IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF CONNECTICUT

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., *Plaintiff*, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES *et al.*, *Defendants*.	Civil Action No. 3:23-CV-01103-RNC

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

Robert A. Long, Jr. (*pro hac vice*)
Kevin F. King (*pro hac vice*)
Thomas Brugato (*pro hac vice*)
Michael M. Maya (*pro hac vice*)
COVINGTON & BURLING LLP
850 Tenth Street, NW
Washington, DC 20001-4956
Tel.: (202) 662-6000
Fax: (202) 662-6291

James T. Shearin [01326]
Marcy Tench Stovall [14238]
PULLMAN & COMLEY, LLC
850 Main Street
P.O. Box 7006
Bridgeport, CT 06601-7006
Juris No. 47892
Tel.: (203) 330-2000
Fax: (203) 576-8888
jtshearin@pullcom.com

Counsel for Plaintiff
Boehringer Ingelheim Pharmaceuticals, Inc.

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INTRODUCTION AND SUMMARY OF ARGUMENT

The Constitution requires Congress to turn square corners when enacting laws that burden constitutional rights. Even when Congress has a strong "desire to improve the public condition," that "is not enough to warrant achieving the desire by a shorter cut than the constitutional way." *Horne v. USDA*, 576 U.S. 350, 362 (2015) (quoting *Pennsylvania Coal Co. v. Mahon*, 260 U.S. 393, 416 (1922) (Holmes, J.)). The Medicare Drug Price Negotiation Program ("Program") fails that test because it repeatedly relies on shortcuts that infringe regulated parties' rights under the First, Fifth, and Eighth Amendments.

Defendants—acting through the Centers for Medicare and Medicaid Services ("CMS")—recently issued an order subjecting Jardiance®, a groundbreaking medication marketed by Plaintiff Boehringer Ingelheim Pharmaceuticals, Inc. ("BI"), to the Program. As a result, BI must engage in a process the Inflation Reduction Act ("IRA") describes as a "negotiation" with CMS regarding a "maximum fair price" for Jardiance®. But that process is a sham from beginning to end. Stripped of its misleading labels and procedural smokescreens, the Program amounts to Government price setting without key safeguards required by the Constitution. The "agreement" that purportedly begins the "negotiation" process is not an agreement, but a set of mandates issued by CMS in its capacity as a regulator. The "negotiations" themselves are not bilateral bargaining but a performative exercise that ends with CMS—the same agency that pays for the drugs subject to the Program—unilaterally picking the price it will pay. And the IRA, which governs the Program, not only prohibits judicial review of the price caps CMS imposes, but also requires BI to grant a broad range of Medicare participants "access" to Jardiance® on the terms dictated by CMS, on pain of *billions* of dollars in penalties. Congress has enacted price-setting regimes in the past, but none of them cast aside the constitutional rights of regulated parties in the ways the Program does here.

Congress could have pursued its aims in much simpler fashion, empowering CMS to adopt price regulations in the same manner as other federal agencies. But that approach would have left a clear line of accountability between the Program's architects and the inevitable downstream consequences of their action: sharp reductions in development of innovative new medicines and the availability of life-saving treatments, particularly for rare diseases and patient populations with special needs, such as children. By clothing the Program in the garb of voluntary negotiations, while compelling regulated parties to participate through elaborate mandates, Congress sought to avoid responsibility for those harmful consequences.

The question in this case is whether Congress took "a shorter cut than the constitutional way" in designing the Program. *Horne*, 576 U.S. at 362 (cleaned up). The answer is yes, for four reasons.

First, the Program violates BI's Fifth Amendment due process rights. Despite depriving BI of multiple constitutionally protected property interests, the Program omits procedural protections that courts have held are essential components of due process. The Program provides no meaningful opportunity to be heard by an impartial decision maker. Indeed, CMS has both a statutory duty and a built-in financial incentive to drive the maximum price as low as possible. The Program's so-called negotiations also do not provide adequate process: the Program lacks ascertainable standards for setting the price for Jardiance®; CMS is not obligated to disclose the evidence it relies upon; and CMS need not engage in reasoned decisionmaking or consider BI's submissions during the "negotiation" process. That the IRA forecloses judicial and administrative review of CMS's actions only exacerbates these constitutional injuries.

Second, the Program violates the Fifth Amendment's Takings Clause. The IRA empowers third parties to take possession of BI's Jardiance® on terms set by CMS and ensures that access

through expansive coverage requirements. As a result, BI will be forced to hand over its Jardiance® products, losing the rights to control the disposition of that property and to exclude others from accessing it against BI's will. The IRA does not afford BI just compensation for this appropriation, but instead requires CMS to pay far less than the fair market value guaranteed by the Constitution.

Third, the IRA violates the First Amendment by compelling BI to endorse the Government's preferred narrative regarding the Program. The IRA inflicts that harm by forcing BI to sign an "agreement" stating that the company will "negotiate" a "maximum fair price" for Jardiance®—thus falsely conveying that BI has voluntarily agreed to participate in the Program, that the Program involves arms-length negotiations, and that the Program results in a "fair" price for Jardiance® products. None of those compelled statements are necessary for CMS to adopt Medicare price regulations, but all of them are necessary to carry out Congress's carefully orchestrated avoidance of accountability for the Program's adverse effects. BI disagrees with the Government's messages and cannot constitutionally be compelled to convey them.

Fourth, the Program violates the Eighth Amendment's Excessive Fines Clause. Under the IRA, BI will be subject to a penalty, labeled as a tax, on every domestic sale of Jardiance® if BI does not comply with CMS's order to participate in the Program. This penalty *starts* at nearly twice the gross revenues of Jardiance® sales nationwide and balloons to *19 times* the gross revenues until BI accedes to the Program's requirements—resulting in fines of between $500 million and $5.5 billion *per week*. Congress understood that these extravagant penalty provisions would not generate a single dollar of revenue because they are so punitive and disproportionate that no rational manufacturer would ever trigger their application.

The Government has gone to great lengths to sidestep these constitutional violations by portraying the Program as voluntary. According to the Government, the Program gives BI the

"options" of paying the unconstitutionally excessive penalties described above or withdrawing Jardiance® *and all of BI's other products* from Medicare and Medicaid, which together account for approximately 40 percent of the U.S. pharmaceutical market. Each of these purported options is a mirage that would be financially ruinous for BI and devastating to the millions of patients BI serves. Collectively, these "options" make plain that the Program is voluntary in name only. But even if the Program were voluntary, it would still raise similar concerns by unconstitutionally conditioning BI's participation in Medicare and Medicaid on relinquishment of the rights discussed above. Voluntary or not (and it is decidedly not), the Program is unconstitutional.

Apart from these constitutional violations, CMS violated bedrock administrative procedures in implementing the Program. CMS promulgated the "Manufacturer Agreement," which is a legislative rule given its sweeping scope and obligations, without conducting required notice-and-comment proceedings. Accordingly, the Court should set aside the Agreement.

By August 1, 2024, in the absence of judicial intervention, BI will be required to sign a further agreement adopting a specific "maximum fair price" for Jardiance®. *See* 42 U.S.C. §§ 1320f(d)(2)(B), 1320f(b)(4)(B), 1320f-3(a)(1). Given the irreparable harm that would result from that agreement, BI respectfully requests that the Court hold a hearing on the parties' cross-motions for summary judgment promptly after the close of briefing and issue a ruling on those motions before the August 1, 2024 deadline.

BACKGROUND

I. The Prescription Drug Market and Pharmaceutical Innovation.

The U.S. pharmaceutical industry is at the forefront of the worldwide quest for innovative treatments that allow patients to live longer, healthier lives. Drugs developed in the United States

"account for almost half" of the "medicines under development globally."[1] Innovators like BI, however, face daunting odds and incur great financial risk when developing new drugs. For every 5,000 compounds that enter preclinical testing, only one will obtain Food and Drug Administration ("FDA") approval—a success rate of just 0.02 percent.[2] Even among compounds that reach the clinical trial stage, only 12 percent are approved by FDA.[3] All told, an approved drug on average requires billions of dollars of investment.[4] And even then, only 20 percent of FDA-approved drugs that make it to market recoup the costs incurred in their *own* development—let alone provide funding for the many projects that fail.[5]

Because of the enormous costs and failure rate associated with developing new drugs, investments in innovation depend on the revenues from the tiny fraction of drugs that receive FDA approval and the small subset of those that achieve market success. *See* Marsh Decl. ¶ 17. The small number "of successful projects that result in new commercialized drugs have to provide enough revenue to justify the investment" in the large number of "failed compounds."[6]

Medicare and Medicaid are essential to the economics of this innovation ecosystem. Together, they account for nearly 40 percent of U.S. prescription drug spending.[7] Through these programs, the Government acts as both a dominant market participant and a regulator, serving as

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[1] David H. Crean, *Is the USA's Innovation Leadership Position At-Risk?*, Pharma Boardroom (Nov. 13, 2020), https://perma.cc/2JN2-W7PC.

[2] *See* Shearin Decl. Ex. E at 837.

[3] *See* Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20, 23 (2016), https://perma.cc/QB83-CBFZ.

[4] *See id.* at 26.

[5] *See* Shearin Decl. Ex. G at 1004.

[6] *Id.* Ex. F at 4.

[7] *See id.* Ex. H; *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 699 (3d Cir. 2023) ("[t]he federal government dominates the healthcare market," "paying for almost half the annual nationwide spending on prescription drugs" (citing Cong. Budget Off., *Prescription Drug Prices: Spending, Use, and Prices* 8 (2022))).

the ultimate payer for a large proportion of the drugs dispensed to elderly, disabled, and lower-income patients. Medicare Part D provides these benefits for self-administered prescription drugs to any Medicare beneficiary who chooses to enroll. Under Part D, CMS pays private health insurance plans for a portion of the cost of such drugs. In turn, plan sponsors pay pharmacies negotiated, market-based prices for covered drugs and negotiate competitive rebates from manufacturers (which in return receive improved access to patients). When Congress created Medicare Part D in 2003, it prohibited the Department of Health and Human Services ("HHS") from "interfer[ing] with the negotiations between drug manufacturers[,] pharmacies[,] and [private health plans]" regarding the price of Part D drugs. 42 U.S.C. § 1395w-111(i). This complex system serves important goals: manufacturers are compensated for their products at market-based rates, enabling the drug innovation ecosystem to thrive, and ultimately providing improved treatments for patients.

II. The Inflation Reduction Act's Drug Price Negotiation Program.

The IRA, enacted in 2022, marks a sea change from this established system by imposing price controls manufacturers have no choice but to accept. The IRA requires the Secretary of HHS to administer the Program, 42 U.S.C. § 1320f(a); the Secretary has delegated that authority to CMS. Under the guise of a "negotiation" process, CMS is to unilaterally impose a so-called "maximum fair price" for each selected drug, *id.* § 1320f-2(a)(1), which establishes a ceiling for how much manufacturers may charge Medicare participants for their drugs, *see id.* § 1320f-2(a)(1)–(3).

Implementation of the Program began in 2023, starting with identification of the 50 qualifying drugs "with the highest total expenditures under [Medicare] [P]art D." *Id.* § 1320f-1(d)(1)(A). CMS was required, by September 1, 2023, to publish an order selecting ten of those 50 drugs for the Program's first year. *See id.* §§ 1320f(d)(1), 1320f-1(a)(1), 1320f-3(g). CMS's

order, issued on August 29, 2023, selected BI's drug Jardiance®. Shearin Decl. Ex. A. More drugs are to be added to the Program in subsequent years. *See* 42 U.S.C. § 1320f-1(a)(2)–(4).

