NO. _____

In the
Supreme Court of the United States

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

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,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Third Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

The Inflation Reduction Act grants the Centers for Medicare and Medicaid Services ("CMS") unprecedented and unfettered authority to impose price controls on pharmaceutical products. As interpreted by the government, the statute includes no enforceable standards or procedures to guide and constrain CMS's price-setting decisions; authorizes the agency to implement price controls by imposing new binding rules at whim, unconstrained by the Administrative Procedure Act's procedural and judicial review requirements; and forces manufacturers to express the view that any price CMS dictates is the "maximum fair price." Although the statute levels an enterprise-crippling penalty on any manufacturer that does not comply, CMS claims that no constitutional constraints apply because the agency says it will not enforce the statute's multi-billion-dollar penalties if a manufacturer stops selling all of its products to the more than 140 million individuals who participate in Medicare and Medicaid.

The questions presented are:

1. Is the separation of powers violated when an agency exercises sweeping price-setting and rule-making authority with no constraints to ensure that it acts reasonably and within lawful bounds?

2. Is the federal government permitted to sidestep all constitutional constraints in the course of dictating the price of pharmaceutical sales made to a huge segment of the American population when such pricing is dictated in connection with a government-funded financial-assistance program, like Medicare?

PARTIES TO THE PROCEEDING

Petitioners Novo Nordisk Inc. and Novo Nordisk Pharma Inc. were Plaintiffs-Appellants below.

Respondents Secretary, U.S. Department of Health and Human Services; U.S. Department of Health and Human Services; Administrator, Centers for Medicare & Medicaid Services; and Centers for Medicare & Medicaid Services were Defendants-Appellees below.

CORPORATE DISCLOSURE STATEMENT

Novo Nordisk Inc. and Novo Nordisk Pharma Inc. are wholly owned by Novo Nordisk US Commercial Holdings, Inc. No other company owns 10% or more of Novo Nordisk US Commercial Holdings, Inc.'s stock.

RELATED PROCEEDINGS

The following proceedings are directly related to this petition under Rule 14.1(b)(iii):

United States Court of Appeals (3d Cir.):

Novo Nordisk Inc. v. Sec'y U.S. Dep't of Health & Hum. Servs., 154 F.4th 105 (3d Cir.). Judgment entered October 6, 2025.

United States District Court (D.N.J.):

Novo Nordisk Inc. v. Becerra, 2024 WL 3594413 (D.N.J.) Judgment entered July 31, 2024.

Other related cases:

United States Court of Appeals (5th Cir. / W.D. Tex.):

Nat'l Infusion Ctr. v. Kennedy, No. 25-50661 (5th Cir.) (argued October 7, 2025).

Nat'l Infusion Ctr. Ass'n v. Kennedy, --- F. Supp. 3d ---, 2025 WL 2380454 (W.D. Tex.). Judgment entered August 7, 2025.

Nat'l Infusion Ctr. Ass'n v. Becerra, 116 F.4th 488 (5th Cir.). Judgment entered September 20, 2024.

Nat'l Infusion Ctr. Ass'n v. Becerra, 716 F. Supp. 3d 478 (W.D. Tex.). Judgment entered February 12, 2024.

United States Court of Appeals (D.C. Cir. / D.D.C.)

Teva Pharms. USA, Inc. v. Kennedy, 2025 WL 3240267 (D.D.C.). Judgment entered November 20, 2025, *appeal docketed*, No. 25-5425 (D.C. Cir. Nov. 30, 2025).

Supreme Court of the United States (U.S.):

AstraZeneca Pharms. LP v. Kennedy, No. 25-348 (petition for certiorari filed September 19, 2025).

AstraZeneca Pharms. LP v. Sec'y U.S. Dep't of Health & Hum. Servs., 137 F.4th 116 (3d Cir.) Judgment entered May 8, 2025.

AstraZeneca Pharms. LP v. Sec'y U.S. Dep't of Health & Hum. Servs., 719 F. Supp. 3d 377 (D. Del.) Judgment entered March 1, 2024.

Bristol Myers Squibb Co. v. Kennedy, No. 25A519 (application for extension to file petition for certiorari to December 19, 2025, granted on November 6, 2025).

Janssen Pharms., Inc. v. Kennedy, No. 25A514 (application for extension to file petition for certiorari to December 19, 2025, granted on November 5, 2025).

Bristol Myers Squibb Co. v. Sec'y U.S. Dep't of Health & Hum. Servs., 155 F.4th 245 (3d Cir.) Judgment entered September 4, 2025.

Bristol Myers Squibb Co. v. Becerra, 2024 WL 1855054 (D.N.J.). Judgment entered April 29, 2024.

Novartis Pharms. Corp. v. Kennedy, No. 25A587 (application for extension to file petition for certiorari to January 23, 2026, granted on December 11, 2025).

Novartis Pharms. Corp. v. Sec'y U.S. Dep't of Health & Hum. Servs., 155 F.4th 223 (3d Cir.). Judgment entered September 11, 2025.

Novartis Pharms. Corp. v. Becerra, 2024 WL 4524357 (D.N.J.). Judgment entered October 18, 2024.

Boehringer Ingelheim Pharms., Inc. v. Dep't of Health & Hum. Servs., No. 25A357 (application for extension to file petition for certiorari to January 5, 2026, granted on September 29, 2025).

Boehringer Ingelheim Pharms., Inc. v. U.S. Dep't of Health & Hum. Servs., 150 F.4th 76 (2d Cir.). Judgment entered August 7, 2025.

Boehringer Ingelheim Pharms., Inc. v. U.S. Dep't of Health & Hum. Servs., 2024 WL 3292657 (D. Conn.). Judgment entered July 9, 2024.

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Allowing administrative agencies to evade rule-of-law constraints when dictating prices for goods sold in interstate commerce poses risks to our system of constitutional government. Because price controls are politically expedient but often lead to shortages and a loss in innovation, the government has an incentive to blur lines of accountability. Price controls also raise concerns that the government could appropriate property for self-interested reasons or set prices at an arbitrary or improper level.

This Court's precedents provide clear instructions on what is required to safeguard lawful, transparent, and accountable government: Congress must establish *both* standards to guide the agency's exercise of delegated authority *and* constraints to ensure that the agency acts lawfully and within the bounds of that authority. The requirement that Congress supply both *guidance* and *constraints* preserves the separation of powers and other constitutional values by ensuring that Congress is responsible for setting legislative policy and regulated parties have a remedy when faced with improper or otherwise unlawful agency action.

Congress sidestepped these constitutional limits when it granted CMS unbridled powers to impose price controls on pharmaceutical products under the Inflation Reduction Act ("IRA"). In a break from more than a century of precedent—going further than even the most sweeping delegations permitted during wartime emergencies—the IRA authorizes CMS to set prices on medications sold to a huge segment of the American population with no enforceable standards or

procedures to ensure that its prices are permissible and reached through a lawful process. As interpreted by the government, the statute bars any administrative or judicial review of CMS's price-setting decisions, including what price to impose, how many products to select, and what manufacturers to target. Moreover, as interpreted by the government, the statute authorizes CMS to use "guidance" to issue binding substantive rules, exempt from judicial review and the Administrative Procedure Act's requirements for reasoned decision-making. The IRA also contains a compelled-speech mandate, demanding that manufacturers express the view that any price CMS dictates is the result of a "negotiation" and the "maximum fair price."

In its decision below, the Third Circuit uncritically accepted CMS's expansive interpretation. The Third Circuit effectively concluded that Congress has handed CMS unreviewable and unfettered discretion to rewrite the statute to change the number of products subject to price controls, set prices at any level the agency chooses, and issue "guidance" that imposes new binding substantive obligations on manufacturers. That judicial imprimatur on an unprecedented evasion of constitutional safeguards calls out for this Court's review for two independent reasons.

First, the Court's intervention is necessary to restore the separation of powers, which requires that when Congress delegates price-setting and rule-making authority to an administrative agency, it must include statutory requirements to guide and constrain the agency's actions. In conflict with the teachings of

both this Court's precedents and decisions from other courts of appeals, the Third Circuit's decision asserts that because Congress listed certain factors for CMS to consider, it is irrelevant that the statute bars judicial review and includes no enforceable standards or procedures to constrain the agency's price-setting and rule-making actions. The decision is wrong and, if left uncorrected, will expand agencies' ability to exercise sweeping powers with no essential constraints.

Second, the Court should grant certiorari to clarify the limits on the federal government's powers to regulate prices in connection with a program that provides financial assistance to a very large portion of the American population. Under the Third Circuit's decision, the government is exempt from due process and other constitutional requirements when it forces parties to relinquish their constitutional rights as a condition of selling their products to private parties who make their purchases using government-funded financial assistance. But both this Court and other circuit courts have made clear that the government cannot use its powers to compel constitutional violations, and unconstitutional conditions must be reviewed carefully to avoid abuse.

These recurring questions are exceptionally important to the lawful operation of the nation's healthcare markets and to the preservation of our constitutional system. The decision below sets a dangerous precedent that allows agencies to exercise unchecked, coercive authority. It also blesses a scheme that forces manufacturers to relinquish their constitutional rights or else be barred from selling

products to some 140 million individuals. Because this case presents an opportune vehicle to address these issues, the Court should grant certiorari.

OPINIONS BELOW

The opinion of the Court of Appeals for the Third Circuit is reported at 154 F.4th 105 and reproduced at App.1-17. The opinion of the District Court for the District of New Jersey is unreported, but available at 2024 WL 3594413 and reproduced at App.18-40.

JURISDICTION

The Third Circuit issued its decision on October 6, 2025. App.1. This Court has jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The relevant constitutional and statutory provisions are reproduced in the appendix. App.60-91.

STATEMENT OF THE CASE

A. Background

1. The nation's prescription drug markets, and the prices that patients pay for medications, have historically been subject to market forces. Congress has relied on a system of limited patents to protect innovation and a streamlined approval regime to create incentives for companies to develop and launch generic versions of innovator products. *See* 35 U.S.C. § 156; 21 U.S.C. § 355(j); 42 U.S.C. § 262(k). Those efforts have made the United States a world leader in drug development. *See* Amitabh Chandra et al., *Comprehensive Measurement of Biopharmaceutical*

R&D Investment, Nature Revs. Drug Discovery (Aug. 6, 2024).

In that market-based system, the "list prices" for drugs are rarely the prices that manufacturers receive or that patients pay. Instead, pharmacy benefit managers, working on behalf of employers or health-insurance companies, negotiate substantial discounts (often through rebates). *See* PhRMA, Follow the Dollar: How the Pharmaceutical Distribution and Payment System Shapes Medicine 5-7 (2025). Health insurers then work with the pharmacy benefit managers to determine how much patients pay. *Id.*

In 2006, the federal government began providing financial assistance to prescription drug insurance plans through Medicare Part D. *See* Laura A. Wreschnig, Cong. Rsch. Serv., No. R40611, Medicare Part D Prescription Drug Benefit (Nov. 14, 2023). Part D plans are private insurance plans available to Medicare-eligible individuals. In exchange for offering coverage for specific drugs, these plans receive significant subsidies from the government. *Id.* at 1.

At that time, Congress denied CMS any authority to regulate prices, presumably recognizing the self-dealing concerns that would arise if the government were to regulate the prices of products sold to individuals whose purchases the government is financially supporting. Congress made clear that CMS 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). As a result, the market-based

system that applied to non-subsidized private insurance also applied to Part D plans.

The government's regulatory influence has steadily expanded. Medicare now covers 67.6 million people, approximately a quarter of all American adults. *See* Bds. of Trs. of Fed. Hosp. Ins. & Fed. Supp. Med. Ins. Tr. Funds, The 2025 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplemental Medical Insurance Trust Funds 6 (2025). CMS's subsidies under Medicare Part D are projected to reach $140 billion in 2026. *Id.* at 113. Moreover, due to its expansion in 2010, the government's Medicaid program now covers 80 million Americans. *See* Robin Rudowitz et al., KFF, Medicaid 101, at 1 (2025). The government controls almost half the nation's healthcare markets, *see id.,* and the prices paid in those markets are often incorporated into the "average sales prices" of drugs, which then influences reimbursement rates in both public and private markets. *See* 90 Fed. Reg. 49,266, 49,542-43 (Nov. 5, 2025).

2. In 2022, Congress enacted the IRA through reconciliation and with a tie-breaking vote from the Vice President. *See* 168 Cong. Rec. S4051, S4201 (daily ed. Aug. 6, 2022). The statute authorizes CMS to impose price controls on pharmaceutical products that manufacturers sell to individuals who receive financial assistance through Medicare. 42 U.S.C. § 1320f(a). The IRA's supporters described it as allowing CMS to "negotiate" prices. *See id.* (entitled "Price Negotiation Program"). In fact, the scheme has none of the features of a real negotiation; it forces manufacturers to provide access to their products at

prices dictated by CMS or, if they refuse, pay an enterprise-threatening penalty. *See* 26 U.S.C. § 5000D(b)(1)-(4). The statute's supporters were clear that by regulating prices of sales to individuals covered by Medicare, the statute would help commercial purchasers and payors to drive down prices in other markets. *See* Press Release, White House, Fact Sheet: President Biden Calls on Congress to Lower Prescription Drug Prices (Aug. 12, 2021) ("[I]t's not just Medicare beneficiaries [who] would benefit. If Medicare makes the prices it negotiates available to commercial payors, too, costs for employer health insurance would fall ….").

The statute grants sweeping powers to CMS to regulate the prices of products that have the largest Medicare expenditures. Beginning in 2026, Congress mandated that CMS shall set prices on no more than "10 negotiation-eligible drugs," which are defined as drug or biological "products" that have been on the market for at least 7 years (drug products) and 11 years (biological products) since being approved by the Food and Drug Administration ("FDA"). 42 U.S.C. § 1320f-1(a)(1), (e)(1). The number of products CMS is supposed to target for price controls increases over time. *Id*. § 1320f-1(a)(2)-(4). But Congress wanted CMS to start slowly. For the first three years, Congress directed CMS to implement price controls using only "program instruction or other forms of program guidance." Pub. L. No. 117-169, §§ 11001(c), 11002(c), 136 Stat. 1818, 1854, 1862 (2022).

The statute includes 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), (c)(3)(A)-(C), (b)(2)(F); 38 U.S.C. § 8126(h)(5). The statute states that CMS must "aim[] to achieve the *lowest maximum* fair price for each selected drug." 42 U.S.C. § 1320f-3(b)(1) (emphasis added). But it defines "maximum fair price" to be whatever price CMS dictates. *Id.* § 1320f(c)(3) ("The term 'maximum fair price' means, … the price negotiated pursuant to section 1320f-3 of this title ….''). The statute lists certain factors CMS is supposed to "consider," including research-and-development costs, current cost, federal financial support, and alternative treatments. *Id.* § 1320f-3(e). But it contains no enforceable standards to govern how CMS applies and weighs those factors (or even ensures that it considers them at all).

Congress's limited guidance is empty because the statute contains no judicially enforceable constraints or procedures. After CMS proposes a price, the manufacturer may make a "counteroffer" within 30 days. *Id.* § 1320f-3(b)(2). But CMS may disregard the counteroffer and impose any price it prefers for any undisclosed reason. *Id.* No hearing is required. *Id.* No neutral administrator is available. *Id.* And the statute bars administrative or judicial review of CMS's decisions, including which products to subject to price controls and what prices to impose. *Id.* § 1320f-7(3).

If a manufacturer refuses to sell its selected products at CMS's prescribed price, the IRA imposes extreme penalties. *See* 26 U.S.C. § 5000D(b)(1)-(4). The so-called "excise tax" penalty accrues daily and can quickly reach up to *19 times* the product's daily sales, amounting to billions of dollars. Cong. Rsch.

