No. 25-749, 25-751

In the

Supreme Court of the United States

JANSSEN PHARMACEUTICALS, INC.,
Petitioner,

v.

ROBERT F. KENNEDY, SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.,
Respondents.

BRISTOL MYERS SQUIB COMPANY,
Petitioner,

v.

ROBERT F. KENNEDY, SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.,
Respondents.

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

BRIEF OF AMICI CURIAE ADVANCING AMERICAN FREEDOM; AMERICAN ENCORE; ET AL. IN SUPPORT OF PETITIONERS
(Additional Amici Curiae Listed on Inside Cover)

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QUESTIONS PRESENTED

1. Whether the Program violates the Fifth Amendment's Takings Clause by forcing manufacturers to sell medicines to Medicare beneficiaries at below-market prices.

2. Whether the Program violates the First Amendment by compelling manufacturers to expressly "agree" with the government's narrative that its dictated amount is the medicine's "maximum fair price," set through a voluntary negotiation.

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STATEMENT OF INTEREST OF AMICI CURIAE

Advancing American Freedom (AAF) is a nonprofit organization that promotes and defends policies that elevate traditional American values, including freedom from arbitrary power.[1] AAF "will continue to serve as a beacon for conservative ideas, a reminder to all branches of government of their responsibilities to the nation,"[2] and believes American prosperity depends on ordered liberty and self-government.[3] AAF files this brief on behalf of its 150,374 members nationwide including 10,486 in the Third Circuit.

Amici American Encore; Americans For Fair Treatment; Donald T. Eason, President, Center for Urban Renewal and Education; Robert K. Fischer, Conservatives of Faith; Charlie Gerow; Tim Jones, Former Speaker, Missouri House, Founder, Leadership Institute for America; Liberty Justice Center; National Center for Public Policy Research; Rio Grande Foundation; Rick Santorum, Former Senator 1995-2007; Paul Stam, Former Speaker Pro Tem, NC House of Representatives; and Taxpayers Protection Alliance believe that the Constitution's limits on federal power are essential to the preservation of American liberty and prosperity.

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[1] All parties received timely notice of the filing of this amicus brief. No counsel for a party authored this brief in whole or in part. No person other than Amicus Curiae and its counsel made any monetary contribution intended to fund the preparation or submission of this brief.

[2] Edwin J. Feulner, Jr., Conservatives Stalk the House: The Story of the Republican Study Committee, 212 (Green Hill Publishers, Inc. 1983).

[3] Independence Index: Measuring Life, Liberty and the Pursuit of Happiness, Advancing American Freedom available at https://advancingamericanfreedom.com/aaff-independence-index/.

INTRODUCTION AND SUMMARY OF THE ARGUMENT

Medicare and Medicaid together account for almost half of the nation's expenditures on prescription drugs. *AstraZeneca Pharms. LP v. Sec'y U.S. Dep't of Health & Hum. Servs.*, No. 24-1819, slip op. at 6-7 (3d Cir. May 8, 2025). In 2022, seeking to leverage leviathan for a political win, Congress passed and President Biden signed the Inflation Reduction Act ("IRA") among the provisions of which was a new prescription drug price "negotiation" program for Medicare. *Id.* at 7. Under the IRA, the Centers for Medicare and Medicaid Services ("CMS") is tasked with selecting a certain number of drugs each year based on statutorily defined criteria. *Janssen Pharmaceuticals, Inc. v. Secretary United States Dept. of Health and Human Services*, No. 24-1821, slip op. at 14 (3d Cir. Sept. 4, 2025).

Once a manufacturer's drug is selected, it can either agree to participate in a price "negotiation" or it can opt out. *Id.* at 14-15. However, if it opts out, it must withdraw "all of its drugs (not just those selected for negotiation) from coverage in two programs: (1) Medicare Part D's Manufacturer Discount Program or its predecessor, the Coverage Gap Discount Program, and (2) the Medicaid Drug Rebate Program." *Id.* at 17.

If the manufacturer agrees to participate but cannot reach a price agreement with CMS, the selected drugs will be subject to an excise tax that begins at 185.71% and escalates daily to 1,900% by 270 days. *Id.* at 16. Under this "negotiation" program, CMS made the manufacturers who brought this case "an offer [they] [couldn't] refuse." *Id.* at 26 (Hardiman, C.J., dissenting) (quoting THE GODFATHER, (Paramount Pictures (1972)).

