No. 24-2510

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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

Appellants,

v.

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

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

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REPLY BRIEF FOR APPELLANTS

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INTRODUCTION

The government's response confirms that the Centers for Medicare & Medicaid Services ("CMS") is asserting powers that violate the Inflation Reduction Act ("IRA") and contravene core principles of administrative and constitutional law.

First, the agency has violated clear statutory mandates. The IRA directs CMS to impose price controls on no more than 10 drug or biological "products." Yet CMS has imposed price controls on 15 different products. When Congress enacted the IRA to regulate the prices of the nation's most-utilized medications, it used the term "products" and expressly cross-referenced the definitions of drug and biological "products" applied by the Food and Drug Administration ("FDA"), the regulatory body charged with overseeing the approval and licensure of pharmaceutical products in the United States. In contravention of the statute, CMS has deemed groups of multiple products that contain the same "active ingredient" or "active moiety" to be a single drug—an invented definition that lacks statutory support. Although Congress granted CMS narrow authority to apply prices across "dosage forms" and

"strengths," CMS's novel definition extends far beyond what the statute permits.

CMS also asserts unprecedented powers to impose binding substantive obligations—to make new law—without complying with the notice-and-comment and judicial-review requirements of the Administrative Procedure Act ("APA"). Even though Congress has not exempted CMS from the APA, the government contends that Congress's direction to "implement" the IRA through "guidance" until 2029 unleashes CMS to issue substantive rules with no protections to ensure that it acts reasonably and within the statute's bounds. If CMS's interpretation were correct, it would mean that Congress has granted CMS unchecked legislative powers. That serious separation-of-powers problem is readily avoided by applying the statute's plain language. "Guidance" has an established meaning; it refers to agency actions that are non-binding and do not carry the force of law. CMS identifies no case that has ever permitted an agency to promulgate binding, substantive rules through "guidance."

Contrary to CMS's assertions, no judicial review bar applies here. Review bars must be interpreted narrowly; no bar purports to prevent

courts from enforcing limits Congress imposed on the number of products subject to price controls; and Congress gave CMS no authority to rewrite statutory definitions. Properly interpreted, the review bars shield "determinations" made by CMS concerning the "total expenditures" that are necessary for a product to fall within the definitions set by Congress. They do not allow CMS to expand the statute's scope, change statutory definitions, or evade the IRA's express numerical limits.

Second, the agency's interpretation and application of the IRA violates the Constitution's due process, separation of powers, and free speech requirements. Never before has a statute simultaneously stripped away so many constitutional safeguards necessary to protect private rights and ensure public accountability. CMS asserts that participation in its price-control regime is "voluntary." But "voluntariness" cannot cure a violation of the Constitution's structural protections. And, in any event, CMS's regime does not involve a voluntary exchange in a competitive market where the government is procuring goods for itself. CMS is exercising sovereign powers to regulate the prices of products sold to tens of millions of Americans and to coerce

manufacturers, like Novo Nordisk, into accepting the agency's demands. That is not voluntary, and CMS is not exempt from the Constitution.

ARGUMENT

I. CMS's Actions Violate Plain Statutory Requirements.

CMS has violated two express limits on its authority: (1) Congress's mandate that the agency impose price controls on no more than 10 drug or biological products for 2026, and (2) Congress's directive that the agency implement the statute through "program guidance" until 2029.

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

CMS does not dispute that the IRA prohibits it from imposing price controls on more than "10 negotiation-eligible drugs" in 2026. Resp.Br. 34 (quoting 42 U.S.C. § 1320f-1(a)(1)). Nor does it dispute that Congress defined "negotiation-eligible drug" as a drug "product" (singular) or a biological "product" (singular) that has been approved or licensed by FDA *and* marketed for at least 7 or 11 years, respectively. *See* 42 U.S.C. § 1320f-1(d)(1), (e)(1). CMS has thus violated the statute's 10-drug limit by attempting to regulate the prices of 15 different products and treating six different Novo Nordisk products, from two distinct families, as a single "drug." Op.Br. 24-33.

1. CMS contends that the statutory provisions permitting aggregation of products with different "dosage forms" and "strengths" for limited purposes also allow it to impose price controls on all products from the same manufacturer that share the same "active ingredient" or "active moiety." Resp.Br. 15-16; CMS, Medicare Drug Price Negotiation Program: Revised Guidance § 30.1 (June 30, 2023) ("Guidance"). That cannot be correct. Drug and biological products have many more characteristics than their dosage forms and strengths, and the law has long distinguished between, on one hand, individual FDA-approved products and, on the other, their core molecule (active moiety) or substance (active ingredient). *See* Appx107.

The IRA's provisions permit CMS to aggregate across different "dosage forms" and "strengths" in only two instances: (1) when evaluating whether an FDA-approved or licensed "product" meets the high-spend thresholds and (2) when applying a price. *See* 42 U.S.C. §§ 1320f-1(d)(3)(B), (e)(1); *id.* § 1320f-5(a)(2). Congress thus ensured that if a product is subject to price controls, manufacturers cannot avoid the CMS-imposed price by marketing the product in a different strength (*e.g.*, a 5 mg pill instead of a 2.5 mg pill) or dosage form (*e.g.*, a liquid instead of a

pill). But Congress also recognized the severe threat that price controls pose to innovation and thus declined to allow CMS to apply price controls more broadly.

