

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.

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

Defendants-Appellees.

No. 24-3868

Appeal from the United States District Court for the Southern District of Ohio at Dayton.
No. 3:23-cv-00156—Michael J. Newman, District Judge.

Argued: June 11, 2025

Decided and Filed: August 6, 2025

Before: GILMAN, DAVIS, and MATHIS, Circuit Judges.

COUNSEL

ARGUED: Jeffrey S. Bucholtz, KING & SPALDING LLP, Washington, D.C., for Appellants. Maxwell A. Baldi, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Appellees. **ON BRIEF:** Jeffrey S. Bucholtz, Alexander Kazam, Christine M. Carletta, E. Caroline Freeman, KING & SPALDING LLP, Washington, D.C., Tami H. Kirby, PORTER WRIGHT MORRIS & ARTHUR LLP, Dayton, Ohio, Jennifer B. Dickey, Andrew R. Varcoe, U.S. CHAMBER LITIGATION CENTER, Washington, D.C., for Appellants. Maxwell A. Baldi, Catherine Padhi, Lindsey Powell, Michael S. Raab, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Appellees. Paul W. Hughes, Andrew A. Lyons-Berg, Emmett Witkovsky-Eldred, MCDERMOTT WILL & EMERY LLP, Washington, D.C., Jeffrey B. Wall, SULLIVAN & CROMWELL LLP, Washington, D.C., for Amici Curiae.

OPINION

RONALD LEE GILMAN, Circuit Judge. In August 2022, Congress passed the Inflation Reduction Act, which gave the Secretary of the U.S. Department of Health and Human Services (HHS) the ability to negotiate prices for drugs manufactured by companies that choose to sell to Medicare and Medicaid under the Drug Price Negotiation Program. The Dayton Area Chamber of Commerce (the Dayton Chamber), the Ohio Chamber of Commerce (the Ohio Chamber), the Michigan Chamber of Commerce (the Michigan Chamber), and the Chamber of Commerce of the United States of America (the U.S. Chamber) (collectively, Plaintiffs) sued HHS, the Centers for Medicare & Medicaid Services (CMS), and the agencies’ heads (collectively, the government) on behalf of their pharmaceutical-manufacturer members, challenging the constitutionality of the Drug Price Negotiation Program.

Plaintiffs claimed that the Program amounted to the government’s attempt to “displace[] market forces and set[] prices on targeted products through central planning.” They based their challenge on the United States Constitution’s Due Process Clause, Excessive Fines Clause, and First Amendment. In addition, Plaintiffs contended that Congress exceeded its legislative powers. They requested both declaratory and injunctive relief.

The government moved to dismiss the complaint on the basis that the Dayton Chamber lacked associational standing because the lawsuit was not germane to the Dayton Chamber’s purposes, making venue in the Southern District of Ohio improper. Agreeing with the government, the district court dismissed the case for improper venue. For the reasons set forth below, we **AFFIRM** the judgment of the district court.

I. BACKGROUND**A. Plaintiffs and their pharmaceutical members**

Plaintiffs are four chambers of commerce that exist to promote their respective business interests. The Dayton Chamber has 2,200 member businesses and organizations in a 14-county

area around Dayton, Ohio. It “strives to improve the region’s business climate and overall standard of living through public policy advocacy, economic development initiatives, and providing networking and training opportunities for its members.” In the words of the President and CEO of the Dayton Chamber, the organization “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.” The district court characterized the Dayton Chamber’s purpose as “improving the business climate in Dayton, Ohio.”

The Ohio Chamber has “nearly 8,000 members, including individually owned and operated businesses serving small communities as well as publicly traded corporations operating on a global scale.” It “develops public policy positions on both state and federal matters for the benefit of its members.” The Ohio Chamber’s mission includes advocacy for “an affordable and sustainable market-based health care system that promotes access to quality health care for all Ohioans.”

As for the Michigan Chamber, it has nearly 4,000 members that employ more than one million people. Its “goal is to achieve policies that benefit members, their employees, and in turn the people of the State of Michigan by enhancing the quality of life for Michigan families.” The Michigan Chamber uses “its voice to advance member priorities through legislative, legal, and political action.”

