

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION AT DAYTON

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

Plaintiffs,

Case No. 3:23-cv-156

vs.

XAVIER BECERRA,
In his Official Capacity as Secretary
of the U.S. Department of Health
and Human Services, *et al.*,

District Judge Michael J. Newman
Magistrate Judge Peter B. Silvain, Jr.

Defendants.

ORDER: (1) DENYING PLAINTIFFS’ MOTION FOR SUMMARY JUDGMENT (Doc. No. 64); (2) GRANTING DEFENDANTS’ MOTION TO DISMISS (Doc. No. 71); (3) DISMISSING THIS CASE WITHOUT PREJUDICE; AND (4) TERMINATING THIS CASE ON THE DOCKET

I. SUMMARY

This is a civil case in which Plaintiffs—four Chambers of Commerce—challenge the constitutionality of the Drug Price Negotiation Program created by the federal Inflation Reduction Act, 42 U.S.C. §§ 1320(f), *et seq.*, which began requiring drug manufacturers to comply with its provisions on October 1, 2023. This case is before the Court on Plaintiffs’ motion for summary judgment (Doc. No. 64) and Defendants’ motion to dismiss—or, in the alternative—cross-motion for summary judgment (Doc. No. 71). Plaintiffs and Defendants have responded and replied to the corresponding motions (Doc. Nos. 90, 94). Thus, these motions are ripe for review.

The threshold question is whether Plaintiffs have standing to bring this case under Article III of the Constitution. The Supreme Court recently reiterated that “Article III standing is a

‘bedrock constitutional requirement that this Court has applied to all manner of important disputes.’” *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 378 (2024) (quoting *United States v. Texas*, 599 U.S. 670, 675 (2023)). Standing is a fundamental component of separation of powers that helps limit the jurisdiction of federal courts to only cases and controversies. *Id.* The purpose of standing is to “screen[] out plaintiffs who might have only a general legal, moral, ideological or policy objection to a particular government action.” *Id.* at 381.

Here, Plaintiffs are Chambers of Commerce that do not have standing to sue in their own right. Instead, Plaintiffs claim to have standing under the theory of associational standing, which allows associations in some circumstances to sue on behalf of their members who have standing. However, three Plaintiffs—the Dayton Area Chamber of Commerce, the Ohio Chamber of Commerce, and the Michigan Chamber of Commerce—do not have associational standing and must be dismissed. The fourth Plaintiff—the U.S. Chamber of Commerce—arguably has associational standing. However, the U.S. Chamber of Commerce alone would have needed to file suit in a different venue. Because this case was filed in the Southern District of Ohio based on the presence of the dismissed Plaintiffs, the Court dismisses this case without prejudice due to improper venue.

II. BACKGROUND

On August 16, 2022, Congress passed, and the President signed into law, the Inflation Reduction Act of 2022 (“IRA”), 42 U.S.C. §§ 1320(f), *et seq.* The IRA created a Drug Price Negotiation Program (“Program”), which grants the Secretary of the Department of Health and Human Services (“Secretary”) the authority to negotiate with drug manufacturers the price of certain medications covered under Medicare. 42 U.S.C. § 1320(f).

A. The Parties

Plaintiffs are the Dayton Area Chamber of Commerce (“Dayton Area Chamber”), the Ohio Chamber of Commerce (“Ohio Chamber”), the Michigan Chamber of Commerce (“Michigan Chamber”), and the U.S. Chamber of Commerce (“U.S. Chamber”). Doc. No. 57 at PageID 606. Each Plaintiff is an organization with many members from different industries. *Id.* at PageID 614-15; U.S. CHAMBER OF COMMERCE, <https://www.uschamber.com/about> (last visited Aug. 8, 2024); OHIO CHAMBER OF COMMERCE, <https://ohiochamber.com/about-us/mission/> (last visited Aug. 8, 2024); MICHIGAN CHAMBER OF COMMERCE, <https://www.michamber.com/mission/#> (last visited Aug. 8, 2024); DAYTON AREA CHAMBER OF COMMERCE, <https://daytonchamber.org/about/> (last visited Aug. 8, 2024). These organizations exist to represent the interests of businesses in their respective regions. *Id.*

Defendants are Xavier Becerra, in his official capacity as Secretary of the U.S. Department of Health and Human Services (“HHS”); HHS itself; Chiquita Brooks-LaSure, in her official capacity as Administrator of the Centers for Medicare and Medicaid Services (“CMS”)¹; and CMS itself. Doc. No. 57 at PageID 615. Defendants are tasked with implementing the Program created by the IRA. 42 U.S.C. § 1320(f).

