No. 24-2510

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

NOVO NORDISK INC., *et al.*,

Plaintiffs-Appellants,

v.

SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants-Appellees.

On Appeal from the United States District Court
for the District of New Jersey

BRIEF FOR APPELLEES

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INTRODUCTION

For more than 30 years, Congress has established limits on the amounts that federal agencies will pay for prescription drugs. Manufacturers that wish to sell their drugs to the Departments of Defense and Veterans Affairs, for example, do so subject to statutorily defined ceiling prices, and both agencies have authority to negotiate prices below those ceilings. *See* 38 U.S.C. § 8126(a)-(h). In the Inflation Reduction Act of 2022, Pub. L. No. 117-169, 136 Stat. 1818 (IRA), Congress gave the Secretary of Health and Human Services (HHS) similar authority to address the extraordinary and unsustainable increase in the prices that Medicare pays for pharmaceutical products that lack generic competition and that account for a disproportionate share of Medicare's expenses. 42 U.S.C. §§ 1320f(a), 1320f-1(b), (d), (e). Under the IRA's Drug Price Negotiation Program, the Centers for Medicare & Medicaid Services (CMS) can now negotiate the prices that Medicare will pay for a select group of high-expenditure drugs. A manufacturer that disagrees with the program terms or with the price the government is willing to pay is under no legal obligation to participate in the program.

The program protects taxpayers and the public fisc by prioritizing the drugs that account for the highest Medicare expenditures. The IRA therefore directs CMS to rank drugs that are eligible for negotiation based on these expenditures, and to select the highest-ranking drugs on the list for negotiation. In doing so, CMS must consider aggregate spending "across dosage forms and strengths of [a] drug, including new formulations of the drug, such as an extended release formulation, and not based on the specific formulation or . . . package type of the drug." 42 U.S.C. § 1320f-1(d)(3)(B). This means that CMS cannot focus solely on a particular version of the drug—such as one with a modified absorption rate—when determining whether the drug qualifies for negotiation. By adopting this approach, the statute aims to capture the overall financial impact of a drug on Medicare, regardless of variations in the drug's formulation or packaging.

This lawsuit concerns a synthetic insulin called "insulin aspart," which is manufactured by plaintiff Novo Nordisk, Inc. (collectively, with plaintiff Novo Nordisk Pharma, Inc., "Novo") for the treatment of diabetes. Novo sells insulin aspart in various forms to suit different patient preferences and needs. For example, a patient can administer the insulin

from a vial, using a syringe to inject it subcutaneously. Patients can also use single-use insulin pens filled with the same solution, or pre-filled cartridges that are inserted into reusable insulin pens. Novo additionally offers a faster-acting formulation of insulin aspart, also available in these various package types. CMS determined that this set of insulin aspart products accounts for some of the highest Medicare expenditures and selected it for negotiation.

Novo filed suit challenging CMS's selection of these products as inconsistent with the IRA and the Administrative Procedure Act (APA) and challenging the IRA provisions establishing the Negotiation Program as unconstitutional.

The district court correctly concluded that it lacked jurisdiction to review Novo's statutory claims. In enacting the IRA, Congress expressly stated that there "shall be no administrative or judicial review" of certain administrative actions that CMS takes in the course of implementing the Negotiation Program. 42 U.S.C. § 1320f-7. Key among these is CMS's "selection of drugs" for negotiation. *Id.* § 1320f-7(2). Novo argues that CMS erred in selecting different forms of its insulin aspart drug for

negotiation, but this argument is precluded from judicial review and is meritless in any event.

Novo's constitutional challenges also lack merit. The IRA raises no nondelegation concerns because Congress provided ample direction to guide CMS's implementation of the program, easily surpassing the intelligible-principle standard. And Novo's due process claim fails for the independent reason that Novo lacks a protected interest in selling its drugs to the government at a particular price. Finally, Novo's First Amendment argument also fails because, in prescribing rules for determining the price that drug manufacturers may charge Medicare, the IRA regulates conduct, not speech.

STATEMENT OF JURISDICTION

Novo invoked the district court's jurisdiction pursuant to 28 U.S.C. §§ 1331, 1346. JA49. The district court's jurisdiction over Novo's statutory claims is contested. *See infra* pp. 29-40. On July 31, 2024, the district court granted the government's motion for summary judgment and entered a final judgment in the government's favor. JA4. Novo Nordisk filed a timely notice of appeal on August 14, 2024. JA1; *see* Fed. R. App. P. 4(a)(1)(B). This Court has jurisdiction pursuant to 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES

1. Whether the district court correctly held that it lacks jurisdiction to review Novo's challenge to CMS's selection of different forms of Novo's insulin aspart drug for negotiation, and whether this challenge fails on the merits in any event.

2. Whether the district court correctly held that Novo's constitutional claims fail on the merits because the statute raises no nondelegation concerns, deprives Novo of no constitutionally protected interests, and does not regulate protected speech.

STATEMENT OF THE CASE

A. Medicare and the Escalating Cost of Prescription Drug Coverage

Medicare provides federally funded health coverage for individuals who are 65 or older or who have certain disabilities or medical conditions. 42 U.S.C. § 1395 *et seq.* CMS administers Medicare on behalf of the HHS Secretary.

Medicare is divided into "Parts" that set forth the terms by which Medicare will pay for specific benefits. *See Northeast Hosp. Corp. v. Sebelius*, 657 F.3d 1, 2 (D.C. Cir. 2011). Medicare Part B covers outpatient care as

well as the cost of drugs administered as part of that care. *Cares Cmty. Health v. HHS*, 944 F.3d 950, 953 (D.C. Cir. 2019). Medicare Part D, which Congress added in 2003, provides "a voluntary prescription drug benefit program that subsidizes the cost of prescription drugs and prescription drug insurance premiums for Medicare enrollees." *United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 749 (3d Cir. 2017); *see* 42 U.S.C. § 1395w-101 *et seq.* In enacting Part D, Congress initially barred CMS from negotiating prices for drugs covered under Part D or otherwise interfering in the arrangements between drug manufacturers and insurance plans. 42 U.S.C. § 1395w-111(i). But, over time, that model led to skyrocketing drug prices that saddled beneficiaries with unaffordable copays and threatened the long-term solvency of the program.

The cost to the federal government of providing prescription drug coverage under Medicare Part B and Part D is immense. In 2021 alone, the federal government spent more than $250 billion on drugs covered by these programs. *See* KFF, *10 Prescription Drugs Accounted for $48 Billion in Medicare Part D Spending in 2021, or More Than One-Fifth of Part D Spending That Year* (July 12, 2023), https://perma.cc/4CYL-KYRM. That figure has risen dramatically over the last decade and is "projected to continue rising

during the coming decade, placing increasing fiscal pressure[]" on the federal budget. Office of the Assistant Sec'y for Planning & Evaluation, HHS, *Report to Congress: Prescription Drug Pricing* 8 (May 20, 2020), https://perma.cc/5GEN-LZ7F (2020 HHS Report to Congress). Medicare Part D spending in particular "is projected to increase faster than any other category of health spending." S. Rep. No. 116-120, at 4 (2019).

In addition to its effects on the federal treasury, the high cost of prescription drug coverage directly burdens Medicare beneficiaries by affecting their premiums and out-of-pocket payments. Because Part B premiums are automatically set to cover 25% of aggregate Part B spending, higher total spending on prescription drug coverage results in higher premiums for individual enrollees. *See* 2020 HHS Report to Congress 11. Beneficiaries also pay 20% of their Part B prescription drug costs out of pocket. Part D premiums are similarly based on a plan's anticipated costs, and many Part D plans likewise require beneficiaries to pay additional cost-sharing amounts.

A "relatively small number of drugs are responsible for a disproportionately large share of Medicare costs." H.R. Rep. No. 116-324, pt. 2, at 37 (2019). In 2018, "the top ten highest-cost drugs by total

spending accounted for 46 percent of spending in Medicare Part B" and "18 percent of spending in . . . Part D." 2020 HHS Report to Congress, at 7. By 2021, the top 10 drugs by total spending accounted for 22% of spending under Part D. *See* Juliette Cubanski & Tricia Neuman, *A Small Number of Drugs Account for a Large Share of Medicare Part D Spending*, KFF (July 12, 2023), https://perma.cc/2PF2-336Z.

These rising costs are in large part attributable to manufacturers' considerable latitude in dictating the prices that Medicare pays for the most expensive drugs. Because drug prices under Medicare Part B and Part D were tied to the price manufacturers charged private buyers, *see* 42 U.S.C. §§ 1395w-3a(b), 1395w-101 *et seq.*, manufacturers of drugs with no generic competition could "effectively set[] [their] own Medicare payment rate[s]" by dictating sales prices in the broader market. Medicare Payment Advisory Comm'n, *Report to the Congress: Medicare and the Health Care Delivery System* 84 (June 2022), https://perma.cc/5X4R-KCHC. Drug companies' substantial leeway in this respect was compounded by the significant legal and practical obstacles to market entry faced by generic competitors, along with the practice of many manufacturers of protecting their market share by entering into "settlements" with generic

manufacturers to limit generic marketing. *See, e.g.*, Sarah M. E. Gabriele & William B. Feldman, *The Problem of Limited-Supply Agreements for Medicare Price Negotiation,* 330 JAMA 1223 (2023). In addition, manufacturers of brand-name drugs often avoid generic competition by introducing minor changes to a drug and shifting patients to that new version—which lacks generic competitors—in a strategy known as "product hopping." H.R. Rep. No. 116-695, at 3 (2020). As a result of these factors, there are in many instances "no market forces to apply downward pressure to provide lowered prices to the millions who have coverage for such medicines under Medicare." H.R. Rep. No. 116-324, pt. 2, at 37-38.

