Nos. 24-1820 & 24-1821

In the

United States Court of Appeals

for the

Third Circuit

BRISTOL MYERS SQUIBB CO.,
Plaintiff-Appellant,
v.
U.S. SECRETARY OF HEALTH AND HUMAN SERVICES, et al.,
Defendant-Appellees.

JANSSEN PHARMACEUTICALS, INC.,
Plaintiff-Appellant,
v.
U.S. SECRETARY OF HEALTH AND HUMAN SERVICES, et al.,
Defendants-Appellees.

On Appeal from the United States District Court
for the District of New Jersey
Case Nos. 3:23-cv-3335 & 3:23-cv-3818, Hon. Zahid N. Quraishi

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BRIEF OF *AMICUS CURIAE* THE NATIONAL ASSOCIATION OF MANUFACTURERS IN SUPPORT OF PLAINTIFFS-APPELLANTS

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CORPORATE DISCLOSURE

Pursuant to Third Circuit Local Appellate Rule 26.1.1 and Federal Rule of Appellate Procedure 26.1, *amicus curiae* hereby certifies that it has no parent corporations and that no publicly held corporations own 10% or more of its stock.

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STATEMENT OF INTEREST OF AMICUS CURIAE[1]

The National Association of Manufacturers (NAM) is the largest manufacturing association in the United States, representing 14,000 manufacturers in all 50 states and in every industrial sector. Manufacturing is a vital engine of the American economy, employing nearly 13 million men and women, and contributing $2.89 trillion to the economy annually. Manufacturers in the United States also power the economy by driving innovation forward. Manufacturing accounts for over half of all private-sector research and development (R&D) in the nation, and manufacturers have been awarded more patents than any other sector in the economy. *See* NAM, *Competing to Win* 30 (2024), perma.cc/2TRJ-NBUJ. Within the manufacturing sector, pharmaceutical manufacturers play an outsized role in contributing to the innovation-led economy.

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 requires assurance for manufacturers who

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[1] This brief has not been authored, in whole or in part, by counsel to any party in this appeal. No party or counsel to any party contributed money intended to fund preparation or submission of this brief. No person, other than the *amicus*, its members, or its counsel, contributed money that was intended to fund preparation or submission of this brief. Plaintiff-Appellants and Defendants-Appellees consented to the filing of this brief.

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 prescription drugs that have been selected for the Program's scheme of price controls. 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 is not only devastating to 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 Taking Clause.

The NAM has a significant interest in these cases. It counts as its members many pharmaceutical innovators, including companies whose drug products have been selected for the Program. As the voice of the manufacturing sector, the NAM is also concerned more broadly about unconsti-

tutional government overreach that curtails innovation and harms the competitiveness of American industry. The NAM files this brief to underscore that the government may not circumvent the Constitution's protections for property rights simply by imposing unconstitutional conditions on government benefits to coerce private individuals and entities into "agreeing" to relinquish their property interests.

INTRODUCTION

Each year, the Nation's drugmakers invest hundreds 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 final approval from the Food and Drug Administration (FDA).

Both because of the costs of development and because of the enormous demand for many pharmaceuticals, drug prices have increased in recent years. 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 manufacturer would voluntarily agree to such an economically catastrophic deal, Congress converted its offer into one drug manufacturers 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 ruinous 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.

This is no choice at all—but that is all Congress has offered to drug manufacturers. The Drug Price Negotiation Program (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.

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 access to their drugs at or below the MFP to Medicare beneficiaries. *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 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 for marketing, 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 the non-federal average manufacturer 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, the drug manufacturers are stripped of any bargaining power, since the excise tax removes any real choice to walk away from the "negotiations." 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/25JB-LY7D. The MFP that a drugmaker "agrees" to at the end of this "negotiation" process is therefore effectively a government-dictated price.

The manufacturer of a selected drug is bound by its previous "agreement"—entered into on pain of having all domestic sales subject to the draconian excise tax—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 millions of vulnerable patients off from the drugs that they depend on.

