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.**

MEMORANDUM IN SUPPORT OF MOTION FOR A PRELIMINARY INJUNCTION

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INTRODUCTION

Rushed through Congress without debate using the budget reconciliation process and enacted on a bare-party line vote, the "Inflation Reduction Act of 2022" (IRA) dramatically expanded bureaucratic control over the pharmaceutical industry through its misleadingly named "Drug Price Negotiation Program." 42 U.S.C. § 1320f *et seq*. A "negotiation" implies a voluntary transaction between two parties. But the reality of this statute is just the opposite. The IRA delegates vast, essentially unfettered power to the Secretary of Health and Human Services to force manufacturers to sell their products at whatever prices the Secretary imposes.

That price-control scheme is directly contrary to longstanding Sixth Circuit precedent. In *Michigan Bell Tel. Co. v. Engler*, 257 F.3d 587 (2001), the Sixth Circuit held that a price-control scheme must "adequately safeguard against imposition of confiscatory rates" by providing, at minimum, a "guarantee" of "a fair and reasonable rate of return on investment." *Id.* at 594–95 & n.4. That is, "due process *guarantees* a fair and reasonable regulatory rate, not just the *possibility* of acquiring such a rate from an authority selecting rates within a prescribed range." *Id*. (emphasis added). But the "Drug Price Negotiation Program" fails to do anything of the sort. To the contrary, the IRA gives the Secretary free rein to set prices unilaterally, with no meaningful safeguards to ensure the constitutionally required guarantee of a just and reasonable rate of return. Compounding the constitutional injury, the statute denies administrative and judicial review of the Secretary's decisions and camouflages the reality of bureaucratic price controls by requiring manufacturers to "agree" to "negotiate" with the Secretary and to "agree" that the price set by the Secretary is the "maximum fair price" for their products. Under *Michigan Bell*, this price-control scheme violates due process.

As set forth more fully in Plaintiffs' complaint, the IRA's draconian price-control program violates several other bedrock constitutional requirements. The IRA flouts the separation of powers

by giving the Secretary unreviewable power to set arbitrarily low prices for a major national industry in the Secretary's sole discretion. It forces manufacturers to "agree" to the government-set price by threatening them with a crushing so-called "excise tax" that violates the Excessive Fines Clause and exceeds Congress's enumerated powers. And it violates the First Amendment by compelling manufacturers to "agree" publicly that the government-set price is the "maximum *fair* price," no matter how strenuously they disagree.

This motion for preliminary relief focuses solely on the Due Process Clause, however, because a straightforward application of *Michigan Bell* would protect Plaintiffs' interests and preserve the status quo to allow them to litigate the merits of all of their claims. Indeed, in *Michigan Bell*, a unanimous Sixth Circuit panel *affirmed* a preliminary injunction against one price-setting provision and *reversed* the denial of a PI against another—on the same grounds advanced by Plaintiffs here. *See* 257 F.3d at 590. In particular, when the government sets prices, it must afford parties certain procedural safeguards to ensure the constitutional minimum of just and reasonable prices and a fair return on investment. *Id.* at 592–93. The IRA not only lacks those required safeguards, but affirmatively imposes a cap on prices that is well below market value *and* directs HHS to aim for the "lowest" price. 42 U.S.C. § 1320f-3(b)(1). The IRA therefore *invites* "confiscatory rates," violating due process. *Michigan Bell*, 257 F.3d at 592–95.

The constitutional harm that Plaintiffs' members face is certain and impending, absent preliminary relief. The IRA requires HHS to publish the list of drugs it has selected for price controls by September 1, 2023, and requires the manufacturers of those drugs to "agree" to "negotiate" by October 1—thereby subjecting themselves to an unconstitutional process whose outcome will be whatever the Secretary unilaterally decrees. Plaintiffs' members include manufacturers whose drugs are expected to be selected and who have therefore already suffered,

and will suffer, substantial irreparable harm. Because all the preliminary injunction factors weigh strongly in Plaintiffs' favor, this Court should enjoin the implementation of the IRA's price-control program, as required by *Michigan Bell*. *See id.* at 590.

BACKGROUND

I. The Prescription Drug Market

Prescription drug pricing in our country has historically been market-driven. Although the federal government is the largest market participant, Congress long required the government to provide reimbursement for drugs in Medicare using formulas tied to market prices. Medicare Part B covers a range of outpatient healthcare services, including drugs that physicians administer to their patients, 42 U.S.C. § 1395k(a)(1); *id*. § 1395x(s)(2)(A), and since 2005, Medicare Part B has reimbursed providers 106% of a drug's Average Sales Price, which is the average price to commercial purchasers in the United States inclusive of rebates and other discounts, s*ee id*. § 1395w-3a. Medicare Part D, which covers self-administered prescription drugs, is managed by private insurers who contract with HHS to provide a prescription drug benefit, and those private insurers have negotiated drug prices with pharmaceutical manufacturers. Before the IRA, in Part D's "non-interference clause," Congress prohibited HHS from setting drug prices or "interfer[ing]" in those market-based negotiations. *Id*. § 1395w-111(i).

