan Bell*. Because it is entirely voluntary, the Negotiation Program "simply does not involve a forced taking of property by the state." *Minn. Ass'n*, 742 F.2d at 446.

[5] In any event, any delay between when a manufacturer gives notice of its withdrawal and when that withdrawal takes effect is a function of those other statutory provisions of the SSA—*not* the Negotiation Program provisions of the IRA that Plaintiffs challenge. And although Plaintiffs express some skepticism, they have not actually challenged CMS's interpretation, which operates to their benefit (and which they thus would lack standing to contest). *See* Pls.' Br. at 9 n.4.

B. Plaintiffs' Fifth Amendment theory is meritless, even on its own terms.

Even setting aside the well-settled precedent rejecting Fifth Amendment challenges to Medicare reimbursement caps—and accepting Plaintiffs' erroneous framing of their challenge as raising due process concerns—Plaintiffs' Fifth Amendment claim fails for several additional reasons.

1. The Due Process Clause protects against the deprivation "of life, liberty, or property, without due process of law." U.S. Const. amend. V. But the threshold "inquiry in every due process challenge is whether the plaintiff has been deprived of a protected interest." *American Mfrs. Mut. Ins. Co. v. Sullivan*, 526 U.S. 40, 59 (1999). A protected property interest arises where an individual has "a legitimate claim of entitlement" to a particular benefit, not merely a "unilateral expectation" or "abstract need or desire" for it. *Board of Regents of State Colls. v. Roth*, 408 U.S. 564, 577 (1972). These property interests are "not created by the Constitution, they are created and their dimensions are defined by existing rules or understandings that stem from an independent source such as state law." *Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 538 (1985) (internal quotation omitted).

Here, Plaintiffs assert that manufacturers have such property interests in the drugs they *own*. *See* Pls.' Br. at 16. But, unlike utilities that are required by law to sell property in which they have invested to the public, pharmaceutical manufacturers have no inherent entitlement—and therefore no property interest—in the privilege of selling their drugs *to Medicare*, at any price. *Contra* Pls.' Br. at 17 (alleging "promise of future sales"). As a general matter, "[t]he Constitution does not guarantee the unrestricted privilege to engage in a business or to conduct it as one pleases." *Nebbia v. People of State of New York*, 291 U.S. 502, 527-28 (1934). And that is even more obviously true when the business in question operates in a heavily regulated space or requires an outlay of taxpayer funds. *See, e.g.*, *Ruckelshaus*, 467 U.S. at 1006-07; *see also Minn. Ass'n*, 742 F.2d at 446-47 (Hospitals that "serve medical assistance recipients have no constitutional right to be free from [government] controls on the rates they charge [patients] who do not receive medical assistance."); *Pennell v. City of San Jose*, 485 U.S. 1, 11–12 (1988) ("[W]e have recognized that the government may intervene in the marketplace to regulate rates or prices that are artificially inflated as a result of the existence of a monopoly or near monopoly."). So courts have repeatedly emphasized that, because participation in Medicare and

Medicaid is voluntary, "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); *Painter v. Shalala*, 97 F.3d 1351, 1358 (10th Cir. 1996) (holding that a physician has no property interest in "having his [Medicare] reimbursement payments calculated in a specific manner").

Indeed, crediting Plaintiffs' claim that manufacturers have a protected property interest in Medicare sales would mean that the manufacturers have a *constitutional* right to dictate the government's expenditures. But it is well established that "Congress may attach appropriate conditions to federal taxing and spending programs to preserve its control over the use of federal funds." *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 579 (2012); *see also 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."); *cf. Ray Baillie Trash Hauling, Inc. v. Kleppe*, 477 F.2d 696, 709 (5th Cir. 1973) (noting that it "has long been recognized that the government, like private individuals and businesses, has the power 'to determine those with whom it will deal, and to fix the terms and conditions upon which it will make needed purchases'" (quoting *Perkins v. Lukens Steel Co.*, 310 U.S. 113, 127 (1940)). Not surprisingly then, the Sixth Circuit has explicitly rejected the core premise of Plaintiffs' theory, noting that "those who opt to participate in Medicare are not assured of revenues." *Livingston Care Ctr.*, 934 F.2d at 721. Just as a defense contractor could not build an aircraft carrier and force an unwilling Pentagon to buy it (at any price), so too manufacturers cannot force their drugs onto the government at unilaterally dictated rates.

