

No. 24-3868

**UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT**

DAYTON AREA CHAMBER OF COMMERCE; OHIO CHAMBER OF COMMERCE;
MICHIGAN CHAMBER OF COMMERCE; CHAMBER OF COMMERCE OF THE
UNITED STATES OF AMERICA,

Plaintiffs-Appellants,

v.

XAVIER BECERRA, in his official capacity as Secretary of the US
Department of Health and Human Services;
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES;
CHIQUITA BROOKS-LASURE, in her official capacity as
Administrator of the Centers for Medicare and Medicaid Services;
CENTERS FOR MEDICARE AND MEDICAID SERVICES,
Defendants-Appellees.

On Appeal from the United States District Court for the Southern
District of Ohio, No. 3:23-cv-00156, Hon. Michael J. Newman

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CORPORATE DISCLOSURE STATEMENT

Plaintiffs-Appellants make the following disclosures under Sixth Circuit Rule 26.1(b)(1-2):

1. Is any Plaintiff a subsidiary or affiliate of a publicly owned corporation? No.

2. Is there a publicly owned corporation, not a party to the appeal or an *amicus*, that has a substantial financial interest in the outcome of this litigation by reason of insurance, a franchise agreement, or indemnity agreement? None known.

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STATEMENT IN SUPPORT OF ORAL ARGUMENT

Pursuant to Federal Rule of Appellate Procedure 34(a) and Sixth Circuit Rule 34(a), Plaintiffs respectfully request oral argument. Oral argument is warranted because this appeal stems from a constitutional challenge to a major federal program with nationwide implications and the district court's order dismissing Plaintiffs' suit for lack of venue has importance for many organizations seeking to litigate under the doctrine of associational standing.

INTRODUCTION

Chambers of commerce—groups of businesses joining together to promote and protect their interests—are as old as our country itself. That is because businesses have long recognized the need to band together to educate the people and their representatives about what policies will promote economic growth and what policies will stymie it. They have also recognized the value in pooling resources to challenge policies in court and have frequently done so.

In this case, the district court erred as a matter of law in holding that three chambers of commerce lacked standing to challenge a statute that will force their members to lower the prices that those members can charge for their goods. It erroneously conflated the first and second parts of the associational-standing test, importing an Article III injury analysis into the question whether a suit is germane to an association's purposes. The district court effectively created a new legal rule that a chamber of commerce can represent its members' interests only if those interests are uniquely localized within a region—for example, if the member is headquartered there. And it then dismissed the suit for lack of venue.

That ruling has no basis in associational-standing precedent, in common sense, or in economics. Businesses frequently sell goods or services in areas far from their headquarters, and they plainly have an interest in their ability to do so. Thus, it is no surprise that businesses join chambers of commerce around the country and that those chambers of commerce represent their interests. Here, the challenged law will directly affect the price of goods that the chambers' members will receive for their goods in the region of special interest to each chamber, and the chambers have an interest in challenging it, on behalf of both members in the pharmaceutical industry and other members with a stake in resisting unconstitutional price controls on lawful articles of commerce.

This Court should reverse. Each chamber easily meets the familiar requirements of associational standing: Each has identified at least one member who is directly harmed by the price-setting law that they challenge; the predictable effects of the law, including economic harm to their members, are germane to their interests in promoting the economic climate in their respective regions; and the facial constitutional challenges that they brought do not require the participation of any

individual member. This Court should vindicate the chambers' associational rights and allow them to proceed with their suit.

JURISDICTION

The district court had jurisdiction under 28 U.S.C. §§ 1331 and 1346. On August 8, 2024, the court entered a final order dismissing Plaintiffs' claims for improper venue. Plaintiffs filed a timely notice of appeal on October 4, 2024. This Court has jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES

1. Whether this case is germane to the purposes of the Dayton Area Chamber of Commerce.

2. Whether Plaintiffs otherwise satisfy the requirements of associational standing.

STATEMENT OF THE CASE

I. The Challenged Law

This case concerns an unprecedented system of price controls that applies to prescription drugs in certain federal health care programs. Medicare covers prescription drugs either through Medicare Part B, for drugs that physicians administer to their patients, 42 U.S.C. §§ 1395k(a)(1), 1395x(s)(2)(A), or Part D, for self-administered

prescription drugs. Since 2005, Medicare Part B has reimbursed providers 106% of a drug's Average Sales Price, which is the average price to commercial purchasers in the United States inclusive of rebates and other discounts. *Id.* § 1395w-3a. And since Part D's enactment in 2003, Medicare Part D reimbursements have been determined by negotiations between pharmaceutical manufacturers and the private insurers that contract with the Centers for Medicare & Medicaid Services ("CMS") to provide the Medicare Part D plans in the first place. Congress prohibited the Department of Health and Human Services ("HHS") from setting prices or otherwise "interfer[ing]" in those market-based negotiations. *Id.* § 1395w-111(i).

In August 2022, by razor-thin margins, Congress passed the Inflation Reduction Act, which includes a Drug-Price Negotiation Program ("the Program") that would revolutionize this approach. *Id.* § 1320f(a). Under the Act, the Secretary of HHS will select certain drugs for the Program each year. Once a manufacturer's drug is selected, it must (1) "agree" to enter "negotiation" with HHS over the price of its selected drug, (2) submit detailed, sensitive information to HHS, and (3) "agree" to the "maximum fair price" set by HHS. 26 U.S.C.

§ 5000D(b)(1)–(4). HHS begins the “negotiation” “by making a maximum offer of between 40% and 75% of a market-based benchmark; there is no limit to how low HHS’s offer can be.” *Nat’l Infusion Ctr. Ass’n v. Becerra*, 116 F.4th 488, 495 (5th Cir. 2024) (“NICA”); see 42 U.S.C. § 1320f-3(b)(2)(F), (c)(1)(C)(i), (c)(3). The manufacturer is permitted to “counteroffer”—and then HHS is empowered to set whatever price it wants and compel the manufacturer to endorse that price as the “maximum fair price.” *Id.* § 1320f-3(b)(2)(C)–(D), (c)(1). As a result of the statutory ceiling, the government-imposed price will be at least 25-60% below market-price benchmarks and could be much lower. *Id.* § 1320f-3(c)(1)(C), (b)(2)(F). Indeed, the prices for the first selected drugs were as much as 79% lower than the list price.¹

If a manufacturer declines to participate in the Program’s “negotiation” or to agree to HHS’s chosen price, the manufacturer is subject to an escalating “tax” on “all sales of the drug (not just Medicare sales) that starts at 185.7% of the drug’s price and rises to 1,900%

¹ See CMS, Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026 (Aug. 2024) (“Selected Drugs Fact Sheet”), available at <https://www.cms.gov/newsroom/fact-sheets/medicare-drug-price-negotiation-program-negotiated-prices-initial-price-applicability-year-2026>.

depending on the duration of noncompliance.” *NICA*, 116 F.4th at 495; *see* 26 U.S.C. § 5000D(a), (b). The Congressional Budget Office predicted that this so-called “tax” “would raise no revenue because no manufacturer could afford to pay it.” *NICA*, 116 F.4th at 495.

The only way for a manufacturer to avoid this “tax” is to agree to HHS’s chosen price or—in theory—to withdraw from Medicare and Medicaid entirely, meaning that *all* of the manufacturer’s drugs (not just the drug selected for “negotiation”) would become unavailable to patients in both programs. 26 U.S.C. § 5000D(c); 42 U.S.C. § 1396r-8(a)(1). But even if a manufacturer wanted to withdraw, it could not do so in time to avoid the Program’s penalties; Congress mandated a delay of 11 to 23 months, depending on the timing during the calendar year, for a notice of withdrawal to take effect. *See* 42 U.S.C. § 1395w-114a(b)(4)(B)(ii) (Medicare Coverage Gap Agreement); *id.* § 1395w-114c(b)(4)(B)(ii) (“Manufacturer Discount Agreement” under IRA).

The Program will expand over time. Congress directed HHS to select ten drugs for the Program in 2023 for the 2026 price applicability year.² By February 1, 2025, HHS must select 15 more Part D drugs for

² *See* Selected Drugs Fact Sheet at 1.

2027, then 15 more Part D and Part B drugs for 2028 in the next round, and 20 more Part D and Part B drugs for 2029 and every year thereafter. 42 U.S.C. §§ 1320f(b)(3), 1320f-1(a)(1)–(4). By 2029, then, as many as 60 different drugs will be price-controlled.

