UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
Trenton

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

PLAINTIFFS' MEMORANDUM IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

Government programs that dictate the prices charged for products sold in interstate commerce pose challenges for rule-of-law values and the Constitution's separation of powers. Choosing which products should be subject to government-dictated prices—and thus which manufacturers will be denied their common-law right to charge market-based prices—requires a careful exercise of legislative judgment. The choices that Congress makes must be protected from evasion or revision by executive branch officials. Similarly, dictating the prices that manufacturers may charge implicates important public interests and private rights. Because the public will be irreparably harmed if prices are set at levels that lead to shortages or undermine beneficial innovation, and because manufacturers are constitutionally entitled to a reasonable return on their investments, when Congress enacts a price-setting statute it must include both *standards* to cabin executive discretion and adequate *processes* to protect against the imposition of arbitrary or confiscatory prices. These constitutional safeguards are essential to ensuring lawful, transparent, and accountable government.

The actions taken by the Centers for Medicare & Medicaid Services ("CMS"), on behalf of the Secretary of the U.S. Department of Health and Human Services ("HHS"), to implement the Inflation Reduction Act of 2022 ("IRA") are unlawful because they violate the statute's plain text. Congress directed that price controls would be imposed in the program's first year on no more than 10 drug or biological products, and only on products that have been approved or licensed by the Food and Drug Administration

("FDA") for at least 7 years (in the case of drug products) or at least 11 years (in the case of biological products). CMS has violated these express statutory mandates by imposing price controls on aggregated *groupings* of products—comprising far more than 10 individual products—merely because the different products contain the same "active moiety" or "active ingredient" (terms that appear nowhere in the statute). By grouping products in this way, CMS is also trying to impose price controls on products that have not been approved or licensed for the requisite 7- or 11-year period. These and other deviations from the IRA's plain text far exceed CMS's delegated authority and result in departures from the IRA's statutory terms that are in conflict with decades of well-established FDA regulation and policy.

CMS is also disregarding express limits that Congress placed on the agency's authority to create and impose new substantive legal obligations. Recognizing that new requirements could burden manufacturers and harm patients' access to needed medications, the IRA instructs that CMS "shall" implement its provisions through "guidance" and *withholds rulemaking authority* from the agency until after the program has been in existence for at least 3 years. Violating that mandate, CMS seeks to impose new obligations on manufacturers as a condition of providing their drugs to patients in large segments of the nation's prescription-drug market. Those obligations go far beyond what is permissible in guidance because they operate as binding legal rules that cannot be imposed without complying with notice-and-comment procedures. Because CMS has not complied with those requirements, its "guidance" is unlawful.

CMS's statutory rewrite reinforces and exacerbates the IRA's grave underlying constitutional problems. Where, as here, a statute delegates broad authority to an agency to set prices, Congress must provide an intelligible principle to control the agency's price-setting decisions. Not only does the IRA fail to include any intelligible principle governing the prices set by CMS, it combines that sweeping delegation with other constitutional violations that blur lines of accountability and undermine the Constitution's essential structural protections. More specifically, the IRA lacks adequate procedures to protect against unfair and confiscatory pricing; attempts to strip the judiciary of the power to review CMS's highly consequential price-setting decisions; and imposes a compelled speech requirement that forces manufacturers to "agree" that any price imposed by CMS is the "maximum fair price," no matter how unreasonable, arbitrary, or unfair the price might be. No statute in this nation's history—not even during wartime—has delegated such broad and unchecked price-setting authority to an administrative agency and simultaneously stripped away so many constitutional safeguards necessary to protect individual rights and the broader public interest.

The Court should vacate CMS's guidance, strike down CMS's ultra vires actions imposing price controls on aggregated groupings of products manufactured by plaintiffs Novo Nordisk Inc. and Novo Nordisk Pharma, Inc. (together "Novo"), and direct CMS to comply with the statute as written by Congress. Granting complete relief should prevent CMS from applying the IRA to Novo. If that is not the case, the Court

should strike down the IRA in its entirety as an unprecedented departure from the Constitution's essential norms and structural guarantees.

BACKGROUND

A. Drug Pricing Before the Inflation Reduction Act

Relying on the ability to sell their products at market-based prices, manufacturers have invested billions of dollars in discovering, developing, and commercializing new medications and improving existing ones. They have made those investments because drug pricing in this country has historically been informed by market forces, which has allowed manufacturers to take on the monumental risks and seek to recover the staggering costs associated with pharmaceutical innovation.

Pharmaceutical manufacturers annually invest billions of dollars in research and development, conduct rigorous preclinical and clinical testing, and shepherd new and improved medications through a lengthy FDA-approval and licensing process, with no certainty that any new product will ever be approved, marketed, or sold. The average cost of bringing a single new product to market is estimated to be more than $2 billion, and the process takes an average of 10 to 15 years. *See* CBO, No. 57025, Research and Development in the Pharmaceutical Industry, at 14 (Apr. 2021); GAO, No. GAO-20-215SP, Artificial Intelligence in Health Care, at 34 (Dec. 2019). Only about 1 in 5000 potential products successfully navigates these hurdles—the vast majority are never approved. *See* Paula Carracedo-Reboredo et al., *A Review on Machine Learning Approaches and Trends in Drug Discovery*, 19 Computational & Structural Biotech. J. 4538, 4547 (2021).

Until now, the federal government has recognized that bureaucratic interference can increase costs and threaten the pace of development and innovation of therapies. Because the government acts as both a regulator and the "domina[nt]" market participant, *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 699 (3d Cir. 2023), there is a recognized danger that the government will use price-setting procedures to further its own financial and parochial interests at the expense of private rights and the broader public interest. Medicare Part D's authors thus recognized that prohibiting agency officials from interfering with market-based prices was a "fundamental protection" necessary to prevent "price fixing by the CMS bureaucracy." 149 Cong. Rec. S15624 (daily ed. Nov. 23, 2003) (statement of Sen. Grassley).

These concerns have become more important as the government has taken over ever larger portions of the nation's healthcare markets. Medicare Part D, for instance, began as a comparatively small part of the nation's prescription drug market. That is no longer the case. About 53 million individuals are currently enrolled in Medicare Part D, and "Medicare Part D drug expenditures" have "exceeded $200 billion" per year. GAO, No. GAO-23-105270, Medicare Part D: CMS Should Monitor Effects of Rebates on Plan Formularies and Beneficiary Spending (Sept. 2023); *see also* Assistant Sec'y of Planning & Evaluation, Office of Health Pol'y, No. HP-2023-19, Inflation Reduction Act Research Series—Medicare Enrollees' Use and Out-of-Pocket Expenditures for Drugs Selected for Negotiation under the Medicare Drug Price Negotiation Program, at 2 (July 7, 2023). The government now dominates large swaths

of the market and accounts for "almost half the annual nationwide spending on prescription drugs." *Sanofi Aventis*, 58 F.4th at 699 (citing CBO, No. 57050, Prescription Drugs: Spending, Use, and Prices, at 8 (Jan. 2022)).

B. The Inflation Reduction Act

In August 2022, Congress enacted the IRA. In a stark deviation from historical practice, the statute's drug-pricing provisions direct CMS to impose price controls on an expanding number of manufacturers' prescription medications.

Recognizing that regulating prices for too many products all at once would cause massive upheaval, the statute expressly limits which products may be subjected to government-imposed prices. Congress mandated that, for 2026, CMS may set prices on only 10 drug or biological products. 42 U.S.C. § 1320f-1(a)(1), (e)(1). In 2027 and 2028, CMS may set prices on an additional 15 products per year. *Id.* § 1320f-1(a)(2), (3). And in 2029 and beyond, the statute authorizes price controls on an additional 20 products per year. *Id.* § 1320f-1(a)(4).

Congress also mandated that manufacturers would be stripped of their right to charge market-based prices only *after* a specified period of unburdened sales. Congress prohibited CMS from setting prices for any drug product approved for less than 7 years or any biological product licensed for less than 11 years. 42 U.S.C. § 1320f-1(e)(1). Congress also made clear that a drug or biological product may not be subject to price controls if it faces marketed generic or biosimilar competition. *Id.*

The statute provides clear instructions on how CMS should determine which products should be subject to price controls. Congress mandated which drug and biological products would be eligible for inclusion in the price control program, and then directed CMS to rank each eligible marketed drug and biological product according to Medicare's total gross expenditures. 42 U.S.C. § 1320f-1(b). In deciding which products meet the statute's high-spend requirement, the statute directs CMS to "use data" aggregated across certain specified product characteristics—in particular, across "dosage forms and strengths of the drug, including new formulations …, such as an extended release formulation, and not based on the specific formulation or package size or package type of the drug." *Id.* § 1320f-1(d)(3)(B). The statute does not authorize aggregation based on other features of a drug product.

Recognizing the risk that CMS would overstep in its implementation of the IRA, which could unfairly burden manufacturers and harm patients, Congress deliberately prohibited the agency from creating or imposing new substantive obligations with the force of law. Although the statute in other contexts instructs executive officials to "prescribe such regulations and other guidance as are necessary or appropriate to carry out … the purposes of this section," *see* Pub. L. No. 117-169, § 10201, 136 Stat. 1818, 1831 (2022) (amending § 4501(f)), the IRA withholds any authority for CMS to promulgate binding regulations for three years. Instead, the statute directs that CMS "shall implement this section … for 2026, 2027, and 2028 by program instruction or other forms of program guidance." *Id.* §§ 11001(c), 11002(c), 136 Stat. at 1854, 1862.

Despite carefully limiting CMS's rulemaking authority and which products are eligible for price controls, the IRA contains no meaningful standards to govern the "maximum fair prices" imposed by CMS. There is no statutory requirement that the prices be just and reasonable, or that CMS protect innovation or patient access, avoid shortages, or set prices at fair and non-confiscatory levels. The statute instead includes a breathtakingly expansive delegation for CMS to set prices at any level it chooses.

Rather than take responsibility for the consequences of its novel price-control regime, Congress ladened the IRA with provisions that blur lines of accountability. Most notably, the statute labels the price-setting process a "negotiation," suggesting that manufacturers have a meaningful say in the prices imposed. In fact, however, the process bears no resemblance to a "negotiation" in any sense of the term. The hallmarks of a true "negotiation" are that the parties have equal bargaining powers and neither party will be forced into a position it does not support. The "negotiation" contemplated by the IRA strays far from those basic requirements. Instead, the statute mandates that any manufacturer of a product targeted for price controls must disclose highly sensitive data that no manufacturer would voluntarily disclose. *See* 42 U.S.C. § 1320f-2(a); *see also* Hauda Decl. ¶¶ 55–59. After considering that information, CMS unilaterally proposes a price below a statutory ceiling, which can be no higher than 40% to 75% of the product's average price to non-federal purchasers. 42 U.S.C. § 1320f-3(c)(1)(C), (b)(2)(F); 38 U.S.C. § 8126(h)(5). Apart from this price ceiling, the statute contains no standard, methodology, or other instruction to guide CMS's price-setting

decision. The statute leaves the price to CMS's unfettered discretion, with nothing more than a suggestion to "ai[m] to achieve the lowest maximum fair price for each selected drug." 42 U.S.C. § 1320f-3(b)(1).

Manufacturers also have no reasonable or practical ability to escape the government's unilateral price controls. If a manufacturer refuses to sell at CMS's prescribed price, the manufacturer is punished with one of two untenable outcomes—either (1) paying a ruinous penalty indefinitely or (2) withdrawing *all* of its products from Medicare and Medicaid (even products not subject to CMS's price controls) after months of paying the penalty. 26 U.S.C. § 5000D(b)(1)–(4). The penalty—mislabeled an "excise tax"—accrues daily and can range from nearly double the product's daily sales revenue to up to *19 times* the product's total daily sales revenue. Cong. Rsch. Serv., No. R47202, Tax Provisions in the Inflation Reduction Act of 2022 (H.R. 5376), at 4 tbl. 2 (Aug. 10, 2022). A manufacturer can stop the penalty from accruing only by withdrawing *all* of its products from Medicare and Medicaid—which is practically impossible and would be devastating for Medicare and Medicaid patients. *See* Hauda Decl. ¶¶ 66–67, 77. As noted above, the federal government has taken control of nearly half of the nation's prescription drug market, and over a hundred million patients in the federal government programs depend on having access to manufacturers' drugs. Moreover, even if a manufacturer could withdraw all of its products from such a sizeable part of the market, it would still face months of daily penalties because the statute mandates that it takes 11 to 23 months after a manufacturer submits a notice for

a withdrawal to take effect. *See* 42 U.S.C. § 1395w-114a(b)(4)(B)(ii); 42 C.F.R. § 423.2345(b)(2); 42 U.S.C. § 1395w-114c(b)(4)(B)(ii).

The statute includes other provisions that further obscure lines of accountability. Perhaps most notably, the statute bars judicial review of many of the agency's most consequential decisions, including the agency's selection of which 10 drug or biological products to subject to price controls, its determination of which products meet the eligibility criteria to be classified as "qualifying single source drugs," and its determination of what price should be deemed "the maximum fair price." 42 U.S.C. § 1320f-7. In Orwellian fashion, the statute also forces manufacturers to agree publicly that CMS's imposed price is the "maximum fair price" or face crushing daily "excise taxes." 26 U.S.C. § 5000D.

C. CMS's Final Guidance

On June 30, 2023, CMS issued a 198-page "guidance" document. *See* CMS, Medicare Drug Price Negotiation Program: Revised Guidance (June 30, 2023) ("Final Guidance"). Given the IRA's unprecedented provisions—and the risks to patients, providers, and other stakeholders of disrupting the nation's healthcare markets and product-development pipeline—one would have expected CMS to take a modest approach. Instead, the agency's guidance goes far beyond announcing CMS's policy decisions and imposes substantial new binding obligations on manufacturers. *See id.* at 131–32.

First, the agency has eliminated the statute's careful limits on the number and types of products eligible for price controls. According to CMS, it is not limited to imposing price controls on only 10 drug or biological products, as the statute directs, but instead may dictate prices across entire families of products that contain the same *active moieties* (in the case of drug products) or the same *active ingredients* (in the case of biological products). Final Guidance § 30.1. CMS has thus transformed the IRA's provisions from a pricing scheme for drug and biological products into a pricing scheme for "active moieties" and "active ingredients"—and has disregarded the specific safety and efficacy analysis that must support product approval decisions. CMS's guidance also disregards essential statutory criteria by imposing price controls on products that were approved or licensed less than 7 or 11 years ago based on an earlier approval of a different drug product containing the same active moiety or a different biological product containing the same active ingredient. *See id.*

Second, the guidance purports to regulate products that the statute excludes from price controls. The IRA directs that CMS may not set prices for any product that is (1) the "reference listed drug" for any drug product that is "approved and marketed under section 355(j)" (commonly known as a generic drug) or (2) "the reference product for any biological product that is licensed and marketed under section 262(k)" (commonly known as a biosimilar). 42 U.S.C. § 1320f-1(e). That mandate reflects Congress's intent to deny CMS authority to impose price controls on products subject to marketed generic or biosimilar competition, since multi-source drugs already face

price pressure from competition. Nothing in the statute grants CMS authority to evaluate for itself the *quality* or *amount* of competition. Rather than staying within the statute's bounds, however, the agency will remove price controls only if a competitor engages in what CMS, in its sole discretion, deems to be "bona fide" marketing. Final Guidance § 30.1. The guidance asserts that CMS will "monitor" the market to determine, based on the "totality of circumstances," whether "meaningful competition" exists. *Id.* at 74 & § 90.4. Such an amorphous standard, which can be applied arbitrarily and inconsistently, is contrary to the IRA.

Third, the guidance imposes a host of other new substantive requirements found nowhere in the statute. For example, the guidance redefines the term "manufacturer" and divides it into two types of entities—a "primary manufacturer" and a "secondary manufacturer." Final Guidance § 40. While the statute defines "manufacturer" broadly to include any entity engaged in "the production, preparation, propagation, compounding, conversion, or processing of prescription drug products" or in the "packaging, repackaging, labeling, relabeling, or distribution of prescription drug products," 38 U.S.C. § 8126(h)(4)(B); 42 U.S.C. § 1320f(c)(1)., CMS's guidance defines a "primary manufacturer" as the entity that holds the new drug application ("NDA") or biologics licensing application ("BLA") for the selected drug and relegates all others to "secondary manufacturer" status. Final Guidance § 40. This artificial distinction has real consequences, as primary manufacturers are responsible under CMS's guidance for collecting data and monitoring compliance for secondary manufacturers, even though

critical pricing data is rarely shared between manufacturers for competitive and antitrust reasons. *See id.* §§ 40, 50.1, 90.2. In addition, the guidance imposes new data collection requirements, forcing manufacturers to submit large quantities of highly sensitive and confidential information not required by the statute. For instance, instead of requesting research-and-development costs, as the statute permits, CMS breaks this request down into five unique sub-elements, each of which includes additional definitions, instructions, and de facto sub-requirements that go beyond what the statute provides in its text. *See id.* App. C.