Other federal agencies, including the Department of Defense, the Department of Veterans Affairs, and the Coast Guard, operate their drug benefit programs differently and have not been subject to skyrocketing costs. Pharmaceutical companies that wish to sell drugs to these agencies have long been required to negotiate with the government and reach agreements subject to statutorily defined ceiling prices. *See* 38 U.S.C. § 8126(a)-(h). Manufacturer agreement to do so is a condition on participation in Medicaid, even though the DOD, VA, and Coast Guard programs are part of a separate statutory framework that operates

independently of Medicaid. 42 U.S.C. § 1396r-8(a)(1). As a result of these requirements, manufacturers often sell drugs to the Departments of Defense and Veterans Affairs for roughly half as much as they charge Medicare Part D. *See* Cong. Budget Office, *A Comparison of Brand-Name Drug Prices Among Selected Federal Programs* 16 (Feb. 2021), https://perma.cc/ YY2E-GM97. "[I]f Medicare had received the same discounts as the Departments of Defense and Veterans Affairs, taxpayers would have saved" billions. Staff of H. Comm. on Oversight & Reform, *Drug Pricing Investigation: AbbVie—Humira and Imbruvica* 13-15 (May 2021), https://perma.cc/Z2KG-ZKW3.

B. The IRA's Drug Price Negotiation Program

In enacting the IRA, Congress empowered the HHS Secretary, acting through CMS, to negotiate the prices that Medicare pays for certain drugs, just as the Departments of Defense and Veterans Affairs have done for decades. *See* IRA §§ 11001-11003, 136 Stat. at 1833-64 (codified at 42 U.S.C. §§ 1320f–1320f-7 and 26 U.S.C. § 5000D). The Negotiation Program applies only to manufacturers that choose to participate in Medicare and Medicaid, and even then it governs only the prices that Medicare pays for certain

drugs. 42 U.S.C. § 1320f-1(b), (d). The program does not apply to the prices paid by other buyers of those drugs.

By statute, the only drugs eligible for selection in the Negotiation Program are "qualifying single source drug[s]"—*i.e.*, those that have no generic or biosimilar competitors and that have been on the market for at least seven years (for drugs) and 11 years (for biologics). 42 U.S.C. § 1320f-1(e). From the resulting list of drugs, the IRA directs the agency to rank the drugs according to total Medicare expenditures, and to select the top 10 drugs on the list for participation in the first negotiation cycle. *Id.* § 1320f-1(a)(1). Additional drugs are to be selected for future negotiation cycles. *Id.* § 1320f-1(a)(2)-(4).

The IRA directs that, when determining whether a drug satisfies the criteria for negotiation eligibility, CMS must 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 type of the drug." 42 U.S.C. § 1320f-1(d)(3)(B); *see also id.* § 1320f-5(a)(2). This requirement ensures that the selection of high-expenditure drugs for negotiation is based on the full scope of Medicare spending on a drug, regardless of variations in

formulation or packaging. By directing CMS to consider the total expenditures for a drug across its variations, the statute thus ensures that the Negotiation Program is focused on the drugs that have the most significant financial impact on the Medicare program as a whole. This approach also avoids creating an incentive for manufacturers to circumvent the negotiation process by introducing minor variations or new formulations of a drug that would otherwise qualify for negotiation based on total expenditures.

After selecting the negotiation-eligible drugs with the highest Medicare expenditures in aggregate, CMS signs agreements with manufacturers that are willing to engage in the negotiation process. 42 U.S.C. § 1320f-2. The object of the negotiations is to reach agreement on what the statute refers to as the "maximum fair price" that Medicare will pay for each selected drug. *Id.* § 1320f-3. To guide the negotiation process, Congress imposed a "[c]eiling for [the] maximum fair price," which is based on specified pricing data for each drug, *id.* § 1320f-3(c), and it directed the agency to "aim[] to achieve the lowest maximum fair price" that the manufacturer will accept, *id.* § 1320f-3(b)(1). If negotiations are successful, the manufacturer signs an addendum to the negotiation

agreement establishing the maximum price at which the drug will be made available to Medicare beneficiaries. *Id.* § 1320f-3.

Congress specified that, for drugs selected for the first negotiation cycle, any negotiated prices will take effect for Part D on January 1, 2026. 42 U.S.C. § 1320f(b)(1), (2).[1] To ensure that negotiated prices can be implemented by that date, Congress established a series of interim deadlines to govern the process. *Id.* § 1320f(d). And to ensure that litigation would not disrupt negotiations, Congress expressly prohibited judicial review of certain agency determinations, including the determination of qualifying single source drugs and negotiation-eligible drugs and the selection of drugs for negotiation. *Id.* § 1320f-7.

In enacting the Negotiation Program, Congress thus altered the terms of its offer to purchase drugs for Medicare, and a drug manufacturer that does not wish to participate in the Negotiation Program has several options. Because participation in Medicare is voluntary, JA12, a manufacturer may withdraw from Medicare and Medicaid, and thus not be

[1] For Medicare Part B, the drug-selection and negotiations occur on a later timeframe, and any negotiated prices will take effect in 2028. *See* 42 U.S.C. § 1320f-1(a)(3).

subject to any of the Negotiation Program's requirements. 26 U.S.C. § 5000D(c)(1); *see also* 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 120-21 (June 30, 2023), https://perma.cc/K6QB-C3MM (Revised Guidance). Alternatively, a manufacturer may transfer its ownership of the selected drug to another entity and continue to sell other drugs to Medicare. *See* Revised Guidance 131-32. A manufacturer that pursues neither of these options may continue to sell the selected drug to Medicare beneficiaries at non-negotiated prices subject to an excise tax. *See* 26 U.S.C. § 5000D(a)-(h); *see also* Internal Revenue Service Notice No. 2023-52, 2023-35 I.R.B. 650 (Aug. 4, 2023), https://perma.cc/B9JZ-ZG7P (IRS Notice). The tax will be imposed only on the manufacturer's "sales of designated drugs dispensed, furnished, or administered to individuals under the terms of Medicare"—*i.e.*, not on drugs dispensed, furnished, or administered outside of Medicare. IRS Notice 3.

C. The Negotiation Program's Implementation

1. In addition to establishing the statutory requirements above, Congress instructed the agency to implement the Negotiation Program

through "program instruction or other forms of program guidance" for the first few negotiation cycles. IRA § 11001(c), 136 Stat. at 1854. In March 2023, CMS issued initial guidance explaining how it planned to implement certain aspects of the statute and soliciting public comment on that planned approach. *See* CMS, *Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments* (Mar. 15, 2023), https://perma.cc/8X4K-CVD8. After considering thousands of comments, CMS published the Revised Guidance in June 2023. Revised Guidance 1. The Revised Guidance applies only to the first negotiation cycle—*i.e.*, to selected drugs for which a negotiated price could first take effect in 2026. *Id.*

The Revised Guidance explains how CMS determines what constitutes a "qualifying single source drug" that may be selected for negotiation. 42 U.S.C. § 1320f-1(e). The IRA specifically "directs CMS to establish procedures 'to compute and apply the maximum fair price across different strengths and dosage forms of a selected drug and not based on the specific formulation or package size or package type of such drug.'" Revised Guidance 11 (quoting 42 U.S.C. § 1320f-5(a)(2)). The Revised

Guidance explains that CMS will consider a qualifying single source drug to include "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." Revised Guidance 99 (footnote omitted).[2] This means that if one company produces several forms of a drug with the same active ingredient (and no additional active ingredients, *see* Revised Guidance 100), these various forms will be considered collectively under the provisions of the IRA that require aggregation across dosage forms, package types, and formulations. Revised Guidance 99-100 (citing 42 U.S.C. § 1320f-1(d)(3)(B)).

CMS acknowledged that some commenters had suggested that a qualifying single source drug must be defined "in reference to a distinct . . . BLA," such that products licensed under different applications could never be considered together as one negotiation-eligible drug. Revised Guidance 11. In responding to this comment, CMS observed that the IRA

[2] A BLA is an application that must be approved by FDA before a manufacturer can legally market a biologic in the United States. *See* 42 U.S.C. § 262(a).

"necessarily establish[es] that the statutory negotiation procedures apply more broadly than a distinct . . . BLA," because it requires CMS to aggregate data "'across dosage forms and strengths of the drug, including *new* formulations of the drug.'" *Id.* (quoting 42 U.S.C. § 1320f-1(d)(3)(B)) (emphasis added).

The Revised Guidance also sets out procedures for manufacturers that choose not to participate in the Negotiation Program. Revised Guidance 129-31. In those circumstances, CMS will "facilitate an expeditious termination of" a manufacturer's Medicare agreements before the manufacturer would incur liability for any excise tax, so long as the manufacturer notifies the agency of its desire to withdraw at least 30 days in advance of when the tax would otherwise begin to accrue. Revised Guidance 33-34.

2. In August 2023, CMS published the list of drugs selected for the first negotiation cycle. *See* Press Release, HHS, *HHS Selects the First Drugs for Medicare Drug Price Negotiation* (Aug. 29, 2023), https://perma.cc/A36P-Z88Z. The 10 drugs selected accounted for more than $50 billion of gross Medicare Part D spending between June 2022 and May 2023, and Medicare beneficiaries paid a total of $3.4 billion in out-of-pocket costs for those

drugs in 2022 alone. *See* CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026* (Aug. 2023), https://perma.cc/X37F-RC94.

