IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

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

Plaintiffs,

v.

XAVIER BECERRA, *et al.*,

Defendants.

No. 3:23-cv-00156-TMR-PBS

Judge Thomas M. Rose

OPPOSITION TO MOTION TO DISMISS

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INTRODUCTION

When President Biden signed the Inflation Reduction Act into law, he declared that "Big Pharma lost" because "Medicare will have the power to . . . lower prescription drug prices."[1] Now, faced with a constitutional challenge to the IRA's price-control program, the government claims that the IRA may not cause any harm to pharmaceutical manufacturers after all and that Plaintiffs therefore lack standing. The government's objections do not withstand scrutiny.

The government makes no *merits* arguments for dismissal of *any* of Plaintiffs' claims. And while the government seeks dismissal of the entire action on standing and ripeness grounds, the government discusses only Plaintiffs' due process claim, overlooking Plaintiffs' other four claims. Like the government's arguments on the merits in response to Plaintiffs' motion for a preliminary injunction, its standing and ripeness objections stem from a fundamental misunderstanding of the nature of Plaintiffs' claims. Ignoring Plaintiffs' evidence and the allegations set forth in the complaint, the government erroneously asserts that "*all* [Plaintiffs'] alleged harms derive from a fear" of unfairly low *prices*. MTD 8 (emphasis added). Based on that faulty premise, the government argues that Plaintiffs cannot bring any of their claims "before any prices are agreed upon" or even "before any new prices take effect (in 2026)." MTD 1. But as Plaintiffs made clear in their complaint (and motion), their suit is a facial challenge to the unconstitutional price-control regime legislated by Congress. *See* Compl. ¶¶ 3–5, 8–10, 23; PI Mot. 2. That is, Plaintiffs are challenging a scheme of *existing* statutory mandates and procedures, not simply *anticipated* future *prices,* as violating the separation of powers, due process, the Excessive Fines Clause, and the First

[1] President Joseph Biden, Jr., Remarks by President Biden on the Passage of H.R. 5376, the Inflation Reduction Act of 2022 (Sept. 13, 2022), https://www.whitehouse.gov/briefing-room/speeches-remarks/2022/09/13/remarks-by-president-biden-on-the-passage-of-h-r-5376-the-inflation-reduction-act-of-2022/.

Amendment, and as unauthorized by any enumerated power of Congress. None of these claims is dependent on a specific price being set for a particular product; they challenge the statutory scheme on its face.

As a result of the IRA's unconstitutional scheme, Plaintiffs' members have already suffered, and will continue to suffer, substantial economic harm. Indeed, CMS itself warned manufacturers that they "*need* to take *a number* of actions *well in advance* of September 1, 2023," the deadline for publishing the list of selected drugs. Memorandum from CMS on Revised Guidance for Medicare Drug Price Negotiation Program ("Revised Guidance"), at 9 (June 30, 2023), https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf (emphasis added). In just a few weeks, manufacturers must submit a massive set of complex, commercially sensitive information to CMS (or face $1 million per day penalties) and "agree" to participate in the sham "negotiation" process (or face a crushing "excise tax" penalty). *See* PI Mot. 1, 3, 10, 19; Staff Decl. ¶ 5–9, 15. These are concrete injuries, and they are occurring now. The government does not even acknowledge, let alone try to dispute, these present injuries. Instead, the government tries to make them irrelevant, laboring to recharacterize Plaintiffs' facial challenge to the enacted statute as an as-applied challenge to future CMS pricing decisions. The government's ripeness argument repackages its injury-in-fact argument and fails for the same reasons.

The government's associational standing objections fare no better. First, the government faults Plaintiffs for identifying as one affected member AbbVie, which manufactures, packages, and labels IMBRUVICA®, a drug widely expected to be selected for the IRA's price controls. The government contends that AbbVie's wholly-owned subsidiary, Pharmacyclics, is the only affected entity because CMS—under its recently finalized guidance—considers Pharmacyclics to be the

"Primary Manufacturer" because it is the holder of the "New Drug Applications" (NDAs) for IMBRUVICA. But the fact that Pharmacyclics is *also* injured does not negate any of Plaintiffs' allegations and evidence of harm *to AbbVie*. It simply means that *both* companies are injured.

There can be no dispute that AbbVie meets the *statutory* definition of "manufacturer" (which does not distinguish between "primary" or "secondary" manufacturers). And AbbVie is already, and will continue, bearing most of the costs of the IRA as to IMBRUVICA, as further explained below. The government cannot use non-binding guidance to close the courthouse doors to aggrieved parties, much less to parties who have mounted a constitutional challenge to the statute that the guidance purports to interpret. Although Plaintiffs can therefore rest on their original papers, given the government's factual attack on Plaintiffs' standing (MTD 13 n.3) and for avoidance of doubt, Plaintiffs have submitted a supplemental declaration explaining the respective roles of AbbVie and Pharmacyclics. *See* Supplemental Declaration of Michael C. Staff ("Staff Suppl. Decl.").

Second, the government argues that Plaintiffs do not meet the associational standing test because, the government says, the requested relief requires participation by individual members. It is well established, however, that "[t]he individual participation of an organization's members is 'not normally necessary,'" where, as here, an "'association seeks prospective or injunctive relief for its members.'" *Sandusky Cnty. Democratic Party v. Blackwell*, 387 F.3d 565, 574 (6th Cir. 2004) (per curiam) (quoting *United Food & Com. Workers Union Local 751 v. Brown Grp., Inc*., 517 U.S. 544, 546 (1996)). Because Plaintiffs' claims raise only facial challenges to a statute and seek only "prospective or injunctive relief," *id.* (quoting *United Food & Com. Workers*, 387 F.3d at 546), they do not require "individualized proof" and "are thus properly resolved in a group context," *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 344 (1977). Ignoring that

binding precedent, the government argues that because one or more of Plaintiffs' members have brought their own separate suits, Plaintiffs should be precluded from suing on behalf of *any* of their members. The government's concerns about "gamesmanship and chaos" are not only speculative, but misplaced. MTD 17 (quotation omitted). Any of Plaintiffs' members who have brought separate suits will be bound by judgments in those suits. Concerns about potential future judgments in other cases, pending in other courts, are no basis to reinvent associational standing doctrine to bar Plaintiffs from obtaining relief in *this* case that would benefit their interested members, including members who have not brought their own suits.