On August 29, 2023, CMS announced the products it plans to subject to price controls in 2026. In addition to at least 9 other distinct products, CMS identified 6 different products manufactured by Novo for which the agency intends to dictate a single price. In other words, while the IRA authorizes CMS to set prices on only 10 products, the agency has ignored that limit and subjected multiple Novo products to price controls that otherwise would not satisfy the IRA's criteria. Facing a crushing excise tax and unable to withdraw its entire portfolio of products from government healthcare programs, Novo had no option but to execute a "negotiation" agreement with CMS, while preserving its litigation rights. *See* CMS, Manufacturer Agreements for Selected Drugs for Initial Price Applicability Year 2026 (Oct. 3, 2023); Hauda Decl. ¶¶ 50, 52 & Exs. E, F.

STANDING

Novo has standing to challenge both CMS's actions and the IRA. Novo's standing is "self-evident" because its products are the direct "'object of the [agency] action … at issue.'" *Sierra Club v. EPA*, 292 F.3d 895, 900 (D.C. Cir. 2002) (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561–62 (1992)). Novo faces at least four concrete and particular injuries, which are traceable to CMS and the IRA and would be redressed by granting the relief that Novo seeks.

First, because CMS has targeted six different Novo products for price controls, the company faces imminent injury by being forced to participate in an unfair and one-sided "negotiation" process and by being forced to sell its products at dictated prices. *See* Hauda Decl. ¶¶ 53–54, 62–70; *Horne v. Dep't of Agric.*, 576 U.S. 350, 363 (2015) (the government deprives a company of property when it demands property in exchange for a price "set at the government's discretion"). Novo contends that CMS's approach violates its statutory rights. *See Zivotofksy ex rel. Ari Z. v. Secretary of State*, 444 F.3d 614, 619 (D.C. Cir. 2006) (recognizing that a violation of an "individual right" conferred by a statute is a "concrete and particular injury for standing purposes").

Second, Novo faces the infringement of its constitutional rights, including its rights to due process and free speech. *See Spokeo, Inc. v. Robins*, 578 U.S. 330, 340 (2016) (such "intangible injuries" to constitutional rights satisfy the Article III injury-in-fact requirement). These constitutional injuries are ongoing and future constitutional

injuries are imminent unless the Court strikes down CMS's unlawful actions and the IRA's unlawful provisions.

Third, Novo has incurred and will continue to incur significant costs complying with CMS's requirements that it disclose highly sensitive and confidential trade secret and commercial information to CMS. *See* Hauda Decl. ¶¶ 61, 63; 42 U.S.C. §§ 1320f(d)(5)(A), 1320f-2(a)(4), 1320f-3(b)(2)(A); *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2204 (2021) ("If a defendant has caused … monetary injury to the plaintiff, the plaintiff has suffered a concrete injury in fact under Article III."); *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1003–04 (1984) (acknowledging that trade-secret information is property under the Constitution). Novo treats this information as highly confidential and would not ordinarily share it with the government or any other potential contracting partner.

Fourth, Novo faces an imminent financial injury if it tries to withdraw from CMS's price-setting scheme, either by being forced to pay a massive excise tax or by losing access to approximately half of the prescription-drug market for all its products. *See* Hauda Decl. ¶¶ 64–67; 26 U.S.C. § 5000D(b)(1)–(4), (c); 42 U.S.C. §§ 1396r-8(a)(1), 1395w-114a(b)(4)(B)(ii), 1395w-114c(b)(4)(B)(ii); *California v. Texas*, 141 S. Ct. 2104, 2114 (2021) (standing arises when an injury "is the result of a statute's actual or threatened enforcement, whether today or in the future" (emphasis omitted)).

LEGAL STANDARD

When "there is no genuine issue as to any material fact," summary judgment is appropriate if "the moving party is entitled to judgment as a matter of law." *Stepan Co. v. Callahan Co.*, 568 F. Supp. 2d 546, 549 (D.N.J. 2008). A reviewing court must set aside agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

ARGUMENT

I. CMS's Actions Violate the Inflation Reduction Act's Express Mandates.

Because the "role" of a court is to apply a "statute as it is written," *Burrage v. United States*, 571 U.S. 204, 218 (2014), CMS's decision to subject at least 15 products—including 6 different Novo products—to price controls should not be allowed to stand. Because CMS's approach violates multiple express statutory mandates, the agency's ultra vires actions should be declared unlawful and vacated. *Am. Bankers Ass'n v. Nat'l Credit Union Admin.*, 934 F.3d 649, 673 (D.C. Cir. 2019) ("When a rule is contrary to law, the 'ordinary practice is to vacate' it."); *Ind. & Mich. Elec. Co. v. Fed. Power Comm'n*, 502 F.2d 336, 343 (D.C. Cir. 1974) (invalidating an ultra vires order).

A. CMS Has Unlawfully Imposed Price Controls on Products that Congress Specifically Excluded.

Determining what products are eligible for price controls—and which manufacturers must bear the burden of government-imposed prices—is a legislative function. *See Int'l Harvester Co. v. Missouri*, 234 U.S. 199, 215 (1914) ("determin[ing] upon what differences a distinction may be made for the purpose of statutory classification"

is "a matter of legislative judgment"). It is therefore essential that courts enforce the lines that Congress draws. Here, CMS has imposed price controls on far more products than Congress authorized and on products that Congress determined would not be subject to price controls. The result is an ultra vires regulatory scheme that violates the statute's express mandates, stymies innovation, and harms patients.

1. CMS's Approach Exceeds the Numerical Statutory Limit Mandated by Congress.

The IRA authorizes CMS to impose price controls on only 10 products in 2026, reflecting Congress's intent that CMS should dictate prices on a discrete number of products, which would expand gradually over time. 42 U.S.C. § 1320f-1(a); *Cf. RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. 639, 645 (2012) ("Congress [] enacted a comprehensive scheme and [] deliberately targeted specific problems with specific solutions."). CMS has violated the statute's clear and express mandate by imposing price controls on more than 10 products.

The IRA directs CMS to follow three steps in identifying which 10 "negotiation-eligible drugs" will be subject to price controls: *First*, CMS must identify "drug products" and "biological products" that have been either (1) approved by FDA under section 505(c) of the Federal Food, Drug, and Cosmetic Act ("FDCA") for at least 7 years (in the case of drug products) or (2) licensed by FDA under section 351(a) of the Public Health Service Act ("PHSA") for at least 11 years (in the case of biological products). *See* 42 U.S.C. § 1320f-1(e)(1)(A)(ii), (B)(ii). *Second*, CMS must eliminate any

product that faces competition because it is either a reference-listed drug or a reference product for a marketed generic drug or biosimilar product approved or licensed by FDA. *See id.* § 1320f-1(e)(1)(A)(iii), (B)(iii) (citing section 505(j) of the FDCA, 21 U.S.C. § 355(j) and section 351(k) of the PHSA, 42 U.S.C. § 262(k)). *Third*, CMS is required to "use data that is aggregated across dosage forms and strengths" to identify the top 10 high-spend products. *Id.* § 1320f-1(d)(3)(B).

Instead of complying with these express mandates, CMS has grouped together different products and subjected the entire grouping to price controls. With respect to Novo, the agency's "tenth" selection encompasses *six different biological products*—approved separately and at different times by FDA over two decades—as a single "negotiation-eligible drug." *See* Hauda Decl. ¶¶ 26–41, 47.

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

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

Press Release, HHS, *HHS Selects the First Drugs for Medicare Drug Price Negotiation* (Aug. 29, 2023). CMS accomplished this evasion of the statute's numerical restriction by lumping together all biological products by the same manufacturer that contain the same active ingredient and treating the aggregated grouping as a single selected drug.

See Final Guidance § 30.1. On that basis, CMS grouped together multiple Novo products because they share insulin aspart as an active ingredient: FIASP® vial (approved 2017), FIASP® FlexTouch (approved 2017), FIASP® PenFill (approved 2018), NovoLog® vial (approved 2000), NovoLog® PenFill® (approved 2000), NovoLog® FlexPen® (approved 2001).[1]

CMS cannot evade the statute's careful limit on how many products can be subjected to price controls—no more than 10—by deeming six different products a single selected drug based on the products' active ingredient. The approvals required for negotiation eligibility under the IRA are specific to individual drug or biological products. *See* 42 U.S.C. § 1320f-1(e)(1)(A)(i), (B)(i) (citing 21 U.S.C. § 355(c) and 42 U.S.C. § 262(a)). And the IRA says nothing about active moieties or active ingredients, and nothing authorizes CMS to dictate prices for groupings of products.

The Supreme Court rejected CMS's approach forty years ago. The term "drug," in the FDCA's "'new drug'" definition and approval requirements, the Court concluded, does *not* refer "only to the active ingredient in a drug product" but rather to "the entire product." *United States v. Generix Drug Corp.*, 460 U.S. 453, 454 (1983). In other words, a "'drug'" approved by FDA "refers to the product itself, and not simply

[1] There is no date of first licensure for the NovoLog® and FIASP® products. By operation of the Biologics Price Competition Act, the approved NDA for the FIASP® products and the approved NDA for the NovoLog® products were "deemed" to be approved BLAs as of March 23, 2020. *See* Pub. L. No. 111-148, § 7002(e)(4), 124 Stat. 119, 817 (2010); 42 U.S.C. § 262(k)(7)(D)(i).

the product's active ingredients." *United States v. Undetermined Quantities of an Article of Drug ... (Anucort HC Suppositories)*, 709 F. Supp. 511, 514–15 (D.N.J. 1987), *aff'd sub nom. Appeal of G & W Labs., Inc.*, 857 F.2d 1464 (3d Cir. 1988) (Table). Citing this long-established interpretation, FDA recently explained that for decades it "has interpreted the word 'drug' in the term 'new drug' to refer to the entire drug product and not just its active ingredient." 86 Fed. Reg. 28,605, 28,606 (May 27, 2021). FDA's approval, and the data that a manufacturer must submit in support of that approval, must be product specific in order to ensure the safety and effectiveness of the drug or biological product *as it will be used by the patient*. Approval of an active ingredient would be insufficient, since "[a]n active ingredient can have different effects on the body depending on the formulation of the drug and its route of administration (*e.g.*, topical vs. intravenous), among other things." *Id.*; *see* Laney Decl. ¶ 26.

Far from indicating any intent to reject this well-known understanding, the IRA expressly incorporates the *product-specific* approval requirement by requiring that any product subject to price controls be approved or licensed by FDA under the FDCA (or PHSA). *See* 42 U.S.C. § 1320f-1(e)(1) (incorporating § 1860D-2(e) [42 U.S.C. § 1395w-102(e)], which incorporates the definitions in § 1927(k)(2) [42 U.S.C. § 1396r-8(k)(2)], referring to drugs and biological products approved under 21 U.S.C. § 355(c) and 42 U.S.C. § 262(a), respectively); *see also Lorillard v. Pons*, 434 U.S. 575, 583 (1978) ("where words are employed in a statute which had at the time a well-known meaning … they are presumed to have been used in that sense unless the context compels to the

contrary"). FDA approves and licenses single finished drug and biological *products*; it does not approve or license aggregated families of products containing the same "active moieties" or "active ingredients." Hauda Decl. ¶¶ 9–23, 42–46. Moreover, only "single" products can serve as the "reference listed drug" or "reference product" for any other approved drug product or licensed biological product. *See* 42 U.S.C. § 262(i)(4) (explaining that "[t]he term 'reference product' means the *single* biological product licensed … against which a biological product is evaluated" (emphasis added)), *see also id.* § 262(k)(5) (noting that a "biological product ... may not be evaluated against more than 1 reference product"); 21 U.S.C. § 355(j)(2)(D) (prohibiting a generic applicant from amending its application to change its reference listed drug); 21 C.F.R. § 314.3 ("the listed drug identified by FDA [is] the drug product upon which an applicant relies in seeking approval of its ANDA"); *see also* 42 U.S.C. § 262(k)(2)(A)(i). The guidance impermissibly contorts the statutory requirements because "reference listed drugs" and "reference products" cannot be identified by active ingredient alone.

2. CMS's Approach Violates Multiple Other Express Statutory Provisions.

By imposing price controls on entire families of Novo products, CMS has not only violated the statute's express requirement that the agency set prices on no more than 10 products, it has also violated at least three other statutory mandates. These violations dramatically change the statute and undermine its express purposes.

First, CMS is imposing price controls on products that have not been on the market for the length of time required by Congress. The IRA states that products are subject to price controls only if they have been approved or licensed for at least 7 or 11 years. 42 U.S.C. § 1320f-1(e)(1)). Instead of complying with that requirement, CMS has applied "the earliest date of approval or licensure of the initial FDA application number assigned to the NDA/BLA holder for the active moiety/active ingredient …." Final Guidance § 30.1. In other words, CMS has taken the earliest date of approval for *any* product within its aggregated grouping of products and applied that date to sweep in all remaining products, even if they have not been approved for at least 7 or 11 years.

That is a dramatic substantive change to the statute. Under the IRA as written, none of Novo's FIASP® products would be subject to price controls, as none has been approved or licensed for more than the required 11 years. The FDA approved FIASP® vial and FIASP® FlexTouch® in 2017, and FIASP® Penfill® in 2018. *See* Hauda Decl. ¶ 38. Yet CMS seeks to impose price controls on all of these products merely because they share the same active ingredient.[2] That is flatly contrary to the statute and Congress's decision that CMS may not dictate prices unless and until a biological product has been licensed by FDA and on the market for at least 11 years.

[2] FDA approved a new product—FIASP® Pumpcart® Cartridge—in June 2023. Although it has not yet aggregated this product with the other insulin aspart products for price controls, CMS has asked Novo to submit data and information relevant to this product.

Second, CMS's approach violates the IRA's high-spend requirements. CMS listed the "Total Part D Gross Covered Prescription Drug Costs from June 2022–May 2023" for the aggregated family of insulin aspart products at $2,576,586,000. *See* Hauda Decl. ¶ 49. That number is incorrect, fails to adhere to the IRA's "use of data" provision, and cannot form the basis for CMS's selection of the NovoLog® and FIASP® products. Given the total Part D gross totals for other drug products and biological products, one of those products likely would have been selected instead of the aggregated NovoLog® and FIASP® products. *See id.*

Third, CMS's approach vitiates the IRA's careful differentiation between Part B drugs (physician-administered drugs and drugs self-administered through durable medical equipment in the home) and Part D drugs (other drugs administered by the patient at home). Under the statute, only Part D drugs are subject to price controls beginning in 2026; Part B drugs are exempt until 2028. *See* 42 U.S.C. § 1320f-1(a)(1)–(3). In certain instances, while Part D may cover some of a manufacturer's drug or biological products that share an active moiety or active ingredient, Part B may cover others. A drug product that is packaged in a pre-filled syringe for patient self-administration would be Part D, while a lyophilized drug product for physician (office) administration would be Part B—even though both had the same active ingredient or active moiety. Similarly, some of Novo's FIASP® products are covered primarily under Part D, and others are covered primarily under Part B. *See* Hauda Decl. ¶ 25. Under CMS's approach, however, the agency has included Part B products on the list of

products subject to price controls in 2026, directly contrary to Congress's expressed intent.

3. CMS's Approach Cannot Be Reconciled with FDA's Approval and Licensing Process.

CMS's approach creates significant tension with FDA's review and approval of products under the FDCA and PHSA in a way that Congress could not have intended. *See Morton v. Moncari*, 417 U.S. 535, 551 (1974) (courts should interpret statutes in harmony and give "effect to both if possible"). As noted above, the specific FDCA and PHSA sections cross-referenced in the IRA address FDA's approval and licensing provisions for drug and biological products. *See* 42 U.S.C. § 1320f-1(e)(1)(A)(i), (B)(i). These provisions necessarily apply on a single product-by-product basis in order to ensure safe and effective use by patients. CMS's approach is flatly at odds with FDA's decades-old approach to regulating drug and biological products. *See George v. McDonough*, 142 S. Ct. 1953, 1963 (2022) (noting that when Congress "employs a term of art," that usage suffices to "adop[t] the cluster of ideas that were attached to each borrowed word") (quoting *FAA v. Cooper*, 566 U.S. 284, 292 (2012)).

