UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

DAYTON AREA CHAMBER OF COMMERCE *et al.*, Plaintiffs, v. XAVIER BECERRA *et al.*, Defendants.	Civil Action No. 3:23-cv-00156-MJN-PBS Judge Michael J. Newman Magistrate Judge Peter B. Silvain, Jr.

DEFENDANTS' REPLY IN SUPPORT OF THEIR MOTION TO DISMISS

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INTRODUCTION

Plaintiffs beseech this Court to issue a hurried, unprecedented, and facial constitutional ruling that would stop the Inflation Reduction Act's Medicare Drug Price Negotiation Program before it gets off the ground—two and a half years before any price changes even take effect. But tellingly, Plaintiffs do not dispute any of the core premises of Defendants' motion to dismiss: (1) that manufacturer revenue may ultimately be flat (or even higher) if a manufacturer's drug is selected for negotiation; (2) that the only member of any of the Plaintiff associations identified in the complaint (AbbVie) is *not* the manufacturer of Imbruvica for purposes of the Negotiation Program but merely owns shares in a separate corporation (Pharmacyclics) that is; and (3) that drug manufacturers who have brought their own lawsuits in other districts—four of them at the time of Defendants' motion to dismiss, six now—cannot be allowed to simultaneously litigate their claims here by proxy, giving Plaintiffs' member-manufacturers multiple bites at the same apple. Each of those undisputed premises is independently sufficient to grant Defendants' motion.

Plaintiffs' latest filings give this Court a peek behind the curtain of the Chamber of Commerce's strategy of policymaking-by-litigation. Nowhere do Plaintiffs forthrightly acknowledge what is now obvious (and, again, apparently undisputed): that "critical portions of Plaintiffs' submissions—including their sworn declarations—appear to be inaccurate," by attributing to their one identified member (AbbVie) a series of regulatory responsibilities that will actually fall on a different corporation (Pharmacyclics). Defs.' Mot. to Dismiss ("MTD") at 13 n.2, ECF No. 33. Plaintiffs instead offer some breaking news: suddenly, both AbbVie *and* Pharmacyclics are "members of Plaintiffs." Pls.' Opp'n to Mot. to Dismiss ("Pls.' Opp'n") at 13, ECF No. 50. But one has to read to paragraph 28 of Plaintiffs' "supplemental" declaration to fully appreciate the jurisdictional house of cards on which this entire lawsuit now rests: Pharmacyclics—a corporation headquartered in Sunnyvale, California—apparently "joined" the Dayton Area Chamber of Commerce on an unspecified date "in August 2023," Suppl. Decl. of Michael C. Staff ¶ 28, ECF No. 50-1—presumably after the filing of Defendants' motion to dismiss on August 11, and certainly (and more importantly) after the filing of the complaint on July 14.

Plaintiffs' scramble to belatedly patch up these jurisdictional defects is revealing—but more importantly, it is also ineffective. That is because "[i]t has long been the case that 'the jurisdiction of the court depends upon the state of things at the time of the action brought.'" *Grupo Dataflux v. Atlas Global Grp.*, 541 U.S. 567, 570 (2004) (quoting *Mollan v. Torrance*, 22 U.S. (9 Wheat.) 537, 539 (1824))—another point that Plaintiffs do not dispute. So whatever Pharmacyclics's newly minted association membership might mean for future litigation between these parties, it has no bearing on the question raised by Defendants' motion to dismiss: whether the operative complaint is sufficient to carry Plaintiffs' burden to establish subject-matter jurisdiction.

Even if some of Defendants' arguments for dismissal could conceivably be affected by the filing of a *new* complaint—a possibility that Plaintiffs have expressed no interest in—that would not be true for others. After all, companies that actually manufacture and sell prescription drugs—including some that are members of at least one of these Plaintiffs—continue to file their own lawsuits, bringing essentially the same claims that Plaintiffs bring here, creating a risk of just the sort of remedial quagmire that the associational standing doctrine is designed to prevent. And although Plaintiffs originally offered soaring rhetoric about the end of the pharmaceutical industry as we know it, they have now retreated to the far more modest claim that it is (in their view) "unlikely . . . that a manufacturer" would "benefit[] in some way from the IRA." Pls.' Opp'n at 10 n.8. But that uncertainty over the financial effects of price negotiation on manufacturers—yet again, an area of apparent common ground between the parties—defeats, rather than supports, their claim to Article III standing (and also illustrates why their claims are unripe). Defendants agree that it is *possible* that some manufacturers will eventually earn lower profits after negotiated prices actually go into effect in 2026. But "allegations of *possible* future injury are not sufficient" to establish jurisdiction. *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013) (internal quotation marks omitted).

To Plaintiffs, these are apparently all just "hyper-technical argument[s]" that the Court should regard as "much ado about nothing." Pls.' Opp'n at 13. But to the Supreme Court, "Article III standing is not merely a troublesome hurdle to be overcome if possible so as to reach the 'merits' of a lawsuit which a party desires to have adjudicated; it is a part of the basic charter promulgated by the

Framers of the Constitution at Philadelphia in 1787." *United States v. Texas*, 143 S. Ct. 1964, 1969 (2023) (internal quotation marks omitted). And Defendants' prudential (*i.e.*, non-jurisdictional) arguments for dismissal are firmly grounded in bedrock principles of equity, justiciability, and respect for the corporate form. These principles cannot be cast aside just because the pharmaceutical industry wants to protect the status quo—in which Medicare beneficiaries and the American taxpayer pay more than anyone else on the planet for the same prescription drugs.

Plaintiffs' complaint should be dismissed.

ARGUMENT

I. Plaintiffs Lack Article III Standing

A. Plaintiffs' alleged injuries are speculative.

1. Defendants' motion to dismiss explained—both with citations to the key statutory provisions and with a detailed explanatory hypothetical—why "it is possible that manufacturers will agree to prices that result in flat or even *greater* revenue for them." MTD at 8–10. Plaintiffs mostly respond with rhetoric and generalities—but, critically, do not dispute the core premise. That alone is a substantial shift: the complaint professed certainty that "pharmaceutical manufacturers" would reluctantly agree "to sell their drugs at unfairly low, government-mandated prices," and that plummeting prices would surely "disrupt and endanger vital research and development" and cause a variety of other "catastrophic" consequences. Compl. ¶¶ 6, 102, 184, ECF No. 1. Now, Plaintiffs have fallen back to a far less dramatic claim: that manufacturers face only an "ominous *forecast*," because (according to Plaintiffs) it is "*unlikely* . . . that a manufacturer" would "benefit[] in some way from the IRA." Pls.' Opp'n at 9, 10 n.8 (emphases added).