For drugs selected for the Program's first year, like Jardiance®, the IRA dictates that the manufacturer "shall enter into [an] agreemen[t]" with CMS no later than October 1, 2023, to "negotiate" a "maximum fair price." *Id.* §§ 1320f(d)(2)(A), 1320f-2(a). CMS unilaterally drafted this "Manufacturer Agreement" and declared its terms "final"—all without providing manufacturers an opportunity to comment or propose revisions. Shearin Decl. Ex. B at 30; *see also id.* Ex. C. After signing the Manufacturer Agreement, the manufacturer shall "agree to" the price determined by CMS by August 1, 2024. 42 U.S.C. §§ 1320f(d)(2)(B), 1320f-2(a)(1). If a manufacturer of a selected drug fails to execute either of these "agreements"—to negotiate or to the CMS-imposed "maximum fair price"—it is automatically subjected to excise tax penalties on *all* domestic sales of that drug that begin at 186 percent and escalate to 1,900 percent—nineteen times the gross sales revenues—after nine months. *See* 26 U.S.C. § 5000D(a), (b)(1), (d).[8] This penalty takes effect the day after the "agreement" deadline lapses and continues until the manufacturer complies with the Program's requirements. *Id.* § 5000D(b)(1)(A), (b)(2)(A).

The IRA sets a ceiling on the "maximum fair price" for a selected drug. Specifically, the "maximum fair price" cannot exceed the lower of (1) what Medicare Part D and Medicare Advantage plans have paid for the drug (net of all rebates) or (2) a percentage of a benchmark price equal to what wholesalers and retail pharmacies paid for the drug in 2021 (adjusted for inflation). *See* 42 U.S.C. § 1320f-3(c)(1)–(3). The latter, percentage-based ceiling depends on how long the drug has been on the market; the ceiling starts at 75 percent of the benchmark price, decreases to 65 percent of that price for drugs that have been approved for at least 12 years, and

[8] *See also* Shearin Decl. Ex. L at 4, tbl. 2. (explaining how the tax rates are computed).

then further decreases to 40 percent of the benchmark price for drugs that have been approved for at least 16 years. *See id.* § 1320f-3(c)(3)(A), 1320f-3(c)(3)(C), (5). For the vast majority of drugs, including Jardiance®, the IRA does not prescribe any floor for the "maximum fair price," meaning that CMS may select any price below the ceiling—in theory, all the way down to one cent. *See id.* § 1320f-3(d) (inapplicable temporary price floor "for small biotech drugs").

The process that results in a "maximum fair price" is not a true "negotiation," but instead involves unilateral price setting by CMS. The agency makes an initial "offer" of a "maximum fair price" for the selected drug, and the manufacturer may make a "counteroffer" within 30 days. *Id.* § 1320f-3(b)(2)(B)–(D). CMS need only provide a "concise justification" for its offer. *Id.* § 1320f-3(b)(2)(B). A manufacturer's counteroffer must be based exclusively on a narrow, enumerated set of factors. *See id.* § 1320f-3(b)(2)(C), (e). Although CMS must "respond in writing" to that counteroffer, *id.* § 1320f-3(b)(2)(C), (D), the response need not be grounded in the record, reflect reasoned decisionmaking, or satisfy any other criteria. CMS then issues a "final offer" by July 15, 2024, which the manufacturer must accept—or else pay the excise tax penalties described above, *see id.* §§ 1320f-3(b)(2)(E), 1320f-4(a). The IRA requires CMS to pursue "*the lowest maximum fair price* for each selected drug," *id.* § 1320f-3(b)(1) (emphasis added), and prohibits any "administrative or judicial review" of the prices imposed by CMS, *id.* § 1320f-7(3).

Beginning on January 1, 2026, the manufacturer of a selected drug must provide hospitals, physicians, and other Medicare participants "access" to the drug at the "maximum fair price." *Id.* § 1320f-2(a). Along with other aspects of the IRA that expand Medicare coverage for selected drugs, this right of access means that manufacturers will be required to transfer their drug products to these third parties on CMS's terms. Manufacturers that fail to comply face civil monetary

penalties equal to ten times the difference between the price actually charged for the drug and the "maximum fair price." *Id.* § 1320f-6(a).

III. The Program's Adverse Effects on BI and Jardiance®.

BI's Jardiance® is approved for a variety of uses, including lowering blood sugar in patients with type 2 diabetes and reducing the risk of cardiovascular death in adults with type 2 diabetes or heart disease. Marsh Decl. ¶ 5.[9] FDA first approved Jardiance® in 2014, following BI's investment of billions of dollars and years of research and development. Since then, FDA has approved several additional indications for Jardiance® based on BI's continuing research and development—thus allowing the drug to help a broad range of patient populations. *See id.* ¶ 5. For example, a 2015 landmark clinical trial showed that Jardiance® produces a statistically significant reduction of adverse cardiovascular outcomes in patients with type 2 diabetes and established cardiovascular disease, revolutionizing treatment guidelines around the world. Later clinical trials led FDA to approve Jardiance® for use in reducing the risk of cardiovascular death in adults with heart failure and adults with type 2 diabetes, and also in treating type 2 diabetes in children 10 years and older. *See id.* ¶ 5; *see also supra* note 9. Earlier this month, FDA issued a further approval for use of Jardiance® to reduce the risk of end-stage kidney disease, cardiovascular death, and hospitalization in adults with chronic kidney disease. *See id.* ¶ 5; *see also supra* note 9.

Because CMS selected Jardiance® for the Program, BI is required by statute to sign the Manufacturer Agreement by October 1, 2023, stating that BI will participate in a price-setting "negotiation" with CMS. Marsh Decl. ¶ 11; 42 U.S.C. §§ 1320f(d)(2), 1320f-2(a). Should BI

[9] BI holds the New Drug Application ("NDA") for Jardiance®. *See* FDA, *FDA-Approved Drugs Listing for NDA 204629*, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process.

refuse to sign, it would have to pay a crushing penalty—$500 million per week initially, increasing to over $5.5 billion per week—on every domestic sale of Jardiance®. *See* 26 U.S.C. § 5000D(d); Marsh Decl. ¶ 16. Alternatively, the IRA provides that the Program's requirements and penalties would not apply to BI if the company withdrew *all* of its products—not just Jardiance®—from Medicare and Medicaid. *See* 26 U.S.C. § 5000D(c).

Jardiance®'s selection poses a serious threat to BI's ability to develop innovative new treatments. BI's continued investments depend on revenues from the small fraction of its drugs that are approved by FDA and succeed in the marketplace, such as Jardiance®. *See* Marsh Decl. ¶ 17. A significant portion of those revenues come from Medicare and Medicaid, through which BI makes all of its drugs (numbering more than 20) available. Indeed, Medicare and Medicaid revenues account for more than half of BI's U.S. net sales in many years and made up more than 55 percent of the company's U.S. net sales in 2022. *Id.* ¶ 7.

For similar reasons, withdrawing *all* of BI's drugs from Medicare and Medicaid is not an option. *See id.* ¶ 17. Such a drastic measure would deprive BI of the resources it needs to continue developing innovative treatments and would force patients who rely on BI drugs to switch to other treatments that may be less effective or cause adverse reactions. *See id.* Where BI's drug is the only FDA-approved treatment for a particular condition or subset of patients—as is the case with Spevigo®, which treats a rare, lifelong skin disease—forced withdrawal from Medicare and Medicaid would leave patients in those programs without insurance for *any* FDA-approved treatment. *See id.* ¶ 19. BI cannot walk away from its ethical obligation and longstanding commitment to its patients in that way. *See id.* ¶ 18.

LEGAL STANDARD

"Summary judgment is appropriate if the record establishes that 'there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.'"

McCutcheon v. Colgate-Palmolive Co., 62 F.4th 674, 686 (2d Cir. 2023) (quoting Fed. R. Civ. P. 56(a)). Here, the parties have stipulated that "this case … can properly be resolved through" cross-motions for summary judgment, ECF 16 ¶ 2, because neither party needs discovery to obtain "information that is essential to" its position, *Trebor Sportswear Co. v. Limited Stores, Inc.*, 865 F.2d 506, 511–12 (2d Cir. 1989) (cleaned up), and BI's claims "presen[t] legal questions regarding the constitutionality of a federal statute (and the validity of related administrative action)," ECF 16 ¶ 2; *see also New York v. HHS*, 414 F. Supp. 3d 475, 516 (S.D.N.Y. 2019) (typical Rule 56 standard "does not apply" where plaintiff is challenging federal agency action (citation omitted)).

ARGUMENT

I. The Program's One-Sided Procedures Violate BI's Due Process Rights.

The Program discards bedrock procedural safeguards present in other price-setting programs and, in doing so, violates BI's Fifth Amendment due process rights. "The fundamental requirement of due process is the opportunity to be heard 'at a meaningful time and in a meaningful manner,'" *Mathews v. Eldridge*, 424 U.S. 319, 333 (1976) (quoting *Armstrong v. Manzo*, 380 U.S. 545, 552 (1965)), by a "neutral and detached" decisionmaker, *Concrete Pipe & Prods. of Cal., Inc. v. Constr. Laborers Pension Tr. for S. Cal.*, 508 U.S. 602, 617–18 (1993). The "whole purpose" of these protections is to prevent "arbitrary deprivations of liberty or freedom." *Honda Motor Co. v. Oberg*, 512 U.S. 415, 434 (1994).

The Program fails to satisfy these requirements. It strips BI of constitutionally protected property interests without affording BI anything close to the procedures or meaningful hearing due process requires. Because CMS has issued an order selecting Jardiance® for the Program, BI is faced with a Hobson's choice between paying confiscatory penalties or engaging in a performative "negotiation" in which an agency with a financial stake will dictate a price for BI's drug—unconstrained by ascertainable standards, any guarantee that the resulting price will be fair and

equitable, or the prospect of administrative or judicial review. That scheme violates BI's due process rights multiple times over. Indeed, as far as BI is aware, no court has ever upheld a scheme that deprives regulated parties of core procedural safeguards in the way the Program does here.

A. BI's Property Interests Are At Stake.

In analyzing a procedural due process claim, "[t]he threshold issue is always whether the plaintiff has a property or liberty interest protected by the Constitution." *Narumanchi v. Bd. of Trs. of Conn. State Univ.*, 850 F.2d 70, 72 (2d Cir. 1988). Here, the Program strips BI of multiple constitutionally protected property interests.

First, the Program will deprive BI of its property interest in physical doses of Jardiance®. As the owner of the drugs, BI holds rights that include "the rights to possess, use and dispose of" those drugs, *Horne v. Dep't of Agric.*, 576 U.S. 350, 361–62 (2015) (quoting *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 435 (1982)), as well as the "right of access" to those drugs and the crucial "right to exclude" others from them, *Cedar Point Nursery v. Hassid*, 141 S. Ct. 1063, 2072 (2021).[10] The Program overrides those rights by granting eligible beneficiaries and their providers "access" to Jardiance® tablets on terms BI would never voluntarily accept. *See* 42 U.S.C. § 1320f-2(a)(3).

