

No. 24-3868

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IN THE UNITED STATES COURT OF APPEALS  
FOR THE SIXTH CIRCUIT

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DAYTON AREA CHAMBER OF COMMERCE, *et al.*,

Plaintiffs-Appellants,

v.

ROBERT F. KENNEDY, JR., *in his official capacity as Secretary of the  
U.S. Department of Health and Human Services, et al.*

Defendants-Appellees.

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On Appeal from the United States District Court  
for the Southern District of Ohio

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**BRIEF FOR APPELLEES**

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## INTRODUCTION

The U.S. Chamber of Commerce and three regional chambers sued the federal government in the Southern District of Ohio on behalf of out-of-state drug manufacturer Pharmacyclics, LLC. Plaintiffs challenge the Medicare Drug Price Negotiation Program, which allows the government to negotiate the price that Medicare will pay for certain high expenditure drugs.

There is no dispute that plaintiffs lack standing to sue in their own right. Nor is there any dispute that Pharmacyclics could have filed suit directly—as did seven of the ten manufacturers with a drug selected for the first round of the Negotiation Program. But instead of filing suit in the Northern District of California, where it is headquartered, Pharmacyclics joined the Dayton Area Chamber of Commerce to facilitate proceedings in a district of its choice.

The district court correctly held that the Dayton Chamber—the only plaintiff for which venue would be proper in the Western Division of the Southern District of Ohio—lacks associational standing to sue on behalf of Pharmacyclics. The interests at stake in this challenge to the terms on which Medicare will pay for certain drugs are not germane to the Dayton Chamber’s stated purpose of “improv[ing] the region’s business climate.”

Br. 8. Indeed, plaintiffs have provided no information connecting the interests that Pharmacyclics seeks to vindicate in this lawsuit to the Dayton area business community.

In the absence of a genuine organizational interest in the outcome of this litigation, the presence of the Dayton Chamber in this lawsuit serves only to abet improper forum shopping, and the district court refused to countenance this “attempt[ ] to manipulate the system and manufacture standing to obtain a favorable venue.” Order, R. 102, Page ID # 1572. An amicus brief filed by 149 local and regional chambers of commerce illustrates the problem with plaintiffs’ approach: Under that theory, Pharmacyclics could have joined any of those organizations, which could then sue on its behalf essentially anywhere in the country. The district court properly dismissed the case without prejudice for lack of venue based on the Dayton Chamber’s lack of standing.

### **STATEMENT OF JURISDICTION**

Plaintiffs invoked the jurisdiction of the district court under 28 U.S.C. §§ 1331 and 1346. Complaint, R. 1, Page ID # 8. The district court granted the government’s motion to dismiss and entered final judgment in favor of defendants on August 8, 2024. Judgment, R. 103, Page ID # 1574. Plaintiffs

timely noticed this appeal on October 4, 2024. Notice of Appeal, R. 105, Page ID # 1579; *see* Fed. R. App. P. 4(a)(1)(B). This Court has jurisdiction under 28 U.S.C. § 1291.

### **STATEMENT OF THE ISSUES**

I. Whether the district court correctly held that a regional chamber of commerce lacks associational standing to sue on behalf of an out-of-state drug manufacturer alleging that limits on Medicare payments for certain high-expenditure drugs violate its constitutional rights when such claims are not germane to the chamber's stated purpose of improving the regional business climate.

II. Whether the district court properly exercised its broad discretion to dismiss rather than transfer this case.

### **STATEMENT OF THE CASE**

#### **A. Statutory Background**

1. Congress created Medicare in 1965. Social Security Amendments of 1965, Pub. L. 89-97, tit. I, 79 Stat. 286, 290-353. Medicare provides federally funded health coverage for individuals who are 65 or older or who have certain disabilities or medical conditions. 42 U.S.C. § 1395 *et seq.* The Centers for Medicare & Medicaid Services (CMS) administers Medicare on

behalf of the Secretary of Health and Human Services (HHS). Initially, Medicare paid for outpatient prescription drugs only when administered by a health care practitioner in certain care settings. *See* 42 U.S.C. §§ 1395k(a)(1), 1395x(s)(2)(A).

In 2003, Congress enacted Medicare Part D to provide “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.* In enacting Part D, Congress initially barred CMS from negotiating Part D drug prices or otherwise interfering in the arrangements between drug manufacturers and insurance plans. 42 U.S.C. § 1395w-111(i); *see also* Michelle Singer, *Under the Influence*, CBS News (Mar. 29, 2007), <https://perma.cc/5U9Z-M2YS> (documenting extensive industry efforts to lobby for price-negotiation bar in lead-up to enactment of Part D).

2. In the Inflation Reduction Act of 2022 (IRA), Pub. L. No. 117-169, 136 Stat. 1818, Congress gave the Secretary of HHS authority to address the extraordinary and unsustainable increase in the prices that Medicare pays for pharmaceutical products that lack generic competition and that account



for a disproportionate share of Medicare's expenses. 42 U.S.C. §§ 1320f(a), 1320f-1(b), (d), (e). Under the IRA's Drug Price Negotiation Program, CMS can now negotiate the prices that Medicare will pay for a select group of drugs manufactured by pharmaceutical companies that choose to sell drugs to Medicare and Medicaid, just as the Department of Defense, the Department of Veterans Affairs, and the Coast Guard have done for decades. *See* IRA §§ 11001–11003, 136 Stat. at 1833–64 (codified at 42 U.S.C. §§ 1320f-1320f-7 and 26 U.S.C. § 5000D).

By statute, only certain pharmaceuticals are eligible for selection in the Negotiation Program: those that account for the highest Medicare expenditures, that have no generic or biosimilar competitors, and that have been on the market for at least seven years (for drugs) or 11 years (for biologics). *See* 42 U.S.C. § 1320f-1(d), (e). For the first negotiation cycle, CMS selected ten of these drugs with the highest Medicare expenditures for participation in negotiations. *Id.* § 1320f-1(a). CMS selected fifteen additional drugs for the second negotiation cycle, and additional drugs are to be selected for future cycles.

After selecting the drugs, CMS signs a Manufacturer Agreement with those manufacturers that are willing to engage in the negotiation process.

42 U.S.C. § 1320f-2. The object of the negotiations is to reach agreement on what the IRA terms a “maximum fair price” that Medicare will pay for each selected drug. *Id.* § 1320f-3. If negotiations are successful, the manufacturer signs an addendum to the Manufacturer Agreement establishing the maximum price at which the drug will be made available to Medicare beneficiaries. *Id.*

A drug manufacturer that does not wish to participate in the Negotiation Program may withdraw from participation in Medicare and Medicaid, may transfer its ownership of the selected drug to another entity, or may continue to sell the selected drug to Medicare beneficiaries at non-negotiated prices subject to an excise tax. 26 U.S.C. § 5000D(a)-(h); CMS, *Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 - 1198 of the Social Security Act for Initial Price Applicability Year 2026*, at 132–33 (June 30, 2023), <https://perma.cc/K6QB-C3MM> (Revised Guidance); *see also* Internal Revenue Service Notice No. 2023-52 (Aug. 4, 2023), <https://perma.cc/B9JZ-ZG7P>.

