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

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

Plaintiffs,

v.

XAVIER BECERRA, *et al.*,

Defendants.

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

Judge Thomas M. Rose

Magistrate Judge Peter B. Silvain, Jr.

REPLY IN SUPPORT OF MOTION FOR A PRELIMINARY INJUNCTION

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INTRODUCTION

The IRA's price-control program is packaged in euphemisms about "negotiations" and "fair" prices. But a process where one side gets to unilaterally dictate the result is a "negotiation" only in name. And a price set unilaterally by the government with (1) no requirement of reasonableness; (2) no administrative or judicial review, and (3) no direction except that it should be the "lowest" price, cannot be understood as fair, or as consistent with *Michigan Bell*. The IRA requires manufacturers to "agree" by October 1 to provide access to their products at whatever price the government decides to pick. No manufacturer would do that voluntarily. So to coerce such "agreement," Congress imposed an astronomical, unaffordable "excise tax" penalty. Manufacturers cannot escape that so-called "tax." This is not only because the statute restricts manufacturers' ability to exit the program. It is also because withdrawing from federal healthcare programs is not an option: it would deny beneficiaries access to vital medicines and cut manufacturers off from half of the market for all of their prescription drugs, not only the ones selected for price controls. The substance of the IRA's price-control program, in short, belies its euphemistic language.

The government sidesteps the substance. In its brief, it contends that the IRA is merely an invitation to a two-way discussion at the "negotiating table" (Opp. 1); that setting prices on manufacturers' products "does not implicate property interests" (Opp. 2); that the program is "entirely voluntary" (Opp. 12); and—adding words to the statute that are not there—that Congress directed CMS to "'aim[] to achieve the lowest maximum fair price' *that manufacturers will accept*" (Opp. 5) (emphasis added). But the government cannot rewrite the statute through non-binding "guidance" and legal briefs that obscure the reality of this unprecedented price-control program.

Unable to rebut Plaintiffs' due-process challenge, the government tries to rewrite that too, recasting it as a takings claim. In a motion that "focuse[d] solely on the Due Process Clause,"

PI Mot. 2, Plaintiffs argued that the IRA's price-control program violates due process on its face because it lacks adequate "procedural safeguards," including statutory standards and judicial review, PI Mot. 1-2, 11-18, 20. That is a challenge to the procedures that Congress legislated—an argument that the price-control scheme lacks the procedural protections necessary to ensure basic fairness. *See, e.g.*, *Michigan Bell Tel. Co. v. Engler*, 257 F.3d 587, 594-95 & n.4 (6th Cir. 2001). It is not a claim that any particular price to be chosen by the Secretary will effect a taking. The Court will scour Plaintiffs' papers in vain looking for any takings claim. Yet the government's main response to Plaintiffs' due process claim is to try to knock down an imagined takings claim.

Michigan Bell requires an injunction here to maintain the status quo. The government tries to sidestep *Michigan Bell* by suggesting that the Sixth Circuit misunderstood its own decision; by rebranding it a *Takings Clause* case; and then by arguing that it was silently overruled by a takings discussion in a *statutory interpretation* case, *Verizon Commc'ns, Inc. v. FCC*, 535 U.S. 467 (2002). But the Sixth Circuit knew what it was talking about: "The *Due Process* Clause requires . . . adequate[ ] *safeguards* against confiscatory rates." *Michigan Bell*, 257 F.3d at 593 (emphasis added). Nothing in *Verizon* disturbed that holding. Indeed, *Verizon* did not even mention due process. Moreover, this Court applied *Michigan Bell* two years after *Verizon* in granting a preliminary injunction on a facial *due process* claim. *Monongahela Power Co. v. Schriber*, 322 F. Supp. 2d 902, 918–19 (S.D. Ohio 2004), *as modified on reconsideration* (June 14, 2004) (Sargus, J.); *see also id.* at 906 (referencing "binding precedent from the Supreme Court and the Sixth Circuit"). In addition, the government altogether ignores Plaintiffs' argument under *Mathews v. Eldridge*, 424 U.S. 319 (1976)—indisputably a procedural due process case. *See* PI Mot. 16–18.

Nor can the government's efforts to portray the IRA price-control program as "voluntary" fix the due process problem. By statute, manufacturers are legally prohibited from withdrawing

from Medicare Part D—and, consequently, are trapped in the IRA's price-control regime—for at least 11 to 23 months. Recognizing that this renders its "voluntariness" argument dead on arrival, the government has tried to rewrite the statute on the fly through "guidance." But non-binding guidance from an agency cannot change what Congress enacted. And even if manufacturers were legally authorized to withdraw immediately, the government's theory—that due process meaningfully protects public utilities, but not private pharmaceutical companies—would still be wrong. The Due Process Clause is a structural guarantee against the arbitrary exercise of government power, and its fundamental protections do not hinge on whether a victim of government arbitrariness is "*legally compelled*" to engage in regulated activity. Opp. 8. The government cannot take over large swaths of the economy and force market participants to relinquish their constitutional rights as a condition of selling their products.

