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 and Human Services; Xavier Becerra, *in his official capacity as Secretary of Health and Human Services*, Centers for Medicare and Medicaid Services, Chiquita Brooks-Lasure, *in her official capacity as administrator of Centers for Medicare and Medicaid Services*

Defendants-Appellees

On Appeal from the U.S. District Court for the District of Connecticut
No. 23-cv-01103, Hon. Michael P. Shea

BRIEF OF *AMICUS CURIAE* INDEPENDENT WOMEN'S LAW CENTER

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CORPORATE DISCLOSURE STATEMENT

Independent Women's Law Center is a project of Independent Women's Forum, a 501(c)(3) non-profit, non-partisan organization. It has no parent corporation, and no publicly held corporation holds a 10% or greater ownership interest in it.

/s/ D. Adam Candeub
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STATEMENT OF *AMICUS* INTEREST

The backbone of our nation's elderly and disabled-youth care is female. More than 60% of caregivers to adults and children with disabilities are women. So are a large portion of individuals in need of long-term care and pharmaceuticals. Women typically outlive their spouses, thus relying on care from younger women.

When government interference prohibits innovative drugs from reaching the market—as the Inflation Reduction Act does—women shoulder the burden of the many sad realities. The Independent Women's Law Center (IWLC) files this brief to explain the government's unconstitutional taking that threatens access to the choices women deserve as we care for our aging mothers or rely on our hard-working daughters.

Amicus curiae IWLC is a project of the Independent Women's Forum (IWF), a non-profit, non-partisan 501(c)(3) organization founded by women to foster education and debate about legal, social, and economic policy issues. IWF promotes access to free markets and the marketplace of ideas and supports policies that expand liberty, encourage personal responsibility, and limit the reach of government. IWLC supports this mission by advocating for equal opportunity, individual liberty, and respect for the American constitutional order.[1]

[1] The Federal Rule of Appellate Procedure 29(a)(2) permits this filing because all parties consented. No party's counsel authored this brief in whole or part. Nor did any person or entity other than the *amicus curiae* and its counsel contribute money to fund this brief's preparation or submission.

SUMMARY OF ARGUMENT

This case arises out of the government's decision to list Jardiance—a drug produced by plaintiff Boehringer Ingelheim Pharmaceuticals, Inc. (BI)—as a "negotiation-eligible" drug selected under the Inflation Reduction Act of 2022 (IRA), Pub. L. No. 117-169 §§11001–03, 136 Stat. 1818 (codified in pertinent part at 42 U.S.C. §§1320f–1320f-7 & 26 U.S.C. §5000D). The District Court fully describes the statute. *Boehringer Ingelheim Pharms., Inc. v. United States Dep't of Health & Hum. Servs.*, No. 3:23-CV-01103, 2024 WL 3292657, at *1–6 (D. Conn. July 3, 2024). Here, we address only the provisions most salient to the proper disposition of this case. The IRA seeks to address the high prices of valuable key drugs in long use which face no competition from a generic equivalent under the Biologics Price Competition and Innovation Act of 2009. *See* Pub. L. No. 111-148 §§7001–03, 124 Stat. 119 (2010). Thus, the government annually puts together a list of ten such highly valued pharmaceutical products that account for a disproportionate share of Medicare's expenses. 42 U.S.C. §§1320f(a), 1320f-1(b), (d), (e). Thereafter, the IRA instructs the Department of Health and Human Services (HHS), which delegated its authority to the Centers for Medicare and Medicaid Services (CMS), to negotiate price reductions with the patent holders of such drugs by an elaborate administrative process that leaves the patentee drug companies three unpalatable choices in a statutory "Hobson's trilemma":

First, drug companies may sell drugs pursuant to a statutory "negotiation," where CMS dictates prices using an arcane (and nonreviewable) formula[2] for a so-called

[2] The IRA provides: "There shall be no administrative or judicial review" of (1) the determination of which drugs are negotiation eligible, (2) the selection of drugs for the Drug Price Negotiation Program, or (3) the final selected maximum fair price. 42 U.S.C. § 1320f-7(2)–(3).

"maximum fair price" for all sales to all buyers covered by the IRA, including individuals, health care providers, and pharmacies.

Second, companies that refuse CMS's prices are then "exposed to a potential excise tax liability," *Boehringer*, 2024 WL 3292657 at *3 (quotation marks omitted)—a civil penalty equal to ten times the difference between the actual selling price of the drug and the maximum fair price.[3]

Third, the companies can withdraw *all* of their products from the markets over which CMS exercises total monopoly control (drugs for Medicare and Medicaid enrollees), thereby denying these firms any access to roughly 45% of the U.S. prescription drug market. Congressional Budget Office, *Prescription Drugs: Spending, Use, and Prices* (Jan. 2022), https://tinyurl.com/yfevctkn. By design, these losses exceed a drug company's total losses under either of the first two options, compromising their ability to operate profitably in *both* the Medicare market *and* the unregulated private market.

