No. 24-3868

In the

United States Court of Appeals

for the Sixth Circuit

DAYTON AREA CHAMBER OF COMMERCE; OHIO CHAMBER OF COMMERCE; MICHIGAN CHAMBER OF COMMERCE; U.S. CHAMBER OF COMMERCE,

Plaintiffs-Appellants,

- v. -

XAVIER BECERRA, in his official capacity as Secretary of the U.S. Department of Health and Human Services; United States Department of Health and Human Services; Chiquita Brooks-Lasure, in her official capacity as Administrator of the Centers for Medicare and Medicaid Services; Centers for Medicare and Medicaid Services; Centers for Medicare and Medicaid Services; Centers for Medicare and Medicaid Services.

 $Defendants \hbox{-} Appellees.$

On appeal from the United States District Court for the Southern District of Ohio, Case No. 3:23-cv-00156

BRIEF OF THE NATIONAL ASSOCIATION
OF MANUFACTURERS AND STATE MANUFACTURING
ASSOCIATIONS AS AMICI CURIAE
IN SUPPORT OF APPELLANTS

ERICA T. KLENICKI
MICHAEL A. TILGHMAN II
NAM Legal Center
733 10th Street NW,
Suite 700
Washington, DC 20001
(202) 637-3000

Paul W. Hughes
Andrew A. Lyons-Berg
Emmett Witkovsky-Eldred
McDermott Will & Emery LLP
500 North Capitol Street NW
Washington, DC 20001
(202) 756-8000

Counsel for amici curiae

CORPORATE DISCLOSURE STATEMENT

Pursuant to Circuit Rule 26.1, amici state the following:

1. Are amici subsidiaries or affiliates of a publicly owned corpo-

ration?

No. Amici the National Association of Manufacturers and various state

manufacturing associations are nonprofit trade associations with no publicly

traded shares and are not the affiliates or subsidiaries of any publicly owned

corporation.

2. Is there a publicly owned corporation, not a party to the ap-

peal, that has a financial interest in the outcome?

None known.

Dated: December 30, 2024

/s/ Paul W. Hughes

Paul W. Hughes

i

TABLE OF CONTENTS

Table of Authorities	iii
Introduction and Interest of the Am	ici Curiae1
Argument	10
I. The district court wrongly discolocal associations play in matter	ounted the critical role that ers of national significance11
A. Associations play an impor Supreme Court has repeat	tant litigating role, as the edly recognized11
B. Local associations, just like effective voices for member small.	•
II. The district court misapplied the associational standing	ne requirements of21
A. Opposing governmental ac named members is obvious association's purpose	8 8
· ·	on of members is not active relief, as courts have 28
Conclusion	29

TABLE OF AUTHORITIES

Cases

ABC of Kansas v. Perez, No. 4:16-169 (E.D. Ark. 2016)	18
Association of Am. Physicians & Surgeons, Inc. v. Texas Med. Bd., 627 F.3d 547 (5th Cir. 2010)	1. 22. 24
Association of American Physicians & Surgeons v. United States Food & Drug Administration, 13 F.4th 531 (6th Cir. 2021)	
Building & Constr. Trades Council of Buffalo v. Downtown Dev., Inc., 448 F.3d 138 (2nd Cir. 2006)	22
Children's Health Def. v. United States Food & Drug Admin., 2022 WL 2704554 (6th Cir. July 12, 2022)	28
Citizens Ass'n of Georgetown v. Simonson, 403 F.2d 175 (D.C. Cir. 1968)	13
Coalition for Responsible Regul., Inc. v. E.P.A., 684 F.3d 102 (D.C. Cir. 2012)	18
FDA v. All. for Hippocratic Med., 602 U.S. 367 (2024)	29
In re Fin. Oversight & Mgmt. Bd. for Puerto Rico, 110 F.4th 295 (1st Cir. 2024)	13
Friends of the Earth, Inc. v. Chevron Chem. Co., 129 F.3d 826 (5th Cir. 1997)	13
Harlem Valley Transportation Ass'n v. Stafford, 360 F. Supp. 1057 (S.D.N.Y 1973)	12
Hospital Council of W. Pennsylvania v. City of Pittsburgh, 949 F.2d 83 (3d Cir. 1991)	23
Humane Soc. of the U.S. v. Hodel, 840 F.2d 45 (D.C. Cir. 1988)	22, 23

Cases—continued

Hunt v. Washington State Apple Advert. Comm'n, 432 U.S. 333 (1977)	17
International Union, United Auto., Aerospace & Agr. Implement Workers of Am. v. Brock, 477 U.S. 274 (1986)	passim
Joint Anti-Fascist Refugee Committee v. McGrath, 341 U.S. 123 (1951)	12
Lodge 1858, Am. Fed'n of Gov't Emp. v. Paine, 436 F.2d 882 (D.C. Cir. 1970)	13
NAACP v. Button, 371 U.S. 415 (1963)	14
National Ass'n of Manufacturers & Kentucky Ass'n of Manufacturers v. Sec. & Exch. Comm'n, No. 23-3749 (6th Cir. 2023)	9, 18
National Ass'n of Manufacturers v. Dep't of Treasury, 10 F.4th 1279 (Fed. Cir. 2021)	9
National Ass'n of Manufacturers v. Perez, 103 F. Supp. 3d 7 (D.D.C. 2015)	18
National Ass'n of Manufacturers v. United States Sec. & Exch. Comm'n, 105 F.4th 802 (5th Cir. 2024)	9
National Coal Ass'n v. Lujan, 979 F.2d 1548 (D.C. Cir. 1992)	22
National Truck Equip. Ass'n v. Nat'l Highway Traffic Safety Admin., 972 F.2d 669 (6th Cir. 1992)	23
Neighborhood Action Coal. v. City of Canton, 882 F.2d 1012 (6th Cir. 1989)	28
Plano Chamber of Commerce v. Perez 4:16-CV-732 (E.D. Tex. 2017)	18
Presidio Golf Club v. Nat'l Park Serv., 155 F.3d 1153 (9th Cir. 1998)	22