Finally, the U.S. Chamber has approximately 300,000 direct members. The U.S. Chamber’s mission is to advocate for policies that enable businesses to grow and create jobs in their communities. To accomplish this, the U.S. Chamber supports private pharmaceutical and life-sciences companies’ ability to invest in new treatments.

Plaintiffs each have members that are subject to the Drug Price Negotiation Program. Relevant to this appeal, the members include AbbVie Inc. and its wholly owned subsidiary Pharmacylics LLC, the latter being the FDA new-drug application holder and manufacturer of the drug IMBRUVICA®. IMBRUVICA® was selected as one of the first drugs to be subject to the Drug Price Negotiation Program. Pharmacylics is a Delaware limited-liability company

headquartered in Sunnyvale, California. AbbVie is a Delaware corporation headquartered in North Chicago, Illinois.

At the beginning of this litigation in June 2023, Pharmacyclics was not a member of either the Dayton Chamber or the Ohio Chamber, but it joined both Chambers in August 2023. On the other hand, Pharmacyclics has been a member of the U.S. Chamber and the Michigan Chamber through AbbVie's membership in those organizations. AbbVie has been a member of the U.S. Chamber, the Michigan Chamber, and the Dayton Chamber since before this lawsuit was filed, and its membership in the Ohio Chamber became effective less than a week thereafter.

B. Inflation Reduction Act

Medicare, which is administered by CMS on behalf of the Secretary of HHS, provides federally funded health coverage for individuals who are 65 or older and those who have specified disabilities or certain medical conditions. *See* 42 U.S.C. § 1395 *et seq.* Prescription drugs are covered either through Medicare Part B (for drugs directly administered by physicians) or Part D (for self-administered prescription drugs). *See id.* §§ 1395k(a)(1), 1395x(s)(2)(A), 1395w-102. When Congress enacted Medicare Part D, it prohibited CMS from negotiating drug prices, so Part D drug reimbursements have been determined by negotiations between the pharmaceutical manufacturers and private insurers that contract with CMS. *See* 42 U.S.C. § 1395w-111(i); *see also* CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026* (Aug. 15, 2024), <https://www.cms.gov/newsroom/fact-sheets/medicare-drug-price-negotiation-program-negotiated-prices-initial-price-applicability-year-2026>. Medicare Part B reimburses providers 106% of a drug's average sales price, or the average price to commercial purchasers in the United States. *See* 42 U.S.C. § 1395w-3a.

In August 2022, Congress passed the Inflation Reduction Act, which gave the HHS Secretary—who then delegated his authority to CMS, *see* 88 Fed. Reg. 1390 (Jan. 10, 2023)—the ability to negotiate prices for certain drugs manufactured by companies that choose to sell their drugs to Medicare and Medicaid. *See* IRA, Pub. L. No. 117-169, §§ 11001–11003, 136 Stat. 1818, 1833–64 (2022) (codified at 42 U.S.C. §§ 1320f to -7 and 26 U.S.C. § 5000D). Under the Drug Price Negotiation Program, CMS selects certain pharmaceuticals to be

negotiated. Those selected have the highest Medicare expenditures with no generic or biosimilar competitors and have been licensed for at least seven years (for drugs) or 11 years (for biologics). See 42 U.S.C. § 1320f-1(d), (e), (f); 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). CMS invites the manufacturers of these selected drugs to enter into a Manufacturer Agreement in which the manufacturer agrees to negotiate with CMS to reach a “maximum fair price.” See 42 U.S.C. § 1320f-2(a). The negotiation begins with CMS proposing an initial offer, to which the manufacturer may make a counteroffer. See 42 U.S.C. § 1320f-3(b)(2). At the end of the process, CMS sends a final offer to the manufacturer. *Id.*

CMS selected the first 10 drugs to be negotiated under the Program in August 2023. See HHS, *HHS Selects the First Drugs for Medicare Drug Price Negotiation* (Aug. 29, 2023), <https://perma.cc/A36P-Z88Z>. One of these drugs was IMBRUVICA®, which is used to treat blood cancer. *Id.* CMS negotiated with the manufacturers of the selected drugs during the spring and summer of 2024, including three negotiation meetings with each company to discuss offers and review relevant evidence. See CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026* (Aug. 15, 2024), <https://perma.cc/6MVG-BZP8>. It reached agreement with all 10 of the manufacturers. In January 2025, CMS selected drugs to participate in 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>. This list also includes drugs associated with AbbVie.