To the contrary, courts have long recognized that certain "conditions" are unconstitutional because they impose pressure to surrender constitutional rights. The Sixth Circuit has observed that this well-established principle protects private, non-utility businesses from attempts to condition government benefits on the surrender of their due process rights. *R.S.W.W., Inc. v. City of Keego Harbor*, 397 F.3d 427, 434–36 (6th Cir. 2005). And the Supreme Court applied similar reasoning to a Medicaid funding condition in *National Federation of Independent Business v. Sebelius* (*NFIB*), 567 U.S. 519 (2012). There, as here, the threatened loss was an economic "gun to the head." *Id.* at 581. The government is not reasonable when it suggests that manufacturers could dodge the bullet by cutting off sales of all their drugs to Medicare beneficiaries. Opp. 1, 5, 9-12, 16. Withdrawing completely from government healthcare programs would deprive millions of Americans of critical medications, causing irreparable harm to the public as well as to manufacturers. Similarly untenable is the government's suggestion (Opp. 11 & n.4) that

manufacturers stop selling (or divest) drugs selected for price controls—as if the solution to a constitutional violation is for the plaintiff to give up, or as if the aim of the IRA were to eliminate Americans' access to medications.

The government also fails to grapple seriously with Plaintiffs' arguments and evidence regarding the other preliminary injunction factors. Ignoring the irreparable harm that manufacturers are already enduring and will increasingly suffer because of the IRA's unconstitutional process, the government argues that no harm can occur until specific "prices" take effect. Yet again, the government is confused: Plaintiffs are challenging *existing* statutory *procedures*, not *anticipated* future *prices*. Under *Michigan Bell*, the procedures must be enjoined.

ARGUMENT

I. Plaintiffs Are Likely to Succeed on the Merits.

The government's failure to engage with Plaintiffs' due process claim is, in a sense, not surprising. Plaintiffs have demonstrated a high likelihood of success on that claim, and at the very least "questions going to the merits so serious, substantial, difficult, and doubtful as to make them a fair ground for litigation." *Stryker Emp. Co. v. Abbas*, 60 F.4th 372, 385 (6th Cir. 2023). The government may have objections to *Michigan Bell*, but *Michigan Bell* is binding Sixth Circuit precedent and dictates the result here. That conclusion is reinforced by *Eldridge*'s test for procedural due process, *see* PI Mot. 16–18, which the government never mentions.

A. Plaintiffs' Due Process Claim Is Meritorious.

Michigan Bell held that under "the Due Process Clause," a price-control regime is unconstitutional unless it "adequately safeguards against confiscatory rates, and therefore, ensures a constitutional rate of return." 257 F.3d at 593. The *Michigan Bell* plaintiffs did not challenge any specific rates set by the Public Service Commission. Rather, they argued that certain statutes "violate the Due Process Clause" on their "fac[e]" because "they do not provide *a mechanism*

through which telephone service providers may ensure that they receive a just and reasonable rate of return." *Id.* at 591 (emphasis added). While the plaintiffs were utilities, the court's reasoning did not turn on that fact. Indeed, after announcing that "[t]he Due Process Clause requires a mechanism through which a regulated utility may challenge the imposition of rates which may be confiscatory," the court cited a series of due process cases brought by private insurance companies. *Id.* at 593 (citing, *e.g.*, *Calfarm Ins. Co. v. Deukmejian*, 771 P.2d 1247, 1254 (Cal. 1989)).

As in *Michigan Bell*, Plaintiffs' due process claim focuses on statutory procedures (and the lack thereof), not specific prices. As the government acknowledges, "Congress did not impose a floor" on prices. Opp. 5. Instead, it imposed a *ceiling* well below market prices and directed the Secretary to aim for the "lowest" price. PI Mot. 13. These unusual features of the IRA create a "grave risk" of arbitrary, discriminatory, and confiscatory pricing, PI Mot. 9, and highlight the need for rigorous procedures, such as statutory standards and judicial review, to mitigate that risk. *See* PI Mot. 16–17 (discussing "risk of an erroneous deprivation" element of *Eldridge* test). Yet as Plaintiffs explained, the IRA provides even fewer procedural safeguards than the price-setting provisions invalidated in *Michigan Bell*. The IRA dispenses with any legal standard of reasonableness or fairness and bars judicial review of HHS's unilateral price decisions. PI Mot. 13–16. Congress's elimination of all procedural safeguards—and its deployment of "negotiation" camouflage—suggests that Congress *intended* the Secretary to pick prices that would not meet the usual "just and reasonable" standard or would otherwise fail judicial review for arbitrariness. PI Mot. 13, 17. Plaintiffs have been crystal clear that their claim is a facial due-process challenge to the "unconstitutional process" set forth in the IRA. PI Mot. 2.[1]

[1] *See also, e.g.*, Compl. ¶¶ 147–148 ("Due process requires procedural protections"); *id.* ¶ 149 ("The IRA" lacks "adequate procedural safeguards"); *id.* ¶ 172 ("[The IRA] dispens[es] with

Lacking any response to *Michigan Bell*, the government contends that it has been overruled sub silentio by *Verizon*. Opp. 14–16. But the government fails to acknowledge that *Verizon* involved only a takings claim, while the Sixth Circuit's *Michigan Bell* decision involved only a due process claim. Although the plaintiffs in *Michigan Bell* had separately raised a takings claim, the district court there expressly distinguished that claim from the facial due process challenge:

> The Takings Clause challenges that Plaintiffs have brought in their complaints are separate, and different, from their facial due process attack on the statute. As this Court understands it, the Takings Clause challenge would be an "as applied" challenge to the result of the statute—*i.e*., that the rates resulting from the implementation of the statute are confiscatory. That is different from the argument the Court encounters today—namely that the statute on its face violates the Due Process Clause because it provides *no mechanism by which the Plaintiffs may seek relief* from any allegedly confiscatory rates.

