No. 24-2092

In the United States Court of Appeals for the Second Circuit

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,
Plaintiff-Appellant,

v.

UNITED STATES DEPARTMENT OF HEALTH & HUMAN SERVICES, ET AL.,
Defendants-Appellees.

On Appeal from the United States District Court
for the District of Connecticut

BRIEF *AMICUS CURIAE* OF THE NEW CIVIL LIBERTIES ALLIANCE IN SUPPORT OF PLAINTIFF-APPELLANT AND REVERSAL

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rules of Appellate Procedure 26.1(a) and 29(a)(4)(A), the undersigned counsel certifies that *amicus curiae* the New Civil Liberties Alliance is a nonprofit organization under the laws of the District of Columbia. It has no parent corporation, and no publicly held corporation owns 10 percent or more of its stock.

/s/ *Gregory Dolin*
Gregory Dolin

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INTEREST OF AMICUS CURIAE[1]

The New Civil Liberties Alliance ("NCLA") is a nonpartisan, nonprofit civil-rights organization devoted to defending constitutional freedoms from the administrative state's depredations. Professor Philip Hamburger founded NCLA to challenge multiple constitutional defects in the modern administrative state through original litigation, *amicus curiae* briefs, and other advocacy.

The "civil liberties" of the organization's name include rights at least as old as the U.S. Constitution itself: jury trials, due process of law, and the right to live under laws made by the nation's elected legislators through constitutionally prescribed channels (*i.e.*, the right to self-government). These selfsame civil rights are also very contemporary—and in dire need of vindication—precisely because Congress, executive

[1] The undersigned certifies that no counsel for a party authored this brief in whole or in part, and that no person or entity, other than NCLA and its counsel, made a monetary contribution intended to fund the preparation and submission of this brief. Fed. R. App. P. 29(a)(4)(E); and LR 29.1. The undersigned further represents that all parties have consented to the filing of this brief. Fed. R. App. P. 29(a)(2).

branch officials, administrative agencies, and even some courts have neglected them for so long.

NCLA aims to defend civil liberties—primarily by asserting constitutional constraints on the modern administrative state. Although Americans still enjoy the shell of their Republic, a very different sort of government has developed within it—a type that the Constitution was designed to prevent. Here, NCLA is interested in the operation of the "unconstitutional conditions" doctrine, which prevents Congress from indirectly accomplishing what the Constitution forbids it from doing directly. Our purpose as *amicus* is to emphasize the importance of preserving constitutional rights against attempts to subvert them through what the Supreme Court of the United States calls "extortion."

STATEMENT OF THE CASE

Dissatisfied with how much it has been spending on medications covered by Medicare, Congress included in the Inflation Reduction Act of 2022 (IRA) a mandate for the Secretary of Health and Human Services[2] to "establish a Drug Price Negotiation Program" (the Program). 42 U.S.C. § 1320f *et seq*. After identifying the medications comprising the greatest total expense to Medicare (the Selected Drugs), the Program directs HHS to negotiate a sub-market price at which covered consumers may purchase them. 42 U.S.C. §§ 1320f-1, 1320f-3. To achieve this cost reduction, the IRA clothes HHS with two personae: (1) A market-dominating participant in negotiations with manufacturers of the Selected Drugs,[3] and (2) a government actor with the power to exclude recalcitrant manufacturers from the relevant market, as well as impose taxes and penalties on those who resist its overtures. So, when the IRA says pharmaceutical companies must "negotiate … maximum fair prices

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[2] This brief will refer to the appellees collectively as "HHS."

[3] The district court in *AstraZeneca Pharms. LP v. Becerra*, No. CV 23-931-CFC, 2024 WL 895036 (D. Del. Mar. 1, 2024), helpfully described the extent of this power.

for such selected drugs," 42 U.S.C. § 1320f, HHS enters the process in a dominant position.

But HHS does not rely solely on its power as a market participant when "negotiating" prices. It also brings to bear something no private actor has—the power to punish its negotiating counterparty for not coming to terms. If a manufacturer does not enter into an Agreement to accept the "negotiated" price for the Selected Drugs from customers covered by Medicare, the IRA imposes a tax that ranges from approximately 186% to 1,900% of the manufacturer's gross daily sales of the Selected Drugs. 26 U.S.C. § 5000D. If the manufacturer *does* execute an Agreement but nonetheless insists on charging market value for the Selected Drugs, the IRA imposes a penalty in an amount equal to 10 times the difference between the "negotiated" price and the actual sales price of the Selected Drugs. 42 U.S.C. § 1320f-6(a). The only methods by which manufacturers may avoid these taxes and penalties are to either surrender their Fifth Amendment rights or withdraw all their products—all of them, not just the Selected Drugs—from the Medicare market. 26 U.S.C. § 5000D(c).

