No. 24-2510

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

NOVO NORDISK INC.;
NOVO NORDISK PHARMA, INC.,

Appellants,

v.

SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ADMINISTRATOR, CENTERS FOR MEDICARE & MEDICAID SERVICES; CENTERS FOR MEDICARE & MEDICAID SERVICES.

On Appeal from the United States District Court for the District of New Jersey, No. 3:23-cv-20814, Hon. Zahid N. Quraishi

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OPENING BRIEF FOR APPELLANTS

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October 15, 2024

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 and Third Circuit LAR 26.1, Appellants Novo Nordisk Inc. and Novo Nordisk Pharma Inc. hereby certify that Novo Nordisk US Commercial Holdings, Inc. owns 100% of Novo Nordisk Inc. and Novo Nordisk Pharma, Inc. Novo Nordisk US Commercial Holdings, Inc. is a publicly traded company. No publicly traded corporation owns more than ten percent of its stock.

Date: October 15, 2024

/s/ Ashley C. Parrish
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INTRODUCTION

Several cases are pending in courts across the country—including before this Court—that challenge the constitutionality of the provisions in the Inflation Reduction Act ("IRA") directing the Centers for Medicare & Medicaid Services ("CMS") to impose price controls on certain medications. This case is different. It presents unique questions of statutory interpretation, focusing on actions taken by CMS to implement and apply the statute. Those actions violate the statute's plain text, conflict with decades of settled precedent, and confirm that CMS's price-control regime is unconstitutional.

First, the agency has unlawfully rewritten the statute's express numerical limits. The statute directs CMS to impose price controls in 2026 on no more than "10 negotiation-eligible" drug or biologic products. 42 U.S.C. § 1320f-1(a)(1). Instead of carrying out that mandate, CMS has imposed price controls on *groups* of products—more than 15 products in total—aggregating together six different Novo Nordisk products as a single "negotiation-eligible drug" merely because they contain the same "active ingredient." CMS's decision to impose price controls on an aggregated grouping of different Novo Nordisk products—products that

underwent different clinical trials, with different patient populations, and obtained approval from FDA at different times—violates the statute's strict 10-product limit, defies long-standing Supreme Court precedent, and conflicts with multiple other statutory requirements, including Congress's command that a biological product cannot be subject to price controls unless it has been on the market for at least 11 years.

Second, the agency has violated the IRA's mandate that CMS must implement the IRA's provisions through "program guidance" for the first three years (until 2029). *See* Pub. L. No. 117-169, §§ 11001(c), 11002(c), 136 Stat. 1818, 1854, 1862 (2022). CMS has promulgated new rules and substantive obligations that it concedes are intended to be binding and carry the force of law. According to CMS, Congress's direction to proceed by guidance should be construed to grant CMS unbounded power to make new law without having to comply with *any* procedural rulemaking requirements. That not only contravenes the IRA's plain text, it violates the Administrative Procedure Act ("APA") and the Medicare statute, which prohibit agencies from imposing substantive rules without following notice-and-comments procedures subject to judicial review.

Third, CMS asserts that the statute and the agency's actions should be free from constitutional scrutiny because participation in CMS's price-control regime is purportedly "voluntary." CMS does not deny that the statute imposes an enterprise-crippling "excise tax" penalty on any manufacturer that seeks to avoid price controls. Nor can it reasonably dispute that it is exercising coercive regulatory powers that no ordinary market participant possesses. CMS nonetheless contends that the Constitution's safeguards are irrelevant because, under its guidance, it will allow manufacturers to escape price controls if they withdraw *all their products* from Medicare and Medicaid (not just the products subject to price controls under the IRA), and effectively exit the interstate market for some 60 million citizens who rely on these government programs for life-saving medicines. This type of argument—that the government can circumvent constitutional limits on its powers by threatening to revoke unrelated or disproportionate government benefits—has been squarely rejected by the Supreme Court. The government cannot coerce manufacturers into participating in a one-sided "negotiation" process and accepting whatever price CMS demands and then pretend that its price-control program is "voluntary."

More fundamentally, no party can consent to a violation of the Constitution's structural protections. Our system of constitutional checks and balances is especially important where, as here, CMS has interpreted the statute to provide no procedures and no intelligible principle to ensure that the prices unilaterally dictated by the agency are within constitutional bounds. Indeed, CMS claims open-ended discretion to impose any price it chooses, no matter how arbitrary, discriminatory, or confiscatory, with no judicial review to protect either private rights or the broader public interest. The statute also includes a gratuitous compelled-speech mandate, requiring manufacturers to "agree" that the prices dictated by CMS are "maximum fair prices," regardless of how low or disastrous those prices might be.

The agency's position departs from basic rules of administrative law and constitutional government. Agencies are bound by the statutes they implement and are not allowed to rewrite them. Agencies have no authority to act beyond the powers delegated by Congress, and when agencies promulgate new substantive rules they must comply with the APA, including its notice-and-comment procedures and requirements for judicial review. Statutes authorizing price controls, even those

implemented during the most pressing war-time emergencies, must contain standards and procedures to ensure that agencies act within constitutional bounds. And no statute can compel regulated parties to speak the government's preferred message or else face enterprise-threatening penalties.

Because CMS's actions are unlawful and its interpretation of the statute is unconstitutional, this Court should vacate CMS's final actions, strike down the agency's unprecedented price-control regime, and remand with instructions for the district court to grant Novo Nordisk's requests for declaratory and injunctive relief.

STATEMENT OF JURISDICTION

This Court has jurisdiction under 28 U.S.C. § 1291 because Novo Nordisk timely appealed from a final judgment. *See* Appx.1-3. The district court had jurisdiction under 28 U.S.C. § 1331.

STATEMENT OF THE ISSUES

1. Whether CMS violated the IRA by imposing price controls on 15 different drug and biological products beginning in 2026, aggregating together six different Novo Nordisk products licensed and approved at different times, even though the statute directs CMS to impose price controls on no more than 10 products, CMS's approach results in

regulating the prices of products that have not been on the market for the number of years required by Congress, and without aggregation none of Novo Nordisk's products would have qualified for price controls.

2. Whether CMS violated the IRA, as well as the Administrative Procedure Act and Medicare Act, by promulgating new binding substantive rules without complying with the essential procedural and judicial-review requirements that govern rulemaking and even though Congress mandated that CMS "shall" implement the statute using only "program guidance" for the first three years.

3. Whether the IRA as implemented and applied by CMS violates the Constitution by granting the agency sweeping authority to take manufacturers' intellectual property and force access to their products at whatever prices the agency unilaterally dictates while providing no procedures to protect private rights and the public interest, nor any intelligible principle to constrain the agency and prevent it from imposing arbitrary, discriminatory, or confiscatory prices.

4. Whether the IRA violates the Constitution by compelling manufacturers to state that they "agree" with the government's viewpoint that CMS's dictated prices are "maximum fair prices."

5. Whether CMS can escape constitutional scrutiny by asserting that participation in its price-control scheme is "voluntary," even though the statute imposes an enterprising-crippling fine on any manufacturer that tries to avoid price controls, and CMS is not procuring manufacturer's products for the government but is instead exercising coercive regulatory powers that no market participant possesses.

6. Whether the district court erred in failing to consider the merits of CMS's statutory violations on a novel theory—at odds with settled precedent—that Novo Nordisk lacks Article III standing merely because one form of relief the company sought would stop CMS from acting unlawfully and thus also benefit third parties.

7. Whether the district court correctly rejected the government's request that the statute's judicial review bars be interpreted broadly to cover a statutory mandate that does not fall within their express terms and would grant CMS carte blanch to engage in ultra vires conduct.

STATEMENT OF RELATED CASES

This case has not previously come before the Court. Three other cases challenging the IRA are currently being considered in case numbers 24-1820, 24-1821, and 24-1819.

STATEMENT OF THE CASE

A. The Inflation Reduction Act

In August 2022, Congress enacted the IRA, which authorizes CMS to establish a "Drug Price Negotiation Program." 42 U.S.C. § 1320f(a). The IRA's supporters sold it to the public as permitting CMS to "negotiate" prices, but the regulatory scheme does not contemplate anything resembling an actual negotiation. Instead, as interpreted and applied by CMS, the statute coerces manufacturers to turn over confidential pricing information and to sell their products to the 60 million people covered by Medicare and Medicaid at any price that CMS unilaterally dictates. If a manufacturer does not accept the price dictated by CMS, it faces massive fines or complete expulsion from the federal Medicare and Medicaid programs.

The IRA's provisions depart from a long history of market-based pricing. Relying on their ability to recover market prices, manufacturers have invested billions in research and development; conducted rigorous, decades-long preclinical and clinical testing; and shepherded new and improved medications through a lengthy approval and licensing process before the Food & Drug Administration ("FDA"). The average cost of bringing a new product to market is more than $2 billion, and the process

takes on average 10 to 15 years. *See* CBO, No. 57025, Research and Development in the Pharmaceutical Industry, at 14 (Apr. 2021); GAO, No. GAO-20-215SP, Artificial Intelligence in Health Care, at 34 (Dec. 2019). Only about 1 in 5,000 products successfully navigates these hurdles. *See* Paula Carracedo-Reboredo et al., *A Review on Machine Learning Approaches and Trends in Drug Discovery*, 19 Computational & Structural Biotech. J. 4538, 4547 (2021).

The prices manufacturers receive must account for these costs. Under the market-based system, the "list prices"—the prices that garner headlines—are not the prices that manufacturers typically receive or that patients typically pay. Pharmacy benefit managers, working on behalf of employers or health-insurance companies, negotiate substantial discounts (often through rebates). Health insurers then work with pharmacy benefit managers to determine how much patients pay.

Under the pre-IRA framework, the same general approach applied when the government was involved. CMS contracted with private health insurers to provide Part D prescription drug benefits, and those private insurers would negotiate prices. Although CMS benefitted, it could "not interfere with the negotiations between drug manufacturers and

pharmacies and [prescription drug plan] sponsors," nor "institute a price structure for the reimbursement of covered part D drugs." 42 U.S.C. § 1395w-111(i).

Disrupting substantial reliance interests, the IRA eliminates the market-based system that has fueled advances in lifesaving and life-enhancing medications. For a specified number of certain drug and biologic products that account for the highest amount of government spending, the IRA grants CMS unbounded and unreviewable discretion to set any prices it chooses.

The IRA's Limits. The IRA strictly limits the number of products that CMS is permitted to subject to price controls. Congress mandated that, for 2026, CMS may set prices on only "10 negotiation-eligible drugs." 42 U.S.C. § 1320f-1(a)(1), (e)(1). That number increases over time. *Id*. § 1320f-1(a)(2)-(4).

The IRA defines a "negotiation-eligible drug" in the singular to be "*a* drug or biological *product*" that satisfies certain requirements. *Id.* § 1320f-1(e) (emphasis added). A drug product may be eligible for price controls *only* if: (1) it was approved and marketed as a new drug under 21 U.S.C. § 355(c); (2) at least 7 years have elapsed since its approval

date; and (3) the product is not the listed drug for any generic version approved and marketed under 21 U.S.C. § 355(j). *See* 42 U.S.C. § 1320f-1(e)(1)(A). A biological product is eligible only if (1) it is licensed and marketed under 42 U.S.C. § 262(a); (2) "at least 11 years" have "elapsed since the date of such licensure"; and (3) the product "is not the reference product of any biological product … licensed and marketed under section 262(k)." *Id.* § 1320f-1(e)(1)(B).

The statute contains precise instructions for identifying which products may be subject to price controls. It then grants CMS narrow discretion to "determine" which products should be excepted or exempted and to develop a final list of "negotiation-eligible" products. *See* 42 U.S.C. § 1320f-1(d)(2) (granting discretion to determine exceptions for small biotech drugs); *id.* § 1320f-1(e)(3) (granting discretion to determine exclusions for low-spend drugs). CMS must then rank each product according to Medicare's total gross expenditures and decide which products to regulate with price controls. *Id.* § 1320f-1(b). In completing this ranking, the statute instructs CMS to "use data" aggregated across "dosage forms and strengths of the drug, including new formulations …, such as an extended release formulation ….." *Id.* § 1320f-1(d)(3)(B). The

statute does not authorize aggregation based on other product features, such as route of administration, device presentation, or conditions of use.

CMS's Price-Setting. Although Congress prescribed the number of products subject to price-control regulation, Congress included no downward limit on the prices CMS may impose. The only limit is a ceiling: CMS's price can be no higher than 40% to 75% of the product's average price to non-federal purchasers. 42 U.S.C. § 1320f-3(c)(1)(C), (b)(2)(F); 38 U.S.C. § 8126(h)(5). The statute lists factors CMS must "consider," including research and development costs, current cost, federal financial support, and evidence about alternative treatments. *See* 42 U.S.C. § 1320f-3(e). But the statute contains no standard or instruction constraining how CMS weighs those factors. Instead, the statute directs—in self-contradictory terms—that CMS must "ai[m] to achieve the *lowest maximum* fair price for each selected drug." *Id.* § 1320f-3(b)(1) (emphasis added). The statute defines "maximum fair price" to be whatever price CMS dictates. *Id.* § 1320f(c)(3).

The statute also lacks any procedures to ensure that the agency's prices are not arbitrary, discriminatory, or confiscatory. After CMS proposes a price, the manufacturer is permitted to make a "counteroffer"

within 30 days. *Id.* § 1320f-2(b)(2). But CMS may disregard the counteroffer and impose any price it prefers. No hearing is required. And the statute prohibits administrative or judicial review of the price CMS sets. *Id.* § 1320f-7(3).

The IRA's Penalties. If a manufacturer refuses to sell at CMS's prescribed price, it faces crippling penalties. *See* 26 U.S.C. § 5000D(b)(1)-(4). The statutory penalty—mislabeled an "excise tax"—accrues daily and ranges from nearly double to *19 times* the product's total daily sales revenue. Cong. Rsch. Serv., No. R47202, Tax Provisions in the Inflation Reduction Act of 2022 (H.R. 5376), at 4 tbl. 2 (Aug. 10, 2022). The statute offers no practical way to avoid these excessive penalties. Although a manufacturer can in theory withdraw *all of its products* from Medicare and Medicaid, no manufacturer could afford to exit a market that serves some 60 million patients and, in any event, it takes 11 to 23 months after a manufacturer submits a notice for a withdrawal to take effect. *See* 42 U.S.C. § 1395w-114a(b)(4)(B)(ii); *id.* § 1395w-114c(b)(4)(B)(ii); 42 C.F.R. § 423.2345(b)(2).