In enacting the Program, Congress thus created a system where the government can name its price for a product and then punish manufacturers for failing to provide drugs at that price. 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 an ultimatum" 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 by labeling this a "negotiation."

I. THE PROGRAM EFFECTS AN UNCOMPENSATED, *PER SE* TAKING.

Patented drugs manufactured by Plaintiffs Bristol Myers Squibb Co. (BMS) and Janssen Pharmaceuticals, Inc. (Janssen) were among the drugs selected by CMS for "negotiations" to "agree" on MFPs in the initial price applicability period. In the district court, BMS and Janssen argued that the Program violates the Fifth Amendment because the requirement that they provide Medicare beneficiaries and their healthcare providers "access" to the selected drugs at heavily discounted prices 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. No matter how one approaches it, the government cannot require drug manufacturers to surrender their drugs at rates below those which manufacturers would voluntarily accept absent punitive coercion.

A. Forced transfer of title, as much as a physical appropriation, effects a *per se* taking.

In *Horne*, the Supreme Court held that 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 requires 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.

The district court rejected this straightforward theory on the sole basis that the Program does not "require a manufacturer to physically transmit or transport drugs at the agreed price." *Bristol Myers Squibb Co. v. Becerra*, 2024 WL 1855054, at *5-*6 (D.N.J. Apr. 29, 2024). Facially, this is not correct—drugs would be of little use to patients or medical providers who could not physically possess them. But that aside, there was simply no suggestion in *Horne* that the government *only* accomplishes a *per se* taking when it "physically takes possession of an interest in property." 576 U.S. at 357 (quotation marks omitted).

To the contrary, the Court 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." *Id*. at 362 (quoting *Loretto v. Teleprompter Manhattan CATV Corp*., 458 U.S. 419, 431 (1982)). Both physical appropriation and the forced transfer of title qualify as *per se* takings, since in both circumstances the owner of personal property "lose[s] the entire 'bundle' of property rights" in the property—"the rights to possess, use and dispose of" it. *Id*. at 361-362 (quoting *Loretto*, 458 U.S. at 435). Even supposing that the Program involves no

physical appropriation of Plaintiffs' drug products, the Program's "access" requirement therefore still amounts to a *per se* taking of Plaintiffs' property in their drug products, provided the requirement forces manufacturers to transfer *title* to their drug products.

That is precisely what the "access" requirement does. Drug manufacturers are bound by the "agreements" they enter into with CMS to sell their selected drug products to Medicare beneficiaries and their healthcare providers at or below the government-dictated MFP. A forced sale is, definitionally, a forced transfer of title. *See, e.g.*, U.C.C. § 2-106(1) ("A 'sale' consists in the passing of title from the seller to the buyer for a price."). Here, Plaintiffs are bound to sell their selected drug products to Medicare patients and providers. Upon sale, title to these products passes from manufacturers to Medicare patients and providers, who from that moment hold the rights to "possess, use, and dispose of" the drug products.[2] And that sale is forced—manufacturers who turn over their property at artificially low prices do so only upon the threat of harsh penalties. *See* 42 U.S.C. § 1320f-6(a).

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[2] It is no answer to the takings problem that title passes to private individuals rather than the government. *See Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2072 (2021) (explaining that the "essential question" in distinguishing *per se* from regulatory takings is whether "the government has physically taken property for itself *or someone else*—by whatever means—or has instead restricted a property owner's ability to use his own property") (emphasis added).