Even that figure understates the scope of the Program. In guidance, CMS, which is administering the program on behalf of HHS, has taken a maximalist view of what constitutes a single “drug.” *See* Memorandum from CMS on Revised Guidance for Medicare Drug Price Negotiation Program, at 99–100 (June 30, 2023) (“Revised Guidance”), *available at* <https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf>. This view sweeps in different products—that have different dosage forms and strengths, were subject to separate clinical trials, help different patient populations, and have different treatment indications—merely because they contain the same active moiety (*i.e.*, molecular basis) or active ingredient and are marketed by the same holder of a new-drug or biologics-license application. *Id.*

Despite the risk that the Program would lead to arbitrary, confiscatory, or discriminatory prices, Congress insulated much of it from

scrutiny. Section 1320f-7 of the IRA provides that there will be “no administrative or judicial review” of HHS’s “determination of negotiation-eligible drugs under section 1320f-1(d),” “selection of drugs under section 1320f-1(b),” or “determination of a maximum fair price.” The IRA further directs HHS to “implement” the program “for 2026, 2027, and 2028 by program instruction or other forms of program guidance.” 42 U.S.C. § 1320f note.

II. Plaintiffs and Their Members

Plaintiffs are four chambers of commerce representing members that include companies of every size in a wide range of industries, including pharmaceutical manufacturers directly subject to the IRA’s price-control scheme.

The Dayton Area Chamber of Commerce brings together over 2,200 businesses and organizations in a 14-county area surrounding Dayton. R.29-2 (Kershner Declaration), PageID#171 ¶ 4. It strives to improve the region’s business climate through public policy advocacy. *Id.* The Dayton Area Chamber “commits to its members and the greater Dayton region that it will strive for a business friendly legislative and regulatory environment that encourages the growth and economic prosperity of

businesses.” *Id.*, PageID#171 ¶ 6. As part of that mission, it “advocates for a legal and political environment that will allow its members to compete in a free market to control costs.” *Id.*

The Ohio Chamber of Commerce has nearly 7,000 members. R.29-4 (Long Declaration), PageID#181 ¶ 4. As an advocate and resource for its members, the Ohio Chamber develops public-policy positions for its members’ benefit on both state and federal matters. *Id.* The Ohio Chamber’s mission includes advocacy for an affordable, sustainable, market-based health care system that promotes access to quality health care for all Ohioans. *Id.*, PageID#181–82 ¶ 6. As part of that mission, it opposes government regulations that discourage innovation and deny its members a fair return on their investments in the health care space. *Id.*

The Michigan Chamber of Commerce represents approximately 4,000 members, which employ more than 1 million people. R.29-3 (Holcomb Declaration), PageID#176 ¶ 4. Its goal is to advance its members’ public-policy priorities through legislative, legal, and political action. *Id.*

The Chamber of Commerce of the United States of America (“U.S. Chamber”) is the world’s largest business federation, with approximately

300,000 direct members. R.29-6 (Quaadman Declaration), PageID#194 ¶ 4. Its mission is to advocate for policies that enable businesses to grow and create jobs in their communities. *Id.*, PageID#194–95 ¶ 6. As part of that mission, the U.S. Chamber supports the ability of private companies at every stage of innovation in the pharmaceutical and life sciences industry to invest in new therapies and treatments. *Id.*

All four Plaintiffs have members that are directly subject to the IRA's price controls. *See* R.29-2 (Kershner Declaration), PageID#171 ¶ 5 (Dayton Chamber); R.29-4 (Long Declaration), PageID#181 ¶ 5 (Ohio Chamber); R.29-3 (Holcomb Declaration), PageID#176 ¶ 5 (Michigan Chamber) R.29-6 (Quaadman Declaration), PageID#194 ¶ 5 (U.S. Chamber). These members include AbbVie Inc. and its wholly owned subsidiary Pharmacyclics LLC, which manufacture IMBRUVICA®, one of the drugs already selected by CMS for price controls. R.49-1 (Staff Supp. Declaration), PageID#393, 395–97 ¶¶ 5, 13–21; R.29-5 (Staff Declaration), PageID#185 ¶ 2; R.49-1 (Staff Supp. Declaration), PageID#398 ¶ 29.³

³ IMBRUVICA was originally developed by Pharmacyclics, which AbbVie acquired in 2015. R.49-1 (Staff Supp. Declaration), PageID#394

III. Procedural History

Plaintiffs filed suit in June 2023, pleading claims that the IRA violates the separation of powers, the Due Process Clause, the Excessive Fines Clause, and the First Amendment and exceeds Congress’s legislative powers. R.1 (Complaint), PageID#1. Plaintiffs requested declaratory and injunctive relief, naming as defendants HHS, CMS, and the heads of those agencies in their official capacities (collectively, the “government”).

Plaintiffs moved for a preliminary injunction, anticipating that their members would be among the manufacturers whose drugs would soon be selected for price controls. *See* R.29-1 (Preliminary Inj. Memo.), PageID#156–57. The government moved to dismiss. R.33 (Motion to Dismiss), PageID#204. The government argued that Plaintiffs lacked

¶¶ 8–10. Because Pharmacyclics remains the holder of the FDA new drug applications for IMBRUVICA, CMS’s guidance deems Pharmacyclics the “Primary Manufacturer” of IMBRUVICA. *See* Revised Guidance at 118. In reality, however, AbbVie performs most of the functions falling within the statutory definition of “manufacturer” with respect to IMBRUVICA. R.49-1 (Staff Supp. Declaration), PageID#395–96 ¶¶ 13–17. Because both AbbVie and Pharmacyclics are members of all four Plaintiffs, any distinction between them is immaterial for purposes of this appeal, and for simplicity this brief therefore uses “AbbVie” to refer to the two entities collectively.

standing because their alleged injuries were speculative, *id.*, PageID#219–22, that they had not identified a member with standing, *id.*, PageID#223–27, and that the relief requested required participation by individual members, *id.*, PageID#227–30. As a fallback, the government contended that venue would not be proper if the court agreed with the government’s member-standing and member-participation arguments with respect to the Dayton Area Chamber. *Id.*, PageID#227. The government never challenged the germaneness of the lawsuit to the purposes of the Dayton Area Chamber or of any other Plaintiff. *See generally* R.33 (Motion to Dismiss); R.52 (Motion to Dismiss Reply).

The district court denied both sides’ motions. R.55 (Order), PageID#601. Plaintiffs subsequently filed an amended and supplemental complaint, which asserted the same claims. R.57 (Amended Complaint), PageID#606. By that time, HHS had selected IMBRUVICA for price controls. *See* R.57 (Amended Complaint), PageID#616 ¶ 37.

The parties then filed cross-motions for summary judgment, and the government simultaneously moved to dismiss. The government no longer contested that Plaintiffs had identified at least one member with an Article III injury-in-fact. Instead, the government argued for the first

time that this lawsuit is not germane to the purposes of the Dayton Area Chamber of Commerce. R.71 (Defs.’ Combined Motion to Dismiss and Cross-Motion for Summ. J.), PageID#842–45. The government did not challenge the germaneness element for any other Plaintiff. On the individual-participation prong of the associational-standing test, the government argued that all Plaintiffs lacked standing because the existence of “multiple suits by individual drug manufacturers” challenging the constitutionality of the IRA made this suit “unworkable.” *Id.*, PageID#848.