The government claims that the inclusion of this third option protects the IRA from charges of any uncompensated taking by making their participation in the program "voluntary," *Boehringer*, 2024 WL 3292657 at *8, *14, notwithstanding the "large economic cost" of withdrawing from Medicare and Medicaid, *id.* at *8. Yet the supposed voluntary agreement fails to acknowledge, let alone mention, that the ironclad control CMS exercises over every aspect of the government's purchasing protocol gives it total monopoly power.

The government forgets that voluntary consent by either buyers or sellers is *never* a

[3] We ignore the semantic dispute whether to describe the tax "as a 186 to 1900 percent tax or a 65 to 95 percent tax." *Boehringer,* 2024 WL at *5 n.3. Either way the large dollar loss is the same.

defense to a charge of illegal use of monopoly or monopsony power. Showing that the buyers voluntarily agreed to pay a higher price for their products—or that sellers agreed to accept a lower price for theirs—cannot cure an antitrust violation. If it did, such a defense would gut the antitrust laws by blocking all claims from the only people who have standing to bring private causes of action. To prevail against an antitrust claim, every defendant, including CMS, has to offer an efficiency justification for its action, which is not supplied here.

If a drug company remains in Medicare and Medicaid, the IRA either forces it to transfer its drugs ("property" under the Takings Clause) to third parties at dramatically reduced prices or alternatively pay a confiscatory tax. Either way, private property is taken for public use for less than fair market value. By ignoring this antitrust dimension, the District Court misread the Supreme Court's dispositive opinion in *National Federation of Independent Business v. Sebelius,* 567 U.S. 519 (2012) (*NFIB)*. There, the Court explicitly rejected the District Court's crabbed notion of voluntary consent, describing instead a "gun to the head." *Id.* at 581 (op. of Roberts, C.J.).

In *NFIB,* the Court ruled that the choice the federal government gave States—expand their Medicare programs or accept a huge financial hit by forgoing all existing federal Medicare support a State received—was unconstitutional. The same degree of coercion that is an unconstitutional form of "commandeering" cannot be used to abridge individual rights—both are an illicit use of state monopoly power. Together, the doctrine of unconstitutional conditions and the Takings Clause prevent the IRA's unconstitutional grab of federal power.

ARGUMENT

I. BACKGROUND

In this case, the government has used aggressive pricing strategies to strip BI of revenue it had received from selling Jardiance to pharmacies and other parties that the CMS supports and regulates under the IRA's Drug Price Negotiation Program (the "Program"). 42 U.S.C. §1320f, *et seq*. Previously, federal law prohibited CMS from interfering in negotiations between drug companies and pharmacies, 42 U.S.C. §1395w-111(i), so drug companies and pharmacies bargained over price, each knowing that it could retreat to its prior position if the two sides failed to strike a bargain.

The IRA reversed this market-based, voluntary approach by letting CMS directly negotiate prices with drug companies for brand-name Medicare Part B and Part D drugs. 42 U.S.C. §1320f; 26 U.S.C. §5000D. CMS ranks the fifty qualifying single-source drugs with the highest total Part D expenditures from highest to lowest, by expenditure. Finally, CMS selects ten drugs for the 2026 price period, fifteen drugs for the 2027 and 2028 price periods, and twenty drugs for all subsequent price periods for the Program. *See* Centers for Medicare & Medicaid Services at 104–08 (June 30, 2023) (CMS Guidance), https://tinyurl.com/CMSGuidance26.

Once CMS selects drugs, the Inflation Reduction Act allows CMS to set prices, employing a dressed-up system of strict controls to set a "maximum fair price," 42 U.S.C. §1320f-3(c), which in no way approximates the drug's fair market value needed to avoid an unconstitutional taking. Producing new drugs requires high, initial fixed costs—companies spend immense amounts on R&D and regulatory approval. *See* Joseph A. DiMasi et al., *The price of innovation: new estimates of drug development costs,* 22 J.

Health Econ. 151, 154–56 (2003); *see also* John F. Duffy, *The Marginal Cost Controversy in Intellectual Property*, 71 U. Chi. L. Rev. 37 (2004). Thereafter, they incur a low marginal cost for producing each dose. But because of their high fixed costs, most drugs cannot be profitable unless drug companies can bargain for higher prices from users willing and able to pay more than their marginal cost of production. To recover the high initial fixed cost of drug development, companies reach different bargains with different customers. This standard pricing scheme for drugs is wrecked if those front-end costs cannot be spread over a base that includes government purchases under Part D, as drug companies cannot receive fair market value if forced to sell to the government monopsonist at an "average non-Federal average manufacturer price." *See* 42 U.S.C. §1320f-3(c)(1)(C)(i)-(ii). Because this price is further reduced by 40% to 75%, 42 U.S.C. §1320f-3(c)(3), the "maximum fair price" is guaranteed to be much lower than a drug's fair market value.

