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' REPLY IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT AND RESPONSE TO DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

The brief filed by the Centers for Medicare & Medicaid Services ("CMS") confirms that the agency is unable to defend either its actions or the Inflation Reduction Act ("IRA") on their own terms. No one disputes the government has general authority to decide how much to pay when purchasing products for its own use. But imposing price controls and confidential-information disclosure requirements on targeted manufacturers for the benefit of private purchasers—such as the millions of patients who participate in Medicare—poses particular challenges for the rule of law. When imposing price controls, CMS must comply with Congress's statutory commands, and Congress must comply with constitutional requirements essential for ensuring lawful, transparent, and accountable government. CMS has no authority to violate or rewrite the IRA's mandates or to unilaterally exempt itself from the requirements of the Administrative Procedure Act ("APA"). Congress cannot delegate unchecked price-setting authority to CMS with no cognizable standards to constrain the agency and no procedures to protect against arbitrary or confiscatory prices. Nor can it coerce manufacturers into speaking the government's preferred message—forcing them to agree that the imposed price is a "maximum fair" price—or else face penalties so massive that no manufacturer could afford to pay them.

First, the Court should vacate CMS's guidance and other actions because CMS has violated the statute. Congress granted CMS limited authority to impose price controls on no more than 10 eligible 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 (for drug products) or 11 years (for biological products). CMS has violated those mandates by imposing price controls on at least 15 different drug and biological products, including products that have not been approved or licensed for the requisite 7 or 11 years. As it relates to Novo Nordisk ("Novo"), CMS has redefined and recharacterized Novo's FIASP® biological products as one and the same as Novo's Novolog® products, even though the FIASP® products were developed and approved separately and are wholly distinct products with different clinical profiles.

CMS contends that it is entitled to disregard Congress's mandates and impose price controls on groups of products that contain the same "active moiety" or "active ingredient." But there is no textual support for its position. The statute permits aggregation only for limited purposes and only across products with different dosage forms and strengths. Those provisions do not apply here and, even if they did apply, they do not allow CMS to aggregate products that differ by device presentation, route of administration, clinical use profiles, or other characteristics.

CMS contends that Novo's challenges are foreclosed by the statute's judicial review bars, but the precise numerical requirements that CMS has violated are not within the scope of those bars. CMS's limited discretion to decide *which* products to select does not override Congress's clear direction that *no more than 10* products are "eligible" for price controls in 2026. Judicial review bars must be interpreted narrowly and, in all events, do not apply when an agency violates express statutory mandates.

Second, the Court should vacate CMS's guidance because it imposes new legal obligations on manufacturers without complying with the APA's notice-and-comment requirements. CMS acknowledges that its guidance imposes new substantive obligations, but it identifies nothing in the IRA that exempts CMS from the APA. CMS appears to believe it has *carte blanche* to make new law—changing statutory definitions, imposing new burdensome information disclosure requirements, and imposing other regulatory obligations—with no procedures to ensure that CMS stays within the bounds of its authority. The agency again has no support for its position. CMS cannot unilaterally opt out of the APA's requirements, which are essential to ensuring that agencies do not exercise improper lawmaking authority.

Third, the IRA's price-control program is unconstitutional because it combines a sweeping and improper delegation of price-setting authority with no judicial review, a lack of procedures to protect against arbitrary and confiscatory prices, and a compelled-speech requirement. CMS asserts that no court has struck down a statute on non-delegation grounds for 90 years, but the IRA is unprecedented, and CMS's position is inconsistent with the Supreme Court's most recent separation-of-powers precedents. CMS is unable to identify any statute that has ever been upheld that simultaneously strips away so many layers of essential constitutional protections. CMS instead invites the Court to ignore the IRA's constitutional violations because participation in its price-control scheme is purportedly "voluntary." But that misdirection does not help CMS, as the IRA's provisions are intentionally coercive, there is no practical way to avoid

CMS's price controls, and parties cannot waive structural constitutional protections. Nor can they be forced to relinquish constitutional rights in return for selling their products in interstate commerce. The 10 manufacturers targeted by CMS have no ability to escape the IRA's price-control process without facing impossible fines and being forced to stop selling *all* of their products to millions of patients. The government cannot take over half the nation's drug market and then strong-arm a targeted group of manufacturers into surrendering their constitutional rights by threatening massive penalties that no manufacturer could afford to pay.

ARGUMENT

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

CMS has exceeded its statutory authority because it has imposed price controls on more products than Congress authorized and on products that Congress expressly determined were not eligible. Because the result is an ultra vires regulatory action that violates the statute's express requirements, no judicial review bar applies.

A. CMS Has Imposed Price Controls on Products that Congress Specifically Excluded as Not Eligible.

CMS's position—that it is entitled to (1) group together multiple products because they contain the same "active moiety" or "active ingredient" and (2) rewrite the definitions that FDA applies when approving and licensing products—violates the statute's plain text. The IRA authorizes CMS to impose price controls in 2026 on no more than "10 negotiation-eligible drugs." 42 U.S.C. § 1320f-1(a). The statute also

specifies that a negotiation-eligible drug is either (1) a "drug *product*" that has been *approved by FDA* under section 505(c) of the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(c), *for at least 7 years*, or (2) a "biological *product*" that has been *licensed by FDA* under section 351(a) of the Public Health Service Act ("PHSA"), 42 U.S.C. § 262(a), *for at least 11 years*. 42 U.S.C. § 1320f-1(e)(1)(A)(ii), (B)(ii) (emphasis added).

CMS has violated these express mandates. It has grouped together 6 different Novo biological products as a single "product" merely because they contain the same "active ingredient," even though they are distinct products that were approved at different times, have different presentations, and come from entirely different product families with clinically meaningful differences. *See* Laney Decl. ¶¶ 30–46; Hauda Decl. ¶¶ 26–41. CMS has also sought to impose price controls on biological products—including all of the products in the FIASP® family of products—that have not been licensed for at least 11 years. *See* Hauda Decl. ¶ 38. Indeed, it is telling that CMS's brief makes only passing reference to the FIASP® products (on pages 11 and 22), and then inaccurately refers to all of the different products uniformly as Novolog®. But the unrebutted evidence shows that the FIASP® and Novolog® products were developed, approved, and licensed through different FDA applications, involving various and different clinical trials, and with clinically meaningful differences for patients. *See* Laney Decl. ¶¶ 30–46; Hauda Decl. ¶¶ 26–41.

CMS does not dispute that it is subjecting more than 10 products to price controls in 2026. It concedes that the IRA never refers to "active moiety" or "active ingredient." Opp. 24. It acknowledges that, under the sections of the FDCA and PHSA referenced in the IRA, FDA approves or licenses specific *products* and not *groupings of products*. *See* Opp. 21 ("FDA approves drugs and biologics on a product-by-product basis"). Nor does CMS dispute that several of the Novo biological products have not been licensed for the required 11 years. It says nothing about the significant structural and clinical differences between the distinct Novolog® and FIASP® products.

