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

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

Plaintiffs,

Case No. 3:23-cv-156

vs.

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

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

Defendants.

ORDER: (1) DENYING DEFENDANTS' MOTION TO DISMISS (Doc. No. 33); (2) DENYING PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION (Doc. No. 29); (3) REQUIRING PLAINTIFFS TO FILE AN AMENDED COMPLAINT BY OCTOBER 13, 2023; (4) REQUIRING THE PARTIES TO FILE A RULE 26(f) REPORT BY OCTOBER 13, 2023; AND (5) REFERRING THIS CASE TO MAGISTRATE JUDGE SILVAIN TO SUPERVISE DISCOVERY IN THE INTERIM

I. Summary

Separation of powers is fundamental to the structure of the federal government. To maintain the separation of powers, Article III of the United States Constitution limits the subject matter jurisdiction of federal courts; Article III requires that federal courts only hear certain cases and controversies. For a federal court to have subject matter jurisdiction over a case or controversy, a plaintiff must show both standing and ripeness. A plaintiff can establish standing by showing a personal legal interest that the defendant has allegedly invaded. A plaintiff can show that a claim is ripe by explaining why it is not too early for a court to resolve the dispute.

This is a civil case for which Plaintiffs—four Chambers of Commerce—challenge the constitutionality of the Drug Price Negotiation Program created by the federal Inflation Reduction Act, 42 U.S.C. §§ 1320(f), *et seq*, which is scheduled to start requiring drug manufacturers to comply with its provisions later this week, on October 1, 2023. This case is before the Court on Defendants' Federal Rule of Civil Procedure 12(b)(1) motion to dismiss for lack of subject matter jurisdiction and Plaintiffs' Fed. R. Civ. P. 65(a) motion for a preliminary injunction to prevent the implementation of that Program.

A. Motion to Dismiss

Having carefully and thoroughly considered the pleadings and briefing in support of, and in opposition to, the dismissal motion, along with the procedural posture of this case, *see infra*, the efficient and appropriate way forward is to permit Plaintiffs to amend their initial complaint and allow the parties to move forward with limited discovery. Following the taking of limited discovery and the filing of an amended complaint, the Court will entertain the filing of one or more renewed motion(s) to dismiss. At this early juncture of the case, the Court expresses no opinion as to whether or not Plaintiffs have standing. Based on the limited record before it, the Court notes that Plaintiffs have satisfied their duty to bring good-faith legal and factual contentions concerning standing under Fed. R. Civ. P. 11(b). A final determination on standing issues will be made following a short (60-day) discovery period and—assuming they are filed—renewed motions to dismiss. If those renewed motions are not filed, the Court will consider Defendants' standing arguments hereafter on summary judgment review. Proceeding in this manner will ensure that the Court reviews these arguments only after appropriate discovery has been completed and will guarantee that the Court's consideration of the parties' standing arguments is not premature. Plaintiffs are ordered to file an amended complaint within fourteen (14) days, i.e., October 13,

2023. Defendants shall have until October 27, 2023, to renew their motion to dismiss if they so choose.

B. Motion for a Preliminary Injunction

As to Plaintiffs' motion for a preliminary injunction, they have demonstrated neither a strong likelihood of success nor irreparable harm. Consequently, their request for immediate preliminary injunctive relief—to stop implementation of the Program on or before October 1, 2023—is denied. Given that denial, the Court need not (and does not) address the breadth of potential injunctive relief (whether statewide within Ohio's borders, or nationwide).

II. Background

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

A. The Program

The Program requires the Secretary to select and publish a list of ten (10) drugs by September 1, 2023 to be subject to price negotiation. Doc. No. 1 at PageID 17; 42 U.S.C. § 1320f(d)(1). The manufacturer of each selected drug must then enter into an agreement with the Secretary on October 1, 2023 to take part in the price negotiation process. Doc. No. 1 at PageID 17; 42 U.S.C. § 1320f(d)(2)(A). If a manufacturer of a selected drug does not enter into an agreement by that date, it must pay an excise tax on all U.S. sales of that drug, unless it withdraws all of its drugs from federal healthcare programs. Doc. No. 1 at PageID 24-26; 26 U.S.C. §§ 5000D(b)(1), 5000D(c). By October 2, 2023, each manufacturer of a selected drug must also

submit information to the Secretary. Doc. No. 1 at PageID 19; 42 U.S.C. §§ 1320f(d)(5)(A), 1320f-2(a)(4). The information that a manufacturer must submit includes, *inter alia*, research and development costs, unit production costs, patent applications, and market data. Doc. No. 1 at PageID 19; 42 U.S.C. § 1320f-3(e). If a manufacturer has agreed to participate in the Program but fails to provide the requested information, it is subject to a $1 million civil penalty for every day of the violation. Doc. No. 1 at PageID 19-20; 42 U.S.C. § 1320f-6(c).

After this information is provided, the Secretary and manufacturers must negotiate a "maximum fair price" for each drug. Doc. No. 1 at PageID 18; 42 U.S.C. § 1320f-3(a)(1). This process begins when the Secretary issues an initial price offer to the manufacturer based upon several factors including, *inter alia*, evidence about alternative treatments. Doc. No. 1 at PageID 20; 42 U.S.C. §§ 1320f-3(b)(2)(B), 1320f-3(e)(1)-(2). The manufacturer must either accept the offer or propose a counteroffer to the Secretary. Doc. No. 1 at PageID 18; 42 U.S.C. § 1320f-3(b)(2)(C). After the manufacturer accepts the offer or the Secretary responds to the counteroffer, the Secretary then sets the maximum fair price for the drug by August 1, 2024. Doc. No. 1 at PageID 18; 42 U.S.C. § 1320f(d)(5). This price is to be published by September 1, 2024. Doc. No. 1 at PageID 18; 42 U.S.C. §§ 1320f(a)(3), 1320f(d)(6). These prices then go into effect on January 1, 2026. Doc. No. 1 at PageID 18; 42 U.S.C. § 1320f(d)(5).