By aggregating products based on "active ingredient" or "active moiety," CMS has grouped together products that—regardless of their "dosage forms" and "strengths"—have different routes of administration, device presentations, conditions of use, and other defining characteristics. That approach impermissibly renders the statute's limited aggregation provisions "insignificant," *Corley v. United States*, 556 U.S. 303, 314 (2009), and violates basic principles of statutory construction, *see Popa v. Harriet Carter Gifts, Inc.*, 52 F.4th 121, 128 (3d Cir. 2022) (the "inclusion of a specific matter in a statute implies the exclusion of other matters"). If every product with the same active ingredient or moiety is subject to price controls, the statute's specific and repeated references to dosage forms and strengths are meaningless.

Novo Nordisk's six different products showcase the defects in CMS's position. The Novolog® family consists of three distinct rapid-acting insulin products, *see* Appx108-110, 191-192, and the FIASP® family consists of three distinct *ultra*-rapid-acting insulin products, *see*

Appx110-112, Appx192-194. The six products have different device presentations and conditions of use, and the two families are used for different purposes, by different patients. *See* Appx194-200 (describing these clinical differences). The prescribing information for each is different, reflecting the different "onset of action and dosing regimens" and "the differing clinical studies that supported FDA approval of the different product[]" at different times. Appx193. They are clinically different products that cannot be substituted for each other, Appx199-200; indeed, FDA required "different marketing applications and different proprietary names" for the two families, Appx113. No doctor or patient would say that a FIASP® pre-filled pen product is the same as a Novolog® vial product, or that the products differ only by dosage form and strength.

With no answer to these irrefutable facts, CMS suggests—for the first time—that products with the same active ingredient or moiety are mere "formulations" of each other. *See FPC v. Texaco Inc.*, 417 U.S. 380, 397 (1974) (courts may not accept "appellate counsel's post hoc rationalizations for agency action"). But the statute uses "formulation" in a far narrower sense. Section 1320f-5(a)(2) permits CMS to "compute

and apply the maximum fair price across different strengths and dosage forms of a selected drug and not based on the specific formulation or package size or package type of such drug." 42 U.S.C. § 1320f-5(a)(2). The "specific formulation" language thus clarifies how CMS should aggregate across "different strengths and dosage forms." *Id.*; *see also id.* § 1320f-1(d)(3)(B). Nothing in the statute permits CMS to aggregate products that differ in ways beyond "dosage form" and "strengths."

2. CMS contends that it is "inappropriate" to consider FDA's "product-specific approval framework" under the Food, Drug, and Cosmetic Act ("FDCA"). Resp.Br. 45-47. But the IRA repeatedly references and incorporates the FDCA's provisions—at least 10 times in subsection 1320f-1(e) alone. *See* 42 U.S.C. § 1320f-1(e)(1)(A)(i), (e)(1)(A)(ii), (e)(1)(A)(iii), (e)(1)(B)(i), (e)(1)(B)(ii), (e)(1)(B)(iii), (e)(2)(A), (e)(2)(B)(i), (e)(2)(B)(ii)(I), (e)(3)(A). The statute mandates that no product is subject to price controls unless it has been approved or licensed by FDA, has been marketed for at least 7 or 11 years, and is not a "listed drug" or "reference product" for a generic or biosimilar product. *See id.* § 1320f-1(d)(1), (e)(1); *see also* Appx110-112 (listing licensure dates for Novo Nordisk products). FDA does not approve or license active

ingredients or moieties; nor does an ingredient or moiety ever serve as a "listed drug" or "reference product." CMS's approach ignores the IRA's explicit incorporation of the FDCA's framework.

By cross-referencing the FDCA, Congress made clear that the key statutory terms—drug and biological products—should be interpreted in the same manner as they have been interpreted in the FDCA context. *See United States v. Generix Drug Corp.*, 460 U.S. 453, 459 (1983) ("The term 'drug' … include[s] entire drug products, complete with active and inactive ingredients."); 86 Fed. Reg. 28,605, 28,606 (May 27, 2021) (FDA has long "interpreted the word 'drug' in the term 'new drug' to refer to the entire drug product and not just its active ingredient"). CMS provides no basis for concluding that Congress *sub silentio* departed from those settled understandings. *See Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 243 (2011) (Congress is assumed to adopt settled definitions of terms in later-enacted statutes).

c. Retreating to policy, CMS contends that Congress's product-specific definition would allow manufacturers to avoid price controls by "serially introduc[ing] slight variations or formulations of a drug." Resp.Br. 47-48. But CMS "cannot rewrite [the] statute just to serve a

perceived statutory 'spirit.'" *Landstar Express Am., Inc. v. Fed. Mar. Comm'n*, 569 F.3d 493, 500 (D.C. Cir. 2009). Nor would it make sense to do so given the threat that price controls pose to innovation. *See Rodriguez v. United States*, 480 U.S. 522, 525-26 (1987) (per curiam) ("no legislation pursues its purposes at all costs").

Congress addressed the risk that manufacturers might develop "slight variations or formulations" by allowing CMS to aggregate across "dosage forms" and "strengths," and by connecting CMS's price controls to FDA's product-specific approval decisions. It takes years for a manufacturer to obtain FDA's permission to market a new product, making "product hopping" more difficult than CMS suggests. *See* 21 U.S.C. § 355(c); 42 U.S.C. § 262(a). Congress chose to protect innovation by directing CMS to proceed gradually and limiting price controls to only 10 products in 2026. CMS should not "be permitted to override Congress's considered judgment" by rewriting the statute. *Prestol Espinal v. Att'y Gen.*, 653 F.3d 213, 222 (3d Cir. 2011).