The list includes a drug containing a synthetic insulin called insulin aspart, which is sold by Novo for the treatment of diabetes at mealtimes. Novo sells this drug in two different formulations, each of which is available in different package types (or "presentations"), such as vials, disposable insulin pens, and reusable insulin pens. *See, e.g.*, NovoMedlink, *Frequently Asked Questions About Fiasp*®, https://perma.cc/ZZQ3-65VP (noting that "Fiasp® is available in the following presentations," including a vial, disposable insulin pen, and cartridges for a reusable pen); JA108 (describing, as one example, "a biological product that is packaged in a pre-filled syringe"); FDA, *Structured Product Labeling Resources Package Type*, https://www.fda.gov/industry/structured-product-labeling-resources/package-type.

The original insulin aspart formulation, NovoLog, is taken shortly before a meal to help control blood sugar. Novo also created a faster-acting version of NovoLog, called Fiasp, by adding vitamin B3 to increase the speed of initial insulin absorption. *See* NovoMedlink, *Frequently Asked*

Questions About Fiasp®, https://perma.cc/ZZQ3-65VP (explaining that the "active molecule in Fiasp® is identical to NovoLog®, but the formulation has been adjusted to increase the speed of initial insulin absorption"); Fiasp®, *What is Fiasp*®, https://perma.cc/AD9K-Y7LZ ("Fiasp® is insulin aspart in a formulation with a form of vitamin B3 (niacinamide), which speeds up how fast your body absorbs" the dose.); Fiasp®: New Fast-Acting Insulin Approved in the US, Novo Nordisk Share Mag., No. 3 – 2017, at 10, https://perma.cc/BXT5-YCET ("Fiasp® is . . . NovoLog[] in an innovative formulation . . . ."). The faster-acting version can be taken at the start of a meal or shortly thereafter.

Both formulations—NovoLog and Fiasp—are available in various package types to suit different patient preferences. As noted above, a patient can administer the insulin from a vial, using a syringe to draw up the insulin and inject it subcutaneously. Patients can also use pre-filled, single-use insulin pens; or, alternatively, pre-filled cartridges that are inserted into reusable insulin pens. Each of these options is marketed under a different brand name—*e.g.*, NovoLog PenFill for the regular cartridges, and Fiasp PenFill for the faster-acting cartridges. Consistent with the statutory command to select drugs according to the total Medicare

spending on the drug overall, inclusive of formulations with adjusted absorption rates, 42 U.S.C. § 1320f-1(d)(3)(B), CMS grouped these different forms of the drug together in the selection and negotiation process. *See* CMS, *Medicare Drug Price Negotiation Program: Manufacturer Agreements for Selected Drugs for Initial Price Applicability Year 2026* (Oct. 3, 2023), https://perma.cc/3222-VPEE.

CMS engaged in robust negotiations with the manufacturers of each of the drugs selected for the first negotiation cycle. In accordance with the schedule established by Congress, CMS presented Novo and the other manufacturers of selected drugs with initial offers by February 1, 2024. *See* CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026* (Aug. 15, 2024), https://perma.cc/6MVG-BZP8. Each participating manufacturer responded with a counteroffer by March 2, 2024. *Id.* CMS subsequently held three negotiation meetings with each company to discuss the offers and relevant evidence. *Id.* Many companies proposed revised counteroffers during these meetings, and CMS accepted four of these revised counteroffers outright. *Id.* By August 1, 2024, CMS and the participating manufacturers had agreed to a negotiated price for each of the 10 selected drugs. *Id.* Assuming that none

of the 10 manufacturers withdraws from Medicare and Medicaid by December 2025, these prices will take effect on January 1, 2026. 42 U.S.C. §§ 1320f(b), (d), 1320f-2(a), 1320f-3(b).

D. Prior Proceedings

In September 2023, Novo filed this action, asserting statutory challenges to CMS's implementation of the Negotiation Program under the IRA and the APA, and constitutional challenges to the IRA under the nondelegation doctrine, as well as under the Due Process Clause of the Fifth Amendment and the First Amendment. JA86-98.

The statutory claims challenge two aspects of CMS's implementation of the program for the first year of eligibility: (1) CMS's decision to select Novo's insulin aspart drug in its different forms for negotiation, JA98; and (2) CMS's issuance of guidance that bears on the selection of drugs for the first round of negotiation, JA96. Novo's constitutional claims allege that the Negotiation Program violates the nondelegation doctrine, deprives Novo of a protected property interest without adequate procedural protections, and compels speech in violation of the First Amendment, JA86-92. The parties filed cross-motions for summary judgment, and the

district court denied Novo's motion and granted the government's motion in full.

1. The district court rejected Novo's statutory arguments on the merits for lack of jurisdiction. The court explained that the IRA "expressly precludes" judicial review of "[t]he selection of drugs" for negotiation, including the predicate "determination[s]" of what qualifies as a "negotiation-eligible drug[]" and a "qualifying single source drug[]." JA9 (quoting 42 U.S.C. § 1320f-7). "By this provision, Congress has divested this Court of jurisdiction to consider challenges under the APA to [these] determinations." JA9. The court explained that this preclusion provision also resolves Novo's argument that CMS acted *ultra vires*, emphasizing that "judicial review of ultra vires agency action is available only 'where . . . there is *no express statutory preclusion* of all judicial review.'" JA9 (quoting *Federal Express Corp. v. Department of Commerce*, 39 F.4th 756, 763 (D.C. Cir. 2022)). And to the extent that Novo asked the court to "set aside the selection of *other companies'* drugs" for negotiation, the court concluded that Novo failed to demonstrate standing to do so. JA11 (emphasis added).

2. The district court rejected Novo's constitutional claims on the merits. The court explained that Novo's "participation in the program is

voluntary," that the program "does not compel [Novo's] speech," and that the "Due Process Clause does not protect [Novo's] desired, but not inherent, right to continue selling its drugs to Medicare at a 'fair market value.'" JA13. The court observed that Novo had failed to show the deprivation of cognizable property rights that could give rise to a due process claim. *See* JA16. And it explained that there was no merit to Novo's nondelegation argument because the IRA "conveys a specific, delineated task to CMS, and it explains the scope and parameters of the delegation throughout the statute." JA20.

3. Other drug manufacturers and interest groups have filed related suits challenging the constitutionality and implementation of the Negotiation Program. To date, district courts in four other cases have considered such claims on the merits, and all have rejected them. *Novartis Pharm. Corp. v. Becerra*, No. 23-14221, 2024 WL 4524357 (D.N.J. Oct. 18, 2024), *appeal docketed*, No. 24-2968 (3d Cir. Oct. 22, 2024); *Boehringer Ingelheim Pharm., Inc. v. HHS*, No. 23-1103, 2024 WL 3292657 (D. Conn. July 3, 2024), *appeal docketed*, No. 24-2092 (2d Cir. Aug. 8, 2024); *Bristol Myers Squibb Co. v. Becerra*, Nos. 23-3335, 23-3818, 2024 WL 1855054 (D.N.J. Apr. 29, 2024), *argued*, Nos. 24-1820, 24-1821 (3d Cir. Oct. 30, 2024); *AstraZeneca*

Pharm. LP v. Becerra, 719 F. Supp. 3d (D. Del. 2024), *argued*, No. 24-1819 (3d Cir. Oct. 30, 2024); *see also Dayton Area Chamber of Commerce v. Becerra*, No. 23-156, 2024 WL 3741510 (S.D. Ohio Aug. 8, 2024), *appeal docketed*, No. 24-3868 (6th Cir. Oct. 8, 2024). Two district court cases raising related issues remain pending. *Merck & Co. v. Becerra*, No. 23-1615 (D.D.C. filed June 6, 2023); *National Infusion Ctr. Ass'n v. Becerra*, No. 23-707 (W.D. Tex. filed June 21, 2023).

SUMMARY OF ARGUMENT

I. This lawsuit concerns a synthetic insulin called "insulin aspart" that is made by Novo for the treatment of diabetes. Novo sells two formulations of insulin aspart in various package types, including disposable and reusable insulin pens, and it contends that CMS erred in selecting these different forms of its insulin aspart drug for negotiation.

A. The IRA expressly precludes review of Novo's statutory challenge to CMS's implementation of the Negotiation Program, and Novo's arguments are in any event meritless. The IRA provides that there "shall be no administrative or judicial review" of CMS's "selection of drugs" or its predicate "determination of negotiation-eligible drugs." 42 U.S.C. § 1320f-7(2). These provisions squarely preclude judicial review of the

claim that CMS erred in determining that multiple forms of Novo's insulin aspart drug should be considered together for negotiation. And they likewise preclude review of Novo's procedural challenge to that determination.

B. CMS's selection of Novo's drug is in any event correct on the merits, as the IRA directs CMS to consider all dosage forms, strengths, and "new formulations" of a drug together at every step of the negotiation process. 42 U.S.C. § 1320f-1(d)(3)(B); *see id.* §§ 1320f-3(e)(1)(D), 1320f-5(a)(2). That directive is consistent with the program goal of identifying and targeting the drugs that have the most significant financial impact on Medicare as a whole, regardless of variations in formulation and packaging. CMS appropriately followed this instruction in selecting Novo's insulin aspart drug for negotiation.