To be sure, this scheme of forced sales results in nominal payments to drug manufacturers in exchange for title to the drugs. But, as the Court emphasized in *Horne*, "once there is a taking … any payment from the Government in connection with that action goes, at most, to the question of just compensation." *Id*. at 364. The measure of just compensation for a taking is "the market value of the property at the time of the taking." *Id*. at 368-369 (quoting *United States v. 50 Acres of Land*, 469 U.S. 24, 29 (1984)). Since the IRA establishes a ceiling on the MFP that CMS can propose during the negotiation process, and that ceiling can at most be 75 percent of the selected drug's fair market value (42 U.S.C. § 1320f-3(c)), the Program inflicts a *per se* taking of Plaintiffs' personal property in their drug products without paying just compensation.

B. Strict legal compulsion is not a precondition for a *per se* taking.

The district court attempted to skirt the Supreme Court's clear and on-point holdings by insisting that "the Program neither requires nor forces Plaintiffs to … sell their drugs." *Bristol Myers Squibb*, 2024 WL 1855054, at *6. The court reasoned that, while manufacturers would incur severe penalties if they fail to provide Medicare patients and providers "access" to their drug products at the MFP, they can avoid the "access" requirement by completely withdrawing from Medicare and Medicaid sales. *See id.* at *7. As

such, the district court reasoned, manufacturers are not *strictly* "legally compelled" to sell their drugs at the MFP under the Program. *Id*. at *5.

1. Any facial appeal to the district court's approach withers in light of the Supreme 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.

Thus, in *Loretto*, the Court held that a New York law requiring landlords of rental properties to allow cable television companies to install cable facilities on their properties worked a *per se* taking to the extent of the permanent physical occupation on the landlords' properties. 458 U.S. at 434-435. While the Court expressly 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 law "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 not a taking just so long as the government provides a formal legal option—no matter how financially onerous and therefore practically empty—for the

owner to avoid the invasion would, the Court concluded, "prove too much," allowing the government to subvert the Fifth Amendment's protections for property rights. *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 there 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 for that product does not affect 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 a free pass to circumvent the Constitution's protections for property rights. *Horne*, 576 U.S. at 365. As the Court emphasized, "property rights 'cannot be so easily manipulated.'" *Id*. (quoting *Loretto*, 458 U.S. at 439 n.17).

2. Drug manufacturers have only a completely abstract "option" to withdraw entirely from the Medicare and Medicaid markets for prescription

drugs because these programs account for a dominant—and increasing—share of spending on pharmaceuticals. 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/NM6U-TLPK. 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/C9Q8-CE6Q.

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/KGE7-HQ3L. In light of this market data, it cannot be doubted that the "federal government dominates the healthcare market," and in particular the market for prescription drugs. *Sanofi*, 58 F.4th at 699.

Given the outsized and growing share of the market for prescription drugs captured by the Medicare and Medicaid programs, any drugmaker that abandoned Medicare and Medicaid sales would face a devastating competitive disadvantage. The "option" to exit from the Medicare and Medicaid

markets is, from a commercial standpoint, a purely hypothetical option. 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 that they depend on to meet their urgent—even life-threatening—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 give Medicare patients and providers "access" to their drugs at the MFP—i.e., to sell their products at the government-dictated, below-market price. This forced transfer is a *per se* taking without just compensation forbidden by the Fifth Amendment.

II. THE PROGRAM'S COERCIVE STRUCTURE IMPOSES AN UNCONSTITUTIONAL CONDITION ON PARTICIPATION IN MEDICARE.

The government's defense of the Program as consistent with the Fifth Amendment because participation in Medicare and Medicaid is optional 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.

A. Congress cannot require forced transfers as a condition that would be a taking if imposed directly.

In ruling that the unconstitutional conditions doctrine does not even apply because the Program does not independently violate the Constitution by appropriating manufacturers' property through direct legal compulsion, the district court fundamentally misunderstood the purpose of the doctrine and the circumstances where it is implicated.

1. 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 "prevent[s] the government from coercing people into giving them up." *Koontz*, 570 U.S. at 604.

