Nos. 25-749 & 25-751

In the Supreme Court of the United States

JANSSEN PHARMACEUTICALS INC., *Petitioner*, v. ROBERT F. KENNEDY, JR. et al., *Respondents.*	BRISTOL MYERS SQUIBB COMPANY, *Petitioner*, v. ROBERT F. KENNEDY, JR. et al., *Respondents.*

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

BRIEF OF THE NATIONAL ASSOCIATION OF MANUFACTURERS AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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INTRODUCTION AND INTEREST OF THE *AMICUS CURIAE*[1]

The National Association of Manufacturers (NAM) is the largest manufacturing association in the United States, representing small and large manufacturers in all fifty States and in every industrial sector. Manufacturing employs nearly 13 million people, contributes $2.9 trillion to the economy annually, has the largest economic impact of any major sector, and accounts for over half of all private-sector research and development in the Nation, fostering the innovation that is vital for this economic ecosystem to thrive. The NAM is the voice of the manufacturing community and leading advocate for a policy agenda that helps manufacturers compete in the global economy and create jobs across the United States.

Within the manufacturing sector, pharmaceutical manufacturers play an outsized role in contributing to the innovation-led economy. Each year, the Nation's drugmakers invest tens of billions of dollars into the research and development of novel, lifesaving and life-altering therapies. Drug development is a regulatorily complex and inherently uncertain endeavor—many potential therapies, for one reason or another, never progress through the full development cycle to receive

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[1] Pursuant to Supreme Court Rule 37.6, *amicus curiae* states that no counsel for any party authored this brief in whole or in part and that no entity or person, aside from *amicus curiae* and its counsel, made any monetary contribution intended to fund the preparation or submission of this brief. *Amicus curiae* further states that counsel of record for all parties received notice of its intention to file an *amicus curiae* brief at least 10 days prior to the due date for such briefs pursuant to Supreme Court Rule 37.2.

final approval from the Food and Drug Administration (FDA).

To maintain American industry's innovative edge, it is essential to ensure that manufacturers enjoy strong incentives to invest in R&D and other activities that expand the frontier of technology and discover novel solutions. Incentivizing innovation, in turn, requires assurance for manufacturers who undertake risky investments in R&D that they will be able to earn a competitive return on their investment.

But the Drug Price Negotiation Program (Program) established by the Inflation Reduction Act is designed precisely to *deprive* drug manufacturers of fair market returns for their innovative products. Through a forced "negotiation" process, the government imposes a below-market maximum price on Medicare sales of drugs to which the Program applies. Unless they accept the financially ruinous option of withdrawing from the Medicare and Medicaid markets altogether, manufacturers of the selected drugs must sell those drugs to Medicare beneficiaries and their healthcare providers at the government-dictated price.

This command-economy approach to drug pricing not only undermines drug manufacturers' incentives to innovate, but it also abuses the federal government's dominance of the market for prescription drugs to coerce drugmakers into "agreeing" to a taking of their property without just compensation, in violation of the Fifth Amendment's Takings Clause.

SUMMARY OF ARGUMENT

In 2022, Congress sought to curb Medicare spending as part of the Inflation Reduction Act (IRA), which established a requirement that the manufacturers of

the most popular drugs enter negotiations with federal agencies to set a maximum price for sales of those drugs to Medicare patients. Congress further required that those prices be set far below the value of the drugs on the free market.

Knowing that no drugmaker would voluntarily agree to such a deal, Congress made manufacturers an offer they cannot refuse. It subjected manufacturers to a steep excise tax on Medicare *and* non-Medicare sales until they reach an "agreement" with the government, and provided that the only way for manufacturers to avoid these harmful consequences is to withdraw completely from participation in Medicare and Medicaid. That alternative, Congress knew, was equally unpalatable—the federal government dominates the prescription drug market, making withdrawal a practical impossibility for nearly all manufacturers.

The Constitution does not allow Congress to put manufacturers to this Hobson's choice. The Program demands forced transfers of property at rates far below market value, in clear violation of the Fifth Amendment's Takings Clause. And even if manufacturers could withdraw from Medicare and Medicaid, that would at most turn the Program's requirements into unconstitutional conditions on access to a federal program. The Third Circuit's contrary holding subverts the Constitution's protections and allows the government to demand *any* property as a condition of market access simply due to its ballooning size.