Michigan Bell Tel. Co. v. Engler, No. 00-cv-73207, 2000 U.S. Dist. LEXIS 20876, at *47 n.12 (E.D. Mich. Sept. 14, 2000) (emphasis altered) (citation omitted). On appeal, the Sixth Circuit thus addressed *only* the due process claim.

In contrast, *Verizon* addressed a takings issue in the context of a statutory interpretation question. The case concerned a statute that authorized the FCC to regulate rate-setting standards for state utility commissions. The statute required that rate-setting be "just and reasonable," "based on the cost," and "nondiscriminatory." 47 U.S.C. § 252(d)(1). The Court rejected the argument that the "based on the cost" provision unambiguously required the inclusion of certain historical expenditures. 535 U.S. at 501. In the process, the Court rejected the argument that any other interpretation would inevitably create Takings Clause problems, noting that the Court had "never

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notice-and-comment rulemaking, fail[s] to legislate any price-setting standard . . . fail[s] to create any transparent procedures for the 'negotiation' process, and bar[s] judicial review"); PI Mot. 2 ("[W]hen the government sets prices, it must afford parties certain procedural safeguards"); *id*. at 13 (highlighting lack of "mechanism[s]" such as statutory standards and judicial or administrative review); *id.* at 15–16 ("[T]he IRA lacks all of these required procedural protections").

considered a *taking* challenge on a ratesetting methodology without being presented with specific rate orders alleged to be confiscatory." *Id.* at 524 (emphasis added).

The *Verizon* Court thus discussed a takings issue in the context of a constitutional-avoidance argument about an entirely different statute. The Court did not say one word about due process. No due process claim was before it. Moreover, as explained by the *Michigan Bell* district court, there is a simple and fundamental distinction between a procedural due process challenge to a statute on its face and a takings challenge to a specific rate resulting from application of the statute. *See supra* at 6. "[A] procedural due process claim . . . is instantly cognizable in federal court without requiring a final decision" by "the responsible . . . agency." *Nasierowski Bros. Inv. Co. v. City of Sterling Heights*, 949 F.2d 890, 894 (6th Cir. 1991). Where the statutory procedures do not pass constitutional muster, the regime should be enjoined as a matter of due process, just as in *Michigan Bell*; there is no justification for forcing a party to go through unconstitutional procedures before challenging them. *See id.*; *Seguin v. City of Sterling Heights*, 968 F.2d 584, 589–90 (6th Cir. 1992) ("Because the plaintiffs are making a facial challenge to the statutes themselves, any procedural infirmity would not be cured by the subsequent application of the statute"); *cf. Axon Enter., Inc. v. FTC*, 598 U.S. 175, 191–92 (2023) ("subjection to an illegitimate proceeding" is a "'here-and-now injury'" that is "impossible to remedy once the proceeding is over" (quoting *Seila Law LLC v. Consumer Fin. Prot. Bureau*, 140 S. Ct. 2183, 2196 (2020))).[2]

Far from being "irreconcilable" with *Michigan Bell*'s due process holding (Opp. 14), *Verizon* reinforces it.[3] The procedural safeguards in the statute at issue in *Verizon* were far more

[2] To be clear, while Plaintiffs have not asserted a takings claim, a facial takings claim may also be ripe and meritorious where it is clear that the result of the challenged regime will be a taking.

[3] In later proceedings in *Michigan Bell*, the Sixth Circuit *declined* to vacate its opinion in light of *Verizon* and instead dismissed the subsequent appeal in light of the parties' settlement. *Michigan*

robust than in the IRA. The statute prescribed a "just and reasonable" standard, and there was a mechanism by which companies could "show that the pricing methodology, as applied to them, will result in confiscatory rates." *Verizon*, 535 U.S. at 528 n.39 (quotation marks omitted). That kind of "mechanism" was missing from the scheme in *Michigan Bell*, 257 F.3d at 593, and is missing from the IRA. Also unlike the IRA, the statute in *Verizon* authorized judicial review of FCC actions. 535 U.S. at 524. It thus may not be an accident that no procedural due process challenge was before the Court. In short, like *Michigan Bell*, *Verizon* highlights the IRA's unprecedented failure to provide basic safeguards, such as "[t]he familiar mandate . . . that rates be 'just and reasonable.'" *Id*. at 477.

B. The IRA Price-Control Program Is Coercive, Not Voluntary.

Verizon aside, the government's argument rests on the claim that participation in the IRA price-control program is "wholly voluntary." Opp. 7. The government's theory is that, "unlike utilities," pharmaceutical companies are not "required by law" to sell products or services, so Congress has carte blanche to strip away basic procedural protections and impose a regime that invites arbitrary, discriminatory, and confiscatory results. Opp. 2, 13. That theory is contrary to the Constitution. In any event, the IRA price-control program is coercive, not voluntary, and the government's "solutions" to that problem are unlawful and impracticable.

