United States Court of Appeals

for the

Third Circuit

Case Nos. 24-1820, 24-1821

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 and 3-23-CV-03818

BRIEF OF ATLANTIC LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF APPELLANTS AND REVERSAL

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

INTEREST OF THE *AMICUS CURIAE* [1]

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* * *

[1] Appellants and Appellees have consented to the filing of this brief. In accordance with Federal Rule of Appellate Procedure 29(a)(4)(E), undersigned counsel hereby states that no party's counsel authored this brief in whole or part, and no party or party's counsel, and no person other than the *amicus curiae*, its supporters, or its counsel, contributed money that was intended to fund preparing or submitting the brief.

The question presented by this appeal is whether the Inflation Reduction Act's Drug Price Negotiation Program, 42 U.S.C. § 1320f *et seq.*, violates the Fifth Amendment's Takings/Just Compensation Clause and/or the First Amendment's Free Speech Clause. Challenging the constitutionality of government-imposed price controls—here, the so-called "maximum fair price" that pharmaceutical manufacturers can charge under Medicare/Medicaid for their most innovative, widely prescribed, brand-name products—squarely aligns with ALF's free-enterprise and limited-government advocacy missions.

Sound science also is at stake in this case. The discovery and development of new life-saving drugs is an arduous, extraordinarily expensive, multi-phase scientific process that requires a continuous infusion of funds derived from sales of the tiny fraction of potential products that survive extensive preclinical laboratory research, human clinical testing, and Food and Drug Administration (FDA) regulatory review and approval.

INTRODUCTION

Plaintiffs-Appellants Bristol Myers Squibb Company ("BMS") and Janssen Pharmaceuticals, Inc. ("Janssen") filed these consolidated actions in New Jersey federal district court challenging the constitutionality of the highly politicized, misleadingly named, "Drug Price Negotiation Program," ("the Program"), 42 U.S.C. § 1320f *et seq*., enacted as part of the Inflation Reduction Act of 2022. Appellants are the research-oriented companies that developed Eliquis and Xarelto, respectively—blood clot-prevention medications that the Centers for Medicare & Medicaid Services has selected as "negotiation eligible drugs" that can be sold within the enormous Medicare/Medicaid system *only* at a sharply discounted, government-dictated, "maximum fair price." *See* App. 5, 13;[2] 42 U.S.C. §§ 1320f-1 & 1320f-2; BMS Br. at 5-7; Janssen Br. at 1-2.

In its unpublished opinion granting summary judgment to the government, the district court rejected Appellants' arguments that the Program violates the Fifth Amendment by effecting a physical taking of

[2] The district court's unpublished opinion in reproduced in the Appendix, Vol. 1, at A3-28.

their property without payment of just compensation, and the First Amendment by compelling commercial speech that expresses the government's viewpoint and political messaging about the Program's alleged nature and virtues. App. 20, 26-27. The district court's analysis of these constitutional issues is predicated on the legal fiction that Appellants' participation in Medicare/Medicaid and the Drug Price Negotiation Program is voluntary. According to the court, Appellants' supposed voluntary participation defeats their claims that the Program infringes their constitutional rights. App. 15, 19-22.

On appeal, Appellants are challenging the district court's conclusions "that the Program is not a physical taking, that the Program does not compel Plaintiffs' speech, and that Plaintiffs' participation in the Program is voluntary." App. 26.

Appellants also contend, as they did in district court, that even if their participation in the Program is deemed voluntary, the Program is invalid under the unconstitutional conditions doctrine. *See* BMS Br. at 42-45; Janssen Br. at 51-56. This well-established doctrine applies insofar as pharmaceutical manufacturers—*regardless* of whether the Program is "voluntary"—are required, as a condition for participation, to

relinquish their constitutional rights to just compensation and freedom of speech. Because the Constitution expressly and unequivocally prohibits the government from abridging these fundamental rights—"Congress shall make no law . . . abridging the freedom of speech"; "nor shall private property by taken for public use, without just compensation"—they cannot be circumvented by forcing pharmaceutical manufacturers to surrender them as a condition for participating in the Program.