Congress's market-oriented approach to price-setting reflected two fundamental realities. First, in the healthcare field, the federal government is not only a major regulator, but also the "domina[nt]" market participant. *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 699 (3d Cir. 2023). Through Medicare and Medicaid, it accounts for "almost half the annual nationwide spending on prescription drugs." *Id*. (citing Cong. Budget Off., Prescription Drugs: Spending, Use, and Prices 8 (2022)). This dual role raises the obvious danger that the government will use self-serving rules to tilt the playing field in its favor, disadvantage other market participants, and effectively impose

price controls that would alter the entire market. The dual role also creates the temptation for actions that transgress the limits on government enshrined in our Constitution.

Second, Congress's market-focused approach reflected the realities of the drug development and approval process, which is notoriously challenging and expensive. Companies invest billions of dollars in research and development to discover new drugs, conduct rigorous pre-clinical and clinical testing, and shepherd drugs through the lengthy FDA approval process, with no certainty that a drug will ever make it to the pharmacy shelves. The average cost of bringing a single new drug to market is commonly estimated to be more than $2 billion,[1] and the process takes an average of 10 to 15 years.[2] Only about 1 in 5000 potential new drugs successfully navigates these hurdles; the vast majority are never approved for patient use.[3] When a drug does succeed, therefore, companies need to be able to make returns that offset the costs of the numerous experimental drugs that fail. Recognizing that economic imperative, Congress favored market-based pricing mechanisms that respected manufacturers' property rights and allowed the United States to become the world leader in pharmaceutical innovation.

II. The Inflation Reduction Act

A. The IRA's Unprecedented Provisions

In the IRA, Congress delegated sweeping power to HHS to reshape the U.S. pharmaceutical industry through the "Drug Price Negotiation Program." 42 U.S.C. § 1320f(a). The

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[1] Stephen Ezell, Info. Tech. & Innovation Found., Ensuring U.S. Biopharmaceutical Competitiveness, at 30 (July 2020), https://www2.itif.org/2020-biopharma-competitiveness.pdf.

[2] GAO, No. GAO-20-2155P, Artificial Intelligence in Health Care, at 34 (Dec. 20, 2019), https://www.gao.gov/assets/gao-20-215sp.pdf.

[3] Paula Carracedo-Reboredo et al., *A Review on Machine Learning Approaches and Trends in Drug Discovery*, 19 Computational & Structural Biotech. J. 4538 (Aug. 20, 2021), https://www.sciencedirect.com/science/article/pii/S2001037021003421.

program, which abandons Congress's previous reliance on market prices and on other safeguards to prevent HHS from abusing its dual role, will soon encompass dozens of the most important and most widely used prescription drugs. By delegation to the Centers for Medicare & Medicaid Services (CMS), HHS has begun implementing the program, including through a 198-page "guidance" document issued on June 30. *See* Memorandum from CMS on Revised Guidance for Medicare Drug Price Negotiation Program (June 30, 2023), https://www.cms.gov/files/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf ("Revised Guidance").

The IRA requires the Secretary to rank "negotiation-eligible drugs" based on Medicare expenditures over the past year and to subject a certain number of such drugs to the "negotiation" process. *See* 42 U.S.C. § 1320f-1(b)(1)(A)–(B). HHS must meet the following deadlines:

- September 1, 2023 – The Secretary must publish the ten Medicare Part D drugs selected for "negotiation." *Id.* § 1320f(d)(1).
- October 1, 2023 – Manufacturers of selected drugs must sign "agreements" to "negotiate." *Id.* § 1320f(d)(2)(a).
- October 2, 2023 – Manufacturers must submit extensive data requested by the Secretary. *Id.* § 1320f(d)(5)(A).
- February 1, 2024 – HHS must transmit its initial "offer" for the "maximum fair price" for each selected drug. *Id.* § 1320f(d)(5)(B).
- March 2, 2024 – Each manufacturer must either accept HHS's offer or send a "counteroffer." *Id.* § 1320f-3(b)(2)(C)(i).
- August 1, 2024 – HHS must decide the prices it is imposing, thereby ending the "negotiation" process. *Id.* § 1320f(d)(5).
- September 1, 2024 – HHS publishes the "maximum fair prices." *Id.* § 1320f(d)(6).
- January 1, 2026 – The prices go into effect.

This process repeats annually, with 15 more Part D drugs selected for 2027 by February 1, 2024; 15 more Part D and Part B drugs selected for 2028 by February 1, 2025; and 20 more Part D and Part B drugs selected for 2029 and each year thereafter. *Id.* §§ 1320f(b)(3), 1320f-1(a)(1)–(4).