The first problem with the government's theory is that the Due Process Clause does not exist solely to protect public utilities. As noted above, *Michigan Bell* itself relied on Ninth Circuit and state supreme court cases upholding due process challenges to price controls on private insurance companies. 257 F.3d at 593–95; *see also Geeslin v. State Farm Lloyds*, 255 S.W.3d 786,

Bell Tel. Co. v. Engler, 72 F. App'x 380, 386 (6th Cir. 2003). And this Court applied *Michigan Bell* to grant a preliminary injunction on due process grounds the next year—two years after *Verizon*. *Monongahela Power*, 322 F. Supp. 2d at 918-19.

795 (Tex. App. 2008). The Supreme Court has also applied the Due Process Clause in contexts where the claimant was not legally obligated to engage in the regulated activity. *See, e.g.*, *Eldridge*, 424 U.S. at 323 (Social Security benefits); *Nebbia v. New York*, 291 U.S. 502, 539 (1934) (subjecting price floor on milk to due process scrutiny); *Barry v. Barchi*, 443 U.S. 55, 64 (1979) (recognizing horse trainers' "substantial" interest in retaining occupational licenses); *Goldberg v. Kelly*, 397 U.S. 254 (1970) (welfare benefits). Similarly, in *Keego Harbor*, the Sixth Circuit indicated that a city could not, consistent with due process, pressure a brewery to change its hours (without pre-deprivation proceedings) by threatening to withhold administrative approvals. 397 F.3d at 436. On the government's theory, the Sixth Circuit should instead have told the brewery to pound sand—after all, it was not legally obligated to sell beer.

The government derives its flawed theory from a takings discussion in a wartime emergency case involving rent controls in "defense areas." Opp. 8 (citing *Bowles v. Willingham*, 321 U.S. 503, 508, 517–18 (1944)); *see, e.g.*, *Garelick v. Sullivan*, 987 F.2d 913, 916 (2d Cir. 1993) (citing *Bowles*). But *Bowles* is readily distinguishable—as even that thumbnail description makes clear. Unlike the IRA, the scheme in *Bowles* provided for "generally fair and equitable" rents *and* a system of administrative and judicial review—*even in wartime*. 321 U.S. at 509–10, 517, 519. And the Court emphasized deference to wartime measures, explaining that it "need not determine what constitutional limits there are to price-fixing legislation" because "Congress was dealing here with conditions created by activities resulting from a great war effort." *Id.* at 519. Even so, the Court entertained a due process challenge without suggesting that it was out of bounds because landlords had no obligation to be landlords. *Id.* Nothing in the Constitution suggests that pharmaceutical manufacturers lack protection against arbitrary or confiscatory price controls.

In any event, manufacturers *are* legally obligated to remain in the price-control program—at least for the lengthy period specified by statute before a withdrawal from Medicare takes effect. *See* PI Mot. 8–9 & n.4. During that period, if a manufacturer does not "agree" to the government's price, it is immediately subject to the excise "tax," even *before* the price goes into effect. The "tax" applies while the manufacturer participates in Medicare. *See* 26 U.S.C. § 5000D. And federal law creates only two distinct pathways for terminating participation—one for termination by the Secretary (for misconduct), and the other for termination by the manufacturer ("for any reason"):

> (B) **Termination**
>
> > (i) **By the Secretary**
> >
> > The Secretary may provide for termination of an agreement under this section for a knowing and willful violation of the requirements of the agreement or other good cause shown. . . . The Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination, and such hearing shall take place prior to the effective date of the termination with sufficient time for such effective date to be repealed if the Secretary determines appropriate.
> >
> > (ii) **By a manufacturer**
> >
> > A manufacturer may terminate an agreement under this section for any reason. Any such termination shall be effective, with respect to a plan year—(I) if the termination occurs before January 30 of a plan year, as of the day after the end of the plan year; and (II) if the termination occurs on or after January 30 of a plan year, as of the day after the end of the succeeding plan year.

42 U.S.C. § 1395w-114a(b)(4)(B). Under the first provision, when "the Secretary" seeks to terminate a manufacturer for misconduct (*i.e.*, a "knowing and willful violation of the requirements of the agreement or other good cause shown"), the manufacturer has the right to a "hearing" before the effective date of the termination. *Id.* § 1395w-114a(b)(4)(B)(i). In the second provision, Congress spelled out a very different procedure for the very different situation where a *manufacturer* wishes to terminate *its own* participation: "a manufacturer" may terminate "for any reason" (and no hearing is provided in such a case), but must wait 11 to 23 months after giving

notice. *Id.* § 1395w-114a(b)(4)(B)(ii). The text and structure of these provisions make clear that "good cause shown" under the first provision cannot be so broad as to include a manufacturer's voluntary termination. Such a broad interpretation would ignore the significance of the "knowing and willful violation" language in the first provision, which circumscribes the meaning of "other good cause shown." *See Sprietsma v. Mercury Marine,* 537 U.S. 51, 63 (2002) ("[A] word is known by the company it keeps"). Just as important, swallowing voluntary terminations "[b]y a manufacturer" within the first provision would render the second provision "wholly superfluous," *Duncan v. Walker*, 533 U.S. 167, 174 (2001).