At bottom, the Program will hurt manufacturers, patients, and the Medicare and Medicaid programs. Underpaying for drugs will stifle innovation, leading to fewer new therapies. And the government's

position—that manufacturers can simply withdraw from Medicare and Medicaid—threatens to deprive the Nation's most vulnerable citizens of needed medications.

ARGUMENT

The IRA established the Program to enable Medicare to obtain lower prices on drugs from prescription drug manufacturers. See Pub. L. No. 117-169, §§ 11001-11004, 136 Stat. 1818, 1833-1864 (2022). For each "price applicability period," the Program directs the Centers for Medicare & Medicaid Services (CMS) to select a specified number of drugs with the highest total Medicare expenditures as targets for price renegotiation. 42 U.S.C. §§ 1320f(a)(1), 1320f-1(b)(1), (d)(1). By a deadline set by the IRA, the manufacturers of the selected drugs must "negotiate to determine * * * a maximum fair price" (MFP) and "enter into agreements" with CMS to provide Medicare beneficiaries access to their drugs at or below the MFP. *Id*. § 1320f-2(a).

For each day that the manufacturer of a selected drug fails to reach an "agreement" with CMS after the statutory deadline, every domestic sale of the drug is subject to a punishing "excise tax." 26 U.S.C. § 5000D(b)(1)(A). This tax—imposed on all sales, both through Medicare and in the private market—starts at 186% of the selected drug's price and escalates to 1900% depending on the duration of "[n]oncompliance." See Cong. Rsch. Serv., R47202, *Tax Provisions in the Inflation Reduction Act of 2022 (H.R. 5376)* 4 (2022).

Manufacturers of selected drugs thus have little real choice but to "agree" to negotiate an MFP for their drugs. But these "negotiations" lack the flexibility to

allow CMS and manufacturers to reach a truly agreed-upon price. Instead, each Program "negotiation" is heavily regulated and stacked in CMS's favor. The IRA imposes a ceiling price that CMS may not exceed when negotiating the MFP. 42 U.S.C. § 1320f-3(b)(2)(F), (c). Depending on how long the drug has been approved, this ceiling can be as low as 40 percent of the non-federal average manufacturer price (which approximates the market price), and no higher than 75 percent of that price. *Id*. § 1320f-3(c). The IRA also directs CMS to aim to achieve the lowest MFP for each selected drug. *Id*. § 1320f-3(b)(1).

Most importantly, drug manufacturers are stripped of any bargaining power, since the excise tax removes any real ability to walk away. A Program negotiation is thus "a negotiation only in the Vito Corleone sense—an offer one can't refuse." Daniel Hemel, *A Complete Breakdown of the Good, the Bad, and the Ugly in the Inflation Reduction Act*, Slate (Aug. 10, 2022), perma.cc/3V8L-ZD3G. The MFP that a drugmaker "agrees" to is therefore effectively a government-dictated price.

The manufacturer of a selected drug is bound by its previous "agreement"—entered into on pain of a draconian excise tax on all domestic sales—to provide "access" to the drug at the MFP for Medicare beneficiaries and their healthcare providers. In other words, the manufacturer is required to sell the drug at the artificially low price effectively dictated by CMS. This requirement is enforced by severe civil monetary penalties: A manufacturer who charges above the MFP for Medicare sales is liable for ten times the difference between the drug's sale price and the MFP for each sale. 42 U.S.C. § 1320f-6(a).

The only way that manufacturers of drugs selected for the Program can avoid this scheme of forced sales at confiscatory prices is by withdrawing all of their drugs from the Medicare and Medicaid markets altogether. See 26 U.S.C. § 5000D(c)(1)(A)(i); 42 U.S.C. § 1395w-153(a). But since these federal programs account for "almost half the annual nationwide spending on prescription drugs" (*Sanofi Aventis U.S. LLC* v. *HHS*, 58 F.4th 696, 699 (3d Cir. 2023)), a complete exit from Medicare and Medicaid sales is commercially untenable for almost all drug manufacturers—not to mention an ethically unacceptable option that would cut off millions of vulnerable patients from the drugs they depend on.

