IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TEVA PHARMACEUTICALS USA, INC., *et al.*, Plaintiffs, v. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of Health and Human Services, *et al.*, Defendants.	No. 1:25-cv-00113-SLS

BRIEF OF ECONOMISTS AND SCHOLARS OF HEALTH POLICY AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION AND INTEREST OF *AMICI CURIAE*[1]

This case concerns the constitutionality of the Inflation Reduction Act's drug pricing provisions. Amici are economists and health policy scholars who focus their work on healthcare markets and pharmaceutical drug pricing. They do not directly address the parties' competing constitutional arguments. Instead, they submit this brief to provide the Court with the background necessary to understand the context in which those arguments arise—context concerning the economics of the Medicare market; the relationship between intellectual property rights, drug prices, and innovation; continued investment in research and development efforts by industry; and the Inflation Reduction Act's role in correcting for market failure and restoring bargaining equity. Amici are:

Richard G. Frank
Margaret T. Morris Professor of Health Economics Emeritus, Harvard Medical School; Leonard D. Schaeffer Chair in Economic Studies, The Brookings Institution

Fiona M. Scott Morton
Theodore Nierenberg Professor of Economics, Yale School of Management

Aaron S. Kesselheim
Professor of Medicine,
Brigham and Women's Hospital/Harvard Medical School

Gerard F. Anderson
Professor of Health Policy & Management,
Johns Hopkins University Bloomberg School Public Health; Professor of Medicine,
Johns Hopkins University School of Medicine

Rena M. Conti
Associated Professor,
Questrom Business School, Boston University

[1] No party or counsel for a party—nor any person other than Amici and their counsel—authored this brief in whole or in part or contributed any money intended to fund its preparation or submission.

David M. Cutler
Otto Eckstein Professor of Applied Economics Harvard University

Jack Hoadley
Research Professor Emeritus,
Health Policy Institute, McCourt School of Public Policy, Georgetown University

The plaintiffs assert that the Inflation Reduction Act's Negotiation Program harms the "virtuous cycle" of drug development, and "compels" drug companies to cap prices at the "price dictated by" the government, thus "leaving American patients worse-off." Mot. for S.J., ECF No. 15-1, at 1, 3, 11, 12. This brief shows how plaintiffs' contentions reflect an overly simplistic and a misleading account of the prescription-drug market.

The market for prescription drugs does not function like other markets.[2] In the bread market, for example, there are no laws that prevent direct competition among sellers to skew prices and demand. Consumers can decide which bread they prefer to purchase, based on taste, ingredients, price, and other characteristics, and which bakery to buy from. A bakery must set its prices to satisfy consumers and meet its competition. In the drug market, however, the relationship between sellers and consumers is not as unfettered. To provide a period of guaranteed revenue that promotes recoupment of investment in drug development, the government provides drug companies with patents and several years of exclusivity—making a particular drug the only available product of that specific formulation for *at least* 5 years, and for 12–14 years on average. During that time, drug companies use their market power to set prices well above the costs of production and distribution. Far from reflecting the drug's true value, the prices set during these periods reflect the market exclusivity under which drug manufacturers operate.[3] This exclusivity

[2] Rena M. Conti, et al., The Myth of the Free Market for Pharmaceuticals, 309:16 New Eng. J. Med., 1448, 1448–1450 (Apr. 25, 2024).

[3] David H. Howard, et al., *Pricing in the Market for Anticancer Drugs*, 29 J. Econ. Perspectives 139 (2015).

forces payors like Medicare to pay whatever prices the manufacturers demand for brand-name drugs without generic alternatives.

The Inflation Reduction Act takes several steps to correct course. It gives Medicare the authority to negotiate prices for drugs that have been on the market for at least 9–13 years. By doing so, it provides beneficiaries with more bargaining power to counter the pharmaceutical monopolist in establishing a price. The harm to true innovation is likely to be negligible because any drug eligible for negotiation will almost certainly have already recouped its investment many times over prior to being subject to negotiated prices. This brief explains how, contrary to plaintiffs' contentions, the Inflation Reduction Act pushes the drug market's dynamics closer to a competitive equilibrium, not further away.

ARGUMENT

I. TENSIONS BETWEEN INCENTIVES FOR INNOVATION AND CONSUMER PROTECTION FRAME THE MECHANICS OF THE PRESCRIPTION DRUG MARKET.