The district court dismissed the complaint. As relevant to this brief, it opined that there can be no "Takings Clause" claim because manufacturers can avoid the Program's taxes and penalties by withdrawing all their business from the Medicare market. *Boehringer Ingelheim Pharmaceuticals, Inc. v. HHS*, 2024 WL 3292657, slip op. at 8 (D. Conn. July 3, 2024) (hereinafter "Dist. Ct. Op."). This, the court said, makes manufacturers' negotiation of sub-market prices a voluntary decision. *Id*. at 8, 12.

ARGUMENT

The IRA does not send HHS forth merely as a market participant to engage in arm's-length contract negotiations with pharmaceutical companies for purchase of the Selected Drugs. Nor does it simply announce the maximum price the government is willing to pay for the medications it wants to purchase. Instead, it appears Congress modeled the Program on the brutish dynamics common to clichéd mafia movies: "Nice business you got there; it would be a shame if anything were to happen to it."

The Program departs from the genre in only one respect—whereas the stereotypical mob enforcer leaves the threats veiled, Congress makes them explicit: Accept sub-market payments for the Selected Drugs or the government will either ban all your products from the Medicare market or destroy the economic value of the Selected Drugs (and maybe even the rest of your business). As the United States Supreme Court confirmed just last term, the proper term for this type of behavior is not negotiation, but—and this is the word the *Court* chose—"extortion." *Sheetz v. Cnty. of El Dorado*, 601 U.S. 267, 275 (2024).

It may be politically popular to curtail the constitutional rights of mega-companies that lay golden eggs, but if Congress can do this to pharmaceutical companies, it can do it to mom-and-pop businesses, too. Americans deserve better than a Congress that engages in extortionate behavior. More importantly, they have a *right* to be free from such quintessential underworld conduct.

The "unconstitutional conditions" doctrine provides the framework for vindicating that right. Broadly speaking, it forbids the government from making participation in an otherwise lawful activity contingent on the surrender of a constitutionally-protected right. In this case, the Program makes it impossible for the manufacturers to sell their products in the Medicare market without "consenting" to the surrender of rights protected by the Takings Clause. Because the unconstitutional conditions doctrine forbids Congress from subverting the plaintiffs' constitutional rights in this manner, the district court must be reversed.

I. ANATOMY OF AN UNCONSTITUTIONAL CONDITION

Constitutional rights are not annoyances to be evaded through sophisticated indirection and manipulation. They are to be honored frankly and in full, because they "would be of little value if they could be indirectly denied or manipulated out of existence." *Harman v. Forssenius*, 380 U.S. 528, 540 (1965) (cleaned up). By now, it should be a given that the Constitution "nullifies sophisticated as well as simple-minded modes of impairing the right[s] [it] guarantee[s]." *Id.* at 540–41 (internal quotations omitted). That axiom is essential, "[f]or if the government could deny a benefit to a person because" he insists on his constitutional rights, "his exercise of those freedoms would in effect be penalized and inhibited." *Perry v. Sindermann*, 408 U.S. 593, 597 (1972). This, in turn, "would allow the government to produce a result which it could not command directly." *Id.* (cleaned up). Almost 100 years ago, the Supreme Court condemned this practice in no small part because it knew that condoning such machinations would endanger *all* constitutional rights: "If the state may compel the surrender of one constitutional right as a condition of its favor, it may, in like manner, compel a surrender of all. It is inconceivable that guaranties embedded in the Constitution of the United States may thus be manipulated out of existence." *Frost & Frost Trucking v. R.R. Comm'n of Cal.*, 271 U.S. 583, 594 (1926). Inconceivable, indeed.

Nonetheless, both the district court and the government failed to recognize the unconstitutional condition that lies at the heart of the Program—the mechanism without which the Congressional goal of making the Selected Drugs available to Medicare customers at less than market value would be impossible. Therefore, to assist in the ready recognition of such devices, this section of the brief provides an anatomy of an unconstitutional condition, as well as a review of some of the leading cases that illustrate how the mechanism is used to subvert constitutionally-protected rights.