Novo also errs in arguing that CMS impermissibly issued guidance bearing on manufacturers' substantive obligations under the statute. The IRA expressly directs CMS to "implement" the Negotiation Program for 2026, 2027, and 2028 "by program instruction or other forms of program guidance." IRA § 11001(c), 136 Stat. at 1854. Novo incongruously argues that this provision *prohibits* CMS from issuing program documents

concerning the substantive obligations of participating drug manufacturers on the grounds that "guidance," by its very nature, must be nonbinding. But that reading is at odds with the statute's directive to "implement" the Negotiation Program through program instruction or guidance. Indeed, it is difficult to see how Congress intended CMS to identify negotiation-eligible drugs, select them for negotiation, and enter into binding contracts with manufacturers if CMS were limited to purely advisory measures that do not address participants' substantive obligations under the program.

II. Novo also asserts that the IRA violates the nondelegation doctrine, the Due Process Clause of the Fifth Amendment, and the First Amendment, but none of these constitutional arguments withstands scrutiny.

A. Novo's nondelegation argument is wholly out of step with decades of precedent from the Supreme Court, which has "over and over upheld even very broad delegations" for 90 years. *Gundy v. United States*, 588 U.S. 128, 146 (2019) (plurality opinion). As Novo acknowledges (Br. 11), the IRA provides "precise instructions" to CMS for implementing the Negotiation Program and comes nowhere close to the boundaries of permissible delegations long upheld by the Supreme Court.

Novo's due process arguments likewise fail. The threshold "inquiry in every due process challenge is whether the plaintiff has been deprived of a protected interest" in liberty or property, *American Mfrs. Mut. Ins. Co. v. Sullivan*, 526 U.S. 40, 59 (1999), and Novo fails to identify any such deprivation. Contrary to Novo's assertion, the Constitution does not recognize a right to a "reasonable return on investment," JA90 (quotation marks omitted), and "[n]o one is entitled to sell the Government drugs at prices the Government won't agree to pay," JA16 (alteration omitted) (quoting *AstraZeneca Pharm. LP v. Becerra*, 719 F. Supp. 3d 377, 395 (D. Del. 2024)).

Novo is likewise mistaken in asserting that it will suffer a cognizable deprivation when it sells its drug to Medicare at the negotiated price, or when it shares business information with CMS consistent with the program terms. Novo is under no legal obligation to accept the terms of the government's offer to purchase its drug, and Novo's acceptance of that offer does not entail a deprivation of protected property rights. The government has broad discretion to determine the terms on which it makes purchases, and Novo has no constitutional right to more favorable terms. Even where business realities create strong financial incentives to

participate in Medicare—and thus to accept the terms of the Negotiation Program—courts have emphasized that participation is nonetheless voluntary, and the terms set by the government do not implicate the Fifth Amendment. Novo's contrary view would upend decades of established contracting practices across other critical industries, including the defense sector, in which the government wields substantial market power.

B. Finally, there is no substance to Novo's undeveloped compelled-speech argument. Novo objects that any manufacturer that participates in the program must sign an agreement to negotiate, and, if negotiations prove successful, an agreement to honor the negotiated price. These agreements are not speech; they are commercial contracts governing the negotiation process and the parties' associated conduct. In any event, Novo is not compelled to sign these agreements because participation in Medicare (and the Negotiation Program, by extension) is voluntary.

STANDARD OF REVIEW

This Court "review[s] the grant or denial of summary judgment de novo." *Canada v. Samuel Grossi & Sons, Inc.*, 49 F.4th 340, 345 (3d Cir. 2022) (quotation marks omitted).

ARGUMENT

I. The Court lacks jurisdiction over Novo's challenge to CMS's implementation of the Negotiation Program, and the challenge is in any event meritless.

A. The IRA expressly precludes review of Novo's statutory claims.

1. The Court lacks jurisdiction to resolve Novo's statutory claims because Congress expressly provided that there "shall be no administrative or judicial review" of CMS's "selection of drugs," its "determination of negotiation-eligible drugs," or its "determination of qualifying single source drugs." 42 U.S.C. § 1320f-7(2). Those prohibitions encompass the interpretation that Novo challenges and the procedures the agency followed in adopting that interpretation.

It is well established that "Congress may determine a lower federal court's subject-matter jurisdiction." *Kontrick v. Ryan*, 540 U.S. 443, 452 (2004). While there is a "strong presumption that Congress intends judicial review of administrative action," *Bowen v. Michigan Acad. of Family Physicians*, 476 U.S. 667, 670 (1986), when Congress "provides that 'there shall be no administrative or judicial review' of specified agency actions, its intent to bar review is clear." *DCH Regional Med. Ctr. v. Azar*, 925 F.3d 503, 505-06 (D.C. Cir. 2019) (citation omitted) (quoting 42 U.S.C.

§ 1395nn(i)(3)(I)); *see* 5 U.S.C. § 701(a)(1) (confirming that APA review is unavailable where "statutes preclude judicial review"). The only question in those circumstances is "whether the challenged action falls 'within the preclusive scope' of the statute." *DCH Regional*, 925 F.3d at 506 (quoting *Knapp Med. Ctr. v. Hargan*, 875 F.3d 1125, 1128 (D.C. Cir. 2017)). Novo's challenge to CMS's interpretation of the terms "qualifying single source drug" and "negotiation-eligible drug," and to the procedures the agency followed in adopting those interpretations, falls squarely within the IRA's bar on administrative and judicial review.

2. Novo takes issue with the selection of its drug for negotiation. It argues that "the IRA authorizes CMS to impose price controls in 2026 on no more than '10 negotiation-eligible drugs,'" Br. 23 (quoting 42 U.S.C. § 1320f-1(a)(1)), and that CMS exceeded its authority in construing "negotiation-eligible drug" to encompass "all biological products 'with the same active ingredient and the same holder of a Biologics License Application (BLA), inclusive of products that are marketed pursuant to different BLAs,'" Br. 24-25 (emphases omitted) (quoting Revised Guidance § 30.1, at 99). By its terms, Novo's argument challenges the agency's interpretation of "negotiation-eligible drug" and the underlying

interpretation of "qualifying single source drug." And Novo seeks declaratory and injunctive relief precluding the "selection of" Novo's drug. *See* JA 99.

The plain text of the IRA makes clear that "[t]here shall be no administrative or judicial review" of those agency determinations. 42 U.S.C. § 1320f-7(2). The preclusive scope of that provision is broad insofar as it covers all aspects of the agency's "selection of drugs" for negotiation—including the steps that precede selection, such as the agency's "determination of qualifying single source drugs" and its "determination of negotiation-eligible drugs." *Id.* Congress thus made clear its intent to preclude review not just of individual drug-selection decisions—which Novo also challenges here—but also of the administrative steps leading to the selection.

The statute's emphasis on the agency's "determination[s]" confirms this conclusion. As this Court explained in construing a different statutory review bar, "[t]he word 'determine' means 'to fix conclusively or authoritatively' as well as 'to come to a decision concerning as the result of investigation or reasoning.'" *Bakran v. Secretary, Dep't of Homeland Sec.*, 894 F.3d 557, 563 (3d Cir. 2018) (quoting *Webster's Third New International*

Dictionary 616 (1993)). Thus, in precluding review of the agency's "determination" of qualifying single source drugs and its "determination" of negotiation-eligible drugs, Congress shielded from review both the agency's identification of such drugs and "the process by which the [agency] reache[d] this decision." *Id.*; *see John Balko & Assocs., Inc. v. Secretary of HHS*, 555 F. App'x 188, 193 (3d Cir. 2014) (rejecting an attempt to distinguish between "the procedures used in arriving at [a] determination" and "the merits of the determination itself").

Courts have adopted a similar approach in construing the Medicare statute's other review bars. The D.C. Circuit explained that a statute precluding administrative and judicial review of "the awarding of contracts," 42 U.S.C. § 1395w-3(b)(12), is not limited to "the awarding of a single contract but" rather applies "to the 'awarding of contracts' generally." *Texas All. for Home Care Servs. v. Sebelius*, 681 F.3d 402, 409-10 (D.C. Cir. 2012). The court further explained that, because the process of awarding contracts "requires the formulation and application of financial standards," the statute's bar on review extends to an agency rule adopting such standards. *Id.*

In another context, the court similarly held that a statutory bar on administrative or judicial review of "'[a]ny estimate of the Secretary for purposes of determining [specified] factors'" precluded review of a challenge to "'the methodology adopted and employed' by HHS to calculate" one of those factors. *DCH Regional*, 925 F.3d at 505 (first alteration in original). The court explained that a "distinction between methodology and estimates would eviscerate the statutory bar" against review because "almost any challenge to an estimate could be recast as a challenge to its underlying methodology." *Id.* at 506. Because the "method" used by the agency and challenged by the plaintiff was "inextricably intertwined" with the "estimate," the court held that the statute "precludes review of both." *Id.* at 507; *see Florida Health Scis. Ctr., Inc. v. Secretary of HHS*, 830 F.3d 515, 519 (D.C. Cir. 2016). The analysis in this case is even more straightforward because Novo expressly challenges both the selection of its drug and the agency interpretations underlying that selection.

There is no substance to Novo's contention that its challenge is limited to the number of drugs the agency selected under 42 U.S.C. § 1320f-1(a)(1), and therefore does not concern CMS's "selection of drugs under

section 1320f-1(b)," its "determination of negotiation-eligible drugs under section 1320f-1(d)," or its "determination of qualifying single source drugs under section 1320f-1(e)." Section 1320f-1(a)(1) directs CMS to "select and publish a list of . . . 10 negotiation-eligible drugs described in subparagraph (A) of subsection (d)(1)" for "the initial price applicability year 2026." There is no dispute that this provision requires the selection of 10 negotiation-eligible drugs. The dispute instead centers on the meaning of "negotiation-eligible drug[] described in [§ 1320f-1(d)(1)(A)]," as Novo explains in urging that CMS erred in "aggregat[ing] together six different Novo Nordisk products as a single 'negotiation-eligible drug' merely because they contain the same 'active ingredient,'" Br. 1; *see* Br. 5, 29; JA 53. Novo's argument thus directly challenges CMS's determination of what constitutes a "negotiation-eligible drug[] described in [section 1320f-1(d)]," 42 U.S.C. § 1320f-1(a)(1)—a determination for which § 1320f-7(2) expressly precludes review.