Congress has thus created a system under which the government can name its price for a product and then punish manufacturers for failing to provide it. Such an extortionate scheme is plainly unconstitutional. The government's only real defense is that Congress termed this extortion "negotiation"—but "[t]he service of an ultimatum does not constitute a negotiation" where "the other party has no choice except to accept the offer or accede to the demand." *Erie Lackawanna Rwy. Co.* v. *Lighter Captains Union*, 338 F. Supp. 955, 964-965 (D.N.J. 1972). Congress cannot avoid the Program's unconstitutional nature through semantics.

More, the issues presented in the petitions are exceptionally important. Even setting aside the significant negative consequences for drug development posed by the decision below, the Third Circuit's reasoning would nullify a wide swath of constitutional constraints on Congress's power. If Congress can force companies to forfeit constitutional protections by

restricting access to economic sectors dominated by government spending, then the Constitution offers them no real protection at all.

The Court should grant the petitions and correct the Third Circuit's serious error.

I. THE PROGRAM IS UNLAWFUL.

A. The Program effects an uncompensated, *per se* taking.

Patented drugs manufactured by petitioners Bristol Myers Squibb Co. and Janssen Pharmaceuticals Inc. were among those selected by CMS for "negotiations" in the initial price applicability period. But by requiring manufacturers to provide the selected drugs at heavily discounted prices, the Program works a *per se* taking of their personal property without just compensation. In the case of such categorical invasions of property rights, even if the government action does not "'deprive[] the owner of all economically valuable use' of the affected property," courts will still find a taking. *Horne* v. *Dep't of Agric.*, 576 U.S. 350, 363 (2015) (quoting *Tahoe-Sierra Pres. Council, Inc.* v. *Tahoe Reg'l Plan Agency*, 535 U.S. 302, 323 (2002)).

The Program effects a classic, *per se* taking because it requires transfers of title to the selected drugs from the drugs' manufacturers to third parties, for less than the drugs' value. No matter how one approaches it, the government cannot require drug manufacturers to surrender their drugs at prices below those which manufacturers would voluntarily accept absent punitive coercion.

1. The government "has a categorical duty to pay just compensation" whenever it "appropriate[s] personal property." *Horne*, 576 U.S. at 358. *Horne*

concerned an order under the Agricultural Marketing Agreement Act of 1937 which required raisin growers to turn over a percentage of their crops to the government. *Id.* at 355. The Court held that the regulatory requirement—though styled as an "agreement"— was a "clear physical taking" because "[a]ctual raisins are transferred" and "[t]itle to the raisins passes" from the growers to the government. *Id.* at 361. Raisin farmers thus suffered a "physical appropriation of [their] property," giving rise to a "*per se* taking" that required compensation without further analysis. *Id.* at 360 (emphasis omitted). The same is true of drugs required to be tendered to the government under the Program's agreements at prices below the drugs' actual value.[2]

The Third Circuit attempted to skirt the Court's clear and on-point holdings by insisting that because withdrawal from Medicare and Medicaid is an option under the Program, manufacturers' "choice" to sell drugs at the government-mandated rate "is not a taking." Janssen Pet. App. 32a. The court reasoned that if manufacturers "dislike the prices the government is willing to pay, they are free to stop doing business

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[2] The district court incorrectly held that the Program does not amount to a taking because it does not "require a manufacturer to physically transmit or transport drugs at the agreed price." Janssen Pet. App. 101a. For one, this is not correct—drugs would be of little use to patients or medical providers who could not physically possess them. And the Court has made clear that the forced transfer of title effects a *per se* taking just as surely as physical possession and occupation, equating the government's "actual taking of possession and control" of personal property with the transfer to the government of "title and ownership." *Horne*, 576 U.S. at 362 (quoting *Loretto* v. *Teleprompter Manhattan CATV Corp*., 458 U.S. 419, 431 (1982)).

with the government." *Id.* at 16a. Thus, the court reasoned, there is no "government mandate" to sell the drugs, and so there is no taking. *Id.* at 17a.

Any facial appeal to the Third Circuit's approach cannot stand in light of the Court's clear teaching that a taking need not be backed by strict legal compulsion. A scheme that requires property owners to transfer title to their property to the government or third parties effects *per se* takings of property, even if the government does not close off every legal option for owners to avoid the scheme. The formal availability of a financially ruinous option cannot save the Program from constitutional infirmity under the Takings Clause.