This *amicus curiae* brief endeavors to help inform the Court's decision-making by providing additional background on the unconstitutional conditions doctrine as it relates to this case. Our brief also discusses why the Program's industry-crippling price controls seriously undermine pharmaceutical companies' ability to engage in the high-financial-risk process of new drug discovery and development, and for that reason, ultimately *harms* the public interest.

ARGUMENT

The District Court's Judgment Should Be Reversed

A. The unconstitutional conditions doctrine invalidates the Drug Price Negotiation Program regardless of whether a pharmaceutical manufacturer's participation is "voluntary"

Appellants persuasively argue that their constitutional rights are violated by the Drug Price Negotiation Program's built-in mandates—*e.g.*, the Program's requirement that a pharmaceutical manufacturer either participate in "negotiations" to reach "agreement" on a "maximum fair price" for its government-selected brand-name product or incur enormous financial penalties. Even if the Program's mandates are viewed merely as conditions for voluntary participation in the Program, they are *unconstitutional* conditions, and thus render the Program invalid.

1. The unconstitutional conditions doctrine reflects an "overarching principle . . . that vindicates the Constitution's enumerated rights by preventing the government from coercing people into giving them up." *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013). "[R]egardless of whether the government ultimately succeeds in pressuring someone into forfeiting a constitutional right, the

unconstitutional conditions doctrine forbids burdening the Constitution's enumerated rights by coercively withholding benefits from those who exercise them." *Id.* at 606; *see also Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1377 n.4 (2018) ("The doctrine prevents the Government from using conditions 'to produce a result which it could not command directly.'") (quoting *Perry v. Sindermann*, 408 U.S. 593, 597 (1972)).

Even though "[v]irtually all of [the Supreme Court's] unconstitutional conditions cases involve a gratuitous governmental benefit of some kind . . . [the Court has] 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*, 570 U.S. at 608; *see* Kathleen M. Sullivan, *Unconstitutional Conditions*, 102 Harv. L. Rev. 1413, 1415 (1989) ("The doctrine of unconstitutional conditions holds that the government may not grant a benefit on the condition that the beneficiary surrender a constitutional right, even if the government may withhold the benefit altogether.").

In short, the doctrine "limits the ability of governments to force individuals to choose between retaining a right and enjoying a

government benefit." Kay L. Levine et al., *Protecting State Constitutional Rights from Unconstitutional Conditions*, 56 U.C. Davis L. Rev. 247, 249-50 (2022). It thus "reflects the triumph of the view that government may not do indirectly what it may not do directly over the view that the greater power to deny a benefit includes the lesser power to impose a condition on its receipt." Sullivan, *supra* at 1415.

From an historical perspective, the unconstitutional conditions doctrine goes at least as far back as *Frost & Frost Trucking Co. v. Railroad Commission of California*, 271 U.S. 583, 598 (1926) ("a state is without power to impose an unconstitutional requirement as a condition for granting a privilege"); *see Koslow v. Pennsylvania*, 302 F.3d 161, 173, 174 (3d Cir. 2002) (quoting *Frost & Frost*); *see generally* Louis W. Fisher, *Contracting Around the Constitution: An Anticommodificationist Perspective On Unconstitutional Conditions*, 21 U. Pa. J. Const. L. 1167, 1176-79 (2019) (presenting "A Brief Doctrinal History" of unconstitutional conditions jurisprudence).

"[T]he modern administrative state [has] contributed to the proliferation of unconstitutional conditions problems." *Id.* This escalation of governmental power is reflected by the Supreme Court's

numerous decisions applying the unconstitutional conditions doctrine in a variety of contexts. *See, e.g. Koontz*, 570 U.S. at 608 (collecting cases). Unconstitutional conditions cases include takings in violation of the Fifth Amendment. *See, e.g.*, *Sheetz v. City and Cnty. of El Dorado, Cal.*, 144 S. Ct. 893, 900 (2024) ("Our decisions in *Nollan* [*v. Cal. Coastal Comm'n*, 483 U.S. 825 (1987)] and *Dolan* [*v. City of Tigard*, 512 U.S. 374 (1994)] address [the] potential abuse of the permitting process. There, we set out a two-part test modeled on the unconstitutional conditions doctrine."); *Koontz*, 570 U.S. at 604 ("*Nollan* and *Dolan* involve a special application of this doctrine") (internal quotation marks omitted).