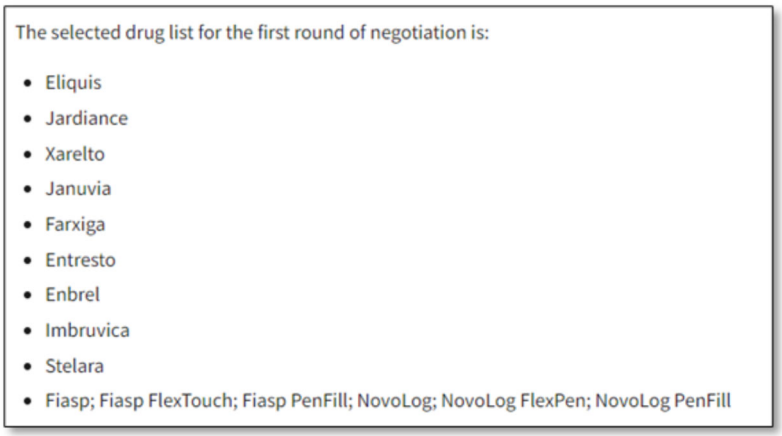
Serv., No. R47202, Tax Provisions in the Inflation Reduction Act of 2022 (H.R. 5376), at 4 tbl. 2 (2022). The statute offers no practical way for a manufacturer to avoid these excessive penalties (apart from surrendering to CMS's price controls). Although a manufacturer can eventually escape by withdrawing *all of its products* from both Medicare and Medicaid, 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).

3. In applying the IRA's provisions, CMS has taken advantage of the lack of statutory constraints. In June 2023, CMS issued a 198-page "guidance" document. *See* CMS, Medicare Drug Price Negotiation Program: Revised Guidance (June 30, 2023) ("Guidance"). As CMS acknowledged, that document imposes new binding rules, requirements, and obligations. *See* Dkt. 37-1 at 29-34; *see also* Guidance § 40.7. For example, instead of setting prices for 10 products for the first year, as Congress directed, the guidance imposes price controls on *groups* of products manufactured by the same company containing the same active moieties (drug products) or the same active ingredients (biological products). Guidance § 30.1. The guidance requires manufacturers to turn over confidential, competitive pricing information not required by the statute and that no party would share in any real negotiation. *Id.* § 40.2. The guidance also forces manufacturers to agree that they will be bound by any future guidance that CMS might ever issue. *Id.* § 40.7.

B. Procedural History

Petitioner Novo Nordisk is the U.S.-based affiliate of a global healthcare company, with the purpose to drive change to defeat diabetes and other serious chronic diseases, such as obesity and rare blood and endocrine diseases. It holds multiple new drug applications and biologics license applications approved by FDA.

1. In August 2023, CMS announced a list of products subject to price controls, starting in 2026. In addition to at least nine other products, CMS selected six Novo Nordisk products that were separately approved and licensed by FDA at different times: Fiasp®, Fiasp FlexTouch®, Fiasp PenFill®, NovoLog®, NovoLog FlexPen®, and NovoLog Penfill®. CMS counted these six products as a single drug toward the statute's 10-drug limit.



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* 3d Cir. Appx172.

These products differ not only in dosage forms and strengths, but also in numerous other essential characteristics, including different device presentations and conditions of use. *See* App.52-58. The products are used for different purposes by different patients; the prescribing information is different; and different clinical studies were completed to support FDA approval. *See* App.52-58. Most of the products have not been on the market for the required statutory period. CMS has never disputed that these are separate "products"; it merely contends that it can regulate multiple "products" as a single "negotiation-eligible drug" and, in any event, whatever it decides is exempt from judicial review. *See* Dkt. 37-1 at 21, 23.

2. Petitioner filed suit, bringing both as-applied and facial challenges. It asserted that the IRA, as interpreted by CMS, violates separation of powers, the Due Process Clause, and the First Amendment. It challenged CMS's selection of more than 10 drugs. And it argued that CMS violated the APA, Medicare Act, and IRA by issuing binding rules without following notice-and-comment procedures.

The district court granted summary judgment in CMS's favor. The court concluded that CMS's actions escape due process scrutiny because the drug-pricing scheme is purportedly "voluntary." App.27-40. It determined that the statute overcomes separation-of-powers concerns because "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*." App.39; *see also* App.39 ("[T]he preclusion of judicial review is not

related to the nondelegation doctrine."). The court also reached the astonishing conclusion, never argued by the government, that Novo Nordisk lacked standing because a ruling in its favor could benefit third parties. App.25-27.

3. Novo Nordisk's appeal was assigned to the same Third Circuit panel as three other appeals. Two opinions were announced before the decision in this case and form part of the Third Circuit's reasoning here.

In *AstraZeneca Pharmaceuticals LP v. Secretary,* the Third Circuit concluded that CMS's pricing scheme did not infringe on AstraZeneca's "property rights" because "[t]here is no protected property interest in selling goods to Medicare beneficiaries … at a price higher than what the government is willing to pay when it reimburses those costs." 137 F.4th 116, 125-26 (3d Cir. 2025), *cert. petition docketed*, No. 25-348 (U.S. Sep. 24, 2025). According to the court, CMS "only sets prices for drugs *that CMS pays for* when it reimburses sponsors" and therefore sales to individuals who receive financial support through Medicare "are not private market transactions, regardless of the private hands through which CMS's funds pass." *Id.* at 126.

In *Bristol Myers Squibb Co. v. Secretary* (*BMS*), a divided opinion rejected arguments that the IRA "(1) effects an uncompensated taking …, (2) compels speech in violation of the First Amendment, and (3) imposes unconstitutional conditions on participation." 155 F.4th 245, 252 (3d Cir. 2025). The decision turned on the same premise: "If the Companies dislike the prices the government is

willing to pay, they are free to stop doing business with the government." *Id.* at 255. The court also concluded that by directing CMS to issue "guidance," the IRA exempted the agency from the APA's procedural and judicial-review requirements. *Id.* at 260 & n.18.

Judge Hardiman dissented. He concluded that the "majority errs fundamentally when it concludes that the Companies voluntarily joined the Program." *Id.* at 280 (Hardiman, J., dissenting). He explained that the IRA "forces the Companies to turn over their property to Medicare beneficiaries by threatening them with ruinous excise tax liability," which they could not avoid by declining to sell their products to individuals who receive support through Medicare or Medicaid because "the excise tax would not have been suspended until the terminations of their Medicare agreements became effective, which would have taken 11 to 23 months." *Id.* at 273, 280. Judge Hardiman also explained that "[t]he terms 'guidance' and 'program instruction' refer to nonbinding interpretive rules and policy statements." *Id.* at 277 n.6. "So the statutory note's instruction that CMS must 'implement' the Program through guidance and program instruction does not direct CMS to take any action that would conflict with the APA's notice and comment requirements. After all, it would be oxymoronic to say an agency may promulgate legislative rules by issuing 'guidance.'" *Id.*

In its decision below, the Third Circuit also affirmed in favor of the government. Addressing petitioner's statutory arguments, the court interpreted the IRA to foreclose review, effectively

concluding that CMS has free rein to impose price controls on more products that Congress authorized. App.9-13. Applying its *BMS* decision, the court rejected petitioner's argument that CMS violated the APA, Medicare Act, and IRA by issuing binding rules without following notice-and-comment procedures. App.13-15. According to the court, the IRA "expressly permits CMS to promulgate legislative rules by issuing guidance." App.14. The Third Circuit also concluded that the lack of constraints—judicial review, adequate procedures, and free speech—is irrelevant to the separation-of-powers inquiry. App.17 n.3. In the court's view, the statute satisfies the intelligible-principle test because it includes "rules governing which products may be subject to price controls," a ceiling on how high the price can be set, and certain factors CMS should consider in setting prices. App.15-16.

REASONS FOR GRANTING THE PETITION

This case raises two important issues that warrant certiorari: *First*, the decision below held that the lack of judicially enforceable constraints on an agency's price-setting and rulemaking authority are irrelevant to the separation of powers. *Second*, the decision held that the federal government operates free from constitutional constraints when it regulates the prices of products sold to a huge segment of the American population—those who receive financial assistance through a government-funded program. Taken together, the Third Circuit's decision sanctions an unprecedented delegation of boundless, unchecked powers.

I. The Court Should Grant Review to Address Whether the IRA Violates the Separation of Powers.

When Congress delegates authority to an executive agency, the agency's discretion must be both "sufficiently guided" and adequately "constrained." *FCC v. Consumers' Rsch.*, 606 U.S. 656, 664 (2025). As interpreted by the Third Circuit, the IRA's price-control provisions violate these requirements. The decision below cannot be reconciled with this Court's precedents or decisions from other courts.

A. The decision below cannot be reconciled with this Court's precedents.

1. This Court evaluates congressional delegations by applying an "intelligible principle" test. Under that test, Congress must set forth "the general policy and standards," *id.* at 703 (Kavanaugh, J., concurring), to which an agency is "directed to conform." *Mistretta v. United States*, 488 U.S. 361, 372 (1989) (quoting *J.W. Hampton, Jr. & Co. v. United States*, 276 U.S. 394, 409 (1928)). The Court evaluates whether the statute includes adequate guidance and "how tight the constraints" are that Congress has imposed. *Consumers' Rsch.*, 606 U.S. at 680.

These requirements—sufficient *guidance* and adequate *constraints*—are central to protecting the Constitution's separation of powers. This Court has recognized that, although Congress has leeway to legislate in an "increasingly complex society, replete with ever changing and more technical problems," *Mistretta*, 488 U.S. at 372, at "some point … the responsibilities assigned can become so extensive and

so unconstrained" that a grant of regulatory powers will go too far. *Loving v. United States*, 517 U.S. 748, 777 (1996) (Scalia, J., concurring in part). If Congress were permitted to grant agencies sweeping authority without guidance and constraints, the Constitution's "'entire structure'" would "'make no sense,'" as it would eliminate safeguards essential to protecting "liberties, minority rights, fair notice, and the rule of law." *Gundy v. United States*, 588 U.S. 128, 155, 156 (2019) (Gorsuch, J., dissenting); *see also Stern v. Marshall*, 564 U.S. 462, 483-84 (2011) (the separation of powers protects liberty and individual rights).

2. In evaluating Congress's delegations, this Court has emphasized the importance of appropriate procedural constraints. To prevent a "pure delegation of legislative power," Congress must "enjoin upon" an 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). "[A]dministrative policies affecting individual rights and obligations" must "be promulgated pursuant to certain stated procedures so as to avoid the inherently arbitrary nature of unpublished ad hoc determinations." *Morton v. Ruiz*, 415 U.S. 199, 232 (1974); *Chrysler Corp. v. Brown*, 441 U.S. 281, 303 (1979). In addition, to ensure that agencies are accountable, their actions must be both reasonable and reasonably explained. *See Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

This Court's precedents have also generally presupposed the existence of judicial review to ensure that agencies "when implementing legislation *are*

constrained—namely, by the scope of Congress's authorization and by any restrictions set forth in th[e] statutory text." *Consumers' Rsch.*, 606 U.S. at 705 (Kavanaugh, J., concurring). A court must be able to "ascertain whether the will of Congress has been obeyed," *Skinner v. Mid-America Pipeline Co.*, 490 U.S. 212, 218 (1989) (quoting *Mistretta*, 488 U.S. at 379), to avoid "arbitrary deprivations of liberty or property," *Honda Motor Co. v. Oberg*, 512 U.S. 415, 434 (1994). The "investiture of a public body with discretion … carries [with] it as a necessary incident the command that the limits of a sound discretion be not transcended; which, by necessary implication, carries with it the existence of judicial power to correct wrong done by such excess." *United States v. Atchinson, Topeka, & Santa Fe Ry. Co.*, 234 U.S. 476, 491 (1914); *see also INS v. Chadha*, 462 U.S. 919, 953-54 n.16 (1983).

Judicial review not only ensures that an agency acts within its delegated powers; it protects Congress's prerogatives and ensures that courts are able to ensure the "steady, upright and impartial administration of the laws." *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 385, 394-96, 404 (2024). In *Gundy*, for example, this Court acknowledged that a broad interpretation of the statute could violate the separation of powers, so it adopted a narrowing construction. 588 U.S. at 136; *see also Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 575 (1988) (rejecting agency interpretation to save statute from constitutional problems). In many other cases too, the Court has relied on the availability of judicial review as an essential constraint to guard against assertions

of unprecedented powers. *See Biden v. Nebraska*, 600 U.S. 477, 501 (2023); *West Virginia v. EPA*, 597 U.S. 697, 728 (2022). Without judicial review, the requirement that agencies remain within "the boundaries of [their] delegated authority" would be a nullity, which raises particular concerns when agencies regulate private rights. *Am. Power & Light Co. v. SEC*, 329 U.S. 90, 105 (1946) ("Private rights are protected by access to the courts to test the application of the policy in the light of [Congress's] legislative declarations").

3. This Court has long applied these principles to ensure that Congress provides both guidance and constraints when authorizing agencies to regulate prices or issue rules with substantive effect. An enduring body of administrative law has developed to constrain agency decision-making under the umbrella of the APA's default procedural and judicial-review requirements.

In 1935, nine years before the APA, this Court struck down provisions of the National Industrial Recovery Act that granted the President unchecked authority to impose price controls, fix wages, and adopt other requirements in connection with the sale of chickens. *See A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 551 (1935). The Court recognized that Congress had "supplie[d] no standards for any trade, industry, or activity," *id.* at 541, and the statute "dispense[d] with … judicial review to give assurance that the action of the commission [was] taken within its statutory authority," *id.* at 533. In a related decision, the Court struck down other provisions of the same statute granting an agency

broad authority to regulate the production and sale of oil. *See Panama Refin. Co. v. Ryan*, 293 U.S. 388 (1935). The Court stressed that it was "not dealing with action which, appropriately belonging to the executive province, is not the subject of judicial review" and therefore concluded that there had to be enforceable standards to which the executive was bound to comply. *Id.* at 431-32. In both cases, the Court's decisions recognized that "the substantive question of how much power Congress may delegate is inextricably linked to the agency procedures and judicial review provisions that accompany the delegation." Michael S. Greve, *Delegation in Context* 7 (George Mason Univ., Antonin Scalia L. Sch. CSAS Working Paper 23-09, 2023).

Congress has since generally ensured—even during wartime—that when delegating price-setting and rule-making authority, it has provided adequate standards, procedural constraints, and an opportunity for judicial review. For instance, parties subject to price controls under the Emergency Price Control Act of 1942, Pub. L. No. 77-421, 56 Stat. 23, were entitled to an "administrative hearing" and, if necessary, "full judicial review." *Yakus v. United States*, 321 U.S. 414, 436, 437 (1944). The wartime statute included not only standards to guide the agency but also procedures "[]capable of affording due process," and it guaranteed judicial review of "all questions of law, including the question whether the Administrator's determination [was] supported by evidence." *Id.* at 435, 437.

In 1946, Congress enacted the APA, a compromise on "which opposing social and political forces" came "to rest," *Vt. Yankee Nuclear Power Corp. v. Nat. Res. Def.*

Council, Inc., 435 U.S. 519, 523 (1978), to establish default constraints that apply to virtually all forms of "agency" or "agency action." Antonin Scalia, *Vermont Yankee: The APA, the D.C. Circuit, and the Supreme Court*, 1978 Sup. Ct. Rev. 345, 360-63 (1978). The APA "sets forth the procedures by which federal agencies are accountable to the public and their actions subject to review by the courts." *Franklin v. Massachusetts*, 505 U.S. 788, 796 (1992). In this way, the APA protects the separation of powers and other constitutional values by requiring agencies to follow certain procedures when issuing substantive rules and "subject[ing] their decisions to judicial review." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 537 (2009) (Kennedy, J. concurring). These constraints reconcile a complex, democratic society's demands for the expertise and efficiencies of "a vast and varied federal bureaucracy," with the imperatives of lawful, accountable government. *Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 499 (2010).

4. The Third Circuit's analysis cannot be squared with these essential principles. The Third Circuit accepted the government's position that the IRA exempts CMS's price-setting and rule-making decisions from the APA's requirements and effectively grants the agency unreviewable discretion to do as it pleases. Accordingly, although petitioner challenged CMS's decision to impose price controls in 2026 on 15 products, instead of the 10 that Congress directed, the Third Circuit held that no court could review that alleged statutory violation. *Cf. Teva Pharms. USA, Inc. v. Kennedy*, 2025 WL 3240267, at *6-9 (D.D.C. Nov. 20, 2025) (declining to read the judicial review bars so broadly), *appeal docketed*, No. 25-5425 (D.C.