In *Loretto*, for example, the Court held that a New York law requiring landlords of rental properties to allow cable television companies to install cable equipment on their properties worked a *per se* taking to the extent of the permanent physical occupation. 458 U.S. at 434-435. While the Court observed that landlords "could avoid the requirements" of the law by "ceasing to rent the building to tenants" (*id.* at 439 n.17), the Court denied that the scheme "was not a taking because a landlord could avoid the requirement by ceasing to be a landlord." *Horne*, 576 U.S. at 365. The argument that a governmental invasion of property is constitutionally permissible so long as the government provides a formal legal option to avoid it—no matter how financially onerous or practically empty—would, the Court concluded, "prove too much." *Loretto*, 458 U.S. at 439 n.17. To ensure that the Takings Clause has meaning, the Court reasoned, "a landlord's ability to rent his property may not be conditioned on his forfeiting the right to compensation" for an appropriation of his property. *Id.*

The Court reaffirmed this principle in *Horne*, rejecting the government's contention that the reserve raisin requirement was permissible because growers of raisin-variety grapes voluntarily participated in the raisin market. The Court recognized the hypothetical option for growers to sell their grapes as table grapes or for use in juice or wine instead of as raisins. But it held that the formal option for sellers of a product to avoid a scheme of government appropriations by exiting the market does not alter the *per se* takings analysis. It is "wrong as a matter of law" to suggest that the existence of such practically useless options gives the government free rein to circumvent the Fifth Amendment. *Horne*, 576 U.S. at 365. As the Court emphasized, "property rights 'cannot be so easily manipulated.'" *Ibid*. (quoting *Loretto*, 458 U.S. at 439 n.17).

2. Drug manufacturers have only an "illusory" option to withdraw entirely from the Medicare and Medicaid markets for prescription drugs because these programs account for a dominant share of spending on pharmaceuticals. Janssen Pet. App. 72a (Hardiman, J., dissenting). Since the launch of Medicare Part D in 2006, Medicare has increasingly become a major payer for prescription drugs. By 2015, 35 million Americans were enrolled in Medicare Part D. Peter Olson & Louise Sheiner, *The Hutchins Center Explains: Prescription Drug Spending*, Brookings Institution (Apr. 26, 2017), perma.cc/8NMS-HT9P. By 2021, Medicare Part D's contribution to domestic expenditures on prescription drugs had risen to 32%, making it the second largest payer for retail drugs after private insurance. Emma Wagner et al., *What Are the Recent and Forecasted Trends in Prescription*

Drug Spending?, Peterson-KFF Health System Tracker (Sept. 15, 2023), perma.cc/B9AK-HGEC.

When combined, the Medicare and Medicaid prescription drug market accounts for about 45% of U.S. spending on retail prescription drugs. Cong. Budget Off., *Prescription Drugs: Spending, Use, and Prices* 8 (2022), perma.cc/R2Q9-96AZ. In light of this market data, it cannot be doubted that the "federal government dominates" the market for prescription drugs. *Sanofi*, 58 F.4th at 699.

Given the outsized and growing share of the prescription-drug market represented by Medicare and Medicaid, any drugmaker that abandoned Medicare and Medicaid sales would face a devastating competitive disadvantage. The "choice" to exit the Medicare and Medicaid markets (Janssen Pet. App. 32a) is, from a commercial standpoint, a purely hypothetical one. And since there are tens of millions of Medicare and Medicaid beneficiaries, a drugmaker that withdrew from these programs entirely would also be cutting off countless patients from the drugs they depend on to meet their healthcare needs.

In sum, that manufacturers could *technically* avoid a taking by exiting the Medicare and Medicaid markets makes no difference to the takings analysis. Short of that commercially infeasible and ethically fraught step, manufacturers will be required to sell their products at the government-dictated, below-market MFP. This forced transfer is a *per se* taking without just compensation forbidden by the Fifth Amendment.

B. The Program imposes an unconstitutional condition on participation in Medicare.

The Third Circuit's defense of the Program as consistent with the Fifth Amendment, on the grounds that participation in Medicare and Medicaid is optional, also runs headlong into the unconstitutional conditions doctrine. That doctrine generally prohibits the government from conditioning the availability of valuable benefits on the recipients' agreement to give up their constitutional rights. Instead, conditions are permissible only in the narrow circumstance where they are a proportionate means of serving the legitimate purpose behind the benefit scheme.