2. In any event, Plaintiffs' due process theory—based almost entirely on the Sixth Circuit's 2001 decision in *Michigan Bell*—is irreconcilable with the Supreme Court's 2002 decision in *Verizon*, 535 U.S. 467.

The Court in *Verizon* confronted a challenge by telephone carriers to a Federal Communications Commission (FCC) rule that "require[d] state utility commissions to set the rates charged by the" companies for certain property "on a forward-looking basis untied to the[ir] investment." 535 U.S. at 475. Petitioners claimed that "a methodology so divorced from investment actually made will lead to a taking of property." *Id.* at 523. The Court summarily rejected this

contention. As the Court noted, the carriers' claim was "not . . . usual" because they did not "argue that any particular, actual [] rate is 'so unjust as to be confiscatory,' that is, [] threatening [their] 'financial integrity,'" but instead challenged the methodology on its face. *Id.* 523-24 (quoting *Duquesne Light*, 488 U.S. at 307, 312). The Court explained that it had "never considered a taking challenge on a ratesetting methodology without being presented with specific rate orders alleged to be confiscatory." *Id.* (citing *Duquesne Light*, 488 U.S. at 303–304). And "the general rule is that any question about the constitutionality of ratesetting is raised by rates, not methods." *Id.* at 525.

So too here. As explained in greater detail in Defendants' motion to dismiss, Plaintiffs are not challenging any particular price—nor could they, given that CMS has not yet even selected the drugs that will be negotiated, much less signed a pricing agreement with any manufacturer. *See* MTD at 7-8, 19. Rather, Plaintiffs are challenging the methodology by which that price will be negotiated, as well as the limitations on administrative and judicial review. As in *Verizon*, Plaintiffs are thus not arguing that any "particular, actual" price threatens manufacturers' "financial integrity," but rather merely raise the specter that some future price *might* do so. *Verizon*, 535 U.S. at 524. Yet that is exactly the kind of challenge that raises no "question" of "constitutionality," per the Supreme Court. *Id.* at 523-25.

Notably, Plaintiffs do not even cite *Verizon*. Instead, they rely entirely on the Sixth Circuit's earlier *Michigan Bell* decision. *See* Pls.' Br. at 11-16. But the Sixth Circuit's conclusion that a state statute facially did not afford adequate *methodology* to protect against confiscatory rates cannot survive *Verizon*'s reasoning. *Compare Michigan Bell*, 257 F.3d at 594 (holding that methodology "does not guarantee a constitutionally adequate rate of return . . . because it merely permits [] service providers to cover costs, and does not ensure a fair and reasonable rate of return on investment"), *with Verizon*, 535 U.S. at 523-25 (rejecting argument that "a methodology [] divorced from investment actually made will lead to a taking of property").[6] Thus, even if Plaintiffs had alleged that the IRA threatens their

[6] In subsequent proceedings in *Michigan Bell,* the Sixth Circuit had no occasion to address *Verizon* in light of petitioners' voluntary motion to dismiss the appeal, which mooted the case. *Michigan Bell Tel. Co. v. Engler*, 72 F. App'x 380, 386 (6th Cir. 2003) (dismissing appeal). As the Sixth Circuit

"financial integrity"—which *Verizon* established as the standard, but which Plaintiffs do not meet given that (unlike utilities) they are not required to sell the fruit of their investments—this claim would still fail.

