Nos. 24-1820 & 24-1821

United States Court of Appeals for the Third Circuit

BRISTOL MYERS SQUIBB COMPANY,

Plaintiff-Appellant,

v.

XAVIER BECERRA, *ET AL.*,

Defendants-Appellees.

JANSSEN PHARMACEUTICALS, INC.,

Plaintiff-Appellant,

v.

XAVIER BECERRA, *ET AL.*,

Defendants-Appellees.

On Appeal from the United States District Court for the District of New Jersey, Nos. 3:23-cv-03335 & 3:23-cv-03818

BRIEF OF *AMICUS CURIAE* INDEPENDENT WOMEN'S FORUM SUPPORTING APPELLANTS AND REVERSAL

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CORPORATE DISCLOSURE STATEMENT

The Independent Women's Forum is 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.

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STATEMENT OF *AMICUS* INTEREST

The backbone of our nation's elderly and disabled youth care is female. Women make up more than 60% of caregivers to adults and children with disabilities as well as 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, women shoulder the burden of many sad realities. The Independent Women's Forum (IWF) is 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.

The Federal Rule of Appellate Procedure 29(a)(2) permit 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 intended to fund this brief's preparation or submission.

SUMMARY OF ARGUMENT

The Fifth Amendment places the government under "a categorical duty to pay just compensation" when taking property from private parties. *Horne v. Dep't of Agric.,* 576 U.S. 350, 358 (2015). To determine just compensation, "[t]he Court . . . employ[s] the concept of fair market value." *United States v. 564.54 Acres of Land*, 441 U.S. 506, 511 (1979). Fair market value (FMV) is "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); *see also Almota Farmers Elevator & Warehouse Co. v. United States*, 409 U.S. 470, 474 (1973).

The Inflation Reduction Act is purportedly aimed at reducing drug prices but does so by circumventing the constitutional mandate for paying FMV for property the government takes. The Act forces drug companies to choose an option from this statutory "Hobson's trilemma"—each of which makes them worse off:

- *First,* drug companies may sell drugs pursuant to a purported "negotiation," in which the price is dictated by the Centers for

Medicare and Medicaid Services (CMS) under its formula for a so-called "maximum fair price" that is calculated to ensure pharmaceutical companies receive *less* than FMV for their patented products;

- *Second,* they can refuse CMS's price and pay a confiscatory tax; or
- *Third,* they can withdraw *all* of their products from the markets over which CMS exercises 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) (Medicare and Medicaid "beneficiaries . . . were responsible for about 45 percent of nationwide spending on retail prescription drugs"). By design, these losses exceed the total losses from exercising either of the first two options, with devastating consequences to the ability of these companies to operate profitably in *both* the Medicare market *and* the unregulated private market.

The Act puts drug companies to a nominal choice that is, in reality, no choice at all: because companies cannot survive without access to the CMS-regulated markets, companies participate in this market and thus

must transfer their drugs (their "property" for Takings Clause purposes) to third parties at dramatically reduced prices or else pay a confiscatory tax. Either way, property is taken for public use at less than the drugs' FMV. That constitutes a taking without just compensation. (The District Court suggests, without any textual support, that a drug company could continue to sell listed drugs to private parties without any penalty. This reading has no support in the IRA's text, as Bristol Myers Squibb shows, and other courts have rejected this reading. (Bristol Myers Squibb Op. Br. 18-23) We do not address it here.).

The District Court excused the government's dragooning of private property on the grounds that the drug companies suffered no harm if they voluntarily chose to participate in CMS's negotiation program. But, in so doing, that court paid no heed to the Supreme Court's dispositive opinion in *National Federation of Independent Business v. Sebelius,* 567 U.S. 519 (2012) ("*NFIB")*, which explicitly rejected the District Court's crabbed notion of voluntary consent, describing instead a "gun to the head." 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.

Finally, *even if* the decision to participate in CMS's program is voluntary in some sense, it still falls under the unconstitutional-conditions doctrine because it denies benefits (access to CMS-regulated markets) to entities that assert their right not to be deprived of their property without just compensation. This provides an alternative basis for reversal.

