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

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

Plaintiffs,

v.

XAVIER BECERRA, *et al.*,

Defendants.

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

Judge Michael J. Newman

Magistrate Judge Peter B. Silvain, Jr.

PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Pursuant to Rule 56 of the Federal Rules of Civil Procedure and Rule 7.2 of the Local Civil Rules of the United States District Court for the Southern District of Ohio, Plaintiffs hereby respectfully move this Court for summary judgment on all of Plaintiffs' claims. The grounds for this Motion are set forth in the accompanying Memorandum in Support. Additionally, the Third Declaration of Michael C. Staff is attached hereto as Exhibit A in support of this Motion.

Dated: November 8, 2023

Respectfully submitted,

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MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Constitutional Provisions

Statutes

Regulations

Other Authorities

INTRODUCTION AND SUMMARY OF ARGUMENT

Constitutional problems in statutes sometimes come "clad, so to speak, in sheep's clothing." *Plaut v. Spendthrift Farm, Inc*., 1 F.3d 1487, 1490 (6th Cir. 1993) (quoting *Morrison v. Olson*, 487 U.S. 654, 699 (1988) (Scalia, J., dissenting)), *aff'd*, 514 U.S. 211, 240 (1995). This is just such a case. The statute bears a seemingly innocuous title: the "Drug Price Negotiation Program," enacted as part of the Inflation Reduction Act of 2022, 42 U.S.C. § 1320f *et seq*. And its provisions are clothed in the language of "agreement" and "fairness." But strip away the garb, and what is left is an unprecedented and unconstitutional regime of involuntary price controls. The program dramatically transforms the market-based pricing rules that have governed Medicare for decades. And manufacturers—many of which joined Medicare long ago and made billions of dollars of investments in reliance on its promise of market-oriented pricing—have no escape.

A "negotiation" implies a voluntary transaction between two parties. The reality here is just the opposite. Enacted by Congress on a bare party-line vote, the IRA delegates virtually unfettered power to the Secretary of Health and Human Services to dictate the terms of trade in one of the nation's most important industries. Disguised as a mere extension of Medicare, the IRA price-control program is in reality a new central planning regime that forces pharmaceutical manufacturers to make their products available in government healthcare programs at arbitrarily set prices, shielded from judicial review for error or illegality—and forces them to endorse those prices as "fair." The IRA program, which captures companies that joined Medicare long before the program was enacted, cannot be defended as voluntary. *See, e.g., Nat'l Fed'n of Indep. Bus. v. Sebelius* (*NFIB*), 567 U.S. 519, 582 (2012). And the program violates the separation of powers and several other bedrock constitutional requirements.

First, the scheme violates Sixth Circuit precedent elucidating the minimum due process requirements for price-control regimes because it does not "adequately safeguard against

imposition of confiscatory rates." *Michigan Bell Tel. Co. v. Engler*, 257 F.3d 587, 594 (6th Cir. 2001). When the government sets prices, it must afford certain procedural safeguards to ensure the constitutional minimum of just and reasonable prices. The IRA not only lacks those safeguards, but imposes a below-market *ceiling* on prices and directs HHS—a self-interested regulator and payor—to aim for the "lowest" price. The IRA is therefore invalid under *Michigan Bell*. And while this Court need not apply the general balancing test for procedural due process set forth in *Mathews v. Eldridge*, 424 U.S. 319, 334–35 (1976), that test only underscores the IRA's constitutional defects.

Although this Court denied Plaintiffs' motion for a preliminary injunction based on the due process claim, this Court held only that "at this initial stage in the litigation process, it is too early to know—with the degree of certainty necessary for a preliminary injunction—that Plaintiffs have a strong likelihood of succeeding on the merits of their due process claim." Dkt. 55 at PageID 597. This Court did not dispute that *Michigan Bell* remains binding precedent and that price-control regimes must comply with its due process requirements. Rather, this Court suggested that *Michigan Bell* may not apply here because, as some older, non-IRA-related, cases indicated in dicta, "participation in Medicare . . . is a completely voluntary choice." *Id.* at PageID 596. But Plaintiffs' challenge does not turn on whether the decision to participate in Medicare in the first place was voluntary. What matters is that *the IRA*, which significantly *amends* the Medicare statute, is *not* voluntary. The IRA "is in reality a *new* program," not a mere continuation of "the *existing* . . . program." *NFIB*, 567 U.S. at 582 (emphasis added). As a matter of both law and fact, manufacturers have no way to escape from it. With the benefit of full consideration on the merits, therefore, this Court should conclude that the program is unconstitutional under both *Michigan Bell* and *Eldridge*.

Second, the price-control program violates the Excessive Fines Clause of the Eighth Amendment. The statute forces manufacturers to pretend to "negotiate" and then "agree" to the government's unilaterally set price by threatening them with an enormous so-called "excise tax" for noncompliance. Despite its label, this fee is in reality a "grossly disproportionate" penalty that rises to as much as 1,900% of the market price of the drug on every sale and is therefore unconstitutional. *United States v. Bajakajian*, 524 U.S. 321, 334 (1998). The penalty is so exorbitant that the government itself does not expect it to produce a penny of revenue—because no one can afford to pay it. It is an excessive fine hiding in plain sight.

Third, the "excise tax" is not authorized by Congress's enumerated powers. It cannot be justified as an exercise of the taxing power; unlike a real tax, it will raise no revenue. Rather, it is an "exceedingly heavy" penalty designed to coerce manufacturers. *NFIB*, 567 U.S. at 565. Nor is the penalty authorized by the Commerce Clause. That Clause gives Congress "the power to *regulate* commerce, not to *compel* it." *Id*. at 555. The "excise tax" requires manufacturers to "agree" to "provide access" to their drugs at the Secretary's chosen price. This compulsion to engage in commercial activity is beyond the scope of Congress's enumerated powers.

Fourth, the IRA violates the First Amendment by compelling manufacturers to endorse the government's political spin. The IRA forces manufacturers to pretend, and to declare publicly, that they "agree" to "negotiations" and to the government-set price and that that price is the "maximum fair price." Under well-established First Amendment principles, however, the government cannot "co-opt" manufacturers "to deliver its message for it." *Nat'l Inst. of Fam. & Life Advocs. v. Becerra* (*NIFLA*), 138 S. Ct. 2361, 2376 (2018).

Finally, the IRA's price-control program flouts the separation of powers. The program allows the Secretary to dominate the $600 billion pharmaceutical industry by giving the Secretary

unreviewable power to compel sales in government healthcare programs at arbitrarily low prices set in the Secretary's sole discretion. This novel scheme violates the nondelegation doctrine, which prohibits Congress from evading accountability by delegating legislative decisions to the executive. At a minimum, when Congress authorizes an administrative agency to displace market forces and set prices on targeted products, it must include constitutional safeguards, such as statutory standards to prevent arbitrary, discriminatory, or confiscatory pricing; meaningful opportunities for public input on key decisions; and crucially, judicial review. Such checks and balances are especially important where, as here, the agency is acting both as a regulator and in its own self-interest as the dominant market participant. Yet, in an unprecedented break from our constitutional tradition, Congress built *none* of those protections into the IRA. Instead, Congress insulated itself from accountability by delegating vast policymaking power to the executive, and then insulated itself further by expressly prohibiting administrative and judicial review of the agency's price-setting and other consequential decisions.

Just as the "multilevel protection from removal" that the Supreme Court invalidated in *Free Enterprise Fund v. Public Co. Accounting Oversight Board*, 561 U.S. 477, 484 (2010), was "contrary to Article II's vesting of executive power in the President," the multilevel insulation from accountability here is contrary to Article I's vesting of "all legislative powers" in Congress. *Id.* (quotation marks and brackets omitted). This layer upon layer of accountability-destroying contrivances amounts to "delegation running riot," *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 553 (1935) (Cardozo, J., concurring), and is "incompatible with the Constitution's separation of powers," *Free Enterprise Fund*, 561 U.S. at 498.

The government has tried to obscure many of these defects by portraying the IRA as merely a "voluntary" condition on manufacturers' participation in Medicare and Medicaid. But that

portrayal is fundamentally flawed. As noted above, the IRA is not voluntary. First, even if a manufacturer could somehow afford to withdraw *all* of its drugs from Medicare and Medicaid (as would be necessary to avoid the IRA), due to statutory requirements, that withdrawal would not take effect for 11 to 23 months. *See* 42 U.S.C. § 1395w-114a. During that time, the manufacturer would be subject to the IRA's punitive "excise tax." *See* 26 U.S.C. § 5000D. Second, under the "unconstitutional conditions doctrine," the government "'cannot constitutionally condition the receipt of a benefit . . . on an agreement to refrain from exercising one's constitutional rights.'" *R.S.W.W., Inc. v. City of Keego Harbor*, 397 F.3d 427, 434–36 (6th Cir. 2005) (quoting *G & V Lounge, Inc. v. Mich. Liquor Control Comm'n*, 23 F.3d 1071, 1077 (6th Cir. 1994)). The government cannot induce manufacturers to accept the IRA's violations of their constitutional rights as the "voluntary" price of participation in Medicare and Medicaid. Third, whether participation in pre-IRA Medicare or Medicaid could be considered "voluntary" is beside the point: the IRA is "a new program." *NFIB*, 567 U.S. at 582. As the Supreme Court recognized when it struck down a coercive Medicaid condition in *NFIB*, the "threatened loss" of participation here—in longstanding healthcare programs that comprise nearly half of the market—is coercive "economic dragooning." *Id.*

The IRA's price-control program will have devastating effects on America's world-leading pharmaceutical sector and will deprive millions of Americans of life-saving and life-enhancing drugs. But this case is about even more than the fate of a vitally important industry and all of the people who depend on it. This case is about ensuring that Congress respects the constitutional limits that protect the rights of every American and every American business.

BACKGROUND

I. The Federal Healthcare and Prescription Drug Markets

To understand how the IRA transforms American healthcare, including Medicare and Medicaid, it is important to understand how prescription drug markets have traditionally functioned. Historically, prescription drug pricing in our country has 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). 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, *see id*. § 1395w-3a. Medicare Part D, which was enacted in 2003, covers self-administered prescription drugs and is managed by private insurers who contract with HHS to provide a drug benefit. Before the IRA, those private insurers negotiated drug prices with pharmaceutical manufacturers without interference by the government. Indeed, before the IRA, in Part D's "non-interference clause," Congress expressly prohibited HHS from setting drug prices or "interfer[ing]" in those market-based negotiations. *Id.* § 1395w-111(i). This market-oriented model attracted manufacturers to invest billions of dollars in developing innovative drugs that serve Medicare beneficiaries.

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 CBO, 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. Indeed, Medicare Part D's sponsors called the "noninterference" clause a "fundamental protection" against "price fixing by the CMS bureaucracy." 149 Cong. Rec. S15624 (daily ed. Nov. 23, 2003) (statement of Sen. Grassley).

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.

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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. 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, 4547 (Aug. 20, 2021), https://www.sciencedirect.com/science/article/pii/S2001037021003421.

II. The Inflation Reduction Act

A. The IRA's Unprecedented Provisions

In August 2022, by razor-thin margins along party lines, Congress passed the unprecedented bill now known as the Inflation Reduction Act. After signing the bill into law, President Biden declared that "Big Pharma lost" because "Medicare will have the power to . . . lower prescription drug prices."[4] To achieve that overriding goal, the IRA delegates sweeping power to HHS through the "Drug Price Negotiation Program." 42 U.S.C. § 1320f(a).

The program, which abandons Congress's longstanding reliance on market prices and the Part D "non-interference" clause, already covers ten of the most important and most widely used prescription "drugs," and it will soon encompass dozens more. HHS has been implementing the program by delegation to CMS, which has proceeded by issuing reams of non-binding guidance instead of undergoing notice-and-comment rulemaking. On March 15, 2023, CMS released a 91-page "initial guidance" document addressing various aspects of the drug selection and price-setting process.[5] On June 30, CMS followed up with a 198-page "revised guidance" document.[6]

i. Drug selection provisions

In 2023, the IRA requires the Secretary to rank "negotiation-eligible drugs" based on total expenditures under Medicare over the past year (initially looking only to Part D and then expanding to both Part B and Part D). 42 U.S.C. § 1320f-1(b)(1)(A)–(B). Because total expenditures are a function of volume as well as price, this ranking will include many of the most

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

[5] *See* Memorandum from CMS on Medicare Drug Price Negotiation Program (Mar. 15, 2023) ("Initial Guidance"), *available at* https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf.