B. CMS's Final Guidance

Congress directed CMS to implement price controls through *guidance* for the first three years: CMS "shall implement this section … for 2026, 2027, and 2028 by program instruction or other forms of program guidance." Pub. L. No. 117-169 §§ 11001(c), 11002(c), 136 Stat. at 1854, 1862. Unlike other places in the Act, no provision authorizes CMS to "prescribe … regulations" during that three-year period. *See id.* § 10201, 136 Stat. at 1831 (amending § 4501(f)).

On June 30, 2023, CMS issued a 198-page "guidance" document. *See* CMS, Medicare Drug Price Negotiation Program: Revised Guidance (June 30, 2023) ("Guidance"). The document goes far beyond announcing non-binding policy. As CMS concedes, the document is replete with new rules, requirements, and obligations. *See* Dkt. 37-1 at 29-34; *see also* Guidance § 40.7. The agency admits it did not comply with the APA or Medicare Act requirements that govern the promulgation of substantive rules; instead, it asserts that it can create new law—impose binding substantive obligations—in its discretion.

CMS's "guidance" rewrites the statute to regulate the prices of more products than Congress authorized. According to CMS, it is not limited

to imposing price controls on only 10 products, as the statute directs, but instead may dictate prices across *groups* of products containing the same active moieties (in the case of drug products) or the same active ingredients (in the case of biological products). Guidance § 30.1. CMS further asserts that it can impose price controls on products that, contrary to the statute, were approved or licensed less than 7 or 11 years ago—so long as FDA approved or licensed at an earlier time a different product with the same active moiety or active ingredient. *See id.* In other words, CMS takes the position that Congress's 7-or-11-year requirement can be disregarded when aggregating products that contain the same activity moiety or active ingredient.

CMS's guidance also expands the agency's authority to commandeer proprietary information. The guidance forces manufacturers to turn over highly sensitive, confidential information not required by the statute. *See* Guidance App. C. The guidance regulates the one-sided "negotiation" process, directing what information can be exchanged and controlling the timing and number of meetings. *Id.* §§ 40.22, 60, 60.4. In addition, CMS's guidance tries to rewrite the statute's penalty scheme, purporting to allow manufacturers to exit

Medicare and Medicaid on a more expedited basis than the statute permits. *Id.* § 40.6.

C. CMS Implements the Statute

On August 29, 2023, CMS announced the products it plans to regulate with price controls in 2026. In addition to at least nine other products, CMS identified six Novo Nordisk products—each separately approved and licensed by FDA—for which CMS will dictate a single price: Fiasp®, Fiasp FlexTouch®, Fiasp PenFill®, NovoLog®, NovoLog FlexPen®, and NovoLog Penfill®.


The selected drug list for the first round of negotiation is:

- Eliquis
- Jardiance
- Xarelto
- Januvia
- Farxiga
- Entresto
- Enbrel
- Imbruvica
- Stelara
- Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill

Press Release, HHS, *HHS Selects the First Drugs for Medicare Drug Price Negotiation* (Aug. 29, 2023); *see also* Appx172. CMS admits that this "tenth" pick encompasses multiple products. *See* Dkt. 37-1 at 2.

Facing a crushing excise-tax penalty, Novo Nordisk had no option but to execute an agreement with CMS, while preserving its litigation rights. *See* CMS, Manufacturer Agreements for Selected Drugs for Initial Price Applicability Year 2026 (Oct. 3, 2023); Appx115-116 ¶¶ 50, 52, Appx175-179. The standardized agreement requires Novo Nordisk to comply not only with the agency's guidance but also any future guidance the agency might at any time decide to issue. *See* Appx175-179. It also forces Novo Nordisk to "agree" that it "and CMS have engaged in negotiation of the price" and that both "agree to [the] price … published by CMS." CMS, Medicare Drug Price Negotiation Program Agreement Template, at 7, *available at* https://tinyurl.com/bdhr8skc.

On August 15, 2024, CMS announced the prices for 2026. *See* Press Release, CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026* (Aug. 15, 2024). For Novo Nordisk's six products, which each have their own market price, CMS imposed a single price that it asserts slashes list prices by 76%. *Id.*

D. Procedural Background

In September 2023, Novo Nordisk commenced the underlying litigation, claiming that CMS violated the IRA by imposing price controls on more than 10 products and by disregarding the IRA's guidance-only mandate. It also claimed that the IRA violates the Constitution.

The district court granted summary judgment in CMS's favor. The court held that Novo Nordisk lacks standing to challenge CMS's decision to impose price controls on six of its products. *See* Appx10-11. The court acknowledged Novo Nordisk's argument that CMS issued new rules without complying with the APA, but offered no further analysis. Appx7. The court concluded that the IRA escapes constitutional scrutiny because CMS's scheme is "voluntary" and the statute contains enough of an intelligible principle to overcome nondelegation concerns. Appx7-21.

SUMMARY OF ARGUMENT

1. The district court failed to enforce the statute's plain text (a) by allowing CMS to regulate prices for 15 different products, even though the statute imposes a strict 10-product limit, and (b) by failing to correct CMS's violation of the statute's guidance-only mandate.

a. The IRA authorizes CMS to impose price controls in 2026 on "10 negotiation-eligible drugs." 42 U.S.C. § 1320f-1(a)(1). Under

the statute's plain text, "10 negotiation-eligible drugs" means no more than 10 *products*. *Id.* The statute defines a "negotiation eligible drug" as "*a* drug or biological *product*." *Id.* § 1320f-1(e)(1) (emphasis added). And it defines a "negotiation eligible drug" by incorporating definitions from a settled FDA-approval regime, where the Supreme Court has long held that the term "drug" refers to an individual drug or biological *product*. *Id.* § 1396r-8(k)(2)); *United States v. Generix Drug Corp.*, 460 U.S. 453, 454 (1983) (the term "drug" in § 355 refers to "the entire product"). The statute's framework confirms the product-specific definition by allowing aggregation of products for only narrow, limited purposes. *See* 42 U.S.C. §§ 1320f-1(d)(3)(B), 1320f-5(a)(2).

Contrary to the district court's conclusion, Novo Nordisk has standing to challenge CMS's imposition of price controls on six of its products. Breaking from settled precedent, the court held that Novo Nordisk lacked standing because the relief it sought would also benefit third parties. Appx11. That decision is factually and legally wrong. Novo Nordisk sought declaratory relief that its products had been "improperly aggregated" and were "not properly subject to price controls under the statute," and it asked the court to enjoin "CMS from applying

price controls to any of [Novo Nordisk's] products that are improperly aggregated." Appx99 (Prayer for Relief) ¶ C-I. Moreover, whether the relief sought could benefit third parties has no bearing on standing because the relief will redress an injury suffered by Novo Nordisk that is traceable to CMS's actions. *Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc.*, 528 U.S. 167, 185-86 (2000).

b. CMS violated the statute's guidance-only mandate and basic administrative-law principles by promulgating substantive rules without following necessary procedures. The IRA provides that CMS "*shall* implement [price controls] for 2026, 2027, and 2028, by program instruction or other forms of *program guidance*." 42 U.S.C. § 1320f note (emphasis added). The term "guidance" has established meaning and refers to policy statements or interpretive rules that do not include binding substantive obligations. CMS is not authorized for three years (until 2029) to exercise legislative-like powers to impose new substantive obligations on regulated parties. And, in any event, even after three years have elapsed, CMS must comply with rulemaking procedures under the APA and Medicare Act when exercising those powers. 5 U.S.C. § 553; 42 U.S.C. § 1395hh(a)(2). CMS concedes that the document it

labels "guidance" imposes binding substantive obligations on manufacturers without complying with essential rulemaking procedures. Dkt. 37-1 at 29-34.

2. As interpreted and applied by CMS, the IRA price-control scheme is unconstitutional. Although CMS is taking manufacturers' confidential information and forcing manufacturers to transfer their products to patients at whatever price CMS dictates, the statute strips away layers of constitutional protections that are essential to safeguarding both private rights and the public interest.

a. The IRA's price-control scheme lacks procedures and statutory standards necessary to ensure that CMS's price-setting edicts are constitutionally appropriate, non-arbitrary, and not confiscatory. The statute's novel provisions have no historical precedent. Never before has the government regulated prices under a scheme that (i) has no procedures to ensure that the agency acts within constitutional bounds, while barring judicial review, and (ii) gives an agency standardless discretion to set prices as low as it wants. Even statutes that tested constitutional limits during wartime included protections that are absent here. The "lack" of any "historical precedent" is a "telling indication of a

severe constitutional problem." *Free Enter. Fund v. PCOAB*, 561 U.S. 477, 505 (2010).

b. Contrary to CMS's argument, it cannot evade constitutional requirements by characterizing the IRA's price controls as "voluntary." A party's consent cannot cure a structural constitutional violation. Moreover, the IRA is coercive, forcing manufacturers seeking to avoid CMS-imposed price controls to pay an enterprise-crippling penalty or stop selling *all of their products* in the Medicaid and Medicare channels—that is extortion, not a voluntary exchange. 26 U.S.C. § 5000D; 42 U.S.C. § 1320f-6. Nor can CMS exercise sweeping regulatory powers and then pretend that it is a mere market participant.

c. The statute's unconstitutionality is confirmed by its gratuitous compelled-speech requirement. The statute forces manufacturers to express the government's preferred message that the prices dictated by CMS are agreed-on and reflect "maximum fair prices."

STANDARD OF REVIEW

This Court reviews de novo the grant of summary judgment. *Mabey Bridge & Shore Inc. v. Schoch*, 666 F.3d 862, 867-68 (3d Cir. 2012). The Court "must set aside agency action that is '…not in accordance with

law.'" *La. Forestry Ass'n v. Sec'y U.S. Dep't of Lab.*, 745 F.3d 653, 669 (3d Cir. 2014) (quoting 5 U.S.C. § 706(2)(A)).

ARGUMENT

I. CMS Has Violated the IRA's 10-Drug Limit and Express Guidance-Only Mandate.

The IRA directs CMS to impose price controls on no more than 10 drug or biological products, and it instructs CMS to implement the statute's price-controls through "program guidance" for the first three years, denying CMS rulemaking authority until 2029. These provisions reflect Congress's judgment that price controls should be imposed incrementally and in strict adherence to the statute. CMS has violated both requirements. This Court should vacate CMS's purported "guidance" and direct the agency to comply with the statute's mandates.

A. CMS Has Violated the IRA's 10-Drug Limit.

CMS's decision to regulate more than 10 drug or biological products violates the IRA's plain text. The IRA authorizes CMS to impose price controls in 2026 on no more than "10 negotiation-eligible drugs," 42 U.S.C. § 1320f-1(a)(1), and the statute defines a "negotiation-eligible drug" to be "a drug or biological product." *Id.* § 1320f-1(e)(1). Instead of complying with the statute, CMS has aggregated together different

products containing the same active ingredient or active moiety to impose price controls on at least 15 different products, including six of Novo Nordisk's biological products. The district court failed to enforce the statute's plain text and instead applied a novel standing theory that even the government did not advance.

1. The statute expressly limits CMS to imposing price controls on no more than 10 products.

An administrative agency has a "duty" to comply with a statute's commands and may "not to supplant" them "with others it may prefer." *SAS Inst. Inc. v. Iancu*, 584 U.S. 357, 363 (2018). The IRA explicitly adopts a product-specific definition. And nearly every feature of the statutory framework confirms as much—indeed, the words "a biological *product*" appear *fourteen times* in 42 U.S.C. § 1320f-1 alone. When Congress delegates authority to an agency, a court must "fix[] the boundaries of [that] delegated authority" and strike down agency action that violates the statute. *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2261, 2263 (2024) (citing 5 U.S.C. § 706(2)(A)).

1. In its guidance, CMS redefined a "negotiation-eligible drug" to encompass *all* drug *products* that share the "same active moiety and the same holder of a New Drug Application (NDA), inclusive of products

that are marketed pursuant to different NDAs" and all biological products "with the same active ingredient and the same holder of a Biologics License Application (BLA), inclusive of products that are marketed pursuant to different BLAs." Guidance § 30.1 (footnote omitted). CMS's focus on setting prices for an active ingredient or active moiety represents a dramatic departure from the statute's plain terms.

A drug or biological *product* is different from an active ingredient or active moiety. As FDA has explained, "[a]n active ingredient can have different effects on the body depending on the formulation of the drug and its route of administration … among other things." 86 Fed. Reg. 28,605, 28,606 (May 27, 2021). For biological products, the difference between "a … biological product" and an "active ingredient" is even more stark. "In contrast to most drugs that are chemically synthesized and their structure is known, most biologics are complex mixtures that are not easily identified or characterized." *What Are 'Biologics' Questions and Answers*, FDA.gov (Feb. 6, 2018). Due to their complexity, for some biological products, "active ingredients may not be precisely identifiable or may only be known to a limited extent." HHS, Fiscal Year 2021: Food

and Drug Administration Justification of Estimates for Appropriations Committees, at 36 (2021).

Because an active ingredient or active moiety can have different effects depending on how it is incorporated into a particular product, the FDA has long "interpreted the word 'drug' in the term 'new drug' to refer to the entire drug product and not just its active ingredient." 86 Fed. Reg. at 28,606. The Supreme Court has likewise held that the term "drug" in section 355 of the FDCA refers to "the entire product" and not just the active ingredient. *Generix Drug*, 460 U.S. at 454. When deciding whether to approve a new drug, "FDA carefully evaluates, for *each* drug *product*, not only the active ingredient but also information" about that particular product's "formulation, route of administration, labeling, inactive ingredients, bioavailability, and manufacturing process." 86 Fed. Reg. at 28,606 (emphasis added).