Once a manufacturer's drug is selected, it must enter into "negotiations" with the Secretary. *Id.* § 1320f-3. These are negotiations in name only. In a genuine negotiation, if the parties do not agree, either party can walk away. Not under the IRA. A manufacturer faces a massive penalty

misleadingly called an "excise tax" (explained below) if it fails to do any of these things required by the IRA: (1) "agree" to enter into "negotiation," (2) submit detailed, sensitive information to HHS, and (3) "agree" to the "maximum fair price" set by HHS. 26 U.S.C. § 5000D(b)(1)–(4). The IRA directs HHS to make an "offer" and the manufacturer to "counteroffer." 42 U.S.C. § 1320f-3(b)(2)(C)–(D). But after the manufacturer "counteroffers," HHS is empowered to set whatever price it wants and calling it the "maximum fair price." The IRA's references to "negotiations" and "agreements" on "fair" prices are thus pure doublespeak—expedient labels used to mask the reality of unilateral price controls.

Throughout the process, HHS can demand detailed information, including confidential and proprietary information that a manufacturer would not ordinarily share with another market participant. *Id.* § 1320f-2(a)(4). Under threat of millions of dollars in civil penalties, manufacturers must "compl[y] with" whatever requirements HHS decides are "necessary for purposes of administering the program and monitoring compliance." *Id.* §§ 1320f-6(c), 1320f-2(a)(5). And the IRA imposes no standards to govern HHS's use of that information to set prices; it merely directs HHS to "consider" the information provided by the manufacturer, including certain cost information, prior federal financial support, data on patent applications, revenue and sales volume data, and information about alternative treatments. *Id.* § 1320f-3(e). The IRA directs HHS "to develop and use a consistent methodology and process … for negotiations … that aims to achieve the *lowest* maximum fair price for each selected drug." *Id.* § 1320f-3(b)(1) (emphasis added). But a direction to aim *consistently* for the "lowest" price only underscores the constitutional problem: the IRA offers no protections against confiscatory prices and does not guarantee a fair return.

Most obviously, the term "maximum fair price" is not defined by reference to any external standard of fairness; it is simply the "price negotiated" (*i.e.*, dictated) "pursuant to section 1320f-

3." *Id*. § 1320f. As CMS admits, while the statute requires CMS to "consider" certain "factors," "CMS has discretion to determine how or to what degree each factor should be considered." Revised Guidance at 144. In other words, the manufacturer's information goes into a black box, and out comes whatever HHS, unconstrained by any legal standard, chooses to "offer." Similarly, while HHS says it will meet with manufacturers, *id*. at 152, the statute is silent regarding how HHS is supposed to decide whether to accept a manufacturer's "counteroffer." The statute says only that the Secretary must "respond in writing." *Id*. § 1320f-3(b)(2)(D). Offering to meet is a legally empty gesture without a statutory standard governing the agency's response.

Although the IRA does not guarantee any minimum "floor" below which HHS may not descend in setting a price for a drug (apart from a narrow, temporary exception for certain "small biotech" drugs), the IRA does set a *ceiling* for the "negotiations." *Id*. § 1320f-3. That ceiling is the lowest number yielded by various alternative calculation methods. Each of these methods results in a price well below the market price. For example, the IRA limits the ceiling for "negotiations" to between 40% and 75% of a drug's Non-Federal Average Manufacturer Price (Non-FAMP). *Id*. § 1320f-3(c)(1)(C), (b)(2)(F). Non-FAMP is a measurement of the drug's average net sales price to commercial purchasers after all price concessions effectuated through wholesalers, including all discounts and rebates. 38 U.S.C. § 8126(h)(5). Forty to 75% of that net price is a very low price.

Once the Secretary chooses a final price, the IRA requires the manufacturer to "agree[]" to that price—which HHS then publishes as the "maximum fair price"—and to "agree[]" to provide access to the drug at that price to Medicare beneficiaries. *See id*. §§ 1320f-2(a), 1320f-3(a), 1320f(c)(2). As a result of the IRA's price ceiling, this government-imposed price will start out at least 25% to 60% below market-price benchmarks, but it of course could be much lower. *See id*. § 1320f-3(c)(1)(C), (b)(2)(F). Manufacturers that agree to this price but fail to provide access to

the drug at it owe a civil monetary penalty of *10 times* the difference between the price charged and the "maximum fair price," multiplied by the total number of units sold. *Id*. § 1320f-6(a).