For the reasons explained in Defendants' motion, it is, in fact, quite possible that manufacturers will be unharmed or even benefit from inclusion in this Program. MTD at 8–10. And although it is difficult to precisely forecast all of the winners and losers (if any) before the statute has been implemented fully, Plaintiffs bear the burden to identify at least one named member that faces an actual or imminent Article III injury—that is, an identified member's injury "must be '*certainly* impending,' not merely a '*possible* future injury.'" *Weiser v. Benson*, 48 F.4th 617, 623 (6th Cir. 2022)

(quoting *Clapper*, 568 U.S. at 409, 411)).[1] So even if Plaintiffs had shown "a statistical probability that *some* of [their] members are threatened with concrete injury," that would not be enough. *Summers v. Earth Island Inst.*, 555 U.S. 488, 497 (2009) (emphasis added) (rejecting the "statistical probability" theory of associational standing as a "novel approach" that "would make a mockery" of Article III); *see infra* Section I.B.1 (discussing Plaintiffs' failure to identify any member with standing).[2]

Setting aside the uncertain effects on manufacturer revenue from negotiated prices, Defendants have also explained that "a drug being selected for negotiation will also trigger" some "unequivocal *benefits* to its manufacturer: in particular, an exemption from the otherwise large and growing obligations on manufacturers to provide discounts on brand-name drugs and biologics used by Medicare Part D beneficiaries." MTD at 10. In response, Plaintiffs again do not dispute that this is how the statute works—nor could they. Instead, they protest glibly that "no manufacturer would voluntarily take a large price cut to avoid a small price cut." Pls.' Opp'n at 10. Well, sure—but Plaintiffs never even allege that the *possible* losses to manufacturers (if any) caused by price negotiations will actually be larger than the *certain* savings from their new exemption from the legal obligation to pay these discounts. Without a plausible and specific allegation to that effect, the Court has no basis to assume that *any* manufacturer will be worse off once the dust settles from these statutory changes.[3]

The Court need not take the government's word for it. Just last week, Lars Fruergaard Jørgensen, the CEO of Novo Nordisk—a drug manufacturer that appears to be a member of Plaintiff

[1] Plaintiffs cite *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158–59 (2014), for the proposition that a "substantial risk" of harm is enough, Pls.' Opp'n at 5, but that case is about the unique standing issues raised by pre-enforcement challenges to criminal (or punitive) laws. As more recent Sixth Circuit authority confirms, Plaintiffs in a case like this one must show a "*certainly* impending" future injury. *See Weiser*, 48 F.4th at 623 (quoting *Clapper*, 568 U.S. at 409).

[2] With respect to Imbruvica in particular, Plaintiffs do cite one article, which (using data from 2020) provides an estimated comparison of hypothetical ceiling prices and rebates in an effort to estimate possible savings *to Medicare* for the first negotiation cycle. *See* Pls.' Opp'n at 10 n.6. But that article does not include any comprehensive effort to forecast actual financial outcomes *for manufacturers* of selected drugs, which is the key question for purposes of Article III standing.

[3] Plaintiffs insist (only in a one-sentence footnote), that it would "not defeat standing" even if "a manufacturer benefited in some way" from the IRA. Pls.' Opp'n at 10 n.8. Even if this argument had been preserved, *but see, e.g.*, *Moorer v. Baptist Mem'l Health Care Sys.*, 398 F.3d 469, 487 (6th Cir. 2005) (argument waived because it appeared only "[i]n a single sentence in a footnote"), the principle that Plaintiffs are vaguely referencing applies only "once injury is shown," Pls.' Opp'n at 10 n.8. Plaintiffs have not shown any injury here, for all the reasons explained above. Furthermore, the benefits that manufacturers of selected drugs will reap do not derive from other, otherwise unrelated features of their "relationship with the defendant," *id.*—those benefits come directly from the IRA itself. *See* 42 U.S.C. § 1395w-114c(g)(2)(B).

the U.S. Chamber of Commerce[4]—answered questions about the Drug Price Negotiation Program in a televised interview. When asked about the selection of Novo Nordisk's insulin drug (NovoLog) for negotiation, Mr. Jørgensen explained that, because of "significant rebates" already in place, the selection of NovoLog for the first round of price negotiations is "not something that affects our business" and is "not something that is going to significantly impact our financials." *Novo Nordisk CEO: Not exactly clear yet what Medicare price negotiations will do for financials*, YouTube (Aug. 30, 2023), https://www.youtube.com/watch?v=5dRf9Gx78n8. In other words, the scenario described in Defendants' motion—that drug manufacturers might not be worse off, even if Medicare achieves some savings from price negotiation—is not just some purely theoretical possibility, but rather is exactly what at least one pharmaceutical CEO expects to happen.

Attempting to resuscitate their claims of financial harm, Plaintiffs turn to a hodgepodge of other, unorthodox sources of circumstantial evidence, none of which will be useful to the Court—for the simple reason that this "evidence" is at least as consistent with Defendants' theory as Plaintiffs'. For example, Plaintiffs now try to spin to their benefit the facts that "drug manufacturers lobbied hard against the IRA's price controls" and that, after those efforts failed, "manufacturers have filed several suits around the country challenging the statute." Pls.' Opp'n at 8–9 (internal quotation marks omitted). But there is nothing surprising about the largest lobbying enterprise in the country, or some of the largest drug manufacturers in the world, trying to leverage whatever power they can muster to prevent an outcome that *might* cause at least *some* manufacturers financial harm. There is a constitutional right to lobby against a policy that risks only a "possible future injury"—but there is a constitutional bar against suing over one. *Clapper*, 568 U.S. at 409 (emphasis omitted).

Likewise, the President's high-level statements like "[w]e beat Pharma this year, and it mattered," Pls.' Opp'n at 9, refer to that same unsuccessful lobbying campaign; nothing about those statements is at all inconsistent with Defendants' more granular explanation of why Plaintiffs' theory of injury ignores critical uncertainties. The same is true of Secretary Becerra's statement of intent to

[4] *See* Scott Hall, U.S. Chamber of Commerce, *Novo Nordisk Solutions During the Pandemic* (Sept. 2, 2021), https://perma.cc/3L5D-TPM8.

"continue to attack these high prescription drug prices." *Id.* Even assuming that remark was solely about the Negotiation Program (rather than other ongoing policy efforts), Defendants have already explained why Medicare beneficiaries could achieve significant savings—even if manufacturers see flat or even higher revenues and (nominal) prices fall. *See* MTD at 9 ("These rebates mean that manufacturers' revenues are lower—sometimes significantly—than their drugs' stated prices.").