3. In August 2023, CMS published the list of drugs selected for the first negotiation cycle. *See* HHS, *HHS Selects the First Drugs for Medicare*

*Drug Price Negotiation* (Aug. 29, 2023), <https://perma.cc/A36P-Z88Z>. The ten drugs selected accounted for more than \$50 billion of gross Medicare Part D spending between June 2022 and May 2023, and Medicare beneficiaries paid a total of \$3.4 billion in out-of-pocket costs for those drugs in 2022 alone. *See id.*; CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026* (Aug. 2023), <https://perma.cc/X37F-RC94>. The selected drugs for the initial cycle include Imbruvica, which is used to treat blood cancer. *Id.* Pharmacyclics LLC holds the FDA-approved new drug applications for Imbruvica and was thus invited to execute a Manufacturer Agreement with CMS to negotiate the price of its drug. *See* CMS, *Medicare Drug Price Negotiation Program: Manufacturer Agreements for Selected Drugs for Initial Price Applicability Year 2026* (Oct. 3, 2023), <https://perma.cc/3222-VPEE>. Negotiations proceeded over the spring and summer of 2024. *See id.*

In accordance with the schedule established by Congress, CMS presented Pharmacyclics and the other manufacturers of selected drugs with initial offers. *See* CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026* (Aug. 15, 2024), <https://perma.cc/6MVG-BZP8>. The manufacturers responded to the initial

offers with counteroffers. *Id.* CMS subsequently held three negotiation meetings with each company to discuss the offers and relevant evidence. *Id.* Many companies proposed revised counteroffers during these meetings, and CMS accepted four of these revised counteroffers outright, and reached agreement with a fifth manufacturer on a negotiated price. *Id.* CMS then sent final written offers to manufacturers of the five remaining drugs. By August 1, 2024, CMS and the participating manufacturers had agreed to a negotiated price for each of the ten selected drugs. *Id.* Assuming that none of the ten manufacturers withdraws from Medicare and Medicaid by December 2025, these prices will take effect on January 1, 2026. 42 U.S.C. §§ 1320f(b), (d), 1320f-2(a), 1320f-3(b).

In January 2025, CMS published a list of drugs covered by the Negotiation Program for the second cycle of negotiations. *See* CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2027* (Jan. 17, 2025), <https://perma.cc/SNY6-3KRL>. The list includes drugs associated with Pharmacyclics's parent company, AbbVie. *See id.*

## **B. Factual Background and Prior Proceedings**

1. Plaintiffs are four chambers of commerce—three regional and one national. The Dayton Area Chamber of Commerce is headquartered in Dayton, Ohio, and represents “more than 2,200 businesses and organizations in a 14-county area surrounding Dayton[.]” Order, R. 102, Page ID # 1564, 1571. The Ohio Chamber of Commerce is headquartered in Columbus, Ohio, and represents “businesses throughout the Buckeye State.” *Id.*, Page ID # 1566, 1571. The Michigan Chamber of Commerce is headquartered in Lansing, Michigan, and “is Michigan’s leading state-wide business advocacy organization, representing approximately 4,000 members.” *Id.*, Page ID # 1566, 1571. And the U.S. Chamber of Commerce is headquartered in Washington, D.C., and has a nationwide membership base. *Id.*, Page ID # 1566, 1571.

Each of the three regional Chambers exists to promote business interests in its region. The Dayton Chamber was founded “to give area businesses a central, unified voice.” Dayton Area Chamber of Comm., *History*, <https://perma.cc/4SFF-M5Y3>. According to its bylaws, the purpose of the Dayton Chamber is to “promote and advance the business interests of the greater Dayton, Ohio region.” Dayton Area Chamber of Comm., *Bylaws*

art. I., § 4 (approved May 15, 2013), <https://perma.cc/KM5K-R6XY>. It holds itself out as having a “regional perspective” and states that its “reach extends across 14 counties” which, it claims, “provides a powerful platform to promote economic growth and prosperity across the Dayton region.” Dayton Area Chamber of Comm., *Our Reach*, <https://perma.cc/C79X-XMY3>.

The Ohio Chamber was incorporated “to promote the general welfare of the people and stimulate the private business of the State of Ohio.” Articles of Incorporation of Ohio Chamber of Commerce (Mar. 13, 1946) (available from Ohio Sec’y of State at <https://perma.cc/2P5D-GAUF>). The Ohio Chamber envisions “[a] growing and prosperous economic and business climate in Ohio.” Ohio Chamber of Comm., *Vision, Mission & Values*, <https://perma.cc/G52Q-LN84>. And it encourages members to join in order “to shape policy at the state level.” Ohio Chamber of Comm., *Membership Binder 4* (2023), <https://perma.cc/GXM5-XMPU>; *see also id.* at 5 (listing policy priorities for 135th session of Ohio General Assembly); *id.* at 7 (detailing impact of “the Ohio Chamber’s lobbying efforts at the Statehouse” on the finances of Ohio businesses); *id.* at 8–9 (list of “policy victories” over six-year period describing only Ohio state enactments).

The Michigan Chamber calls itself “the Great Lakes State’s leading statewide business advocacy organization” with members in each of Michigan’s 83 counties and explains that it “works tirelessly to ensure Michigan is the best place to do business, live, work and play.” Michigan Chamber of Comm., *Mission*, <https://perma.cc/82NH-QZFA>. It encourages members to join because it “fight[s] for free enterprise in Lansing,” connects members to “a diverse statewide business network,” and “help[s] Michigan businesses succeed, save money and strengthen their bottom line.” Michigan Chamber of Comm., *Why the MI Chamber?*, <https://perma.cc/5DP6-ZDMK>. Its “legislative priorities reflect its commitment to delivering powerful advocacy and being the leading voice for business at the State Capitol.” Michigan Chamber of Comm., *Legislative Priorities*, <https://perma.cc/Y2KT-Y3DM>. *Compare* Mich Chamber of Comm., *Key Bills and Issues*, Michigan, All Categories, <https://perma.cc/4WET-LPAB> (listing more than 50 state bills), *with id.* Federal, All Categories (listing zero bills).

In contrast, the U.S. Chamber nationally “represent[s] the unified interests of the U.S. business community.” U.S. Chamber of Comm., *The U.S. Chamber’s History*, <https://perma.cc/9GKD-LBQ2>.

2. In June 2023, plaintiffs sued HHS and CMS to challenge the Negotiation Program. Complaint, R. 1, Page ID # 1–57. Their complaint identified only one member, AbbVie, Inc., affected by the Negotiation Program, and claimed that AbbVie was a member only of the Dayton Chamber and the U.S. Chamber. Complaint, R. 1, Page ID # 10; Staff Declaration, R. 29-5, Page ID # 185. AbbVie later asserted that it was also a member of the Michigan Chamber “before this action was filed.” Second Staff Declaration, R. 49-1, Page ID # 397. And after the litigation commenced, AbbVie joined the Ohio Chamber. *Id.*, Page ID # 398.

AbbVie is a Delaware corporation headquartered in North Chicago, Illinois. AbbVie, Inc., Form 10-Q (Nov. 4, 2024), <https://perma.cc/CB2Q-VKQ9>. AbbVie researches and manufactures biopharmaceuticals, Staff Declaration, R. 29-5, Page ID # 185, but it is not the holder of the Imbruvica new drug applications and accordingly was not the entity that negotiated with CMS after Imbruvica was selected for negotiation. *See* Revised Guidance 118 (explaining that the primary manufacturer of a drug is the entity that meets the statutory requirements and holds the new drug application(s)).



Rather, Pharmacyclics, LLC—an AbbVie subsidiary—is the holder of the Imbruvica new drug applications and the entity that agreed to sell Imbruvica to Medicare customers through the Negotiation Program. Third Staff Declaration, R. 64-1, Page ID # 777; CMS, *Negotiated Prices for Initial Price Applicability Year 2026*, *supra*, at 2. Pharmacyclics is a Delaware limited liability company, Delaware Sec’y of State, *Certificate of Merger* (June 12, 2015), <https://perma.cc/858T-J9PS>, that is headquartered in Sunnyvale, California. AbbVie, Press Release, AbbVie Completes Acquisition of Pharmacyclics (May 26, 2015), *cited in* Second Staff Declaration, R. 49-1, Page ID # 394.

When the litigation commenced in June 2023, Pharmacyclics was not a member of the Dayton and Ohio Chambers. After the government raised this point in its first motion to dismiss, Motion to Dismiss, R. 33, Page ID # 219, in August 2023 “Pharmacyclics joined the Dayton and Ohio Chambers in its own name,” Second Staff Declaration, R. 49-1, Page ID # 398. Plaintiffs assert that “Pharmacyclics, as a wholly[ ]owned subsidiary of AbbVie, has been a member of the [U.S. Chamber] and the Michigan Chamber of Commerce by virtue of AbbVie’s membership in these organizations.” *Id.*, Page ID # 398.