This economic model is hardly unique to drugs. Indeed, almost two hundred years ago, the Supreme Court recognized the validity of this traditional approach of giving third parties exclusive contract rights to build bridges over rivers, by charging super-competitive prices for several years until they have recovered their fixed costs. Thereafter, the tolls were sharply decreased. *See Charles River Bridge Co. v. Warren Bridge Co.*, 36 U.S. 420, 536–37 (1837). The Supreme Court long understood what today's Congress does not: businesses will not invest in products or services if they cannot recoup up-front, fixed costs.

What can a company do if it does not like CMS's offered price? The Program only lets it exit failed negotiations by withdrawing all its products from the CMS registry.

The government claims this option of leaving CMS makes the drug companies' decision to stay in the Program and receive the regulated price for its drugs a voluntary, non-coercive choice. But this is illusory. CMS is by law the sole buyer in this market, holding a monopoly over the portfolio of every drug company given to the 91,786,257 Medicaid enrollees, CHIP (Children Health Insurance Program) enrollees, and dual enrollees, along with 67.7 million Medicare enrollees. *See* CMS, *2023 Medicaid & CHIP Beneficiaries at a Glance* (Apr. 2023), https://tinyurl.com/4vbtxytw; Data.CMS.gov, *Medicare Monthly Enrollment*, https://tinyurl.com/mr3nsxva. All told, that is well over a third of all Americans, and 45% of the prescription drug market. Congressional Budget Office, *Prescription Drugs: Spending, Use, and Prices*, *supra*.

Short of that drastic step, the company has only one remaining option. It can subject itself to a punitive excise tax that gives the government the lion's share of the proceeds of the drug's total sales. No matter which horn of this trilemma BI embraces, it is unambiguously worse off than it was before the new Program was put into place. When a property is worth $1,000, the government does not meet its takings obligations by offering to buy it for $500. It must always pay full value.

II. THE IRA'S "ECONOMIC DRAGOONING" OF DRUG COMPANIES' PROPERTY IS A TAKING UNDER THE CONSTITUTION AND AN UNCONSTITUTIONAL COERCIVE CONDITION.

The government claims that BI cannot complain about its coerced financial losses because it can exit failed negotiations with CMS and sell only to private parties. The reasoning in *NFIB* shows why CMS's Program is coercive for constitutional purposes. *NFIB* reviewed the Affordable Care Act's Medicaid expansion, which pushed States to

join an ostensible "voluntary" expansion of Medicaid offerings. As inducements, the federal government increased its support for the States' Medicaid programs. 42 U.S.C. §1396d(y)(1). That support remained at 100 percent through 2016, declining gradually to 90 percent thereafter. Could States opt out? Yes. But any State that refused could be stripped of "*all* of its federal Medicaid funds." *NFIB*, 567 U.S at 542 (majority op.).

The Spending Clause, U.S. Const. art. I, §8, cl. 1, gives Congress the power to fund Medicaid, but does not give Congress the authority to coerce States by using this power. *See South Dakota v. Dole*, 483 U.S. 203, 211 (1987). The government's ability to make conditional offers, such as the Medicaid expansion, under the Spending Clause turns on "whether the State voluntarily and knowingly accepts the terms of the 'contract.'" *NFIB*, 567 U.S at 577 (op. of Roberts, C.J.). Applying this principle, the Chief Justice's opinion held that threatening to strip non-participating States of *all* their Medicaid funding violated the constitutional bar on coercive offers. *Id.* at 580. That is because "the financial inducement offered by Congress" were "so coercive as to pass the point at which pressure turns into compulsion," *id.* (internal quotation marks omitted), which is to say, "*economic dragooning*." *Id.* at 582 (emphasis added). The Chief Justice reasoned that:

> A State that opts out of the Affordable Care Act's expansion in health care coverage thus stands to lose not merely a relatively small percentage of its existing Medicaid funding, but *all* of it. … The threatened loss of over 10 percent of a State's overall budget … is economic dragooning that leaves the States with no real option but to acquiesce in the Medicaid expansion.

Id. at 581–82 (quotations and citations omitted).

