NOS. 24-1820, 24-1821

IN THE 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
(Case Nos. 23-cv-3335 & 23-cv-3818) (District Judge Zahid N. Quraishi)

BRIEF OF WASHINGTON LEGAL FOUNDATION AS AMICUS CURIAE SUPPORTING APPELLANTS AND REVERSAL

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July 15, 2024

United States Court of Appeals for the Third Circuit

Corporate Disclosure Statement and Statement of Financial Interest

No. 24-1820, 24-1821

Bristol Myers Squibb Company & Janssen Pharmaceuticals, Inc.

v.

Xavier Becerra, et al.

Instructions

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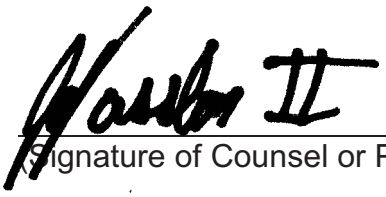

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Dated: July 15, 2024

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INTEREST OF AMICUS CURIAE*

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INTRODUCTION

The Inflation Reduction Act of 2022, Pub. L. No. 117-169, 136 Stat. 1818, included an unprecedented provision that ended decades of a market-based system for prescription-drug reimbursement. In its place, the IRA enacted the laughably named "Drug Price Negotiation Program." The Program requires pharmaceutical manufacturers to engage in sham

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* No party's counsel authored any part of this brief. No one, apart from WLF and its counsel, contributed money intended to fund the brief's preparation or submission. All parties consented to WLF's filing this brief.

"negotiations," which ultimately determine the prices for some of the most important and most prescribed drugs in the world.

Under the IRA, no statutory standard controls how the government sets the prices, and no judicial review of that process is possible. Rather, the Centers for Medicare & Medicaid Services has total discretion when choosing prices. For example, CMS could decide that a drug that sells for $1,000 per pill on the open market will be reimbursed at only $0.01 per pill.

There is no escape hatch for pharmaceutical manufacturers that do not wish to participate in the Program. The government is essentially strong-arming pharmaceutical manufacturers to fix their prices. If the pharmaceutical manufacturers "negotiate" with the government and agree to prices that the government thinks are "fair," then the government takes valuable drugs for below-market prices and the incentive to innovate plummets. But if the pharmaceutical manufacturers decline to negotiate, they face a penalty so steep that even Congress thought that not one pharmaceutical manufacturer would be dumb enough to pick that option. The only remaining choice, we are told, is for pharmaceutical manufacturers to stop participating in Medicare

and Medicaid. But even if that were possible—and it's not—exiting Medicare and Medicaid is not financially feasible. So in the end, the government is taking property without just compensation. Because the Constitution forbids uncompensated takings, the District Court erred in entering summary judgment for Defendants.

STATEMENT

Most elderly and disabled Americans receive their health insurance—including prescription-drug coverage—through Medicare. Like other insurers, Medicare does not regulate prices. Rather, it reimburses providers for services and products provided to plan participants. For drugs furnished incident to a physician's services, reimbursement is based on market prices. Similarly, reimbursement is also market-based for drugs not administered by physicians; the method for deciding the market-based price is just different.

The Program, however, directly sets the prices that pharmaceutical manufacturers must sell some drugs for. Each year, CMS announces new drugs that are subject to the Program. The drug-selection process is dictated by statute. Price-setting, on the other hand, is largely left to CMS's discretion. With one minor exception, there is no floor for the price

set by CMS—only a ceiling. Below the ceiling, CMS can set any price it chooses.

Walking away from the Program is not an option. There are steep daily penalties for any manufacturer that fails to participate in the Program. The only way for a pharmaceutical manufacturer to escape those penalties is to completely withdraw from Medicare and Medicaid. Yet even if a manufacturer could bear the costs of withdrawing from Medicare and Medicaid, they cannot do so for between 11 and 23 months. Thus, they are forced to either participate in the Program during that time or face the IRA's staggering penalties.

After the IRA's enactment, Bristol Myers Squibb and Janssen sued, challenging the Program's constitutionality. While the case was pending, CMS announced the first ten drugs to be included in the Program. Those drugs included Bristol Myers Squibb's Eliquis (used to prevent blood clots and strokes) and Janssen's Xarelto (also used to prevent blood clots and strokes) and Stelara (used to treat psoriatic arthritis).