Cases—continued

Students for Fair Admissions, Inc. v. President & Fellows of Harvard Coll.,	
600 U.S. 181 (2023)	13, 21, 25
Tyler v. Hennepin Cnty., 598 U.S. 631 (2023)	24
United Food & Com. Workers Union Local 751 v. Brown Grp., Inc.,	90
517 U.S. 544 (1996)	28
573 U.S. 302 (2014)	18
Warth v. Seldin, 422 U.S. 490 (1975)	29
Statutes	
42 U.S.C. § 1320f(a)	2
Other Authorities	
Comment, Kelsey McCowan Heilman, <i>The Rights of Others:</i> Protection and Advocacy Organization's Associational Standing to Sue, 157 U. Penn. L. Rev. 237 (2008)	14
Conference of State Manufacturers Associations, The National Association of Manufacturers	
Glenn D. Magpantay, Associational Rights and Standing: Does Citizens United Require Constitutional Symmetry Between the First Amendment and Article III?, 15 N.Y.U. J. Legis &	•
Pub. Pol'y 667 (2012)	
Letter to Donald J. Trump, President-Elect (Dec. 5, 2024)	19
Letter to Gina Raimondo, Secretary of Commerce (June 12, 2024)	19
Letter to Senator Charles Schumer, et. al. (May 20, 2024)	
Note, From Net to Sword: Organizational Representatives Litigating Their Members' Claims, 1974 U. Ill. L. Forum 663	
UUU	

Other Authorities—continued

Press Release, Manufacturing Associations Launch Coalition	
to Curb Regulatory Onslaught in Washington (June 22,	
2023)	19

INTRODUCTION AND INTEREST OF THE AMICI CURIAE¹

The district court's decision below represents a clean break from the associational standing principles long enshrined in Supreme Court and Sixth Circuit case law. Not only is the district court's decision therefore legally erroneous, it also badly misconstrues the nature and role of state and local business associations. The Supreme Court's governing associational standing test—and its "undemanding" germaneness requirement (e.g. Association of Am. Physicians & Surgeons, Inc. v. Texas Med. Bd., 627 F.3d 547, 550 n.2 (5th Cir. 2010))—is the law of the land, and courts must faithfully apply it. Because the district court did not do so here, the judgment must be reversed.

a. Pharmaceutical manufacturers AbbVie and Pharmacyclics are members of the Dayton Area Chamber of Commerce, a business association with 2,200 members doing business in the 14-county Dayton, Ohio area, whose mission is to improve the region's business climate through advocacy, networking, and economic development initiatives. These companies' decision to voluntarily associate with the Dayton Area Chamber sends the unmistakable

¹ Pursuant to Fed. R. App. P. 29(a)(2) and (4)(E), *amici* state that no party's counsel authored this brief in whole or in part; no party or party's counsel contributed money intended to fund the preparation of this brief; and no person other than *amicus*, its members, or its counsel contributed money intended to fund the preparation of this brief. The parties have consented to the filing of this brief.

signal that the companies consider themselves to be a part of the Dayton Area ea business community. It also demonstrates that they trust the Dayton Area Chamber to represent their interests as it advocates for them as part of that community. After all, that is the Dayton Area Chamber's purpose: to champion the business interests of its members, and thereby promote a business-friendly environment in the Dayton area, including through federal policy. The same is true for the manufacturers' affiliation with statewide chambers of commerce for Michigan and Ohio, which also exist to champion the interests of their members, and, ultimately to foster a favorable business environment in their states.

The impetus of this litigation is a provision in the Inflation Reduction Act requiring the manufacturers of certain drugs to negotiate the drugs' prices with the Secretary of Health and Human Services as a condition for participating in Medicare and Medicaid. See 42 U.S.C. § 1320f(a). The government has designated IMBRUVICA®, a drug manufactured by AbbVie and Pharmacyclics, as one of the ten drugs subject to negotiation. There is thus no question that AbbVie and Pharmacyclics have suffered an Article III injury that would give them standing to sue. Nor is there any question that they are bona fide members of the Dayton Area Chamber and the Ohio and Michigan chambers.

Yet, though these associations' purpose is to foster a favorable business environment in their region by advocating for their members, the district court held that they lack standing to sue on behalf of AbbVie and Pharmacyclics. In particular, the court held that representing these companies' interests is not germane to the associations' purpose, for seemingly no other reason than because the companies are not *based* in the Dayton area, Ohio, or Michigan. The court also indicated—contrary to decades of Supreme Court and Sixth Circuit precedent—that the individual participation of the associations' members might be necessary even though the organization sought only injunctive relief against the government. The court thus dismissed the case, as the Western Division of the Southern District of Ohio is not a proper venue to consider claims by the only plaintiff the court concluded *might* have standing—the Chamber of Commerce of the United States.