In their operative complaint, plaintiffs allege that the Negotiation Program violates the nondelegation doctrine, deprives manufacturers of selected drugs of property without due process, permits the imposition of excessive fines, exceeds Congress's enumerated powers, and compels protected speech. Amended Complaint, R. 57, Page ID # 649–71. Plaintiffs allege that implementing the Negotiation Program will adversely harm AbbVie and Pharmacyclics, *id.*, Page ID # 616–21, as well as “[m]any of Plaintiffs’ members,” *id.*, Page ID # 621, which are never identified. Plaintiffs sought declaratory relief and a preliminary and permanent injunction prohibiting HHS from implementing the Negotiation Program. *Id.*, Page ID # 671–72; Motion for Preliminary Injunction, R. 29, Page ID # 139.

3. After some initial motions practice, *see* Order, R. 55, Page ID # 574–601 (denying plaintiffs’ motion for preliminary injunction and denying the government’s initial motion to dismiss in order to allow plaintiffs to file an amended complaint), the district court granted the government’s renewed motion to dismiss, *see* Order, R. 102, Page ID # 1555–73 (also denying plaintiffs’ motion for summary judgment).

The district court held that the Dayton, Ohio, and Michigan Chambers lack associational standing because they failed to show that the organizations' purposes are germane to this litigation. Order, R. 102, Page ID # 1563–66. Looking to the complaint and plaintiffs' declarations, the district court found that the purpose of the Dayton Chamber is “improving the business climate in Dayton, Ohio,” and it rejected plaintiffs' unsupported contention that the Dayton Chamber has a wider purpose. *Id.*, Page ID # 1564. The district court took judicial notice that Pharmacyclics is “based out of California” and that AbbVie is “located in Illinois, California, Massachusetts, and Washington, D.C.” *Id.*, Page ID # 1565. Because plaintiffs failed to “connect[ ] the interests of Pharmacyclics or AbbVie to the business climate in the Dayton area,” the district court held that “the interests at stake in this lawsuit are not germane” to the purpose of the Dayton Chamber. *Id.*, Page ID # 1565. The district court made the same finding for the Ohio and Michigan Chambers. Order, R. 102, Page ID # 1566 (finding that both have a purpose of promoting business interests within their State).

The district court explained that “Pharmacyclics and AbbVie are large pharmaceutical companies that could have sued on their own in a federal

court in a different state. Instead, plaintiffs have attempted to manipulate the system and manufacture standing to obtain a favorable venue.” Order, R. 102, Page ID # 1572. Emphasizing the breadth of plaintiffs’ argument, the court noted that a holding that “the Dayton Area Chamber of Commerce had standing in this case . . . would 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.*, Page ID # 1572.

While the district court concluded that the U.S. Chamber had plausibly alleged standing, Order, R. 102, Page ID # 1569, it determined that the U.S. Chamber could not establish venue in the district. Because plaintiffs did not request a transfer to any district in which venue would lie for the U.S. Chamber, and because of “[p]laintiffs’ artfulness in choosing this venue,” the district court exercised its discretion to dismiss this case without prejudice rather than transferring the case, *id.*, Page ID # 1572. Rather than refile their complaint in a permissible venue, plaintiffs filed a notice of appeal.

4. Other drug manufacturers and interest groups have filed related suits across the country challenging the constitutionality and implementation of the Negotiation Program. The first year of the Negotiation Program

covers ten drugs produced by ten companies. *See* CMS, *Negotiated Prices for Initial Price Applicability Year 2026*, *supra*, at 2.

Seven of those ten manufacturers filed suit directly to challenge the Negotiation Program. *See AstraZeneca Pharm. LP v. Becerra*, 719 F. Supp. 3d. 377 (D. Del. 2024), *appeal pending*, No. 24-1819 (3d Cir.); *Bristol Myers Squibb Co. v. Becerra*, Nos. 23-cv-3335, 23-cv-3818, 2024 WL 1855054 (D.N.J. Apr. 29, 2024) (consolidated opinion resolving challenges by Bristol Myers Squibb Co. and Janssen Pharmaceuticals, Inc.), *appeals pending*, Nos. 24-1810, 24-1821 (3d Cir.); *Boehringer Ingelheim Pharms., Inc. v. HHS*, No. 3:23-cv-1103, 2024 WL 3292657 (D. Conn. July 3, 2024); *Novo Nordisk Inc. v. Becerra*, No. 23-20814, 2024 WL 3594413 (D.N.J. July 31, 2024), *appeal pending*, No. 24-2510 (3d Cir.); *Novartis Pharms. Corp. v. Becerra*, No. 23-cv-14221, 2024 WL 4524357 (D.N.J. Oct. 18, 2024), *appeal pending*, No. 24-2968 (3d Cir.); *Merck & Co. v. Becerra*, No. 1:23-cv-1615 (D.D.C. filed June 6, 2023). As for the other three manufacturers, Pharmacyclics indirectly challenged the Negotiation Program through this litigation. Immunex Corp. did not sue directly, although its parent company Amgen has participated in litigation in the Western District of Texas. *See* Declaration of Patrick Costello, ECF No. 35-6, *National Infusion Ctrs. Ass'n v. Becerra*, No. 1:23-

cv-707 (W.D. Tex. June 21, 2023). And while the tenth manufacturer, Janssen Biotech, Inc., did not sue directly, its sister company, Janssen Pharmaceuticals, is challenging the Negotiation Program in court.

### SUMMARY OF ARGUMENT

I. This suit to vindicate the rights of a California-based pharmaceutical company in connection with a program establishing the terms on which Medicare will pay for certain drugs has no meaningful relationship to the Dayton Area Chamber of Commerce’s stated purpose of promoting regional business interests. The district court correctly held that the Dayton Chamber therefore lacks associational standing and rejected plaintiffs’ efforts at forum-shopping.

The question on appeal turns largely on the characterization of the Dayton Chamber’s purpose and the interests at stake in this litigation. Even under plaintiffs’ expansive view of associational standing, the germaneness inquiry demands that litigation interests must “reasonably tend to further the general interests that individual members sought to vindicate in joining the association” and must “bear[ ] a reasonable connection to the association’s knowledge and experience.” Br. 27 (quoting *Building & Constr. Trades Council v. Downtown Dev., Inc.*, 448 F.3d 138, 149 (2d Cir. 2006)).

The record confirms the Dayton Chamber’s more specific regional purpose and its lack of a sufficient connection to the particular interests furthered by this litigation. *See, e.g.*, Amended Complaint, R. 57, Page ID # 614 (“[T]he Dayton Area Chamber of Commerce brings together more than 2,200 businesses and organizations in a 14-county area surrounding Dayton, Ohio and strives to improve the region’s business climate and overall standard of living.”).

Plaintiffs ignore these specific statements and instead assert that the standard is met here because the litigation seeks to “combat government overreach” and promote “free enterprise,” Br. 16, thereby furthering the Dayton Chamber’s purpose of cultivating “a business friendly legislative and regulatory environment that encourages the growth and economic prosperity of businesses,” Br. 25. Stated at plaintiffs’ preferred level of generality, the scope of associational standing—and the attendant opportunities for forum-shopping—would be limitless. And the parties in these cases would be allowed to proceed notwithstanding the lack of a direct connection to the controversy that Article III requires. The district court correctly rejected plaintiffs’ argument that the Dayton Chamber has a sufficient connection to these claims addressing the rights of an out-of-state pharmaceutical company

simply because it is a business association and the litigation could affect business.

The district court reached the same correct conclusions for the Ohio and Michigan Chambers as well, concluding that the stated purpose of each organization focuses on the businesses in their respective States.