B. The Program

This action arises out of Plaintiffs’ claims challenging the constitutionality of the Program. Doc. No. 57. The Court has already provided a brief overview of the Program in a previous Order. Thus, the Court incorporates by reference Section II(A) of its Order denying Defendants’ first motion to dismiss. Doc. No. 55 at PageID 576-77. Additionally, in considering a similar challenge brought by Plaintiffs AstraZeneca Pharmaceuticals LP and AstraZeneca AB, our sister court in

¹ CMS is a federal government agency charged with administering federal healthcare programs. CENTERS FOR MEDICARE AND MEDICAID SERVICES, <https://www.cms.gov/about-cms> (last visited Aug. 8, 2024).

Delaware provided a detailed background of Medicare and the Program. *See AstraZeneca Pharms. LP v. Becerra*, No. 23-931, 2024 WL 895036, at *1-5 (D. Del. Mar. 1, 2024). Given the court’s meticulously crafted factual background, and for judicial economy, this Court also incorporates by reference the description of the Program set forth by the Delaware District Court.

C. The Program’s Impact on the Drug “IMBRUVICA”®

“IMBRUVICA®”—a drug used to treat blood cancers—was one of ten drugs selected for the Program on August 29, 2023. Doc. No. 57 at PageID 616.² “IMBRUVICA®” was originally developed by Pharmacyclics LLC (“Pharmacyclics”). Doc. No. 57 at PageID 617. Pharmacyclics holds the FDA-approved New Drug Applications for “IMBRUVICA®”. *Id.* It is based in the Bay Area, California. PHARMACYCLICS: AN ABBVIE COMPANY, <https://www.pharmacyclics.com/> (last visited Aug. 8 2024). Pharmacyclics is a wholly-owned subsidiary of AbbVie Inc. (“AbbVie”). Doc. No. 57 at PageID 617. AbbVie is involved “in producing, preparing, packaging, labeling, and distributing IMBRUVICA®”. *Id.* at PageID 616. AbbVie’s headquarters is located in North Chicago, Illinois. ABBVIE: UNITED STATES, <https://www.abbvie.com/contact-center/locations/united-states.html> (last visited Aug. 8, 2024). It also has offices in California, Massachusetts, and Washington, D.C. *Id.* Both Pharmacyclics and AbbVie are members of all four Plaintiff associations. Doc. No. 57 at PageID 616-17.

Market analysts had predicted that “IMBRUVICA®” would be selected for the Program before the Secretary confirmed this result. *Id.* at PageID 618. To prepare to comply with the Program’s requirements if “IMBRUVICA®” were selected, AbbVie and Pharmacyclics began incurring “significant costs” to collect information for submission to CMS by October 2, 2023. *Id.*

² *Fact Sheet: Biden-Harris Administration Announces First Ten Drugs Selected for Medicare Price Negotiation*, THE WHITE HOUSE. <https://www.whitehouse.gov/briefing-room/statements-releases/2023/08/29/fact-sheet-biden-harris-administration-announces-first-ten-drugs-selected-for-medicare-price-negotiation/> (last visited Aug. 8, 2024).