2. Four features of the IRA require a product-specific definition and cannot be reconciled with CMS's group-of-products approach:

First, the statute directs that, for the initial price-applicability year, CMS may impose prices on only "10 negotiation-eligible drugs." 42 U.S.C. § 1320f-1(a)(1). The statute defines a "negotiation-eligible drug"

to be a "qualifying single source drug" that is either (1) "*a* drug or biological *product*" or (2) a "covered part D drug (as defined in section 1395w-102(e) …." *Id.* § 1320f-1(d)(1), (e)(1) (emphasis added). Section 1395w-102(e) incorporates the definitions of 42 U.S.C. § 1396r-8(k)(2)), which refer to products approved or licensed by FDA under 21 U.S.C. § 355(c) or 42 U.S.C. § 262(a). As CMS concedes, "FDA approves drugs and biologics on a product-by-product basis." Dkt. 37-1 at 21; *see George v. McDonough*, 596 U.S. 740, 753 (2022) (when Congress "employs a term of art," that usage suffices to "adop[t] the cluster of ideas that were attached to each borrowed word").

Second, the statute mandates that a negotiation-eligible drug be "approved under section 355(c) of Title 21 and [be] marketed pursuant to such approval" or be "licensed under section 262(a) of this title and [be] marketed under section 262 of this title." 42 U.S.C. § 1320f-1(e)(1)(A)(i), (B)(i). As CMS concedes, that provision cross-references FDA's product-specific approval and licensing authority. Dkt. 37-1 at 21. FDA does not approve or license "active ingredients" or "active moieties," and no manufacturer may market a product merely because FDA has approved

or licensed some other product containing the same active ingredient or active moiety.

Third, the statute requires that a specific amount of time must elapse from the date a marketed product is approved or licensed before it may be saddled with price controls. For "[d]rug products," this means "a drug … that is approved [by FDA] under section 355(c)" and "for which … at least 7 years will have elapsed since the date of such approval." 42 U.S.C. § 1320f-1(e)(1)(A). For "[b]iological products," this means "[a] biological product … that is licensed [by FDA] under section 262(a)" and "for which … at least 11 years will have elapsed since the date of such licensure." *Id.* § 1320f-1(e)(1)(B).

The statute's requirement to identify "*the* date of such approval" and "*the* date of such licensure" underscores that CMS must look at a discrete date on which FDA approved or licensed a particular product. *See Niz-Chavez v. Garland*, 593 U.S. 155, 166 (2021) (Congress's use of "a definite article with a singular noun" refers to "a discrete thing"). Under CMS's group-of-drugs approach, however, there may be numerous different approval dates. As a workaround, CMS asserts power to impose price controls on drug or biological products approved within the past 7

or 11 years, so long as FDA approved some other product from the same manufacturer with the same active moiety/active ingredient before the statutory period elapsed. *See* Guidance § 30.1. Accordingly, despite the statutory definition mandating that a negotiation-eligible drug be "a biological product … for which … at least 11 years will have elapsed since the date of [its] licensure," CMS has imposed the same price controls on six different biological products manufactured by Novo Nordisk, treating them as a single product even though three were approved less than 11 years ago. *See* Appx11 ¶ 38 (FDA approved FIASP® vial and FIASP® FlexTouch® in 2017, and FIASP® Penfill® in 2018).

Fourth, the statute excludes from price controls any drug that is a "listed drug" or "reference product." 42 U.S.C. § 1320f-1(e)(1)(A), (B). Only a "single" product can serve as the "listed drug" or "reference product" for any other approved drug product or licensed biological product. *See id.* § 262(i)(4) ("[t]he term 'reference product' means the single biological product licensed … against which a biological product is evaluated"); *id.* § 262(k)(5) (noting that a "biological product ... may not be evaluated against more than 1 reference product"); 21 U.S.C. § 355(j)(2)(D) (prohibiting a generic applicant from amending its

application to change its reference listed drug); 21 C.F.R. § 314.3 ("the listed drug identified by FDA [is] the drug product upon which an applicant relies in seeking approval of its ANDA"). An active ingredient or active moiety cannot serve as a listed drug or a reference product.

3. Unlike CMS's approach, the IRA's product-specific definition avoids unnecessary tension with other statutory provisions. For example, CMS's guidance throws into question regulatory exclusivities Congress created to encourage innovation. FDA makes determinations of three-year "new clinical investigation[]" exclusivity on a product-specific basis. *See* 21 U.S.C. § 355(c)(3)(E)(iii)-(iv), (j)(5)(F)(iii)-(iv); 21 C.F.R. § 314.108. The IRA's product-specific definition preserves this exclusivity. If a manufacturer creates a new product with a different route of administration (one better suited to treating certain patients, for example), that product would be eligible for three years of exclusivity, allowing the manufacturer to set prices without competition. *See* 21 U.S.C. § 355(c)(3)(E)(iii)-(iv), (j)(5)(F)(iii)-(iv). Under CMS's approach, however, the new product would be subject to immediate price controls if it contains the same active moiety as a different product approved more than 7 years ago. That undermines Congress's exclusivity and creates a

significant disincentive to manufacturer research, development, and investment. *See Morton v. Moncari*, 417 U.S. 535, 551 (1974) (courts should interpret statutes in harmony and give "effect to both if possible").

4. Although CMS has grouped together different products from the same manufacturer with the same "active ingredient" or "active moiety," nothing in the IRA's text references those terms. When Congress intends for an agency to look to the active ingredient (or active moiety) of a set of drugs, it says so expressly. In section 505(c) of the FDCA, for example, Congress directed FDA to determine whether a drug has the same "active moiety" as another approved drug to determine eligibility for new chemical entity exclusivity. 21 U.S.C. § 355(c)(3)(E)(ii), (iii). And for biological products, Congress created priority review for "a biological product, no active ingredient of which has been approved in any other application …." 21 U.S.C. § 360bbb-4a(a)(4)(D).

CMS's only statutory hook—the IRA's limited aggregation provisions—undermines its group-of-products approach. In evaluating whether a product qualifies as a high-spend drug, the IRA allows CMS to "use data that is aggregated across dosage forms and strengths of the drug." 42 U.S.C. § 1320f-1(d)(3)(B). In applying a price, the statute

similarly instructs CMS to do so "across different strengths and dosage forms of a selected drug." *Id.* § 1320f-5(a)(2). Although CMS tries to tether its position to these provisions, the instruction to aggregate information related to dosage forms and strengths for limited purposes is only meaningful if aggregation is not otherwise permitted. If CMS were correct that Congress authorized it to apply price controls to active moieties or active ingredients—rather than individual products—there would be no dosage forms, strengths, or formulations to aggregate because the aggregated "drug" would already encompass all the product's different dosage forms, strengths, and formulations. CMS's "reading is thus at odds with one of the most basic interpretive canons, that '[a] statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant." *Corley v. United States*, 556 U.S. 303, 314 (2009) (quoting *Hibbs v. Winn*, 542 U.S. 88, 101 (2004)).

CMS has also gone much further than aggregating across dosage forms and strengths. *See* Appx192-200. Numerous product-specific characteristics—including route of administration, device presentation, manufacturing process, and inactive ingredients (in addition to dosage

form and strength)—affect the safety and effectiveness, and thus approvability, of a product. As FDA has explained, it evaluates "not only the active ingredient but also information about the drug's formulation, route of administration, labeling, inactive ingredients, bioavailability, and manufacturing processes." 86 Fed. Reg. at 28,606; 21 C.F.R. §§ 314.3(b), 210.3(b)(4). Accordingly, although the statute authorizes limited aggregation for some purposes, it does not authorize aggregation by "active moiety" or "active ingredient" or permit CMS to aggregate products with different device presentations, routes of administration, or other differing conditions of use. Had CMS followed the IRA's text, it could not have chosen to aggregate six of Novo Nordisk's products, and without aggregation, none of those products would likely meet the high-spend requirement necessary to be included in "negotiations" and subject to CMS-imposed price controls. *See* Appx115 ¶ 49.

In sum, Congress's instruction that CMS may regulate only 10 negotiation-eligible drugs in 2026 limits CMS to regulating 10 drug or biological products. By imposing price controls on at least 15 products—including six of Novo Nordisk's products—CMS violated the statute.

2. The district court's standing ruling is flawed.

Instead of enforcing the statutory text, the district court concluded that Novo Nordisk lacks standing to challenge CMS's actions because a form of relief that Novo Nordisk seeks could benefit third parties. The district court's ruling is factually and legally wrong, and it violates settled precedent.

Novo Nordisk's standing is "self-evident" because its products are the direct "'object of the [agency] action … at issue.'" *Sierra Club v. EPA*, 292 F.3d 895, 900 (D.C. Cir. 2002) (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561-62 (1992)). CMS is dictating prices for *six* Novo Nordisk products—Fiasp®, Fiasp FlexTouch®, Fiasp PenFill®, NovoLog®, NovoLog FlexPen®, and NovoLog Penfill®—and violating the statute by treating them as a single biological product. *See* Appx172. Because CMS is regulating the prices for six products—products that were approved and licensed through different FDA applications; involved different clinical trials and have clinically meaningful differences for patients; and none of which would individually account for enough Medicare spending to warrant price controls—Novo Nordisk has standing to challenge the

lawfulness of CMS's actions. *See* Appx194-200 ¶¶ 30-46; Appx108-112 ¶¶ 26-41, 49; *see also* Appx50-55 ¶¶ 34-46.

It cannot be reasonably disputed that Novo Nordisk satisfies the three-part test for standing—injury, traceability, and redressability. *TransUnion LLC v. Ramirez*, 594 U.S. 413, 423 (2021). *First*, the company has been injured by being forced to participate in an unfair "negotiation" process and faces imminent injury by being forced to provide access to its products at CMS-dictated prices (starting in 2026). *See* Appx116-117 ¶¶ 53-54, Appx119-121 ¶¶ 62-70; *Horne v. Dep't of Agric.*, 576 U.S. 350, 363 (2015) (the government deprives a company of property when it demands property in exchange for a price "set at the government's discretion"). *Second*, Novo Nordisk has incurred and will continue to incur significant costs in being forced to turn over highly sensitive, confidential trade secret and commercial information to CMS. *See* Appx118-119 ¶¶ 61, 63; 42 U.S.C. §§ 1320f(d)(5)(A), 1320f-2(a)(4), 1320f-3(b)(2)(A); *TransUnion*, 594 U.S. at 425 (monetary injury is a "concrete injury in fact under Article III."); *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1003-04 (1984) (trade-secret information is property). *Third*, Novo Nordisk faces an ongoing violation of its constitutional

rights. *See* Appx86-92; *Spokeo, Inc. v. Robins*, 578 U.S. 330, 340 (2016) (injuries to constitutional rights satisfy the Article III injury-in-fact requirement). *Fourth*, Novo Nordisk faces imminent injury if it tries to withdraw *all of its products* from Medicare and Medicaid, either by being saddled with a massive excise-tax penalty or by losing access to some 60 million Medicare and Medicaid patients, many of whom depend on its life-saving products. *See* Appx119-120 ¶¶ 64-67; 26 U.S.C. § 5000D(b)(1)-(4), (c); 42 U.S.C. §§ 1396r-8(a)(1), 1395w-114a(b)(4)(B)(ii), 1395w-114c(b)(4)(B)(ii); *California v. Texas*, 593 U.S. 659, 670 (2021) (standing exists when injury "is the result of a statute's actual or threatened enforcement, whether today or in the future").

In briefing below, CMS urged the district court to limit the *scope* of relief, arguing in a footnote that "[t]o the extent Novo [Nordisk] asks [the court] to set aside the selection of *other* companies' drugs for negotiation, that relief is overbroad and unnecessary to remedy the injuries Novo alleges to suffer." Dkt. 37-1 at 14 n.3. That position reflects what Justice Kavanaugh recently criticized as a novel, "far-reaching argument that the APA does not allow vacatur." *Corner Post, Inc. v. Bd. of Fed. Rsrv. Sys.*, 144 S. Ct. 2440, 2460-61 (2024) (Kavanaugh, J., concurring). The

district court transformed CMS's footnote into the lynchpin of its analysis. According to the court, Novo Nordisk "failed to demonstrate the standing required for [its] final statutory challenge" because the relief it seeks might also benefit third parties. *See* Appx11.

That decision is wrong. Novo Nordisk sought a declaratory judgment that its products had been "improperly aggregated" and were "not properly subject to price controls," and it asked the court to enjoin "CMS from applying price controls to any of [Novo Nordisk's] products that are improperly aggregated." Appx99 (Prayer for Relief) ¶¶ C-I. So even if the district court could not "set aside the selection of *other* companies' drugs," as CMS contended, Dkt. 37-1 at 14 n.3, the court could not avoid addressing CMS's unlawful actions against Novo Nordisk.

Moreover, how a court decides to craft an appropriate remedy has no bearing on a plaintiff's standing to seek relief in the first place. *See Lewis v. Casey*, 518 U.S. 343, 358-60 & n.7 (1996) (the Court's "holding regarding the inappropriateness of systemwide relief … does not rest upon the application of standing rules"). The very case on which the district court relied confirms as much. *See* Appx11. In *Friends of the Earth*, the Supreme Court rejected a form of the position adopted by the

district court, holding that plaintiffs had standing to seek civil penalties even though the penalties were paid to a third party—the government. 528 U.S. at 185-86. Relief need not be narrowly tailored to affect only the plaintiff. *Id.* Under the APA, "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." 5 U.S.C. § 702. Because Novo Nordisk is undeniably aggrieved by CMS's unlawful actions, Novo Nordisk has standing to sue.

In addition to reversing the district court's standing ruling, this Court should resolve the merits of Novo Nordisk's statutory claim. That claim presents a clear question of law, which this Court reviews de novo. *See Paredes v. Attorney General*, 528 F.3d 196, 198 (3d Cir. 2008). And prudential concerns weigh decisively in favor of settling the issues in this appeal. *See Jerri v. Harran*, 625 F. App'x 574, 579 (3d Cir. 2015) (addressing whether it was "prudent to remand"). CMS's unlawful interpretation has already injured and will continue to injure Novo Nordisk, and a merits decision would conserve resources as any future ruling from the district court on remand would inevitably be challenged

on appeal. There is accordingly no benefit in waiting to address the merits.