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

CMS has violated the IRA's mandate that CMS implement the statute only through "program instruction or other forms of program

guidance" for the first three years. 42 U.S.C. § 1320f note. By imposing what CMS concedes are new binding and substantive requirements through guidance, CMS has also violated the APA and the Medicare Act, which prohibit agencies from issuing rules without complying with notice-and-comment procedures and subjecting their rules to judicial review. *See* 5 U.S.C. § 553(b), (c); 42 U.S.C. § 1395hh(a)(2).[1] These requirements are an essential part of an administrative-law system that allows "unelected administrators, who are not directly accountable to the populace," to impose binding legal requirements—to make new law—because they force those administrators "to justify their quasi-legislative rulemaking before an informed and skeptical public." *New Jersey v. HHS*, 670 F.2d 1262, 1281 (3d Cir. 1981).

The APA applies unless Congress "expressly" directs an agency to use alternative, constitutionally adequate procedures. 5 U.S.C. § 559. CMS ignores this bedrock principle. It instead argues that because Congress directed it to "implement" the IRA through "program guidance,"

[1] CMS admits that it has not complied with the APA's notice-and-comment procedures. *See* Dkt. 37-1 at 30. It also specifically refused to consider comments on its decision to aggregate products. *See* CMS, Medicare Drug Price Negotiation Program: Initial Memorandum (Mar. 15, 2023), https://perma.cc/8X4K-CVD8.

Congress granted CMS unfettered rulemaking powers. 42 U.S.C. § 1320f note; Resp.Br. 48-50. According to the government, "Congress authorized CMS to promulgate [binding] substantive standards *without* observing" the APA's procedures. Dkt. 37-1 at 30.

The notion that Congress's reference to "implementation" accomplishes this constitutionally problematic result conflicts with longstanding precedent requiring Congress to "plainly express[]" its intent to "depart from normal APA procedures." *Asiana Airlines v. FAA*, 134 F.3d 393, 398 (D.C. Cir. 1998). It also cannot be reconciled with the IRA's plain language. CMS cannot dispute that "guidance" describes agency documents that do *not* carry the binding force of law. *See* Op.Br. 40-41 (citing authorities). The IRA's direction for CMS to proceed by "guidance" thus complements Congress's intent that price controls would be phased-in gradually.

CMS identifies no court that has interpreted a statutory instruction to proceed by "guidance" to allow an agency to create binding substantive rules. Nor has CMS identified any plausible reason it could not proceed by guidance. The examples it provides—identifying negotiation-eligible drugs, selecting certain products for price controls, and entering into

agreements with manufacturers, *see* Resp.Br. 49—are decisions that CMS could make without exercising general *rulemaking* authority. Novo Nordisk does not argue that CMS lacks authority to take any action, just that it cannot use guidance to issue binding *substantive rules* without complying with the APA.

If accepted, CMS's position would open a door to unchecked exercises by the executive of arbitrary quasi-legislative powers, which is anathema to "our democratic system of government." *Am. Fed'n of Lab. & Cong. of Indus. Orgs. v. NLRB*, 471 F. Supp. 3d 228, 238 (D.D.C. 2020) (Jackson, J.); *United States ex rel. Champion Lumber Co. v. Fisher*, 227 U.S. 445, 448-49 (1913) ("arbitrary power resides nowhere in our system of government"). If a mere direction by Congress to "implement" a statute authorizes the agency to make new law, freed from the APA's requirements, that would dismantle the Constitution's "regime of separate and divided powers." *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2261 (2024). The canon of constitutional avoidance thus weighs decisively in favor of enforcing the IRA's guidance-only mandate consistent with its plain meaning. *See Legal Servs. Corp. v. Velazquez*, 531 U.S. 533, 545 (2001).

C. This Court Has Jurisdiction to Enforce the Statute's Requirements.

There is no impediment to addressing the merits of CMS's statutory violations. The statute's review bars do not apply, and Novo Nordisk has standing to bring this litigation.

1. No judicial review bar applies.

Parties adversely affected by final agency action are entitled to judicial review. 5 U.S.C. §§ 702, 704. To "dislodge" this rule, CMS must identify "'clear and convincing evidence'" that Congress intended to withdraw review. *Kucana v. Holder*, 558 U.S. 233, 252 (2010); *United States v. Dohou*, 948 F.3d 621, 626-27 (3d Cir. 2020). "There is no such evidence here." *Kucana*, 558 U.S. at 252.

Congress did not grant CMS authority to change the number of products subject to price controls or shield from judicial review CMS's decision to violate the 10-drug limit in section 1320f-1(a). The review bars apply only to specified determinations under sub-sections (b), (d), (e), and (f): "[t]he selection of drugs," the "determination of negotiation-eligible drugs," "the determination of qualifying single source drugs," and "the application of section 1320f-1(f)." 42 U.S.C. § 1320f-7(2). As the district court recognized, the text of those provisions does *not* cover

subsection (a). Appx10 ("the ten-product limit … is not exempted from judicial review"). Nor do the review bars encompass Congress's instruction for CMS to implement the statute through guidance until 2029. *See* 42 U.S.C. § 1320f note.

CMS does not and cannot seriously dispute that its actions would be subject to judicial review if it openly acknowledged that it was exceeding the statute's 10-drug limit. It nonetheless contends that the review bars apply because of the *way* the agency exceeded the 10-drug limit—by concocting a new definition of a "negotiation-eligible drug" that consists of multiple products. Resp.Br. 30-38. But an agency "cannot do indirectly what [it] is barred from doing directly," *NRA v. Vullo*, 602 U.S. 175, 190 (2024), and "arguments against judicial review cannot override the text of the statute." *Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724, 734 (2022). Congress chose to bar review of only specific discrete determinations; it did not extend those bars to encompass other related actions, something Congress knows how to do. *See Dohou*, 948 F.3d at 626 (noting that a judicial review bar "omit[ted] capacious phrases like 'relating to'").