II. The district court did not abuse its discretion in dismissing rather than transferring this case. The district court found that only the U.S. Chamber of Commerce plausibly had standing to sue, that venue as to that plaintiff was improper, and that plaintiffs did not request a transfer to the venue in which the U.S. Chamber resides.

The district court necessarily did not abuse its discretion in failing to grant a transfer the plaintiffs never requested. Likewise, even if the Michigan or Ohio Chamber had standing, the district court did not abuse its discretion in declining to transfer this case. And plaintiffs in any event cannot show prejudice from a dismissal without prejudice entered years before their statute of limitations has run.

### **STANDARD OF REVIEW**

“A district court’s dismissal for lack of subject matter jurisdiction is reviewed de novo, accepting as true any factual findings of the district court



unless they are clearly erroneous.” *Abbott v. United States*, 78 F.4th 887, 896 (6th Cir. 2023). The “purpose” of an organization in the standing inquiry is a question of historical fact, *see Pierce v. Underwood*, 487 U.S. 552, 561 (1988) (elucidating law-fact distinction), which is reviewed for clear error, *see Thomas v. City of Memphis*, 996 F.3d 318, 323 (6th Cir. 2021). “The decision of whether to dismiss or transfer is within the district court’s sound discretion” and is reviewed for abuse of discretion. *First of Michigan Corp. v. Bramlet*, 141 F.3d 260, 262 (6th Cir. 1998).

## ARGUMENT

### **I. The Dayton Area Chamber of Commerce lacks associational standing to pursue claims on behalf of Pharmacyclics.**

#### **A. An association may sue on behalf of a member with standing only if the interest of the litigation is germane to the organization’s purpose.**

Article III requires that a plaintiff “have a ‘personal stake’ in the dispute.” *FDA v. Alliance for Hippocratic Med.*, 602 U.S. 367, 379 (2024).

At a minimum, a “plaintiff must have (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) (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61 (1992)).

Ordinarily, a plaintiff can assert only his own rights, *Warth v. Seldin*, 422 U.S. 490, 499 (1975), but a membership association may sue on behalf of its members if “(1) its members would otherwise have standing to sue in their own right; (2) the interests that the suit seeks to protect are germane to the organization’s purpose; and (3) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit,” *Association of Am. Physicians & Surgeons v. FDA*, 13 F.4th 531, 537 (6th Cir. 2021) (quotation marks omitted). This rule acknowledges that such organizations may draw on “specialized expertise and research resources relating to the subject matter of the lawsuit that individual plaintiffs lack” and thus may sharpen the adversarial presentation of “difficult questions.” *International Union, United Auto. Workers of Am. v. Brock*, 477 U.S. 274, 289 (1986) (cleaned up). The plaintiff bears the burden of establishing standing. *Lujan*, 504 U.S. at 561.

At issue here is the requirement that an organization’s purpose be germane to the interests the lawsuit seeks to protect. Germaneness serves the “modest yet important [goal] of preventing litigious organizations from forcing the federal courts to resolve numerous issues as to which the organizations themselves enjoy little expertise and about which few of their

members demonstrably care.” *Humane Soc’y of the U.S. v. Hodel*, 840 F.2d 45, 57 (D.C. Cir. 1988). The requirement recognizes that “an organization with a diverse membership could readily produce a sufficient number of members claiming constitutionally cognizable injuries from governmental actions” to allow it to sue on virtually any topic, essentially “becoming [a] law firm[ ] with standing,” absent a need to demonstrate a meaningful connection between the litigation and the group’s purpose. *Id.* at 57, 58 (quotation marks omitted).

To satisfy the germaneness requirement, it is not enough to show that a member of an organization has standing to sue. The member’s interests that the litigation seeks to vindicate must also relate to the organization’s purpose. *See, e.g., Pacific Nw. Generating Co-Op v. Brown*, 38 F.3d 1058, 1063 (9th Cir. 1994) (power generating cooperative could not assert its members’ aesthetic and recreational interests in suit challenging Endangered Species Act designations); *White’s Place, Inc. v. Glover*, 222 F.3d 1327, 1327 n.1, 1330 (11th Cir. 2000) (erotic-dancing business could not assert its employees’ free speech rights related to a public protest against an adult entertainment ordinance). Plaintiffs do not dispute that the germaneness inquiry requires a connection between the interests furthered

by the litigation and the organization's purpose. Br. 26–27. The dispute instead centers on the proper characterization of these interests and the sufficiency of their fit.

**B. This litigation is not germane to the organizational purposes of the Dayton Area Chamber of Commerce.**

As the district court correctly concluded, the Dayton Area Chamber of Commerce failed to carry its burden of demonstrating that the interests this litigation seeks to vindicate are germane to the group's stated purpose of improving the Dayton area's business climate. Order, R. 102, Page ID # 1566–67. The litigation asserts violations of the constitutional rights of a pharmaceutical company that is headquartered in California and organized in Delaware.<sup>1</sup> That company's interest in the price at which it can sell drugs

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<sup>1</sup> The Court need not address plaintiffs' assertion that AbbVie would have standing to sue in its own right because AbbVie's standing does not bear on whether the interests of this litigation are germane to the Dayton Chambers' purpose. But it is in any event well established that plaintiffs may not pierce the corporate veil to establish standing. *See In re RCS Engineered Prods. Co., Inc.*, 102 F.3d 223, 226 (6th Cir. 1996). AbbVie could not sue as the sole stockholder in Pharmacyclics because “an action to redress injuries to a corporation cannot be maintained by a stockholder in his own name.” *Canderm Pharmacal, Ltd. v. Elder Pharms., Inc.*, 862 F.2d 597, 602–03 (6th Cir. 1988) (cleaned up); *see In re Troutman Enterprises, Inc.*, 286 F.3d 359, 364 (6th Cir. 2002). Nor has AbbVie raised a viable injury “separate and distinct from that suffered by” Pharmacyclics. *See Gaff v. FDIC*, 814 F.2d 311, 315 (6th Cir. 1987).

to Medicare, and the scope of its rights under that program, are not germane to the regional purpose of the Dayton Chamber. The Dayton Chamber's characterization of its purpose in litigation documents as "encourag[ing] the growth and economic prosperity of businesses" more generally is untenably vague and at odds with the distinctly regional purpose documented in the record and credited by the district court. Plaintiffs have failed to provide the necessary assurance that the group has "a stake in the resolution of the dispute" beyond the vindication of broad policy interests so as to put it "in a position to serve as the defendant's natural adversary." *United Food & Com. Workers Union Loc. 751 v. Brown Grp., Inc.*, 517 U.S. 544, 555–56 (1996).

1. The "purpose" of an organization in the standing inquiry is a question of historical fact, *see Pierce v. Underwood*, 487 U.S. 552, 561 (1988), which is reviewed for clear error, *see Thomas v. City of Memphis*, 996 F.3d 318, 323 (6th Cir. 2021). *See generally* Harry T. Edwards & Linda A. Elliot, *Federal Standards of Review: Review of District Court Decisions and Agencies Actions* 7–18 (3d ed. 2018) (explaining that questions of fact turn on inferences from evidence rather than abstract legal principles). The district court did not clearly err in finding that the Dayton Chamber's purpose is to promote Dayton-area business interests. The district court relied on

plaintiffs' complaint, which explained that “the Dayton Area Chamber of Commerce brings together more than 2,200 businesses and organizations in a 14-county area surrounding Dayton, Ohio and strives to improve the region's business climate and overall standard of living,” to find that “the purpose of this organization appears to be improving the business climate in Dayton, Ohio.” Order, R. 102, Page ID # 1564 (cleaned up) (quoting Amended Complaint, R. 57, Page ID # 614).