B. CMS Has Violated the IRA's Guidance-Only Mandate.

CMS admits that in implementing the IRA's price-control provisions, it has imposed sweeping new requirements—substantive rules—that it deems binding. That violates the statute's command that CMS "shall implement [the statute's price controls] for 2026, 2027, and 2028, by program instruction or other forms of program guidance." 42 U.S.C. § 1320f note; *see Kingdomware Techs., Inc. v. United States*, 579 U.S. 162, 172 (2016) (noting that "shall" usually "imposes a mandatory duty"). It also violates the APA and Medicare Act because CMS has not followed the notice-and-comment procedures (followed by judicial review) that are required when an agency exercises rulemaking powers. CMS instead contends that by directing the agency to proceed by guidance, Congress sub silentio eliminated those requirements and freed the agency to make new law on an ad hoc basis. *See Morton v. Ruiz*, 415 U.S. 199, 232 (1974) (discussing the "inherently arbitrary nature" of ad hoc agency determinations).

CMS's position is untenable, violating both the statute and the Constitution. When Congress enacted the IRA, it sought to contain the risks that price controls could pose to innovation and the well-being of the nation's healthcare system. Effectively instructing CMS to start modestly and hew closely to the statute, Congress directed CMS to proceed by guidance—not rulemaking—for the first three years. The terms "guidance" and "program instruction" are synonymous with *non-binding* interpretive rules and statements of policy. *See Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96-97 (2015) (interpretive rules and policy statements "do not have the force and effect of law"); *see also Kisor v. Wilkie*, 588 U.S. 558, 583 (2019); *cf.* Ronald M. Levin, *Rulemaking and the Guidance Exemption*, 70 Admin. L. Rev. 263, 266 (2018) ("The essence of the distinction is that legislative rules have the force of law and guidance does not."). As explained by the Administrative Conference, "policy statements and interpretive rules are exempt from the APA's requirements for the issuance of legislative rules (including notice and comment) and are often referred to as 'guidance' or 'guidance documents' (although usage varies)." Admin. Conf. of the U.S., Recommendation

2017-5, Agency Guidance Through Policy Statements, 82 Fed. Reg. 61,728, 61,734 (Dec. 29, 2017) (footnote omitted).

CMS conceded before the district court that the document it labels "guidance" imposes new substantive requirements that carry the force and effect of law. Dkt. 37-1 at 29-34; *see also* Appx176-179 (standardized agreement requiring Novo Nordisk to comply with current and future guidance). The imposition of these substantive requirements exceeds CMS's statutory authority. No alchemy can transform Congress's instruction to proceed by "guidance" into authorization to engage in legislative rulemaking. In any event, even if Congress had not included its guidance-only mandate, the agency has not complied with the notice-and-comment and judicial-review requirements of the APA and Medicare Act, or even identified any alternative constitutionally adequate procedures that apply. *See* Dkt. 37-1 at 29-30; *see also* 5 U.S.C. § 553(b), (c); *see also* 42 U.S.C. § 1395hh(a)(2); *SBC Inc. v. FCC*, 414 F.3d 486, 495, 497 (3d Cir. 2005) (legislative rules are "subject to the notice and comment requirements" because they "create new law, rights, or duties"); *see also Azar v. Allina Health Servs.*, 587 U.S. 566, 568 (2019) (when an

agency establishes a "substantive legal standard" affecting Medicare, it must satisfy notice-and-comment obligations).

CMS contends that Congress should be assumed to have "authorize[d] CMS to promulgate substantive standards *without* observing [the APA's] procedures" because it would otherwise be too difficult to implement the statute. Dkt. 37-1 at 30-32; *but see Asiana Airlines v. FAA*, 134 F.3d 393, 398 (D.C. Cir. 1998) ("[s]tatutory language imposing strict deadlines, standing alone, does not" justify "departure from standard notice and comment"). But CMS has never identified *any case* holding that mere "guidance" may be used to make new law without complying with notice-and-comment procedures. If CMS were correct, it would overthrow decades of settled precedent. *See Ruiz*, 415 U.S. at 232 (an agency's power to "make rules that affect substantial individual rights and obligations carries with it the responsibility not only to remain consistent with the governing legislation, but also to employ procedures that conform to the law" (citations omitted)). In 1946, Congress enacted the APA as "the culmination of a comprehensive rethinking of the place of administrative agencies in a regime of separate and divided powers." *Loper*, 144 S. Ct. at 2261. Under the APA's "formula," agencies are

permitted to exercise rulemaking powers but only if they comply with the APA's essential procedural requirements and subject their rules to judicial review, which is necessary to ensure lawful, transparent, and accountable government. *See* 5 U.S.C. § 553.

CMS's assertion that it can create new law through guidance and in its unreviewable discretion eviscerates essential safeguards necessary to prevent agencies from imposing their "unchecked will." *United States v. Brown*, 381 U.S. 437, 443 (1965); *see also* The Federalist No. 47 (James Madison) ("the very definition of tyranny"). Congress cannot have authorized such a sweeping—and constitutionally problematic—expansion in regulatory power merely by directing CMS to proceed by "program guidance" until 2029. By ignoring that mandate and issuing binding substantive standards, CMS has violated the IRA, the APA, and the Medicare statute.

C. No Judicial Review Bars Apply.

Before the district court, CMS asserted that Novo Nordisk's statutory argument—challenging CMS's violation of the statute's 10-product limit—is precluded by the IRA's judicial review bars. The district court effectively rejected that argument, recognizing that the "ten-

product limit" in the statute "is not exempted from judicial review by the IRA." Appx10. Novo Nordisk's challenge does not fall within the scope of any review bar, and CMS's attempt to expand its price-control regulations beyond what Congress permitted is ultra vires. *See Advanced Disposal Servs. E., Inc. v. NLRB*, 820 F.3d 592, 600 (3d Cir. 2016) (rejecting suggestion that ultra vires actions can be "insulated from judicial review").

The statutory provision that includes the 10-product limit—set forth in section 1320f-1(a)(1)—is not subject to any judicial review bar. The statute bars review of only certain determinations made by CMS under subsections (b) and (d)–(f). *See id.* 42 U.S.C. § 1320f-7. Because the judicial review bars do not expressly cover subsection (a), there is no impediment to considering CMS's statutory violation. "[A]rguments against judicial review cannot override the text of the statute." *Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724, 734 (2022).

The government has argued that the review bars should be interpreted broadly to sweep in subsection (a), but that is contrary to the strong presumption in favor of "judicial review of administrative action." *Kucana v. Holder*, 558 U.S. 233, 251-52 (2010); *see also E.O.H.C. v. Sec'y*,

U.S. Dep't of Homeland Sec., 950 F.3d 177, 184 (3d Cir. 2020). Because "Congress legislates with knowledge of the presumption," only "clear and convincing evidence" is sufficient to "dislodge" it. *Kucana*, 558 U.S. at 252; *Mach Mining, LLC v. EEOC*, 575 U.S. 480, 486 (2015) (noting the government's "heavy burden"). There is no "clear and convincing evidence" that Congress granted CMS unreviewable authority to impose price controls on aggregated groupings of products. Just the opposite. The 10-product limit is essential to Congress's judgment that price controls should be imposed incrementally and not all at once. That should end the government's argument.

Moreover, CMS's statutory authority to "determine" which products should be exempt or excluded from Congress's definitions of "negotiation-eligible drugs" and "qualifying single source drugs" does not grant the agency broader authority to override the statute's mandated definitions. Congress dictated the outer bounds of products subject to price controls and granted CMS authority to limit, not expand, the universe of products falling within Congress's definitions. When Congress authorizes an agency to exercise definitional authority, it does so in clear and unequivocal terms. *See, e.g.*, 42 U.S.C. § 18022(b)(1) (instructing that

"the Secretary shall define the essential health benefits"); *id.* § 1395w-141(f)(1)(B) (directing that "the Secretary shall define the terms 'income' and 'family size'"). The IRA's judicial-review bars apply only to block review of the discretionary *determinations* the Secretary is permitted to make "under" each provision. For example, the statute directs that in identifying which single-source drugs qualify for price controls CMS may *exclude* certain "low spend Medicare" products "as *determined* by the Secretary," 42 U.S.C. § 1320f-1(e)(3)(B) (emphasis added). Similarly, section 1320f-1(d) grants CMS discretion—"as *determined* by the Secretary"—to create *exceptions* for small biotech products, *id.* § 1320f-1(d)(2)(i), (ii) (emphasis added). Those "*determinations*" are both protected from judicial review. *Id.* § 1320f-7(2).

Nothing in the statute suggests that Congress intended to grant CMS unreviewable authority to change the definitional parameters within which CMS's determinations must be made. *See Am. Clinical Lab'y Ass'n v. Azar*, 931 F.3d 1195, 1204 (D.C. Cir. 2019) ("Even where … a statutory provision expressly prohibits judicial review, the presumption applies to dictate that such a provision be read narrowly."). To the contrary, the statute's text mirrors common sense: When a statute

includes mandates within which an agency is instructed to make certain determinations, Congress's decision to preclude review of the agency's determinations does not bar judicial review when the agency violates the mandates that Congress imposed. *See Amgen, Inc. v. Smith*, 357 F.3d 103, 113 (D.C. Cir. 2004) (noting risk that "agencies could characterize … unauthorized action as falling within the scope of a no-review provision").

Accepting CMS's position—that it can rewrite the statute and regulate the prices of any number of drugs it chooses—would obviously violate the Constitution. *See SEC v. Jarkesy*, 144 S. Ct. 2117, 2132 (2024) (explaining that "matters concerning private rights may not be removed from Article III courts"). As the Supreme Court has explained, agencies' power to act is "authoritatively prescribed by Congress" and, therefore, when they act "beyond their jurisdiction, what they do is ultra vires." *City of Arlington v. FCC*, 569 U.S. 290, 297 (2013); *see also 1621 Route 22 W. Operating Co. v. NLRB*, 825 F.3d 128, 140 (3d Cir. 2016). An agency engages in ultra vires conduct when it has "disregarded a specific and unambiguous statutory directive," violated a "specific command," or patently misconstrued a statute. *Griffith v. Fed. Lab. Rels. Auth.*, 842

F.2d 487, 493 (D.C. Cir. 1988). Ultra vires decisions can and must be corrected by a court of law.

II. As Implemented and Applied by CMS, the IRA's Price-Control Provisions Are Unconstitutional.

CMS's statutory rewrites, and its claim of unchecked rulemaking authority, render fatal the pervasive constitutional infirmities that infect the IRA. By stripping away multiple layers of constitutional safeguards, the IRA goes far beyond any price-control statute ever upheld against constitutional challenge. *See Seila Law LLC v. CFPB*, 591 U.S. 197, 215, 221-23 (2020) (rejecting novel statutory scheme relaxing constitutional requirements on multiple dimensions).

This Court need not decide in this case, however, whether some ultra-aggressive, but still permissible, construction could in theory save the statute from *facial* invalidity. While Novo Nordisk preserves its facial challenge for purposes of any remand proceedings, it asserts for purposes of this appeal the invalidity of the statute as interpreted and applied by CMS. Accordingly, in order to resolve this case, the Court need only address the statute's *as-applied* invalidity. As explained below, the statute's price-control provisions, as interpreted and applied by CMS, violate the Constitution's due-process and separation-of-powers

requirements and also contravene the First Amendment and its protections against compelled speech.

A. The IRA's Price-Control Provisions Violate Due Process and Separation of Powers.

1. The Constitution's structural requirements safeguard private rights from impermissible encroachment and also protect the public interest by ensuring that the government remains accountable to the will of the People. *See Free Enter.*, 561 U.S. at 496; *Seila Law*, 591 U.S. at 222-23. *see also* The Federalist Nos. 48, 51 (James Madison). Applying these well-settled principles, the Supreme Court has held that when Congress delegates authority to an agency, it must "lay down by legislative act an intelligible principle to which" the agency "is directed to conform." *Panama Refining Co. v. Ryan*, 293 U.S. 388, 429-30 (1935); *see also Marshall Field & Co. v. Clark*, 143 U.S. 649, 692 (1892). Congress must further "enjoin upon [the agency] a certain course of procedure and certain rules of decision in the performance of its function." *Wichita R. & Light Co. v. Pub. Utils. Comm'n*, 260 U.S. 48, 59 (1922). As a "fundamental requirement of due process," regulated parties must be afforded an "opportunity to be heard," *Matthews v. Eldridge*, 424 U.S. 319, 333 (1976), before a "neutral and detached" decisionmaker,

Concrete Pipe & Prods. of Cal., Inc. v. Constr. Laborers Pension Tr., 508 U.S. 602, 617-18 (1993); *see also Frein v. Pa. State Police,* 47 F.4th 247, 257 (3d Cir. 2022) ("The core of due process is an opportunity to be heard at a meaningful time and in a meaningful manner"). And adequate judicial review is required to avoid "arbitrary deprivations of liberty or property." *Honda Motor Co. v. Oberg*, 512 U.S. 415, 434 (1994).

These principles apply with particular force in the context of government-imposed price controls. *See Yakus v. United States*, 321 U.S. 414, 435 (1944) (there must be a "statutory procedure that is capable of affording due process"); *see also FPC v. Nat. Gas Pipeline Co.*, 315 U.S. 575, 586 (1942) (courts should not intervene to change prices "[o]nce a fair hearing has been given" and as long as agencies act "within the ambit of their statutory authority"). Adequate procedures are paramount to ensuring proper accountability: If government-imposed prices are arbitrary, discriminatory, or too low, property owners will suffer constitutional harm and the public will face shortages and a lack of innovation. Courts have thus struck down legislative schemes that lack procedures to "adequately safeguard[] against confiscatory rates, and therefore, ensure[] a constitutional rate of return." *Mich. Bell Tel. Co. v.*

Engler, 257 F.3d 587, 594-96 (6th Cir. 2001); *Guar. Nat'l Ins. Co. v. Gates*, 916 F.2d 508, 512 (9th Cir. 1990) (invalidating law freezing prices because it provided no "mechanism to guarantee a constitutionally required fair and reasonable return").