Moreover, CMS's expansive interpretation of the judicial review bars cannot be reconciled with the statute's text or structure. The IRA's grant of authority is much more precise than CMS suggests—it directs CMS to "determine[]" "total expenditures" associated with individual FDA-approved drug and biological products and then to exclude or exempt certain products from price controls based on those determinations. *See* Addendum (reproducing relevant statutory text). Congress thus directed CMS to "exclude" a product from price controls if it qualifies as a "[l]ow spend Medicare" product, "as determined by the Secretary," 42 U.S.C. § 1320f-1(e)(3)(B), and to "except[]" a small biotech product from the statutory requirements if it meets certain expenditure thresholds, "as determined by the Secretary," *id.* § 1320f-1(d)(2)(A)(i), (ii). Those are the "determinations" that Congress committed to the Secretary and shielded from review. Congress did not grant CMS unreviewable authority to ignore statutory definitions and expand the number of products subject to price controls. Because the review bars are at least "reasonably susceptible" to this narrower interpretation, the Court must adopt the reading that allows for judicial review. *Guerrero-Lasprilla v. Barr*, 589 U.S. 221, 229 (2020).

In *American Clinical Laboratory Association v. Azar*, the D.C. Circuit rejected a similar argument to the one CMS advances here. *See* 931 F.3d 1195, 1204-08 (D.C. Cir. 2019). The court determined that when Congress barred "challenges to the 'establishment of payment amounts'" under Medicare, it did *not* "prevent review of the rule delineating the data collection practices that precede and inform the setting of those amounts." *Id.* at 1205. Distinguishing many of the cases cited by CMS here, the court explained that the review bar did not "subsume the data collection process" nor was "the gathering of data … 'inextricably intertwined' with the establishment of payment rates." *Id.* at 1206.

The D.C. Circuit distinguished between determinations that fell within the agency's unreviewable judgment—such as deciding how to perform a calculation or make an estimate—and separate statutory obligations that Congress imposed on the agency and would expect a court to enforce. The same logic applies here. Congress's limit on the number of products CMS may subject to price controls is neither subsumed in nor inextricably intertwined with either CMS's determinations of *which* products meet certain expenditure thresholds or

which products to select for price controls after ranking them based on its expenditure calculations. *See* 42 U.S.C. § 1320f-1(a), (d), (e).

If CMS were correct, it could subject an unlimited number of products to price controls by rewriting the statute's definitions through binding "guidance." For example, CMS could redefine "negotiation-eligible drug" to encompass all products that have a common indication or therapeutic use—sweeping together all cancer medications, pain killers, or heartburn medications. That would violate the statute, but according to CMS there is nothing any court could do about it.

The same logic and reasoning make short work of CMS's argument against reviewing its violation of the IRA's guidance-only mandate. In challenging CMS's "guidance," Novo Nordisk is not challenging CMS's determinations as to *which* particular drug or biological products meet the statutory expenditure requirements necessary to be excepted or exempted from price controls or *which* of the remaining products to select for price controls. *Cf. Yale New Haven Hosp. v. Becerra*, 56 F.4th 9, 26 (2d Cir. 2022) (holding that a provision precluding review of an "estimate" precluded both substantive and procedural challenges to that estimate). Novo Nordisk instead challenges CMS's unlawful promulgation of

binding substantive requirements without complying with the APA or Medicare Act. Many of the requirements in CMS's guidance are not even plausibly related to any review-barred determination—such as CMS's extra-statutory requirements regarding the confidential information manufacturers must submit. *See* Dkt. 28-1 at 37.

In any event, even if the review bars could be read to implicitly preclude review, the Court can still review CMS's actions because the agency has "'disregarded a specific and unambiguous statutory directive'" and violated a "'specific command' of a statute." *Griffith v. Fed. Lab. Rels. Auth.*, 842 F.2d 487, 493 (D.C. Cir. 1988). Contrary to CMS's assertions, Novo Nordisk's claims are not expressly precluded by any review bar, and the IRA's 10-drug limit for 2026 is as clear a mandate as one could imagine. *Id.*; *Am. Hosp. Ass'n v. Azar*, 964 F.3d 1230, 1238 (D.C. Cir. 2020). Violating that mandate is *ultra vires* action that courts are entitled—and obligated—to correct.

2. Novo Nordisk has standing.

CMS does not defend the district court's ruling that Novo Nordisk lacks standing to challenge CMS's violation of the IRA's 10-drug-limit.

Appx10-11. Novo Nordisk's standing is "self-evident" because its products are an "object" of the challenged agency action. Op.Br. 34-38.

In a footnote, CMS raises the same argument it advanced before the district court—not that Novo Nordisk lacks standing to mount a challenge at all, but that any relief should be limited to Novo Nordisk because courts lack jurisdiction to set aside agency action in a way that would benefit third parties. *See* Resp.Br. 38 n.3. This "far-reaching argument that the APA does not allow vacatur" defies the APA's plain text and decades of Supreme Court precedent. *Corner Post, Inc. v. Bd. of Governors of Fed. Rsrv. Sys.*, 603 U.S. 799, 827 (2024) (Kavanaugh, J., concurring); Op.Br. 36-38. It also ignores precedent, which recognizes that vacatur is especially appropriate when otherwise the Court would be "legally sanction[ing] an agency's disregard of its statutory or regulatory mandate." *Comité de Apoyo a Los Trabajadores Agricolas v. Perez*, 774 F.3d 173, 191 (3d Cir. 2014).

