Nos. 25-749, 25-751

In the

Supreme Court of the United States

JANSSEN PHARMACEUTICALS INC.,
Petitioner,
v.
ROBERT F. KENNEDY, SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.,
Respondents.

BRISTOL MYERS SQUIBB COMPANY,
Petitioner,
v.
ROBERT F. KENNEDY, SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.,
Respondents.

On Petitions for Writs of Certiorari to the United States Court of Appeals for the Third Circuit

BRIEF OF THE BIOTECHNOLOGY INNOVATION ORGANIZATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICUS CURIAE*[1]

The Biotechnology Innovation Organization ("BIO") submits this brief as *amicus curiae* in support of petitioners Janssen Pharmaceuticals, Inc. ("Janssen") in No. 25-749 and Bristol Myers Squibb Company ("BMS") in No. 25-751.

BIO is the principal trade association representing the biotechnology industry in all fifty States and abroad. BIO has approximately 1,000 members, ranging from small startup companies and biotechnology centers to research universities and Fortune 500 companies. Most of BIO's members are small companies that have yet to bring products to market or attain profitability. Roughly 80% of BIO's corporate members have annual revenues under $25 million. These members rely heavily on venture capital and other private investment.

BIO and its members are dedicated to advancing biotechnology to address critical challenges in public health. BIO's core objectives are to protect and expand innovation and reduce legal, regulatory, and economic barriers that may impede patient access to safe and effective medicines. The organization strives to advance the public value of biotechnology, centering its policy and advocacy work on the interests of the public. Through these efforts, BIO seeks to ensure that biotechnology is not only

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[1] In accordance with this Court's Rule 37.6, *amicus curiae* states that no counsel for any party authored this brief in whole or in part, and that no party, counsel for a party, or person other than *amicus curiae*, its members, or its counsel, made any monetary contribution intended to fund the preparation or submission of this brief. Counsel of record received timely notice of *amicus*'s intent to file this brief under this Court's Rule 37.2.

accessible but developed and deployed in a manner that maximizes public benefit and serves the Nation's long-term welfare.

BIO and its members have a significant interest in this case because the decision below validated an unconstitutional statute that will devastate the biopharmaceutical industry and ultimately reduce investment and funding that BIO's members depend on when developing novel, lifesaving prescription medications.

INTRODUCTION AND SUMMARY OF ARGUMENT

BMS and Janssen assert compelling reasons why this Court should grant certiorari and review the Third Circuit's decision upholding the Inflation Reduction Act's ("IRA") Medicare Drug Price Negotiation Program (the "Program"). Petitioners present critical, unsettled questions under the First and Fifth Amendments that deserve this Court's scrutiny. The Program imposes extraordinary economic coercion, strong-arming pharmaceutical manufacturers into providing participants in Government programs with access to their medications at below-market rates, thereby violating the Fifth Amendment's Takings Clause. The Program also bullies manufacturers into endorsing a government message with which they do not agree, thereby violating the First Amendment. The Program effectuates this coercion by requiring non-participating companies to choose between two economically infeasible alternatives: (1) pay an "enterprise-crippling" excise tax (a "ruinous" monetary sanction that no manufacturer could ever

endure), *see* Pet.App.49a, 57a[2] (Hardiman, J., dissenting), or (2) withdraw their entire drug portfolio from Medicare and Medicaid (an unsustainable option that no manufacturer could ever select).

In this brief, *amicus* explains why these issues merit this Court's attention. If left standing, the Program will deal a devastating blow to the future of biopharmaceutical research and development ("R&D"). Manufacturers rely on Medicare and Medicaid spending for as much as 65% of their annual revenue. They reinvest billions of dollars of that revenue each year into discovering the next lifesaving medication. The illusory "option" for manufacturers to avoid the Program by abandoning more than half the market for their entire portfolio (not just the drug(s) selected into the Program) is not something any manufacturer could "choose" to do—at least not if it wants to continue bringing new, lifesaving biopharmaceutical medicines to market.