NFIB translates effortlessly into this context, where the target of government coercion is no longer a State, but drug companies. If the gun to the head or dragooning

metaphor works *there*, then surely it works *here*. Nonetheless the District Court rejected this inference by insisting that the coercion principle applies only to federalism cases under the anticommandeering doctrine. *Boehringer,* 2024 WL 3292657 at *15. The District Court wrongly argued that, although the anticommandeering doctrine "prevent[s] Congress from interfering with state governments by placing overly controlling conditions on federal dollars," "[n]o similar limit on Congress' spending powers applies here." *Boehringer*, 2024 WL 3292657, at *15. That statement fails to recognize that *NFIB* had no occasion to examine the use of the unconstitutional conditions doctrine in property cases. Just that was done in *Nollan v. California Coastal Commission*, 483 U.S. 825 (1987) and *Dolan v. Tigard*, 512 U.S. 374 (1994), both directly on point.

This principle returns, like Banquo's ghost, as a persistent reminder of government overstepping its power either in its relationship with the States or private actors. Richard A. Epstein, *Foreword: Unconstitutional Conditions, State Power and the Limits of Consent*, 102 Harv. L. Rev. 4, 11 (1988). That "ubiquitous problem," *id.* at 5 (capitalization altered), takes up the same form in dealing with *state* regulation of land use, employment, speech, and benefits supplied to individuals by both state and federal governments.

Voluntary acceptance in both cases does not come from the lack of consent but emerges from the legal fact that the consent of a party who faces government-induced monopoly does not bound that party. This was true of the Medicaid expansion's offer to States: heads you expand your state Medicaid program or tails you lose Medicaid funding. It is also true of the IRA's offer to the drug companies: heads you sell drugs at CMS's below-fair-market-value fixed price or tails you lose a major segment of your market or pay an excise tax.

Federalism issues are therefore only one facet of the unconstitutional conditions doctrine. The point is implicitly acknowledged by the District Court when it relies on the voluntariness argument in *Minnesota Association of Health Care Facilities v. Minnesota Department of Public Welfare*, 742 F.2d 442 (8th Cir. 1985), where no federal interest was implicated. *Boehringer,* 2024 WL 3292657 at *12. There, state law conditioned participation in Medicaid on the willingness of a nursing home to keep its charges to non-Medicaid patients to no more than 10 percent in excess of its charges to Medicaid patients. The opinion once again concluded that "the present case simply does not involve a forced taking of property by the state. Minnesota nursing homes, unlike public utilities, have the freedom to decide whether to remain in business and thus subject themselves voluntarily to the limits imposed by Minnesota on the return they obtain from investment of their assets in nursing home operations." *Minnesota Ass'n of Health Care Facilities*, 742 F.2d at 446.

But in its misguided comparison to public utilities, *Minnesota Association of Health Care Facilities* ignored that the unconstitutional conditions doctrine negates the power of consent whenever the state possesses monopoly power. The court fails to note that rate regulation for public utilities and common carriers properly responds to their monopoly power, or that public-utility law has developed numerous approaches to pricing to ensure that regulated entities receive a fair market value return on their investments. *See Duquesne Light Co. v. Barasch*, 488 U.S. 299, 310–316 (1988) (describing these approaches from an historical perspective). But, unlike the electricity grid, water supply, or other regulated industries, there is a competitive market for nursing homes. Thus, just as government can place conditions on actors in a competitive market, who have

the freedom to seek other customers, government cannot place similar conditions when the government, itself, exercises monopoly power, as does CMS.

The District Court relies on two other cases that make the same conceptual error. *See, e.g.*, *Garelick v. Sullivan*, 987 F.2d 913 (2d Cir. 1993) (limiting amounts anesthesiologists could charge Medicare in the provision of anesthesiologic services); *Baker County Medical Services, Inc. v. U.S. Attorney General*, 763 F.3d 1274 (11th Cir. 2014) (requiring hospitals to treat federal detainees at Medicare rate on basis that it had opted into Medicare and Emergency Medical Treatment and Active Labor Act (EMTALA)). These cases ignore both the monopoly issue and its intimate relationship to the unconstitutional conditions doctrine.

Last, the District Court wrongly compares this case to the hard bargaining in dealing with cost-plus contracting with the Veterans Health Administration and defense contracts, citing *Eli Lilly & Co. v. United States Department of Health & Human Servsices*, No. 1:21-CV-00081, 2021 WL 5039566 at *21 (S.D. Ind. Oct. 29, 2021). *See Boehringer,* 2024 WL 3292657 at *13. But in bargaining with contractors, the government never threatens any potential contracting party with the loss of all their federal business if they do not accede to the price demanded in any potential negotiation.

III. ARTIFICIAL RESTRICTIONS ON PRICING RESULT IN CONSTITUTIONAL VIOLATIONS UNDER THE LAW OF TAKINGS AND UNCONSTITUTIONAL CONDITIONS.