3. Novo's challenge to the form of the guidance also falls squarely within the scope of the review bar, as it concerns the sufficiency of CMS's procedures in making the substantive determinations for which Congress precluded review, and seeks to set aside that substantive determination.

Although Novo broadly asserts that CMS effectively issued a legislative rule without appropriate procedures, Br. 39-43, its procedural concerns track its substantive ones.

Novo contends that CMS did not follow proper procedures in interpreting the term "negotiation-eligible drug" to include products made by the same manufacturer and having the same active ingredient even if approved under separate NDAs. JA97. As discussed, the IRA expressly precludes review of that substantive interpretation. And where Congress precludes review of a particular determination, a court "may not 'inquire whether' the [determination] . . . was the result of a 'procedurally defective' notice-and-comment rulemaking process any more than [it] may question actions by the Secretary that were 'arbitrary, capricious,' or otherwise *substantively* 'defective.'" *Yale New Haven Hosp. v. Becerra*, 56 F.4th 9, 26 (2d Cir. 2022). Thus, a prohibition against review of a substantive determination also precludes review of a claim that CMS "failed to abide by adequate notice-and-comment rulemaking procedures" in arriving at that determination. *Id.* at 13; *see also John Balko*, 555 F. App'x at 193 (rejecting an attempt to distinguish between "the procedures used in arriving at [a] determination" and "the merits of the determination itself").

The provisions at issue are unlike those in *American Clinical Laboratory Ass'n v. Azar*, in which the D.C. Circuit held that a statute providing for no administrative or judicial review "of the establishment of payment amounts" did not preclude review of a separate rule that "detailed the framework for data collection" even though the data collected would be used in establishing payment amounts. 931 F.3d 1195, 1204-05 (D.C. Cir. 2019). The court explained that the challenged rulemaking implemented a separate statutory provision that "imposes new obligations on private parties," thereby addressing a distinct subject from "the rate-setting provisions affect[ing] reimbursements for Medicare services" for which Congress precluded review. *Id.* at 1205-06. Congress also "required that the parameters for that data collection be established through notice and comment rulemaking," part of the purpose of which "is to ensure the parties develop a record for judicial review." *Id.* at 1206. In those circumstances, where the challenged rule was promulgated pursuant to separate authority to address a discrete subject, and where Congress required procedures suggesting the availability of review, the court declined to hold that review was precluded. By contrast, Novo challenges the procedures CMS followed in issuing the guidance that contains the

substantive determination for which Congress precluded review. *See* JA97. And Congress expressly directed CMS not to undertake notice-and-comment rulemaking in issuing that guidance, IRA § 11001(c), 136 Stat. at 1854—consistent with its general intent to preclude review of these determinations.

The relief Novo seeks confirms that the IRA precludes review of its statutory claims. The complaint asks the Court to "[e]njoin CMS from . . . considering multiple drug products or multiple biological products to be a single 'drug,' [qualifying single source drug], or negotiation-eligible drug"; "[d]eclare that Novo's products have been improperly aggregated and are not properly subject to price controls under the statute"; "[e]njoin CMS from applying price controls to any of Novo's products that are improperly aggregated"; and "[d]eclare that the CMS's final revised guidance is invalid, unconstitutional, ultra vires, and/or unenforceable." JA99. Both claims thus seek to undo CMS's determinations of "qualifying single source drugs" and "negotiation-eligible drugs," as well as the agency's selection of Novo's drug for negotiation. Granting such relief would

undermine the very determinations that Congress expressly shielded from review.[3]

4. Novo cannot avoid this result by invoking the *ultra vires* doctrine. Such claims may proceed "only when three requirements are met: '(i) the statutory preclusion of review is implied rather than express; (ii) there is no alternative procedure for review of the statutory claim; and (iii) the agency plainly act[ed] in excess of its delegated powers and contrary to a specific prohibition in the statute that is clear and mandatory.'" *DCH Regional*, 925 F.3d at 509 (quoting *Nyunt v. Chairman, Broad. Bd. of Governors*, 589 F.3d 445, 449 (D.C. Cir. 2009)). Novo's *ultra vires* argument fails at the first step because the IRA "express[ly]" bars review of Novo's claims. *Id.*; *see Florida Health*, 830 F.3d at 519. The argument also fails at the third step because there is no contention that "the agency plainly act[ed] . . . contrary to a

[3] To the extent that Novo seeks to have CMS's selection of *other* companies' drugs set aside, *see* Br. 23, 36-37, such relief would run afoul of Article III limits, as that relief is overbroad and unnecessary to remedy the injuries Novo alleges to suffer. *See DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 335 (2006) (emphasizing that "a plaintiff must demonstrate standing separately for each form of relief sought"). Courts lack constitutional or equitable authority to grant such relief. *See Hollingsworth v. Perry*, 570 U.S. 693, 708 (2013) ("[I]n the ordinary course, a litigant must assert his or her own legal rights and interests, and cannot rest a claim to relief on the legal rights or interests of third parties." (quotation marks omitted)).

specific prohibition in the statute that is clear and mandatory." *DCH Regional*, 925 F.3d at 509 (quotation marks omitted).

To the extent Novo contends that "Congress's decision to preclude review of the agency's determinations does not bar judicial review when the agency violates the mandates that Congress imposed," Br. 47, its argument is circular and would eviscerate the statutory limits on review. It of course is not the case that a claim alleging a statutory violation for which review is otherwise precluded becomes reviewable simply because it alleges a statutory violation. A plaintiff alleging *ultra vires* action "must show a 'patent violation of agency authority.'" *American Clinical Lab.*, 931 F.3d at 1208. In applying that standard, courts have rejected attempts "to 'couch[]' this type of reasonableness challenge 'in terms of the agency's exceeding its statutorily-defined authority.'" *Florida Health*, 830 F.3d at 522-23 (alteration in original) (quoting *Northwest Airlines, Inc. v. FAA*, 14 F.3d 64, 73 (D.C. Cir. 1994)); *see Solar Turbines Inc. v. Seif*, 879 F.2d 1073, 1077 (3d Cir. 1989) (rejecting a plaintiff's attempt to avoid limitations on review of agency action by styling the claim as one seeking review of *ultra vires* action). "*Ultra vires* review is intended to be of extremely limited scope, and it represents a more difficult course than would review under the

APA." *American Clinical Lab.*, 931 F.3d at 1208 (alteration and quotation marks omitted). Here, Congress directed CMS "to operationalize th[ese] important term[s]," *id.*, and to "implement" the Negotiation Program "for 2026, 2027, and 2028 by program instruction or other forms of program guidance," IRA § 11001(c), 136 Stat. at 1854. CMS followed that directive, along with Congress's command to use "data that is aggregated across dosage forms and strengths of the drug, including new formulations of the drug." 42 U.S.C. § 1320f-1(d)(3)(B). That action plainly is not *ultra vires*.

B. Novo's statutory claims in any event fail on the merits.

There is no merit to Novo's arguments that CMS's implementation of the Negotiation Program is substantively or procedurally deficient.

1. CMS appropriately considered the different forms of Novo's insulin aspart drug in the negotiation process, as directed by the IRA.

a. The Negotiation Program targets for negotiation those drugs that impose the highest cost burden on Medicare, regardless of variations in formulation or packaging. To achieve this goal, the IRA requires CMS to consider all dosage forms, strengths, and formulations of a drug together, "and not based on the specific formulation or package size or package type of such drug." 42 U.S.C. § 1320f-5(a)(2); *see also id.* § 1320f-1(d)(3)(B). This

requirement applies at each stage of the process—from the identification and selection of negotiation-eligible drugs to the negotiations themselves, and finally (if negotiations succeed) to the application of a negotiated price.

The first steps involve identifying "negotiation-eligible drugs" according to Medicare spending data, ranking these drugs according to this data, and then selecting the top 10 drugs on the list for negotiation. When calculating Medicare expenditures for a drug at each of these steps, CMS must aggregate the spending data "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 type* of the drug." 42 U.S.C. § 1320f-1(d)(3)(B) (emphasis added). By requiring CMS to consider the total expenditures for a drug across its variations, the statute ensures that CMS identifies and selects the drugs that have the most significant financial impact on Medicare as a whole.

The next steps in the process are in keeping with this approach. Once CMS selects a drug for negotiation, CMS is required to consider all "applications and approvals," in the plural, "for the drug," in the singular, when determining how much to offer in negotiations. 42 U.S.C. § 1320f-3(e)(1)(D). This step, like the earlier ones, contemplates that one drug may

be offered in a number of forms that may correspond to different applications or approvals. And CMS is expressly required to consider all forms of the drug together in calculating an offer price. Finally, after negotiations are completed and a price is established, CMS must "apply the maximum fair price across different strengths and dosage forms of a selected drug and not based on the specific formulation or package size or package type" of the drug. *Id.* § 1320f-5(a)(2). The IRA thus contemplates that there may be multiple formulations and package types of a selected drug and directs CMS to apply the negotiated price to each formulation.