The District Court granted Defendants' summary-judgment motions. It found that (1) the Program is not a taking under the Fifth Amendment; (2) the Program is voluntary; (3) the Program does not

compel Plaintiffs to speak; and (4) given the first three holdings, there were no viable unconstitutional conditions claims. In other words, the District Court reached the merits of Plaintiffs' claims but denied relief.

SUMMARY OF ARGUMENT

I.A. Pharmaceutical manufacturers lack any choice whether to participate in the Program. The District Court's holding that pharmaceutical manufacturers can simply withdraw from Medicare and Medicaid glosses over statutes prohibiting such withdrawal without 11 to 23 months' notice. Defendants' interpretation of the statutes, which the District Court adopted, is wrong as a matter of law because it conflicts with the statutes' plain language. At minimum, pharmaceutical manufacturers must participate in the Program for between 11 and 23 months.

B. Even if pharmaceutical manufacturers could immediately withdraw from the Program, participation in the Program is involuntary. Those programs account for about half of all pharmaceutical purchases in the United States. Thus, it is economically crippling for pharmaceutical manufacturers not to participate in the Program.

C. The last way Defendants argue that participating in the Program is voluntary is that pharmaceutical manufacturers can choose to pay the "excise tax" instead of participating in the Program. But everyone from the Joint Committee on Taxation to the Congressional Budget Office recognizes that this is not a choice for pharmaceutical manufacturers. The excise tax requires pharmaceutical manufacturers to increase their prices by 1,900%. No rational actor would choose to pay that "tax."

II. Even if participation in the Program were voluntary, requiring pharmaceutical companies to provide drugs at a deep discount is an unconstitutional condition. Congress cannot force pharmaceutical manufacturers to forfeit their right to be free from uncompensated takings as a condition of participating in the Medicare and Medicaid programs. Yet that is what the Program requires.

III. The Program severely limits the potential profits that pharmaceutical manufacturers can make from developing expensive, life-saving drugs. They may even have to give away their products at a loss. That will slow innovation in the pharmaceutical space because the number of research projects with a positive expected value will fall. This

decreased innovation means that fewer new drugs that improve Americans' lives will come to market. In other words, some people will likely lose their lives if pharmaceutical manufacturers must participate in the Program.

ARGUMENT

I. PHARMACEUTICAL MANUFACTURERS' PARTICIPATION IN THE PROGRAM IS INVOLUNTARY.

The District Court found that Plaintiffs' participation in the Program is "voluntary." This erroneous holding warrants reversing and remanding for entry of judgment in Plaintiffs' favor.

A. The District Court Incorrectly Adopted Defendants' Erroneous Statutory Interpretation Permitting Plaintiffs To Withdraw From Medicare And Medicaid With 30 Days' Notice.

In analyzing whether Program participation is voluntary, the District Court relied on Defendants' representations at oral argument rather than reading the statutes. Pharmaceutical manufacturers must participate in the Program for at least 11 to 23 months. This is because to withdraw from Medicare and Medicaid, pharmaceutical manufacturers must give that much notice before withdrawing.

The relevant statute provides that a decision to withdraw from Medicare and Medicaid is effective on January 1 of the following year if notice is given "before January 30" and "if the [withdrawal] occurs on or after January 30 of a plan year," the notice is effective "as of the day after the end of the succeeding plan year." 42 U.S.C. § 1395w-114a(b)(4)(B)(ii). In other words, the quickest that a pharmaceutical manufacturer can withdraw from Medicare is in 11 months if notice is given on January 30. If notice is given on January 31, the pharmaceutical company must wait 23 months to withdraw.

The District Court, however, rejected this argument in a single footnote without citing the statutory language or engaging in any statutory analysis. Rather, the District Court's footnote addressing whether pharmaceutical manufacturers may withdraw from the Program cites only statements from Defendants' attorneys at oral argument and Defendants' brief. This was error. As the Supreme Court has repeatedly admonished, the "trust us" argument from the government must be disregarded. The Constitution "does not leave us at the mercy of *noblesse oblige*." *United States v. Stevens*, 559 U.S. 460, 480

(2010); *see FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 255 (2012) (applying the rule in the administrative context).

Defendants contend that pharmaceutical manufacturers can withdraw with 30 days' notice. And the District Court bought that argument. In its view, "the HHS Secretary can terminate a manufacturer's agreement before the manufacturer would incur liability for any excise tax, so long as the manufacturer notifies CMS of its desire to withdraw at least 30 days in advance of when that tax would otherwise begin to accrue." J.A. 6 n.8 (cleaned up). This distorts the statute.