CMS's approach also has serious consequences for patients. Despite Congress's intent to gradually build a price-control program to avoid discouraging manufacturers from investing in new life-saving and life-enhancing products, CMS's approach does just the opposite, undermining the incentive structure for ensuring continued investment in research, innovation, and improvements to medicines.

It is difficult to understate the ways in which CMS's approach conflicts with the regulation of drug and biological product development and approval under the FDCA and PHSA. For example, CMS has merged the meaning of "active moiety" and "active ingredient"—which mean different things under FDA's long-standing definitions—in a way that is scientifically inappropriate and factually incorrect. *See* 21 C.F.R. § 314.3; *see also Amarin Pharms. Ir. Ltd. v. FDA*, 106 F. Supp. 3d 196, 212 (D.D.C. 2015). For instance, drug products may share an active moiety but differ in active ingredients, and active ingredients may contain multiple active moieties. As FDA has recognized, active ingredients in biological products may not be readily discernable or identifiable. *See* 42 U.S.C. § 262(k); *see also* HHS, Fiscal Year 2021: Food and Drug Administration Justification of Estimates for Appropriations Committees, at 36 ("Due to their complexity, these products' 'active ingredients' may not be precisely identifiable or may only be known to a limited extent.").

CMS's approach also undermines the value of certain regulatory exclusivities Congress created to incentivize innovation. For instance, FDA makes determinations of three-year "new clinical investigation[]" exclusivity on a product-specific basis. *See* 21 U.S.C. § 355(c)(3)(E)(iii)–(iv), (j)(5)(F)(iii)–(iv); 21 C.F.R. § 314.108. Under Congress's product-specific approach, this exclusivity is preserved because it does not last more than 7 or 11 years from the time the specific product is approved. By aggregating products, however, CMS undermines the value of exclusivity. If a manufacturer conducted new clinical investigations essential to the development and

approval of a new product with a different route of administration (one better suited to treating patients with a particular type of disease, for example), that product would be eligible for three years of exclusivity (with the ability for that manufacturer to set prices during the exclusivity period without competition). *See* 21 U.S.C. § 355(c)(3)(E)(iii)–(iv), (j)(5)(F)(iii)–(iv). Under CMS's approach, however, that new product would be subject to price controls immediately upon approval merely because it contains the same active moiety as a different product approved and licensed more than 7 years ago. That directly undermines the value of FDA's exclusivity and presents a significant disincentive to investment.

The IRA clearly cross-references FDA's product-specific approval and licensing processes, and there is no evidence that Congress intended to subject entire groupings for products with the same "active moiety" or "active ingredients" to price controls. If Congress had intended such a broad sweep, the statute would have expressly applied price controls to any product with the same active moiety or active ingredient, ensuring that all competitors were subject to the same price controls, rather than singling out specific manufacturers of an identified active moiety or active ingredient as CMS has done. The fact that Congress did not make that choice—and did not even mention active moieties or active ingredients—further confirms that Congress intended to target specific drug and biological *products*, not entire *families* of products.

4. CMS Has No Justification for Its Departure from the Statutory Requirements.

CMS's justification for aggregating products with the same active ingredient is that Congress required CMS to consider certain aggregated data when evaluating whether a product qualifies as a "Part D High Spend Drug." *See* 42 U.S.C. § 1320f-1(d)(3)(B). In particular, Congress instructed CMS to "use data that is aggregated across dosage forms and strengths of the drug" when calculating total expenditures related to a qualifying single source drug. *Id.* But Congress's instruction to use aggregated "data" for a narrow, limited purpose cannot justify CMS's decision to impose price controls on and across entire families of products. CMS has gone much further than aggregating all dosage forms and strengths of a drug when it selected every product containing insulin aspart for price controls. CMS's aggregation stretches across products—including Novo's Novolog® and FIASP® products—that are far more varied than simply differences in dosage form or strength. *See* Laney Decl. ¶¶ 23–46.

When FDA approves or licenses a drug or biological product, it does so based on its evaluation of the safety and efficacy of the specific product that will be used by a patient. Evaluation of the active moiety or active ingredient is only part of the equation. Numerous product-specific characteristics—including the product's route of administration, device presentation, manufacturing process, and inactive ingredients (in addition to dosage form and strength)—affect the safety and effectiveness, and hence approvability, of each product. As FDA has explained, it evaluates "not only the active

ingredient but also information about the drug's formulation, route of administration, labeling, inactive ingredients, bioavailability, and manufacturing processes." 86 Fed. Reg. at 28,606; 21 C.F.R. §§ 314.3(b), 210.3(b)(4) (defining a "drug product" to refer to "a finished dosage form, for example, tablet, capsule, solution, etc., that contains an active drug ingredient generally, but not necessarily, in association with inactive ingredients"). Accordingly, although the statute's "data use" provision authorizes limited aggregation for some purposes, it does not authorize aggregation by "active moiety" or "active ingredient" or permit CMS to aggregate products with different device presentations, routes of administration, or other differing conditions of use.

CMS's reading of the word "drug" renders the "use of data" instruction nonsensical. If Congress had directed that active moieties or active ingredients—rather than drugs and biological products—be subjected to price controls, there would be no dosage forms, strengths, or formulations of a drug to aggregate because the "drug" would already encompass all of the product's different dosage forms, strengths, and formulations. The same is true of the statutory instruction to establish "procedures to compute and apply the maximum fair price across different strengths and dosage forms of a selected drug." 42 U.S.C. § 1320f-5(a)(2). CMS's "reading is thus at odds with one of the most basic interpretive canons, that '[a] statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant." *Corley v. United States*, 556 U.S. 303, 314 (2009) (alteration omitted) (quoting *Hibbs v. Winn*, 542 U.S. 88, 101 (2004)).

In contrast, under a proper interpretation—consistent with the Supreme Court's decision and FDA's approach—the "dosage form and strength" provision is meaningful: Congress instructed CMS to aggregate data across dosage forms and strengths for the purpose of determining whether a product qualifies as a "high spend" product. Congress did not instruct CMS to subject families of products to price controls or to ignore differences between products. Congress did not empower CMS to aggregate across formulations with different device presentations, routes of administration, clinical use profiles, and other characteristics—such as the NovoLog® and FIASP® products. *See* Hauda Decl. ¶¶ 2641; Laney Decl. ¶¶ 23–46. Nor did it authorize CMS to aggregate products by "active ingredient" (or "active moiety")—terms that appear nowhere in the IRA.

When Congress intends for an agency to look to the active ingredient (or active moiety) of a drug or set of drugs, Congress says so expressly. In section 505(c) of the FDCA, for example, Congress directed FDA to determine whether a drug has the same "active moiety" as another approved drug to determine eligibility for new chemical entity exclusivity. 21 U.S.C.§ 355(c)(3)(E)(ii), (iii); *see also* 21 U.S.C. § 360bbb-4a(a)(4)(D) (grant priority review in certain circumstances for "a biological product, no active ingredient of which has been approved in any other application …"). Congress included no such provision in the IRA. CMS's regulation of more than 10 products through its aggregation of different products violates the statute's express mandates.

B. No Judicial Review Bar Applies to Prevent the Court from Striking Down CMS's Ultra Vires Statutory Rewrite.

The Administrative Procedure Act provides that a person adversely affected by final agency action is entitled to judicial review. 5 U.S.C. §§ 702, 704. Only if a statute clearly and convincingly bars judicial review is review foreclosed. *See Guerrero-Lasparilla v. Barr*, 140 S. Ct. 1062, 1069 (2020). A statute bars judicial review only if it is not "reasonably susceptible" to a "divergent interpretation." *Id.* And "judicial review remains available" when an agency has "engaged in 'shenanigans' by exceeding its statutory bounds." *SAS Inst., Inc., v. Iancu*, 138 S. Ct. 1348, 1359 (2018).

Congress did not preclude judicial review of CMS's compliance with the statutory mandate that only 10 drug products be eligible for price controls. The requirement that CMS impose price controls on no more than 10 drug products in 2026 is found in subsection (a) of 42 U.S.C. § 1320f-1. The IRA's judicial review bar extends to certain selections and determinations under subsections (b), (d), (e), and (f), but it does not cover subsection (a). 42 U.S.C. § 1320f-7. It does not include capacious language, such as barring claims "relating to" any aspect of the selection or determination process. *Cf. United States v. Dohou*, 948 F.3d 621, 626 (3d Cir. 2020) (it is relevant "when a jurisdiction-stripping provision … omits capacious phrases like 'relating to.'"). Congress knew how to bar review of the 10-drug limit but chose not to do so.

To the extent CMS argues that this Court should extend the judicial-review bar to cover subsection (a), the Court should decline. As the Supreme Court has explained,

"arguments against judicial review cannot override the text of the statute." *Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724, 733 (2022). And they certainly cannot overcome the "strong presumption in favor of judicial review of administrative action." *E.O.H.C. v. Sec'y DHS*, 950 F.3d 177, 184 (3d Cir. 2020); *see also Dohou*, 948 F.3d at 626–27 ("Before reading a statute so broadly as to strip us of the power to review an executive determination, we require clear and convincing evidence.").

Nor can CMS evade review by arguing that § 1320f-7 covers its unsupportable "active moiety" / "active ingredient" approach. The IRA does not grant CMS the power to re-define the term "drug product" or "biological product" nor the process by which such products are approved and licensed. It certainly does not insulate CMS from judicial review of its attempts to do so.

The IRA's judicial review bar applies only to CMS's application of the statutory requirements to the data and information it is authorized to collect—specifically, the agency's (1) "selection" of which (but not how many) drug and biological products should be subject to price controls, (2) "determination" of which such products are negotiation-eligible, (3) "determination" of whether products are qualifying single source drugs, and (4) "determination" of a maximum fair price. 42 U.S.C. § 1320f-7. The agency's power to "determine" or "select" which products are subject to price controls—undertaking the calculations necessary to apply the plain statutory requirements to the facts and data at its disposal—does not grant the agency the more-expansive power to redefine the applicable statutory terms against which those

determinations must be made. When Congress delegates definitional authority to an agency, it knows what to say. *See, e.g.*, 42 U.S.C. § 18022(b)(1) (instructing that "the Secretary shall define the essential health benefits …"); 42 U.S.C. § 1395w-141(f)(1)(B) (directing that "the Secretary shall define the terms 'income' and 'family size'"); 42 U.S.C. § 1395w-4(j)(1) (granting the Secretary authority to "define surgical service[]"). Congress did not authorize CMS to rewrite the IRA's underlying statutory definitions.

This understanding is reinforced by the "well-settled" presumption "favoring interpretations of statutes to allow judicial review of administrative action." *Kucana v. Holder*, 558 U.S. 233, 251–52 (2010); *see also E.O.H.C.*, 950 F.3d at 184 (same). Because "Congress legislates with knowledge of the presumption," only "clear and convincing evidence" is sufficient to "dislodge" it. *Kucana*, 558 U.S. at 252; *see also Mach Mining, LLC v. EEOC*, 575 U.S. 480, 486 (2015) (noting the government's "heavy burden" to overcome the presumption).

There is no such evidence here. Had Congress intended CMS to redefine statutory terms and insulate those definitions from judicial review, it would have (1) delegated that definitional authority to CMS and (2) expressly insulated it from review. Congress did no such thing. And for good reason: delegating unreviewable lawmaking authority to an executive agency would raise serious constitutional concerns. *See Jennings v. Rodriguez*, 583 U.S. 281, 286 (2018) ("[A] court may shun an interpretation that raises serious constitutional doubts"). It is one thing to shield from review an agency's discretionary decisions concerning how to analyze data and select *which* 10

products are subject to price controls. It is another to ignore the statutory mandate, select more than 10 products, and then defend the agency's position not on its merits but on grounds that the redefinition expands the review bars to allow the agency to escape Congress's commands. *See Amgen Inc. v. Smith*, 357 F.3d 103, 113 (D.C. Cir. 2004) (recognizing that the scope of a judicial review bar is often "intertwined with the question of whether the agency has authority for the challenged action").

Courts have long rejected that gambit, recognizing that courts retain jurisdiction whenever an agency's action is ultra vires. "If an agency exceeds 'its statutory bounds, judicial review remains available' to curb the rogue action." *Am. Clinical Lab'y Ass'n v. Azar*, 931 F.3d 1195, 1203, 1208 (D.C. Cir. 2019) (quoting *SAS Inst.*, 138 S. Ct. at 1359); *Advanced Disposal Servs. E., Inc. v. NLRB*, 820 F.3d 592, 600 (3d Cir. 2016). That is true "[e]ven where Congress is understood generally to have precluded review." *Griffith v. Fed. Lab. Rels. Auth.*, 842 F.2d 487, 492 (D.C. Cir. 1988); *see Lepre v. Dep't of Lab.*, 275 F.3d 59, 73 (D.C. Cir. 2001); *Dart v. United States*, 848 F.2d 217, 224 (D.C. Cir. 1988). As the Supreme Court has explained, agencies' power to act is "authoritatively prescribed by Congress" and, therefore, when they act improperly or "beyond their jurisdiction, what they do is ultra vires." *City of Arlington v. FCC*, 569 U.S. 290, 297 (2013); *see also 1621 Route 22 W. Operating Co. v. NLRB*, 825 F.3d 128, 140 (3d Cir. 2016). An agency action is ultra vires when the agency has exceeded its statutory authority, "disregarded a specific and unambiguous statutory directive," violated a statute's "specific command," or patently misconstrued the statute. *Griffith*, 842 F.2d at 493.

CMS's decision to target more than 10 drug and biological products for price controls—and to impose price controls on products that have not been approved or licensed for the period mandated by Congress—is ultra vires because it rewrites the statute's plain text and exceeds the specific, numerical cap that Congress imposed on the agency's exercise of regulatory authority. *See SAS Inst.*, 138 S. Ct. at 1355 ("Where a statute's language carries a plain meaning, the duty of an administrative agency is to follow its commands as written, not to supplant those commands with others it may prefer."); *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 328 (2014) (noting the "core administrative-law principle that an agency may not rewrite clear statutory terms to suit its own sense of how the statute should operate"). This Court has both the authority and constitutional duty to require that CMS abide by the IRA's clear mandates.

II. CMS Has Violated Both the Inflation Reduction Act and the Administrative Procedure Act by Imposing New Substantive Rules.

Congress recognized the risk that CMS would deviate from the statutory requirements and, in doing so, irreparably damage the nation's drug markets and patients' access to medicine. To address that risk, the statute directs that CMS "shall implement [the IRA's price control program] for 2026, 2027, and 2028, by program instruction or other forms of program guidance." 42 U.S.C. § 1320f note; *see Kingdomeware Techs., Inc. v. United States*, 579 U.S. 162, 172 (2016) (noting that "shall" usually "imposes a mandatory duty"). By requiring CMS to proceed only by "guidance," the statute makes clear that Congress granted the agency no authority to impose new

binding requirements during that time. In short, Congress intended the agency to implement the statute as written and deprived it of any rulemaking authority.

Congress's instruction that CMS proceed only by guidance is important. Under the APA, agency guidance can have no legal consequences and no binding force and effect. *See Kisor v. Wilkie*, 139 S. Ct. 2400, 2420 (2019). In contrast, when an agency seeks to create new duties or to impose new legal obligations, it must comply with notice-and-comment rulemaking procedures. *See SBC Inc. v. FCC*, 414 F.3d 486, 495, 497 (3d Cir. 2005) (noting that legislative rules are "subject to notice and comment requirements" because they "'create new law, rights, or duties.'"); *see also Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1808 (2019) (noting that when the government wishes to establish a "substantive legal standard" affecting Medicare, it must satisfy notice-and-comment obligations). To issue a valid rule, an agency "shall … publish[]" a "[g]eneral notice of proposed rule making" "in the Federal Register," and "give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments." 5 U.S.C. § 553(b), (c); *see also* 42 U.S.C. § 1395hh(a)(2).