B. The Program's Impact on the Drug "IMBRUVICA"®

Plaintiffs assert that some of their Chambers' members will be harmed by the Program. Doc. No. 1 at PageID 10. Specifically, Plaintiffs state that the biopharmaceutical company AbbVie—a member of the Dayton Area Chamber of Commerce and the U.S. Chamber of Commerce—"markets the drug IMBRUVICA®" and will be injured by the Program. *Id.* Plaintiffs explain that "[m]arket analysts expect IMBRUVICA® to be among the ten drugs" the

Secretary will select for the Program on September 1, 2023. *Id.* Plaintiffs' prediction was correct: IMBRUVICA® was selected for the program. Doc. No. 54 at PageID 471.[1]

C. The Parties' Positions

Plaintiffs are the Dayton Area Chamber of Commerce, the Ohio Chamber of Commerce, the Michigan Chamber of Commerce, and the U.S. Chamber of Commerce. Doc. No. 1 at PageID 1. Each Plaintiff is an organization with many members from different industries. *Id.* at PageID 8-9; U.S. CHAMBER OF COMMERCE, https://www.uschamber.com/about (last visited Sept. 28, 2023); OHIO CHAMBER OF COMMERCE, https://ohiochamber.com/about-us/mission/ (last visited Sept. 28, 2023); MICHIGAN CHAMBER OF COMMERCE, https://www.michamber.com/mission/# (last visited Sept. 28, 2023); DAYTON AREA CHAMBER OF COMMERCE, https://daytonchamber.org/about/ (last visited Sept. 28, 2023). These organizations exist to represent the interests of businesses in their respective regions. *Id.*

The IRA's creation of the Program, in Plaintiffs' view, "created an unprecedented, one-sided regime that forces manufacturers to sell drugs at government-set prices." Doc. No. 1 at PageID 2. Plaintiffs assert that the IRA avoids alerting the public to this reality by adopting a euphemism—"Drug Price Negotiation Program"—for a "novel experiment that dramatically expands bureaucratic control over the private economy." *Id*. Plaintiffs argue, "The appropriate term for this is 'mandated price control,' not 'negotiation.'" *Id*.

Defendants are Xavier Becerra, in his official capacity as Secretary of the U.S. Department of Health and Human Services ("HHS"); HHS itself; Chiquita Brooks-LaSure, in her official

[1] *Fact Sheet: Biden-Harris Administration Announces First Ten Drugs Selected for Medicare Price Negotiation*, THE WHITE HOUSE. https://www.whitehouse.gov/briefing-room/statements-releases/ 2023/ 08/ 29/ fact - sheet - biden - harris - administration - announces - first - ten - drugs - selected - for – medicare - price - negotiation/ (last visited Sept. 26, 2023).

capacity as Administrator of the Centers for Medicare and Medicaid Services ("CMS")[2]; and CMS itself. *Id.* at PageID 8-11. Defendants are tasked with implementing the Program created by the IRA. 42 U.S.C. § 1320(f).

Defendants see the Program very differently than Plaintiffs. They say that it authorizes "Medicare to try and negotiate a better deal for patients and the American taxpayer on some of the pharmaceutical industry's most lucrative drugs." Doc. No. 33 at PageID 213. Defendants explain, "Prior to the IRA, Congress had not granted the Secretary [of Health and Humans Services] the authority to negotiate with drug manufacturers for the costs of covered medications under Medicare." *Id*. at PageID 215. Defendants state that although this lack of authority to negotiate drug prices was at first "relatively economical, it has led to rapidly rising costs to Medicare in recent years…. The result has been a shift of financial burden to the Medicare program, which undermines the program's premise of leveraging market competition to reduce prices to beneficiaries and taxpayers." *Id*.

D. Procedural Posture

Plaintiffs challenge the constitutionality of the Program. They claim it runs afoul of (1) the fundamental separation of powers the U.S. Constitution vests in each branch of Government in Articles I, II, and III; (2) the Due Process Clause of the Fifth Amendment; (3) the Excessive Fines Clause of the Eighth Amendment; (4) the legislative authority vested in Congress; and (5) the Free Speech Clause of the First Amendment. Doc. No. 1 at PageID 33-56. Plaintiffs filed their complaint on June 9, 2023, before the Secretary published HHS's list of ten drugs. *Id.* at PageID 56.

[2] CMS is a federal government agency charged with administering federal healthcare programs. CENTERS FOR MEDICARE AND MEDICAID SERVICES, https://www.cms.gov/about-cms (last visited Sept. 28, 2023).

This case[3] is presently before the Court upon two fully-briefed motions: first, Plaintiffs' motion for a preliminary injunction (Doc. No. 29), Defendants' opposition memorandum (Doc. No. 34), amici curiae's[4] opposition memoranda (Doc. Nos. 47, 48), and Plaintiffs' reply memorandum (Doc. No. 49); second, Defendants' motion to dismiss (Doc. No. 34), Plaintiffs' opposition memorandum (Doc. No. 50), and Defendants' reply memorandum (Doc. No. 52). Counsel for both sides presented oral argument in a hearing on September 15, 2023, conducted with the Court via GoTo Meeting video conferencing (Doc. No. 54).

III. Jurisdiction

"Article III's restriction of the judicial power to Cases and Controversies is properly understood to mean cases and controversies of the sort traditionally amenable to, and resolved by, the judicial process." *Uzuegbunam v. Preczewski*, 592 U.S. ——, 141 S. Ct. 792, 798 (2021) (quotation marks omitted) (quoting *Vt. Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 774 (2000)). Standing is an indispensable part of the case or controversy requirement of Article III. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992). Standing analysis "is particularly rigorous when reaching the merits of the dispute would force the Court to decide whether an action taken by one of the other two branches of the Federal Government was unconstitutional." *Parsons v. U.S. Dep't of Just.*, 801 F.3d 701, 710 (6th Cir. 2015) (internal

[3] This case is one of multiple cases that have been filed in U.S. District Courts across the country challenging the constitutionality of the Program. However, this is the only case in which the plaintiffs seek a preliminary injunction. At the time of writing, the Court found seven other pending cases in district courts other than the Southern District of Ohio, including: *AstraZeneca Pharms. LP v. Becerra*, No. 1:23-cv-931 (D. Del. Aug. 25, 2023); *Boehringer Ingelheim Pharms., Inc. v. U.S. Dep't of Health and Hum. Servs.*, No. 3:23-cv-1103 (D. Conn. Aug. 18, 2023); *Janssen Pharms, Inc. v. Becerra*, No. 3:23-cv-3818 (D.N.J. July 18, 2023); *Nat'l Infusion Center Ass'n v. Becerra*, No. 1:23-cv-707 (W.D. Tex. June 21, 2023); *Merck & Co., Inc. v. Becerra*, No. 1:23-cv-1615 (D.D.C. June 6, 2023); *Novartis Pharms. Corp. v. Becerra*, No. 3:23-cv-14221 (D.N.J. Sept. 1, 2023); and *Bristol Myers Squibb Co. v. Becerra*, No. 3:23-cv-3335 (D.N.J. June 16, 2023). Another case was filed, but voluntarily dismissed: *Astellas Pharma US, Inc. v. Dep't of Health and Hum. Servs.*, No. 1:23-cv-4578 (N.D. Ill. July 14, 2023).