AbbVie and Pharmacyclics “employees were engaged in identifying, collecting, reviewing, and preparing to submit the data required under the IRA.” *Id.* at PageID 618-19. AbbVie also hired outside consulting firms and created a new internal department to assist with compliance with the Program’s requirements. *Id.*

Pharmacyclics signed an agreement to participate in the Program by October 1, 2023. *Id.* at PageID 619, 628. In participating in the Program, Pharmacyclics and AbbVie will need to spend time and money to ensure compliance and avoid “excise taxes” on the sales of “IMBRUVICA®”. *Id.* at PageID 619-20. AbbVie and Pharmacyclics fear that the Secretary will use the Program to set an “unreasonably low ‘maximum fair price,’ which will be substantially lower than current market prices for “IMBRUVICA®”. *Id.* at PageID 621. Even if the Secretary determines the “maximum fair price” for “IMBRUVICA®” is the statutory ceiling price, this would be “a dramatic discount to recently prevailing prices” for the drug. *Id.* HHS will publish the “maximum fair price” for “IMBRUVICA®” on September 1, 2024, and this price will go into effect on January 1, 2026. *Id.* at PageID 628-29.

D. Procedural Posture

Plaintiffs claim the Program runs afoul of (1) the fundamental separation of powers the U.S. Constitution vests in each branch of Government in Articles I, II, and III; (2) the Due Process Clause of the Fifth Amendment; (3) the Excessive Fines Clause of the Eighth Amendment; (4) the legislative authority vested in Congress; and (5) the Free Speech Clause of the First Amendment. Doc. No. 57 at PageID 649-71. Plaintiffs filed their initial complaint on June 9, 2023, before the Secretary published HHS’s list of ten drugs. Doc. No. 1 at PageID 56. Plaintiffs also filed a motion for a preliminary injunction (Doc. No. 29) and Defendants filed a motion to dismiss (Doc. No. 33).

On September 29, 2023, the Court denied both Plaintiffs' motion for a preliminary injunction and Defendants' first motion to dismiss. Doc. No. 55. This Order gave Plaintiffs the opportunity to amend their complaint to elaborate on the facts establishing standing while also allowing the Program to continue during the litigation process. *Id.* at PageID 575-76. Plaintiffs filed an amended complaint shortly thereafter. Doc. No. 57.

This case is presently before the Court upon two fully-briefed motions: Plaintiffs' motion for summary judgment (Doc. No. 64) and Defendants' motion to dismiss for lack of jurisdiction and improper venue—or, in the alternative—cross-motion for summary judgment (Doc. No. 71).

III. JURISDICTION

“Article III’s restriction of the judicial power to Cases and Controversies is properly understood to mean cases and controversies of the sort traditionally amenable to, and resolved by, the judicial process.” *Uzuegbunam v. Preczewski*, 592 U.S. 279, 141 S. Ct. 792, 798 (2021) (quotation marks omitted) (quoting *Vt. Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 774 (2000)). Standing is an indispensable part of the case or controversy requirement of Article III. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992). Standing analysis “is particularly rigorous when reaching the merits of the dispute would force the Court to decide whether an action taken by one of the other two branches of the Federal Government was unconstitutional.” *Parsons v. U.S. Dep’t of Just.*, 801 F.3d 701, 710 (6th Cir. 2015) (internal citations and quotations omitted). “To have standing, a plaintiff must allege (1) an injury in fact (2) that’s traceable to the defendant’s conduct and (3) that the courts can redress.” *Gerber v. Herskovitz*, 14 F.4th 500, 505 (6th Cir. 2021) (citing *Lujan*, 504 U.S. at 559–61). A plaintiff must show, “by affidavit or other evidence, specific facts supporting each element of standing” if standing is not self-evident. *Sierra Club v. U.S. EPA*, 793 F.3d 656, 662 (6th Cir. 2015).

Additionally, a plaintiff who raises multiple causes of action must establish standing separately for each claim. *Waskul v. Washtenaw Cnty. Cmty. Mental Health*, 900 F.3d 250, 255 (6th Cir. 2018).

A. Standing Legal Standard

The Court incorporates by reference the legal standards for a motion to dismiss on account of lack of standing set forth in Section III(A) in its previous Order denying Defendants' first motion to dismiss. Doc. No. 55 at PageID 581-83.