ARGUMENT

I. BACKGROUND

This case arises from the government's efforts to use aggressive pricing strategies to strip Bristol Myers Squibb (BMS) and Janssen of profits they had received from selling their most valuable drugs to pharmacies that the Centers for Medicare & Medicaid Services (CMS) support and regulate. The United States carried out this effort through the Drug Price Negotiation Program (the "Program"), which the Inflation Reduction Act created. Before this law's enactment CMS was prohibited by law from interfering in negotiations between drug companies and pharmacies. 42 U.S.C. § 1395w-111(i). Under this simpler system, drug companies and pharmacies bargained over price, each knowing that it could retain the benefits of its prior position if the two sides could not strike a

bargain.

The Inflation Reduction Act reversed this market-based, voluntary approach. CMS now negotiates prices directly with drug companies for brand-name Medicare Part B and Part D drugs. 42 U.S.C. § 1320f; 26 U.S.C. § 5000D. CMS identifies the fifty qualifying single-source drugs with the highest total Part D expenditures. CMS then ranks these drugs, 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, *Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026* at 104–08 (June 30, 2023) ("*CMS Guidance*").

Once CMS selects drugs, the Inflation Reduction Act allows CMS to set prices, employing a dressed-up system of strict controls. Companies submit data to CMS. 42 U.S.C. § 1320f-2(a)(4). CMS then makes "a written initial offer that contains [its] proposal for the *maximum fair price* of the drug." 42 U.S.C. § 1320f-3(b)(2)(B) (emphasis added). "Not later than 30 days after" receiving the initial offer, the manufacturer must either

accept such offer or propose a counteroffer. 42 U.S.C. § 1320f-3(b)(2)(C). If the parties have not agreed on a price by a statutorily defined date in a given price period, the manufacturer becomes subject to the excise tax penalties. 26 U.S.C. § 5000D; 42 U.S.C. § 1320f-3(b)(2)(E); *CMS Guidance* at 169. All prior bargaining is done in the shadow of CMS's robust regulatory authority.

How does the CMS calculate its "maximum fair price?" The answer is murky. The statute says that the "maximum fair price negotiated . . . for a selected drug . . . shall not exceed the lower of" the amount calculated under one of two subsections. 42 U.S.C. § 1320f-3(c)(1)(A). One of those subsections sets prices based on "the average non-Federal average manufacturer price for such drug for 2021, . . . increased by the percentage increase in the consumer price index for all urban consumers . . . ." *Id.* § 1320f-3(c)(1)(C)(i). And this price is then lowered by certain applicable percentages, ranging from 75 to 40%. 42 U.S.C. § 1320f-3(c)(3). Last, CMS has discretion to further lower the price by relying on numerous factors, including whether the drug has "therapeutic alternatives" or received "prior Federal financial support." *CMS Guidance* at 132, 150.

Understanding why the "maximum fair price" in no way

approximates the constitutionally required FMV turns on understanding drug pricing economics. 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 bear a low marginal cost for producing each dose. But because of the high fixed costs, most drugs cannot be profitable unless drug companies can bargain for higher prices from other users willing and able to pay more than their marginal cost of production of the standard dosage. 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, and drug companies cannot receive FMV 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). 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 its FMV.

This economic model is hardly unique to drugs. Indeed, almost two hundred years ago, the Supreme Court recognized this approach's validity when it examined contracts giving third parties exclusive rights to build bridges over rivers, allowing them to charge supercompetitive prices for several years until they recovered their fixed costs. Thereafter, 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 upfront, 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 by law holds a monopoly over the portfolio of every drug company given to the 91,786,257 Medicaid and CHIP (Children Health Insurance Program) enrollees and dual enrollees, Centers for Medicare & Medicaid Services, *2023 Medicaid & CHIP Beneficiaries*

at a Glance (Apr. 2023), https://tinyurl.com/4vbtxytw, and the 67.2 million, Data.CMS.gov, Medicare Monthly Enrollment, https://tinyurl.com/mr3nsxva—well over a third of all Americans

Short of that drastic step, the company has two options, equally unpalatable. It can accede to the stipulated prices dictated by the government. Or, it can resist its price demands by subjecting itself to a punitive tax beginning at 186% and escalating to 1,900% of the medicine's total daily revenue from all sources. Congressional Research Service, *Tax Provisions in the Inflation Reduction Act of 2022 (H.R. 5376)* 4 tbl. 2 (2022); 26 U.S.C. § 5000D. No matter which horn of this trilemma that BMS or Janssen embraces, each is left unambiguously worse off than it would have been if the new Program had never been put into place.