[6] *See* Memorandum from CMS on Revised Guidance for Medicare Drug Price Negotiation Program (June 30, 2023) ("Revised Guidance"), *available at* https://www.cms.gov/files/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf.

commonly used drugs, regardless of whether there is a basis for thinking those drugs are overpriced. That is particularly true given that CMS is calculating total Medicare expenditures on a gross basis, not based on amounts "actually paid" by Medicare after taking account of rebates or other forms of remuneration. *See* Revised Guidance at 18; 88 Fed. Reg. 22,120, 22,259–63 (Apr. 12, 2023).

The IRA defines "negotiation-eligible drugs" to include all "qualifying single-source drugs." 42 U.S.C. § 1320f-1(d)(1), (e)(1). In its guidance, CMS has taken a maximally broad view of what constitutes a single "drug." *See* Revised Guidance at 99–100. It sweeps in different products—that have different dosage forms and strengths, that were subject to separate clinical trials, that help different patient populations, and that have different treatment indications—merely because they contain the same active moiety (*i.e.*, molecular basis) or active ingredient and are marketed by the same holder of an FDA new drug application or biologics license application. CMS has thus defined as a single "drug" a wide range of different drug products. *Id*. As a result, the IRA's price controls will apply to a far greater number of drug products than the dozens of drugs formally "selected." And despite the critical importance of this drug definition and the substantial legal consequences that flow from it, CMS refused to follow notice-and-comment rulemaking procedures. Instead, CMS stated that it "is issuing guidance [on that subject] as final, without a comment solicitation." Initial Guidance at 2; *see* Revised Guidance at 8–11.

HHS must meet the following deadlines (with deadlines that have passed in italics):

- *September 1, 2023 – The Secretary must publish the ten Medicare Part D drugs selected for "negotiation." 42 U.S.C. § 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 determine 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, 2025; 15 more Part D and Part B drugs selected for 2028 by February 1, 2026; 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). CMS has warned that "manufacturers need to take a number of actions well in advance" of the potential selection of their drugs, including "gather[ing] information for potential submission to CMS." Revised Guidance at 9. If manufacturers fail to submit the required information on time, they are subject to $1 million-per-day penalties and the "excise tax." *See* 42 U.S.C. §§ 1320f-2(a)(4)–(5), 1320f-6(b); 26 U.S.C. § 5000D(b)(4).

The number of drugs subject to "negotiation" compounds over time: once a drug is selected, it remains selected until HHS determines that a generic or biosimilar version of the drug is approved or licensed and marketed pursuant to that approval. 42 U.S.C. § 1320f-1(c)(1). By 2029, as many as 60 different "drugs" (including many more drug products) will be subject to price-setting.

ii. Forced "negotiation" provisions

Once a manufacturer's drug is selected, it must "agree" to enter into "negotiations" with the Secretary. 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 described as an "excise tax"—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 to call it the "maximum fair price." The IRA's references to "negotiations" and "agreements" on "fair" prices are pure doublespeak—labels used to mask the reality of unilateral price controls.

Throughout the process, HHS can demand detailed information, including confidential and proprietary data. *Id*. § 1320f-2(a)(4). Under threat of millions of dollars in 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; the IRA 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: a lack of procedural protections to prevent confiscatory pricing and ensure 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(c)(3). As CMS admits, while the statute requires CMS to "consider" certain "factors," "CMS has the discretion to determine how and 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 number that HHS, unconstrained by any legal standard, chooses to "offer." Similarly, while HHS says that 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." 42 U.S.C. § 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 measure 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.

The so-called "agreement" to "negotiate" is a blank check to CMS to saddle manufacturers with whatever burdens it wants. CMS's Template "Agreement" gives CMS unilateral power to change the terms of the "agreement" at any time for any reason. *See* CMS, Medicare Drug Price Negotiation Program Agreement ("CMS Template"), at 4, https://www.cms.gov/files/document/inflation-reduction-act-manufacturer-agreement-template.pdf. It expressly disclaims

responsibility for any costs incurred by manufacturers. *Id*. And it commits manufacturers to agree to whatever the government, in its statutorily unreviewable discretion, ultimately deems the "maximum fair price." *Id*. at 2.

iii. Government-imposed price

Once CMS chooses a final price, the IRA requires the manufacturer to "agree[]" to that price—which CMS then publishes as the "maximum fair price"—and to "agree[]" to provide access to the drug at that price to Medicare beneficiaries. *See* 42 U.S.C. §§ 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). The Congressional Budget Office estimated that CMS's price controls would lower net prices—the prices that manufacturers actually receive—for selected drugs by roughly 50% on average. *See* CBO, No. 58850, How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act, at 10 (Feb. 2023), https://www.cbo.gov/system/files/2023-02/58850-IRA-Drug-Provs.pdf. Manufacturers that "agree" to this price, but fail to provide access at that price, 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. 42 U.S.C. § 1320f-6(a).

iv. Misnamed "excise tax"

If the manufacturer refuses to "agree" to CMS'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 CMS dictates—it is hit with the massive "excise tax." On its face, the text of the statute indicates that 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).[7] Although the IRA styles this penalty an "excise tax," in reality it is an astronomical daily fine that continues until the manufacturer caves. 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.

Under the convoluted statutory formula, the "excise tax" is "an amount such that the applicable percentage is equal to the ratio of (1) such tax, divided by (2) the sum of such tax and the price for which so sold." 26 U.S.C. § 5000D(a). The "applicable percentage[s]" are 65% for the first 90 days of noncompliance, 75% for the next 90 days, 85% for the next 90 days, and 95% for any day after that. *See id.* § 5000D(d). That means, for example, that if a drug's "pre-tax" price is $100 and the applicable percentage is 65%, the "tax" is approximately $185 (so that the "tax" of $185 equals 65% of $285, the sum of the "tax" and the "pre-tax" price of the drug). In that instance, the "tax" would be 185% of the "pre-tax" price. If the applicable percentage were 95%, the "tax" would be $1,900 on a $100 drug ($1,900 is 95% of $2,000, the sum of the "tax" and the "pre-tax" price), which represents 1,900% of the "pre-tax" price.[8]

Perhaps the clearest proof that the "excise tax" is simply a weapon compelling manufacturers to "agree" to "negotiate" and not a real tax is the recognition by Congress's own budget office (and the Joint Committee on Taxation) that the "tax" would raise precisely *zero* revenue. *See* CBO, Estimated Budgetary Effects of Public Law 117-169, to Provide for Reconciliation Pursuant to Title II of S. Con. Res. 14, at 5, https://www.cbo.gov/system/files/2022-

[7] In response to litigation, the government has suggested that the "excise tax" applies only to sales "under the terms of Medicare" and has cited temporary guidance endorsing that interpretation. *See* IRS, Notice No. 2023-52, Section 5000D Excise Tax on Sales of Designated Drugs; Reporting and Payment of the Tax (Aug. 4, 2023), https://www.irs.gov/pub/irs-drop/n-23-52.pdf. But the text of 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 programs).

[8] The IRS guidance confirms this calculus. *See* IRS, Notice No. 2023-52 at 2–3.

09/PL117-169_9-7-22.pdf; Jt. Comm. on Tax'n, No. JCX-46-21, Estimated Budget Effects of the Revenue Provisions of Title XIII, at 8 (Nov. 19, 2021), https://bit.ly/3plC4cd.

If the manufacturer "agrees" to "negotiate," but refuses to "agree" to the "maximum fair price" set by HHS, the "excise tax" kicks in the next day. 26 U.S.C. § 5000D(b)(2). For the ten drugs that have already been selected, that will be as early as August 2, 2024. The "tax" accrues every day until the manufacturer enters into an "agreement" with HHS, the drug in question ceases to be eligible for "negotiation," or the manufacturer successfully withdraws *all* of its drugs from Medicare Part D and Medicaid. 26 U.S.C. § 5000D(c); *see* 42 U.S.C. § 1396r-8(a)(1); 42 U.S.C. §§ 1395w-114a(b)(4)(B)(ii), 1395w-114c(b)(4)(B)(ii).

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 all of its products.[9] For example, for AbbVie and Pharmacyclics, that would mean withdrawing not only IMBRUVICA® but more than 85 other critical medicines. *See* Staff Decl. at PageID 191 ¶ 18. Second, in any event, a manufacturer legally cannot withdraw in time to avoid the IRA's penalties; Congress mandated an 11-to-23-month delay, 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 U.S.C. § 1395w-114c(b)(4)(B)(ii) ("Manufacturer Discount Agreement" under IRA).[10] As a result, if a manufacturer attempted to terminate its

[9] HHS and CMS are in the process of promulgating a regulation to codify their "longstanding policy" under which affiliated entities are treated together for purposes of Medicare and Medicaid such that an entire corporate family must be either "all in" or "all out." Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program, 88 Fed. Reg. 34,238, 34,256 (May 26, 2023).

[10] With respect to the Medicare Coverage Gap agreement, if the manufacturer provides notice of termination before January 30 of a calendar year, the termination does not become effective until the day after the end of the calendar year (a minimum of 11 months). *See* 42 U.S.C. § 1395w-114a. If the manufacturer provides notice on or after January

participation in June 2023 when this suit was filed, 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." Thus, there is no escaping the IRA's price controls.[11]

v. Limits on judicial and administrative review

Despite—or maybe because of—the grave risks that HHS would impose arbitrary, confiscatory, or discriminatory prices, Congress went to great lengths to insulate the price-control program from scrutiny. Section 1320f-7 of 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, including:

- the "determination of a unit, with respect to a drug or biological product"
- the "selection of drugs under section 1320f-1(b)"
- the "determination of negotiation-eligible drugs under section 1320f-1(d)"
- the "determination of qualifying single source drugs under section 1320f-1(e)"
- the "determination of a maximum fair price"

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 providing for notice-and-comment rulemaking for key HHS decisions, the IRA directs HHS to "implement" the program "for 2026,

30, the termination does not become effective until the day after the next year (up to 23 months later). *Id.* This delayed withdrawal process works the same way under the "manufacturer discount program" agreement created by the IRA itself (except that "January 30" is changed to "January 31"). *See* 42 U.S.C. § 1395w-114c.

[11] 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 as discussed below, *see infra* section I.C, that purported "fix" does not work because it conflicts with the statute.

2027, and 2028 by program instruction or other forms of program guidance." 42 U.S.C. § 1320f-1 note.

vi. Compelled speech

The IRA not only forces manufacturers to sell their products at government-set prices; it compels manufacturers to parrot the government's talking points about what the IRA is and does. Not only must companies accept unfairly low prices; they must affirmatively enter into "agreements" to "negotiate" a "maximum fair price." 42 U.S.C. § 1320f-2(a). And then they must again "agree" to the so-called "maximum fair price." *Id.* This compelled endorsement of the government's viewpoints serves no purpose other than to disguise the IRA's unlawful power grab, obscure responsibility for its destructive effects, and thereby avoid public scrutiny. The IRA thus seeks to evade judicial, administrative, and even public oversight; from top to bottom, it is designed to camouflage its radical mandates and insulate the government from accountability.

B. The IRA's Harmful Consequences for Plaintiffs' Members and the Public

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) at PageID 194 ¶ 5; Kershner Decl. (Dayton Area Chamber) at PageID 171 ¶ 5; Long Decl. (Ohio Chamber) at PageID 181 ¶ 5; Holcomb Decl. (Michigan Chamber) at PageID 176 ¶ 5. For example, several of Plaintiffs' members produce or distribute drugs that are frequently prescribed to Medicare Part D beneficiaries. Some of these drugs have already been selected for price controls, and others will be on subsequent lists. One of the selected drugs is IMBRUVICA®, which is manufactured by AbbVie and Pharmacyclics, each of which is a member of all four Plaintiffs. *See* Staff Decl. at

PageID 186 ¶ 5; Staff. Suppl. Decl. at PageID 395–97 ¶¶ 13–21.[12] Because of IMBRUVICA®'s selection, AbbVie was forced to write down the value of IMBRUVICA® by more than $2 billion, more than halving its carrying value on AbbVie's books. Staff Third Decl. ¶ 9. To avoid the crushing "excise tax" and penalties of $1 million per day of noncompliance, AbbVie and its wholly owned subsidiary Pharmacyclics were required to collect large amounts of complex, commercially sensitive data for submission to CMS by October 2, 2023. *Id.* ¶ 5. To avoid immediately triggering the "tax," Pharmacyclics (through AbbVie) was also forced to sign under protest an "agreement" to "negotiate" with CMS. *See id*. ¶¶ 3–4.

The IRA not only promises to decimate manufacturers' revenues as a result of government price-setting, but compels Plaintiffs' members to incur a variety of other substantial, unrecoverable costs, including but not limited to the expenditure of employee time and financial resources to collect large amounts of complex data for submission to CMS and the costs of participating in the "negotiation" process itself, such as analyzing CMS's "offer," preparing a detailed "counteroffer," and complying with any requests from CMS for additional data. *See id.* ¶¶ 5–9.