The court's standing analysis was wrong. The court unjustifiably disregarded the important role that state and local business and trade associations, just like their national counterparts, play in federal litigation. State and local associations are invaluable: they closely engage with businesses on the ground, creating vital channels of communication from main street all the way up to the halls of federal power. Because they are so attuned to the experiences of their members—and the needs of the community at large—they are also well situated to effectively represent the interests of their members, in-

cluding in court. There can be no doubt that it is germane to a business association's purpose to oppose legislation and agency action that harms its members, and the fact that the Dayton Area Chamber is a local association makes it no less qualified to weigh in. The same goes for statewide trade associations.

b. This issue hits close to home for *amici* the National Association of Manufacturers (the NAM) and its numerous statewide partners and allies. The NAM is the largest manufacturing association in the United States, representing small and large manufacturers in every industrial sector and in all 50 states. Manufacturing employs nearly 13 million men and women, contributes \$2.9 trillion to the U.S. economy annually, has the largest economic impact of any major sector, and accounts for over half of all private-sector research and development in the Nation. The NAM is the voice of the manufacturing community and the leading advocate for a policy agenda that helps manufacturers compete in the global economy and create jobs across the United States.

The Connecticut Business and Industry Association (CBIA) is a Connecticut, nonpartisan, not-for-profit 501(c)(6) founded in 1815 and is the oldest, largest, statewide manufacturing association in Connecticut. Connecticut's more than 4,500 manufacturers are responsible for more than twelve percent of Connecticut's GDP—second largest in the state—and more than

1,000 Connecticut manufacturing companies currently hold CBIA membership, representing more than half of Connecticut's manufacturing workforce. CBIA's mission is to advocate for economic growth policies that make Connecticut a top state for businesses, creating opportunities for all Connecticut residents. Core to this advocacy is the growth of Connecticut's manufacturing sector, which hosts the second-highest defense spending per capital, the third-highest aerospace production in the US, and where each manufacturing job supports four additional jobs in the state economy. The CBIA works actively in the judicial and legislative arenas to further this objective and has filed amicus curiae briefs in other important cases affecting manufacturers' interests in Connecticut.

The Illinois Manufacturers' Association (IMA) is an Illinois not-for-profit corporation founded in 1893 and among the nation's oldest and largest statewide manufacturing associations. More than 4,000 Illinois manufacturing companies currently hold IMA membership. The IMA's members, which include businesses of all sizes, employ nearly seventy-five percent of Illinois' manufacturing workforce. The IMA's mission is to preserve and strengthen the Illinois manufacturing base by providing information to and advocating on behalf of member companies on issues that relate to the Illinois business climate, including tax policy, environmental regulation, labor law, HR policy, energy, health care, insurance, education and workforce, and matters that

impact the industrial sector. The IMA works actively in the judicial and legislative arenas in furtherance of this objective and has filed *amicus curiae* briefs in other important cases affecting manufacturers' interests in Illinois.

The Iowa Association of Business and Industry (ABI) is the largest business network in Iowa, representing over 1,500 business members that employ more than 330,000 Iowans. The ABI's members come from all 99 counties and all industry sectors, including manufacturers, retailers, insurance companies, financial institutions, health care organizations, and educational institutions. The Iowa Association of Business and Industry (ABI) has served as the state's unified voice for business since 1903. ABI's mission is to nurture a favorable business, economic, governmental and social climate within the state of Iowa so citizens have the opportunity to enjoy the highest possible quality of life. Among other things, ABI represents the interests of its members by filing *amicus curiae* briefs in cases involving issues of concern to the business community.

The Kentucky Association of Manufacturers (KAM), one of the oldest state manufacturers organizations in America, is the leading voice of industry, business, and free enterprise in Kentucky. Founded in 1911, KAM works to promote and grow manufacturing and the Commonwealth's overall economy to create greater economic opportunities for Kentuckians and Kentucky

communities. It does so primarily through its public policy activities vis-à-vis all three branches of state and federal government, including offering *amici curiae* briefs in important litigation affecting Kentucky's private sector; and through its advocacy across the entire range of policy issues impacting American business. KAM members span the state's economy and range in size from startups to many of the Commonwealth's largest private sector employers.

The Michigan Manufacturers Association (MMA) is a Michigan not-for-profit corporation founded in 1922 and is one of the country's largest manufacturing associations. The MMA is the leading advocacy voice in the state dedicated to the interest of Michigan manufacturers consisting of over 1,700 members ranging from small manufacturers with fewer than 50 employees to the world's largest and most well-known corporations. Manufacturers in Michigan employ 605,700 people and produce \$99.6 billion in total manufacturing output. The MMA and its members have a direct interest in this matter since the Court's decision would impact the terms and conditions of operation for the industry, the Association, and its members. The MMA actively works in both the legislative and judicial arena and has filed *amicus briefs* in several cases affecting Michigan manufacturers and the manufacturing industry.

The New Jersey Business and Industry Association (NJBIA) is the state's largest organization of employers, with a membership consisting of more than 7,000 companies reflecting all industries and representing every region of New Jersey. Founded in 1910, NJBIA strives to provide information, services, and advocacy for its member companies to build a more prosperous New Jersey. Its membership ranges from most of the 100 largest employers in New Jersey to thousands of small and medium-sized employers from every sector of the economy. A primary goal of NJBIA is to reduce the costs of doing business in New Jersey, including by limiting unwarranted litigation burdens, to promote economic growth for all New Jerseyans.