A. The development of prescription drugs is costly and offset by government subsidies.

Research and development costs for new prescription drugs are high,[4] because the process to develop a prescription drug is long, and clinical trials are expensive. Increasingly, research and development of new prescription drugs is financed by venture capital and mergers and acquisitions and less through drug companies' own funding. This trend is evidenced by venture-capital

[4] Richard G. Frank & Caitlin Rowley, *Medicare Negotiations Won't Keep Big Pharma From Making a Fortune*, Bloomberg (Sept. 5, 2023).

placements, merger-and- acquisition investment data, and pharmaceutical company earnings calls.[5]

Although most new drugs are brought to the market by private companies, the federal government underwrites a substantial amount of cost, risk, and uncertainty. The government invests in drug research primarily through the National Institutes of Health ("NIH"). Reviews show that every single drug approved by the FDA from 2010–2016 linked back to NIH-funded research and that 99.4% of drugs approved from 2010–2019 received NIH funding at some point in development.[6] In contrast to private pharmaceutical companies, the federal government generally receives very limited royalties or financial return on these investments.[7] The federal government also assures that brand drugs are safe, effective, and accurately labeled.[8]

Once a drug receives FDA approval, the manufacturer's priority is to maximize profits. The U.S. government aids this effort by providing manufacturers with two types of market exclusivity for new drugs that could otherwise be easily duplicated: patents and exclusivity periods. These measures block direct competition for a period determined by Congress to balance

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[5] Ned Pagliarulo & Jacob Bell, *Biotech MCA is on the Upswing. Here are the Latest Deals*, BioPharma Dive (August 13, 2024), https://perma.cc/VBT9-GCW8; Oppenheimer, *Biopharma Private Placement Insights: Q3 2024 Update* (2024); Roche, *Roche Holding AG (RHHBY) Q3 2024 Earnings Call* (July 25, 2024), https://perma.cc/3PF6-S4H8; Amgen, *Amgen '34 Earnings Call* (August 6, 2024), https://amgen2.rev.vbrick.com/#/videos/af04f17e-e666-4e6d-a54e-52786141ddba.

[6] Ekaterina G. Cleary, et al., *Contribution of NIH Funding to New Drug Approvals 3010- 3016*, 115 Proc. Nat'l Acad. Scis. USA 10, 2329-34 (2018); Ekaterina G. Cleary, et al., *Comparison of Research Spending on New Drug Approvals by the National Institutes of Health vs. the Pharmaceutical Industry, 3010–3019*, 4 JAMA Health F. 4 (2023).

[7] U.S. Gov't Accountability Off., GAO-21-52*, Biomedical Research: NIH Should Public Report More Information about the Licensing of Its Intellectual Property* 2, 7 (2020) (NIH received up to $2 billion in royalties from its contributions to 34 drugs sold from 1991-2019, compared to $36 billion contributed to research in 2018 *alone*).

[8] Jeremy A. Green & Scott H. Podolsky, *Reform, Regulation, and Pharmaceuticals—The Kefauver-Harris Amendments at 50*, 367 N. Eng. J. Med. 16, 1481-83 (2012).

profit for the innovator and access to lower-cost medications for patients.[9] First, the government grants drug patents to manufacturers. Patents last about 20 years from the date of application. A drug's primary patent is on the underlying active ingredient and is usually obtained well before FDA approval, around the time of drug discovery. But manufacturers can, and do, obtain numerous additional patents on other formulations, uses, and manufacturing methods for an already successful drug. This process can create a thicket of dozens or even hundreds of patents that block generic entry for many years after the initial patent expires.

Second, other federal statutes provide guaranteed minimum periods of exclusivity by preventing the FDA from approving competing products for a minimum number of years after regulatory approval. Small-molecule drugs, those derived from chemical processes, are protected for at least 5 years; drugs for rare diseases are protected for 7 years; and biologic drugs, those derived from living organisms, are protected for 12 years.[10] During this time, generic or biosimilar versions of a brand-name drug cannot be sold, and any profits from sales of the treatment are controlled exclusively by the developer.[11] Large companies use various tactics to extend exclusivity periods past the expiration of initial patents—including settling patent challenges by generic firms, delaying patent filing, refusing to provide samples to generic firms, filing pretextual "citizen petitions" against competitors to delay market entry, and engaging in product hopping (a

[9] Richard G. Frank & Paul B. Ginsburg, *Pharmaceutical Industry Profits and Research and Development*, Brookings (Nov. 17, 2017).