The Court should accordingly vacate CMS's unlawful actions and direct CMS to comply with the IRA's 10-drug limit and guidance-only mandate.

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

The Constitution provides interconnected safeguards—including due process, separation of powers, and freedom of speech—to protect private rights and the public interest. CMS purports to "disentangle[]" these constitutional issues, seeking to defend each aspect of its novel scheme in isolation. Resp.Br. 50. But recognizing that simultaneous deviations from constitutional norms are often more pernicious than the sum of their parts, the Supreme Court has rejected CMS's approach and instructed courts "to review separation-of-powers challenges holistically." *Consumers' Rsch. v. FCC*, 109 F.4th 743, 778 (5th Cir. 2024) (en banc) (discussing Supreme Court precedent).

The IRA departs on multiple dimensions from constitutional requirements. It lacks procedures to ensure that CMS-imposed prices are neither arbitrary nor confiscatory; it has no statutory baseline to govern the agency's price-setting decisions; it provides no review before a neutral adjudicator; and it forces regulated parties to speak the government's preferred message. These departures are all independent constitutional violations but, at a minimum, combining these features *together* in a single statutory scheme violates the Constitution. CMS has

not identified any statute or executive action—even in wartime emergencies—that disregards so many Constitutional safeguards all at once. *See Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 505 (2010) (a "telling indication of [a] severe constitutional problem … is the lack of historical precedent").

A. CMS Has Violated Due Process and the Separation of Powers.

1. CMS does not dispute that the IRA lacks any procedures to ensure that CMS's price setting complies with due process. *See* Op.Br. 52. CMS instead contends that no due process protections apply because regulating the price of Novo Nordisk's products purportedly does not interfere with Novo Nordisk's rights. In fact, Novo Nordisk has a property interest in both its drugs and its proprietary information, and CMS's actions interfere with both.

As applied by CMS, the IRA requires Novo Nordisk to provide "access" to its drugs to more than 60 million Americans at CMS-imposed "maximum fair prices" (or else face enterprise-threatening penalties or be forced to remove *all* of its products from federal healthcare programs). 42 U.S.C. § 1320f-2. Even CMS admits that when a statutory scheme compels a company "to provide" its property to third parties, the Due

Process Clause applies. Resp.Br. 54-55. As courts have recognized, private parties have a "right … to fix the price at which [they] will sell" their products. *Old Dearborn Distrib. Co. v. Seagram-Distillers Corp.*, 299 U.S. 183, 192 (1936). Where the government interferes with that right, due process requirements are implicated. *Bowles v. Willingham*, 321 U.S. 503, 513-14 & n.9 (1944).

CMS argues that "Novo [Nordisk] remains free to sell its drugs—at any price—to any willing buyer" and that the IRA merely "establishes the maximum prices the *government* will pay for certain drugs." Resp.Br. 55 n.5. The IRA's text says otherwise. The government is not purchasing the products for itself; it is serving as an insurer and, in that role, regulating the prices of products sold to more than 60 million Medicare-eligible citizens. The statute requires manufacturers to provide "access" to the CMS-imposed price to "maximum fair price eligible *individuals*" and "hospitals, physicians, and other providers of services and suppliers with respect to" such individuals. 42 U.S.C. § 1320f-2(a)(3). The IRA does not limit the amount of money the government pays for its own purchases; instead, it expressly limits the

amount of money manufacturers can charge to millions of individuals and their providers. That is a quintessential price-setting scheme.

Due process protections likewise attach when the government demands that a party turn over proprietary commercial information. *See* Resp.Br. 56 n.6 (discussing "interest in [Novo Nordisk's] proprietary commercial information"); *Axon Enter., Inc. v. FTC*, 598 U.S. 175, 204 (2023) (Thomas, J., concurring). CMS has no response, except to contend that the argument was not raised. Resp.Br. 56 n.6. That is incorrect. As Novo Nordisk's opening brief explains, CMS "forced [the company] to turn over highly sensitive, confidential trade secret and commercial information to CMS." Op.Br. 35; Appx14 (district court acknowledging Novo Nordisk's argument that it has "a property interest … in the confidential information that CMS is forcing it to disclose").

Contrary to CMS's suggestions, Novo Nordisk does not contend that it can sell its products at any price it wants. Instead, it argues that the price either has to be set by the free market or, if it is to be set by the government, through a constitutionally permissible process. Novo Nordisk also argues that CMS cannot force it to turn over confidential, proprietary information or subject it to other binding substantive

requirements without following constitutionally adequate procedures. The government cannot take over a market, regulate prices sold in that market, and then fail to comply with due process requirements necessary to protect private rights and the public interest.

2. The lack of adequate procedures is compounded by the IRA's failure to include any substantive standards to govern CMS's price-setting decisions: CMS has unfettered discretion to set as low a price as it wants, and the statute bars judicial review of the price CMS imposes. Op.Br. 52-55. CMS suggests that separation-of-powers constraints are a relic from another time. Resp.Br. 51; *but cf. Consumers' Rsch.*, 109 F.4th at 778. In fact, the Supreme Court's separation-of-powers precedent remains binding, and statutes conferring "virtually unfettered" discretion on agencies remain unconstitutional. *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 532-33, 542 (1935); *see also Yakus v. United States*, 321 U.S. 414, 426 (1944) (standards must be "sufficiently definite and precise to enable Congress, the courts and the public to ascertain" whether the agency "has conformed").

The separation-of-powers concerns are pronounced here because the IRA lacks any historical precedent. *See Free Enter.*, 561 U.S. at 505.