Oregon Business & Industry (OBI) is a non-profit mutual benefit corporation with members organized under the laws of the state of Oregon. OBI has approximately 1,600 members and, as a general business association, is recognized as the state chamber of commerce. OBI's members come from various industries and all parts of the state geographically. OBI exists to strengthen Oregon's economy to achieve a healthy, prosperous, and competitive Oregon for the benefit of present and future generations.

Founded in 1909 by Bucks County industrialist Joseph Grundy, the Pennsylvania Manufacturers' Association (PMA) is the statewide non-profit trade organization representing the \$100 billion manufacturing sector in Pennsylvania's public policy process. PMA works to advance a pro-growth,

pro-production agenda in Harrisburg to improve our competitiveness with other U.S. states. Manufacturing employs more than a half-million Pennsylvanians on the plant floor, and that core manufacturing activity sustains millions of additional Pennsylvania jobs through supply chains, distribution networks, and vendors of industrial services.

The mission of the Rhode Island Manufacturers Association (RIMA) is to be the unified voice of the Ocean State's 1,600 manufacturers. RIMA advocates at the federal, state, and local levels for sensible policy solutions that strengthen manufacturing and serves as a bridge connecting its members with the resources they need to compete and grow.

Wisconsin Manufacturers and Commerce Inc. (WMC) is Wisconsin's chamber of commerce and manufacturers' association. With member businesses of all sizes and across all sectors of Wisconsin's economy, WMC is the largest business trade association in Wisconsin. Since its founding in 1911, WMC has been dedicated to making Wisconsin the most competitive state in the nation in which to conduct business.

The NAM and its state partners frequently assert associational standing to represent their members in federal court. See, e.g., National Ass'n of Manufacturers v. United States Sec. & Exch. Comm'n, 105 F.4th 802, 806 (5th Cir. 2024); National Ass'n of Manufacturers v. Dep't of Treasury, 10 F.4th 1279, 1281 (Fed. Cir. 2021); National Ass'n of Manufacturers & Kentucky

Ass'n of Manufacturers v. Sec. & Exch. Comm'n, No. 23-3749 (6th Cir. 2023). Amici thus have a vested interest in ensuring that federal courts respect the principles of associational standing. More than that, amici understand well the importance of state and local business and trade associations to be the first line of defense in promoting strong local economies, which are the building blocks of a thriving national economy. Local associations are vital and effective champions for their members in a variety of forums, including federal court, and including on issues of national importance.

ARGUMENT

The district court's analysis fundamentally misunderstood the role of state and local business associations like the Dayton Area Chamber and the Ohio and Michigan Chambers of Commerce. Though the Dayton Area Chamber's activities may be directed at improving the business environment in the Dayton area, that regional focus in no way disqualifies such a local association from weighing in on issues of national importance, including on behalf of members who happen to be based elsewhere. As demonstrated by *amici's* experience as a national trade association and a collection of state associations working side by side, trade associations at all levels are essential and effective voices for the interests of their communities.

Properly understood as such, there is no doubt that advocating for its members in court, including AbbVie and Pharmacyclics, is germane to the Dayton Area Chamber's purpose. Likewise, there can be no doubt that statewide business associations have standing to advocate for their members on issues that affect those members and the statewide business environment.

I. The district court wrongly discounted the critical role that local associations play in matters of national significance.

The district court's standing analysis suffers from a fundamental misconception: the court simply assumed that a regional business association has no business representing members who are based outside the local area, as if such ties are inherently suspect, or a regional association lacks the wherewithal to be an effective spokesperson on issues of national interest. Not so. As a matter of practical experience and common sense, in today's interconnected economic system, it is unremarkable that companies based in California or Illinois would have substantial ties with the business communities of the Dayton area, Ohio, and Michigan such that the economic representative of that area can be an effective representative to seek redress of those companies' injuries.

A. Associations play an important litigating role, as the Supreme Court has repeatedly recognized.

The Supreme Court has been clear that associational standing is "advantageous both to the individuals represented and to the judicial system as a whole." *International Union, United Auto., Aerospace & Agr. Implement Workers of Am. v. Brock*, 477 U.S. 274, 289 (1986). As the Court explained in

Brock, associations suing with a collective voice are able to "draw upon a pre-existing reservoir of expertise and capital," aiding potentially outmatched individual members by providing not only the financial resources to effectively "vindicate the[ir] interests" but also "specialized expertise and research resources relating to the subject matter of the lawsuit that individual plaintiffs lack." *Id.* (quoting Note, From Net to Sword: Organizational Representatives Litigating Their Members' Claims, 1974 U. Ill. L. Forum 663, 669). Associational standing thus strikes an effective balance, preserving the "concrete adverseness" that is the bedrock of the Article III case-and-controversy requirement while enhancing the quality of litigation to ensure the "illumination of difficult questions," to the benefit of both "courts and plaintiffs." *Id.* (alteration incorporated) (quoting *Harlem Valley Transportation Ass'n v. Stafford*, 360 F. Supp. 1057, 1065 (S.D.N.Y 1973)).

In short, "the 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." Brock, 477 U.S. at 290. And "the only practical judicial policy" is to "permit the association or corporation in a single case to vindicate the interests of all." Id. (quoting Joint Anti-Fascist Refugee Committee v. McGrath, 341 U.S. 123, 187 (1951) (Jackson, J., concurring)). After all, when individuals or companies voluntari-

ly "band together," that declaration of a common purpose "provide[s] some guarantee that the association will work to promote their interests." *Id*.