Cir. Nov. 30, 2025). Similarly, the Third Circuit concluded that the statute "expressly permits CMS to promulgate legislative rules by issuing guidance" exempt from the APA's procedural and judicial-review requirements. App.14.

Neither the government nor the court below identified any statute that has ever lawfully delegated such sweeping and unreviewable authority to an agency. *Cf. Free Enter.*, 561 U.S. at 505 (lack of "historical precedent" often reflects a "constitutional problem"). Nonetheless, the Third Circuit concluded that the lack of any constraints is irrelevant to the separation-of-powers inquiry. App.16-17 & n.3. Finding that the statute "clears the 'intelligible principle' hurdle," the court noted that the IRA has some *guidance* because it includes "detailed rules governing which products may be subject to price controls," "limits the number of products that may be selected," "grants CMS only narrow discretion to determine whether certain products should be excepted," "sets a price ceiling," and identifies "certain factors" that the agency must consider when setting a price. App.15-16.

The court below declined to consider that the statute imposes no *constraints* on the agency's price-setting and rule-making authority, even though it effectively acknowledged, *see* App.9-15, that the few "limits" provided by statute are unenforceable. *Cf. Consumers' Rsch.*, 606 U.S. at 682 (if a statutory standard is "indeterminate," an agency can "turn it into anything the [agency] wants"). The result is to unleash the agency from any guidance that Congress did provide and to reposit in CMS unchecked

legislative, executive, and judicial powers—"the very definition of tyranny." The Federalist No. 47 (James Madison).

B. The Third Circuit's analysis conflicts with precedent from other Circuits.

The Third Circuit's analysis cannot be reconciled with reasoning from other courts, including the Eighth, Ninth, and D.C. Circuits. Those circuits have interpreted this Court's separation-of-powers cases to require an analysis of relevant constraints, like judicial review and notice-and-comment procedures, when evaluating a delegation of regulatory powers.

1. In *United States v. Garfinkel*, 29 F.3d 451 (8th Cir. 1994), the Eighth Circuit held that the standards enunciated by law, the existence of judicial review, and mandated compliance with APA procedures are relevant to a nondelegation challenge. In that case, the Eighth Circuit reviewed a statutory provision regarding the use of experimental drugs. Although the court rejected the nondelegation challenge, it did so principally because of the existence of adequate constraints: "[W]e hold that the standards enunciated by the Act, along with judicial review and the procedural requirements dictated by the APA, impose sufficient restraints upon FDA to satisfy the constitutional concerns underlying the nondelegation doctrine." *Id.* at 459; *see also Beall Constr. Co. v. OSHA*, 507 F.2d 1041, 1045 (8th Cir. 1974) (delegation to agency, "with the right of judicial review retained, does not violate the separation of powers").

The Ninth Circuit has likewise recognized that "the availability of judicial review is a factor weighing

in favor of upholding a statute against a nondelegation challenge." *United States v. Bozarov*, 974 F.2d 1037, 1042 (9th Cir. 1992). Although the Ninth Circuit recognized that judicial review is not "always constitutionally required," *id.* at 1042-43, the Third Circuit's refusal to consider these statutory aspects together diverges from the Ninth Circuit's approach. *See also Beorschig v. Trans-Pecos Pipeline, L.L.C.*, 872 F.3d 701, 709 (5th Cir. 2017) (holding that the availability of judicial review meant plaintiff was unlikely to succeed on non-delegation challenge); *Olenhouse v. Commodity Credit Corp.*, 42 F.3d 1560, 1573, 1574 (10th Cir. 1994) (describing judicial review as serving an "essential function").

2. More broadly, the Third Circuit's decision is in tension with decisions from the D.C. Circuit recognizing that the APA's constraints—its procedural and judicial review requirements—are important to protecting the separation of powers. *See Chamber of Com. v. Reich*, 74 F.3d 1322, 1332 (D.C. Cir. 1996) (it is "untenable to conclude that there are no judicially enforceable limitations on presidential actions"). As the D.C. Circuit has recognized, the APA's "notice-and-comment rulemaking" and judicial-review provisions ensure that the agency, "in carrying out its essentially legislative task, has infused the administrative process with the degree of openness, explanation, and participatory democracy" so as to "negate[] the dangers of arbitrariness and irrationality in the formulation of rules." *N.J., Dep't of Env't Prot. v. EPA*, 626 F.2d 1038, 1045 (D.C. Cir. 1980)). The APA is thus "Congress's most effective and enduring solutions to the central dilemma" of "reconciling the agencies' need to perform effectively

with the necessity that the law must provide that the governors shall be governed and the regulators shall be regulated, if our present form of government is to endure" *Am. Bus. Ass'n v. United States,* 627 F.2d 525, 528 (D.C. Cir. 1980) (quotation marks omitted).

3. In holding that Congress exempted CMS from the APA and granted the agency unreviewable powers to impose binding legal requirements through "guidance," the Third Circuit's decision departs from the most foundational constructs of administrative law. *See BMS*, 155 F.4th at 277 n.6 (Hardiman, J., dissenting); *see also Am. Pub. Gas Ass'n v. U.S. Dep't of Energy*, 72 F.4th 1324, 1340 (D.C. Cir. 2023) (departures from the APA are "narrowly construed and only reluctantly countenanced"). Without the APA's procedural and judicial review provisions—or some other alternative, constitutionally adequate constraints—there is nothing to "protect[] a free people from the danger of coercive state power undergirding pronouncements that lack the essential attributes of deliberativeness present in statutes." *Cmty. Nutrition Inst. v. Young*, 818 F.2d 943, 951 (D.C. Cir. 1987) (Starr, J., concurring in part).

In short, in contrast with the Third Circuit, at least three other circuits recognize that the existence of bare statutory "guidance" is not the only relevant inquiry to understanding whether a statute (or an agency's interpretation) comports with the rule of law. The availability of adequate "constraints" is essential to protecting the separation of powers. Review is warranted to bring uniformity to decisions addressing this issue.

II. The Court Should Grant Review to Address Whether Constitutional Constraints Apply When an Agency Regulates Private Conduct Cloaked in the Disguise of Acting as a Market Participant.

The Court should also grant review because, even though the IRA fails to protect manufacturers' due process rights (with no hearing or other procedural protections), the Third Circuit declined to apply any level of constitutional scrutiny to CMS's price-control scheme. It instead accepted the government's position that when a manufacturer engages in transactions with individuals who receive government-funded financial assistance—a huge segment of the American population—no constitutional constraints apply. It thus accepted that a manufacturer can be forced to relinquish its constitutional rights as a condition of selling its products into a regulated market. In accepting that position, the Third Circuit's decision departs from this Court's precedent and splits from other circuits.

A. The decision below cannot be reconciled with this Court's precedents.

1. The exercise of the government's powers is subject to constitutional constraints. *Champion v. Ames*, 188 U.S. 321, 362-63 (1903). That principle applies when the government regulates directly through an exercise of its commerce powers or indirectly through an exercise of its spending powers. *See Speiser v. Randall*, 357 U.S. 513, 526 (1958) (noting the government cannot accomplish indirectly "a result which [the government] could not command directly").

This Court has rejected attempts by the government to insulate its regulatory actions from constitutional scrutiny. *See 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"). In *Carter v. Carter Coal Co.*, the Court held that an "agreement" to participate in a regulatory price-setting program "lack[ed] the essential element of consent" because it threatened substantial taxes for noncompliance. 298 U.S. 238, 289 (1936); *see also Union Pac. R.R. v. Pub. Serv. Comm'n*, 248 U.S. 67, 70 (1918) (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."). In *Horne v. Department of Agriculture*, the Court held that the government could not take farmers' raisins without paying just compensation even if the farmers could exit the market and sell their grapes elsewhere. *See* 576 U.S. 350, 365 (2015); *see also Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 488-89 (2013) (rejecting argument that manufacturers could avoid conflict between state and federal law by choosing to stop selling products). And in *National Federation of Independent Business v. Sebelius* (*NFIB*), the Court concluded that Congress could not force the States to accept a Medicaid expansion by threatening the withdrawal of Medicaid funding. 567 U.S. 519, 579-80 (2012). Although the Medicaid expansion may have been "in form voluntary," *Frost*, 271 U.S. at 593, the Court concluded 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," 567 U.S. at 582. That financial threat was "a gun to the head." *Id.* at 581.

Consistent with these precedents, 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). The government cannot, for example, condition payment for services to combat HIV/AIDS on a nonprofit adopting a viewpoint "outside the contours of the program." *Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc.*, 570 U.S. 205, 214-15 (2013). Moreover, although the government may condition the receipt of a *public* benefit on a waiver of constitutional rights, the condition must be proportional and have an "essential nexus" to the benefit conferred. *Nollan v. Cal. Coastal Comm'n*, 483 U.S. 825, 837 (1987); *Dolan v. City of Tigard*, 512 U.S. 374, 387 (1994) (noting risk that regulation becomes an "out-and-out plan of extortion"). Even where, unlike here, the government is acting as a market participant to procure products for itself, the Constitution imposes limits on what strings it can attach. The government may influence "a discrete, identifiable class of economic activity" within that market but may not go any "further." *S.-Cent. Timber Dev., Inc. v. Wunnicke*, 467 U.S. 82, 98 (1984). Any "asserted power of choice is illusory" when Congress uses "coercion by economic pressure." *United States v. Butler*, 297 U.S. 1, 70-71 (1936).

2. The Third Circuit's decision runs afoul of these principles. The court did not deny that CMS's price-setting scheme would pose constitutional problems if the only ways for a manufacturer to avoid price controls were to pay a fine or halt all sales of its drug. *See BMS*, 155 F.4th at 255; *AstraZeneca*, 137 F.4th at 126; *see also* Oral Argument at 18:22-19:10, *Nat'l Infusion Ctr. v. Kennedy*, No. 25-50661 (5th Cir. Oct. 7, 2025) (the government answering the court's question at oral argument: Q: "[I]f we were to find a protected property interest … would you agree there is no adequate process given …?" A: "I mean, in that there's not process, yes" Q: "[F]ront-end process or back-end process?" A: "Yes."). The Third Circuit nonetheless accepted CMS's lullaby argument that its price-control "[p]rogram is … voluntary" because the agency in non-binding guidance "promised" (at least until it changes its mind) "to offer manufacturers a 30-day exit" from both Medicare and Medicaid, which would "enable a manufacturer to avoid excise tax liability." App.7. The court concluded that no analysis was required to determine whether forcing manufacturers to relinquish their rights—as a condition of engaging in commercial transactions with the more than 140 million people who participate in Medicare or Medicaid—was consistent with the Constitution. *See* App.7.

The Third Circuit declined to apply *NFIB*'s reasoning to address whether the government "crossed the line distinguishing encouragement from coercion," 567 U.S. at 579, asserting that coercion concerns "are simply not present" when "the federal government contracts with private parties, rather than dealing with separate sovereigns." *BMS*, 155

F.4th at 259. But the court made no attempt to explain why sovereign states are more susceptible to economic dragooning than individual manufacturers. Nor did it even attempt to draw a distinction between circumstances where the government procures goods for itself as a market participant and when it regulates the price of goods to reduce the level of financial assistance it provides to private purchasers.

The Third Circuit also declined to apply the unconstitutional conditions doctrine. Petitioner argued that there was no reasonable connection between CMS's unilaterally dictated price on a drug sold to individuals covered by Medicare Part D plans and its threat to prohibit a manufacturer from selling any of its products to the 140 million individuals covered by Medicare or Medicaid—programs that cover almost 40% of the U.S. population and account for more than $150 billion in annual prescription-drug spending. 3d Cir. Opening Br. 60-61. Petitioner referenced this Court's precedent to explain that "the unconstitutional conditions doctrine applies in a wide range of contexts." 3d Cir. Reply Br. 29-30 (citing *Sheetz v. County of El Dorado*, 601 U.S. 267, 279 (2024)). But the Third Circuit declined to analyze the relationship between CMS's "condition" and "benefit," holding instead that this doctrine applied to deprivations of property only in the "land-use interest" context. *Sheetz*, 601 U.S. at 275-76.

The Constitution is meaningless if agencies can provide financial assistance to participants in the nation's interstate markets, decide to regulate transactions occurring in those markets, and then make continued access depend on forfeiting

constitutional rights. *See U.S. Term Limits, Inc. v. Thornton*, 514 U.S. 779, 829 (1995) ("The Constitution 'nullifies sophisticated as well as simple-minded modes' of infringing on constitutional protections."). If the government were correct, there would be no limits on the government's ability to wield its vast economic and regulatory powers to coerce parties to give up their rights. *Cf. Trinity Lutheran Church of Columbia, Inc. v. Comer*, 582 U.S. 449, 466 (2017). The government could manipulate any market—for any product or good—by positioning itself as an intermediary and setting prices free of constitutional constraints. That cannot be the law.

B. The Third Circuit's decision is in tension with decisions from multiple Circuits.

The Third Circuit's decision creates a divide in lower court authority over whether the IRA is subject to scrutiny for failing to provide due process. It also diverges from decisions of other circuits, which have recognized that the government cannot use a "benefits" program to coerce regulated parties into relinquishing their constitutional rights and that, even in the absence of coercion, conditions must have a sufficient nexus to any benefit conferred.

1. The Third Circuit's decision sets up a 2-1 split over whether the IRA's drug-pricing scheme implicates due-process concerns. Under the government's scheme, manufacturers lack a meaningful opportunity to be heard before—or even after—CMS imposes price controls on manufacturers' selected products. The Second and Third Circuits sidestepped this due process violation by limiting *NFIB* to the federalism context and ignoring its anti-

coercion holding. They could not deny that the statute's billion-dollar penalties represent a very large "gun to the head," but they determined that, through non-binding guidance, the agency had offered manufacturers a 30-day window to dodge the bullet. Accordingly, they concluded that no constitutional scrutiny applies because manufacturers could "voluntarily" either surrender to the government's prices or exit the market entirely. *See Boehringer Ingelheim Pharms., Inc. v. HHS*, 150 F.4th 76, 97 (2d Cir. 2025).

In contrast, the Fifth Circuit held in *National Infusion Center Association v. Becerra* that the plaintiff adequately alleged a cognizable due process injury resulting from the IRA's price-setting scheme. 116 F.4th 488, 499-500 (5th Cir. 2024). The Fifth Circuit recognized that when "key determinations," such as "when [CMS] can reject a manufacturer's counteroffer and the selection of particular drugs" are "made without notice and comment and insulated from administrative or judicial review," there is a "substantial risk" that affected parties "will be erroneously deprived of important property interests." *Id.* at 503. It also recognized that the "consequences of failing to reach an agreement with [CMS] are severe." *Id.* at 500. "A manufacturer that chooses to walk away from negotiations without reaching an agreement must remove *every* drug that it produces from Medicare coverage, not just the drug that is the subject of the negotiation." *Id.* It explained that "even if [CMS] offered a price that made sales of a particular drug unprofitable, the manufacturer still might agree to the unprofitable price because doing so is preferable to losing the Medicare market for all of its drugs." *Id.*

Put differently, "the penalties the Program imposes make reaching an agreement all but certain." *Id.*

Unlike the Third Circuit, the Fifth Circuit understood that the government's price-control scheme will injure affected businesses. *Id.* at 503. It further understood that it would violate due process to carry out this scheme without giving those businesses the opportunity to be heard. *Id.* Having held that the plaintiff sufficiently alleged a due process injury, the Fifth Circuit remanded for further proceedings. The case is currently back on appeal, and oral argument was held in October. *See Nat'l Infusion Ctr. v. Kennedy*, No. 25-50661 (5th Cir. filed Aug. 15, 2025).

2. In refusing to apply the unconstitutional conditions doctrine, the Third Circuit's decision also diverges from decisions in the First, Fourth, Seventh, Ninth, and Eleventh Circuits.