The price controls at issue in this case are not only economically disastrous,[4] they are illegal. The government of the United States, created by the Constitution, is "one of enumerated powers." *McCulloch v. Maryland*, 17 U.S. 316, 405 (1819). An "enumeration of powers is also a limitation of powers, because '[t]he enumeration presupposes something not enumerated.'" *Gibbons v. Ogden*, 22 U.S. 1, 9 (1824). That fact was made explicit by the ratification of the Tenth Amendment: "The powers not delegated to the United States by the Constitution . . . are reserved to the States respectively, or to the people." U.S. Const. amend X. Thus, all federal action must grow directly out of one of its specified powers.

This case presents the Court with the opportunity to reconsider its interpretation of the General Welfare Clause of Article I, Section 8. "There are serious problems" with the Court's understanding of the Congress's authority over spending, *Health and Hospital Corp. of Marion County v. Talevski*, No. 21-806, slip op. at 12 (June 8, 2023) (Thomas, J., dissenting), and the result has been a significant increase in federal power beyond constitutional bounds. Congress and the administrative state, sometimes at congressional direction and other times not, use the Federal Government's power of the purse as an "unconstitutional pathway for control."[5]

The Court should also consider the limitations imposed on government price manipulation that may

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[4] Tim Chapman, Marc Wheat, *A Better Prescription for Affordable Medicine*, National Review (August 28, 2025 6:30 AM) https://www.nationalreview.com/2025/08/a-better-prescription-for-affordable-medicine/.

[5] Philip Hamburger, *Purchasing Submission: Conditions, Power, and Freedom* 5 (Harvard University Press 2021).

arise from the Takings Clause. U.S. Const. amend V. When the government acts as a buyer, it can, of course, engage in good faith price negotiations with sellers. On the other hand, when the government seeks to use its position to impose conditions on market participation and to expropriate value from companies without just compensation, it has exceeded the limits of its power.

The Court should grant the Petition for Certiorari and rule for Petitioners.

I. Congress's Authority to Spend Arises from the Necessary and Proper Clause, Not the General Welfare Clause.

A. The General Welfare Clause of Article I, Section 8, Clause 1 does not grant Congress an independent spending power.

Article I grants Congress the power "To lay and collect Taxes, Duties, Imposts and Excises, to pay the Debts and provide for the common Defense and general Welfare of the United States; but all Duties, Imposts and Excises shall be uniform throughout the United States." U.S. Const. art. I § 8 cl. 1. This provision does not grant Congress an independent spending power. *See, Health and Hospital Corp. of Marion County v. Talevski*, No. 21-806, slip op. at 12 (June 8, 2023) (Thomas, J., dissenting) ("[W]hile Congress undoubtedly possesses the power to direct the expenditure of federal funds, it is important to note that the Constitution contains no 'spending clause.' From the beginning, some have located the spending power in the General Welfare Clause, and that view has generally been accepted by this Court's modern doctrine . . . Yet, there are serious problems with that view."). *But see*, *Nat'l Fed'n of Indep. Bus.* v.

Sebelius, 567 U.S. 519, 576 (2012) (Opinion of Roberts, C.J.) ("The Spending Clause grants Congress the power 'to pay the Debts and provide for the . . . general Welfare of the United States.'").

This Court has referred to the phrase, "to pay the Debts and provide for the common Defense and general welfare of the United States," as the "Spending Clause," *South Dakota v. Dole*, 483 U.S. 203, 206 (1987), and has interpreted it as a grant of spending power to Congress that is "not limited by direct grants of legislative power found in the Constitution." *Id.* (internal quotation marks omitted) (quoting *United States v. Butler*, 297 U.S. 1, 66 (1936)). Although the Court explained in *Butler* that the power conveyed by the "Spending Clause" is not unlimited, it undermined any supposed limitations by "requir[ing] a showing that by no reasonable possibility can the challenged legislation fall within the wide range of discretion permitted to Congress." *Butler*, 297 U.S. at 67. "The real-life result of this interpretation is that Congress can, and does, spend money on pretty much whatever it wants."[6]

This expansive reading was first advanced by Alexander Hamilton and later Joseph Story, before being adopted by the Court.[7] The Hamilton-Story interpretation of Article I, Section 8, Clause 1, however, is not supported by the text of the Constitution or its history. "The General Welfare Clause is simply part of the Taxing Clause" and is "most naturally read as a qualification on the

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[6] Robert G. Natelson, *The General Welfare Clause and the Public Trust: An Essay in Original Understanding*, 52 U. Kan. L. Rev. 1, 9 (2003).