2. Rather than establishing that they actually face some "*certainly* impending" financial harm, *Clapper*, 568 U.S. at 409, Plaintiffs make a remarkable pivot, protesting that their lawsuit is not about financial harm—or even drug prices—at all. They go so far as to declare that the government is "misconstruing the nature of Plaintiffs' claims" by suggesting that they are concerned about "*anticipated* future prices." Pls.' Opp'n at 1, 19. Plaintiffs insist that it "is irrelevant" that their unnamed members might ultimately profit from the selection of a drug, because that result will have sprung from what they consider to be "an unconstitutional process," and that is enough. *Id.* at 8. Plaintiffs are wrong—both about the contents of their own complaint, and on the law.

First, as for the complaint, even a cursory review will confirm that Plaintiffs' alleged theory of injury *is* dominated by "a fear that their members will reluctantly agree to 'prices so low as to deprive manufacturers of their property without due process of law.'" MTD at 8 (quoting Compl. ¶ 167). Although Plaintiffs describe those price-related fears in many ways—*e.g.*, prices that are "unfairly low," Compl. ¶ 6, or "especially low," *id.* ¶ 170, or "rock-bottom," *id.* ¶ 195, or "below-market," *id.* ¶ 217—Plaintiffs' theory of injury unavoidably turns on their assertion that the Secretary will have broad discretion and that, as a result, manufacturers will ultimately face prices that Plaintiffs think are too low. In fact, in the only paragraph of the complaint that discusses AbbVie—Plaintiffs' only named member—they allege little more than that AbbVie will reluctantly "'agree' to the Secretary's unreasonably low 'maximum fair price,' which will be substantially lower than current market prices for IMBRUVICA." *Id.* ¶ 32. In total, the words "price," "prices," and "pricing" appear in the complaint over 250 times. A few dozen of the more relevant examples are sampled in the margin.[5]

[5] *See, e.g.*, Compl. ¶ 6 ("unfairly low, government-mandated **prices**"); *id.* ¶ 9 ("a **price** as low as he or she chooses"); *id.* ¶ 12 ("**prices** that are reasonable and market-based, rather than confiscatory or arbitrary"); *id.* ¶ 17 ("unchecked power to the Secretary to set a **price** as low as he or she wishes"); *id.* ¶ 18 ("review to ensure that the **prices**

Plaintiffs protest that they "are not challenging any *specific* prices that will be set by the agency," Pls.' Opp'n at 7 (emphasis added)—which is correct, at least in a sense. After all, those prices have not yet been negotiated, and won't be known for another year or so. But that mismatch—between Plaintiffs' legal theory of possible financial harm caused by "unreasonably low" prices, Compl. ¶ 32, and the genuine uncertainty that remains about those prices—creates Plaintiffs' standing problem. (It also shows why their claims are not ripe, *see infra* at 18-20, and why their facial challenge must fail.)

Second, on the law, Plaintiffs seem to think that, because "their suit is a facial challenge to" what they describe as an "unconstitutional price-control regime legislated by Congress," Pls.' Opp'n at 1, they need not show any concrete injury, other than exposure to allegedly unconstitutional procedures. That is incorrect—"[n]o concrete harm, no standing." *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2214 (2021). In particular, the Supreme Court has "never held a litigant who asserts [a procedural] right is excused from demonstrating that it has a 'concrete interest that is affected by the deprivation' of the claimed right." *Dep't of Educ. v. Brown*, 143 S. Ct. 2343, 2351 (2023) (quoting *Summers*, 555 U.S. at 496). To the contrary: "the 'deprivation of a procedural right without some concrete interest that is affected by the deprivation—a procedural right *in vacuo*—is insufficient to create Article III standing.'" *Id.* at 2351–52 (quoting *Summers*, 555 U.S. at 496).

Plaintiffs stitch together a few quotes from the Sixth Circuit's opinion in *Rice v. Village of Johnstown*, in an effort to suggest that being "subject to the [IRA's] allegedly unconstitutional process" is enough to "demonstrate[] injury-in-fact." Pls.' Opp'n at 7 (quoting 30 F.4th 584, 591 (6th Cir. 2022)). But that case stands for the opposite proposition: that "merely stating a procedural injury is

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set by HHS are reasonable and fair"); *id.* ("confiscatory or arbitrary **prices**"); *id.* ¶ 22 ("HHS's **price** controls will dramatically reduce manufacturers' ability to invest in research and development"); *id.* ¶ 32 ("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.* ¶ 52 ("regardless of whether there is any basis for thinking that those drugs are **overpriced**"); *id.* ¶ 71 ("whatever low **price** HHS chooses"); *id.* ¶ 80 ("Each alternative results in a price well below the market **price**."); *id.* ("40% to 75% of that net **price** is a very low **price**"); *id.* ¶ 84 ("CMS's **price** controls will lower net **prices**"); *id.* ¶ 86 ("The Secretary aims for the lowest **price**"); *id.* ¶ 149 ("fix **prices** at the 'lowest' level"); *id.* ¶ 161 ("expectations that they will be able to sell their drugs at a reasonable **price**"); *id.* ¶ 164 ("far below market **prices**"); *id.* ¶ 166 ("unconstitutionally confiscatory and arbitrary **prices**"); *id.* ¶ 167 ("**prices** so low as to deprive manufacturers of their property without due process of law"); *id.* ¶ 170 ("likely to face 'maximum fair **prices**' that are unfairly low and arbitrary"); *id.* ("especially low 'maximum fair **prices**'"); *id.* ¶ 173 ("**prices** as low as it wants"); *id.* ¶ 195 ("whatever rock-bottom **price** the Secretary dictates"); *id.* ¶ 217 ("below-market **prices** set by the government") (all emphases added).

not enough" for Article III standing, even on a procedural-due-process claim. *Rice*, 30 F.4th at 591 (emphasis added) (quoting *Summers*, 555 U.S. at 496). There, the Rice family's "procedural injury" was "tied to the family's economic interest in developing its property," and the Sixth Circuit concluded both (1) that the "family's application was subject to the [agency's] allegedly unconstitutional process" *and* (2) that the "outcome" of that process actually "affected the family's ability to develop its land." *Id.* Plaintiffs here have (at most) alleged the former sort of injury, a procedural right *in vacuo*—not the latter, a "concrete interest that is affected by the deprivation." *Id.* Without both, Plaintiffs' theory of procedural injury just doesn't work, as a matter of black-letter law.[6]

For similar reasons, Plaintiffs' procedural-injury "argument is at odds with the rule that '[p]rocess is not an end in itself.'" *Town of Castle Rock v. Gonzales*, 545 U.S. 748, 771 (2005) (quoting *Olim v. Wakinekona*, 461 U.S. 238, 250 (1983)). Instead, "[i]ts constitutional purpose is to protect a *substantive* interest to which the individual has a legitimate claim of entitlement." *Id.* (emphasis added). "As succinctly stated by the Sixth Circuit, '[t]here is no due process right to due process.'" *Lee v. Univ. of Michigan-Dearborn*, No. 5:06-cv-66, 2007 WL 2827828, at *6 (W.D. Mich. Sept. 27, 2007) (quoting *Bell-Bay v. Luna*, 142 F.3d 431 (6th Cir. 1998)); *see Seal v. Morgan*, 229 F.3d 567, 574 (6th Cir. 2000) ("There is no abstract federal constitutional right to process for process's sake."). These procedural-due-process principles cannot be squared with Plaintiffs' theory of injury, in which complaints about procedures, standing alone, make any claim "instantly cognizable" in federal court, Pls.' Opp'n at 7—even if there is no underlying "substantive interest" at stake, *Castle Rock*, 545 U.S. at 771.