If the manufacturer refuses to "agree" to the Secretary's chosen price—or, for that matter, refuses to participate in the sham "negotiation" process at the front end, knowing that it will be stuck "agreeing" to whatever price the Secretary dictates—it is hit with the massive "excise tax." This penalty amounts to multiples of *all* U.S. sales of "the designated drug"—not just sales in connection with federal healthcare programs. 26 U.S.C. § 5000D(a), (b). Although the IRA styles this penalty an "excise tax," in reality it is an astronomical daily fine that continues until the manufacturer caves. Under the statutory formula, the "excise tax" starts at about 185% and quickly rises to 1,900% of the selected drug's price, so that the fine for a $100 drug would be $1,900. *See* Cong. Rsch. Serv., No. R47202, Tax Provisions in the Inflation Reduction Act of 2022 (H.R. 5376), at 29 (2022), https://crsreports.congress.gov/product/pdf/R/R47202.

Manufacturers cannot escape the vise created by this program. First, even if it were possible to avoid the price-setting scheme by withdrawing from Medicare and Medicaid, no manufacturer could afford to do so and leave tens of millions of Medicare and Medicaid patients without access to its products. Second, in any event, a manufacturer legally cannot withdraw in time to avoid the IRA's penalties. That is because Congress mandated that when a manufacturer opts to withdraw, it takes 11 to 23 months, depending on the timing during the calendar year, for a notice of withdrawal to take effect. *See* 42 U.S.C. § 1395w-114a(b)(4)(B)(ii) (Medicare Coverage Gap Agreement); 42 C.F.R. § 423.2345(b)(2) (same); 42 U.S.C. § 1395w-114c(b)(4)(B)(ii) ("Manufacturer Discount Agreement" under IRA). As a result, if a manufacturer attempted to terminate its participation in July 2023, the termination would not take effect until January 1, 2025. The manufacturer would be trapped: it would have to wait for a year and a half before "none of

the drugs of the manufacturer of the designated drug are covered" by Medicare or Medicaid, 26 U.S.C. § 5000D(c)(1)(A)(ii), and during that lengthy period it would remain subject to the crippling "excise tax."[4] Thus, there is no escaping the IRA's price controls.

Despite—or maybe because of—the grave risks that HHS would impose confiscatory prices, Congress went to great lengths to insulate the price-control program from scrutiny. The IRA provides that there will be "no administrative or judicial review" of HHS's key determinations regarding which drugs will be subject to price controls or of the prices it sets. 42 U.S.C. § 1320f-7. The IRA combines that curtailment of back-end judicial review with a disregard of basic procedural protections on the front end. For example, instead of affording manufacturers notice or opportunity to be heard regarding key decisions that HHS will make, the IRA directs HHS to "implement" the program "for 2026, 2027, and 2028 by program instruction or other forms of program guidance." *Id.* § 1320f-1 note.

B. The IRA's Harmful Consequences for Plaintiffs' Members

Plaintiffs represent members that include a wide variety of companies of every size in a wide range of industries, including pharmaceutical manufacturers that are directly subject to the IRA's unlawful price-control scheme. *See* Quaadman Decl. (U.S. Chamber) ¶ 5; Kershner Decl. (Dayton Area Chamber) ¶ 5; Long Decl. (Ohio Chamber) ¶ 5; Holcomb Decl. (Michigan Chamber) ¶ 5. For example, several of Plaintiffs' members market drugs that are frequently prescribed to

[4] CMS's non-binding June 30 guidance suggests that a manufacturer could withdraw from federal healthcare programs faster than the statutes discussed in the text permit. *See* Revised Guidance at 120–21, 129–31. But CMS cannot evade the detailed timing limitations that Congress specifically imposed on termination "[b]y a manufacturer" by treating a termination by a manufacturer as if it is a termination "[b]y the Secretary." *Compare* 42 U.S.C. § 1395w-114a(b)(4)(B)(i) *with id.* § 1395w-114a(b)(4)(B)(ii). Despite CMS's desire to paint the price-control program as "voluntary," an agency guidance document cannot undo statutory mandates. Nor can an agency solve by "guidance" a constitutional defect in a statute.

Medicare Part D beneficiaries. Based on CMS data on Part D expenditures, internal analyses, and studies by market analysts, a number of these drugs are expected to be on the September 1 list of drugs selected for price controls, and other products will be on subsequent lists. These include AbbVie's drug IMBRUVICA®. *See* Staff Decl. ¶ 5. The IRA compels Plaintiffs' members to gather and submit sensitive commercial information regarding these products, incur other unrecoverable compliance costs, "agree" to "negotiate" with the Secretary, and subject themselves to a price-control program that lacks adequate safeguards to ensure just and reasonable prices and a fair return on investment. *See* Staff Decl. ¶¶ 6–19; *Michigan Bell*, 257 F.3d at 594–95.