In response to litigation, CMS issued non-binding guidance attempting to undo Congress's carefully delineated distinction between these two different types of termination and the 11-to-23-month waiting period prescribed by Congress for termination by a manufacturer. Opp. 10–11. But agencies cannot "rewrite and recast plain statutory text." *Citizens for Resp. & Ethics in Washington v. Fed. Election Comm'n*, 904 F.3d 1014, 1018 (D.C. Cir. 2018) (per curiam). The wisdom of that rule is apparent here: CMS's proposal to treat a *manufacturer*'s notice of termination as a termination *by the Secretary* runs headlong into the text and structure of the statute.

It also creates absurdities. Treating a manufacturer's own termination as action by the Secretary means that a manufacturer receives a hearing on *its own* request for termination. That is nonsensical, which is why Congress provided for a hearing only when it is the Secretary pursuing termination for alleged misconduct or similar good cause. Yet CMS, in its effort to write a new statute from the two very different pathways created by Congress, felt compelled to gesture to the manufacturer's statutory hearing right—only to simultaneously acknowledge that a hearing serves no purpose given that it is really the manufacturer doing the terminating. CMS thus advises both that "it will *automatically* grant such termination requests upon receipt" and that "CMS shall, upon

written request from such Primary Manufacturer, provide a hearing concerning its termination request"—the same request that CMS has just said it will already have automatically granted. Revised Guidance for Medicare Drug Price Negotiation Program ("Revised Guidance"), at 121 (June 30, 2023), https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf. (emphasis added). The knots that CMS has tied itself in are a sure sign that it is taking liberties with the statute. And because the guidance is non-binding, CMS can always change its mind. The law, in short, remains what Congress enacted: a price-setting scheme from which manufacturers cannot escape in time to avoid the "excise tax" penalty.

Moreover, even if the statute were different and manufacturers could withdraw in time to avoid the "excise tax," that would not solve the IRA's due process problems. The government cannot encourage the surrender of constitutional rights by withholding benefits, even supposedly "gratuitous" ones. *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 608 (2013) (collecting cases). "Even though a person has no right to a valuable governmental benefit and even though the government may deny him the benefit for any number of reasons, there are some reasons upon which the government may not rely." *Keego Harbor*, 397 F.3d at 434 (quotation marks omitted). The government may not "condition[] benefits on a citizen's agreement to surrender due process rights." *Id*. For example, a city may not withhold benefits to pressure a brewery to "choose between its due process rights in certain hours of operation and the desired city approvals." *Id.* at 436. Here, likewise, even if participation in Medicare and Medicaid were wholly voluntary, the government could not coerce manufacturers into the IRA's unconstitutional process by threatening to cut off access to half the prescription-drug market.

The Supreme Court applied similar reasoning, in circumstances with important similarities to this case, in *NFIB*. There, Congress pressured States to accept a Medicaid expansion by

threatening the withdrawal of all Medicaid funding. The Court held that "[t]he threatened loss of over 10 percent of a State's overall budget . . . is economic dragooning that leaves the States with no real option but to acquiesce in the Medicaid expansion." *NFIB*, 567 U.S. at 582. That financial threat was "a gun to the head." *Id.* at 581. And while Congress "styled" the expansion as part of Medicaid, it was effectively a "new health care program" because States "could hardly anticipate" that Congress would "transform" Medicaid so "dramatically." *Id.* at 584–85.

The IRA involves similar "economic dragooning." Declining to acknowledge the reality of the situation for manufacturers, the government says "[t]he choice is theirs." Opp. 1. But Congress knew that withdrawing all products from federal healthcare programs would be economic suicide—not a "real option." *NFIB*, 567 U.S. at 582. That is why Congress could enact this scheme without worrying that Medicare beneficiaries would suddenly lose access to needed drugs. If States, with all the tools at their disposal, are vulnerable to financial coercion, private entities are even more vulnerable to the "ruinous" "loss of federal funds." *Doe v. Univ. of Scis.*, 961 F.3d 203, 213 (3d Cir. 2020). And the government does not dispute that Medicare and Medicaid comprise nearly 50% of annual nationwide spending on prescription drugs, *see Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 699 (3d Cir. 2023), or that the IRA dramatically transforms Medicare.[4] In short, the "asserted power of choice" is "illusory." *United States v. Butler*, 297 U.S. 1, 71 (1936).[5]

[4] Although the government tries to liken the IRA to drug-price programs run by the Defense Department and the VA, there is no comparison. Those programs comprise a tiny fraction of the healthcare market. *See* Katherine Keisler-Starkey & Lisa N. Bunch, *Health Insurance Coverage in the United States: 2021*, Census.gov (Sept. 13, 2022), https://www.census.gov/library/publications/2022/demo/p60-278.html. And they tie government prices to prices offered to commercial customers. *See* General Services Acquisition Manual, Change No. 168 GSAM Case 2023-G509, pt. 538 (2023), https://www.acquisition.gov/gsam/part-538.