A. Unconstitutional Conditions: A List of Elements

An unconstitutional condition comprises the following four elements: (1) the objective; (2) a constitutional right; (3) the desideratum; and (4) the condition. The objective, as the name implies, is an essential component of the program's goal—it is the behavior the government wishes to extort from the targeted entity. The constitutional right is a protection vouchsafed to the target that would be violated if the government attempted to achieve its objective directly. And the desideratum is the bait. It is something the government knows the target wants to do, or keep, or avoid. It is rarely constitutionally-protected,[4] and is always something that can be described as voluntary in nature.[5] Its function is to serve as the lever upon which the fourth element acts. That element—the condition—is what makes it possible for the government to indirectly achieve what it could not do directly. The condition is an

[4] For the rare circumstance in which the desideratum enjoys express constitutional protection, see *Simmons v. United States*, 390 U.S. 377 (1968) (striking an attempt to pit the Fifth Amendment's protection against self-incrimination against the Fourth Amendment's right to be free of unreasonable searches and seizures), and *Milewski v. Town of Dover*, 2017 WI 79, 377 Wis. 2d 38 (striking an attempt to pit the right to challenge a property tax assessment, protected by Wisconsin's constitution, against the Fourth Amendment's right to be free of unreasonable searches and seizures).

[5] "Virtually all of our unconstitutional conditions cases involve a gratuitous governmental benefit of some kind. … Yet we have repeatedly rejected the argument that if the government need not confer a benefit at all, it can withhold the benefit because someone refuses to give up constitutional rights." *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 608 (2013).

exercise of governmental authority that either bars the target's access to the desideratum, or makes its enjoyment so counterproductive that the target will choose to surrender its constitutional right to avoid the condition's operation. Each element is easily identifiable in the leading unconstitutional conditions cases, as discussed below.

B. Unconstitutional Conditions: An Exploration

Dividing these cases into two groups will demonstrate there is no circumstance under which the Program could be considered constitutionally sound. The first group illustrates the basics of the elements in operation. The second group clarifies that, *pace* HHS's argument in the district court, the Spending Clause does not exempt the government from this doctrine.

1. The Basic Unconstitutional Conditions Cases

One early case involved California's goal of protecting common carriers from competition by private carriers. *Frost Trucking,* 271 U.S. at 591 (1926). To that end, it enacted a scheme that forbade transportation companies from using the State's roads without a permit issued by the Railroad Commission. *Id.* at 592. As relevant here, the permit conditions imposed all the obligations and burdens of common carriers on private-carrier applicants. *Id.* Consequently, private carriers were faced with this choice: either cease operating as a transportation company in California or become, in essence, a common carrier.

Each of the elements is immediately apparent. The State's objective was to turn private carriers into common carriers to protect the latter from the former. It couldn't do this directly, however, because "consistently with the due process clause of the Fourteenth Amendment," the target "cannot be converted against his will into a common carrier by mere legislative command." *Id.* The target's desideratum, of course, was to operate on the State's roads as a private carrier. So, to accomplish indirectly what it could not do directly, the State imposed the condition: Access to the State's roads would be denied unless the target "voluntarily" relinquished its constitutionally-protected right not to become a common carrier.

In ruling that California could not indirectly achieve the objective by imposing the condition on Frost's desideratum, the Court offered the classic expression of how unconstitutional conditions operate. "It would be a palpable incongruity," it said, "to strike down an act of state legislation which, by words of express divestment, seeks to strip the citizen of rights guaranteed by the federal Constitution, but to uphold an act by which the same result is accomplished under the guise of a surrender of a right in exchange for a valuable privilege which the state threatens otherwise to withhold." *Id.* at 593.

The "voluntary" surrender truly was nothing but a guise. The Court didn't miss that the purpose of the condition was to use the desideratum as a means of coercing the target into forfeiting its constitutional right: "In reality, the carrier is given no choice, except a choice between the rock and the whirlpool—an option to forego a privilege which may be vital to his livelihood or submit to a requirement which may constitute an intolerable burden." *Id.* If this gambit were permissible, it said, then "constitutional guaranties, so carefully safeguarded against direct assault, are open to destruction by the indirect, but no less effective, process of requiring a surrender, which, *though in form voluntary*, in fact *lacks none of the elements of compulsion*." *Id.* (emphasis supplied). The Court held the condition unconstitutional.

A more recent case, *Horne v. Dep't of Agric.*, 576 U.S. 350 (2015), also usefully illustrates the elements of an unconstitutional condition.[6] There, a Department of Agriculture program required farmers who grew grapes for raisin production to "physically set aside" a percentage of their crops "for the account of the Government, free of charge." *Id.* at 354. "The Government then sells, allocates, or otherwise disposes of the raisins in ways it determines are best suited to maintaining an orderly market." *Id.*

The elements follow the same pattern as *Frost Trucking*. The government's objective was to obtain the farmers' property free of charge for the purpose of stabilizing the raisin market. The farmers' desideratum, on the other hand, was to retain the property rights in their raisins. Because the objective describes what the Court said is a "classic taking," *id.* at 357, the Agriculture Department could not accomplish it directly. So, stymied by the constitutional right, it imposed the condition:

[6] In their district court briefs, the manufacturers cited *Horne* to correctly illustrate how the Program effects a physical, *per se* taking of the Selected Drugs. The purpose for addressing *Horne* here is to demonstrate the operation of the unconstitutional conditions doctrine in the Takings Clause context.