[4] Amici Curiae are AARP, AARP Foundation, Public Citizens, Patients for Affordable Drugs Now, Doctors for America, Protect Our Care, and Families USA. *See* Doc. Nos. 47, 48.

citations and quotations omitted). "To have standing, a plaintiff must allege (1) an injury in fact (2) that's traceable to the defendant's conduct and (3) that the courts can redress." *Gerber v. Herskovitz*, 14 F.4th 500, 505 (6th Cir. 2021) (citing *Lujan*, 504 U.S. at 559–61).

The requirement that a plaintiff suffer an injury-in-fact is "the 'irreducible constitutional minimum' of standing." *Ass'n of Am. Physicians & Surgeons v. U. S. Food and Drug Admin.*, 13 F.4th 531, 538 (6th Cir. 2021) (quoting *Lujan*, 504 U.S. at 560). Associations, such as a Chamber of Commerce, have standing to sue on behalf of one or more of its members if those members have been injured, even if the association itself is not directly impacted by a defendant's actions. *Waskul v. Washtenaw Cnty. Cmty. Mental Health*, 900 F.3d 250, 253 (6th Cir. 2018). Nevertheless, it is critical that the association identifies at least one of its members who has standing. *Ass'n of Am. Physicians & Surgeons*, 13 F.4th at 543. To establish associational standing, the association must show that "[1] its members would otherwise have standing to sue in their own right, [2] the interests at stake are germane to the organization's purpose, and [3] neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Waskul*, 900 F.3d at 254–55 (citing *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977) (internal quotation marks omitted)).

A. Legal Standards

Defendants have moved to dismiss on account of Plaintiffs' supposed lack of associational standing. Doc. No. 33 at PageID 232. To survive a motion to dismiss on standing grounds, standing must be "facially plausible" in the complaint. *Ashcroft v. Iqbal*, 556 U.S. 662, 663 (2009); *Ass'n of Am. Physicians & Surgeons*, 13 F.4th at 543. Plaintiffs have the burden of demonstrating "standing as to each claim and each type of relief sought." *Patterson v. United HealthCare Ins. Co.*, 76 F.4th 487, 493 (6th Cir. 2023). The Court must determine whether Plaintiffs assert a

"'plausible claim' that one of its members has standing." *Ass'n of Am. Physicians & Surgeons*, 13 F.4th at 544 (quoting *Iqbal*, 556 U.S. at 679). A complaint states a plausible claim when it states "enough facts to raise a reasonable expectation that discovery will reveal evidence" that a plaintiff has standing. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 545 (2007). Once one plaintiff has demonstrated standing, a court has jurisdiction to consider the ultimate merits of the claims raised by that plaintiff. *Mays v. LaRose*, 951 F.3d 775, 782 (6th Cir. 2020) (citing *Vill. of Arlington Heights v. Metro. Hous. Dev. Corp.*, 429 U.S. 252, 264 & n.9 (1977)). Standing may be clarified through the filing of an amended complaint. *Warth v. Seldin*, 422 U.S. 490, 501 (1975). Leave to amend must be "freely" given "when justice so requires." Fed. R. Civ. P. 15(a)(2).

A Rule 12(b)(1) motion can challenge lack of subject matter jurisdiction in two ways: a facial attack and a factual attack. *Abbott v. Mich.*, 474 F.3d 324, 328 (6th Cir. 2007) (citing *DLX, Inc. v. Ky.*, 381 F.3d 511, 516 (6th Cir. 2004)). "A facial attack on the subject-matter jurisdiction alleged in the complaint questions merely the sufficiency of the pleading." *Gentek Bldg. Prods., Inc. v. Sherwin-Williams Co.*, 491 F.3d 320, 330 (6th Cir. 2007) (quoting *Ohio Nat'l Life Ins. Co. v. United States*, 922 F.2d 320, 325 (6th Cir. 1990)). Where there is a facial attack on standing, the Court "must accept as true all material allegations of the complaint, and must construe the complaint in favor of the complaining party." *Parsons*, 801 F.3d at 710 (quoting *Warth*, 422 U.S. at 501). This "analysis must be confined to the four corners of the complaint." *Id.* at 706.

Conversely, a factual attack allows the court to consider evidence outside the pleadings and to "weigh evidence to confirm the existence of the factual predicates for subject-matter jurisdiction." *Carrier Corp. v. Outokumpu Oyj*, 673 F.3d 430, 440 (6th Cir. 2012) (citations omitted). A court may look to amendments to the complaint, affidavits, and other materials on the record in determining whether Plaintiffs have adequately demonstrated standing. *Warth*, 422 U.S.

at 501; *see also Plunderbund Media, L.L.C. v. DeWine*, 753 Fed.App'x 362, 366 (6th Cir. 2018) (authorizing a review of preliminary injunction documents, such as declarations).

Defendants do not clarify the type of challenge they make in their motion to dismiss, but it appears that they alternatively make both a facial and factual attack on the Court's subject matter jurisdiction. *Compare* Doc. No. 33 at PageID 220 (asserting a facial challenge that the claimed injuries in the complaint are hypothetical and speculative) *with id.* at PageID 225 (asserting a factual challenge that Plaintiffs named a member that would not be regulated under the statute). After careful, thorough, and extensive consideration of the complaint and briefing in support of, and in opposition to, the motion to dismiss, it is in the interest of justice that the Court look beyond the complaint to determine whether Plaintiffs have standing at this early stage in the case. *See Warth*, 422 U.S. at 501 (explaining that "it is within the trial court's power to allow or require the plaintiff to supply, by amendment to the complaint or by affidavits, further particularized allegations of fact deemed supportive of standing"). Therefore—in reviewing the issue of associational standing—the Court will consider the briefing on the motion to dismiss as well as Plaintiffs' declarations in support of their motion for a preliminary injunction.[5]

B. The Parties' Positions

In their motion to dismiss, Defendants contend that Plaintiffs have failed to demonstrate they have standing to challenge the IRA's constitutionality. Doc. No. 33 at PageID 218. They reason, first, that Plaintiffs' alleged injuries are speculative and, second, that Plaintiffs lack associational standing. *Id*. at PageID 218-30. Additionally, Defendants argue that the claims presented are not yet ripe because Plaintiffs will not suffer an injury until a new price set under the

[5] In opposition to Plaintiffs' motion to dismiss, Plaintiffs rely on these declarations and a declaration attached to their memorandum opposing Defendants' motion to dismiss. Doc. No. 29-1; Doc. No. 29-2; Doc. No. 29-3; Doc. No. 29-4; Doc. No. 29-5; Doc. No. 29-6; Doc. No. 50-1.