Judicially noticeable public records confirm that “[t]he purposes of the [Dayton Chamber] are to promote and advance the business interests of the greater Dayton, Ohio region.” Dayton Area Chamber of Commerce, *Bylaws* art. I., § 4 (approved May 15, 2013), <https://perma.cc/KM5K-R6XY> (emphasis added); see *Humane Soc’y*, 840 F.2d at 59 (explaining that a statement of purpose in an organization's bylaws offers “strong evidence of purpose”). And the organization holds itself out as having a “regional perspective.” Dayton Area Chamber of Comm., *Our Reach*, <https://perma.cc/C79X-XMY3>. The district court thus had ample basis for finding that the Dayton Chamber's mission is to serve businesses in the Dayton area.

Plaintiffs' assertion (at 32) that the Dayton Chamber has a broader purpose is contradicted by plaintiffs' own evidence and comes nowhere close

to showing that the district court committed clear error. In its own declaration, the Dayton Chamber describes its efforts in distinctly local terms, emphasizing that the Chamber “strives to improve the region’s business climate” and is “recognized for its innovating programs and outstanding contribution to positive change in the region.” Kershner Declaration, R. 29-2, Page ID # 171. Plaintiffs fare no better in citing an op-ed written by the presidents of the Dayton and Ohio Chambers while this litigation was pending. Br. 31 (citing Chris Kershner & Steve Stivers, *Voice of Dayton Business: Ohio Businesses Cannot Stand for Government Overreach*, Dayton Daily News (June 25, 2023), <https://perma.cc/KJ5Y-BHCK>). A group cannot establish standing through post hoc revisions to its statement of purpose, much less in an op-ed announcing the very litigation in which it seeks to establish standing. And the op-ed in any event confirms the Dayton Chamber’s interest in “protect[ing] the future well-being of businesses *in the Dayton area.*” *Id.* (emphasis added).

Plaintiffs’ opening brief acknowledges that regional limitation in referring to “the Dayton Area Chamber’s purpose of promoting a business-friendly environment in the Dayton region.” Br. 17. To the extent plaintiffs suggest that the Dayton Chamber has a broader purpose of “safeguard[ing]

the principles of free enterprise,” Br. 31 (quoting ), and advocating “for a business friendly legislative and regulatory environment,” Kershner Declaration, R. 29-2, Page ID # 171, those statements fail to acknowledge the substantial evidence of the Dayton Chamber’s expressly regional interests. Plaintiffs’ more specific contention that the Dayton Chamber’s purpose is to “protect[ ] its members’ interests in an innovative, affordable health care system,” Br. 17, lacks any support in the record.

The suggestion that the Dayton Chamber has a national purpose is also in tension with the proliferation of Chambers of Commerce representing scores of local and regional interests, in addition to a U.S. Chamber of Commerce that serves a national purpose germane to this litigation (but without a connection to the chosen venue). *See* Order, R. 102, Page ID # 1566; *cf.* U.S. Chamber of Comm., *The U.S. Chamber’s History*, <https://perma.cc/9GKD-LBQ2> (explaining that the U.S. Chamber nationally “represent[s] the unified interests of the U.S. business community”).

The district court appropriately rejected plaintiffs’ attempt to generalize the organization’s purpose at such a high level of abstractness that it would be germane to, and thus support standing to challenge, any federal law touching on the economy—which is to say, nearly any federal law.



The district court made the same appropriate findings for the Ohio and Michigan Chambers. *See* Order, R. 102., Page ID # 1566. The district court did not clearly err in relying on plaintiffs' complaint, *see id.*, Page ID # 1566 (quoting Amended Complaint, R. 57, Page ID # 614), to find that each organization has a distinctly regional purpose. The record only underscores the regional focus of the Ohio and Michigan Chambers. *See* Holcomb Declaration, R. 29-3, Page ID # 176 (describing Michigan Chamber's ultimate goal as benefiting "the people of the State of Michigan by enhancing the quality of life for Michigan families"); Long Declaration, R. 29-4, Page ID # 181 (explaining that the Ohio Chamber is an "Ohio organization" and that it advocates in favor of "quality, affordable health care for all Ohioans"). To the extent plaintiffs have even managed to preserve their argument with respect to the Ohio and Michigan Chambers, *compare United States v. Johnson*, 467 F.3d 559, 564 (6th Cir. 2006) (failure to apply law to facts forfeits argument), *with* Br. 51–52, they have not shown that the district court clearly erred.

2. The district court correctly concluded that this litigation is not germane to the Dayton Chamber's regional purpose. The litigation asserts violations of the constitutional rights of a California-based pharmaceutical company and "elaborate[s] on how the Program's requirements have created 'significant costs and burdens' for" the company and its Illinois-based corporate parent. Order, R. 102, Page ID # 1564. The germaneness inquiry asks whether an organizational plaintiff suing on behalf of a third party has a sufficient connection to the litigation to satisfy the constitutional minimum of standing. *See Humane Soc'y*, 840 F.2d at 58. Pharmacyclics's interest in the price at which it can sell drugs to Medicare, and the scope of its rights under the Negotiation Program, are not germane to the distinctly regional purposes of the Dayton Chamber.

Relying on the harm to Pharmacyclics, plaintiffs assert that this suit seeks to "prevent the IRA from 'depriving Plaintiffs' members of their constitutional rights, making it more difficult for them to operate their businesses, and stifling healthcare innovations that all of us depend on.'" Order, R. 102, Page ID # 1564 (quoting Doc. No. 57 at Page ID # 616). But plaintiffs cannot establish standing based solely on an interest in vindicating its members' rights without regard to how those rights relate to plaintiffs'

organizational purpose. The standing of an association's member, while necessary to associational standing, is expressly insufficient to establish germaneness—otherwise the first prong of the inquiry would wholly subsume the second. *See Humane Soc'y*, 840 F.2d at 57. Accordingly, while Pharmacyclics' allegations of harm would support suit by that company, they are not sufficient to establish that the litigation is germane to the purpose of the organizations that actually brought suit.

To establish a connection to the Dayton Chamber, plaintiffs attempt to frame the interests at stake in the litigation at a higher level of generality. They assert that “the Dayton region is not an isolated backwater disconnected from the national economy,” and its “residents and businesses bear the costs of sweeping new federal laws.” Br. 32–33. And they contend “that this lawsuit aims to defend free enterprise, economic prosperity, and the future well-being of businesses in the Dayton area and beyond.” Order, R. 102, Page ID # 1564 (quoting Doc. No. 90 at Page ID # 1248); *see* Br. 35 (characterizing the case as “a challenge to government overreach that threatens to hamper economic prosperity and create an unfavorable environment for business, including in the Dayton area”). But plaintiffs offer no support for the idea that such vague and sweeping concerns about

economic ripple effects can serve to establish the necessary connection between a regional organization's purpose and a challenge of this kind.

Plaintiffs cannot avoid this suit's lack of germaneness to the Dayton Chamber's purpose by characterizing the litigation interests in abstract terms. This is fundamentally a case about the rights of an out-of-region pharmaceutical manufacturer. While it also has implications for other pharmaceutical manufacturers whose drugs have been selected for negotiation, the Dayton Chamber lacks any demonstrated "knowledge and experience" specific to that industry or the broader subject of this litigation, *Br. 27 (quoting Building & Constr. Trades Council, 448 F.3d at 149)*, and the industry has no meaningful presence in the region. The litigation relates to the Dayton Chamber's interests only insofar as it may concern principles of free enterprise and affect the economy very generally. But framing these interests at such a high level of generality eviscerates the requirements of Article III standing and would allow essentially any regional organization to sue over any national policy as long as the organization can assert a general interest in broad economic, environmental, or similar effects. That has never been the law.

The Eighth Circuit in *Minnesota Federation of Teachers v. Randall*, 891 F.2d 1354 (8th Cir. 1989), rejected a similar attempt to frame an organizational purpose and litigation interests in broad terms that would largely eliminate the germaneness requirement. In that case, a teachers' union representing thousands of elementary and secondary school teachers challenged on Establishment Clause grounds a law reallocating funds from public secondary schools to religiously affiliated colleges. *Id.* at 1355. The union alleged that the reallocation could reduce the number of dues-paying teachers or the pool of money available for teacher salaries, thereby undermining the interests of both the union and its members. *Id.* at 1358. Notwithstanding the facial connection between a teacher's union and legislation affecting public school funding, the Eighth Circuit held that the germaneness requirement was not met because the suit sought to vindicate the union members' First Amendment interest in avoiding the use of their tax money to support sectarian schools, and the union's purpose was unrelated to its members' interests as taxpayers. Taking note of the "organization's specifically stated purposes" and the specific interests asserted in the litigation, the court held that the union lacked standing even though it had a general interest in the litigation. *Id.* at 1359.