Farmers would be prohibited from selling raisins unless they surrendered rights protected by the Takings Clause of the Fifth Amendment. The Court saw through the indirection and affirmed that constitutional rights cannot be so easily defeated. "The Government has broad powers," it said, "but the means it uses to achieve its ends must be 'consistent with the letter and spirit of the constitution.'" *Id.* at 362 (quoting *McCulloch v. Maryland*, 4 Wheat. 316, 421 (1819)).

It is worth noting that here, as in all unconstitutional conditions cases, the farmers' desideratum was a voluntary thing. California asserted that the farmers didn't *have* to make raisins; they could have chosen to make wine instead, thereby avoiding the set-aside requirement. The Court dismissed this claim with no small amount of disdain: "'Let them sell wine' is probably not much more comforting to the raisin growers than similar retorts have been to others throughout history." *Id.* at 365. So, it held that "[s]elling produce in interstate commerce, although certainly subject to reasonable government regulation, is … not a special governmental benefit that the Government may hold hostage, to be ransomed by the waiver of constitutional protection." *Id.* at 366.

The elements of an unconstitutional condition function in the same manner wherever they appear. And where they exist, the Court declares their operation unconstitutional. *See, e.g.*, *Frost Trucking*, 271 U.S. at 598 (collecting cases); *Murdock v. Pennsylvania*, 319 U.S. 105 (1943); *Speiser v. Randall*, 357 U.S. 513 (1958); *Harman*, 380 U.S. 528 (1965); *Simmons v. United States*, 390 U.S. 377 (1968); *Perry*, 408 U.S. at 596–97; *Rutan v. Republican Party of Illinois*, 497 U.S. 62 (1990).

2. The Spending Clause Cases

There is no Spending Clause exception to the unconstitutional conditions doctrine, contrary to HHS's suggestion in its district court briefing.[7] Indeed, it may be that the Supreme Court is even more sensitive to this gambit in this context than in others, as demonstrated by its opinion in *Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc.*, 570 U.S. 205 (2013). There, the Court considered the Leadership Act, an effort to combat global HIV/AIDS by funding aligned nongovernmental organizations (NGOs). The program forbade any of the funds (with a few

[7] *See* Mem. of Law in Opp. to Pl.'s Mot. for Summ. J. and in Support of Cross-Mot. at 43, ECF No. 48-1 (hereinafter "HHS Dist. Ct. Brief").

exceptions) from going to "any group or organization that does not have a policy explicitly opposing prostitution and sex trafficking … ." *Id.* at 210. The Court interpreted this provision (the "Policy Requirement") as a mandate that fund recipients "explicitly agree with the Government's policy to oppose prostitution and sex trafficking," *id.* at 213, to which some NGOs objected on First Amendment grounds.

The unconstitutional condition elements followed the normal pattern. The government's objective was to impose its views on the fund recipients as part of its effort to combat HIV/AIDS around the world. It couldn't do that directly because, as the Court observed, "[w]ere it enacted as a direct regulation of speech, the Policy Requirement would plainly violate the First Amendment." *Id.* The NGOs' desideratum was to access the funds so they could continue the global fight. So, the Leadership Act leveraged the desideratum with this condition: No funds without relinquishing constitutional rights.

In concluding the condition was unconstitutional, the Court acknowledged that, as part of Congress's Spending Clause authority, it may "impose limits on the use of such funds to ensure they are used in the manner Congress intends." *Id.* It also recognized that "if a party objects to a condition on the receipt of federal funding, its recourse is to decline the funds." *Id.* at 214. But not all such conditions are orthodox: "In some cases, a funding condition can result in an unconstitutional burden … ." *Id.* (citing *Rumsfeld v. Forum for Acad. & Institutional Rts., Inc.*, 547 U.S. 47, 59 (2006) (First Amendment imposes "a limit on Congress' ability to place conditions on the receipt of funds.")).

The Court explained that the line separating legitimate from unconstitutional funding conditions "is between conditions that define the limits of the government spending program—those that specify the activities Congress wants to subsidize—and conditions that seek to leverage funding to regulate" constitutional rights that are "outside the contours of the program itself." *Id.* at 214–15. In discerning that line, the Court was quick to say it wouldn't tolerate sophistry: "We have held, however, that 'Congress cannot recast a condition on funding as a mere definition of its program in every case, lest the First Amendment be reduced to a simple semantic exercise.'" *Id.* at 215 (quoting *Legal Servs. Corp. v. Velazquez*, 531 U.S. 533, 547 (2001)). Perhaps it doesn't need to be said, but the Court assuredly would not countenance the reduction of any other constitutional right to a "simple semantic exercise" either.