The unconstitutional conditions doctrine also applies to government-imposed conditions that infringe upon freedom of speech. *See, e.g.*, *Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc.*, 570 U.S. 205, 214 (2013) ("[W]e have held that the Government may not deny a benefit to a person on a basis that infringes his constitutionally protected . . . freedom of speech even if he has no entitlement to that benefit.") (internal quotation marks omitted); *Elrod v. Burns*, 427 U.S. 347, 358 n.11 (1976) (noting the Court's "[p]rotection of First Amendment interests" by "invalidation of conditions"); *Perry v. Sindermann*, 408 U.S.

at 597 (the government "may not deny a benefit to a person on a basis that infringes his constitutionally protected interests—especially, his interest in freedom of speech"). "In *Perry*, the Court broadly rejected the validity of limitations on First Amendment rights as a condition to the receipt of a governmental benefit . . . ." *Elrod*, 427 U.S. at 359.

2. The district court's rejection of Appellants' constitutional claims is predicated on the supposed voluntariness of their participation in the Medicare/Medicaid system generally and the Drug Price Negotiation Program in particular.

According to the district court's takings analysis, "there is no physical appropriation taking place," in part because "setting aside their factual arguments, Plaintiffs fail to show how they are being *legally* compelled to participate in the Program." App. 12. Oblivious to reality, the court's opinion repeatedly asserts that "a manufacturer's participation in the Program is voluntary." App. 16; *see, e.g.*, *id.* at 10, 15-20,21-22, 27.

The opinion acknowledges that Medicare/Medicaid "is a significant (but not the sole) buyer of pharmaceuticals in the United States." App. 20. But without factual basis, it rejects Appellants' argument that

"[c]ompletely withdrawing from almost half the domestic pharmaceutical market is not commercially feasible." App. 17. The opinion contends—unrealistically if not disingenuously—that "[s]elling to Medicare is a choice Plaintiffs can accept or not accept . . . Selling to Medicare may be less profitable than it was before institution of the Program, but that does not make [Plaintiffs'] decision to participate any less voluntary." App. 19, 20.

Along the same lines, the district court's opinion states that "[a] threshold issue for their Compelled Speech claim is whether Plaintiffs are compelled to participate in the Program." App. 21. But "the Court has already concluded that the Program is voluntary, and that Plaintiffs are not being compelled or forced to participate in the Program. Accordingly, the Court rejects Plaintiffs' arguments that rely on involuntariness as the basis of their compelled speech claim." App. 22.

Appellants' briefs explain why their participation in either Medicare/Medicaid or the Program cannot reasonably be viewed as voluntary. *See, e.g.*, BMS Br. at 8, 18, 46; Janssen Br. at 19, 21, 33-35. Indeed, the Centers for Medicare & Medicaid Services reports that as of

March 2024, there were 67.2 million individuals enrolled in Medicare[3] and 75.6 million individuals in Medicaid.[4] Appellants' supposed option of "exiting from sales to Medicare," App. 20, therefore, would be financial suicide that no publicly held company would commit. Nor should the government want to induce Appellants and similarly situated pharmaceutical companies to deprive more than 140 million Medicare/Medicaid participants (i.e., almost half the nation) of state-of-the-art, life-saving drugs; *see* BMS Br. at 4; Janssen Br. at 1, 3, 9.

The district court nonetheless was persuaded by the government that pharmaceutical manufacturers' participation in the Program is voluntary, and thus, that imposition of the Program's requirements is consensual. *See, e.g.*, App. 9 (quoting the government's contention that because the Inflation Reduction Act was enacted under the Spending Clause, the Program "operates based on consent"); App. 15-16 ("[T]he parties have not identified any authority holding that participation in the Medicare system is involuntary.").

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[3] *See* Data.CMS.gov, https://tinyurl.com/ytu3deyd.

[4] *See* Medicaid.gov, https://tinyurl.com/466tdur6.

Based on Appellants' supposed voluntary, *i.e.*, consensual, participation in the Program, the court somehow concluded that it neither effects a taking of property nor compels or regulates speech. *See* App. 27-28. And based on this erroneous conclusion, the court summarily found that the unconstitutional conditions doctrine "does not apply." App. 28.