NFIB's outcome rests on conceptually rigorous foundations—which, if applied to this case, demonstrate that CMS's Program constitutes "economic dragooning." Consider two scenarios where each number represents the losses sustained from the three options.

	Tax	CMS's "negotiated" price	Withdrawal from CMS markets
Scenario I	-100	-150	0
Scenario II	-100	-150	-1000

In Scenario I, withdrawal from CMS markets costs a drug company zero because it has no other products in those markets. At this point, the relative loss from CMS's low sales prices or the excise tax is irrelevant, given the credible threat of the exit, as in any competitive market. Because there is no coercion in this case, the company will voluntarily choose *not* to sell to the government. If the government wants the goods, it has to pay the price negotiated in the unregulated market, i.e., its fair market value.

In Scenario II, the story is different. Here, the withdrawal option is so costly that it coerces the drug company to sell to the government at the dictated price. Indeed, as long as the Program keeps a drug company's losses under 1000, CMS can set the price it chooses. While the drug company will accept the price "voluntarily," it will never obtain its fair market value, even though that figure sets the correct baseline for compensation in all takings cases. Suppose many independent parties are active in a competitive market. In that case, any transaction that creates gain for both parties only enhances the opportunities for trade for third parties, generating a large social improvement. But those positive third-party effects are never found dictated prices—or, as in this situation, with markets where CMS's market power can impose costs on sellers by shutting them out of the market. Because it is simply impossible to produce innovative, profitable drugs without access to markets that CMS controls, the Program gives BI a choice analogous to that between your money (sell your drugs at below fair market

value) or your life (pay the excise tax). CMS does not make this choice any better by using its monopoly power by offering a phantom third option less palatable than the first two—the death of your family (stop doing business with CMS).

Further, a drug company's consent to the trilemma does not cure its coercion. Start with an undisputed proposition under the antitrust laws: when a cartel sets supra-competitive prices, it has committed a per se antitrust violation. It is no answer to either criminal charges, state or federal, or to private actions seeking treble damages, to state the truism that the buyers who consented to the price increases were better off than they would have been if they had just refused to deal. That consent is uniformly disregarded so that the law can attack the two major monopoly vices: lost consumer surplus to consumers who stay in the market, albeit at a higher price, and the losses to those consumers who exit the market (and thus cannot be identified for bringing suit), thereby losing their gains from participating in a competitive market. It is too administratively difficult to allow numerous non-buyers to sue, so suits by actual purchasers who agreed to pay the stipulated price are the only way to bring these challenges.

CMS thus acts coercively, notwithstanding BI's option to exit the market. This insight—some "choices" are not choices—is commonplace. In contracts, offers accepted under duress are void. *See* RESTATEMENT (SECOND) OF CONTRACTS §175. The law similarly finds no voluntary choice when a person agrees to a contract that leaves them better off under conditions of necessity, where, as under monopoly, there is only one choice. In the classic case, *Post v. Jones*, 60 U.S. 150 (1856), the Richmond, a ship laden with oil and whalebone, was stranded at sea and therefore sold at a makeshift auction large quantities of its cargo to a rescue ship in a transaction that left her better off than

losing everything. Nonetheless, when she returned to port, her owners sued to obtain their cargo's fair market value. Justice Robert Grier, writing for the Court, set aside that auction as a "contrivance" where "the master of the Richmond was hopeless, helpless, and passive—where there was no market, no money, no competition—where one party had absolute power, and the other no choice but submission." *Id.* at 159. He also rejected the contention that "the sale was justifiable and valid, because it was better for the interests of all concerned to accept what was offered, than suffer a total loss." *Id.* at 160. To avoid exploitation, the salvor had to accept reasonable compensation for his services, i.e., the fair market value, the same risk-adjusted competitive rate of return that prevents the government from using its monopsony power to strip pharmaceutical companies like BI of their patent protection. *See* Wayne T. Brough, *Liability Salvage—By Private Ordering*, 19 J. Legal Stud. 95 (1990).

In response, CMS may claim it does not act as a monopolist who sells but as a monopsonist who buys. No matter; the overall resource analysis is the same. Low subsidized prices invite too many buyers to enter the market, including those who would not purchase without the subsidy. Those excessive sales represent a social loss, given the actual cost of production is higher than the price paid to the seller. Hence, sellers who consent to lower prices are still allowed under the standard antitrust analysis to sue for their losses.