This case, illustrating the Program's coercion, began when CMS selected BMS's Eliquis and Janssen's Xarelto. *Bristol Myers Squibb Co. v. Becerra*, Slip Op., 2024 WL 1855054 at *2. Both are blood thinners with $18.2 and $7.4 billion in sales in 2022. Brian Buntz, *The 50 best-selling pharmaceuticals of 2022*, DRUG DISCOVERY & DEVELOPMENT (Apr. 18, 2023), https://tinyurl.com/yt9hb79y. Large as those sales are, they are far less than these companies' total sales through CMS-regulated markets.

Hoping to retain access to these markets without abiding the government's confiscatory demands, the companies filed this suit.

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

The government claims that drug companies cannot complain about being coerced into surrendering their property below FMV because they can exit failed negotiations with CMS and sell to private parties. Accepting this position, the District Court reasoned that "manufacturers selected to participate in the Program will not face any fee, tax, or fine if they initially choose not to participate in the Program. . . . There are alternatives for Plaintiffs to explore should they choose, including exiting from sales to Medicare in the first instance." Slip Op., 2024 WL 1855054 at *8.

But the IRA coerces the drug companies into accepting the government's terms. Choose the Program and be forced to sell your property at the CMS's price, which is not FMV. Don't choose the Program and either pay a tax or CMS bars access to essential parts of the pharmaceutical market. All choices make companies worse off.

The reasoning in *NFIB,* 567 U.S. 519, shows why CMS's Program is constitutionally coercive. The case reviewed the Affordable Care Act's Medicaid expansion, 42 U.S.C. § 1396d(a) et seq. The expansion 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 not to participate? In theory, yes. But any State that refused could be stripped of "*all* of its federal Medicaid funds." *NFIB*, 567 U.S at 542.

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 through the use of 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. Applying this principle, the Chief Justice's opinion concluded that threatening to strip non-participating States of *all* their Medicaid funding violated the constitutional bar on

coercive offers. *Id.*; *accord id.* at 647-89 (Scalia, Kennedy, Thomas, and Alito, JJ, dissenting). The opinion distinguished whether "the financial inducement offered by Congress" is "so coercive as to pass the point at which 'pressure turns into compulsion' to become '*economic dragooning*.'" *Id.* at 580 (op. of Roberts, C.J.) (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, which the District Court ignores, 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*. Voluntary acceptance in both cases does not come from the lack of consent but emerges from the legal fact that a party who faces government-induced economic pressure cannot make a voluntary choice. This is true whether Medicare Expansion's offer to States: heads you expand your state Medicare program or tails you lose Medicare funding—or IRA's offer to the drug companies: heads you sell

drugs at CMS's fixed price or tails you lose a major segment of your market or pay an excise tax.

NFIB and Court precedent are less clear as to what level of "economic dragooning" extinguishes legally voluntary choice. *See Dole*, 483 U.S. 203. Takings and unconstitutional conditions law, especially when combined with economic analysis, however, provides measures for "economic dragooning" as examined in the next sections—and demonstrates that CMS's Program is unconstitutional.

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, demonstrates that CMS's Program goes too far in "economic dragooning" so as to constitute a taking or unconstitutional condition. 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 a price determined by the same kind of bargaining that takes place in the unregulated market, i.e., its FMV.