Following this statutory framework, CMS explained in the Revised Guidance that it will consider a qualifying single source drug to include "all dosage forms and strengths of the 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." Revised Guidance 99 (footnote omitted). Applying that interpretation, it determined that the different forms of Novo's insulin aspart drug accounted for some of the highest Medicare expenditures when considered together, and it properly selected them for negotiation.

At present, Novo offers two formulations of this insulin aspart drug: the original form (NovoLog), and a faster-acting version (Fiasp). Novo explains that in creating Fiasp, it "adjusted" the original NovoLog "formulation . . . to increase the speed of initial insulin absorption." NovoMedlink, *Frequently Asked Questions About Fiasp®*, https://perma.cc/ZZQ3-65VP; *see also* Novo Nordisk, *About Fiasp®*, https://perma.cc/9DHQ-C2MQ (explaining that Novo added vitamin B3 to the formula, which "speeds up how fast your body absorbs" the insulin). These two formulations have the same active ingredient (insulin aspart), and are each available in different package types (vials, disposable insulin pens, and reusable insulin pens) to suit various patient needs. Given the IRA's instruction that CMS should select drugs based on information "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 type of the drug," 42 U.S.C. § 1320f-1(d)(3)(B), CMS did not err in selecting these multiple forms of the drug for negotiation.

b. Novo acknowledges that the IRA requires CMS to aggregate expenditure data across dosage forms and formulations in determining

which drugs are eligible for negotiation, in ranking the drugs according to expenditures, and in selecting the top drugs from this list for negotiation. Br. 11 (citing 42 U.S.C. § 1320f-1(b), (d)(3)(B)). Novo also acknowledges that once the parties have agreed to the negotiated price, CMS must apply the negotiated price across each dosage form and formulation of the drug. Br. 31-32 (citing 42 U.S.C. § 1320f-5(a)(2)). Novo thus recognizes that the IRA "allow[s] aggregation of products"—apparently including Novo's insulin aspart products—at the drug-selection stage, as well as when CMS applies the negotiated price "across different strengths and dosage forms of a selected drug." Br. 19, 31-32. But Novo nonetheless contends that these limited provisions do not permit CMS to "impose price controls on an aggregated grouping of different Novo Nordisk products" as a general matter. Br. 1-2.

This interpretation of the statute is untenable and self-contradictory. Novo's principal contention is that CMS may group products (including its insulin aspart products) for some purposes but not others, and it argues that CMS exceeded its authority by selecting six of Novo's insulin aspart products for negotiation. But the statutory provisions Novo cites as permitting aggregation for certain purposes (sections 1320f-1(d)(3)(B),

1320f-1(b), and 1320f-5(a)(2)) expressly govern the identification and selection of negotiation-eligible drugs, as well as the application of the negotiated price. This is not a "narrow" or isolated allowance; from start to finish, the grouping of products in this way is a fundamental part of the program's design and operation as articulated in the IRA.

c. Novo does not address the inconsistency between its concession that the IRA requires aggregation of products for purposes of eligibility, ranking, and pricing, and its insistence that CMS must treat each product separately for purposes of selection. Instead, Novo turns to a different statutory scheme—the Food, Drug, and Cosmetic Act (FDCA)—to argue that aggregation of products for selection is inappropriate in this separate context. But the IRA and the FDCA are different statutes with fundamentally different objectives and functions. Novo's reliance on FDA's product-specific approval framework to argue for a product-specific approach by CMS misunderstands the statutory design and cannot be reconciled with the text of the IRA.

FDA approves drugs and biologics on a product-by-product basis to ensure the safety, efficacy, and quality of each specific formulation, package type, and manufacturing process (among other things). In the

context of FDA approvals, setting aside distinctions between dosage forms, strengths, and formulations would be inappropriate, as it would prevent FDA from evaluating the safety of these various aspects of each finished product. But in the context of the Negotiation Program, considering those forms of a drug together permits CMS to identify the drugs with the greatest financial impact on Medicare overall, consistent with the purpose of the program.

The debate about aggregation across products for the purposes of IRA negotiations is fully resolved by the statute's instruction to aggregate "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 type of the drug." 42 U.S.C. § 1320f-1(d)(3)(B); *see id.* § 1320f-5(a)(2). Novo nonetheless attempts to infer a contrary command from other IRA provisions that reference the FDA approval process. For example, Novo urges that its view is compelled by the statute's requirement that a biologic is not eligible for negotiation unless at least 11 years have elapsed since licensure. In Novo's view, each new product approval triggers a new clock, even when the product is just a different package type or formulation of the same drug. But that argument

is again irreconcilable with the IRA's command to aggregate "across . . . *new* formulations of the drug" for this purpose. *Id.* § 1320f-1(d)(3)(B) (emphasis added). CMS reasonably determined that the relevant date is the earliest approval date of a product in the set, Revised Guidance 101, ensuring that the introduction of variations of the drug do not alter its eligibility. The alternate interpretation urged by Novo, by contrast, would force CMS to exclude newer formulations of high-expenditure drugs despite the statutory command to "includ[e]" them, 42 U.S.C. § 1320f-1(d)(3)(B).

The implications of Novo's proposed approach are striking, as Novo insists that CMS must treat each of its insulin aspart products as separate drugs, no matter how minor the differences between them. For example, Novo sells NovoLog in vials, disposable insulin pens, and reusable insulin pens. According to Novo, these are to be treated as three distinct drugs for purposes of the Negotiation Program, even though they are filled with the same formulation of insulin aspart. This interpretation is fundamentally inconsistent with the statutory framework—it would render meaningless the statute's requirement to aggregate data across "dosage forms," "strengths," and "formulations" of a drug in the selection process, and it

would prevent the Negotiation Program from identifying the drugs responsible for the greatest Medicare expenditures. Moreover, it would incentivize manufacturers to serially introduce slight variations or formulations of a drug that would otherwise qualify for negotiation in order to circumvent the negotiation. The IRA provides no support for that approach and indeed commands the opposite.

2. CMS implemented the Negotiation Program through guidance consistent with the IRA's instructions.

Novo's argument that CMS violated the IRA and the APA by issuing "binding substantive standards" without notice and comment, Br. 43, also rests on an implausible reading of the statutory text. The IRA expressly directs CMS to "implement" the Negotiation Program for 2026, 2027, and 2028 "by program instruction or other forms of program guidance." IRA § 11001(c), 136 Stat. at 1854. Under any conceivable reading of this text, Congress authorized CMS to operationalize the program through "instruction" or "guidance" documents without utilizing notice and comment procedures for the first three negotiation cycles.

Incongruously, Novo contends that this provision *prohibits* CMS from issuing program documents that bear on the substantive obligations of

participating drug manufacturers. Novo reaches this illogical conclusion by zeroing in on the IRA's use of the word "guidance" and insisting that "guidance," by its very nature, must be nonbinding. Br. 40. But this artificially narrow construction of this provision loses sight of the full statutory command, which is to "*implement*" the Negotiation Program "by program instruction or other forms of program guidance." IRA § 11001(c), 136 Stat. at 1854 (emphasis added).

Novo's interpretation would render the statute's directive to "implement" the Negotiation Program meaningless. "To 'implement,' . . . means to 'carry out' or to 'accomplish.'" *Public Int. Legal Found., Inc. v. Bellows*, 92 F.4th 36, 47 (1st Cir. 2024). If CMS were limited to purely nonbinding, advisory measures, it is hard to see how Congress intended CMS to identify negotiation-eligible drugs, select them for negotiation, and enter into binding agreements with manufacturers. Novo's strained interpretation of this provision would leave CMS unable to carry out Congress's directives during the first three years of the program. That view would transform a directive meant to promote efficient program implementation into a tool for delay, thereby undermining the IRA's

purpose of establishing a functional program that delivers timely cost savings to Medicare and its beneficiaries.[4]

II. The district court correctly rejected Novo's constitutional claims.

A. The Negotiation Program is consistent with principles of due process and separation of powers.

Novo's principal constitutional argument blurs concepts of nondelegation and due process in an attempt to create the appearance of a constitutional claim where none exists. When the doctrines are properly disentangled, it is clear that neither supports Novo's assertion of unconstitutionality. Like other longstanding drug-pricing programs, and in keeping with other cost-control provisions of the Medicare program, the Negotiation Program sets forth a detailed process for CMS to work with drug manufacturers to reduce the program costs of certain high-expenditure drugs. That process is wholly consistent with the constitutional principles that Novo invokes.

[4] To the extent Novo grounds this argument in its contention that CMS's guidance is inconsistent with the text of the IRA (Br. 14-15), the argument merely repackages Novo's substantive and *ultra vires* objections to the agency's implementation of the IRA and fails for the same reasons.

1. Despite its acknowledgment that the IRA gives CMS "precise instructions" and grants it only "narrow discretion" in relevant respects, Br. 11, Novo urges that the statute runs afoul of nondelegation principles. This argument is wholly out of step with decades of Supreme Court precedent. "Only twice in this country's history (and that in a single year) [has the Court] found a delegation excessive—in each case because 'Congress had failed to articulate *any* policy or standard' to confine discretion." *Gundy v. United States*, 588 U.S. 128, 146 (2019) (plurality opinion) (quoting *Mistretta v. United States*, 488 U.S. 361, 373 n.7 (1989)) (citing *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495 (1935); *Panama Ref. Co. v. Ryan*, 293 U.S. 388 (1935)). In the 90 years since, the Court has "over and over upheld even very broad delegations." *Id.* It has, for example, "approved delegations to various agencies to regulate in the 'public interest.'" *Id.* (quoting *National Broad. Co. v. United States*, 319 U.S. 190, 216 (1943); *New York Cent. Sec. Corp. v. United States,* 287 U.S. 12, 24 (1932)). It has "sustained authorizations for agencies to set 'fair and equitable' prices and 'just and reasonable' rates." *Id.* (quoting *Yakus v. United States*, 321 U.S. 414, 422, 427 (1944); *Federal Power Comm'n v. Hope Nat. Gas Co.*, 320 U.S. 591, 595 (1944)). And it has "more recently affirmed a

delegation to an agency to issue whatever air quality standards are 'requisite to protect the public health.'" *Id.* (quoting *Whitman v. American Trucking Ass'ns*, 531 U.S. 457, 472 (2001)).