Given these concrete harms to Plaintiffs' members, including AbbVie and Pharmacyclics, Plaintiffs unquestionably have standing to challenge the IRA's drug-pricing provisions. It is well-established that "compliance costs are a recognized harm for purposes of Article III" standing. *Kentucky v. Yellen*, 54 F.4th 325, 342–43 (6th Cir. 2022) (finding Article III injury where plaintiff needed to spend "time and money" to ensure compliance with American Rescue Plan Act of 2021); *see also Czyzewski v. Jevic Holding Corp*., 580 U.S. 451, 464 (2017) ("For standing purposes, a loss of even a small amount of money is ordinarily an 'injury.'"). Plaintiffs have associational

[12] IMBRUVICA® was originally developed by Pharmacyclics, AbbVie's wholly owned subsidiary. *See* Staff. Suppl. Decl. at PageID 394 ¶ 7. Because Pharmacyclics remains the holder of the FDA "new drug applications" (NDAs) for IMBRUVICA®, CMS's guidance deems Pharmacyclics the "Primary Manufacturer" of IMBRUVICA®. *See* Revised Guidance at 118. Like AbbVie, Pharmacyclics is a member of all four Plaintiffs. Staff. Suppl. Decl. at PageID 393 ¶ 5.

standing because at least one of their members has standing, this case is undisputedly germane to their organizational missions, and they seek only "prospective or injunctive relief," which (unlike a typical damages claim) does not require individualized proof and therefore does not require the individual participation of members. *See Sandusky Cnty. Democratic Party v. Blackwell*, 387 F.3d 565, 574 (6th Cir. 2004) (per curiam) (quoting *United Food & Com. Workers Union Loc. 751 v. Brown Grp., Inc.*, 517 U.S. 544, 546 (1996)).

The IRA will also inflict grave harm on the broader public by stunting critically important medical innovation. Given the diminished ability of manufacturers to make a fair return on their investment and cover their losses (not only on the drug selected for price controls, but on the many more drugs that never see the light of day), continued research and development on many potential new treatments will no longer be economically viable. For example, one study of Medicare Part D price controls found that they would reduce life expectancy by two years and that any short-term savings would be outweighed by far greater losses in human welfare.[13] Already, companies have been forced to cancel promising research on treatments for cancer and other serious ailments.[14]

ARGUMENT

I. The IRA's Price-Control Program Violates the Due Process Clause.

The IRA's unusual structure is marred by a fatal constitutional defect: a lack of adequate procedures to protect against unconstitutional deprivations of manufacturers' property. Under the Fifth Amendment's Due Process Clause, the government may not deprive anyone of "life, liberty,

[13] Gigi Moreno et al., *The Long-Term Impact of Price Controls in Medicare Part D*, 20 J. Forum Health Econ. Pol'y 1 (Jan. 20, 2017), https://pubmed.ncbi.nlm.nih.gov/31419906/.

[14] Josh Nathan-Kazis, *Novartis CEO: Some Cancer Drugs Dropped From Pipeline Because of Medicare Price Negotiations*, Barron's (May 19, 2023), https://www.barrons.com/articles/novartis-stock-price-ceo-cancer-drug-medicare-e9b0fcb7; Reuters, *Roche: Have Abandoned Some Trials Due to U.S. Drug Pricing Plans* (July 27, 2023), https://tinyurl.com/y36zwb72; Angelica Peebles, *Alnylam Halts Work on Eye Drug, Citing New US Law Over Pricing*, Bloomberg (Oct. 27, 2022), https://www.bloomberg.com/news/articles/2022-10-27/alnylam-halts-work-on-eye-drug--citing-new-us-law-over-pricing.

or property" without "due process of law." In the context of price-control laws, which can cause serious deprivations if prices are set too low, 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*, the Due Process Clause requires a set of procedures that "adequately safeguards against confiscatory rates, and therefore, ensures a constitutional rate of return." 257 F.3d at 592–93; *accord Monongahela Power Co. v. Schriber*, 322 F. Supp. 2d 902, 918–19 (S.D. Ohio 2004), *as modified on reconsideration* (June 14, 2004); *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"). A price-control regime that lacks those essential safeguards would also inevitably fail the Supreme Court's due-process balancing test laid out in *Mathews v. Eldridge*, 424 U.S. 319 (1976).

The IRA lacks 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 any opportunity for error correction.

Moreover, contrary to the government's contention, the IRA's flagrant due process problem cannot be avoided by framing the IRA as merely a condition on participation in Medicare. At the preliminary injunction stage, this Court declined to find a "strong likelihood of success[]" on the merits of Plaintiffs' due process claim because "at th[at] initial stage" it was "too early to know—

with the degree of certainty necessary" that the claim would prevail. Dkt. 55 at PageID 597. The reason for the Court's hesitation was a series of pre-IRA cases stating that participation in Medicare was a "voluntary choice." *Id.* at PageID 596. If manufacturers could simply "opt out" of Medicare, the Court suggested, *Michigan Bell*'s reasoning would not apply. *Id.* Now that this case can be considered directly on the merits, however, the Court should not hesitate to apply *Michigan Bell* and *Eldridge*. For at least three reasons, the theoretical possibility of opting out of Medicare does not solve the IRA's due process problems, and the government's effort to evade due process scrutiny fails.

First, manufacturers have no lawful way to exit Medicare immediately. Second, under the "unconstitutional conditions doctrine," the government "'cannot constitutionally condition the receipt of a benefit . . . on an agreement to refrain from exercising one's constitutional rights." *Keego Harbor*, 397 F.3d at 434–36 (quoting *G & V Lounge*, 23 F.3d at 1077). And third, as the Supreme Court made clear in *NFIB*, the relevant question is not whether Medicare or Medicaid *by itself* (the "existing" program) is or was coercive, but whether the new condition that Congress is attempting to attach to it (the "new program") is coercive. *See NFIB*, 567 U.S. at 581–85. The Medicaid expansion program in *NFIB* was therefore coercive even though states legally could have avoided that program by opting out of Medicaid altogether. Here, likewise, Congress cannot put an economic "gun to the head" of manufacturers and give them the illusory "choice" to either accept price controls without due process protections under the IRA (*i.e.*, surrender your constitutional rights) or withdraw *all* your drugs from Medicare and Medicaid (*i.e.*, sacrifice your livelihood). *Id.* at 581, 587. That is "no real option." *Id.* at 582.

A. The Price-Control Program Is Unconstitutional Under the *Michigan Bell* Test.

Michigan Bell held unconstitutional "on its face" a price-setting statute that lacked adequate safeguards against confiscatory pricing. 257 F.3d at 594. 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*. (quotation marks omitted). 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 (emphasis omitted). 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.

The IRA is even less protective of 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 *invites* arbitrary and confiscatory prices, while shutting the door to administrative and judicial review that could allow for correction of such constitutional errors.[15] The IRA's veneer of "negotiation" is an attempt to conceal that 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 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 without any possibility of judicial oversight. 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* Revised Guidance at 144.

Moreover, nothing in the IRA even encourages, let alone requires, the agency to meet the constitutional minimum of a "fair and reasonable rate of return on investment." *Michigan Bell*,

[15] 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 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 infra* section IV.

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. 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 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.

For these reasons, 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 1,900% 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, Estimated Budgetary Effects of Public Law 117-169, to Provide for Reconciliation Pursuant to Title II of S. Con. Res. 14, at 5. 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 infra* section I.C. Indeed, Congress counted on withdrawal not being a real option: if manufacturers of the most widely used prescription drugs withdrew from Medicare and Medicaid, tens of millions of Americans would lose access to critically needed and often life-sustaining medications—a public health crisis that Congress could not have intended to risk.

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. But that 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, it follows that the IRA's price-control regime is unconstitutional.

B. The Price-Control Program Is also Unconstitutional Under the *Eldridge* Test.

The Supreme Court's general due-process balancing test, as set forth in *Mathews v. Eldridge*, 424 U.S. 319 (1976), leads 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 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). By way of illustration, in the case of IMBRUVICA®, as a result of AbbVie's and Pharmacyclics' continued innovation and investment to demonstrate that the medicine was safe and effective for multiple types of blood cancers, the Patent and Trademark Office protected the drug with patents extending out to 2036. Staff Third Decl. ¶ 11. AbbVie further invested in litigation to enforce those

patents against would-be infringers, reaching a settlement with some generic manufacturers and prevailing in court against others. Ordinarily, this patent protection includes protecting the patent-holder's right to set prices during the patent term. *See Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1373 (Fed. Cir. 2007). The IRA's price-setting provisions deprive pharmaceutical manufacturers of that and other property interests.

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 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 & 16 U.S.C. § 825*l* (providing for judicial review of Federal Energy Regulatory Commission rate-setting); *cf. Hicks v. Comm'r of Soc. Sec.*, 909 F.3d 786, 796–98 (6th Cir. 2018) (citation and quotation marks omitted) (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 even administrative review of key decisions. And the risk of unfair decisionmaking is heightened here because CMS is not only the price-setter but also the ultimate payor—creating an obvious risk of self-serving actions.

Nor does the IRA provide meaningful process on the front end. *Cf. Mobil Oil Expl. & Producing Se. Inc. v. United Distrib. Cos.*, 498 U.S. 211, 218 (1991) (noting use of notice-and-comment rulemaking for gas-pricing rules). In fact, Congress told HHS to implement the program "by program instruction or other forms of program guidance." 42 U.S.C. § 1320f-1 note; Revised Guidance at 1. While courts sometimes afford the government leeway to use "less elaborate predeprivation process" where "elaborate procedures for postdeprivation review are in place," the IRA denies post-deprivation review altogether. *Shoemaker v. City of Howell*, 795 F.3d 553, 559 (6th Cir. 2015) (citation and quotation marks omitted).

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 unprecedented in omitting all of these traditional safeguards. That departure from "historical practices" is yet another sign of the IRA's deficiency. *United States v. Silvestre-Gregorio*, 983 F.3d 848, 852 n.1 (6th Cir. 2020).

Thus, whether one applies *Michigan Bell* or *Eldridge*, the result is the same: the IRA's price-control program violates the Due Process Clause and must be held unconstitutional.

C. The IRA's Price-Control Program Is Coercive, Not Voluntary.

The IRA's constitutional problems cannot be solved by pretending that manufacturers have willingly subjected themselves to the IRA by virtue of their continued participation in Medicare and Medicaid. In the first place, manufacturers are legally required to continue participating in Medicare because the law governing the withdrawal process prevents manufacturers from terminating their participation for a period of at least 11 to 23 months. And in any event, framing the IRA as a condition on Medicare and Medicaid participation does not exempt it from constitutional scrutiny; it instead merely highlights the question whether the condition is constitutional. Under the "unconstitutional conditions doctrine," courts have long recognized that

certain "conditions" are unconstitutional because they pressure parties to "surrender [constitutional] rights." *Keego Harbor*, 397 F.3d at 434–36.

The Supreme Court applied similar reasoning when it struck down a Medicaid funding condition in *NFIB*. 567 U.S. at 581. There, as here, Congress tried to portray a transformative new program as a mere extension of an existing federal health program. There, as here, Congress could not have directly mandated the new requirements that it wanted to impose, leading Congress to couch its desired mandates as a "choice." And there, as here, the threatened loss of existing payment streams was an economic "gun to the head," making that purported "choice" illusory. *Id.* at 581, 587. Similarly untenable is the suggestion that manufacturers stop selling (or divest) drugs selected for the IRA's 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. At best, those unworkable proposals merely rearrange the constitutional violations.

i. Manufacturers cannot lawfully withdraw from the IRA's price-control program for a period of 11 to 23 months.

Manufacturers are legally obligated to remain in the IRA's price-control program—at least for the lengthy period specified by statute before a withdrawal from Medicare and other federal healthcare programs takes effect. 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, Medicaid, or the IRA-created "manufacturer discount program." *See* 26 U.S.C. § 5000D. And federal law creates only two distinct pathways for terminating participation in those programs—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); *see also id.* § 1395w-114c (materially identical provisions for withdrawal from IRA-created "manufacturer discount program" agreement). Under the first provision, when "the Secretary" seeks to terminate a manufacturer for misconduct involuntarily (*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 voluntarily: "a manufacturer" may terminate "for any reason" (and no hearing is provided) 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, 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" (quoting *Gustafson v. Alloyd Co.*, 513 U.S. 561, 575 (1995)). Just as important, swallowing voluntary terminations "[b]y a

manufacturer" within the first provision would render the second one "wholly superfluous." *Duncan v. Walker*, 533 U.S. 167, 174 (2001).