[6] Plaintiffs also cite two thirty-year-old Sixth Circuit cases for the idea that their claims are "instantly cognizable" in federal court just because they challenge government procedures as unconstitutional. Pls.' Opp'n at 7. Plaintiffs overread what those cases meant in the 1990s, but, in any event, neither is good law today. *Compare Seguin v. City of Sterling Heights*, 968 F.2d 584, 588 (6th Cir. 1992) (interpreting the scope of an exception to *Williamson County Regional Planning Commission v. Hamilton Bank,* 473 U.S. 172 (1985)), *and Nasierowski Bros. Inv. Co. v. City of Sterling Heights*, 949 F.2d 890, 894 (6th Cir. 1991) (same), *with Knick v. Twp. of Scott*, 139 S. Ct. 2162, 2179 (2019) ("*Williamson County* is overruled."). Even on their own terms, in each of those cases, the government had taken a concrete step that actually imposed a real-world injury on the plaintiff. For example, in *Nasierowski*, a city had adopted a zoning ordinance that "exert[ed] a severely detrimental impact on his ability to use the property in a manner consistent with his legitimate expectations," and that "in and of itself inflicted immediate injury." 949 F.2d at 895. Plaintiffs also cite *Axon Enterprises, Inc. v. FTC*, but the rule announced in that case applies only to certain "extraordinary claims" that are "fundamental, even existential" to the structure of a federal agency. 598 U.S. 175, 180 (2023). That "extraordinary" factual predicate is missing here—none of Plaintiffs' claims "challenges . . . the structure or very existence of an agency," which was the key feature of *Axon* (a case about *Thunder Basin* channeling of an Appointments Clause claim, issues with no connection to this case). *Id.* at 189.

3. Unable to meaningfully dispute that their theory of financial harm is both plagued by critical uncertainties and central to their complaint, Plaintiffs now throw in various alternative, miscellaneous theories of injury. None has merit.

Plaintiffs first complain about preparatory work, asserting that "AbbVie has already incurred significant costs to comply with the IRA's burdensome and data-intensive requirements." Pls.' Opp'n at 5. But the sorts of activities that Plaintiffs reference are routine corporate minutiae like "the '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.'" Pls.' Opp'n at 6 (emphasis added) (quoting CMS, Medicare Drug Price Negotiation Program: Revised Guidance 20 (June 30, 2023), https://perma.cc/K6QB-C3MM ("Revised Guidance")). Plaintiffs cite no authority for the idea that preparing for possible future legal obligations by (1) having a meeting, (2) reading a statute, or (3) starting to gather information for "potential" submission to the government qualifies as the sort of "physical, monetary, or cognizable intangible harm traditionally recognized as providing a basis for a lawsuit in American courts." *TransUnion*, 141 S. Ct. at 2206. Defendants likewise are aware of no such authority. These are not concrete and cognizable Article III injuries; they are banal features of office life, especially in a heavily regulated industry like this one.

More fundamentally, these activities were not "requirements" at all. Plaintiffs refer to the sensible suggestion in CMS's revised guidance that at least some manufacturers "may" need to take some steps "to prepare for the possibility that a drug that they manufacture will be included on the selected drug list." Revised Guidance at 9. But there were no legal *obligations* to do so, and no legal consequences for refusing. On this issue, Plaintiffs misread a passage in the revised guidance, which refers to "the complexity of the preparation that *must be undertaken in advance* of the publication of the selected drug list by September 1, 2023." Pls.' Opp'n at 5 (quoting Revised Guidance at 20) (emphasis added by Plaintiffs). But that quote comes from a discussion about the "complexity of the preparation that must be undertaken" *by CMS*—not by manufacturers. Revised Guidance at 20.

To be sure, it may have been wise for *Pharmacyclics* to do some preparation ahead of time, given the prediction (which turned out to be correct[7]) that its drug, Imbruvica, would be selected for negotiation—but that sort of prudence cannot be the basis for a federal lawsuit. *See TransUnion*, 141 S. Ct. at 2206. And *AbbVie* was certainly not obligated (or even encouraged) to do anything at all, because no drug for which it holds the new drug application (NDA) was selected. So, for example, even if *some* "manufacturers must submit" certain "information to CMS" in the coming months, Pls.' Opp'n at 2, 6, AbbVie isn't one of them. And although Pharmacyclics is the only relevant company for purposes of these preparatory activities, AbbVie (as the only member named in the complaint) is the only relevant company for purposes of associational standing. *See infra* at 12-16.

Plaintiffs also protest that Defendants "ignore[] the impending First Amendment injury to Plaintiffs' members" that will be caused "by compelling them to voice the government's (misleading) talking points." Pls.' Opp'n at 6. That sentence is followed by no citation to any statutory provision (nor to CMS guidance)—because no such requirement exists. What Plaintiffs may have in mind is what they described in their complaint as a "gag order" in CMS's *proposed* initial guidance, which (in Plaintiffs' words) would have "purport[ed] to prohibit manufacturers from telling the truth about the 'negotiations.'" Compl. ¶ 113. That (uncharitable) description of the *proposed* initial guidance aside, there is no such provision in the revised guidance. Now, it is clear that manufacturers "may choose to publicly disclose information regarding any aspect of the negotiation process at any time." Revised Guidance at 37. Plaintiffs have failed to update their rhetoric to match updates to CMS guidance.

In any event, there is an important reason why Plaintiffs describe their alleged First Amendment injury as affecting "Plaintiffs' members" only in the abstract, without actually identifying any of those members. Pls.' Opp'n at 6. That is because, even accepting Plaintiffs' First Amendment theory in its entirety, the sort of compelled-speech concerns that Plaintiffs are purportedly worried about would (at most) affect *Pharmacyclics*, not AbbVie—after all, AbbVie will not be asked to sign any negotiation or pricing agreements. *See infra* at 13. So those alleged injuries are irrelevant here. And

[7] *See* CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026* (Aug. 29, 2023), https://perma.cc/9ZSM-9QAG (selecting Eliquis, Jardiance, Xarelto, Januvia, Farxiga, Entresto, Enbrel, Imbruvica, Stelara, and Fiasp/NovoLog).

they are even more obviously irrelevant to Plaintiffs' motion for a preliminary injunction, for the straightforward reason that Plaintiffs did not seek preliminary relief on their First Amendment claim. *See* Defs.' Opp'n at 7 n.1, ECF No. 34 (citing *Heid v. Mohr*, 2020 WL 13561751, at *5 (6th Cir. 2020)).