On that understanding, the Supreme Court has repeatedly refused to "abandon settled principles of associational standing." *Brock*, 477 U.S. at 290. Indeed, just two terms ago, the Court reaffirmed that when "an organization has identified members and represents them in good faith," that is enough to establish the association's standing, without "requir[ing] further scrutiny into how the organization operates." Students for Fair Admissions, Inc. v. President & Fellows of Harvard Coll., 600 U.S. 181, 201 (2023). Other courts have said much the same. See, e.g., In re Fin. Oversight & Mgmt. Bd. for Puerto Rico, 110 F.4th 295, 311-19 (1st Cir. 2024) (explaining that courts should avoid inflexible associational standing analyses that undermine the standing of associations that are well "positioned to represent their [members'] needs and realities" in federal court); Friends of the Earth, Inc. v. Chevron Chem. Co., 129 F.3d 826, 827-29 (5th Cir. 1997) (similar); Lodge 1858, Am. Fed'n of Gov't Emp. v. Paine, 436 F.2d 882, 894 (D.C. Cir. 1970) ("Organizational representation ... is calculated to produce the intelligent, vigorous, adversary representation of interests required when the 'association is an authorized spokesman organized to promote these interests for its individual members." (quoting Citizens Ass'n of Georgetown v. Simonson, 403 F.2d 175, 176 (D.C. Cir. 1968) (per curiam)).

A significant scholarly consensus has also emerged around the importance of associational standing, with researchers documenting how associations litigating on behalf of members aid the modern-day federal court system in resolving issues efficiently and correctly, with the assistance of the best possible presentation of issues by parties. For instance, research shows that "[o]rganizations have resources and expertise that their members lack," and "individuals often face significant economic and other barriers to bringing suit in the adversarial system." Comment, Kelsey McCowan Heilman, The Rights of Others: Protection and Advocacy Organization's Associational Standing to Sue, 157 U. Penn. L. Rev. 237, 252 (2008) (explaining how associational standing "create[s] incentives for wronged individuals" to vindicate their rights). That is particularly so in cases involving associations representing groups and individuals that lack political power. See, e.g., Glenn D. Magpantay, Associational Rights and Standing: Does Citizens United Require Constitutional Symmetry Between the First Amendment and Article III?, 15 N.Y.U. J. Legis & Pub. Pol'y 667, 694–95 (2012) (describing how associational standing in voting rights cases empowers voters to overcome concerns about privacy and retaliation that are barriers to individual litigation); *NAACP v*. Button, 371 U.S. 415, 428 (1963) (stating that "association for litigation may be the most effective form of political association," particularly for those lacking political power as individuals).

Association of American Physicians & Surgeons v. United States Food & Drug Administration, 13 F.4th 531, 542 (6th Cir. 2021), upon which the district court heavily relied, does not sanction a departure from established associational standing principles. Though that opinion expressed uncertainty about the conceptual underpinnings of the associational standing doctrine (see id. at 538-542), that discussion was purely academic. Thus, the panel correctly noted that, whatever doubts it might have had, this Court nonetheless "must stick to [the Supreme Court's] directly on-point" precedent on the "associational-standing test," rather than (as the district court did here) chart out a new path based on doubt or disagreement with binding precedent. Id. at 542.2

In sum, associations play a vital role in the federal court system, defending rights that might go undefended if individuals are forced to litigate alone, pooling resources and expertise to allow parties and courts alike to benefit from the highest caliber advocacy, and all the while ensuring that is-

² The Court in *Ass'n of American Physicians & Surgeons* thus rejected associational standing on the grounds that the identified members did not suffer Article III injury and lack of causation, not that—as here—an indisputable injury caused by the challenged agency action was somehow insufficiently connected to the geographical location of the associational plaintiff. 13 F.4th at 542-547.

sues litigated in federal court have the sharp adversity that the Constitution demands.

B. Local associations, just like national ones, are effective voices for members on matters big and small.

The district court's conclusion that the Dayton Area Chamber of Commerce and the two statewide associations—unlike the United States Chamber of Commerce—lack standing reflects a mistaken and belittling assumption that state and local associations, unlike their nationwide counterparts, are not effective or appropriate voices to vindicate their members' interests on issues of national importance. That is wrong.

1. Amici—consisting of a national trade association and several state trade associations—certainly appreciate the value and power of an entire industry joining together, coast to coast, to speak as one voice on an issue. But amici's experience has also proven that that work requires effective national and local advocates working together, combining resources and on-the-ground relationships to be effective champions for businesses across the country in matters of local and national importance. After all, state and local affiliates represent the closest line of communication and partnership with any given community's manufacturers and other businesses.

Indeed, the NAM works hand-in-hand with the Conference of State Manufacturing Associations, as well as its individual state and regional partners and allies, to understand how federal laws and regulations affect businesses on the ground, as well as to mobilize local communities to change federal policy from the ground up. See Conference of State Manufacturers Associations, The National Association of Manufacturers https://perma.cc/5QZY-5LQE. In an interconnected economy where virtually every business is tapped into the national ecosystem of interstate commerce, it can be only be expected that a local business community will be directly affected by federal policymaking—and therefore deserves a seat at the table in shaping that policy.