In *Lebron v. Secretary of Florida Department of Children & Families*, the Eleventh Circuit applied this Court's nexus-and-proportionality framework to hold that conditions placed on Temporary Assistance to Needy Families were unconstitutional. 772 F.3d 1352, 1365 (11th Cir. 2014). It explained that there was "no essential nexus" between the condition, suspicion-less drug testing, and the state's interests in ensuring TANF-recipient job readiness, ensuring that the government program met its child-welfare and family-stability goals, and ensuring that public funds were used for their intended person. *Id.* "Put differently, the fit [wa]s not reasonably proportionated to the harms the State s[ought] to avoid." *Id.*

Similarly, the Fourth Circuit in *Litman v. George Mason University* considered whether Congress could condition the receipt of federal funds on a waiver of Eleventh Amendment immunity. 186 F.3d 544, 552-53 (4th Cir. 1999). The Fourth Circuit recognized that government-imposed conditions "must have limits" because "an unlimited Spending Clause power could circumvent the entire constitutional structure." *Id.* It explained that "any conditions imposed must 'bear some relationship to the purpose of the federal spending'" and "the financial inducement must not be 'so coercive as to pass the point where pressure turns into compulsion.'" *Id.*

Other circuits have likewise recognized that the unconstitutional conditions doctrine is not limited to isolated contexts, like free speech or land use. For instance, in *National Amusements, Inc. v. Town of Dedham*, the First Circuit considered whether a municipality improperly conditioned the grant of licenses on theaters agreeing not to show movies at certain times of day. 43 F.3d 731, 733-34 (1st Cir. 1995). Applying the "nexus" rule, the court explained that "'the legitimacy of a government proposal depends on the degree of relatedness between the condition on a benefit and the reasons why government may withhold the benefit altogether.'" *Id.* at 747-48. Similarly, in *Stavrianoudakis v. United States Fish & Wildlife Service*, a case involving falconry, the Ninth Circuit observed that "the unconstitutional conditions doctrine forbids burdening the Constitution's enumerated rights by *coercively* withholding benefits from those who exercise them." 108 F.4th 1128, 1137 (9th Cir. 2024) (emphasis added); *see also United States v. Ryan*, 810

F.2d 650, 656 (7th Cir. 1987) ("[T]he doctrine … precludes the government from coercing the waiver of a constitutional right.").

These cases all applied the unconstitutional conditions framework to analyze the permissibility of conditions imposed by the government. By declining to apply that framework, the Third Circuit deviated from the reasoning of these sister circuits.

III. The Questions Presented Are Important, and This Case Is an Opportune Vehicle to Address Them.

The questions presented are of exceptional legal and practical importance. The lower court's decision did not turn on any disputed facts, and its resolution of the questions presented was outcome-determinative. The case is thus an appropriate vehicle to address those questions, enforce essential constraints on the actions of administrative agencies, and resolve confusion in the lower courts.

A. The constitutionality of the IRA's price-control scheme "is of great importance to consumers of pharmaceutical drugs, the companies that provide them, and the public at large." *BMS*, 155 F.4th at 289 (Hardiman, J., dissenting). If CMS's price-control scheme is not brought into compliance with the Constitution, it will continue to expand, with more than 100 "products" saddled with price controls within a decade. *See* 42 U.S.C. § 1320f-1. As noted above, the Medicaid and Medicare markets regulated by CMS cover more than 140 million individuals and 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).

Moreover, if the Court does not act now, the damage to the nation's healthcare system may be irreparable. CMS has already selected more products for its second round of price controls, and it has again exceeded the statute's numerical limits by aggregating multiple products as a single "drug." With no constraints on CMS's price-setting and rule-making decisions, the agency will continue to exercise unchecked powers to regulate manufacturers and the sales they make every day to millions of Americans. And because those decisions are made under the guise of a sham "negotiation" process—with no reasoned decision-making requirements, no procedural protections, and no judicial review—there is no transparency; no assurance of fair, non-arbitrary decision-making; and no ready way for the public to hold Congress and the Executive Branch accountable.

The consequences of this unprecedented scheme are already being felt. Investments in innovation have decreased, price constraints are erasing the incentive to develop competitive generic products, and new research is not occurring. Reports have, for example, noted "a sharp decline in investment" in the wake of the IRA, which could "potentially stifl[e] the development of new therapies," Greg Licholai, *Inflation Reduction Act Unintended Consequences for Medical Innovation*, Forbes (Feb. 3, 2025), and they have identified an IRA-driven reduction in follow-on approvals for drugs to treat early stage cancers, *see* Tomas J. Philipson, *Biden's IRA Is Harming Cancer Patients*, WSJ (Nov. 30, 2025). Because of the federal

government's market dominance, CMS's price controls threaten to disrupt companies' ability to make the investments needed to bring new products to market, a process that takes (on average) 10 to 15 years and costs more than $2 billion, with only about 1 in 5,000 potential new drugs obtaining approval and reaching patients. *See* GAO, No. GAO-20-215SP, Artificial Intelligence in Health Care 34 (Dec. 2019); Stephen Ezell, Info. Tech. & Innovation Found., Ensuring U.S. Biopharmaceutical Competitiveness 29-30 (2020). Moreover, patients are not expected to see any meaningful benefit from CMS-dictated prices. Because of how insurance works, premiums for non-low-income beneficiaries in standalone Part D plans are expected to *increase* by 32% in 2026. *See* Kylie Stengel et al., *Part D Choices Continue to Shrink with Fewer PDPs in 2026*, Avalere Health (Oct. 2, 2025); *see also* Rahel Ehrenberg et al., IQVIA, The Impact of Formulary Controls on Medicare Patients in Five Chronic Areas 1, 7 (2025).

B. This case also presents an opportune occasion for this Court to arrest the concerning trend of the Executive Branch asserting unconstrained control over wide swaths of the nation's economy. "At least five Justices have already expressed an interest in reconsidering this Court's approach to Congress's delegations of legislative power." *Allstates Refractory Contractors, LLC v. Su*, 144 S. Ct. 2490, 2491 (2024) (Thomas, J., dissenting for the denial of certiorari) (citing *Paul v. United States*, 589 U.S. 1087, 1087 (2019) (statement of Kavanaugh, J., respecting denial of certiorari); *Gundy*, 588 U.S. at 149 (Alito, J., concurring in judgment); *Gundy*, 588 U.S. at 164 (Gorsuch, J., joined by Roberts, C.J., and Thomas, J.,

dissenting)). No Justice has suggested that the intelligible-principle test is too strict or that courts should relax it by allowing administrative agencies to exercise unconstrainted discretion to set prices and issue regulations. And there is no reason the Third Circuit's decision should be the last word on the constitutionality of a statute with even less constraints than emergency wartime measures that, until now, were viewed as the low watermark for permissible delegations. The Court's intervention is required to confirm that, whatever the scope of permissible delegations, agencies cannot be permitted to exercise unconstrained powers when regulating sales to a very large segment of the economy.

Any change in legal regime that functions, as the Third Circuit's decision does below, to replace settled administrative law requirements—adequate procedural protections, reasoned decision-making, and judicial review—with sweeping, unreviewable authorization for agencies to do as they please, opens a door to arbitrary and even tyrannical government. The Court should defuse that risk by granting review.

CONCLUSION

The Court should grant the petition for certiorari.

Respectfully submitted,

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December 22, 2025

APPENDIX

TABLE OF APPENDICES

Appendix A

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 24-2510

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
(D.C. No. 3:23-cv-20814)

District Judge: Honorable Zahid N. Quraishi

Argued on April 8, 2025

PRECENDENTIAL

(Filed: October 6, 2025)
Document 95

Before: HARDIMAN, PHIPPS, and FREEMAN,
Circuit Judges.

* * *

[counsel block omitted]

OPINION OF THE COURT

HARDIMAN, *Circuit Judge*.

The Inflation Reduction Act of 2022 (the Act) established the "Drug Price Negotiation Program" (the Program) to reduce prescription drug expenditures. The Program directs the Department of Health and Human Services (HHS)—through the Centers for Medicare and Medicaid Services (CMS)—to negotiate prices with drug manufacturers. *See* 42 U.S.C. § 1320f(a)(3).

Novo Nordisk appeals a summary judgment rejecting its statutory and constitutional challenges to the Program. It contends that CMS violated the Act by deeming six of its products to be one "negotiation-eligible drug" and by imposing binding regulations on manufacturers without following notice and comment procedures. It also argues that the Program violates the nondelegation doctrine, the Fifth Amendment's Due Process Clause, and the First Amendment. We will affirm.

I

"Medicare is a federal medical insurance program for people ages sixty-five and older and for younger people with certain disabilities." *AstraZeneca Pharms. LP v. Sec'y U.S. Dep't of HHS*, 137 F.4th 116, 119 (3d Cir. 2025). "Medicaid is a joint federal and state program that provides medical coverage for people with limited incomes." *Id.*

The Program at issue in this appeal targets Medicare Parts B and D. *See id.* at 120. Part B is a "supplemental insurance program that covers outpatient care, including certain prescription drugs that are typically administered by a physician." *Id.* Part D is a "prescription drug benefit program that subsidizes the cost of prescription drugs and prescription drug insurance premiums for Medicare enrollees." *Id.* (citation omitted).

Part D is administered through prescription drug plans operated by private insurers called "sponsors." *Id.* Sponsors bid to be accepted into Medicare Part D and contract with CMS for reimbursement. *See* 42 U.S.C. §§ 1395w-111–1395w-112; *see also* 42 C.F.R. § 423.301 *et seq.* (setting forth rules for reimbursing sponsors). Sponsors, in turn, work with subcontractors, such as pharmacy benefit managers, who process claims and perform other administrative tasks. *See AstraZeneca*, 137 F.4th at 120. Those subcontractors then work with the pharmacies that dispense prescription drugs to Medicare Part D beneficiaries. *See id.*

When Congress enacted Part D in 2003, it prohibited CMS from "interfer[ing] with the negotiations between drug manufacturers and pharmacies and . . . sponsors" and from "institut[ing] a price structure for the reimbursement of covered part D drugs." 42 U.S.C. § 1395w-111(i)(1), (3) (2003). Almost twenty years later, however, the Act created an exception, directing CMS to "negotiate . . . maximum fair prices" for certain drugs, *id.* § 1320f(a)(3), subject to price ceilings derived from a benchmark market-based price, *id.* § 1320f-3(c). "[A]

selected drug's 'maximum fair price' applies beginning in a given drug-pricing period (a period of one calendar year), the first of which is 2026, until the drug is no longer eligible for negotiation or the price is renegotiated." *AstraZeneca*, 137 F.4th at 120 (citing 42 U.S.C. §§ 1320f(b)(1)–(2), 1320f-1(c), 1320f-3(f)).

The Act required CMS to select ten drugs for the first drug-pricing period. *See* 42 U.S.C. §§ 1320f(d), 1320f-1(a). As the Program ramps up, CMS must select 15 more drugs per year for the 2027 and 2028 drug-pricing periods and up to 20 more drugs per year for 2029 and subsequent drug-pricing periods. *See id.* § 1320f-1(a). The selected drugs must have accounted for the largest costs for Medicare that prior year. *See id.* § 1320f-1(b)(1)(A). And once selected, a drug remains in the Program until CMS determines that a generic or biosimilar version of the drug has been approved and is being marketed. *See id.* §§ 1320f-1(c)(1), 1320f-2(b).

After selecting a drug for the Program, CMS must "enter into [an] agreement[]" with the drug's manufacturer to "negotiate . . . a maximum fair price for such selected drug." *Id.* § 1320f-2(a)(1). For the first round of selections, the manufacturer of a selected drug had until October 1, 2023, to enter an agreement to "negotiate" a "maximum fair price" for the drug. *See id.* § 1320f(b)(4), (d)(2)(A).

CMS drafted a template agreement that manufacturers must sign to comply with this negotiation obligation. *See* CMS, *Medicare Drug Price Negotiation Program Agreement*, https://perma.cc/ZC3E-XCQ5 (last visited June 20, 2025), at 1–6 (hereinafter Agreement). The Agreement states that

"CMS and the Manufacturer agree" that they "shall negotiate to determine (and, by not later than the last date of [the negotiation] period, agree to) a maximum fair price for the Selected Drug." *Id.* at 2; *see also* 42 U.S.C. § 1320f-2(a)(1).

Once a manufacturer signs the Agreement, the agency makes a "written initial offer." 42 U.S.C. § 1320f-3(b)(2)(B). The agency must issue the offer by a statutory deadline, propose a "maximum fair price," and include a concise justification for the offer based on statutory criteria. *Id.* The manufacturer then has 30 days to accept the offer or make a counteroffer. *See id.* § 1320f-3(b)(2)(C). CMS must respond in writing to any counteroffer. *See id.* § 1320f-3(b)(2)(D).

Negotiations for the first round of selections were to end by August 1, 2024. *See* 42 U.S.C. §§ 1320f(b)(4), (d)(2)(B), (d)(5)(C), 1320f-3(b)(2)(E). Before that deadline, the manufacturer had to "respond in writing" to the agency "by either accepting or rejecting the final offer." CMS, *Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2026*, at 158 (June 30, 2023) (2023 Revised Guidance), https://perma.cc/AV2Z-4F9U. The agency and manufacturers must follow a similar process for future drug-pricing periods, except the deadlines will be set for different times of the calendar year. *See* 42 U.S.C. § 1320f-3(b)(2).

The Act sets a price ceiling for selected drugs that CMS cannot exceed when it makes a manufacturer an offer. *Id.* § 1320f-3(c)(1)(A). And it requires CMS to "aim[] to achieve the lowest maximum fair price for

each selected drug," *id.* § 1320f-3(b)(1), not to exceed 75 percent of a benchmark based on private market prices for the drug, *id.* § 1320f-3(b)(2)(F), (c)(1)(C), (c)(3). Lower price ceilings (65 or 40 percent) apply to drugs that have been approved for a longer time (at least 12 or 16 years, respectively). *Id.* There is no price floor, but the offer must be "justified" based on certain factors identified in the statute. *Id.* § 1320f-3(b)(2)(B), (b)(2)(C)(ii), (e). The Act forecloses judicial review of, among other things, CMS's pricing decisions, selection of drugs, and determinations about which drugs are eligible for selection. *See id.* § 1320f-7(2).

Together with the Agreement, CMS created a template addendum a manufacturer must sign to formalize a price for its selected drug. *See* Agreement at 7–9. The addendum states that "[t]he parties agree to a price of [$]," which the addendum's recitals note is called a "maximum fair price" in the statute. *Id.* at 7. Once the process is completed, the Act directs CMS to publish the "maximum fair price" that it "negotiated with the manufacturer" and its "explanation" for the price. 42 U.S.C. § 1320f-4(a).

Once signed, the Agreement obliges the manufacturer to "provide access to such price" for its selected drug to Medicare beneficiaries beginning in 2026. Agreement at 2; 42 U.S.C. § 1320f-2(a)(1). Failure to do so triggers a civil monetary penalty of ten times the difference between the price charged and the maximum fair price for every unit sold. 42 U.S.C. § 1320f-6(a). An offending manufacturer also will be subject to a civil monetary penalty of $1,000,000 for each day the Agreement was violated. *Id.* § 1320f-6(c).

After CMS includes a drug in the Program, the manufacturer can walk away and choose not to do business with the government. But if a manufacturer continues to participate in certain Medicare and Medicaid programs without signing an agreement under the Program, it must pay a daily excise tax that begins at 185.71 percent and rises to 1,900 percent of the selected drug's total daily revenues from all domestic sales. *See* 26 U.S.C. § 5000D.

We have held that the Act provides an escape hatch for a company that declines to participate in the Program. A manufacturer can cause the excise tax to be "[s]uspen[ded]" by terminating its extant Medicare and Medicaid agreements under the Medicare Coverage Gap Discount Program, the Manufacturer Discount Program, and the Medicaid Drug Rebate Program. *Id.* § 5000D(c); *Bristol Myers Squibb v. Sec'y U.S. Dep't of HHS*, ___ F.4th ____, ____, 2025 WL 2537005, at *3 (3d Cir. Sept. 4, 2025).