B. Plaintiffs lack associational standing.

Plaintiffs' efforts to salvage their assertions of associational standing fare no better. "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 v. Washtenaw Cnty. Cmty. Mental Health*, 900 F.3d 250, 254–55 (6th Cir. 2018) (citing *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977)). Plaintiffs still fail to satisfy the first and third requirements.

1. Plaintiffs have not identified any member with Article III standing.

Plaintiffs do not dispute that they failed to identify any member of the Ohio or Michigan Chambers in their complaint, which is reason enough to dismiss those Plaintiffs. *See* MTD at 11–12. As to the U.S. Chamber and Dayton Area Chamber, Plaintiffs' assertions regarding AbbVie—and the allegations in their supplemental declaration—confirm, rather than refute, that they lack standing.

a. Plaintiffs correctly acknowledge in their preliminary-injunction reply that, "[t]o be sure, an association must identify at least one affected member to demonstrate standing," Pls.' Reply at 20, ECF No. 49—but then they suggest the opposite in their motion-to-dismiss opposition, Pls.' Opp'n at 13. They had it right the first time.

In their opposition, Plaintiffs contend that "it is not clear" that they are required to "nam[e]" an individual member. *Id.* But they rely on mischaracterized dicta from a single inapposite and out-of-circuit case, *National Council of La Raza v. Cegavske*, 800 F.3d 1032 (9th Cir. 2015). In *National Council*, the Ninth Circuit held that the plaintiff organizations had direct *organizational* standing (a distinct theory that Plaintiffs do not assert here). *Id.* at 1039–41. It then observed that the plaintiffs had also alleged associational standing, and it noted in dicta that it was "not convinced that . . . an injured member of an organization must *always* be specifically identified." *Id.* at 1041 (emphasis added).

What matters here is that Plaintiffs cannot overcome the unequivocal directive of the *Sixth* Circuit, as correctly summarized in Plaintiffs' preliminary-injunction reply: to establish associational standing, each Plaintiff "must show that one of its *named members*" has standing. *Waskul*, 900 F.3d at 255 (emphasis added); *see also Summers*, 555 U.S. at 498 ("[T]he law of organizational standing . . . require[s] plaintiff-organizations to make specific allegations establishing that at least one identified member had suffered or would suffer harm."); *accord* Pls.' Reply at 20. Plaintiffs have not done so.

b. Plaintiffs now confirm, for the first time, that Pharmacyclics (an AbbVie subsidiary) is a distinct corporation and holds all the NDAs for Imbruvica—not AbbVie. *See* Suppl. Decl. ¶¶ 5, 12. Pharmacyclics is therefore "the manufacturer" with which CMS will negotiate a price for Imbruvica—not AbbVie. 42 U.S.C. § 1320f-2(a)(1); *see* Revised Guidance at 118. Plaintiffs make clear, moreover, that Pharmacyclics was not a member of any Plaintiff association when the complaint was filed. *See* Suppl. Decl. ¶ 28. Although Pharmacyclics—a separate "company based in the Bay Area, California," https://www.pharmacyclics.com—appears to have taken a sudden interest in the Ohio business community by joining the Dayton and Ohio Chambers just last month, such post-filing developments cannot retroactively fill jurisdictional gaps in the complaint.[8] Suppl. Decl. ¶ 28; *see Crawford v. U.S. Dep't of Treasury*, 868 F.3d 438, 457 (6th Cir. 2017) ("[W]e assess standing as of the time a suit is filed." (citation omitted)); *see also, e.g.*, *Grupo Dataflux*, 541 U.S. at 570 ("It has long been the case that 'the jurisdiction of the court depends upon the state of things at the time of the action brought.'" (quoting *Mollan*, 22 U.S. at 539)). And even if Plaintiffs could now allege in a *different* complaint that Pharmacyclics is a member (in its own right) of the Plaintiff associations, Plaintiffs cannot avoid dismissal of the operative complaint through new allegations in their opposition brief and supplemental declaration, particularly about events that post-date the filing of the complaint. *See, e.g.*, *Roulhac v. Sw. Reg'l Transit Auth.*, No. 1:07-cv-408, 2008 WL 920354, at *4 (S.D. Ohio Mar. 31, 2008).

[8] Plaintiffs' supplemental declaration also states that Pharmacyclics is a member of the U.S. Chamber and Michigan Chamber "by virtue of AbbVie's membership." Suppl. Decl. ¶ 27. It is not clear what Plaintiffs mean by that, but they appear to be suggesting (implausibly) that any subsidiaries of any member corporation are necessarily and automatically also members of the Plaintiff associations. Even if that suggestion were credible on its face—and it is hard to imagine the U.S. Chamber of Commerce being so cavalier about the corporate form—the declaration contradicts that theory in the very next paragraph, by admitting that Pharmacyclics "joined the Dayton and Ohio Chambers *in its own name*" on an unspecified date "in August 2023." *Id.* ¶ 28 (emphasis added).

The Court need go no further—after all, there is only one complaint before the Court, and it remains insufficient to demonstrate jurisdiction.[9]

c. In any event, Plaintiffs' new assertions are still not enough to avoid dismissal, even if they could be considered now. For one, Plaintiffs wrongly assert that Defendants' argument is "premised on the notion that *only* Pharmacyclics could suffer injury-in-fact from the IRA." Pls.' Opp'n at 13. But Defendants merely point out that the obligations that Plaintiffs' complaint alleges *AbbVie* faces under the Program are in fact obligations of *Pharmacyclics*, as the manufacturer of Imbruvica designated to participate in the negotiation. *See* MTD at 13. In response, Plaintiffs assert that AbbVie fits within the general statutory definition of "a manufacturer." Pls.' Opp'n at 14 (citing 42 U.S.C. §§ 1320f, 1395w-3a(c)(6)(A), 1396r-8(k)(5)). But whether AbbVie could be considered "a manufacturer" for certain purposes is irrelevant to whether it would have standing to challenge the Negotiation Program.