Program takes effect on January 1, 2026. *Id*. at PageID 218-19.

Plaintiffs maintain that they have amply established the three elements of Article III standing. Doc. No. 50 at PageID 410. Relying on their complaint and preliminary injunction declarations, they argue that each Chamber has "members who are subject to the IRA and who will therefore suffer economic harm and other concrete injuries as a direct result of the IRA's price-control regime." *Id.* Plaintiffs assert that "[e]njoining that unconstitutional regime will prevent those injuries." *Id*.

C. Standing Analysis

Defendants, seeking dismissal, maintain that Plaintiffs have not properly identified a member that is a manufacturer of a drug that could potentially be subjected to the Program. Doc. No. 33 at PageID 224. Alternatively, Defendants assert that even if Plaintiffs have referenced a Chambers member who is a drug manufacturer, they have not shown an injury-in-fact. *Id.* at PageID 219. The motion to dismiss does not dispute that Plaintiffs satisfy the second associational standing requirement. Finally, Defendants argue that—even if standing does exist here—Plaintiffs' members should be required to participate in the lawsuit individually, not in their capacity as Chambers members. *Id.* at PageID 227.

i. Identification of Members

The Sixth Circuit has made clear that "an organization must do more than identify a likelihood that the defendant's conduct will harm an unknown member in light of the organization's extensive size or membership base." *Ass'n of Am. Physicians & Surgeons*, 13 F.4th at 543. Instead, an association must "identify a member who has suffered (or is about to suffer) a concrete and particularized injury from the defendant's conduct." *Id.*

Plaintiffs allege that they "have associational standing because each of them has members

that will be directly subject to the IRA's price controls and adversely affected by them and thus would have standing to sue in their own right; because the interests Plaintiffs seek to protect are germane to their policy aims; and because neither the claims asserted nor the relief requested requires an individual member to participate in this suit." Doc. No. 1 at PageID 10. In their initial complaint, Plaintiffs name only one member of the Dayton Area Chamber of Commerce and the U.S. Chamber of Commerce: AbbVie. *Id.* AbbVie is a global biopharmaceutical company—headquartered in Illinois—that develops and markets drugs and other treatments. Doc. No. 29-5 at PageID 185-86; ABBVIE, https://www.abbvie.com/contact-center/locations/united-states.html (last visited Sept. 26, 2023). AbbVie participates in the Medicare Part D and Medicaid healthcare programs. Doc. No. 29-5 at PageID 186.

Plaintiffs contend that AbbVie "markets the drug IMBRUVICA®." Doc. No. 1 at PageID 10. Plaintiffs assert, "[m]arket analysts expect IMBRUVICA® to be among the ten drugs selected by the Secretary for the IRA's price controls by September 1, 2023." *Id.* In the complaint—which was filed prior to the Secretary's final selection of the ten drugs published by September 1, 2023—Plaintiffs allege, "[i]f IMBRUVICA® is selected, AbbVie will be forced to enter 'negotiations' with the Secretary, disclose competitively sensitive proprietary information about IMBRUVICA® to the Secretary, and 'agree' to the Secretary's unreasonably low 'maximum fair price,' which will be substantially lower than current market prices for IMBRUVICA®." *Id.*

Defendants claim that, according to the IRA's definition of "manufacturer," *see* 42 U.S.C. §§ 1320f(c)(1); 1395w-3a(c)(6)(A); 1396r-8(k)(5), AbbVie is not a manufacturer of the drug IMBRUVICA® because it only markets the drug. Doc. No. 33 at PageID 224. Defendants assert that a non-party—Pharmacyclics—is the manufacturer of IMBRUVICA® that would ultimately be subjected to the Program's requirements. *Id.* at PageID 225. Although Pharmacyclics is wholly

owned by AbbVie, Defendants contend that AbbVie would not be subjected to the Program's legal obligations. *Id.* at PageID 225-26.

Plaintiffs assert that naming AbbVie in the complaint—and Pharmacyclics in a declaration in support of the motion for a preliminary injunction—as members of the Dayton Area Chamber of Commerce and the U.S. Chamber of Commerce suffices to satisfy the first requirement of associational standing. Doc. No. 50 at PageID 418. Additionally, Plaintiffs claim that both AbbVie and Pharmacyclics can be considered "manufacturers" under the IRA sufficient to demonstrate associational standing. *Id.*

The Court recognizes that each associational plaintiff must name a specific member that has suffered—or imminently will suffer—a "concrete and particularized injury." *Ass'n of Am. Physicians & Surgeons*, 13 F.4th at 543. The complaint does not name or otherwise identify a specific member of two Plaintiffs: the Ohio Chamber of Commerce and the Michigan Chamber of Commerce. Therefore, because leave to amend is freely granted, it is in the interest of justice to give Plaintiffs leave to amend the complaint to identify specific members of those two Chambers who they claim are manufacturers of the drugs selected for the Program. Additionally, it is in the interest of justice to allow Plaintiffs to amend the complaint to clarify whether AbbVie is indeed the manufacturer of IMBRUVICA® which will be subject to the Program's requirements. If appropriate, discovery may be taken on these issues, *see infra*.

ii. Article III Standing of AbbVie

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

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

Defendants first assert that AbbVie has not satisfied the injury-in-fact requirement. Doc. No. 33 at PageID 219. To satisfy the first standing element, the injury suffered "must be concrete, particularized, and actual or imminent." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013). The injury cannot be "too speculative" or merely a "possible future injury." *Id.*

In the complaint, Plaintiffs broadly claim that their Chambers members will suffer several types of harm as a result of the IRA. Plaintiffs allege that "[t]he IRA will deprive Plaintiffs' members of their constitutional rights, make it more difficult for them to operate their businesses, and stifle healthcare innovations." Doc. No. 1 at PageID 10. The complaint also states that Plaintiffs' members will be harmed because the IRA will require "the disclosure of competitively sensitive proprietary information, including trade secrets." *Id.* When alleging injury specific to AbbVie, Plaintiffs merely "expect" IMBRUVICA® to be selected for the Program based on market analytics. *Id.* The complaint contemplates that "[i]f IMBRUVICA® is selected, AbbVie will" incur alleged harms. *Id.* Plaintiffs do not allege in their complaint that any harm had already occurred. *See generally id.*

In their opposition memorandum, however, Plaintiffs claim their "members have *already* been harmed." Doc. No. 50 at PageID 410. Plaintiffs assert "that AbbVie has already incurred significant costs to comply with the IRA's burdensome and data-intensive requirements." *Id.* Plaintiffs do not cite any cases that support their contention that preparing to comply with a statute constitutes an injury-in-fact. *See generally id.* Plaintiffs also argue that their First Amendment claims are sufficient to satisfy the injury-in-fact requirement. *Id.* at PageID 411; Doc. No. 1 at

PageID 52-56.

