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-TMR-PBS

Judge Thomas M. Rose

Magistrate Judge Peter B. Silvain, Jr.

DEFENDANTS' MOTION TO DISMISS

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Pursuant to Federal Rule of Civil Procedure 12(b), Defendants move to dismiss Plaintiffs' complaint, in its entirety, for the reasons stated in the accompanying memorandum of law.

Dated: August 11, 2023

Respectfully submitted,

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DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS

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INTRODUCTION

Plaintiffs do not manufacture or sell prescription drugs. Rather, the U.S. Chamber of Commerce and its affiliates are, by some metrics, the largest lobbying enterprise in the United States; they filed this lawsuit to achieve through the courts what they tried and failed to achieve through the legislative process. Plaintiffs seek a court order that would nullify key provisions of the Inflation Reduction Act (IRA), in which Congress authorized Medicare to try and negotiate a better deal for patients and the American taxpayer on some of the pharmaceutical industry's most lucrative drugs. Underscoring the degree to which this suit is driven by policy objections rather than any concrete injury, Plaintiffs seek that relief before any drugs are selected for the program (a few weeks from now), before any prices are agreed upon (by August 2024), and before any new prices take effect (in 2026).

Plaintiffs' legal theory—that this statute is facially unconstitutional—lacks merit, as detailed in Defendants' concurrently filed opposition to Plaintiffs' motion for a preliminary injunction. In short, Plaintiffs' hyperbolic claims that price negotiations will somehow deprive drug manufacturers of their property ignore an unbroken line of precedent establishing that "participation in the Medicare program is a voluntary undertaking." *Livingston Care Ctr. v. United States*, 934 F.2d 719, 720 (6th Cir. 1991). The voluntariness of participation in Medicare defeats Plaintiffs' strained attempts to analogize this case to one Sixth Circuit decision about regulated utilities—*Michigan Bell Telephone Company v. Engler*, 257 F.3d 587 (6th Cir. 2001)—which was, in any event, effectively overruled by the Supreme Court the next year, in a decision that Plaintiffs do not cite. *See Verizon Commc'ns, Inc. v. FCC*, 535 U.S. 467 (2002). But the Court need not (and should not) reach the merits at all, because Plaintiffs have failed to carry their threshold burden to establish subject-matter jurisdiction for any of their claims.

Plaintiffs have not demonstrated Article III standing, for multiple independent reasons. *First*, before drugs are selected and prices are negotiated, Plaintiffs can only speculate about whether the manufacturers that they purport to represent will be harmed by these statutory changes. *Second*, as membership associations, Plaintiffs can show standing only if (among other things) they can each identify at least one member that would otherwise have standing on its own. Two of the four Plaintiffs have not even tried to identify a single member. The other two identified one member, AbbVie—

which apparently markets, but does not manufacture, a drug that Plaintiffs predict will be selected, and thus is several layers removed from the legal obligations that Plaintiffs challenge. Because only the manufacturer of a selected drug will be asked to negotiate on price, Plaintiffs' allegations of injury to AbbVie arising from those negotiations cannot support jurisdiction. And even if Plaintiffs had identified members that manufacture selected drugs (and even if those manufacturers otherwise had standing), *this* Court can entertain this suit only if the Dayton Area Chamber of Commerce had identified such a member, as its residence in this District is the only basis for venue alleged in the complaint. *See* Compl. ¶¶ 26, 27, 32, ECF No. 1; 28 U.S.C. § 1391(e)(1)(C). It has not done so. *Third*, even if Plaintiffs had identified such members, Plaintiffs would still lack associational standing because participation of their individual members would be required for this Court to issue equitable and orderly relief. Simply put, because multiple individual manufacturers have brought their own suits around the country—including at least one of the Plaintiffs' (otherwise unidentified) members—granting the broad relief that Plaintiffs seek risks a practical morass of overlapping judgments, and gives individual manufacturers multiple bites at the apple, in violation of equitable and prudential limits on justiciability.

Even if Plaintiffs had standing, they fail to overcome the independent jurisdictional hurdle of ripeness. To the extent that AbbVie will ever suffer any financial injury, it would not be until 2026, when any new prices would take effect. And actual price negotiations are necessary for the Court to evaluate whether, for example, the (mostly unidentified) manufacturers that Plaintiffs purport to represent really will face "prices so low as to deprive [them] of their property without due process of law," Compl. ¶ 167—which requires knowing, most obviously, what those prices will be.

The Court should therefore dismiss Plaintiffs' complaint, in its entirety, for lack of subject-matter jurisdiction, and then deny Plaintiffs' motion for a preliminary injunction as moot.