The district court dismissed the case for improper venue. R.102 (Final Order), PageID#1556. The court questioned the continued validity of the Supreme Court’s associational-standing doctrine, citing dicta from a panel of this Court and a separate opinion by a single Supreme Court justice. *Id.*, PageID#1561–62 (citing *Ass’n of Am. Physicians & Surgeons v. FDA*, 13 F.4th 531, 537–42 (6th Cir. 2021) (“AAPS”); *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 402 (2024) (Thomas, J., concurring)). The court acknowledged that the Supreme Court’s three-part associational-standing test had not been “specifically overruled,” but stated that it

would apply that test with special attention to what it called “the ultimate goals of the standing requirement.” *Id.*

The district court assumed, without deciding, that each Plaintiff had a member that would have standing to bring the claims in its own right. R.102 (Final Order), PageID#1563. The court concluded that the government had not forfeited its germaneness argument by omitting it from its first motion to dismiss, asserting that the government was making “the same” argument about venue—*i.e.*, that venue was improper—even though its legal theory was different. *Id.*, PageID#1570. Turning to the substance of the germaneness issue, the court said it would “adopt a narrow interpretation” of the interests at stake in this lawsuit. *Id.*, PageID#1565. Applying that “narrow interpretation,” the court concluded that this suit is not germane to the purposes of the Dayton Area Chamber because the two named members, AbbVie and Pharmacyclics, are not based in the Dayton area. *Id.* As for the Program’s “potential downstream effects,” including on investment in the pharmaceutical industry more generally, the court dismissed those effects as “far too speculative” to be germane to the Dayton Area Chamber. *Id.*, PageID#1564–65. The court then went beyond what the

government had argued by finding that the suit was *also* not germane to the purposes of the Ohio and Michigan Chambers. *Id.*, PageID#1566. Only the U.S. Chamber, with its “nationwide” purpose, the court concluded, could satisfy the germaneness element. *Id.*

The court also commented upon the prudential requirement that neither the claims asserted nor the relief requested necessitate the participation of individual members. *Id.*, PageID#1567. The court acknowledged the “general rule” that this requirement is satisfied when a suit raises pure questions of law and seeks declaratory or injunctive relief. *Id.* Characterizing the case law on this requirement as “scarce,” however, the court “question[ed]” whether “individual member participation in this case would be required and would defeat associational standing for the only remaining Plaintiff,” the U.S. Chamber. *Id.*, PageID#1567–68 (citing *All. for Hippocratic Med.*, 602 U.S. at 400–01 (Thomas, J., concurring)).

Having determined that the Dayton Area Chamber lacked standing, the court found that venue was not proper in the Western Division of the Southern District of Ohio. *Id.*, PageID#1571. Because the court had also found, *sua sponte*, that the Ohio Chamber lacked

associational standing, the court declined to transfer the case to the Eastern Division of the Southern District of Ohio. *Id.*, PageID#1571–72.

STANDARD OF REVIEW

This Court reviews de novo a district court’s conclusions of law, including “a district court’s determination of standing,” *Pedreira v. Ky. Baptist Homes for Child., Inc.*, 579 F.3d 722, 728 (6th Cir. 2009), a district court’s determination of improper venue, *Michigan Corp. v. Bramlet*, 141 F.3d 260, 262 (6th Cir. 1998), and all other errors in the “application of law to the facts,” *Charvat v. GVN Mich., Inc.*, 561 F.3d 623, 627 (6th Cir. 2009).

SUMMARY OF ARGUMENT

The district court dismissed Plaintiffs’ claims for improper venue based on a novel theory of associational standing that runs afoul of settled doctrine. Plaintiffs easily satisfy the well-established three-part test for associational standing. First, each Plaintiff identified at least one member that would have standing in its own right to assert these claims. Second, this lawsuit, which combats unconstitutional government overreach that harms the pharmaceutical industry as a whole and threatens to set dangerous precedents for free enterprise beyond any single industry, is germane to each Plaintiff’s purpose. For example, it is

germane to the Dayton Area Chamber's purpose of promoting a business-friendly environment in the Dayton region and protecting its members' interests in an innovative, affordable health care system that lowers costs through market forces rather than government coercion. Third, because Plaintiffs' claims present pure questions of law and Plaintiffs request only prospective relief, this suit does not require the participation of individual members. Each Plaintiff therefore has associational standing, and venue is proper in the Western Division of the Southern District of Ohio.

In concluding otherwise, the district court applied a cramped view of associational-standing doctrine that it sought to root in inapposite dicta and a single-Justice concurrence questioning the validity of the Supreme Court's associational-standing doctrine altogether. But those opinions did not change controlling law or license the district court to remake associational-standing doctrine. In fact, in one of its key precedents on associational standing, the Supreme Court squarely rejected a prior attempt by the government to get the doctrine overruled.

This Court should reverse the district court's decision and, to avoid the need for successive piecemeal appeals on threshold issues, should

hold that Plaintiffs satisfy all of the requirements for associational standing.

ARGUMENT

I. The district court erred in dismissing Plaintiffs' claims for improper venue.

The district court's decision to dismiss this case for improper venue was premised on the court's unprecedented application of the established three-part test for associational standing—especially the modest requirement that the lawsuit be germane to the organizational plaintiff's purpose. An association has standing “on behalf of its members ‘when [(a)] its members would otherwise have standing to sue in their own right, [(b)] the interests at stake are germane to the organization's purpose, and [(c)] neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit.’” *Memphis A. Philip Randolph Inst. v. Hargett*, 2 F.4th 548, 555 (6th Cir. 2021) (quoting *Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc.*, 528 U.S. 167, 181 (2000)). Each of the plaintiffs easily satisfies all three elements.

A. The Dayton Area Chamber, Ohio Chamber, and Michigan Chamber have standing.

In concluding that this lawsuit is not germane to the purposes of the Dayton Area Chamber, the Ohio Chamber, or the Michigan Chamber, the district court applied an unrecognizable version of the germaneness requirement and ignored those chambers' legitimate stake in opposing unconstitutional government overreach that has nationwide implications, including in their regions. Because the Dayton Area Chamber is the venue-supporting plaintiff for the Western Division of the Southern District of Ohio, Plaintiffs focus the below analysis on that chamber.

1. At least one member of the Dayton Area Chamber of Commerce would have standing to sue in its own right.

The court merely “assume[d], without holding,” that the Dayton Area Chamber satisfied the first prong of the associational-standing test. R.102 (Final Order), PageID#1563. Yet even the government did not contest that prong, and for good reason. To establish that one of its members has Article III standing, an association need only show that the member “(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.” *Waskul v. Washtenaw Cnty. Cmty. Mental Health*, 900 F.3d 250, 255 (6th Cir. 2018) (quoting *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016)). “When the suit is one challenging the legality of government action” and an entity is itself “an object of the action,” “there is ordinarily little question that the action ... has caused [it] injury, and that a judgment preventing or requiring the action will redress it.” *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561–62 (1992). One way to demonstrate an injury-in-fact is with an actual or anticipated “economic injury.” *Clinton v. City of New York*, 524 U.S. 417, 432 (1998). Even in the absence of a probable economic injury, however, a “procedural injury” may suffice, *Doe v. Univ. of Mich.*, 78 F.4th 929, 944 n.4 (6th Cir. 2023); a plaintiff “who has been accorded a procedural right to protect his concrete interests can assert that right without meeting all the normal standards for redressability and immediacy.” *Parsons v. DOJ*, 801 F.3d 701, 712 (6th Cir. 2015) (quoting *Lujan*, 504 U.S. at 572 n.7); see also *Rice v. Vill. of Johnstown*, 30 F.4th 584, 589–91 (6th Cir. 2022) (holding that plaintiffs had standing where they alleged that town’s delegation of legislative power to zoning commission violated their due-

process rights). A procedural injury that is “tied to” an “economic interest” is sufficient. *Rice*, 30 F.4th at 591.

The Dayton Area Chamber’s members include pharmaceutical manufacturers that already are and will continue to be direct “object[s]” of the IRA’s unlawful price-control regime. *Lujan*, 504 U.S. at 561; see R.29-2 (Kershner Declaration), PageID#171 ¶ 5. AbbVie and Pharmacyclics’ drug IMBRUVICA was one of the first drugs that CMS selected for price controls. See R.64-1 (Third Staff Declaration), PageID#777–78 ¶¶ 3–7. AbbVie and Pharmacyclics have indisputably suffered, and will continue to suffer, economic injury from the Program. Because of IMBRUVICA’s selection, AbbVie was forced to write down the value of IMBRUVICA by more than \$2 billion. *Id.*, PageID#779 ¶ 9. To avoid the crushing “excise tax” and penalties of \$1 million per day of noncompliance, dozens of AbbVie and Pharmacyclics employees spent months collecting large amounts of complex, commercially sensitive data for submission to CMS. *Id.*, PageID#778 ¶ 5. The threat of the astronomical “tax” also compelled Pharmacyclics (through AbbVie) to sign under protest an “agreement” to “negotiate” with CMS. *Id.*, PageID#777–78 ¶¶ 3–4. And the “negotiation” required, and the

provisions for operationalizing access to the “maximum fair price” continue to require, a team of AbbVie and Pharmacyclics employees to engage in time-intensive and expensive work. *Id.*, PageID#779 ¶ 8. Such “compliance costs are a recognized harm for purposes of Article III” standing. *Kentucky v. Yellen*, 54 F.4th 325, 342–43 (6th Cir. 2022).