The statute relied on by Defendants and the District Court provides that the Secretary may terminate a pharmaceutical manufacturer's participation in Medicare and Medicaid "for a knowing and willful violation of the requirements of the agreement or other good cause shown. . . . The Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination." 42 U.S.C. § 1395w-114a(b)(4)(B)(i). As the statute's plain language shows, this is a punitive provision.

The statute identifies two ways for pharmaceutical manufacturers to exit Medicare. The first is after the 11-to-23 month waiting period

when the pharmaceutical manufacturer provides notice of its intent to withdraw from Medicare. The second requires the Secretary to kick pharmaceutical manufacturers out of Medicare involuntarily because of misconduct. Treating a manufacturer's own request for termination as a punitive agency action would mean that a manufacturer receives a hearing on its own purportedly voluntary exit from Medicare. That is nonsensical.

The "good cause shown" provision in Section 1395w-114a(b)(4)(B)(i) does not include a manufacturer's voluntary termination. Such an interpretation disregards the "knowing and willful violation" language, which limits the meaning of "other good cause shown." *See Dubin v. United States*, 599 U.S. 110, 124 (2023) ("Under the familiar interpretive canon *noscitur a sociis*, a word is known by the company it keeps." (cleaned up))*; United States v. Henderson*, 80 F.4th 207, 213 (3d Cir. 2023) ("A term in a statute is given more precise content by the neighboring words with which it is associated." (cleaned up)).

Moreover, including pharmaceutical manufacturers' voluntary withdrawals from Medicare and Medicaid in Section 1395w-114a(b)(4)(B)(i) makes Section 1395w-114a(b)(4)(B)(ii) "wholly

superfluous." *Rowland v. Bissell Homecare, Inc.*, 73 F.4th 177, 182 (3d Cir. 2023) (quoting *Duncan v. Walker*, 533 U.S. 167, 174 (2001)). The superfluidity problem here is magnified because it "would render superfluous another part of the same statutory scheme." *Marx v. Gen. Revenue Corp.*, 568 U.S. 371, 386 (2013).

That is not the only superfluidity problem with Defendants' and the District Court's interpretation of Section 1395w-114a(b)(4)(B)(i). It also makes the due-process protections included in the statute superfluous. There is no reason for a pharmaceutical manufacturer to request a hearing if they want out of Medicare and Medicaid. Such a hearing would only delay the exit it seeks. The due-process protection is included in the statute because that section is meant to be punitive. In other words, Congress recognized that to prevent the Secretary from acting arbitrarily it must protect pharmaceutical manufacturers that the Secretary seeks to punish. Allowing pharmaceutical manufacturers to withdraw from Medicare with only 30 days' notice instead of 11 to 23 months' notice is not punishment. Rather, it is an ultra vires action.

True, CMS issued non-binding guidance that adopted Defendants' and the District Court's interpretation of "good cause." But a "core

administrative-law principle" is that "an agency may not rewrite clear statutory terms to suit its own sense of how the statute should operate." *Madrid-Mancia v. Att'y Gen. of U.S.*, 72 F.4th 508, 520 (3d Cir. 2023) (quoting *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 328 (2014)). Allowing CMS to rewrite the statute so that pharmaceutical manufacturers can withdraw from Medicare and Medicaid with only 30 days' notice "would deal a severe blow to the Constitution's separation of powers." *Util. Air Regul. Grp.*, 573 U.S. at 327. Thus, the District Court erred in holding that pharmaceutical manufacturers could withdraw from Medicare and Medicaid after giving only 30 days' notice. Plaintiffs' participation in the Program is therefore involuntary.

B. Even If Plaintiffs Could Withdraw From Medicare And Medicaid With 30 Days' Notice, Their Participation In The Program Is Involuntary.

Even if the District Court were correct, and Plaintiffs could withdraw from Medicare and Medicaid with only 30 days' notice, that does not make their participation in the Program voluntary. A careful examination of how America's pharmaceutical industry works shows that Plaintiffs lack a meaningful choice. Thus, their participation in the Program is involuntary.