CMS points to a handful of *procurement* regimes run by the Department of Defense and related agencies that are nothing like the IRA. *See* Resp.Br. 1, 9-10, 60-61. CMS does not argue that any of those regimes lack procedural protections or bar judicial review. *See* 38 U.S.C. § 8126(a)-(h) (containing no judicial review bar); *Coal. for Common Sense in Gov't Procurement v. Sec'y of Veterans Affs.*, 464 F.3d 1306, 1312, 1317 (Fed. Cir. 2006) (reviewing agency's interpretation of 38 U.S.C. § 8126). More fundamentally, none of CMS's examples empower a government agency to set the prices at which millions of *individuals* can access a manufacturer's products. 42 U.S.C. §§ 1320f-2(a)(3), 1320f(c)(2) (defining "maximum fair price eligible individual"). CMS's reliance on procurement regimes and the "defense industry … analogy" only underscores the IRA's novelty. Resp.Br. 61. CMS is not buying drugs (or warships or weapons) for the government; it is acting as an *insurer* and, in that role, regulating prices of products sold in interstate commerce to non-governmental entities. The IRA's plain text makes clear that CMS *is* limiting what Novo Nordisk may charge to private citizens and providers. 42 U.S.C. § 1320f-2(a)(3).

CMS cannot find an adequate analogy because there is none. CMS is targeting a discrete group of drug manufacturers and forcing them to sell their products to tens of millions of people at whatever price CMS dictates. The price setting occurs without procedures to ensure constitutionally permissible prices, without congressionally imposed standards, without a neutral adjudicator, and without judicial review. The unprecedented scheme—unlike any example that CMS cites—is unconstitutional. *See Free Enter.*, 561 U.S. at 505.

B. CMS's "Voluntariness" Arguments Fail.

CMS does not dispute that the IRA violates the Constitution if, as Novo Nordisk contends, manufacturers are compelled to turn over their property at whatever price the agency dictates. CMS instead asserts that the Constitution is irrelevant because, in its view, the IRA's novel price-control scheme is entirely "voluntary." Resp.Br. 56-63. That is wrong, for multiple reasons.

1. Parties "cannot by consent cure" violations of the Constitution's structural guarantees. *Commodity Futures Trading Comm'n v. Schor*, 478 U.S. 833, 850-51 (1986). The separation of powers "not only preserves to litigants their [private] interest[s]"; it "also serves

as an inseparable element of the constitutional system of checks and balances." *Id.* at 850. Due process requirements serve a similar function, as adequate procedures are essential to ensure that executive officials do not engage in unconstitutional deprivations. *Murray's Lessee v. Hoboken Land & Improvement Co.*, 59 U.S. (18 How.) 272, 276 (1855) (due process ensures that the executive acts in accord with the "law of the land").[2] Accordingly, regardless of whether the IRA's price controls are characterized as voluntary, manufacturers are entitled to press their due process and separation-of-powers challenges because CMS-imposed price controls substantially "affect[]" manufacturers' "businesses" and there are no adequate front-end or back-end protections to ensure that CMS acts in accordance with law. *See Nat'l Infusion Ctr. Ass'n v. Becerra*, 116 F.4th 488, 503 (5th Cir. 2024).

2.. In any event, the IRA's price-control scheme is coercive, not voluntary. CMS is compelling Novo Nordisk to turn over its products to millions of individuals and providers at an artificially low price. And

[2] Consistent with these principles, the Supreme Court has repeatedly applied a due-process analysis when evaluating public programs. *See Matthews v. Eldridge*, 424 U.S. 319 (1976) (social security benefits); *Goss v. Lopez*, 419 U.S. 565 (1975) (public school suspension); *Slochower v. Bd. of Higher Educ.*, 350 U.S. 551 (1956) (public employment).

Novo Nordisk can avoid CMS's price controls only by paying an enterprise-threatening penalty, halting sales of its drug in all channels, or having *all* of its products kicked out of Medicare and Medicaid. Actions taken under threat of taxes or fines are not voluntary. Op.Br. 59. Nor are actions voluntary when the only option to avoid regulation is by exiting the market. *Id.* CMS does not contest either of these points.

3. CMS nonetheless contends that it is entitled to force manufacturers—as a condition of selling their products to the millions of Americans who participate in Medicare and Medicaid—to relinquish their constitutional rights because those programs provide "financial benefits." Resp.Br. 60. That position cannot be squared with precedent or the reality of how the IRA's price-control regime operates.

The Constitution prohibits the government from "withhold[ing] [a] benefit because someone refuses to give up constitutional rights." *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 608 (2013). Nor can the government use public benefits to "pressure [a] person into doing" what "the government could not have constitutionally ordered the person asserting the claim to do." *Id.* at 612; *Sheetz v. County of El Dorado*, 601 U.S. 267, 279 (2024) (the unconstitutional conditions doctrine applies in

a wide range of contexts). To satisfy the unconstitutional-conditions doctrine, the government must establish "a nexus and rough proportionality between the government's demand" and the conditioned benefit. *Koontz*, 570 U.S. at 599 (quotation marks omitted).

CMS does not even attempt to meet that standard. In *National Federation of Independent Business v. Sebelius*, the Supreme Court held that Congress could not condition a state's participation in Medicaid on its acceptance of new regulatory conditions. 567 U.S. 519, 578, 581, 587 (2012). CMS responds that *NFIB* turned on federalism concerns. Resp.Br. 57-58. But CMS fails to explain why federalism is more important than other constitutional rights. And, in any event, this Court has already noted that *NFIB*'s reasoning applies "[s]imilarly" to non-state actors. *See Doe v. Univ. of Scis.*, 961 F.3d 203, 213 (3d Cir. 2020).

