NO. 25-761

In the
Supreme Court of the United States

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

v.

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

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

REPLY BRIEF FOR PETITIONERS

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CORPORATE DISCLOSURE STATEMENT

The corporate disclosure statement accompanying the petition for a writ of certiorari remains accurate.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

REPLY BRIEF

The government's brief confirms the urgent need for this Court's intervention. The government does not contest the monumental impact of the IRA's price-control scheme on the nation, the pharmaceutical industry, or the millions of Americans who depend on innovative medications. Nor does it identify any precedent for the IRA. No executive agency has ever been empowered to promulgate rules and dictate prices with no judicially enforceable standards or administrative procedures to safeguard lawful, accountable government. Nor has this Court ever countenanced allowing executive agencies to issue substantive regulations and regulate prices free of all constitutional constraints. The government's radical position is a bid for unbounded powers never permitted in our Republic's history. It seeks to wield those powers to force manufacturers into an impossible dilemma—transfer their products at whatever price the government dictates or lose access to markets serving more than 140 million Americans.

Much of the government's brief defends a fictive statute conjured only for litigation purposes. The government asserts, for example, that the IRA "empower[s]" CMS "to negotiate" prices, BIO 5, but no negotiation occurs in any ordinary sense of the word. The statute allows CMS to impose any price it chooses, and a manufacturer must accede to that price or pay enterprise-crippling penalties. Drawing inapt comparisons to procurement, the government also contends that the IRA "governs only the prices that Medicare pays for certain drugs." *Id.* That too is deeply misleading. The IRA does not involve the government

purchasing drugs for itself; nor does it simply limit the amount Medicare will pay. The government is exercising sovereign regulatory powers, dictating the prices a manufacturer is permitted to charge in private transactions with patients covered by private healthcare plans subsidized through Medicare. In addition, the government urges this Court not to worry about the IRA's far-reaching consequences, suggesting that the statute applies only to "certain drugs"—just ten in the first cycle—that are "eligible" because they "have been on the market for at least seven years (or 11 years, for biological products)," *id.* at 5, 10. In fact, freed from judicial review, CMS has rewritten the statute to impose price controls on far more products than Congress authorized, including three Novo Nordisk biological products that have been on the market for fewer than 11 years.

The statute Congress actually enacted defies the Constitution's separation of powers because it grants the agency sweeping rulemaking and price-setting authority with no "sufficient[] guid[ance]" or adequate "constrain[ts]." *FCC v. Consumers' Rsch.*, 606 U.S. 656, 664 (2025). Under the Third Circuit's interpretation, the statute allows the agency to issue binding regulations without following notice-and-comment procedures, bars any administrative or judicial review, and leaves executive officials free to do whatever they please. The government's brief all but concedes the point, claiming that no constraints are necessary. BIO 18-20. But that position cannot be squared with this Court's precedents, and it conflicts with decisions from other courts of appeals recognizing the importance of judicial review and adequate procedures when evaluating congressional

delegations. This Court has often debated the extent of Congress's authority to delegate legislative and regulatory powers, but those debates have consistently occurred against the backdrop of the Administrative Procedure Act and its essential procedural and judicial-review provisions (or alternative statutory schemes providing similar protections). Never before has an agency been permitted to exercise unbounded and unreviewable powers to issue new regulations and dictate prices in sales to millions of Americans.

The statute also violates due process. Executive agencies cannot impose price controls without adequate procedures to ensure that they act reasonably and within lawful bounds, and to protect against arbitrary or confiscatory prices. The government nonetheless argues that a loophole exists because it has given manufacturers an impossible choice: succumb to its demands or stop selling any products to the substantial segment of the American population that receives financial assistance through Medicare or Medicaid. BIO 20-22. In the government's telling, because manufacturers can "voluntarily" choose to leave the subsidized markets, no private rights are at stake and no constitutional constraints apply. That position contravenes this Court's instructions in *National Federation of Independent Business v. Sebelius* (*NFIB*), 567 U.S. 519, 577-80 (2012), conflicts with the unconstitutional conditions doctrine, and diverges sharply from other circuit authority.

The Court should grant review.