LEGAL STANDARD

"A district court must balance four factors when considering a motion for a preliminary injunction: (1) whether the movant has a strong likelihood of success on the merits; (2) whether the movant would suffer irreparable injury absent the injunction; (3) whether the injunction would cause substantial harm to others; and (4) whether the public interest would be served by the issuance of an injunction." *Poffenbarger v. Kendall*, 588 F. Supp. 3d 770, 783 (S.D. Ohio 2022) (quoting *Bays v. City of Fairborn*, 668 F.3d 814, 818–19 (6th Cir. 2012)). The third and fourth factors "merge" when "the Government is the opposing party." *Id*. (quoting *Wilson v. Williams*, 961 F.3d 829, 845 (6th Cir. 2020)). Where a plaintiff has shown a strong likelihood of success on a constitutional claim, the equities weigh so heavily in the plaintiff's favor that it is "'usually ... unnecessary to dwell on the remaining three factors.'" *Id*. (quoting *Roberts v. Neace*, 958 F.3d 409, 416 (6th Cir. 2020) (per curiam)).

ARGUMENT

I. Plaintiffs are likely to succeed on the merits of their due process claim because the IRA's price-control regime violates well-established due process principles.

To demonstrate a strong likelihood of success on the merits, "it is ordinarily sufficient if the plaintiff has raised questions going to the merits so serious, substantial, difficult, and doubtful as to make them a fair ground for litigation." *Id.*; *accord Stryker Emp. Co. v. Abbas*, 60 F.4th 372, 385 (6th Cir. 2023). Plaintiffs' due process claim easily meets and exceeds that standard, because the IRA's price-control program is plainly unconstitutional under Sixth Circuit precedent elucidating the minimum due process requirements for administrative price-control regimes.

Michigan Bell explains how due process applies here. The Due Process Clause of the Fifth Amendment prohibits the federal government from depriving anyone of "life, liberty, or property" without "due process of law." In the context of price-control laws, the Supreme Court has long held that "[p]rice control is 'unconstitutional ... if arbitrary, discriminatory, or demonstrably irrelevant to the policy the legislature is free to adopt.'" *In re Permian Basin Area Rate Cases*, 390 U.S. 747, 769–70 (1968) (quoting *Nebbia v. New York*, 291 U.S. 502, 539 (1934)). Government-set prices must at least be "just and reasonable." *Id.* (citing *Fed. Power Comm'n v. Nat. Gas Pipeline Co.*, 315 U.S. 575, 586 (1942)). And as the Sixth Circuit explained in *Michigan Bell*, a price-control statute is unconstitutional unless it "adequately safeguards against confiscatory rates, and therefore, ensures a constitutional rate of return," which includes "a fair and reasonable rate of return on investment." 257 F.3d at 593; *see also Guar. Nat'l Ins. Co. v. Gates*, 916 F.2d 508, 512 (9th Cir. 1990) (invalidating Nevada law freezing insurance rates because it provided no "mechanism to guarantee a constitutionally required fair and reasonable return"); *Monongahela Power Co. v. Schriber*, 322 F. Supp. 2d 902, 918–19 (S.D. Ohio 2004), *as modified on reconsideration* (June 14, 2004) (granting preliminary injunction against price-control statute in

electric power industry). The IRA lacks any mechanism for providing those vital protections. It has no statutory standard requiring just and reasonable prices. And it expressly prohibits judicial—and even administrative—review of HHS's unilateral price determinations. Indeed, from all appearances, the IRA is designed to *encourage* the imposition of confiscatory prices without providing any opportunity for error correction.

Michigan Bell held unconstitutional "*on its face*" a price-setting statute that lacked protections from confiscatory pricing. 257 F.3d at 594 (emphasis added). There, the Sixth Circuit considered a facial constitutional challenge to a Michigan statute that imposed a temporary rate freeze on certain telephone services "except for services the [agency] deemed competitive." *Id*. at 590. The court held that this "competitive opt-out provision" failed to "safeguard against imposition of confiscatory rates" because, among other reasons, it did not "address the reasonableness" of the rates and did not "provide for timely relief from confiscatory rates." *Id.* at 594. Although the companies had "other unregulated income streams," they could not be "required to subsidize their regulated services with income from rates either deemed to be competitive, or with revenues generated from unregulated services." *Id.* (citing *Brooks-Scanlon Co. v. R.R. Comm'n*, 251 U.S. 396 (1920)).

It made no difference to the Sixth Circuit's conclusion that "other provisions" of the statute "arguably *attemp[ted]* to ensure the plaintiffs receive a constitutional rate of return," including statutory language purporting to guarantee that rates be "just and reasonable." *Id*. (emphasis added). Upon examination, these provisions "[did] not guarantee a constitutionally adequate rate of return" because they "merely permit[ted] telephone service providers to cover *costs*, and [did] not ensure a fair and reasonable rate of return on investment." *Id.* at 594–96. Because "merely providing for a return which only covers costs is inadequate under well-established due process

standards," these provisions did not provide "an adequate safeguard against confiscatory rates." *Id.* For the same reason, in addition to holding that the rate-freeze provision violated due process, the court also invalidated a provision that abolished a fee traditionally charged by telephone companies "without providing a mechanism to safeguard the right to earn a constitutional rate of return." *Id.* at 596 (affirming preliminary injunction against rate-freeze provision and reversing denial of PI against fee-elimination provision).