The *Agency for Int'l Dev.* dissent, in contrast, viewed the Policy Requirement as "nothing more than a means of selecting suitable agents to implement the Government's chosen strategy … ." *Id.* at 221 (Scalia, J., dissenting). That's not an inaccurate characterization of the requirement, yet the majority still concluded the Policy Requirement was an unconstitutional condition. So, the Court appears to be at least as sensitive to indirect deprivations of constitutional rights through the exercise of the Spending Clause as in other contexts.

Congress's employment of the Spending Clause in *NFIB v. Sebelius*, 567 U.S. 519 (2012), also contained an unconstitutional condition. In the district court, HHS dismissed this as an inapposite federalism case. But a proper analysis reveals that the "federalism" aspect simply comprised the second element (the constitutional right) in the anatomy of an unconstitutional condition.

The Patient Protection and Affordable Care Act (the ACA), to the extent it is relevant here, expanded the Medicaid program by giving "funds to the States on the condition that they provide specified health care to all citizens whose income falls below a certain threshold." *Id.* at 531. If a State failed to do so, "it may lose not only the federal funding for those requirements, but *all* of its federal Medicaid funds." *Id.* at 542 (emphasis supplied).

The unconstitutional condition elements are not difficult to identify. The ACA's objective, with respect to the Medicaid program, was to compel the States to expand the population of individuals eligible for coverage. This, however, is not something Congress could accomplish directly. The Court acknowledged that it has "long recognized that Congress may use this power [(the Spending Clause)] to grant federal funds to the States, and may condition such a grant upon the States' taking certain actions that Congress could not require them to take." *Id.* at 576 (cleaned up). But the power is not boundless, and "the Constitution has never been understood to confer upon Congress the ability to require the States to govern according to Congress' instructions." *Id.* at 577. This limitation prevented Congress from achieving its objective directly because "federal legislation that commandeers a State's legislative or administrative apparatus for federal purposes" violates the Constitution. *Id.* This anti-commandeering principle was the second element of an unconstitutional condition (the constitutional right)—that is, the State's sovereignty within a federalist system. So, the ACA leveraged the States' desideratum (continuation of federal Medicaid funding) by imposing this condition: Release your right to legislate your own Medicaid policies, or lose all Medicaid funding entirely. The Court declared the condition unconstitutional because "[t]he Constitution simply does not give Congress the authority to require the States to regulate," and this is true "whether Congress directly commands a State to regulate or indirectly coerces a State to adopt a federal regulatory system as its own." *Id.* at 578 (internal marks omitted).

Both *Agency for International Development* and *NFIB* demonstrate that the Court will apply the unconstitutional conditions doctrine just as rigorously in Spending Clause cases as it does elsewhere. These opinions, along with the rest of the Court's unconstitutional conditions *oeuvre*, control the disposition of this case and require reversal of the district court.

II. THE PROGRAM'S UNCONSTITUTIONAL CONDITION

The Program contains all the elements of an unconstitutional condition. Congress was explicit about its objective: Empower HHS's beneficiaries (Medicare patients), to obtain the Selected Drugs without paying their market value. But because the manufacturers' desideratum is to sell their products at market value to all who would purchase them, Congress knew they wouldn't willingly go along. Further, Congress presumably knew it could not directly force manufacturers to sell their products to Medicare patients while also compelling them to accept below-market prices without violating the Fifth Amendment.[8] So, the Inflation Reduction Act imposes a condition: Accept less than market value for the Selected Drugs, or either (a) withdraw all products from the Medicare market, or (b) suffer the destruction of the Selected Drugs' entire economic value (and maybe the value of the rest of the business, too). In HHS's telling, however, threatening to exclude a business from a particular market (or imposing crippling taxes) is a non-coercive method of engaging in a voluntary negotiation for below-market prices. But that's about as voluntary and non-coercive as the shopkeeper's payment of protection money to the mob enforcer.

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[8] "The Court has repeatedly held that just compensation normally is to be measured by 'the market value of the property at the time of the taking.'" *Horne*, 576 U.S. at 368–69.

HHS's position is untenable because it studiously avoids an accounting of what the Program's pieces, in combination, actually *do*. Indeed, its argument is curiously anti-gestaltic. It depends on the notion that the Program's whole is—allegedly—much less than the sum of its parts. HHS picks the Program apart into its constituent pieces to determine whether any one of them, alone, is unconstitutional. Thus, it says that negotiating the price of a Selected Drug is a voluntary thing, but it does so while obscuring the market-exclusion sledgehammer it uses to obtain the price it wants. HHS assures the court that the Program is incapable of infringing manufacturers' property interests, but without accounting for the Program's intentionally crippling taxes and the requirement that HHS pay a below-market price for the Selected Drug. It then demands that each of these elements be considered in isolation from the supposedly unrelated fact that—behold(!)—the Program's intended beneficiaries have somehow acquired the manufacturer's property at less than market value pursuant to a transaction in which the sellers did not wish to engage. Nothing to see here, HHS says. Just one market participant freely and voluntarily surrendering its property interests to another for no apparent reason. But legislation is not supposed to be a sporting opportunity to finagle Americans out of their constitutional rights. As the *Frost Trucking* Court said, if a ruse like this can "compel the surrender of one constitutional right as a condition of [the government's] favor, it may, in like manner, compel a surrender of all." 271 U.S. at 594.