It is not just large companies with blockbuster products that will be impacted by the Program's unconstitutional taking. Many of the most important biopharmaceutical developments are made by small and emerging companies that spend years or even decades researching and developing therapies waiting for a single breakthrough. Those companies are backed by investors who are willing to take those long-term financial risks in hopes for a return if the enterprise succeeds. The Program, however, removes those incentives by imposing a pricing structure that ignores the reality that a medication's cost must also

[2] Citations to Pet.App. are to the Appendix to BMS's petition in No. 25-751.

compensate for the billions of dollars invested in R&D for medications that never make it to market. Instead of considering that reality, the Program imposes mandates—masked as "choices"—requiring manufacturers to sell and provide access to their medications at rates well below what could be realized in a free market.

The Program's framework is unconstitutional and poses an existential threat to the future of biopharma. If manufacturers cannot recoup their investments, the Program will result in *less* investment in biopharma and drug R&D and *fewer* medications being developed. Sadly, the impact will be felt most by patients with rare and life-threatening diseases.

ARGUMENT

I. THE IRA'S DRUG PRICE NEGOTIATION PROGRAM WILL BLUNT INNOVATION AND STIFLE DEVELOPMENT OF NEW OR IMPROVED LIFESAVING MEDICATIONS.

This case "is of great importance to consumers of pharmaceutical drugs, the companies that provide them, and the public at large." Pet.App.90a (Hardiman, J., dissenting). The Program, if left standing, will lead to less investment in biopharma and drug R&D and fewer medications being developed. And the impact will not be uniform. Patients with rare and life-threatening diseases will suffer the most.

A. Biotech drug developments cannot thrive in a sham market like the one the Program creates.

The Program misperceives how medications are developed and priced. It incorrectly derives the Government-mandated price of a medication solely from the R&D costs of that medication alone—ignoring the billions of dollars that innovators spend trying to develop medications that never make it to or through clinical trials. But those "failed" projects are critical context because a company that cannot recoup the costs of its failures will not continue investing in future successes.

The prevailing rhetoric notwithstanding, the pharmaceutical industry is not excessively profitable.[3] Pharmaceuticals rank just 15th—behind myriad financial sectors and industries including tobacco, semiconductors, and software. *See* Daniel Gassull et al., *IRA's Impact on the US Biopharma Ecosystem*, Vital Transformation, at 7 (June 1, 2023), https://tinyurl.com/2aa7z8fe; *Margins by Sector (US)*, N.Y. Univ. Stern (Jan. 2024), https://tinyurl.com/nhbxvw4f. The biotech sector—which provides vital R&D to support the biopharmaceutical industry's drug development efforts—is ranked 92nd. *See* Gassull, *supra*, at 7. The

[3] The "problem" of increasing drug prices that the IRA purports to address is also a misconception. According to the Congressional Budget Office, "per capita spending on prescription drugs began to level off in real terms in the mid-2000s and has fallen as a percentage of total spending on health care services and supplies since then." Joel M. Zinberg, *The Arrival of Medicare Drug Price Controls*, Paragon Health Inst., at 1 (Sep. 6, 2023), https://tinyurl.com/bdy8cytc.

reason is simple: Drug development is a cost-intensive, high-risk, yearslong process.

Most medications never make it to market. In 2021, the Congressional Budget Office estimated that nearly 90% of all medications entering clinical trials failed to receive FDA approval. *See Research and Development in the Pharmaceutical Industry*, Cong. Budget Off., at 2 (Apr. 2021), https://tinyurl.com/msumpj5f. That figure does not even account for development efforts that never reach clinical-trial phases. For that reason, the biopharma sector invests a huge component of its revenue on R&D—50% more than the next closest sector (software and internet). *See* Gassull, *supra*, at 11. The biopharma sector allocated 28% of revenue toward R&D in 2022, with biotech firms allocating even more—39%. *See ibid.* In 2019, the pharmaceutical industry invested $83 billion in R&D activities—*ten times* the amount spent in the 1980s (after adjusting for inflation). *See Research and Development in the Pharmaceutical Industry*, *supra*, at 1. This increased investment in R&D depends, at least in part, on profitability from Medicare sales. Margaret E. Blume-Kohout & Neeraj Sood, *Market Size and Innovation: Effects of Medicare Part D on Pharmaceutical Research and Development*, 97 J. Pub. Econ. 327, 335 (2013).