B. Associational Standing

The requirement that a plaintiff suffer an injury-in-fact is “the ‘irreducible constitutional minimum’ of standing.” *Ass’n of Am. Physicians & Surgeons v. U. S. FDA.*, 13 F.4th 531, 538 (6th Cir. 2021) (quoting *Lujan*, 504 U.S. at 560). Associations, such as a Chamber of Commerce, have standing to sue on behalf of one or more of its members if those members have been injured, even if the association itself is not directly impacted by a defendant’s actions. *Waskul*, 900 F.3d at 253. Nevertheless, it is critical that the association identifies at least one of its members who has standing. *Ass’n of Am. Physicians & Surgeons*, 13 F.4th at 543. To establish associational standing, the association must show that “[1] its members would otherwise have standing to sue in their own right, [2] the interests at stake are germane to the organization’s purpose, and [3] neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit.” *Waskul*, 900 F.3d at 254–55 (citing *Hunt v. Wash. State Apple Advert. Comm’n*, 432 U.S. 333, 343 (1977) (internal quotation marks omitted)).

In 2021, the Sixth Circuit questioned whether the existence of associational standing satisfies the constitutional requirements of standing under the Supreme Court’s recent caselaw. *Ass’n of Am. Physicians & Surgeons*, 13 F.4th at 537-42. Additionally—on June 13, 2024—Justice Thomas wrote a concurrence explaining why associational standing “seems to distort our

traditional understanding of the judicial power.” *FDA*, 602 U.S. at 402 (Thomas, J., concurring). However, courts continue to apply the three-part associational standing test because it has not been specifically overruled. *Ass’n of Am. Physicians & Surgeons*, 13 F.4th at 542. Thus, this Court will apply the associational standing test, while also recognizing the ultimate goals of the standing requirement are to limit the power of the judiciary to decide only “Cases” or “Controversies” and to preserve separation of powers between the three branches of government. *See id.* at 536.

1. Identification of Members with Standing

The Sixth Circuit has made clear that an association must “identify a member who has suffered (or is about to suffer) a concrete and particularized injury from the defendant’s conduct.” *Id.*, 13 F.4th at 543. Plaintiffs’ amended complaint identifies both AbbVie and Pharmacyclics as members of all four Plaintiffs. Doc. No. 57 at PageID 616-17. Because either AbbVie or Pharmacyclics is the “manufacturer” of “IMBRUVICA”® that would ultimately be subjected to the Program’s requirements,³ the Court finds that all four Plaintiffs have named a specific member in the amended complaint to administer a proper standing analysis for each of the claims asserted. For purposes of simplicity, the standing analysis will refer to Pharmacyclics as the manufacturer of “IMBRUVICA”®.⁴

In addition to naming a specific member, Plaintiffs must also show that the named member has standing. *Ass’n of Am. Physicians & Surgeons*, 13 F.4th at 543. To demonstrate standing for each claim, Plaintiffs must establish that Pharmacyclics has “(1) suffered an injury-in-fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed

³ This question of fact—whether AbbVie or Pharmacyclics is the manufacturer responsible for “IMBRUVICA”®—is not a material fact in dispute for purposes of determining standing because one (or both) of the companies is the manufacturer, and both are members of all four Plaintiffs.

⁴ The CMS website lists Pharmacyclics as the “participating manufacturer” of “IMBRUVICA”®. FACT SHEET: MEDICARE DRUG PRICE NEGOTIATION PROGRAM, June 2023, <https://www.cms.gov/files/document/fact-sheet-manufacturer-agreements-selected-drugs-ipay-2026.pdf>.

by a favorable judicial decision.” *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016). To survive a motion to dismiss, a plaintiff must plead the components of standing with specificity. *Binno v. Am. Bar Ass’n*, 826 F.3d 338, 344 (6th Cir. 2016).