CMS may terminate a manufacturer's extant Medicare agreements under the Coverage Gap Discount and Manufacturer Discount Programs for "good cause" effective upon 30 days' notice. 42 U.S.C. §§ 1395w-114a(b)(4)(B)(i), 1395w-114c(b)(4)(B)(i). Relying on that authority, CMS promised to offer manufacturers a 30-day exit from the Coverage Gap Discount and Manufacturer Discount Programs upon request, which it said would enable a manufacturer to avoid excise tax liability. 2023 Revised Guidance at 33–34, 120–21. We have held that CMS has statutory authority to do so and that participation in the Program is therefore voluntary. *See Bristol Myers Squibb*, ___ F.4th at ____, 2025 WL 2537005, at *7-8.

II

In the first round of selections, CMS selected six of Novo Nordisk's biological products for inclusion in the Program: Fiasp, Fiasp FlexTouch, Fiasp PenFill, NovoLog, NovoLog FlexPen, and NovoLog PenFill. Novo Nordisk signed an Agreement to participate in the Program by the October 1, 2023, deadline and an addendum setting a "maximum fair price" by the August 1, 2024, deadline.

In September 2023, Novo Nordisk sued HHS and its Secretary along with CMS and its Administrator. As relevant here, it argued that CMS violated the Act by treating its six products as one "negotiation-eligible drug" and by imposing legislative rules without following notice and comment procedures. It also argued that the Program violated the nondelegation doctrine, the Fifth Amendment's Due Process Clause, the First Amendment, and the unconstitutional conditions doctrine.

The parties cross-moved for summary judgment. The District Court denied Novo Nordisk's motion, granted the Government's motion, and entered judgment. *See Novo Nordisk Inc. v. Becerra*, 2024 WL 3594413, at *1 (D.N.J. July 31, 2024). It concluded that it lacked subject matter jurisdiction to review CMS's decision to treat six of Novo Nordisk's products as one negotiation-eligible drug. It also held that Novo Nordisk lacked standing to argue that CMS violated the Act by identifying more than ten drugs for the 2026 drug-pricing period. The District Court rejected Novo Nordisk's unconstitutional conditions and due process claims, reasoning that the Program does not deprive the company of a protected property interest.

Similarly, it rejected the nondelegation claim, concluding that the Act provides CMS with an intelligible principle and deeming the Act's judicial review bar irrelevant. Finally, it rejected the First Amendment claim by reasoning that the Program primarily regulates conduct rather than speech. Novo Nordisk appealed.[1]

III

Novo Nordisk argues that CMS violated the Act when it treated six of Novo Nordisk's products as one negotiation-eligible single-source drug. Because of the Act's judicial review bar, we lack jurisdiction to reach the merits of that statutory claim. *See Wheaton Indus. v. EPA*, 781 F.2d 354, 356–57 (3d Cir. 1986) (treating a statute precluding judicial review of agency action as jurisdictional); *Am. Clinical Lab'y Ass'n v. Azar*, 931 F.3d 1195, 1204–05 (D.C. Cir. 2019) (treating statutory language that "[t]here shall be no administrative or judicial review" as jurisdictional).

Agency action is presumptively subject to judicial review. *See Bouarfa v. Mayorkas*, 604 U.S. 6, 19 (2024). However, this presumption may be overcome by a clear statement of congressional intent to

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[1] The District Court had jurisdiction under 28 U.S.C. § 1331, and we have jurisdiction under 28 U.S.C. § 1291. Our review of the District Court's summary judgment is de novo. *See Canada v. Samuel Grossi & Sons, Inc.*, 49 F.4th 340, 345 (3d Cir. 2022). Summary judgment is appropriate "if the movant shows that 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). We "hold unlawful and set aside agency action" that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

preclude judicial review. *Id.* Although we construe jurisdiction-stripping provisions narrowly, *United States v. Dohou*, 948 F.3d 621, 625 (3d Cir. 2020), we must give effect to Congress's will to set the limits of federal jurisdiction, *see Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 164 (2008).

The Act includes the requisite clear statement. It provides that "[t]here shall be no . . . judicial review of," among other things, "the determination of negotiation-eligible drugs" or "the determination of qualifying single source drugs." 42 U.S.C. § 1320f-7(2). This provision shields from review CMS's treatment of Novo Nordisk's six insulin aspart products as one drug.

CMS announced in the Guidance that, when identifying qualifying single-source drugs, it would group together "all dosage forms and strengths of [a] biological product 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." 2023 Revised Guidance at 99. The six NovoLog and Fiasp products have the same active ingredient and the same holder of a BLA. CMS grouped those six products together and treated them as one biological product during the Program's drug-identification process.

CMS determined that this biological product was a qualifying single-source drug under 42 U.S.C. § 1320f-1(e)(1)(B), and that this single-source drug's associated expenditures through Medicare made it a negotiation-eligible drug under § 1320f-1(d)(1) and (2). We are barred from reviewing that "determination of qualifying single source drugs" and that

"determination of negotiation-eligible drugs." *Id.* § 1320f-7(2). Next, based on a ranking of all negotiation-eligible drugs' Medicare expenditures, CMS selected Novo Nordisk's insulin aspart products for negotiation under § 1320f-1(b)(1). (We are also barred from reviewing that selection, *id.* § 1320f-7(2), and Novo Nordisk does not argue otherwise.)

Novo Nordisk asserts that it is not challenging CMS's "determination of qualifying single source drugs" or its "determination of negotiation-eligible drugs." Instead, it says it challenges an earlier step in the process: CMS's decision to group products into a single potentially qualifying drug. But we have held that when a statute prohibits review of a particular "determination," the bar extends to the ultimate decision *and* "the process by which [the agency] reaches this decision." *Bakran v. Sec'y, DHS*, 894 F.3d 557, 563 (3d Cir. 2018). In *Bakran*, we considered a judicial review bar that covered the Department of Homeland Security's "determin[ation]" about a citizen's risk to a beneficiary relative. *Id.* at 560, 563 (citing 8 U.S.C. § 1252(a)(2)(B)(ii)). We held that the bar applied to a challenge to two DHS memoranda: one that instructed field officers to "rare[ly]" make a no-risk determination, and another that required citizens to prove beyond any reasonable doubt that they posed no risk. *Id.* We explained that the statutory term "determine" means "to fix conclusively or authoritatively" *and* "to come to a decision concerning as the result of investigation or reasoning." *Id.* at 563 (quoting *Determine, Webster's Third New International Dictionary* (1993)); *accord Determination*, *The Merriam-Webster Dictionary* (2022) ("the act of coming to a decision; *also*: the

decision or conclusion reached"). Thus, Congress's choice to make DHS's determinations unreviewable meant that the internal processes DHS used to reach its decisions were also unreviewable. *Bakran*, 894 F.3d at 563–64.

Here, CMS adopted a definition of qualifying single-source drug that led the agency to group Novo Nordisk's products together and ultimately select them for negotiation as one drug. We cannot review CMS's determinations or the internal processes CMS used to make them.

Novo Nordisk resists this conclusion in various ways. Primarily, it attempts to frame the issue as whether CMS complied with the ten-drug limit the Act set for the first program year. But CMS treated Novo Nordisk's related insulin aspart products, collectively, as one qualifying single-source drug—not six. Treating those products as one drug, CMS selected only ten drugs for negotiation. This treatment was part of CMS's "determination of qualifying single source drugs" that is barred from our review. 42 U.S.C. § 1320f-7(2).

Next, Novo Nordisk argues that the judicial review bars only apply to two specific determinations in the Act: determinations to exclude certain low-spend Medicare products from the universe of qualifying single-source drugs and to exclude small biotech products from the universe of negotiation-eligible drugs. *See* 42 U.S.C. § 1320f-1(d)(2), (e)(3)(B); But the text of the judicial review bar plainly applies to a broader set of agency decisions than these exclusions.

Finally, Novo Nordisk argues that CMS's decisions are reviewable as ultra vires agency action. *See Leedom v. Kyne*, 358 U.S. 184 (1958). In its view, the judicial review bar only applies to determinations CMS makes within the bounds of its statutory authority, permitting us to review claims that CMS's determinations exceeded its authority. However, an argument that CMS did not comply with a statutory mandate in making a particular determination is still a challenge to that determination. More to the point, ultra vires review is available "only when an agency has taken action entirely in excess of its delegated powers and contrary to a *specific prohibition* in a statute." *Nuclear Regul. Comm. v. Texas*, 605 U.S. 665, 681 (2025) (internal quotation marks omitted). The Supreme Court has clarified that it is not available when a statute explicitly bars judicial review. *See Bd. of Governors of the Fed. Reserve Sys. v. MCorp Fin., Inc.*, 502 U.S. 32, 44 (1991); *see also DCH Reg'l Med. Ctr. v. Azar*, 925 F.3d 503, 509 (D.C. Cir. 2019) ("Following *MCorp*, there is not much room to contend that courts may disregard statutory bars on judicial review just because the underlying merits seem obvious."). Here, an explicit judicial review bar encompasses Novo Nordisk's claim, so ultra vires review is not available.

IV

Novo Nordisk next contends that CMS violated the Administrative Procedure Act, the Medicare Act, and the Inflation Reduction Act by promulgating legislative rules without following notice and

comment procedures.[2] A statutory note to the Act provides that HHS "shall implement [the Program] . . . for 2026, 2027, and 2028 by program instruction or other forms of program guidance." 42 U.S.C. § 1320f (note); *see also* Inflation Reduction Act of 2022, Pub. L. No. 117-169, § 11001(c), 136 Stat. 1818, 1854 (2022); 42 U.S.C. § 1320f-1 (note); Inflation Reduction Act of 2022, Pub. L. No. 117-169, § 11002(c), 136 Stat. 1818, 1862 (2022). Novo Nordisk argues that this note prohibits CMS from promulgating legislative rules that implement the Program and take effect before 2029.

Ordinarily, CMS must comply with the rulemaking procedures set forth in the APA and Medicare Act when it promulgates legislative rules. *See* 5 U.S.C. § 553; 42 U.S.C. § 1395hh(a)(2). But the APA and Medicare Act recognize that Congress may "expressly" authorize an agency to conduct rulemaking without following those procedures. 5 U.S.C. § 559; 42 U.S.C. § 1395hh(b)(2)(A). In *Bristol Myers Squibb*, this Court concluded that this statutory note expressly permits CMS to promulgate legislative rules by issuing guidance for the first three drug-pricing periods. ___ F.4th at ____ & n. 18, 2025 WL

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[2] The Government argues that Novo Nordisk's challenge to CMS's rulemaking is covered by the Act's judicial review bar. Not so. As discussed above, the review bar applies to CMS's determination of qualifying single source drugs and its determination of negotiation-eligible drugs. *See supra* Section III. Neither of those determinations encompasses CMS's promulgation of legislative guidance implementing the Program as a whole without notice and comment rulemaking.

2537005, at *7-8 & n.18. So we will affirm the District Court's summary judgment on this claim.

V

A

We now turn to Novo Nordisk's constitutional arguments, beginning with its claim that the Act violates the nondelegation doctrine. "The nondelegation doctrine bars Congress from transferring its legislative power to another branch of Government." *Gundy v. United States*, 588 U.S. 128, 132 (2019) (plurality opinion). "If Congress could pass off its legislative power to the executive branch, the vesting clauses, and indeed the entire structure of the Constitution, would make no sense." *Id.* at 155 (Gorsuch, J., dissenting) (citation modified). In considering Novo Nordisk's claim, we ask whether "Congress has supplied an intelligible principle to guide the delegee's use of discretion." *Id.* at 135 (plurality opinion). We conclude that it has.

The Act contains detailed rules governing which products may be subject to price controls. *See* 42 U.S.C. § 1320f-1. It also limits the number of products that may be selected and grants CMS only narrow discretion to determine whether certain products should be excepted. *See id.* § 1320f-1(a), (d)–(f). Under a complex set of criteria, a drug is typically eligible for selection if, among other things, it is a "qualifying single source drug" (1) that has been approved for at least 7 years (or 11 years for biological products) and (2) for which there is no generic or biosimilar product that has been approved and marketed. *Id.* § 1320f-1(d)–(e). Selected medicines must remain in the

Program until CMS determines that a generic or biosimilar version of the drug has been approved and is being marketed. *Id.* § 1320f-1(c)(1).

Along with limiting product selection, the Act constrains CMS's pricing determinations. It sets a price ceiling that the agency cannot exceed, ranging from 75 to 40 percent of a benchmark based on private market prices for the drug, depending on how recently the drug was approved. *Id.* § 1320f-3(b)(2)(F), (c)(1)(C), (c)(3). And although there is no price floor, CMS's offer must be "justified," 42 U.S.C. § 1320f-3(b)(2)(B), (b)(2)(C)(ii), (e), based on certain factors identified in the statute, including "the manufacturer's production and distribution costs, the manufacturer's research and development costs (and the extent to which those costs have been recouped), federal funding for the drug's development, patent rights and statutory exclusivities, FDA product approvals, sales data, and alternative treatments." *AstraZeneca*, 137 F.4th at 121 (citation omitted).

In sum, the Act provides CMS with detailed guidance and restrains its discretion at many turns. Because that guidance clears the "intelligible principle" hurdle, the Program does not violate the nondelegation doctrine.

B

Novo Nordisk also contends that the Act violates the Fifth Amendment's Due Process Clause. We recently rejected this argument when it was advanced by a different manufacturer, *AstraZeneca*, 137 F.4th

at 125–26, and our answer remains the same today: the Act does not violate the Due Process Clause.[3]

C

Finally, we address Novo Nordisk's claim that the Act violates the First Amendment. We decided this issue in *Bristol Myers Squibb*. *See* ___ F.4th at ____, 2025 WL 2537005, at *10-15. For the reasons we explained there, we will affirm the District Court's summary judgment on Novo Nordisk's compelled speech claim.

* * *

The Act's judicial review bar precludes our review of Novo Nordisk's claim about the grouping of its products, the Act provides CMS with an intelligible principle, and Novo Nordisk's remaining statutory and constitutional claims are foreclosed by our precedent. So we will affirm the District Court's judgment.

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[3] Novo Nordisk urges us to take a "holistic[]" view of its due process and nondelegation arguments. Novo Nordisk Br. 54 (quoting *Consumers' Rsch. v. FCC*, 109 F.4th 743, 778 (5th Cir. 2024) (en banc), *rev'd*, 145 S. Ct. 2482 (2025)). In its view, a confluence of issues with the Act work together to violate the separation of powers: the Act delegates a major question to CMS; allows CMS to act without guaranteeing regulated parties significant procedural rights; and forecloses judicial review of CMS's pricing decisions, selection of drugs for negotiation, and determinations about what drugs are eligible for selection. But "[t]wo wrong claims do not make one that is right," so our conclusion about each individual argument resolves Novo Nordisk's "combination claim" as well. *Consumers' Rsch.*, 145 S. Ct. at 2511 (citation modified).

Appendix B

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
Trenton

Civil Action No. 23-20814 (ZNQ) (JBD)

NOVO NORDISK INC., *et al.*,

Plaintiffs,

v.

XAVIER BECERRA, *et al.*,

Defendants.

NOT FOR PUBLICATION

Filed: July 31, 2024
Document 93

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

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[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.

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

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[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.).

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

[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.

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).

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

[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."

(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 (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

[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.

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.

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

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[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).

market value." The Court therefore finds that Plaintiffs' First Amendment claim and its claims challenging the voluntary nature of the Program 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 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

[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.

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

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[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.*

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 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*

[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)).

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.

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

Appendix C

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
Trenton

Civil Action No. 23-20814 (ZNQ) (JBD)

NOVO NORDISK INC., *et al.*,

Plaintiffs,

v.

XAVIER BECERRA, *et al.*,

Defendants.