ARGUMENT

I. The Third Circuit's decision effectively holds that Congress may delegate authority to executive agencies without *any* constraints. App.17 n.3. The court below approved a scheme that, without any opportunity for administrative or judicial review, empowers CMS to set prices at any level it wants with no statutory floor or meaningful guidance, and to issue binding regulations without any procedural safeguards. That places all three powers—legislative, executive, and judicial—in the hands of a single agency, a violation of the separation of powers that has no historical analog even to statutes enacted during wartime emergencies. Pet. 20-22.

Embracing that flawed analysis, the government presses a defanged reading of the intelligible-principle test, asserting that Congress must only sketch the bare outlines of a price-setting scheme before handing the agency unfettered discretion to make substantive policy decisions, including unreviewable authority to change statutory requirements at will. BIO 16. The government argues that Congress's instruction to set the "lowest maximum fair price" is an intelligible principle, despite arguing elsewhere that this term has no substantive content. *See* 3d Cir. Resp. Br. 64-65 (arguing that the term "maximum fair price" "do[es] not convey … any view regarding the value of [a manufacturer's] drugs"); 42 U.S.C. § 1320f(c)(3) (defining term to mean whatever price the government chooses). More fundamentally, the government ignores CMS's claimed power to issue binding, substantive rules without complying with notice-and-comment procedures (or abiding by any

comparable procedural protections). And it finds no fault with freeing the agency's rulemaking, drug-choosing, and price-setting powers from any judicial or administrative oversight. *See* 42 U.S.C. § 1320f-7. To the contrary, it essentially argues that barring judicial review is necessary because courts would otherwise stymie the scheme by requiring the government to act within lawful bounds. *See* BIO 7, 18-20.

The government's position conflicts with this Court's precedent and precedent from multiple circuits. BIO 5. Foundational nondelegation cases highlight the importance of "judicial review to give assurance that the action of the [agency] is taken within its statutory authority." *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 533 (1935). This Court has also repeatedly recognized that judicial review can avoid separation-of-powers problems by correcting an agency's extravagant statutory interpretations. *See* Pet. 17 (citing *Gundy v. United States*, 588 U.S. 128, 136 (2019); *Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 575 (1988)). And this Court has recently reaffirmed that determining what the law requires is a task reserved for the judiciary, not administrative agencies. *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 385 (2024) (citing *Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 177 (1803)); *see also id.* at 414 (Thomas, J., concurring) (giving deference to agencies to interpret the law "compromises th[e] separation of powers"); *see also Learning Res., Inc. v. Trump*, 146 S. Ct. 628, 639 (2026). Similarly, in conflict with the decision below, both the Eighth and Ninth Circuits have recognized that the availability of

judicial review is directly relevant to the separation-of-powers question. Pet. 22-24.

This Court has likewise explained that, when an agency is making new rules, procedural guardrails are necessary to "avoid the inherently arbitrary nature of unpublished ad hoc determinations." *Morton v. Ruiz*, 415 U.S. 199, 232 (1974); *see* Pet. 16, 20-21. As the Court has understood for more than 100 years, it is both "certain rules of decision" and "a certain course of procedure" that constrains an agency and prevents a "pure delegation of legislative power." *Wichita R. & Light Co. v. Pub. Utils. Comm'n*, 260 U.S. 48, 59 (1922). Indeed, our modern administrative state is founded on the premises that agencies must act consistent with Congress's well-articulated commands and abide by certain procedural requirements necessary to ensure accountability, transparency, and public participation. *Cf. N.Y. State Rifle & Pistol Ass'n v. Bruen*, 597 U.S. 1, 96 (2022) (Breyer, J., dissenting) ("The arbitrary-and-capricious standard has thus been used to review important policies concerning health, safety, and immigration, to name just a few examples.").

The government characterizes the requirement that a statute provide both guidance and constraints as an impermissible "combination" theory. BIO 19; *see also Consumers' Rsch.*, 606 U.S. at 697. But this Court's decision in *Consumers' Research* directly undermines that argument. The Court there explained that "the degree of agency discretion that is acceptable varies according to the scope of the power congressionally conferred." 606 U.S. at 673. Separation-of-powers concerns are particularly acute

when, unlike in *Consumers' Research*, Congress's failures to provide guidance and constraints operate on the same "axis" so that "when combined, each compounds the other's effect." 606 U.S. at 697.