In Scenario II, the story is different. At this point, the withdrawal option is so costly that it coerces the drug company to sell to the government at the dictated price. Indeed, so long as the Program keeps a drug company's losses under 1000, CMS can set whatever price it chooses. While the drug company will accept the price "voluntarily," it will never realize its FMV, which is the correct takings baseline in all cases. If many independent parties are active in a competitive market, any transaction that creates gain for both parties only enhances the opportunities for trade for third parties, increasing social welfare. But that proposition is never true with 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.

The District Court opinion addressed none of these objections and ignored the inefficiencies introduced by CMS's unlawful Hobson's trilemma. Instead, the District Court found no taking because the Program is voluntary. The correct analysis, however, is that CMS's monopoly power vitiates the consent of BMS and Janssen. Because it is simply not possible to produce innovative, profitable drugs without the markets to which CMS controls access, the Program gives BMS and Janssen choices that are analogous to those between your money (sell your drugs at below FMV) or your life (pay the excise tax). CMS does not make this choice any better by offering a third option, even 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 a supra-competitive price, 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 increase 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 suit), thereby losing their gains from participating in a competitive market.

CMS is thus coercive, notwithstanding the option to exit the market. This insight—some "choices" are not choices at all—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 him better off under conditions of necessity, where, as under monopoly, there is only one choice. In *Post v. Jones*, 60 U.S. 150 (1856), the Richmond, a ship laden with oil and whalebone, was stranded at sea and therefore sold 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 FMV.

Justice 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 FMV, the same risk-adjusted competitive rate of return that prevents the government from using its monopsony power to strip pharmaceutical companies like BMS and Janssen of their drugs' FMV. *See* Wayne T. Brough, *Liability Salvage—By Private Ordering*, 19 J. LEGAL STUD. 95 (1990).

In response CMS may claim that it does not act as a monopolist who sells but as a monopsonist who buys. No matter: the poor outcome is the same in terms of the overall resource analysis. 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 the sellers who consent to the lower price are still allowed under the standard antitrust analysis to sue for their losses.

CMS's pricing commits a triple sin. First, it harms the potential sellers who never enter the market deterred by the artificially depressed prices, and second, 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 the CMS's mandated price gives 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. Specifically, potential investors will leave the market, resulting in fewer new drugs.

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

The District Court ruled the Inflation Reduction Act is not a taking because pharmaceutical companies freely accept the financial losses the Inflation Reduction Act imposes when they "choose" to participate in the Program. As discussed above, the purported choice cures nothing to

diminish the Fifth Amendment's mandate that no "private property be taken for public use without just compensation." That duty lies first and foremost against the federal government. *See Barron v. Baltimore*, 32 U.S. 243 (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 (similar to those in *Post v. Jones* discussed *supra*) in which a private individual extracts higher price than FMV from government through its positional bargaining power (as the last mile of an intercontinental railway), and (2) expropriation by the government that forces certain individuals to bear a disproportionate fraction of loss denying or understating FMV.

The Supreme Court emphasizes 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 sailing two of its vessels out of Maine waters. The destruction of the lien was the taking of a (partial) interest in the boats, which would have left a subcontractor bearing a huge 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: FMV, 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." *Cartwright*, 411 U.S. at 551.

The FMV 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, and revenue from successful products must cover the costs of "dry holes" that never generate a useful product. *See* Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151 (2003). DiMasi et al. estimated in 2003 a cost of about $802 million dollars for developing new chemical entities, *id.* 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 as to let the drug that enters the market recover its full costs (both fixed and variable) over the patent life. *See* Duffy, 71 U. CHI. L. REV. 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.

And, in fact, IRA's definition of "maximum fair price," which relies on average price (the "non-FAMP"), precludes drug companies from recovering their front-end costs. Essentially, the government picks an averaged-price based on limited data—with absolutely no idea whether the selected 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 as all buyers thereafter insist on the deal that CMS commandeered.

What is worse is that this average price is then lowered by certain applicable percentages, ranging from 75% to 40%, 42 U.S.C. § 1320f-3(c)(3), further distancing the "maximum fair price" from a drug's FMV.