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* CMS, Medicare Drug Price Negotiation Program: Revised Guidance, at 131-32 (June 30, 2023), https://perma.cc/K6QB-C3MM ("Revised Guidance"). Or it can withdraw from the Medicare and Medicaid programs—in which case it will incur no excise tax and no other liability. *See id.* at 33-34, 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

"Article III standing is not merely a troublesome hurdle to be overcome if possible so as to reach the 'merits' of a lawsuit which a party desires to have adjudicated; it is a part of the basic charter promulgated by the Framers of the Constitution at Philadelphia in 1787." *United States v. Texas*, 143 S. Ct. 1964, 1969 (2023) (citation omitted). This lawsuit fails at the threshold, on that foundational principle of separation of powers. And even if Plaintiffs could establish standing, their claims are not

ripe, given critical uncertainties about how this new program will be implemented and what prices (if any) drug manufacturers will agree to. This case should be dismissed.

I. Plaintiffs Lack Article III Standing

Standing is "an essential and unchanging part of the case-or-controversy requirement of Article III." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992). A plaintiff who seeks to establish standing "bears the burden of establishing" that it has "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016). These elements "are not mere pleading requirements but rather an indispensable part of the plaintiff's case." *Lujan*, 504 U.S. at 561. The standing inquiry is "especially rigorous when reaching the merits" would require a court to decide the constitutionality of an act of Congress. *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 408 (2013) (internal quotation marks omitted). Plaintiffs have not carried this burden.

A. Plaintiffs' alleged injuries are speculative.

To support Article III standing, "an injury must be concrete, particularized, and actual or imminent." *Id.* at 409 (citation omitted). "Although imminence is concededly a somewhat elastic concept, it cannot be stretched beyond its purpose, which is to ensure that the alleged injury is not too speculative for Article III purposes—that the injury is *certainly* impending." *Id.* (quoting *Lujan*, 504 U.S. at 565 n.2). The Supreme Court and the Sixth Circuit have "repeatedly reiterated that 'threatened injury must be *certainly impending* to constitute injury in fact,' and that '[a]llegations of *possible* future injury' are not sufficient." *Id.* (quoting *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990)); *accord Weiser v. Benson*, 48 F.4th 617, 623 (6th Cir. 2022) (injury "must be '*certainly* impending,' not merely a '*possible* future injury'" (quoting *Clapper*, 568 U.S. at 409, 411)).

Here, Plaintiffs have filed a facial challenge to a new statute, asserting as their alleged injury the prospect that drug manufacturers (which they suggest are members) will be selected to participate in the Negotiation Program—and that, eventually, those manufacturers will begrudgingly agree "to sell their drugs at unfairly low, government-mandated prices." Compl. ¶ 6. But for several reasons,

these claimed injuries are "conjectural and hypothetical and will not satisfy the injury-in-fact requirement." *Phillips v. DeWine*, 841 F.3d 405, 416 (6th Cir. 2016).

As a threshold matter, the Negotiation Program currently imposes no legal obligations on any drug manufacturer whatsoever. The list of up to 10 drugs that will be selected for the first round of price negotiations has not yet been finalized; that list will be announced in a few weeks, by September 1, 2023. And even if a drug manufactured by one of Plaintiffs' members is selected, that will not retroactively cure this defect in the complaint—after all, "the court must determine whether standing exists at the time of the filing of the complaint only." *NAACP, Cleveland Branch v. City of Parma*, 263 F.3d 513, 526 (6th Cir. 2001); *see also, e.g.*, *Crawford v. U.S. Dep't of Treasury*, 868 F.3d 438, 457 (6th Cir. 2017) ("[W]e assess standing as of the time a suit is filed." (citation omitted)).

Even setting aside the uncertainty about which drugs will be selected (and thus which manufacturers will be asked to negotiate), Plaintiffs can still show only a "*possible* future injury," rather than one that is "*certainly* impending." *Weiser*, 48 F.4th at 623. That is because all their alleged harms derive from a fear that their members will reluctantly agree to "prices so low as to deprive manufacturers of their property without due process of law." Compl. ¶ 167. But before that price is agreed upon—assuming the relevant manufacturers reach an agreement with CMS at all, rather than choosing to withdraw from the program, to pay a tax, or to divest their interest in the drug—there is no way to know whether prices will actually settle at "unfairly low, confiscatory levels," *id.* ¶ 135, or even whether manufacturers of selected drugs are going to be any worse off than they are now. Of course, Plaintiffs do not allege that *anyone* knows what prices (if any) will be negotiated. Nor could they—under the timeline set by Congress, those prices will not be agreed upon until August of 2024, will not be made public until September of 2024, and will not take effect until January of 2026. 42 U.S.C. § 1320f(d).