2. CMS's price-control scheme interferes with Novo Nordisk's private rights. Novo Nordisk has a property interest in the valuable proprietary information that CMS has forced it to turn over. *See Axon Enter., Inc. v. FTC*, 598 U.S. 175, 204 (2023) (Thomas, J., concurring) (explaining that forced "transfer[s] of intellectual property … implicate the core private right to property"). Novo Nordisk also has a right to "possess, use and dispose" of the products CMS seeks to regulate, *Horne*, 576 U.S. at 361-62, as well as the right to determine who has the "right of access" to them, *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 161 (2021). And it has a right to sell its products at prices that allow for a reasonable return on investment. *See Duquesne Light Co. v. Barasch*, 488 U.S. 299, 310 (1989) (a "fair rate of return"); *Old Dearborn Distrib. Co. v. Seagram-Distillers Corp.*, 299 U.S. 183, 192 (1936) (property owners have a "right … to fix the price at which [they] will sell" their products).

3. The IRA's price-control scheme, as applied by CMS, invades these rights and provides no procedural protections against arbitrary, discriminatory, or confiscatory pricing. *See In re Permian Basin Area Rate Cases*, 390 U.S. 747, 769-70 (1968) (price controls are "unconstitutional" if they are arbitrary, discriminatory, or confiscatory). There is no notice-and-comment rulemaking; no hearing on the selection of drugs; no hearing on the price CMS imposes; no neutral adjudicator to ensure that prices are fair and applied in a non-discriminatory fashion; no administrative review of CMS's unilateral decisions; and no judicial review of them either. Where, as here, the statute as interpreted by CMS "provides no process whatsoever," there is a "glaring" constitutional problem. *Schepers v. Comm'r, Ind. Dep't of Corr.*, 691 F.3d 909, 915 (7th Cir. 2012); *see also Nat'l Infusion Ctr. Ass'n v. Becerra*, 116 F.4th 488, 503 (5th Cir. 2024) (plaintiff challenging the IRA had adequately "allege[d] a due process violation based on its lack of opportunity to weigh in on the front end or the back end of a process that substantially affects its … business").

The IRA also provides no limit on CMS's discretion to choose a price as low as it wishes—regardless of whether the dictated price allows for a

reasonable return on investment. The statute sets a ceiling but no floor. 42 U.S.C. § 1320f-3(c)(1)(C), (b)(2)(F). CMS's marching orders are to "ai[m] to achieve the lowest maximum fair price for each selected drug." 42 U.S.C. § 1320f-3(b)(1). But how should CMS choose the lowest price that is also the maximum price and fair? No one knows. In CMS's own words, the statutory "factors" it must consider do not specify "how" the agency should determine what price to impose or "to what degree each factor should be considered." Guidance § 60.3. And the statute defines "maximum fair price" in circular fashion to mean whatever price CMS chooses. *See* 42 U.S.C. § 1320f(c)(3); *see also Panama Refining*, 293 U.S. at 417-18 (invalidating statute that contained only a "general outline of policy" and lacked any "standard or rule"); *see also A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 530, 532-33, 541-42 (1935) (striking down statute with "general aims" but no "standards of legal obligation" to cabin executive action).

The lack of any intelligible principle to constrain CMS's price-setting is made worse by the provision barring judicial review of CMS's "determination of a maximum fair price." 42 U.S.C. § 1320f-7. "Judicial review is the usual vehicle by which executive action is tested to insure

that the will of Congress has been obeyed." *United States v. Touby*, 909 F.2d 759, 768 (3d Cir. 1990). So "[t]he availability of judicial review at some appropriate time insures that the discretion of the executive officer to whom power has been delegated cannot be exercised in an unbridled manner." *Id.*; *see also Corner Post*, 144 S. Ct. at 2463 (Kavanaugh, J., concurring) (noting "basic presumption of judicial review" for parties "adversely affected or aggrieved" by agency action). Moreover, judicial review allows a court to "define the scope of delegated authority" and apply a narrowing construction to avoid "fac[ing] a nondelegation question." *Gundy v. United States*, 588 U.S. 128, 136, 141 (2019) (Kagan, J.). Without judicial review, a court cannot impose substantive standards or hold an agency accountable to them. The agency's interpretation (or misinterpretation) is final.

The district court asserted that "the preclusion of judicial review is not related to the nondelegation doctrine." Appx21. That overlooks the Supreme Court's instruction "to review separation-of-powers challenges holistically." *Consumers' Rsch. v. FCC*, 109 F.4th 743, 778 (5th Cir. 2024) (discussing Supreme Court precedent). It also conflicts with binding precedent. *See Yakus*, 321 U.S. at 426 (standards must be "sufficiently

definite and precise to enable Congress, *the courts* and the public to ascertain" whether agency "has conformed to those standards" (emphasis added)). Statutes are invalid when they confer "virtually unfettered" discretion on agencies, and judicial review is important to ensure "that the action of the [executive] is taken within its statutory authority." *Schechter*, 295 U.S. at 532-33, 542; *see also United States v. Garfinkel*, 29 F.3d 451, 459 (8th Cir. 1994) (citing "[j]udicial review" and "notice and comment rulemaking" as relevant factors in evaluating separation-of-powers challenge).

4. CMS has identified no price-control regime that resembles the IRA. No other regime has ever been applied to strip away so many front-end protections—with no procedures or standards to constrain the agency—while also eliminating essential back-end protections—with no judicial review to safeguard private rights and the public interest. This lack of "historical precedent" is a "telling indication of a severe constitutional problem." *Free Enter.*, 561 U.S. at 505.

Consider government rate-setting in the context of energy transmission services. Congress created a floor—rates must be "just and reasonable"—and statutory procedures apply to cabin the government's

price-setting authority. 16 U.S.C. §§ 824d, 824e, 825*l*. Judicial review is also available to ensure that the government complies with due process, the statutory standard, and the procedural requirements of both the governing statute and the APA. *See* 15 U.S.C. § 717r; 16 U.S.C. § 825*l*. Similarly, when Congress regulated coal prices in the 1930s, it required that any government-fixed "maximum price" must "yield a fair return on the fair value of the property." *Sunshine Anthracite Coal Co. v. Adkins*, 310 U.S. 381, 397 (1940). The regulatory scheme involved "public hearing[s]" and judicial review to assess whether agency decisions were "based on substantial evidence." *Id.* at 390-91.

Even statutes enacted during wartime contained more protections. For example, Congress enacted the Emergency Price Control Act of 1942 to "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 directed an Administrator to set "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 certain levels. Emergency Price Control Act of 1942 ("EPCA"), Pub. L. No. 77-421, § 2(a), 56 Stat. 23, 24. Even this "war emergency measure,"

Adamo Wrecking Co. v. United States, 434 U.S. 275, 290 (1978) (Powell, J., concurring), provided for judicial review of "all questions of law, including … whether the Administrator's determination is supported by evidence." *Yakus*, 321 U.S. at 437. It included a process for an "administrative hearing." *Id.* at 436. And it provided standards to govern the agency's price-setting decisions, requiring that they be "fair and equitable" and "effectuate [the statute's] purposes." EPCA § 2(a).

As interpreted and applied by CMS, the IRA contains none of these protections. The statute gives CMS unfettered discretion to set as low a price as it chooses, with no procedures, standards, hearings, or judicial review.

B. The IRA's Price Setting Scheme Is Not Voluntary.

Lacking any merits defense, CMS argued below that the IRA escapes constitutional scrutiny because participation is purportedly "voluntary." That position is meritless, as it conflicts with the IRA's text, ignores that CMS is exercising coercive regulatory powers, and flouts Supreme Court precedent.

Parties cannot accept structural constitutional violations "by consent." *Commodity Futures Trading Comm'n v. Schor*, 478 U.S. 833,

850-51 (1986); *see also Stern v. Marshall*, 564 U.S. 462, 483 (2011). The Constitution is designed to protect private rights against government self-dealing and to ensure that agencies act in accordance with Congress's legislative judgments, which in the case of price controls requires balancing the benefits of lower prices with the costs of product shortages and undermining innovation. Accordingly, even if the IRA's price controls and participation in Medicare were "voluntary," the statute as interpreted by CMS would still be invalid because it lacks procedures necessary to ensure that CMS acts within the scope of its delegated authority and within constitutional bounds. *See Bowles v. Willingham*, 321 U.S. 503, 513-14 & n.9 (1944) (concluding that "voluntary" rent control program had to satisfy due process).

Moreover, the statutory scheme is *coercive*. CMS is not acting as a mere market participant; it is exercising sovereign *regulatory* powers to dictate the prices at which manufacturers provide access to their products. CMS has conceded that its "guidance" imposes binding substantive requirements on manufacturers that go beyond the statute. And the statute requires manufacturers to submit to CMS's demands or

pay an enterprise-threatening penalty. *See* 26 U.S.C. § 5000D; 42 U.S.C. § 1320f-6; *see also* Dkt. 37-1 at 37.

The Supreme Court has held that actions taken under threat of taxes or fines are not voluntary. The government cannot "impose an unconstitutional burden by the threat of penalties worse than [that burden] in case of a failure to accept it, and then [ ] declare the acceptance voluntary." *Union Pac. R.R. v. Pub. Serv. Comm'n*, 248 U.S. 67, 70 (1918); *see also United States v. Butler*, 297 U.S. 1, 70-71 (1936) (the "asserted power of choice is illusory" when Congress uses "coercion by economic pressure"). For example, in *Carter v. Carter Coal Co.*, the Court held that an "agreement" to participate in a regulatory program "lack[ed] the essential element of consent" because it threatened substantial taxes for noncompliance. 298 U.S. 238, 289 (1936); *see also Thompson v. Deal*, 92 F.2d 478, 484 (D.C. Cir. 1937). The Court has also rejected the argument that constitutional constraints disappear when private parties can avoid regulation by exiting the market and not selling their products. *See Horne,* 576 U.S. at 365 (rejecting argument that raisin growers could avoid a taking by not selling their raisins).

CMS argues that its regulatory workaround renders the program voluntary. *See* Dkt. 37-1 at 38-41. CMS has purported to give manufacturers three "options": (1) pay a massive penalty; (2) stop selling the selected product(s) in all markets and channels; or (3) have *all* of their products expelled from Medicare and Medicaid, which cover some 60 million patients. Dkt. 37-1 at 37; *see also* Guidance 33-34, §§ 40.1, 40.6. CMS contends that the third option solves the constitutional problem because "participation in Medicare is voluntary." Dkt. 37-1 at 34-35.

But the Supreme Court has been clear that executive agencies may not threaten to withhold access to government benefits as a mechanism to achieve "a result which [the government] could not command directly." *Speiser v. Randall*, 357 U.S. 513, 526 (1958); *Frost v. R.R. Comm'n*, 271 U.S. 583, 593-94 (1926) ("inconceivable" that the Constitution's "guarantees" could be "manipulated out of existence"); *see also Koslow v. Pennsylvania*, 302 F.3d 161, 174 (3d Cir. 2002) (noting that "government incentives may be inherently coercive"). The Court has "repeatedly rejected the argument that if the government need not confer a benefit at all, it can withhold the benefit because someone refuses to give up constitutional rights." *Koontz v. St. Johns River Water Mgmt. Dist.*, 570

U.S. 595, 608 (2013) (collecting cases); *see also United States v. Am. Library Ass'n*, 539 U.S. 194, 210 (2003). When Congress requires the surrender of constitutional rights, there must be a reasonable connection and proportionality between the benefit provided and the rights relinquished. *See Koontz*, 570 U.S. at 612; *see also Sheetz v. County of El Dorado*, 601 U.S. 267, 275 (2024) (conditioning benefits on unrelated deprivations of constitutional rights amounts "to an out-and-out plan of extortion").

In *National Federation of Independent Business v. Sebelius (NFIB)*, 567 U.S. 519, 578, 581, 587 (2012), the Supreme Court concluded that forcing an entity to either accept new regulatory conditions or withdraw from Medicaid was not a voluntary choice. There, Congress pressured States to accept a Medicaid expansion by threatening the withdrawal of Medicaid funding. Although the Medicaid expansion may have been "in form voluntary," *Frost*, 271 U.S. at 593, the Court held that "[t]he threatened loss of over 10 percent of a State's overall budget … is economic dragooning that leaves the States with no real option but to acquiesce in the Medicaid expansion," *NFIB*, 567 U.S. at 582. That financial threat was "a gun to the head." *Id.* at 581. And while Congress

"styled" the expansion as part of Medicaid, it was effectively a "new health care program" because states "could hardly anticipate" that Congress would "transform" Medicaid so "dramatically." *Id.* at 584-85.

The same is true here. Congress is pressuring manufacturers to "agree" to CMS-dictated prices by threatening to kick manufacturers and all of their products out of Medicare and Medicaid. That "choice" is illusory. *See id.* at 581-82, 587. If anything, the IRA involves greater "economic dragooning." *Id.* at 582. Whereas federal Medicaid funding comprised 10% of the States' budgets in *NFIB*, the Medicaid and Medicare markets account for nearly *half* of all prescription drug sales in the United States. *See Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 699 (3d Cir. 2023). If States, with all their resources, are vulnerable to financial coercion, private entities are even more vulnerable to the "ruinous" "loss of federal funds." *Doe v. Univ. of Scis.,* 961 F.3d 203, 213 (3d Cir. 2020). Confirming just that, the Fifth Circuit recently held that a plaintiff alleged a due-process violation with respect to the IRA's drug-pricing scheme, rejecting the dissent's view that the scheme should be deemed voluntary. *See Nat'l Infusion*, 116 F.4th at 500 (noting that "economic rationality" and statutory "penalties" make it "all but certain"

manufacturers will be forced to comply); *see also id.* at 513-14 (Ramirez, J., dissenting).

Nor can CMS justify its actions by pretending it is exercising procurement authority as only a market participant. The flexibility the government may have when procuring products for itself does not exist when it exercises sovereign regulatory powers. *See S.-Cent. Timber Dev., Inc. v. Wunnicke*, 467 U.S. 82, 98 (1984) (a state cannot leverage its role as a market participant to evade constitutional limits on its regulatory powers); *Keystone Chapter, Associated Builders & Contractors, Inc. v. Foley*, 37 F.3d 945, 955 n. 15 (3d Cir. 1994) (state not a "market participant" when acting with an "interest in setting policy"); *see also Cardinal Towing & Auto Repair, Inc. v. City of Bedford*, 180 F.3d 686, 691 (5th Cir. 1999) (state not a mere market participant when exercising powers "tantamount to regulation").