C. Procedural history

In June 2023, Plaintiffs sued HHS and CMS to challenge the constitutionality of the Drug Price Negotiation Program. Plaintiffs moved for a preliminary injunction, and the government moved to dismiss the complaint on the basis that Plaintiffs lacked standing and that the venue was improper. At that time, however, the government did not contend that the lawsuit was not germane to the Plaintiffs’ purposes as organizations. The district court denied both parties’

motions, allowed Plaintiffs to amend their initial complaint, and authorized a limited period of discovery.

Following this period of discovery, the government again moved to dismiss, and both parties moved for summary judgment. In its renewed motion to dismiss, the government argued that Plaintiffs did not meet the associational-standing test because the lawsuit was not germane to the purposes of the Dayton Chamber (the government did not make this argument with respect to the other Plaintiffs). They also argued that the suit required participation by the individual drug manufacturers because the existence of separate lawsuits already filed by some of those manufacturers made this lawsuit “unworkable.”

The district court held that none of the regional chambers—the Dayton Chamber, the Ohio Chamber, and the Michigan Chamber—could not satisfy the test for associational standing, causing it to dismiss the complaint due to improper venue. In its decision, the court assumed, without deciding, that the Plaintiffs satisfied the first requirement of associational standing (that its members would have had standing to sue individually). But the court held that this suit was not germane to the purposes of any of the three regional chambers.

Regarding the Plaintiffs’ assertion that the claims did not require the participation of individual members, the district 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). Finally, the court determined that because the Dayton Chamber lacked standing, venue was not proper in the Western Division of the Southern District of Ohio. The court then declined to transfer the case to the Eastern Division of the Southern District of Ohio because it held that the Ohio Chamber also lacked associational standing.

II. ANALYSIS

A. Standard of review

We review a district court’s dismissal for lack of standing *de novo*. *Mosley v. Kohl's Dep't Stores, Inc.*, 942 F.3d 752, 756 (6th Cir. 2019). “For purposes of ruling on a motion to dismiss for want of standing, both the trial and reviewing courts must accept as true all material

allegations of the complaint, and must construe the complaint in favor of the complaining party.” *Warth v. Seldin*, 422 U.S. 490, 501 (1975).

The district court’s determination that Plaintiffs filed their complaint in an improper venue is also reviewed de novo. *First of Mich. Corp. v. Bramlet*, 141 F.3d 260, 262 (6th Cir. 1998). But “[t]he decision of whether to dismiss or transfer is within the district court’s sound discretion” and is reviewed under the abuse-of-discretion standard. *Id.*

B. The interests in this lawsuit are not germane to the purposes of the regional chambers

Article III of the United States Constitution limits the jurisdiction of federal courts to actual “Cases” and “Controversies.” U.S. Const. art. III, § 2, cl. 1. To satisfy this “case-or-controversy” requirement, a plaintiff must establish three elements: (1) an “injury in fact” that is “concrete and particularized,” and “actual or imminent”; (2) “a causal connection between the injury and the conduct” at issue, meaning that the injury must be fairly traceable to the defendant’s action; and (3) a likelihood that the injury would be “redressed by a favorable decision” of the court. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992) (quotation marks and citation omitted).

An association may sue on behalf of its members if “(a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect 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.” *Hunt v. Wash. State Apple Advert. Comm’n*, 432 U.S. 333, 343 (1977). “[T]he doctrine of associational standing recognizes that 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, UAW v. Brock*, 477 U.S. 274, 290 (1986). Requiring that an “association plaintiff be organized for a purpose germane to the subject of its member’s claim raises an assurance that the association’s litigators will themselves have a stake in the resolution of the dispute, and thus be 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). As explained by the Second Circuit in *Building & Construction Trades Council of*

Buffalo v. Downtown Development, Inc., 448 F.3d 138, 149 (2d Cir. 2006), the subject matter of the suit must “bear[] a reasonable connection to the association’s knowledge and experience.”