As compared to these statutes, the Negotiation Program "easily passes muster." *Gundy*, 588 U.S. at 146. Far from granting CMS unfettered discretion, the IRA provides detailed guidance at every step—outlining how negotiation-eligible drugs are identified, ranked, and selected, and specifying the factors CMS must consider when negotiating prices. As noted, Novo itself acknowledges that the IRA "contains *precise instructions* for identifying" selected drugs, "grants CMS *narrow discretion* to 'determine' which products should be . . . exempted and to develop a final list of 'negotiation-eligible' products," and provides further instructions about how CMS must rank and select the final list of drugs for negotiation. Br. 11 (emphases added). It is implausible to suggest that this statute—with its carefully crafted framework to address the rising costs of prescription drugs—even approaches the boundaries of the nondelegation doctrine as articulated by the Supreme Court.

2. Novo's due process argument fares no better. To the extent that the due process argument relies on Novo's allegations of unconstitutional

delegation, those aspects of the argument fail for the reasons already discussed: Given that the "extraordinarily capacious standards" in the statutes described above provide intelligible principles sufficient to satisfy nondelegation concerns, *Gundy*, 588 U.S. at 149 (Alito, J., concurring in the judgment), there is no doubt that the IRA does as well.

Novo's due process theory also suffers from independent, fundamental flaws. The Due Process Clause protects against the deprivation "of life, liberty, or property, without due process of law." U.S. Const. amend. V. Therefore, the threshold "inquiry in every due process challenge is whether the plaintiff has been deprived of a protected interest" in liberty or property. *American Mfrs. Mut. Ins. Co. v. Sullivan*, 526 U.S. 40, 59 (1999); *see* JA15. Novo advances two theories of due process violations, but neither entails a deprivation of a constitutionally protected interest.

a. The first theory (and the one advanced in the complaint, JA88-91) is that Novo has a constitutionally protected "right" to a "reasonable return on investment," and the Negotiation Program burdens that right because "the IRA guarantees no return at all—let alone . . . the constitutional minimum of a 'fair and reasonable return on investment.'" JA90; *see* Br. 50-51 (arguing that statutes are invalid if they "provide[] no 'mechanism to

guarantee a constitutionally required fair and reasonable return'"). As the district court explained, the Constitution simply does not recognize such a right, and Novo "provide[s] no authority, statute, or regulation stating that [it is] inherently entitled to continue Medicare sales at" prices above those established through the Negotiation Program. JA16. To the contrary, "[n]o one is entitled to sell the Government drugs at prices the Government won't agree to pay." JA16 (alteration omitted) (quoting *AstraZeneca Pharm. LP v. Becerra*, 719 F. Supp. 3d 377, 395 (D. Del. 2024)). Thus, Novo'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" that could support a due process claim. JA16 (quotation marks omitted); *see Perkins v. Lukens Steel Co.*, 310 U.S. 113, 127 (1940) (emphasizing the government's broad "power to . . . fix the terms and conditions upon which it will make needed purchases").

Novo's argument to the contrary rests on phrases pulled from cases addressing circumstances that bear no resemblance to the Negotiation Program. In particular, Novo quotes from a set of cases describing a "constitutional rate of return," Br. 50-51, but these all involve companies under statutory mandates to provide services (like public utilities) or

subject to across-the-board rate-setting (like insurance companies). *See id.* (citing *Michigan Bell Tel. Co. v. Engler*, 257 F.3d 587 (6th Cir. 2001) (public utility); *Guaranty Nat'l Ins. Co. v. Gates*, 916 F.2d 508, 512 (9th Cir. 1990) (insurance company); *Duquesne Light Co. v. Barasch*, 488 U.S. 299, 310 (1989) (public utility)). The due process concerns that animate these cases are inapplicable here. Unlike public utilities, which "generally are compelled" by statute "to employ their property to provide services to the public," no statute or regulation requires manufacturers to sell their drugs to Medicare. *See, e.g.*, *Garelick v. Sullivan*, 987 F.2d 913, 916 (2d Cir. 1993). Nor does the Negotiation Program govern the prices that manufacturers can charge non-government buyers, further distinguishing the program from the mandatory, across-the-board rate-setting characteristic of utility and insurance regulation.[5]

[5] To the extent Novo suggests that the IRA is a "price-control scheme," Br. 51, that restricts the prices that manufacturers may charge other buyers in the marketplace, that is simply incorrect. Novo remains free to sell its drugs—at any price—to any willing buyer. The IRA does not limit the prices that Novo may charge non-government buyers for its drugs; it establishes the maximum prices the *government* will pay for certain drugs provided to Medicare beneficiaries.

b. Novo's second due process theory rests on its property interest in the drug itself, but the Negotiation Program does not deprive Novo of this property interest.[6] In offering to purchase drugs on terms that Novo is under no legal obligation to accept, the government is not demanding that Novo turn over its property. And Novo's choice to accept the government's offer and sell its insulin aspart on the proposed terms does not entail a "deprivation" of property.

Novo acknowledges that, as a legal matter, it retains the option not to sell its drug to the government under these conditions. Br. 13. But it contends that the opportunity to participate in Medicare is so profitable as to leave the company with no practical choice but to accept the terms of participation. *Id.* In other words, Novo contends that the government is offering a deal too good for companies to refuse. But the fact that continuing participation in Medicare may be the best available option for

[6] Novo also alludes to an interest in its proprietary commercial information, but Novo fails to explain in what sense the Negotiation Program deprives it of this interest. To the extent that the due process analysis concerning Novo's commercial information rests on a different theory than that applicable to Novo's physical drugs, any such argument is forfeited.

Novo does not mean that participation is in any sense legally compelled, and it does not give rise to a constitutional claim.

Novo's reliance on the Supreme Court's decision in *National Federation of Independent Business v. Sebelius* (*NFIB*), 567 U.S. 519 (2012), to argue otherwise is unavailing. In *NFIB*, the Supreme Court held that Congress's threat to withdraw all existing Medicaid funding from States was so coercive as to "violate[] the basic principle that the Federal Government may not compel the States to enact or administer a federal regulatory program." *Id.* at 575 (plurality opinion) (quotation marks omitted). The Court explained that the government could not threaten to withhold existing grants of Medicaid funding as a means of "coerc[ing] a State to adopt a federal regulatory system as its own." *Id.* at 578. *NFIB*'s analysis thus addresses—and is derived exclusively from cases analyzing—how federalism principles inform what conditions Congress may attach to money it grants to States. *See id.* at 579-81 (plurality opinion); *see also Northport Health Servs. of Ark., LLC v. HHS*, 14 F.4th 856, 869 n.5 (8th Cir. 2021) (explaining that the *NFIB* "coercion" inquiry "describe[s] the federal government's limited constitutional authority under the Spending Clause to regulate the states, not a federal agency's ability to regulate [private]

facilities' use of federal funding" (citation omitted)), *cert. denied*, 143 S. Ct. 294 (2022).

The same analysis does not apply when, rather than using grant conditions to "encourage a State to regulate in a particular way," *NFIB*, 567 U.S. at 576, the government uses its purchasing power to bargain with private sellers for lower drug prices. Novo is not similarly situated to recipients of federal benefits; it is a commercial supplier of drugs that the government purchases for Medicare patients, and it receives billions of dollars annually in exchange for the goods it provides. It "has long been recognized that the government, like private individuals and businesses, has the power 'to determine those with whom it will deal, and to fix the terms and conditions upon which it will make needed purchases.'" *Ray Baillie Trash Hauling, Inc. v. Kleppe*, 477 F.2d 696, 709 (5th Cir. 1973) (quoting *Perkins*, 310 U.S. at 127). Any downward "pressure" on prices that Congress may exert through the terms of its procurement offers is analogous to the leverage of any well-funded market participant, which is of no constitutional import.

Novo resists this conclusion by arguing that the government's broad discretion to set the parameters of its procurement decisions is somehow

limited when the government has a dominant market position that stems from its lawful administration of public programs. Novo argues that in such circumstances, contractors are effectively "forced" to sell to the government because they cannot afford to forgo the profits from the large share of the market the government occupies. This theory runs headlong into well-established precedent holding that, because companies are not required to offer products or services to Medicare beneficiaries, the terms of participation in Medicare cannot amount to a deprivation of property under the Fifth Amendment. Even where "business realities" create "strong financial inducement to participate"—such as, for example, when Medicaid provides the vast majority of a nursing home's revenue—courts have emphasized that participation "is nonetheless voluntary" and that regulations like rate restrictions thus entail no government-mandated deprivation of property. *See Minnesota Ass'n of Health Care Facilities v. Minnesota Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984).[7]

[7] *See also Southeast Ark. Hospice, Inc. v. Burwell*, 815 F.3d 448, 450 (8th Cir. 2016); *Garelick*, 987 F.2d at 916; *Franklin Mem'l Hosp. v. Harvey*, 575 F.3d 121, 129 (1st Cir. 2009); *Burditt v. HHS*, 934 F.2d 1362, 1376 (5th Cir. 1991); *Baptist Hosp. East v. HHS*, 802 F.2d 860, 869-70 (6th Cir. 1986); *Whitney v. Heckler*, 780 F.2d 963, 972 (11th Cir. 1986); *St. Francis Hosp. Ctr. v. Heckler*,

Continued on next page.