Filed: December 8, 2023
Document 30

DECLARATION OF DR. NATHAN LANEY

I, Dr. Nathan Laney, declare as follows pursuant to 28 U.S.C. § 1746

1. I am a resident of Florida. I am over the age of eighteen, and I am competent to provide this declaration.

2. I received an MD in 2003 from the University of Missouri-Kansas City School of Medicine and an MBA from Florida International University in 2022. I am board certified in endocrinology. I have been at Novo Nordisk, Inc. since 2015. I have worked as Regional Medical Liaison – Philadelphia; Regional

Medical Scientist – South Atlantic; Scientific Director, Diabetes TA; and most recently as the Medical Director at Novo Nordisk Inc. Before that, I spent six years as a practicing endocrinologist at St. Luke's Endocrinology & Diabetes. In all of these roles, I have either worked directly with patients or with healthcare professionals on diabetes management options, including insulin selection and dosing, to improve outcomes for patients living with diabetes. In my role as Medical Director at Novo Nordisk Inc., I have been deeply involved in the Company's response to CMS inquiries under the Inflation Reduction Act and other related medical policy discussions.

The Need for Insulin to Manage Diabetes

3. In healthy individuals, beta cells in the pancreas release the hormone insulin to help regulate glucose levels in the blood. At mealtimes, insulin output from the beta cells acutely increases to allow the body to use and/or store glucose released from the digestion of food. Most patients living with diabetes have either Type 1 diabetes (T1D), an autoimmune disease where beta cells have been destroyed by the body's own immune system yielding insufficient and/or total loss of insulin production by the pancreas, or Type 2 diabetes (T2D), where the body suffers from a combination of disorders involving glucose metabolism, including inadequate insulin secretion, insulin resistance, and metabolic syndrome.

4. There is no cure for diabetes. While medicines have improved treatment, if diabetes is not properly controlled, and often even if it is well treated, it can lead over time to complications including vision impairment (or even blindness), loss of kidney

function, and nerve damage which can increase the risk of amputations. Diabetes is also associated with cardiovascular risks, including myocardial infarction, stroke, heart failure, and peripheral arterial disease.

5. Innovations resulting in the development of new products to assist in insulin therapy have provided patients with the necessary tools for managing this chronic disease. Important advances include the development of both prandial—or mealtime—insulins (fast-acting insulins taken at mealtime to prevent excessive elevations in blood sugar levels after the meal) and basal insulins (slower, longer-acting insulins that control blood sugar levels between meals and when the patient is not eating).

Insulin Dosing

6. The cornerstone of diabetes management is ensuring that treatment approaches are tailored to individual patients.

7. Controlling insulin dosing is critical. "In people with type 1 diabetes, treatment with analog insulins is associated with less hypoglycemia and weight gain as well as lower [average blood sugar levels or] A1C compared with human insulins. More recently … insulin formulations with enhanced rapid-action profiles have been introduced … and faster-acting insulin aspart and insulin lispro-aabc may reduce prandial excursions better than [rapid acting analogues or] RAA." Nuha A. ElSayed et al., *Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes—2023*, 43 Diabetes Care S140, S141 (2023) (endnotes omitted) (attached as Exhibit A). However, choosing between appropriate

analogue prandial insulin products is just the starting point. Individual patients must have their insulin doses adjusted and tailored to their individual needs.

8. Because insulin dictates how much sugar cells absorb, too much insulin can cause hypoglycemia, or low blood sugar; too little insulin can cause hyperglycemia, or too high of blood sugar levels in the blood. Increased hypoglycemia increases risk of complications, including decreased sensitivity to hypoglycemia over time which amounts to hypoglycemic unawareness. And, with more hypoglycemic events comes increased risk of impaired cognitive function, heart arrhythmias, and mortality. When increased hyperglycemia leads to overall poor control of diabetes, it can be associated with both microvascular and macrovascular complications. Microvascular complications refer to those conditions affecting organs supplied by smaller blood vessels, and include visual disturbances, or retinopathy; reduced kidney function, or nephropathy; and disorders of the nerves, or neuropathy. In fact, diabetes remains the leading cause of blindness and chronic kidney failure in the United States, and neuropathy significantly increases the risk of these patients to develop foot ulcers and infections that lead to amputations. Macrovascular complications refer to those conditions affecting organs supplied by larger blood vessels, and include conditions like myocardial infarctions, strokes, heart failure, and peripheral arterial disease.

9. Landmark clinical data in patients with both T1D and T2D have shown that targeting appropriate overall blood sugar control reduces the risk of developing microvascular and macrovascular

complications. In terms of appropriate overall blood sugar control, the laboratory measurement historically used to assess overall control is the A1C, which reflects the average glucose levels over the past 3 months. Ideally, the goal is to achieve an A1C level that is below 7%, as this is the threshold lowering the rate of hyperglycemia related complications. *See* Nuha A. ElSayed et al., *Glycemic Targets: Standards of Care in Diabetes—2023*, 46 Diabetes Care S97 (2023) (attached as Exhibit B). A1C is the sum of all glucose exposure, including fasting blood glucose ("FBG") and post prandial glucose ("PPG") levels—blood sugar levels after a meal. This is particularly important at lower A1C levels, where PPG is the predominant contributor to A1C targets. Therefore, while A1C is an important measure, other measurements, such as PPG levels, should also be considered when assessing a person's overall diabetes control. *See* Louis Monnier et al., *Contributions of Fasting and Postprandial Glucose to Hemoglobin A1c*, 12 Endocrine Prac. 42 (2006) (attached as Exhibit C).

10. Once patients are using insulin as part of their diabetes treatment, additional modalities can be implemented to monitor blood sugar control, including continuous glucose monitoring with a device that continuously measures interstitial glucose levels over the course of the day and/or home blood glucose monitoring with a device that measures capillary glucose levels at the time the capillary blood is obtained.

11. Insulin dosing is a complex process that requires the consideration of multiple factors on an individual basis. For patients with T1D and the subset

of patients with T2D who require insulin, insulin coverage is necessary throughout the day. This 24-hour insulin coverage is provided through a basal insulin component and a mealtime insulin component, both of which are intended to maintain blood sugar levels in the desired target range. The basal insulin works in the background to keep blood sugar levels in the desired target range between meals and while the individual is not eating. The mealtime insulin works to keep blood sugar levels after meals, known as PPG, from rising too high.

12. Each patient will have individualized basal and mealtime insulin needs. For example, the basal insulin component can be achieved through once- or twice-daily injections with either the newer, long-acting basal insulin analogues or the older, longer-acting NPH regular insulin, or even through the continuous administration of a rapid acting insulin analogue via an insulin pump. The mealtime component preferably will be met by one of the newer, rapid acting or ultra-rapid acting insulin analogues. Selection and dosing of both the basal insulin and the mealtime insulin will be highly specific to individual patients.

13. Because the underlying disturbances in blood sugar metabolism carry significant differences between patients living with T1D and T2D, the initiation of insulin therapy is different.

14. Most individuals with T1D are treated with multiple daily injections of insulin, including a combination of both prandial insulin and basal insulin, or with continuous subcutaneous infusion of the newer rapid- or ultra-rapid-acting insulin

analogues administered through an external insulin pump. For patients who are living with T1D, in particular, where their B-cells are producing very little to no insulin, insulin therapy is life sustaining. In general, a weight-based approach can be used to initiate insulin therapy, with typical total daily insulin requirements ranging between 0.4-1 unit/kg/day.

15. Patients living with T2D have several other medications available to control blood sugar levels initially in the disease process. Due to the progressive nature of T2D, many individuals with T2D eventually require insulin therapy to overcome progressive declines in insulin production from the B-cells and control their blood sugar levels. These patients typically continue using their oral anti-diabetes medications and/or non-insulin injectable medications to control blood sugar levels, with the exception of classes known to non-discriminately stimulate insulin secretion like the sulfonylurea and glinide classes of diabetes medications. Unlike patients living with T1D, most individuals with T2D will initially add a basal insulin to their non-insulin medications, with use of mealtime insulin initiation reserved for those patients suffering from significant elevations in blood sugar levels (e.g., up into the 300 mg/dL range) or when additional control of blood sugar levels is necessary. The basal insulin dose for those patients is generally initiated using either the fixed starting dose outlined in the FDA-approved product label for the long-acting analogues, or a weight-based dose between 0.1-0.3 units/kg/day, and then titrated upwards until the desired fast blood sugar target is achieved. *See* ElSayed et al. (Exhibit A); Susan L. Samson et al.,

American Association of Clinical Endocrinology Consensus Statement: Comprehensive Type 2 Diabetes Management Algorithm - 2023 Update, 29 Endocrine Prac. 305 (2023) (attached as Exhibit D). When T2D patients need to advance their regimens to include mealtime insulin, the more conservative approach would be to start mealtime insulin at a fixed dose of 4-5 units prior to the largest meal or calculating the starting dose using either 10 percent of the basal insulin or a weight-based approach dose as the starting point.

16. For both T1D and T2D patients who require mealtime insulin, once the total daily insulin dose for a patient is calculated, generally half of the dose is given as the basal insulin component and the other half is split between other meals. The mealtime component is then further divided among the number of meals the individual consumes daily. *See* ElSayed et al. (Exhibit A); Samson et al. (Exhibit D). From this starting point, both T1D and T2D patients must account for *when* their mealtime insulin will start working after it is injected, as well as how to adjust their planned dose based on current blood sugar level, what they are eating, and their activity level—in order to avoid causing either high or low blood sugar levels after meals related to their mealtime insulin. This process is a balancing act between increasing the basal insulin dose to lower fasting blood sugar levels while simultaneously monitoring for when it is appropriate to add or adjust mealtime insulin. If the titration process is not handled with care, these patients are at risk for persistent episodes of high blood sugars levels after meals as well as low blood sugar levels when they are not eating.

17. The dosing regimen will differ across different mealtime insulin formulations, as different insulins are absorbed into the bloodstream at different rates and thus have different rates of onset. For instance, patients that use a short-acting human regular insulin as their mealtime insulin would have to inject their mealtime insulin dose 30 minutes before they even start eating their meal, while the same patient using a rapid acting analogue like NovoLog®, would only have to administer their mealtime dose 5-10 minutes before they start eating. Patients using an ultra-rapid analogue like FIASP® would wait until they start eating or up to 20 minutes after they start eating before they must inject their mealtime insulin. For this reason, among others, the optimal time to administer prandial insulin varies based on the specific insulin product and the needs of the individual patient.

Insulin Administration

18. Taking insulin in pill form is not an option as, under current technology, the insulin in the pill would be broken down like a protein in food and would be ineffective. Insulin is therefore injected, either under the skin (subcutaneously) or intravenously, in order for it to enter the bloodstream and travel to the cells where it exerts its action to regulate blood sugar levels. The need for this type of administration makes insulin delivery devices critical to patient use.

19. Insulin products are generally available in (1) a vial, to be used with a syringe, (2) a pen injector or (3) a pump device.

20. The vial-and-syringe method, which requires the patient to draw up the appropriate amount of insulin through a syringe, can pose risks such as drawing the incorrect insulin dose, and can be particularly challenging for those with vision impairment or dexterity limitations.

21. Pen injectors and insulin pumps can mean more precise and flexible dosing, which can reduce the risk of hyperglycemia (too high blood sugar) and hypoglycemia (too low blood sugar). A pen injector enables the patient to dial in the correct dose, resulting in easier and more accurate administration and less pain on injection—as well as more accurate dosing. Patients can also opt for an insulin pump—a small, computerized device that continuously delivers insulin as programmed.

22. Different injectors and pumps are used for different insulin products. For example, while NovoLog® products and FIASP® products are both available for pump use, the pumps used for the different products are not the same. FIASP® products cannot be used in certain pumps due to risks of occlusion (or blockage in pump tubing); those pumps are labeled only for use with NovoLog® products.

The NovoLog® Products

23. NovoLog® is Novo Nordisk Inc.'s ("Novo") rapid-acting mealtime insulin. It is indicated to improve glycemic control in adults and pediatric patients with diabetes mellitus. The NovoLog® family of products includes: NovoLog® 10 mL (100 units/mL, or "U100") vial; NovoLog® PenFill® 3 mL (U100) cartridges, for use with a reusable insulin pen; and

NovoLog® FlexPen® 3 mL (U100), a single-patient-use prefilled insulin pen. Each of these products is a distinct product that is used for different purposes, but I refer to them together as the "NovoLog® products."

24. Patients administer NovoLog® products 5–10 minutes before a meal; the American Diabetes Association ("ADA") and the American Association of Clinical Endocrinology ("AACE") consider them to be "rapid-acting" insulin products.

The FIASP® Products

25. FIASP® is Novo's *ultra*-rapid-acting mealtime insulin. It is indicated to improve glycemic control in adults and pediatric patients with diabetes mellitus. The FIASP® family of products includes: FIASP® 10 mL (U100) vial; FIASP® FlexTouch® 3 mL (U100), a single-patient-use prefilled insulin pen; FIASP® PenFill® 3 mL (U100) cartridges, for use with a reusable insulin pen; and FIASP® PumpCart®, a 1.6 mL (U100) cartridge for use with insulin pumps. Each of these products is a distinct product that is used for different purposes, but I refer to them together as the "FIASP® products."

26. In addition to different prescribing guidance from the ADA and the AACE for the FIASP® family of products versus the NovoLog® family of products, the FDA-approved prescribing information also differs, reflecting, among other things, these products' different onset of action and dosing regimens, and the differing clinical studies that supported FDA approval of the different products.

27. Onset of appearance for FIASP® products has consistently been shown to be twice as fast as that for

NovoLog® products as a result of the faster onset of exposure and increased initial absorption rate seen with the FIASP® products.

28. The ADA and the AACE consider the FIASP® products to be "ultrarapid-acting" insulin products. Patients administer at their first bite or within 20 minutes after starting a meal. This provides patients with more flexible options for dosing. They can use a FIASP® product right at the start of a meal, up to 20 minutes after starting the meal, or at an interim point, as they deem as optimal to account for factors affecting their dosing.

29. The ADA Standards of Care differentiate "rapid-acting" insulins from "ultra-rapid-acting insulins." ElSayed et al. (Exhibit A at S143). According to the AACE Consensus Statement published in 2023, "Rapid-acting insulin analogs are preferred over human insulin preparations (e.g., regular insulin) because of their comparatively earlier onset of action." Samson et al. (Exhibit D at 319).

The FIASP® and NovoLog® Products Differ in Clinically Meaningful Ways

30. The different products included in the NovoLog® family of products and the FIASP® family of products all contain the same active ingredient, insulin aspart. But that does not mean that all of the different products within each family qualify as a single product. There are meaningful differences between the products in terms of how they are prescribed, dosed, and used by patients. As described above, when a healthcare provider writes an insulin prescription they write it not just for the active

ingredient, but for the dosage and delivery method appropriate for each individual patient based on their needs.

31. The goal of therapy is to provide an insulin regimen that mimics normal insulin secretion, which requires consideration of factors that would affect normal insulin secretion in the body—factors like the individual's current blood sugar level, the size and makeup of the meal, and even the body's current demand for sugar based on recent and/or future activity level.

32. Basal insulin and short-acting human insulin R help control blood sugar levels, but they are too slow to be responsive to mealtime insulin needs. Both the NovoLog® products and the FIASP® products help lower mealtime blood sugar spikes—but they do so at different rates.

33. The FIASP® products are formulated with vitamin B3 (niacinamide) to increase the speed of initial absorption and an amino acid (L-arginine) to stabilize the formulation. As a result, and as reflected in pharmacokinetic and pharmacodynamic clinical studies, the insulin in the FIASP® products enters the bloodstream faster than that in the NovoLog® products, resulting in a faster onset of action. In fact, the onset for FIASP® products is approximately 2.5 minutes, more than twice as fast as NovoLog® products' onset at just over 5 minutes. The onset of the glucose-lowering effect (onset of action) is statistically significantly faster as a result of the faster onset of exposure and increased initial absorption rate seen with the FIASP® products.

34. Because the faster onset of FIASP® products allows for later dosing with respect to the meal, the dose timing is different between the NovoLog® products and the FIASP® products. That is why the FIASP® products can be dosed flexibly, between the start of a meal and up to 20 minutes later, as compared to the NovoLog® products, which are dosed 5-10 minutes *before* the start of a meal.