ARGUMENT

I. Plaintiffs Have Article III Standing.

To establish Article III standing under the doctrine of associational standing, the Sixth Circuit has required an association to "show that one of its named members '(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision.'" *Waskul v. Washtenaw Cnty. Cmty. Mental Health*, 900 F.3d 250, 255 (6th Cir. 2018) (quoting *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016)). "[A]t the pleading stage," standing may be established by the complaint's "allegations of injury resulting from the defendant's conduct." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992). To the extent the government makes a factual attack on standing, however, *see* MTD 13 n.3, this Court may consider evidence beyond the complaint and must "weigh the conflicting evidence" submitted by the parties. *Ohio Nat'l Life Ins. Co. v. United States*, 922 F.2d 320, 325 (6th Cir. 1990).[2] "An injury

[2] To obtain a preliminary injunction, a plaintiff must show a likelihood of success in establishing standing, rather than simply alleging it. *See Waskul*, 900 F.3d at 256 n.4. Plaintiffs' preliminary injunction papers show that they are suffering not merely injury-in-fact but irreparable injury. The government's motion to dismiss, however, seeks *dismissal* of all of Plaintiffs' claims and therefore is governed by Rule 12(b)(1) standards.

sufficient to satisfy Article III must be 'concrete and particularized' and 'actual or imminent, not conjectural or hypothetical.'" *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 (2014) (quoting *Lujan*, 504 U.S. at 560). "An allegation of future injury may suffice if the threatened injury is 'certainly impending,' or there is a 'substantial risk that the harm will occur.'" *Id.* (quoting *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 414 & n.5 (2013)).

Plaintiffs have amply established all three elements of Article III standing. Plaintiffs' well-pleaded allegations and declarations demonstrate that each Plaintiff has members who are subject to the IRA and who will therefore suffer economic harms and other concrete injuries as a direct result of the IRA's price-control regime. Enjoining that unconstitutional regime will prevent those injuries. Nothing more is required for Article III standing. And Plaintiffs likewise satisfy the other requirements for associational standing.

A. Plaintiffs' Injuries Are Actual and Imminent, Not Speculative.

Focusing on the injury-in-fact requirement, the government argues that until "drugs are selected and prices are negotiated," Plaintiffs "can only speculate" about whether their members will be harmed. MTD 1, 7–10. But there is no need to "speculate": Plaintiffs' members have *already* been harmed. The government completely ignores the actual and imminent injuries detailed in AbbVie's declaration. *See* Staff Decl. ¶¶ 7–19. For example, the declaration explains that AbbVie has already incurred significant costs to comply with the IRA's burdensome and data-intensive requirements. *See id.* ¶¶ 7–9. With the list of drugs selected for price controls due to be published in less than a week, the government must know which drugs are on the list; and yet the government conspicuously does *not* suggest that IMBRUVICA will escape inclusion on the list. Meanwhile, CMS has acknowledged "the complexity of the preparation that *must be undertaken in advance* of the publication of the selected drug list by September 1, 2023." Revised Guidance 20 (emphasis added). In particular, CMS has warned that "manufacturers *need* to take *a number*

of actions *well in advance*" of that date. *Id.* at 9 (emphasis added). For example, manufacturers may "need to engage in internal discussions," review the detailed "requirements for participating manufacturers," and "gather information for potential submission to CMS by the statutory deadline of October 2, 2023." *Id.* Within just a few weeks, Plaintiffs' members will have to submit a massive set of complicated, commercially sensitive information to CMS or pay $1-million-per-day penalties. *See* PI Mot. 3, 10, 19. Yet, without addressing any of these concrete burdens on Plaintiffs' members, the government dismisses their injuries as "conjectural and hypothetical." MTD 7–8 (quoting *Phillips v. Dewine*, 841 F.3d 405, 416 (6th Cir. 2016)).

The government also ignores the impending First Amendment injury to Plaintiffs' members. The IRA injures Plaintiffs' members by compelling them to voice the government's (misleading) talking points. Compl. ¶¶ 19, 209–22. Those well-pleaded allegations must be "take[n] . . . as true." *Ohio Nat'l Life Ins. Co*., 922 F.2d at 325. Such "intangible injuries" to First Amendment rights satisfy the Article III injury-in-fact requirement. *Spokeo*, 578 U.S. at 340.

Closing its eyes to Plaintiffs' allegations and evidence, the government bases its injury-in-fact argument on a fundamental misconception about the nature of Plaintiffs' claims. Despite acknowledging that Plaintiffs have brought "a facial challenge" to "[the] statute," the government characterizes Plaintiffs' sole "alleged injury" as the prospect that "manufacturers will begrudgingly agree" to unfairly low prices set by HHS. MTD 7. In essence, the government tries to convert Plaintiffs' *facial* challenge to *the statute* into an *as-applied* challenge to future price-setting decisions *by CMS*. Based on that mischaracterization of Plaintiffs' suit, the government asserts that Plaintiffs' future injury is only "possible," because "there is no way to know whether prices will actually settle" at unfairly low levels. MTD 8.