The district court held that because the Dayton Chamber’s purposes are not germane to “the interests at stake in this lawsuit,” the Dayton Chamber did not have associational standing. It also held that “[t]he Program’s potential downstream effects—on unnamed members in the supply chain, and on unknown investment in all pharmaceutical companies—are far too speculative to connect this lawsuit to the business climate of the Dayton area.”

Whether the interests at stake in this case (which the complaint describes as stopping the government 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”) are germane to the purpose of the Dayton Chamber (which it describes as “improv[ing] the region’s business climate and overall standard of living” and “providing networking and training opportunities for its members”) is far from obvious. One could argue, in fact, that the overall standard of living in the Dayton area would actually improve with lower drug prices for its citizenry. And at best, any possible relation between Pharmacyclics’s and AbbVie’s interests in this lawsuit and the Dayton Chamber’s purposes exists at only a sky-high level of generality. This is especially so because Pharmacyclics and AbbVie have no facilities in the Dayton area or indeed in the entire state of Ohio.

The Dayton Chamber itself acknowledges that its primary purpose is to advocate for a business-friendly environment in the Dayton region. And although Plaintiffs collectively argue that they have a broader purpose of safeguarding the principles of free enterprise and advocating for a business-friendly legislative and regulatory environment, the interests that they aim to protect are greatly attenuated from the regional interests of the Dayton Chamber.

In virtually every case where a challenge to associational standing has failed, the “germaneness” (i.e., the relationship between the subject of the lawsuit and the purpose of the plaintiff association) has been much more direct. *See, e.g., CTIA - The Wireless Ass’n v. Keats*, Nos. 21-5435/5483, 2021 WL 7209356, at *3 (6th Cir. Dec. 3, 2021) (order) (holding 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”); *Online Merchs. Guild v. Cameron*, 995 F.3d 540, 549 (6th Cir. 2021), abrogated on other grounds as recognized by *Tenn. Conf. of NAACP v. Goins*, 139 F.4th 557, 563 (6th Cir. 2025) (holding 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” (cleaned up)); *ACLU of Ohio, Inc. v. Taft*, 385 F.3d 641, 646 (6th Cir. 2004) (noting that “[t]his case addresses citizens’ right to vote and right to equal representation, which falls squarely within the ACLU’s purpose of guaranteeing constitutional and fundamental rights”).

On the other hand, where a challenge to associational standing has been successful, “germaneness” has been found too remote. *See Children’s Health Def. v. U.S. FDA*, No. 21-6203, 2022 WL 2704554, at *3 (6th Cir. July 12, 2022) (holding that a children’s health organization lacked associational standing to challenge a vaccine policy impacting adult military members); *Minn. Fed’n of Tchrs. v. Randall*, 891 F.2d 1354, 1358–59 (8th Cir. 1989) (per curiam) (holding that a teachers’ union lacked associational standing to challenge a state statute where it attempted to represent its members’ interests as taxpayers).

The present case is closer to those holding that an association lacked standing to sue. As in those cases, there is little reason to believe that the Dayton Chamber has any particular knowledge or experience in the subject matter of the lawsuit. It instead appears to be more of a “stalking horse” for Pharmacyclics and AbbVie in seeking a perceived favorable venue that Pharmacyclics and AbbVie could not obtain on their own. The district court reached the same conclusion, reasoning as follows:

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. If the Court found the Dayton Area Chamber of Commerce had standing in this case, it 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. The Court will not adopt a loose interpretation of the standing requirement for the purpose of forum shopping.

We find this reasoning persuasive.

At no point has the Dayton Chamber been able to articulate a limiting principle. Without a limiting principle, a regional chamber of commerce could oppose any government regulation that impacts the national economy so long as a single member has individual standing to challenge the regulation. But existing law in fact provides the key limiting principle—i.e., that “the interests it seeks to protect are germane to the organization’s purpose.” *Hunt v. Wash. State Apple Advert. Comm’n*, 432 U.S. 333, 343 (1977). Based on the cases cited above, that essential link is what is missing here. The subject matter of the litigation—the constitutionality of a federal program applicable only to pharmaceutical manufacturers—is simply not germane to the Dayton Chamber’s purpose of promoting regional business.