The 10% of clinical-trial drugs that make it to market must recoup investments on the 90% that do not. All told, accounting for unsuccessful clinical trials, the estimated median R&D costs per FDA-approved medication between 2009 and 2018 were $1.1 billion. *See* Olivier J. Wouters et al., *Estimated Research and Development Investment Needed to*

Bring a New Medicine to Market, 2009-2018, JAMA (Mar. 3, 2020), https://tinyurl.com/vs9m7fym. A less conservative estimate suggests that R&D costs could be as high as $2.5 billion per medication when accounting for the costs of capital, failed medications, clinical trials, production, distribution, and marketing. P. Dubois et al., *Market Size and Pharmaceutical Innovation*, 46 RAND J. of Econ. 844, 861–863 (2015). Companies must therefore account for *all* R&D costs when pricing the medications that *do* make it to market.

These are considerations that a free-market enterprise accounts for when pricing its products. But the Program replaces the fair market with a compelled pricing model that will not guarantee that profits outstrip losses.

B. The biopharmaceutical industry is already facing cuts to research efforts in the face of the Program's misaligned mandates.

By employing a pricing structure divorced from market or business realities, the Program will severely damage prospects for the development of new medications. If the Program stands, the number of drugs impacted will continuously increase. And there is a "significant negative relationship between" forced-sale regimes and investment in R&D, with some academic studies suggesting a five to six percent decrease in investment for every 10 percent decrease in drug prices. Zinberg, *supra,* at 4. The direct result of the ever-expanding Program is that R&D and innovation will suffer, with fewer medications being developed and even fewer making it to market.

Commentators believe that the Program will severely impact biologics and small molecule drugs "with an average reduction in revenue per therapy of $4.9 billion and $4 billion respectively." Gassull, *supra*, at 2. The conservative estimate is that roughly 139 medications in the next decade may never be developed because of the necessary reduction in R&D investment. *See id.* at 2, 16.

But these aren't just predictions; this is already reality. Manufacturers have already made hard choices to discontinue R&D efforts based on the new economic realities ushered in by the Program. *See, e.g.*, *Life Science Investment Tracker*, Incubate, https://lifesciencetracker.com (last visited Jan. 16, 2026) (noting that 55 research programs have been discontinued since passage of the IRA); Hanke Zhang et al., *The Inflation Reduction Act and Drug Development: Potential Early Signals of Impact on Post-Approval Clinical Trials*, 59 Therapeutic Innovation & Reg. Sci. 781, 784–786 (2025) (estimating that the IRA has led to a 38.4% decrease in industry-funded clinical trials and an even larger 47.3% decline for small molecule drug trials). Shortly after the first drugs were selected into the Program, Pfizer announced its intent to reduce R&D efforts for small molecule drugs, specifically citing the disparity in how the Program treats biologics versus small molecule drugs. *See* Greg Slabodkin, *IRA Drives Pfizer's Decision to Focus on Biologics, Not Small Molecules*, BioSpace (Mar. 4, 2024), https://tinyurl.com/358mdnse. Pfizer's CEO commented that the Program "will force a lot of us to make strategic moves, not based on where the science is taking us but based on where IRA is taking us."

Edited Transcript of Pfizer Inc at Goldman Sachs Global Healthcare Conference, at 10 (June 10, 2024), https://tinyurl.com/yhsvkma3.

The Program will disproportionately impact emerging biopharmaceutical companies—the firms on the frontlines for new and emerging therapies. Many associate the term "Pharma" with multinational pharmaceutical manufacturers like Johnson & Johnson, Merck, and Pfizer. But behind that small pool of recognizable household names are dozens of smaller, unheralded firms of equal import. They are the heart of new drug development, responsible for advanced, cutting-edge therapies that will transform disease treatment. Small and emerging pharmaceutical companies—those whose annual revenue is less than $500 million—"now account for more than 70% of the nearly 3,000 drugs in phase III clinical trials." *Research and Development in the Pharmaceutical Industry*, *supra*, at 4 (citing *The Changing Landscape of Research and Development*, IQVIA Inst. for Hum. Data Sci., at 15 (Apr. 23, 2019), https://tinyurl.com/3x3ywb48). They are also to thank for an increasing number of medications on the market: "Since 2009, about one-third of the new drugs approved by the Food and Drug Administration have been developed by pharmaceutical firms with annual revenues of less than $100 million." *Ibid.* (citing Ulrich Geilinger & Chandra Leo, *HBM New Drug Approval Report*, HBM Partners, at 16 (Jan. 2019)).