In reality, the complex interaction between the Program's constituent parts is what makes it possible to accomplish Congress's objective. It's also what makes it unlawful, as demonstrated by a deeper look at the elements of the Program's unconstitutional condition.

A. The Condition

The Program's condition is a decision taken by Congress in its governmental persona, the purpose of which is to coerce manufacturers into both (1) "negotiating" a below-market price for Selected Drugs; and (2) actually accepting the coercively obtained price. It operates by either forcing the manufacturer entirely out of the Medicare market (26 U.S.C. § 5000D(c)), or by imposing crippling excise taxes and penalties for the failure to "negotiate" or honor a below-market price. This ploy, using taxes and penalties to interpose the government between the target and its desideratum, is just as effective as an outright ban on the desideratum because, as the Court says, "[t]he power to tax the exercise of a privilege is the power to control or suppress its enjoyment." *Murdock*, 319 U.S. at 112. So, when such a condition penalizes the target for insisting on its rights, it is constitutionally impermissible. *Harman*, 380 U.S. at 540 ("It has long been established that a State may not impose a penalty upon those who exercise a right guaranteed by the Constitution."). As we explain next, the excise tax (for failure to "negotiate") and penalties (for failing to honor the "negotiated" price) are just as effective in coercing the manufacturer's "agreement" as the threat to ban it from the Medicare market entirely.

1. Failure to Negotiate

If the manufacturer refuses to enter into an Agreement to negotiate, the IRA punishes it by imposing an excise tax on the sale of Selected Drugs that can be as high as *19 times* the amount of the sale price. 26 U.S.C. § 5000D. The point of the tax is to be so onerous that it would be less economically disastrous for the manufacturer to let Congress use its property (without just compensation) to benefit its chosen designees—in this case, Medicare customers. To enhance the tax's punitive effect even further, Congress applied it not just to the

Selected Drugs purchased by Medicare customers, but to *all* sales of Selected Drugs without regard to the consumer's insurance status. *Id.* Such a tax obviously destroys the economic value of the Selected Drug by appropriating its entire income stream. But that satisfies just 1/19th of the total tax burden. The manufacturer still owes an additional *18 times* the income of the Selected Drug to retire its tax liability. Those funds, obviously, would have to come from the profits of products that have nothing to do with the Program.

HHS asserted a different view of the math (as if one may have different views of math) in the district court, claiming that "the maximum ratio of the tax to the total amount the manufacturer charges for a drug is 95% (not 1900%)." HHS Dist. Ct. Brief at 8. So, it said, in a hypothetical $100 sale "$95 is allocated to the § 5000D tax and $5 is allocated to the price of the designated drug." *Id.* This erroneous conclusion results from two inaccurate premises.

The first is … bold. The IRS (with HHS's endorsement) has purported to overrule Congress by replacing the statutory equation with its own, which it solemnly promises to keep in place until it changes its mind. *Id.* (quoting IRS Notice No. 2023-52, 2023-35 I.R.B. 650 (Aug. 4, 2023)). This new (temporary) equation for the maximum tax is x=.95(y), where "x" equals the amount of the tax and "y" equals the sales price—essentially a 95% sales tax. But the statute says the equation is .95=x/(x + y), and it says it so explicitly that it is not open to debate. 26 U.S.C. § 5000D(a). Those are not the same equations, and they most definitely do not result in the same tax liability. In HHS's example of a $100 sale, solving for "x" (using the *obligatory* statutory equation) means the excise tax is a whopping $1,900, not $95.