In response to litigation, CMS issued non-binding guidance attempting to remove the 11-to-23-month waiting period for manufacturer-initiated terminations by treating such terminations as "good cause" for termination by the Secretary. *See* Revised Guidance at 120–21, 129–31. But a "core administrative-law principle" is that "an agency may not rewrite clear statutory terms to suit its own sense of how the statute should operate." *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 328 (2014). To allow CMS to override Congress's design "would deal a severe blow to the Constitution's separation of powers." *Id*. It would also create absurdities. Treating a manufacturer's own termination as the Secretary's means that a manufacturer receives a hearing on its own request for termination. That is nonsensical, which is why Congress provided a hearing only when it is the Secretary pursuing termination for alleged misconduct or similar good cause.[16]

ii. The IRA is not a valid condition on participation in Medicare and Medicaid.

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 constitutional problems. Courts have long recognized that forcing a regulated entity to choose between two unacceptable outcomes—"the rock and the whirlpool"—is no real choice at all. *United States v. Butler*, 297 U.S. 1, 72 (1936) (quoting *Frost v. R.R. Comm'n*, 271 U.S. 583, 593 (1926)); *see 44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 513 (1996) (plurality opinion) (citing *Frost*, 271 U.S. at 594). And the Supreme

[16] In its guidance, CMS nevertheless 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 at 121 (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.

Court has "repeatedly rejected the argument that if the government need not confer a benefit at all, it can withhold the benefit because someone refuses to give up constitutional rights." *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 608 (2013) (collecting cases); *see, e.g.*, *United States v. Am. Library Ass'n*, 539 U.S. 194, 210 (2003) ("[T]he government may not deny a benefit to a person on a basis that infringes his constitutionally protected . . . freedom of speech even if he has no entitlement to that benefit") (citation and quotation marks omitted). In other words, "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 (quoting *Perry v. Sindermann*, 408 U.S. 593, 597 (1972)).

A few hypotheticals help to illustrate the point. If the government were correct that framing the IRA as a condition on Medicare participation shielded it from constitutional scrutiny, Congress could have instructed CMS to set prices on selected drugs by flipping a coin or spinning a roulette wheel. Or Congress could have added other compelled speech requirements, such as a mandate that pharmaceutical companies take out television ads touting the wisdom and fairness of the IRA. And Congress could have included a gag-order provision preventing manufacturers from publicly revealing what happened in the "negotiations" with CMS. (In fact, CMS itself tried to impose such a gag-order provision in its guidance and only retracted it after a public outcry at the obvious First Amendment violation. *See* Initial Guidance at 30; Revised Guidance at 37.) The purpose of the "unconstitutional conditions" doctrine is to foreclose such unconstitutional maneuvers.

As the Sixth Circuit held in *Keego Harbor*, the unconstitutional conditions doctrine applies with full force to the Due Process Clause. That is, the government may not "condition[] benefits on a citizen's agreement to surrender due process rights." 397 F.3d at 434. In *Keego Harbor*, the Sixth Circuit addressed a brewery's claim that a city had withheld certain administrative approvals

unless it agreed to close at an earlier hour. The brewery may not have had a right to the desired city approval, but the Sixth Circuit made clear that the brewery nonetheless could not be made to "choose between its due process rights in certain hours of operation and the desired city approval." *Id.* at 436. Instead, the Sixth Circuit held that "[p]ursuant to the 'unconstitutional conditions' doctrine, [the city] cannot indirectly force [the brewery] to close at 11:00 p.m. by withholding government benefits." *Id.* As the court explained, that doctrine "made clear that 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." *Id.* at 434 (quoting *Perry*, 408 U.S. at 597). In particular, the government "may not deny a benefit to a person on a basis that infringes his constitutionally protected interests." *Id.* (quoting *Perry*, 408 U.S. at 597). And because due process (like any other constitutional right) is obviously a "constitutionally protected interest," the Sixth Circuit reasoned, that principle "appl[ies] to prohibit the government from conditioning benefits on a citizen's agreement to surrender due process rights." *Id*. at 434–35.

The same prohibition applies here: Congress cannot condition the valuable benefit of Medicare participation on a manufacturer's "agreement" to accept the IRA's lack of due process. *Id.* As *Keego Harbor* makes clear, forcing a private business to "choose between its due process rights" and a government benefit is itself a "due process violation." *Id.* at 436–37. That is, even if participation in Medicare and Medicaid were "a completely voluntary choice," Dkt. 55 at PageID 596, the government cannot condition the benefit of access to nearly half the prescription drug market on a manufacturer's "agreement" to surrender due process or other constitutional rights.

The Supreme Court applied similar reasoning, in circumstances that closely parallel this case, in *NFIB*. There, Congress pressured states to accept a Medicaid expansion by threatening the withdrawal of all Medicaid funding. Although the Medicaid expansion may have been "in form voluntary," *Frost*, 271 U.S. at 593, 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 even more coercive "economic dragooning." Whereas federal Medicaid funding comprised 10% of the states' budgets in *NFIB*, Medicaid and Medicare account for *nearly half* of the prescription drug market. *See Sanofi*, 58 F.4th at 699. If Congress had tied the expansion of Medicaid coverage in *NFIB* to new, incremental funding to account for the expanded coverage requirements—*i.e.*, a state would receive the additional funding only if it accepted the additional obligations—that might have been a real choice. But instead, Congress tied the coverage expansion to *all* funding, so that states' only "choice" was to lose all Medicaid funding or to "agree" to the expansion. Here, despite the Court's decision in *NFIB*, Congress did the same thing. Congress could have tied the IRA's obligations to just the drug at issue—*i.e.*, a given drug would be covered by federal healthcare programs only if the manufacturer agreed to CMS's chosen price for that drug. Even that would have been coercive, given that federal healthcare programs comprise nearly half of the market. But Congress went much farther, guaranteeing that manufacturers would have no choice but to "agree" to the IRA's obligations by tying those obligations to the manufacturer's ability to have *any* of its drugs covered by federal healthcare programs. Because a manufacturer—

in fact, an entire corporate family—must either be "all in" or "all out" of Medicare and Medicaid, a manufacturer has no ability to withdraw a "selected drug" if CMS's "maximum fair price" is unfairly low without withdrawing its entire portfolio of medicines. *See supra* note 9.

Congress knew that for a manufacturer to withdraw all of its products from federal healthcare programs would be economic suicide—not a "real option." *NFIB*, 567 U.S. at 582. (For example, in AbbVie's case, this would require withdrawing products that account for the overwhelming majority of its national net revenues. *See* Staff Third Decl. ¶ 17.) Indeed, Congress counted on that: if Congress had thought withdrawal was a real option, enacting the IRA would have been a reckless gamble that risked Medicare beneficiaries' access to needed drugs. Likewise, in *NFIB*, Congress did not intend to cause a public health crisis by taking away all federal Medicaid funding; Congress could impose its mandates via a nominal "choice" only because Congress knew that states would have no real choice. *See id.* at 581–82, 587. And if states, with all the resources they can marshal, 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).

Like the Medicaid expansion in *NFIB*, moreover, it is indisputable that the IRA dramatically "transform[s]" the federal healthcare programs. 567 U.S. at 583. Manufacturers that signed up to participate in those programs—and invested billions of dollars in developing and distributing drugs that serve beneficiaries—never signed up for the IRA. And companies could "hardly anticipate," *id.* at 584, that Congress would repudiate its longstanding promise of market-based pricing for prescription drugs, especially as reflected in the Medicare Part D "non-interference clause," *see supra* section I. Congress went from *prohibiting* HHS from strong-arming manufacturers to *requiring* HHS to do so. Any "asserted power of choice" here is "illusory." *Butler*, 297 U.S. at 71.

Furthermore, because what is at issue here is *the IRA*, and not Medicare or Medicaid as originally enacted, language in decades-old cases that discuss *pre-IRA* Medicare and Medicaid is not controlling. *See, e.g.*, *Baptist Hosp. E. v. Sec'y of HHS*, 802 F.2d 860, 867–69 (6th Cir. 1986) (addressing challenge to HHS reimbursement regulation that disallowed reimbursement for certain costs a hospital incurred in voluntarily providing unpaid care to "non-Medicare patients"); *Livingston Care Ctr., Inc. v. United States*, 934 F.2d 719, 720 (6th Cir. 1991) (addressing damages claim against HHS and stating in dicta that "participation in the Medicare program is a voluntary undertaking"). Those cases long predate the IRA. They also do not address the Supreme Court's decision in *NFIB* or the Sixth Circuit's decision in *Keego Harbor*. Again, in *NFIB*, the problem was not that Medicaid *itself* was coercive. The problem was that the Medicaid *expansion* was coercive; it required states to "accept" what was in effect a major "new program" or else cut themselves off from a longstanding, critically important "existing" program. *NFIB*, 567 U.S. at 582. Just as the voluntary nature of the preexisting Medicaid program did not mean that Congress could impose a coercive and "transformation[al]" expansion, *id.* at 584, Congress cannot piggyback the IRA's transformational price-control program onto Medicare and Medicaid.

iii. Manufacturers cannot simply divest or stop selling their vital drugs.

As with the government's suggestion that manufacturers pull all of their products out of Medicare and Medicaid, the other "options" the government has proposed for avoiding the IRA's price controls are illusory and impracticable. For instance, the government has suggested that manufacturers "can continue selling [their] drugs" at market-based prices and "pay an excise tax" of up to 1900%, Dkt. 34 at PageID 246—ignoring that Congress's own budget office acknowledged, by projecting zero revenue from the "tax," that no manufacturer could afford to pay it. The government also suggested that a manufacturer "could . . . stop selling the drug." *Id.* at PageID 252 n.4. But that would leave millions of Americans—inside and outside of federal

healthcare programs—without access, at any price, to some of the most important, widely used, and life-sustaining drugs. For example, more than 12,000 Medicare patients currently take IMBRUVICA®, which improves the survival rates of patients with certain types of blood cancer. 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 an invalid state law need not "pull[] [its drug] from the market in order to" avoid that law, *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. Dkt. 34 at PageID 242, 247, 251–52, 258. A company could not sell its interest in a drug at fair market value once it has been selected for price controls—which would follow the drug to any buyer. If the constitutional violations worked by the IRA are not corrected, no sale transaction would allow a company to avoid them. Moreover, 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* Staff Suppl. Decl. at PageID 397 ¶ 23.

For all these reasons, there is no way around the IRA's grave due process failings. The statute must be held unconstitutional.

II. The IRA's Fake "Excise Tax" Violates the Excessive Fines Clause and Exceeds Congress's Enumerated Powers.

To force manufacturers to submit to this unconstitutional scheme, the IRA imposes an enormous so-called "excise tax" on all sales of a manufacturer's drug if the manufacturer refuses to "agree" to the government-set "maximum fair price." 26 U.S.C. § 5000D(b)(1)–(4). This purported "tax," which is in reality an exorbitant penalty designed to cow manufacturers into

compliance with the IRA, is itself unconstitutional because it violates the Excessive Fines Clause. And because the "tax" is not a real tax, it cannot be justified as an exercise of Congress's taxing power or any other enumerated legislative power.

A. The So-Called "Excise Tax" Violates the Excessive Fines Clause.

The Eighth Amendment provides that "[e]xcessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted." U.S. Const. amend. VIII. The Excessive Fines Clause limits the government's ability to "extract payments" out of all proportion to the conduct that triggers the penalty. *Austin v. United States*, 509 U.S. 602, 609–10 (1993). Whether the penalty is criminal or civil, "a monetary demand that is retributive or deterrent and thus intended to punish, even in part, is subject to the limitations of the Excessive Fines Clause." *F.P. Dev., LLC v. Charter Twp. of Canton*, 16 F.4th 198, 208–09 (6th Cir. 2021) (citing *Austin,* 509 U.S. at 621). "The Sixth Circuit employs a two-step excessive fines analysis." *Stevens v. City of Columbus*, No. 2:20-cv-01230, 2021 WL 3562918, at *2–3 (S.D. Ohio Aug. 12, 2021), *aff'd*, No. 21-3755, 2022 WL 2966396 (6th Cir. July 27, 2022). First, courts must determine whether the fine is "punitive or remedial." *Id.* Second, if the fine is "punitive," the court must ask whether it is "grossly disproportionate to the offense." *Id.*; *see Bajakajian*, 524 U.S. at 334.