[10] Favour D. Makurvet, *Biologics vs. Small Molecules: Drug Costs and patient Access*, Med. Drug Discovery, Nov. 23, 2020, at 1.

[11] Food & Drug Administration, *Patents and Exclusivity*, FDA/CDER SBIA Chronicles (May 19, 2015).

practice of forcing patients onto newly patented drugs with slight modifications).[12] Many of these tactics have been pursued by the Federal Trade Commission and Department of Justice as anticompetitive violations of antitrust laws, but the agencies have been unsuccessful in halting these methods entirely.[13] As a result, the exclusivity period for new drugs has been found to extend anywhere from 7–35 years.[14]

B. The drug market is not structured like other free markets.

Protecting innovation through exclusivity comes at the expense of traditional free-market principles. A free market is one in which prices and demand are set by decentralized buyers and sellers making informed purchasing decisions. Unlike other markets in the United States—in which sellers compete for sales without significant intervention—patents and other exclusivity periods grant temporary monopolies to drug companies. Regulations dictate the terms of distribution and discounts, and the market is further complicated by the presence of insurance coverage. In asserting that Medicare has relied on a market-based system, plaintiffs ignore these realities that distort and inflate drug prices far beyond the price that would be set in a truly competitive free market.

In a well-functioning market, the price of a product needs to be set at a level that will incentivize people to purchase it. Here, however, insurance coverage insulates consumers from the true price of a drug because they only pay a small percentage of the cost, eliminating one important catalyst that drug companies have to set reasonable prices. Absent a mechanism to reel back such

[12] Fiona M. Scott Morton & Lysle T. Boller, *Enabling Competition in Pharmaceutical Markets* 2 (Brookings Working Paper No. 30, May 2017); Roger Collier, *Drug Patents: The Evergreening Problem*, 185 Can. Med. Ass'n J. 385 (2013).

[13] Morton & Boller, *Enabling Competition in Pharmaceutical Markets*, at 36.

[14] Benjamin Rome, *Market Exclusivity Length for Drugs with New Generic of Biosimilar Competition*, 3013-3018, 109 Clinical Pharmacology & Therapeutics 2, 367-71 (2021).

practices, like the Negotiation Program, companies can use unfettered market power to hike drug prices far above those that would be palatable to consumers.[15] While such temporary subsidies (through exclusivity periods) may help drug companies recuperate their initial investment, they can hardly claim they're permanently entitled to those benefits.

The end of the exclusivity period plays an important role in recalibrating the market and promoting affordability. When a for-profit company markets a socially valuable patented drug, it is given license to "charge higher than competitive prices" as the only available formulation.[16] Once interchangeable products enter the market, competition naturally pushes prices down, making the drug more accessible to consumers (further lowering out-of-pocket exposure for those with insurance).[17] This competition has always been valued by lawmakers, who passed the Hatch-Waxman Act in 1984 to create a streamlined pathway for generic drugs to come to market when patents and exclusivity periods lapse.[18] Due to the Hatch-Waxman Act and state laws encouraging the use of lower cost generic drugs, spending on previously patent-protected drugs can often fall by as much as 80% within 24 months.[19]

Insurance coverage, like that offered by Medicare Part D, also plays a crucial role in protecting consumers from the growing costs of prescription drugs. Health plans have implemented tiered benefit structures to steer patients and physicians to use generic versions of

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[15] Richard G. Frank & Joseph P. Newhouse, *Should Drug Prices Be Negotiated Under Part D of Medicare? And If So, How?*, 27 Health Affairs 2, 39 (2008).

[16] Morton & Boller, *Enabling Competition in Pharmaceutical Markets*, at 1.

[17] *Id.*

[18] Wendy H. Schacht & John R. Thomas, Cong. Rsch. Serv., R41114, The Hatch-Waxman Act: Over a Quarter Century Later (Mar. 13, 2012).