Under *Michigan Bell*, this is an easy case. The IRA is even less protective of companies' constitutionally protected interests in an adequate rate of return than were the statutory price-setting provisions held invalid in *Michigan Bell*. While attempting to create an illusion of fairness with the label "maximum fair price," the IRA does not guarantee *any* return to manufacturers at all—let alone a just and reasonable one. Whereas the statute in *Michigan Bell* at least guaranteed that companies could recover their costs, the IRA does the opposite. The IRA establishes no price floor (apart from a narrow, time-limited exception for certain small biotech manufacturers), *see* 42 U.S.C. § 1320f-3(b)(2)(F)(ii); establishes an across-the-board *ceiling* well below market prices, *see id*. § 1320f-3(c)(1)(C), (b)(2)(F); and directs the Secretary to aim for "the lowest" price below that ceiling, *id.* § 1320f-3(b)(1). And to make matters even worse, Congress barred "administrative or judicial review" of HHS's "determination of a maximum fair price." *Id*. § 1320f-7.

In sum, far from "adequately safeguard[ing] against imposition of confiscatory rates" as due process requires, *Michigan Bell*, 257 F.3d at 594, the IRA contains multiple features that *invite* the imposition of arbitrary and confiscatory prices, while shutting the door to administrative and judicial review that could allow for correction of such constitutional errors.[5] The IRA's veneer of

[5] To be clear, Plaintiffs do not suggest that a scheme that invited arbitrary and confiscatory price-setting would be constitutional if it provided for judicial review. But the absence of judicial

"negotiation" is an attempt to conceal that blatant violation of due process. If the agency's "offer" is too low, the manufacturer can propose a "counteroffer." 42 U.S.C. § 1320f-3(b)(2)(C)(i). But this affords the manufacturer no real protection: the agency can simply reject the "counteroffer" and impose whatever price it wants—subject only to the IRA's price *ceiling* and its instruction to strive for the "lowest" price, and secure in the knowledge that no court can review that selected price. While the agency is supposed to "consider" various "factors," *id.* § 1320f-3(e), CMS has acknowledged that the statute does not tell it *how* it should consider those factors. *See supra* at 7.

Moreover, nothing in the IRA even *encourages*, let alone requires, the agency to meet the constitutional minimum of a "fair and reasonable return on investment." *Michigan Bell*, 257 F.3d at 594. At best, the IRA merely instructs the agency to consider, as one factor among many in a standardless stew in its unreviewable discretion, the extent to which the manufacturer has recovered certain costs for the selected drug. But providing for recovery of costs alone, without a reasonable return on investment, is simply "inadequate under well-established due process standards." *Id.* at 596.[6] And even if it were *possible* for a "maximum fair price" to be constitutionally adequate—a highly dubious proposition given the low statutory ceiling and Congress's directive to aim for the "lowest" price—the Sixth Circuit has held that such a "possibility" is insufficient: "[I]t is axiomatic that due process *guarantees* a fair and reasonable

review here underscores the constitutional harm. Worse, the combination of Congress's delegation of vast power and the absence of vital safeguards, such as intelligible standards and judicial review, also violates the separation of powers by effectively authorizing HHS to do whatever it wants, subject to no legal standard or procedural protections. *See* Compl. ¶¶ 121–45, Dkt. 1.

[6] Recovery of costs alone is particularly inadequate in the pharmaceutical industry, where each manufacturer must recoup, on each drug that makes it to market, not only its investments in developing that drug but also a portion of the costs incurred in its broader research programs given that the vast majority of researched drugs never make it to market. The IRA appears to instruct HHS to ignore this practical reality in setting prices; at the very least, the IRA indisputably does not guarantee that the price-setting process take account of this crucial consideration.

regulatory rate, not just the *possibility* of acquiring such a rate from an authority selecting rates within a prescribed range containing confiscatory and fair rates." *Id*. at 595 n.4 (emphasis added).