Defendants first maintain that no manufacturer could have had standing to bring a claim challenging the Program until the Secretary published the final list of selected drugs. Doc. No. 33 at PageID 220. Defendants next contend that—even after the Secretary has published the list of selected drugs—a manufacturer of a selected drug could only potentially be harmed once the Secretary sets the drug's maximum fair price. *Id.* at PageID 220. Until that price is set, Plaintiffs would not know whether or not the Program would lower the price of the selected drugs. *Id.* at PageID 220.

Each associational plaintiff must establish that one or more of its members has standing. *Ass'n of Am. Physicians & Surgeons*, 13 F.4th at 543. The complaint identifies only future injuries that may befall AbbVie if IMBRUVICA® is selected for the Program. Doc. No. 1 at PageID 10. Plaintiffs' opposition memorandum raises new allegations about its injuries. As a result, it is in the interest of justice to grant Plaintiffs leave to amend the complaint to further clarify the specific details that, in their view, establish standing, and then for the Court to review the standing issue with finality. Moreover, it is appropriate and reasonable to allow Plaintiffs to update the Court (via an amended pleading) about any additional factual developments that may have an impact on Plaintiffs' standing.

iii. Requirement of Participation of Individual Members

The final prong of the associational standing test bars a suit "when 'the claim asserted [or] the relief requested requires the participation of individual members in the lawsuit.'" *United Food and Com. Workers Union Loc. 751 v. Brown Grp., Inc.*, 517 U.S. 544, 546 (1996) (quoting *Hunt*, 432 U.S. at 343). This prong of the associational standing test is a prudential standing requirement, not a constitutional requirement. *Id.* at 555.

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

Defendants explain that a member of Plaintiff U.S. Chamber of Commerce, Merck, has also filed a claim challenging the Program in other litigation. *See* Doc. No. 33 at PageID 228 (discussing *Merck v. Becerra*, No. 1:23-cv-1615 (D.D.C. June 6, 2023). Defendants contend that because "[d]ifferent courts might reach different conclusions regarding the merits of the same constitutional claims," *Id.* at PageID 229, Plaintiffs could choose to follow the more favorable ruling of one court and ignore an adverse judgment by another court.

In response, Plaintiffs argue that individual members of an association need not participate in a suit "unless the claims or requested relief would require" proof on an individual level. Doc.

No. 50 at PageID 421. Here, Plaintiffs explain that seeking injunctive relief—not damages—allows the members to benefit from an association's suit without the need for the individual member's participation. *Id.* at PageID 421 (citing *Sandusky Cnty. Democratic Party v. Blackwell*, 387 F.3d 565, 573 (6th Cir. 2004)).

Defendants' assertion—that the existence of other pending cases requires the participation of individual members—is unsupported by citations. *See generally* Doc. No. 33 at PageID 229. However, the complaint only conclusively alleges that "neither the claims asserted nor the relief requested requires an individual member to participate in this suit." Doc. No. 1 at PageID 10. Again, it is in the interest of justice that that Court allow Plaintiffs to amend the complaint to explain why individual participation is not needed in this instance.

D. Ripeness

Finally, Defendants argue that Plaintiffs' claims are not ripe. Doc. No. 33 at PageID 230. A claim must be ripe for a federal court to have subject matter jurisdiction. *Doe v. Oberlin Coll.*, 60 F.4th 345, 355 (6th Cir. 2023). Ripeness is a justiciability doctrine "'drawn both from Article III limitations on judicial power and from prudential reasons refusing to exercise jurisdiction.'" *Ky. Press Ass'n, Inc. v. Ky.*, 454 F.3d 505, 509 (6th Cir. 2006) (quoting *Nat'l Park Hosp. Ass'n v. Dep't of the Interior*, 358 U.S. 803, 808 (2003)). The ripeness doctrine "is designed 'to prevent the courts, through premature adjudication, from entangling themselves in abstract disagreements.'" *Ky. Press Ass'n, Inc.*, 454 F.3d at 509 (6th Cir. 2006) (quoting *Thomas v. Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 580 (1985)). "A claim is ripe where it is 'fit for judicial decision' and where 'withholding court consideration' will cause hardship to the parties." *Hill v. Snyder*, 878 F.3d 193, 213 (6th Cir. 2017) (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967)). The Sixth Circuit has created a three-factor test to determine a claim's ripeness: "(1) the

likelihood of the alleged harm; (2) the sufficiency of the factual record 'to produce a fair adjudication of the merits of the parties' respective claims'; and (3) the resulting 'hardship to the parties if judicial relief is denied at this stage in the proceedings.'" *Oberlin Coll.*, 60 F.4th at 355 (quoting *Grace Cmty. Church v. Lenox Twp.*, 544 F.3d 609, 615 (6th Cir. 2008)).

Defendants assert that further factual development through the passage of time—to determine the prices of the drugs selected under the Program—is necessary for the issues to be fit for judicial decision on the merits. Doc. No. 33 at PageID 231. Additionally, they maintain that Plaintiffs will not suffer hardship if the Court withholds consideration of these issues because Plaintiffs cannot suffer a cognizable injury—if any—until the prices determined under the Program go into effect in 2026. *Id.* at PageID 230-31.

In response, Plaintiffs assert that Defendants have mischaracterized the claims. Doc. No. 50 at PageID 424. Plaintiffs contend that they are challenging the IRA's procedures, not the ultimate prices that will be set by the Secretary. *Id.* at PageID 424. Therefore, they argue, their claims are ripe because "[d]rugs will be selected for price controls in less than a week, and manufacturers will be forced to sign 'agreements'—on pain of an 'excise tax' penalty—within a month after that." *Id.* at PageID 424.

Plaintiffs must establish that their claims are ripe. *Oberlin Coll.*, 60 F.4th at 355. At the time the complaint was filed on June 9, 2023, it was unclear whether IMBRUVICA® would be selected for the Program. For the same reason that the complaint is wanting on the specifics of standing, it is in the interest of justice to afford Plaintiffs an opportunity to amend their initial pleading to demonstrate that each of their claims is ripe for review and justiciable, and that they have standing to plead those claims.

Therefore—to further clarify all issues of standing and ripeness—it is in the interest of justice that the Court grant Plaintiffs leave to amend their initial complaint. Consequently, the Court denies, at this early juncture in the litigation and without prejudice to renew, Defendants' motion to dismiss.