Imagine someone points a gun at your head and tells you that if you don't hand over your car keys they will kill you. You have a choice. You can either hand over your car keys and live to see another day, or you can refuse and be killed. According to the District Court, if you turn over your car keys that action was voluntary. The absurdity of such a statement is self-evident. You did not act voluntarily. Rather, you acted under duress and turned over your keys because the alternative was not a reasonable option.

The law "place[s] some limits upon negotiators' ability to use superior bargaining power to coerce acquiescence with their demands." Russell Korobkin et al., *The Law of Bargaining*, 87 Marq. L. Rev. 839, 841 (2004). When a party signs a contract under duress, the agreement is voidable. *See* Ian Ayres & Richard E. Speidel, *Contract Law* 559 (7th ed. 2008) (citation omitted). Duress occurs when "a party's manifestation of assent is induced by an improper threat by the other party that leaves the victim no reasonable alternative." Restatement (Second) of Contracts § 175(1) (1981).

The government cannot put a party between "the rock and the whirlpool." *United States v. Butler*, 297 U.S. 1, 72 (1936) (quotation

omitted). This is because "[i]t would be a palpable incongruity to" bar the government from pressuring private parties to act "by words of express divestment" but allow the pressure by "an act by which the same result is accomplished under the guise of a surrender of a right in exchange for a valuable privilege which the state threatens otherwise to withhold." *Frost v. R.R. Comm'n of Cal.*, 271 U.S. 583, 593 (1926).

The Supreme Court has struck down a federal statute for a less egregious form of coercion than is present here. In the Patient Protection and Affordable Care Act, Congress threatened to end all Medicaid funding if States failed to expand their Medicaid programs. Despite the expansion being "in form voluntary," *Frost*, 271 U.S. at 593, the Court held that "[t]he 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." *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 582 (2012). In other words, Congress placed "a gun to the head" of the States. *Id.* at 581. This, the Court held, Congress could not do and thus struck down the Medicaid expansion as unconstitutional.

The Program is far more coercive than the Medicaid expansion the Court considered in *NFIB*. There, federal Medicaid funding was 10% of States' revenues. Here, Medicaid and Medicare account for almost half of all prescription-drug spending in the United States. *See Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th 696, 699 (3d Cir. 2023) (citing CBO, *Prescription Drugs: Spending, Use, and Prices*, 8 (2022), https://perma.cc/7AUF-LJHD). In other words, if a pharmaceutical manufacturer wanted to opt out of the Program, it would have to forfeit about half of its revenues in the United States. That is five times the amount that the Court found unconstitutionally coercive in *NFIB*.

There was arguably a constitutional way for Congress to accomplish most of its goals when expanding Medicaid in 2010. It could have provided increased federal funding for Medicaid to States that chose to expand Medicaid. This would have given States a real choice on whether to expand Medicaid. But it chose a different, unconstitutional path. It did the same here. Congress could have capped Medicare and Medicaid reimbursements for the drugs identified by CMS. That would have still been coercive because of the high percentage of prescriptions

Medicare and Medicaid cover. But it would have at least had a fighting chance at surviving a constitutional challenge.

A pharmaceutical manufacturer's participation in the Program is not tied only to the drugs identified by CMS. Rather, all drugs the manufacturer makes are excluded from Medicare and Medicaid if the manufacturer opts out after giving the required 11-to-23 months' notice. A pharmaceutical manufacturer's entire corporate structure must choose to either participate in the Program or completely leave Medicare and Medicaid. In other words, a pharmaceutical manufacturer cannot withdraw only one drug if it believes CMS's maximum fair prices are unreasonable. Thus, even if a pharmaceutical manufacturer could withdraw from Medicare and Medicaid with 30 days' notice, its participation in the Program is involuntary.

C. There Is Little Dispute That Paying The "Excise Tax" Is Not An Option.

The only other way to avoid participating in the Program is for pharmaceutical manufacturers to pay an excise tax. But it is not actually a tax. As the then-Speaker of the House of Representatives explained, pharmaceutical manufacturers would face a "steep, escalating *penalty*" if they failed to participate in the Program. Nancy Pelosi, H.R. 3 — Title

Summary (Sept. 19, 2019) (emphasis added), https://perma.cc/YTF6-ULEH. The Joint Committee on Taxation and the Congressional Budget Office agreed that no pharmaceutical manufacturers would choose to pay the excise tax because they were, in fact, draconian penalties. That is why, despite the IRA's calling it a tax, both estimated that the tax would raise no money because no manufacturer could afford to pay it. *See* Joint Comm. on Tax'n, *Estimated Budget Effects of the Revenue Provisions of Title XIII — Committee on Ways and Means, of H.R. 5376, The "Build Back Better Act,"* 8 (Nov. 19, 2021), https://perma.cc/E3Y4-ZRYF; CBO, *Estimated Budgetary Effects of Public Law 117-169*, 5 (Sept. 7, 2022), https://perma.cc/6G7C-T4BZ.