This uncertainty is real. Contrary to the tone of pessimistic inevitability in Plaintiffs' filings, it is possible that manufacturers will agree to prices that result in flat or even *greater* revenue for them. That is because, under the status quo, Medicare Part D drug coverage involves a series of middlemen (often, "Pharmacy Benefit Managers" or "PBMs"), who employ an opaque system of rebates and

other price concessions extracted from the manufacturer. *See Medicare Part D – Direct and Indirect Renumeration*, CMS.gov (Jan. 19, 2017), https://perma.cc/M5V7-VG2F (explaining that "[h]igh priced drugs" are "now increasingly packaged with high rebates"). These rebates and price concessions are important factors in a manufacturer's net revenue for a given product. To take an (admittedly oversimplified) hypothetical, a drug might nominally be priced at $100 per dose but also be subject to a $20 rebate—some of which filters back to the patient or the patient's insurer, some to a middleman (often, a PBM or another participant in the supply chain). The net result ($100 price minus $20 rebate) is $80 in revenue to the manufacturer. These rebates mean that manufacturers' revenues are lower—sometimes significantly—than their drugs' stated prices.

Now, imagine that CMS selects this hypothetical $100 drug for negotiation. First, CMS must determine the statutory "ceiling" price—that is, the highest price that it may offer to a manufacturer of a selected drug—which is calculated using one of two statutory formulae (whichever yields a lower result). *See* 42 U.S.C. § 1320f-3(c)(1)(A). For some drugs, the ceiling price is likely to be the "price of the drug under . . . part D of subchapter XVIII, net of all price concessions," *id.* § 1320f-3(c)(2)(A)—commonly known as the "Part D net price." That price largely reflects the net price that the manufacturer is *already* being paid for selling the drug—but importantly, after accounting for "all price concessions," like rebates. *See id.*

So, in our simplified hypothetical, the statutory "ceiling" price of the selected drug would be $80—not $100, because the $20 rebate is excluded. And if CMS and the manufacturer ultimately agree that the negotiated "maximum fair price" should be equal to the "ceiling" price, then the manufacturer will *still* net $80. In this scenario, the prices paid by Part D beneficiaries will likely go down, but the manufacturer's net revenue on those sales would be unchanged. In those circumstances, manufacturers will not be any worse off—though Medicare beneficiaries and taxpayers will still be better off, as Congress intended.[1]

[1] These are among the reasons why Plaintiffs' explanation of the "ceiling" price is (at best) incomplete. Plaintiffs are correct that one of the two possible ceiling-price formulae uses a percentage of the "non-federal average manufacturer price," or "[n]on-FAMP" price. Mot. for a Prelim. Inj. at 7, ECF No. 29 ("Pls.' Br."). But that price "does not reflect rebates paid by the manufacturer to third-

The uncertainty doesn't stop there. A drug being selected for negotiation will also trigger other unequivocal *benefits* to its manufacturer: in particular, an exemption from the otherwise large and growing obligations on manufacturers to provide discounts on brand-name drugs and biologics used by Medicare Part D beneficiaries, through the Medicare Part D Manufacturer Discount Program. *See* 42 U.S.C. § 1395w-114c. The details are complex, but what matters is that under the IRA, the obligation to pay these discounts will expand, starting in 2025, to include nearly every brand-name drug *except* those selected for negotiation; selected drugs will (for the first time) be exempted from these discount obligations entirely, during the time in which the negotiated price would be in effect. *See id.* § 1395w-114c(g)(2)(B). So even if prices for a selected drug fall, any losses could be offset (or more) by exemption from the obligation to offer these discounts—especially if the "maximum fair price" comes in at or near the ceiling price. Indeed, depending on how all these variables shake out, a manufacturer of a selected drug could even see increased revenue.