The IRA directs CMS to "negotiate" with "*the* manufacturer" of a selected drug, 42 U.S.C. § 1320f-2(a)(1) (emphasis added), which, as CMS guidance confirms, does not mean *any* manufacturer or *all* manufacturers of the selected drug—it means *the* manufacturer who holds the NDA for that drug (*i.e.*, the "primary manufacturer"), *see* Revised Guidance at 118. To establish standing, Plaintiffs must show that AbbVie (their only named member) stands to suffer an actual or imminent injury. *See Clapper*, 568 U.S. at 409. And an alleged injury to AbbVie cannot be imminent if the agency charged with implementing this program has adopted an interpretation that does not subject AbbVie to any of the statutory obligations or responsibilities that Plaintiffs fear. Because CMS's commonsense approach relieves anyone other than the primary manufacturer of the obligations that are described in the complaint, AbbVie lacks standing to challenge those obligations. Pls.' Opp'n at 14.[10]

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[9] It bears repeating (and Plaintiffs do not dispute) that "if the Dayton Area Chamber were dismissed for lack of jurisdiction, venue would not be proper in this District, and dismissal of this lawsuit would then also be required on that basis, under Federal Rule of Civil Procedure 12(b)(3)." MTD at 15. In any event, it is still the case that, "[b]ecause all Plaintiffs lack Article III standing, the Court need not consider the secondary question of whether venue is proper." *Id.*

[10] Plaintiffs do not actually challenge CMS's interpretation of the statutory directive to "negotiate" with "the manufacturer" of a selected drug, as set forth in the revised guidance. Nor could they. After all, CMS's approach operates to manufacturers' benefit, by taking a *narrower* view than Plaintiffs do about who is subject to these statutory obligations. In any event, CMS's determination that the IRA contemplates negotiation with only one manufacturer (*i.e.*, "the" primary manufacturer of a selected drug) is firmly grounded in the statutory text. *See* 42 US.C. § 1320f-2(a)(1). That approach is also necessary as a practical matter; not every company that, say, assists in "labeling" drugs (and therefore could arguably

Ultimately, this sort of misunderstanding by Plaintiffs was a risk inherent in their decision to bring a premature facial challenge to a never-before-implemented statute, and to do so before CMS issued its revised guidance for the Program's first negotiation cycle. That approach has consequences.

d. Under settled principles of shareholder standing, AbbVie's corporate relationship to Pharmacyclics is no help to Plaintiffs here, because AbbVie would not have standing as a shareholder (including as a corporate parent) to bring this suit on behalf of a separate corporation, Pharmacyclics. *See* MTD at 12–15. Plaintiffs do not dispute this general prohibition, which is grounded in basic principles of the corporate form—principles that are presumably quite important to the U.S. Chamber of Commerce and its members, as a general matter. In short, a corporate shareholder cannot bring an action for relief based on alleged injuries to the corporation, even "where the individual is the sole stockholder." *Canderm Pharmacal, Ltd. v. Elder Pharms., Inc.*, 862 F.2d 597, 602–03 (6th Cir. 1988); *see also, e.g.*, *City of Dayton v. A.R. Env't, Inc.*, 886 F. Supp. 2d 775, 778–79 (S.D. Ohio 2012) (Newman, J.). Likewise, "a parent corporation cannot create a subsidiary and then ignore [its] separate corporate existence whenever it would be advantageous to the parent." *Pa. Eng'g Corp. v. Islip Res. Recovery Agency*, 710 F. Supp. 456, 465 (E.D.N.Y. 1989) (internal quotation marks omitted).

There is a narrow exception where "the shareholder suffers an injury separate and distinct from that suffered by other shareholders, or the corporation as an entity." *Gaff v. FDIC*, 814 F.2d 311, 315 (6th Cir.), *reh'g in part*, 828 F.2d 1145 (6th Cir. 1987). Plaintiffs thus try to argue that AbbVie faces "direct injuries" that implicate this exception here, Pls.' Opp'n at 15—but they do not come close to establishing that any of the alleged harms to AbbVie are "separate and distinct" from the harms Pharmacyclics will suffer (on their theory). In fact, every alleged harm to AbbVie is the "indirect or incidental" result of its status as the sole shareholder in Pharmacyclics. *Gaff*, 814 F.2d at 315.

In their opposition, Plaintiffs do not appear to contest that AbbVie suffers no "direct" injury based on their speculation that the negotiated price for Imbruvica will lead to lower profits for Pharmacyclics and, by implication, an eventual decrease in the value of AbbVie's shares. *Compare, e.g.*,

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meet the broader statutory definition of "manufacturer" in the Social Security Act) could, or should, be seated at the price-negotiating table. Pls.' Opp'n at 14 (quoting 42 U.S.C. § 1396r-8(k)(5)).

Suppl. Decl. ¶ 19 (declaring that AbbVie is "injur[ed]" "[w]hen IMBRUVICA's financial performance is impaired (as would occur if IMBRUVICA is given a below-market price in the IRA price-setting process)"), *with* Pls.' Opp'n at 14–15 (in arguing shareholder standing, making no mention of that hypothetical financial injury to AbbVie resulting from a change in Imbruvica's price); *see* MTD at 14. Instead, Plaintiffs assert that some "costs associated with the IRA as to" Imbruvica are "borne by AbbVie." Pls.' Opp'n at 13–14. But they do not identify any specific "costs" at all. *Id.* And the only "burden[]" that they allege AbbVie would have to carry is "gathering information." *Id.* at 15; *see* Suppl. Decl. ¶ 21 ("AbbVie employees have been identifying, collecting, reviewing, and preparing to submit the data required under the IRA[.]"). As explained above, that (untimely) assertion suggests nothing more than routine preparation for possible future legal obligations—even if it had appeared as an actual allegation in the complaint. *See supra* at 9.

More to the point, any *legal* obligation to carry out these preparatory and information-sharing activities because of Imbruvica's selection falls on Pharmacyclics, *not* AbbVie. CMS's revised guidance repeatedly emphasizes that any obligations under this Program fall on the primary manufacturer alone, not any "secondary manufacturer." *E.g.*, Revised Guidance at 80, 89, 118–19. For example, CMS states that "the *Primary Manufacturer will be solely responsible* for compliance with all provisions of the Agreement and will be accountable for ensuring compliance with respect to units of the selected drug manufactured by the Secondary Manufacturer or marketed by any Secondary Manufacturer pursuant to an agreement with the Primary Manufacturer." *Id.* at 119 (emphasis added). Thus, the primary manufacturer's responsibilities include complying with the requirements to "collect and report necessary information applicable to any Secondary Manufacturer(s)" and "ensure that any Secondary Manufacturer(s) make the [negotiated price] available to [eligible] individuals and to pharmacies . . . and other dispensers." *Id.* (citing 42 U.S.C. § 1320f-2(a)(1), (4)). As a result, Pharmacyclics "face[s] all of the legal obligations that AbbVie supposedly fears." MTD at 13. And to the extent that a secondary manufacturer assists a primary manufacturer in meeting the primary manufacturer's compliance obligations, that is attributable not to the challenged statute or any legal obligation on the secondary manufacturer, but rather to the voluntary choices made by those manufacturers in arranging

their business relationships. Of course, Plaintiffs or their members "cannot manufacture standing merely by inflicting harm on themselves." *Clapper*, 568 U.S. at 416.