The reason that pharmaceutical manufacturers cannot afford—and therefore cannot choose—to pay the excise tax is because it would pose an existential threat to their businesses. The tax covers all domestic sales of the drugs at issue, not just Medicare sales. Because of how the tax is calculated, "[t]he excise tax rate" thus "range[s] from 185.71% to 1,900% of the selected drug's price depending on the duration of noncompliance." Cong. Rsch. Serv., *Tax Provisions in the Inflation Reduction Act of 2022 (H.R. 5376)*, 4 (Aug. 10, 2022),

https://perma.cc/HUC9-FDQZ. In other words, the tax forces pharmaceutical manufacturers to raise their prices from 185-1,900%. That means that if a drug "cost $10 pre-tax, it would cost $200 post-tax with $190 of the $200 cost (or 95%, the applicable percentage) being attributable to the excise tax." *Id.* No company in the world would make that choice. There is nothing "voluntary" about it.

* * *

In short, the IRA nominally gives pharmaceutical manufacturers three options. First, participate in the Program. Second, withdraw from Medicare and Medicaid. Or third, pay the excise tax. But, in reality, the IRA aims a gun at the pharmaceutical manufacturers and tells them that they must either participate in the Program or choose bankruptcy via one of two routes. This is not a real choice. Rather, it is illegal economic coercion.

II. EVEN IF PARTICIPATION IN THE PROGRAM WERE VOLUNTARY, IT IS AN UNCONSTITUTIONAL CONDITION.

The government may not condition participation in a program on a party giving up its constitutional rights. *See Koslow v. Pennsylvania*, 302 F.3d 161, 174 (3d Cir. 2002) (explaining the protections private parties enjoy from unconstitutional conditions). This means that the government

cannot, as a condition of participating in a program, require companies to forfeit their "right to just compensation." *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013).

True, the government may place some conditions on companies' participation in federal programs. But for those conditions to pass constitutional muster they must "further the end advanced as the justification for the" conditions. *Nollan v. Cal. Coastal Comm'n*, 483 U.S. 825, 837 (1987). They must also be "rough[ly] proportiona[te]" to the benefit. *Dolan v. City of Tigard*, 512 U.S. 374, 391 (1994). The IRA's conditions fail both prongs of this test.

First, the Program requires pharmaceutical manufacturers to sell *some* of their products at a deeply discounted rate or else see a penalty imposed on *all* the manufacturers' drugs. If the justification is a lower price on drug A, restricting reimbursements for drugs B and C does not further that purpose. Drugs B and C are being used as pawns by CMS to persuade pharmaceutical manufacturers to do what it wants.

Second, threatening pharmaceutical manufacturers with restrictions on their non-Program drugs is not roughly proportionate to the benefit of lower prices on Program drugs. Most pharmaceutical

manufacturers have dozens of drugs that are covered by Medicare and Medicaid. Barring reimbursements for those other drugs because a manufacturer declines to give away one drug at a deeply discounted price is not proportional—it exemplifies disproportionate conditions. Thus, even if participating in the Program is voluntary, the IRA's conditions are unconstitutional.

III. AFFIRMING THE DISTRICT COURT'S ORDER WILL DECREASE PHARMACEUTICAL MANUFACTURERS' INCENTIVE TO INNOVATE.

One reason that pharmaceutical manufacturers devote their limited resources to developing drugs is that they can recover more than their research and development costs when they develop life-saving and life-improving drugs. A recent study shows just how expensive it is to bring new drugs to market. "Between 2009 and 2018, the FDA approved 355 new drugs and biologics." Oliver J. Wouters et al., *Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018*, 323 J. Am. Med. Ass'n 844, 848 (2020). The average cost of getting each drug to market was $1,559,100,000. *See id.* That number, however, may underreport the costs of preclinical trials. Factoring in that potential underreporting, the average cost of bringing

a single drug to market is between $1,782,200,000 and $2,194,100,000. *See id.* at 850.