CMS instead urges the Court to brush aside the statute's precise numerical requirements as mere "contextual clues." *Id.* It argues that when Congress directed the agency to impose price controls on no more than 10 drug or biological "products," it *sub silentio* intended CMS to group together all drug products with the same active moiety and all biological products with the same active ingredient. According to CMS, when Congress directed the agency to impose price controls only on products "approved" and "licensed" by FDA, Congress expected CMS to devise its own definitions rather than applying those terms as understood by FDA when approving and licensing products. CMS's implausible positions cannot be reconciled with the statute's text, controlling precedent, or settled expectations.

1. The Supreme Court interpreted section 355 of title 21—the same statutory section referenced in the IRA—more than thirty years ago. It recognized then that"[t]he term 'drug' is *plainly* intended … to include entire drug products, complete

with active and inactive ingredients." *United States v. Generix Drug Corp.*, 460 U.S. 453, 459 (1983) (emphasis added). The term "new drug" in the drug approval context does not refer "only to the active ingredient in a drug product," but rather to "the entire product." *Id.* at 454. When FDA approves a drug product or licenses a biological product, its decision applies only to that specific product in finished dosage form; it does not sweep in every product that contains the same active moiety or same active ingredient. *See* Novo Br. 19–20.

CMS does not even attempt to distinguish *Generix*. CMS instead contends that because the IRA does not "directly" define "drug," it is free to invent its own definitions. *See* Opp. 24. But when the Supreme Court has "given a term or concept a consistent judicial gloss," this Court should "presume Congress intended the term or concept to have that meaning when it incorporated it into a later-enacted statute." *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 243 (2011); *Ysleta Del Sur Pueblo v. Texas*, 596 U.S. 685, 701 (2022) ("[w]hen the words of the Court['s interpretation] are used in a later statute governing the same subject matter, it is respectful of Congress and of the Court's own processes to give the words the same meaning in the absence of specific direction to the contrary"). With no case to support its position, CMS is left pointing to a letter from the Congressional Budget Office in December 2023—six months *after* the agency issued its guidance. Opp. 24 n.4. That the Congressional Budget Office assumed CMS would apply its own definition when predicting the law's effect says nothing about what the statute requires or what Congress intended.

Contrary to CMS's position, the statute is clear that Congress intended CMS to impose price controls on 10 individual products and not on aggregated groupings of products: the statute refers expressly to "drug *products*" and "biological *products*." 42 U.S.C. § 1320f-1(e) (emphasis added). Nothing in the IRA mentions "active moiet[ies]" or "active ingredients," even though Congress knows well how to use those terms. 21 U.S.C. § 355(c)(3)(E)(ii), (iii); *see also Actavis Elizabeth LLC v. FDA*, 625 F.3d 760, 762–63, 766 (D.C. Cir. 2010) (discussing exclusivities tied to active moieties). By acknowledging that "Congress specified that [a negotiation-eligible drug] must be a 'covered part D drug' that is approved—or a 'biological product' that is licensed—by the FDA," Opp. 21, CMS all but admits that the IRA adopted the product-specific meaning of the terms "drug products" and "biological products" that FDA has long applied when making it product-specific approval and licensing decisions.

2. Other IRA provisions confirm that Congress intended CMS to apply the statute's terms consistent with Supreme Court precedent and FDA practice. The statute mandates that drug and biological products, respectively, are eligible for price controls *only if* they have been approved or licensed by FDA for at least 7 or 11 years. 42 U.S.C. § 1320f-1(e)(1). That requirement is significant because it is undisputed that FDA approves and licenses drugs and biologics "on a product-by-product basis." Opp. 21; *see also* 86 Fed. Reg. 28,605, 28,606 (May 27, 2021) (explaining that for decades FDA "has interpreted the word 'drug' in the term 'new drug' to refer to the entire drug product and not just its active ingredient"). Under a product-specific definition, that

provision makes sense, as each specific product has a date of approval or licensure. Under CMS's view, however, even if a biological product is approved less than 11 years ago, that product is eligible for price controls as long as it shares an active ingredient with a different biological product that was approved more than 11 years ago. CMS has no justification for this improper administrative bootstrapping, except to assert that the statute's critical time limitation does not require looking at "a single *relevant* approval or licensure date." Opp. 25. That impermissibly reads into the statute words that do not exist. *See Biden v. Nebraska*, 600 U.S. 477, 499 (2023) (agencies may not "red pencil[] … existing law").

CMS also cannot reconcile its position with the IRA's express mandate that a product is not eligible for price controls if it is the "listed drug" for any approved and marketed generic drug product, or if it is the "reference product" for any licensed and marketed biosimilar biological product. *See* 42 U.S.C. § 1320f-1(e)(1)(A)(iii), (B)(iii). A "reference product" is not an "active ingredient" but "a particular combination of strength, dosage form, and route of administration for a particular biological product." Mustafa Ünlu, FDA, No. 5255171, Memorandum on Expiration of First Interchangeable Exclusivity ("FIE") When Section 351(l)(6) Litigation Ends Prior to the Submission of an Application for Interchangeability at 3 n.8 (Oct. 3, 2023) ("Ünlu Mem."). Similarly, CMS has no answer to the statutory provisions making clear that, for 2026 and 2027, CMS may impose price controls only on 10 *Part D* products (and not Part B products). *See* 42 U.S.C. § 1320f-1(a)(1)–(3). By redefining product to mean

active-ingredient or active-moiety, CMS has imposed price controls not only on Part D high-spend products *but also* on products not covered by Part D (or only minimally so). *See* Novo Br. 23–24. CMS says that it is "immaterial" "whether a particular drug might also be reimbursed under Part B," Opp. 28, but that ignores Congress's clear statutory exclusion of Part B drugs from price controls for the first two years. *Compare* 42 U.S.C. § 1320f-1(a)(1), (2) with *id.* § 1320f-1(a)(3), (4).

Nor does CMS explain why the Court should interpret the IRA to undermine the regulatory exclusivities that Congress created to incentivize innovation. For example, FDA determines eligibility for a three-year "new clinical investigation[]" exclusivity on a product-specific basis, *see* Novo Br. 25–26, as it does with first interchangeable exclusivity for biological products, *see* Ünlu Mem. at 3. CMS's definition would nullify these exclusivities by exposing new products to price controls *immediately*, merely because they contain the same active moiety or active ingredient as another product. In construing a statute, a court must "respond[] to [the] obligation to avoid conflicts between two statutory regimes ... that in some respects overlap," *Pittsburgh & Lake Erie R.R. v. Ry. Lab. Executives' Ass'n*, 491 U.S. 490, 510 (1989), and apply "rules aiming for harmony over conflict" when interpretating co-existing statutory schemes, *Epic Sys. Corp. v. Lewis*, 584 U.S. 497, 511 (2018). The product-specific definition, as applied by both the Supreme Court and FDA, allows for these two schemes to operate in harmony; CMS's approach does not.

3. The only statutory text CMS identifies in support of its novel position is the IRA's drug-aggregation provisions. *See* Opp. 22–23. But those provisions authorize CMS to aggregate in only three limited instances—none of which apply here: *First*, in the "use of data" provision, the IRA states that "[i]n determining whether a qualifying single source drug" qualifies as a "high spend" drug, CMS "shall use data that is aggregated across dosage forms and strengths *of the drug*, including new formulations *of the drug*, such as an extended release formulation, and not based on the specific formulation or package size or package type *of the drug*." 42 U.S.C. § 1320f-1(d)(1), (3)(B) (emphasis added). *Second*, "[f]or purposes of negotiating the maximum fair price of a selected drug," CMS "shall consider" among other factors "[d]ata on pending and approved patent applications, exclusivities recognized by the Food and Drug Administration, and applications and approvals under section 355(c) of title 21 or section 262(a) of this title for the drug." 42 U.S.C. § 1320f-3(e)(1)(D). *Third*, CMS must establish "procedures to compute and apply the maximum fair price across different strengths and dosage forms of a selected drug and not based on the specific formulation or package size or package type ...." 42 U.S.C. § 1320f-5(a)(2).