At bottom, Plaintiffs' alleged injuries to AbbVie—even if they rose to the level of concrete and cognizable Article III harms—are "actually [alleged injuries] sustained by the corporation" Pharmacyclics and therefore any "action to redress [such] injuries . . . must be brought in the name of the corporation" Pharmacyclics. *Warren v. Mfrs. Nat'l Bank of Detroit*, 759 F.2d 542, 544 (6th Cir. 1985) (internal quotation marks omitted). The Plaintiff associations thus cannot rely on the complaint's allegations regarding alleged injuries to AbbVie. *See, e.g.*, *Waskul*, 900 F.3d at 254–55 (requiring identification of a member that "would otherwise have standing to sue in their own right").[11]

In a throwaway coda, Plaintiffs proclaim that Defendants' shareholder-standing argument is "misplaced" because it derives from a prudential doctrine, rather than Article III. Pls.' Opp'n at 15. Of course, Defendants press both categories of standing arguments: Plaintiffs have failed to allege a valid Article III injury, and their associational-standing theory is foreclosed by the "equitable restriction[s]" imposed by principles of shareholder standing. MTD at 7–18. In any event, the origin of the shareholder-standing doctrine is of no moment: once Defendants have raised the argument, settled principles of prudential standing are just as binding on this Court as the requirements of Article III. After all, "[a] mandatory requirement is still a mandatory requirement, even if not a jurisdictional one." *M.L. Johnson Fam. Props., LLC v. Jewell*, 237 F. Supp. 3d 528, 539 (E.D. Ky. 2017) (Thapar, J.). Prudential or not, Plaintiffs offer no reason to sidestep the "longstanding equitable restriction" imposed by the doctrine of shareholder standing. *In re Troutman Enters., Inc.*, 286 F.3d 359, 364 (6th Cir. 2002) (internal quotation marks omitted).

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[11] Plaintiffs observe in a footnote that the Supreme Court in *Franchise Tax Board v. Alcan Aluminium Ltd.* held that a plaintiff parent corporation had *Article III* standing based on their personal "stake in the outcome of the controversy" regarding a tax that would "lower[] the value of their stockholdings." 493 U.S. 331, 335–36 (1990); *see* Pls.' Opp'n at 15–16 n.11. But that case simply stands for the (undisputed) proposition that the shareholder-standing doctrine is a prudential one, rather than a matter of Article III subject-matter jurisdiction. As to the question of whether the plaintiffs in that case could "meet the prudential requirements of the standing doctrine," *Franchise Tax Bd.*, 493 U.S. at 336, the Court did not decide that issue, because the plaintiffs' action was barred for other reasons. Nevertheless, the Court observed that both circuit courts to rule on the underlying appeals had held that "the compliance costs" and "taxation claims" at issue did "not cause direct or independent harm" to the parent corporations but "were better viewed as merely added costs to the subsidiaries, experienced by the foreign parents as a decline in the value of their ownership interests." *Id.* at 337–38. Much the same could be said here.

2. The relief requested requires participation by individual members.

Plaintiffs also fail to meet the third requirement of the associational standing test. Under that prong, a court must decide whether "the relief requested requires the participation of individual members in the lawsuit." *Ass'n of Am. Physicians & Surgeons v. FDA*, 13 F.4th 531, 537 (6th Cir. 2021) (quoting *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977)). Here, it does. In particular, the pendency of multiple suits by individual drug manufacturers, including Plaintiffs' members, renders an association suit unworkable.

This problem has only gotten worse since Defendants filed their motion to dismiss. At that time, there were pending suits by Merck & Co., Inc., Bristol Myers Squibb Co., Janssen Pharmaceuticals Inc., Astellas Pharma US Inc., and the primary trade association for pharmaceutical companies.[12] Since then, AstraZeneca Pharmaceuticals LP, Boehringer Ingelheim Pharmaceuticals, Inc., and Novartis Pharmaceuticals Corp. have filed new suits, and Astellas's lawsuit has been dismissed (after its selection predictions turned out to be wrong).[13] So the obvious practical question is even more acute now: if, for example, "Merck loses in D.C. but the Chamber wins here, or vice versa, does Merck get relief?" MTD at 17.

According to Plaintiffs, "there is an easy solution to the government's supposed dilemma," which is that "any of Plaintiffs' members who have brought separate suits will be bound by any judgments in those suits that apply to particular plaintiffs." Pls.' Opp'n at 18. In other words, Plaintiffs in *this* case are willing to throw overboard the plaintiffs in the *other* cases (even their own members), when it comes to obtaining any association-wide relief. But what does Merck think about that? Or the others? This Court has no way to know. Plaintiffs have not even disclosed which of the other manufacturers are members. So their "solution" doesn't solve anything at all—the risk of complicated follow-on litigation over preclusion and remedies remains unacceptably high (both in this court and in at least six other courts). "[T]he third prong of the associational standing test" is designed

[12] *Merck & Co. v. Becerra*, No. 1:23-cv-1615 (D.D.C.); *Bristol Myers Squibb Co. v. Becerra*, 3:23-cv-3335 (D.N.J.); *Astellas Pharma US, Inc. v. HHS*, 1:23-cv-4578 (N.D. Ill.); *Janssen Pharms., Inc. v. Becerra*, 3:23-cv-3818 (D.N.J.); *Nat'l Infusion Ctr. Ass'n v. Becerra*, 1:23-cv-707 (W.D. Tex.).

[13] *AstraZeneca Pharms. LP v. Becerra*, No. 1:23-cv-931 (D. Del.); *Boehringer Ingelheim Pharms., Inc. v. HHS*, No. 3:23-cv-1103 (D. Conn.); *Novartis Pharms. Corp. v. Becerra*, 2:23-cv-14221 (D.N.J.).

to promote "administrative convenience and efficiency," *United Food & Com. Workers Union Loc. 751 v. Brown Grp., Inc.*, 517 U.S. 544, 557 (1996)—goals that would be severely undermined by finding associational standing in these circumstances.