As Plaintiffs made clear, however, their suit challenges the IRA's unconstitutional provisions on their face. Compl. ¶¶ 3–5, 8–10, 23. Like the plaintiffs in *Michigan Bell*, Plaintiffs are not challenging any specific prices that will be set by the agency. Rather, for example, Plaintiffs' due process claim is that Congress legislated a defective price-setting process that lacks essential "procedural safeguards" such as statutory standards and judicial review. *See, e.g.*, Compl. ¶¶ 147–49 (emphasizing lack of "procedural protections"); PI Reply 5–6 & n.1 (collecting examples from complaint and motion). That due *process* claim depends on whether the IRA, here and now, "adequately safeguard[s] against" the imposition of arbitrary, discriminatory, and confiscatory prices. PI Mot. 1, 11, 13 (quoting *Michigan Bell Tel. Co. v. Engler*, 257 F.3d 587, 593–94 (6th Cir. 2001)). "Sixth Circuit precedent reflects that . . . a procedural due process claim is instantly cognizable in federal court without requiring a final decision . . . from the responsible agency," because the "infirm process is an injury in itself." *Nasierowski Bros. Inv. Co. v. City of Sterling Heights*, 949 F.2d 890, 894 (6th Cir. 1991) (cleaned up). Because Plaintiffs' members are "subject to the [IRA's] allegedly unconstitutional process," which has already caused them to incur significant costs, Plaintiffs have "demonstrated injury-in-fact." *Rice v. Vill. of Johnstown*, 30 F.4th 584, 591 (6th Cir. 2022).

Treating procedural due process and other facial constitutional claims as "instantly cognizable" makes sense because where procedures are constitutionally inadequate on their face, there is no justification to force a party to endure those procedures and wait to challenge their result. *See, e.g.*, *Seguin v. City of Sterling Heights*, 968 F.2d 584, 589–90 (6th Cir. 1992) ("Because the plaintiffs are making a facial challenge to the statutes themselves, any procedural infirmity would not be cured by the subsequent application of the statute"); *Axon Enter., Inc. v. FTC*, 598 U.S. 175, 191–92 (2023) (recognizing that "subjection to an illegitimate proceeding" that violates

the separation of powers is a "'here-and-now injury'" that is "impossible to remedy once the proceeding is over" (quoting *Seila Law LLC v. Consumer Fin. Prot. Bureau*, 140 S. Ct. 2183, 2196 (2020))); *Lac Vieux Desert Band of Lake Superior Chippewa Indians v. Mich. Gaming Control Bd.*, 172 F.3d 397, 407 (6th Cir. 1999) ("[G]iven the First Amendment context here, a facial challenge is appropriate, and any need for [Plaintiff] to participate in the allegedly unconstitutional bidding process in order to establish standing is obviated").

The government takes issue with Plaintiffs' "pessimis[m]" about the IRA's price-control program because, the government says, it is "possible" that the program will actually redound to some manufacturers' benefit. MTD 8. That speculation is irrelevant, because what *is* inevitable is that Plaintiffs' members will be subjected to an unconstitutional process. Even if it were possible for that statute to produce an occasional "maximum fair price" that was not independently unconstitutional, that would not make the regime constitutional. *Michigan Bell*, 257 F.3d at 595 n.4; Compl. ¶¶ 19, 209–22. And in any event, the government's speculation blinks reality, because the IRA is expressly designed to reduce the prices paid to manufacturers. The IRA "d[oes] not impose a [price] floor." MTD 4–5. Instead, it imposes arbitrary price *ceilings* of 25% to 60% below a market benchmark and then directs HHS to achieve the "lowest" price *below* those ceilings—without any limiting principle of fairness or reasonableness. *See* PI Mot. 6–7, 13.

The government, moreover, is speaking out of both sides of its mouth. Out of one side, the government says it is "[n]ot surprising[ ]" that "drug manufacturers lobbied hard" against the IRA's price controls. PI Opp. 1. Out of the other, when the government wishes to challenge Plaintiffs' standing, it suggests that manufacturers should have lobbied *for* the IRA's price-control program. According to the Congressional Budget Office, the price-control program will save Medicare about

$100 billion over the next decade.[3] But the government would have this Court believe that none of that would come at the expense of manufacturers. Meanwhile, as the government acknowledges, manufacturers have filed several "suits around the country challenging the statute on its face." PI Opp. 1. Yet the government suggests these manufacturers do not know their own interests because the IRA could "result in flat or even *greater* revenue for them." MTD 8.

President Biden was more candid in his speech announcing the signing of the IRA: "We beat Pharma this year, and it mattered."[4] His HHS Secretary, Xavier Becerra, echoed that sentiment in a recent interview about the IRA: "[L]ike rolling thunder, we're going to continue to attack these high prescription drug prices."[5]

The Secretary's ominous forecast for manufacturers is correct. The Secretary's lawyers' agnosticism depends, to begin with, on the highly dubious assumption that CMS will pick the statutory "'ceiling' price" as the "maximum fair price." MTD 9 (quotation marks omitted). As the government itself notes, the ceiling price is "the *highest* price that [CMS] may offer." *Id.* (emphasis added). And the IRA instructs CMS to achieve the "*lowest*" price. 42 U.S.C. § 1320f-3(b)(1) (emphasis added). In light of that statutory mandate and the hammers at CMS's disposal, including the astronomical "excise tax" penalty, it would be unreasonable to assume that CMS will do the

[3] CBO, Estimated Budgetary Effects of Public Law 117-169, to Provide for Reconciliation Pursuant to Title II of S. Con. Res. 14 (Sept. 7, 2022), https://www.cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf.

[4] President Joseph Biden, Jr., Remarks by President Biden Celebrating Labor Day and the Dignity of American Workers (Sept. 5, 2022), https://www.whitehouse.gov/briefing-room/speeches-remarks/2022/09/05/remarks-by-president-biden-celebrating-labor-day-and-the-dignity-of-american-workers/.