The government has a choice: it can either (1) act like a market participant and purchase products for itself at whatever price the market allows or (2) exercise regulatory powers and comply with the Constitution's commands. What it cannot do is exercise regulatory powers to "dominate" the market and unilaterally set prices. *Sanofi*

Aventis, 58 F.4th at 699. No ordinary market participant could lawfully engage in the sort of action that the government has taken here.

The cases on which CMS has relied—*Garelick v. Sullivan*, 987 F.2d 919 (2d Cir. 1993), and *Baker County Medical Services, Inc. v. U.S. Attorney General*, 763 F.3d 1274 (11th Cir. 2014)—are readily distinguished. They rejected regulatory takings claims on the theory that price regulation does not give rise to a taking "where the regulated group is not required to participate in the regulated industry." *Garelick*, 987 F.2d at 917; *Baker*, 763 F.3d at 1276. That theory has since been rejected by the Supreme Court. *See Horne*, 576 U.S. at 365. Moreover, none of CMS's cases address the government action present here—where participation was *coerced* by an enterprise-crippling penalty, the government has taken over the entire market, the government has exercised regulatory powers beyond those of an ordinary market participant, no due process protections were followed, no standards constrain the agency's price-setting decisions, and the statute bars administrative or judicial review.

The Constitution would be meaningless if agencies could take over the nation's interstate markets and make access to those markets depend

on forfeiting constitutional rights. *See U.S. Term Limits, Inc. v. Thornton*, 514 U.S. 779, 829 (1995) ("[t]he Constitution 'nullifies sophisticated as well as simpleminded modes' of infringing on constitutional protections" (quoting *Lane v. Wilson*, 307 U.S. 268, 275 (1939))). If CMS were correct, there would be no limit on the rights the government could force parties to forsake as a condition of participating in Medicare and Medicaid. *Cf. Trinity Lutheran Church of Columbia, Inc v. Comer*, 582 U.S. 449, 466 (2017). The government could also manipulate any market—for any product sold in interstate commerce—by positioning itself as an intermediary and setting prices free of constitutional constraint. That cannot be the law.

C. The IRA's Compelled-Speech Requirements Confirm That The Scheme Is Unconstitutional.

The conclusion that the IRA is unconstitutional and coercive is confirmed by its gratuitous compelled-speech requirement. The statute requires manufacturers to say in writing that they "agree" that the price imposed by CMS is the "maximum fair" price. 42 U.S.C. § 1320f-2(a). That requirement would be unnecessary if participation were voluntary. *See Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc.*, 570 U.S. 205, 218 (2013) (holding that Congress may not use funding conditions to express

"the Government's view on an issue of public concern"). Forcing manufacturers to express the government's preferred viewpoint is unconstitutional. *See Wooley v. Maynard*, 430 U.S. 705, 717 (1977).

The district court concluded that the IRA's compelled-speech requirements "regulate[] conduct, not speech" and are "merely incidental mechanisms used during the price-setting process." Appx13. That mischaracterizes how the price-setting process operates. An "involuntary affirmation of objected-to beliefs" is a textbook example of unconstitutionally compelled speech. *Janus v. Am. Fed'n of State, Cnty., & Mun. Emps., Council 31*, 585 U.S. 878, 893 (2018); *see also Fulton v. City of Philadelphia*, 593 U.S. 522, 540 (2021) (contractual requirement imposed a burden on free exercise). Nor has CMS ever identified any valid reason to force manufacturers to say anything about the prices it imposes. *Cf. Sorrell v. IMS Health Inc.*, 564 U.S. 552, 567 (2011) (noting that "an ordinance against outdoor fires might forbid burning a flag" which would be an incidental speech restriction). The only apparent reason is to blur lines of accountability by deceiving the public into believing that prices are "fair" and decided by "agreement" when in fact they are imposed unilaterally and by decree.

Because the IRA compels speech, it must be narrowly tailored to serve a compelling governmental interest. *Nat'l Inst. of Fam. & Life Advocs. v. Becerra*, 585 U.S. 755, 766 (2018). The government here has no valid interest in forcing Novo Nordisk to serve as a "courier" for its preferred viewpoint or preventing open debate about the prices CMS dictates. *Wooley*, 430 U.S. at 717. Compelling speech is not necessary to set drug prices, and much less burdensome alternatives "are obvious." *U.S.W., Inc. v. FCC*, 182 F.3d 1224, 1238 (10th Cir. 1999).

* * *

Nothing prevents Congress from lawfully regulating prices or empowering CMS to negotiate as a market participant. But CMS cannot rewrite statutes or exempt itself from essential administrative law requirements. Nor can CMS be permitted to interpret a statute as granting it unconstrained power to force access to manufacturers' products at as low a price as it desires with no administrative process, no statutory standard, and no judicial review to ensure the agency acts lawfully and within constitutional bounds.

CONCLUSION

The Court should reverse the district court's decision and hold unlawful CMS's actions against Novo Nordisk.

Respectfully submitted,

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October 15, 2024

CERTIFICATE OF COMPLIANCE

1. Pursuant to Local Rule 28.3(d), I hereby certify that I, Ashley C. Parrish, counsel for Appellants, am a member in good standing of the bar of the United States Court of Appeals for the Third Circuit.

2. This brief complies with the type-volume requirements of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 12,871 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f).

3. The brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) and 3d Cir. L.A.R. 32.1(c) because it has been prepared in a proportionally spaced typeface using Microsoft Word 365 ProPlus in Century Schoolbook 14-point font.

4. Pursuant to Local Rule 31.1(c), I hereby certify that the text of the electronic brief is identical to the text in the paper copies, and that it has been scanned for viruses using McAfee Endpoint Security, Version 10.7.1, and no virus was detected.

Date: October 15, 2024

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CERTIFICATE OF SERVICE

I hereby certify that on October 15, 2024, I electronically filed the foregoing document with the Clerk of the Court for the United States Court of Appeals for the Third Circuit by using the CM/ECF system, thereby serving all registered counsel of record.

/s/Ashley C. Parrish
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No. 24-2510

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

NOVO NORDISK INC.;
NOVO NORDISK PHARMA, INC.,
Appellants,

v.

SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ADMINISTRATOR, CENTERS FOR MEDICARE & MEDICAID SERVICES; CENTERS FOR MEDICARE & MEDICAID SERVICES.

On Appeal from the United States District Court for the District of New Jersey, No. 3:23-cv-20814, Hon. Zahid N. Quraishi

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JOINT APPENDIX

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
Trenton

NOVO NORDISK INC., *et al.*, *Plaintiffs*, v. XAVIER BECERRA, *et al.*, *Defendants*.	No. 3:23-cv-20814-ZNQ-JBD

PLAINTIFFS' NOTICE OF APPEAL
TO THE U.S. COURT OF APPEALS FOR THE THIRD CIRCUIT

Notice is hereby given that Novo Nordisk Inc. and Novo Nordisk Pharma, Inc., Plaintiffs in the above-named case, hereby appeal to the United States Court of Appeals for the Third Circuit from the Order (ECF No. 94) of the United States District Court for the District of New Jersey entered in this case on July 31, 2024, and from all underlying and related findings, orders, decisions, rulings, and opinions, including but not limited to the Opinion (ECF No. 93) of the United States District Court for the District of New Jersey also entered in this case on July 31, 2024.

Dated: August 14, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on August 14, 2024, a true and correct copy of the foregoing Notice of Appeal was electronically filed with the Clerk of Court using the CM/ECF system which will send notification to all counsel of record.

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Counsel for Novo Nordisk Inc.
and Novo Nordisk Pharma, Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NOVO NORDISK INC., *et al.*, Plaintiffs, v. **XAVIER BECERRA, *et al.*,** Defendants.	Civil Action No. 23-20814 (ZNQ) (JBD) **ORDER**

QURAISHI, District Judge

THIS MATTER comes before the Court upon Cross-Motions for Summary Judgment. Plaintiffs Novo Nordisk Inc. and Novo Nordisk Pharma, Inc. (collectively, "Plaintiffs" or "Novo") filed a Motion for Summary Judgment. ("Plaintiffs' Motion", ECF No. 28.) Defendants Xavier Becerra, Chiquita Brooks-Lasure, U.S. Department of Health & Human Services ("HHS"), and Centers for Medicare & Medicaid Services ("CMS") (collectively, "Defendants") filed a Cross-Motion for Summary Judgment. ("Defendants' Cross-Motion", ECF No. 37.) For the reasons set forth in the accompanying Opinion,

IT IS on this **31st** day of **July 2024,**

ORDERED that Defendants' Cross-Motion (ECF No. 37) is hereby **GRANTED**; and it is further

ORDERED that Judgment is hereby entered for Defendants and against Plaintiffs as to all claims; and it is further

ORDERED that Plaintiffs' Motion (ECF No. 28) is hereby **DENIED**; and it is further

ORDERED that the Clerk is instructed to mark this matter **CLOSED**.

s/ Zahid N. Quraishi
ZAHID N. QURAISHI
UNITED STATES DISTRICT JUDGE

NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NOVO NORDISK INC., *et al.*, Plaintiffs, v. **XAVIER BECERRA, *et al.***, Defendants.	Civil Action No. 23-20814 (ZNQ) (JBD) **OPINION**

QURAISHI, District Judge

THIS MATTER comes before the Court upon Cross-Motions for Summary Judgment. Plaintiffs Novo Nordisk Inc. and Novo Nordisk Pharma, Inc. (collectively, "Plaintiffs") filed a Motion for Summary Judgment. ("Plaintiffs' Motion", ECF No. 28.) Plaintiffs filed a brief in support of their Motion. ("Plfs.' Moving Br.", ECF No. 28-1.) Defendants Xavier Becerra, Chiquita Brooks-Lasure, U.S. Department of Health & Human Services ("HHS"), and Centers for Medicare & Medicaid Services ("CMS") (collectively, "Defendants") filed a Cross-Motion for Summary Judgment. ("Defendants' Cross-Motion", ECF No. 37.) Defendants filed a combined brief in support of their Cross-Motion and in opposition to Plaintiffs' Motion. ("Defs.' Cross-Br.", ECF No. 37.1.) Plaintiffs then filed a combined brief in opposition to Defendants' Cross-Motion and reply in support of their Motion. ("Plfs.' Reply Br.", ECF No. 82.) Defendants waived their right to file a reply in support of their Cross-Motion and instead stand on the arguments made in

their prior filings and at oral argument, which the Court held on March 7, 2024 ("Oral Arg. Tr.", ECF No. 91).[1] (ECF No. 92.)

The Court has carefully considered the parties' submissions and oral argument.[2] For the reasons set forth below, the Court will GRANT Defendants' Cross-Motion and DENY Plaintiffs' Motion.

I. BACKGROUND AND PROCEDURAL HISTORY

This case is one of multiple challenges to the Drug Price Negotiation Program ("Program") created by the Inflation Reduction Act of 2022, Pub. L. No. 117-169 ("IRA"), filed across several federal district courts.[3] In addition to the present case, there are three other cases challenging the Program before the undersigned. *See Bristol Myers Squibb Co. v. Becerra*, Civ. No. 23-3335 (D.N.J.); *Janssen Pharms., Inc. v. Becerra*, Civ. No. 23-3818 (D.N.J.); *Novartis Pharms. Corp. v. Becerra*, Civ. No. 23-14221 (D.N.J.). On April 29, 2024, the Court issued an Opinion granting summary judgment in favor of Defendants Becerra, Brooks-Lasure, HHS, CMS, and Ananda V. Burra against Plaintiffs BMS and Janssen's Fifth Amendment Takings Clause claim, First Amendment Compelled Speech claim, and unconstitutional conditions doctrine claim. *BMS v. Becerra*, Civ. No. 23-3335, 2024 WL 1855054 (D.N.J. Apr. 29, 2024) [hereinafter *BMS-Janssen*]. Given the parties' familiarity with the IRA and the Program, the Court incorporates by reference

[1] Given the significant overlap between the present case and the three other cases challenging the Program before the undersigned, Defendants have extensively briefed their arguments across submissions made in this case, in the three other cases, and at oral argument.

[2] Several amicus briefs have also been filed. The amici include: Intellectual Property Law and Health Law Scholars, Center for American Progress, NAACP, UnidosUS Action Fund, The Century Foundation, AARP, AARP Foundation, Public Citizen, Patients for Affordable Drugs Now, Doctors for America, Protect Our Care, Families USA, American Public Health Association, American College of Physicians, Society of General Internal Medicine, American Geriatrics Society, American Society of Hematology, Nationally Recognized Healthcare and Medicare Experts, Economists and Scholars of Health Policy, Abrams Institute for Freedom of Expression, and Alliance for Aging Research.

[3] *See Dayton Area Chamber of Com. v. Becerra*, Civ. No. 23-156 (S.D. Ohio); *AstraZeneca Pharms. L.P. v. Becerra*, Civ. No. 23-931 (D. Del.); *Nat'l Infusion Ctr. Ass'n v. Becerra*, Civ. No. 23-707 (W.D. Tex.); *Boehringer Ingelheim Pharms., Inc. v. HHS*, Civ. No. 23-1103 (D. Conn.); *Merck & Co., Inc. v. Becerra*, Civ. No. 23-1615 (D.D.C.).

the background of this dispute as set forth in *BMS-Janssen* and provides the relevant procedural history as follows.

Plaintiffs initiated the present action by filing a Complaint on September 29, 2023. ("Compl.", ECF No. 1.) Plaintiffs Novo Nordisk Inc. and Novo Nordisk Pharma, Inc. are a part of Novo Nordisk, a global healthcare company and pharmaceutical manufacturer. (*Id.* ¶¶ 27–29.) Novo Nordisk Inc. is the U.S.-based affiliate of Novo Nordisk and it seeks to "defeat diabetes and other serious chronic disease, such as obesity, and rare blood and rare endocrine diseases." (*Id.* ¶ 27.) Novo Nordisk Pharma, Inc. "supplies unbranded biologic versions of Novo Nordisk insulin products." (*Id.* ¶ 28.) Among other medications, Plaintiffs manufacture NovoLog, NovoLog FlexPen, and NovoLog PenFill (collectively, the "NovoLog Products") and FIASP, FIASP Flextouch, and FIASP Penfill (collectively, the "FIASP Products"). (*Id.* ¶ 34.) On August 29, 2023, CMS aggregated the three NovoLog Products and the three FIASP Products as a single "selected drug" (hereinafter, "Novo's Selected Drug") subject to the first round of the Program. (*Id.* ¶ 42.)