Of course, Defendants agree with Plaintiffs that no manufacturer should get multiple bites at the same apple. But that outcome lays bare the bizarre practical results risked by allowing this lawsuit to proceed. Six pharmaceutical companies asserting interests in drugs selected for negotiation have *already* filed their own separate lawsuits—and the individual primary manufacturers are the only ones that could be entitled to (or in need of) any remedy.[14] Under these circumstances, even accepting *Plaintiffs'* remedial theory, the vast majority of affected manufacturers would not be entitled to any relief in this case—even if Plaintiffs prevail. Indeed, if Novo Nordisk had also sued, Pharmacyclics would be the only manufacturer left unaccounted for by separate litigation.[15]

Under these extraordinary circumstances, an association suit is impractical and inequitable. Accordingly, because "the relief requested requires the participation of individual members in the lawsuit," *Ass'n of Am. Physicians*, 13 F.4th at 537 (quoting *Hunt*, 432 U.S. at 343), this lawsuit should be dismissed for lack of associational standing. At a minimum, however, under these circumstances, any relief would have to be limited to member-manufacturers of selected drugs who are not already represented in separate lawsuits. Even on Plaintiffs' theory, that would be a very short list.

II. Plaintiffs' Claims Are Not Ripe

Standing and ripeness are "[t]wo related doctrines of justiciability[,] each originating in the case-or-controversy requirement of Article III." *Trump v. New York*, 141 S. Ct. 530, 535 (2020). So, for reasons similar to the reasons why Plaintiffs lack standing, *see supra* Section I, Plaintiffs' claims are also not ripe. In short, before any new prices are actually negotiated, Plaintiffs' claims "rest[] upon contingent future events that may not occur as anticipated, or indeed may not occur at all." *Texas v. United States*, 523 U.S. 296, 300 (1998) (internal quotation marks omitted).

[14] That number ignores manufacturers purportedly represented by PhRMA (their trade association) in *National Infusion Center Association* in the Western District of Texas. Also, some manufacturers had multiple drugs selected.

[15] Another odd feature of Plaintiffs' approach: because AbbVie is not the primary manufacturer of any selected drug, it is not even clear that an injunction in its favor would have any effect on negotiations over the price of Imbruvica—which will be conducted between CMS and Pharmacyclics, and to which AbbVie has not been invited to participate.

Plaintiffs struggle mightily to resist the notion that their claims have anything to do with the final (and currently unknown) negotiated price of selected drugs. *But see supra* at 6-7 n.5 (citing dozens of allegations about Plaintiffs' fears of a "rock-bottom price," Compl. ¶ 195). Plaintiffs seem to think that focusing on the Due Process Clause (rather than the Takings Clause) and repeating that theirs is a facial challenge (rather than an as-applied one) solves all their jurisdictional problems caused by price uncertainty. *See* Pls.' Opp'n at 19 (accusing Defendants of "misconstruing the nature of Plaintiffs' claims"). But even if that were a fair reading of Plaintiffs' complaint,[16] it is no solution at all.

For starters, given Plaintiffs' theory of injury, there is no relevant daylight in this case between takings and due process theories. *See, e.g.*, *Duquesne Light Co. v. Barasch*, 488 U.S. 299, 307 (1989) (explaining that "Constitution[al] protect[ion] [of] utilities from . . . confiscatory" rates derives from "the Takings Clause of the Fifth Amendment") (cited in Compl. ¶ 153). This is especially true for purposes of standing. Plaintiffs' due-process-related allegations rest on fears of, for example, "unconstitutionally confiscatory and arbitrary prices," or "prices so low as to deprive manufacturers of their property without due process of law." Compl. ¶¶ 166–67. And "to succeed on a procedural due process claim, plaintiffs must demonstrate both a deprivation of a constitutionally protected property or liberty interest *and* that the deprivation occurred without due process of law." *Kovacic v. Cuyahoga Cnty. Dep't of Child. & Fam. Servs.*, 809 F. Supp. 2d 754, 775 (N.D. Ohio 2011) (emphasis added), *aff'd* 724 F.3d 687 (6th Cir. 2013); *accord Kennedy v. City of Cincinnati*, 595 F.3d 327, 334 (6th Cir. 2010). Plaintiffs cannot yet show any actual or imminent "deprivation" at all—just as they could show no taking—given the uncertainty over whether any of Plaintiffs' members will ever face "prices so low as to" violate the Constitution. Compl. ¶ 167. That is (at least) a ripeness problem, because "further factual development would significantly advance [the Court's] ability to deal with the legal issues presented." *Nat'l Park Hosp. Ass'n v. Dep't of Interior*, 538 U.S. 803, 812 (2003) (citation omitted).

[16] It is not. Plaintiffs suggest that the government has "imagined" that their utility-rate-regulation theory is more appropriately conceived of as a takings claim, and that "[t]he Court will scour Plaintiffs' papers in vain looking for any takings claim." Pls.' Reply at 2. In fact, Plaintiffs allege in the complaint that the "confiscatory" pricing that they fear "would effect a taking." Compl. ¶ 166; *see also id.* ¶ 135 ("Congress . . . did not even gesture at the constitutional necessity of protecting against confiscatory price controls and takings of private property without just compensation.").

These sorts of uncertainties are surely among the reasons why the Supreme Court "has never considered a taking challenge on a ratesetting methodology without being presented with specific rate orders alleged to be confiscatory." *Verizon Commc'ns, Inc. v. FCC*, 535 U.S. 467, 524 (2002). In other words, "the general rule is that any question about the constitutionality of ratesetting is raised by rates, not methods." *Id.* at 525. This makes sense—if prices turn out to be similar to what they have been in the past, there would be no basis to conclude, for example, that prices are "so 'unjust' as to be confiscatory," or anything close to it. Compl. ¶ 153 (quoting *Duquesne Light*, 488 U.S. at 307); *see Duquesne*, 488 U.S. at 308, 316 (holding that for public utilities, "[i]f the *rate* does not afford sufficient compensation" it might violate the Takings Clause, but "[t]he Constitution within broad limits leaves the States free to decide what ratesetting *methodology* best meets their needs" (emphases added)).

* * *

"Striking down an Act of Congress 'is the gravest and most delicate duty that [a federal court] is called on to perform.'" *Shelby Cnty. v. Holder*, 570 U.S. 529, 556 (2013) (quoting *Blodgett v. Holden*, 275 U.S. 142, 148 (1927) (Holmes, J., concurring)). It is now clear that, in their haste to obtain the first court order addressing the constitutionality of the IRA's Negotiation Program, Plaintiffs overlooked important details of jurisdiction and justiciability, and materially misunderstood critical provisions of the statute and CMS's guidance. Before seeking sweeping relief of nationwide significance in a facial constitutional challenge, it was Plaintiffs' burden to get those details right. They did not. Their complaint should be dismissed.

CONCLUSION

The complaint should be dismissed in its entirety under Federal Rule of Civil Procedure 12(b).

Dated: September 8, 2023

Respectfully submitted,

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