The IRA's so-called "excise tax" clearly falls on the "punitive" side of the line. A "punitive" exaction is intended "to deter and to punish." *Austin*, 509 U.S. at 622. "Deter[ring]" non-compliance with a statute "has traditionally been viewed as a goal of punishment." *Bajakajian*, 524 U.S. at 329. In contrast, a monetary demand is "wholly remedial," and therefore outside the purview of the Excessive Fines Clause, when it is "related only to 'damages sustained by society or to the cost of enforcing the law.'" *F.P. Dev.*, 16 F.4th at 208–09 (quoting *United States v. Ward*, 448 U.S. 242, 254 (1980)). In other words, a remedial demand merely "compensat[es] the Government for a loss." *Bajakajian*, 524 U.S. at 329. For purposes of this inquiry, what matters is

not how the exaction is "labeled" by Congress, but the substance of the exaction. *Dep't of Revenue v. Kurth Ranch*, 511 U.S. 767, 780 (1994); *see NFIB*, 567 U.S. at 565–66 (citing *Kurth Ranch* and taking a "functional approach" to distinguishing between a penalty and a true tax for constitutional purposes). "Economic penalties imposed to deter willful noncompliance with the law are fines by any other name." *Tyler v. Hennepin County*, 598 U.S. 631, 649–50 (2023) (Gorsuch, J., joined by Jackson, J., concurring).

In evaluating the substance, courts look to the size of the demand and its apparent purpose. "[A]t some point, an exaction labeled as a tax approaches punishment." *Kurth Ranch*, 511 U.S. at 780. For example, in *Kurth Ranch*, a portion of the tax was "eight times the drugs' market value." *Id.* at 774 & n.12, 781; *see also Dye v. Frank,* 355 F.3d 1102, 1104–05 (7th Cir. 2004) ("A 'tax' that is five times the value of the item taxed is remarkably high and is more consistent with punishing . . . than with raising revenue"). A fine is also "at least partially punitive insofar as it seeks to bring [parties] into compliance" with a regulatory scheme. *Stevens*, 2021 WL 3562918, at *4; *see Carter v. Carter Coal Co.*, 298 U.S. 238, 289 (1936) ("It is very clear that the 'excise tax' is not imposed for revenue but exacted as a penalty to compel compliance with the regulatory provisions of the act").

The IRA's "excise tax" obviously is not "wholly remedial." *F.P. Dev.*, 16 F.4th at 209. The "tax" rate is so high that Congress's own budget office does not believe it will produce any revenue—and thus it cannot be expected to compensate the government for anything. *See supra* section II.A.iv. Rather, the manifest purpose of the "tax" is its *in terrorem* effect on manufacturers, who will have no choice but to "agree" to CMS's chosen price, no matter how confiscatory and unfair. This is unlike any ordinary "excise tax" designed to collect revenue or discourage the use of a product with harmful effects. It is an extraordinary penalty masquerading as an excise tax.

That this penalty is "grossly disproportionate" to the culpability of the conduct it punishes is equally obvious. *Bajakajian*, 524 U.S. at 334. A penalty of 19 times a product's price is so disproportionate as to be unheard of even for a truly "reprehensib[le]" offense. *Cooper Indus., Inc. v. Leatherman Tool Grp., Inc.*, 532 U.S. 424, 435 (2001); *cf. BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 576 (1996) (indicating that "violence or the threat of violence," "trickery," "deceit," and "indifference to or reckless disregard for the health and safety of others" are "aggravating factors associated with particularly reprehensible conduct" (quotation marks omitted)). And here, a manufacturer's refusal to "agree" to "negotiate" or to "agree" that CMS's chosen price is the "maximum fair price" would not entail any reprehensible conduct at all. Whether the "excise tax" applies to all sales of the selected drug (as the statute says) or only sales involving Medicare and Medicaid (as the government has claimed in guidance, *see supra* section II.A.iv), a penalty of 19 times revenue is, without a doubt, "grossly disproportionate." *Bajakajian*, 524 U.S. at 334. Thus, the IRA's fake "excise tax" violates the Excessive Fines Clause.

That conclusion is so inescapable that the government may attempt, yet again, to throw up a procedural roadblock and argue that the Anti-Injunction Act leaves the Court powerless to enforce the Excessive Fines Clause even if the "excise tax" is in reality an unconstitutional penalty. That statute generally bars suits filed "for the purpose of restraining the assessment or collection of any tax." 26 U.S.C. § 7421. Instead, taxes can "ordinarily be challenged only after they are paid, by suing for a refund." *NFIB*, 567 U.S. at 543. Even if an exaction is not a "tax" for constitutional purposes, it may qualify as a "tax" for AIA purposes if identified as such by statute. *Id.* at 543. But even assuming that the IRA's "excise tax" is a "tax" for AIA purposes, the AIA does not bar Plaintiffs' claim.

The Supreme Court has recognized important exceptions to the AIA. One exception applies when the plaintiff would suffer "irreparable injury" if not permitted to challenge the tax and "'it is clear that under no circumstances could the Government ultimately prevail'" on the merits. *Bob Jones Univ. v. Simon*, 416 U.S. 725, 737 (1974) (quoting *Enochs v. Williams Packing & Navigation Co.*, 370 U.S. 1, 7 (1962)). That is this case. Any manufacturer that attempted to pay a penalty of 19 times the price of its product would suffer ruinous harm. And a penalty of that magnitude for the "offense" of selling lawful products at market prices is so plainly excessive that the government could not hope to prevail on the merits of an Excessive Fines Clause challenge. Another exception to the AIA applies when Congress has not provided "an alternative legal way to challenge the validity of a tax." *South Carolina v. Regan*, 465 U.S. 367, 373 (1984). Generally, the "availability of a refund suit" precludes application of the *Regan* exception because taxpayers can pay the tax first and obtain full compensation later. *Id*. at 375–76. But here, a refund suit is not meaningfully "available" because no manufacturer could afford to pay the crippling "excise tax."

"For good reason, the protection against excessive fines has been a constant shield throughout Anglo-American history: Exorbitant tolls undermine other constitutional liberties." *Timbs v. Indiana*, 139 S. Ct. 682, 689 (2019). That is precisely the sinister effect of the IRA's "excise tax"; it is the intolerably harsh punishment that forces manufacturers to engage in the sham "negotiation" process and "agree" that CMS's unfairly low price is the "maximum fair price." Indeed, the unprecedented features of the IRA's "excise tax" make it the poster child for why the AIA does not, and cannot, bar claims like Plaintiffs'. The AIA bars suits for "the purpose of restraining *the assessment or collection* of any tax." 26 U.S.C. § 7421 (emphasis added). It exists to "protect[] the Government's ability to collect a consistent stream of revenue." *NFIB*, 567 U.S. at 543. That purpose is irrelevant here, given that Congress does not expect the "excise tax" ever

to be "assess[ed]" or "collect[ed]." *See* Erin M. Hawley, *The Equitable Anti-Injunction Act*, 90 Notre Dame L. Rev. 81, 124 (2014) ("[W]hile the pay-now, litigate-later system makes sense when applied to revenue-raising measures, the government's fiscal interests in summary and stringent enforcement do not apply when the measure accomplishes a regulatory purpose"). Whether the IRA's "excise tax" is enjoined or not, it will raise precisely the same amount of revenue: zero.

If the AIA allowed Congress to defeat the Excessive Fines Clause so easily—by imposing penalties so excessive that no one could pay them and labeling those penalties "taxes" so no one could challenge them—the Excessive Fines Clause would be a dead letter, not a "constant shield." *Timbs*, 139 S. Ct. at 689. The AIA does not require that absurd result—and if it did, the AIA would be unconstitutional as applied to this case. *See Bowen v. Mich. Acad. of Fam. Physicians*, 476 U.S. 667, 681 n.12 (1986) (recognizing the "serious" constitutional questions that would arise if a federal statute were construed to deny a judicial forum for constitutional claims). The Court should hold that the "excise tax" contravenes the Excessive Fines Clause.

B. The So-Called "Excise Tax" Exceeds Congress's Enumerated Powers.

The IRA's misnamed "excise tax" is also unconstitutional because it is not authorized by any enumerated power of Congress. A cardinal principle of the Constitution is that the federal government is a government of "limited and enumerated powers." *Alden v. Maine*, 527 U.S. 706, 713 (1999). As Justice Story explained long ago, "[b]eing an instrument of limited and enumerated powers, it follows irresistibly, that what is not conferred, is withheld[.]" 3 J. Story, Commentaries on the Constitution of the United States § 1900 (1833); *see also* The Federalist No. 45 (James Madison) ("The powers delegated by the proposed Constitution to the federal government are few and defined"). Article I sets forth the enumerated powers of Congress. It provides that "[a]ll legislative Powers *herein granted* shall be vested in a Congress of the United States." U.S. Const. art. I (emphasis added); *see United States v. Rife*, 33 F.4th 838, 844 (6th Cir. 2022) ("The powers

of the legislature are defined, and limited" (quoting *Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 176 (1803))), *cert. denied*, 143 S. Ct. 356 (2022) (Mem.). None of the powers enumerated in Article I authorizes Congress to impose a misnamed "excise tax" that applies only when private companies refuse to sell their products at whatever price the government declares.

i. The "excise tax" is not within Congress's taxing power.

The "excise tax" is not authorized by Congress's taxing power because it is a penalty, not a true tax. The Taxing Clause provides that Congress may "lay and collect Taxes, Duties, Imposts and Excises, to pay the Debts and provide for the common Defence and general Welfare of the United States." Art. I, § 8, cl. 1. The "constitutional question" of what qualifies as a "tax" within the meaning of that provision is "not controlled by Congress's choice of label." *NFIB*, 567 U.S. at 564. Rather, courts must use a "functional approach" to distinguish between genuine taxes and penalties. *Id.* at 565. While nearly all taxes influence behavior to some degree, Congress's "ability to use its taxing power to influence conduct is not without limits." *Id.* at 572. "'[T]here comes a time in the extension of the penalizing features of the so-called tax when it loses its character as such and becomes a mere penalty with the characteristics of regulation and punishment.'" *Id.* at 573 (quoting *Kurth Ranch*, 511 U.S. at 779).

Although the line between taxes and penalties may not always be cleanly drawn, which side of the line the "excise tax" is on is clear. The "essential feature of any tax" is that "[i]t produces at least some revenue for the government." *Id.* at 564; *accord Liberty Univ., Inc. v. Lew*, 733 F.3d 72, 97 (4th Cir. 2013). In *NFIB*, for example, the monetary exaction imposed on an individual for failing to purchase health insurance was expected to yield "considerable revenue"—according to the CBO, about "$4 billion per year." 567 U.S. at 564, 567. Here, in contrast, the CBO and Congress's Joint Committee on Taxation both projected that the excise tax will raise *no* revenue whatsoever. The so-called "excise tax" thus lacks the "essential feature of any tax." *Id.* at 564.

If that were not enough, the "excise tax" bears another telltale sign of a coercive penalty: it "impose[s] an exceedingly heavy burden." *Id.* at 565. In *NFIB*, given the modest burden of the exaction on individuals who declined to buy insurance, the Court noted that it "may often be a reasonable financial decision to make the payment rather than purchase insurance." *Id.* at 566. The Court contrasted that exaction with the "'prohibitory' financial punishment" imposed in the *Bailey v. Drexel Furniture Co.* (*Child Labor Tax Case*), 259 U.S. 20, 36–37 (1922), where the so-called "tax" amounted to 10% of the company's net income—"an exceedingly heavy burden." 567 U.S. at 565–66. Here, as the CBO's projection of zero revenue reflects, the 1,900% "excise tax" is the very definition of a "prohibitive" financial punishment; no manufacturer could or would opt to pay it.

ii. The "excise tax" is not within Congress's Commerce Clause power.

Nor can the "excise tax" be justified as an exercise of Congress's power under the Commerce Clause. The Commerce Clause authorizes Congress "[t]o regulate Commerce . . . among the several States." Art. I, § 8, cl. 3. Importantly, the power to "regulate" interstate commerce does not encompass the power to "create" commerce that does not already exist. As Chief Justice Roberts explained in *NFIB*, "[t]he Framers gave Congress the power to *regulate* commerce, not to *compel* it." 567 U.S. at 555. "[F]or over 200 years both [the Court's] decisions and Congress's actions have reflected this understanding." *Id.*; *accord id.* at 647–57 (Scalia, J., joined by Kennedy, J., Thomas, J., and Alito, J., dissenting on other grounds).