Despite the Court’s Order questioning whether Plaintiffs have standing to bring any of these claims (Doc. No. 55), Plaintiffs assert that they “unquestionably have standing” and do not elaborate on the injury, causation, or redressability issues for any of their five claims (Doc. No. 64 at PageID 731-32). They briefly allege that Pharmacyclics’s compliance costs generally give it “standing to challenge the IRA’s drug-pricing provisions.” *Id.* at PageID 731. If the Court were to allow this case to proceed, it would need to analyze Pharmacyclics’s standing to bring each claim separately. However—to evaluate the second prong of the associational standing test below—the Court assumes, without holding, that Pharmacyclics would have standing to bring all five claims.

2. Organizations’ Purposes

The second prong of the associational standing test “asks whether the interests that an association’s suit seeks to vindicate are ‘germane’ to its purpose.” *Ass’n of Am. Physicians & Surgeons*, 13 F.4th at 542. It is unclear whether this element is a constitutional or prudential requirement. *United Food and Com. Workers Union Loc. 751 v. Brown Grp., Inc.*, 517 U.S. 544, 554-55 (1996); *Ass’n of Am. Physicians & Surgeons*, 13 F.4th at 542. However, this “second prong is [...] complementary to the first.” *United Food and Com. Workers Union Loc. 751*, 517 U.S. at 555. The “demand 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.” *Id.* at 555-56. To assess this prong of associational standing, the Court addresses the purposes of each of the Plaintiff associations.

a. Dayton Area Chamber of Commerce

Plaintiffs assert in their amended complaint 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.” Doc. No. 57 at PageID 614. From this limited information, the purpose of this organization appears to be improving the business climate in Dayton, Ohio.

Plaintiffs argue that the interests they seek to protect in this suit are germane to the Dayton Area Chamber’s purpose. Doc. No. 90 at PageID 1249. In their amended complaint, Plaintiffs explain the 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.” Doc. No. 57 at PageID 616. Additionally, Plaintiffs want to stop their members from being required to disclose “competitively sensitive proprietary information, including trade secrets.” *Id.* Specifically, Plaintiffs elaborate on how the Program’s requirements have created “significant costs and burdens” for AbbVie and Pharmacyclics. *Id.* at 618.

However, in their opposition to Defendants’ motion to dismiss, Plaintiffs present a broader view of the interests the lawsuit seeks to protect. *See* Doc. No. 90 at PageID 1246-51. Plaintiffs assert that this lawsuit aims to defend free enterprise, economic prosperity, and the future well-being of businesses in the Dayton area and beyond. *Id.* at PageID 1248. They claim that because Dayton is a part of the larger national economy, “other enterprises in the supply chain” in the area

will inevitably be affected by the legislation and “all companies” will be “harmed by the precedent set by the IRA provisions.” *Id.* at PageID 1279.

The Court finds that it is more appropriate to adopt a narrow interpretation of the interests at stake in this lawsuit. Associational standing was created to allow an association to sue on behalf of its members that have suffered injury. *See Waskul*, 900 F.3d at 253. Thus, the interests at stake in this lawsuit are the constitutional rights of the affected members of the Plaintiff associations. Plaintiffs have only named two members: AbbVie and Pharmacyclics. Doc. No. 57 at PageID 616-17. Using publicly available information, the Court has determined that Pharmacyclics is based out of California (PHARMACYCLICS: AN ABBVIE COMPANY, <https://www.pharmacyclics.com/> (last visited Aug. 8, 2024)) and AbbVie is located in Illinois, California, Massachusetts, and Washington, D.C. (ABBVIE: UNITED STATES, <https://www.abbvie.com/contact-center/locations/united-states.html> (last visited Aug. 8, 2024)). Plaintiffs have provided no information—in their amended complaint or otherwise—directly connecting the interests of Pharmacyclics or AbbVie to the business climate in the Dayton area. The 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. *See generally Ass’n of Am. Physicians & Surgeons*, 13 F.4th at 546 (concluding that mere speculation about the potential influence of an agency authorization on “choices made by independent actors not before the court does not suffice to plead” associational standing (internal citations and quotations omitted)).