To be sure, it is possible that the "maximum fair price" for some selected drugs will be lower than the ceiling price—perhaps significantly so. After all, Congress directed CMS to "aim[] to achieve the lowest maximum fair price" that it can persuade manufacturers to accept. 42 U.S.C. § 1320f-3(b)(1). But there is no way to know whether (or to what extent) Congress's "aims" will be successful, until the negotiation process plays out. *See* Christopher Adams & Evan Herrnstadt, *Model of Drug Price Negotiations Under the Elijah E. Cummings Lower Drug Costs Now Act* 13 (Cong. Budget Off., Working Paper No. 20201-01, 2021), https://perma.cc/UGA9-SMR5 (discussing expectation of roughly equal bargaining power between CMS and manufacturers of selected drugs, due in part to CMS's desire to avoid an outcome in which important drugs become unavailable to Medicare patients). Until then, Plaintiffs have shown only a "*possible* future injury" to manufacturers, rather than one that is "*certainly* impending." *Weiser*, 48 F.4th at 623 (quoting *Clapper*, 568 U.S. at 409, 411). That isn't enough.

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party payers (such as insurance companies or [PBMs])," and so it substantially overstates the net revenue that a manufacturer would expect to receive from a given drug. CBO, *A Comparison of Brand-Name Drug Prices Among Selected Federal Programs* 34 (Feb. 2021), https://perma.cc/34GE-3MKR. So to the extent that Plaintiffs imply that revenues (or even prices) for selected drugs will necessarily fall by "40% to 75%," Compl. ¶ 80, they are mistaken.

B. Plaintiffs lack associational standing.

Because Plaintiffs are membership associations—rather than manufacturers who may be directly affected by the statute—they must also satisfy additional requirements for associational standing. "An association has standing to bring suit on behalf of its members when [1] its members would otherwise have standing to sue in their own right, [2] the interests at stake are germane to the organization's purpose, and [3] neither the claim requested nor the relief requested requires the participation of individual members in the lawsuit." *Waskul v. Washtenaw Cnty. Cmty. Mental Health*, 900 F.3d 250, 254–55 (6th Cir. 2018) (citing *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977)). Plaintiffs have not satisfied (and cannot satisfy) these requirements, either.

1. Plaintiffs have not identified any member with Article III standing.

In determining whether an association has Article III standing, courts must "vigilantly ensure that [the] association's members have incurred a personal injury." *Ass'n of Am. Physicians & Surgeons v. FDA*, 13 F.4th 531, 534 (6th Cir. 2021). It is not enough to "identify a likelihood that the defendant's conduct will harm an unknown member"—each plaintiff association "must instead identify a member who has suffered (or is about to suffer) a concrete and particularized injury from the defendant's conduct" and "must show that its requested relief will redress this injury." *Id.* at 543; *see also Summers v. Earth Island Inst.*, 555 U.S. 488, 498 (2009) ("[T]he law of organizational standing . . . require[s] plaintiff-organizations to make specific allegations establishing that at least one identified member had suffered or would suffer harm."). And "just as an individual must demonstrate standing for each claim he seeks to press *and* for each form of relief sought, so too must an association that relies upon an individual member for standing purposes." *Waskul*, 900 F.3d at 253 (citations omitted).

As an initial matter, two Plaintiffs—the Ohio Chamber of Commerce and the Michigan Chamber of Commerce—do not even try to identify a single member that will be harmed by the Negotiation Program (in the complaint or elsewhere). *See* Decl. of James Holcomb. ¶ 5, ECF No. 29-3 (asserting that "[t]he Michigan Chamber has members who will be directly subject to the [Negotiation Program] and whom market analysts expect will have drugs listed among the ten drugs selected" but identifying zero members); Decl. of M. Anthony Long ¶ 5, ECF No. 29-4 (same, for the

Ohio Chamber). Those two Plaintiffs should be dismissed for that reason alone. *See Ass'n of Am. Physicians & Surgeons*, 13 F.4th at 543.

The Dayton Area and U.S. Chambers of Commerce do identify one member in the complaint—AbbVie—but their allegations come nowhere close to demonstrating an imminent, direct injury to AbbVie resulting from the Negotiation Program. They allege merely that AbbVie "markets the drug IMBRUVICA." Compl. ¶ 32; Pls.' Br. at 18; Decl. of Michael C. Staff ¶ 5, ECF No. 29-5 ("Staff Decl."). But even if Imbruvica is selected for negotiation by September 1—which is far from certain, at least as of the date of this filing, *see supra* at 8—Plaintiffs' allegation that AbbVie markets Imbruvica is not enough to show that AbbVie would have Article III standing.

Plaintiffs' repeated and unexplained assertions that AbbVie, as an Imbruvica marketer, faces imminent Article III injury (even irreparable harm) because of upcoming price negotiations are implausible and contradicted by the statute. *See* Pls.' Br. at 18–19 (asserting without support that AbbVie "would be forced to enter 'negotiations,'" disclose information, and agree to a price for Imbruvica); Staff Decl. ¶ 11. Contrary to Plaintiffs' suggestion, the IRA does not contemplate a seat at the negotiating table for a company that only *markets* a selected drug—and Plaintiffs cite nothing to the contrary. *See* 42 U.S.C. § 1320f(a)(1) (directing CMS to negotiate with "the manufacturer" of the selected drug).