35. Being able to take a FIASP® product after starting a meal is very important. As described above, each mealtime insulin dose is driven by how much the person eats, what they eat, and when they eat it, *i.e.*, is subject to hunger, availability, and interruptions. The patient must tailor the dose for each meal, to account for the meal itself, as well as to make other adjustments, such as adjustments related to exercise. For example, a patient planning to eat a meal heavy in carbohydrates will have a different insulin need from a patient eating a low-carbohydrate meal. But ultra-fast-acting insulins can be dosed based on food *actually consumed* instead of estimates of what might be consumed.

36. The ability to wait until after a meal has been decided upon, ordered, or even consumed, offers a considerable benefit to some patients. For pediatric and elderly patients, for example, there is a real concern that they will not eat as expected, which can require dose adjustments after a meal or result in hypoglycemia. In a survey of parents of pediatric patients with Type 1 diabetes, 81% indicated that, at least once a week, their children ate more or less food than anticipated after dosing mealtime insulin. *See* Wendy Lane et al., *Exploring the Burden of Mealtime*

Insulin Dosing in Adults and Children with Type 1 Diabetes, 39 Clinical Diabetes J. 347 (2021) (attached as Exhibit E). And for all patients, there can be interruptions—a child may need something just as the person is sitting down to eat after dosing, or a waiter at a restaurant may inform the patient that their selection is not available after placing an order and administering an insulin dose accordingly.

37. A patient using a rapid-acting insulin must eat the planned amount once dosed, or they may experience hypoglycemia, with the side effects that ensue. Nocturnal hypoglycemia also can occur if a patient does not eat enough food after taking an insulin dose or taking more insulin that prescribed in the evening. In a survey of adults with Type 1 diabetes, 58% of patients reported a need for additional food intake as a corrective action to prevent hypoglycemia at least once a week. *See id.* (Exhibit E).

38. The flexibility of ultra-rapid-acting insulin, however, allows a patient to ensure what they are eating—and that they are in fact consuming it—*before* dosing. That, in turn, enables a person to best match their insulin dose to their actual intake, minimizing the chance of taking too much or too little insulin (which can have adverse consequences and could lead to adverse events or serious adverse events). The improved flexibility in timing of mealtime and post-meal dosing can therefore improve therapeutic adherence which could lead to better glycemic control. *See id.* (Exhibit E). For a patient taking insulin on a daily basis, this flexibility is absolutely key to quality of life, controlling their diabetes, and avoiding daily highs and lows.

39. In addition to the added flexibility of ultra-rapid mealtime insulin for some patients, the differences in onset timing can result in lower PPG levels after a meal. In a survey of adults with Type 1 diabetes, 91% reported experiencing challenges with mealtime insulin dosing, including the need to inject more insulin after a meal because of eating more or different food than anticipated. *See id.* (Exhibit E).

40. High PPG levels have been linked to the development of vascular complications and other adverse effects. *See* Kenneth S. Hershon et al., *Importance of Postprandial Glucose in Relation to A1c and Cardiovascular Disease*, 37 Clinical Diabetes J. 250 (2019) (attached as Exhibit F).

41. Too little insulin, and for patients with Type 2 diabetes, the loss of early phase endogenous insulin secretion, contributes to elevated PPG levels after a meal, but with improved dosing flexibility and other clinical characteristics of a ultra rapid acting insulins, PPG levels can be better controlled. When administered at mealtime, FIASP® outperformed NovoLog® in terms of significantly reducing 1-hour PPG increments in both Type 1 and Type 2 diabetes patients in multiple clinical trials. *See* David Russell-Jones et al., *Fast-Acting Insulin Aspart Improves Glycemic Control in Basal-Bolus Treatment for Type 1 Diabetes: Results of a 26-Week Multicenter, Active-Controlled, Treat-to-Target, Randomized, Parallel-Group Trial (Onset 1)*, 40 Diabetes Care 943 (2017) (attached as Exhibit G); Keith Bowering et al., *Faster Aspart Versus Insulin Aspart as Part of a Basal-Bolus Regimen in Inadequately Controlled Type 2 Diabetes: The Onset 2 Trial*, 40 Diabetes Care 951 (2017)

(attached as Exhibit H). This, in turn, can result in fewer instances of immediate post-prandial hypoglycemia, complications and long-term clinical impacts. A randomized, blinded clinical trial in adults with Type 2 diabetes found a lower relative risk of severe hypoglycemia for FIASP® compared to NovoLog®. *See* Wendy S. Lane et al., *A Randomized Trial Evaluating the Efficacy and Safety of Fast-Acting Insulin Aspart Compared With Insulin Aspart, Both in Combination With Insulin Degludec With or Without Metformin, in Adults With Type 2 Diabetes (ONSET 9)*, 43 Diabetes Care 1710 (2020) (attached as Exhibit I).

42. Thus, the ADA Standards of Care have recognized that ultra rapid-acting insulins like the FIASP® products may reduce prandial excursions better than rapid-acting insulins like NovoLog®. In fact, there is a demonstrated statistically significant reduction in A1C in patients with T1D when FIASP® was dosed at mealtime versus NovoLog® dosed at mealtime. *See* Russell-Jones et al. (Exhibit G).

43. Because of these differences, it is medically critical to appropriately differentiate between the different NovoLog® products and the different FIASP® products to avoid inadvertent substitution and the potential for medication errors—particularly given the disparate injection timing of the different products.

44. For instance, if a patient administered a NovoLog product® after starting a meal, they would have a blood sugar spike; if a patient administered a FIASP® product several minutes before starting a meal, they would risk hypoglycemia. In addition, as

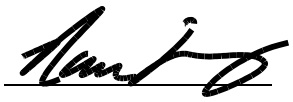
with all drugs, users of a product within the NovoLog® family of products inadvertently administered a product within the FIASP family of products (or vice versa) without changing their dosing procedure accordingly, they may experience adverse events.

45. Confusion between a FIASP® product and a NovoLog® product when used in an insulin pump can result in occlusion (or blockage in pump tubing), which can result in nondelivery of needed insulin, which could lead to an individual with Type 1 diabetes to develop a life-threatening condition called diabetic ketoacidosis, or DKA. While DKA can develop following short periods of insulin nondelivery over the course of minutes to hours in patients with Type 1 diabetes, those living with Type 2 diabetes also could be at risk for developing an alternate condition called hyperosmolar hyperglycemic state, though this would generally require much longer periods of insulin nondelivery over days rather than minutes or hours, as well as cessation of other diabetes medications used to control glucose levels.

46. A healthcare provider would not prescribe a NovoLog® product *and* a FIASP® product, nor would a healthcare provider transition patients between these products without significant discussion and training related to dosing regimens and delivery devices.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 07 day of December, 2023.

By: 

Appendix D

Relevant Constitutional and Statutory Provisions

U.S. Const. art. 1, § 1

All legislative Powers herein granted shall be vested in a Congress of the United States, which shall consist of a Senate and House of Representatives.

U.S. Const. amend. V

No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a Grand Jury, except in cases arising in the land or naval forces, or in the Militia, when in actual service in time of War or public danger; nor shall any person be subject for the same offence to be twice put in jeopardy of life or limb; nor shall be compelled in any criminal case to be a witness against himself, nor be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation.

26 U.S.C. § 5000D(b). Designated drugs during noncompliance periods

* * *

(b) Noncompliance periods

A day is described in this subsection with respect to a designated drug if it is a day during one of the following periods:

(1) The period beginning on the March 1st (or, in the case of initial price applicability year 2026, the October 2nd) immediately following the date on which such drug is included on the list published under section 1192(a) of the Social Security Act and ending on the earlier of-

(A) the first date on which the manufacturer of such designated drug has in place an agreement described in section 1193(a) of such Act with respect to such drug, or

(B) the date that the Secretary of Health and Human Services has made a determination described in section 1192(c)(1) of such Act with respect to such designated drug.

(2) The period beginning on the November 2nd immediately following the March 1st described in paragraph (1) (or, in the case of initial price applicability year 2026, the August 2nd immediately following the October 2nd described in such paragraph) and ending on the earlier of-

(A) the first date on which the manufacturer of such designated drug and the Secretary of Health and Human Services have agreed to a maximum fair price under an agreement

described in section 1193(a) of the Social Security Act, or

(B) the date that the Secretary of Health and Human Services has made a determination described in section 1192(c)(1) of such Act with respect to such designated drug.

(3) In the case of any designated drug which is a selected drug (as defined in section 1192(c) of the Social Security Act) that the Secretary of Health and Human Services has selected for renegotiation under section 1194(f) of such Act, the period beginning on the November 2nd of the year that begins 2 years prior to the first initial price applicability year of the price applicability period for which the maximum fair price established pursuant to such renegotiation applies and ending on the earlier of-

(A) the first date on which the manufacturer of such designated drug has agreed to a renegotiated maximum fair price under such agreement, or

(B) the date that the Secretary of Health and Human Services has made a determination described in section 1192(c)(1) of such Act with respect to such designated drug.

(4) With respect to information that is required to be submitted to the Secretary of Health and Human Services under an agreement described in section 1193(a) of the Social Security Act, the period beginning on the date on which such Secretary certifies that such information is

overdue and ending on the date that such information is so submitted.

* * *

42 U.S.C. § 1320f. Establishment of program

(a) In general

The Secretary shall establish a Drug Price Negotiation Program (in this part referred to as the "program"). Under the program, with respect to each price applicability period, the Secretary shall —

(1) publish a list of selected drugs in accordance with section 1320f-1 of this title;

(2) enter into agreements with manufacturers of selected drugs with respect to such period, in accordance with section 1320f-2 of this title;

(3) negotiate and, if applicable, renegotiate maximum fair prices for such selected drugs, in accordance with section 1320f-3 of this title;

(4) carry out the publication and administrative duties and compliance monitoring in accordance with sections 1320f-4 and 1320f-5 of this title.

* * *

(c) Other definitions

For purposes of this part:

(1) Manufacturer

The term "manufacturer" has the meaning given that term in section 1395w-3a(c)(6)(A) of this title.

(2) Maximum fair price eligible individual

The term "maximum fair price eligible individual" means, with respect to a selected drug —

(A) in the case such drug is dispensed to the individual at a pharmacy, by a mail order service, or by another dispenser, an individual who is enrolled in a prescription drug plan under part D of subchapter XVIII or an MA-PD plan under part C of such subchapter if coverage is provided under such plan for such selected drug; and

(B) in the case such drug is furnished or administered to the individual by a hospital, physician, or other provider of services or supplier, an individual who is enrolled under part B of subchapter XVIII, including an individual who is enrolled in an MA plan under part C of such subchapter, if payment may be made under part B for such selected drug.

(3) Maximum fair price

The term "maximum fair price" means, with respect to a year during a price applicability period and with respect to a selected drug (as defined in section 1320f-1(c) of this title) with respect to such period, the price negotiated pursuant to section 1320f-3 of this title, and updated pursuant to section 1320f-4(b) of this title, as applicable, for such drug and year.

(4) Reference product

The term "reference product" has the meaning given such term in section 262(i) of this title.

(5) Total expenditures

The term "total expenditures" includes, in the case of expenditures with respect to part D of subchapter XVIII, the total gross covered prescription drug costs (as defined in section 1395w-115(b)(3) of this title). The term "total expenditures" excludes, in the case of expenditures with respect to part B of such subchapter, expenditures for a drug or biological product that are bundled or packaged into the payment for another service.

(6) Unit

The term "unit" means, with respect to a drug or biological product, the lowest identifiable amount (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological product that is dispensed or furnished.

* * *

42 U.S.C. § 1320f-1. Selection of negotiation-eligible drugs as selected drugs

(a) In general

Not later than the selected drug publication date with respect to an initial price applicability year, in accordance with subsection (b), the Secretary shall select and publish a list of —

(1) with respect to the initial price applicability year 2026, 10 negotiation-eligible drugs described in subparagraph (A) of subsection (d)(1), but not subparagraph (B) of such subsection, with respect to such year (or, all (if such number is less than 10) such negotiation-eligible drugs with respect to such year);

(2) with respect to the initial price applicability year 2027, 15 negotiation-eligible drugs described in subparagraph (A) of subsection (d)(1), but not subparagraph (B) of such subsection, with respect to such year (or, all (if such number is less than 15) such negotiation-eligible drugs with respect to such year);

(3) with respect to the initial price applicability year 2028, 15 negotiation-eligible drugs described in subparagraph (A) or (B) of subsection (d)(1) with respect to such year (or, all (if such number is less than 15) such negotiation-eligible drugs with respect to such year); and

(4) with respect to the initial price applicability year 2029 or a subsequent year, 20 negotiation-eligible drugs described in subparagraph (A) or (B) of subsection (d)(1), with respect to such year

(or, all (if such number is less than 20) such negotiation-eligible drugs with respect to such year).

Subject to subsection (c)(2) and section 1320f-3(f)(5) of this title, each drug published on the list pursuant to the previous sentence and subsection (b)(3) shall be subject to the negotiation process under section 1320f-3 of this title for the negotiation period with respect to such initial price applicability year (and the renegotiation process under such section as applicable for any subsequent year during the applicable price applicability period).

(b) Selection of drugs

(1) In general

In carrying out subsection (a), subject to paragraph (2), the Secretary shall, with respect to an initial price applicability year, do the following:

(A) Rank negotiation-eligible drugs described in subsection (d)(1) according to the total expenditures for such drugs under parts B and D of subchapter XVIII, as determined by the Secretary, during the most recent period of 12 months prior to the selected drug publication date (but ending not later than October 31 of the year prior to the year of such drug publication date), with respect to such year, for which data are available, with the negotiation-eligible drugs with the highest total expenditures being ranked the highest.

(B) Select from such ranked drugs with respect to such year the negotiation-eligible drugs with the highest such rankings.

(C) In the case of a biological product for which the inclusion of the biological product as a selected drug on a list published under subsection (a) has been delayed under subsection (f)(2), remove such biological product from the rankings under subparagraph (A) before making the selections under subparagraph (B).

(2) High spend part D drugs for 2026 and 2027

With respect to the initial price applicability year 2026 and with respect to the initial price applicability year 2027, the Secretary shall apply paragraph (1) as if the reference to "negotiation-eligible drugs described in subsection (d)(1)" were a reference to "negotiation-eligible drugs described in subsection (d)(1)(A)" and as if the reference to "total expenditures for such drugs under parts B and D of subchapter XVIII" were a reference to "total expenditures for such drugs under part D of subchapter XVIII."

(3) Inclusion of delayed biological products

Pursuant to subparagraphs (B)(ii)(I) and (C)(i) of subsection (f)(2), the Secretary shall select and include on the list published under subsection (a) the biological products described in such subparagraphs. Such biological products shall count towards the required number of drugs to be selected under subsection (a)(1).

(c) Selected drug

(1) In general

For purposes of this part, in accordance with subsection (e)(2) and subject to paragraph (2), each negotiation-eligible drug included on the list published under subsection (a) with respect to an initial price applicability year shall be referred to as a "selected drug" with respect to such year and each subsequent year beginning before the first year that begins at least 9 months after the date on which the Secretary determines at least one drug or biological product —

(A) is approved or licensed (as applicable) —

(i) under section 355(j) of title 21 using such drug as the listed drug; or

(ii) under section 262(k) of this title using such drug as the reference product; and

(B) is marketed pursuant to such approval or licensure.

(2) Clarification

A negotiation-eligible drug —

(A) that is included on the list published under subsection (a) with respect to an initial price applicability year; and

(B) for which the Secretary makes a determination described in paragraph (1) before or during the negotiation period with respect to such initial price applicability year;

shall not be subject to the negotiation process under section 1320f-3 of this title with respect to such negotiation period and shall continue to be considered a selected drug under this part with respect to the number of negotiation-eligible drugs published on the list under subsection (a) with respect to such initial price applicability year.