Instead of complying with the IRA and the APA, however, CMS has issued binding rules in the guise of policy guidance. The agency cannot dispute that its final guidance goes far beyond the requirements imposed by the statute itself. From "beginning to end," the guidance "reads like a ukase. It commands, it requires, it orders, it dictates." *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1023 (D.C. Cir. 2000). And it has been applied by CMS "in a way that indicates it is binding." *Gen. Elec. Co. v. EPA*,

290 F.3d 377, 383 (D.C. Cir. 2002). Indeed, the guidance has been used to set the terms of the "agreements" that manufacturers are forced to sign. These contractual provisions, which go beyond the statute's requirements, are legislative rules subject to the APA's notice-and-comment requirements. *Am. Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1053–54 (D.C. Cir. 1987); *see also Nat'l Ass'n of Psychiatric Treatment Ctrs. for Child. v. Weinberger*, 658 F. Supp. 48, 54 (D. Colo. 1987) (holding APA applied to agency attempt to make "prescriptive changes in overall contents of all participation agreements … [that] amount[ed] to policy changes of significant import").

The guidance also goes far beyond merely "interpreting" the IRA. As noted above, CMS has redefined "drug product" and "biological product"—departing from their settled meanings—so as to materially expand the number of products subject to price controls. *See Pa. Dep't of Human Servs. v. United States*, 897 F.3d 497, 505 (3d Cir. 2018) (explaining that interpretive rules "do not add language to or amend language in the statute"). Similarly, the statute states in clear terms that products subject to marketed generic or biosimilar competition "shall not be subject to the negotiation process." 42 U.S.C. § 1320f-1(c); *see id.* § 1320f-1(e)(1)(A)(iii), (B)(iii) (citing 21 U.S.C. § 355(j); 42 U.S.C. § 262(k)); 21 C.F.R. § 314.3 (defining "commercial marketing"). Yet CMS's guidance changes the statutory test by purporting to authorize CMS to engage in a "holistic" analysis to determine when competition is sufficiently "meaningful" that the agency deems competition to be "bona fide." Final Guidance at 72 & § 30.1; *see also City of Arlington*, 569 U.S. at 307 ("Where Congress has established a clear line, the

agency cannot go beyond it[.]"). The same is true of many of CMS's other additions that it has treated as having binding and substantive consequences, including its decision to abandon the IRA's definition of a "manufacturer" in favor of newly defined terms—"primary" and "secondary" manufacturers—that do not appear in the statute, *see* Final Guidance § 40, and its decision to both restrict and expand the types of information that manufacturers may or are required to submit as part of the "negotiation" process. *See* Hauda Decl. ¶ 55; Final Guidance App. C.

If Congress wanted to grant CMS authority to impose new obligations on manufacturers without complying with notice-and-comment requirements, it would have said so expressly, or at least directed CMS to promulgate rules to govern the first three years of the program. But for good reason, it did not. Instead, Congress directed the agency to proceed through guidance alone. 42 U.S.C. § 1320f note. Congress's command that CMS proceed by guidance means the agency must refrain from imposing substantive obligations that stray from the statute's plain text.

III. The Inflation Reduction Act's Unprecedented Drug-Pricing Provisions Are Constitutionally Invalid.

If the Court vacates CMS's actions—striking down CMS's unlawful aggregation and preventing it from imposing price controls on Novo products—it may be able to avoid reaching the constitutional claims raised in Novo's complaint. But if complete relief is not granted to Novo on those grounds, this Court will be forced to consider the IRA's grave constitutional problems and the reality that its provisions depart from

any price-control statute that has ever previously been upheld against constitutional challenge. Through its unprecedented provisions, Congress has committed egregious violations of the Constitution's separation-of-powers, due process, and free speech guarantees by delegating unfettered power to CMS to set prices, removing the judiciary's ability to ensure that the CMS-imposed prices are not arbitrary or confiscatory, and requiring manufacturers to mouth the government's preferred message about "fairness" on pain of severe penalties. Each individual constitutional violation warrants this Court's intervention; the simultaneous removal of multiple layers of constitutional protections demands it. *See Seila Law LLC v. CFPB*, 140 S. Ct. 2183, 2198, 2202 (2020).

A. The Inflation Reduction Act Unlawfully Eliminates Accountability by Combining a Sweeping Delegation of Power with Other Constitutional Violations.

The Constitution provides overlapping safeguards to ensure democratic accountability and to protect individual liberty. The structure of the federal government—separating powers in different branches—is "designed to preserve the liberty of all the people," *Collins v. Yellen*, 141 S. Ct. 1761, 1780 (2021), and to ensure that both Congress and the Executive remain accountable to the citizenry, *Free Enter. Fund v. PCAOB*, 561 U.S. 477, 496 (2010); *Seila Law*, 140 S. Ct. at 2202. The Fifth Amendment's Due Process Clause reinforces those aims by prohibiting the government from depriving a person of "life, liberty or property" without "due process of law." Nathan S. Chapman & Michael W. McConnell, *Due Process as Separation of Powers*, 121

Yale L.J. 1672, 1758–60 (2012). Rooted in principles dating back to the *Magna Carta,* due process safeguards both legislative independence and individual rights by protecting against arbitrary administrative actions, *Murray's Lessee v. Hoboken Land & Imp. Co.*, 59 U.S. (18 How.) 272, 276 (1855), and by ensuring an affected party's baseline procedural right to be heard, *Mathews v. Eldridge*, 424 U.S. 319, 333 (1976). Similarly, the First Amendment is "fundamental" to our "constitutional system" by maintaining "the opportunity for free political discussion," so "that the government may be responsive to the will of the people and that changes may be obtained by lawful means." *N.Y. Times Co. v. Sullivan*, 376 U.S. 254, 269 (1964).

The IRA's novel price-setting scheme strips away all three of these constitutional safeguards in a bid to avoid public accountability for its infringement of private rights. Even if one of the violations could be tolerated individually, the "combined" nature of the violations creates "a new situation" that cannot stand. *Free Enter. Fund*, 561 U.S. at 483–84; *Seila Law*, 140 S. Ct. at 2202.

1. The Statute Violates Separation of Powers

It is well settled that "Congress may not constitutionally delegate its legislative power to" any other branch of government and must always "lay down by legislative act an intelligible principle to which" the official with delegated authority "is directed to conform." *Touby v. United States*, 500 U.S. 160, 165 (1991); *see also Marshall Field & Co. v. Clark*, 143 U.S. 649, 692 (1892). The Constitution reflects the lessons of "hard experience 'that abandonment of separated powers led directly to the loss of

accountable, impartial government, which, in turn, led inevitably to the loss of due process and individual rights.'" *Egan v. Del. River Port Auth.*, 851 F.3d 263, 278 (3d Cir. 2017) (Jordan, J., concurring).

The Supreme Court's modern non-delegation doctrine cases are often summarized as applying an "intelligible principle" test. *Gundy v. United States*, 139 S. Ct. 2116, 2123 (2019) (plurality). But controlling precedent requires more than merely considering whether Congress has articulated an intelligible principle—that is, some ascertainable legislative standard to which the agency's decision-making must conform. Context matters, including the nature of the delegation, the degree to which the delegation endangers private rights, and the history of similar regulation. *See A.L.A Schechter Poultry Corp. v. United States*, 295 U.S. 495, 541 (1935) (striking down statute that was "without precedent"). The "degree of agency discretion that is acceptable varies according to the scope of the power congressionally conferred." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 475 (2001). When a statute involves a broad grant of delegated authority, Congress must stay within the bounds of precedent. It cannot strip away multiple layers of constitutional protections, create a "novel structure," *Free Enter. Fund*, 561 U.S. at 496, and concentrate "significant governmental power" in an agency "accountable to no one." *Seila Law*, 140 S. Ct. at 2203.

The IRA fails these constitutional requirements both because of the breadth of authority granted to CMS and the lack of constitutional safeguards necessary to protect the important public interests and private rights at stake. Most significantly, the IRA

delegates to CMS power to set prices with no intelligible principle to guide and constrain the agency's price-setting decisions. Apart from an already low ceiling price, there is no legal standard to govern CMS's price-setting decision and no limits on how low (or confiscatory) a price CMS might dictate. The statute defines "maximum fair price" not by reference to any standard of fairness or reasonableness, but merely as the "price negotiated"—that is, the price unilaterally dictated by CMS. *See* 42 U.S.C. § 1320f(c)(3). Moreover, although the IRA includes a list of "factors" that the agency must "consider," *id.* § 1320f-3, CMS has conceded that the statute "does not specify how the [agency] should determine" what price to impose "or to what degree each factor should be considered." Final Guidance § 60.3. In short, the IRA grants CMS unconstrained authority to impose whatever prices the agency might select in its unfettered discretion.

That alone constitutes an unlawful delegation of legislative power. The power to control the price at which private parties sell their products raises significant risks of unfair regulatory targeting. While Congress may delegate authority for an agency to perform the calculations necessary to determine an appropriate price, Congress must articulate the underlying standards to ensure that prices are constitutionally permissible. The requirement that Congress set forth "ascertainable standards" is essential, as "the existence of an absolute and uncontrolled discretion in an agency of government vested with the administration of a vast program" creates "an intolerable invitation to abuse." *Holmes v. N.Y. City Hous. Auth.*, 398 F.2d 262, 265 (2d Cir. 1968).

The lack of an intelligible principle is made worse by Congress's decision to withdraw judicial review of CMS's price-setting decisions. *See* 42 U.S.C. § 1320f-7; *United States v. Garfinkel*, 29 F.3d 451, 458–59 (8th Cir. 1994) (Judicial review "is a factor weighing in favor of upholding a statute against a nondelegation challenge."). That removal of judicial protection—another "significant and unusual" deviation from standard mechanisms for ensuring accountability, *Free Enter. Fund*, 561 U.S. at 506—heightens the nondelegation concerns because "judicial review perfects a delegated-lawmaking scheme by assuring that the exercise of such power remains within statutory bounds." *Touby*, 500 U.S. at 170 (Marshall, J., concurring). By stripping away review, Congress has provided mere suggestions for CMS to consider, not requirements to which the agency "is directed to conform." *Touby*, 500 U.S. at 165; *cf. United States v. Touby*, 909 F.2d 759, 768 (3d Cir. 1990) (noting that "[j]udicial review is the usual vehicle by which executive action is tested to insure that the will of Congress has been obeyed").

In short, Congress must provide adequate standards "such that a court [can] ascertain whether the will of Congress has been obeyed." *Skinner v. Mid-Am. Pipeline Co.*, 490 U.S. 212, 218 (1989). Stripping away this "layer" of insulation from accountability "makes a difference." *Free Enter. Fund*, 561 U.S. at 495. With no intelligible principle, and with the further violations discussed below, the IRA is unconstitutional.

2. The Statute Violates Due Process

The IRA's price-setting scheme compounds its separation-of-powers violations by eliminating essential due process protections. The Fifth Amendment's Due Process Clause provides that government may not deprive anyone of "life, liberty or property" without "due process of law." U.S. Const. amend. V. As relevant here, due process constrains the government in two fundamental ways:

First, due process ensures that the executive acts "as authorized by law." *Murray's Lessee*, 59 U.S. at 276; *Hamdi v. Rumsfeld*, 542 U.S. 507, 589 (2004) (Thomas, J., dissenting) ("the Due Process Clause requires … that our Government must proceed according to the 'law of the land'—that is according to written constitutional and statutory provisions"). The Supreme Court has repeatedly emphasized this core feature of our Constitution: due process protects "the individual against arbitrary action of government." *Wolff v. McDonnell*, 418 U.S. 539, 558 (1974); *see also Honda Motor Co. v. Oberg*, 512 U.S. 415, 434 (1994) (due process protects against "arbitrary deprivations of liberty or property"). Rather than ensure that CMS acts in line with statutory requirements, the IRA invites arbitrary action by withdrawing judicial review from the price-setting regime's core features, including choosing what prices to set. *See Oberg*, 512 U.S. at 421 ("our analysis in this case should focus on [the law's] departure from traditional procedures"); *see also Bowles v. Willingham*, 321 U.S. 503, 521 (1944) ("where Congress has provided for judicial review after the regulations or orders have been made effective it has done all that due process under the war emergency requires").

Second, due process requires that the government's deprivation of rights be accompanied by certain "procedural protections characteristic of judicial process." Chapman & McConnell, 121 Yale L.J. at 1679; *Mathews*, 424 U.S. at 335. The Supreme Court's decision in *Oberg* reflects this protection. There, the Court held that a provision in the Oregon Constitution limiting (but not prohibiting) judicial review of the amount of punitive damages awarded by a jury was inconsistent with due process. *See Oberg*, 512 U.S. at 418. "[The] abrogation of a well-established common-law protection against arbitrary deprivations of property raises a presumption that its procedures violate the Due Process Clause." *Id.* at 430.

On this front too, the IRA falls short. Despite the substantial rights at play, the IRA abrogates the ordinary common-law protection of judicial review and even forecloses administrative review of CMS's actions. *See* 42 U.S.C. § 1320f-7. There can be no doubt that the private interests endangered by the IRA are substantial. *See Mathews*, 424 U.S. at 335. The IRA threatens Novo's rights to sell its products at market-based prices and undermines Novo's investments and research programs. *See* Hauda Decl. ¶¶ 67–69, 75–77; *see also Old Dearborn Distrib. Co. v. Seagram-Distillers Corp.*, 299 U.S. 183, 192 (1936) (noting the "well-settled general principle that the right of the owner of property to fix the price at which he will sell it is an inherent attribute of the property itself" and protected by the Fifth Amendment). Novo has relied on the promise of future sales—and the ability to charge market-based prices—when developing and patenting its innovative drugs and biological products, including investing in products

that never made it to market. *See King Instruments Corp. v. Perego*, 65 F.3d 941, 950 (Fed. Cir. 1995). The IRA interferes with Novo's rights by requiring Novo to provide "access" to its products on terms that Novo would never voluntarily accept. *Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2072 (2021); *Horne*, 576 U.S. at 361–62.

Exacerbating these weighty concerns, the risks of an erroneous deprivation are very high. *See Mathews,* 424 U.S. at 335. When government controls prices, it must include adequate procedures to "safeguard against imposition of confiscatory rates" and to ensure that private property owners ultimately receive "a fair and reasonable return on investment." *Michigan Bell Tel. Co. v. Engler*, 257 F.3d 587, 594–96 (6th Cir. 2001). Yet the IRA includes no procedures to protect against arbitrary or confiscatory pricing. There is no guarantee that CMS will set a price that will allow Novo to obtain any return on its investments—let alone a just and reasonable one. *See id.* at 595 n.4 (explaining that due process requires adequate procedures to ensure a "fair and reasonable" price, not just the "possibility" that the regulator might not impose a confiscatory price).

For Novo's products, the IRA imposes an across-the-board ceiling price that is already very low, 42 U.S.C. § 1320f-3(c)(1)(C), (b)(2)(F), directs CMS to aim for "the lowest" price, *id.* § 1320f-3(b)(1), and includes no floor or standards to ensure a reasonable return. Nor is it any consolation that Novo might hypothetically increase prices in the non-Medicare/non-Medicaid markets. A party cannot be "required to subsidize their regulated" products with "revenues generated from unregulated services." *Michigan Bell*, 257 F.3d at 594–96 (citing *Brooks-Scanlon Co. v. R.R. Comm'n*,

251 U.S. 396 (1920)). Where, as here, a statutory program "provides *no process* whatsoever," the government has a "glaring problem" that "alone" compels the conclusion that the program is unconstitutional. *Schepers v. Comm'r, Ind. Dep't of Corr.*, 691 F.3d 909, 915 (7th Cir. 2012).

The statutory process does not even provide a meaningful opportunity for a hearing or any opportunity to respond to the evidence on which the agency relies. *See Mathews*, 424 U.S. at 333. Due process requires the government to provide regulated parties with access to the evidence against them and an "opportunity to meet it." *Id.* at 348; *see Townley v. Heckler*, 748 F.2d 109, 114 (2d Cir. 1984) (agency violated due process by relying on evidence that it did not give claimant opportunity to rebut). But the IRA does not require CMS to disclose to Novo the evidence on which it will rely in setting the "maximum fair price" for Novo's different products. Although Novo is permitted to make a counteroffer in response to CMS's "initial offer," 42 U.S.C. § 1320f-3(b)(2)(B), *see also id.* § 1320f-3(b)(2)(C)(ii), (e), the IRA does not require CMS to do anything with this counteroffer, beyond "respond[ing] in writing to" it. *Id.* § 1320f-3(b)(2)(D). CMS need not provide a reasoned explanation for its response or take any steps to show that it is acting reasonably. That empty procedure is insufficient and falls far short of minimum constitutional requirements. *See Ohio Bell Tel. Co. v. Pub. Utils. Comm'r*, 301 U.S. 292, 302 (1937); c*f. Connecticut v. Doehr*, 501 U.S. 1, 4 (1991) (explaining that law authorizing deprivation of property without prior notice or hearing or extraordinary circumstances violates due process). "The core of due process is an

opportunity to be heard at a meaningful time and in a meaningful manner." *Frein v. Pa. State Police*, 47 F.4th 247, 257 (3d Cir. 2022). The IRA bars any such opportunity.