[7] *Id.* at 8.

substantive taxing power." *Talevski*, No. 21-806, slip op. at 12 (Thomas, J., dissenting).

The history of the text of Article I, Section 8, Clause 1, shows that it does not grant Congress a general spending power. As Professor Phillip Hamburger has explained, the constitutional convention replaced an errant semicolon after the word "Excises" with a comma, making it "abundantly clear that the phrase about 'providing for . . . general welfare' was merely a limitation on the taxing power, not a spending power."[8] Further, the phrase "general welfare" was used in drafts and the final versions of both the Articles of Confederation and the Constitution.[9] The phrase "seems to have been shorthand for 'the benefit of the interests we have in common rather than the benefit of particular localities or parties," and thus "was essentially not a phrase of power, but of *limitation*."[10]

Further, the Hamilton-Story interpretation makes a mess of the "elegantly drawn"[11] Constitution by rendering surplusage the enumeration of several of Congress's powers[12] and by reading a subordinate clause as a grant of independent power when no other provision of Article I, section 8 is structured in that

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[8] *Id*.

[9] *Id*. at 29.

[10] *Id*. (emphasis in original).

[11] *Id*. at 14.

[12] Powers rendered surplusage by the Hamilton-Story reading include the powers to "support Armies," "maintain a Navy," "purchase 'forts, Magazines, [and] Arsenals," "establish Post Offices and Post Roads," "constitute Tribunals inferior to the supreme Court," and "purchase 'dock-Yards and other needful Buildings.'" *Id*, at 12-13 (alteration in original).

way.[13] Another of the Hamilton-Story reading's "serious textual defects"[14] is that it anachronistically assumes that "pay" and "provide for" are synonyms when, in fact, the Constitution's use of the word "provide" "embodies an element of futurity inconsistent with immediate spending or appropriation."[15]

In practice, the Hamilton-Story view has converted the national government from one of limited enumerated powers directed at national and general ends to one that has wide-ranging powers that can reach local concerns. Hamilton and Story themselves rejected this outcome. For example, Hamilton argued that appropriations must be for a purpose that is "general, and not local." *Butler*, 297 U.S. at 67. James Monroe, "an advocate of Hamilton's doctrine," wrote that Congress "certainly" does not have the power "to raise and appropriate the money to any and every purpose according to their will and pleasure." *Id.* That reading is consistent with Hamilton's assurance in the Federalist Papers that such matters as "the supervision of agriculture and of other concerns of a similar nature, all those things, in short, which are proper to be provided for by local legislation, can never be desirable cares of a general jurisdiction."[16] Story, too, "ma[d]e it clear that the powers of taxation and appropriation extend only to matters of national, as

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[13] Unlike every other enumerated power, the Hamilton-Story reading of Article I, Section 8, Clause 1 is that it "grants an authority to tax, then grants authority to spend, then doubles back to restrict the authority to tax." *Id.* at 14.

[14] *Id.* at 12.

[15] *Id.* at 15-16.

[16] Federalist No. 17 at 81 (Alexander Hamilton) (George Carey & James McClellan eds., 2001).

distinguished from local, welfare." *Butler*, 297 U.S. at 67.

Congress's power to appropriate funds, then, is not a legitimate exercise of power under Article I, Section 8, Clause 1. Instead, Congress may spend federal funds when doing so is "necessary and proper for carrying into Execution" the enumerated powers of the federal government. U.S. Const. art. I § 8 cl. 18.

B. Laws enacted by Congress that are not a direct exercise of one of its enumerated powers must be necessary and proper exercises of one of the government's enumerated powers.

Along with its enumerated powers, Article I grants Congress the power to enact laws that are "necessary and proper for carrying into execution" the national government's other enumerated powers. U.S. Const. art. I, § 8, cl. 18. The Court has "long" read the Necessary and Proper Clause "to give Congress great latitude in exercising its powers," in part because of the Court's "general reticence to invalidate the acts of the Nation's elected leaders."[17]

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[17] Here and in the context of the "limits" of the "Spending Clause" discussed above, the Court has granted Congress wide latitude in defining the limits of its own powers. However, Alexander Hamilton in Federalist 78 explained in detail why this should not be so.