(d) Negotiation-eligible drug

(1) In general

For purposes of this part, subject to paragraph (2), the term "negotiation-eligible drug" means, with respect to the selected drug publication date with respect to an initial price applicability year, a qualifying single source drug, as defined in subsection (e), that is described in either of the following subparagraphs (or, with respect to the initial price applicability year 2026 or 2027, that is described in subparagraph (A)):

(A) Part D high spend drugs

The qualifying single source drug is, determined in accordance with subsection (e)(2), among the 50 qualifying single source drugs with the highest total expenditures under part D of subchapter XVIII, as determined by the Secretary in accordance with paragraph (3), during the most recent 12-month period for which data are available prior to such selected drug publication date (but ending no later than October 31 of the year prior to the year of such drug publication date).

(B) Part B high spend drugs

The qualifying single source drug is, determined in accordance with subsection (e)(2), among the 50 qualifying single source drugs with the highest total expenditures under part B of subchapter XVIII, as determined by the Secretary in accordance with paragraph (3), during such most recent 12-month period, as described in subparagraph (A).

(2) Exception for small biotech drugs

(A) In general

Subject to subparagraph (C), the term "negotiation-eligible drug" shall not include, with respect to the initial price applicability years 2026, 2027, and 2028, a qualifying single source drug that meets either of the following:

(i) Part D drugs

The total expenditures for the qualifying single source drug under part D of subchapter XVIII, as determined by the Secretary in accordance with paragraph (3)(B), during 2021 —

(I) are equal to or less than 1 percent of the total expenditures under such part D, as so determined, for all covered part D drugs (as defined in section 1395w-102(e) of this title) during such year; and

(II) are equal to at least 80 percent of the total expenditures under such part D,

as so determined, for all covered part D drugs for which the manufacturer of the drug has an agreement in effect under section 1395w-114a of this title during such year.

(ii) Part B drugs

The total expenditures for the qualifying single source drug under part B of subchapter XVIII, as determined by the Secretary in accordance with paragraph (3)(B), during 2021—

(I) are equal to or less than 1 percent of the total expenditures under such part B, as so determined, for all qualifying single source drugs for which payment may be made under such part B during such year; and

(II) are equal to at least 80 percent of the total expenditures under such part B, as so determined, for all qualifying single source drugs of the manufacturer for which payment may be made under such part B during such year.

(B) Clarifications relating to manufacturers

(i) Aggregation rule

All persons treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 shall be treated as one manufacturer for purposes of this paragraph.

(ii) Limitation

A drug shall not be considered to be a qualifying single source drug described in clause (i) or (ii) of subparagraph (A) if the manufacturer of such drug is acquired after 2021 by another manufacturer that does not meet the definition of a specified manufacturer under section 1395w-114c(g)(4)(B)(ii) of this title, effective at the beginning of the plan year immediately following such acquisition or, in the case of an acquisition before 2025, effective January 1, 2025.

(C) Drugs not included as small biotech drugs

A new formulation, such as an extended release formulation, of a qualifying single source drug shall not be considered a qualifying single source drug described in subparagraph (A).

(3) Clarifications and determinations

(A) Previously selected drugs and small biotech drugs excluded

In applying subparagraphs (A) and (B) of paragraph (1), the Secretary shall not consider or count —

(i) drugs that are already selected drugs; and

(ii) for initial price applicability years 2026, 2027, and 2028, qualifying single source drugs described in paragraph (2)(A).

(B) Use of data

In determining whether a qualifying single source drug satisfies any of the criteria described in paragraph (1) or (2), the Secretary shall use data that is aggregated across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation, and not based on the specific formulation or package size or package type of the drug.

(e) Qualifying single source drug

(1) In general

For purposes of this part, the term "qualifying single source drug" means, with respect to an initial price applicability year, subject to paragraphs (2) and (3), a covered part D drug (as defined in section 1395w-102(e) of this title) that is described in any of the following or a drug or biological product for which payment may be made under part B of subchapter XVIII that is described in any of the following:

(A) Drug products

A drug —

(i) that is approved under section 355(c) of title 21 and is marketed pursuant to such approval;

(ii) for which, as of the selected drug publication date with respect to such initial price applicability year, at least 7 years will have elapsed since the date of such approval; and

(iii) that is not the listed drug for any drug that is approved and marketed under section 355(j) of such title.

(B) Biological products

A biological product —

(i) that is licensed under section 262(a) of this title and is marketed under section 262 of this title;

(ii) for which, as of the selected drug publication date with respect to such initial price applicability year, at least 11 years will have elapsed since the date of such licensure; and

(iii) that is not the reference product for any biological product that is licensed and marketed under section 262(k) of this title.

(2) Treatment of authorized generic drugs

(A) In general

In the case of a qualifying single source drug described in subparagraph (A) or (B) of paragraph (1) that is the listed drug (as such term is used in section 355(j) of title 21) or a product described in clause (ii) of subparagraph (B), with respect to an authorized generic drug, in applying the provisions of this part, such authorized generic drug and such listed drug or such product shall be treated as the same qualifying single source drug.

(B) Authorized generic drug defined

For purposes of this paragraph, the term "authorized generic drug" means —

(i) in the case of a drug, an authorized generic drug (as such term is defined in section 355(t)(3) of title 21); and

(ii) in the case of a biological product, a product that —

(I) has been licensed under section 262(a) of this title; 1 and

(II) is marketed, sold, or distributed directly or indirectly to retail class of trade under a different labeling, packaging (other than repackaging as the reference product in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trade mark than the reference product.

(3) Exclusions

In this part, the term "qualifying single source drug" does not include any of the following:

(A) Certain orphan drugs

A drug that is designated as a drug for only one rare disease or condition under section 360bb of title 21 and for which the only approved indication (or indications) is for such disease or condition.

(B) Low spend medicare drugs

A drug or biological product with respect to which the total expenditures under parts B and D of subchapter XVIII, as determined by the Secretary in accordance with subsection (d)(3)(B) —

(i) with respect to initial price applicability year 2026, is less than, during the period beginning on June 1, 2022, and ending on May 31, 2023, $200,000,000;

(ii) with respect to initial price applicability year 2027, is less than, during the most recent 12-month period applicable under subparagraphs (A) and (B) of subsection (d)(1) for such year, the dollar amount specified in clause (i) increased by the annual percentage increase in the consumer price index for all urban consumers (all items; United States city average) for the period beginning on June 1, 2023, and ending on September 30, 2024; or

(iii) with respect to a subsequent initial price applicability year, is less than, during the most recent 12-month period applicable under subparagraphs (A) and (B) of subsection (d)(1) for such year, the dollar amount specified in this subparagraph for the previous initial price applicability year increased by the annual percentage increase in such

consumer price index for the 12-month period ending on September 30 of the year prior to the year of the selected drug publication date with respect to such subsequent initial price applicability year.

(C) Plasma-derived products

A biological product that is derived from human whole blood or plasma.

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42 U.S.C. § 1320f-3. Negotiation and renegotiation process

(a) In general

For purposes of this part, under an agreement under section 1320f-2 of this title between the Secretary and a manufacturer of a selected drug (or selected drugs), with respect to the period for which such agreement is in effect and in accordance with subsections (b), (c), and (d), the Secretary and the manufacturer —

(1) shall during the negotiation period with respect to such drug, in accordance with this section, negotiate a maximum fair price for such drug for the purpose described in section 1320f-2(a)(1) of this title; and

(2) renegotiate, in accordance with the process specified pursuant to subsection (f), such maximum fair price for such drug for the purpose described in section 1320f-2(a)(2) of this title if such drug is a renegotiation-eligible drug under such subsection.

(b) Negotiation process requirements

(1) Methodology and process

The Secretary shall develop and use a consistent methodology and process, in accordance with paragraph (2), for negotiations under subsection (a) that aims to achieve the lowest maximum fair price for each selected drug.

(2) Specific elements of negotiation process

As part of the negotiation process under this section, with respect to a selected drug and the negotiation period with respect to the initial price applicability year with respect to such drug, the following shall apply:

(A) Submission of information

Not later than March 1 of the year of the selected drug publication date, with respect to the selected drug, the manufacturer of the drug shall submit to the Secretary, in accordance with section 1320f-2(a)(4) of this title, the information described in such section.

(B) Initial offer by Secretary

Not later than the June 1 following the selected drug publication date, the Secretary shall provide the manufacturer of the selected drug with a written initial offer that contains the Secretary's proposal for the maximum fair price of the drug and a concise justification based on the factors described in subsection (e) that were used in developing such offer.

(C) Response to initial offer

(i) In general

Not later than 30 days after the date of receipt of an initial offer under subparagraph (B), the manufacturer shall either accept such offer or propose a counteroffer to such offer.

(ii) Counteroffer requirements

If a manufacturer proposes a counteroffer, such counteroffer —

(I) shall be in writing; and

(II) shall be justified based on the factors described in subsection (e).

(D) Response to counteroffer

After receiving a counteroffer under subparagraph (C), the Secretary shall respond in writing to such counteroffer.

(E) Deadline

All negotiations between the Secretary and the manufacturer of the selected drug shall end prior to the first day of November following the selected drug publication date, with respect to the initial price applicability year.

(F) Limitations on offer amount

In negotiating the maximum fair price of a selected drug, with respect to the initial price applicability year for the selected drug, and, as applicable, in renegotiating the maximum fair price for such drug, with respect to a subsequent year during the price applicability period for such drug, the Secretary shall not offer (or agree to a counteroffer for) a maximum fair price for the selected drug that —

(i) exceeds the ceiling determined under subsection (c) for the selected drug and year; or

(ii) as applicable, is less than the floor determined under subsection (d) for the selected drug and year.

(c) Ceiling for maximum fair price

(1) General ceiling

(A) In general

The maximum fair price negotiated under this section for a selected drug, with respect to the first initial price applicability year of the price applicability period with respect to such drug, shall not exceed the lower of the amount under subparagraph (B) or the amount under subparagraph (C).

(B) Subparagraph (B) amount

An amount equal to the following:

(i) Covered part D drug

In the case of a covered part D drug (as defined in section 1395w-102(e) of this title), the sum of the plan specific enrollment weighted amounts for each prescription drug plan or MA-PD plan (as determined under paragraph (2)).

(ii) Part B drug or biological

In the case of a drug or biological product for which payment may be made under part B of subchapter XVIII, the

payment amount under section 1395w-3a(b)(4) of this title for the drug or biological product for the year prior to the year of the selected drug publication date with respect to the initial price applicability year for the drug or biological product.

(C) Subparagraph (C) amount

An amount equal to the applicable percent described in paragraph (3), with respect to such drug, of the following:

(i) Initial price applicability year 2026

In the case of a selected drug with respect to which such initial price applicability year is 2026, the average non-Federal average manufacturer price for such drug for 2021 (or, in the case that there is not an average non-Federal average manufacturer price available for such drug for 2021, for the first full year following the market entry for such drug), increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from September 2021 (or December of such first full year following the market entry), as applicable, to September of the year prior to the year of the selected drug publication date with respect to such initial price applicability year.

(ii) Initial price applicability year 2027 and subsequent years

In the case of a selected drug with respect to which such initial price applicability year is 2027 or a subsequent year, the lower of —

(I) the average non-Federal average manufacturer price for such drug for 2021 (or, in the case that there is not an average non-Federal average manufacturer price available for such drug for 2021, for the first full year following the market entry for such drug), increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from September 2021 (or December of such first full year following the market entry), as applicable, to September of the year prior to the year of the selected drug publication date with respect to such initial price applicability year; or

(II) the average non-Federal average manufacturer price for such drug for the year prior to the selected drug publication date with respect to such initial price applicability year.

(2) Plan specific enrollment weighted amount

For purposes of paragraph (1)(B)(i), the plan specific enrollment weighted amount for a prescription drug plan or an MA-PD plan with

respect to a covered Part D drug is an amount equal to the product of —

(A) the negotiated price of the drug under such plan under part D of subchapter XVIII, net of all price concessions received by such plan or pharmacy benefit managers on behalf of such plan, for the most recent year for which data is available; and

(B) a fraction —

(i) the numerator of which is the total number of individuals enrolled in such plan in such year; and

(ii) the denominator of which is the total number of individuals enrolled in a prescription drug plan or an MA-PD plan in such year.

(3) Applicable percent described

For purposes of this subsection, the applicable percent described in this paragraph is the following:

(A) Short-monopoly drugs and vaccines

With respect to a selected drug (other than an extended-monopoly drug and a long-monopoly drug), 75 percent.

(B) Extended-monopoly drugs

With respect to an extended-monopoly drug, 65 percent.

(C) Long-monopoly drugs

With respect to a long-monopoly drug, 40 percent.

(4) Extended-monopoly drug defined

(A) In general

In this part, subject to subparagraph (B), the term "extended-monopoly drug" means, with respect to an initial price applicability year, a selected drug for which at least 12 years, but fewer than 16 years, have elapsed since the date of approval of such drug under section 355(c) of title 21 or since the date of licensure of such drug under section 262(a) of this title, as applicable.

(B) Exclusions

The term "extended-monopoly drug" shall not include any of the following:

(i) A vaccine that is licensed under section 262 of this title and marketed pursuant to such section.

(ii) A selected drug for which a manufacturer had an agreement under this part with the Secretary with respect to an initial price applicability year that is before 2030.

(C) Clarification

Nothing in subparagraph (B)(ii) shall limit the transition of a selected drug described in paragraph (3)(A) to a long-

monopoly drug if the selected drug meets the definition of a long-monopoly drug.

(5) Long-monopoly drug defined

(A) In general

In this part, subject to subparagraph (B), the term "long-monopoly drug" means, with respect to an initial price applicability year, a selected drug for which at least 16 years have elapsed since the date of approval of such drug under section 355(c) of title 21 or since the date of licensure of such drug under section 262(a) of this title, as applicable.

(B) Exclusion

The term “long-monopoly drug” shall not include a vaccine that is licensed under section 262 of this title and marketed pursuant to such section.

(6) Average non-Federal average manufacturer price

In this part, the term "average non-Federal average manufacturer price" means the average of the non-Federal average manufacturer price (as defined in section 8126(h)(5) of title 38) for the 4 calendar quarters of the year involved.

* * *

(e) Factors

For purposes of negotiating the maximum fair price of a selected drug under this part with the manufacturer of the drug, the Secretary shall consider the following factors, as applicable to the drug, as the

basis for determining the offers and counteroffers under subsection (b) for the drug:

(1) Manufacturer-specific data

The following data, with respect to such selected drug, as submitted by the manufacturer:

(A) Research and development costs of the manufacturer for the drug and the extent to which the manufacturer has recouped research and development costs.

(B) Current unit costs of production and distribution of the drug.

(C) Prior Federal financial support for novel therapeutic discovery and development with respect to the drug.

(D) Data on pending and approved patent applications, exclusivities recognized by the Food and Drug Administration, and applications and approvals under section 355(c) of title 21 or section 262(a) of this title for the drug.

(E) Market data and revenue and sales volume data for the drug in the United States.

(2) Evidence about alternative treatments

The following evidence, as available, with respect to such selected drug and therapeutic alternatives to such drug:

(A) The extent to which such drug represents a therapeutic advance as compared to existing therapeutic alternatives and the costs of such existing therapeutic alternatives.

(B) Prescribing information approved by the Food and Drug Administration for such drug and therapeutic alternatives to such drug.

(C) Comparative effectiveness of such drug and therapeutic alternatives to such drug, taking into consideration the effects of such drug and therapeutic alternatives to such drug on specific populations, such as individuals with disabilities, the elderly, the terminally ill, children, and other patient populations.

(D) The extent to which such drug and therapeutic alternatives to such drug address unmet medical needs for a condition for which treatment or diagnosis is not addressed adequately by available therapy.

In using evidence described in subparagraph (C), the Secretary shall not use evidence from comparative clinical effectiveness research in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.

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42 U.S.C. § 1320f-7. Limitation on administrative and judicial review

There shall be no administrative or judicial review of any of the following:

(1) The determination of a unit, with respect to a drug or biological product, pursuant to section 1320f(c)(6) of this title.

(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.

(3) The determination of a maximum fair price under subsection (b) or (f) of section 1320f-3 of this title.

(4) The determination of renegotiation-eligible drugs under section 1320f-3(f)(2) of this title and the selection of renegotiation-eligible drugs under section 1320f-3(f)(3) of this title.