Plaintiffs allege four claims in their Complaint. (*Id.* ¶¶ 152–94.) Counts I and II comprise of Plaintiffs' constitutional challenges to the IRA. In Count I, Plaintiffs allege that the IRA violates separation of powers ("Separation of Powers" claim) and the Fifth Amendment's Due Process Clause ("Due Process Clause" claim). (*Id.* ¶¶ 152–67.) In Count II, Plaintiffs allege that the IRA violates the First Amendment because the Program compels Plaintiffs' speech ("First Amendment claim"). (*Id.* ¶¶ 168–76.) Counts III and IV comprise of Plaintiffs' statutory challenges. In Count III, Plaintiffs allege that CMS violated the Administrative Procedure Act ("APA") and the Social Security Act by imposing new legal obligations without complying with notice-and-comment rulemaking procedures. (*Id.* ¶¶ 177–86.) Finally, in Count IV, Plaintiffs allege that CMS's

actions, including aggregating and combining the NovoLog Products and the FIASP Products as a single drug, are ultra vires and violate express mandates of the IRA. (*Id.* ¶¶ 178–94.)

The parties "conferred and agree that this case raises legal questions that are properly resolved through dispositive motions, without the need for discovery or trial." (ECF No. 16 at 1.) Accordingly, the Court exempted the parties from filing statements of fact under Local Civil Rule 56.1(a) and set a briefing schedule for the instant summary judgment motions. (ECF No. 24.)

II. JURISDICTION

The Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331.

III. LEGAL STANDARD

A motion for summary judgment may be granted when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). If there is "no genuine dispute over material facts," then courts "will order judgment to be entered in favor of the party deserving judgment in light of the law and undisputed facts." *Iberia Foods Corp. v. Romeo*, 150 F.3d 298 (3d Cir. 1998).

IV. DISCUSSION

A. STATUTORY CHALLENGES

Plaintiffs accuse the Program of violating the IRA's own express mandates in four ways. First, CMS's method of grouping Plaintiffs' products effectively exceeds the total limit of ten products set by the statute. (Plfs.' Moving Br. at 17–20.) Second, the selection runs afoul of the statute's prohibition against imposing price controls on biological products that have not been approved for at least eleven years. (*Id.* at 22.) Third, the improper aggregation of Plaintiffs' products reaches the wrong result with respect to them being sufficiently "high-spend" to merit selection for price control. (*Id.* at 23.) Finally, CMS's treatment of Plaintiffs' products blurs the

line between their products that are reimbursable under distinct Medicare Parts B and D. (*Id.*) The distinction is meaningful to Plaintiffs because, while Part B products are eligible for price controls in 2026, Part D products are not eligible until 2028. (*Id.*)

Defendants respond that Plaintiffs lack standing to seek relief with respect to the total number of products that CMS chose for price controls. (Defs.' Cross-Br. at 14 n.3.) As to Plaintiffs' remaining arguments, Defendants asserts that this Court lacks subject matter jurisdiction. (*Id.* at 13–20.)

1. Subject Matter Jurisdiction to Consider Statutory Challenges

It is undisputed that the IRA includes a provision that expressly precludes "administrative or judicial review" of:

> (2) The selection of drugs under section 1320f-1(b) of this title, the determination of negotiation-eligible drugs under section 1320f-1(d) of this title, and the determination of qualifying single source drugs under section 1320f-1(e) of this title the application of section 1320f-1(f) of this title,

42 U.S.C. § 1320f-7. By this provision, Congress has divested this Court of jurisdiction to consider challenges under the APA to CMS's determinations under 1320f-1(b),(d),(e), and (f). Moreover, because it is an express statutory preclusion it also effectively prohibits this Court from reviewing those determinations on so-called *ultra vires* principles. *See Fed. Express Corp. v. United States Dep't of Com.*, 39 F.4th 756, 764 (D.C. Cir. 2022) (judicial review of ultra vires agency action is available only "where (i) there is *no express statutory preclusion* of all judicial review; (ii) there is no alternative procedure for review of the statutory claim; and (iii) the agency plainly acts in excess of its delegated powers and contrary to a specific prohibition in the statute that is clear and mandatory.") (emphasis added); *see also Leedom v. Kyne*, 358 U.S. 184, 188 (1958).

Based on the foregoing, the Court concludes that it lacks subject matter jurisdiction to consider challenges to CMS's underlying determinations that led to its identification of Novo's Selected Drug.

2. Plaintiffs' Standing to Challenge the Total Number of Drugs Selected by CMS for Price Control

What remains is Plaintiffs' challenge based on their assertion that CMS has effectively identified fifteen products, way beyond the ten products authorized by the IRA for price control in 2026. Assuming for the sake of argument that Plaintiffs are correct,[4] the ten-product limit is set forth in 42 U.S.C. § 1320f-1(a)(1), which is not exempted from judicial review by the IRA. *See* 42 U.S.C § 1320f-7. Plaintiffs' challenge on this issue, however, raises the question of their standing to do so.

Article III of the Constitution limits the jurisdiction of federal courts to "Cases" and "Controversies." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 559 (1992). "Part of the case-or-controversy requirement is the requirement that plaintiffs have standing to sue." *Yaw v. Delaware River Basin Comm'n*, 49 F.4th 302, 310 (3d Cir. 2022). To establish standing "a plaintiff must show (i) that he suffered an injury in fact that is concrete, particularized, and actual or imminent; (ii) that the injury was likely caused by the defendant; and (iii) that the injury would likely be redressed by judicial relief." *TransUnion LLC v. Ramirez*, 594 U.S. 413, 423 (2021). The plaintiff, as the party invoking federal jurisdiction, bears the burden of establishing standing. *Id.* Because "standing is not dispensed in gross, a plaintiff who raises multiple causes of action must demonstrate standing for each claim he seeks to press." *In re Schering Plough Corp.*, 678 F.3d 235, 245 (3d Cir. 2012) (internal quotation marks and citation omitted).

[4] If Plaintiffs' premise is incorrect (or CMS's determination is unreviewable), it leads to a relatively straightforward conclusion: Plaintiffs have suffered no injury because CMS properly identified its six products as a single drug, and ten drugs in total were identified in compliance with the IRA.

As set forth above, Defendants challenge Plaintiffs' standing to ask the Court to set aside the selection of other companies' drugs for price controls, i.e., CMS's selection of all ten (or fifteen) drugs. Plaintiffs' Complaint does not seek individual relief based on each of its claims. Rather, the Complaint concludes with a ten-paragraph general prayer for relief based on all of their claims. (*See* Prayer for Relief ¶¶ A–J, Compl. at 59.) Nevertheless, based on its review, the Court agrees with Defendants that the relief sought by Plaintiffs that can be tied to their statutory challenge based on 42 U.S.C. § 1320f-1(a)(1) is overbroad insofar as they seek to enjoin the IRA program as a whole and to declare invalid CMS's entire guidance. (Prayer for Relief ¶¶ C, D, and F.[5]) Accordingly, the Court concludes that Plaintiffs have failed to demonstrate the standing required for their final statutory challenge. *See Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc.*, 528 U.S. 167, 185 (2000) ("[A] plaintiff must demonstrate standing separately for each form of relief sought.")

B. CONSTITUTIONAL CHALLENGES

Plaintiffs also raise several constitutional challenges to the Program. Plaintiffs argue that (1) the IRA violates separation of powers because it lacks an "intelligible principle" in violation of the nondelegation doctrine (Plfs.' Moving Br. at 39–42) and confers "virtually unfettered" price setting discretion to CMS (*id.* at 51–54); (2) the IRA violates the Fifth Amendment's Due Process Clause (*id.* at 43–48); (3) the Program compels Plaintiffs' speech in violation of the First Amendment by requiring them to "espouse the government's preferred views" (*id.* at 48–51); and

[5] For clarity, based on the relief sought, the Court construes paragraphs A and B of the Prayer for Relief as stemming exclusively from Plaintiffs' Constitutional claims and construes paragraphs E, G, and H as stemming from Plaintiffs' challenge to CMS's unreviewable determinations with respect to drug selection. Paragraphs I and J merely seek fees and costs and a general catch-all of "other and further relief as the Court may deem appropriate."

(4) the Program coercively compels Plaintiffs' participation and violates the unconstitutional conditions doctrine (*id.* at 54–60).[6]

In *BMS-Janssen*, the Court addressed nearly identical constitutional challenges that the Plaintiffs make here. Specifically, the Court considered whether the Program violates the Fifth Amendment's Takings Clause, whether the Program compels speech in violation of the First Amendment, and whether the Program violates the unconstitutional conditions doctrine. *BMS-Janssen*, 2024 WL 1855054, at *2–12.

First, the Court found that the Program is neither a physical taking nor a *per se* taking of a manufacturer's drugs. *Id.* at *2–7. Here, Plaintiffs have not alleged a Takings Clause claim but much like the plaintiffs in *BMS-Janssen*, Plaintiffs generally argue that the "IRA's constitutional problems cannot be excused by pretending that manufacturers have voluntarily embraced price controls by virtue of their continued participation in the Medicare and Medicaid programs." (Plfs.' Moving Br. at 54.) To that end, Plaintiffs contend that their participation in the Program is coercive, not voluntary, and that even if Plaintiffs had a "meaningful choice" to participate, the Program nevertheless requires the "surrender of constitutional rights in return for a government benefit." (*Id.* at 54–60.) However, the Court rejected these same arguments in *BMS-Janssen*. The Court concluded that participation in Medicare broadly, and participation in the Program specifically, is voluntary. *BMS-Janssen*, 2024 WL 1855054, at *6–9. The Court explained that "[s]elling to Medicare is a choice Plaintiffs can accept or not accept" and manufacturers have alternative options should they choose not to participate in the Program. *Id.* at *8.

[6] The Court notes that the Complaint neither references the "unconstitutional conditions doctrine" nor does it specifically allege a distinct unconstitutional conditions doctrine claim. (*See generally* Compl.) Similarly, Plaintiffs do not specifically state a claim that the Program is involuntary. (*Id.*) But given the Parties extensively brief these arguments in their submissions, the Court will consider the arguments in the context of Plaintiffs' constitutional challenges.

Next, the Court concluded that the Program does not compel speech in violation of the First Amendment. *Id.* at *9–12. The Court explained that the IRA regulates conduct, not speech, given that the purpose of the IRA is "to determine the price manufacturers may charge for those specific drugs they choose to sell to Medicare." *Id.* at *10–11. Any "speech" aspects of the Program, such as the agreements and negotiations, are merely incidental mechanisms used during the price-setting process. *Id.* at *11. Further, the Court concluded that a manufacturer's signature on the agreements does constitute expressive conduct because the agreements are ordinary commercial contracts executed during the various stages of the Program.[7]

Finally, the Court swiftly rejected the plaintiffs' unconstitutional conditions doctrine claim because the plaintiffs failed to demonstrate how the Program violated either BMS's or Janssen's First or Fifth Amendment rights. *BMS-Janssen*, 2024 WL 1855054, at *12. Given a manufacturer's participation in the Program is a voluntary, and not coerced, undertaking that neither constitutes a physical taking nor compels speech, the Program does not infringe on a manufacturer's constitutional rights. *Id.*

Here, the Court declines to disturb its prior holdings and applies its reasoning and conclusions to the present action. Accordingly, the Court concludes that (1) Plaintiffs' participation in the program is voluntary, (2) the Program does not compel Plaintiffs' speech, and (3) for the reasons discussed below, the Program does not violate the unconstitutional conditions doctrine given the Due Process Clause does not protect Plaintiffs' desired, but not inherent, right to continue selling its drugs to Medicare at a "fair market value." The Court therefore finds that Plaintiffs' First Amendment claim and its claims challenging the voluntary nature of the Program

[7] *See also Boehringer Ingelheim Pharms.*, 2024 WL 3292657, at *15–17 (finding that the Program's agreements regulate conduct, not speech, and that the agreements do not force manufacturers to convey any preferred government message).

fail. As such, only two constitutional challenges remain that the Court must address: whether the Program violates separation of powers and whether the Program violates the Due Process Clause.

3. Due Process Clause Claim

Plaintiffs argue that the Program violates the Fifth Amendment's Due Process Clause in two ways. First, Plaintiffs note that due process must ensure that the "executive acts 'as authorized by law'" and protect individuals from arbitrary acts of government. (Plfs.' Moving Br. at 43 (citing *Murray's Lessee v. Hoboken Land & Improvement Co.*, 59 U.S. (18 How.) 272, 276 (1855); *Wolff v. McDonnell*, 418 U.S. 539, 558 (1974))). To that end, Plaintiffs argue that the Program "invites arbitrary action by withdrawing judicial review from the price-setting regime's core features, including choosing what prices to set." (*Id.*)

Second, Plaintiffs contend that they have a "property interest both in the drug it creates and in the confidential information that CMS is forcing it to disclose," a right to "possess, use and dispose of" their property, a right to sell their drugs at a fair market value, and finally, a "property interest in its expectation that [Plaintiffs] may sell [their] drugs at a fair market value." (Plfs.' Reply Br. at 30–31.) Plaintiffs argue that the Program deprives them of their rights without any procedural protections such as judicial and administrative review. (Plfs.' Moving Br. at 44.) In particular, they note that CMS is not required to disclose any evidence that it relies on in determining the maximum fair prices, and as a result, Plaintiffs have no meaningful opportunity to respond to the evidence that CMS might rely on. (*Id.* at 46.) Therefore, without "traditional procedural safeguards" especially in the price setting context, Plaintiffs argue that their due process rights have been violated.

Defendants argue that Plaintiffs' Due Process Clause claim faces the same fatal law as their other constitutional claims: Plaintiffs have not, and cannot, identify any protected interest at risk of being deprived. (Defs.' Cross-Br. at 54, 56; Oral Arg. Tr. at 172:14–18.) Defendants argue that

while Plaintiffs have a physical property interest in their physical drug, the Program does not infringe on that right given Plaintiffs' participation in the Program is voluntary and they are not forced to make any sales to Medicare in the first place. (Defs.' Cross-Br. at 55.) Further, Defendants emphasize that Plaintiffs do not have a property interest to sell their drugs to Medicare at a particular price nor do they have a right to continued business with the Government. (*Id.* at 54–56.)