The Dayton Chamber is on no firmer ground in speculating that other members in other industries might feel downstream economic harms, Br. 34, or someday be subjected to similar statutory schemes, *see* Br. 31. Plaintiffs assert that, “as a matter of common sense and basic economics, the Program will affect entities that do business with manufacturers, such as suppliers of raw materials, distributors, equipment makers, and builders of laboratories,” and in that way the challenged provisions will “predictably cause[ ] economic injures to others in the chain of commerce.” Br. 34 (cleaned up). But plaintiffs did not plead and have not introduced any evidence that the Negotiation Program will financially harm others in the supply chain, much less others with specific regional ties. *Cf.* Kershner Declaration, R. 29-2, Page ID # 173 (discussing only pharmaceutical manufacturers); Amended Complaint, R. 57, Page ID # 615–22 (same). These speculative concerns are “too attenuated to establish [the Dayton Chamber’s] stake in the resolution of th[is] dispute.” *Children’s Health Def. v. FDA*, No. 21-6203, 2022 WL 2704554, at \*3 (6th Cir. July 12, 2022) (unpublished). For the same reason, the Dayton Chamber cannot invoke standing on behalf of unnamed members who may one day participate in the Negotiation Program or related

programs.<sup>2</sup> *Cf. Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 411–13 (2013) (parties may not rely on speculative injuries to establish standing); *Summers v. Earth Island Inst.*, 555 U.S. 488, 498–99 (2009) (parties may not rely on statistical probability that member will be affected by challenged activity to establish standing).

3. If an organization’s “purpose is detached from the interests at stake in the complaint,” it cannot satisfy the germaneness requirement. *Children’s Health Def.* 2022 WL 2704554, at \*3. This Court’s decision in *Children’s Health Defense* illustrates the point. Children’s Health Defense (CHD) is an advocacy organization that seeks “to end ‘childhood health epidemics by working aggressively to eliminate harmful exposures [from, *inter alia*, vaccines], hold those responsible [for vaccination programs] accountable, and establish safeguards so [alleged vaccine injuries] never happen[ ] again.’” 2022 WL 2704554, at \*3. The organization sought to block the FDA’s approval of COVID-19 vaccines. *Id.* at \*2. It asserted standing on behalf of fifteen of the organization’s “members who were or are serving in the United

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<sup>2</sup> Litigation premised on the possibility that an unnamed member may someday be subject to regulation would also raise significant ripeness concerns. *See City Commc’ns, Inc. v. City of Detroit*, 888 F.2d 1081, 1089 (6th Cir. 1989) (“Ripeness becomes an issue when a case is anchored in future events that may not occur as anticipated, or at all.”)

States military,” asserting that the military would require these members either to receive the COVID-19 vaccine or face adverse consequences. *Id.* The members had “various objections to receiving the vaccine, including religious based objections and concerns regarding the effect the vaccine might have on their ability to have children,” and the organization’s general counsel filed a declaration claiming that “the interests of the declarants who CHD protects are clearly related to CHD’s mission and overarching goals as an organization.” *Id.* (quotation marks omitted).

This Court, however, held that the organization lacked associational standing. It explained that “[t]he connection between a suit concerning the vaccination of adult military members and an organization committed to protecting children’s health is too attenuated to establish [the group’s] stake in the resolution of the dispute and position to serve as FDA’s natural adversary.” *Children’s Health Def.*, 2022 WL 2704554, at \*3 (cleaned up). In reaching that conclusion, the Court rejected the organization’s efforts to frame its purpose broadly. The group’s declarant stated that the “organization aggressively fights to protect all citizens from various forms of tyranny” and health harms, emphasizing that “[a]ll ages are represented in CHD’s advocacy. It is the voice for those oppressed by corporate capture of



Federal agencies.” Holland Declaration ¶¶ 5–6, ECF No. 26, *Children’s Health Defense v. FDA*, 573 F. Supp. 3d 1234 (E.D. Tenn. 2021) (No. 1:21-cv-200). But the Court relied on the group’s pre-litigation characterization of its purpose as protecting children’s health. *See Children’s Health Def.*, 2022 WL 2704554, at \*3.

*Children’s Health Defense* is consistent with the decisions of myriad other courts that regularly reject claims brought by organizations seeking to litigate members’ claims that are not sufficiently related to the organizations’ purpose. *See, e.g., Minnesota Fed’n of Tchrs.*, 891 F.2d at 1359 (purpose of teachers’ union is not germane to litigation to protect members’ interests as taxpayers); *Pacific Nw. Generating Co-Op*, 38 F.3d at 1063 (purpose of electrical cooperative is not germane to litigation to protect aesthetic and recreational interests); *Town of Norwood v. FERC*, 202 F.3d 392, 407 (1st Cir. 2000) (purpose of environmental association not germane to litigation to protect members’ private economic interests); *Central S.D. Co-Op Grazing v. Secretary of USDA*, 266 F.3d 889, 897 (8th Cir. 2001) (purpose of association organized to cooperatively manage grazing lands is not germane to litigation to protect wildlife habitat within those lands); *Ranchers Cattleman Action v. USDA*, 415 F.3d 1078, 1104 (9th Cir. 2005) (purpose of

trade and marketing association is not germane to litigation to halt environmental injuries); *United States v. Metropolitan St. Louis Sewer Dist.*, 569 F.3d 829, 834 (8th Cir. 2009) (purpose of business association focused on utility services not germane to litigation to protect aesthetic and recreational interests); *see also Northeast Ohio Coalition for Homelessness v. Blackwell*, 467 F.3d 999, 1010 (6th Cir 2006) (noting “substantial questions” about ability of labor union and organization dedicated to homelessness issues to raise voting rights claims).

Just as these courts rejected efforts to establish standing when organizations sought to vindicate interests insufficiently related to their purposes, the district court correctly rejected the regional Chambers’ effort to establish standing on vindicate the interests of an out-of-state pharmaceutical company with no meaningful ties to the region.

**C. Plaintiffs’ contrary arguments are meritless and lack any limiting principle.**

1. Plaintiffs and their amici primarily respond to a strawman, asserting that the district court categorically required a nexus between an association and a specific geographical area. *See* Br. 36–39; Kentucky Chamber Br. 12–15; NAM Br. 26–27. But the district court imposed no such requirement in applying the well-established rule that the interests an

associational standing case seeks to vindicate must be germane to the association's purpose.

Locally oriented organizations may of course represent their members in suits challenging federal laws or on matters of national policy when a suit is germane to the organization's actual purpose. A civic association of citizens dedicated to preserving a park in Memphis could easily show that their purpose is germane to litigation challenging an agency decision to route an interstate through their park, whether that agency operates on the municipal, state, or federal level. *Cf. Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402 (1971). But the same association likely could not sue to stop a similar project from destroying a park in Brooklyn—even if a New Yorker directly harmed by the proposed project paid dues and joined the Memphis association, and even if the Memphis association tied its interest in the local park to broader environmental objectives. The reason for that limitation is not geography but organizational purpose. When people come together to form an organization with a locally or regionally oriented mission, only litigation that relates to that mission will satisfy the germaneness inquiry. The district court correctly held that an organization may not avoid that conclusion by articulating its purpose at a very high level of generality—

*e.g.*, by reframing the purpose of protecting a Memphis park as an interest in protecting natural spaces generally.