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 FMV—and then distribute them if it chooses at below cost. In *Pennell v. City of San Jose*, 485 U.S. 1, 15 (1988), the Supreme Court ruled the City of San

Jose's rent control program 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 this way, the government pays for the property through tax revenue appropriated using the democratic process rather than one group, i.e., landlords, foot the bill as commanded by administrative fiat.

B. The District Court's takings analysis ignores long-established economic and constitutional principles, misinterpreting *Horne*.

The District Court ignores these problems, adopting a flawed interpretation of *Horne*. That case involved a government requirement that raisin growers surrender a fraction of their crop 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. *Horne* held that the taking of 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). *Horne*, 576 U.S. at 359–60.

By using a raisin cartel to inflate prices, the Department of Agriculture benefited all growers, the plaintiffs Marvin and Laura Horne included, because these monopoly profits more than offset the losses from foregone sales. *See* Richard A. Epstein, *The Unfinished Business of* Horne v. Department of Agriculture*,* 10 N.Y.U. J. LAW & LIB. 734 (2017). The fact that the Hornes and the other raisin growers might be made *better off* through the government raisin cartel, however, does not affect the takings analysis. By participating in the raisin monopoly, the Hornes did get full compensation, a fact the Court ignored. In contrast, CMS, the government monopolist, deprives BMS and Jannsen of compensation. And, in both cases, there is a taking because the government denies FMV to both sets of plaintiffs.

The District Court, ignoring the monopoly backdrop in *Horne,* focuses on physical appropriations. It states, "Unlike *Horne,* there is no physical appropriation taking place and, setting aside their factual arguments, Plaintiffs fail to show how they are being *legally* compelled to participate in the Program." Slip Op., 2024 WL 1855054 at *5 (emphasis in original). But it is a distinction without a difference to say that no physical taking has occurred. Courts must look at the effects of government

action. Here, CMS and the Department of Agriculture's programs are identical in all relevant respects. Just as the Department of Agriculture ordered the raisin growers to surrender their raisins at less (or perhaps more) than FMV, CMS's trilemma forces BMS and Jannsen to sell their drugs at their detriment for the "maximum fair price," a price calculated using a method that ignores FMV.

IV. Government offers, such as the IRA's, which require companies to choose between options that make both companies and society worse off, are not voluntary.

The District Court also held that the unconstitutional conditions doctrine did not apply to this Program's trilemma. To expose this error, it is necessary to understand that the unconstitutional conditions doctrine, like the general takings law, is a coherent response to the improper exercise of the government's monopoly power within the state. *See* Richard A. Epstein, BARGAINING WITH THE STATE, CH. 4 (1993).

One mechanism governments (and businesses) use to leverage monopoly is "bundling." This technique involves offering or "bundling" two goods only together as a pair—one desired, the other desired less or not at all. But, when a monopolist precludes the possibility of separate purchases of these items, people must buy both components of the bundle

together in order to get the more desirable one at a cost lower than their perceived combined value.

Suppose that the government is the sole seller of fruit, separately offering tomatoes for $25 and bananas for $50. The customer values tomatoes at $10 and bananas at $80. If sold separately, he will buy only bananas for a net gain of $30. But, if forced to buy the bundle at $80, his net gain drops to $5 ($80 – ($50 + $25)) because he has to take the $15 loss to obtain the $20 gain. Thus, the inefficiency comes from the forced combination that the seller monopolist can impose.

Just this inefficiency emerges in permitting when the government uses its monopoly power to bundle a sought-after permit with an unrelated government demand. In *Nollan v. California Coastal Commission,* 483 U.S. 825 (1987), landowners sought a permit to replace a shack with a beach house, increasing their property's FMV by, say, $100,000. The Commission responded that it would grant the permit 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 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 (quoting *J.E.D. Associates, Inc. v. Atkinson*, 432 A.2d 12, 14–15 (N.H. 1981)). Justice Scalia reasoned because the Commission's permitting scheme sought to improve beach-shed access for drivers along the highway, the Commission could impose permit conditions only if they related to preserving that view. The Commission could not use its "regulatory monopoly" to "bundle" the unrelated lateral easement with the building permit.