CMS's pricing thus commits a triple sin. First, it harms the potential pharmaceutical sellers who never enter the market deterred by the artificially depressed prices. Second, it denies consumers additional goods—here, innovative drugs—that would be brought into the market if competitive pricing were allowed. Finally, CMS severs the relationship

between the price or the tax on one side and the value of the drug on the other. Market pricing systems convey information about the relative value of goods that cannot be obtained from arbitrary prices set administratively. Friedrich Hayek, *The Use of Knowledge in Society*, 35 Am. Econ. Rev. 519 (1945). Because CMS's mandated price supplies no information about the relative scarcity of the product, investors have no information about whether the government program is efficient or not, potentially resulting in resource misallocations that go well beyond the negotiating parties. Other potential investors will leave the market, resulting in the introduction of fewer new drugs.

A. The Inflation Reduction Act's Pricing Restrictions Impose an Unconstitutional Taking.

The District Court ruled that the Inflation Reduction Act was not a taking, finding "that BI's participation in Medicare and Medicaid is voluntary, even if BI has a considerable economic incentive to participate." *Boehringer*, 2024 WL 3292657, at *15. As discussed above, the purported "voluntary" choice to participate in Medicare and Medicaid does not negate the Fifth Amendment's mandate that no "private property be taken for public use, without just compensation." U.S. Const. amend. V. That duty lies first and foremost against the federal government. *See Barron v. Baltimore*, 32 U.S. 243, 247–48 (1833). And the CMS fails to discharge the duty.

The Takings Clause represents a durable middle path that allows the government to avoid two pitfalls: (1) holdout problems by private parties in which a private individual extracts a higher price than fair market value from the government through its positional bargaining power (as would, for example, the property owner of a land parcel needed to complete the last mile of an intercontinental railway) and (2) expropriation

by the government that forces specific individuals to bear a disproportionate fraction of loss through denying or understating fair market value.

The Supreme Court has repeatedly emphasized these points. First, property that is held in private hands may be taken for public use only if the private party is paid "just compensation" where "the combination of those two words" leaves "no doubt that the compensation must be a full and perfect equivalent for the property taken," and further that "no private property shall be appropriated to public uses unless a full and exact equivalent for it be returned to the owner." *Monongahela Nav. Co. v. United States*, 148 U.S. 312, 326 (1893).

Second, the standard formulation of this rule is found in *Armstrong v. United States*, 364 U.S. 40 (1960), in which the United States dissolved a valid materialman's lien by removing materials to out-of-state shipyards. The destruction of the lien was the taking of a (partial) interest in the boats, which would have left a subcontractor bearing a considerable fraction of the cost of repairing a boat used to defend all citizens. Justice Hugo Black blunted that maneuver in a terse opinion: "The Fifth Amendment's guarantee that private property shall not be taken for a public use without just compensation was designed to bar Government from forcing some people alone to bear public burdens which, in all fairness and justice, should be borne by the public as a whole." *Id.* at 49.

These two points apply here. The Program mandates a trilemma in which no option gives drug companies what the Constitution requires: fair market value, which the Court has defined as "the price at which the property would change hands between a willing buyer and a willing seller, neither being under any compulsion to buy or to sell and both having reasonable knowledge of relevant facts." *United States v. Cartwright*, 411 U.S. 546,

551 (1973).

The fair market value is, in this context, especially important as just compensation because the cost of production is largely inaccessible. As mentioned, drugs require huge upfront R&D expenditures, such that revenue from successful products must cover the costs of "dry holes" that never generate a useful product. One study estimated in 2003 a cost of about $802 million dollars for developing new chemical entities, DiMasi, *et al.*, *The price of innovation*, 22 J. Health Econ. at 180, or about $1.4 billion in today's dollars.

Given the R&D costs and the relatively small marginal cost of a unit of production, it is impossible to use marginal cost pricing because that first unit could never be sold at a price that reflects all the development costs, while all subsequent pills cost a few dollars at most. Accordingly, initial costs of development must be spread over some large fraction of the units sold so the drug company can recover its full costs (both fixed and variable) over the patent life. The Supreme Court recognized this problem a century ago when reviewing contracts that gave a party the exclusive rights to build bridges over rivers, allowing them to charge supercompetitive prices for several years until they recovered their fixed costs, after which the tolls were sharply decreased. *See Charles River Bridge Co.,* 36 U.S. at 536–37. This standard pricing scheme for drugs is wrecked if those front-end costs cannot be spread over a base that includes government purchases under Part D.

Accordingly, the IRA's crabbed definition of "maximum fair price," which relies on average price (the "non-Federal average manufacturer price"), 42 U.S.C. §1320f-3(C), precludes drug companies from recovering their front-end costs. Essentially, the government picks an average price based on limited data—with absolutely no idea

whether the imposed price will be sufficient to recover R&D costs. In a competitive market, firms selling goods with high initial fixed costs and low marginal costs will bargain with various parties and charge different customers different prices in order to recoup investment. But if CMS, the monopsonist, picks its ad hoc price, the drug company has no assurance that it will recoup its investment—particularly if all buyers thereafter insist on the deal that CMS commandeered.