As explained above, the IRA is even more egregious than the regime at issue in *Michigan Bell.* This is underscored by the draconian penalties that Congress provided to coerce manufacturers to "agree" to "provide access" to their drugs at whatever price the agency dictates. 42 U.S.C. § 1320f-2(a)(1), (2), (3). The "excise tax" of up to 1900% on all sales is so wildly excessive that no one could sell (or buy) a drug subject to it—which is why the Congressional Budget Office projected that it would raise precisely zero dollars in revenue. *See* CBO, How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act (Feb. 2023), https://www.cbo.gov/system/files/2023-02/58850-IRA-Drug-Provs.pdf. Nor is withdrawing from federal healthcare programs an option, both because no manufacturer could afford to do so and because legally it is not possible to withdraw fast enough to avoid the "excise tax." *See supra* at 8–9. Indeed, Congress could not have intended withdrawal to be a real option: that would create a national health crisis as millions of Americans lost access to critically needed and often life-sustaining prescription drugs.

It is no accident that the IRA lacks all of these required procedural protections. Congress portrayed this price-control regime as merely involving "agreements" by manufacturers to "negotiate" "fair" prices in an effort to obscure the reality that this is a price-control regime. But this veneer of voluntariness cannot hide the truth of the statute, nor distinguish it from what has already been held unconstitutional under Sixth Circuit precedent. Because the IRA includes none

of the procedural protections that *Michigan Bell* held are required, the Court should enjoin the IRA's price-control regime.[7]

Because *Michigan Bell* is on point and explains the requirements of due process in the specific context relevant here, this Court need not also apply the general due-process balancing test laid out in *Mathews v. Eldridge*, 424 U.S. 319 (1976). *See Michigan Bell*, 257 F.3d at 592–93 (relying on precedent specific to price controls without applying *Eldridge*); *Monongahela Power*, 322 F. Supp. 2d at 918–19 (same); *cf. Hicks v. Comm'r of Soc. Sec.*, 909 F.3d 786, 796–98 (6th Cir. 2018) (holding that Social Security Administration's "procedures violate longstanding principles of procedural due process that predate the *Mathews* test"). Applying *Eldridge*, however, would independently lead to the same conclusion. Under *Eldridge*, courts weigh "three distinct factors: First, the private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards; and third, the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail." 424 U.S. at 335; *accord Johnson v. City of Saginaw,* 980 F.3d 497, 510 (6th Cir. 2020). These factors strongly favor Plaintiffs.

First, the private interests endangered by the IRA's price controls are enormous. The IRA threatens manufacturers' hard-earned intellectual property, their associated investments and research programs, and their right to sell their products at market-based prices. Manufacturers rely

[7] The IRA's resort to compelled doublespeak also violates the First Amendment. Requiring manufacturers to say they "agree" to the "maximum fair price"—when the truth is that the IRA authorizes HHS to make manufacturers an "offer" they can't refuse—serves no purpose other than to mislead the public about the nature of the price-setting process. That, of course, is not a constitutionally permissible purpose for coercing speech. *See* Compl. ¶¶ 209–22.

on the promise of future sales—and the ability to charge market-based prices—when pioneering and patenting innovative drugs. *See King Instruments v. Perego*, 65 F.3d 941, 950 (Fed. Cir. 1995).

Second, erroneous deprivations are virtually certain and could be substantially mitigated by additional safeguards. Far from containing procedural protections adequate to prevent unconstitutional and erroneous deprivations, the IRA appears designed to *cause* such deprivations and paper them over with a façade of supposedly voluntary "negotiations." Ordinarily, price-control statutes set forth a legal standard that purports to ensure at least just and reasonable prices. *See, e.g.*, *In re Permian Basin Area Rate Cases*, 390 U.S. at 754 (Natural Gas Act); 16 U.S.C. § 824d (Federal Power Act). The IRA, in contrast, not only imposes a ceiling well below market prices but directs the agency to choose the "lowest" price, without any guaranteed minimum. Price-control statutes also ordinarily provide for judicial review to ensure that the agency's price-setting complies with statutory requirements and avoids arbitrary, discriminatory, or confiscatory results. *See, e.g.*, 15 U.S.C § 717r *and* 16 U.S.C. § 825*l* (providing for judicial review of Federal Energy Regulatory Commission rate-setting); *cf. Hicks*, 909 F.3d at 796–98 (emphasizing the importance of "a fair opportunity to rebut the Government's factual assertions before a neutral decisionmaker"). The IRA, in contrast, strips manufacturers of judicial and administrative review. And the risk of unfair decision-making is heightened here because the government is not only the price-setter but the payor—creating an obvious risk of actions distorted by the mixing of the government's two roles.

Third, the government's interest in withholding those well-established procedural safeguards is nonexistent. Federal and state governments have consistently provided these basic protections in similar contexts for generations. The IRA is highly anomalous, if not entirely unprecedented, in omitting all of these traditional safeguards.

Thus, while this case can and should be resolved by a straightforward application of *Michigan Bell*, applying the *Eldridge* test would lead to the same conclusion.