A company that solely markets a selected drug will not be invited to participate in negotiations and would not be party to any resulting agreement; those obligations are reserved exclusively for the "primary manufacturer" of the selected drug—that is, the holder of the new drug application (NDA) or biologics license application (BLA) for purposes of FDA approval. *See* Revised Guidance § 40, at 118 ("To the extent that more than one entity meets the statutory definition of manufacturer for a selected drug . . . , CMS will designate the entity that holds the NDA(s) / BLA(s) for the selected drug to be 'the manufacturer[.]'"). And "[a]s the entity that is party to the Agreement, the Primary Manufacturer will be solely responsible for compliance with all provisions of the Agreement." *Id.* at 119; *compare* Revised Guidance § 40.6, at 129 (discussing options for the "Primary Manufacturer" to "avoid the excise tax" if the manufacturer wishes to terminate the agreement), *with* Staff Decl. ¶ 18

(speculating without explanation that AbbVie would have to withdraw its products from Medicare and Medicaid to avoid an excise tax with respect to Imbruvica). But Plaintiffs have not alleged that AbbVie is likely to be deemed the primary manufacturer for Imbruvica—for good reason.[2]

According to publicly available information,[3] non-party Pharmacyclics—not AbbVie—appears to be the relevant manufacturer: Pharmacyclics holds all three NDAs for Imbruvica;[4] Pharmacyclics is listed as the only labeler for the drug in the FDA's National Drug Code Directory;[5] and the Imbruvica labeling states that the drug is "distributed and marketed by" Pharmacyclics.[6] Accordingly, if Plaintiffs turn out to be correct that Imbruvica will be selected for negotiation, it appears that *Pharmacyclics* would be asked to participate in the Negotiation Program, and *Pharmacyclics* would face all of the legal obligations that AbbVie supposedly fears. *See* Revised Guidance § 40, at 118.

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[2] As a result, the assumptions in many critical portions of Plaintiffs' submissions—including their sworn declarations—appear to be inaccurate. *See, e.g.*, Staff Decl. ¶ 11 (declaring that "the IRA would compel AbbVie . . . to sign a 'negotiation agreement' the terms of which AbbVie has no ability to disagree with," when in fact it appears that it is Pharmacyclics, not AbbVie, that could be asked to sign a pricing agreement for Imbruvica); Compl. ¶ 32 (similar). The Court need not and should not credit these inaccurate assumptions.

[3] The Court can consider these materials, even at the motion-to-dismiss stage, because they support Defendants' factual attack on Plaintiffs' allegations relating to subject-matter jurisdiction. *See, e.g.*, *Ohio Nat'l Life Ins. Co. v. United States*, 922 F.2d 320, 325 (6th Cir. 1990) (noting that on a 12(b)(1) motion "no presumptive truthfulness applies to" disputed "factual allegations" about subject-matter jurisdiction, and that the district court "has wide discretion to allow affidavits, documents," and other materials outside the pleadings to resolve the factual dispute).

[4] *NDA 210563*, U.S. FDA: Drugs@FDA, https://perma.cc/8TFM-Z5GL; *NDA 205552*, U.S. FDA: Drugs@FDA, https://perma.cc/H6BS-4KCT; *NDA 217003*, U.S. FDA: Drugs@FDA, https://perma.cc/VR77-AHFY.

[5] FDA, *National Drug Code Directory*, https://perma.cc/VT4X-AEL8 (select "proprietary Name" and search "Imbruvica").

[6] Imbruvica Prescribing Information (rev. May 2023), https://perma.cc/BS6L-GC9A. The Imbruvica labeling also states that the drug is "marketed by" Janssen Biotech Inc., and makes no mention of AbbVie at all. *Id.* at 55, 58, 64. Janssen has brought its own suit challenging the Negotiation Program in a different court, but its allegations focus on a different drug that it manufactures, and its complaint nowhere mentions Imbruvica. *See* Compl., *Janssen Pharmaceuticals v. Becerra*, No. 3:23-cv-3818 (D.N.J. July 18, 2023), ECF No. 1.