[5] Samantha Manning, *First round of prescription drugs to be announced for Medicare price negotiations Sept. 1*, KIRO7.com (Aug. 14, 2023), https://www.kiro7.com/news/local/first-round-prescription-drugs-be-announced-medicare-price-negotiations-sept-1/I47NYCJ3LZHXNDYLKFIC7HH7YI/.

opposite of what Congress directed. Moreover, even if one indulges the exceedingly unrealistic assumption that CMS will pick the highest legally permissible price, a recent study found that setting the "maximum fair price" for IMBRUVICA at the statutory ceiling would produce a discount nearly three times greater than the amount of the rebates that AbbVie would otherwise pay to pharmacy benefit managers.[6]

As for the supposedly "unequivocal benefits" of having a drug selected for price controls, the government says the drug will be exempted from the much smaller discount generally required under the Medicare Part D Manufacturer Discount Program. MTD 10 (emphasis omitted). But that reasoning makes no sense; no manufacturer would voluntarily take a large price cut to avoid a small price cut. The Medicare Part D discount will amount to only 10% of a beneficiary's annual prescription drug spending that reaches an "initial coverage" layer, and 20% of spending that reaches a far higher "catastrophic" layer.[7] The discounts reflected in the IRA's ceilings, in contrast, do not depend on how much a given beneficiary spends each year, and they range from 25% to 60% lower than a market-based benchmark. *See* 42 U.S.C. § 1320f-3(c)(1)(C), (b)(2)(F). And of course, the IRA then directs the agency to pick the "lowest" price *below* that ceiling. *Id*. § 1320f-3(b)(1).[8]

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[6] Inmaculada Hernandez et al., *Estimated Discounts Generated by Medicare Drug Negotiation in 2026*, 29 J. Managed Care Specialty Pharm. 868 (2023), https://www.jmcp.org/doi/full/10.18553/jmcp.2023.29.8.868.

[7] *See* Juliette Cubanski & Tricia Neuman, *Changes to Medicare Part D in 2024 and 2025 Under the Inflation Reduction Act and How Enrollees Will Benefit*, KFF.org (Apr. 20, 2023), https://www.kff.org/medicare/issue-brief/changes-to-medicare-part-d-in-2024-and-2025-under-the-inflation-reduction-act-and-how-enrollees-will-benefit/.

[8] Even in the unlikely event that a manufacturer benefited in some way from the IRA's price controls, that anomaly would not defeat standing: "[o]nce injury is shown, no attempt is made to ask whether the injury is outweighed by benefits the plaintiff has enjoyed from the relationship with the defendant." 13A Wright & Miller, Fed. Prac. & Proc. Juris. § 3531.4 & n.9 (3d ed.) (collecting cases); *see, e.g., Markva v. Haveman*, 317 F.3d 547, 550, 557–58 (6th Cir. 2003)

The government claims "there is no way to know whether (or to what extent)" it will be "successful" in selecting the "lowest" prices until "the negotiation process plays out." MTD 10. It touts a paper by Congress's budget office as showing an "expectation of roughly equal bargaining power between CMS and manufacturers of selected drugs." *Id*. But as the paper acknowledges, that supposed "expectation" is merely a default assumption, not supported by any analysis, based on CBO's practice of "assign[ing] probabilities of 50 percent" when it believes "it does not have enough information" to actually assess the likelihood of one outcome or another. *See* Christopher Adams & Evan Herrnstadt, CBO's Model of Drug Price Negotiations Under the Elijah E. Cummings Lower Drug Costs Now Act 13 n.27 (CBO, Working Paper No. 2021-01, 2021) 13 n.27, https://perma.cc/UGA9-SMR5. And to the extent that the government is arguing that the IRA's process is fair, that is at best a merits defense, not a basis to dismiss for lack of standing.

In the real world, there is no mystery about which party has the upper hand under the IRA. CMS has the power to set the final "negotiated" price unilaterally. *See* 42 U.S.C. § 1320f-3. CMS wields an "excise tax" penalty of up to 1900% to compel "compliance" and extract "agreement."[9] The manufacturer's only "leverage" would be to withdraw *all* its products from federal healthcare programs if CMS sets a price too low, but that would be a threat of self-harm given that those programs represent half of the market. The government's made-for-litigation agnosticism about the IRA's effects is not convincing.

(rejecting challenge to Article III standing based on argument that other benefits "offset" an injury due to allegedly unlawful policies).

[9] The government never acknowledges that CBO projected that the so-called "excise tax" would raise exactly zero dollars in revenue. Compl. ¶ 103.

B. Plaintiffs Have Established Associational Standing.

The government's associational standing objections likewise fail. "An association has standing to bring suit on behalf of its members when (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 requested nor the relief requested requires the participation of individual members in the lawsuit." *Waskul*, 900 F.3d at 254–55 (citing *Hunt*, 432 U.S. at 343). The government challenges only the first and third elements (and does not dispute that the interests at stake are germane to Plaintiffs' purposes). Under well-established precedent, Plaintiffs easily satisfy all three elements.

As to the first element, Plaintiffs have established that they each have members who are directly affected by the IRA's price controls and thus have shown actual and imminent injury for their members from the IRA's price-control program. As to the third element, Plaintiffs' suit does not require the participation of individual members because this suit is solely a facial constitutional challenge to the statute and seeks only prospective relief, not damages, and therefore does not necessitate "individualized proof." *Hunt*, 432 U.S. at 344. The government does not dispute that basic point, but it argues that associational standing is nonetheless precluded any time a member of an association brings a separate individual suit. That argument contravenes precedent; it would largely nullify the doctrine of associational standing. It is predicated on the false assumption that members who have filed their own suits will engage in "gamesmanship" (MTD 17 (quoting *DHS v. New York*, 140 S. Ct. 599, 601 (2020) (Gorsuch, J., concurring))) by picking and choosing which judgment to follow. Because those members would be bound by judgments in their separate suits, the government's speculative concerns are unfounded and in all events could not justify departing from binding precedent setting forth the longstanding rules of associational standing.