In addition, a manufacturer whose drug is selected is certain to face either “lower prices and corresponding revenue loss,” *NICA*, 116 F.4th at 499, if it accepts HHS’s dictated price (as basic economics drives manufacturers to do) or even more extreme economic harm if it either accepts the 1,900% penalty or exits Medicare entirely. *See id.* at 500. Those economic losses are quintessential Article III injuries. *See Czyewski v. Jevic Holding Corp.*, 580 U.S. 451, 464 (2017) (“For standing purposes, a loss of even a small amount of money is ordinarily an ‘injury.’”). There is also no question that those injuries are traceable to the challenged provisions and redressable by Plaintiffs’ requested declaratory and injunctive relief.

Moreover, manufacturers whose drugs are or will be selected are deprived of procedural rights intended to protect their concrete interests. The Fifth Amendment’s Due Process Clause exists to ensure that no one

is deprived of property without procedural protections. A price-control regime is unconstitutional if it lacks a set of procedures that “adequately safeguards against confiscatory rates, and therefore, ensures a constitutional rate of return.” *Mich. Bell Tel. Co. v. Engler*, 257 F.3d 587, 592–93 (6th Cir. 2001). The Program’s price-control regime has no statutory standard to guard against confiscatory rates; it expressly prohibits judicial review of the rates set by HHS, 42 U.S.C. § 1320f-7; and it does not even guarantee manufacturers and other stakeholders the opportunity to weigh in via notice-and-comment rulemaking. *See id.* § 1320f-1 note. All of these procedural deficiencies are “tied” to manufacturers’ economic interests. *Rice*, 30 F.4th at 591. Therefore, Plaintiffs’ procedural injuries also satisfy Article III. *See Parsons*, 801 F.3d at 711–12; *cf. NICA*, 116 F.4th at 503–04 (finding procedural injury based on IRA’s lack of procedural safeguards).

Despite these economic and procedural injuries, the district court questioned whether Plaintiffs satisfied the member-standing element and said the court “would need to analyze ... each claim separately.” R.102 (Final Order), PageID#1563. Given the court’s hesitation about even this uncontested element of the test for associational standing, this

Court should avoid piecemeal litigation and hold now that Plaintiffs satisfy the first element of associational standing with respect to all five of their claims:

- *Separation of Powers*. Count One asserts that the IRA’s extraordinary delegation of power to HHS violates the separation of powers because it lacks the constitutional safeguards necessary to ensure accountability, rationality, and fairness. R.57 (Amended Complaint), PageID#649–55 ¶¶ 157–81. This violation of separation of powers causes Plaintiffs both economic injuries, because their compliance costs and reduced revenues flow from the unconstitutional delegation, and procedural injuries, because the missing safeguards are tied to concrete economic interests. *See Parsons*, 801 F.3d at 712; *Rice*, 30 F.4th at 591; *Seila Law LLC v. CFPB*, 591 U.S. 197, 211 (2020); *Collins v. Yellen*, 594 U.S. 220, 243–44 (2021).
- *Due Process*. Count Two asserts that the IRA’s lack of procedural protections, including adequate standards for price-setting, notice-and-comment rulemaking, and judicial review, violates due process. R.57 (Amended Complaint), PageID#655–62 ¶¶ 182–212. Again, the deprivation of these essential procedural safeguards, which are tied to concrete economic interests, constitutes a procedural injury that satisfies Article III. *Parsons*, 801 F.3d at 712; *Rice*, 30 F.4th at 591.
- *Excessive Fines*. Count Three asserts that the IRA’s “excise tax” of up to 1,900% is a grossly disproportionate penalty that violates the Eighth Amendment’s prohibition on excessive fines. R.57 (Amended Complaint), PageID#662–65 ¶¶ 213–27. The IRA deploys that penalty to strong-arm manufacturers into accepting the Program’s compliance costs and below-market “negotiated” prices.
- *Lack of Legislative Authority*. Count Four asserts that the so-called “excise tax” exceeds Congress’s legislative authority because it is a penalty rather than a true tax and seeks to compel commerce rather than to regulate it. R.57 (Amended Complaint), PageID#665–68

¶¶ 228–46. This constitutional violation, too, inflicts economic injuries likely to be redressed by Plaintiffs’ requested relief.

- *Compelled speech.* Count Five asserts that the IRA’s provisions forcing manufacturers to pretend that they “agree” to HHS’s price and to endorse that government-set price as the “maximum fair price” violate the First Amendment. R.57 (Amended Complaint), PageID#668–71 ¶¶ 247–59. Compelled speech is an Article III injury; indeed, “[t]he loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury.” *Roman Cath. Diocese v. Cuomo*, 592 U.S. 14, 19 (2020) (per curiam) (quoting *Elrod v. Burns*, 427 U.S. 347, 373 (1976) (plurality op.)). As with the other counts, this injury is traceable to the challenged provisions and likely to be redressed by Plaintiffs’ requested relief.

As this analysis confirms, application of the member-standing requirement here is straightforward and should be resolved now in Plaintiffs’ favor on all of their claims.

2. This lawsuit is germane to the purposes of the Dayton Area Chamber.

The Dayton Area Chamber also readily satisfies the associational-standing doctrine’s modest germaneness requirement. The Dayton Area Chamber “commits to its members and the greater Dayton region that it will strive for a business friendly legislative and regulatory environment that encourages the growth and economic prosperity of businesses.” R.29-2 (Kershner Declaration), PageID#171 ¶ 6; *see* R.1 (Complaint), PageID#9 ¶ 28. The subject of this litigation—a price-control program for

lawful articles of commerce—implicates the rights and interests of a wide range of businesses, including but not limited to the pharmaceutical industry and businesses connected to that industry. Challenging that overreach is obviously relevant to the Dayton Area Chamber’s purpose of advancing a business-friendly regulatory environment and promoting economic prosperity in the region.

The germaneness requirement is “undemanding.” *Nat’l Lime Ass’n v. EPA*, 233 F.3d 625, 636 (D.C. Cir.), *as amended on denial of reh’g* (Feb. 14, 2001) (quoting *Humane Soc’y v. Hodel*, 840 F.2d 45, 58 (D.C. Cir. 1988)); *see also Bldg. & Constr. Trades Council v. Downtown Dev., Inc.*, 448 F.3d 138, 148 (2d Cir. 2006) (same); *Ass’n of Am. Physicians & Surgeons, Inc. v. Tex. Med. Bd.*, 627 F.3d 547, 550 n.2 (5th Cir. 2010) (same); *Presidio Golf Club v. Nat’l Park Serv.*, 155 F.3d 1153, 1159 (9th Cir. 1998) (same); *Schalamar Creek Mobile Homeowner’s Ass’n v. Adler*, 855 F. App’x 546, 553 (11th Cir. 2021) (per curiam) (same). To satisfy this “modest” requirement, all that is necessary is “mere pertinence between litigation subject and organizational purpose.” *Humane Soc’y*, 840 F.2d at 58–59; *accord Int’l Dark-Sky Ass’n v. FCC*, 106 F.4th 1206, 1218 (D.C. Cir. 2024); *Mich. Bldg. & Constr. Trades Council, AFL-CIO v. Snyder*,

846 F. Supp. 2d 766, 778 (E.D. Mich. 2012). The court need only “determine whether an association’s lawsuit would, if successful, reasonably tend to further the general interests that individual members sought to vindicate in joining the association and whether the lawsuit bears a reasonable connection to the association’s knowledge and experience.” *Bldg. & Constr. Trades Council*, 448 F.3d at 149.