The removal of these traditional procedural safeguards is especially harmful in the context of setting prices. Appellate courts have repeatedly struck down legislative schemes that do not include sufficient procedures to "adequately safeguard[] against confiscatory rates, and therefore, ensure[] a constitutional rate of return." *Michigan Bell*, 257 F.3d at 592–93; *see also Guar. Nat'l Ins. Co. v. Gates*, 916 F.2d 508, 512 (9th Cir. 1990) (invalidating Nevada law freezing insurance rates because it provided no "mechanism to guarantee a constitutionally required fair and reasonable return"). Adequate process when determining the prices of drugs is paramount because of the important public interests and private rights at stake. If government-imposed prices are too low, the public will face shortages, a lack of innovation, and other collateral consequences, and the private entity will suffer confiscatory rates. *See In re Permian Basin Area Rate Cases*, 390 U.S. 747, 769–70 (1968) (prices imposed by the government must be "just and reasonable." (citing *Fed. Power Comm'n v. Nat. Gas Pipeline Co.*, 315 U.S. 575, 586 (1942))).

The IRA's lack of any intelligible principle combined with the lack of adequate procedures is especially problematic because the agency here is not only a regulator but also a self-interested market participant with an incentive to "act for 'selfish' or 'arbitrary' reasons." *Rice v. Vill. of Johnstown*, 30 F.4th 584, 589–91 (6th Cir. 2022) (quoting *Washington ex rel. Seattle Title Tr. Co. v. Roberge*, 278 U.S. 116, 122–23 (1928)). CMS is not merely setting a price; it is setting a price for Medicare beneficiaries that it

has promised to insure. As courts have long recognized, an absence of impartiality is most apparent when a decision-maker has a "pecuniary interest in the outcome" of a proceeding. *Tumey v. Ohio*, 273 U.S. 510, 535 (1927); *see also Withrow v. Larkin*, 421 U.S. 35, 47 (1975). As the nation's largest payor for prescription drugs, there is no reason to expect that CMS will protect the private rights of manufacturers or even the interests of patients over its own financial interests. *See, e.g., Ne. Hosp. Corp. v. Sebelius*, 657 F.3d 1, 20 n.1 (D.C. Cir. 2011) (Kavanaugh, J., concurring) (noting HHS's "apparent policy of paying out as little money as possible" even "in derogation of law").

3. The Statute Violates the First Amendment.

Further preventing lawful accountability, the IRA requires manufacturers to say that they "agree" to "negotiate" and that the price unilaterally imposed by CMS is the "maximum fair" price for their drug and biological products. 42 U.S.C. § 1320f-2(a). Although Novo does not agree with these inaccurate characterizations, the statute forces Novo to parrot the government's viewpoint or else face massive penalties. That is unconstitutional. The First Amendment bars the government from "compel[ling] a person to speak its own preferred messages." *303 Creative LLC v. Elenis*, 600 U.S. 570, 586 (2023). As courts have long held, "[g]overnment action that requires stating a particular message favored by the government violates the First Amendment right to refrain from speaking." *Miller v. Mitchell*, 598 F.3d 139, 151 (3d Cir. 2010).

The IRA's "involuntary affirmation of objected-to beliefs" is a textbook example of unconstitutionally compelled speech. *Janus v. Am. Fed'n of State, Cnty., & Mun. Emps.,*

Council 31, 138 S. Ct. 2448, 2464 (2018). By selecting Novo's six products, CMS forced Novo to sign an "agreement" with the agency or face crippling penalties for failing to do so. The IRA requires that the "agreement" state that Novo "agree[s]" to engage in a "negotiation" that will result in CMS imposing a "maximum fair price." 42 U.S.C. § 1320f-2(a). Because the IRA compels Novo to enter this "agreement," the statute forces Novo to espouse the government's preferred views.

CMS cannot fix this constitutional problem by slapping a disclaimer on the compelled speech. The template agreement that manufacturers must sign includes a made-for-litigation provision: "In signing this Agreement, the Manufacturer does not make any statement regarding or endorsement of CMS' views .... Use of the term 'maximum fair price' and other statutory terms throughout this Agreement reflects the parties' intention that such terms be given the meaning specified in the statute and does not reflect any party's views regarding the colloquial meaning of those terms." CMS, Medicare Drug Price Negotiation Program Agreement Template, at 4. But, as the Third Circuit has explained, the fact that a government body "can issue a general disclaimer along with the [required] recitation does not erase the First Amendment infringement at issue here …. Otherwise, the state may infringe on anyone's First Amendment interests at will, so long as the mechanism of such infringement allows the speaker to issue a general disclaimer." *Circle Sch. v. Pappert*, 381 F.3d 172, 182 (3d Cir. 2004). No matter how the agency might back track, the First Amendment violation is baked into

the IRA, which requires manufacturers to "agree[]" to the misnamed "maximum fair price." 26 U.S.C. § 5000D(a)–(b).

Novo would never willingly describe the IRA or CMS's price-setting decisions in these terms. *See* Hauda Decl. ¶ 70. Novo does not agree that the program is voluntary, let alone a "negotiation." Novo must either sign the agreement, incur a crippling "excise tax" penalty, or withdraw all of its products from 50% of the nation's healthcare markets. Novo may not negotiate the terms of the "agreement," and the government has asserted that it can change those terms at any time. *See* Hauda Ex. E §§ II(e), IV(b). Moreover, Novo does not agree that whatever price CMS imposes is the "maximum fair" price, or even *a* fair price. *See* 42 U.S.C. §§ 1320f-2, 1320f-3; Hauda Decl. ¶¶ 53, 70. As noted above, Novo objects to aggregating multiple different products for price controls. Moreover, the IRA mandates a price ceiling—40% to 75% of the drug's average net price to non-federal purchasers. *See* Hauda Decl. ¶¶ 68–69; *see also* 42 U.S.C. § 1320f-3(c)(1)(C), (b)(2)(F). Between 40 and 75 percent of a *net* price is already a very low price (as the net price reflects all discounts and rebates). Whatever the price CMS imposes on Novo's six products, Novo would not voluntarily characterize it as a "maximum fair price." *See* Hauda Decl. ¶ 70.

Laws that compel speech are subject to strict scrutiny and must be narrowly tailored to serve a compelling governmental interest. *Nat'l Inst. of Fam. & Life Advocs. v. Becerra* (*NIFLA*), 138 S. Ct. 2361, 2371 (2018); *C.N. v. Ridgewood Bd. of Educ.*, 430 F.3d 159, 188 (3d Cir. 2005). The IRA fails that test. The government has no valid interest

in forcing Novo to serve as a "courier" for its preferred viewpoint, preventing open debate about the fairness of the price CMS chooses to impose. *Wooley v. Maynard*, 430 U.S. 705, 717 (1977). Nor is the IRA narrowly tailored. Compelling speech is not necessary to set drug prices, and much less burdensome alternatives "are obvious." *U.S.W., Inc. v. FCC*, 182 F.3d 1224, 1238 (10th Cir. 1999). If the government wants to impose price controls, there are no valid reasons manufacturers should not be allowed to express publicly their dissatisfaction with that price. *See NIFLA*, 138 S. Ct. at 2376. Under the First Amendment, the IRA's "compulsion ... plainly violates the Constitution." *Janus*, 138 S. Ct. at 2464.

B. No Comparable Statute Has Ever Been Upheld.

The IRA is unlike any price-setting scheme Congress has ever created. The "lack of historical precedent" for the IRA's price-control program is a "telling indication" that the statute is constitutionally invalid. *Free Enter. Fund*, 561 U.S. at 505–06. Novo is aware of no other statute that grants such sweeping power to an agency, strips away procedures necessary to protecting private rights, eliminates judicial review, and includes a forced-speech requirement. Simply put, the IRA is an "historical anomaly." *Seila Law*, 140 S. Ct. at 2202.

Consider rate-setting regimes for energy transmission. Rates must be "just and reasonable," 16 U.S.C. § 824d, and statutory procedures limit the authority of the Federal Energy Regulatory Commission ("FERC") to set rates. *See* 16 U.S.C. §§ 824d, 824e, 825*l*; *Mobil Oil Expl. & Producing Se. Inc. v. United Distrib. Cos.*, 498 U.S. 211, 218

(1991) (noting use of notice-and-comment rulemaking to "revise the old gas pricing system"). An entire body of law has developed to ensure adequate review of FERC's rate-setting authority so that it is not used in an arbitrary, discriminatory, or otherwise unconstitutional manner. *See In re Permian Basin*, 390 U.S. at 769–70. And judicial review is available to ensure that FERC complies with due process, the statutory standard, and the procedural requirements of the governing statute and the APA. *See, e.g.*, 15 U.S.C § 717r; 16 U.S.C. § 825*l*.

Similarly, when Congress undertook to regulate coal prices in the 1930s, it did not give the Coal Commission carte blanche to drive prices as low as it pleased. Congress instead required that any "maximum price" established for a mine must "yield a fair return on the fair value of the property." *Sunshine Anthracite Coal Co. v. Adkins*, 310 U.S. 381, 397 (1940). Congress also provided that "maximum prices must be fixed at a uniform increase above minimum prices so that in the aggregate they will yield a reasonable return above the weighted average total cost of the district." *Id.*

Even the most controversial laws enacted during wartime—a nadir for the protection of private rights—contained more robust protections than the IRA. For example, Congress enacted the Emergency Price Control Act of 1942, in the middle of World War II, seeking to "create[e] a nationwide system of price controls." *Cmty. Hous. Improvement Program v. City of New York*, 59 F.4th 540, 545 (2d Cir. 2023). The statute directed the Office of the Price Administrator to set such "maximum prices as in his judgment will be generally fair and equitable and will effectuate the purposes of th[e]

Act" when prices had risen or were expected to rise to certain levels. Emergency Price Control Act of 1942 ("EPCA"), Pub. L. No. 77-421, § 2(a), 56 Stat. 23, 24. Even though EPCA was a "war emergency measure," *Adamo Wrecking Co. v. United States*, 434 U.S. 275, 290 (1978) (Powell, J., concurring), it contained multiple layers of protections to protect accountability that are missing in the IRA. For example, EPCA provided for judicial review of "all questions of law, including the question whether the Administrator's determination is supported by evidence." *Yakus v. United States*, 321 U.S. 414, 437 (1944). It included a robust administrative process, where parties could protest price controls and receive an "administrative hearing." *Id.* at 436. And EPCA provided ascertainable standards to govern the Administrator's price-setting decisions, requiring that they be "fair and equitable" and "effectuate [the statute's] purposes." EPCA § 2(a).

In contrast, the Supreme Court has invalided statutes that, like the IRA, confer "virtually unfettered" discretion on the executive to control large parts of the economy. *Schechter*, 295 U.S. at 542. In *Schechter*, the Court struck down the Recovery Act's delegation to the President to create codes of "fair competition," including wage controls, for the poultry industry. Although the Recovery Act set forth "general aims" to guide the President's discretion, Congress had not "itself established the standards of legal obligation" and had thus failed to "perform[] its essential legislative function." *Id.* at 530, 541–42. Contrasting this scheme with the Federal Trade Commission's regulation of "unfair competition," the Court emphasized the lack of "judicial review

to give assurance that the action of the [executive] is taken within its statutory authority" and the absence of "appropriate administrative procedure" to ensure due process. *Id.* at 532–33, 541. Similarly, in *Panama Refining Co. v. Ryan*, the Court invalidated a statute authorizing the President to ban petroleum shipments in excess of state quotas. 293 U.S. 388, 418 (1935). Although the statute contained a "general outline of policy," including "remov[ing] obstructions to the free flow of interstate and foreign commerce" and "favor[ing] the fullest possible utilization of the present productive capacity of industries," those vague directives did not amount to a "standard or rule." *Id.* at 417–18.

C. The IRA's Constitutional Violations Cannot Be Excused.

The IRA's constitutional problems cannot be excused by pretending that manufacturers have voluntarily embraced price controls by virtue of their continued participation in the Medicare and Medicaid programs. Private parties cannot consent to a violation of the Constitution's structural protections, the IRA does not provide manufacturers with any meaningful choice, and forcing manufacturers to forfeit their constitutional rights violates the unconstitutional conditions doctrine.

Parties cannot waive the Constitution's structural protections. Parties cannot accept structural constitutional violations—such as separation of powers violations—"by consent." *Commodity Futures Trading Comm'n v. Schor*, 478 U.S. 833, 850-51 (1986); *see also Stern v. Marshall*, 564 U.S. 462, 483 (2011). Accordingly, even if participation in the federal healthcare programs were voluntary, that does not save the

IRA. More broadly, the government cannot take over an entire segment of the interstate market and then coerce manufacturers into forfeiting their constitutional rights in order to participate in that market. *See Horne*, 576 U.S. at 365 (rejecting argument that party can be forced to decide between exiting a market and forfeiting its constitutional rights); *cf. S.-Cent. Timber Dev., Inc. v. Wunnicke*, 467 U.S. 82, 98 (1984) (explaining that a state cannot leverage its role as a market participant to evade constitutional limits on its regulatory powers). The government's power to set prices when it is procuring products for itself—and the principle that parties can choose freely whether to contract with the government—does not apply when the government is exercising regulatory powers in a market that it "dominates." *Sanofi Aventis,* 58 F.4th at 699. The Constitution would be a particularly thin parchment barrier if the government could wall off half the nation's interstate market and make access to that market depend on forfeiting constitutional rights. *See U.S. Term Limits, Inc. v. Thornton*, 514 U.S. 779, 829 (1995) (noting that "[t]he Constitution 'nullifies sophisticated as well as simple-minded modes' of infringing on constitutional protections" (quoting *Lane v. Wilson*, 307 U.S. 268, 275 (1939))).

Participation in the IRA is coercive, not voluntary. The Supreme Court has long held that actions taken under threat of severe economic coercion are not voluntary. In *Union Pacific Railroad Co. v. Public Service Commission*, for instance, the Court concluded that government could not "impose an unconstitutional burden by the threat of penalties worse than [that burden] in case of a failure to accept it, and then to declare

the acceptance voluntary." 248 U.S. 67, 70 (1918). Economic "duress" negates any purported "choice" between compliance and "grave penalties" because it is "practically impossible not to comply with the terms of the law." *Id.* Likewise, in *United States v. Butler*, the Court recognized that a "regulation is not in fact voluntary," and the "asserted power of choice is illusory," where Congress used "coercion by economic pressure" "to induce to surrender [of a private party's] independence of action." 297 U.S. 1, 70–71 (1936); *see also Carter v. Carter Coal Co.*, 298 U.S. 238, 289 (1936) (concluding that purportedly voluntary "agreement" to participate in coal regulation program was "coerce[d]" and "lack[ed] the essential element of consent" because it was backed by provisions imposing substantial taxes for noncompliance, and observing that "[o]ne who does a thing in order to avoid a penalty does not agree").

The IRA is additionally coercive because manufacturers cannot lawfully withdraw from its price-control program for a period of 11 to 23 months. During that period, if a manufacturer does not "agree" to the government-imposed price, it is immediately subject to a draconian excise "tax" that no manufacturer could afford to pay. *See Thompson v. Deal*, 92 F.2d 478, 484 (D.C. Cir. 1937) (holding that program that required parties to sign an agreement with the government under threat of a "confiscatory" tax "not designed to raise revenue" was coercive). The "tax" applies while the manufacturer participates in Medicare, Medicaid, or the IRA-created "manufacturer discount program." 26 U.S.C. § 5000D.

Perhaps recognizing that participation under the statute is not voluntary, CMS has proposed a workaround, purporting to allow manufacturers to withdraw from its pricing program in 30 days. *See* Final Guidance §§ 40.1–40.2, 40.5–40.6. But that workaround was developed "only in the course of litigation," reflecting a "*post hoc*" tactic "by an agency seeking to defend past [congressional] action against attack." *Valancourt Books, LLC v. Garland*, 82 F.4th 1222, 1237 (D.C. Cir. 2023). It is not binding and, because it was not promulgated through regulations, it cannot change the statute's legal requirements. In any event, as courts have long held, "an agency may not rewrite clear statutory terms to suit its own sense of how the statute should operate." *Util. Air Regul. Grp.*, 573 U.S. at 328. Rewriting a statute is prohibited, even if a rewrite could avoid serious constitutional concerns. *See Stern*, 564 U.S. at 478.