Congress's instruction that CMS, in limited circumstances, may consider different dosage forms, strengths, and formulations of a product only proves that the ordinary definition does *not* include those different dosage forms, strengths, and formulations. It also confirms that, contrary to CMS's approach, the agency lacks general authority to group together products that differ in other ways, such as by route

of administration, device presentation, and conditions of use. If Congress's definition of a "negotiation eligible drug" were the same as CMS's definition—namely, all products that share an active moiety or active ingredient—all of these provisions would be superfluous. Acknowledging as much, CMS in a footnote suggests that this redundancy is "no cause for alarm." Opp. 26 n.5. But as CMS concedes elsewhere, "[o]ne of the most basic interpretive canons, [is] 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." Opp. 23 (quoting *Corley v. United States*, 556 U.S. 303, 314 (2009)). In contrast to CMS's position, the product-specific definition adopted by the Supreme Court and by FDA gives all of these provisions meaning. Congress decided that no more than 10 products would be eligible for price controls; in determining which products meet the "high spend" threshold, however, CMS is permitted to look at aggregated data.

CMS suggests that the IRA contemplates aggregating multiple products as a single "drug" because the statute discusses "dosage forms and strengths of the drug" in the "use of data" provision. *See* 42 U.S.C. § 1320f-1(d)(3)(B). But the most straightforward reading of that provision does not require such linguistic gymnastics. It is naturally read as one would expect Congress to write a data-aggregation provision when a biological product is defined in a product-specific way. CMS's own guidance interpreted the "use of data" language to require consideration of "all dosage forms and strengths of the biological product with the same active ingredient and the same holder

of a [BLA], inclusive of products that are marketed pursuant to different BLAs." Opp. 10 (quoting CMS, Medicare Drug Price Negotiation Program: Revised Guidance at 99 (June 30, 2023)("Final Guidance")). Nothing in the "use of data" provision changes the fundamental meaning of the term "biological product" throughout the statute. In short, the IRA's limited aggregation provisions do not transform the word "negotiation-eligible drug" (meaning a single drug or biological product) to permit changing the number of products eligible for price controls by grouping together all of a manufacturer's products that contain the same active ingredient or active moiety.

4. Lacking statutory or case law support, CMS turns to policy. It asserts that limiting its price-setting authority to 10 products would allow manufacturers to "engage in 'product hopping.'" Opp. 27. That outcome would be "implausible," in CMS's view, because "lowering the costs of Medicare drugs was the primary goal of the IRA." *Id.* But an "agency cannot rewrite a 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 can CMS override the statute's plain text by focusing on its purported "primary" purpose. That maneuver has been rejected by the Supreme Court. *See Rodriguez v. United* States, 480 U.S. 522, 525–26 (1987) (per curiam) ("no legislation pursues its purposes at all costs" and it "frustrates rather than effectuates legislative intent simplistically to assume that *whatever* furthers the statute's primary objective must be the law"). Lowering costs by avoiding "product hopping" is not the IRA's singular goal; in fact, it is not even an articulated goal. Congress designed the IRA to introduce

a "specific solution[]" to purportedly high drug prices by introducing price controls slowly over a limited number of products and expanding CMS's regulatory powers gradually over time. *See RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. 639, 645 (2012); 42 U.S.C. § 1320f-1(a). The statute thus balanced Congress's cost-control objectives against the need to permit innovation that builds on existing approved drug and biological products.

5. Because CMS has defied the IRA's express mandates, this Court should enforce the statute and vacate CMS's unlawful actions, including both its guidance and its decision subjecting Novo's products to price controls. *See* 5 U.S.C. § 706 (a "reviewing court shall … hold unlawful and set aside agency action … found to be … not in accordance with law"). Requiring CMS to comply with the statute would mean that Novo's products would not be eligible for price controls, including because many of its products have not been on the market for 11 years and its individual products would not meet the statute's high-spend requirements. *See* Novo Br. 22–23. In a footnote, CMS argues that this Court has no constitutional authority to vacate the agency's unlawful actions. *See* Opp. 14 n.3. That is incorrect. "The APA empowers courts to 'set aside' unlawful agency action, § 706(2), so the ordinary course is to 'vacat[e] invalid agency action and remand[] the matter to the agency for further review." *Neto v. Thompson*, 506 F. Supp. 3d 239, 253–54 (D.N.J. 2020) (quoting *Comite' De Apoyo A Los Trabajadores Agricolas v. Perez*, 774 F.3d 173, 191 (3d Cir. 2014)). CMS's suggestion that this Court should take it upon itself to re-write CMS's August 2023

publication of which drugs to subject to price controls is misguided and conflicts with the general principle that, while a court must enforce the law, it should not "direct the agency how to act." *Id.* Vacatur is the appropriate remedy.

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. Review is foreclosed only if a statute clearly and convincingly bars judicial review and, even then, only if the agency is acting within the scope of its authority. *See Guerrero-Lasparilla v. Barr*, 140 S. Ct. 1062, 1069 (2020). As Novo's opening brief explains, the statute is reasonably susceptible to a construction that excludes Novo's challenges from the scope of the judicial review bars, CMS has not justified its request to expand the bars, and CMS's actions violate express statutory mandates. *See* Novo Br. 30–34.

1. Congress did not bar judicial review of the *number of drugs* eligible for price controls under § 1320f-1(a)(1). It shielded from review only certain determinations the agency would make concerning *which* drugs to select. *See* Opp. 15. Because the judicial-review bars do not mention subsection (a), *see* 42 U.S.C. § 1320f-7(2), and do not empower CMS to override the statute's precise numerical requirements, that alone is a sufficient basis to reject CMS's position. "[A]rguments against judicial review cannot override the text of the statute." *Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724, 734 (2022).

CMS contends that Novo is challenging CMS's selection decision, which it contends is shielded from review, because the company is contesting "CMS's decision to 'subject … 6 different Novo products[] to price controls.'" Opp. 14 (citing 42 U.S.C. § 1320f-7(2)). But CMS's selective editing is misleading. The quoted portion of Novo's brief says: "CMS's decision to subject at least 15 products—including 6 different Novo products—to price controls should not be allowed to stand." Novo Br. 16. Novo's challenge is rooted in subsection (a)'s limit on *how many* products are eligible for price controls. No judicial-review bar applies to that issue.

CMS next argues that this Court should extend the judicial-review bar to cover subsection (a). *See* Opp. 15–18. There are at least two problems with that argument. *First*, it violates controlling precedent. There is a "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). That presumption requires a bar to be read narrowly "[e]ven where, as here, [it] expressly prohibits judicial review." *Am. Clinical Lab'y Ass'n v. Azar* (*ACLA*), 931 F.3d 1195, 1204 (D.C. Cir. 2019). If "a statutory [review bar] 'is reasonably susceptible to divergent interpretation,'" a court must "'adopt the reading that accords with traditional understandings and basic principles: that executive determinations generally are subject to judicial review.'" *Guerrero-Lasprilla*, 140 S. Ct. at 1069.