The Fifth Amendment's protection against uncompensated takings is one such constitutional guarantee protected against erosion through coercion. In the land-use permitting context, for example, the government will sometimes condition the approval of a development permit on the property owner's agreement to deed an interest in the property to the government. This makes land-use permit applicants "vulnerable to the type of coercion that the unconstitutional conditions doctrine prohibits because the government often has broad discretion to deny a permit that is worth far more than property it would like to take." *Koontz*, 570 U.S. at 604-605. Specifically, "[b]y 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." *Id*. at 605. To prevent the government from evading the requirements of the Takings Clause by coercing property owners into "agreeing" to relinquish their property, the unconstitutional conditions doctrine steps in

to prohibit the government from making "[e]xtortionate demands" in return for granting development permits. *Id*.

What is more, the Supreme Court has recognized that federal programs enacted pursuant to Congress's spending power represent another context of particular concern for the unconstitutional conditions doctrine. While Congress may place conditions, for example, on the flow of federal funds to the states 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)), the Tenth Amendment deprives Congress of "power to issue direct orders to the governments of the States" (*Murphy v. NCAA*, 138 S. Ct. 1461, 1476 (2018)). To ensure that Congress does not abuse the immense leverage that its power to disburse federal funds gives it over the states to apply "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. Given the Supreme Court's application of the unconstitutional conditions doctrine to both the right and the context at issue here, there was no merit to the district court's blind insistence that the doctrine is inapplicable to the Program. The whole point of the unconstitutional conditions doctrine is to prevent the government from bypassing constitutional limits by using coercion instead of direct legal compulsion.

The inquiry is straightforward: Courts ask whether, "*had* the government simply appropriated the" property at issue, "this *would have been* a *per se* … taking." *Lingle v. Chevron U.S.A. Inc*., 544 U.S. 528, 546 (2005) (emphases added). The Program easily meets this threshold. If Congress had enacted legislation that legally compelled drug manufacturers to sell their products to Medicare patients and providers at prices well below their fair market value, that would be a *per se* taking without just compensation. Instead of directly transgressing the Takings Clause in this way, the Program "attempt[s] to pressure" Plaintiffs to agree to sell their products at the below-market MFP by making participation in the entire Medicare and Medicaid markets dependent on such agreement. *Koontz*, 570 U.S. at 612. This attempt to circumvent the Fifth Amendment's protections implicates the unconstitutional conditions doctrine.

B. The Program unconstitutionally coerces Plaintiffs into acquiescing to the forced transfers of their drug products.

1. The Supreme Court has developed different tests in different factual and doctrinal contexts to determine when conditions attached to government benefits become unconstitutional coercion applied by the government to pressure other actors to relinquish constitutional protections to which they are entitled. *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 unconstitutional conditions analysis where, as here, Congress conditions a business's access to a government program on the business's acquiescence to an invasion of its property rights.

First, the condition attached to receiving the government benefit must be *relevant* to the legitimate purpose that underlies the benefit scheme. For example, where the government conditions the approval of a land-use permit on the landowner's agreement to grant an interest in the property to the government, there must be a "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 receiving 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 itself" are unconstitutional. *Agency for Int'l Dev.*, 570 U.S. at 214-215 (emphasis added). Likewise, where the federal government attaches conditions on how state governments may spend federal funds, conditions that "take the form of threats to terminate other significant independent grants" are suspect, and they 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 receiving 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.

2. With this framing in mind, the Program abjectly 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." 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 that the Program seeks to control Medicare spending by lowering the prices of those prescription drugs that incur the highest Medicare expenditures, it aims at a legitimate public purpose.

But the Program does not limit itself to attaching conditions on how much the government is willing to spend on the drugs selected to be subject to price negotiations and the imposition of an MFP. Unless the manufacturer of a selected drug agrees to negotiate with CMS on an MFP and subsequently to sell the drug to Medicare patients and providers at that MFP, *all* domestic sales of the drug—not just Medicare sales—are liable to a punitive excise tax. While the drugmaker of a selected drug formally could avoid the Program's scheme of forced sales at below-market MFPs, the government would then effectively withhold Medicare and Medicaid spending on *all* drugs manufactured by that drugmaker. The Program therefore does not simply 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 agreement by manufacturers of selected drugs to subject themselves to its scheme of forced sales imposes disproportionate burdens on the manufacturers compared to what is "necessary to mitigate harms resulting from" the high prices of the selected drugs to Medicare patients and providers. *Sheetz*, 144 S. Ct. at 900.