Although Pharmacyclics is apparently owned by AbbVie, *see* Staff Decl. ¶ 12, that does not solve Plaintiffs' standing problem, under basic principles of the corporate form and binding Sixth Circuit precedent. That is because a corporate shareholder cannot bring an action for relief based on alleged injuries to the corporation, even "where the individual is the sole stockholder." *Canderm Pharmacal, Ltd. v. Elder Pharms., Inc.*, 862 F.2d 597, 602–03 (6th Cir. 1988) (internal quotation marks omitted). This "longstanding equitable restriction . . . generally prohibits shareholders from initiating actions to enforce the rights of the corporation unless the corporation's management has refused to pursue the same action for reasons other than good-faith business judgment." *In re Troutman Enters., Inc.*, 286 F.3d 359, 364 (6th Cir. 2002) (quoting *Franchise Tax Bd. of Calif. v. Alcan Aluminium Ltd.*, 493 U.S. 331, 336 (1990)).

A narrow exception to this general rule exists where "the shareholder suffers an injury separate and distinct from that suffered by other shareholders, or the corporation as an entity." *Gaff v. Fed. Deposit Ins. Corp.*, 814 F.2d 311, 315 (6th Cir.) (citation omitted), *on reh'g in part*, 828 F.2d 1145 (6th Cir. 1987). But a "depreciation or diminution in the value of a shareholder's corporate stock" is "merely an indirect or incidental injury to an individual shareholder," which is not "the type of direct, personal injury . . . necessary to sustain a direct cause of action." *Id.* (collecting cases). And a speculative diminution in value is the only sort of injury described in Plaintiffs' filings. *See* Staff Decl. ¶ 12 (explaining that when AbbVie invested in Pharmacyclics, "it did so expecting that future market-based revenues from IMBRUVICA" would be higher). Thus, even if Plaintiffs had alleged harms suggesting that *Pharmacyclics* might have standing to sue, *AbbVie*, as a shareholder of Pharmacyclics, *see id.*, could not bring suit on its behalf unless an exception to the general prohibition on shareholder standing were applicable here (and that exception were adequately alleged and substantiated). But Plaintiffs' pleadings—which obscure the relationship between AbbVie and Pharmacyclics in the first place—include no allegations suggesting that AbbVie, as a marketer of Imbruvica, would suffer any "separate and distinct" injury if Imbruvica were selected for negotiation. And absent (at a minimum) specific allegations regarding AbbVie's relationship with Pharmacyclics (contractual or otherwise), Plaintiffs'

conclusory and unsubstantiated assertions that AbbVie faces "extremely significant financial harm" from the Negotiation Program, Pls.' Br. at 19, are insufficient to establish jurisdiction.

In sum, none of the Plaintiffs has made "specific allegations establishing that at least one identified member had suffered or would suffer harm," *Summers*, 555 U.S. at 498—and they therefore all lack associational standing. Their complaint should be dismissed for that reason alone.

On this subject, one additional point warrants mention. Because *all* Plaintiffs lack Article III standing, the Court need not consider the secondary question of whether venue is proper. Defendants note, however, that the only basis for venue that is alleged in the complaint is that Plaintiff the Dayton Area Chamber of Commerce (of which AbbVie is a member) resides in the Southern District of Ohio. *See* 28 U.S.C. § 1391(e)(1)(C); Compl. ¶¶ 26, 27, 32.[7] So 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). Accordingly, to the extent necessary, Defendants also move to dismiss for lack of venue under Rule 12(b)(3).

2. The relief requested requires participation by individual members.

Finally, even if the associations had each identified an individual member with standing, they would *still* lack associational standing because the pendency of multiple suits by individual drug manufacturers—with the potential for more as the process unfolds—renders an association suit unworkable. Under these circumstances, "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).

As the Sixth Circuit has noted in the context of associational standing, "a valid Article III remedy must 'operate with respect to specific parties,' not with respect to a law or regulation 'in the abstract.'" *Id.* (quoting *California v. Texas*, 141 S. Ct. 2104, 2115 (2021)); *see also Texas*, 143 S. Ct. at 1980 (Gorsuch, J., concurring) ("Traditionally, when a federal court finds a remedy merited, it provides party-specific relief, directing the defendant to take or not take some action relative to the plaintiff.").

[7] The residence of the Ohio Chamber of Commerce is unstated in the pleadings, but also irrelevant, because the Ohio Chamber plainly lacks standing for failure to identify any member at all.