State and local business associations are often the best situated to be that collective voice. Just as the Supreme Court has observed with respect to statewide trade associations, such an "association serv[ing] a specialized segment of [a] State's economic community" effectively "represents" that community's members "and provides the means by which they express their collective views and protect their collective interests." *Hunt v. Washington State Apple Advert. Comm'n*, 432 U.S. 333, 345 (1977). After all, local associations are tightly knit—the members share not only industry ties but community ties as well, and they are therefore tapped into local need and able to marshal grassroots relationships to be effective and authentic spokespeople.

The NAM and its state partners and allies have experienced firsthand the power of local associations to leverage their on-the-ground expertise to effectively advocate for their communities. That advocacy happens inside and

outside of the courtroom. For instance, just recently in this circuit, the NAM and its state partner the Kentucky Association of Manufacturers invoked associational standing to submit a petition for review of an SEC rulemaking—a litigation effort that delivered for the associations' members when the SEC promulgated an exemption to the rule in response to the associations' joint administrative advocacy on the same issue. See Motion to Voluntarily Dismiss, National Ass'n of Manufacturers v. Secs. & Exch. Comm'n, No. 23-3749, ECF No. 20 (6th Cir. Nov. 1, 2023). See also, e.g., Coalition for Responsible Regul., Inc. v. E.P.A., 684 F.3d 102, 113 (D.C. Cir. 2012), aff'd in part, rev'd in part sub nom.; Util. Air Regul. Grp. v. E.P.A., 573 U.S. 302 (2014) (the NAM litigating alongside state manufacturing associations from Michigan, Mississippi, Tennessee, West Virginia, and Wisconsin); National Ass'n of Manufacturers v. Perez, 103 F. Supp. 3d 7, 10 (D.D.C. 2015) (the NAM litigating alongside the Virginia Manufacturers Association); ABC of Kansas v. Perez, No. 4:16-169 (E.D. Ark. 2016) (the NAM and its state partner, the Arkansas Chamber of Commerce, litigating alongside other trade associations); *Plano* Chamber of Commerce v. Perez 4:16-CV-732 (E.D. Tex. 2017) (the NAM and its state ally, the Texas Association of Business, litigating alongside other trade associations).

Beyond litigation, the NAM works closely with state manufacturers associations to study how local, state, and federal policy affect manufacturers of all sizes, and the NAM leverages the power of these local relationships to advocate for better policies at all levels of government. As one recent example, the NAM and many of its state and regional partners delivered a letter to the Secretary of Commerce describing how recently proposed agency guidance would damage local economies from the perspective of "manufacturers of all sizes in all areas of the country" who are "are integral to the fabric of our local communities." Letter to Gina Raimondo, Secretary of Commerce (June 12, 2024), available at https://perma.cc/8EPM-RXJL. And state manufacturing associations have been leaders in channeling their members' urgent calls for tax relief (see Letter to Senator Charles Schumer, et. al., (May 20, 2024), available at https://perma.cc/4T4A-KXT9) and regulatory reform (see Letter to Donald J. Trump, President-Elect (Dec. 5, 2024), available at https://perma.cc/C7WM-G7WA).

Indeed, the NAM and many of its state partners recently launched the Coalition for Sensible Regulations to document the cost of federal regulation on manufacturers and advocate for a regulatory environment that will allow businesses to thrive. See Press Release, Manufacturing Associations Launch Coalition to Curb Regulatory Onslaught in Washington (June 22, 2023) https://perma.cc/4TMA-C7XA. That effort would not be possible without the localized insights and deep relationships of state associations.

In short, the NAM's state and local partners are invaluable in their collective efforts to be the voice of the national manufacturing sectors. The NAM thus understands well the power of local associations to champion their communities on the national stage, as well as locally. The district court should not have disregarded the Dayton Area Chamber's role as just such an advocate in this case.

2. Just as in our modern-day system of interstate commerce there can be no doubt that local business communities feel the effects of federal policy-making, it should come as no surprise that many nationwide businesses may be based in one location and yet have significant ties with the business communities of other regions. Naturally, a business doing business in a city, state, or region—even if its headquarters is elsewhere—will endeavor to foster ties with that place's local business community. No doubt, those efforts will include joining state and local business associations, both as a reflection of that company's support for and investment in the local community, but also because what happens in that community *matters* to those who do business there—be it manufacturing or distributing a product there, employing workers there, sourcing supply chains there, or otherwise.

By the same token, what happens to those businesses matters to the local business community, and the community at large. After all, a company like a large drug manufacturer that chooses to do business in a state or community—even if it is not headquartered in that region—will mean jobs, investment, and product circulation to that region, inuring to the benefit of workers, other businesses, and consumers who live there.

In short, there are any number of reasons in today's interconnected economy why a business headquartered in one place would in good faith associate itself with the state and local business community of another place, including by joining in associations that represent the community collectively in litigation and otherwise. The Supreme Court has been clear that those voluntary associations, and the "good faith" representative efforts that emerge from them, must be respected. *Students for Fair Admissions*, 600 U.S. at 201. The district court erred by failing to do so.

II. The district court misapplied the requirements of associational standing.

Had the district court properly appreciated the mission and purpose of a regional business association like the Dayton Area Chamber, or statewide chambers of commerce, there could have been no doubt that these organizations have standing to sue on behalf of their injured members. Put simply, when an organization's purpose is to foster a business-friendly environment for its members, suing to stop legislation or agency action that damages a member's business is clearly germane to that mission. The court needed no more information to find the low bar of the germaneness requirement satisfied here. And the court's analysis of the individual-participation requirement

is simply irreconcilable with decades' worth of practice in this court and every other.