The IRA violates the unconstitutional conditions doctrine. Even if Novo had a meaningful choice, the IRA would still violate the Constitution under the unconstitutional conditions doctrine. That doctrine "is based on the proposition that government incentives may be inherently coercive." *Koslow v. Pennsylvania*, 302 F.3d 161, 174 (3d Cir. 2002). The Supreme Court has "repeatedly rejected the argument that if the government need not confer a benefit at all, it can withhold the benefit because someone refuses to give up constitutional rights." *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 608 (2013) (collecting cases); *see also United States v. Am. Library Ass'n*, 539 U.S. 194, 210 (2003). The government may not condition government benefits to achieve "a result which [it] could not command directly." *Speiser v. Randall*, 357 U.S.

513, 526 (1958); *Frost v. R.R. Comm'n*, 271 U.S. 583, 593–94 (1926) ("inconceivable" that the "guarantees embedded in the Constitution" could be "manipulated out of existence.").

When Congress seeks to require the surrender of constitutional rights in return for a government benefit, there must be a *nexus* and *rough proportionality* between the benefit provided and the constitutional right to be relinquished. *Koontz*, 570 U.S. at 612; *cf. Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc.*, 570 U.S. 205, 214–15 (2013) (the Government cannot "leverage funding to regulate speech outside the contours of the program itself"). The IRA program does not impose any lawful "condition" because its obligations are not a general prerequisite for all manufacturers to participate in Medicare and Medicaid. Instead, they are a unique burden imposed only a small subset of targeted manufacturers. *Cf. Valancourt*, 82 F.4th at 1233 (finding no "voluntary exchange" when property owners received no "incremental benefit" by forgoing their right). Moreover, there is no nexus and rough proportionality between the constitutional rights surrendered and the right for Novo to participate in Medicare and Medicaid. To the contrary, Congress guaranteed that manufacturers like Novo would have no choice but to "agree" to the IRA's obligations by tying those obligations to the manufacturer's ability to have *any* of its drugs covered by federal healthcare programs. Because a manufacturer must either be "all in" or "all out" of Medicare and Medicaid, a manufacturer has no ability to withdraw a "selected drug" if CMS's "maximum fair price" is unfairly low without withdrawing its entire portfolio of medicines from nearly

half the market for prescription drugs. Congress knew that forcing a manufacturer to withdraw all its products from federal healthcare programs would be economic suicide (to say nothing of the harms to patients)—and not a real option.

In *National Federation of Independent Business v. Sebelius* (*NFIB*), 567 U.S. 519, 578, 581 (2012), the Supreme Court evaluated circumstances that closely parallel this case and concluded that forcing an entity to either accept new conditions or withdraw from Medicaid was no real choice. In *NFIB*, Congress pressured states to accept a Medicaid expansion by threatening the withdrawal of all Medicaid funding. Although the Medicaid expansion may have been "in form voluntary," *Frost*, 271 U.S. at 593, the Court held that "[t]he threatened loss of over 10 percent of a State's overall budget … is economic dragooning that leaves the States with no real option but to acquiesce in the Medicaid expansion," *NFIB*, 567 U.S. at 582. That financial threat was "a gun to the head." *Id.* at 581. And while Congress "styled" the expansion as part of Medicaid, it was effectively a "new health care program" because states "could hardly anticipate" that Congress would "transform" Medicaid so "dramatically." *Id.* at 584–85.

The same is true here. Congress is pressuring manufacturers to agree to CMS-imposed prices with no procedural review by threatening to kick the manufacturer and *all of its products* out of Medicare and Medicaid. And as in *NFIB*, the "choice" here is illusory. In both instances, Congress could impose its mandates via a nominal "choice" only because Congress knew that the regulated entity would have no real choice. *See id.* at 581–82, 587. If anything, the IRA involves even more coercive "economic

dragooning." Whereas federal Medicaid funding comprised 10% of the states' budgets in *NFIB*, Medicaid and Medicare account for nearly half of the prescription drug market. *See Sanofi Aventis*, 58 F.4th at 699. If states, with all their resources, are vulnerable to financial coercion, private entities are even more vulnerable to the "ruinous" "loss of federal funds." *Doe v. Univ. of Scis.*, 961 F.3d 203, 213 (3d Cir. 2020).

Like the Medicaid expansion in *NFIB*, it is indisputable that the IRA dramatically "transform[s]" the federal healthcare programs. 567 U.S. at 583. Manufacturers that signed up to participate in those programs—and invested billions of dollars in developing and distributing drugs that treat and cure beneficiaries—never signed up for the IRA. And companies could "hardly anticipate," *id.* at 584, that Congress would repudiate market-based pricing for prescription drugs, especially as reflected in the Medicare Part D "noninterference" clause, *see* 42 U.S.C. § 1395w-111(i). Congress went from prohibiting the government from strong-arming manufacturers to requiring CMS to do so. Any "asserted power of choice" here is "illusory." *Butler*, 297 U.S. at 71. Forcing a regulated entity to choose between two unacceptable outcomes—"the rock and the whirlpool"—is no choice at all. *Id.* at 72 (quoting *Frost*, 271 U.S. at 593); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 513 (1996) (plurality opinion).

CONCLUSION

The Court should enter summary judgment in Novo's favor and vacate CMS's unlawful actions. In the alternative, it should declare the IRA's drug-pricing provisions to be unconstitutional.

Dated: December 8, 2023

Respectfully submitted,

/s/ Israel Dahan

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
Trenton

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

DECLARATION OF DR. NATHAN LANEY

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

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

2. I received an MD in 2003 from the University of Missouri-Kansas City School of Medicine and an MBA from Florida International University in 2022. I am board certified in endocrinology. I have been at Novo Nordisk, Inc. since 2015. I have worked as Regional Medical Liaison - Philadelphia; Regional Medical Scientist - South Atlantic; Scientific Director, Diabetes TA; and most recently as the Medical Director at Novo Nordisk Inc. Before that, I spent six years as a practicing endocrinologist at St. Luke's Endocrinology & Diabetes. In all of these roles, I have either worked directly with patients or with healthcare professionals on diabetes management options, including insulin selection and dosing, to improve outcomes for patients living with diabetes. In my role as Medical Director at Novo Nordisk Inc., I have been deeply

involved in the Company's response to CMS inquiries under the Inflation Reduction Act and other related medical policy discussions.

The Need for Insulin to Manage Diabetes

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

4. There is no cure for diabetes. While medicines have improved treatment, if diabetes is not properly controlled, and often even if it is well treated, it can lead over time to complications including vision impairment (or even blindness), loss of kidney function, and nerve damage which can increase the risk of amputations. Diabetes is also associated with cardiovascular risks, including myocardial infarction, stroke, heart failure, and peripheral arterial disease.

5. Innovations resulting in the development of new products to assist in insulin therapy have provided patients with the necessary tools for managing this chronic disease. Important advances include the development of both prandial—or

mealtime—insulins (fast-acting insulins taken at mealtime to prevent excessive elevations in blood sugar levels after the meal) and basal insulins (slower, longer-acting insulins that control blood sugar levels between meals and when the patient is not eating).

Insulin Dosing

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

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

8. Because insulin dictates how much sugar cells absorb, too much insulin can cause hypoglycemia, or low blood sugar; too little insulin can cause hyperglycemia, or too high of blood sugar levels in the blood. Increased hypoglycemia increases risk

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

9. Landmark clinical data in patients with both T1D and T2D have shown that targeting appropriate overall blood sugar control reduces the risk of developing microvascular and macrovascular complications. In terms of appropriate overall blood sugar control, the laboratory measurement historically used to assess overall control is the A1C, which reflects the average glucose levels over the past 3 months. Ideally, the goal is to achieve an A1C level that is below 7%, as this is the threshold lowering the rate of hyperglycemia related complications. *See* Nuha A. ElSayed et al., *Glycemic Targets: Standards of Care in Diabetes—2023*, 46 Diabetes Care S97 (2023) (attached as Exhibit

B). A1C is the sum of all glucose exposure, including fasting blood glucose ("FBG") and post prandial glucose ("PPG") levels—blood sugar levels after a meal. This is particularly important at lower A1C levels, where PPG is the predominant contributor to A1C targets. Therefore, while A1C is an important measure, other measurements, such as PPG levels, should also be considered when assessing a person's overall diabetes control. *See* Louis Monnier et al., *Contributions of Fasting and Postprandial Glucose to Hemoglobin A1c*, 12 Endocrine Prac. 42 (2006) (attached as Exhibit C).

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

11. Insulin dosing is a complex process that requires the consideration of multiple factors on an individual basis. For patients with T1D and the subset of patients with T2D who require insulin, insulin coverage is necessary throughout the day. This 24-hour insulin coverage is provided through a basal insulin component and a mealtime insulin component, both of which are intended to maintain blood sugar levels in the desired target range. The basal insulin works in the background to keep blood sugar levels in the desired target range between meals and while the individual is not eating. The mealtime insulin works to keep blood sugar levels after meals, known as PPG, from rising too high.

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

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

14. Most individuals with T1D are treated with multiple daily injections of insulin, including a combination of both prandial insulin and basal insulin, or with continuous subcutaneous infusion of the newer rapid- or ultra-rapid-acting insulin analogues administered through an external insulin pump. For patients who are living with T1D, in particular, where their B-cells are producing very little to no insulin, insulin therapy is life sustaining. In general, a weight-based approach can be used to initiate insulin therapy, with typical total daily insulin requirements ranging between 0.4-1 unit/kg/day.

15. Patients living with T2D have several other medications available to control blood sugar levels initially in the disease process. Due to the progressive nature

of T2D, many individuals with T2D eventually require insulin therapy to overcome progressive declines in insulin production from the B-cells and control their blood sugar levels. These patients typically continue using their oral anti-diabetes medications and/or non-insulin injectable medications to control blood sugar levels, with the exception of classes known to non-discriminately stimulate insulin secretion like the sulfonylurea and glinide classes of diabetes medications. Unlike patients living with T1D, most individuals with T2D will initially add a basal insulin to their non-insulin medications, with use of mealtime insulin initiation reserved for those patients suffering from significant elevations in blood sugar levels (e.g., up into the 300 mg/dL range) or when additional control of blood sugar levels is necessary. The basal insulin dose for those patients is generally initiated using either the fixed starting dose outlined in the FDA-approved product label for the long-acting analogues, or a weight-based dose between 0.1-0.3 units/kg/day, and then titrated upwards until the desired fast blood sugar target is achieved. *See* ElSayed et al. (Exhibit A); Susan L. Samson et al., *American Association of Clinical Endocrinology Consensus Statement: Comprehensive Type 2 Diabetes Management Algorithm - 2023 Update*, 29 Endocrine Prac. 305 (2023) (attached as Exhibit D). When T2D patients need to advance their regimens to include mealtime insulin, the more conservative approach would be to start mealtime insulin at a fixed dose of 4-5 units prior to the largest meal or calculating the starting dose using either 10 percent of the basal insulin or a weight-based approach dose as the starting point.

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

17. The dosing regimen will differ across different mealtime insulin formulations, as different insulins are absorbed into the bloodstream at different rates and thus have different rates of onset. For instance, patients that use a short-acting human regular insulin as their mealtime insulin would have to inject their mealtime insulin dose 30 minutes before they even start eating their meal, while the same patient using a rapid acting analogue like NovoLog®, would only have to administer their mealtime dose 5-10 minutes before they start eating. Patients using an ultra-rapid

analogue like FIASP® would wait until they start eating or up to 20 minutes after they start eating before they must inject their mealtime insulin. For this reason, among others, the optimal time to administer prandial insulin varies based on the specific insulin product and the needs of the individual patient.

Insulin Administration

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

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

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

21. Pen injectors and insulin pumps can mean more precise and flexible dosing, which can reduce the risk of hyperglycemia (too high blood sugar) and hypoglycemia (too low blood sugar). A pen injector enables the patient to dial in the correct dose, resulting in easier and more accurate administration and less pain on

injection—as well as more accurate dosing. Patients can also opt for an insulin pump—a small, computerized device that continuously delivers insulin as programmed.

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

The NovoLog® Products

23. NovoLog® is Novo Nordisk Inc.'s ("Novo") rapid-acting mealtime insulin. It is indicated to improve glycemic control in adults and pediatric patients with diabetes mellitus. The NovoLog® family of products includes: NovoLog® 10 mL (100 units/mL, or "U100") vial; NovoLog® PenFill® 3 mL (U100) cartridges, for use with a reusable insulin pen; and NovoLog® FlexPen® 3 mL (U100), a single-patient-use prefilled insulin pen. Each of these products is a distinct product that is used for different purposes, but I refer to them together as the "NovoLog® products."

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

The FIASP® Products

25. FIASP® is Novo's *ultra*-rapid-acting mealtime insulin. It is indicated to improve glycemic control in adults and pediatric patients with diabetes mellitus. The

FIASP® family of products includes: FIASP® 10 mL (U100) vial; FIASP® FlexTouch® 3 mL (U100), a single-patient-use prefilled insulin pen; FIASP® PenFill® 3 mL (U100) cartridges, for use with a reusable insulin pen; and FIASP® PumpCart®, a 1.6 mL (U100) cartridge for use with insulin pumps. Each of these products is a distinct product that is used for different purposes, but I refer to them together as the "FIASP® products."

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

27. Onset of appearance for FIASP® products has consistently been shown to be twice as fast as that for NovoLog® products as a result of the faster onset of exposure and increased initial absorption rate seen with the FIASP® products.

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

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

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

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

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

32. Basal insulin and short-acting human insulin R help control blood sugar levels, but they are too slow to be responsive to mealtime insulin needs. Both the

NovoLog® products and the FIASP® products help lower mealtime blood sugar spikes—but they do so at different rates.

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

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

35. Being able to take a FIASP® product after starting a meal is very important. As described above, each mealtime insulin dose is driven by how much the person eats, what they eat, and when they eat it, *i.e.*, is subject to hunger, availability, and interruptions. The patient must tailor the dose for each meal, to account for the meal itself, as well as to make other adjustments, such as adjustments related to exercise. For

example, a patient planning to eat a meal heavy in carbohydrates will have a different insulin need from a patient eating a low-carbohydrate meal. But ultra-fast-acting insulins can be dosed based on food *actually consumed* instead of estimates of what might be consumed.

36. The ability to wait until after a meal has been decided upon, ordered, or even consumed, offers a considerable benefit to some patients. For pediatric and elderly patients, for example, there is a real concern that they will not eat as expected, which can require dose adjustments after a meal or result in hypoglycemia. In a survey of parents of pediatric patients with Type 1 diabetes, 81% indicated that, at least once a week, their children ate more or less food than anticipated after dosing mealtime insulin. *See* Wendy Lane et al., *Exploring the Burden of Mealtime Insulin Dosing in Adults and Children with Type 1 Diabetes*, 39 Clinical Diabetes J. 347 (2021) (attached as Exhibit E). And for all patients, there can be interruptions—a child may need something just as the person is sitting down to eat after dosing, or a waiter at a restaurant may inform the patient that their selection is not available after placing an order and administering an insulin dose accordingly.

37. A patient using a rapid-acting insulin must eat the planned amount once dosed, or they may experience hypoglycemia, with the side effects that ensue. Nocturnal hypoglycemia also can occur if a patient does not eat enough food after taking an insulin dose or taking more insulin that prescribed in the evening. In a survey of adults with

Type 1 diabetes, 58% of patients reported a need for additional food intake as a corrective action to prevent hypoglycemia at least once a week. *See id.* (Exhibit E).