As explained above, the Program infringes manufacturers' rights to be free of uncompensated takings of their property. The option to withdraw from Medicare and Medicaid to avoid these takings renders acquiescence to a constitutional intrusion a precondition for participation in these federal programs. Because the condition is neither relevant nor proportional to the needs of the Program, it cannot justify the required sacrifice of manufacturers' constitutional rights.

1. Congress cannot effect takings by requiring uncompensated transfers of property to access a government program.

The unconstitutional conditions doctrine prohibits the government from achieving by economic coercion "a result which [it] could not command directly." *Perry* v. *Sindermann*, 408 U.S. 593, 597 (1972) (quoting *Speiser* v. *Randall*, 357 U.S. 513, 526 (1958)). If the federal government could coerce parties entitled to a constitutional protection into "voluntarily" relinquishing those protections, then it could "frustrate"

constitutional constraints whenever it enjoys significant leverage. *Koontz* v. *St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 605 (2013). The Constitution "cannot be so easily manipulated." *Horne*, 576 U.S. at 365 (quoting *Loretto*, 458 U.S. at 439 n.17). To "vindicate[]" the Constitution's protections, the unconstitutional conditions doctrine therefore "prevent[s] the government from coercing people into giving them up." *Koontz*, 570 U.S. at 604.

The Fifth Amendment's guarantee against uncompensated takings is a central subject of the unconstitutional conditions doctrine. In the land-use permitting context, for example, property owners are "vulnerable to the type of coercion that the unconstitutional conditions doctrine prohibits": Absent the doctrine, "by conditioning a building permit on the owner's deeding over a [property interest], the government can pressure an owner into voluntarily giving up property for which the Fifth Amendment would otherwise require just compensation." *Koontz*, 570 U.S. at 604-605. To prevent the government from thus evading the requirements of the Takings Clause, the unconstitutional conditions doctrine steps in to prohibit the government from making "[e]xtortionate demands" in return for granting development permits. *Id*.

The spending power represents another context of particular concern for the unconstitutional conditions doctrine. Congress has no "power to issue direct orders to the governments of the States" (*Murphy* v. *NCAA*, 138 S. Ct. 1461, 1476 (2018)), but it holds significant leverage through conditions on the flow of federal funds, allowing it to "hold out incentives to the States as a method of influencing a State's policy

choices" (*New York* v. *United States*, 505 U.S. 144, 166 (1992)). To ensure that Congress does not abuse this immense leverage—"coercion by economic pressure" (*United States* v. *Butler*, 297 U.S. 1 (1936))—the Court has "consistently invoked the doctrine of unconstitutional conditions as a bar to conditions on federal subsidies [to the States] that would be unconstitutional if imposed by direct command." Kathleen M. Sullivan, *Unconstitutional Conditions*, 102 Harv. L. Rev. 1413, 1431 (1989).

As developed in this context, the unconstitutional conditions doctrine prohibits "financial inducement offered by Congress" that is "so coercive as to pass the point at which 'pressure turns into compulsion.'" *NFIB* v. *Sebelius*, 567 U.S. 519, 580 (2012) (quoting *South Dakota* v. *Dole*, 483 U.S. 203, 211 (1987)).

2. The Program fails the relevance and proportionality tests.

a. The Court has developed different tests in different factual and doctrinal contexts to determine when conditions attached to government benefits become unconstitutional. *See, e.g.*, *NFIB*, 567 U.S. at 580 (federal funding and federalism); *Koontz*, 570 U.S. at 605-606 (land-use permitting and takings); *Agency for Int'l Dev.* v. *All. for Open Society Int'l, Inc.*, 570 U.S. 205, 214-215 (2013) (government funding and free speech). These cases reveal two criteria that guide the analysis where, as here, Congress conditions a business's access to a government program on the business's acquiescence in an invasion of its property rights.

First, the condition attached to the government benefit must be *relevant* to the legitimate purpose that underlies the benefit scheme. For example, where the

government conditions approval of a land-use permit on the landowner's agreement to grant the government an interest in the property, there must be an "essential nexus" "between the condition and the original purpose" of the permitting scheme. *Nollan* v. *Cal. Coastal Comm'n*, 483 U.S. 825, 837 (1987). Unless the permit condition "serves the same governmental purpose as" the permitting scheme, the condition is not a "valid regulation of land use but 'an out-and-out plan of extortion.'" *Id.* (quoting *J.E.D. Assocs., Inc.* v. *Atkinson*, 432 A.2d 12, 14-15 (N.H. 1981)); *see also Sheetz* v. *County of El Dorado*, 144 S. Ct. 893, 900 (2024) (explaining that the "essential nexus" requirement "ensures that the government is acting to further its stated purpose, not leveraging its permitting monopoly to exact private property without paying for it.").