Related principles of equity and Article III provide that the court must be able to bind the parties before it—and only them—to a judgment. *See, e.g.*, *Haaland v. Brackeen*, 143 S. Ct. 1609, 1639 (2023) (no standing where the necessary relief would have to run against non-parties); *Taylor v. Sturgell*, 553 U.S. 880, 898 (2008) ("[O]ur decisions emphasize the fundamental nature of the general rule that a litigant is not bound by a judgment to which she was not a party."). *Cf. Arizona v. Biden*, 40 F.4th 375, 395, 398 (6th Cir. 2022) (Sutton, C.J., concurring) (explaining why "nationwide (or universal) injunctions (or remedies) that bar the federal government from enforcing a law or regulation anywhere and against anyone" should be "eliminated root and branch"). When it comes to suits by associations, the ordered relief, though formally running with respect to the association, benefits the individual members who would otherwise be able to show injury. *Ass'n of Am. Physicians*, 13 F.4th at 540 ("[R]elief in an associational-standing case must benefit (and ameliorate an injury to) the association's members."). In the typical associational-standing case, then, the Sixth Circuit has assumed that such remedies satisfy Article III and related equitable requirements. *See id.*

But that assumption is untenable where a plaintiff association's members also bring their *own* lawsuits seeking to advance the same interests, and to obtain the same remedy. That is the case here: several drug manufacturers have brought their own suits, seeking effectively the same relief as these Plaintiff associations—and at least one of those manufacturers appears to be a member of at least one Plaintiff here. *See, e.g.*, *Merck v. Becerra*, No. 1:23-cv-01615 (D.D.C.); Allison Dembeck, *In Her Own Words*, U.S. Chamber of Commerce (Jan. 27, 2023), https://perma.cc/MAS8-W8B4 (describing Merck as a member of the U.S. Chamber).[8] By filing their own lawsuits, those manufacturers have demonstrated an intent to be bound by *those* courts' judgments, win or lose—not this Court's. And those choices—exercised by four different drug manufacturers, so far—undermine this Court's ability to render a judgment that provides association-wide relief. *Cf., e.g.*, *Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg'l Plan. Agency*, 322 F.3d 1064, 1084 (9th Cir. 2003) ("If the individual members of the

[8] *See also 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.).

Association were not bound by the result of the former litigation, the organization would be free to attack the judgment ad infinitum by arranging for successive actions by different sets of individual member plaintiffs.").

Consider what would happen if Plaintiffs here and individual member manufacturers all continued with simultaneous lawsuits. Different courts might reach different conclusions regarding the merits of the same constitutional claims. If such a conflict arose, drug manufacturers who are also members of one of the association Plaintiffs here would seek to follow the more favorable ruling, while refusing to accept the adverse judgment. The parties might then have to litigate complex questions of preclusion. *See, e.g.*, *Taylor*, 553 U.S. at 894 (discussing circumstances in which "a nonparty may be bound by a judgment because she was 'adequately represented,'" as occurs in "class actions"); *cf. Ass'n of Am. Physicians*, 13 F.4th at 541 ("If members may rely on the injunction if an organization wins, should they be bound by the judgment if it loses?"). That sort of remedial morass is fundamentally inimical to the equitable concerns of "administrative convenience and efficiency" that the associational-standing doctrine was developed in part to promote. *United Food & Com. Workers Union Loc. 751 v. Brown Grp., Inc.*, 517 U.S. 544, 557 (1996); *see, e.g.*, *Brackeen*, 143 S. Ct. at 1639 ("Without preclusive effect, a declaratory judgment is little more than an advisory opinion."). And it could be the case that the government, even having prevailed over a manufacturer in a lawsuit filed by that manufacturer, would never see the benefit of that victory. *See Dep't of Homeland Sec. v. New York*, 140 S. Ct. 599, 601 (2020) (Gorsuch, J., concurring) (lamenting the "gamesmanship and chaos" as well as the "asymmetric" effects of injunctions benefitting non-parties, in which "the government's hope of implementing any new policy could face the long odds of a straight sweep, parlaying a 94-to-0 win in the district courts into a 12-to-0 victory in the courts of appeal").

Here, these concerns are real. Merck, a drug manufacturer, both (1) appears to be a member of Plaintiff the U.S. Chamber of Commerce, and (2) is also a plaintiff in its own (earlier-filed) lawsuit in the District of Columbia. If Merck loses in D.C. but the Chamber wins here, or vice versa, does Merck get relief? And who decides—this Court, or the district court in D.C., where Merck filed its own lawsuit? What if the two courts disagree, even on that secondary remedial question? These

significant questions are precisely the sort of remedial quandaries that the third associational-standing requirement—often described as prudential—seeks to avoid. *See generally Brown Grp.*, 517 U.S. at 557; *Ass'n of Am. Physicians*, 13 F.4th at 540–42. Thus, even if each Plaintiff could otherwise establish Article III standing, because "the relief requested" here "requires the participation" of Plaintiffs' individual members, dismissal is warranted. *Ass'n of Am. Physicians*, 13 F.4th at 537 (citation omitted).