- A. Opposing governmental action damaging to its members is obviously germane to a business association's purpose.
- 1. Courts have uniformly recognized that the requirement that a litigation be germane to the organization's purpose is an "undemanding" standard. See, e.g., Ass'n of Am. Physicians & Surgeons, Inc., 627 F.3d at 550 n.2 (test requires "mere pertinence' between the litigation at issue and the organization's purpose") (quoting Building & Constr. Trades Council of Buffalo v. Downtown Dev., Inc., 448 F.3d 138, 148 (2nd Cir. 2006); National Coal Ass'n v. Lujan, 979 F.2d 1548, 1552 (D.C. Cir. 1992) (same).

Thus, courts have found germane a golf club's effort to assert environmental and historical claims on its members' behalf (*Presidio Golf Club v. Nat'l Park Serv.*, 155 F.3d 1153, 1159 (9th Cir. 1998); a trade union's efforts to stop a mixed-use development (*Bldg. & Constr. Trades Council*, 448 F.3d at 147-149); and the Humane Society's effort to oppose hunting on federal land (*Humane Soc. of the U.S. v. Hodel*, 840 F.2d 45, 59 (D.C. Cir. 1988)), among many other examples of associations asserting claims with far more tenuous connections to their organizational purpose than the state and local chambers of commerce have here.

In *Hodel*—a seminal case on germaneness—the D.C. Circuit stressed the "importance of a reading of the germaneness requirement that does not unduly confine the occasions on which associations may bring legal actions on behalf of members and thus significantly restrict the opportunities of associations to utilize their 'specialized expertise and research resources' relating to the subject matter of the lawsuit." 840 F.2d at 56 (quoting *Brock*, 477 U.S. at 289). Thus, the germaneness factor "require[s] only that an organization's litigation goals be pertinent to its special expertise and the grounds that bring its membership together." *Id.*; *see also id.* at 57 (germaneness requirement exists to prevent "organizational leaders [from] generat[ing] legal actions on issues of little concern even to injured members").

Here, it is obvious why it would be germane to a business association's purpose to undertake litigation opposing legislation and agency action that is harmful to its members. Indeed, the Sixth Circuit has recognized that businesses join the thousands of trade associations organized in the United States "for a variety of reasons," with "two concerns [being] paramount: protection of their economic interests and vitality, and to band together to ensure the promotion of their collective interests." *National Truck Equip. Ass'n v. Nat'l Highway Traffic Safety Admin.*, 972 F.2d 669, 672 n.1 (6th Cir. 1992); see also e.g., Hospital Council of W. Pennsylvania v. City of Pittsburgh, 949 F.2d 83,

88 (3d Cir. 1991) (Alito, J.) (hospital trade association's effort to "protect" the "financial interests of its members" was "clearly" germane).

Focusing on the Dayton Area Chamber, this litigation plainly implicates that association's expertise and the purposes for which its members chose to affiliate with it. See Hodel, 840 F.2d at 56. Indeed, the Dayton Area Chamber provided a declaration to that effect, explaining that it "commits to its members ... that it will strive for a business friendly legislative and regulatory environment that encourages the growth and economic prosperity of businesses." R.29-2 (Kershner Declaration), PageID#171 ¶ 4. Suing on behalf of members affected by federal policy easily clears the low bar of "mere pertinence" to the association's mission. Ass'n of Am. Physicians & Surgeons, Inc., 627 F.3d at 550 n.2. Accordingly, the complaint and accompanying declarations should have sufficed to establish the Dayton Area Chamber's standing, particularly at the motion-to-dismiss stage. See Tyler v. Hennepin Cnty., 598 U.S. 631, 637 (2023) (to survive a motion to dismiss, plaintiff "need not definitively prove" standing, but must merely "plausibly plead[] on the face of [its] complaint" facts supporting standing).

In short, the Dayton Area Chamber's purpose is to champion the business interests of its members, all of whom have presumably affiliated with the association because they share its interest in protecting the business climate in the Dayton area. No doubt, the economic fate of each company that has chosen to affiliate matters to the people of the Dayton area, who depend on those business for jobs, services, lifesaving products, and more. Quite clearly, this litigation—in which the Dayton Area Chamber is attempting to speak up for its members against government action that harms them—is germane to that purpose. Much the same is true of the Ohio and Michigan chambers.

2. The district court never even truly explained what more, in its view, the Dayton Area Chamber needed to allege to establish standing. For instance, the court never questioned that AbbVie and Pharmacyclics are bona fide members of the Dayton Area Chamber—nor could it, consistent with the Supreme Court's admonition in *Students for Fair Admission* against "further scrutiny into how the organization operates" when the association has shown that it represents members in "good faith" who have suffered an Article III injury. 600 U.S. at 201. Nor could it be doubted that the legislation at issue directly affects the Dayton Area Chamber's named members, who manufacture drugs covered by the legislation, or that that the national sweep of this legislative program will obviously reach the Dayton area.

At most, the court noted that "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." R.102 (Final Order), PageID#1656. In other words, the district court assumed that

it could not be germane to a local business association's purpose to challenge regulations on behalf of bona fide members of the association that happen to be located elsewhere. The notion that a local business association like the Dayton Area Chamber lacks standing to weigh in on the constitutionality of federal regulations on behalf of bona fide members who happen to be based outside the region is indefensible.