The IRA breaches that constitutional limit. The astronomical "excise tax" compels commerce by forcing manufacturers to "agree" to sell their products in government healthcare programs at the government's unilaterally imposed prices. That is, the IRA does not merely forbid manufacturers from selling their drugs at a price higher than CMS's "maximum fair price"; it requires manufacturers to "agree" to "provide access" to the "maximum fair price" to "maximum

fair price eligible individuals." 42 U.S.C. § 1320f-2(a)(1), (2), (3). This conscripts manufacturers to engage in commercial activity that they would otherwise prefer to "abstain from." *NFIB*, 567 U.S. at 572. As with the private citizens who objected to purchasing health insurance in *NFIB*, it is the manufacturers' "*failure*" to engage in commercial activity that triggers the penalty. 567 U.S. at 547 (emphasis added); *see United States v. Holmes,* No. 1:20-cr-58-2, 2021 WL 1709778, at *1–2 (S.D. Ohio Apr. 29, 2021) ("[T]he Court specifically differentiated between the individual mandate's impermissible compulsion to '*become* active in commerce by purchasing a product' with the constitutionally permissible regulation of existing commercial activity." (quoting *NFIB*, 567 U.S. at 552)). Indeed, the Supreme Court's Commerce Clause cases "uniformly" describe the power to regulate commerce "as reaching 'activity.'" *NFIB*, 567 U.S. at 551 (collecting cases); *see United States v. Windham,* 53 F.4th 1006, 1011 (6th Cir. 2022) ("[M]odern Commerce Clause jurisprudence has identified three broad categories of *activity* that Congress may regulate" (emphasis added) (quoting *United States v. Morrison*, 528 U.S. 598, 609 (2000))). Like the failure to *buy* a product or service, the failure to *sell* a product or service is "inactivity," not "activity."

Although Congress referred to the "excise tax" as a "tax" on "sale[s]," Congress itself did not expect any actual sales to occur under the crushing weight of the so-called "tax." In reality, then, the "excise tax" is a massive penalty for a manufacturer's noncompliance with the IRA—*i.e.*, its failure to sell its property to government programs on the government's terms, no matter how confiscatory or unfair. To avoid the IRA's crippling penalties, manufacturers must take the affirmative acts of "agreeing" not only to "negotiate" with CMS, but to provide their drugs to government healthcare programs at whatever price CMS chooses. This attempt to dragoon manufacturers into commerce with the government lies beyond Congress's enumerated powers.

III. The IRA's Compelled-Speech Requirements Violate the First Amendment.

The IRA employs another tool to deflect accountability for Congress's legally untenable and politically controversial program: a smokescreen of compelled speech. Congress was not content simply to establish a conventional price-control regime. Congress sought to conceal its coercion of manufacturers under a veneer of voluntary participation by requiring manufacturers to affirm publicly that they "agree" to CMS's dictated price and that CMS's price is the "maximum fair price." 42 U.S.C. § 1320f(d)(1). Such "'involuntary affirmation' of objected-to beliefs," which serves no legitimate government purpose, is unconstitutional compelled speech. *Janus v. Am. Fed'n of State, Cnty., & Mun. Emps., Council 31*, 138 S. Ct. 2448, 2464 (2018) (quoting *W.V. State Bd. of Educ. v. Barnette*, 319 U.S. 624, 633 (1943)).

"The First Amendment protects 'both the right to speak freely and the right to refrain from speaking at all.'" *Thompson v. Marietta Educ. Ass'n*, 972 F.3d 809, 813 (6th Cir. 2020) (quoting *Wooley v. Maynard*, 430 U.S. 705, 714 (1977)). "[C]ompelled speech" is every bit as repugnant to Constitution as "compelled silence." *Meriwether v. Hartop*, 992 F.3d 492, 517 (6th Cir. 2021) (quoting *Riley v. Nat'l Fed'n of Blind of N.C., Inc.*, 487 U.S. 781, 796 (1988)). Indeed, a law compelling speech "require[s] 'even more immediate and urgent grounds' than a law demanding silence." *Janus,* 138 S. Ct. at 2464 (quoting *Barnette,* 319 U.S. at 633). Those who are forced to speak are co-opted into "mouth[ing] support" for the government's favored policies. *Id*. at 2463. The First Amendment recognizes the "basic truth that '[f]orcing free and independent individuals to endorse'—either implicitly or explicitly—'ideas they find objectionable is always demeaning.'" *Thompson*, 972 F.3d at 813 (quoting *Janus*, 138 S. Ct. at 2464). For those reasons, "[l]aws that compel speakers to utter or distribute speech bearing a particular message are subject to the same rigorous scrutiny" as content-based suppression of speech. *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 642 (1994). Under that "strict scrutiny" test, the speech requirement must be "'narrowly

tailored to serve compelling [government] interests.'" *NIFLA*, 138 S. Ct. at 2371 (quoting *Reed v. Town of Gilbert*, 576 U.S. 155, 163 (2015)).

The IRA compels speech by forcing manufacturers to "agree" to "negotiate" and to "'endorse,' . . . implicitly or explicitly," the output of the "negotiation" process. *Thompson*, 972 F.3d at 813 (quoting *Janus*, 138 S. Ct. at 2464). It is one thing for the government to cap prices for a private company's goods or services. It is another for the government to force that company to pretend that it accepted those prices willingly and that those prices are the "maximum fair price"—implying not only that CMS's price is "fair," but that no price higher than CMS's price could also be fair. Manufacturers strenuously disagree with these inaccurate, self-serving characterizations by the government. Yet they are forced to parrot the government's viewpoint.[17]

This compelled-speech regime cannot satisfy any level of First Amendment scrutiny, let alone strict scrutiny. The government has "no legitimate reason," much less a compelling one, to force businesses to convey a false or misleading statement. *Video Software Dealers Ass'n v. Schwarzenegger*, 556 F.3d 950, 967 (9th Cir. 2009), *aff'd sub nom. Brown v. Ent. Merchants Ass'n*, 564 U.S. 786 (2011). That is especially so where, as here, the deception is designed to shield the government from criticism by obscuring who is responsible for its policies and what the true nature of those policies is. And while the government might wish to disseminate its own views about issues such as what drug prices are fair, "where the State's interest is to disseminate an ideology . . . such interest cannot outweigh an individual's First Amendment right to avoid becoming the

[17] In response to litigation, CMS tried to paper over this First Amendment problem by including a disclaimer in its template "agreement": "In signing this Agreement, the Manufacturer does not make any statement regarding or endorsement of CMS' views. . . . Use of the term 'maximum fair price' and other statutory terms throughout this Agreement reflects the parties' intention that such terms be given the meaning specified in the statute and does not reflect any party's views regarding the colloquial meaning of those terms." CMS Template at 4. But no matter what CMS may say, manufacturers are compelled by statute to "agree" to the so-called "maximum fair price." CMS's made-for-litigation disclaimer only underscores that basic reality.

courier for such message." *Wooley*, 430 U.S. at 717; *see also Lehnert v. Ferris Fac. Ass'n*, 500 U.S. 507, 522 (1991) ("The burden upon freedom of expression is particularly great where, as here, the compelled speech is in a public context").

Nor are the IRA's speech requirements tailored—let alone narrowly tailored—to any interest the government may have in regulating prices. It is "particularly" clear that a law burdening speech is not "properly tailored" when much less burdensome alternatives "are obvious." *U.S.W., Inc. v. FCC*, 182 F.3d 1224, 1238 (10th Cir. 1999). Here, Congress could have regulated prices "without burdening a speaker with unwanted speech." *NIFLA*, 138 S. Ct. at 2376 (quoting *Riley,* 487 U.S. at 800). Price controls do not require speech controls. But Congress chose to "co-opt the [pharmaceutical companies] to deliver its message for it." *Id*.

Moreover, even if manufacturers were genuinely free to withdraw from Medicare and Medicaid (they are not, *see supra* section I.C) and thereby avoid the unwanted speech, that would not solve the IRA's First Amendment problem. Under the "unconstitutional conditions doctrine," it is "well-settled" that "the government may not deny a benefit to a person because he exercises a constitutional right." *Koontz*, 570 U.S. at 604 (citations and quotation marks omitted) (collecting cases). The Supreme Court has "made clear" that what the government cannot "command directly," it cannot accomplish indirectly by "deny[ing] a benefit to a person on a basis that infringes his constitutionally protected interests—especially, his interest in freedom of speech." *Perry*, 408 U.S. at 597 (citation and quotation marks omitted). Indeed, even when a condition is not "actually coercive, in the sense of an offer that cannot be refused," it is still unconstitutional if it "seek[s] to leverage funding to regulate speech outside the contours of the program itself." *Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc*., 570 U.S. 205, 214–15 (2013).

Here, this principle means that Congress cannot condition participation in Medicare on the surrender of manufacturers' right to refrain from "'endors[ing]'—either implicitly or explicitly—'ideas they find objectionable.'" *Thompson*, 972 F.3d at 813 (quoting *Janus*, 138 S. Ct. at 2464). The requirement that manufacturers endorse government-set prices as the "maximum fair" prices and as the product of a joint "agreement" is not "'an appropriate requirement for the effective performance' of the [program] in question." *O'Hare Truck Serv., Inc. v. City of Northlake*, 518 U.S. 712, 725 (1996) (quoting *Branti v. Finkel*, 445 U.S. 507, 518 (1980)). And it is not only coercive, but regulates speech "outside the contours" of the IRA's price-control program because it is entirely unnecessary for the functioning of the price controls. *Open Soc'y*, 570 U.S. at 215. Indeed, the compelled speech will likely have spillover effects in private markets, including a potential undermining of manufacturers' negotiating position in private transactions and a loss of customer goodwill due to inevitable comparisons with the market-based, competitively determined prices that prevail today. Whether analyzed as a direct mandate or a condition on government benefits, then, the IRA's compelled-speech requirements violate manufacturers' First Amendment rights.

IV. The IRA's Price-Control Program Violates the Constitution's Separation of Powers.

The "lack of historical precedent" for the structure of the IRA's price-control program is a "telling indication" that it violates separation-of-powers principles. *Free Enterprise Fund*, 561 U.S. at 505–06 (citation and quotation marks omitted). The IRA centralizes vast, unreviewable power in the hands of an administrative agency, without the ordinary protections of due process, to decide the fate of the $600 billion pharmaceutical industry and every American who depends on it. But the IRA not only commandeers a wide swath of the nation's economy—it shakes the foundations of America's constitutional structure. As a unanimous Supreme Court held when it invalidated the National Industrial Recovery Act in *A.L.A. Schechter Poultry Corp. v. United States,* Congress may not in effect delegate its legislative power to the executive branch by

conferring "virtually unfettered" discretion on the executive to regulate private industry. 295 U.S. at 542. Under the non-delegation doctrine as well as broader separation-of-powers principles, the IRA's attempted takeover of a major American industry should meet the same fate.

A. The IRA's Price-Control Program Violates the Supreme Court's Nondelegation and Separation-of-Powers Precedents.

Although the Supreme Court has sustained delegations of substantial discretion to the executive branch in certain contexts, the IRA's price-control program stands out as an "anomaly." *Seila Law LLC v. Consumer Fin. Prot. Bureau,* 140 S. Ct. 2183, 2202 (2020). The Court's modern nondelegation precedents are often summarized with a shorthand formulation—the "intelligible principle" test. *Gundy v. United States*, 139 S. Ct. 2116, 2123 (2019) (plurality). But properly understood, those precedents require more than simply comparing isolated statutory phrases to determine whether a delegation is improper. For example, "[t]he degree of agency discretion that is acceptable varies according to the scope of the power congressionally conferred." *Consumers' Rsch. v. FCC*, 67 F.4th 773, 788 (6th Cir. 2023) (quoting *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 475 (2001)); *accord Allstates Refractory Contractors, LLC v. Su*, 79 F.4th 755, 761 (6th Cir. 2023). Context matters, including the degree which the delegation endangers private rights and the degree to which it comports with a history of similar regulation. *See Consumers' Rsch.*, 67 F.4th at 795 (citing "Congress's history of pursuing universal service" as a factor in upholding a delegation to the FCC); *Schechter Poultry*, 295 U.S. at 541 (noting that the Recovery Act was "without precedent"); *id.* at 552–53 (Cardozo, J., concurring) (emphasizing the Recovery Act's departure from "accepted business standards or accepted norms of ethics" and disruption of "established practice"). It also matters whether a statute has internal "checks and balances," such as notice-and-comment rulemaking, formal hearings, and judicial review. *Allstates*, 79 F.4th at

763; *see, e.g.*, 29 U.S.C. § 655 (providing rigorous procedures for the adoption of OSHA standards, including public hearings and judicial review).