3. For similar reasons, Plaintiffs cannot satisfy the standard for a facial challenge—which is "the most difficult challenge to mount successfully, since the challenger must establish that no set of circumstances exists under which" the Negotiation Program could be constitutionally applied. *United States v. Salerno*, 481 U.S. 739, 745 (1987); *see also Warshak*, 532 F.3d at 529 (Court should be "reluctan[t] to grant relief in the face of facial, as opposed to as-applied, attacks on statutes") (en banc). To state the obvious, Plaintiffs do not yet know whether any of their members will agree to prices that are so low as to threaten their "financial integrity." *Verizon*, 535 U.S. at 524 (quotations omitted); *see* MTD at 8-10. Indeed, as explained in detail in Defendants' motion to dismiss, there are more-than-plausible scenarios in which manufacturers do not lose money at all. *See* MTD at 8-10. Further—as the Sixth Circuit has emphasized—manufacturers can always avoid any supposed deprivation by withdrawing from the Medicare program altogether. *Baptist Hosp.*, 802 F.2d at 869-70. Any of these "conceivable set[s] of circumstances" defeat Plaintiffs' facial challenge. *Salerno*, 481 U.S. at 745.

* * *

At bottom, Plaintiffs' objection to the Negotiation Program is little more than "a dispute with the policy choices" made by Congress, masquerading as constitutional theory. *Franklin Mem'l*, 575 F.3d at 130. Rather than arguing against established precedent, the "better course of action is to seek redress through the . . . political process." *Id.* Plaintiffs' facial constitutional challenge cannot succeed.

II. Plaintiffs Face No Certain and Immediate Irreparable Harm

Nor have Plaintiffs demonstrated that an injunction is necessary to forestall some imminent and irreparable injury. "Irreparable harm is an 'indispensable' requirement for a preliminary injunction, and 'even the strongest showing' on the other factors cannot justify a preliminary injunction if there is no 'imminent and irreparable injury.'" *Memphis A. Philip Randolph Inst. v. Hargett*,

previewed, however, "future litigants may argue about the effect of *Verizon Communication* on th[e] decision." *Id.* Those future litigants are here.

978 F.3d 378, 391 (6th Cir. 2020) (quoting *D.T. v. Sumner Cnty. Schs.*, 942 F.3d 324, 326-27 (6th Cir. 2019)). The standard is high: to "merit a preliminary injunction, an injury 'must be both certain and immediate,' not 'speculative or theoretical.'" *Id.* (quoting *D.T.*, 942 F.3d at 327); *see also Winter*, 555 U.S. at 22 ("Issuing a preliminary injunction based only on a possibility of irreparable harm is inconsistent with our characterization of injunctive relief as an extraordinary remedy."). Establishing such harm is necessarily more difficult than establishing standing. *See, e.g.*, *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997); *Libertarian Party of Ohio v. Husted*, 751 F.3d 403, 417 (6th Cir. 2014) (plaintiff must come forward with more than "scant evidence" to substantiate allegations of harm).

Here, as detailed in Defendants' motion to dismiss, Plaintiffs have—at most—alleged that it is possible that AbbVie's Imbruvica-related financial investments will suffer *starting in 2026*. *See* MTD at 12-14. Those allegations aren't even enough to establish subject-matter jurisdiction, and they do not come remotely close to demonstrating the sort of "imminent and irreparable injury" that is necessary to obtain a preliminary injunction—particularly given the Sixth Circuit's repeated admonition that the harm to be avoided "'must be both certain and immediate,' not 'speculative or theoretical.'" *Hargett*, 978 F.3d at 391 (quoting *D.T.*, 942 F.3d at 326-27). That is even more obvious given the choices presented to any manufacturer that is dissatisfied with this Program—to the extent that manufacturer truly fears irreparable harm from continued participation in Medicare, it is free to withdraw, either now or later, or to divest its interest in the relevant drug. *See supra* at 10-11.

Moreover, even indulging Plaintiffs' speculation about possible future injury, no injunction is warranted because this case can (and presumably will) be litigated to final judgment well before any new prices take effect in 2026. That alone is fatal to Plaintiffs' motion—after all, the "limited purpose" of "a preliminary injunction is merely to preserve the relative positions of the parties until a trial on the merits can be held." *Univ. of Texas v. Camenisch*, 451 U.S. 390, 395 (1981). But final resolution "on the merits," *id.*, can happen well before AbbVie—the only identified member of any Plaintiff association—would suffer any cognizable harm. So there is no "certain and immediate" injury that cannot await litigation in the normal course. *Hargett*, 978 F.3d at 391. All this is presumably why no manufacturer has sought a preliminary injunction—including Merck, Bristol Myers Squibb, Janssen,

and Astellas, each of which has filed its own lawsuit.[7] Despite being entities that—unlike the Chambers of Commerce—actually manufacture and sell drugs and thus might actually be subject to the Negotiation Program, the manufacturers have agreed to unhurried briefing schedules for summary judgment that will not be completed for several months, and have not requested a court decision by any date certain.[8] Plaintiffs here cannot credibly claim a more dire emergency.