It is also a "well-settled general principle that the right of the owner of property to fix the price at which he will sell it is an inherent attribute of the property itself, and as such is within the protection of the Fifth … Amendmen[t]." *Old Dearborn Distrib. Co. v. Seagram-Distillers Corp.*, 299 U.S. 183, 192 (1936). Courts have thus long analyzed price-control regimes through the lens of procedural due process, confirming that such regimes necessarily implicate this property interest

[10] Although *Cedar Point* and *Horne* were decided under the Takings Clause, they are instructive about what constitutes "property" protected by the Due Process Clause. *Story v. Green*, 978 F.2d 60, 62 (2d Cir. 1992). Particularly in light of the presumption of consistent usage, it would make little sense if "property" meant different things in the fourth and fifth clauses of the Fifth Amendment.

even where no one is compelled to engage in a sale. *See Bowles v. Willingham*, 321 U.S. 503, 517 (1944); *Yakus v. United States*, 321 U.S. 414, 438 (1944); *cf. Pennell v. City of San Jose*, 485 U.S. 1, 11 (1988) (price-control regulations subject to due process challenge).

The Program also deprives BI of property interests in its confidential data regarding Jardiance®. The IRA requires BI to turn over to CMS not only sales data, but also whatever other "information that [CMS] requires to carry out the negotiation." 42 U.S.C. § 1320f-2(a)(4). CMS has demanded a range of highly confidential business information, including how much BI has spent researching and developing Jardiance®, the extent to which it has recouped those costs, and unit costs of production and distribution of the drug. Shearin Decl. Ex. B at 133, 188–98. That and other information is valuable to BI and would be valuable to its competitors, and BI accordingly treats the information as confidential. *See* Marsh Decl. ¶ 21. These data are protected as trade secrets under state law,[11] and are thus property protected by the Fifth Amendment. *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1001–03 (1984); *see, e.g.*, *Jazz Pharms., Inc. v. Synchrony Grp.*, 343 F. Supp. 3d 434, 445 (E.D. Pa. 2018) (drug-marketing strategy constituted protected trade secret). CMS cannot order BI to turn over that confidential data, in order to use it against BI, without due process.

B. The Program Deprives BI of Those Interests With Little to No Process.

Price-setting programs typically empower a government agency to establish price caps while granting regulated parties protections necessary to ensure that the caps are procedurally and substantively reasonable. The Program discards that model, resulting in a one-sided scheme with no meaningful external constraints on CMS's action. No court has ever upheld a framework like

[11] Every state protects trade secrets from unauthorized disclosure, and the vast majority of states (including Connecticut) have enacted the Uniform Trade Secrets Act. *See, e.g.*, Conn. Gen. Stat. Ann. § 35-50 *et seq*.

the one at issue here. Indeed, the Program provides even fewer protections than emergency wartime price-control regimes. If meaningful administrative process and judicial review were afforded to thousands of market participants in those circumstances, there is no reason they can, consistent with due process, be withheld from a small number of manufacturers during peacetime.

The Program violates the Fifth Amendment's due process requirements in at least four ways.

First, CMS is inherently biased because it both sets drug prices and pays the lion's share of the price that it sets. "Due process requires a competent and impartial tribunal," regardless of "any particular form of proceeding." *Peters v. Kiff*, 407 U.S. 493, 501 (1972); *see also Concrete Pipe*, 508 U.S. at 617; *Heldman on Behalf of T.H. v. Sobol*, 962 F.2d 148, 154 (2d Cir. 1992). The absence of impartiality—and the resulting due process violation—is most apparent when the decisionmaker has a "pecuniary interest in the outcome" of the proceeding. *Tumey v. Ohio*, 273 U.S. 510, 535 (1927); *see Withrow v. Larkin*, 421 U.S. 35, 47 (1975). Here, the "negotiation" is irrevocably tainted because CMS, the agency that determines the "maximum fair price," also pays a significant share of drug costs, and thus has an obvious financial interest in setting drug prices as low as possible. The IRA compounds the problem by requiring CMS to pursue "*the lowest maximum fair price* for each selected drug." 42 U.S.C. § 1320f-3(b)(1) (emphasis added).

Second, the IRA prohibits any administrative or judicial review of CMS's "maximum fair price" determination, as well as other key CMS actions implementing the Program. *Id.* § 1320f-7(3). In doing so, the Program deprives BI of post-deprivation process and shields CMS from *any* review by an impartial judicial or administrative tribunal—further underscoring the Program's constitutional infirmity. *See Yakus*, 321 U.S. at 444 (there must be "an opportunity to be heard and for judicial review which satisfies the demands of due process"); *Bowles*, 321 U.S. at 521 ("where Congress has provided for judicial review after the regulations or orders have been made

effective it has done all that due process under the war emergency requires"). Although the denial of administrative and judicial review may not *independently* constitute a Fifth Amendment violation, here the *combination* of that denial together with the Program's other shortcuts amounts to a violation of BI's due process rights.

Third, the "negotiation" does not provide an opportunity for a meaningful hearing. *See Mathews*, 424 U.S. at 333. In this "negotiation," CMS first makes an "initial offer" representing its "proposal for the maximum fair price of the drug." 42 U.S.C. § 1320f-3(b)(2)(B). The manufacturer then has 30 days to make a "counteroffer" that is subject to the statute's constraints. *See id.* § 1320f-3(b)(2)(C)(ii), (e). The IRA does not require CMS to do *anything* in response to this counteroffer, beyond "respond[ing] in writing to" it. *Id.* § 1320f-3(b)(2)(D). CMS need not, for example, provide a reasoned explanation for its response to the counteroffer. That threadbare procedure is insufficient. *Cf. Connecticut v. Doehr*, 501 U.S. 1, 4 (1991) (law authorizing deprivation of property without prior notice or hearing or extraordinary circumstances violates Fourteenth Amendment Due Process Clause).

The "negotiation" also falls short of due process because it allows CMS to establish the "maximum fair price" without giving BI an opportunity to respond to the evidence on which the agency relies. Due process requires the Government to provide regulated parties with access to the evidence against them and an "opportunity to meet it." *Mathews*, 424 U.S. at 348 (cleaned up); *see Townley v. Hecker*, 748 F.2d 109, 114 (2d Cir. 1984) (agency violated due process by relying on evidence that it did not give claimant opportunity to rebut). This principle applies even when sensitive government interests are at stake. *See Ralls Corp. v. CFIUS*, 758 F.3d 296, 319 (D.C. Cir. 2014). But the IRA does not require CMS to disclose to BI the evidence on which it will rely in setting the "maximum fair price" for Jardiance® and instead provides that CMS need

only state a "concise justification" for its initial offer. 42 U.S.C. §§ 1320f-3(b)(2)(B), 1320f-4(a)(2)(B). That superficial approach likewise falls short of the constitutional minimum. *See Ohio Bell Tel. Co. v. Pub. Utils. Comm'n*, 301 U.S. 292, 302 (1937).

Fourth, the IRA does not provide ascertainable standards that CMS must follow when determining the "maximum fair price." "The touchstone of due process is protection of the individual against arbitrary action of government." *Wolff v. McDonnell*, 418 U.S. 539, 558 (1974). To guard against arbitrariness, government action must be channeled and limited by "ascertainable standards," lest "the existence of an absolute and uncontrolled discretion in an agency of government vested with the administration of a vast program" prove "an intolerable invitation to abuse." *Holmes v. N.Y.C. Hous. Auth.*, 398 F.2d 262, 265 (2d Cir. 1968). In other words, "the standards prescribed by the" IRA must be "adequate … for judicial review" to be meaningful. *Bowles*, 321 U.S. at 516. Government action unconstrained by such limiting principles offends not only the separation of powers, but also due process. *See Holmes*, 398 F.2d at 264–65; *accord, e.g.*, *White v. Roughton*, 530 F.2d 750, 753 (7th Cir. 1976); *McClendon v. Rosetti*, 460 F.2d 111, 115–16 (2d Cir. 1972).

Although the IRA sets forth certain "factors" that CMS "shall consider," 42 U.S.C. § 1320f-3(e), it does not explain *how* the agency is to weigh them or provide any means to ensure that the agency has, in fact, weighed them. Moreover, the "maximum fair price" is defined as any price that is dictated at the end of the negotiations—there is no requirement that it actually be "fair." *See id.* § 1320f(c)(3). Nothing in the statute curbs CMS's ability to "fix [prices] ... where [it] might like and at whatever levels [it] pleases," *Bowles*, 321 U.S. at 514—no matter how confiscatory those prices might be. Indeed, while the IRA imposes a ceiling on the "maximum fair price," 42 U.S.C. § 1320f-3(c), it imposes no floor, and thus leaves CMS free to determine

that the "fair" price of a drug that a company has invested billions in developing is just one cent per dose. The statute thus not only fails to adequately cabin CMS's discretion, but it fails to prevent the agency from setting prices at levels so low as to be "unfair and inequitable"; it is thus unconstitutional. *See Amalgamated Meat Cutters & Butchers Workmen v. Connally*, 337 F. Supp. 737, 755 (D.D.C. 1971).

C. The Process Provided by the Program Is Constitutionally Inadequate.

As described above, the Program will deprive BI of valuable property interests through a "negotiation" process that is merely a façade for CMS's dictating prices for selected drugs. Because the Program provides BI no meaningful opportunity to be heard, before or after the "maximum fair price" for Jardiance® is set, there is no need to apply the *Mathews* balancing test to determine whether pre-deprivation process is required, or whether post-deprivation process would suffice. *See Lawrence v. Reed*, 406 F.3d 1224, 1233 (10th Cir. 2005) (one "need not understand the niceties of *Mathews* to know" that providing "no hearing whatsoever ... is unconstitutional").[12]

More instructive is a comparison to prior price-control regimes, which further demonstrates the Program's due process failings. Even laws enacted during wartime, at the low-water mark for due process rights, contained significantly more robust procedural protections for affected parties—and the features that allowed the Supreme Court to uphold those programs are absent

[12] Even if the *Mathews* test were relevant, the Program would fail. *First*, the "nature of the private interest that will be affected" is significant. *Turner v. Rogers*, 564 U.S. 431, 444 (2011); *see Mathews*, 424 U.S. at 335. The Program will deprive BI of revenues essential to new drug development, undermining long-term incentives for innovation, and thereby endangering manufacturers and patients alike. *See supra* p. 10. *Second*, the "comparative risk of an erroneous deprivation of [those interests] with and without additional or substitute procedural safeguards" is high, *Turner*, 564 U.S. at 444–45, because the Program allows CMS to dictate prices without meaningful constraints or input from affected parties, creating a grave risk that CMS will set prices at erroneous levels that threaten BI's business and incentives for innovation. *Third*, "the nature and magnitude of any countervailing interest," *id.* at 445, do not support the Government since only ten drugs are at issue and having to follow basic procedural constraints would not significantly burden CMS. *See Francis v. Fiacco*, 942 F.3d 126, 144 (2d Cir. 2019) (third *Mathews* factor did not support government where additional process would affect only a "few" cases).

here. Instead, by enabling CMS to impose price controls without meaningful limits on its discretion, without a meaningful opportunity for BI to be heard, and without *any* prospect of judicial review, the Program presents a "novel context" unmoored from these precedents, which further confirms the Program's constitutional defects. *See Seila Law LLC v. CFPB*, 140 S. Ct. 2183, 2192 (2020).