The Supreme 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 *all* of a state's 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 "economic dragooning" and a "gun to the head." *Id*. at 581-582.

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 the Medicare and Medicaid markets on drug manufacturers' acquiescence to its scheme of forced sales at a below-market MFP threatens to wipe out huge swathes of drugmakers' overall sales. Janssen would lose almost *two thirds* of its total drug sales, for example. If the threatened loss of more than 10 percent of a state's budget was enough for the ACA's Medicaid expansion provisions to exert disproportionate pressure on state governments to accept Medicaid expansion, the threatened loss of almost 50 percent of the U.S. market for prescription drugs is *a fortiori* enough for the Program to exert disproportionate pressure on drugmakers to accept the forced sales scheme.

Because the Program fails the relevance and proportionality tests, it unconstitutionally coerces BMS and Janssen into relinquishing their Fifth Amendment right to just compensation.

III. THE PROGRAM DEVASTATES INCENTIVES TO INNOVATE IN THE PHARMACEUTICAL INDUSTRY.

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

dictated prices fixed at well below market rates will ultimately harm patients—including Medicare beneficiaries—by causing drug development to stagnate, thus depriving patients of access to new and urgently needed therapeutic options.

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/PT9R-LFKU.

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. *See id*. 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 for their innovative products. Any government policy that will dampen sales volume or impair manufacturers' ability to sell their products for their fair market value will undermine this confidence and devastate 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 far below fair market value, or it can exit the Medicare and Medicaid markets, leading to a steep drop in sales volume for the selected drug—and indeed for all of its other drug lines. The inevitable impact of the Program, therefore, is a devastating erosion in the incentives for pharmaceutical innovation. The Program is accordingly 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/48K3-QU6H. One study from the Uni-

versity 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. Phillipson et al., *Policy Brief: The Impact of Price Setting at 9 Years on Small Molecule Innovation Under the Inflation Reduction Act* (2023), perma.cc/QN79-F6DN.

In sum, the Program's unconstitutional overreach will—if left unchecked—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 life-saving and life-changing therapies that drug manufacturers might have developed and brought to market, but for the Program's innovation-stunting effects.

CONCLUSION

The Court should reverse the decision below.

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(g), I hereby certify that this brief:

(i) complies with the type-volume limitation of Rule 32(a)(7) because it contains 5,894 words, excluding the parts of the brief exempted by Rule 32(f); and

(ii) complies with the typeface requirements of Rule 32(a)(5) and the type style requirements of Rule 32(a)(6) because it has been prepared using Microsoft Office Word 2016 and is set in New Century Schoolbook LT Std font in a size equivalent to 14 points or larger.

Pursuant to Third Circuit Local Appellate Rule 31.1(c), I certify that the texts of the electronic brief and paper copies are identical and that Windows Defender has been run on the file and no virus was detected.

Pursuant to Third Circuit Local Appellate Rules 28.3(d) and 46.1(e), I certify that I am a member in good standing of the bar of the United States Court of Appeals for the Third Circuit.

Dated: July 19, 2024 /s/ *Paul W. Hughes*

CERTIFICATE OF SERVICE

I hereby certify that on July 19, 2024, I electronically filed the foregoing brief with the Clerk of this Court using the CM/ECF system, and counsel for all parties will be served by the CM/ECF system.

I further certify that seven paper copies of the foregoing brief were sent to the Clerk's Office via Fedex.

Dated: July 19, 2024 /s/ *Paul W. Hughes*