And as the Supreme Court's recent decisions in *Seila Law* and *Free Enterprise Fund* confirm, even if Congress articulates some minimally "intelligible" principle, that is not the end of the separation-of-powers analysis. Even a delegation with an intelligible principle may violate the separation of powers if it lacks procedural protections commensurate with the scale and importance of the delegation. In *Seila Law*, the Court held the structure of the Consumer Financial Protection Bureau unconstitutional not only because Congress delegated very broad policymaking power to the agency, but because it did so without correspondingly robust checks and balances—such as a multi-member body that could mitigate the unilateral discretion of a single director. Similarly, in *Free Enterprise Fund*, the Court held the structure of the Public Company Accounting Oversight Board unconstitutional not only because the agency wielded substantial policymaking authority, but because it did so under an unprecedented dual layer of protection from accountability to the President. Here, Congress has compounded a nondelegation problem with a related but independent separation-of-powers problem. It has not only failed to constrain the IRA's vast delegation of power to HHS with an intelligible principle, but has failed to supply commensurate procedural safeguards, such as notice-and-comment rulemaking and judicial review, needed to ensure the accountability that the Constitution's separation-of-powers is designed to protect.

Applying these nondelegation and separation-of-powers principles, the Supreme Court has invalidated statutes that confer "virtually unfettered" discretion on the executive branch to control large swaths of the private economy. *Schechter Poultry*, 295 U.S. at 542. In *Schechter Poultry*, the Court struck down the Recovery Act's delegation to the President to create codes of "fair competition," including wage controls, for private industry. Although the Recovery Act set forth

"general aims" to guide the President's discretion, Congress had not "itself established the standards of legal obligation" and had thus failed to "perform[] its essential legislative function." *Id.* at 530, 541–42. Contrasting this statutory scheme with the Federal Trade Commission's regulation of "unfair competition," the Court also emphasized the lack of "judicial review to give assurance that the action of the [executive] is taken within its statutory authority" and the absence of "appropriate administrative procedure," such as quasi-judicial proceedings, to ensure due process. *Id.* at 532–33, 541. Similarly, in *Panama Refining Co. v. Ryan*, the Court invalidated a statute authorizing the President to ban petroleum shipments in excess of state production quotas. 293 U.S. 388, 418 (1935). Although the statute contained a "general outline of policy," including such criteria as "remov[ing] obstructions to the free flow of interstate and foreign commerce" and "favor[ing] the fullest possible utilization of the present productive capacity of industries," these vague directives did not amount to a "standard or rule." *Id.* at 417–18 (quotation marks omitted).

The IRA similarly combines a breathtaking delegation of power with a lack of critical guardrails, including legal standards, "appropriate administrative procedure," and judicial review. *Schechter Poultry*, 295 U.S. at 541. This legal void is all the more striking because unlike in many other delegations, the agency here is not only a regulator but a self-interested market participant with an incentive to "act for 'selfish' or 'arbitrary' reasons." *Rice v. Vill. of Johnstown*, 30 F.4th 584, 589–91 (6th Cir. 2022) (quoting *Washington ex rel. Seattle Title Tr. Co. v. Roberge*, 278 U.S. 116, 122 (1928)). HHS is the nation's largest payor for prescription drugs. Expecting HHS to look out for the property interests and constitutional rights of pharmaceutical manufacturers is like asking the fox to guard the henhouse.

Consider first the dearth of legal standards. The most basic constitutional requirement is that Congress "provide[] an administrative agency with standards guiding its actions such that a

court could ascertain whether the will of Congress has been obeyed." *Skinner v. Mid-Am. Pipeline Co.*, 490 U.S. 212, 218 (1989) (quotation marks omitted). Yet the heart of the IRA's drug-pricing provisions is CMS's standardless discretion to set prices. Apart from a temporary price floor for certain small manufacturers, 42 U.S.C. § 1320f-3(b)(2)(F)(ii), the IRA imposes only a price *ceiling* that ranges from 75% down to 40% of the 2021 non-federal average manufacturer price. *Id.* §§ 1320f-3(c)(1)(C), 1320f-3(b)(2)(F). There is no legal standard whatsoever. Tellingly, the IRA circularly defines the term "maximum fair price" not by reference to any standard of fairness or reasonableness, but simply as the "price negotiated" (*i.e.*, dictated) "pursuant to section 1320f-3." *Id.* § 1320f. Although the IRA lists several "factors" to "consider" in dictating prices, *id.* § 1320f-3, CMS has conceded that the IRA "does not specify how [the agency] should determine an initial offer nor how or to what degree each factor should be considered." Initial Guidance at 47; *accord* Revised Guidance at 144.

That the IRA instructs CMS to "develop and use a consistent methodology and process . . . that aims to achieve the lowest maximum fair price for each selected drug," 42 U.S.C. § 1320f-3(b)(1), only makes matters worse. Again, the IRA defines "maximum fair price" to mean whatever price CMS dictates, *id.* § 1320f. By statutory definition, therefore, the lowest "maximum fair price" is zero. But Congress cannot have intended such an absurd result, so the instruction is meaningless—providing no guidance at all to the agency or to regulated parties. In an attempt to clarify how the agency will exercise its unbounded discretion, CMS has promulgated a 198-page "guidance" document that reads more like a statute than like true guidance. *See generally* Revised Guidance. This only highlights Congress's failure to legislate. An agency cannot cure a nondelegation problem by promulgating rules or guidance. To the contrary, the agency's need to

hypothesize an "intelligible principle" underscores that Congress failed to enact one. *See Whitman*, 531 U.S. at 472–73.

The lack of intelligible legal standards is compounded by the foreclosure of administrative and judicial review—another "significant and unusual" deviation from standard mechanisms of accountability. *Free Enterprise Fund*, 561 U.S. at 506. As courts have consistently recognized, "judicial review is a factor weighing in favor of upholding a statute against a nondelegation challenge." *United States v. Garfinkel*, 29 F.3d 451, 458–59 (8th Cir. 1994) (quotation marks and brackets omitted) (collecting cases); *see Schechter Poultry*, 295 U.S. at 533. Yet the IRA precludes *both* administrative and judicial review of CMS's key determinations, including the selection of "drugs" for price controls and the determination of the so-called "maximum fair price." *See* 42 U.S.C. § 1320f-7. Like so much else in the IRA, then, the price-control "factors" are window-dressing—a hodgepodge of considerations with no mechanism to ensure that they are properly considered. Whereas the Constitution seeks to "constrain[] each branch's use of its power through counterweights in the other branches," *Oklahoma v. United States*, 62 F.4th 221, 228–29 (6th Cir. 2023), the IRA dispenses with the crucial counterweight of judicial review. Similarly, while "compliance with . . . requirements for notice and comment" can enhance public accountability and thereby function as a check on agency discretion, *Garfinkel,* 29 F.3d at 459, the IRA dispenses with notice-and-comment rulemaking and prohibits administrative review of key decisions, no matter how severe the error or legal violation. As in *Free Enterprise Fund*, these "added layer[s]" of insulation from accountability "make[] a difference." 561 U.S. at 495.

B. The Original Understanding of the Nondelegation Doctrine and the Separation of Powers Confirms that the IRA's Structure Is Unconstitutional.

"[T]he Constitution's original meaning is law, absent binding precedent to the contrary." *Rife*, 33 F.4th at 843–44. And where precedents leave room for interpretation, lower courts "should

resolve questions about the scope of those precedents in light of and in the direction of the constitutional text and constitutional history." *PHH Corp. v. Consumer Fin. Prot. Bureau*, 881 F.3d 75, 196 (D.C. Cir. 2018) (en banc) (Kavanaugh, J., joined by Randolph, J., dissenting), *abrogated by Seila Law*, 140 S. Ct. at 2200 (agreeing with then-Judge Kavanaugh's dissent in *PHH*). Because the IRA is so unprecedented, no binding precedent requires upholding it against Plaintiffs' separation of powers challenge. *Cf. Free Enterprise Fund*, 561 U.S. at 483 ("We are asked . . . to consider a new situation not yet encountered by the Court."). And there can be little doubt that the "novel structure" of the IRA's price-control program, *id.* at 496, which gives HHS unreviewable discretion to force sales at rock-bottom prices, violates the original understanding of the Constitution's separation of powers.

No principle is more fundamental to the Constitution's protection of liberty and self-government than the separation of powers. Article I's Vesting Clause vests "*[a]ll* legislative Powers" in the "Congress of the United States." U.S. Const. art. I, § 1 (emphasis added). Article II vests the executive power in the President. U.S. Const. art. II, § 1. And Article III vests the judicial power in the courts. U.S. Const. art. III, § 1. The Founders thus "constrained each branch's use of its power through counterweights in the other branches." *Oklahoma*, 62 F.4th at 228–29. "That is the equilibrium the Constitution demands," and "when one branch impermissibly delegates its powers to another, that balance is broken." *Tiger Lily, LLC v. U.S. Dep't of Hous. & Urb. Dev.*, 5 F.4th 666, 673–74 (6th Cir. 2021) (Thapar, J., concurring).

To preserve that fundamental balance, as the Supreme Court has long held, it is necessary to distinguish between "important subjects, which must be entirely regulated by the legislature itself," and "those of less interest," as to which Congress may afford the executive branch discretion "to fill up the details." *Wayman v. Southard*, 2 U.S. (10 Wheat.) 1, 42–43 (1825). The

Constitution makes Congress "responsive to the will of the people" because Congress wields the awesome power of "'prescrib[ing] the rules by which the duties and rights of every citizen are to be regulated.'" *Tiger Lily*, 5 F.4th at 674 (Thapar, J., concurring) (quoting The Federalist No. 78 (Alexander Hamilton)). "[B]y directing that legislating be done only by elected representatives in a public process, the Constitution sought to ensure that the lines of accountability would be clear." *Jarkesy v. SEC*, 34 F.4th 446, 460 (5th Cir. 2022) (quotation marks omitted), *cert. granted*, 143 S. Ct. 2688 (June 30, 2023) (No. 22-859).

The nondelegation doctrine ensures that Congress cannot palm its constitutional responsibility for major policy decisions off to the executive "to insulate itself from the consequences of hard choices." *Tiger Lily*, 5 F.4th at 674 (Thapar, J., concurring). During the time of the Second Congress, for example, James Madison and other prominent statesmen resisted an attempt to delegate Congress's power to establish postal roads—"high-stakes stuff" for 18th-century Americans—to the President, who would be authorized to select "'such route as [he] shall, from time to time, cause to be established.'" *Id.* (citing Ilan Wurman, *Nondelegation at the Founding*, 130 Yale L. J. 1490, 1506 (2021)). Madison successfully opposed that bill on the ground that to "alienat[e] the powers of the House . . . would be a violation of the Constitution." *Id.* (emphasis omitted).

During the nineteenth century, the Supreme Court continued to recognize that "[C]ongress cannot delegate legislative power to the president"—a "principle universally recognized as vital to the integrity and maintenance of the system of government ordained by the [C]onstitution." *Marshall Field & Co. v. Clark*, 143 U.S. 649, 692 (1892). Yet the Court acknowledged that the executive could carry out interstitial implementation of congressional commands. *See, e.g.*, *In re Kollock*, 165 U.S. 526, 532 (1897) (upholding a statute that assigned the Commissioner of Internal

Revenue responsibility to design tax stamps for margarine packages). The Court also approved a discrete fact-finding role for executive officials under statutes "directing certain measures to be taken upon the happening of particular contingencies, or the ascertainment of particular information." *Miller v. City of New York*, 109 U.S. 385, 393–94 (1883) (upholding a law that made the construction of the Brooklyn Bridge depend on a finding by the Secretary of War that the bridge would not obstruct river navigation).

No one could describe the scope of executive power under the IRA as merely "fill[ing] up the details," *Wayman*, 23 U.S. at 43, or as modest fact-finding to ascertain "particular contingencies," *Miller*, 109 U.S. at 393. When CMS exercises its vast discretion under the IRA—which includes selecting CMS-defined "drugs" for price-setting, dictating the terms of "agreements" that it reserves the right to unilaterally amend, and determining the prices of drugs used by tens of millions of Americans—it is not filling in statutory gaps or doing computational busywork; it is creating sweeping rules of private conduct backed by crippling penalties. Nor is CMS engaged in mere fact-finding to determine whether to trigger the application of a specific congressional policy. Indeed, the IRA does not require CMS to make any particular findings at all in setting prices; the agency need only "consider" a vague list of "factors." 42 U.S.C. § 1320f-3. And even if those factors somehow constrained CMS, there would be no way to hold its feet to the fire because of the IRA's sweeping bars on judicial review. *See id.* § 1320f-7(2)–(3). This turbocharged delegation, which gives an agency unreviewable power to commandeer a major sector of the economy, cannot be reconciled with "[f]ounding[-era] conceptions of separation of powers" and the nondelegation doctrine. *Jarkesy*, 34 F.4th at 460.

C. Comparing the IRA's Price-Control Program with Other Agency Price-Control Schemes Reinforces the Nondelegation and Separation-of-Powers Problems.