Consent, however, is *irrelevant* to operation of the unconstitutional conditions doctrine where, as here, companies must relinquish their constitutional rights (e.g., their rights to just compensation and freedom of speech) as a condition for receiving a governmental benefit (e.g., participation in the Medicare/Medicaid system). *See* Philip A. Hamburger, *Unconstitutional Conditions: The Irrelevance of Consent*, 98 Va. L. Rev. 479 (2012). Therefore, contrary to the district court's opinion, Appellants are correct that "even if their participation in the Program were voluntary, the Program would still violate the unconstitutional conditions doctrine." App. 27.

3. Professor Hamburger's often-cited article on *The Irrelevance of Consent* explains that "consent is irrelevant for conditions that go beyond the government's power." Hamburger, *supra* at 480. He asks:

> Can consent justify the government in exceeding its power?
>
> The key is to distinguish between the role of consent within and beyond the government's constitutional authority. . . . Undoubtedly the government can use consent within its authority, as defined by its various powers; but where these powers are limited, either in themselves or through the [Constitution's] rights and structures, the question is whether the government can rely on consent to justify going beyond these limits and thus beyond its authority. . . .
>
> The answer can be found in the simple recognition that the Constitution is a law. Being a law and, indeed, a law made by the people, *its limits are not alterable by private or state consent*, but only by the consent of the people. . . . Accordingly, the *government cannot escape its constitutional bounds by getting, let alone purchasing, the consent of any lesser body*, whether individuals, private institutions, or states. For such purposes, *their consent is irrelevant*.

Id. at 483 (emphasis added).

In other words, the unconstitutional conditions doctrine establishes that the government cannot alter, much less ignore, the prohibitions imposed by the Bill of Rights on the theory that an individual or corporation has consented to forgo them in return for receiving a governmental benefit. *See* Fisher, *supra* at 1181 ("arguing along with Hamburger and others that the government should be presumptively

prohibited from conditioning receipt of a benefit on waiver of an individual's constitutional rights").

"[T]here is a risk in allowing the government to accomplish indirectly that which it cannot do directly. If a constitutional provision prohibits the government from violating a right, why can the government condition a valuable benefit on a person forsaking that right?" Levine, *supra* at 258; *see also* Ryan C. Williams, *Unconstitutional Conditions and the Constitutional Text*, 172 U. Pa. L. Rev. 747, 800 (2024) ("If the government conditions access to a particular benefit on waiver of a nonwaivable right, then the condition cannot be met without violating the Constitution.").

Legal scholars debate the exact contours of the unconstitutional conditions doctrine. But with the growth of the administrative state,

> the threat from unconstitutional conditions [has] become of central importance, for they have become a *means of evading much of the Constitution, including the Bill of Rights*. Only by recognizing this can one begin to understand the peril of casually assuming that the government can purchase its way out of constitutional rights and other limits.

Hamburger, *supra* at 491 (emphasis added). The unconstitutional conditions doctrine is "charged with safeguarding liberty in the face of

government's ubiquitous programming and extraordinary resources," and "is necessary to ensure that governments cannot circumvent constitutional imperatives simply by purporting to ask rather than tell." Randy J. Kozel, *Leverage*, 62 B.C. L. Rev. 109, 124 (2021).

4. In sum, the district court's conclusion that Appellants' constitutional claims lack merit because their participation in the Program supposedly is voluntary clashes with the unconstitutional conditions doctrine. This is a compelling reason for reversing the district court.

B. If allowed to proceed, the Drug Price Negotiation Program will harm the public interest

The Biden administration has been brazenly using the Drug Price Negotiation Program as a political tool for winning votes by demonizing "Big Pharma"—profitable companies, like Appellants, that continuously invest billions of dollars in discovering, testing, and gaining regulatory approval for, new life-saving drugs and vaccines. For example, on February 1, 2024 the White House issued an "Interested Parties Memo" titled "President Biden Takes On Big Pharma and Is Lowering

Prescription Drug Prices."[5] The memo hyperbolically asserts that "President Biden's drug price negotiation program finally takes on Big Pharma's exorbitant price gouging of seniors, allowing Medicare to put money back in the pockets of American families." Although the White House memo boasts that "This is the first time ever that Medicare is not accepting the drug prices the pharmaceutical companies set," the government, in reality, is using the deceptively named "negotiation" program to *dictate* the significantly discounted prices that Big Pharma companies can charge under Medicare/Medicaid.