[5] The government misleadingly suggests that some manufacturers have "[r]ecognize[d] the viability of" withdrawing from Medicare and Medicaid and have "stated that this is exactly what they might do." Opp. 10 n.2. The government's sole citation—to an article referencing statements

The government claims that a "long line of precedent" holds that participation in Medicare and Medicaid is voluntary. Opp. 2, 7–9. But for multiple reasons, these cases do not help the government. First, these cases do not address whether *the IRA provisions at issue here* (or anything like them)—with their mandatory language, punitive "excise tax," standardless price controls, and prohibitions on judicial review—make for a "voluntary" program. Just as the Medicaid expansion in *NFIB* was unduly coercive (even though Medicaid may not previously have been coercive), the IRA "negotiation" program "transform[s]" Medicare and effectively "enlist[s] [manufacturers] in a new" program. *NFIB*, 567 U.S. at 584. None of the government's "voluntariness" cases addresses *NFIB* or the unconstitutional-conditions doctrine. And most were decided several decades ago (or rely on decades-old cases) when Medicare and Medicaid were much smaller than they are today.

Second, the cases are distinguishable on their own terms—and even affirmatively support Plaintiffs' due process claim. Take, for example, the government's only two cases from the Sixth Circuit. *Livingston Care Ctr., Inc. v. United States*, 934 F.2d 719 (6th Cir. 1991), was a suit by a nursing home seeking damages against the government for an allegedly wrongful Medicare termination. While the court said in dicta that "Medicare is a voluntary undertaking," no holding turned on that question. *Id.* at 720. Rather, the court first held that the damages claim was barred by 42 U.S.C. § 405(h), which eliminated jurisdiction over damages claims arising under the Medicare Act. 934 F.2d at 721–22. The court then turned to a "second and much more complex issue"—whether that jurisdictional bar "violate[d] the due process." *Id.* at 722. Notably, the court recognized that "[i]f Congress completely proscribed the federal courts from hearing constitutional

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by a company CEO—does not remotely support that proposition. The article says nothing about whether any manufacturer could or would withdraw. Rather, it simply notes that, as an unfortunate result of incentives created by IRA price controls, some companies may focus their development and commercialization of new medicines in ways that do not prioritize the Medicare population.

claims, it might violate the due process clause of the [F]ifth Amendment." *Id.* Because Congress had provided an alternative mechanism for judicial review, however, the court found no violation. *Id*. Far from suggesting that Medicare "does not implicate property interests protected by the Fifth Amendment" (Opp. 2), *Livingston* thus confirms that due process principles constrain the government even in the context of a putatively "voluntary" government program.

The government's other Sixth Circuit "voluntariness" case reinforces that conclusion. In *Baptist Hospital East v. Secretary of HHS,* 802 F.2d 860, 870 (6th Cir. 1986), hospitals alleged a "taking without compensation" because an HHS regulation disallowed reimbursement for certain costs incurred in providing unpaid care to "non-Medicare patients." *Id.* at 863, 867. The court held that "[t]he just compensation to which the hospitals are entitled is just compensation for providing health care services for Medicare recipients, not just compensation for operating a health care facility." *Id.* at 869. Thus, although the court went on to assert that Medicare is "wholly voluntary" for healthcare providers, it first recognized that providers *are* "entitled" to "just compensation" for services provided to Medicare. *Id.* Like *Livingston*, then, *Baptist* contradicts the government's sweeping theory that "where an entity voluntarily participates in a price-regulated program or activity" there can be no "deprivation of property at all." Opp. 8.

As with the government's suggestion that manufacturers simply pull out of Medicare, the government's other proposed "options" for avoiding the IRA are illusory and impracticable. For instance, the government offers that manufacturers "can continue selling [their] drugs" at market-based prices and "pay an excise tax" of up to 1900%, Opp. 5—ignoring that Congress's own budget office acknowledged, by projecting *zero* revenue from the "tax," that no manufacturer could afford

to pay it. *See* PI Mot. 15.[6] The government also suggests that a manufacturer "could . . . stop selling the drug." Opp. 11 n.4. But that would leave millions of Medicare beneficiaries without access, at any price, to some of the most important, widely used, and life-sustaining drugs. The government's "stop-selling rationale" is "no solution" to the constitutional quandary the IRA has created. *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 475 (2013). Just as a manufacturer challenging a preempted state law need not "pull[ ] [its drug] from the market in order to" avoid the conflict, *id.*, so also here: the remedy for the IRA's unconstitutional procedures is a *remedy*—not a glib suggestion that manufacturers give up and go home, leaving patients without needed treatments.

Finally, the government's repeated suggestion that manufacturers "divest" their top-selling products is naïve at best. Opp. 1, 6, 10–11, 17. A pharmaceutical company cannot just offload a drug. Transferring ownership, manufacturing, and regulatory registration of a prescription drug is a complex, lengthy, and costly process, requiring FDA approval. *See* Suppl. Staff Decl. ¶ 23. Plus, the company could not sell its interest in the drug at fair market value once it has been selected for price controls—which will follow the drug to any buyer. If the due process violation worked by the IRA is not corrected, no sale transaction would allow a company to avoid it.

II. Plaintiffs Have Demonstrated Irreparable Harm.

The government's argument that there is no imminent irreparable harm is premised on its misunderstanding of Plaintiffs' claim. Ignoring the examples of irreparable harm detailed in Plaintiffs' motion and declaration, the government suggests that Plaintiffs have only "alleged that it is possible that AbbVie's IMBRUVICA-related financial investments will suffer *starting in*

[6] Although the government suggests that the "excise tax" applies only to sales "under the terms of Medicare" and cites temporary guidance endorsing that interpretation, *see* Opp. 5, the statute does not contain any such limitation. *See* 26 U.S.C. § 5000D (describing the "tax" as "imposed on the sale" without language limiting it to government healthcare programs); Compl. ¶¶ 15, 187.