II. Plaintiffs' members will be irreparably harmed without an injunction.

The IRA is already causing irreparable harm to Plaintiffs' members because it is causing them, and will continue to cause them, to suffer unrecoverable economic losses. *Michigan Bell*, once again, is on point and makes the irreparable harm analysis here straightforward. 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. *Michigan Bell*, 257 F.3d at 598 (quotation marks omitted). And even if companies could recoup losses by charging higher prices on other products, the resulting loss of customer goodwill would be "difficult to compute" and thus "amounts to irreparable injury." *Id.* (quotation marks omitted); *see RECO Equip., Inc. v. Wilson*, No. 20-4312, 2021 WL 5013816, at *4 (6th Cir. Oct. 28, 2021). Further, in suits against the government, compliance costs and other economic losses due to the effects of regulation generally constitute irreparable harm because "sovereign immunity bars the [court] from granting [plaintiffs] damages." *Kentucky v. U.S. ex rel. Hagel*, 759 F.3d 588, 599 (6th Cir. 2014); *accord Kentucky v. Biden,* 57 F.4th 545, 555–56 (6th Cir. 2023).[8] For example, AbbVie, which is a member of the Dayton Area Chamber and the U.S. Chamber, markets the drug IMBRUVICA® in the United States. According to CMS data, IMBRUVICA® was among the drugs with the top ten gross annual Part D expenditures for plan year 2021. *See* Staff Decl. ¶ 5. Market analysts expect IMBRUVICA® to be among the drugs selected for the IRA's price controls

[8] More broadly, courts presume irreparable harm in cases involving constitutional violations. *Roberts*, 958 F.3d at 416; *Obama for Am. v. Husted*, 697 F.3d 423, 436 (6th Cir. 2012); *ACLU v. McCreary Cnty.*, 354 F.3d 438, 445 (6th Cir. 2003). The Court need not rely on this presumption, however, because Plaintiffs have shown clear irreparable harm under *Michigan Bell*.

by September 1, 2023. *Id.* If it is, then AbbVie would 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.* ¶¶ 6–8. As explained in more detail in the accompanying declaration, the IRA's price controls would cause AbbVie to suffer extremely significant financial harm, and AbbVie is already incurring, and will continue to incur, substantial costs to comply with the IRA's burdensome requirements. *See id*. ¶¶ 15–19. The agency itself acknowledges that "manufacturers need to take a number of actions well in advance of September 1, 2023, to prepare for the possibility that a drug that they manufacture will be included on the selected drug list." Revised Guidance at 9. And as CMS's template manufacturer "agreement" makes clear, "[a]ctions by the [m]anufacturer for damages are not permitted." CMS, Medicare Drug Price Negotiation Program Agreement, at 4, https://www.cms.gov/files/document/inflation-reduction-act-manufacturer-agreement-template.pdf. Thus, Plaintiffs easily satisfy the irreparable-harm requirement.

III. Enjoining the IRA's unconstitutional price-control program will not harm others and will promote the public interest.

As noted above, "the two remaining preliminary injunction factors—whether issuing the injunction would harm others and where the public interest lies—merge when the government is the defendant." *Kentucky*, 57 F.4th at 556 (citing *Wilson v. Williams*, 961 F.3d 829, 844 (6th Cir. 2020). In a constitutional challenge like this one, these factors generally track the likelihood of success on the merits, because "it is always in the public interest to prevent the violation of a party's constitutional rights," *G & V Lounge, Inc. v. Michigan Liquor Control Comm'n*, 23 F.3d 1071, 1079 (6th Cir. 1994), and "[n]o third party has a right to rely upon a confiscatory rate and no party may benefit from the violation of another party's constitutional rights." *Monongahela*

Power, 322 F. Supp. 2d at 921-22; *see also Michigan Bell*, 257 F.3d at 600 ("The public is certainly interested in the prevention of enforcement of ordinances which may be unconstitutional.") (citation and quotation marks omitted); *Kentucky*, 57 F.4th at 556 ("[A]t bottom, the public interest lies in a correct application of the law[.]") (citation and quotation marks omitted); *Chabad of S. Ohio & Congregation Lubavitch v. Cincinnati*, 363 F.3d 427, 436 (6th Cir. 2004) ("[T]he public interest is served by preventing the violation of constitutional rights[.]").

Moreover, even apart from the paramount public interest in protecting constitutional rights, it is in no one's interest to establish a drug price-control regime bereft of safeguards to prevent arbitrary, discriminatory, and confiscatory prices. Whatever one thinks of the drawbacks and purported benefits of price controls as a general matter, the government has no legitimate excuse for withholding basic procedural safeguards that it has long incorporated into other administrative price-control programs.

CONCLUSION

In light of *Michigan Bell*, this Court should enjoin Defendants from implementing the IRA's drug price-control program.

Dated: July 12, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on July 12, 2023, and in accordance with S.D. Ohio Civ. R. 65.1(b)(1), a true and correct copy of the foregoing Memorandum in Support of a 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.

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