At the political sound bite level, slashing prices for the newest, most innovative, and/or widely used brand-name prescription drugs seems consistent with the public interest. But in reality, this latest form of politically motivated, government-imposed price control is short-sighted: The Program is *detrimental* to the public interest because it diminishes the financial resources that research-oriented companies like Appellants need to reinvest in proprietary new drug research and development (R&D).

[5] https://tinyurl.com/yn6hwbza.

The PhRMA (Pharmaceutical Research and Manufacturers of America) website discusses the societal importance of its members' financial investments in R&D:

> Over the last decade, PhRMA member companies have more than doubled their annual investment in the search for new treatments and cures, including nearly $101 billion in 2022 alone. While these investments continue to build upon previous medical advances, they are just beginning to yield results on the latest breakthroughs, opening the door to entirely new ways to tackle some of the most complex and difficult to treat diseases of our time.
>
> America's biopharmaceutical sector is the most R&D-intensive industry in the U.S. economy. In fact, the biopharmaceutical industry invests on average six times more in R&D as a percentage of sales than all other manufacturing industries.

PhRMA, Research & Development Policy Framework (Jan. 22, 2024);[6]

Developing and commercializing a new prescription drug—including the formidable and time-consuming challenge of obtaining FDA approval—is an extraordinarily costly and financially risky process. Myopically focusing on prices alone fails to take into account the bigger picture—the often insurmountable financial, scientific, regulatory, and/or commercial hurdles that a new drug, even one that shows promise

[6] https://tinyurl.com/2p8ns6dp.

during early testing—must overcome before it can be made available to the public.

FDA's website provides an overview of the five, universally accepted stages of new drug development in the United States:

- Discovery and Development
- Preclinical Research
- Clinical Research
- FDA Review
- FDA Post-Market Safety Monitoring

FDA, The Drug Development Process (Jan. 4, 2018).[7]

Since human health and safety are at stake, each of these successive and arduous stages of new drug development involves rigorous scientific research or testing and/or intensive evaluation of scientific data. "[D]rug discovery and development is unlike any other type of development or innovation process . . . [it] carries far greater uncertainty, and the outcome is rarely assured." PharmaCentral, Drug Discovery and Development: A Step-By-Step Guide (Oct. 22, 2021).[8]

[7] https://tinyurl.com/2p8ns6dp.

[8] https://tinyurl.com/y8hy5mzj.

During Stage 1 (Discovery and Development), "thousands of compounds may be candidates for potential development," but "[a]fter early testing . . . only a small number of compounds look promising and call for further study." FDA, *supra*. During Stage 2 (Preclinical Research), a candidate drug's toxicity is determined, and on that basis, "researchers . . . decide whether the drug should be tested in people." *Id.* Following human trials conducted during Stage 3 (Clinical Research), only 33% of new drug candidates move on to Stage 4 (FDA Review), *id.*, and of those, "[o]nly 12% . . . eventually receive [FDA] approval." PhRMA, *supra*; see *also* Biotechnology Innovation Organization (BIO), Clinical Development Success Rates and Contributing Factors 2011-2020 (Feb. 2021).[9]

"On average, it takes 10-15 years and costs $2.6 billion to develop one new medicine, including the cost of the many failures." PhRMA, *supra*. Given the enormous investment of scientific and financial resources involved in developing a "winner," pharmaceutical companies need to earn an acceptable return to continue engaging in new drug R&D.

[9] https://tinyurl.com/2as33v8y.

For this reason, the Drug Price Negotiation Program not only is unconstitutional, but also harmful to the true public interest.

CONCLUSION

The district court's judgment should be reversed.

Respectfully submitted,

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July 16, 2024

CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limit established by Fed. R. App. P. 29(a)(5) & 32(a)(7)(B) because it contains **3,503** words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

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July 16, 2024

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I certify that on July 16, 2024, I electronically filed the foregoing Brief of Atlantic Legal Foundation As *Amicus Curiae* In Support of Appellants and Reversal with the Clerk of Court of the United States Court of Appeals for the Third Circuit by using the CM/ECF system.

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