4. The Supreme Court's constitutional-conditions doctrine thus confirms what is plain from CMS's implementation of the IRA. A long list of CMS actions establishes that the agency is exercising sovereign regulatory powers that no ordinary market participant ever could.

- Congress legislated monopsonistic control, allowing the government to "dominate[] the healthcare market." *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 699 (3d Cir. 2023).

- CMS forced manufacturers to turn over proprietary information during negotiations. *See* 42 U.S.C. § 1320f-2(a)(4).

- CMS forced manufacturers to agree to comply with any future guidance it may issue, allowing it to unilaterally amend the agreement's terms at will. *See* Appx175-179.

- Federal law prevents manufacturers from withdrawing from CMS's price-control program for months. *See* 42 U.S.C. §§ 1395w-114a(b)(4)(B)(ii), 1395w-114c(b)(4)(B)(ii).

- If a manufacturer wants to withdraw its price-controlled drug from Medicare, CMS forces the manufacturer to withdraw its entire portfolio of products. *See* 26 U.S.C. § 5000D(c); *cf. Allen-Myland, Inc. v. Int'l Bus. Machs. Corp.*, 33 F.3d 194, 200 (3d Cir. 1994) (explaining antitrust prohibition on "tying" products).

- CMS has the authority to levy crippling monetary penalties if manufacturers do not agree to its demands. *See* 42 U.S.C. §§ 1320f-2(a)(5), 1320f-6(c).

- CMS controls the prices for sales to third parties—*i.e.*, individuals enrolled in Medicare and their providers. 42 U.S.C. § 1320f-2(a)(3).

These actions show that CMS is not operating as a mere market participant seeking to procure goods for the government, but rather that CMS is regulating the prices that Novo Nordisk is permitted to charge millions of Americans who obtain medical insurance through the federal government. *See S.-Cent. Timber Dev., Inc. v. Wunnicke*, 467 U.S. 82, 98-99 (1984) (the Constitution places greater restraints on the government acting "as a market regulator" than "as a market participant"). Because

CMS's price control regime is not voluntary, and because CMS has no other defense on the merits, the statute is unconstitutional.

C. The IRA Unconstitutionally Compels Speech.

Confirming that the IRA is coercive, the statute forces Novo Nordisk to express the government's preferred viewpoint—that it "agree[s]" that the imposed price is the "maximum fair" price. 42 U.S.C. § 1320f-2(a). This gratuitous compelled-speech requirement is also unconstitutional.

CMS asserts that free speech is not implicated because manufacturers voluntarily enter into the agreements. Resp.Br. 63. As explained above, the price-control scheme is not voluntary. CMS's argument is even weaker in the First Amendment context, where Congress cannot "demand[] that funding recipients adopt—as their own—the [g]overnment's view on an issue of public concern" even where the requirement is not "actually coercive, in the sense of an offer that cannot be refused." *USAID v. All. for Open Soc'y Int'l, Inc.*, 570 U.S. 205, 214, 218 (2013).

CMS next contends that requiring Novo Nordisk to "agree" that CMS's price is the "maximum fair price" does not implicate protected

speech. But CMS does not cite any case holding that forced written expressions in contracts cannot qualify as compelled speech under the First Amendment. Its argument also contradicts *USAID*. There, the Supreme Court struck down a requirement that a recipient of government funding "*agree in the award document* that it is opposed to 'prostitution and sex trafficking because of the psychological and physical risks they pose.'" *Id.* at 210 (emphasis added). Relatedly, the Supreme Court has distinguished between a law that regulates "how sellers may communicate their prices" (protected speech) with "mine-run price regulation" that "regulate[s] the amount that a [seller] could collect" (incidentally burdening what the seller *says* the product costs). *Expressions Hair Design v. Schneiderman*, 581 U.S. 37, 47 (2017).

CMS also contends that the phrase "maximum fair price" "do[es] not convey … any view regarding the value of the[] drugs." Resp.Br. 64. That defies the words' "ordinary meaning." *Wis. Cent. Ltd. v. United States*, 585 U.S. 274, 277 (2018). "Fair" is not a neutral term of art; it is descriptive word fraught with subjective meaning, and the government knew that forcing manufacturers to "agree" that CMS-dictated prices were "fair" (and that no higher price would be "fair") would have

consequences. *See* Appx44. The government could have mitigated this free speech violation had it simply used the phrase "maximum price," but instead it chose to force manufacturers to "agree" that the imposed price is "fair." Even CMS's cases show that "fair" has substantive meaning. *See United States v. Gen. Dynamics Corp.*, 19 F.3d 770, 771 (2d Cir. 1994) (referencing a statutory provision requiring evidence "that the negotiated price is fair and reasonable"). This compelled speech requirement is an attempt by the government to avoid accountability for the consequences of CMS's price controls.

Finally, CMS relies on boilerplate disclaimers stating that signing an agreement does not reflect an "endorsement of CMS's views" or represent the manufacturers' view on negotiation and fairness. Resp.Br. 65 (quoting Appx178). But this Court has explained that issuing "a general disclaimer along with the [required] recitation does not erase the First Amendment infringement at issue." *Circle Sch. v. Pappert*, 381 F.3d 172, 182 (3d Cir. 2004).

CONCLUSION

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

Respectfully submitted,

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January 3, 2025

CERTIFICATE OF COMPLIANCE

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

2. This brief complies with the type-volume requirements of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 6,495 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f).