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

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

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

41. Too little insulin, and for patients with Type 2 diabetes, the loss of early phase endogenous insulin secretion, contributes to elevated PPG levels after a meal, but with improved dosing flexibility and other clinical characteristics of a ultra rapid acting insulins, PPG levels can be better controlled. When administered at mealtime, FIASP® outperformed NovoLog® in terms of significantly reducing 1-hour PPG increments in both Type 1 and Type 2 diabetes patients in multiple clinical trials. *See* David Russell-Jones et al., *Fast-Acting Insulin Aspart Improves Glycemic Control in Basal-Bolus Treatment for Type 1 Diabetes: Results of a 26-Week Multicenter, Active-Controlled, Treat-to-Target, Randomized, Parallel-Group Trial (Onset 1)*, 40 Diabetes Care 943 (2017) (attached as Exhibit G); Keith Bowering et al., *Faster Aspart Versus Insulin Aspart as Part of a Basal-Bolus Regimen in Inadequately Controlled Type 2 Diabetes: The Onset 2 Trial*, 40 Diabetes Care 951 (2017) (attached as Exhibit H). This, in turn, can result in fewer instances of immediate post-prandial hypoglycemia, complications and long-term clinical impacts. A randomized, blinded clinical trial in adults with Type 2 diabetes found a lower relative risk of severe hypoglycemia for FIASP® compared to NovoLog®. *See* Wendy S. Lane et al., *A Randomized Trial Evaluating the Efficacy and Safety of Fast-Acting Insulin Aspart Compared With Insulin Aspart, Both in Combination With Insulin Degludec With or Without Metformin, in Adults With Type 2 Diabetes (ONSET 9)*, 43 Diabetes Care 1710 (2020) (attached as Exhibit I).

42. Thus, the ADA Standards of Care have recognized that ultra rapid-acting insulins like the FIASP® products may reduce prandial excursions better than rapid-

acting insulins like NovoLog®. In fact, there is a demonstrated statistically significant reduction in A1C in patients with T1D when FIASP® was dosed at mealtime versus NovoLog® dosed at mealtime. *See* Russell-Jones et al. (Exhibit G).

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

44. For instance, if a patient administered a NovoLog product® after starting a meal, they would have a blood sugar spike; if a patient administered a FIASP® product several minutes before starting a meal, they would risk hypoglycemia. In addition, as with all drugs, users of a product within the NovoLog® family of products inadvertently administered a product within the FIASP family of products (or vice versa) without changing their dosing procedure accordingly, they may experience adverse events.

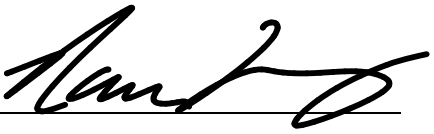
45. Confusion between a FIASP® product and a NovoLog® product when used in an insulin pump can result in occlusion (or blockage in pump tubing), which can result in nondelivery of needed insulin, which could lead to an individual with Type 1 diabetes to develop a life-threatening condition called diabetic ketoacidosis, or DKA. While DKA can develop following short periods of insulin nondelivery over the course of minutes to hours in patients with Type 1 diabetes, those living with Type 2 diabetes also could be at risk for developing an alternate condition called hyperosmolar

hyperglycemic state, though this would generally require much longer periods of insulin nondelivery over days rather than minutes or hours, as well as cessation of other diabetes medications used to control glucose levels.

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

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

Executed on this 07 day of December, 2023.

By: 

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
Trenton

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

DECLARATION OF KAREN M. HAUDA

I, Karen M. Hauda, declare as follows pursuant to 28 U.S.C. § 1746:

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

2. I am the Senior Director for Regulatory Policy at Novo Nordisk Inc. In my role, I oversee regulatory policy strategies and outreach initiatives for Novo Nordisk products, including insulin products. I am integrally involved in the Company's consideration of issues related to the Inflation Reduction Act and its impact on Novo Nordisk Inc.'s regulatory policy.

3. Novo Nordisk Inc. is the U.S.-based affiliate of Novo Nordisk A/S, a global healthcare company founded in 1923 and headquartered in Plainsboro, New Jersey.

4. The Novo Nordisk Foundation, Novo Nordisk A/S's majority stakeholder, is among the top five largest charitable foundations in the world. The

company's mission and actions reflect the Foundation's vision to contribute significantly to research and development that improves the lives of people and sustainability of society.

5. Novo Nordisk Pharma, Inc. supplies unbranded biologic versions of Novo Nordisk insulin products. Novo Nordisk Pharma, Inc.'s headquarters are located in Plainsboro, New Jersey.

6. Novo Nordisk Inc. and Novo Nordisk Pharma, Inc. (collectively "Novo") are committed to improving the lives of people living with serious chronic conditions, including diabetes, bleeding disorders, growth disorders, and obesity.

7. Novo's participation in the Medicare and Medicaid programs accounts for more than one third of the company's sales in the United States.

8. The Centers for Medicare & Medicaid Services ("CMS") has selected six of Novo's different biological products—FIASP® vial; FIASP® FlexTouch®; FIASP® PenFill®; NovoLog® vial; NovoLog® FlexPen®; and NovoLog® PenFill®—for price controls under the Inflation Reduction Act. CMS listed all six of these Novo products as a single "selected drug" solely because they contain the same active ingredient (insulin aspart).

Regulatory Paradigm of Active Ingredients, BLAs, and Biological Products

9. When Congress enacted the Inflation Reduction Act, it expressly referenced the regulatory provisions and framework that have long governed the Food and Drug Administration's ("FDA's") approval and licensure of drug products and

biological products. In the context of that regulatory framework, there are meaningful and well-established differences between "active ingredients," "biologics license applications" ("BLAs"), and individual "biological products."

10. In this declaration, I focus on active ingredients and biological products, as relevant to the six different biological products manufactured by Novo that CMS has subjected to price controls. It is important to note, however, that just as an active ingredient is considerably different from a biological product, an active moiety is considerably different from a drug product. Moreover, active ingredients and active moieties themselves are not the same things; there are complex and critical differences between the two.

11. It is also important to recognize that the regulations governing drug development in this country are complex, and there are a variety of nuances and exceptions that make any general description difficult. With that said, there are important distinctions between a biological product and its active ingredient.

12. ***Active Ingredient***. An active ingredient is the component of a biological product that provides pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or that affects the structure of any function of the body of man or animals. In contrast, "inactive ingredients"—such as excipients—are added to a product for other reasons, such as coloring or preserving the product. They may or may not affect the functioning of the product.

13. ***Biologics License Application***. In order to market a biological product, a manufacturer must have an approved BLA and an effective biologics license. The manufacturer obtains this marketing authorization from FDA by submitting an original BLA, or a supplement to an existing BLA. The submission must contain (among other things) specific information addressing the safety, purity, and potency, as well as the manufacturing establishment(s) and chemistry, manufacturing, and controls ("CMC"), of *each* biological product included or added to the BLA. FDA will grant approval for each product included in or added to the BLA if the manufacturer demonstrates (among other things) that the product meets applicable requirements to ensure its continued safety, purity, and potency.

14. A BLA typically includes multiple products from the same "family" of products—that is products produced by the same manufacturer that share the same core trade name and use the same active ingredient made through the same manufacturing process. In contrast, products representing different families of products and/or sponsored by different manufacturers will be licensed in different BLAs. They will generally have different trade names, use different manufacturing processes, and may treat different diseases, even if the products across the different BLAs might contain the same active ingredient(s).

15. Each product in a family of products covered by a single BLA can be approved and licensed on a different date. For instance, if a manufacturer seeks approval to market a new product within a family of products, FDA will expect that

product to be submitted for approval in a supplement to the same BLA that the manufacturer has used to seek approval and licensure for other products previously approved and licensed using the same BLA number. The date of approval for that product will not be tied to the date on which FDA previously licensed other products under the same BLA.

16. ***Biological Product.*** Although each BLA typically includes a family of products that contain the same active ingredient, each product within the family is different because it typically has its own approved characteristics and conditions of use. Biological products will differ across strengths, dosage forms and dosing regimens, routes of administration, indications, and delivery device presentations, among other things.

17. In considering the approvability of any given insulin product, FDA considers not only the active ingredient and the specific manufacturer's BLA, but also the safety and effectiveness of the product as it will be used by the patient—including final formulation, strength, delivery mode and device, and other aspects of the insulin product in its finished dosage form.

18. Each approved biological products is listed in FDA's Purple Book database, which lists the specific trade name, proper name, strength, dosage form, route of administration, and product presentation for each FDA-licensed biological product.

19. The Purple Book lists four different FIASP® products.

Product Details for: *Fiasp* RETURN TO SEARCH RESULTS

Product Label

Grayed out Product Label links indicate that there is no product label available for the product.

Product Number	Dosage Form	Route of Administration	Strength	Product Presentation	License Type	Proprietary Name	Marketing Status
001	Injection	Intravenous, Subcutaneous	1000UNITS/10ML (100UNITS/ML)	Multi-Dose Vial	351(a)	Fiasp	Rx
002	Injection	Subcutaneous	300UNITS/3ML (100UNITS/ML)	Autoinjector	351(a)	Fiasp	Rx
003	Injection	Subcutaneous	300UNITS/3ML (100UNITS/ML)	Multi-Dose Cartridge	351(a)	Fiasp	Rx
004	Injection	Subcutaneous	160UNITS/1.6ML (100UNITS/ML)	Multi-Dose Cartridge	351(a)	Fiasp	Rx

20. The Purple Book lists five different NovoLog® products, two of which have been discontinued.

Product Details for: *Novolog* RETURN TO SEARCH RESULTS

Product Label

Grayed out Product Label links indicate that there is no product label available for the product.

Product Number	Dosage Form	Route of Administration	Strength	Product Presentation	License Type	Proprietary Name	Marketing Status
001	Injection	Intravenous, Subcutaneous	1,000UNITS/10ML (100UNITS/ML)	Multi-Dose Vial	351(a)	Novolog	Rx
002	Injection	Subcutaneous	300UNITS/3ML (100UNITS/ML)	Multi-Dose Cartridge	351(a)	Novolog	Rx
003	Injection	Subcutaneous	300UNITS/3ML (100UNITS/ML)	Autoinjector	351(a)	Novolog	Rx
004	Injection	Subcutaneous	300UNITS/3ML (100UNITS/ML)	Autoinjector	351(a)	Novolog	Disc
005	Injection	Subcutaneous	300UNITS/3ML (100UNITS/ML)	Autoinjector	351(a)	Novolog	Disc

21. To change a product's dosage form or device presentation, a manufacturer will create a new product that must be evaluated approved and licensed by FDA—after an evaluation of the safety and efficacy of that specific product for patient use—before it can be marketed and sold in interstate commerce. In other words, changing essential characteristics results in a different product that must be separately approved by FDA

before the product may be marketed, and typically must be based on additional clinical and other data submitted to FDA to support that approval.

22. Different biological products can and do share the same active ingredient(s), but they are not by virtue of that shared characteristic the same biological product. Rather, as shown in Figure 1 below, the active ingredient in a product applies to more products than just those in the individual manufacturer's BLA; each BLA in turn is broader than any specific biological product; and each biological product has its own relevant characteristics and conditions of use.

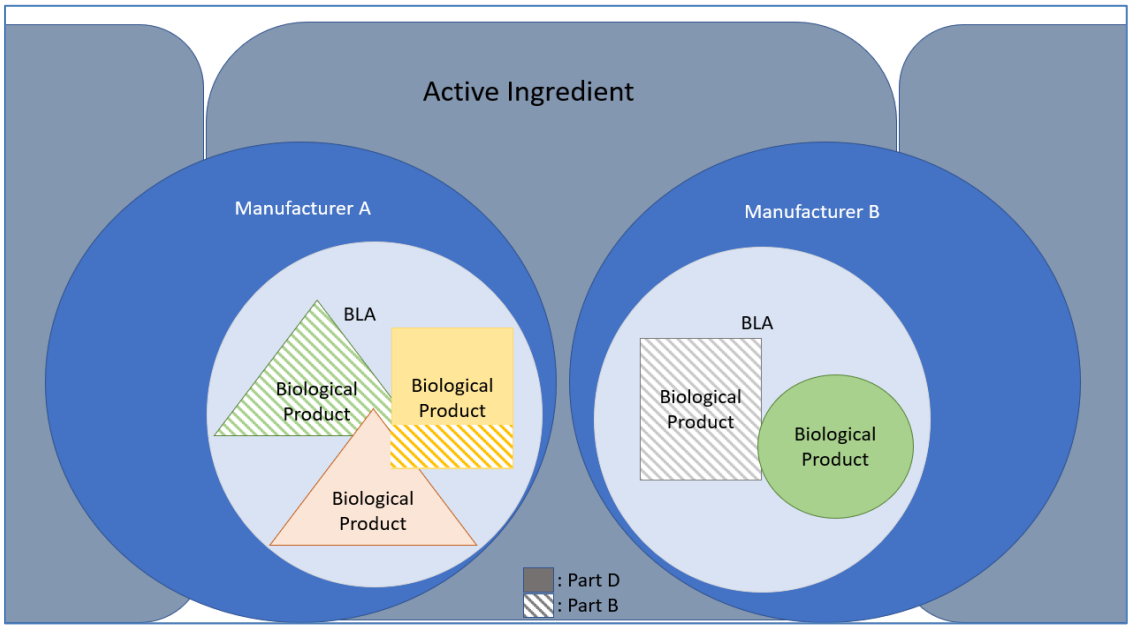


Figure 1

23. The distinct biological products in Figure 1 are represented by the small shapes housed inside the individual BLAs, which are represented by light blue circles within each manufacturer's individual portfolio (the larger dark blue circle). Although each BLA fits within the backdrop of the active ingredient, each contains multiple

individual products.

24. ***Reimbursement for Biological Products***. Coverage of a biological product approved under section 351(a) of the Public Health Service Act (42 U.S.C. § 262(a)) can be under Medicare Part B or Part D. Physician-administered drugs and outpatient drugs self-administered through durable medical equipment will generally be covered by Part B. Other self-administered drugs will generally be covered by Part D. So a biological product that is packaged in a pre-filled syringe for patient self-administration, for example, would be expected to be Part D, while an IV formulation for physician (office) administration would be expected to be Part B.

25. Novo holds multiple BLAs that provide authorization to market dozens of individual biological products. As a general matter, Novo's insulin products that are intended for self-administration through pen injectors and vial/syringes are reimbursed under Part D. Novo's insulin products that are self-administered through durable delivery devices such as insulin pumps are reimbursed under Part B. For instance, FIASP® PumpCart®, which FDA approved earlier this year, is expected to be reimbursed under Part B.

The NovoLog® Family of Products

26. NovoLog® is the trade name for Novo's rapid-acting mealtime insulin that helps with glycemic control in people with diabetes mellitus by lowering mealtime blood sugar spikes. NovoLog® products are administered 5–10 minutes before a meal

and are considered to be "rapid-acting" by the American Diabetes Association ("ADA") and the American Association of Clinical Endocrinology ("AACE").

27. As reflected in the current FDA-approved label, the different products that fall within the NovoLog® family of products are indicated to improve glycemic control in adults and pediatric patients with diabetes mellitus. NovoLog® products are typically used in conjunction with a basal insulin—but not in conjunction with another mealtime insulin.

28. The NovoLog® family of products includes:

- NovoLog® 10 mL (100 units/mL, or "U100") vial;
- NovoLog® PenFill® 3 mL (U100) cartridges, for use with a reusable insulin pen; and
- NovoLog® FlexPen® 3 mL (U100), a single-patient-use prefilled insulin pen.

29. Each of these products is a distinct product that is used for different purposes. For ease of reference, however, I will refer to these three products collectively as the "NovoLog® products."

30. The NovoLog® products are marketed pursuant to an approved BLA held by Novo. The NovoLog® 10 mL vial and the NovoLog® PenFill® 3 mL cartridges were approved by the Food and Drug Administration ("FDA") on June 7, 2000, in New Drug Application ("NDA") 020986. The NovoLog® FlexPen® 3 mL was approved by FDA on January 19, 2001, also in NDA 020986. (On March 23, 2020,

NDA 020986 was "deemed" to be a BLA by operation of section 7002(e)(4) of the Biologics Price Competition and Innovation Act.)

31. Each of the individual FDA approvals of each of the products in the NovoLog® family of products required further clinical and/or human factor studies and new data even though the products are all in the same BLA. Each product within the NovoLog® family provides different advantages to patients.

32. Novo has continued to invest in developments that have allowed for product innovations. For example, Novo received FDA approval of new routes of administration for the NovoLog® 10 mL vial: continuous subcutaneous infusion with an insulin pump was added in 2001, and intravenous use was added in 2005. Similarly, all of the products within the NovoLog® family were approved by FDA for pediatric use in 2005 and 2008 after Novo conducted independent, pediatric-specific clinical studies.

33. Novo makes all of the different NovoLog® products available through Medicare and Medicaid. Covered NovoLog® products are generally reimbursed under Part D.