CMS asks for the opposite presumption, urging the Court to extend the IRA's review bars to prevent "disruption to" its administrative priorities. Opp. 16; *see also* Opp. 15 (contending that the Court should not allow a party to "plead around the

jurisdictional bar"). This Court should reject that invitation. Federal courts have a "virtually unflagging obligation … to exercise the jurisdiction given them." *Colo. River Water Conservation Dist. v. United States*, 424 U.S. 800, 817 (1976). Moreover, the IRA's review bars are reasonably susceptible to an interpretation that, although Congress shielded from review the agency's determination as to *which* products to select for price controls, Congress did not intend to foreclose review of an attempt by CMS to impose price controls on more products than Congress authorized. None of the cases discussed by CMS involve precluding judicial review of an agency's decision violating an express mandate in a separate statutory subsection *not* covered by the judicial review bar. *See ACLA*, 931 F.3d at 1206 (holding that judicial review bar did not apply to "separate and distinct subsection" of statute not covered by the bar).

Second, the statute provides CMS with no authority to change the number of products subject to price controls. *See* Novo Br. 31–32. With no answer to this point, CMS contends that its "active ingredient" "methodology" is ""inextricably intertwined with the' determinations Congress expressly insulated from review." Opp. 18 (quoting *DCH Reg'l Med. Ctr. v. Azar*, 925 F.3d 503, 507 (D.C. Cir. 2019)). That makes no sense. Exercising discretion to determine *which* products from a group of eligible products will be selected for price controls is not the same as changing *how many* products Congress specified are eligible in the first instance.

The precedent on which CMS relies underscores the material differences between those cases and this one. In *Florida Health Sciences Center v. HHS*, the court

determined that a judicial review bar insulating CMS's estimate of a hospital's amount of uncompensated care shielded a challenge to CMS's decision to use "March instead of April as the cutoff date for hospitals to update their Medicaid data" used to estimate that uncompensated care. 830 F.3d 515, 522 (D.C. Cir. 2016); *see also DCH Reg'l*, 925 F.3d at 507, 510 (concluding that methodology for estimating the amount of uncompensated care could not be separated from estimate of the appropriate payment for that care). In *Texas Alliance for Home Care Services v. Sebelius*, the court held that a provision precluding review of a decision to deny a government contract also foreclosed review of the financial standards applied to determine whether bidders are sufficiently financially sound to be awarded a contract. 681 F.3d 402, 410 (D.C. Cir. 2012). In *Yale New Haven Hospital v. Becerra*, the court held that a provision precluding review of an "estimate" precluded both substantive and procedural challenges to the estimate. *See* 56 F.4th 9, 26 (2d Cir. 2022).

None of these cases apply here. Congress's mandate as to *how many* products are eligible for price controls is distinct from the separate discretionary decision CMS makes as to *which* products to select. Imagine a statute that instructs a zoo to pick 10 wild-eligible lions to be released into the Serengeti and gives the zoo discretion to select which wild-eligible lions to release. The zoo could apply a methodology of its choosing in making that decision—selecting the 10 youngest lions or, perhaps, the 10 strongest. But the zoo would have no right to re-define a "wild-eligible lion" to be "any group of

lions that live together" and then use that definition to release 15 lions. That is not a methodological decision; it is a rewrite of the statute's precise numerical requirements.

3. Even if the review bars applied, CMS's actions are reviewable because they are ultra vires. *See* Novo Br. 33–34. CMS's actions violate express statutory mandates, including Congress's directives to limit products eligible for price controls to (a) no more than 10 in number, (b) only products approved (or licensed) by FDA, and (c) only products not approved or licensed for 7 or 11 years. *See Griffith v. Fed. Lab. Rels. Auth.*, 842 F.2d 487, 493 (D.C. Cir. 1988) (agency action is ultra vires if its "disregard[s] a specific and unambiguous statutory directive").

CMS argues that ultra vires review is never available when a "statute *expressly* precludes review." Opp. 19. But the statute does not *expressly* preclude review of Novo's claims, which is why CMS is forced to rely on cases that find judicial review barred by implication. The statute is clearly susceptible to an interpretation that allows CMS to determine which products are qualifying single source drugs and which products will be selected for price controls without also authorizing CMS to ignore Congress's unambiguous directions on the number of products eligible for price controls and how many years must elapse before a product becomes eligible.

CMS's position is also legally incorrect: "Even where Congress is understood generally to have precluded review," judicial review remains available to curb rogue agency conduct. *Griffith*, 842 F.2d at 492. While Congress may insulate an agency's execution of the law, when an "agency has acted outside the scope of its statutory

mandate," a "jurisdiction-stripping provision does not apply." *Am. Hosp. Ass'n v. Azar*, 964 F.3d 1230, 1238 (D.C. Cir. 2020); *City of Arlington v. FCC*, 569 U.S. 290, 297 (2013) (when agencies act "beyond their jurisdiction, what they do is ultra vires").

The question before this Court is whether the judicial review bars should be interpreted to allow CMS to override "precise" numerical requirements that Congress imposed. *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 326 (2014) (rejecting agency rewrite of "precise numerical thresholds"). If Novo is correct—that CMS has violated express statutory mandates by improperly aggregating products that otherwise would not be eligible for price controls—the judicial review bars do not apply because CMS has not acted within its delegated powers, and Congress did not grant CMS authority to rewrite the statute. *See Am. Hosp. Ass'n*, 964 F.3d at 1239. Congress cannot insulate from review agency actions taken outside a statute's reach. *Cf. Murray's Lessee v. Hoboken Land & Improvement Co.*, 59 U.S. (18 How.) 272, 276 (1855) (the Executive must act only as authorized by law). Because CMS "exceed[ed] its statutory bounds" here, "judicial review remains available." *SAS Inst. Inc., v. Iancu*, 138 S. Ct. 1348, 1359 (2018).

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

CMS's guidance should also be vacated because the agency has imposed new substantive standards that go beyond the statute's plain text, even though Congress mandated that the agency "shall" proceed only by "guidance" for the first three years. 42 U.S.C. § 1320f note. As the Supreme Court has held, an agency may not impose

binding requirements on regulated parties through mere guidance, policy statements, or interpretive rules. *See Kisor v. Wilkie*, 139 S. Ct. 2400, 2420 (2019) (a binding, legislative rule "(to be valid) must go through notice and comment"); *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 97 (2015) (the "absence of a notice-and-comment obligation ... comes at a price," as interpretative rules "'do not have the force and effect of law'").