But *Nollan*'s analysis ignores the underlying economics. Recall that the government's constitutional exercise of eminent domain requires individuals to sell to the government only if the sale improves overall social welfare. But bundling, which hides the value parties place on each separate element, makes it impossible to decide whether this condition is ever met. In *Nollan*, no one can determine whether the easement was worth

more to the state than it cost 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. So if forced to take or leave the bundle (build your house *and* surrender the easement), they would have taken it, as all their neighbors did. But that proposition also holds if the value of the easement to the public is $100, and the loss to the Nollans is $150, so that now that second transaction is a social loss, 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).

Rather than analyze the Program's unconstitutional conditions, the District Court ducked the issue, dismissing the unconstitutional conditions argument because, "as Defendants succinctly observed at oral argument, 'there's no constitutional right in danger of being trampled,'" Slip Op., 2024 WL 1855054 at *12 (citing Oral Arg. Tr. 58:2–4)—except of course the confiscation of their goods in violation of the Fifth Amendment. The doctrine of unconstitutional conditions guards against the government using bundling to extract wealth from specific firms, i.e.,

"trample" on their Fifth Amendment rights, without going through the democratic process and fully compensating for each element in the bundle.

In refusing to recognize this principle, the District Court echoes *Davis v. Massachusetts*, 167 U.S. 43 (1897). There, the state legislature adopted an ordinance allowing Boston to exclude any person from using the Boston Commons in the same way that a private owner has the right to exclude members of the public from their 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, if the government provides for some service or funding as a general matter, it may condition and limit access to that service.

But, in later cases, the Court saw that *Davis* missed the differences between public and private property. First, the government, as trustee for the public, owes duties of care and loyalty, and must show cause for excluding from public spaces *any* individual or group of individuals. Second, while *Davis* correctly observes that the "greater" power includes the lesser power, both *Davis* and the lower court got the rank order

backward. In fact, the right to exclude everyone or no one is the lesser power. Rather, the power to exclude selectively is the greater power because it lets the state single out one person for oppressive treatment. The law typically relies on powerful nondiscrimination presumptions against singling out individuals for speech restrictions, differential rate regulations, or a thousand other abuses. In contrast, the decision to let everyone or no one in receives mild constitutional scrutiny because nondiscrimination rules protect all comers.

It is therefore no surprise that the Court later rejected *Davis* in *Hague v. CIO*, 307 U.S. 496 (1939), stating:

> 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.

These words resonate here. The Program gives government the right to single out those drugs that it wishes to regulate. It then compounds the mistake by failing to distinguish between the very different treatment of consent in competitive markets, where it is decisive, and in monopoly markets, where it is irrelevant. What leads to social gains in the former setting leads to systematic losses in the latter. These

observations transfer into constitutional imperatives to stop this ill-conceived Program's wasteful practices under both the Takings Clause and the doctrine of unconstitutional conditions.

CONCLUSION

The Court should reverse the District Court's judgment.

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COMBINED CERTIFICATIONS

In accordance with the Federal Rules of Appellate Procedure and the Local Rules of this Court, I hereby certify the following:

1. I am a member in good standing of the Bar of this Court.

2. This Brief complies with the type-volume limitations of Fed. R. App. P.32(a)(7)(B) because it contains 6,339 words, excluding the parts exempted by Fed. R. App. P. 32(f).

3. This Brief complies with the typeface and type-style requirements of Fed.R. App. P. 32(a)(5) & (a)(6) because it has been prepared using Microsoft Word in a proportionally spaced 14-point font (Century Schoolbook) in the text and the footnotes.

4 The text of the electronic Brief is identical to the text in the paper copies.

5. The electronic file containing the Brief was scanned for viruses using Microsoft Defender for Endpoint, and no virus was detected.

/s/ D. Adam Candeub Dated: July 19, 2024
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CERTIFICATE OF SERVICE

I hereby certify that on July 19, 2024, this brief was electronically filed with the Clerk of Court using the appellate CM/ECF system.

/s/ D. Adam Candeub Dated: July 19, 2024
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