> There is no position which depends on clearer principles, than that every act of a delegated authority, contrary to the tenor of the commission under which it is exercised, is void. No legislative act, therefore, contrary to the Constitution, can be valid. To deny this, would be to affirm, that the deputy is greater than his principal; that the servant is above his master; that the representatives of the people are superior to the

Sebelius, 567 U.S. at 537. (Opinion of Roberts, C.J.) In doing so, it has set loose the lion the Framers of the Constitution sought to cage.

The original meaning of the Necessary and Proper Clause is much narrower than the Court has, at times, read it. The Clause "does not license the exercise of any 'great substantive and independent power[s]' beyond those specifically enumerated." *Sebelius*, 567 U.S. at 559 (Opinion of Roberts, C.J.) (quoting *McCulloch*, 4 Wheat. at 411, 421). Rather, "the Necessary and Proper Clause is exceeded . . . when [congressional action] violates the background principle of enumerated (and hence limited) federal power." *Sebelius*, 567 U.S. at 653 (Scalia, J., dissenting). The Necessary and Proper Clause merely "ensure[s] that the Congress shall have all means at

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> people themselves; that men acting by virtue of powers, may do not only what their powers do not authorize, but what they forbid. If it be said that the legislative body are themselves the constitutional judges of their own powers, and that the construction they put upon them is conclusive upon the other departments, it may be answered, that this cannot be the natural presumption, where it is not to be collected from any particular provisions in the Constitution. It is not otherwise to be supposed, that the Constitution could intend to enable the representatives of the people to substitute their WILL to that of their constituents. It is far more rational to suppose, that the courts were designed to be an intermediate body between the people and the legislature, in order, among other things, to keep the latter within the limits assigned to their authority.

Federalist No. 78 at 403 (Alexander Hamilton) (George Carey & James McClellan eds., The Liberty Fund 2001).

its disposal to reach the heads of power that admittedly fall within its grasp . . . Congress shall not fail because it lacks the means of implementation."[18] The clause is not "a pretext . . . for the accomplishment of objects not entrusted to the government." *Raich*, 545 U.S. at 66 (Thomas, J., dissenting) (quoting *McCulloch*, 4 Wheat. at 423) (internal quotation marks omitted). As Hamilton explained in Federalist 33, the power granted to Congress by the Necessary and Proper Clause is only to effectuate the government's other powers.[19]

Even Chief Justice John Marshall, in his famous explication of the clause, generally taken to be an expansive reading, demanded that the "means . . . consist with the letter and spirit of the constitution." *McCulloch*, 4 Wheat. at 421. As Justice Thomas has explained, *McCulloch* created a two-part test for compliance with the Necessary and Proper Clause:

> First, the law must be directed toward a "legitimate" end, which *McCulloch* defines as one "within the scope of the [C]onstitution"—that is, the powers expressly delegated to the Federal Government by some provision in the Constitution . . . Second, there must be a necessary and proper fit between the "means" (the federal law) and the "end" (the enumerated power or powers) it is designed to serve . . . The means Congress selects will be deemed "necessary" if they are "appropriate" and

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[18] Richard A. Epstein, *The Proper Scope of the Commerce Power*, 73 Va. L. Rev. 1387, 1397–98 (1987).

[19] Federalist No. 33 at 159 (Alexander Hamilton) (George Carey & James McClellan eds., 2001).

> "plainly adapted" to the exercise of an enumerated power, and "proper" if they are not otherwise "prohibited" by the Constitution and not "[in]consistent" with its "letter and spirit."

United States v. Comstock, 560 U.S. 126, 160-61 (2010) (Thomas, J., dissenting) (alteration in original) (quoting *McCulloch*, 4 Wheat. at 421). Both the letter and the spirit of the Constitution require Congress to exercise its power under the clause "in a manner consistent with basic constitutional principles." *Gonzales v. Raich*, 545 U.S. 1, 52 (2005) (O'Connor, J. dissenting) (citing *Garcia v. San Antonio Metro. Transit Auth.*, 469 U.S. 528, 585 (1985) (O'Connor, J., dissenting)).

Thus, when Congress seeks to appropriate money, it must point clearly either to a direct authorization to do so or must show that doing so is a valid exercise of power "necessary and proper" to effectuating some enumerated federal power.

II. This Case Presents the Court with an Opportunity to Consider the Damage Caused to Our Constitutional System by an Unchecked Power to Spend.