Thus, the Court finds that the interests at stake in this lawsuit are not germane to the Dayton Area Chamber’s purpose. The Dayton Area Chamber therefore lacks associational standing to bring these claims and must be dismissed from this case.

b. Ohio Chamber of Commerce and Michigan Chamber of Commerce

Plaintiffs state the “Ohio Chamber of Commerce [...] has long been an advocate and a resource for businesses throughout the Buckeye State.” Doc. No. 57 at PageID 614. The Ohio Chamber “develops public policy positions on both state and federal matters for the benefit of its [nearly 8,000] members.” *Id.* Plaintiffs also contend that the “Michigan Chamber of Commerce is Michigan’s leading state-wide business advocacy organization, representing approximately 4,000 members.” *Id.* at PageID 614. The goal of the Michigan Chamber “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.” *Id.*

For the same reasons that the interests at stake are not germane to the Dayton Area Chamber’s purpose, they are also not germane to either the Ohio Chamber or the Michigan Chamber’s purposes because Plaintiffs have not explained how any named members have interests in Ohio or Michigan. Thus, the Ohio Chamber and the Michigan Chamber lack associational standing to bring these claims and must be dismissed from this case.

c. U.S. Chamber of Commerce

Finally, Plaintiffs state the U.S. Chamber “is the world’s largest business federation” that “represents approximately 300,000 members” and, among other things, “works with federal and state governments to improve our nation’s healthcare system.” Doc. No. 57 at PageID 614.

The membership base and overall purpose of the U.S. Chamber extend nationwide. AbbVie and Pharmacyclics—its two named members—are headquartered in the United States. Thus, the U.S. Chamber’s purpose—of improving business conditions in the United States—is sufficiently related to the interests this lawsuit seeks to vindicate to satisfy the second prong of the associational standing test.

3. Requirement of Participation of Individual Members

The final prong of the associational standing test bars a suit “when ‘the claim asserted [or] the relief requested requires the participation of individual members in the lawsuit.’” *United Food and Com. Workers Union Loc. 75*, 517 U.S. at 546 (1996) (quoting *Hunt*, 432 U.S. at 343). This prong of the associational standing test is a prudential standing requirement, not a constitutional requirement. *Id.* at 555.

The Court recognizes that the caselaw regarding this aspect of associational standing is scarce. *See, e.g., Int’l Union, United Auto., Aerospace and Agric. Implement Workers of Am. v. Brock*, 477 U.S. 274, 287-88 (1986) (concluding individual union members need not participate in a suit challenging an agency’s interpretation of statute provision); *Warth v. Seldin*, 422 U.S. 490, 515-16 (holding that an organization of construction firms could not seek damages for the firms because each injury would require “individualized proof”); *Universal Life Church Monastery Storehouse v. Nabors*, 35 F.4th 1021, 1040 (6th Cir. 2022) (concluding individual participation was not necessary for a church organization to seek an injunction on their members’ behalf against a county clerk that refused to issue marriage licenses to members). However, the general rule is that individual participation of members “is not normally necessary when an association seeks prospective or injunctive relief for its members[,]” but may be required when the association is seeking damages. *United Food and Com. Workers Union Loc. 751*, 517 U.S. at 546. When a “suit raises a pure question of law” and the “individual circumstances” of each member are not required to render a decision, individual participation of the members is not required. *Int’l Union, United Auto., Aerospace and Agric. Implement Workers of Am.*, 477 U.S. at 287.

Recently, however, Justice Thomas elaborated on the potential redressability problems that may arise under the associational standing doctrine. *FDA*, 602 U.S. at 400-01 (Thomas, J.,

concurring). He observed that “[t]he party who needs the remedy—the injured member—is not before the court” so it is “questionable whether ‘relief to these nonparties ... exceed[s] constitutional bounds.’” *Id.* (quoting *Ass’n of Am. Physicians & Surgeons*, 13 F.4th at 540). This case poses the same remedial problem Justice Thomas contemplates: if the Program were found unconstitutional, the Court may have to grant a broad, or universal, injunction because an injunction barring the enforcement of the Program only against the associational plaintiffs would not redress the alleged injury of the members. *See id.* at 401.