IV. Preliminary Injunction

Preliminary injunctions are "extraordinary remed[ies] never awarded as of right." *Winter v. Natural Resources Defense Council, Inc.*, 555 U.S. 7, 24 (2008) (citing *Munaf v. Green*, 553 U.S. 674, 689-90 (2008)). Courts should order preliminary injunctions "only if the movant carries his or her burden of proving that the circumstances clearly demand it." *Overstreet v. Lexington-Fayette Urban Cnty. Gov't*, 305 F.3d 566, 573 (6th Cir. 2002) (citing *Leary v. Daeschner*, 228 F.3d 729, 736 (6th Cir. 2000)).

To determine whether a preliminary injunction should issue, the Court must balance four factors: "(1) whether the movant has shown a strong likelihood of success on the merits; (2) whether the movant will suffer irreparable harm if the injunction is not issued; (3) whether the issuance of the injunction would cause substantial harm to others; and (4) whether the public interest would be served by issuing the injunction." *Id.* The harm to others "and the public interest factors 'merge when the Government is the opposing party.'" *Wilson v. Williams*, 961 F.3d 829, 844 (6th Cir. 2020) (quoting *Nken v. Holder*, 556 U.S. 418 (2009)). Sixth Circuit precedent dictates that "[t]hese factors are not prerequisites that must be met, but are interrelated considerations that must be balanced together." *Commonwealth v. Beshear*, 981 F.3d 505, 508 (6th Cir. 2020).

A. The Parties' Positions

Plaintiffs argue the first factor weighs in their favor because they are likely to succeed on

the merits of their due process claim. Doc. No. 29-1 at PageID 158.[6] Plaintiffs believe the Program—its procedure and participation mandates—is merely "strongarming" by another name, which threatens their ability to both: (1) participate in Medicare Part D and (2) remain profitable. *See generally id.* at PageID 161-62. The rest of their arguments supporting preliminary injunctive relief follow from that due process claim. *Id.* at PageID 165-67. Plaintiffs believe that members subject to the Program will suffer—and already have suffered—irreparable economic harm, and that this alleged unconstitutional program is not outweighed by any benefits and thus goes against the public interest. *Id.*

Defendants view Plaintiffs' due process claim as an insufficient basis for injunctive relief for a multitude of reasons. Doc. No. 34 at PageID 248. First, Defendants argue the Program cannot be confiscatory because participation in it, and in Medicare generally, is voluntary. *Id.* at PageID 249. Second, Defendants contend that the Fifth Amendment Due Process Clause does not protect property interests in the sale of a product—like a pharmaceutical drug—to the Government. *Id.* Third, regarding injunctive relief generally, Defendants argue Plaintiffs face no certain and immediate irreparable harm. *Id.* at PageID 257. Fourth, Defendants suggest the public interest disfavors injunctive relief. *Id.* at PageID 260. Finally, Defendants believe Plaintiffs' request is overbroad[7] and therefore does not satisfy the requirements necessary for injunctive relief.[8] *Id.*

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[6] Although Plaintiffs' Complaint raises four other claims, their motion for a preliminary injunction focuses only on their due process claim. Doc. No. 29-1 at PageID 149.

[7] Defendants' overbreadth argument references the handful of other pending lawsuits regarding the Program in district courts across the country. Doc. No. 34 at PageID 261; *see supra*, N. 3. Defendants believe issuing a preliminary injunction in this Court would—or, at least, could—"deprive Defendants of the benefits of prevailing against specific manufacturers." *Id.* Essentially, Defendants argue that granting injunctive relief, without specifying a narrow scope, may have a national impact. *Id.*

[8] The Court recognizes that nationwide injunctions are generally disfavored because granting them runs the risk of "tak[ing] the judicial power beyond its traditionally understood uses." *Arizona v. Biden*, 31 F.4th 469, 483-84 (6th Cir. 2022) (Sutton, J., concurring). However, the scope of any preliminary injunctive relief need not be addressed here, as Plaintiffs' motion for a preliminary injunction will not be granted.

B. Preliminary Injunction Analysis

i. Strong Likelihood of Success on the Merits of Plaintiffs' Due Process Claim

Because the Court, at this early juncture in the litigation, cannot tell with certainty whether or not Plaintiffs have standing to raise each of their claims, *see supra* p. 13, they necessarily cannot have a strong likelihood of success on the merits of their due process claim. As such, the extraordinary relief afforded by granting a preliminary injunction would be inappropriate in this instance. Assuming, *arguendo*, the Plaintiffs could now show standing, the Court will provide an analysis explaining why a preliminary injunction will not be granted in this case.

The Fifth Amendment of the United States Constitution protects individuals from deprivation by the federal government of "life, liberty, or property" without "due process of law." U.S. CONST., amend. V. To demonstrate a strong likelihood of success on the merits of a constitutional challenge at the preliminary injunction stage, Plaintiffs must demonstrate that "no set of circumstances exists under which [the Program] would be valid." *U.S. v. Salerno*, 481 U.S. 739, 745 (1987). So, to warrant injunctive relief, Plaintiffs must show that no set of circumstances exist where the Program would be constitutionally valid under the Fifth Amendment Due Process Clause. *Id.* They have not done so.

Plaintiffs rely heavily on *Mich. Bell Tel. Co. v. Engler*, 257 F.3d 587 (6th Cir. 2001) to show that the Program's price setting procedures will impose unconstitutional "confiscatory rates" on them. *See* Doc. No. 29-1 at PageID 149 (citing *Mich. Bell*, 257 F.3d at 592-595). In *Mich.Bell*, the Sixth Circuit considered whether two preliminary injunctions would be appropriate to enjoin a state government from enforcing provisions of a state statute that (1) abolished a certain fee imposed upon telephone customers and (2) froze telephone rates for certain providers. 257 F.3d at 589. The statute went into effect immediately when it was signed by the governor. *Id.* The

service providers sued under a due process theory, arguing the provisions were "facially unconstitutional because they [did] not provide a mechanism through which…providers may ensure that they receive a just and reasonable rate of return on their investment." *Id.*

The Sixth Circuit ultimately: (1) affirmed the district court's granting of a preliminary injunction regarding the fee imposed upon telephone customers and (2) reversed the district court's denial of a preliminary injunction as to the rate freeze. *Id.* at 600. The court justified this conclusion by finding the state statute, which compelled participation by the plaintiff telephone companies, denied them of their right to a "fair and reasonable rate of return." *Id.* This denial of a fair and reasonable rate of return subjected the plaintiffs to confiscatory rates, thereby violating their constitutional due process rights. *Id.* at 595.