Of course, averages are just that. The actual cost for bringing a drug to market varies widely. For example, it cost only $143,200,000 to bring Crofelemer (an antidiarrhea drug) to market. Wouters, 323 J. Am. Med. Ass'n at 848. But it cost almost 52 times that amount—$7,424,200,000—to bring Dupilumab (a drug for eczema) to market. *See id.* To put that latter figure in perspective, it cost the same to bring one drug to market as Lyft's entire market capitalization. *See Lyft*, CompaniesMarketCap (Apr. 4, 2024), https://perma.cc/8J22-CS9G.

Despite the enormous costs of bringing drugs to market, the number of drugs that have become available has gone up over the past decade. *See* CBO, *Research & Development in the Pharmaceutical Industry*, 1 (Apr. 2021), https://perma.cc/D8L4-3XUQ. This is because the amount that pharmaceutical manufacturers spend on research and development today "is about 10 times what the industry spent per year in the 1980s, after adjusting for the effects of inflation." *Id.* The percentage of revenues spent on research and development has also

doubled over the past two decades. *See id.* In other words, pharmaceutical manufacturers see a reason to innovate in the current market.

The reason that pharmaceutical manufacturers are willing to increase their investment in research and development makes sense to any undergraduate economics major. Pharmaceutical manufacturers' "spending decisions depend on" the "[a]nticipated lifetime global revenues from a new drug." *Research & Development in the Pharmaceutical Industry* at 1. The anticipated lifetime revenue from drugs will plummet with the Program in place. Like most products, pharmaceutical manufacturers have a point estimate of how much revenue a drug will produce. But there are error bars around that estimate. In other words, the amount of revenue could be higher or lower.

Contrary to Defendants' arguments, CMS is not a normal participant in the prescription-drug market. As noted above, Medicare supports about half of the pharmaceutical expenditures in the United States. *Sanofi*, 58 F.4th at 699 (citation omitted). That means that even if every other participant in the market were a single individual, the Herfindahl-Hirschman Index would be 2,500—well above the 1,800 lower-bound for a "highly-concentrated" market. *See* U.S. Dep't of Justice

& Fed. Trade Comm'n, *Merger Guidelines* § 2.1 (2023). That one market participant is so large that it alone pushes the HHI above 1,800 shows that CMS is not a normal market participant.

That is why the Program essentially cuts off the right tail of the expected-revenue curve. Because companies know that they will receive less revenue for half of their drug sales if the drug is successful, they will have to decrease their point estimates for how much money drugs will bring in. And this decrease in the expected lifetime revenue of drugs will lead pharmaceutical manufacturers to decrease funding for research and development. Those projects that have a small positive expected value under the current system will have a negative expected value with the Program in place. So pharmaceutical manufacturers will not pursue those projects.

As detailed above, increased research and development funding is what allows for more drugs to hit the market. Decreased research and development funding means that fewer drugs will come to market. Most of the drugs that won't come to market because of the Program's implementation would have helped society. Some would have increased people's quality of life. Other drugs would have extended people's lives by

decades. In short, this Court's affirming the District Court's order would harm Americans by decreasing the supply of life-enhancing and life-saving drugs on the market.

CONCLUSION

This Court should reverse and remand with instructions to enter judgment for Plaintiffs.

Respectfully submitted,

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July 15, 2024

CERTIFICATE OF COMPLIANCE

I certify that: (1) this brief complies with the type-volume limits of Federal Rule of Appellate Procedure 29(a)(5) as it contains 4,368 words, excluding the parts exempted by Federal Rule of Appellate Procedure 32(f); (2) this brief complies with the typeface and type-style requirements of Federal Rules of Appellate Procedure 32(a)(5) and (6) because it uses 14-point Century Schoolbook font; (3) Both attorneys whose names appear on this brief are members of this Court's bar; (4) the texts of the electronic brief and paper copies are identical; and (5) that McAfee LiveSafe was run on the file and did not detect a virus.

/s/ John M. Masslon II
John M. Masslon II
Counsel for Amicus Curiae
Washington Legal Foundation

July 15, 2024

CERTIFICATE OF SERVICE

I certify that, on July 15, 2024, I served all counsel of record via the Court's CM/ECF system.

/s/ John M. Masslon II
John M. Masslon II
Counsel for Amicus Curiae
Washington Legal Foundation

July 15, 2024