Moreover, Justice Thomas warns that “it is not clear whether [an] adverse judgment” against associational plaintiffs “would bind the members[,]” and the “underlying members might be able to assert the exact same issues or claims in a suit in their own names.” *Id.* at 403. Here, Defendants claim—and Plaintiffs do not dispute—that another drug manufacturing member of Plaintiff U.S. Chamber, Merck, has already filed a claim challenging the Program in another district court. *See* Doc. No. 71 at PageID 849 (discussing *Merck v. Becerra*, No. 1:23-cv-1615 (D.D.C. June 6, 2023)). If the Court were to rule on the merits in this case, it is unclear whether Merck would be bound by that decision. Thus, the Court questions whether individual member participation in this case would be required and would defeat associational standing for the only remaining Plaintiff.

C. Standing Conclusion

“No principle is more fundamental to the judiciary’s proper role in our system of government than the constitutional limitation of federal-court jurisdiction to actual cases or controversies.” *FDA*, 602 U.S. at 397 (quoting *Simon v. E. Ky. Welfare Rts Org.*, 426 U.S. 26, 37 (1976)). No citizen—or association—has “standing to challenge a government regulation simply because the plaintiff believes that the government is acting illegally.” *Id.* at 381. While

Plaintiffs may have sincere legal and policy objections to the Program, only the U.S. Chamber has sufficiently established that the interests at stake are germane to the association's purpose. Even then, it remains questionable whether participation of individual members would be required in this case due to members of the U.S. Chamber maintaining parallel litigation in another federal court. *See* Doc. No. 71 at PageID 849 (discussing *Merck*).

Thus, the Dayton Chamber, the Ohio Chamber, and the Michigan Chamber do not have standing to bring these claims. The only Plaintiff that may plausibly have standing is the U.S. Chamber.

IV. VENUE

A. Defendants May Assert an Improper Venue Defense

28 U.S.C. § 1406 and Fed. R. Civ. P. 12(b)(3) govern the procedures for dismissal due to improper venue. Section 1406(a) provides that “[t]he district court of a district in which is filed a case laying venue in the wrong division or district shall dismiss, or if it be in the interest of justice, transfer such case to any district or division in which it could have been brought.” A party may move to dismiss a case for “improper venue” under Rule 12(b)(3). To determine whether venue is proper, courts look to 28 U.S.C. § 1391. Section 1391(e)(1) states that, when a government agency is the defendant, venue is proper “in any judicial district in which [...] the plaintiff resides if no real property is involved in the action.” Plaintiffs bear the burden of establishing that venue is proper. *Tanyike v. United States*, 603 F.Supp.3d 572, 576 (S.D. Ohio 2022).

The venue defense may be waived if not properly asserted by a party in a responsive pleading or motion. Fed. R. Civ. P. 12(g)(2), 12(h)(1). In their first motion to dismiss, Defendants noted that if “Dayton Area Chamber were dismissed for lack of jurisdiction, venue would not be proper in this district, and dismissal of this lawsuit would then also be required on that basis, under

Federal Rule of Civil Procedure 12(b)(3).” Doc. No. 33 at PageID 277. Defendants asserted that the Dayton Area Chamber lacked associational standing because it had not identified a member with standing and participation would be required of any individual members. *Id.* at PageID 214.

Now, in their renewed motion to dismiss, Defendants again assert that “[o]nce the Dayton Area Chamber is dismissed for lack of standing, the rest follows as a matter of course [because] Rule 12(b)(3) calls for dismissal of an action if venue is ‘improper.’” Doc. No. 71 at PageID 846 (quoting *Atl. Marine Const. Co. v. U.S. Dist. Ct. for W. Dist. Of Texas*, 571 U.S. 49, 55 (2013)). Defendants now argue that the Dayton Area Chamber lacks associational standing because this lawsuit is not germane to the organization’s purpose and individual members would be required to participate in the case. *Id.* at PageID 843, 848. Plaintiffs assert, on the other hand, that Defendants have waived their improper venue defense based on the germaneness requirement because they did not raise this specific argument in their first motion to dismiss. Doc. No. 90 at PageID 1243.