Precedent concerning the Emergency Price Control Act of 1942 ("EPCA"), Pub. L. No. 77-421, 56 Stat. 23, illustrates the point. EPCA, enacted shortly after the United States entered World War II, sought to curb "inflationary pressures brought about in part by" the war "and creat[e] a nationwide system of price controls." *Cmty. Hous. Improvement Program v. City of New York*, 59 F.4th 540, 545 (2d Cir. 2023). The statute created an Office of the Price Administrator and charged the Administrator with prescribing such "maximum prices as in his judgment will be generally fair and equitable and will effectuate the purposes of th[e] Act," when prices had risen or were expected to rise to prescribed levels. EPCA § 2(a). Even though EPCA was a "war emergency measure," *Adamo Wrecking Co. v. United States*, 434 U.S. 275, 290 (1978) (Powell, J., concurring), it provided multiple procedural protections the Program lacks.

First, EPCA provided for review by multiple layers of impartial authorities: the Administrator, a special court of appeals, and the Supreme Court. *See Yakus*, 321 U.S. at 418–19, 433, 435; *Bowles*, 321 U.S. at 516, 520–21; *Lockerty v. Phillips*, 319 U.S. 182, 188–89 (1943).

Second, EPCA allowed for judicial "review [of] all questions of law, including the question whether the Administrator's determination is supported by evidence," and even allowed for introduction of new evidence in certain circumstances. *Yakus*, 321 U.S. at 437.

Third, EPCA provided a robust administrative process by which regulated parties could protest particular price controls and receive an "administrative hearing" at which they could

"presen[t] documentary evidence, affidavits[,] and briefs." *Id.* at 436; *see generally id.* at 435–37. After the hearing, the Administrator was required to "inform the protestant of the grounds for his decision denying a protest." *Id.* at 436. Judicial review was available based on "[t]hese materials and the grounds for decision which they furnished." *Bowles*, 321 U.S. at 515.

Fourth, EPCA provided ascertainable standards to guide the Administrator's discretion, namely, that when prices rose to a prescribed level, the Administrator should set prices that were "fair and equitable" and would "effectuate th[e statute's] purposes." EPCA § 2(a); *see also id.* § 1(a) (statement of purposes); *Bowles*, 321 U.S. at 513–14 ("There is no grant of unbridled administrative discretion[.]"); *cf. Yakus*, 321 U.S. at 426 (rejecting nondelegation challenge because EPCA provided "sufficiently definite and precise" standards).

Those protections played a key role in the Supreme Court's decisions upholding provisions of EPCA against due process challenges. *See Bowles*, 321 U.S. at 509–10, 521 (rent-control provisions); *Yakus*, 321 U.S. at 431–43 (provisions regarding judicial review). But these protections are notably absent from the Program. As discussed above, the Program provides no meaningful constraint on how CMS determines the "maximum fair price" and lacks any safeguard against CMS's selection of unfair, inequitable, and confiscatory prices. *See supra* p. 8. The IRA fails to ensure a meaningful administrative hearing because it does not require CMS to provide a reasoned response to the manufacturer's position, does not allow the manufacturer to review and rebut evidence on which CMS relies, and shields key determinations, including the "maximum fair price," from *any* oversight by courts or other impartial arbiters. *See* 42 U.S.C. § 1320f-7(3).

The Program's departure from this prior price-control regime is particularly stark given that EPCA was upheld in the context of "the urgency and exigencies of wartime price regulation," *Yakus*, 321 U.S. at 435, and provided substantial administrative and judicial process even though

it affected "thousands" of landlords and a broad range of other market participants, *see Bowles*, 321 U.S. at 521. No less is required as to ten pharmaceutical companies in a time of peace.[13]

II. The Program Effects a Physical Taking of BI's Jardiance® Products.

The Program also violates BI's property rights under the Takings Clause by forcing BI to transfer Jardiance® tablets to third parties on the Government's terms and capping BI's compensation well below market-based prices. The Program thus goes far beyond regulating drug prices by effecting a physical taking of BI's property without just compensation, in violation of the Fifth Amendment.

The Takings Clause prohibits the Government from appropriating private property without just compensation. U.S. Const. amend. V. This protection applies to personal property, including products like the Jardiance® tablets BI manufactures and sells. *See Horne*, 576 U.S. at 359. The Takings Clause thus safeguards not only BI's "rights to possess, use and dispose of" its Jardiance® tablets, *id.* at 360 (cleaned up), but also BI's "fundamental" and "essential" "right to exclude others" from accessing its property, *Kaiser Aetna v. United States*, 444 U.S. 164, 176 (1979). Yet when the Government appropriates these property rights "for itself or a third party," it inflicts a physical taking. *Cedar Point Nursery*, 141 S. Ct. at 2071. When a physical taking occurs, a "simple, per se rule" applies: the Government "must pay for what it takes." *Id.*[14]

[13] Declaratory and injunctive relief is appropriate because here the Court can "say in advance of resort to the statutory procedure that it is incapable of affording due process," such that BI's "constitutional rights have been or will be infringed." *Yakus*, 321 U.S. at 435; *see also Hodel v. Va. Surface Min. & Reclamation Ass'n*, 452 U.S. 264, 302 (1981) ("The relevant inquiry is not whether a[n administrative] order should have been issued in a particular case, but whether the statutory procedure itself is incapable of affording due process.").

[14] Because BI brings only a physical takings claim, the Court need not consider the factors involved in the "ad hoc, factual inquiry" for regulatory takings claims. *Penn Cent. Transp. Co. v. City of New York*, 438 U.S. 104, 124 (1978); *see also Horne*, 576 U.S. at 362 (physical takings are "of such a unique character that [they are] a taking without regard to other factors that a court might ordinarily examine" (cleaned up)).

Physical takings can occur in several ways, at least two of which are relevant here: (1) forcing an owner to transfer property to another, *see Horne*, 576 U.S. at 364; and (2) granting third parties access to the owner's property, thus eliminating the owner's rights to exclude and to control the disposition of its property, *see Cedar Point*, 141 S. Ct. at 2072.

In *Horne*, regulations forced raisin growers to "physical[ly] surrender" some of their crops "to the Government, free of charge." 576 U.S. at 355, 364. That "actual taking of possession and control" meant that the growers had lost key property rights in their raisins, including the "right to control their [raisins'] disposition." *Id.* at 361–62, 364 (cleaned up). This forced transfer was "a clear physical taking." *Id.* at 361, 367. The fact that the growers retained a contingent right to receive payment for their raisins, at a level determined by the Government, did not undermine that conclusion, *see id.* at 362–63, just as the owner's continued ability "to economically benefit from the property" was irrelevant to the takings analysis in *Loretto*, *see* 458 U.S. at 430.

The Court similarly found a physical taking in *Cedar Point*. There, California had granted union organizers a "right of access" to "the premises of an agricultural employer" for several days throughout the year. 141 S. Ct. at 2069 (cleaned up). While the state had not actually "acquir[ed] title to" the employer's property (as in *Horne*), this third-party right of access on the state's terms still inflicted a "physical takin[g] requiring just compensation." This was so because the law replaced "the owner's right to exclude" with third parties' "right to invade." *Id.* at 2072, 2074. As in *Loretto*, the fact that the employer retained ownership of its property was immaterial; what counted was the Government's nonconsensual appropriation of the employer's rights to use and exclude others from the property. *See id.* at 2072–74.

The Program suffers from the same constitutional defects. As in *Horne*, BI will be forced to transfer its Jardiance® products to third parties. And as in *Cedar Point*, the IRA grants third

parties a statutory right to access BI's Jardiance® tablets. The combination of this forced transfer and third-party access prevent BI from exercising its rights to exclude and to control the disposition of its Jardiance® tablets, appropriating BI's ability to choose whether, and on what terms, others may take possession of its property.

This taking starts with the IRA's access requirement. BI will be obligated to "provid[e]" Medicare Part D enrollees, hospitals, physicians, and other dispensing providers "access to the maximum fair price … with respect to [its] selected drug" Jardiance®. 42 U.S.C. § 1320f-2(a)(3); *see also* Shearin Decl. Ex. C at 1. Due to this access requirement, BI will no longer be able to decide whether, and on what terms, it is willing to offer Jardiance® tablets for sale. Instead, Medicare participants will have the right to obtain Jardiance® tablets at the CMS-dictated price, and BI will have no choice but to comply when participants exercise that right. *See* 42 U.S.C. § 1320f-6(a) (imposing civil monetary penalties for failure to "provide access to" that price). Simply put, the access requirement replaces BI's property rights in its Jardiance® tablets with third parties' right to access those tablets on the Government's terms.

The IRA cements third-party access through its formulary inclusion requirement. Before the IRA, BI retained the right to negotiate with Medicare Part D plan sponsors to determine the pricing and availability of Jardiance® through Part D plans to enrollees. Now, however, every Part D plan *must* include Jardiance® on its list of covered drugs (a list commonly referred to as a plan's "Part D formulary"), subject to the terms established through the Program. *See id.* § 1395w-104(b)(3)(I). This requirement expands the breadth of the taking by providing every Medicare enrollee access to Jardiance® through a Part D plan. Moreover, the requirement strips BI of the right to "control" the "use and dispos[ition] of" its Jardiance® tablets by eliminating BI's ability to negotiate whether Jardiance® should be included on a Part D plan formulary and if so, the

specifications (including price) for that participation. *See Horne*, 576 U.S. at 361–62, 364 (cleaned up).

As in *Horne* and *Cedar Point*, the IRA enforces this taking through severe penalties. *See supra* pp. 7, 9–10; *see also* 42 U.S.C. § 1320f-6(a), (c); 26 U.S.C. § 5000D. The growers in *Horne* were assessed a civil penalty for failing to turn over their raisins. 576 U.S. at 356. And the employers in *Cedar Point* were met with unfair labor practice sanctions for refusing to grant access. 141 S. Ct. at 2069, 2070. That these property owners *could* have incurred penalties to avoid giving up their property rights did not change the fact that a taking had occurred. *See, e.g.*, *Horne*, 576 U.S. at 356 (finding a physical taking *despite* the growers refusing to surrender their raisins and being assessed a penalty). "Just as the alternative of a fine in *Horne* did not save the statute from constituting a taking," *Valancourt Books, LLC v. Garland*, 2023 WL 5536195, at *9 (D.C. Cir. Aug. 29, 2023), the Program's purported options of paying crippling excise tax penalties or completely withdrawing from Medicare and Medicaid do not remediate the IRA's taking.

The Program also ensures that BI will not be justly compensated for these takings. *See Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg'l Plan. Agency*, 535 U.S. 302, 322 (2002) (physical taking triggers the Government's "categorical duty to compensate the former owner"). That BI receives *some* compensation for its drugs does not solve the problem. *See Horne*, 576 U.S. at 364 ("[O]nce there is a taking, as in the case of a physical appropriation, any payment from the Government in connection with that action goes, at most, to the question of just compensation."). Just compensation is "measured by the market value of the property at the time of the taking." *United States v. 50 Acres of Land*, 469 U.S. 24, 29 (1984) (cleaned up); *accord Horne*, 576 U.S. 366–69; *Ford Motor Credit Co. v. NYC Police Dep't*, 503 F.3d 186, 191 (2d Cir. 2007). Yet the IRA caps the "maximum fair price"—i.e., the most compensation BI can receive for its lost

property—below market-based prices. *See* 42 U.S.C. § 1320f-3(c)(1). The IRA then obligates CMS to drive the maximum fair price below that ceiling to "achieve the lowest maximum fair price for each selected drug." *Id.* § 1320f-3(b)(1). Thus, no matter what price CMS ends up selecting for BI's Jardiance® tablets, BI's compensation will always be below market value.