1. CMS's opposition appears to forget that an agency's powers are limited by the Constitution. While agencies may exercise quasi-legislative powers, they are permitted to do so *only if* they comply with the APA, which is designed to ensure a "degree of openness, explanation, and participatory democracy." *Am. Bus Ass'n v. United States*, 627 F.2d 525, 528 (D.C. Cir. 1980); *DHS v. Regents of Univ. of Cal.*, 140 S. Ct. 1891, 1905 (2020) (explaining that the APA "sets forth the procedures by which federal agencies are accountable to the public and their actions subject to review by the courts" (quoting *Franklin v. Massachusetts*, 505 U.S. 788, 796 (1992))). Both the APA and the Medicare Act mandate that CMS may not impose new substantive obligations without complying with notice-and-comment procedures. *See* 5 U.S.C. § 553; *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1817 (2019). Those procedures protect "a free people from the danger of coercive state power undergirding pronouncements that lack the essential attributes of deliberativeness present in statutes." *Cmty. Nutrition Inst. v. Young*, 818 F.2d 943, 951 (D.C. Cir. 1987) (Starr, J., concurring).

Because of the constitutional values at stake, APA procedures are mandatory unless Congress has clearly and expressly carved out an exception. "Exemptions from

the terms of the Administrative Procedure Act are not lightly to be presumed." *Marcello v. Bonds*, 349 U.S. 302, 310 (1955); *Dickinson v. Zurko*, 527 U.S. 150, 155 (1999). When Congress intends to deviate from the APA's procedure, "Congress's intent to make a substantive change [must] be clear." *Ass'n of Data Processing Serv. Orgs., Inc. v. Bd. of Governors of Fed. Rsrv. Sys.*, 745 F.2d 677, 686 (D.C. Cir. 1984).

2. CMS does *not* deny that the new obligations imposed by its guidance are intended to have the binding force of law. Opp. 30. Nor does it point to any statement from Congress exempting the agency from the APA and Medicare Act. CMS instead takes the extraordinary position that Congress has *impliedly* granted the agency *carte-blanche* to promulgate substantive, industry-altering legal requirements—to make new law—without following any APA-type procedures. In CMS's view, because Congress set strict statutory deadlines, the IRA "cannot be reconciled with the notice and comment requirements" of the APA or the Medicare Act. Opp. 30. According to CMS, it would be "absurd" to require the agency to comply. Opp. 32.

There is nothing "absurd" about requiring CMS to follow proper procedures before imposing new requirements carrying the force of law. Nor is it difficult to understand why Congress directed CMS to proceed by guidance for the first three years. Congress must have understood that the IRA would have far-reaching consequences for patients and innovation, and it must have recognized that CMS lacks expertise regulating drug pricing (and needed time and experience before it could be trusted to impose new legal requirements). Congress thus wanted CMS to start slowly and to

focus for the first three years on modestly implementing the statute. Congress's directives in the IRA are "entirely compatible with the APA." *Citizens for Resp. & Ethics in Washington v. FEC*, 993 F.3d 880, 890 (D.C. Cir. 2021).

The case CMS cites, *Asiana Airlines v. FAA*, undercuts its position. *Asiana* recognized that "[s]tatutory language imposing strict deadlines, *standing alone*, does not" justify "departure from standard notice and comment." 134 F.3d 393, 398 (D.C. Cir. 1998). *Asiana* concluded that Congress intended to set aside the APA's baseline procedures but only because the statute created an alternative set of constitutionally adequate procedures. *Id.* Because Congress established alternative procedures for issuing binding rules, there was no "reasonable construction of" the relevant statute "that would harmonize with simultaneous application of" the APA's requirements. *Id.*

Here, in sharp contrast, Congress did not establish any alternative constitutionally adequate procedures. Nor does the IRA say anything about the APA. This case is thus analogous to those where Congress has *not expressly abrogated* the APA. In *Mann Construction, Inc. v. United States*, 27 F.4th 1138, 1145 (6th Cir. 2022), the Sixth Circuit rejected a similar argument by the government, concluding that "Congress did not change the background procedural requirements of the APA or otherwise indicate an exemption from those requirements in a 'clear' or 'plain' way that would make the APA's procedures inapplicable." *Id.* at 1146. In *Lake Carriers' Ass'n v. EPA*, 652 F.3d 1, 6 (D.C. Cir. 2011) (per curiam), the D.C. Circuit refused to exempt the government from the APA, recognizing that nothing in the Clean Water Act reflected "the requisite

'plain express[ion]' of congressional intent to supersede the APA's requirements." *Id.* Other cases have reached similar conclusions. *See Lane v. U.S. Dep't of Agric.*, 120 F.3d 106, 109 (8th Cir. 1997); *California v. Azar*, 911 F.3d 558, 579 (9th Cir. 2018).

It is CMS's position—not Novo's—that seeks "repeal[] by implication." Opp. 32. Suspending CMS's rulemaking authority for three years until the agency develops experience and necessary expertise is not a repeal. But *sub silentio* authorizing an agency to promulgate legislative rules through guidance—as CMS argues—*is* an implied repeal of the APA. As CMS acknowledges, "repeals by implication are not favored." *Morton v. Mancari*, 417 U.S. 535, 549 (1974); Opp. 32. CMS's position relies on "the doubtful proposition that Congress sought to accomplish in a 'surpassingly strange manner' what it could have accomplished in a much more straightforward way." *Allina*, 139 S. Ct. at 1813 (quoting *RadLAX*, 566 U.S. at 647). If Congress intended to exempt CMS from the APA, it would have said so.

3. CMS's extreme position means that if the Court does not vacate the agency's unlawful actions, it has no choice but to strike down the IRA. Congress cannot delegate substantive rulemaking authority to an agency without either requiring the agency to comply with the APA or establishing alternative constitutionally adequate rulemaking procedures to protect private rights and ensure accountability. *See Mann Constr., Inc.*, 27 F.4th at 1142–43 (APA procedures "shine[] a light on delegations of authority from Congress to an executive-branch agency to ensure they remain subject to public scrutiny"). CMS cites no case that allows an agency to impose new substantive

obligations—obligations that have the force of law and intrude on private interests—through mere guidance and with no publicly accountable process.

CMS's position cannot be permissible. As the Third Circuit has admonished, notice-and-comment procedures exist "to ensure that unelected administrators, who are not directly accountable to the populace, are forced to justify their quasi-legislative rulemaking before an informed and skeptical public." *New Jersey v. HHS*, 670 F.2d 1262, 1281 (3d Cir. 1981). If "men must turn square corners when they deal with the government, it cannot be too much to expect the government to turn square corners when it deals with them." *Niz-Chavez v. Garland*, 593 U.S. 155, 172 (2021).

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

The Supreme Court has cautioned that "the most telling indication of [a] severe constitutional problem" with a statute that vests powers in the executive "is [a] lack of historical precedent" to support it. *Seila Law LLC v. Consumer Fin. Prot. Bureau*, 140 S. Ct. 2183, 2201 (2020) (quoting *Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 505 (2010) (cleaned up)). Statutes raise particular concerns where, as here, they "combine[]" multiple layers of constitutional violations in a novel scheme. *Free Enter.*, 561 U.S. at 483–84; *Seila Law*, 140 S. Ct. at 2204. CMS has no response to these fundamental points. It does not identify any price-control statute ever previously upheld by the courts that simultaneously strips away so many constitutional safeguards.

A. The Statute Violates Multiple Constitutional Requirements.

When considering the constitutionality of a statute, a court must evaluate the statute in context and as a whole, taking into account all of its provisions. The IRA is unprecedented because it (1) lacks any intelligible principle to guide the agency's price-setting decisions, (2) provides no procedures to prevent confiscatory or arbitrary pricing, (3) compels manufacturers to speak the government's preferred message, (4) imposes prohibitive penalties if a manufacturer does not obey, (5) bars judicial review of the agency's most consequential decisions, and (6) according to CMS exempts the agency from the APA. The statute's provisions thus violate multiple constitutional requirements designed to protect public accountability and private rights.