2. In asserting that the germaneness inquiry is not rigorous, plaintiffs make too much of references to germaneness as requiring “mere pertinence.” *See* Br. 26, 37–38. That language originates in the D.C. Circuit’s *Humane Society* decision. 840 F.2d at 56. In that case, the district court looked only to an organization’s certificate of incorporation to narrowly determine its purpose. *Id.* at 53. The D.C. Circuit rejected that approach, holding that litigation need not be “central” to the organization’s purpose, but must still be “pertinent to its special expertise and the grounds that bring its membership together.” *Id.* at 56–57. The court indicated that this inquiry requires a “close relationship” between the organization’s purpose and the interests of the litigation, noting that associational standing is meant to enable organizations “to utilize their ‘specialized expertise and research resources’ relating to the subject matter of the lawsuit.” *Id.* at 56 (quotation marks omitted). The court thus cautioned against allowing suit on matters beyond an “association’s area of competence or reason for existence,” *id.* at 57—a conclusion in keeping with other cases holding that germaneness requires a direct relationship between an organization’s special competence

and the “interests of the [members] it purportedly represents.” *McKinney v. U.S. Dep’t of Treasury*, 799 F.2d 1544, 1553 (Fed. Cir. 1986); *see, e.g., Metropolitan St. Louis Sewer Dist.*, 569 F.3d at 834 (holding that the purpose of a business association focused on commercial interests in utility matters was not germane to litigation to redress environmental injury). Here, there is no direct relationship between the Dayton Chambers’ special regional competence and Pharmacyclics’ rights under the Negotiation Program.

While plaintiffs assert that “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,” only one of the seven cases plaintiffs cite for this point raised a contested question of germaneness. *See* Br. 27 (citing *Universal Life Church Monastery Storehouse v. Nabors*, 35 F.4th 1021, 1036 (6th Cir. 2022); *CTIA - The Wireless Ass’n v. Keats*, Nos. 21-5435, 21-5483, 2021 WL 7209356, at \*3 (6th Cir. Dec. 3, 2021) (unpublished); *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)). The passing analysis in the six cases in which germaneness was not disputed does not support plaintiffs’ view that courts apply the germaneness requirement uncritically when that element is actually contested.<sup>3</sup> *Cf. Arizona Christian Sch. Tuition Org. v. Winn*, 563 U.S. 125, 144 (2011) (“When a potential jurisdictional defect is neither noted nor discussed in a federal decision, the decision does not stand for the proposition that no defect existed.”).

In the only one of these cases in which germaneness was disputed, the scope of the dispute was narrow and unrelated to the issue here: The defendants argued that the organization failed to meet its burden to establish germaneness because it relied only on “bare assertions” and “unpleaded

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<sup>3</sup> See First Br. of Defendants-Appellants 25–31, *Universal Life Church Monastery Storehouse v. Nabors*, 35 F.4th 1021 (6th Cir. 2022) (Nos. 21-5048, 21-5100, 21-5055, 21-5057, 21-5058, 21-5059) (arguing only that no plaintiff had demonstrated an injury in fact); Br. of Att’y Gen. 17–26, *Online Merchants Guild v. Cameron*, 995 F.3d 540 (6th Cir. 2021) (No. 20-5723) (conceding germaneness and arguing only that no member would have standing to sue in his own right); Br. of State Defendants-Appellees, *Fednav, Ltd. v. Chester*, 547 F.3d 607, 615 (6th Cir. 2008) (No. 07-2083) (not contesting standing); Br. of Appellee, *ACLU v. Taft*, 385 F.3d 641 (6th Cir. ) (No. 02-3924) (not contesting standing); Br. of Defendants/Appellants at 13, *Doe v. Porter*, 370 F.3d 558, 562 (6th Cir. 2004) (Nos. 02-5316, 02-5823) (arguing only that no member would have standing to sue in his own right); Br. for Appellant, *Adland v. Russ* 307 F.3d 471 (6th Cir. 2002) (No. 00-6139) (not contesting standing).

facts.” Br. of Defendants-Appellants/Cross-Appellees 21–22, *CTIA - The Wireless Ass’n v. Keats*, 2021 WL 7209356, (6th Cir. Dec. 3, 2021) (Nos. 21-5435, 21-5483). This Court rejected that argument after finding a sufficiently detailed statement of purpose in the organization’s complaint, which alleged that the national organization “‘vigorously advocates at all levels of government for policies that foster continued wireless innovation and investment’” and asserted that “[c]hallenging the 911 service charge imposed on its members falls within the scope of CTIA’s mission of representing and advocating for the wireless communications industry.” *CTIA*, 2021 WL 7209356, at \*3.

The defendants in *CTIA* did not contest that the organization’s purpose would be germane to the litigation if adequately pleaded, and this Court did not closely examine that question. In any event, a national association organized for the purpose of protecting national wireless interests plainly has a more direct nexus to litigation challenging a national wireless policy than the nexus presented here, where a regional business association seeks to vindicate the constitutional rights of an out-of-state pharmaceutical manufacturer. A similarly close relationship is evident in other cases plaintiffs cite. *See, e.g., Online Merchants*, 995 F.3d 549 (allowing

representative suit by association formed for the express purpose of promoting a “free and fairly-regulated online marketplace” where the suit challenged the constitutionality of a state price-gouging law).

3. Plaintiffs’ view (Br. 34–35) that they need not show any link between their members’ injuries and their organizational purposes cannot be reconciled with the Eighth Circuit’s decision in *Minnesota Federation of Teachers v. Randall*, 891 F.2d 1354. In rejecting a teachers’ union’s argument for representing their members in a taxpayer challenge to a law that diverted funding from public schools, the court required a nexus between the *injury* suffered by the organization’s members and the organization’s purpose. Under plaintiffs’ test, which looks to the broadly stated interests of an organization’s entire membership, *see* Br. 37–40, *Minnesota Federation of Teachers* would have come out the other way because public school teachers obviously have an interest in avoiding a decrease in funding for the schools that employ them. While the Court need not reach this issue because plaintiffs would fail any germaneness test, the Eighth Circuit’s understanding of germaneness is more consistent with traditional notions of Article III standing. *See, e.g., Spokeo, Inc. v. Robins*, 578 U.S. 330, 339 (2016) (emphasizing that Article III requires a legally



cognizable injury, which “must affect the plaintiff in a personal and individual way”).

Plaintiffs’ reliance on *Center for Sustainable Economy v. Jewell*, 779 F.3d 588 (D.C. Cir. 2015), is unavailing. Asking whether the plaintiff organization had demonstrated “pertinence between litigation subject and organizational purpose,” *id.* at 597 (quoting *Humane Soc’y*, 840 F.2d at 58), the D.C. Circuit found a sufficient fit between the organizational purpose of a national environmental advocacy association and the litigation’s interest in protecting natural areas used by the organization’s named members. As in *CTIA*, the fit between the organization’s national purpose and the interests furthered by the litigation was much closer in *Center for Sustainable Economy* than the fit alleged here, where a distinctly regional chamber of commerce with expressly regional interests seeks to challenge the constitutionality of a federal Medicare law that does not directly or specifically implicate the local business interests that the Chamber seeks to protect. Even then, associational standing in *Center for Sustainable Economy* was treated as a close question, with Judge Sentelle explaining in dissent that the more specific aesthetic and economic interests asserted by

the individual members were not sufficiently related to the interests asserted by the petitioner organization. *Id.* at 614 (Sentelle, J., dissenting).