Plaintiffs argue that the Program is analogous to the claims at issue in *Mich. Bell*. They conclude the Program will constrain its members to be subject to confiscatory rates if it moves forward. In *Mich. Bell*, the Sixth Circuit found a violation of due process rights where utility rates imposed by the State were so unreasonable and unjust that they were considered confiscatory. *Id.* at 593. The *Mich. Bell* opinion relied on *Duquesne Light Co. v. Barasch*, 488 U.S. 299 (1989), which held that "the Constitution protects utilities from being limited to a charge for their property serving the public which is so 'unjust' as to be confiscatory." *Id.* at 307 (citing *Covington & Lexington Turnpike Road Co. v. Sandford*, 164 U.S. 578, 597 (1896)).

Defendants argue that *Mich. Bell* is inapplicable because voluntary programs like Medicare cannot, as a matter of law, yield confiscatory rates. *See* Doc. No. 34 at PageID 249-253. The Court agrees.

It is true that "[p]rice control is 'unconstitutional…if arbitrary, discriminatory, or demonstrably irrelevant to the policy'" under a due process analysis. *In re Permian Basin Area*

Rate Cases, 390 U.S. 747, 769-770 (1968) (quoting *Nebbia v. People of N.Y.*, 291 U.S. 502, 539 (1934)). It is also true that, "[t]he Constitution does not guarantee the unrestricted privilege to engage in a business or to conduct it as one pleases." *Nebbia*, 291 U.S. at 527-28. Further, "the right to conduct a business, or to pursue a calling, may be conditioned" by regulation of such activity. *Id.* at 528.

The law established in the Sixth Circuit and beyond is clear: participation in Medicare, no matter how vital it may be to a business model, is a completely voluntary choice. *See Baptist Hosp. East v. Sec'y of HHS*, 802 F.2d 860, 869 (6th Cir. 1986) ("[P]articipation in the Medicare program is wholly voluntary. If any provider fears that its participation will drive it to insolvency, it may withdraw from participation"); *Livingston Care Center, Inc. v. U.S.*, 934 F.2d 719, 720 (6th Cir. 1991) ("Providers of health care who choose to participate in the federally sponsored program for the aged and disabled do so with no guarantee of solvency…those who opt to participate in Medicare are not assured of revenues") (citations omitted); *Minn. Ass'n of Health Care Facilities, Inc. v. Minn. Dep't of Public Welfare*, 742 F.2d 442 (8th Cir. 1984) ("Despite the financial inducement to participate in Medicaid, a nursing home's decision to do so is nonetheless voluntary"). Thus, the Program's eventual "maximum fair price" cannot be considered confiscatory because pharmaceutical manufacturers who do not wish to participate in the Program have the ability—practical or not—to opt out of Medicare entirely. *Baptist Hosp.*, F.2d 860 at 869. As there is no constitutional right (or requirement) to engage in business with the government, the consequences of that participation cannot be considered a constitutional violation. *Livingston Care*, 934 F.2d at 720. Because Plaintiffs are not legally compelled to participate in the Program—or in Medicare generally—they have not shown a strong likelihood of success on the merits of their due process claim. *See generally id.*; *Baptist Hosp.*, F.2d 860; *Minn. Ass'n*, 742 F.2d 442.

In light of these cases, and at this initial stage in the litigation process, it is too early to know—with the degree of certainty necessary for a preliminary injunction—that Plaintiffs have a strong likelihood of succeeding on the merits of their due process claim. Thus, this factor weighs in favor of Defendants.

ii. Irreparable Harm to Plaintiffs

For irreparable harm to meet the standard for a preliminary injunction, "the harm alleged must be both certain and immediate, rather than speculative or theoretical." *Mich. Coal. of Radioactive Material Users, Inc. v. Griepentrog*, 945 F.2d 150, 154 (6th Cir. 1991) (citing *Wis. Gas Co. v. Fed. Energy Regul. Comm'n*, 758 F.2d 669, 674 (D.C. Cir. 1985)). Economic loss generally "does not constitute irreparable harm, in and of itself." *State of Ohio ex rel. Celebrezze v. Nuclear Regulatory Com'n*, 812 F.2d 288, 290 (6th Cir. 1987) (citing *Wis. Gas Co. v. F.E.R.C.*, 758 F.2d 699, 674 (D.C. Cir. 1985)). "An injury is irreparable if it is not 'fully compensable by monetary damages.'" *S. Glazer's Distribs. of Ohio, LLC v. Great Lakes Brewing Co.*, 860 F.3d 844, 852 (6th Cir. 2017) (quoting *Obama for Am. v. Husted*, 697 F.3d 423, 436 (6th Cir. 2012)).

Plaintiffs argue irreparable harm is not only imminent or inevitable; it has already manifested. *See* Doc. No. 29-1 at PageID 165-66; Doc. No. 29-5 at PageID 187, ¶ 7. They allege AbbVie began allocating resources to prepare for the possibility[9]—and now reality[10]—of their pharmaceutical product IMBRUVICA® appearing on the CMS list of drugs subject to the Program. Doc. No. 29-5 at PageID 187, ¶ 7. Such resources include "devoting financial and

[9] When Plaintiffs filed their motion for preliminary injunctive relief (Doc. No. 29), Plaintiffs suspected, but could not be sure, that IMBRUVICA® would appear on the initial CMS list of drugs subject to the Program.
[10] On August 29, 2023, CMS released the first group of drugs that will be part of the Program. As Plaintiffs predicted, IMBRUVICA® was on that list. *See* Theresa C. Carnegie, Lauren M. Moldawer, *CMS Announces Drug List for Inflation Reduction Act Price Negotiations*, MINTZ, (Aug. 29, 2023). https://www.mintz.com/insights - center/ viewpoints/ 2801/ 2023 - 08 - 29 - cms - announces - drug - list - inflation-reduction-act-price.

human resources" to research the Program, its requirements, and procedures manufacturers should follow come October 2, 2023[11], if their product appears on the list. *Id.* Notably, the extent of this already-existing harm is unknown, as the record is bereft of any information regarding how much time, money, and other resources have been devoted to preparing for Program compliance. *See* Doc. No. 29-1 at PageID 165-66; Doc. No. 29-5 at PageID 187, ¶ 7. As Plaintiffs themselves point out, regardless of the outcome of their motion for a preliminary injunction, they would be unable to recover costs already expended preparing to comply with the Program. Doc. No. 29-1 at PageID 165 (citing *Kentucky v. U.S. ex rel. Hagel*, 759 F.3d 588, 599 (6th Cir. 2014) (arguing that "sovereign immunity bars the [court] from granting [plaintiffs] damages")). It is unclear to the Court, then, how granting the injunction would remedy any alleged injury that has already occurred. *Cf. id.*