In line with the cases cited above, this Court typically finds the germaneness requirement satisfied after only a brief comparison of the organization’s stated mission with the general subject matter of the suit. *See, e.g., Universal Life Church Monastery Storehouse v. Nabors*, 35 F.4th 1021, 1036 (6th Cir. 2022); *CTIA - The Wireless Ass’n v. Keats*, 2021 WL 7209356, at *3 (6th Cir. Dec. 3, 2021); *Online Merchants Guild v. Cameron*, 995 F.3d 540, 549 (6th Cir. 2021); *Fednav, Ltd. v. Chester*, 547 F.3d 607, 615 (6th Cir. 2008); *ACLU of Ohio, Inc. v. Taft*, 385 F.3d 641, 646 (6th Cir. 2004); *Doe v. Porter*, 370 F.3d 558, 562 (6th Cir. 2004); *Adland v. Russ*, 307 F.3d 471, 478–79 (6th Cir. 2002). On the rare occasions when this Court has rejected associational standing for lack of germaneness, it has done so only when the lawsuit is clearly “detached” from the organization’s “stated mission.” *See, e.g., Children’s Health Def.*

v. FDA, 2022 WL 2704554, at *3 (6th Cir. July 12, 2022) (holding that children’s health organization lacked standing to challenge forced vaccination of *adult* military members).

Notably, a district court in the Fifth Circuit recently upheld the standing of the Fort Worth Chamber of Commerce in circumstances that the court described as “remarkably similar” to this case. *Chamber of Commerce v. Consumer Fin. Prot. Bureau*, No. 24-cv-213, slip op. at 7 (N.D. Tex. Dec. 6, 2024) (“*Fort Worth Chamber*”). The Fort Worth Chamber was “the only plaintiff located within” the venue, *id.* at 2, it was challenging a federal banking regulation not specific to any region of the country, *id.* at 1–2, “none of the actual banks or credit card issuers affected ... [were] headquartered in the Fort Worth Division,” *id.* at 2, and the Fort Worth Chamber’s mission was to “cultivat[e] a thriving business climate in the Fort Worth region,” *id.* at 6 (quotation marks omitted). The government raised a strikingly “similar germaneness challenge” to this “similar plaintiff” with a “distinctly localized mission.” *Id.* at 7. Recognizing that “the bar is set unmistakably low” for germaneness, however, the court rejected the government’s challenge and swiftly concluded that the suit was sufficiently related to the Fort Worth

Chamber's mission. *Id.* at 5–8. The court expressly declined to follow the approach taken by the district court in this case, finding that controlling Fifth Circuit precedent “leaves little room for dismissing parties based on geographical ties” or “equitable” considerations. *Id.* at 7.

Courts' widespread acknowledgment that germaneness is a low bar aligns with the Supreme Court's guidance. As the Court has explained, “the primary reason people join an organization is often to create an effective vehicle for vindicating interests that they share with others.” *Int'l Union, United Auto., Aerospace & Agric. Implement Workers v. Brock*, 477 U.S. 274, 290 (1986) (“UAW”). “The very forces that cause individuals to band together in an association will ... provide some guarantee that the association will work to promote their interests.” *Id.* This “self-policing character” of voluntary associations reinforces “the importance of a reading of the germaneness requirement that does not unduly confine the occasions on which associations may bring legal actions on behalf of members.” *Humane Soc'y*, 840 F.2d at 56 (citing *UAW*, 477 U.S. at 290).

The Dayton Area Chamber easily meets the “low threshold” set by the germaneness requirement, *Ass'n of Am. Physicians*, 627 F.3d at 550

n.2, because it was “organized for a purpose germane to the subject of [the] claim[s]” in this litigation, *United Food & Com. Workers Union Loc. 751 v. Brown Grp., Inc.*, 517 U.S. 544, 555–56 (1996). The Dayton Area Chamber “strives to improve the region’s business climate ... through public policy advocacy,” R.57 (Amended Complaint), PageID#614 ¶ 28, and “commits to its members and the greater Dayton region” that it will advocate for “a business friendly legislative and regulatory environment,” R.29-2 (Kershner Declaration), PageID#171 ¶ 6. Notably, “[a]s part of that mission,” the Dayton Area Chamber “opposes governmental actions that price[-]set for private industry” and “advocates for a legal and political environment that will allow its members to compete in a free market to control costs.” *Id.*

This litigation is clearly “pertinen[t]” to those purposes. *Humane Soc’y*, 840 F.2d at 58. The complaint alleges that the Program imposes price controls on lawful products without essential procedural safeguards, compels the speech of private businesses, coerces businesses with the threat of excessive fines, and exceeds Congress’s limited and enumerated powers. R.57 (Amended Complaint), PageID#651–71 ¶¶ 169–81, 190–212, 220–27, 229–46, 252–59. Although the most

immediate and direct impact of the challenged policies falls on pharmaceutical companies (including Plaintiffs' members), businesses in other fields likewise have an important stake in resisting this kind of government overreach. See Chris Kershner & Steve Stivers, *Voice of Dayton Business: Ohio Businesses Cannot Stand for Government Overreach*, Dayton Daily News (June 25, 2023), <http://tinyurl.com/4fvkedsk> (joint op-ed by presidents of Dayton Area Chamber and Ohio Chamber) (explaining that “[i]f the government can establish price controls for essential medicines through an opaque regime without allowing for judicial review, it sets a dangerous precedent that could extend to other vital industries” and that standing up against such “detrimental measures” is necessary “to safeguard the principles of free enterprise and protect the future well-being of businesses in the Dayton area, the State of Ohio and the United States”). Because the Dayton Area Chamber’s goals in this litigation are related to its purposes and achieving its goals will advance its members’ interests, it “readily meets the germaneness requirement.” *Ctr. for Sustainable Economy v. Jewell*, 779 F.3d 588, 597 (D.C. Cir. 2015).

Moreover, contrary to the government's suggestion in the district court, *see* R.71 (Defs.' Combined Motion to Dismiss and Cross-Motion for Summ. J.), PageID#843, the Dayton region is not an isolated backwater disconnected from the national economy. Dayton is one of the largest cities in one of the most populous states in the country—a state whose \$885 billion GDP would make it roughly the twentieth-largest economy in the world.⁴ The Dayton metropolitan region is home to more than 800,000 residents⁵ and thousands of businesses, including companies in the pharmaceutical and health care industry.⁶ Its residents and

⁴ *See* U.S. Bureau of Econ. Analysis, Gross Domestic Product: All Industry Total in Ohio (Sept. 27, 2024) *in* Fed. Rsrv. Bank of St. Louis, *Economic Data*, <https://fred.stlouisfed.org/series/OHNGSP>; World Bank Grp., *GDP (current US\$)* (2024), https://data.worldbank.org/indicator/NY.GDP.MKTP.CD?most_recent_value_desc=true.

⁵ U.S. Census Bureau, No. CBSA-EST2023-ALLDATA, *Datasets: Annual Resident Population Estimates and Estimated Components of Resident Population Change for Metropolitan and Micropolitan Statistical Areas and Their Geographic Components for the United States: April 1, 2020 to July 1, 2023* (Mar. 2024), <https://www.census.gov/data/tables/time-series/demo/popest/2020s-total-metro-and-micro-statistical-areas.html>.

⁶ *See, e.g.,* Dayton Dev. Coal., *Healthcare* (2024), <https://daytonregion.com/healthcare>; Ohio Life Scis., *Life Sciences in Ohio's Six Regions* (2024), <https://ohiolifesciences.org/ohio/> (“The life sciences industry’s economic impact is felt throughout the state, with life sciences-related companies found in 83 of 88 Ohio counties, and all six Ohio regions have experienced growth while playing a role in advancing

businesses bear the costs of sweeping new federal laws and have every right to join together to challenge national policies that threaten their interests. In short, it's no wonder that the Dayton Area Chamber is concerned enough about the Program to have brought this lawsuit.

The district court's suggestion that the only "interests at stake" in this suit are those of AbbVie and Pharmacyclics, *see* R.102 (Final Order), PageID#1565, misunderstands the Program. The Program applies to every pharmaceutical manufacturer regardless of size, except for a narrow, "[t]emporary" price floor for some of the smallest manufacturers. *See* 42 U.S.C. § 1320f-3(b)(2)(F)(ii), (d). Over the next several years, "a larger and larger percentage of drugs on the market will be subject to" the challenged provisions. *NICA*, 116 F.4th at 498 n.7. And "one way or [an]other, selection of a" drug "leads to lower revenue" for the manufacturer. *Id.* at 501. Even companies that do not currently market a drug set for price controls will likely face reduced prospects for

critical discoveries."); Adare Pharma Sols., *Our Facilities* (2024), <https://adarepharmasolutions.com/facilities/> (featuring 179,000 square-foot research center in Dayton suburb of Vandalia); Press Release, Nat'l Resilience, Inc., *Resilience Announces Expansion in West Chester* (Dec. 11, 2023), <https://resilience.com/news/resilience-announces-expansion-in-west-chester>.

investment because the price-control regime limits the potential returns to investors on any drug that achieves enough success in the market to meet the criteria for negotiation-eligibility. *Cf. id.* at 502 (“By putting [businesses’] revenue in jeopardy, the Program threatens their ability to raise debt and capital *now*, regardless of whether their drugs have been selected or not”).