Declaratory relief is appropriate in light of those characteristics. The relevant factors include whether such relief will "clarif[y] or settl[e] the legal issues involved," "finalize the controversy and offer relief from uncertainty," further "judicial efficiency and judicial economy," and "whether there is a better or more effective remedy." *Admiral Ins. Co. v. Niagara Transformer Corp.*, 57 F.4th 85, 99–100 (2d Cir. 2023) (cleaned up). These factors all weigh in BI's favor. Definitively settling whether the Program effects a physical taking without just compensation will remove uncertainty for both the Government and BI before the Program's mandates go into effect. Resolving this issue now will also avoid protracted litigation and repeated lawsuits each time BI is forced to hand over a dose of Jardiance® on the Government's terms. *See Di Giovanni v. Camden Fire Ins. Ass'n*, 296 U.S. 64, 70 (1935). Moreover, courts often find declaratory relief the appropriate remedy in situations such as these before a taking has actually occurred. *See, e.g.*, *Ruckelshaus*, 467 U.S. at 998, 1013 (holding that disclosure of trade secrets to federal agency "*will* constitute a taking" (emphasis added)); *Pharm. Res. & Mfrs. of Am. v. Williams*, 64 F.4th 932, 942 (8th Cir. 2023) ("*PhRMA*") (granting declaratory relief where insulin manufacturer would otherwise need to "repeatedly bring new suits to obtain just compensation for all the insulin taken by the Act"); *Valancourt Books*, 2023 WL 5536195, at *3, *6 (holding that requirement to "provide physical copies of books" effected a "classic taking" in suit for declaratory relief). Indeed, as the Supreme Court has noted, declaratory relief "allows individuals threatened with a taking to seek a declaration of the constitutionality of the disputed governmental action before potentially

uncompensable damages are sustained." *Duke Power Co. v. Carolina Env't Study Grp.*, 438 U.S. 59, 71 n.15 (1978). Such is the case here.[15]

III. The Program Compels BI's Speech in Violation of the First Amendment.

A. The IRA Unlawfully Compels BI's Speech.

The IRA violates BI's First Amendment rights by compelling BI to echo the Government's preferred narrative regarding the Program. "[T]he First Amendment protects the right to decide what to say and what not to say." *Burns v. Martuscello*, 890 F.3d 77, 84 (2d Cir. 2018) (cleaned up); *accord Janus v. Am. Fed'n of State, Cnty., & Mun. Emps., Council 31*, 138 S. Ct. 2448, 2463 (2018). This "right not to speak" is "central to our system of government" and "must be jealously guarded." *Burns*, 890 F.3d at 85. Government thus "cannot tell people that there are things they must say" without "plainly violat[ing] the First Amendment." *New Hope Fam. Servs., Inc. v. Poole*, 966 F.3d 145, 170 (2d Cir. 2020) (cleaned up). These constitutional protections are an especially important bulwark against "governmental efforts to require [individuals] to make statements [they] believe are false." *Jackler v. Byrne*, 658 F.3d 225, 241 (2d. Cir. 2011).

The IRA transgresses these principles. Because CMS selected Jardiance® for the Program, BI has until October 1, 2023, to sign an "agreement" to comply with the Program's terms. *See* 42 U.S.C. §§ 1320f(b)(4), (d)(2)(A), 1320f-2(a). The IRA requires that agreement to state that the manufacturer "agree[s]" to participate in the Program and engage in a "negotiation" that will result

[15] While "*enjoin*[*ing*] the government's action effecting a taking" is generally inappropriate when "an adequate provision for obtaining just compensation exists," *Knick v. Township of Scott*, 139 S. Ct. 2162, 2176 (2019) (emphasis added), BI seeks only *declaratory* relief, *see* ECF 1 ¶ 199. Even if *Knick* were applicable, declaratory relief would still be available because BI lacks an adequate remedy: the IRA authorizes a repetitive (and essentially endless) series of new, *per se* takings while Jardiance® is subject to the Program, leaving BI to "repeatedly bring new suits to obtain just compensation" each time a shipment of Jardiance® tablets is taken. *PhRMA*, 64 F.4th at 942 (cleaned up). The problem, however, is that "[a]n inverse condemnation action to reimburse a manufacturer for each discrete alleged taking is *incapable of compensating* the manufacturers for the repetitive, future takings that will occur under the Act's requirements." *Id.* at 945 (emphasis added).

in an agreed-upon "maximum fair price." *Id.* § 1320f-2(a). The text of the Manufacturer Agreement issued unilaterally by CMS conveys these messages with even greater clarity.[16] Signing that document will convey to a reasonable observer that BI "manifest[s] [its] assent" to all of these messages. *Thomas James Assocs., Inc. v. Jameson*, 102 F.3d 60, 65 n.2 (2d Cir. 1996); *see also John Doe No. 1 v. Reed*, 561 U.S. 186, 194–95 (2010) (signing a petition expresses views and thus implicates First Amendment rights). Yet because the IRA *compels* BI's signature, *see infra* Part V, it forces BI to express the Government's messages, "vitiat[ing]" BI's right to decide which messages it will and will not speak. *Burns*, 890 F.3d at 84. But for the IRA's compulsion, BI would not convey these messages. *See* Marsh Decl. ¶¶ 13–14.

BI strongly disagrees with the messages it is being forced to express. *See Jackler*, 658 F.3d at 241; *see also Hurley v. Irish-Am. Gay, Lesbian & Bisexual Grp. of Boston*, 515 U.S. 557, 573 (1995) (Government "may not compel affirmance of a belief with which the speaker disagrees"). The IRA requires BI to communicate that it has voluntarily agreed to participate in the Program. *See* 42 U.S.C. § 1320f-2(a). Yet BI disagrees that the Program involves a voluntary agreement. CMS issued the Manufacturer Agreement on a take-it-or-leave-it basis with no mechanism for manufacturers to propose changes, *see generally* Shearin Decl. Ex. D; it designated the Agreement as "final" upon issuance and did not provide manufacturers with an opportunity to comment after making its terms public, *see id.* Ex. B at 30; and CMS has pointedly reminded manufacturers of the financially ruinous consequences of failing to sign the Agreement, *see id.* Ex. B § 40.1. CMS

[16] *See* Shearin Decl. Ex. C at 1 ("the Manufacturer, on its own behalf … hereby agree[s] to the following"), § II ("CMS and the Manufacturer agree ... [that] [d]uring the negotiation period … CMS and the Manufacturer shall negotiate to determine … a maximum fair price[.]"), § V ("By signing the Agreement, the Manufacturer agrees to abide by all provisions set forth in this Agreement[.]"), add. 1 ("the Manufacturer and CMS have engaged in negotiation of the price for the Selected Drug … [and] now agree to a price").

even claims the power to unilaterally change the terms of the Agreement *after* BI has signed it. *See id.* Ex. C §§ II(e), IV(b).

The IRA likewise forces BI to communicate that the Program involves an actual "negotiation." *See, e.g.*, 42 U.S.C. § 1320f-2; Shearin Decl. Ex. C at 1. But BI disagrees with this message as well. A true negotiation ends only when both parties voluntarily agree to the terms. *See* Black's Law Dictionary (11th ed. 2019) (defining "negotiation" as a "consensual bargaining process"). To be sure, the Program is designed to *look* like a negotiation, with CMS's offer, a manufacturer's counter, and CMS's response. *See* 42 U.S.C. § 1320f-3(b)(2); Shearin Decl. Ex. B § 60.4. Yet behind this performative exchange loom the same threats compelling BI to participate in the Program: paying ruinous excise tax penalties or withdrawing all of its products from Medicare and Medicaid. As with its "choice" to participate in the Program, BI's ability to negotiate over Jardiance®'s price is illusory—it must accept the Government's preferred price because it has no other choice. *See* Marsh Decl. ¶¶ 14–17.

Moreover, the IRA requires BI to convey that this "negotiation" will result in a price for Jardiance® that is not only "fair", but also the "*maximum* fair price," implying that all higher prices are unfair. *See* 42 U.S.C. §§ 1320f-2, 1320f-3; Shearin Decl. Ex. C at 1 (agreeing to "negotiate to determine a … 'maximum fair price'"), §§ II(a), (c), add. 1. But as discussed above, CMS will set the price for Jardiance® at the "lowest" "maximum fair price" and below market-based prices, *see supra* pp. 7–8, 24, despite market value being the accepted metric for determining a fair price, *see Horne*, 576 U.S. at 368–70. What is more, fairness connotes "impartiality" or "disinteres[t]." Black's Law Dictionary (11th ed. 2019). The Program, however, lacks a neutral arbiter: with the threat of penalties in one hand and a shield from judicial review in the other, the agency commissioned with driving drug prices down to lower its own costs sets these purportedly "fair"

prices. Thus, BI maintains that any price CMS selects for Jardiance® will be *un*fair. *See* Marsh Decl. ¶¶ 13–14. BI should not be compelled "to affirm in one breath that which [it] would deny in the next." *Pac. Gas & Elec. Co. v. Pub. Util. Comm'n of Cal.*, 475 U.S. 1, 16 (1986) ("*PG&E*").

Because the IRA "compel[s] [BI] to utter or distribute speech bearing a particular message," it is subject to "the most exacting scrutiny." *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 642 (1994); *accord Burns*, 890 F.3d at 85. Strict scrutiny applies because the Government "necessarily alters the content of [BI's] speech" and imposes a "content-based regulation of speech" when it "[m]andat[es] speech that [BI] would not otherwise make." *Riley v. Nat'l Fed. of the Blind of N.C., Inc.*, 487 U.S. 781, 795 (1988); *accord Nat'l Inst. of Fam. & Life Advocs. v. Becerra*, 138 S. Ct. 2361, 2371 (2018) ("*NIFLA*").

The IRA fails that test because compelling BI's speech is not "a narrowly tailored means of serving a compelling [governmental] interest." *PG&E*, 475 U.S. at 19. Indeed, the Government has *no* valid interest (much less a compelling one) in forcing private parties to echo its messages, nor does it have a legitimate interest in deceiving the public as to the Program's true nature. Yet that is exactly what the Program does: conscript unwilling manufacturers to feign agreement so that the Government can avoid full responsibility for the Program's inevitable harms to pharmaceutical innovation and patient treatment options. Even considering the IRA's stated interest of reducing drug costs, *see* 42 U.S.C. § 1320f-3(b)(1), compelling speech is not necessary to the Program: CMS could still set drug prices without forcing manufacturers to sign a faux Agreement that furthers the Government's message. Price-setting programs frequently operate without a purported contract between regulator and regulated, but taking that approach here would force the Government to take accountability for the Program's effects and deprive the Government

of the politically popular[17] argument that the Program merely involves empowering CMS to negotiate Medicare drug prices.[18] The First Amendment exists to protect "uninhibited, robust, and wide-open" debate, *N.Y. Times Co. v. Sullivan*, 376 U.S. 254, 270 (1964), from such governmental efforts to "manipulate the public debate through coercion," *Turner*, 512 U.S. at 641.[19]

These First Amendment violations "unquestionably constitut[e] irreparable injury." *Elrod v. Burns*, 427 U.S. 347, 373 (1976); *see also, e.g.*, *NIFLA*, 138 S. Ct. at 2370. Accordingly, the Court should invalidate the Agreement and enjoin Defendants from enforcing its terms, and the Program's penalties, against BI.