The Court finds that Defendants did not waive their improper venue defense. Defendants clearly asserted—in both motions to dismiss—that they were moving to dismiss for lack of venue under Rule 12(b)(3) if the Dayton Area Chamber lacks associational standing and is dismissed for lack of jurisdiction. Doc. No. 33 at PageID 277; Doc. No. 71 at PageID 846. While Defendants’ underlying reasoning concerning the Dayton Area Chamber’s lack of associational standing has changed, their general argument about venue—that it is improper if the Dayton Area Chamber lacks associational standing—is the same. Unlike an improper venue defense, standing is a jurisdictional requirement that “cannot be waived or forfeited.” *Virginia House of Delegates v. Bethune-Hill*, 587 U.S. 658, 662-63 (2019). Thus, because only the standing portion of

Defendants' argument has changed, the Court will consider Defendants' motion to dismiss based on improper venue.

B. Improper Venue Analysis

In their amended complaint, Plaintiffs assert that “[v]enue is proper in this judicial district under 28 U.S.C. § 1391(e) because [...] at least one Plaintiff resides in this district.” Doc. No. 57 at PageID 613. The Dayton Area Chamber is located in Dayton, Ohio. DAYTON AREA CHAMBER OF COMMERCE, <https://daytonchamber.org/about/> (last visited Aug. 8, 2024). The Ohio Chamber is located in Columbus, Ohio. OHIO CHAMBER OF COMMERCE, <https://ohiochamber.com/about-us/mission/> (last visited Aug. 8, 2024). The U.S. Chamber and the Michigan Chamber are both located outside the state of Ohio. U.S. CHAMBER OF COMMERCE, <https://www.uschamber.com/about/contact-us> (last visited Aug. 8, 2024) (located in Washington, D.C.); MICHIGAN CHAMBER OF COMMERCE, <https://www.michamber.com/mission/#> (last visited Aug. 8, 2024) (located in Lansing, Michigan).

Thus, venue is only proper in the Western Division of the Southern District of Ohio if the Dayton Area Chamber is a plaintiff in this case. S.D. Ohio Local Rule 82.1; *see, e.g., Miller v. Albright*, 523 U.S. 420, 427 (1998). Because the Court has determined that the Dayton Area Chamber must be dismissed due to lack of standing, venue is no longer proper in the Western Division of the Southern District of Ohio. Therefore, the Court must determine whether it is in the interest of justice to dismiss or transfer the case pursuant to Rule 12(b)(3).

Plaintiffs assert that the proper remedy would be to transfer this case to the Eastern Division of the Southern District of Ohio because the Ohio Chamber resides in Columbus. Doc. No. 90 at PageID 1251-52. However, the Court has also found that the Ohio Chamber lacks associational

standing. Plaintiffs do not propose an alternative venue for the situation in which only the U.S. Chamber remains a plaintiff in this case. *See id.*

The Court has broad discretion in determining whether to dismiss or transfer a case for improper venue. *Stanifer v. Brannan*, 564 F.3d 455, 456-57 (6th Cir. 2009). Here, three Plaintiffs in this case lack standing to bring these claims, and only one remains. Even the remaining Plaintiff's standing is questionable, as its individual members may be required to participate in the litigation. Given the U.S. Chamber's unstable foundation for associational standing and the Plaintiffs' artfulness in choosing this venue, it is in the interest of justice to dismiss this case without prejudice.

V. CONCLUSION

Although Plaintiffs bring these claims to challenge Congress's potential violation of separation of powers, the Court would transgress the very same ideal by asserting jurisdiction over this case. 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.

For the foregoing reasons, the Court: (1) **DENIES** Plaintiffs' motion for summary judgment (Doc. No. 64); (2) **GRANTS** Defendants' motion to dismiss (Doc. No. 71); and (3) **DISMISSES** this case without prejudice. This case is **TERMINATED** on the docket.

IT IS SO ORDERED.

August 8, 2024

s/Michael J. Newman
Hon. Michael J. Newman
United States District Judge