1. Plaintiffs have identified at least one member with Article III standing.

The government's hyper-technical argument about the corporate relationship between AbbVie and its wholly-owned subsidiary Pharmacyclics is much ado about nothing. The government contends that Plaintiffs should have named Pharmacyclics, rather than AbbVie, because Pharmacyclics holds the New Drug Applications for IMBRUVICA and thus, under CMS guidance, qualifies as the "primary manufacturer" with primary responsibility for the "negotiations" with CMS. *See* MTD 11–15. As an initial matter, it is not clear that, especially at the pleading stage, an association must "identify" an affected member by *naming* the member (as opposed to describing the member(s) in more general terms). *See, e.g.*, *Nat'l Council of La Raza v. Cegavske,* 800 F.3d 1032, 1041 (9th Cir. 2015) (where member injury is "relatively clear, rather than merely speculative," and "where the defendant need not know the identity of a particular member to understand and respond to an organization's claim of injury," there is "no purpose to be served by requiring an organization to identify by name the member or members injured"). But in any event, Plaintiffs *have* named at least one affected member—AbbVie. For the avoidance of any doubt, Plaintiffs have submitted a declaration explaining the respective roles of AbbVie and Pharmacyclics (both of which are members of Plaintiffs) and how both entities face present and imminent harm from the IRA's unconstitutional process.

The government's focus on Pharmacyclics is premised on the notion that *only* Pharmacyclics could suffer injury-in-fact from the IRA relating to IMBRUVICA. That is wrong; the fact that Pharmacyclics is *also* injured by the IRA does not mean that AbbVie has not suffered an "Article III injury" in its own right. MTD 12. That is true not only for the reasons discussed above, but because (1) AbbVie is a "manufacturer" of IMBRUVICA under the statutory definition; and (2) AbbVie is suffering separate and distinct injuries of its own because most of the costs associated with the IRA as to IMBRUVICA have been, and will continue to be, borne by AbbVie,

Staff Suppl. Decl. ¶ 21 so the government's principle that shareholders lack standing to sue for injuries to the corporation they own, *see* MTD 14, is not applicable.

The government argues that Plaintiffs' assertion of Article III injury to AbbVie is "contradicted by *the statute*" because under CMS *guidance*, Pharmacyclics is considered the "primary manufacturer." MTD 12 (emphasis added). This argument is wrong on multiple levels. As an initial matter, the statute's definition of a covered "manufacturer," which does not distinguish between "primary" and "secondary" manufacturers, is indisputably broad enough to encompass AbbVie. Via cross-references, the IRA defines a "manufacturer" subject to the price-control program, in relevant part, as "any entity which is engaged in—(A) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products . . . or (B) in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products." 42 U.S.C. § 1396r-8(k)(5); *see id.* § 1320f (cross-referencing § 1395w-3a(c)(6)(A), which in turn references § 1396r-8(k)(5)). AbbVie is engaged in the production, preparation, packaging, and labeling of IMBRUVICA. Staff Suppl. Decl. ¶¶ 13–17. AbbVie therefore meets the definition of "manufacturer" under the statute. The government cannot deploy informal, non-binding guidance to close the courthouse doors to a manufacturer, *as defined by the statute*, who is challenging the statute as unconstitutional.[10] Moreover, regardless of the dichotomy proposed by CMS's guidance,

[10] The government's effort to distinguish between AbbVie and Pharmacyclics here is ironic: its longstanding practice is *not* to distinguish between members of a corporate family for purposes of participation in Medicare and Medicaid. For example, in a recent proposed rule, HHS and CMS stated: "We believe it would be directly contrary to Congressional intent to apply the definition of a manufacturer in a manner that would permit a manufacturer (that is by forming a subsidiary corporation) to exclude some of its drugs from the drug rebate program. Our proposal would prevent manufacturers from manipulating the system as to select drugs . . . and codify a longstanding policy[.] As such, *we continue to believe that when defining a manufacturer, the term 'entity' should be interpreted to include parent, brother-sister, or subsidiary corporations*[.]" Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity

AbbVie has incurred and will continue to incur most of the costs of the IRA as to IMBRUVICA, including the costs and burdens of gathering information to prepare for the prospect that IMBRUVICA is selected and those of taking the lead in the "negotiations" in that event. Staff Suppl. Decl. ¶¶ 19, 21. AbbVie thus is already incurring, and will continue to incur, costs in its own right and will be subject to that unconstitutional process.

Because AbbVie is incurring its own direct injury, distinct from the injury to Pharmacyclics, the government misses the point in invoking the "general" "equitable restriction" prohibiting shareholders from "initiating actions to enforce the rights of the corporation." MTD 14 (quoting *In re Troutman Enters., Inc.*, 286 F.3d 359, 364 (6th Cir. 2002)). As the government admits, that general restriction does not apply "where the shareholder suffers an injury separate and distinct from that suffered by other shareholders, or the corporation as an entity." *Id*. (quotation marks omitted). That is this case, because the IRA's unconstitutional process is causing AbbVie direct injuries that are distinct from the harm inflicted on Pharmacyclics and that go well beyond "a speculative diminution in value" of AbbVie's stock ownership of Pharmacyclics. *Id*. Thus, AbbVie satisfies all of the requirements of standing in its own right.

The government's reliance on this "shareholder standing" rule is also misplaced because the government challenges *only* Plaintiffs' "Article III standing," MTD 11, 14, but this principle is merely a "prudential" standing rule, *not* a "constitutional requirement[] of Article III." *Franchise Tax Bd. v. Alcan Aluminium Ltd*., 493 U.S. 331, 335–36 (1990).[11] As a result, even if the

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Updates Under the Medicaid Drug Rebate Program, 88 Fed. Reg. 34,238, 34,256 (May 26, 2023) (emphasis added) (footnote omitted).