B. The Manufacturer Agreement's Disclaimer Exacerbates, Rather than Cures, the First Amendment Violation.

Facing similar constitutional claims in other lawsuits, CMS included a provision in the Manufacturer Agreement aimed at fending off First Amendment claims. The provision states that a manufacturer, in signing the Agreement, "does not make any statement regarding or endors[ing] … CMS' views, and makes no representation or promise beyond its intention to comply with its obligations" under the Agreement. Shearin Decl. Ex. C § IV(f). Aside from this

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[17] *Compare* National Tracking Poll #2109099, at 13, Morning Consult (Sept. 16–19, 2021), https://perma.cc/9XCL-JECJ (American public supports "allowing the federal government to directly negotiate with drug companies to get a lower price on medications"); *with id.* at 17 (less than half of Americans support "effectively allowing the federal government to set the prices of drugs").

[18] The President and CMS Administrator Brooks-LaSure have repeatedly advanced this argument in support of the Program. *See, e.g.*, Remarks by Pres. Biden on Medicare and the Inflation Reduction Act (Sept. 27, 2022), https://www.whitehouse.gov/briefing-room/speeches-remarks/2022/09/27/remarks-by-president-biden-on-medicare-and-the-inflation-reduction-act/ ("Medicare will finally get the power to negotiate lower prescription drug prices."); Michael Erman & Patrick Wingrove, *U.S. Will Allow Drugmakers to Discuss Medicare Drug Price Negotiations*, Reuters (June 30, 2023), https://www.nasdaq.com/articles/u.s.-will-allow-drugmakers-to-discuss-medicare-drug-price-negotiations (quoting Administrator Brooks-LaSure statement that Program involves "negotiat[ing] with us directly").

[19] The lesser scrutiny that applies to certain types of compelled *commercial* speech does not apply here because the Program goes well beyond "mandat[ing] the disclosure of 'purely factual and uncontroversial information,'" and instead compels BI to further the Government's message. *See Safelite Group, Inc. v. Jepsen*, 764 F.3d 258, 263 (2d Cir. 2014) (quoting *Zauderer v. Off. of Disciplinary Couns.*, 471 U.S. 626, 651 (1985)). Even if that lower standard applied, however, the Program would still fail because the Government has no valid interest in compelling manufacturers' speech and doing so is unnecessary to the Program.

provision being "nothing more than [a] convenient litigating position," *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 213 (1988), CMS's "administrative gamesmanship" fails for multiple reasons, *Mid Continent Nail Corp. v. United States*, 846 F.3d 1364, 1381 (Fed. Cir. 2017).

First, it is doctrinally irrelevant. The First Amendment protects against compelled speech regardless of whether the speaker adopts the Government's message as its own. *See W. Va. State Bd. of Educ. v. Barnette*, 319 U.S. 624, 633 (1943) (finding compelled speech unconstitutional even when uttered "without belief and by a gesture barren of meaning"). *Second*, the disclaimer provision compels *more* speech (as CMS unilaterally included it in the Agreement and is forcing BI to assent). Additional compelled speech does not negate already compelled speech. *Third*, the disclaimer provision's attempted waiver of constitutional rights is unenforceable due to the Program's coercive nature. *See Twin City Pipe Line Co. v. Harding Glass Co.*, 283 U.S. 353, 356–57 (1931) (contractual terms are unenforceable when they "contraven[e] … public policy" or "the Constitution"). *Fourth*, CMS cannot brush aside the constitutional infirmity in an agreement of its own creation because the *statute* is the source of the speech mandate and thus creates the constitutional injury. *See* 42 U.S.C. § 1320f-2(a); *cf. Whitman v. Am. Trucking Assocs.*, 531 U.S. 457, 472–73 (2001) (agency interpretation cannot cure an unconstitutional statute). *Fifth*, a provision buried in the middle of the Agreement will not change the public's perception of the "overwhelmingly apparent" message expressed by signing the Agreement: that BI agreed to participate in the Program and engage in an arms-length negotiation of a fair price for Jardiance®. *See Texas v. Johnson*, 491 U.S. 397, 404, 405 (1989) (expressive conduct is evaluated in "the context in which it occurred," including "the likelihood … that the message would have be understood by those who viewed it").

IV. The IRA Imposes Excessive Fines in Violation of the Eighth Amendment.

To ensure that manufacturers submit to the Program, the IRA imposes massive penalties, posing as "excise taxes," on manufacturers that do not participate in the Program. That "tax" requires manufacturers to pay a multiple of the value of *all* domestic sales of the selected drug, beginning at 186 percent of gross sales revenues and escalating to 1,900 percent, for each day that the manufacturer does not participate in the Program. *See* 26 U.S.C. § 5000D(a), (b)(1), (d). These extortionate penalties violate the Excessive Fines Clause of the Eighth Amendment.

A monetary sanction is a "fin[e]" within the meaning of the Eighth Amendment if it "serv[es] in part to punish," *Austin v. United States*, 509 U.S. 602, 610 (1993), for example by "[d]eterr[ing]" disfavored conduct without "serv[ing] the remedial purpose of compensating the Government for a loss," *United States v. Bajakajian*, 524 U.S. 321, 329 (1998). Even if an exaction can be said to have some remedial purpose, "the Excessive Fines Clause applies" if "the law 'cannot fairly be said *solely* to serve a remedial purpose.'" *Tyler v. Hennepin County*, 598 U.S. 631, 648 (2023) (Gorsuch, J., joined by Jackson, J., concurring) (quoting *Austin*, 509 U.S. at 610).

The IRA's "excise tax" is a fine within the meaning of the Excessive Fines Clause, notwithstanding its label, because it is punitive and coercive, and it lacks a true remedial purpose. The penalties are designed to force manufacturers to participate in the Program and to accept the CMS-imposed "maximum fair price." Although Congress labeled the exaction as a "tax," for constitutional purposes substance trumps form and the fine's "practical characteristics" are controlling. *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 565 (2012) ("*NFIB*"); *see also United States v. Constantine*, 296 U.S. 287, 294–95 (1935) (finding $1,000 tax on unlawful liquor sales to be a penalty because "a penalty ... cannot be converted into a tax by so naming it," courts must focus on the provision's "purpose and operation, regardless of name," and "the exaction in question [wa]s highly exorbitant"); *Dep't of Rev. of Montana v. Kurth Ranch*, 511 U.S. 767, 779

(1994) ("[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." (cleaned up)).

When a so-called "tax" imposes an "exceedingly heavy burden" and is not expected to raise any revenue at all, it is not a tax for constitutional purposes. *NFIB*, 567 U.S. at 565. The Program's excise tax penalty falls within that category because it is so onerous that no manufacturer would ever willingly incur it. This is self-evident from the extortionate amount of the penalties, and it is confirmed by the Joint Committee on Taxation's projection that a nearly identical provision in predecessor legislation would not raise a single dollar of revenue. *See* Shearin Decl. Ex. I at 8. As the Congressional Budget Office ("CBO") explained in its report on the Program's budgetary effects, "drug manufacturers will comply with the negotiation process because the costs of not doing so are greater than the revenue loss from lower, negotiated prices." *Id.* Ex J. at 10.

The excise tax penalty is also an unconstitutionally excessive fine. "The touchstone of the constitutional inquiry under the Excessive Fines Clause is the principle of proportionality: The amount of the forfeiture must bear some relationship to the gravity of the offense that it is designed to punish." *Bajakajian*, 524 U.S. at 334 (citing *Austin*, 509 U.S. at 622–23). In evaluating proportionality, courts consider "(1) the degree of the defendant's reprehensibility or culpability; (2) the relationship between the penalty and the harm to the victim caused by the defendant's actions; and (3) the sanctions imposed in other cases for comparable misconduct." *Cooper Indus., Inc. v. Leatherman Tool Grp., Inc.*, 532 U.S. 424, 425 (2001) (citations omitted).

Here, proportionality is not a close question. To start, "reprehensibility or culpability" is nonexistent when the "offense" being punished is declining to participate in the Program's one-

sided and unconstitutionally coercive price-setting scheme. Moreover, there is no reasonable relationship between the outsized penalty and any "harm" caused by a manufacturer's failure to acquiesce in the Program's requirements. As soon as a manufacturer triggers the "tax," for each day a manufacturer remains "noncompliant," it faces a penalty, starting at 186 percent of the total daily domestic gross revenues for the drug and escalating to an astronomical 1,900 percent—*nineteen times* gross sales revenue—within nine months. *See* 26 U.S.C. § 5000D(a), (b)(1), (d). As applied to BI, those provisions mean that the company would face penalties of between $500 million and $5.5 billion *per week*. *See* Marsh Decl. ¶ 16.

Numerous features of the penalty demonstrate its disproportionality. The penalty amount is a multiple of the value of the product, not a fraction. *See* 26 U.S.C. § 5000D(a), (d) (setting forth the formula and rates); *see* Shearin Decl. Ex. L at 4, tbl. 2 (computing the applicable tax rates).[20] The penalty applies to all domestic sales of the drug, not just sales through Medicare. *Id.* § 5000D(a). The penalty can begin accruing more than two years before the January 1, 2026 effective date of the CMS-dictated price. *See id.* § 5000D(a)(1). Finally, BI is aware of no other statute that imposes similar sanctions "for comparable misconduct." *Cooper Indus.*, 532 U.S. at 435. For example, the penalty for civil tax *fraud* is "an amount equal to 75 percent of the portion of the underpayment which is attributable to fraud." 26 U.S.C. § 6663(a). All told, the excise tax penalty at issue here is a fine, is excessive, and therefore is unconstitutional.

[20] In an attempt to minimize the excessive nature of this "tax", the IRS issued a Notice announcing its intent to propose implementing regulations. *See* Shearin Decl. Ex. K. The Notice cannot cure these constitutional flaws. The Notice disregards the statutory text, which imposes the tax on any "sale by the manufacturer … of any designated drug," 26 U.S.C. § 5000D(a), and thus, contrary to the Notice's claims, is not limited to sales under Medicare. The Notice also attempts to minimize the tax by suggesting that the price paid by the purchaser will be presumed to *include* the tax. Shearin Decl. Ex. K § 3.02. This sleight of hand, however, results in the same tax-to-value ratio: the maximum tax would still constitute 1,900 percent of the actual value of the product (e.g., a $2000 sale would consist of $1900 in tax and only $100 in actual product value). In all events, even a 95 percent tax is an extraordinary and punitive levy.

The Anti-Injunction Act does not bar this Court from adjudicating this Eighth Amendment claim. While the Anti-Injunction Act provides that "no suit for the purpose of restraining the assessment or collection of any tax shall be maintained in any court by any person," *id.* § 7421(a), the Act does not bar relief where a plaintiff who would otherwise suffer irreparable injury can demonstrate "certainty of success on the merits." *Bob Jones Univ. v. Simon*, 416 U.S. 725, 737 (1974) (citing *Enochs v. Williams Packing & Nav. Co.*, 370 U.S. 1, 6–7 (1962)). Here, BI would suffer irreparable injury by being forced either to participate in the Program or pay ruinous excise tax penalties, and for the reasons given above, there is a certainty of success on the merits (*i.e.*, the "excise tax" is an unconstitutionally excessive fine). Nor would suing for a refund each time the "tax" is levied be an adequate legal remedy, as "su[ing] to recover it back would necessitate a multiplicity of suits," *Hill v. Wallace*, 259 U.S. 44, 47, 62 (1922), and the enormity of the fine would make it impractical for BI to pay it for any meaningful period of time.