A similar criterion applies where the government places speech-related conditions on government funding. While conditions that specify the activities to which the funds may be put are permissible since they "define the limits of the government spending program" itself, "conditions that seek to leverage funding to regulate speech *outside* the contours of the program" are unconstitutional. *Agency for Int'l Dev.*, 570 U.S. at 214-215 (emphasis added). Likewise, where the federal government attaches conditions on States' spending of federal funds, conditions that "take the form of threats to terminate other significant independent grants" are suspect, and are "properly viewed as a means of pressuring the States to accept policy changes." *NFIB*, 567 U.S. at 580.

Second, the burdens created by the condition must be *proportionate* to the social problems the government is seeking to tackle by demanding the condition.

In the land-use permitting context, where the government conditions the approval of a development permit on the landowner's dedication of property to the public, the required dedication must be "related both in nature and extent to the impact of the proposed development." *Dolan* v. *City of Tigard*, 512 U.S. 374, 391 (1994). Permit conditions "must have 'rough proportionality' to the development's impact on the land-use interest": They may not require a landowner "to give up more than is necessary to mitigate harms resulting from new development." *Sheetz*, 144 S. Ct. at 900.

In the federalism context, where a condition attached to federal funding does not govern the use of the funds themselves, courts must ask whether the "financial inducement offered by Congress" is disproportionate in the sense that it is "so coercive as to pass the point at which 'pressure turns into compulsion.'" *NFIB*, 567 U.S. at 580 (quoting *Dole*, 483 U.S. at 211). That point comes when the threatened denial of funds becomes "economic dragooning that leaves the States with no real option but to acquiesce" in federal policy. *Id*. at 582.

b. The Program fails the tests of relevance and proportionality.

The Constitution empowers Congress to "lay and collect Taxes, Duties, Imposts, and Excises" to "provide for the . . . general Welfare of the United States." U.S. Const. Art. I, § 8, cl. 1. The Court has recognized that Congress has broad power under this Spending Clause "to authorize expenditure of public moneys for public purposes," which is "not limited by the direct grants of legislative power found in the Constitution." *Dole*, 483 U.S. at 207. Congress's spending power encompasses the power to establish the Medicare

program to provide health insurance to elderly and disabled Americans, including the Part D program to provide coverage for prescription drugs. *Becerra* v. *Empire Health Found.*, 142 S. Ct. 2354, 2359 (2022). Congress may also properly seek to control Medicare expenditures. To the extent the Program seeks to control Medicare spending by lowering the prices of some prescription drugs, it arguably aims at a legitimate public purpose.

But the Program does not simply establish a maximum price the government is willing to pay for specified drugs. Instead, unless the manufacturer of a selected drug agrees to negotiate with CMS and sell the drug to Medicare patients and providers at the MFP, all domestic sales of the drug—not just Medicare sales—are liable to a punitive excise tax. And while a manufacturer theoretically could avoid the Program's scheme of forced sales at below-market MFPs, it could do so only by forgoing access to Medicare and Medicaid spending on *all* the drugs in its portfolio. The Program therefore does not just impose conditions on how the government will spend federal funds on the selected high-spend drugs, but issues "threats to terminate other significant independent grants." *NFIB*, 567 U.S. at 580. As such, the Program's conditions are not "relevant" to its legitimate purpose.

Nor are the conditions proportionate. The Program's conditioning of *any* participation in the Medicare and Medicaid markets on manufacturers' agreement to forced, below-market sales imposes burdens disproportionate to what is "necessary to mitigate harms resulting from" allegedly high prices of the selected drugs. *Sheetz*, 144 S. Ct. at 900.