1. ***The IRA Violates Separation of Powers.*** The IRA contains no intelligible principle to constrain CMS's price-setting decisions and bars judicial review of those decisions. In response, CMS emphasizes that the IRA directs the agency to consider certain "evidence" and "data." Opp. 64–65. But a direction to consider information is not sufficient. Congress has provided no constitutionally adequate standard to ensure that CMS's unilateral price-setting decisions will not result in prices that are arbitrary, confiscatory, or otherwise impermissible. Because the "maximum fair price" is whatever CMS says it will be, nothing in the statute "constrict[s] the [agency's] discretion to a narrow and defined category." Opp. 64 (quoting *United States v. Ambert*, 561 F.3d 1202, 1214 (11th Cir. 2009)).

CMS emphasizes that the Supreme Court has upheld broad delegations, but none of those cases are analogous. For instance, in *FPC v. Hope Natural Gas Co.*, Congress required rates to be "just and reasonable" and permitted the agency's rate orders to be "challenged in the courts." 320 U.S. 591, 602 (1944). Similarly, in *Yakus v. United States*, the statute required prices to be "fair and equitable" and aggrieved parties were entitled to judicial review. 321 U.S. 414, 431–33 (1944). In contrast, the IRA includes an even broader delegation with less protections, which is notable because wartime emergency delegations, as in *Yaku*s, are considered a high-water mark for permissible delegations. *See Panama Refining Co. v. Ryan*, 293 U.S. 388, 422 (1935) (noting the executive's heightened "authority" during wartime); *Lichter v. United States*, 334 U.S. 742, 754, 784–86 (1948) (similar). While CMS suggests that "Congress simply cannot do its job" without resorting to standardless and unreviewable delegations of power, Opp. 64, the opposite is true: Congress has not done its job unless it provides an intelligible principle and opportunities for judicial review, which are necessary to ensure that the agency's decisions are not arbitrary or discriminatory and remain within constitutional bounds.

The rest of CMS's non-delegation cases, which do not involve price controls, are readily distinguished. None of the statutes at issue foreclosed judicial review and all contained some minimum standard of fairness against which the agency's decision could be assessed. In *National Broadcasting Co. v. United States*, although Congress permitted the FCC to regulate radio broadcast licensing as required by "public interest, convenience, or necessity," 319 U.S. 190, 225–26 (1943), the Court held that, in context,

the statutory standard referred to "the interest of the listening public in 'the larger and more effective use of radio.'" *Id.* at 216 (quoting 47 U.S.C. § 303(g)). The Court also noted that the agency promulgated regulations after a robust notice-and-comment rulemaking process, including testimony by "96 witnesses" over "73 days" of hearings, *id.* at 195, and those regulations were subject to judicial review to ensure they were "based upon findings supported by evidence." *Id.* at 224. Similarly, the statute in *American Power & Light Co. v. SEC* included standards that required the agency to ensure that the corporate structure of a registered company was not "unduly or unnecessarily" complicated and did not "unfairly or inequitably distribute voting power," 329 U.S. 90, 98, 104 (1946), and the agency's determinations were also subject to judicial review. *Id.* at 105; *see also id.* at 106 (noting that because "legislative policies and standards" were "clear," judicial review could "safeguard[] against statutory or constitutional excesses").

CMS contends that there is no "logical connection" between judicial review and separation-of-powers concerns. Opp. 67. But that connection has been established in a long line of precedent recognizing that a broad delegation is less concerning when courts are available to protect private and public interests. *See Am. Power*, 329 U.S. at 105–06 (emphasizing "access to the courts to test the application" of statutory standards and guard "against statutory or constitutional excesses"); *Touby v. United States*, 500 U.S. 160, 168–69 (1991) (considering whether judicial review provisions were "sufficient to permit a court to 'ascertain whether the will of Congress has been obeyed'"); *A.L.A. Schechter Poulty Corp. v. United States*, 295 U.S. 495, 533, 541–42 (1935)

(noting lack of "administrative procedure[s]" such as "judicial review to give assurance that the action of the [delegee] is taken within its statutory authority"); *see also United States v. Garfinkel*, 29 F.3d 451, 459 (8th Cir. 1994) (collecting cases) (citing "[j]udicial review" and "notice and comment" rulemaking as relevant factors in evaluating a nondelegation challenge).

CMS suggests that while the "*availability*" of judicial review may *favor* upholding a delegation, the "*preclusion*" of review is not a factor *against* upholding a delegation. *See* Opp. 67. That argument makes no sense, as the lack of judicial review exacerbates concerns that the agency is exercising lawmaking powers and in a way that blurs accountability and intrudes on individual freedoms. *See Boumediene v. Bush*, 553 U.S. 723, 742–43 (2008) (discussing the constitutional values served by enforcing separation of powers). CMS relies on *United States v. Bozarov*, 974 F.2d 1037, 1045 (9th Cir. 1992), but it distorts what that case actually says. In *Bozarov*, the court evaluated the delegation *in context* and held only that "the availability of review is not *always* a constitutional necessity." *Id.* at 1042 (emphasis added); *see id.* ("preclusion of review may in some cases be constitutional"). Because the statute "involve[d] matters of foreign policy and national security"—where "broad delegations" are more appropriate because of the inherent "political nature of the decisions and the compelling need for uniformity"—the Court held that the judicial review bar was constitutionally permissible, as long as it was interpreted to permit constitutional challenges. *Id.* at 1044. None of those

considerations apply here. Regulating prices of sales in interstate commerce is not analogous to implementing foreign policy and protecting national security.

It also makes no difference that Congress generally has power to restrict the jurisdiction of the lower courts. Opp. 67–68. It is the unprecedented combination of a vast delegation of authority, with no limiting principle and no safeguards (such as judicial review), that here provides the "telling indication" Congress has violated the Constitution's separation of powers. *Free Enter.*, 561 U.S. at 505–06.

2. ***The IRA Violates Due Process.*** The IRA's price-setting scheme compounds the separation-of-powers concerns by eliminating essential due process protections. CMS does not dispute that the IRA contains no procedures to protect against arbitrary and confiscatory prices. Novo Br. 44. It does not deny that the statute provides no meaningful opportunity for a hearing or to respond to the evidence on which the agency relies when setting prices. *See id.* at 46. Nor does it dispute that CMS is a self-interested and dominant market participant. *See id.* at 47.

CMS contends that due process is not needed because manufacturers do not have "an inherent entitlement—and therefore do not have a property interest—in selling their drugs to Medicare at any particular price." Opp. 55. That strawman is misleading. Novo seeks to sell its drugs to the elderly and to patients with disabilities, and CMS cannot extinguish Novo's constitutional rights by setting itself up as a middleman that oversees the nation's interstate markets. It cannot be reasonably disputed that Novo has a property interest both in the drugs it creates and in the

confidential information that CMS is forcing it to disclose. *See* Novo Br. 43–48. As the owner, Novo has "'the rights to possess, use and dispose of'" its property, including selling it at a fair market value. *Horne v. Dep't of Agric.*, 576 U.S. 350, 361–62 (2015) (quoting *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 435 (1982)). It is a "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 as such is within the protection of the Fifth ... Amendment[]." *Old Dearborn Distrib. Co. v. Seagram-Distillers Corp.*, 299 U.S. 183, 192 (1936).