That is the case here: The IRA's minimal guidance, the lack of rulemaking procedures, and the inability of any court to review or restrain CMS's legal interpretation or actions all operate on the same "axis" to "compound" the same "effect"—the unprecedented consolidation of authority in a single, unaccountable agency. The government has identified no other statute in our country's history that has so dramatically violated separation-of-powers principles. Nor is there any reason to allow such a radical departure now: While some Justices have suggested that it is time to *strengthen* the nondelegation doctrine, *see* Pet. 36-37 (collecting cases), no Justice has ever proposed so drastically *weakening* it.

II. The IRA also violates due process requirements by granting CMS unreviewable authority to impose any price it wishes with no procedural safeguards to ensure that the agency acts reasonably and within constitutional bounds. *See* Pet. 3-4. The government cannot avoid basic due process limitations by pretending that it is acting as an ordinary market participant. Pet. 25-26, 29-30 (citing *U.S. Term Limits, Inc. v. Thornton*, 514 U.S. 779, 829 (1995); *Speiser v. Randall*, 357 U.S. 513, 526 (1958)). Imposing massive "excise tax" penalties on any company that fails to fall on bended knee is not something a market participant can do. Nor can a market participant prohibit a company from selling to patients in markets that serve 140 million people.

Because the government is exercising sovereign powers to regulate prices, and not acting as a mere market participant, it must abide by constitutional constraints. *See* Pet. 27 (discussing *S.-Cent. Timber Dev., Inc. v. Wunnicke*, 467 U.S. 82, 98 (1984)).

The government's arguments to the contrary are misguided. *First*, the government asserts that it is leveraging the "lucrative nature of Medicare and Medicaid" to reduce prices. BIO 21. But, as noted, the government is not purchasing products for itself. It is wielding coercive regulatory powers to force manufacturers to transfer their products to patients or else either face ruinous fines or be forced to stop supplying their drugs to some 140 million Americans. *Carter v. Carter Coal Co.*, 298 U.S. 238, 289 (1936) (consent to price-setting program invalid because of punitive tax); *Horne v. Dep't of Agric.*, 576 U.S. 350, 365 (2015) (theoretical option to exit market did not negate constitutional violation); *NFIB*, 567 U.S. at 577-80 (coercive to exert undue influence through financial inducement).

Second, the government argues that no constitutional constraints apply because manufacturers can choose to exit the markets where patients are subsidized through federal healthcare programs. BIO 20-21. In *NFIB*, however, this Court made clear that the government cannot establish unrelated, financially devastating conditions for the ability to participate in federal spending programs. *See* 567 U.S. at 577. As the Court reasoned, because the "legitimacy of Congress's exercise of the spending power" rests on whether the recipient "voluntarily and knowingly accepts the terms of the contract," courts

must "scrutinize Spending Clause legislation to ensure that Congress is not using financial inducements to exert a power akin to undue influence." *Id.* The government urges this Court to cabin *NFIB* to the federalism context, but it offers no reason why the constitutional rights of individuals deserve less protection than the rights of States. *See Medina v. Planned Parenthood S. Atl.*, 606 U.S. 357, 374 n.5 (2025) ("[O]ur spending-power cases have applied similar principles to state and private recipients of federal aid."). Indeed, the very purpose of our federalist structure is to prevent the government from accruing too much power and infringing on "individual liberty." *NFIB*, 567 U.S. at 577.

Third, the government contends that it may impose "program-specific requirements" as long as they are "relevant to the program's purpose and leave the grantee unfettered in its other activities." BIO 21. But that is not the test adopted by this Court, which has required that program conditions be both relevant *and* proportionate. *See* Pet. 26-27 (citing *Nollan v. Cal. Coastal Comm'n*, 483 U.S. 825, 837 (1987); *Dolan v. City of Tigard*, 512 U.S. 374, 387 (1994)). Far from limiting that principle to the land-use context, BIO 21-22, this Court regularly evaluates proportionality to reject unconstitutional conditions. *See NFIB*, 567 U.S. at 579-80; *Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc.*, 570 U.S. 205, 215 (2013); *Sheetz v. County of El Dorado*, 601 U.S. 267, 279 (2024) (explaining that the unconstitutional conditions doctrine applies "in other contexts"). Following this guidance, appellate courts have performed the nexus-and-proportionality analysis in contexts not involving land-use regulation. *See* Pet. 29.