Because smaller and emerging pharmaceutical firms operate with less revenue and tighter margins,[4] they will suffer the most from the Program's economic disincentives. Small biotechnology firms depend on investment from market participants who believe they have a chance for a return. Because the Program will prevent even major pharmaceutical manufacturers from recouping their R&D investment, investors will be disincentivized to fund the smaller, start-up companies that are on the front lines.

BIO's market research shows that the Program will reduce available capital in start-up firms by 30%, which will in turn restrict the availability of working capital to fund further investments. *See* Gassull, *supra*, at 33. That is an impact to the tune of *billions* of dollars. In one study, 76% of respondents at the grassroots level of biotech drug development reported already seeing less funding for small molecule programs compared to biologics because of the Program. *See* Steven Potts, *Measuring the Damage: IRA's Impact on Small Molecule Drug Development*, No Patient Left Behind (Mar. 31, 2024), https://tinyurl.com/2rwz9xhv. For example, IGM Biosciences, a small clinical-stage biotechnology company, reported its concern that the Program's "cost containment measures . . . may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates if approved." IGM Biosciences, Inc. Form 10-Q for Quarterly Period

[4] In 2014, for example, "the 25 largest drug companies received more than 70 percent of industry revenues." *Research and Development in the Pharmaceutical Industry*, *supra*, at 4.

Ended Sep. 30, 2023, at 45 (Nov. 13, 2023), https://tinyurl.com/jzvutsw4.

The economic impacts of decreased R&D will also extend beyond reduced revenue and less R&D expenditures. Revenue loss inevitably leads to job loss. Some models have predicted a loss of anywhere between 66,800 and 135,900 direct jobs as well as between 342,000 and 676,000 indirect jobs in the U.S. biopharma ecosystem. *See* Gassull, *supra*, at 2, 29–30, 40. Indeed, less than a month after forecasting concerns about profitability and product commercialization, IGM Biosciences announced a 22% workforce reduction "given the difficult conditions in the capital markets for our industry." *IGM Biosciences Announces Strategic Pipeline Prioritization and Cash Runway Extension*, IGM Biosciences (Dec. 5, 2023), https://tinyurl.com/48z3d3xe. Many other companies have announced similar layoffs or negative outlooks since the IRA was passed. *See Life Science Investment Tracker*, *supra*.

Less revenue due to the Program's impractical pricing structure means less revenue to allocate to R&D, leading to fewer research sites, fewer researchers, fewer research programs, and fewer lifesaving medications. Consider, for example, if the Program had been enacted in 2014, which provides a decade of revenue and R&D data to simulate the real implications of the Program. The results are stunning. One study identified nearly 50 drug therapies sold today that likely would never have made it to market under the Program's economic realities and consequences. *See* Gassull, *supra*, at 2.

C. The Program hurts patients—especially those with rare diseases—the most.

Manufacturers and other members of the biopharma sector cannot ignore economic realities. The Program imposes an unrealistic forced-sale regime that will slash revenue, directly reducing R&D resources. In that climate, biopharmaceutical companies must make difficult choices—choosing certain diseases to research over others and triaging their shrinking pool of resources.

Yet the population that suffers the most isn't manufacturers; it is the patients that need new and expanded medications to improve their quality of life and treat various conditions and diseases. Those patients will suffer because biopharmaceutical companies will have no choice but to reduce their R&D spend because of the inadequate revenue the Program provides. These are revenues that would have supported development opportunities. As mentioned above, the *conservative* estimate is that the Program's revenue reductions will result in roughly 139 medications over the next 10 years never being developed. *See* Gassull, *supra*, at 2. The industry has already seen companies abandon existing clinical trials, pointing to the Program as a significant influence on their clinical development decisions. *See* Suchita Shah et al., *Navigating the Inflation Reduction Act's Impact on Drug Pricing and Innovation*, Bos. Consulting Grp. (Sep. 14, 2023), https://tinyurl.com/yc7r339d.