The Court's treatment of the proportionality criterion in *NFIB* is instructive. There, the Court considered the Medicaid expansion provisions in the Patient Protection and Affordable Care Act (ACA), which gave Medicaid funding to the States only "on the condition that they provide specified health care to all citizens whose income falls below a certain threshold." *NFIB*, 567 U.S. at 351. Specifically, the ACA "threaten[ed] to withhold all of a State's Medicaid grants," unless the State accepted Medicaid expansion. *Id*. at 575. The Court held that the ACA's conditioning of States' entire Medicaid funding, including existing Medicaid funds, on its acceptance of Medicaid expansion exerted disproportionate pressure on the state governments. Observing that "Medicaid spending account[ed] for over 20 percent of the average State's total budget, with federal funds covering 50 to 83 percent of those costs," the Court concluded that the "threatened loss of over 10 percent of a State's overall budget" was impermissible "economic dragooning" and a "gun to the head." *Id*. at 581-582.

Just so here: Because Medicare and Medicaid account for "almost half the annual nationwide spending on prescription drugs" (*Sanofi*, 58 F.4th at 699), the Program's conditioning of participation in those programs on manufacturers' acquiescence to below-market sales threatens to hugely impact drugmakers' overall revenues. Janssen would lose almost *two thirds* of its total drug sales, for example, if it were shut out of Medicare and Medicaid. Janssen Pet. 10. If the threatened loss of "over 10 percent" of a State's budget was enough for the ACA's Medicaid expansion to constitute disproportionate "economic dragooning" (*NFIB*, 567 U.S. at 582), the threatened loss of almost

50 percent of the U.S. market for prescription drugs—and more for certain manufacturers—is *a fortiori* enough for the Program to do the same.

The Program thus unconstitutionally coerces drug manufacturers into relinquishing their Fifth Amendment right to just compensation for the *per se* physical taking it effects.

3. The Third Circuit erroneously and artificially cabined the unconstitutional conditions doctrine.

In light of the Court's consistent application of the unconstitutional conditions doctrine to the right at issue here, there was no merit to the Third Circuit's refusal "to subject the Program to scrutiny." Janssen Pet. App. 30a.

The Third Circuit declined to undertake the required analysis solely based on its observation that this Court "has not expanded the *Nollan-Dolan* test beyond conditions on land-use permitting." Janssen Pet. App. 30a-31a.[3] But the Court has applied the unconstitutional conditions framework "in a variety of contexts" to safeguard a variety of constitutional rights. *Koontz*, 570 U.S. at 604 (citing cases concerning tax-exempt status, education funding, political employment, university employment, and the right to travel and healthcare benefits). Indeed, it has described the "unconstitutional conditions doctrine" as "an overarching principle * * * that vindicates the Constitution's enumerated rights by preventing the

[3] The court provided only a thinly reasoned footnote asserting in the alternative that the Program would pass unconstitutional-conditions scrutiny. Janssen Pet. App. 31a n.21. As described above, that is incorrect.

government from coercing people into giving them up." *Ibid.* There is no reason to believe that such an "overarching" component of the constitutional order is limited to particular rights or contexts.

To the contrary, this Court has rejected attempts to relegate particular rights to "second-class" status or "subject" a right "to an entirely different body of rules than the other Bill of Rights guarantees." *N.Y. State Rifle & Pistol Ass'n* v. *Bruen*, 597 U.S. 1, 70 (2022) (quoting *McDonald* v. *City of Chicago*, 561 U.S. 742, 780 (2010)). The unconstitutional conditions doctrine has broadly been held to prevent the government from conditioning ostensibly voluntary federal spending programs on relinquishment of constitutional rights in the First Amendment and federalism contexts. *Agency for Int'l Dev.*, 570 U.S. at 214-215; *NFIB*, 567 U.S. at 580. The Fifth Amendment's guarantee of just compensation for deprivations of property should be no different. Indeed, "there are few [constitutional] safeguards * * * against oppression and the exercise of arbitrary power" that are "of more ancient origin or of greater value to the citizen." *United States* v. *Russell*, 80 U.S. (13 Wall.) 623, 627 (1871).