2026." Opp. 17. Plaintiffs' members have *already* suffered, and will continue to suffer, substantial irreparable harm because of the IRA's sham "negotiation" process—which requires them to "agree[]" to participate "by October 1, 2023." Opp. 6; PI Mot. 18–19; Staff Decl. 7–19. The IRA's "'infirm process is an injury in itself,'" *Nasierowski*, 949 F.2d at 894, and as in *Michigan Bell*, Plaintiffs' members are not required to slog through that defective process before challenging it on its face. *See supra* at 7; *Michigan Bell*, 257 F.3d at 594–95 & n.4.

A case where there is "no legal avenue open to the company by which to recoup its financial losses" is "a classic example of a situation in which a party will suffer irreparable harm" absent a preliminary injunction. 257 F.3d at 598 (quotation marks omitted). And here, the government does not even acknowledge, let alone rebut, Plaintiffs' evidence that their members are *already* suffering unrecoverable losses. For example, manufacturers are already incurring substantial compliance costs, and within just a few weeks manufacturers with selected drugs will have to submit a massive set of complicated, commercially sensitive information to CMS, on pain of $1-million-per-day penalties. *See* PI Mot. 3, 10, 19; Staff Decl. ¶¶ 7, 9. Indeed, CMS has warned that "manufacturers *need* to take a number of actions *well in advance* of September 1, 2023." Revised Guidance 9 (emphasis added). The government does not deny that the IRA's complex, data-intensive "negotiation" process imposes substantial burdens. Nor does it deny that, because of sovereign immunity, those economic losses cannot be recouped. By ignoring Plaintiffs' evidence, the government has forfeited any argument that the evidence is not adequate to support an injunction, just as it has forfeited its chance to address Plaintiffs' reliance on the presumption of irreparable harm in cases involving constitutional violations. *See* PI Mot. 18 n.8 (collecting cases).[7]

[7] The government suggests that a preliminary injunction is not warranted here because the plaintiffs in certain other suits have not yet sought such relief. Opp. 18. Litigation decisions by parties in other cases (largely raising different claims) are not a basis for denying relief in this case.

Finally, after arguing that Plaintiffs sued *too early* and that the suit is "premature," Opp. 2, the government says Plaintiffs sought relief *too late*. Opp. 18–19. But Plaintiffs' timing is eminently reasonable. *See York Risk Servs. Grp., Inc. v. Couture*, 787 F. App'x 301, 309 (6th Cir. 2019) (delay in seeking injunctive relief may weigh against finding irreparable harm only if delay is "unreasonable"). Plaintiffs' members needed time to evaluate the IRA and assess the likelihood that their drugs would be selected, especially in light of CMS's evolving guidance. CMS only issued its revised guidance—spanning 198 pages, and significantly amending its previous recent guidance—less than two months ago, and Plaintiffs moved for a preliminary injunction a mere 12 days later. If Plaintiffs had sought relief earlier, the government surely would have argued that it was premature. And if Plaintiffs had waited any longer, this Court might not have had sufficient time to consider the motion before the IRA's October 1, 2023 deadline for "agreeing" to "negotiate." The government cannot have it both ways. Plaintiffs have shown irreparable harm.

III. The Public Interest Favors Injunctive Relief.

After downplaying the impact of the IRA's new price-control program on manufacturers, the government turns around and claims that it is a program of "immense" significance and that "[d]erailing" it will "inflict grave harm" on the nation. Opp. 19. But the government does not dispute that "it is always in the public interest to prevent the violation of a party's constitutional rights." PI Mot. 19 (quoting *G&V Lounge, Inc. v. Mich. Liquor Control Comm'n*, 23 F.3d 1071, 1079 (6th Cir. 1994)); *see also* PI Mot. 19–20 (collecting cases). This factor thus favors Plaintiffs.

The two non-precedential, single-Justice opinions cited by the government are neither binding nor on point. In both cases, which involved requests to stay lower-court injunctions against statutes, the Justices expressed skepticism of the *merits* of the constitutional challenges. *See Walters v. Nat'l Ass'n of Radiation Survivors,* 468 U.S. 1323, 1324 (1984) (Rehnquist, J., in chambers) (noting that statute had been "on the books for more than 120 years"); *Maryland v.*

King, 567 U.S. 1301, 1302 (2012) (Roberts, C.J., in chambers) (noting that statute served important public safety purposes and finding "reasonable probability" that the Court would grant certiorari).

Because Plaintiffs have demonstrated a likelihood of success on the merits of their constitutional claim, this Court need not consider the policy arguments raised by the government and its amici. But even taken on their own terms, those arguments are misleading. For example, the government and its amici assume that the government can "reduce costs"—*without reducing innovation or supply*—simply by mandating below-market prices. Opp. 19; *see, e.g.*, Public Citizen Br. 10; AARP Br. 15. That assumption flies in the face of common sense. Even Congress's own budget office predicted that the IRA would eliminate potentially life-enhancing or life-saving medical breakthroughs by reducing incentives for investment and innovation.[8] Meanwhile, an independent University of Chicago study indicates that the IRA's impact would be far greater—nearly 150 fewer new drugs over the next two decades, leading to a significant reduction in Americans' life expectancy.[9] The government and its amici ignore these weighty considerations.