V. The Program Is Not Voluntary.

The Government seeks to sidestep the Program's constitutional shortcomings by arguing that manufacturers' obligations stem only from their "voluntary participation" in the Program. *E.g.*, Shearin Decl. Ex. B at 129. But the Program is designed to make it practically and legally impossible for manufacturers to avoid participating. That makes sense: the Government *needs* manufacturers to participate in the Program in order for the most widely used prescription drugs to be available through Medicare, and so has structured the Program in a way that guarantees that outcome. Thus, manufacturers' participation is not "voluntary" in any meaningful sense.

As discussed above, if BI does not enter into an agreement to "negotiate" the price of Jardiance®, it will begin incurring billions of dollars in excise "tax" penalties. *See supra* pp. 9–10; Marsh Decl. ¶ 16. Given these draconian consequences, there is no reasonable sense in which BI's participation in the Program is voluntary. *See NFIB*, 567 U.S. at 582.

Alternatively, the IRA purports to offer manufacturers the option of avoiding the "negotiation" and these coercive excise tax penalties by withdrawing *all* of their drugs from Medicare and Medicaid altogether. *See* 26 U.S.C. § 5000D(c). That is not a real option for BI. To avoid accepting the "negotiated" price or incurring ruinous penalties, BI would have to withdraw all of its products, more than 20 drugs, from Medicare and Medicaid, which would cut the company off from nearly half the U.S. healthcare market. *See* Marsh Decl. ¶¶ 7, 9, 17. Indeed, more than half of BI's net sales come from Medicare and Medicaid in many years, including more than 55 percent in 2022. *See id.* ¶ 7. Forcing BI to abandon that market is "economic dragooning that leaves [BI] with no real option but to acquiesce" in the Program. *NFIB*, 567 U.S. at 582 (Federal Government could not condition Medicaid funding, representing 10 percent of state budgets, on states' implementation of Medicaid expansion); *see also Tenoco Oil Co. v. Dep't of Consumer Affs.*, 876 F.2d 1013, 1027 n.21 (1st Cir. 1989) ("supposed freedom to temporarily leave the market may be largely illusory" where "such a course might very well be economically prohibitive"); *Fisher v. United States*, 148 Fed. Cl. 478 (2020) (coercion present where "there is no choice, in any meaningful sense" because "there is only one realistic option").

Moreover, withdrawing BI's drugs would leave millions of Medicare and Medicaid patients (including more than 1.3 million Jardiance® patients in Medicare alone) without insurance for drugs they rely upon to treat serious, often life-threatening conditions. *See* Marsh Decl. ¶¶ 8, 18. Many of those patients would have to switch from their current medication to other treatments that would be less effective or cause adverse reactions, and some patients would be left without insurance for any FDA-approved treatment. *See id.* ¶¶ 18–19. In similar circumstances, courts have recognized that it defies reality to consider withdrawal from the market a realistic option. For example, in connection with an order imposing price controls on rice imports to Puerto Rico, a

court observed that "[c]ertainly it was not contemplated that the order would stop the importation of this necessity of the Puerto Rican people. Accordingly the application of the principle that the members of the industry could escape loss by withdrawing from the business of importing rice is not an honest answer to the question at issue." *Mora v. Mejias*, 223 F.2d 814, 817 (1st Cir. 1955). So too here.

When enacting the IRA, Congress was well aware that the statute would leave manufacturers with no choice but to accept the Government-imposed "maximum fair price." As discussed above, Congress and the CBO both concluded that the excise tax penalty would raise no revenue because no manufacturer could pay it. *See supra* p. 32. Indeed, mandatory participation is central to the Program's design. The Government needs manufacturers to submit to the Program so that the most widely prescribed drugs will remain available to the millions of Americans who depend on Medicare and Medicaid for health insurance. It would defeat Congress's purpose—and the Government's public messages in promoting the IRA—if Medicare and Medicaid patients lost access to their drugs. Congress addressed that dynamic by making the Program voluntary in name but mandatory in practice.

Courts have repeatedly concluded that actions taken under threat of severe economic coercion are not voluntary. In *NFIB*, the Supreme Court rejected congressional attempts to "economic[ally] dragoo[n] … States" so that they had "no real option but to acquiesce in the Medicaid expansion." 567 U.S. at 582. The Supreme Court reached a similar conclusion in *Union Pacific Rail Road Co. v. Public Service Commission*, a case involving regulation of private parties, concluding that the Government may not "impose an unconstitutional burden by threat of penalties worse than [that burden] in case of failure to accept it, and then to declare the acceptance voluntary." 248 U.S. 67, 70 (1918). In such circumstances, economic "duress" negates any

purported "choice" between compliance and "grave penalties" because it is "practically impossible *not* to comply with the terms of the law." *Id.* Likewise, in *United States v. Butler*, the Court recognized that a "regulation is not in fact voluntary," and the "asserted power of choice illusory," where Congress had used "coercion by economic pressure" "to induce to surrender [of a private party's] independence of action." 297 U.S. 1, 70–71 (1936); *see also Carter v. Carter Coal Co.*, 298 U.S. 238, 289 (1936) (concluding that purportedly voluntary "agreement" to participate in coal regulation program was "coerce[d]" and "lack[ed] the essential element of consent" because it was backed by provisions imposing substantial taxes for noncompliance, and observing that "[o]ne who does a thing in order to avoid a penalty does not agree").

Relying on those principles, the D.C. Circuit has held that a similarly structured federal program for cotton growers was not voluntary. *See Thompson v. Deal*, 92 F.2d 478 (D.C. Cir. 1937). The program at issue in *Thompson* required growers to sign an agreement with the Secretary of Agriculture to adhere to production limits imposed under threat of a "confiscatory" tax "not designed to raise revenue" but to "coerc[e]" the Government's cotton production quotas. *See id.* at 480, 484. "No farmer, therefore, was in position to refuse to sign the agreement which the act required and to accept his allotment as the Secretary made it." *Id.* at 484. Growers who produced more than their allotment faced four illusory options (not unlike the purported options BI faces under the Program): (1) pay 50 percent of the excess cotton's value in taxes; (2) sell the excess cotton without paying the tax and be fined and imprisoned for noncompliance; (3) hold on to the cotton and receive no return; or (4) purchase certificates, at 40 percent of the cotton's value, to sell the excess cotton tax-free. *See id.* at 480–81, 484. Growers "chose the least of the evils and purchased certificates," arguing that "they made the payments under duress." *Id.* at 481. The court agreed, holding that the growers involuntarily purchased the certificates under duress "to

prevent great property loss or heavy penalties [as] there [was] no adequate remedy except to submit to an unjust or illegal demand and then seek redress in the courts." *Id.* at 484 (cleaned up). The same is true here.

Moreover, even if a manufacturer wished to withdraw from Medicare and Medicaid rather than agree to the "negotiation," the structure of the Program makes it legally impossible to do so before incurring substantial penalties. Under the IRA, a manufacturer's request to withdraw from Medicare and Medicaid does not take effect until at least 11 months and up to 23 months after it is submitted. 42 U.S.C. § 1395w-114a(b)(4)(B)(ii). Manufacturers who do not "negotiate" will thus incur enormous penalties while waiting for their withdrawal request to be granted.

Presumably recognizing that this lengthy delay undermines its position that the Program is voluntary, CMS has issued guidance purporting to create an accelerated pathway for manufacturers to terminate participation in Medicare and Medicaid. *See* Shearin Decl. Ex. B at 33–34, 129–31. Under that pathway, CMS has stated that it will treat termination requests by manufacturers as terminations by the Government for "willful violation ... or other good cause," which are subject to only a 30- or 60-day delay. 42 U.S.C. §§ 1395w-114a(b)(4)(B)(i)–(ii), 1396r-8(b)(4)(B)(i); Shearin Decl. Ex. B at 33–34, 129–31. But the text and structure of the relevant statutory provisions foreclose CMS's attempt to "rewrite clear statutory terms to suit its own sense of how the statute should operate" through nonbinding guidance. *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 328 (2014). By treating termination requests *by manufacturers* as termination requests *by the Government*, the guidance conflates distinct provisions of the IRA and ignores the timing provisions applicable only to manufacturers. *Compare* 42 U.S.C. § 1395w-114a(4)(B)(i), *with id.* § 1395w-114a(4)(B)(ii).

Nor can the government avoid the conclusion that a taking has occurred by relying on inapposite caselaw about voluntary participation in a marketplace. For example, the Government relies on *Garelick v. Sullivan*, 987 F.2d 913 (2d Cir. 1993), which rejected a takings challenge to provisions limiting the amounts anesthesiologists could charge Medicare beneficiaries, because the anesthesiologists "voluntarily participate[d] in a price-regulated program or activity" and suffered "no legal compulsion." *Id.* at 916. Unlike in *Garelick*, however, BI and other manufacturers *are* effectively "compelled to engage in price regulated activity." *Id*. And in any event, *Garelick*'s reasoning—which was limited to takings claims—is inconsistent with the Supreme Court's later decision in *Horne*, which rejected the notion that a physical exaction is not a taking because the owners voluntarily chose to participate in the relevant market. *See* 576 U.S. 365–66 (raisin-reserve requirement a taking even if farmers could have avoided it by growing other crops); *see also Valancourt Books*, 2023 WL 5536195, at *6.[21]

VI. Even if the Program Were Voluntary, It Would Violate the Unconstitutional Conditions Doctrine.

Even if participation in the Program were voluntary, the Program would still be unconstitutional. Congress cannot lawfully condition BI's participation in Medicare and Medicaid on its participation in the Program and the resulting relinquishment of constitutional rights. "It is settled law that the government may not, as a general rule, grant even a gratuitous benefit on condition that the beneficiary relinquish a constitutional right." *O'Connor v. Pierson*, 426 F.3d

[21] To the extent *Garelick*'s reasoning remains good law, Supreme Court precedent makes clear it is limited to takings claims. For example, the price-control regimes in *Bowles* and *Yakus* did not compel anyone to sell price-controlled goods or provide rent-controlled housing, yet the Court analyzed due process and other constitutional challenges against those regimes in detail, demonstrating that "voluntariness" alone does not shield price-control regimes from constitutional scrutiny. *Compare Bowles*, 321 U.S. at 517 (noting that "[t]here is no requirement that the apartments in question be used for purposes which bring them under the Act."), *with id.* at 519–20 (separately discussing due process claim); *see also Yakus*, 321 U.S. at 438 (statute "provide[d] that no one shall be compelled to sell any commodity").