What is more, as a matter of “[c]ommon sense and basic economics,” *Carpenters Indus. Council v. Zinke*, 854 F.3d 1, 6 (D.C. Cir. 2017), the Program will affect entities that do business with manufacturers, such as suppliers of raw materials, distributors, equipment makers, and builders of laboratories. “[T]his is one of the ‘familiar circumstances’ where government regulation” predictably causes “‘economic injuries to others in the chain’” of commerce. *NICA*, 116 F.4th at 501–02 (quoting *All. for Hippocratic Med.*, 602 U.S. at 384). And as discussed above, even beyond that extensive chain of commerce, many more companies have a legitimate stake in opposing the precedent set by establishing black-box government control over basic business decisions.

“Germaneness requires ‘pertinence between litigation subject and organizational purpose[,]’ not ... germaneness of members’ injuries to

organizational purpose.” *Ctr. for Sustainable Economy*, 779 F.3d at 597 n.9 (quoting *Humane Soc’y*, 840 F.2d at 58–59). The subject of this litigation—a challenge to government overreach that threatens to hamper economic prosperity and create an unfavorable environment for business, including in the Dayton area—is plainly relevant to the Dayton Area Chamber’s goal of promoting a pro-business environment in the Dayton region. That connection is all that is required. *See Neighborhood Action Coal. v. City of Canton*, 882 F.2d 1012, 1017 (6th Cir. 1989) (finding associational standing where “the interests [the association] seeks to protect in this lawsuit are germane to its purpose”).

Despite this settled doctrine, the district court took a dramatically different approach. The court briefly acknowledged Plaintiffs’ position that this suit seeks to protect businesses’ constitutional rights, defend free-market principles against a price-control regime with implications well beyond the pharmaceutical industry, and promote economic prosperity in the Dayton area and nationwide. *See* R.102 (Final Order), PageID#1564–65. But the court then expressly adopted a “narrow interpretation of the interests at stake in this lawsuit.” *Id.*, PageID#1565. It defined those interests as limited to “the constitutional rights” of

Plaintiffs' *named* members, AbbVie and Pharmacyclics. *Id.* And it found that because neither AbbVie nor Pharmacyclics is headquartered in the Dayton area and Plaintiffs "provided no information ... directly connecting the interests of Pharmacyclics or AbbVie to the business climate in the Dayton area," there was only a "speculative" connection between the suit and the Dayton Area Chamber's purpose. *Id.*

None of those leaps of reasoning has any basis in precedent. *Cf. Fort Worth Chamber*, slip op. at 7–8 ("[W]hile the *Dayton* court felt free to 'adopt a narrow interpretation of the interests at stake in [that] lawsuit,' this Court does not recognize a similar freedom to do so." (quoting R.102 (Final Order), PageID#1565)). Indeed, the district court did not cite *any* authority for its "narrow" interpretation of germaneness. It did cite *Waskul*, 900 F.3d at 255, for the proposition that associational standing "was created to allow an association to sue on behalf of its members that have suffered injury," R.102 (Final Order), PageID#1565. But *Waskul* merely reaffirmed the well-established rule that an association need only show that "*one* of its members" has suffered an Article III injury to meet the first prong of the associational-standing test. 900 F.3d at 255 (quoting *United Food*, 517 U.S. at 554–55 (emphasis added)). Neither *Waskul* nor

any other decision of this Court has held that the only “interests at stake” in an association’s suit are the Article III injuries of specifically identified members, or for that matter that those interests need to be tied in a particular way to a particular geographic area.

The district court’s analysis is contrary to a veritable wall of precedent. *See supra*, pp. 26–28; *Ctr. for Sustainable Economy*, 779 F.3d at 597 n.9 (emphasizing that germaneness only “requires ‘pertinence between litigation subject and organizational purpose[,]’ not ... germaneness of members’ injuries to organizational purpose”). For example, in *Hunt v. Washington State Apple Advertising Commission*, the Supreme Court held that the plaintiff organization’s “attempt to remedy” specific members’ injuries “*and to secure the industry’s right to publicize its grading system*” for apples was germane to its purpose. 432 U.S. 333, 344 (1977) (emphasis added). Under the approach of the district court here, because only “some Washington apple growers and dealers” had shown Article III injuries, *id.* at 343, the only “interests at stake” would have been those members’ injuries, not the industry’s broader agenda. Similarly, in environmental cases, courts do not confine their understanding of the “interests at stake” in a suit to the particular

injuries suffered by identified members as a result of a particular project; they recognize that the suit vindicates broader interests that align with environmental organizations' goals. *Id.* at 353. *See, e.g., Oak Ridge Env't Peace All. v. Perry*, 412 F. Supp. 3d 786, 799–801, 831 (E.D. Tenn. 2019) (framing the interest at stake as “protecting the environment from the risks associated with nuclear weapons”); *Kentuckians for Commonwealth v. U.S. Army Corps of Eng'rs*, 963 F. Supp. 2d 670, 679–80 & n.4 (W.D. Ky. 2013) (holding that germaneness requirement was satisfied as to Sierra Club and social-justice organization where suit challenged Army Corps' alleged failure to adequately consider environmental justice concerns when granting permit for discharge of mining debris).

The district court's insistence on limiting the interests at stake to the Article III injuries of named members, and then requiring evidence of a nexus between those interests and a specific geographic area, is also inconsistent with decisions—including binding authority from this Court—in which courts find the germaneness requirement satisfied *before* identifying which member(s) have suffered an Article III injury. For example, in *Online Merchants Guild v. Cameron*, this Court found that a trade association for online merchants whose purpose was “to

advocate for a free and fairly-regulated online marketplace” had associational standing to assert its claim that Kentucky’s enforcement of its price-gouging laws violated the dormant commerce clause. 995 F.3d at 544, 549 (quotation marks omitted). The Court held that there was “no question” that “addressing price gouging as it relates to eCommerce falls within the scope of the Guild’s mission, to advocate for a free and fairly-regulated online marketplace.” *Id.* at 549 (quotation marks omitted). Notably, the Court defined the interests at stake in the suit—“addressing price gouging as it relates to eCommerce,” *id.*—*before* even addressing whether there was an association member who had suffered an injury in fact, *id.* at 552. Under the district court’s approach, in contrast, the Court should have considered first, and exclusively, the interest of Jones & Panda, LLC in selling hand sanitizer and respirators on Amazon at certain prices. *Id.* at 546.

Other courts have likewise assessed germaneness before turning to the first prong of the test in some cases. *See, e.g., Competitive Enter. Inst. v. Nat’l Highway Traffic Safety Admin.*, 901 F.2d 107, 111–12 (D.C. Cir. 1990); *Tenn. Riverkeeper, Inc. v. City of Lawrenceburg ex rel. Lawrenceburg Bd. of Utils. Comm’n*, 2023 WL 4611816, at *4 (M.D. Tenn.

July 18, 2023); *FreshWater Accountability Project v. Patriot Water Treatment, LLC*, 2018 WL 4899089, at *7 (N.D. Ohio Oct. 9, 2018). Indeed, courts have even found the germaneness requirement satisfied in the *absence* of any Article III injury to a member. *See, e.g., Belevender v. Magi Enters., Inc.*, 2007 WL 671316, at *5–6 (N.D. Ohio Feb. 28, 2007); *Greenlining Inst. v. FCC*, 802 F. App'x 232, 234 (9th Cir. 2020).

In attempting to defend its cramped interpretation of germaneness, the district court asserted that the “potential downstream effects” of the Program “on unnamed members in the supply chain, and on unknown investment in all pharmaceutical companies,” were “too speculative.” R.102 (Final Order), PageID#1565. As purported authority for this point, the court cited *AAPS*, 13 F.4th at 546. But that portion of *AAPS* held only that certain alleged injuries were too speculative to satisfy the associational-standing test’s *first* prong—a member with an Article III injury; that holding had nothing to do with the germaneness of the suit, which *AAPS* did not address at all. *See id.* at 545–57.