HHS's second erroneous premise is that the manufacturer may simply include the excise tax in "the total amount the manufacturer charges for a drug." HHS Dist. Ct. Brief at 8. HHS apparently intends the court to believe the manufacturer won't suffer the tax burden because it will ultimately land on others. But HHS knows this isn't so. As we describe below (starting at page 32), the Centers for Medicare & Medicaid Services (CMS) intends to implement the Program in a way that requires manufacturers to rebate to their customers any amount that exceeds the HHS-mandated price. So, if a manufacturer includes the tax in the sale price, it will just end up rebating it later. It could hardly be otherwise. Ensuring the tax burden remains with the manufacturer is an essential element of the Program, the whole point of which is to force manufacturers to sell Selected Drugs to Medicare customers at below-market prices. This would be impossible, of course, if manufacturers could shift to others the very tax burden that was supposed to cow them into accepting HHS's mandated price in the first place. Besides, if HHS's position is truly an option, the IRA provision that makes the tax nondeductible would be entirely superfluous. Inflation Reduction Act, Pub. L. No. 117-169, § 11003(b), 136 Stat. 1818, 1862 (2022). The tax really is meant to punish the manufacturer as painfully as the statutory equation says.

Perhaps HHS offered its alternative view because this type of draconian punishment is a bad look for Congress. But the text does exactly what Congress so clearly intended—flex its matchless power by imposing on manufacturers (not others in the supply chain) a punishment so stunning and intolerable that they will succumb to a "negotiated" deprivation of their constitutional rights. And so, by making it unthinkable for the manufacturers to suffer its application, the condition does exactly what it is supposed to do.

2. Failure to Sell at the "Negotiated" Price

If the manufacturer *does* enter into an Agreement and negotiates a "maximum fair price" for the Selected Drugs, but fails to honor it, the consequences are different, but equally devastating. The parties appear to agree the Program imposes a penalty in an amount equal to 10 times the difference between the "negotiated" price and the actual price for the Selected Drugs. 42 U.S.C. § 1320f-6(a). Consequently, the price received by the manufacturer, net of the penalty, is even less than the "negotiated" price, which was already below the market value. This aspect of the condition also serves its purpose with ruthless efficiency. In a choice between accepting a below-market price and accepting a price that is even further below market (by operation of the penalty), the only rational decision is the former. And not even HHS suggests this penalty could be passed along to the consumer.

* * *

In sum, the condition puts the manufacturers to this Hobson's choice: Relinquish your constitutionally-protected right to receive just compensation for your property, or choose between (a) exiting the Medicare market entirely, and (b) shouldering taxes or penalties so ruinous they will destroy the economic value of the Selected Drugs (as well as products that have nothing to do with the Program). This extorted "agreement" to sell the Selected Drugs at below-market prices is an unconstitutional racket indistinguishable from how the mob extorts protection money—by making the alternative unthinkable.

B. The Constitutional Right

In the Fifth Amendment's list of limitations on government power, the Takings Clause says "nor shall private property be taken for public use, without just compensation." U.S. Const. amend. V. This protection applies to the manufacturers' interest in the Selected Drugs as much as it does to any other form of property.[9] Whether the government keeps the property for its own use or transfers it to its chosen designee makes no difference to the "takings" analysis. *See, e.g., Kelo v. City of New*

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[9] The *Horne* Court said "[t]he first question presented asks 'Whether the government's 'categorical duty' under the Fifth Amendment to pay just compensation when it 'physically takes possession of an interest in property' applies only to real property and not to personal property.' The answer is no." *Horne*, 576 U.S. at 357 (citations omitted). "The Government has a categorical duty to pay just compensation when it takes your car, just as when it takes your home." *Id*. at 358.

London, 545 U.S. 469 (2005); *Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg'l Plan. Agency*, 535 U.S. 302, 322 (2002) (collecting cases).

The question, therefore, is the same here as it was in *Horne*: "Whether a governmental mandate to relinquish specific, identifiable property as a 'condition' on permission to engage in commerce effects a per se taking." *Horne*, 576 U.S. at 364–65. The Supreme Court said the answer is "yes." *Id.* The circumstances here map onto the *Horne* question perfectly. The government mandates that drug manufacturers relinquish property rights in the Selected Drugs as a condition on permission to engage in commerce in the Medicare market. The district court, however, rejected the *Horne* formulation because it doesn't think banning a manufacturer from the relevant market has any significance: "[B]ecause BI can opt out of Medicare and Medicaid, it has not been deprived of property for the purpose[] of its . . . Takings Clause claim[]."[10] This observation entirely misses the point of the unconstitutional conditions doctrine. Targets of such schemes may *always* choose to give up their desiderata to avoid the condition's hammer—that's not an

[10] Dist. Ct. Op. at 8.

absolution of the condition, it's a condemnation. The district court's observation is also a not-so-subtle rebuke of the *Horne* Court for not rejecting the takings claim. The farmers, after all, could have just opted out of the raisin market to avoid the loss of their property.

So, the only open question (because the district court may not countermand *Horne*) is whether the Program requires manufacturers to "relinquish specific, identifiable property." As in *Horne*, the answer is "yes." Of *course* there is a physical appropriation taking place. How else could the Selected Drugs—physical, tangible, personal property—involuntarily wind up in the possession of Congress's intended beneficiaries by operation of federal law? Some parts of the mechanism by which this occurs are not altogether clear, but the parts that *are* clear make the Program irretrievably unconstitutional.