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

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

Date: January 3, 2025

/s/Ashley C. Parrish
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CERTIFICATE OF SERVICE

I hereby certify that on January 3, 2025, I electronically filed the foregoing document with the Clerk of the Court for the United States Court of Appeals for the Third Circuit by using the CM/ECF system, thereby serving all registered counsel of record.

/s/Ashley C. Parrish
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RELEVANT STATUTORY PROVISIONS

STATUTORY PROVISION	SECRETARY'S AUTHORITY	REVIEW BAR
42 U.S.C. § 1320f note: "IMPLEMENTATION FOR 2026 THROUGH 2028.—The Secretary of Health and Human Services ***shall implement*** this section, including the amendments by this section, for 2026, 2027, and 2028 ***by program instruction or other forms of program guidance***."	Statute directs Secretary to implement through program guidance until 2029.	None.
42 U.S.C. § 1320f-1 (a): "IN GENERAL.—Not later than the selected drug publication date … the Secretary shall select and publish a list of—(1) with respect to the initial price applicability year 2026, ***10 negotiation-eligible drugs***… with respect to such year (or, all (if such number is less than 10) such negotiation-eligible drugs with respect to such year) …."	Statute permits price controls to be imposed on no more than 10 drug or biological products.	None.

RELEVANT STATUTORY PROVISIONS

42 U.S.C. § 1320f-1(b): SELECTION OF DRUGS.— "(1) IN GENERAL.—In carrying out subsection (a) …, the Secretary shall, with respect to an initial price applicability year, … (A) Rank negotiation-eligible drugs described in subsection (d)(1) according to ***total expenditures*** for such drugs …, ***as determined by the Secretary*** …with the negotiation-eligible drugs with the highest ***total expenditures*** being ranked the highest" and "(B) Select from such ranked drugs with respect to such year the negotiation-eligible drugs with the highest such rankings."	Statute directs Secretary to "rank" and "select" drugs according to highest total expenditures, as "determined" by the Secretary.	42 U.S.C. § 1320f-7: "There shall be no administrative or judicial review of … (2) The selection of drugs under section 1320f-1(b)…."

RELEVANT STATUTORY PROVISIONS

42 U.S.C. § 1320f-1(d): NEGOTIATION-ELIGIBLE DRUG "(1) IN GENERAL—For purposes of this part, subject to subparagraph (2), ***the term 'negotiation-eligible drug' means*** … ***a qualifying single source drug as defined in subsection (e)*** that is "among the 50 qualifying single source drugs with the highest ***total expenditures*** …, ***as determined by the Secretary*** …." for Part B or Part D drugs. "(2) ***EXCEPTION*** FOR SMALL BIOTECH DRUGS—… (A) [T]he term 'negotiation-eligible drug' ***shall not include***, with respect to initial price applicability years 2026, 2027, and 2028, a qualifying single source drug that … (i) [t]he ***total expenditures*** … under part D …, ***as determined by the Secretary*** …" meet certain percent thresholds or (ii) [t[he ***total expenditures*** … under part B …, ***as determined by the Secretary*** …" meet certain percentage thresholds."	Statute defines "negotiation-eligible drug" to mean a "qualifying single source drug as defined in subsection (e) that is also among the 50 drug or biological products with the highest total expenditures, as "determined" by the Secretary. Statute authorizes the Secretary to apply "exception" to drug or biological products that meet certain total expenditure thresholds, as "determined" by the Secretary	42 U.S.C. § 1320f-7: "There shall be no administrative or judicial review of … (2) the determination of negotiation-eligible drugs under section 1320f-1(d) …."

RELEVANT STATUTORY PROVISIONS

42 U.S.C. § 1320f-1(e): QUALIFYING SINGLE SOURCE DRUG.— "(1) IN GENERAL.—For purposes of this part, ***the term 'qualifying single source drug' means***, with respect to an initial price applicability year … a covered part D drug … or a drug or biological product for which payment may be made under part B that is described in any of the following: (A) ***DRUG PRODUCTS***.—A drug— (i) that is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act and is marketed pursuant to such approval; (ii) for which … at least 7 years have elapsed since the date of such approval; and (iii) that is not the listed drug for any drug that is approved and marketed under section 505(j) off such Act. (B) ***BIOLOGICAL PRODUCTS***.—a biological product— (i) that is licensed under section 351(a) of the Public Health Service Act and is marketed under section 351 of such Act; (ii) for which … at least 11 years have elapsed since the date of such licensure; and (iii) that is not the reference product for any	Statute defines "qualifying single source drug" to mean drug or biological products approved or licensed by FDA for 7 or 11 years, respectively, that are not subject to generic or biosimilar competition. Statute authorizes the Secretary to "exclude" certain low spend Medicare drugs from the definition if they meet certain total expenditure amounts, as "determined" by the Secretary.	42 U.S.C. § 1320f-7: "There shall be no administrative or judicial review of … (2) the determination of qualifying single source drugs under section 1320f-1(e) …."

biological product that is licensed and marketed under section 351(k) of such Act. …" (3) ***EXCLUSIONS***.—In this part, ***the term 'qualifying single source drug' does not include*** any of the following: (A) CERTAIN ORPHAN DRUGS.—A drug that is designated as a drug for only one rare disease or condition under section 526 of the Federal Food, Drug, and Cosmetic Act and for which the approved indication (or indications) is for such disease or condition. (B) LOW SPEND MEDICARE DRUGS.—A drug or biological product with respect to which the ***total expenditures*** under Parts B and D …, ***as determined by the Secretary*** …" meet certain amounts.		