That analysis should be relevant here. Because the government is not actually negotiating prices on particular products but "threaten[ing] to withhold" all Medicare and Medicaid spending for any manufacturer that does not accede to its demands, it is imposing an unlawful condition—trying to accomplish indirectly what it is prohibited from achieving directly. *NFIB*, 567 U.S. at 580.

Fourth, the government asserts that manufacturers lack a protected property interest in selling their drugs at any particular price. BIO 22. That strawman only underscores the extremes to which the government must go to defend its unprecedented scheme. Requiring the government to provide due process does not mean that it has no ability to regulate. Novo Nordisk's point is much more basic: The government cannot control the prices in private sales to patients through an arbitrary process that the government itself admits lacks procedural protections. *See* Pet. 28. As at least one circuit has suggested, that violates due process. *See* Pet. 31-32 (citing *Nat'l Infusion Ctr. Ass'n v. Becerra*, 116 F.4th 488, 499-500 (5th Cir. 2024)).

This Court has recognized that the government's past failure to use an attractive and obvious power is potent evidence that the power is not constitutionally available. *See Printz v. United States*, 521 U.S. 898, 905 (1997). It is therefore significant that, despite more than two centuries of experience with price controls—for water and electricity, gas and transportation, livestock and food—no case cited by the government has ever authorized an agency to

impose price controls with no due process or review mechanism whatsoever.

III. Six different petitions highlight the IRA's far-reaching consequences for the American public, the constitutional ruptures the IRA creates, and the urgent need for this Court's review. *See* BIO 29 (collecting petitions). Unless the Court grants review now, the IRA will irreversibly transform the nation's healthcare markets, with disastrous, destabilizing effects. Subjecting market participants to price controls and an agency's unreviewable whims may be politically expedient, but it is destined to increase premiums, decrease the number of new drugs in development, and destroy the incentive structure that has allowed America to become a leader in developing lifesaving and life-improving medications. Pet. 30, 35-36.

These interconnected cases likewise raise troubling questions as to how far the precedential aftershocks of the government's constitutional departures will radiate. As the other petitions explain, this unprecedented rulemaking and price-setting scheme tears apart the First Amendment's protection against compelled speech, the Fifth Amendment's promises of no takings without just compensation and no deprivation of property without due process, and the Eighth Amendment's guarantee against excessive fines. It also sets a dangerous precedent that greenlights the government's ability to structure federal programs to circumvent longstanding constraints on regulation. Any change in legal regimes that results, as the government celebrates here, in a ransom of constitutional rights as a condition for an

industry to continue engaging in commercial activities involving a large segment of the population demands this Court's review.

Beyond the individual practical and legal harms the IRA inflicts, this extraordinary case threatens a dramatic expansion of government power. Before the IRA, courts enforced the Constitution by requiring that any rulemaking and price-setting powers delegated to executive agencies be both guided and constrained by law. Now, the IRA provides a framework for future Congresses to dodge political accountability by consolidating law-making, law-interpreting, and law-implementing authority in a single executive agency—leaving the nation's most important industries at the mercy of that agency's unguided and unconstrained improvisation. As the IRA illustrates, such a paradigm shift not only defies the vesting clauses, it undermines core constitutional rights. Justice Scalia cautioned that rights on paper are inadequate to protect Americans from the awesome power of government: "Every tinhorn dictator in the world today has a bill of rights. … It's the structure of government that prevents anybody from seizing all the power." The Kalb Report, *Justices Ruth Bader Ginsburg & Antonin Scalia*, at 10:10-10:35 (YouTube, Apr. 14, 2014), https://www.press.org/newsroom/video/kalb-report-justices-ruth-bader-ginsburg-antonin-scalia.

This petition alone raises that fundamental separation-of-powers question. Members of this Court have repeatedly sought an appropriate vehicle to safeguard against unlawful delegations of power to the Executive. *See* Pet. 36-37 (collecting opinions).

This case is that vehicle. The government raises no procedural hurdles to addressing the separation-of-powers question. And the divide between the petition's position and the government's could not be more clear. Nor is there any dispute that the second question on the government's ability to use its spending powers to circumvent the Constitution is cleanly presented. Because this Court can and should address these foundational questions, Novo Nordisk urges the Court to grant review.

CONCLUSION

The Court should grant the petition for certiorari.

Respectfully submitted,

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