Present harm aside, Plaintiffs' assertions of irreparable harm rest primarily on claims of future *economic* harms they may suffer absent the requested injunctive relief. Plaintiffs argue that the Program will specifically harm AbbVie. See Doc. No. 29-1 at PageID 165-66; Doc. No. 29-5 at PageID 185-192. In their belief, AbbVie's only choices are to (1) subject itself to "potentially confiscatory pricing," (2) suffer a penalty that will be "literally unbearable," or (3) withdraw from Medicare—none of which are realistic to AbbVie. Doc. No. 29-5 at PageID 191, ¶ ¶ 15-16. However, Plaintiffs acknowledge that, although they understand how negotiations under the Program will proceed, they do not know how the maximum fair price will be determined or what it will be. *See generally* Doc. No. 29-1 at PageID 154; Doc. No. 29-6 at PageID 194-97. As such,

[11] The Court specifies October 2, 2023 as the implementation date of policies and procedures associated with the Program because October 1, 2023 is the deadline for manufacturers to opt in or out of the Program; compliance measures begin October 2. *See* Doc. No. 29-1 at PageID 152.

there is no certainty that any harm will occur if the Program continues and Plaintiffs comply with it. *See generally* Doc. No. 29-1 at PageID 152; Doc. No. 34 at PageID 258-59.

The Court is not convinced that granting Plaintiffs preliminary injunctive relief will protect them from imminent and irreparable harm. *Cf. Mich. Bell*, 257 F.3d at 598. Any economic harm—which, on its own, is insufficient to satisfy this prong of a preliminary injunction analysis—will not occur for years in the future. *See* Doc. No. 34 at PageID 247 (citing 42 U.S.C. §§ 1320f(b); 1320f-2(a)); *Nuclear Regulatory Comm'n*, 812 F.2d at 280 (citing *Wisconsin Gas Co.*, 758 F.2d at 674). Predictions regarding the ultimate "maximum fair price" decided by the Secretary cannot be made with the amount of accuracy that would necessitate a finding of irreparable harm. See *Id.* at PageID 258. Further, the Court does not know what groups will even suffer this alleged possible harm. *See generally* Doc. No. 29-1 at PageID 156. Each Plaintiff individually states that at least some of its members will be affected by the Program (*See* Doc. No. 29-2 at PageID 173, ¶ 12; Doc. No. 29-3 at PageID, 178, ¶ 12; Doc. No. 29-4 at PageID 183, ¶ 12; Doc. No. 29-6 at PageID 197, ¶ 12), but the *only* member whom Plaintiffs now identify is AbbVie (and its subsidiary, Pharmacyclics), through its product, IMBRUVICA®. *See* Doc. No. 29-1 at PageID 157, 165-66; Doc. No. 29-5 at PageID 185-192.

Finally, Plaintiffs discuss the possibility of harm to their reputation amongst consumers. See Doc. No. 29-1 at PageID 165; Doc. No. 29-6 at PageID 297, ¶ 13. They argue that increasing prices on other products will be needed to negate the possible loss in revenue from the Program. Plaintiffs contend, "the resulting loss of customer goodwill would be 'difficult to compute' and this 'amounts to irreparable injury.'" Doc. No. 29-1 at PageID 165 (quoting *Mich. Bell*, 257 F.3d at 589). This argument, however, oversimplifies the pharmaceutical industry and its relationship with consumers. Comparing utility providers and rates (as was the case in *Mich. Bell*) to

pharmaceutical companies that are manufacturers is misleading. *See Garelick v. Sullivan*, 987 F.2d 913, 916 (2d Cir. 1984) ("Because utilities generally are compelled to employ their property to provide services to the public, the Fifth Amendment requires regulators to provide utilities with reasonable compensation for their services. By contrast, where a service provider voluntarily participates in a price-regulated program or activity, there is no legal compulsion to provide service") (citations omitted).

At this point, the harm alleged is not immediate, and it is too speculative to stop the Program through preliminary injunctive relief. This factor, therefore, weighs in favor of Defendants.

iii. Harm to the Public and Promotion of the Public Interest

As noted above, the third and fourth preliminary injunction factors merge when the Government is the opposing party. *Wilson*, 961 F.3d at 845. Because Plaintiffs, at this early point in the litigation, cannot clearly show that: (1) they will succeed on the merits of their due process claim; and (2) they will likely suffer irreparable injury absent injunctive relief, the Court does not have to continue its inquiry. *See D.T. v. Sumner Cnty. Schools*, 942 F.3d 324, 327 (6th Cir. 2019) ("When one factor is dispositive, a district court need not consider the others") (citing *NHL Players' Ass'n v. Plymouth Whalers Hockey Club*, 325 F.3d 712, 717 (6th Cir. 2003)).

Although the Court is not required to reach the last two merged factors, it will briefly do so. Plaintiffs argue not only an absence of harm to others and the public interest in the event injunctive relief is granted, but further suggest that issuing injunctive relief will *promote* the public interest because "the public is certainly interested in the prevention of enforcement of ordinances which may be unconstitutional." *Planned Parenthood Ass'n of Cincinnati, Inc. v. City of Cincinnati*, 822 F.2d 1390, 1400 (6th Cir. 1987). However, as explained above, Plaintiffs have

not shown—and the Court cannot determine—whether or not there is a strong likelihood the Program is or is not unconstitutional. Because the likelihood of success on the merits of the constitutional claims here is uncertain, the public interest is not endangered in the absence of preliminary injunctive relief. *See Overstreet*, 305 F.3d 566, 579 (finding that the public interest was promoted by denying a request for preliminary injunctive relief where plaintiff could not demonstrate violation of a constitutional right). Plaintiffs' interests do not outweigh the public interest.

Plaintiffs have not met their burden of establishing that the extraordinary remedy of a preliminary injunction must issue. Accordingly, Plaintiffs' request for injunctive relief is denied.

V. Conclusion

For the foregoing reasons, the Court: (1) **DENIES** Defendants' motion to dismiss (Doc. No. 33); and (2) **DENIES** Plaintiffs' motion for a preliminary injunction (Doc. No. 29). It is hereby **ORDERED** that Plaintiffs shall file an amended complaint by October 13, 2023. Defendants shall have until October 27, 2023 to renew their motion to dismiss if they so choose. This matter is **REFERRED** to the assigned Magistrate Judge to supervise discovery. By October 13, 2023, the parties shall file a proposed Fed. R. Civ. P. 26(f) calendar for the Court's review, after which the Court plans to issue a scheduling order pursuant to Fed. R. Civ. P. 16(b).

IT IS SO ORDERED.

September 29, 2023

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