Moreover, the government has for decades offered to purchase drugs subject to an extensive set of statutory and regulatory requirements that Novo has previously accepted. For example, as a condition on its participation in Medicaid, Novo has long been required to enter into agreements that give the Department of Defense, the Department of Veterans Affairs, and the Coast Guard the option to purchase drugs at negotiated prices at or below statutory ceilings. *See* 38 U.S.C. § 8126(a)-(h). Pursuant to another condition on Medicaid participation, Novo has likewise entered into agreements to provide drugs to certain healthcare facilities subject to statutory price ceilings. *See Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 113 (2011) (describing requirements under Section 340B of the Public Health Services Act). These requirements do not amount to a constitutional deprivation of property; they are simply terms that Novo has long chosen to accept in exchange for the financial benefits that these programs confer.

Novo's theory would also upend decades of established contracting practices across other critical industries in which the government is the

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714 F.2d 872, 875-76 (7th Cir. 1983) (per curiam); *Baker Cty. Med. Servs., Inc. v. U.S. Attorney Gen.*, 763 F.3d 1274, 1279-80 (11th Cir. 2014).

dominant or sole buyer. The defense industry offers a compelling analogy: The government is often the only purchaser in that sector, having prohibited or severely restricted the sale of arms and aircraft to private parties and foreign governments. This dominant market position, which is a direct result of the government's exercise of sovereign authority to regulate, lies behind every negotiation with defense contractors. But no court has ever suggested that the government's market position raises coercion concerns of constitutional significance, even though a defense company's very survival depends on government contracts.

Despite the government's market dominance, the defense industry thrives under these conditions. This is because of a critical dynamic that Novo's argument overlooks: Even in markets in which the government is a dominant purchaser, manufacturers often retain significant bargaining power. While the government uses its dominant market position to negotiate for lower prices, defense contractors leverage the government's desire for specific military technologies to negotiate favorable terms. This interdependence gives both parties strong incentives to reach agreement and ensures that negotiations are not one-sided.

The same is true for prescription drugs. While the government may try to use its purchasing power to negotiate better prices on behalf of taxpayers, drug companies wield substantial power given the government's significant interest in providing coverage for critical medicines. That is particularly true here: The Negotiation Program applies only to drugs without generic or biosimilar competition, *see* 42 U.S.C. § 1320f-1(e), so if the government fails to reach a deal, Medicare beneficiaries may be left without adequate alternatives for some of the most widely used drugs on the market. The government therefore has a strong interest in reaching a deal under which these important drugs can continue to be covered.

Far from "forcing" Novo to sell its products at a government-dictated rate, the IRA leaves Novo free to negotiate pricing with any buyers in the marketplace, including the government. Just as defense contractors remain free to accept or reject the government's contractual terms despite the government's overwhelmingly dominant market position, so too are pharmaceutical companies that participate in Medicare and Medicaid, which occupy a far less significant portion of the prescription drug market. While Novo cannot require the government to buy its drugs at its preferred

price, it may avail itself of the leverage resulting from its exclusive right to sell its insulin aspart products. Novo also remains free to negotiate different prices with other buyers and to choose not to sell its drugs to any buyer, including the government, if the parties do not agree on a price.

B. The Negotiation Program is also consistent with the First Amendment.

Novo's brief concludes with an undeveloped compelled-speech argument that fails to meaningfully engage with relevant First Amendment standards. The suggestion that the Negotiation Program impermissibly compels manufacturers' speech by requiring them to enter agreements to negotiate and to honor any agreed-upon prices fails at the outset because participation in the Negotiation Program, like participation in Medicare generally, is voluntary. Plaintiffs are not compelled to enter any agreements if they choose not to. *See Miller v. Mitchell*, 598 F.3d 139, 152 (3d Cir. 2010) ("A violation of the First Amendment right against compelled speech occurs only in the context of actual compulsion . . . ." (quotation marks omitted)). The challenged agreements in any event implicate commercial conduct rather than protected speech. The agreements are the mechanisms by which the government sets the terms of the negotiation

process and memorializes the outcomes of the price negotiations. JA13. Novo identifies no authority supporting the contention that commercial agreements of this type entail protected expression. *See Sorrell v. IMS Health Inc.*, 564 U.S. 552, 567 (2011) ("[T]he First Amendment does not prevent restrictions directed at commerce or conduct from imposing incidental burdens on speech.").

Finally, Novo errs in asserting that the use of statutory terms of art that are defined in the IRA (such as "maximum fair price") requires it to endorse any ideological viewpoint. These terms of art accurately describe the operation of the program and do not convey or require plaintiffs to endorse any view regarding the value of their drugs. As an initial matter, Congress's use of the term "maximum fair price" is in keeping with longstanding regulatory requirements that contracting prices be determined to be "fair," and these requirements have never been thought to raise First Amendment concerns. *See United States v. General Dynamics Corp.*, 19 F.3d 770, 771 (2d Cir. 1994) (statute requires that "the proposed ship purchaser and the shipyard submit backup cost details and evidence that the negotiated price is fair and reasonable" to obtain federal subsidy); *Air Borealis Ltd. P'ship v. United States*, 167 Fed. Cl. 370, 389 (2023)

(contractor allowed to certify that price is "fair and reasonable" in lieu of providing cost data to government purchaser); *Harvey Radio Labs, Inc. v. United States*, 115 F. Supp. 444, 445 (Ct. Cl. 1953) (contract provides that "the Contractor will negotiate to reduce the contract price to an amount representing fair and reasonable compensation for the performance of the contract").

The agreements here, moreover, state explicitly that a manufacturer's signature reflects neither an "endorsement of CMS' views" nor a representation of the manufacturers' views concerning the fairness of prices. JA178. And they explain that the use "of the term 'maximum fair price' and other statutory terms throughout th[e] Agreement reflects the parties' intention that such terms be given the meaning specified in the statute and does not reflect any party's views regarding the colloquial meaning of those terms." JA178. This language confirms that the agreements use statutory terms as a way of ensuring a consistent understanding of the program terms and the parties' obligations by reference to the statute, not as a means of compelling manufacturers to express a view about the value of their drugs.

CONCLUSION

For the foregoing reasons, the judgment of the district court should be affirmed.

Respectfully submitted,

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DECEMBER 2024

COMBINED CERTIFICATIONS

1. Government counsel are not required to be members of the bar of this Court.

2. This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B)(i) because it contains 12,896 words. This brief also complies with the typeface and type-style requirements of Rule 32(a)(5)-(6) because it uses Book Antiqua 14-point font, a proportionally spaced typeface.

3. On December 16, 2024, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Third Circuit by using the appellate CM/ECF system. Service will be accomplished by the appellate CM/ECF system.

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s/ Catherine Padhi
CATHERINE PADHI

ADDENDUM

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42 U.S.C. § 1320f-1 (excerpt) – 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

* * *

(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 [M]edicare 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.

* * *

42 U.S.C. § 1320f-5 – Administrative duties and compliance monitoring

(a) Administrative duties

For purposes of section 1320f(a)(4) of this title, the administrative duties described in this section are the following:

(1) The establishment of procedures to ensure that the maximum fair price for a selected drug is applied before—

(A) any coverage or financial assistance under other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of maximum fair price eligible individuals; and (

B) any other discounts.

(2) The establishment of procedures to compute and apply the maximum fair price across different strengths and dosage forms of a selected drug and not based on the specific formulation or package size or package type of such drug.

(3) The establishment of procedures to carry out the provisions of this part, as applicable, with respect to—

(A) maximum fair price eligible individuals who are enrolled in a prescription drug plan under part D of subchapter XVIII or an MA–PD plan under part C of such subchapter; and

(B) maximum fair price eligible individuals who are enrolled under part B of such subchapter, including who are enrolled in an MA plan under part C of such subchapter.

(4) The establishment of a negotiation process and renegotiation process in accordance with section 1320f–3 of this title.

(5) The establishment of a process for manufacturers to submit information described in section 1320f–3(b)(2)(A) of this title.

(6) The sharing with the Secretary of the Treasury of such information as is necessary to determine the tax imposed by section 5000D of the Internal Revenue Code of 1986, including the application of such tax to a manufacturer, producer, or importer or the determination of any date

described in section 5000D(c)(1) of such Code. For purposes of the preceding sentence, such information shall include—

(A) the date on which the Secretary receives notification of any termination of an agreement under the Medicare coverage gap discount program under section 1395w–114a of this title and the date on which any subsequent agreement under such program is entered into;

(B) the date on which the Secretary receives notification of any termination of an agreement under the manufacturer discount program under section 1395w–114c of this title and the date on which any subsequent agreement under such program is entered into; and

(C) the date on which the Secretary receives notification of any termination of a rebate agreement described in section 1396r–8(b) of this title and the date on which any subsequent rebate agreement described in such section is entered into.

(7) The establishment of procedures for purposes of applying subsections (d)(2)(B) and (f)(1)(C) of section 1320f–1 of this title.

(b) Compliance monitoring

The Secretary shall monitor compliance by a manufacturer with the terms of an agreement under section 1320f–2 of this title and establish a mechanism through which violations of such terms shall be reported.

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 [1] the determination of qualifying single source drugs under section 1320f–1(e) of this title the [2] 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.