Finally, like the U.S. government singling out the contractor in *Armstrong,* the CMS singles out pharmaceutical companies to bear the entire cost of its regulatory efforts. Instead, CMS should buy drugs at fair market value—and then distribute them if it chooses at below cost. In *Pennell v. City of San Jose*, 485 U.S. 1 (1988), the Supreme Court considered whether the City of San Jose's rent-control program constituted a taking. Justice Scalia's concurrence argued that the constitutionally proper regulatory approach calls for the government to offer below-market rentals or sales *after* it buys what property it needs at market price. *Id.* at 22–23 (Scalia, J., concurring in part and dissenting in part). In this way, the government pays for the property through tax revenue appropriated using the democratic process, rather than forcing one group (landlords) to foot the bill.

B. The District Court's Takings Analysis Ignores Long-Established Economic and Constitutional Principles in Dealing with the Line Between Physical and Regulatory Takings.

In *Horne v. United States*, 576 U.S. 350 (2015), the Department of Agriculture required that raisin growers surrender a fraction of their crop each to the Department of Agriculture, which would then dispose of these raisins through exporters, foreign markets, charities, or, in some instances, physical destruction—all to create artificial

shortages to keep prices high. *Id.* at 354. *Horne* held that taking these raisins was a physical taking compensable under the per se compensation rule announced in *Loretto v. Teleprompter Manhattan CATV*, 458 U.S. 419 (1982). *See Horne*, 576 U.S. at 361–62.

The District Court concluded *Horne* did not apply to this regulatory situation because the raisin regulation was "enforced … by physically appropriating the Hornes' raisins," whereas "the government … in this case is regulating the price of drugs or services only at the moment the service provider or seller chooses to sell." *Boehringer*, 2024 WL 3292657, at *13–14. But that oversimplification fails. In the context of the IRA, it does not matter whether the government takes possession of the drugs so that it can be charged with a per se physical taking, *see Loretto*, 458 U.S. 419, or whether it just took constructive possession of the drugs when it ordered their owners to sell the drugs to private parties at the low stipulated price.[4]

Instead, given the IRA's control over the transaction, it must be recharacterized as first, the government takes the drugs, and, second, sells them to various buyers, remitting the below-market revenues to the drug companies. Looking to the economic reality of the transaction avoids the District Court's confused and legalistic discussion of whether or not the government takes physical possession in order to determine whether a taking has occurred. Recharacterizing the IRA into its economically salient features allows for a coherent explication and application of takings law.

The Supreme Court has long accepted this recharacterization in private-law

[4] Typically, in property law, establishing constructive possession grants the owner the right to obtain physical control or a variety of rights over someone else's physical control of that property. *United States v. Herrera*, 446 F.3d 283, 287 (2d Cir. 2006) (constructive possession involves "dominion and control" over the item).

transactions. In *Lucas v. Earl*, 281 U.S. 111 (1930), Earl's employer paid his earnings to his wife pursuant to a contract between Earl and his wife that required all earnings that either spouse received to be held in joint tenancy. *Id.* at 113–14. As a result, Earl claimed only half of his earnings for income tax purposes until Justice Holmes exposed the ruse:

> There is no doubt that the statute could tax salaries to those who earned them and provide that the tax could not be escaped by anticipatory arrangements and contracts however skillfully devised to prevent the salary when paid from vesting even for a second in the man who earned it. That seems to us the import of the statute before us and we think that no distinction can be taken according to the motives leading to the arrangement by which the fruits are attributed to a different tree from that on which they grew.

Id. at 114-15.

The same scrutiny over devious recharacterization applies as strongly to government as to private parties.

IV. GOVERNMENT OFFERS, SUCH AS THE IRA'S, THAT REQUIRE COMPANIES TO CHOOSE BETWEEN OPTIONS THAT MAKE BOTH COMPANIES AND SOCIETY WORSE OFF ARE NOT VOLUNTARY.

Combatting the evasions and indirect ways government can deprive individuals and firms of the fair market value of their property exposed in Part III is a key function of the unconstitutional conditions doctrine. Another mechanism applicable in this case that governments (and businesses) use to leverage their monopoly power is "bundling," which involves offering or "bundling" two goods only together as a pair—one desired, but the other desired less or not at all. When a monopolist precludes the possibility of separate purchases of these items, people must buy both components of the bundle together in order to purchase the more desirable one at a cost lower than their perceived

combined value.