4. If accepted, plaintiffs' position would enable any company to pay the Dayton Chamber a membership fee to sue on its behalf in the Southern District of Ohio. The amicus brief filed by the Kentucky Chamber of Commerce—joined by 149 local and regional chambers of commerce—illustrates how far plaintiffs' argument goes. Kentucky Chamber Br. at iii, 19–23. Under plaintiffs' view of associational standing, Pharmacyclics could have joined any of these organizations—from Aiken, South Carolina, to Vail Valley, Colorado—and thereby conferred Article III standing on that group. *See id.* 19–23. Based on that long list of groups with similarly generalizable business interests, Pharmacyclics could have exchanged membership dues for venue in judicial districts in any of the eleven numbered circuits. *See id.*

This theory is inconsistent both with the purposes of associational standing and with longstanding principles against forum shopping. Associational standing assumes that members join organizations to promote a common purpose. *See Brock*, 477 U.S. at 275–76. But if a new member may join an existing group (here, during the pendency of litigation) and thereby enable the group to sue on matters that relate to its purpose only if

both the litigation and the group are described at the highest level of generality, the doctrine collapses into a free pass to forum shop. Plaintiffs' theory comes with all the harms attendant in allowing litigants to cherry-pick courts, *see Gulf Oil Corp. v. Gilbert*, 330 U.S. 501, 508–09 (1947), without regard for any factual connection between the case and the forum.

The tension identified in several cases between the associational standing doctrine and modern standing jurisprudence further militates against the adoption of plaintiffs' sweeping view. *See, e.g., Association of Am. Physicians*, 13 F.4th at 538; *Alliance for Hippocratic Med.*, 602 U.S. at 398–405 (Thomas, J., concurring) (calling for reconsideration of associational standing doctrine); *Industrial Energy Consumers of Am. v. FERC*, 125 F.4th 1156, 1167–68 (D.C. Cir. 2025) (Henderson, J., concurring) (same); *see also* Michael T. Morely & F. Andrew Hessick, *Against Associational Standing*, 91 U. Chi. L. Rev. 1539 (2024) (arguing, *inter alia*, that associational standing is inconsistent with Article III). “[I]f it is dubious whether a precedent is correct as an original matter, [courts] should tread carefully before extending it.” *Preterm-Cleveland v. McCloud*, 994 F.3d 512, 543 (6th Cir. 2021) (*en banc*) (Bush, J., concurring) (citation marks omitted),

*abrogated on other grounds by Dobbs v. Jackson Women’s Health Org.*, 597 U.S. 215 (2022).

**D. Plaintiffs’ claims also require the participation of individual members.**

The conclusion that the Dayton Chamber’s regional purpose is not germane to the specific interests this lawsuit seeks to vindicate suffices to resolve these proceedings, and the Court therefore need not address whether plaintiffs lack standing for the additional reason that their claims require the participation of individual members. While individual participation of members generally is not necessary when an association seeks prospective or injunctive relief for its members, the relaxation of that rule may raise redressability issues because the “party who needs the remedy—the injured member—is not before the court,” and it is “questionable whether ‘relief to these nonparties . . . exceed[s] constitutional bounds.’” *Alliance for Hippocratic Med.*, 602 U.S. at 400–01 (Thomas, J., concurring) (quoting *Association of Am. Physicians*, 13 F.4th at 540). Problems may also arise from the lack of clarity as to whether an adverse judgment against an associational plaintiff would bind its members. *See id.* at 403.

Here, at least one another member of the U.S. Chamber had already filed a claim challenging the Negotiation Program in another district court

when these plaintiffs brought suit. *See Merck v. Becerra*, No. 1:23-cv-1615 (D.D.C. filed June 6, 2023). And the strangeness of this suit is underscored by the fact that nearly every other pharmaceutical manufacturer with a drug selected for the first round of negotiation likewise brought suit on its own behalf, in a district where venue was proper, rather than shopping the claim to a regional chamber of commerce to arrive in the venue of its choice. This suit concerns a pharmaceutical company's interest in commanding a higher price for drugs sales to Medicare than the government is offering to pay. Those claims are appropriately asserted by the company with a concrete stake in the claims, and the district court appropriately "question[ed] whether individual member participation in this case would be required" in these circumstances so as to "defeat associational standing" for all four plaintiffs. Order, R. 102, Page ID # 1568.

**II. The district court acted within its broad discretion when it declined to transfer this case.**

The district court correctly held that, because the Dayton Area Chamber of Commerce lacks standing, venue is not proper in the Western Division of the Southern District of Ohio. Order, R. 102, Page ID # 1571. No other plaintiff is located in that Division. *Id.* And the court reasonably

concluded that it was not in the interests of justice to transfer the case to another Division or District, rather than dismissing without prejudice. *Id.*

The U.S. Chamber of Commerce is the only plaintiff that the district court found potentially has standing. Venue for the U.S. Chamber would be proper only in the District of Columbia, *see* 28 U.S.C. § 1391(e)(1); Order, R. 102, Page ID # 1571, and plaintiffs never requested a transfer to that venue. The district court necessarily did not abuse its discretion in declining a transfer that plaintiffs never sought. *Cosmichrome, Inc. v. Spectra Chrome, LLC*, 504 F. App'x 468, 472 (6th Cir. 2012) (unpublished) (citing *Allstate Ins. Co. v. Green*, 831 F.2d 145, 148 (6th Cir.1987)) (“Because Plaintiffs never moved for a transfer, they cannot now contend that the district court abused a discretion that it was never asked to exercise.”). Plaintiffs’ contention that the district court should have transferred the case to the Southern District’s Eastern Division, where they assert the Ohio Chamber of Commerce is located, is at odds with the court’s conclusion that the Ohio Chamber, like the Dayton Chamber, lacks standing. Order, R. 102, Page ID # 1569.

The district court’s decision was appropriately informed by observations of plaintiffs’ “artfulness in choosing this venue.” Order, R. 102,

Page ID # 1572. “District courts often dismiss a case, rather than transfer it under Section 1406(a), if the plaintiff’s attorney reasonably could have foreseen that the forum in which the suit was filed was improper and the court decides that similar conduct should be discouraged.” *Stanifer v. Brannan*, 564 F.3d 455, 460 (6th Cir. 2009) (cleaned up) (quoting 3 Charles A. Wright, et al., *Federal Practice & Procedure* § 3827 at 602–04 (3d ed. 1998)). The district court acted well within its discretion in choosing to dismiss a case obviously filed in the wrong venue. And plaintiffs do nothing to undermine the district court’s conclusion that transfer was not warranted. *Cf.* Br. 51 (arguing only that “[t]ransfer would have been consistent with th[e] purpose of encouraging the efficient adjudication of the merits”).

The district court dismissed this case without prejudice, Judgment, R. 103, Page ID # 1574, and any plaintiff that can establish standing may refile this case in a district where venue lies. Because such a plaintiff would be in the same position it would have been in had it not filed this suit, and because the statute of limitations for claims against the government has not run, *see* 8 U.S.C. § 2401(a), any error in not transferring would be harmless. *See Bechuck v. Home Depot U.S.A., Inc.*, 814 F.3d 287, 297–98 (5th Cir. 2016).

## CONCLUSION

For the foregoing reasons, the judgment of the district court should be affirmed.

Respectfully submitted,

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## CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 10,468 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)–(6) because it was prepared using Word for Microsoft 365 in Century Expanded BT 14-point font, a proportionally spaced typeface.

*/s/ Maxwell A. Baldi*  
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## CERTIFICATE OF SERVICE

I hereby certify that on February 21, 2025, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Sixth Circuit by using the appellate CM/ECF system.

/s/ Maxwell A. Baldi  
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**DESIGNATION OF RELEVANT  
DISTRICT COURT DOCUMENTS**

Pursuant to Sixth Circuit Rule 28(b)(1)(A)(i), the government designates the following district court documents as relevant:

<b>Record Entry</b>	<b>Description</b>	<b>Page ID # Range</b>
R. 1	Complaint	1-57
R. 29	Motion for Preliminary Injunction	139-42
R. 29-2	Kershner Declaration	170-74
R. 29-3	Holcomb Declaration	175-79
R. 29-4	Long Declaration	180-84
R. 29-5	Staff Declaration	185-92
R. 49-1	Second Staff Declaration	393-99
R. 64-1	Third Staff Declaration	776-81
R. 57	Amended Complaint	606-73
R. 102	Order	1555-73
R. 103	Judgment	1574
R. 105	Notice of Appeal	1579-81