Finally, Plaintiffs' own litigation choices undermine their assertions of harm. "[A] party requesting a preliminary injunction must generally show reasonable diligence." *Benisek v. Lamone*, 138 S. Ct. 1942, 1944 (2018). For that reason, "a lengthy delay in seeking injunctive relief may weigh against a finding of irreparable harm." *York Risk Servs. Grp., Inc. v. Couture*, 787 F. App'x 301, 309 (6th Cir. 2019). Plaintiffs have known the timelines of the Negotiation Program since August 16, 2022, when the IRA was enacted. *See* 42 U.S.C. § 1320f(d) (establishing program "timing for initial price applicability year 2026"). Yet, having decided to challenge the Negotiation Program facially, before any prices are negotiated, Plaintiffs still waited until *July* of this year to seek an injunction. Such "[a] delay by plaintiff after learning of the threatened harm may be taken as an indication that the harm would not be serious enough to justify a preliminary injunction." 11A Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, Federal Practice and Procedure § 2948.1 (2d ed. 1995).

Courts within the Sixth Circuit and around the country have rejected claims of irreparable harm after delays that are comparable to (or shorter than) Plaintiffs' 11-month delay here. *See, e.g.*, *Ng v. Bd. of Regents of Univ. of Minn.*, 64 F.4th 992, 998 (8th Cir. 2023) (13-month delay was "unreasonable" and "alone sufficient" to deny preliminary injunction); *Wreal, LLC v. Amazon.com, Inc.*, 840 F.3d 1244, 1248 (11th Cir. 2016) ("A delay in seeking a preliminary injunction of even only a few months—though not necessarily fatal—militates against a finding of irreparable harm."); *Vita-Mix Corp. v. Tristar Prod., Inc.*, No. 1:07 CV 275, 2008 WL 11383504, at *9 (N.D. Ohio Sept. 30, 2008) ("[N]umerous

[7] *See Merck v. Becerra*, 1:23-cv-01615 (D.D.C.); *Bristol Myers Squibb Co. v. Becerra*, 3:23-cv-3335 (D.N.J.); *Astellas Pharma US, Inc. v. HHS*, 1:23-cv-4578 (N.D. Ill.); *Janssen Pharmaceuticals, Inc. v. Becerra*, 3:23-cv-3818 (D.N.J.).

[8] *See Merck v. Becerra*, Joint Mot. to Set Schedule, ECF No. 13, 1:23-cv-01615 (D.D.C.); *Bristol Myers Squibb Co. v. Becerra*, Scheduling Letter, ECF No. 34, 3:23-cv-3335 (D.N.J.); *Janssen Pharmaceuticals, Inc. v. Becerra*, Scheduling Letter, ECF No. 13, 3:23-cv-3818 (D.N.J.).

courts have recognized that any presumption of irreparable injury . . . is rebutted by a delay of even a few months in seeking preliminary injunctive relief." (collecting cases)). That lack of urgency undermines whatever is left of Plaintiffs' assertions of irreparable harm.

III. The Public Interest Disfavors Injunctive Relief

On the other side of the ledger, the harm to the government and the public from an injunction would be immense. "Congress is a coequal branch of government whose Members take the same oath . . . to uphold the Constitution of the United States." *Rostker v. Goldberg*, 453 U.S. 57, 64 (1981). So "[t]he presumption of constitutionality which attaches to every Act of Congress is not merely a factor to be considered in evaluating success on the merits, but an equity to be considered in favor of [the government] in balancing hardships." *Walters v. Nat'l Ass'n of Radiation Survivors*, 468 U.S. 1323, 1324 (1984) (Rehnquist, J., in chambers). The government "suffers a form of irreparable injury" when it "is enjoined by a court from effectuating [a] statute[] enacted by representatives of its people." *Maryland v. King*, 567 U.S. 1301, 1303 (2012) (Roberts, C.J., in chambers).