[11] In *Alcan Aluminium*, foreign parent companies challenged California tax policies that allegedly harmed their American subsidiaries. *Id*. at 333. The Supreme Court held that "[the parent companies] have Article III standing to challenge the taxes that their wholly owned subsidiaries are required to pay." *Id*. at 336. The Court explained that the tax policies allegedly "cause actual

government were correct in its premise that AbbVie's injury is merely derivative of Pharmacyclics' (it is not), that would not affect AbbVie's Article III standing.

2. The relief requested does not require participation by individual members.

The government's argument regarding the third element of associational standing is also baseless. As the Supreme Court has long held, a suit does not require the participation of individual members unless the claims or requested relief would require "individualized proof." *Int'l Union, United Auto., Aerospace & Agric. Implement Workers v. Brock*, 477 U.S. 274, 287–88 (1986) (quoting *Warth v. Seldin*, 422 U.S. 490, 515–16 (1975)). For example, an "organization of construction firms" may lack standing to "seek damages for the profits and business lost by its members" because any such injury would be "'peculiar to the individual member concerned, and both the fact and extent of injury would require individualized proof.'" *Id.* (quoting *Warth*, 422 U.S. at 515–16). In contrast, "[t]he individual participation of an organization's members is 'not normally necessary when an association seeks prospective or injunctive relief for its members.'" *Sandusky*, 387 F.3d at 573 (quoting *United Food*, 517 U.S. at 546). "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." *Waskul v. Washtenaw Cnty. Cmty. Mental Health*, 979 F.3d 426, 442 (6th Cir. 2020) (quoting *Warth*, 422 U.S. at 515). For example, a suit that raises a "pure question of law" and seeks only injunctive relief does not "require[] the . . . [c]ourt to consider the

financial injury to [the parent companies] by illegally reducing the return on their investments in [the subsidiaries] and by lowering the value of their stockholdings." *Id*. And a "judicial determination" that the tax policies are unconstitutional "would prevent such injuries." *Id*. "That is all that is required for Article III standing." *Id*.; *see also Zurich Ins. Co. v. Logitrans, Inc.*, 297 F.3d 528, 533–34 (6th Cir. 2002) (Gilman, J., concurring).

individual circumstances of any aggrieved [association] member." *Int'l Union*, 477 U.S. at 287–88.

Plaintiffs' suit falls into the category of cases that do not require "individualized proof" and "are thus properly resolved in a group context." *Hunt*, 432 U.S. at 344. As a facial constitutional challenge to a statute, Plaintiffs' suit raises only "pure question[s] of law." *Int'l Union*, 477 U.S. at 287. Plaintiffs do not seek damages or any other relief that would require member-by-member proceedings. Plaintiffs seek only "prospective relief," *id.*—*i.e.*, declaratory and injunctive relief. Compl. ¶¶ 223–32. Thus, neither the claims nor the relief requested requires the participation of individual members.

The government does not dispute any of this, but it proposes grafting a new requirement onto the established associational-standing test. *See* MTD 15–18. Even where the test is fully satisfied, the government contends that a court should deny standing where some of the association's members "also bring their *own* lawsuits seeking to advance the same interests, and to obtain the same remedy." MTD 16. The government's apparent concern is that, because one or more of Plaintiffs' members have filed their own individual suits, "[d]ifferent courts might reach different conclusions regarding the merits of the same constitutional claims." MTD 17. If and when that happens, the government frets, manufacturers may engage in "gamesmanship" by invoking favorable judgments and disregarding unfavorable ones, creating "chaos." *Id.* (quoting *New York*, 140 S. Ct. at 601 (Gorsuch, J., concurring)).

The government's concerns are misplaced and, in any event, are not a basis for ignoring binding precedent mandating the test for associational standing. For one thing, the separate suits brought by several individual manufacturers largely raise different claims, and there is no immediate prospect of a judgment in any of those cases. For another thing, to the extent the claims

overlap, there is an easy solution to the government's supposed dilemma—and it does not require reinventing the doctrine of associational standing.[12] Instead, courts can simply recognize that any of Plaintiffs' members who have brought separate suits will be bound by any judgments in those suits that apply to particular plaintiffs therein. As the government itself acknowledges, "[b]y filing their own lawsuits, those manufacturers have demonstrated an intent to be bound by *those* courts' judgments, win or lose." MTD 16. That common-sense principle suffices to resolve the government's objection. The fact that one or more of Plaintiffs' members have filed their own suits is not a basis to preclude Plaintiffs from litigating this action on behalf of their members, including members who have *not* filed suit.

II. Plaintiffs' Claims Are Ripe.

As the government acknowledges, its ripeness argument is "similar in kind" to its argument regarding injury-in-fact. MTD 18. Ripeness turns on "the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967). For many of the same reasons that Plaintiffs have established an Article III injury-in-fact, *see supra* 4–15, Plaintiffs' claims are ripe for this Court's consideration.

The government contends that Plaintiffs "will suffer no hardship" and that their suit lacks "'fitness . . . for judicial decision'" because, the government says, no "concrete injury is imminent." MTD 18–19 (quoting *Abbott Labs.*, 387 U.S. at 149). This argument repackages the government's injury-in-fact challenge and fails for the same reasons. The IRA's defective process

[12] The government relies heavily on dicta in a Sixth Circuit opinion questioning the doctrine of associational standing. *See, e.g.*, MTD 15–17 (citing *Ass'n of Am. Physicians & Surgeons v. FDA*, 13 F.4th 531 (6th Cir. 2021)). The government fails to acknowledge that the opinion went on to *reject* that dicta as contrary to "directly on-point" Supreme Court precedent. *Id.* at 542. And the Supreme Court reaffirmed associational standing in a major decision just two months ago. *See Students for Fair Admissions, Inc. v. President & Fellows of Harvard Coll.,* 143 S. Ct. 2141, 2157–59 (2023).

could hardly be *more* imminent. Drugs will be selected for price controls in less than a week, and manufacturers will be forced to sign "agreements"—on pain of a crushing "excise tax" penalty—within a month after that. CMS itself has acknowledged that manufacturers already need to do work to prepare for the potential selection of their drugs and the submission of required data (on pain of $1 million per-day penalties). *See supra* 5.