IV. The Scope of Plaintiffs' Requested Relief Is Appropriate.

The government's final contention is that even if Plaintiffs "prevail on every issue," the relief they have requested is "too broad." Opp. 19. Even though Plaintiffs have brought a facial due process challenge to the IRA's sham "negotiation" process, the government asserts that Plaintiffs have "no interest" in enjoining that process "writ large." Opp. 19–20. According to the

[8] *See* CBO, Estimated Budgetary Effects of Subtitle I of Reconciliation Recommendations for Prescription Drug Legislation, as Posted by the Senate Committee on Finance on July 6, 2022 (rev. July 13, 2022), https://www.cbo.gov/system/files/2022-07/senSubtitle1_Finance.pdf.

[9] Tomas J. Philipson & Troy Durie, Univ. of Chi., Issue Brief: The Impact of HR 5376 on Biopharmaceutical Innovation and Patient Health, at 2 (Nov. 29, 2021), *available at* https://bpb-us-w2.wpmucdn.com/voices.uchicago.edu/dist/d/3128/files/2021/08/Issue-Brief-Drug-Pricing-in-HR-5376-11.30.pdf.

government's novel theory of associational standing, any injunction here should protect only the Plaintiff-associations' named members. That approach is not consistent with binding case law.

Because Plaintiffs have satisfied the elements of associational standing, they can pursue injunctive relief on behalf of all injured members who have not opted out of this suit. *See* MTD Opp. 4–18. "If in a proper case the association seeks a declaration, injunction, or some other form of prospective relief, it can reasonably be supposed that the remedy, if granted, will inure to the benefit of those members of the association actually injured." *Waskul v. Washtenaw Cnty. Cmty. Mental Health*, 979 F.3d 426, 442 (6th Cir. 2020) (quotation marks omitted)). Contrary to the government's suggestion, there is no additional requirement that every injured member be named. To be sure, an association must identify at least one affected member to demonstrate standing to obtain an injunction. *See Summers v. Earth Island Inst.,* 555 U.S. 488, 498 (2009). But the government cites no authority for the proposition that, *after* the association has established associational standing and prevailed, *relief* is limited to named members. *See Universal Life Church Monastery Storehouse v. Nabors*, 35 F.4th 1021, 1040 (6th Cir. 2022) ("[A]ssociational-standing doctrine requires neither [named member's] individual participation for [the association] to secure an injunction on their *and other members*' behalf." (emphasis added)). Indeed, the Sixth Circuit very recently rejected that approach in a lawsuit brought by the U.S. Chamber; the court entered an injunction pending appeal that protects all the plaintiffs' members, not just the named declarants, even though the government sought to narrow the relief. *Kentucky v. EPA*, Nos. 23-5343, 23-5345 (6th Cir. May 10, 2023) (order granting injunction pending appeal). The relief Plaintiffs requested in their motion and proposed order is entirely appropriate.

CONCLUSION

This Court should grant Plaintiffs' motion for a preliminary injunction.

Dated: August 25, 2023 Respectfully submitted,

KING & SPALDING LLP

/s/Jeffrey S. Bucholtz

Jeffrey S. Bucholtz (*pro hac vice*)
**Trial Attorney*
Christine M. Carletta (*pro hac vice*)
Alexander Kazam (*pro hac vice*)
1700 Pennsylvania Avenue NW
Washington, DC 20006
(202) 737-0500
jbucholtz@kslaw.com
ccarletta@kslaw.com
akazam@kslaw.com

Gregory A. Ruehlmann (No. 0093071)
1180 Peachtree Street NE
Suite 1600
Atlanta, GA 30309
(404) 572-4600
gruehlmann@kslaw.com

Attorneys for Plaintiffs Dayton Area Chamber of Commerce, Ohio Chamber of Commerce, Michigan Chamber of Commerce, and Chamber of Commerce of the United States of America

PORTER WRIGHT MORRIS & ARTHUR LLP

/s/ Tami H. Kirby

Tami H. Kirby (No. 0078473)
Emma M. Walton (No. 0100024)
One South Main Street, Suite 1600
Dayton, OH 45402
Tel. (937) 449-6721
Fax (937) 449-6820
tkirby@porterwright.com

U.S. CHAMBER LITIGATION CENTER

Andrew R. Varcoe (*pro hac vice*)
Jennifer B. Dickey (*pro hac vice*)
1615 H Street NW
Washington, DC 20062
(202) 463-5337

Attorneys for Plaintiff Chamber of Commerce of the United States of America

CERTIFICATE OF SERVICE

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

/s/ Tami H. Kirby

Tami H. Kirby (No. 0078473)

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

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

Plaintiffs,

v.

XAVIER BECERRA, *et al.*,

Defendants.

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

Judge Thomas M. Rose

Magistrate Judge Peter B. Silvain, Jr.

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

I, Michael E. Staff, declare as follows:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Executed this 24th day of August, 2023.

Michael C. Staff 8/24/2023

Michael C. Staff