After years of effort, Congress has finally enacted a law that builds on time-tested models to reduce costs and put Medicare on a path toward fiscal sustainability. Derailing that program before it starts would inflict grave harm to the government, Medicare beneficiaries, and the American taxpayer.

IV. Plaintiffs' Requested Relief Is Overbroad

Even if Plaintiffs were to prevail on every issue above, the relief they have requested is still too broad. Sixth Circuit precedent dictates that "district court[s] should limit the scope of [an] injunction to the conduct 'which has been found to have been pursued or is related to [what was] proven unlawful.'" *Howe v. City of Akron*, 801 F.3d 718, 753 (6th Cir. 2015) (quoting *EEOC v. Wilson Metal Casket Co.*, 24 F.3d 836, 842 (6th Cir. 1994)). The Court "need not grant the total relief sought by the applicant but may mold its decree to meet the exigencies of the particular case." *Trump v. Int'l Refugee Assistance Project*, 582 U.S. 571, 579–80 (2017) (citation omitted).

Here, the Plaintiff associations can have no interest in enjoining the operation of the Negotiation Program writ large: after all, CMS will not be sitting down at the negotiating table with the U.S. Chamber of Commerce or any other named Plaintiff in this case. *See, e.g.*, *Ass'n of Am.*

Physicians & Surgeons v. FDA, 13 F.4th 531, 537 (6th Cir. 2021) ("[A] valid Article III remedy must 'operate with respect to specific parties,' not with respect to a law or regulation 'in the abstract.'" (quoting *California v. Texas*, 141 S. Ct. 2104, 2115 (2021))). Rather, Plaintiffs could only plausibly claim an interest in enjoining the Negotiation Program with respect to *specific*, identified members whose drugs may be selected for negotiation. *See, e.g.*, *id.* at 540 ("[R]elief in an associational-standing case must benefit (and ameliorate an injury to) the association's members."); *see generally* MTD at 15-17. The only member Plaintiffs have identified is AbbVie. So, even assuming AbbVie manufactures a drug that is selected for negotiation, any relief should be limited to AbbVie.

This limitation is particularly important given that numerous other manufacturers are currently seeking to vindicate their interests through their own independent lawsuits. *See supra* n.7. Those suits should have an opportunity to proceed on their own schedules, without interference from this case. *See, e.g.*, *Arizona v. Biden*, 31 F.4th 469, 484 (6th Cir. 2022) (Sutton, C.J., concurring) (noting the "Article III" and "practical problems" created by non-party-specific relief, including that such remedies "short-circuit the decisionmaking benefits of having different courts weigh in on vexing questions of law and allowing the best ideas to percolate to the top"); *Louisiana v. Becerra*, 20 F.4th 260, 264 (5th Cir. 2021) (noting that "[p]rinciples of judicial restraint" counsel against granting overbroad relief when "[o]ther courts are considering these same issues" in pending cases).

Simply put, this Court should not countenance Plaintiffs' attempt to secure relief that would short-circuit other litigation or deprive Defendants of the benefits of prevailing against specific manufacturers. *See Dep't of Homeland Sec. v. New York*, 140 S. Ct. 599, 601 (2020) (Gorsuch, J., concurring) ("If a single successful challenge is enough to stay the challenged rule across the country, the government's hope of implementing any new policy could face the long odds of a straight sweep[.]"); *see also United States v. Mendoza*, 464 U.S. 154 (1984) (holding, for similar reasons, that the doctrine of nonmutual offensive collateral estoppel does not apply to the federal government). Thus, even if the Court were inclined to enter an injunction, it should limit that injunction to AbbVie.

CONCLUSION

The Court should deny Plaintiffs' motion for a preliminary injunction.

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Respectfully submitted,

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