The court erred in conflating the first two prongs of the associational-standing doctrine. *Cf. FreshWater*, 2018 WL 4899089, at *7 n.7 (rejecting defendant’s argument that an organization’s purpose was

“merely a generalized grievance” because that argument “confuses the issues” of germaneness and injury-in-fact, the latter of which “does not pertain to whether an organization’s purpose is germane to any given litigation” (quotation marks omitted); *Greenlining*, 802 F. App’x at 234 (finding germaneness requirement satisfied despite lack of “*immediate*” or “*direct*” injury to satisfy Article III (cleaned up)). And in any event, as discussed above, the upstream and downstream effects of the Program here are not “rank speculation,” *AAPS*, 13 F.4th at 546, but a matter of “[c]ommon sense and basic economics,” *Carpenters Indus. Council*, 854 F.3d at 6; see *NICA*, 116 F.4th at 501–02; *All. for Hippocratic Med.*, 602 U.S. at 384–85.

The district court seemed concerned in part by dicta in a prior decision of this Court and a separate opinion by a single Supreme Court justice questioning associational standing. See R.102 (Final Order), PageID#1561–62 (citing *AAPS*, 13 F.4th at 537–42; *All. for Hippocratic Med.*, 602 U.S. at 402 (Thomas, J., concurring)). But in *AAPS*, this Court expressly recognized that the “current test” for associational standing is the one the Supreme Court set out in *Hunt* and that courts “must stick to [the Supreme Court’s] directly on-point precedent.” 13 F.4th at 537,

542; *see also id.* at 547 (Siler, J., concurring) (declining to join discussion of propriety of associational-standing doctrine “as I believe it is unnecessary to the resolution of the case”). And the majority in *AAPS* never suggested that courts should limit associational standing by applying the germaneness requirement restrictively; to the contrary, the majority noted that the germaneness requirement appeared to be prudential rather than constitutional and expressed skepticism that it was proper to *decline* jurisdiction based on a prudential requirement. *Id.* at 542 (maj. op.). Meanwhile, although Justice Thomas criticized associational-standing doctrine in a concurring opinion, he agreed that the Supreme Court has “consistently applie[d] the doctrine” and joined the Court’s opinion in that case in full. 602 U.S. at 405 (Thomas, J., concurring); *see also, e.g., Students for Fair Admissions, Inc. v. Presidents & Fellows of Harvard Coll.*, 600 U.S. 181, 199–201 (2023) (opinion of the Court, joined in full by Justice Thomas, applying associational-standing doctrine).

3. Plaintiffs’ claims and requested relief do not require the participation of individual members.

The district court also questioned whether Plaintiffs satisfy the third prong of the associational-standing test. Under that prong, an

association may sue when “neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit.” *Hunt*, 432 U.S. at 343. The Supreme Court has identified this element as a “prudential” requirement. *United Food*, 517 U.S. at 557. Plaintiffs’ suit undisputedly raises pure questions of law and seeks only declaratory and injunctive relief that does not require individualized proof, so there is no need for members’ individual participation.

The inquiry under the member-participation prong focuses on the nature of the claim and the type of relief requested. A claim that “raises a pure question of law” and does not require the court “to consider the individual circumstances of any ... member” does not require the participation of individual members. *UAW*, 477 U.S. at 287. A request for “prospective or injunctive relief” generally does not require individualized determinations and therefore satisfies this element. *United Food*, 517 U.S. at 546; *see also, e.g., Fednav*, 547 F.3d at 615 (explaining that “none of the Associations’ claims or their requested relief ... require the participation of their members in the lawsuit” because they seek only injunctive or declaratory relief and “do not, for example, seek individualized damages that only a member could obtain”); *Bldg. &*

Constr. Trades Council, 448 F.3d at 150 (“[T]he third prong of *Hunt* concerns claims that would require ‘individualized proof,’ such as claims for damages.” (quoting *Bano v. Union Carbide Corp.*, 361 F.3d 696, 714 (2d Cir. 2004))).

Plaintiffs’ suit raises pure issues of law regarding the facial constitutionality of the Program, and Plaintiffs seek only prospective relief. To determine whether the Program violates the separation of powers, the Due Process Clause, or the First Amendment, for example, one need only assess the statute in light of the Constitution, without reference to the individual circumstances of Plaintiffs’ members. Unlike a claim for damages, which typically depends on the “fact and extent of injury” to each individual member of an association, Plaintiffs’ requested injunctive and declaratory relief does not require “individualized proof.” *UAW*, 477 U.S. at 287 (quoting *Warth v. Seldin*, 422 U.S. 490, 515–16 (1975)). Therefore, Plaintiffs easily satisfy the third prong of the associational-standing test.

The district court characterized the “caselaw regarding this aspect of associational standing” as “scarce,” R.102 (Final Order), PageID#1567, but abundant precedent supports the conclusion that Plaintiffs satisfy

this prong. *See, e.g., United Food*, 517 U.S. at 546; *Fednav*, 547 F.3d at 615; *UAW*, 477 U.S. at 287; *Barry v. Lyon*, 834 F.3d 706, 716 (6th Cir. 2016); *see generally* R.90 (Pltfs.’ Combined Summ. J. Opposition and Reply), PageID#1238–42. Neither the government nor the district court identified a single case in which a court held that a suit seeking prospective relief, such as the declaratory and injunctive relief Plaintiffs seek here, failed this requirement.

The district court also suggested that Plaintiffs might nevertheless fail this prong because “another drug manufacturing member” has “already filed a claim challenging the Program in another district court.” R.102 (Final Order), PageID#1568. The court did not explain why a question about whether that member would be “bound” by an eventual judgment on the merits in this case should preclude associational standing for organizations made up of many members. *Id.* Nor did the court cite any authority for considering this issue under the third prong of the associational-standing test. To avoid the need for further litigation over this element, this Court should reaffirm its precedent and hold that individual-member participation in this suit is not required.

B. The district court’s narrowing of associational standing contravenes Supreme Court precedent and cannot be justified by separation-of-powers principles.

The district court’s constricted application of associational standing was misguided, particularly because the Supreme Court itself has expressly declined to take that course. This is not the first time the government has sought to cabin or eliminate the doctrine of associational standing. *See UAW*, 477 U.S. at 288. Yet even though the Supreme Court soundly rejected the government’s effort to gut associational standing in *UAW*, the district court accepted the government’s invitation to do just that in this case. The district court also mistakenly suggested that allowing this suit to proceed in the Southern District of Ohio would contravene separation-of-powers principles.

1. The Supreme Court has recognized associational standing through more than half a century of precedent, up to and including decisions applying the doctrine in the past few years. *See, e.g., Nat’l Motor Freight Traffic Ass’n v. United States*, 372 U.S. 246, 247 (1963) (per curiam); *Students for Fair Admissions*, 600 U.S. at 199–200; *see also All. for Hippocratic Med.*, 602 U.S. at 405 (Thomas, J., concurring) (“[T]he Court consistently applies the [associational-standing] doctrine”). Not

only has this precedent “not been specifically overruled,” R.102 (Final Order), PageID#1562; the Court specifically *refused* a previous request by the government to “reconsider and reject the principles of associational standing set out” in its precedent and instead “reaffirm[ed]” those principles. *UAW*, 477 U.S. at 288, 290.

Of particular relevance here, *UAW* reaffirmed those principles over an objection that the Court’s application of the germaneness requirement was not demanding enough. In dissent, Justice Powell acknowledged that the goal of the litigation—challenging the Secretary of Labor’s interpretation of eligibility requirements for certain unemployment benefits—was “‘germane’ to the UAW’s purpose in the sense that one of its goals is to secure such benefits for its workers.” *Id.* at 296–97 (Powell, J., dissenting). Calling that understanding of germaneness too “formalistic,” however, Justice Powell would have held that germaneness is not satisfied when the number of members with a concrete stake is “small,” or when an association “may have reasons for instituting a suit—such as the publicity that attends a major case—other than to assert rights of its members.” *Id.* at 297 (Powell, J., dissenting). Yet the Court declined to adopt that more stringent approach, instead holding that

there was “little question” that the suit met the germaneness requirement. *Id.* at 286 (maj. op.).