Although the government can undoubtedly negotiate prices when it is purchasing goods and services for its own use, when it uses its purchasing power as a means of regulation, it has exceeded the bounds of the spending authority that is necessary and proper to the exercise of the government's enumerated powers.

Because Congress lacks an independent spending power, its myriad uses of federal funds to accomplish things not within its delegated powers constitute

"unconstitutional pathway[s] of control."[20] This often comes in the form of conditions imposed on recipients of federal funds. Conditions are reasonable and necessary when they "define what government is lawfully buying or supporting with a grant."[21] However, "regulatory conditions are those that substitute for statutes in regulating Americans."[22] Professor Hamburger suggests several factors that may demonstrate that a condition is regulatory, including that they are "disproportionately large, nongermane, or otherwise 'off.'"[23] Fundamentally, when Congress or the administrative state uses conditions to accomplish what it could not accomplish directly, it illegitimately circumvents the Constitution and its carefully defined limits on federal power, threatening the liberty of the people with death by check.

In *South Dakota v. Dole*, the Supreme Court upheld Congress's use of federal funds to induce states to raise the drinking age to 21. 483 U.S. 203 (1986). The Court found that its precedents, rather than establishing "a prohibition on the indirect achievement of objectives which Congress is not empowered to achieve directly," instead stood "for the unexceptional proposition that the power may not be used to induce the States to engage in activities that would themselves be unconstitutional." *Id.* at 210.

According to Justice Scalia, "it is a mistake to think that the Bill of Rights is the defining, or even the most

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[20] Hamburger, *supra* note 4 at 5.
[21] *Id.* at 61.
[22] *Id.* at 63.
[23] *Id.*

important, feature of American democracy."[24] Rather, it is the structure that keeps Americans free. "Structure is everything."[25] Yet, the Court's interpretation of the "spending power" in *Dole* turns that arrangement on its head. Congress can collect taxpayer dollars and use them to buy state compliance with no limits except those explicitly enumerated in the Constitution.

This use of conditioned spending is not limited to states. "Rather than regulate through law and public consent," Professor Hamburger writes, the government makes different deals with various parts of society."[26] The government then often "selectively offer[s] waivers" so that the government is "not only mak[ing] separate deals with different constituencies but also makes separate compromises when the initial deals are so tough as to be impracticable."[27]

This conditional spending also allows the government to buy off political opposition. Government may thus purchase "the acquiescence of many who might have publicly resisted the regulation."[28] And these conditions may have been unable to garner the support necessary to survive Congress or even the rulemaking process.[29] This particularly harms those parties, like smaller businesses, left out of the deal, because "[i]n buying off

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[24] Antonin Scalia, Foreword: The Importance of Structure in Constitutional Interpretation, 83 NOTRE DAME L. REV. 1417, 1417 (2008).
[25] *Id.* at 1418.
[26] Hamburger, *supra* note 4 at 104.
[27] *Id.*
[28] *Id.* at 105.
[29] *Id.*

some of the potential opponents of a regulation, the government deprives other opponents of the allies they would need to mount successful political resistance."[30]

Here, politically unpopular entities, drug manufacturing companies, are the targets of a policy that is designed to siphon off economic value for the benefit of Medicare participants. Rather than attempting to directly cap drug prices, Congress has sought to add conditions to its spending on prescription drugs to force drug companies to accept lower prices than they otherwise would.

These conditions are not germane to the purchase of the goods themselves but are instead an attempt to regulate. Whether the government covers one drug for Medicare recipients is not germane to whether it covers another. The government could have sought to negotiate the price of individual drugs on the understanding that, if it and manufacturers could not agree on a price, the government would not cover that specific drug. Instead, the government sought to leverage its "spending power" to force drug manufacturers to acquiesce. In doing so, it acted as a regulator, not a purchaser and thus attempted to bypass the public consent necessary for valid legislation.

The recent aggressive economic policy of the Executive Branch, from taking equity stakes in numerous companies without compensation, to engaging in selective anti-trust investigations, to subpoenaing the Chair of the Federal Reserve, demonstrates a great need for a resurgence of constitutional norms. Among them, the Takings

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[30] *Id.* at 106.

Clause, which provides a critical constitutional protection for, and recognition of the value of, private property, is in particular need of restoration. If the government must pay just compensation to private entities before it expropriates private property, much injustice may be prevented before it begins. This case provides the Court with an opportunity to reinforce that essential constitutional protection.

CONCLUSION

For the forgoing reasons, the Court should grant certiorari and rule for Petitioners.

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