Novo also has a property interest in its expectation that it may sell its drugs at a fair market value. Novo invested billions of dollars developing its different drugs on Congress's promise that it would be able to sell them to patients without government interference. *See* Novo Br. 5. When Congress created Medicare Part D, it prohibited CMS from "interfer[ing] with the negotiations between drug manufacturers and pharmacies and [prescription drug plan] sponsors," 42 U.S.C. § 1395w-111(i), and the statute's sponsors called that "noninterference" commitment a "fundamental protection" against "price fixing by the CMS bureaucracy." 149 Cong. Rec. S15,624 (daily ed. Nov. 23, 2003) (statement of Sen. Grassley). Novo therefore has a property interest in its "legitimate claim of entitlement" based on years of "rules and understandings, promulgated and fostered by" the government. *Perry v. Sindermann*, 408 U.S. 593, 602–03 (1972) (citing *Sindermann v. Perry*, 430 F.2d 939, 943 (5th Cir. 1970)).

Contrary to CMS's position, courts have always subjected price-control regimes to procedural due process scrutiny, even when the regulated entity is not forced to sell its products. *See Bowles v. Willingham*, 321 U.S. 503, 520 (1944) (noting that "property rights are involved"). Indeed, the challenger in *Bowles* contested wartime rent-control measures, and the Court considered due process challenges to those measures. *See id.* at 517–21. That analysis would have made no sense if the owners' decision to voluntarily rent their property precluded them from asserting a protected property interest. Moreover, if CMS were no longer bound by due process requirements when making decisions involving the Medicare program, it could act for arbitrary or discriminatory reasons. That simply is not the law. *See Buckley v. Valeo*, 424 U.S. 1, 93 (1976) (per curiam) (explaining that while the words "[e]qual protection" do not appear in the text, the Fifth Amendment's Due Process clause includes an equal protection element).

3. ***The IRA Violates the First Amendment.*** The IRA forces manufacturers, including Novo, to endorse CMS's preferred viewpoint under the threat of massive penalties. That is a textbook violation of the First Amendment, which 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); *Janus v. Am. Fed'n of State, Cnty., & Mun. Emps.*, 138 S. Ct. 2448, 2464 (2018). The government may neither "prohibit the expression of an idea," *Texas v. Johnson*, 491 U.S. 397, 414 (1989), nor compel a person to speak. *See Miller v. Mitchell*, 598 F.3d 139, 151–52 (3d Cir. 2010). Any government

effort to compel speech is subject to strict scrutiny and must be narrowly tailored to serve a compelling interest. *Nat'l Inst. of Fam. & Life Advocs. v. Becerra*, 585 U.S. 755, 766 (2018); *C.N. v. Ridgewood Bd. of Educ.*, 430 F.3d 159, 188 (3d Cir. 2005).

CMS cannot show that the IRA meets these demanding standards. CMS instead argues that forcing Novo to sign an agreement saying that the price unilaterally imposed by CMS is a maximum fair price does not qualify as speech. Opp. 57. According to CMS, that forced expressive conduct is part of contract negotiations that are "'incidental to the ... regulation of conduct.'" *Id.* (quoting *Rumsfeld v. Forum for Acad. & Inst. Rights, Inc.*, 547 U.S. 47, 62 (2006)). But CMS does not cite a single case holding that contracts are not protected by the First Amendment.

Nor is it possible to reconcile CMS's position with reality. The IRA's requirement that Novo enter an "agreement" (implying mutual assent) to engage in a "negotiation" (implying the ability to freely withdraw without facing punitive fines) that leads to imposing a "maximum fair price" (implying that both parties agree that the price is fair and that no higher price could be fair) is not *incidental*, it is *intentional*. Congress did not state that the conclusion of the IRA's "negotiation" process would involving imposing a "Medicare Federal Price." Instead, Congress intentionally used the terms "maximum" and "fair" as a means to communicate that the price set by CMS would be understood to be the highest permissible price and that the parties agree that this upper limit is fair. Congress could have established a price-control regime that did not require manufacturers to agree that the price imposed was a fair and maximum

price. That is generally what statutes and implementing regulations do—they regulate conduct. Instead, Congress chose a route that clearly "implicate[s] the First Amendment ... more than 'typical price regulation,' which 'would simply regulate the amount [of money] that a [manufacturer] could collect.'" Opp. 58 (quoting *Expressions Hair Design v. Schneiderman*, 581 U.S. 37, 47 (2017)).

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

CMS contends that the IRA's constitutional violations should be excused because Novo can purportedly choose whether to participate in the IRA's price-control program or stop selling products to Medicare and Medicaid patients. Opp. 2. But the statute's price controls are not voluntary, and forcing certain manufacturers to choose between exiting a market entirely or relinquishing their constitutional rights is not permissible. A party cannot consent to a violation of the Constitution's structural protections, and requiring manufacturers to forfeit their rights violates the unconstitutional conditions doctrine.

1. Congress intentionally structured the IRA to be coercive. By subjecting six of Novo's products to price controls, CMS has imposed on Novo the legal obligation to "enter into agreements," "negotiate to determine … a maximum fair price," provide "access" to its six products at that price, submit confidential data, and "compl[y]" with any other requirements CMS deems "necessary." 42 U.S.C. § 1320f-2(a). Manufacturers cannot lawfully withdraw from CMS's 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 severe penalty, an "excise tax" that no manufacturer could afford to pay. 26 U.S.C. § 5000D.

Focusing on cases involving reimbursement paid to hospitals, CMS argues that "participation in Medicare is voluntary." Opp. 36. But those cases were almost all decided before CMS became the dominant market participant and in situations where the option not to deal with the government remained a legal and practical option. They also involved requirements that apply to all market participants equally, and none involved a forced speech requirement. The IRA is materially different. Selling drugs at CMS-imposed prices and speaking the government's preferred message is not a condition imposed on all manufacturers; it is a "gun to the head" of only those manufacturers CMS has chosen to target. *See* Novo Br. 59.

CMS also contends that Novo can "opt out" by withdrawing from half of the nation's healthcare markets (and stop selling to patients insured through Medicare and Medicaid). *See* Opp. 35. But "opting out" is no real option; to do so takes time, and Novo would have to withdraw *all* of its drug products, not just the six targeted for price controls. Moreover, Novo never "opt-ed in" or chose to participate in the IRA; it was forced into this position by CMS. Among the hundreds of companies participating in the Medicare program, only 10 companies are required to "negotiate" the price of their products in the first year of CMS's price-control program. No other federal program involves the government targeting only a few private entities and then levying massive excise tax penalties if they do not surrender their constitutional rights. While

participation is often a condition of receiving federal funding, *see* 42 U.S.C. §§ 1396r-8(a)(5)–(6), 1395cc(a)(1)(I)(i), the decision to enter those programs in the first place lies with the private party, not the government, and there is no fine, let alone a crippling one, for choosing not to participate. That is not true in the case of the IRA.