The Program commandeers the manufacturers' property for the benefit of Congressional designees without payment of just compensation. That much is certain. What is less clear is how, as a practical matter, the various parties are supposed to handle the quotidian transactions that will move the Selected Drugs through the supply chain to the consumer at HHS-mandated prices. Congress apparently intends HHS to finish its legislative project, because it didn't say anything about this.

HHS could choose between two potential methods of structuring the transactions, neither of which would solve the Program's constitutional infirmity. One would operate prospectively from the front end of the supply chain, the other would operate retroactively from the back end. The first option would surely be recognizable to the government: HHS could order the manufacturers to load government-contracted semis full of Selected Drugs, for which it would pay the compulsively "negotiated" below-market price. This approach would be indistinguishable from the raisin set-aside program at issue in *Horne*, and it would be unconstitutional for the same reason.[11]

HHS appears to favor the alternative approach, which maintains the only two substantive elements relevant to a takings analysis: (1) it still accomplishes the transfer of physical possession of the Selected

[11] Whether the government takes a percentage of the owner's property with no payment at all, or takes a percentage discount for what it buys, it still obtains the same percentage of the owner's property without just compensation.

Drugs to the Program's beneficiaries in an involuntary transaction; and (2) it still compels manufacturers to accept less than just compensation for their property. The distinctive feature of this alternative is that HHS would retroactively manipulate already-completed transactions to give Medicare customers the benefit of coercively "negotiated" prices. Here's how it would work.

The supply chain between manufacturers and the consumer will always involve at least one intermediary; how many is not important, so let's say the manufacturer sells to a wholesaler, who then sells to the pharmacy. At the point of sale to the wholesaler, neither the manufacturer nor HHS can know how many of the pills will ultimately be purchased by Medicare customers (as opposed to private-plan customers, or customers with no insurance at all). So, the manufacturer must set a single price for the entire sale, which will be passed through the supply chain to the consumer and, if applicable, Medicare or a private insurance plan.

Under this approach, HHS lies in wait until the manufacturer transfers possession of the Selected Drugs to the wholesaler. At some point between that event and the Medicare customer's purchase of his prescription from the pharmacy, HHS would step in to restructure the already-completed transactions to bring the purchase price down to the "negotiated" price. That restructuring would then work its way back up the supply chain through a rebate or some other mechanism by which the manufacturer would have to divest some part of the sale price—if, that is, it wanted to save itself from the business-destroying penalties. This is the approach the CMS (one of the parties to this case) favors. In its draft guidance explaining the Program, it said a manufacturer "may meet its statutory obligation … to make the MFP [maximum fair price] available to dispensing entities by retrospectively providing reimbursement for the difference between the dispensing entity's acquisition cost and the MFP … ." Dep't of Health and Hum. Servs., Ctrs. for Medicare & Medicaid Servs., *Draft Guidance on the Medicare Drug Price Negotiation Program* at 50 (May 3, 2024).

This approach predictably (and intentionally) results in a taking: The manufacturer would be unable to refuse the sale (because it would have already concluded and the property would no longer be in its possession), and the condition's penalties would compel him to forfeit enough of the sale price to drive it down to the "negotiated" below-market price. The net effect of the restructuring is to retroactively create a transaction in which the manufacturer did not voluntarily engage. Such a transaction violates the "right to exclude"—that is, the right to hold one's property against all the world, which "is universally held to be a fundamental element of the property right, and is one of the most essential sticks in the bundle of rights that are commonly characterized as property." *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 150 (2021) (cleaned up). *Et voila*, the Program has effected an involuntary transfer of private physical property to the government's chosen beneficiaries without payment of just compensation.

C. The Spending Clause

The Spending Clause does not excuse the Program's unconstitutional condition. Yes, Congress may create "conditions that define the limits of the government spending program." *Agency for Int'l Dev.*, 570 U.S. at 214. In this case, that might involve capping the amount HHS may spend on the Selected Drugs. But the condition goes far, far beyond that limited category. It is designed and intended to extort manufacturers into giving up their constitutional rights. In the Court's language, the condition belongs to that category of "conditions that seek to leverage funding to regulate" constitutional rights that are "outside the contours of the program itself." *Id.* at 214–15. It is a transparent and ham-fisted attempt to subvert what the Constitution protects. Surely, constitutional rights can't be sidestepped *that* easily.

CONCLUSION

For all these reasons, the district court must be reversed and the condition must be declared unconstitutional.

Respectfully submitted,

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Dated: November 8, 2024

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I hereby certify that on November 8, 2024, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which sent notification of such filing to all counsel of record.

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