As the courts of appeals have recognized, the germaneness prong is not intended to “perform [a] considerable screening function.” *Humane Soc’y*, 840 F.2d at 54. The interests at stake in the litigation need not “be *central* to a group’s organic purpose,” nor even “closely tethered.” *Id.* at 53 & n.10. Instead, as the Supreme Court’s “strong[] endors[ement]” of associational-standing doctrine in *UAW* reflects, *id.* at 55, the germaneness requirement must be applied in light of the “special features, advantageous both to the individuals represented and to the judicial system as a whole, that distinguish suits by associations on behalf of their members from class actions,” *UAW*, 477 U.S. at 289. The “primary reason people join an organization is often to create an effective vehicle for vindicating interests that they share with others,” and those same motivating forces help ensure “that the association will work to promote their interests.” *Id.* at 290. In keeping with those features, “the very brevity” of the Supreme Court’s analysis of the germaneness requirement indicates that it is no “high hurdle.” *Humane Soc’y*, 840 F.2d at 56 n.17. Instead, it is satisfied when “an association’s lawsuit would,

if successful, reasonably tend to further the general interests that individual members sought to vindicate in joining the association.” *Bldg. & Constr. Trades Council*, 448 F.3d at 149.

2. In concluding its standing analysis, the district court suggested that allowing Plaintiffs to sue in the Southern District of Ohio would somehow undermine the Constitution’s separation of powers. R.102 (Final Order), PageID#1568–69. Just the opposite is true. Exercising jurisdiction where it exists vindicates, rather than vitiates, the separation of powers because “courts have a ‘virtually unflagging’ duty to exercise the jurisdiction that Congress has granted them.” *In re Schubert*, 2023 WL 2663257, at *2 (6th Cir. Mar. 28, 2023) (quoting *Lexmark Int’l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 126 (2014)). “[T]he Supreme Court has clarified that a court may not limit its jurisdiction for prudential or policy reasons.” *Id.* (citing *Lexmark*, 572 U.S. at 125–27).

“[T]he general rule says the plaintiff is the master of her complaint and gets to choose where and how to sue.” *K.B. ex rel. Qassis v. Methodist Healthcare - Memphis Hosps.*, 929 F.3d 795, 799 (6th Cir. 2019). Whether some of Plaintiffs’ members are “large pharmaceutical companies” that “could have sued on their own in a federal court in another state,” R.102

(Final Order), PageID#1572, has nothing to do with whether Plaintiffs have standing to bring their claims in *this* suit. Nor, in any event, would recognizing the Dayton Area Chamber’s standing here “open the door” for “any individual or company to bypass venue rules by becoming a member of any association remotely related to a challenged law or regulation.” *Id.* As discussed above, the goals of this lawsuit are well within the organizational purposes of the Dayton Area Chamber and the commitments it has made to its members and the Dayton region. Plaintiffs fully complied with the rules of venue and jurisdiction and are fully entitled to litigate this suit in Dayton, just as they would also be free to litigate it where the other Plaintiffs reside.

II. At a minimum, the district court should have transferred the case to the Eastern Division of the Southern District of Ohio, where the Ohio Chamber of Commerce resides.

Even if venue had been lacking in the Western Division of the Southern District of Ohio (and it was not, as explained above), the district court further erred by dismissing the case rather than transferring it to the Eastern Division, as Plaintiffs had proposed if the court found that the Dayton Area Chamber lacked standing, *see* R.90 (Pltfs.’ Combined Summ. J. Opposition and Reply), PageID#1251–52. The purpose of 28

U.S.C. § 1406(a), which permits a district court to transfer a case “to any district or division in which it could have been brought,” is to “remov[e] whatever obstacles may impede an expeditious and orderly adjudication of cases and controversies on their merits.” *Goldlawr, Inc. v. Heiman*, 369 U.S. 463, 466–67 (1962), *superseded by statute on other grounds as recognized by Franco v. Mabe Trucking Co.*, 3 F.4th 788, 793–94 (5th Cir. 2021); *see also Flynn v. Greg Anthony Constr. Co.*, 95 F. App’x 726, 741 (6th Cir. 2003) (describing “ultimate goal of allowing cases to be decided on their substantive merits”). Transfer would have been consistent with that purpose of encouraging the efficient adjudication of the merits; the district court’s dismissal undermined that purpose.

Essentially the same reasons discussed above with respect to the Dayton Area Chamber support the associational standing of the Ohio and Michigan Chambers. First, at least one member of each has standing. Pharmacylics and AbbVie are members of the Ohio and Michigan Chambers. R.49-1 (Staff Supp. Declaration), PageID#398 ¶¶ 28–29. Second, this suit is germane to each chamber’s purpose. The Ohio Chamber advocates for its nearly 7,000 members across the state and “develops public policy positions on both state and federal matters for the

benefit of its members.” R.29-4 (Long Declaration), PageID#181 ¶ 4. “As part of that mission, the Ohio Chamber supports responsible, increased price transparency for health care services,” and “opposes ... government regulations that discourage innovation and deny its members a fair return on their investments in the health care space.” *Id.*, PageID#181–82 ¶ 6. This suit advances the Ohio Chamber’s goals. Similarly, the Michigan Chamber “advocates for market-friendly, consumer driven reforms” and “opposes ... federal regulations” that undermine investment and innovation. R.29-3 (Holcomb Declaration), PageID#176–77 ¶ 6. Finally, as discussed above, neither the claims asserted nor the relief requested requires the participation of individual members.

The district court’s determination that the Ohio and Michigan Chambers lacked standing, R.102 (Final Order), PageID#1571–72, was based on the same erroneous germaneness analysis as for the Dayton Area Chamber. *Id.*, PageID#1566. Notably, the government did not even dispute that this suit was germane to either the Ohio or Michigan Chamber’s purposes. *See* R.71 (Defs.’ Combined Motion to Dismiss and Cross-Motion for Summ. J.), PageID#842–51. Because the court’s standing determination was legal error, so too was its decision to dismiss

rather than transfer. *See 1st of Mich. Corp. v. Bramlet*, 141 F.3d 260, 262, 264 (6th Cir. 1998) (reviewing de novo determination that venue was improper; reversing dismissal). Here, transfer within the court's own district to the Eastern Division, where the Ohio Chamber resides, would have been appropriate.

CONCLUSION

For the reasons set forth above, this Court should reverse and remand for the district court to consider the merits of Plaintiffs' claims.

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December 23, 2024

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitations of Federal Rule of Appellate Procedure 32(a)(7)(B) and 6 Cir. R. 32(b), because it contains 10,433 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f).

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6). This brief has been prepared in a proportionally spaced typeface using Microsoft Word 365 MSO in 14-point Century Schoolbook font.

Date: December 23, 2024

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CERTIFICATE OF SERVICE

I hereby certify that on December 23, 2024, I electronically filed the foregoing document with the Clerk of the Court for the United States Court of Appeals for the Sixth Circuit by using the appellate CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

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ADDENDUM**Designation of Relevant District Court Documents**

| RE | Description | PageID |
|-----------|--|---------------|
| 29-2 | Supplemental Dayton Area Chamber of Commerce Declaration of Chris Kershner in Support of Motion for Preliminary Junction | 170–174 |
| 29-3 | Supplemental Michigan Chamber of Commerce Declaration of James Holcomb in Support of Motion for Preliminary Junction | 175–179 |
| 29-4 | Supplemental Ohio Chamber of Commerce Declaration of M. Anthony Long in Support of Motion for Preliminary Junction | 180–184 |
| 29-5 | Supplemental Declaration of Michael C. Staff in Support of Motion for Preliminary Junction | 185–192 |
| 29-6 | Supplemental United States Chamber of Commerce Declaration of Thomas Quaadman in Support of Motion for Preliminary Junction | 193–198 |
| 49-1 | Supplemental Declaration of Michael C. Staff in Support of Plaintiffs' Reply in Support of Motion for Preliminary Injunction | 393–399 |
| 55 | Order Denying Defendants' Motion to Dismiss and Denying Plaintiffs' Motion for a Preliminary Injunction | 574–601 |
| 57 | Amended Complaint | 606–673 |
| 64-1 | Third Declaration of Michael C. Staff in Support of Plaintiffs' Motion for Summary Judgment | 777–781 |
| 102 | Order Denying Plaintiffs' Motion for Summary Judgment and Granting Defendants' Motion to Dismiss | 1555–1573 |
| 103 | Judgment | 1574 |
| 105 | Notice of Appeal | 1579–1581 |