CMS argues that participation (even temporary participation) does not matter because "negotiated prices" do not take effect until January 1, 2026. Opp. 40. But that ignores the many injuries Novo has suffered and will continue to suffer before January 2026 that stem from its compelled participation, including ongoing violations of its constitutional rights and the forced disclosure of confidential information.

2. In any event, no party can consent to structural constitutional violations. Novo Br. 54–55. Nor can the government take over a large segment of the interstate market and then force manufacturers to bargain away their constitutional rights in exchange for access. *Id.* "It is settled law that the government may not, as a general rule, grant even a gratuitous benefit on condition that the beneficiary relinquish a constitutional right." *O'Connor v. Pierson*, 426 F.3d 187, 201 (2d Cir. 2005) (quotation marks omitted); *accord Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 606 (2013); *Dolan v. City of Tigard*, 512 U.S. 374, 385 (1994); *S.-Cent. Timber Dev., Inc. v. Wunnicke*, 467 U.S. 82, 98 (1984). Indeed, the government cannot impose conditions to achieve a result that it "could not command directly" without running afoul of the unconstitutional conditions doctrine. *Speiser v. Randall*, 357 U.S. 513, 526 (1958).

Contrary to CMS's position, which relies on outdated lower court cases, the Supreme Court has rejected arguments that "voluntary" participation in a government-controlled market allows the government to escape constitutional requirements. *See Horne,* 576 U.S. at 366 (holding that selling products "in interstate commerce" is "not a special governmental benefit that the Government may hold hostage, to be ransomed by the waiver of constitutional protection"); *cf. Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 475–76 (2013) (rejecting argument that manufacturer can avoid regulatory burden of conflicting state and federal laws by leaving the market). In *National Federation of Independent Business v. Sebelius* (*NFIB*), 567 U.S. 519, 578 (2012), the Supreme Court concluded that forcing an entity to either accept new conditions or withdraw from Medicaid was not a permissible choice. *Id.* at 581. As with the Medicaid expansion in *NFIB*, the IRA is "a *new* program" that "Congress is forcing [manufacturers] to accept" "by threatening the funds for the *existing* [Medicare and] Medicaid program." *Id.* at 582 (emphasis added). Accordingly, "[p]revious Medica[re] amendments simply do not fall into the same category as the one at stake here." *Id.* at 585. The "original" programs were never designed as price-control programs intended to dominate the market and leverage the government's regulatory powers to allow beneficiaries to obtain drugs at far below market value. In fact, Medicare Part D's longstanding non-interference clause was designed to prevent such a shift. *See* Cong. Rec. S15,624 (daily ed. Nov. 23, 2003) (statement of Sen. Grassley). The IRA turns all that on its head, in a manner that Novo "could hardly anticipate." *NFIB*, 567 U.S. at 584.

Seeking to distinguish *NFIB*, the government asserts that the case addresses only federalism questions. Opp. 44–45. But a condition that is coercive for states is equally coercive to private parties. *See* Novo Br. 59–60; *cf. Doe v. Univ. of Scis.*, 961 F.3d 203, 213 (3d Cir. 2020) (applying concept of "economic dragooning" to private colleges receiving federal funds (quoting *NFIB*, 567 U.S. at 582)). CMS argues that the *NFIB* coercion inquiry "does not make sense" because, in its view, the IRA "merely set terms for how the federal government will pay for goods in the market." Opp. 45. But CMS is no ordinary market participant, and it is not purchasing goods for itself. It has taken over the market governing sales to the elderly and disabled—almost 50% of all sales in the United States. It is thus acting not as a market-participant but as a regulator. Not even the most "well-funded" market participant could impose a 1,900% "excise tax" penalty on potential counterparty for refusing to enter into an "agreement." Nor could a market participant require the provision of confidential and proprietary information that Novo would not ordinarily share, *see* 42 U.S.C. § 1320f-2(a)(4), backed by civil monetary penalties of $1 million per day, *id.* §§ 1320f-6(c), 1320f-2(a)(5).

If CMS's position were correct, the Constitution would impose no meaningful limits on government to control the sale of private property. Consider meat prices. Under our Constitution, the government cannot force farmers to sell their livestock to the public at below-market prices. *See Horne*, 576 U.S. at 358 (discussing this classic example of governmental abuse). It would make no difference if the government took over half the interstate market—creating a government-run program to serve half the

population—and told farmers they could escape price controls only if they first turned over confidential information, paid massive fines, and eventually exited the market by agreeing to stop selling not only their livestock, but also all of their other produce and wares. That is precisely the type of abuse that *NFIB* and other cases have rejected.

CMS contends that the unconstitutional conditions doctrine does not apply because Novo purportedly does not have a property interest in selling its drugs to the elderly and disabled (i.e., Medicare beneficiaries). Opp. 50–51. That is incorrect for all the reasons noted above, and the government also misstates the test. The unconstitutional conditions doctrine prohibits requiring an individual to surrender its constitutional rights "in exchange for [even] a discretionary benefit conferred by the government." *Dolan*, 512 U.S. at 385. It does not require a showing that the individual has a non-discretionary right to the benefit. In any event, as explained above, Novo has an underlying property right to "'to possess, use and dispose of'" its prescription drugs and the confidential information CMS is forcing it to disclose. *Horne*, 576 U.S. at 361–62 (quoting *Loretto*, 458 U.S. at 435). Price-control regimes have always been subject to procedural due process concerns, even in wartime situations. *See Yakus*, 321 U.S. at 431–33.

Elsewhere in its opposition, CMS contends that, like a government contractor, "Novo has no vested right to conduct business with the government at all, and no vested property right to continue participating in Medicare." Opp. 50–51. Not only is it incorrect to say that Novo must show that it has a vested right, but CMS

mischaracterizes Novo's position. The IRA is unconstitutional because it seeks to condition Novo's ability to sell *any* drugs to almost half the nation's market—that is, to tens of millions of elderly and disabled patients—on Novo forfeiting its constitutional rights, including its rights to free speech and to have drug prices regulated through a fair process that protects against arbitrary or confiscatory rates.

Nor has CMS shown that the condition imposed is proportional to the benefit sought. *See Koontz*, 570 U.S. at 605–06; Novo Br. 58–59. CMS sidesteps the issue by claiming that the proportionality principle is limited to land-use cases. Opp. 52–53. But it provides no basis for that position. Although the initial cases that articulated the proportionality test involved "misuse of the power of land-use regulation," *Koontz*, 570 U.S. at 599, there is no evidence the Supreme Court intended to cabin its constitutional reasoning to such a limited context. The Court relied on precedent across a range of contexts, *see Dolan*, 512 U.S. at 385, and similar proportionality principles have appeared in other contexts, *see Mem'l Hosp. v. Maricopa County*, 415 U.S. 250, 258–59 & n.13 (1974).

In short, the IRA is unlawful because requiring Novo to grant Medicare participants "access" to Novo's products at CMS-imposed prices violates the First Amendment, the Fifth Amendment, and Separation of Powers. Novo cannot "volunteer" to waive these rights and Congress is not permitted to ask it to do so.

CONCLUSION

The Court should enter judgment in Novo's favor and vacate CMS's unlawful actions. Alternatively, it should declare the IRA's provisions unconstitutional.

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Respectfully submitted,

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