187, 201 (2d Cir. 2005) (cleaned up); *accord Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 606 (2013). In other words, the Government cannot use "as a stick" the "granting and withholding of benefits … to coerce recipients of those benefits to engage in certain behaviors" where requiring recipients to engage in those same behaviors "would be a constitutional violation." *Goe v. Zucker*, 43 F.4th 19, 34 n.16 (2d Cir. 2022). This protection prevents the Government from "produc[ing] a result which [it] could not command directly," *Speiser v. Randall*, 357 U.S. 513, 526 (1958), and "vindicates the Constitution's enumerated rights by preventing the government from coercing people into giving them up," *Koontz*, 570 U.S. at 604. Even when an individual "has no 'right' to a valuable governmental benefit," these protections apply with full force. *Perry v. Sindermann*, 408 U.S. 593, 597 (1972); *accord O'Connor*, 426 F.3d at 201.

Even assuming Program participation were voluntary, it would become a condition of BI's ability to participate in Medicare and Medicaid. BI markets more than 20 products reimbursed by Medicare and Medicaid. Marsh Decl. ¶ 7. Because of the IRA, however, BI must now withdraw all of its products from Medicare and Medicaid *unless* it submits to the Program's requirements. *See* 26 U.S.C. § 5000D(c). As CMS has explained, "the IRA expressly connects" a manufacturer's participation in the Program to the manufacturer's "participation in [Medicare and Medicaid]." Shearin Decl. Ex. B § 40.1. And because the Program deprives BI of its constitutional rights, *see supra* Parts I–III, giving BI the option of participating in the purportedly voluntary Program would thus "condition certain government benefits" (i.e., BI's broader Medicare and Medicaid participation) "on the relinquishment of constitutional rights." *Boy Scouts of Am. v. Wyman*, 335 F.3d 80, 91 (2d Cir. 2003).

This condition is unconstitutional in at least three distinct ways.

1. In the due process context, a condition is unconstitutional when the Government "condition[s] benefits on a citizen's agreement to surrender due process rights." *R.S.W.W., Inc. v. City of Keego Harbor*, 397 F.3d 427, 434 (6th Cir. 2005). This inquiry is straightforward: What the Constitutional protects "against direct assault," it also protects "by the indirect, but no less effective process of requiring a surrender, which, though in form voluntary, in fact lacks none of the elements of compulsion." *Frost v. R.R. Comm'n of Cal.*, 271 U.S. 583, 593 (1926); *see also Koontz*, 570 U.S. at 604. The Constitution precludes the Government from directly depriving BI of its property without due process of law, *see Dusenbery v. United States*, 534 U.S. 161, 167 (2002), and so the Government cannot do so indirectly. By making Medicare and Medicaid participation contingent on Program participation, the Government would unconstitutionally require BI to give up its due process rights to obtain a government benefit. *See supra* Part I. "It would be a palpable incongruity" to allow the Government to indirectly require BI to give up its property without due process "under the guise of a[n] … exchange" for a benefit, when the Government could not do so directly. *Frost*, 271 U.S. at 593.

2. In the takings context, a condition is unconstitutional when there is either no connection or no rough proportionality "between the property that the Government demands and the social costs" of the granted benefit. *Koontz*, 570 U.S. at 605–06. The Program fails under both prongs.

First, there is no connection. The IRA provides no explanation (nor has CMS) as to why Medicare and Medicaid participation relates to BI's property rights in Jardiance®. Forced appropriation of those rights does not "internaliz[e]" any "negative externalities" or "social costs" associated with Medicare or Medicaid participation. *Id.* This is especially so because BI offers more than 20 products through these programs and helps millions of patients each year, creating social *benefits*, not social costs. Marsh Decl. ¶¶ 8, 18. Without this connection, the Government

is "left … in the position of simply trying to obtain [BI's property] through gimmickry [by] an out-and-out plan of extortion." *Dolan v. City of Tigard*, 512 U.S. 374, 387 (1994) (cleaned up).

Second, assuming there were some connection between BI's property rights in Jardiance® and BI's broader Medicare and Medicaid participation, the gross disproportionality of the Program's participation conditions is plain. The Program involves only one BI drug—Jardiance®—and only because of that drug's use in one Medicare program—Medicare Part D. *See* 42 U.S.C. § 1320f-1(b)(2), (d)(1)(A). Yet the IRA conditions BI's ability to offer *all* of its products in *every* part of Medicare and Medicaid. *See* Marsh Decl. ¶17; 26 U.S.C. § 5000D. The IRA also leverages BI's existing Medicare and Medicaid agreements to compel future conduct (i.e., sales of Jardiance® products at the "maximum fair price" starting in 2026)—a coercive tactic the Supreme Court rebuffed when Congress tried to "penalize States that choose not to participate in [a] new [federal] program by taking away their existing Medicaid funding." *NFIB*, 567 U.S. at 585. The Government cannot deny BI the benefit of participating in Medicare and Medicaid simply because BI "exercises a constitutional right" to control the disposition of, and set the terms of access to, its property. *Koontz*, 570 U.S. at 604 (cleaned up).

3. In the First Amendment context, a condition is unconstitutional if individuals are "requir[ed] … to profess a specific belief" to receive a government benefit. *USAID v. All. For Open Soc'y Int'l*, 570 U.S. 205, 218–19 (2013). Congress could not, for example, condition federal funding on recipients first "agree[ing] in the [funding] award document that [they are] opposed to prostitution and sex trafficking." *Id.* at 210. That condition was unconstitutional because, by compelling speech, Congress "affect[ed] protected conduct outside the scope of the federally funded program" and thus went beyond its ability to choose what conduct it would and would not fund. *Id.* at 218 (cleaned up). Similarly here, BI's continued ability to offer its products in

Medicare and Medicaid turns on BI's signing an agreement and conveying messages it would not otherwise express: that the Program involves a voluntary agreement, an arms-length negotiation, and a fair price for Jardiance®. And, as in *USAID*, this compelled speech affects only "protected conduct *outside* the scope of" Medicare and Medicaid, as Congress could have achieved its goal of lowering drug prices *without* requiring manufacturers "to pledge allegiance to the Government's policy." *Id.* at 218, 220; *see also supra* pp. 28–29.

Regardless of the right involved, the conclusion is the same: a voluntary Program would still condition "a valuable privilege which the [Government] threatens to otherwise withhold" on "the relinquishment of constitutional rights." *Frost*, 271 U.S. at 593–94. The reality, of course, is that the Program is *not* voluntary. *See supra* Part V. But were it otherwise, BI's only "choice" would be "between the rock and the whirlpool—an option to forego a privilege which [is] vital to [its] livelihood or submit to a requirement which … constitutes an intolerable burden." *Frost*, 271 U.S. at 593. The Constitution precludes the Government from foisting that choice on BI and indirectly "manipulat[ing]" its constitutional rights "out of existence." *Id.* at 594.

VII. The Manufacturer Agreement Violates the Administrative Procedure Act and Medicare Act.

CMS compounded the IRA's constitutional violations by implementing the Program in a way that violates the Administrative Procedure Act ("APA") and the Medicare Act. Specifically, CMS issued the form Manufacturer Agreement summarily, without providing an opportunity for comment on its terms. That omission was improper because the Agreement, which imposes substantive requirements on manufacturers and obligates them to comply with CMS's guidance, is a legislative rule subject to mandatory notice-and-comment procedures.

CMS openly acknowledged its refusal to accept comments, stating that "[i]n light of the complexity of the actions the agency must undertake" to implement the Program, "CMS will not

provide a comment period on the Agreement." Shearin Decl. Ex. B at 30. Consistent with that approach, CMS published the Agreement on July 3, 2023, *id.* Ex. D, and described that document as "the final text of the Agreement," *id.* Decl. Ex. B at 30—all without providing manufacturers an opportunity to comment on the Agreement before it was finalized.

That rushed process was unlawful. Under the APA, agency action purporting to "impose legally binding obligations or prohibitions on regulated parties—and that would be the basis for an enforcement action for violations of those obligations or requirements" is a "legislative rule" that must be promulgated using notice-and-comment procedures. *Nat'l Mining Ass'n v. McCarthy*, 758 F.3d 243, 251 (D.C. Cir. 2014). The Medicare Act similarly requires notice and comment for any "rule, requirement, or other statement of policy … that establishes or changes a substantive legal standard." 42 U.S.C. § 1395hh(a)(2); *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1810–11 (2019).

Legislative rules "bind members of the agency and the public" and can impose on them "obligations … distinct from, and in addition to, those imposed by statute." *Sweet v. Sheahan*, 235 F.3d 80, 91 (2d Cir. 2000). The key factor in identifying a legislative rule is whether an action has "actual legal effect." *Cal. Cmtys. Against Toxics v. EPA*, 934 F.3d 627, 635 (D.C. Cir 2019) (citing *Nat'l Mining Ass'n*, 758 F.3d at 252).

The Manufacturer Agreement is a legislative rule—and thus triggered the notice-and-comment requirement—because it establishes substantive standards for the Program, sets forth a basis for enforcement, and creates legal obligations for manufacturers. *See Sweet*, 235 F.3d at 92. The Agreement changes manufacturers' existing rights by imposing new duties on them, which (like violations of the governing statute) are enforced through imposition of excise tax penalties and additional civil monetary penalties. *See Gonnella v. SEC*, 954 F.3d 536, 546 (2d Cir. 2020); *see also* Shearin Decl. Ex. C § IV(j).

The Agreement differs from an ordinary contract because it contains broad, regulatory terms that establish various Program requirements in the first instance. *See, e.g.*, Shearin Decl. Ex. B at 93 (Agreement spells out "Program requirements for participating manufacturers"). Under the Agreement, manufacturers "shall comply with requirements determined by CMS to be necessary for purposes of administering the" Program, and "CMS retains authority to amend th[e] Agreement" after the fact, without the manufacturer's consent. *Id.* Ex. C §§ II(e), IV(b). Those are mandates issued by CMS in its capacity as a regulator, not contractual terms between consenting parties. The programmatic nature of the Agreement is also apparent from its terms that require manufacturers to comply with all future CMS guidance—thus elevating the guidance from its usual, sub-regulatory status to binding law. *See id.* §§ II preamble, II(e), IV(b).

Where a program is implemented via contractual arrangements, "any contract provisions that are legislative are subject to [the APA's] notice and comment requirements." *Am. Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1053–54 (D.C. Cir. 1987). Thus, CMS "may not hide behind its authority to contract in order to evade the APA. Otherwise it could implement the entire … program through contract provisions,"—including provisions incorporating its own guidance—"without promulgating a single regulation or allowing for any public participation. Congress could not have intended so extraordinary a possibility without expressly saying so." *Id.* at 1054. CMS issued the Agreement in violation of these principles.

CONCLUSION

For the foregoing reasons, the Court should enter summary judgment for BI, declare that the Program is unconstitutional, set aside CMS's Manufacturer Agreement, and enjoin enforcement of the Program's requirements against BI.

Respectfully submitted,

/s/ James T. Shearin

James T. Shearin [01326]
Marcy Tench Stovall [14238]
PULLMAN & COMLEY, LLC
850 Main Street
P.O. Box 7006
Bridgeport, CT 06601-7006
Juris No. 47892
Tel.: (203) 330-2000
Fax: (203) 576-8888
jtshearin@pullcom.com

Counsel for Plaintiff
Boehringer Ingelheim Pharmaceuticals, Inc.

Robert A. Long, Jr. (*pro hac vice*)
Kevin F. King (*pro hac vice*)
Thomas Brugato (*pro hac vice*)
Michael M. Maya (*pro hac vice*)
COVINGTON & BURLING LLP
850 Tenth Street, NW
Washington, DC 20001-4956
Tel.: (202) 662-6000
Fax: (202) 662-6291

September 27, 2023