Patients who suffer from extremely rare diseases stand to lose the most. Although the Program provides a negotiation exemption for orphan drugs

that treat rare diseases, that exemption creates a misaligned incentive. The exemption lasts only for as long as that orphan drug has not been approved for any non-orphan uses. But that structure disincentivizes manufacturers from researching additional indications for orphan drugs to expand their scope of treatment. Put another way, the Program creates an economic incentive for manufacturers *not* to research and identify additional diseases—especially less-rare ones—that an orphan drug may treat. To maintain that negotiation exemption and preserve R&D resources, manufacturers will face the harsh reality that they must forego additional potential indications for drugs to ensure that they can afford future R&D. *See also NORD's Position on IRA/CMS Drug Negotiation Price Program*, Nat'l Org. for Rare Disorders (Feb. 22, 2024), https://tinyurl.com/ycsvrbxc.

The problem is particularly acute for orphan drugs, but it is not limited to them. The Program disincentivizes post-approval R&D for *all* new drug indications. The Program's price-setting provisions commence at a pre-determined point once a medication is approved, which sets a value for a medication that fails to account for future opportunity, thereby disincentivizing and cutting off that future R&D. There is no incentive for manufacturers to invest in post-approval R&D to develop and identify new indications for medications if the federal Government can unilaterally set a medication's price (and ostensibly determine its value) before any future research and approvals are carried out. *NORD's Position on IRA/CMS Drug Negotiation Price Program*, *supra*. With medication

"values" frozen in time, manufacturers will have no choice but to reduce investment of R&D for additional indications of already-approved medications.

As a practical matter, certain "indications and disease areas with assets . . . require the company to launch with an indication with a small addressable market before launching larger indications." Shah, *supra*. The Program hurts development in those disease areas because it can establish a medication's price based on the small market at the time of approval, without accounting for a delayed peak in revenue and value after further R&D identifies additional indications and expands the medication's use.

And again, the impact is disproportionate—heavily affecting already-vulnerable patient populations in disease areas like oncology and immunology where many medications receive additional approvals *years* after their initial approval. Those later indications are critical to cancer patients, offering potentially vital and lifesaving treatment options. But yet again, the Program ignores those research and market realities, setting a price benchmark for medications after initial approval and failing to account for (and therefore disincentivizing) future R&D to expand those medications' uses. There is no incentive for manufacturers to invest in post-approval research if the Government has already set an inflexible price that will not reflect post-approval developments or account for the additional R&D needed for new indications. Indeed, pharmaceutical manufacturer Eli Lilly already announced the cancellation of ongoing blood cancer studies "[i]n light of the Inflation Reduction Act." Joe Grogan, *The*

Inflation Reduction Act is Already Killing Potential Cures, Wall St. J., Nov. 3, 2022, https://tinyurl.com/35ew3yeh.

Consider, too, the detrimental impact on innovation and development for small molecule drugs generally. On average, post-approval clinical trials for small molecule drugs start within three years of approval, but the indications based on those trials are not obtained until seven and a half years after the first approval. *See* Julie Patterson et al., *Unintended Consequences of the Inflation Reduction Act: Clinical Development Toward Subsequent Indications*, 30 Am. J. Managed Care 82–86 (Feb. 2024), https://tinyurl.com/ms7df6b5. But under the Program, small molecule drugs are eligible for price "negotiation" 7 years after initial approval, with the "negotiated" prices effective at 9 years post-approval. *Ibid.* This timeline reorients the economic incentives around R&D for small molecule drugs, forcing researchers and manufacturers to shape their development decisions around the Program's price timing and concerns about price erosion, rather than encouraging decisions that are grounded in science and patients' wellbeing. *Ibid.*

* * *

The Program poses an existential threat to the future of the biopharmaceutical industry and drug development in this nation. And the patients who need new treatments the most will suffer the most. Given these critically high stakes, this Court should grant review to consider the important constitutional issues presented.