The FIASP® Family of Products

34. FIASP® is the trade name for Novo's *ultra*-rapid-acting mealtime insulin that controls blood sugar around mealtimes for patients with diabetes mellitus. FIASP® products are administered at first bite or within 20 minutes after starting a meal and are considered to be "ultra-rapid-acting" by the ADA and the AACE. The

ADA and the AACE provide different prescribing guidance for the FIASP® family of products than they do for the NovoLog® family of products.

35. As reflected in the FDA-approved label, the different products that fall within the FIASP® family of products are indicated to improve glycemic control in adults and pediatric patients with diabetes mellitus. FIASP® products are typically used in conjunction with a basal insulin—but not in conjunction with another mealtime insulin.

36. The FIASP® family of products includes:

- FIASP® 10 mL (U100) vial;
- FIASP® FlexTouch® 3 mL (U100), a single-patient-use prefilled insulin pen;
- FIASP® PenFill® 3 mL (U100) cartridges, for use with a reusable insulin pen; and
- FIASP® PumpCart®, a 1.6 mL (U100) cartridge for use with insulin pumps.

37. Each of these products is a distinct product that is used for different purposes. For ease of reference, however, I will refer to these four products collectively as the "FIASP® products."

38. The FIASP® products are marketed pursuant to an approved BLA held by Novo. The first FIASP® products (the 10 mL vial and FIASP® FlexTouch® 3 mL products) were approved by FDA on September 29, 2017, in NDA 208751, after 17 formulation attempts. The FIASP® PenFill® 3 mL cartridge product was separately approved by FDA on September 24, 2018, also in NDA 208751. (On March 23, 2020,

NDA 208751 was "deemed" to be a BLA by operation of section 7002(e)(4) of the Biologics Price Competition and Innovation Act.)

39. The FIASP® family of products prescribing information differs from that of the NovoLog® family of products due to its different response rate of biological activity.

40. Novo has continued to invest in developing new and innovative products in the FIASP® family of products. For example, Novo received FDA approval of the FIASP® 10 mL vial for continuous subcutaneous infusion with an insulin pump in 2019. FDA approved pediatric use (including pump use) in 2019. And *just this year*, on June 21, 2023, FDA approved the FIASP® PumpCart®, a 1.6 mL cartridge. The FIASP® PumpCart® represents a significant advancement for patients, who will no longer need to manually fill pump cartridges.

41. Novo makes all of the different FIASP® products available through Medicare and Medicaid. The FIASP® products are generally reimbursed under Part D; however, some of the FIASP® products are reimbursed under Part B, including FIASP® PenFill® and FIASP® PumpCart®.

FDA Regulation

42. The "active ingredient" in the NovoLog® products and FIASP® products is insulin aspart, but each NovoLog® product and each FIASP® product is a distinct biological product. Each FDA approval for each of the products was specific to that individual product, in its finished dosage form, based on product-specific CMC

data as well as data from individual clinical studies and human factors studies that supported the marketing application for that specific product.

43. FDA did not approve an independent active ingredient of "insulin aspart" when it approved any of the NovoLog® or FIASP® products. FDA did not approve "NovoLog®"; it separately approved the NovoLog® vial, the NovoLog® FlexPen®, and the NovoLog® PenFill®. FDA also did not approve "FIASP®"; it separately approved each of the FIASP® products—and each independently and separately from (and in a wholly different marketing application from) the NovoLog® products.

44. FDA required different marketing applications and different proprietary names for the NovoLog® products and the FIASP® products. Novo consulted with FDA regarding the development of the first FIASP® products. FDA was clear that a separate NDA was needed and that a supplement to the NDA for the NovoLog® products would not suffice. FDA explained that the agency understood the new product "to be a standalone insulin product, not in the same line as Novolog and the Novolog pre-mixes." FDA, End of Phase 2 Meeting Minutes, at 5 (Mar. 2, 2011) (publicly available version) (attached as Exhibit A).

45. FDA has generally recognized the importance of distinguishing biological products that share a nonproprietary name—like "insulin aspart" for NovoLog® and FIASP®. In the context of the NovoLog® products and the FIASP® products, FDA explained that product differentiation is necessary to appropriately track adverse events and facilitate effective pharmacovigilance for biological products.

46. For new biological products, FDA assigns a unique, meaningless, four-letter suffix to the nonproprietary name of newly approved biological products. *See* FDA, Guidance for Industry: Nonproprietary Naming of Biological Products (Jan. 2017) (attached as Exhibit B). While insulin products approved in NDAs generally were not assigned suffixes, insulin products approved in BLAs after March 23, 2020 have been assigned unique suffixes, regardless of common active ingredients. As FDA has explained, such treatment differentiation is necessary for safe use and pharmacovigilance of biological products. *See* FDA, Draft Guidance for Industry: Nonproprietary Naming of Biological Products: Update (Mar. 2019) (attached as Exhibit C). For example, FDA assigned the nonproprietary name "insulin lispro" to Humalog, a fast-acting product with insulin lispro as its active ingredient—but when FDA approved the BLA for Lyumjev, an ultra-rapid-acting insulin lispro made by the same manufacturer, it assigned the nonproprietary name "insulin lispro-aabc" to differentiate between the different products.

CMS's Selected Drug List

47. On August 29, 2023, CMS aggregated each of the NovoLog® products and each of the FIASP® products approved and marketed at the time, and the Agency deemed them all to be a *single* "selected drug" because they share the same active ingredient. CMS listed six different NovoLog® products and FIASP® products as a single entry on its list of drugs selected for price controls: "Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill." (CMS did not include

the FIASP® PumpCart® cartridge.) CMS, Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026, at 1 (Aug. 2023) (attached as Exhibit D).

48. CMS did not aggregate any of the NovoLog® Mix products (*e.g.*, the NovoLog® Mix 70/30 FlexPen®), even though those products have been approved and marketed for more than the requisite amount of time required by the statute. Insulin aspart is the primary active ingredient in the NovoLog® Mix 70/30 products, making CMS's aggregation of the FIASP® and NovoLog® products, but not the NovoLog® Mix 70/30 products, entirely arbitrary and illogical.

49. CMS listed the "Total Part D Gross Covered Prescription Drug Costs from June 2022-May 2023" for the aggregated insulin aspart "selected drug" at $2,576,586,000. Even if the NovoLog® FlexPen® (which had the highest total part D gross covered costs of any NovoLog® product during the relevant time period) were aggregated consistent with the IRA's "use of data" provision to evaluate total expenditures, the total would still be less than $2,576,586,000. Given the total Part D expenditures for other drug products and biological products, one of those other products would likely have been selected instead of the aggregated NovoLog® and FIASP® products.

The "Agreement" Novo Was Required to Sign

50. No later than October 1, 2023, Novo was required, under threat of usurious penalties, to sign the "Manufacturer Agreement" provided by CMS (attached

as Exhibit E). That "Agreement" states that Novo "agrees" to participate in the "negotiation" with CMS to set a "maximum fair price" for the six different NovoLog® and FIASP® products.

51. The "Agreement" also states that Novo "agrees" to the terms used in the agreement including "Selected Drug," to CMS's guidance, and that "CMS retains authority to amend this Agreement to reflect changes in law, regulation, or guidance"—whether or not any notice of such amendments is provided.

52. Novo was not permitted to negotiate the terms or conditions of the "Agreement"—including those to which Novo does not agree and would have modified if negotiation had been permitted. As stated in the cover letter included in Novo's "Agreement," sent to CMS on September 29, 2023, Novo did not agree with CMS's assertions, requirements, or characterizations concerning the statute or CMS's actions, including CMS's characterizations of Novo's actions in, for example, signing the "Medicare Drug Price Negotiation Program Agreement." A copy of that letter is attached as Exhibit F.

53. Novo does not agree that CMS's drug pricing program involves a genuine "negotiation" or that the prices imposed by CMS are or will be "fair" as they relate to any of the individual products or the aggregated "insulin aspart" products listed by CMS as a selected drug. Novo also does not agree to any terms set by CMS in the future, nor does it want to permit CMS to make any unilateral changes it desires to the

"Agreement" and provide notice of such changes to Novo only when it deems such notice to be appropriate.

54. Novo does not wish to participate in CMS's drug price control program. It would not have signed the Agreement but for the draconian penalties threatened for noncompliance with CMS's commands.

Information Collection Requirements

55. By October 2, 2023, Novo was required to submit an unprecedented and voluminous amount of information to CMS, including highly sensitive and confidential trade secret and commercial information about the NovoLog® products, the FIASP® products, and other Novo products in development. *See* CMS, Medicare Drug Price Negotiation Program: Revised Guidance ("Final Guidance"), at App. C (June 30, 2023). This information included, among other things, certain aspects of research and development costs, current unit costs of production and distribution, patent and regulatory information, and market data and sales volume. At the same time, CMS restricted the information Novo could submit (*e.g.*, CMS's narrow conception of costs associated with failed or abandoned products). *See id.*

56. Novo was required by CMS to submit a single submission related to therapeutic alternatives for the six different NovoLog® and FIASP® products, even though the alternatives differ between rapid-acting and ultra-rapid-acting insulins. Novo was required to submit information related to certain aspects of the research and development costs for six different NovoLog® and FIASP® products in a single

submission as well, even though each product has a different research and development history and set of costs. For example, the development of the FIASP® products underwent testing of seventeen different formulations.

57. FIASP® Pumpcart® does not appear by name on CMS's selected drugs list, but CMS has required Novo to submit confidential business information regarding this product too.

58. Novo did not want to submit this highly sensitive, valuable, and confidential data to the government. Novo would not share this information with contracting partners in the ordinary course.

59. Any information that was shared with a contracting party in the normal course of contracting would be governed by confidentiality provisions created and approved by Novo. Here, however, Novo had no choice but to accede to CMS's demands in light of the massive penalties described below and no opportunity to build appropriate confidentiality protections.

60. Novo does not contract with other manufacturers in the way envisioned by CMS's guidance, *i.e.*, as a "Primary Manufacturer" with the ability to demand sensitive information from—and impose specific sales prices on—a "Secondary Manufacturer."

61. Novo incurred substantial costs to collect this information and disclose it to CMS. Moreover, Novo has incurred opportunity costs, as its employees are being diverted from other tasks, including more than several thousand full-time employee hours spent preparing Novo's submission to CMS.

"Negotiation" of the NovoLog® Products and FIASP® Products

62. Although labeled a "drug price negotiation program," the statute does not allow for anything that could be remotely characterized as an actual negotiation between CMS and Novo. Novo has not had—and does not anticipate having—any genuine negotiations with CMS.

63. Novo does not wish to be a party to these "negotiations" nor to have a "maximum fair price" assigned to any of its products (and any other "insulin aspart product" that CMS may decide to include). But the statute's debilitating penalties mean that Novo does not have a choice. Novo therefore continues to incur substantial costs related to this "negotiation" with CMS.

64. In particular, a failure to sign the "Agreement" would have subjected Novo to one of two penalties: (1) an exorbitant daily penalty of up to 1900% of the drug's sales revenue of each of the NovoLog® and FIASP® products (not just those on sales for use by Medicare beneficiaries); or (2) forced withdrawal of *all* of Novo's products from both Medicare and Medicaid (including those that are not under selection for "negotiation") *after* paying the daily penalty for months.

65. If Novo declined to participate in the "negotiation" and continued to sell its NovoLog® and FIASP® products, based on 2022 sales, the penalty start at tens of millions of dollars per day and would grow rapidly. If Novo did not comply for longer than 270 days, the 1900% daily penalty would apply, meaning that Novo would be liable to pay a penalty of more than $400 million dollars per day— for a total approaching

$60 billion over the course of a single year. Paying these crippling penalties is not an option and Novo could not realistically do so.

66. Exiting from Medicare and Medicaid would mean that patients would lose their insurance coverage for the six different NovoLog® and FIASP® products—as well as for *all* of Novo's other products in these government programs. Different estimates suggest that there are at least 100 million patients in the Medicare and Medicaid programs, combined. Millions of those patients, who depend on Novo's products, would be without treatment at the end of an exit process. That is an intolerable result from Novo's perspective, particularly as it means that patients would have to transition to other, potentially less safe or less effective, treatments. For instance, as reflected in the FDA-approved labeling for the NovoLog® products and the FDA-approved labeling for the FIASP® products, changes in insulin regimens, including switching to insulins from different manufacturers, can affect glycemic control.

67. Exiting all of its products from Medicare and Medicaid would also mean result in a loss of more than one third of Novo's U.S. sales, which would undermine Novo's financial ability to continue improving existing treatments and developing new ones. It would also damage Novo's reputation as a longstanding and reliable provider of life-saving insulin products to patients.

The "Maximum Fair Price"

68. Novo expects CMS to make an initial "offer" of a "maximum fair price" for its insulin aspart products (below a statutory ceiling), and then to impose any price it chooses (below the price ceiling) with no lower limit.

69. The statutory ceiling price does not account for investments in manufacturing to ensure capacity and broad access for patients, for example, nor for costs related to general diabetes research and diabetes education. In just the last five years, the Novo Nordisk Foundation has funded 31 projects totaling $111 million, providing opportunities for grantees to collaborate with U.S.-based universities, university hospitals, biotechnology companies and smaller employers. It also does not account for forward-looking research conducted with a focus on the next therapeutic advance—things like once-weekly basal insulin, glucose sensitive insulin, diabetes cell therapy, and, critically, a cure.

70. The provisions of the Inflation Reduction Act and the terms of the "Manufacturer Agreement" require Novo to convey that it entered into "negotiations" with CMS, that it "agreed" to the CMS-mandated price, and that it endorses this price as the "maximum fair price." For the reasons described above, Novo does not agree that there is a genuine "negotiation." Nor does Novo "agree" to the price or that the confiscatory price should be considered "fair," much less the "maximum fair price" for the different products.

Biosimilar Competition

71. Novo is aware of at least four development programs for biosimilars referencing NovoLog® products that have been publicly announced. I expect that one or more of these biosimilars will be approved and marketed before the end of the negotiation period and/or implementation of the "maximum fair price" for initial price applicability year 2026.

72. Despite the statute's express provisions, CMS's guidance states that the agency will not exit Novo from the "negotiation" process, even after a biosimilar insulin aspart is approved and marketed, unless CMS determines that such marketing is "bona fide."

73. CMS has indicated in guidance that it will make this decision according to an extra-statutory standard that differs from the well-established definition of "commercial marketing" as the introduction or delivery for introduction into interstate commerce of a drug or biological product.

74. In determining whether and when a biosimilar is "bona fide" marketed, CMS intends to consider both Prescription Drug Event ("PDE") data and Average Manufacturer Price ("AMP") data reported by manufacturers. PDE data, however, is insufficiently time-sensitive, as formulary access can take months and mid-year formulary changes for biosimilars are often delayed. AMP data is similarly limited, as it may not exist for a biosimilar competitor if, for example, the biosimilar applicant is not a participant in the Medicaid Rebate Drug Program. CMS's calculation of "bona

fide marketing" is based on incomplete data that itself often lags behind commercial realities.

The Impact of CMS's Approach

75. Novo spends massive amounts each year to develop new targets, formulations, and indications, as well as new therapies—continuously updating its pipeline to reflect evolving science and research into areas of unmet patient need. In the past 5 years alone, Novo has spent $12 billion on research and development. But most research and development efforts fail over the course of development. For example, as mentioned, the development of the FIASP® products underwent testing of seventeen different formulations. Similarly, an early program to develop the first rapid-acting insulin analog, known as insulin x10 was underway for about 5 years until we stopped the program in the pre-clinical phase. Other programs, in the 1990s and 2000s, attempted without success to develop an injection free insulin to respond to patient concerns and fears when using needles, including attempts to develop an inhaled insulin product known as AERx.

76. Novo has been serving patients with diabetes for 100 years. The company invests substantial amounts in research and development of new and improved insulin products that make a difference in patients' lives, and continues to research and seek a cure. Given the low success rates for progressing a drug from target identification to approval, Novo's ability to pursue such innovations, including in new areas of unmet

need, depends on the company's ability to recoup costs from its marketed products and reinvest in development and educational programs.

77. In addition, Medicare and Medicaid comprise a substantial portion of the marketplace. If Novo withdrew all of its products from these federal programs, it would negatively impact the available resources to the company in order to innovate, improve and further develop its existing products—to the detriment of patients and Novo Nordisk's longstanding reputation of services to the diabetes community.

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

Executed on this 07 day of December, 2023.

By: KM Hauda