Although the government briefly suggests that, even if Plaintiffs have standing, this Court should defer consideration until CMS sets specific "maximum fair prices," that is yet another instance of the government misconstruing the nature of Plaintiffs' claims. Plaintiffs' claims challenge the law's illegal mandates and procedures, not specific prices. *See supra* 1–2, 5–7. The government's request to forestall judgment on the IRA's *facial* constitutionality until "further factual development" has occurred, MTD 19 (quoting *Nat'l Park Hosp. Ass'n v. DOI*, 538 U.S. 803, 812 (2003)), makes no sense. "Because the plaintiffs are making a facial challenge to the statutes themselves, any procedural infirmity would not be cured by the subsequent application of the statute." *Seguin*, 968 F.2d at 589–90; *see also McCoy-Elkhorn Coal Corp. v. EPA*, 622 F.2d 260, 264–65 (6th Cir. 1980) ("Because this appeal raises a facial attack on the constitutionality of the statute and presents a purely legal question, we will never be in a better position to decide the issues."). In short, "the ripeness standard has been met here." *McCoy-Elkhorn Coal Corp.*, 622 F.2d at 264.

CONCLUSION

The motion to dismiss should be denied. In the alternative, if the Court grants the motion to dismiss, the Court should allow Plaintiffs to file an amended complaint.

Dated: August 25, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on August 25, 2023, a true and correct copy of the foregoing Opposition to the Motion to Dismiss was electronically filed with the Clerk of Court using the CM/ECF system, which will send notification to all counsel of record.

/s/ Tami H. Kirby

Tami H. Kirby (No. 0078473)

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

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

Plaintiffs,

v.

XAVIER BECERRA, *et al.*,

Defendants.

No. 3:23-cv-00156-TMR-PBS

Judge Thomas M. Rose

Magistrate Judge Peter B. Silvain, Jr.

SUPPLEMENTAL DECLARATION OF MICHAEL C. STAFF IN SUPPORT OF PLAINTIFFS' REPLY IN SUPPORT OF THEIR MOTION FOR PRELIMINARY INJUNCTION AND OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

I, Michael E. Staff, declare as follows:

1. I am Vice President, Inflation Reduction Act (IRA) Product and Channel Strategies, for AbbVie Inc. ("AbbVie").

2. I submit this declaration in further support of Plaintiffs' Motion for Preliminary Injunction and Reply as well as their Opposition to Defendants' Motion to Dismiss.

3. This declaration supplements my previous Declaration in Support of Plaintiffs' Motion for Preliminary Injunction (July 11, 2023) and incorporates herein by reference my explanation of AbbVie's products and the harm AbbVie will face if the IRA is not enjoined.

4. As explained in my previous declaration, AbbVie is a global research-based biopharmaceutical company that develops and markets innovative drug therapies.

5. Pharmacyclics LLC is a wholly-owned subsidiary of AbbVie.

6. IMBRUVICA® is an oral, once-daily therapy that inhibits a protein called Bruton's tyrosine kinase. Imbruvica currently is approved by FDA for the treatment of chronic lymphocytic

leukemia, small lymphocytic lymphoma, Waldenstrom's macroglobulinemia, and chronic graft versus host diseases, in certain patients.

7. IMBRUVICA® was originally developed by Pharmacyclics, Inc.

8. On March 4, 2015, AbbVie announced that it had entered into a definitive agreement to acquire Pharmacyclics, Inc. and its flagship asset IMBRUVICA® for approximately 21 billion dollars. *See, e.g.*, Press Release, AbbVie, AbbVie to Acquire Pharmacyclics, Including Its Blockbuster Product Imbruvica®, Creating an Industry Leading Hematological Oncology Franchise (Mar. 4, 2015), https://news.abbvie.com/news/abbvie-to-acquire-pharmacyclics-including-its-blockbuster-product-imbruvica-creating-an-industry-leading-hematological-oncology-franchise.htm.

9. On May 26, 2015, AbbVie completed that acquisition. *See, e.g.*, Financial Release, AbbVie Completes Acquisition of Pharmacyclics, AbbVie.com (May 26, 2015), https://investors.abbvie.com/news-releases/news-release-details/abbvie-completes-acquisition-pharmacyclics.

10. That day, Pharmacyclics, Inc. merged into Oxford Amherst LLC (a wholly owned subsidiary of AbbVie) and changed its name to Pharmacyclics LLC ("Pharmacyclics"). AbbVie Form 10-K, Exh. 2.3 (Feb. 27, 2019), https://www.sec.gov/Archives/edgar/data/1551152/000110465915017787/a156032_3ex2d1.htm.htm. As a result of those transactions, Pharmacyclics LLC became, and has remained, a wholly-owned subsidiary of AbbVie.

11. As part of AbbVie and Pharmacyclics' Agreement and Plan of Reorganization, AbbVie agreed to maintain Pharmacyclics' name, to continue to market "Imbruvica®" under that

trade name, and to keep Pharmacyclics as "the primary operating entity which owns and markets Imbruvica® (ibrutinib) in the United States" for at least 5 years, until 2020. *Id.* at Section 7.16.

12. Accordingly, Pharmacyclics has remained the holder of the New Drug Applications (NDAs) for IMBRUVICA®: **NDA 210563**, U.S. FDA: Drugs@FDA, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=210563; **NDA 205552**, U.S. FDA: Drugs@FDA, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=220555; **NDA 217003**, U.S. FDA: Drugs@FDA, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=217003.