II. THE IRA'S DRUG PRICE NEGOTIATION PROGRAM IS TEXTBOOK COERCION.

The Fifth Amendment questions in these cases turn upon the Program's coerced appropriation of pharmaceutical manufacturers' drug products. BMS's and Janssen's petitions present an important, compelling question about whether participation in the Program is truly voluntary or whether the market realities of Medicare and Medicaid[5] make the "choice" to participate illusory. Participation in the Program is anything but voluntary, and the Third Circuit's contrary reasoning ignores reality. The Program is nothing but thinly veiled coercion that fails any level of constitutional scrutiny. The IRA coerces pharmaceutical manufacturers' participation in the Program because manufacturers cannot, as a practical matter, stop selling their products to Medicare. Medicare is the 800-pound gorilla in the pharmaceutical market, particularly for the medications that the Program targets. As the Third Circuit and other federal courts of appeals have recognized, "[t]he federal government dominates the healthcare market. Through Medicare and Medicaid, it pays for almost half the annual nationwide spending on prescription drugs." *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th 696, 699 (3d Cir. 2023) (citing Cong. Budget Off., *Prescription Drugs: Spending, Use, and Prices* 8 (2022)); *see also* Pet.App.34a (majority op.) (acknowledging that the Government is "far and away the largest buyer" of prescription medications). *Cf. Lewis v. AbbVie Inc.*, 152 F.4th 807, 812 (7th Cir.

[5] For simplicity, *amicus* will refer to Medicare and Medicaid collectively as "Medicare."

2025) ("Medicare and Medicaid account for roughly 40% of annual prescription drug spending in the United States."); *Northport Health Servs. of Ark., LLC v. U.S. Dep't of Health & Hum. Servs.*, 14 F.4th 856, 863 (8th Cir. 2021) (discussing the Government's enormous Medicare and Medicaid annual spending). The federal Government wields its overwhelming "market power to get drug makers to subsidize healthcare." *Sanofi*, 58 F.4th at 699. That overwhelming "market power" means the consequences of avoiding the Program threaten participants' commercial viability altogether.

Because Medicare represents such a large majority of the pharmaceutical market, requiring a manufacturer to withdraw all its drugs from Medicare to avoid giving up its property at a below-market price would be tantamount to requiring the manufacturer to stop selling prescription medications altogether. Take for example, Janssen's Xarelto, used to "treat[] and help prevent blood clots and reduce[] the risk of stroke." CA3 Joint Appendix 793. As Janssen explained to the district court below, Medicare and Medicaid accounted "for more than 60%" of Xarelto prescriptions in the United States in 2022. *Ibid.* And that is just one product from among the Program's first round of selections. But the constitutional question presented is broader than a single manufacturer or a single product. The Program is designed to target prescription medications with high Medicare Part B and Part D utilization and expenditures. *See* 42 U.S.C. § 1320f-1; *AstraZeneca v. Sec'y*, 137 F.4th 116, 119–120 (3d Cir. 2025). In the future, the Program will likely and eventually target prescription medications that are used almost

exclusively by aging patients in the Medicare demographic. As a result, even if the Program is not immediately crippling for the medications or manufacturers currently targeted by the Program, it surely will be for future innovators looking to develop lifesaving medications. And as discussed above, these detrimental effects on the development of lifesaving medications will be felt well beyond the nearly half of Americans covered by Medicare.

BMS's and Janssen's petitions present an ideal opportunity for this Court to not only address the Third Circuit's misapplication of this Court's precedent in *Horne v. Department of Agriculture*, 576 U.S. 351 (2015), *see* BMS Pet. at 15–16; Janssen Pet. at 24–25, but also the Program's uniquely coercive impact on the prescription-drug market. The Government's involvement in the prescription-drug market through Medicare is unique, presenting important and novel questions of federal law about whether pharmaceutical manufacturers' participation in the Program is truly voluntary.

Below, the Third Circuit improperly and summarily rejected BMS's and Janssen's arguments about the coercive nature of the Program by drawing an inapt analogy to cases involving totally different markets. For example, the court cited cases considering the markets for non-profit hospitals and nursing homes. *See Franklin Mem'l Hosp. v. Harvey*, 575 F.3d 121, 129–130 (1st Cir. 2009); *St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 873 (7th Cir. 1983) (per curium); *Burditt v. U.S. Dep't of Health & Hum. Servs.*, 934 F.2d 1362, 1376 (5th Cir. 1991); *Livingston Care Ctr., Inc. v. United States*, 934 F.2d 719, 720 (6th Cir. 1991); *Baker Cnty. Med. Servs., Inc.*