Nor is there any reason to distinguish the permitting context from this one. Just as in *Koontz*, drug manufacturers are "vulnerable to the type of coercion that the unconstitutional conditions doctrine prohibits because the government often has broad discretion to deny a [benefit] that is worth far more than property it would like to take." 570 U.S. at 604-605. "So long as" access to the Medicare and Medicaid markets "is more valuable than" the value of the property the government is extorting, "the owner is likely to accede to the government's demand, no matter how

unreasonable." *Ibid.* Thus, just as in *Koontz*, "[e]xtortionate demands of this sort frustrate the Fifth Amendment right to just compensation, and the unconstitutional conditions doctrine prohibits them." *Ibid.*

The results of the court of appeals' holding—if permitted to stand—are startling. If the Third Circuit's view prevails, the Constitution will impose no restriction on the government's ability to extort property from market participants, so long as the specific context at issue is something other than "land-use permitting." Janssen Pet. App. 30a-31a. The government could require private universities to transfer ownership of acres of university property as a precondition to applying for federal research grants. It could demand that all visa applicants provide permanent easements for federal employees to enter their homes. Or it could insist that all users of federal infrastructure render unto the government any piece of real, personal, or intellectual property imaginable—all without any restrictions, because of the thin illusion of choice.

These absurd scenarios, and more besides, are precisely what the unconstitutional conditions doctrine exists to prevent. The Third Circuit's decision seriously undermines that doctrine, putting the Constitution's substantive protections at risk. It cannot stand.

II. THE PROGRAM UNDERMINES INCENTIVES TO INNOVATE IN THE PHARMACEUTICAL INDUSTRY.

The Program's unconstitutional scheme to economically coerce the manufacturers of selected drugs into selling their products at government-dictated

below-market prices will ultimately harm patients—including Medicare beneficiaries—by causing drug development to stagnate, preventing access to new and urgently needed therapeutic options. This is an issue of exceptional importance to drug manufacturers as well as the countless patients who benefit from innovative pharmaceuticals every day.

Pharmaceutical manufacturers invest heavily in innovation, devoting $83 billion to R&D in 2019 alone. For that year, drug companies on average spent about one-quarter of their revenues on R&D, a revenue share larger than that of other knowledge-based industries. The industry's commitment to innovation has paid off: The number of new drugs approved each year has grown compared to historical trends. On average, the FDA approved 38 new drugs per year from 2010 through 2019, an uptick of 60 percent over the yearly average in the previous decade. See Cong. Budget Off., *Research and Development in the Pharmaceutical Industry* 1 (2021), perma.cc/AQP6-PASY.

To sustain this innovative ecosystem, drugmakers need incentives to invest in R&D. Developing new drugs is a costly and uncertain process. The average R&D cost per new drug has been estimated at more than $2 billion. What is more, many potential drugs never make it to market: only about 12 percent of drugs entering clinical trials are ultimately approved by the FDA. The drug development process can also be drawn out, taking a decade or more, during which time the drugmaker receives no financial return on its investment. Cong. Budget Office, *supra*, at 2.

Drug manufacturers will only have the confidence to make expensive and risky investments in R&D if they expect a competitive revenue stream in the event

an investigational product proves successful. Any government policy that will dampen sales volume or impair manufacturers' ability to sell products for their fair market value will shake this confidence and undermine incentives for innovation within the pharmaceutical industry.

The Program threatens exactly that. Once a manufacturer's drug is selected, it faces only two options. It can either acquiesce in the Program's scheme of forced sales at the government-dictated MFP, which will artificially depress the price of the drug below fair market value, or it can exit the Medicare and Medicaid markets, leading to a steep drop in sales for *all* of its drug lines. The inevitable impact of the Program, therefore, is a serious erosion in the incentives for pharmaceutical innovation.

The Program accordingly is projected to cause a drop in the number of drugs that will be introduced to the U.S. market over the coming decade. Cong. Budget Off., *Estimated Budgetary Effects of Subtitle I of Reconciliation Recommendations for Prescription Drug Legislation* 5 (2022), perma.cc/AQP6-PASY. One study from the University of Chicago has estimated that the Program will lead to a $232.1 billion reduction in pharmaceutical R&D investment over 20 years, which in turn will mean 79 fewer new drugs and 109 fewer post-approval indications for these drugs. Tomas J. Philipson et al., *Policy Brief: The Impact of Price Setting at 9 Years on Small Molecule Innovation Under the Inflation Reduction Act* (2023), perma.cc/A7T4-49CA.

In sum, the Program's unconstitutional overreach, if left unchecked, will harm innovation in the American pharmaceutical industry for decades to

come. Those who will ultimately bear the brunt of this blow to medical innovation are the millions of patients who will lose out on the life-changing—or even life-saving—therapies that might have been developed and brought to market, but for the Program's innovation-stunting effects.

CONCLUSION

The Court should grant the petitions.

Respectfully submitted.

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