As explained above, it is elementary that a business based in one location would nonetheless have any number of reasons that it would choose to associate with the business community of another location due to a variety of possible ties it might have with that region. In an interconnected economy, what happens to a company based in California or Illinois can matter quite a lot to the business community of Dayton, Ohio, and vice versa, let alone the statewide business community of states like Ohio and Michigan. Pharmacyclics and AbbVie's decision to affiliate with the Dayton Area Chamber of Commerce is thus unremarkable. It certainly provided the district court with no basis to conclude that the Dayton Area Chamber is an inappropriate representative for members who have voluntarily associated with the organization on the understanding that the chamber would be the businesses' voice.

To the contrary, and as the Supreme Court has made clear, Pharmacyclics and AbbVie's to decision to "band together" with other businesses in the Dayton Area should have provided the district court, in and of itself, "some guarantee that the [Dayton Area Chamber] will work to promote their interests." *Brock*, 477 U.S. at 290. After all, why would companies join a regional business association if not because they believe they have significant ties to or shared interests with that region's business community? The district court should have respected that decision to voluntarily associate rather than presume that a local association has no business defending members if they happen to be based somewhere else, irrespective of the strength of the interest those members may have in the region.

The district court repeated the same errors in analyzing whether the litigation was germane to the purpose of the Ohio or Michigan chamber of commerce. Though the flaws in the district court's reasoning were identical, if anything, the analysis was even *more* problematic because the court conducted that analysis *sua sponte*. Even the government had not challenged the germaneness of the litigation to those state associations. And it is easy to understand why not: there can simply be no doubt that organizations championing the business interests of an *entire state* have standing to represent members directly affected by government action that will devastate those particular members and will surely have an enormous economic impact on the state as a whole.

B. The individual participation of members is not necessary in suits for injunctive relief, as courts have routinely held.

Though the district court did not rest its holding on this ground, it also erred in surmising that the individual participation of AbbVie and Pharmacyclics might be necessary in this case. While the district court admitted to uncertainty about what this requirement entails, the Supreme Court and the Sixth Circuit have been anything but uncertain. Repeatedly, they have clarified that the individual-participation requirement is implicated in suits for damages, where it is necessary for individual members to participate so that the court can award the appropriate damages to the appropriate parties. See, e.g., United Food & Com. Workers Union Local 751 v. Brown Grp., Inc., 517 U.S. 544, 546 (1996) (individual "participation would be required in an action for damages to an association's members"); Neighborhood Action Coal. v. City of Canton, 882 F.2d 1012, 1017 (6th Cir. 1989) (association lacked standing to seek compensatory damages on behalf of individual members).

On the other hand, time and again, the Supreme Court and the Sixth Circuit have reiterated that there is no need for individual member participation in cases seeking injunctive relief. See, e.g., Children's Health Def. v. United States Food & Drug Admin., 2022 WL 2704554, at *3 n.2 (6th Cir. July 12, 2022) ("The Supreme Court has explained that 'individual participation' is usually unnecessary 'when an association seeks prospective or injunction'

tive relief for its members.") (quoting *United Food & Com. Workers Union Local 751*, 517 U.S. at 546); *Brock*, 477 U.S. at 287 (stating that suits raising a "pure question of law" do not need the individual participation of members); *Warth v. Seldin*, 422 U.S. 490, 515 (1975) ("If in a proper case the association seeks a declaration, injunction, or some other form of prospective relief, it can reasonably be supposed that the remedy, if granted, will inure to the benefit of those members of the association actually injured.").

The only authorities the district court cited to justify breaking with this tradition, were, tellingly, statements from *Ass'n of American Physicians & Surgeons*, 13 F.4th at 542, which the panel acknowledged were dicta and did not signal a doctrinal departure from the traditional associational standing test, and Justice Thomas's solo concurring opinion in *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 378 (2024). Plainly enough, neither of these references justified the district court in defying decades of precedent to suggest that an association seeking injunctive relief cannot do so without the individual participation of its members.

CONCLUSION

For the foregoing reasons, the Court should reverse the judgment of the district court.

Dated: December 30, 2024 Respectfully submitted,

ERICA T. KLENICKI
MICHAEL A. TILGHMAN II
NAM Legal Center
733 10th Street NW,
Suite 700
Washington, DC 20001
(202) 637-3000

/S/ Paul W. Hughes
PAUL W. HUGHES
ANDREW A. LYONS-BERG
EMMETT WITKOVSKY-ELDRED
McDermott Will & Emery LLP
500 North Capitol Street NW
Washington, DC 20001
(202) 756-8000

CERTIFICATE OF SERVICE

I certify that that on December 30, 2024, I caused the foregoing brief to be served electronically on all parties via the Court's CM/ECF system.

Dated: December 30, 2024 /s/ Paul W. Hughes

Paul W. Hughes

CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(a)(7)(C), the under-

signed counsel for Plaintiff-Appellants certifies that this brief:

(i) complies with the type-volume limitation of Rule 29(a)(5) because

it contains 6,497 words, including footnotes and excluding the parts of the

brief exempted by Rule 32(f); and

(ii) complies with the typeface requirements of Rule 32(a)(5) and the

type style requirements of Rule 32(a)(6) because it has been prepared using

Microsoft Office Word 365 and is set in New Century Schoolbook font in a

size equivalent to 14 points or larger.

Dated: December 30, 2024

/s/ Paul W. Hughes

Paul W. Hughes