The Court can dispose of Plaintiffs' Due Process Clause claim quickly because the Due Process Clause is not implicated here. "The first inquiry in every due process challenge is whether the plaintiff has been deprived of a protected interest in 'property' or 'liberty.'" *Am. Mfrs. Mut. Ins. Co. v. Sullivan*, 526 U.S. 40, 59 (1999) (citing U.S. Const. amend. XIV). Here, the Court must first conclude that Plaintiffs have been deprived of a protected interest before it can consider whether the IRA and the Program comport with due process. *Id.* The Court will not reach the second question because Plaintiffs cannot demonstrate any deprivation of a protected interest.[8]

Plaintiffs argue that they have three protected interests: a property interest in their physical drugs, a property interest to sell their drugs at a fair market value, and a property interest in continued sales with Medicare at a fair market value. (Plfs.' Reply at 30–31.) At best, Plaintiffs can establish only one cognizable property right—a protected interest in the physical drugs—which Defendants do not dispute. (Defs.' Cross-Br. at 54.) However, it is unclear to the Court, and Defendants, how Plaintiffs are deprived of that right given that their participation in the

[8] The Third Circuit has noted that "determining what constitutes the impairment of a protected property interest for purposes of due process . . . is a distinct inquiry from determining what constitutes a taking for the purposes of the Takings Clause." *Burns v. Pa. Dep't of Correction*, 544 F.3d 279, 287 n.3 (2008). The Third Circuit sought to clarify that "property" is defined more narrowly in the Takings Clause context than in a due process challenge. *Id.* (internal citations omitted). The Court acknowledges this distinction but confirms that Plaintiffs' participation in the Program is voluntary under the contexts of both a Takings Clause and due process challenge. As such, "voluntary participation in a government program should [not] amount to a deprivation of property any more than it amounts to a taking of property." *Boehringer Ingelheim Pharms.*, 2024 WL 3292657, at *14.

Program is voluntary. As the Court explained at length in *BMS-Janssen*, a pharmaceutical manufacturer's participation in the Program, and its choice to sell to Medicare generally, is voluntary. *BMS-Janssen*, 2024 WL 1855054, at *6–9. Plaintiffs cannot conflate any financial or practical compulsion that participation in Medicare might exact with legal compulsion that obligates participation in either Medicare or the Program. Therefore, Plaintiffs cannot plausibly maintain that Defendants are depriving Plaintiffs of their physical drugs if they are not being coerced or compelled to give them up in the first instance.

Plaintiffs' two remaining "protected interests" are not cognizable rights. Notably, Plaintiffs provide no authority, statute, or regulation stating that they are inherently entitled to continue Medicare sales at their preferred price. This is because courts have routinely held otherwise. "The government has the fundamental right to decide how it will spend taxpayer money. Likewise, Plaintiffs have the fundamental right to decide whether they want to sell their drug to a specific purchaser under the conditions set." *BMS-Janssen*, 2024 WL 1855054, at *8 (internal citations omitted); *see also AstraZeneca Pharms.*, 2024 WL 895036, at *15 ("No one . . . is entitled to sell the Government drugs at prices the Government won't agree to pay." (citing *Coyne-Delany Co., Inc. v. Cap. Dev. Bd. of State of Ill.*, 616 F.2d 341, 342 (7th Cir. 1980))). In *AstraZeneca*, the district court addressed a similar due process challenge against the Program and found that plaintiff AstraZeneca Pharmaceutical LP's "'desire' or even 'expectation' to sell its drugs to the Government at the higher prices it once enjoyed does not create a protected property interest" and that "because AstraZeneca has no legitimate claim of entitlement to sell its drugs to the Government at any price other than what the Government is willing to pay, its due process claim fails as a matter of law." 2024 WL 895036, at *15 (citing *Town of Castle Rock, Colo. v. Gonzales*, 545 U.S. 748, 756 (2005)). Consistent with the Court's holding in *BMS-Janssen*, here,

the Court again concludes that because Plaintiffs' participation in the Program is voluntary, Plaintiffs do not have a protected property interest to sell drugs to Medicare at their professed "fair market value" nor do they have a property interest in their expectation that they will continue selling their drugs to Medicare at a fair market value.[9] Accordingly, Plaintiffs cannot demonstrate that the Program deprives them of a protected interest and therefore their Due Process Clause claim fails as a matter of law.

4. Separation of Powers

Plaintiffs' Separation of Powers claim is largely premised on the nondelegation doctrine. Plaintiffs argue that the IRA violates the nondelegation doctrine because when Congress enacted the IRA, it failed to articulate an "intelligible principle to which" CMS "is directed to conform." (Plfs.' Moving Br. at 39 (quoting *Touby v. United States*, 500 U.S. 160, 165 (1991)). Plaintiffs recognize that the IRA defines maximum fair price and that it provides a list of factors that CMS must consider in reaching the maximum fair price, but they argue that the IRA does not explain how CMS should determine the prices or how to weigh and consider each factor. (*Id.* at 41.) Further, Plaintiffs argue that nondelegation concerns are heightened by "Congress's decision to withdraw judicial review of CMS's price-setting decisions" because the IRA's price-setting scheme lacks a standard mechanism of ensuring accountability. (*Id.* at 42.) Along these lines, Plaintiffs suggest that the IRA is "unlike any price-setting scheme Congress has ever created." (*Id.* at 51.) They claim that the IRA confers "virtually unfettered" discretion on CMS to "control large

[9] Unlike Plaintiffs in this case, the plaintiff in *Boehringer Ingelheim Pharmaceuticals* did not argue that it had a protected property interest to sell its drugs through Medicare or that it was entitled to a particular rate of reimbursement. 2024 WL 3292657, at *14 n.3. The district court nevertheless clarified that the plaintiff could not even make such an argument "because no statute or regulation entitles it to sell its products to the government at all, let alone to do so at a particular rate of reimbursement." *Id.*

parts of the economy" and argue that it should be invalidated. (*Id.* at 53 (citing *A.L.A Schechter Poultry Corp. v. United States*, 295 U.S. 495, 542 (1935))).

Here, the Court disagrees and concludes that Plaintiffs' arguments, and the IRA generally, does not run afoul of the nondelegation doctrine for the reasons set forth below.

Article I of the Constitution provides that "[a]ll legislative Powers herein granted shall be vested in a Congress of the United States" and "[a]ccompanying that assignment of power to Congress is a bar on its further delegation." *Gundy v. United States*, 558 U.S. 128, 135 (2019) (plurality opinion). Though Congress may not transfer to the Executive or Judicial branch "powers which are strictly and exclusively legislative," *Wayman v. Southard*, 23 U.S. (10 Wheat.) 1, 42–43 (1825), the Constitution permits Congress the "necessary resources of flexibility and practicality to perform its function." *Yakus v. United States*, 321 U.S. 414, 425 (1944) (internal quotation marks omitted). To that end, "Congress may 'obtain the assistance of its coordinate Branches'—and in particular, may confer substantial discretion on executive agencies to implement and enforce the laws.'" *Gundy*, 588 U.S. at 135 (plurality opinion) (quoting *Mistretta v. United States*, 488 U.S. 361, 372 (1989)). The Supreme Court has "held, time and again, that a statutory delegation is constitutional as long as congress 'lay[s] down by legislative act an intelligible principle to which the person or body authorized to [exercise the delegated authority] is directed to conform.'" *Id.* (quoting *Mistretta*, 488 U.S. at 372).

The Supreme Court has consistently explained that the standards to satisfy an intelligible principle to guide an agency's exercise of authority "are not demanding." *Id.* at 146 (plurality opinion). It is well accepted that it is "constitutionally sufficient if Congress clearly delineates the general policy, the public agency which is to apply it, and the boundaries of this delegated authority." *Am. Power & Light Co. v. SEC*, 329 U.S. 90, 105 (1946). Accordingly, to determine

whether Congress has articulated an intelligible principle to CMS, the Court must review the statutory language of the IRA to determine "what task it delegates and what instructions it provides." *Gundy*, 588 U.S. at 135–36 (plurality opinion). "[O]nce a court interprets the statute, it may find that the constitutional question all but answers itself." *Id.* at 136.

The Court rejects Plaintiffs' position that the IRA fails to articulate an intelligible principle and that it lacks necessary safeguards that leaves CMS with unfettered power. The IRA is a statute that directs the Secretary of HHS, acting through CMS, to establish the Program. 42 U.S.C. § 1320f(a). The IRA then describes the core functions and elements of the Program, including instructing CMS to: (1) publish a list of selected drugs; (2) enter into agreements with the manufacturers of the selected drugs; and (3) negotiate and renegotiate maximum fair prices for the selected drugs. § 1320f(a)(1)–(3). Arguably, the Court could find that Congress satisfied the constitutional standard setting forth an intelligible principle to CMS within just the first subsection of the IRA. *See Am. Power & Light Co.*, 329 U.S. at 105.

However, a review of the IRA reveals that the statute provides significantly much more guidance than Plaintiffs claim. In particular, § 1320f-3 focuses on the "negotiation and renegotiation process." Specifically, § 1320f-3(c) explains how CMS shall determine the ceiling for the maximum fair price and § 1320f-3(e) sets forth specific criteria that CMS "shall consider . . . as the basis for determining the offers and counteroffers" for the maximum fair price of a selected drug. There are two categories of factors. The first category of factors covers "manufacturer-specific data" for a particular drug, including research and development costs, production and developments costs, patent application data, market data, revenue, and sales volume data. § 1320f-3(e)(1). The second category of factors covers "evidence about alternative treatments" and includes evidence such as whether a selected drug "represents a therapeutic

advance as compared to existing therapeutic alternatives," FDA approved prescribing information for the selected drug and its therapeutic alternatives, and the comparative effectiveness of the selected drug and its therapeutic alternatives. § 1320f-3(e)(2). Having considered and reviewed the statute, the Court finds that Congress's delegation in the IRA easily passes constitutional muster because it articulates an "intelligible principle" to guide CMS during the negotiation process. The IRA conveys a specific, delineated task to CMS, and it explains the scope and parameters of the delegation throughout the statute. The statute sets forth a broad delegation to CMS to negotiate maximum fair prices for selected drugs, but it also narrowly defines relevant terms, sets forth the timelines for the various applicability periods, and provides CMS with guidance during the price negotiation phase.

It is undisputed that since 1935, the Supreme Court "has uniformly rejected nondelegation arguments and has upheld provisions that authorized agencies to adopt important rules pursuant to extraordinarily capacious standards." *Gundy*, 588 U.S. at 148–49 (Alito, J., concurring). Notably, the Supreme Court has found a delegation to be excessive in only two cases, both in 1935, where "Congress had failed to articulate *any* policy or standard" to confine discretion. *Mistretta*, 488 U.S. at 373 n.7 (emphasis added); *see Schechter*, 295 U.S. 495 (1935); *Panama Refining Co. v. Ryan*, 293 U.S. 388 (1935). Given the various directions and considerations set forth in the IRA, it certainly cannot be said that Congress failed to articulate *any* intelligible principle in the IRA and Plaintiffs' attempts to compare the IRA to the delegations in *Schechter* or *Panama Refining* are not successful. Finding that the IRA fails to delegate an intelligible principle to CMS would disturb nearly century-long precedent upholding very broad delegations to agencies to regulate "in the public interest" and to "'set fair and equitable' prices and 'just and reasonable' rates." *See*

Gundy, 588 U.S. at 146 (plurality opinion) (first quoting *Nat'l Broad. Co. v. United States*, 319, U.S. 190, 216 (1943); then quoting *Yakus*, 321 U.S. at 427).

Further, Plaintiffs' argument that the nondelegation doctrine is violated because CMS's decisions are not subject to judicial review is misplaced. The Court agrees with Defendants that the preclusion of judicial review is not related to the nondelegation doctrine. (Defs.' Cross-Br. at 67.) As Defendants note, the nondelegation doctrine focuses on "the power Congress has delegated to the Executive Branch, *on the front end*—not whether the exercise of that power is subject to otherwise-unrelated constraints, *on the back end*." (*Id.*) (emphasis added). Plaintiffs do not cite to any authority that stands for the proposition that Congress's decision to preclude judicial review triggers a violation of the nondelegation doctrine issue.[10] In fact, courts have consistently considered statutes that preclude judicial review and have not indicated that such preclusion violates the nondelegation doctrine. *See, e.g.*, *Heckler v. Chaney*, 470 U.S. 821 (1985) (discussing that the APA precludes judicial review of certain decisions); *United States v. Erika, Inc.*, 456 U.S. 201, 208 (1982) (discussing that Medicare precludes judicial review of certain determinations and claims); *Yale New Haven Hosp. v. Becerra*, 56 F.4th 9 (2d Cir. 2022) (same). Given the Court does not find that the IRA violates the nondelegation doctrine under the traditional intelligible doctrine test, the Court declines to extend the nondelegation doctrine to find that the IRA's lack of judicial review creates a nondelegation doctrine violation. Accordingly, for the reasons provided, the Court concludes that the IRA does not violate the nondelegation doctrine and it does not violate separation of powers.

[10] Rather, Plaintiffs merely cite to an Eighth Circuit case for the proposition that "[j]udicial review is a factor weighing in favor of upholding a statute against a nondelegation challenge." *United States v. Garfinkel*, 29 F.3d 451, 459 (8th Cir. 1994) (quoting *United States v. Bozarov*, 974 F.2d 1037, 1042 (9th Cir. 1992)).

V. CONCLUSION

For the reasons stated above, the Court will GRANT Defendants' Cross-Motion for Summary Judgment (ECF No. 37) and DENY Plaintiffs' Motion for Summary Judgment (ECF No. 28). An appropriate Order will follow.

Date: **July 31, 2024**

s/ Zahid N. Quraishi
ZAHID N. QURAISHI
UNITED STATES DISTRICT JUDGE

CERTIFICATE OF SERVICE

I hereby certify that on October 15, 2024, I electronically filed the foregoing document with the Clerk of the Court for the United States Court of Appeals for the Third Circuit by using the CM/ECF system, thereby serving all registered counsel of record.

/s/Ashley C. Parrish
Ashley C. Parrish

Counsel for Appellants