Nor can the government claim that Congress needed to structure the IRA as it did. Congress has repeatedly established administrative price-control regimes that contain the very safeguards missing from the IRA. The IRA is thus "a historical anomaly." *Seila Law*, 140 S. Ct. at 2202.

For example, consider rate-setting for energy transmission. Rates must be, at the very least, "just and reasonable," 16 U.S.C. § 824d. A comprehensive body of law has been developed to ensure adequate review of the Federal Energy Regulatory Commission's (FERC's) rate-setting authority so that it is not used in an arbitrary, discriminatory, or otherwise unconstitutional manner. *See, e.g., In re Permian Basin Area Rate Cases*, 390 U.S. at 769–70. Statutory procedures limit FERC's authority to set rates and provide opportunities for public hearings. *See* 16 U.S.C. §§ 824d, 824e, 825*l*; *Mobil Oil Expl.*, 498 U.S. at 218 (noting use of notice-and-comment rulemaking to "revise the old gas pricing system"). And importantly, judicial review is available to ensure that FERC complies with due process, the statutory standard, and the procedural requirements of the governing statute and the APA. *See, e.g.*, 15 U.S.C § 717r; 16 U.S.C. § 825*l*. The IRA lacks these basic safeguards.

Likewise, when Congress undertook to regulate coal prices in the 1930s, it did not give the Coal Commission carte blanche to drive prices as low as it pleased. Congress expressly required that any "maximum price" established for a mine must "yield a fair return on the fair value of the property." *Sunshine Anthracite Coal Co. v. Adkins*, 310 U.S. 381, 397 (1940). Further, Congress provided that "maximum prices must be fixed at a uniform increase above minimum prices so that in the aggregate they will yield a reasonable return above the weighted average total cost of the district." *Id.*; *see id.* (before setting maximum prices, Commission must first determine that doing so is "necessary in order to protect the consumer against unreasonably high prices"). Congress has

no excuse for omitting meaningful legal standards, opportunities for administrative and judicial review, and other procedural safeguards from the IRA.

D. The IRA Impermissibly Insulates Vast Policymaking Power from Accountability.

Separation-of-powers and nondelegation principles are animated by the concern that elected representatives will use delegation to evade accountability for consequential policy decisions. The IRA's delegation of vast, unreviewable power to HHS raises precisely that core problem in two main ways. First, Congress abdicated its own responsibility by delegating massive power to the agency. When Congress legislates, elected representatives must engage in a lengthy, public process of consensus-building subject to the constitutional requirements of bicameralism and presentment. "[T]hat accountability evaporates if a person or entity other than Congress," such as an administrative agency, "exercises legislative power." *Jarkesy*, 34 F.4th at 460. Second, Congress "multiplied" that "dispersion of responsibility" further by "shelter[ing] the bureaucracy['s]" key determinations behind strict judicial review bars and dispensing with notice-and-comment rulemaking. *Free Enterprise Fund*, 561 U.S. at 497. Congress has not only "insulate[d] *itself* from the consequences of hard choices" by delegating to HHS, *Tiger Lily*, 5 F.4th at 674 (Thapar, J., concurring) (emphasis added), it has insulated *HHS* from accountability too. Just as the "multilevel protection from removal" in *Free Enterprise Fund* was "contrary to Article II's vesting of executive power in the President," 561 U.S. at 484, the multilevel protection from accountability here is contrary to Article I's vesting of "all legislative powers" in Congress.

From top to bottom—the sham "negotiation" process; the "maximum fair price" provisions that require manufacturers to endorse government-set prices as "fair"; the misnamed "excise tax" that is so immense that not even the government expects it to yield revenue; the toothless price-setting "factors" that leave CMS to do as it pleases; the direction to make policy through program

guidance instead of notice-and-comment; and the bars on judicial and administrative review—the price-control program is designed to undermine transparency and dodge accountability. The IRA's deceptions are designed to shield the government from criticism by obfuscating who is responsible for its policies and what the true nature of those policies is.

Similarly, the IRA's sweeping delegation is designed to shield Congress from the inevitable blowback for counterproductive policies. Congress can take credit for supposedly taking action to lower drug costs, and then blame CMS when price controls lead to reduced innovation, cancelled drug trials, job losses, and higher health care costs. CMS need not subject its decision-making process to public scrutiny through notice-and-comment rulemaking. And when CMS's decisions are challenged as illegal, it can hide behind the IRA's judicial review bars. This unaccountable structure "lack[s] . . . historical precedent" and slips the bounds of the separation of powers. *Free Enterprise Fund*, 561 S. Ct. at 505–06 (quoting 537 F.3d 667, 699 (D.C. Cir. 2008) (Kavanaugh, J., dissenting)).

* * *

For all of these reasons, this Court should declare the challenged provisions of the IRA unconstitutional. *See* 28 U.S.C. § 2201 (Declaratory Judgment Act). And when courts invalidate a statute on facial constitutional grounds, they typically enjoin the government from implementing it. *See, e.g.*, *Riley*, 487 U.S. at 803 (affirming permanent injunction of unconstitutional compelled-speech provisions of statute); *NFIB*, 567 U.S. at 588 (enjoining enforcement of unconstitutional Medicaid expansion program); *Byrd v. Tenn. Wine & Spirits Retailers Ass'n*, 259 F. Supp. 3d 785, 797–98 (M.D. Tenn. 2017) (declaring statute unconstitutional under Commerce Clause and enjoining its enforcement), *aff'd*, 883 F.3d 608 (6th Cir. 2018), *aff'd sub nom. Tenn. Wine & Spirits Retailers Ass'n v. Thomas*, 139 S. Ct. 2449 (2019); *Baltimore & Ohio R.R. Co. v. City of Piqua*,

No. C-3-85-312, 1986 WL 8254, at *7 (S.D. Ohio June 30, 1986) (declaring statute unconstitutional under Supremacy Clause and permanently enjoining its enforcement). This Court should do the same here.

CONCLUSION

The Court should grant summary judgment in favor of Plaintiffs on all of their claims.

Dated: November 8, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 8, 2023, a true and correct copy of the foregoing Motion for Summary Judgment and Memorandum in Support 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)

EXHIBIT A

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*.	Civil Action No. 3:23-cv-00156-MJN-PBS Judge Michael J. Newman Magistrate Judge Peter B. Silvain, Jr.

THIRD DECLARATION OF MICHAEL C. STAFF, SUBMITTED IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

I, Michael C. 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 support of Plaintiffs' Motion For Summary Judgment. This declaration supplements my first and second declarations, which were submitted in this case on July 11, 2023, and August 25, 2023.

3. Kevin Buckbee, AbbVie's Senior Vice President, Controller, signed the Medicare Drug Price Negotiation Program Agreement on behalf of Pharmacyclics LLC, and he submitted it to The Centers for Medicare & Medicaid Services ("CMS") on September 30, 2023. CMS countersigned the agreement that same day.

4. Before submitting the agreement, Mr. Buckbee sent a letter to CMS stating that AbbVie's and Pharmacyclics' agreement does not waive any of their arguments or objections to the IRA's Drug Price Negotiation Provisions or CMS's current or future implementation or

application of them, including but not limited to those arguments and objections asserted by Plaintiffs in this case. This preservation of rights by AbbVie and Pharmacyclics is, among other things, consistent with Paragraph IV(g) of the Medicare Drug Price Negotiation Program Agreement, which states: "Nothing in this Agreement shall be construed to require or authorize the commission of any act contrary to law."

5. In a multi-day process that concluded on October 2, 2023, AbbVie (on behalf of Pharmacyclics) submitted the IMBRUVICA®-related data required by the IRA, upon penalty of $1 million per-day and imposition of the "excise tax" if the data were not submitted on time or were deemed insufficient by CMS.

6. This data took dozens of employees from AbbVie and Pharmacyclics months to identify, collect, organize, prepare, and enter into CMS's data-submission portal. The data contained proprietary and business-sensitive trade secrets that AbbVie and Pharmacyclics would not provide to any other price-negotiating counterparty, and would not have provided to CMS but for the threat of the $1 million per-day penalty and imposition of the "excise tax." AbbVie's data submission included over eight hundred fifty (850) separate required record entries, plus additional required patent files, along with over eight thousand (8000) words of required explanation of the record entries.

7. On October 20, 2023, AbbVie (on behalf of Pharmacyclics) submitted additional information to CMS, to provide further context and explanation of the data regarding IMBRUVICA® that was required under the IRA. AbbVie representatives also traveled to meet with CMS representatives in-person at their offices on October 27 to further discuss the submitted IMBRUVICA® information.

8. Going forward, a team of AbbVie and Pharmacyclics employees will have to continue to work on the remaining steps of the drug price negotiation process, including (a) evaluating CMS's initial price offer for IMBRUVICA®, (b) formulating a "counteroffer" that complies with CMS's detailed requirements, and (c) otherwise continuing to engage with CMS throughout the process. AbbVie and Pharmacyclics will also have to commit employee time and financial resources to operationalize the provisions of the IRA that require manufacturers to provide access to the "maximum fair price" for "maximum fair price eligible individuals."

9. On October 27, 2023, AbbVie announced in its third-quarter financial earnings release that IMBRUVICA®'s selection under the IRA drug price negotiation provisions contributed to a significant decrease in the estimated future cash flows of IMBRUVICA®, resulting in AbbVie recording a $2.1 billion impairment, reducing AbbVie's intangible asset carrying value of IMBRUVICA® by more than half. https://news.abbvie.com/news/press-releases/abbvie-reports-third-quarter-2023-financial-results.htm.

10. AbbVie's October 27 third-quarter earnings release also disclosed that AbbVie's Immunology products HUMIRA®, SKYRIZI®, AND RINVOQ® combined for more than 52% of AbbVie's U.S. Net Revenues and that AbbVie's portfolio of Neuroscience products, which include VRAYLAR® AND UBRELVY® among others, accounted for more than 16% of AbbVie's U.S. Net Revenues. These AbbVie products (and dozens more) are covered by Medicare and other federal healthcare programs.

11. IMBRUVICA® was initially approved to treat Mantle Cell Lymphoma in 2013. Pharmacyclics (and AbbVie after it acquired Pharmacyclics) continued to invest in research to establish that Imbruvica was safe and effective to treat more types of blood cancers and other diseases. As a result of this research investment, the U.S. FDA approved IMBRUVICA® to treat

Chronic Lymphocytic Leukemia in 2014, Waldenstrom's Macroglobulinemia in 2015, and Chronic Graft Versus Host Disease in 2017, among other diseases. AbbVie and Pharmacyclics also invested in innovation to make IMBRUVICA® easier for patients to take, resulting in multiple formulations: capsules, tables, and an oral suspension liquid. The U.S. Patent and Trademark Office recognized these novel and useful efforts by issuing multiple patents covering these innovations. The IMBRUVICA® capsule formulation patent extends into 2033. The IMBRUVICA® tablet formulation patent extends through 2036.

12. AbbVie and Pharmacyclics have taken steps to enforce the patents protecting their research and innovation investments where necessary.

13. In litigation against generic IMBRUVICA® capsule makers, AbbVie settled for an agreement allowing those generics to come to market in 2032. *See* https://www.sec.gov/Archives/edgar/data/1551152/000110465921107639/tm2125525d1_8k.htm.

14. In litigation against generic IMBRUVICA® tablet makers, AbbVie prevailed in the Federal Circuit Court of Appeals, successfully enforcing its patents through their full terms. https://cafc.uscourts.gov/opinions-orders/21-2270.OPINION.11-15-2022_2033497.pdf

15. More than 12,000 Medicare patients currently take IMBRUVICA® for just one of its indications alone: Chronic Lymphocytic Leukemia. Clinical research shows that IMBRUVICA® improves survival rates for patients with Chronic Lymphocytic Leukemia. *E.g.,* https://news.abbvie.com/news/imbruvica-ibrutinib-data-in-chronic-lymphocytic-leukemia-cll-show-up-to-seven-years-progression-free-survival-pfs-in-80-percent-previously-untreated-patients-longest-follow-up-for-brutons-tyrosine-kinase-inhibitor-to-date.htm.

16. Medicare patients take other drugs on the initial IRA drug price negotiation program list to prevent blood clots and strokes (ELIQUIS®, XARELTO®), control their diabetes

(JARDIANCE®, JANUVIA®, FARXIGA®, FIASP®, NOVOLOG®), reduce their risk of kidney failure (FARXIGA®), and reduce their risk of heart failure (FARXIGA®, ENTRESTO®), among other conditions treated by the drugs on that initial list, according to their FDA-approved prescribing information.

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

Executed this 7th day of November, 2023.

Michael C. Staff