The absence of that essential link also bars associational standing by either the Ohio Chamber or the Michigan Chamber. Like the Dayton Chamber, the Ohio Chamber’s and the Michigan Chamber’s regional purposes are too “detached” from the interests at stake in the litigation, and they are not “natural adversar[ies]” of the government here. *See Children’s Health Def.*, 2022 WL 2704554 at *3 (quotation marks omitted). We thus find no error in the district court’s ruling that these two chambers failed to demonstrate how their regional purposes fit within the scope of the interests asserted in this lawsuit.

There are, however, two aspects of the district court’s opinion that should be clarified. First, our holding that the Dayton Chamber’s purposes are not germane to the interests in this suit should not be read to mean that only associations with explicitly national purposes may represent interests that are national in nature. The fact that a federal law applies nationwide often means that states and regions within the country are impacted. For example, if the regional arm of a civil-rights organization located in a border city sued to challenge the constitutionality of a federal immigration law or action directly affecting that city, there likely would be little question that the subject of the suit would be germane to the purpose of the organization. *See, e.g., Immigrant Legal Res. Ctr. v. Wolf*, 491 F. Supp. 3d 520, 543 (N.D. Cal. 2020) (involving a challenge to a federal action where the government made no objection to the regional plaintiffs’ associational standing). The difference here is that the regional purposes of the Dayton Chamber are far removed from the interests being challenged in this lawsuit.

Second, the district court seemed to rely in part on the fact that neither Pharmacyclics nor AbbVie have headquarters or facilities in the Dayton area. But companies that are based in one place often have business interests in other places in which they sell their products, and associations in those other places might be well equipped to represent the interests of their nonresident members. *Cf. Hunt*, 432 U.S. at 344–45 (holding that a Washington state commission whose purpose was to promote and protect Washington’s apple industry had standing to challenge the constitutionality of a North Carolina statute requiring that apples sold in or shipped to North Carolina be identified only by the federal grade and not state-given grades). In sum, the fact that neither Pharmacyclics nor AbbVie has a headquarters or any facilities in the Dayton area is not fatal to associational standing, but that fact combined with the lack of any direct connection between the Dayton Chamber’s purposes and the issues at stake in this lawsuit is.

C. Participation of individual members

The district court also raised concerns regarding the Plaintiffs’ ability to satisfy the third prong of the associational-standing doctrine—that “neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit.” *See id.* at 343. Because we are affirming on the basis that the district court did not err in finding that the Dayton Chamber, the Ohio Chamber, and the Michigan Chamber cannot meet the germaneness requirement—which, as explained below, makes venue improper—we need not address this issue as it relates to the U.S. Chamber.

D. Proper disposition after a finding of improper venue

This leaves the question of whether the district court properly disposed of the lawsuit. A district court generally has broad discretion in determining whether to dismiss or transfer a case for lack of proper venue. *See Stanifer v. Brannan*, 564 F.3d 455, 456–57 (6th Cir. 2009). The court based its decision to dismiss the case on its determination that neither the Dayton Chamber nor the Ohio Chamber satisfied the test for associational standing, making venue improper in Ohio. The court did not err in reaching that conclusion.

Under 28 U.S.C. § 1391(e)(1)(C), plaintiffs can sue federal-government defendants in the venue where “the plaintiff resides if no real property is involved in the action.” The complaint alleges that “at least one Plaintiff resides in” the Southern District of Ohio, making venue proper there under § 1391(e). But, as discussed above, both the Dayton Chamber and the Ohio Chamber lack standing to sue. Without those organizations as parties to the suit, no plaintiff resides in the Southern District of Ohio.

As a result, the district court did not err in concluding that venue was improper in that district. *See Miller v. Albright*, 523 U.S. 420, 427 (1998) (suggesting that venue was improper under § 1391(e) after the district court dismissed the plaintiff residing in the venue for lack of standing). And because Plaintiffs did not identify an appropriate venue outside of Ohio that the case could be transferred to if the Dayton Chamber and the Ohio Chamber lacked standing, the district court did not abuse its discretion in dismissing this case for lack of proper venue.

III. CONCLUSION

For all of the reasons set forth above, we **AFFIRM** the judgment of the district court.