Suppose that the government, as the sole seller of fruit, separately offers tomatoes for $25 per package and bananas for $50. The customer values tomatoes at $10 and bananas at $80. If sold separately, he will pay only $50 for bananas, yielding a net gain of $30. But, if forced to buy the bundle at $80, he will do so, even though his net gain drops to $5 ($80 – ($50 + $25)), for now he must absorb the $15 loss on tomatoes to obtain the $20 gain on the bananas. Thus, the inefficiency (i.e. the reduced surplus) comes from a seller monopolist's joining of the two goods.

Just this inefficiency emerges in building permitting when the government uses its monopoly power to bundle a sought-after permit with an unrelated government demand. In *Nollan,* 483 U.S. 825, landowners sought a permit to replace a shack with a beach house, increasing their property's fair market value by, say, $100,000. The Commission responded that it would grant the permit only if the Nollans agreed to convey a lateral easement across the front of their beach house, running between two public parks. The Nollans built their house without the permit and then defended against the government's subsequent suit on the ground that the proposed lateral easement was an unconstitutional condition.

Anticipating *NFIB's* reference to "economic dragooning," *Nollan* upheld their position, excoriating the Commission that "unless the permit condition serves the same governmental purpose as the development ban, the building restriction is not a valid regulation of land use but 'an out-and-out plan of *extortion*.'" *Nollan,* 483 U.S. at 837 (citation omitted) (emphasis added). Why extortion? Because the bundling makes it impossible for anyone to determine whether the easement was worth more to the State

than it costs the Nollans. *See* Richard A. Epstein, *The Harms and Benefits of* Nollan *&* Dolan*,* 15 N. Ill. Univ. L. Rev. 479 (1995). The building permit is no doubt more valuable to the Nollans than the loss of the lateral easement. If the government bundles the permit and the easement, the Nollans will take the deal. Yet, that gambit results in a social loss if the easement's value to the public is $100, and the loss to the Nollans is $150, which would not happen if the easement were separately priced. *See* Richard A. Epstein, *The Permit Power Meets the Constitution*, 81 Iowa L. Rev. 407 (1995).

In cases like this, moreover, the unconstitutional conditions doctrine ensures that the government does not "trample" anyone's Fifth Amendment rights. In refusing to recognize this principle here, the District Court echoes *Davis v. Massachusetts*, 167 U.S. 43 (1897), which upheld a local ordinance allowing Boston to exclude any person from using the Boston Commons just as a private party may exclude members of the public from his or her house. The Court ruled that "[t]he right to absolutely exclude all right to use necessarily includes the authority to determine under what circumstances such use may be availed of, as the greater power contains the lesser." *Id.* at 48. In other words, *Davis* accepted the view that the government can add whatever condition it chooses when allowing access to any public property or goods or services it provides.

The Court effectively overruled *Davis* in *Hague v. CIO*, 307 U.S. 496 (1939), by stressing the key differences between public and private property. First, the government, as trustee for the public, owes duties of care and loyalty that require it to show cause for excluding from public spaces *any* individual or group of individuals. Second, the *Davis* case inverted the "greater" and "lesser" powers. In fact, the right to exclude everyone or no one imposes a strong nondiscrimination principle that here would

prevent the government from requisitioning some but not other drugs. In *Hague*, the Court imposed this limit on state power:

> Wherever the title of streets and parks may rest, they have immemorially been held in trust for the use of the public …. Such use of the streets and public places has, from ancient times, been a part of the privileges, immunities, rights, and liberties of citizens.

Id. at 515–16.

These words resonate here. The IRA gives government the right to single out those drugs that it wishes to regulate. It then compounds that error by failing to distinguish between the benefits of consent in competitive markets and its abuse in monopoly markets. The consent that leads to social gains in the former setting leads to systematic losses in the latter. The same constitutional imperative should stop the IRA's ill-conceived, wasteful practices under both the Takings Clause and the doctrine of unconstitutional conditions.

CONCLUSION

The Court should reverse the District Court's judgment.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitations of Circuit Rule 32.1(a)(4)(A) and Local Rule 29.1(c) because it contains 6,640 words, exclusive of the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f).

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in Garamond and 14 point font.

/s/ D. Adam Candeub
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Dated: November 8, 2024

CERTIFICATE OF SERVICE

I hereby certify that I caused the foregoing brief to be filed with the Clerk of the Court for the United States Court of Appeals for the Second Circuit by using the ACMS system on November 8, 2024. I certify that all participants in the case are registered ACMS users and that service will be accomplished by the ACMS system. I also certify that I caused six copies of the foregoing brief to be delivered to the Clerk of Court for the United States Court of Appeals for the Second Circuit via overnight courier.

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Dated: November 8, 2024