13. Nevertheless, AbbVie engages in activities relating to IMBRUVICA® that are contained in the IRA's statutory definition of "manufacturer" under 42 U.S.C. §§ 1302f(c)(1), 1395w-3a(c)(6)(A), and 1396r-8(k)(5)—including the "production," "preparation," "packaging," and "labeling" of IMBRUVICA®.

14. There are three different formulations of IMBRUVICA®: oral suspension, capsules, and tablets. As set out in documents submitted to, and approved by, the FDA, AbbVie performs activities of a "manufacturer" for all three of these formulations.

15. For the oral suspension, AbbVie receives the bulk powder active ingredient at an AbbVie manufacturing facility and produces the finished oral suspension drug substance. AbbVie then fills that product into bottles, which AbbVie packages with syringes used for injecting the product, and labels those packages with the FDA-required product labeling. AbbVie then delivers that packaged and labeled product to distributors.

16. For the capsule formulation of IMBRUVICA®, AbbVie receives bulk capsules at an AbbVie facility and packages those capsules in sealed blister-packs, which AbbVie then labels

with the FDA-required product labeling. AbbVie then delivers that packaged and labeled product to distributors.

17. For the tablet formulation of IMBRUVICA®, AbbVie receives bulk powdered active ingredient at an AbbVie manufacturing facility and produces tablets. AbbVie then adds various coatings and colorings to the tablets, and packages them in blister-packs and bottles. AbbVie labels those packages with the FDA-required product labeling and delivers them to distributors.

18. Pharmacyclics is not a publicly traded company and does not independently report its financial performance. Rather, AbbVie reports IMBRUVICA® sales in its own consolidated financial statements. *See, e.g.*, AbbVie Form 10-K (Feb. 17, 2023), https://investors.abbvie.com/node/17526/html.

19. When IMBRUVICA®'s financial performance is impaired (as would occur if IMBRUVICA® is given a below-market price in the IRA price-setting process), AbbVie suffers the resulting injury. For example, a July 29, 2022, article by Bloomberg, titled "AbbVie Slides After Cutting Sales Outlook On Cancer Drug Decline," reported that "*AbbVie Inc.* shares slide more than 6% Friday after the company cut its full-year sales outlook on weak performance from cancer drug Imbruvica." https://www.bloomberg.com/news/articles/2022-07-29/abbvie-slides-after-cutting-sales-outlook-on-cancer-drug-decline#xj4y7vzkg (emphasis added).

20. AbbVie is commonly referred to as the manufacturer of IMBRUVICA®. *See, e.g.*, Michael Erman et al., *Bristol Myers, Pfizer, AbbVie drugs likely to face US. price negotiation*, Reuters.com (March 13, 2023), https://reut.rs/3pQgPmH; Spencer Kimball, *Biden administration will select first 10 drugs for Medicare price negotiations by September*, CNBC.com (Jan. 11,

2023), https://www.cnbc.com/2023/01/11/biden-administration-will-select-drugs-for-medicare-price-negotiations-by-september.html.

21. AbbVie has borne, and will continue to bear, the vast majority of the costs and burdens associated with the potential selection of IMBRUVICA® for the IRA's price-setting process by September 1, 2023. More than 30 AbbVie employees have been identifying, collecting, reviewing, and preparing to submit the data required under the IRA in the event IMBRUVICA® is selected, far greater than the number of Pharmacyclics employees who have been involved in that process. And, if IMBRUVICA® is selected, personnel employed by AbbVie will conduct the "negotiation" process for IMBRUVICA®.

22. AbbVie will be bound by the "maximum fair price" set for IMBRUVICA® and AbbVie's consolidated financial performance will be impacted by that price.

23. AbbVie could not simply or quickly "divest" IMBRUVICA® to avoid the price-control program. Transferring ownership, manufacturing capabilities, and regulatory registration of any prescription drug is a complex, lengthy, and costly process that requires regulatory approvals.

24. For these reasons and all the reasons provided in my previous declaration, AbbVie manufactures IMBRUVICA®, is being irreparably harmed now by the prospect that IMBRUVICA® will be included on the selected drug list to be published by September 1, 2023, and will be further irreparably harmed if IMBRUVICA® is included on the list.

25. AbbVie was a member of the Chamber of Commerce of the United States of America, the Michigan Chamber of Commerce, and the Dayton Area Chamber of Commerce, Plaintiffs in this action, before this action was filed.

26. AbbVie's membership in the Ohio Chamber of Commerce became effective less than a week after this action was filed.

27. Pharmacyclics, as a wholly-owned subsidiary of AbbVie, has been a member of the Chamber of Commerce of the United States of America and the Michigan Chamber of Commerce by virtue of AbbVie's membership in these organizations.

28. Pharmacyclics joined the Dayton and Ohio Chambers in its own name in August 2023.

29. Both AbbVie and Pharmacyclics are currently members of all four chambers.

30. AbbVie also manufactures Humira®. *See, e.g.*, Humira Prescribing Information (rev. Feb. 2021), https://www.rxabbvie.com/pdf/humira.pdf.

31. AbbVie holds the approved biologics license application ("BLA") for Humira® (adalimumab), which was first licensed by FDA under section 351(a) of the Public Health Service Act ("PHSA") in 2002. *See BLA #125057*, U.S. FDA: Drugs@FDA, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm? event=BasicSearch.process. AbbVie is listed as the only labeler for the drug in the FDA's National Drug Code Directory. FDA, *National Drug Code Directory*, https://www.accessdata.fda.gov/scripts/cder/ndc/index.cfm (select "proprietary Name" and search "Humira").

32. For reasons provided in my previous declaration and supplemented in this declaration, AbbVie will be harmed if Humira® is selected for price-setting.

Pursuant to 28 U.S.C. §1746, I declare that the foregoing is true and correct.

Executed this 24th day of August, 2023.

Michael C. Staff 8/24/2023

Michael C. Staff