v. Attorney General, 763 F.3d 1274, 1279–1280 (11th Cir. 2014); *Minn. Ass'n of Health Care Facilities, Inc. v. Minn. Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984). The Court also cited to Takings cases brought by physicians and a medical equipment provider. *See Garelick v. Sullivan*, 987 F.2d 913, 916–917 (2d Cir. 1993); *Key Med. Supply, Inc. v. Burwell*, 764 F.3d 955, 965–966 (8th Cir. 2014). But those markets are nothing like the prescription-drug market, and the cases analyzing those markets say nothing about the coercive impact of requiring a manufacturer to completely withdraw its entire portfolio from Medicare if it wants to avoid an illegal taking.[6] *See also* Pet.App.56a–57a (Hardiman, J., dissenting) ("The Act forces the Companies to turn over their property to Medicare beneficiaries by threatening them with ruinous excise tax liability. Although participation in Medicare and Medicaid is voluntary, participation in the Program is not.").

Non-profit hospitals and nursing home providers, like those in the cases cited by the Third Circuit, are not like the biotech innovators and pharmaceutical manufacturers targeted by the Program. Hospitals and nursing homes serve small localities, meaning that the impact of being deprived of Medicare patients in a small geographic segment simply means that local providers may "opt not to participate [in Medicare and] are free to serve persons not covered by Medicare and those potential Medicare recipients

[6] The only case cited by the Third Circuit that addresses the relevant prescription-drug market is *Boehringer Ingelheim Pharmaceuticals, Inc. v. U.S. Department of Health & Human Services*, 150 F.4th 76, 91 (2d Cir. 2025), where the Second Circuit likewise analogized to many of the same cases in error.

who are willing to forego Medicare benefits for the services provided." *St. Francis Hosp. Ctr.*, 714 F.2d at 875. That option does not exist for pharmaceutical manufacturers, which provide lifesaving medications for patients nationwide and rely on that nationwide revenue to recoup their huge R&D investments and to fund future investments in emergent companies developing the next line of lifesaving medications. Nor is it reasonable or realistic to expect patients to forego their Medicare benefits to pay for the medications targeted by the Program. Those products are some of the most widely prescribed medications, primarily because of their extremely high effectiveness in treating severe, life-altering diseases.

There are also other practical differences that greatly impact patients. If a provider chooses to not treat Medicare patients, the impact on those patients is simply that they must drive further or obtain care from a less-preferred physician. But for medications like those targeted by the Program, there is only one seller. If that seller opts out of selling to Medicare, Medicare patients in dire need of critical lifesaving medications will be left without options. That result would undermine Medicare's core purpose to ensure adequate health care for elderly and disabled persons. And reputationally, a pharmaceutical company would have a difficult time explaining a decision not to provide lifesaving medicines to some of America's sickest patients. The Government has forced manufacturers into a trap they cannot possibly escape. *See also* Pet.App.57a (Hardiman, J., dissenting) ("The Act's threat of excise taxes and civil penalties looms like a sword of Damocles, creating a de facto mandate to participate.").

Consequently, the "voluntariness" analysis is decidedly different for pharmaceutical companies than for other participants. Health care providers can, and do, opt out of participation in Medicare, and the governing regulations even provide a roadmap for doing so. *See* 42 C.F.R. § 405.420. But here, there is no evidence in the record that any manufacturer has *ever* offered its products only to patients not covered by Medicare. And for good reason: It is simply not an economically feasible alternative. That reveals the fundamental flaw in the Program: either participation *or* non-participation in the Program might drive a pharmaceutical manufacturer to insolvency.

The Program thus presents nothing but an illusion of "choice"—manufacturers must either "voluntarily" participate in the Program's "negotiations" or withdraw entirely from Medicare. That "byzantine scheme" leaves no choice at all. Pet.App.91a (Hardiman, J., dissenting). This coerced participation in the Program violates the constitutional rights of BMS and Janssen and threatens to unravel the market for development of innovative and lifesaving medications.

CONCLUSION

The questions presented are exceptionally important, and the Third Circuit's holding that the IRA's extreme coercion shields it from constitutional scrutiny sets a dangerous precedent that warrants immediate review.

The Court should grant the petitions for writs of certiorari.

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