II. Plaintiffs' Claims Are Not Ripe

For reasons that are conceptually distinct but similar in kind to the problems with Plaintiffs' theory of standing, their claims are also not ripe. "Ripeness is a justiciability doctrine designed 'to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties.'" *Nat'l Park Hosp. Ass'n v. Dep't of Interior*, 538 U.S. 803, 807–08 (2003) (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 148–49 (1967)). "A claim is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." *Texas v. United States*, 523 U.S. 296, 300 (1998). The "ripeness doctrine is drawn both from Article III limitations on judicial power and from prudential reasons for refusing to exercise jurisdiction." *Reno v. Cath. Soc. Servs., Inc.*, 509 U.S. 43, 57 n.18 (1993). In analyzing ripeness, the key considerations are "the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Abbott Labs.*, 387 U.S. at 149. Both favor dismissal here.

First, Plaintiffs will suffer no hardship from "withholding court consideration" until (if ever) a concrete injury is imminent. *Id.* As discussed above, AbbVie is the only member of any of the Plaintiff associations identified in the complaint. Even if Plaintiffs had sufficiently alleged that AbbVie had a financial interest in Imbruvica that could support standing as a general matter, *but see supra* at 12-15, any such interest is years away from being affected by these statutory changes. If Imbruvica is selected, and if Pharmacyclics and CMS agree to a negotiated price by August 2024, that price will not take effect until 2026. 42 U.S.C. § 1320f(d). And everything that might happen in the interim—Imbruvica being selected on September 1, 2023, Pharmacyclics agreeing to negotiate on October 1,

2023, CMS and Pharmacyclics negotiating and ultimately agreeing to a price in August 2024, that price being announced in September 2024—would have no judicially cognizable effects on AbbVie, unless and until the price of Imbruvica falls (even assuming that AbbVie has a financial interest in Imbruvica aside from its status as a shareholder of Pharmacyclics). So to the extent AbbVie would ever suffer a cognizable injury, it would not occur until 2026.

Second, as for the "fitness of the issues for judicial decision," *Abbott Labs.*, 387 U.S. at 149, for similar reasons, "further factual development would significantly advance [the Court's] ability to deal with the legal issues presented," *Nat'l Park Hosp. Ass'n*, 538 U.S. at 812 (citation omitted). As discussed above, *see supra* at 8-10, especially given the complicated role played by rebates and middlemen, it is possible that Medicare could achieve savings even if the "maximum fair price" falls at or near the "ceiling price," leaving manufacturers in essentially the same position they are in now.

These uncertainties are especially acute with respect to the only claim on which Plaintiffs seek preliminary relief. For that Fifth Amendment claim, the actual price is not just *relevant* to Plaintiffs' theory of injury or liability; essentially, it *is* their theory: that (starting in 2026) they will face "prices so low as to deprive manufacturers of their property without due process of law." Compl. ¶ 167. Setting aside Defendants' threshold arguments (and Plaintiffs' misstatements about the relevant legal standard), it would be impossible for the Court to evaluate the merits of that claim without even knowing what those prices will be. *See supra* at 8-10. At an absolute minimum, that claim should thus be dismissed for lack of subject-matter jurisdiction (which would also necessarily result in denial of Plaintiffs' motion for a preliminary injunction). *See, e.g.*, *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2208 (2021) ("[S]tanding is not dispensed in gross; rather, plaintiffs must demonstrate standing for each claim that they press and for each form of relief that they seek.").

* * *

"Article III grants federal courts the power to redress harms that defendants cause plaintiffs, not a freewheeling power to hold defendants accountable for legal infractions." *Id.* at 2205 (citation omitted). The U.S. Chamber of Commerce and its affiliates do not face any concrete, particularized, or imminent Article III injury because of the Negotiation Program, nor do any of their members—

including AbbVie, the only member that any of the Plaintiffs has identified. And Plaintiffs do not present any claims that are fit for judicial resolution at this early stage, before any drugs have been selected for negotiation and any prices have been agreed upon. Their recourse is to the political branches.

CONCLUSION

The complaint should be dismissed, in its entirety, under Federal Rule of Civil Procedure 12(b).

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Respectfully submitted,

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