[19] Yan Song & Douglas Barthold, *The Effects of State-Level Pharmacist Regulations on Generic Substitution of Prescription Drugs*, 27 Health Econ 1717, 1717-37 (2018); Chana A. Sacks et al., *Assessment of Variation in State Regulation of Generic Drug and Interchangeable Biologic Substitutions*, 181 JAMA Internal Med. 1, 16-22 (2021).

drugs when possible.[20] These policies reduce costs incurred by consumers, especially because generic drugs are dispensed more than 90% of the time when they are available.[21] While formulary design can reduce costs when a generic is available, plans' negotiating position is limited where there is only one or a few drugs on the market to treat a specific disease. Even with tools like formulary design, Medicare Part D plans are forced—whether by consumer demand or regulatory requirements—to cover certain drugs without negotiating power to drive down prices.[22]

Imagine a hypothetical drug that is worth $100 to many consumers. Because Medicare enrollees are insured, they pay only 20% of the cost of the drug at the time the consumer buys it. If a consumer is willing to pay $100, the pharmaceutical company will immediately realize that it can raise price up to $500 without losing customers. The government notices this high price because it raises the cost of Medicare and limits funds that can be used for other healthcare needs. After *10 years* of this pricing model, the Inflation Reduction Act allows the government to bargain for lower prices (perhaps $300). Yet, plaintiffs effectively claim that any price below $500 violates "free-market principles," and the only acceptable outcome is for the government to continue paying $500 forever. The economic absurdity of this claim is self-evident.

C. Higher drug prices do not directly correlate with an increase in innovation.

Drug prices aren't the touchstone of innovation that drug companies make them out to be. Empirical studies show that, on average, an increase in the expected number of patients and total

[20] Richard G. Frank, *Prescription Drug Prices: Why Do Some Pay More Than Others Do?*, 20 Health Affs. 2, 115-128 (2001).

[21] Cong. Budget Off., *Prescription Drugs: Spending and Prices* 2 (2022).

[22] Mark Duggan & Fiona Scott Morton, *The Effect of Medicare Part D on Pharmaceutical Prices and Utilization*, Am. Econ. Rev. 2010;100:590–607; Cong. Budget Off., *Prices for and Spending on Specialty Drugs in Medicare Part D and Medicaid* (2019).

revenue of a drug cause more investment and more product entry.[23] Newer studies provide insight into exactly what kind of products are entering the market: These studies find that much of the entry is not "innovation," but rather replication or rebranding of existing drugs. While the number of new drugs entering the market increased after the introduction of Medicare Part D, one study showed that the new drugs were almost entirely in areas with five or more existing therapies, offering little by way of meaningful innovation.[24] A review of FDA approvals from 2007-2017 revealed that only about one-third of the new drugs in that period had "high therapeutic value," or in other words, offered more than a minimal improvement over drugs or other treatments that were already available.[25] Companies also advertise low therapeutic value drugs widely,[26] and low therapeutic value drugs accounted for $19.3 billion in Medicare spending in 2020, 55% of the total amount spent on the top-50 selling drugs.[27] Further, drug companies took existing drugs that were viewed as insufficiently profitable before the creation of Medicare Part D and relaunched them as the drug market grew, while the market overall showed little evidence of increases in patents or publications.[28] Much of the present pharmaceutical research and development spending is devoted

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[23] Pierre Dubois, et al., *Market Size and Pharmaceutical Innovation* 11 (TSE Working Paper, March 2014); Wesley Yin, *Market Incentives Pharmaceutical Innovation*, 27 J. Health Econ. 4, 1060-77 (2008).

[24] David Dranove, et al., *Pharmaceutical Profits and the Social Value of Innovation* 1, 10 (NBER Working Paper No. 20212, 2014).

[25] Thomas J. Hwang, Aaron S. Kesselheim, et al., *Association between FDA and EMA Expedited Approval Programs and Therapeutic Value of New Medicines: Retrospective Cohort Study*, 371 British Med. J., 1 (2020).

[26] Neeraj G. Patel, et al., *Therapeutic value of drugs frequently marketed using direct-to-consumer television advertising, 3015-3031*, 6 JAMA Network Open 1, 1-3 (2023).

[27] Alexander C. Eligman, et al., *Added Therapeutic Benefit of Top-Selling Brand-Name Drugs in Medicare*, 15 JAMA 1283, 1283-89 (2023).

[28] Dennis Byrski, et al., *Market Size & Research: Evidence from the Pharmaceutical Industry* 2 (Planck Inst. Rsch. Paper No. 21-16, May 2021).

to previously-approved products; indeed, a study of all FDA approvals of brand name products from 2011-2021 found that only 36% of companies' expenditures were related to new products, with all other spending focused on extensions of existing drug franchises.[29] The rules and structure of the market incentivize this kind of prioritization. The pharmaceutical market structure focuses attention on those drugs for which profits are highest, with little consideration of their added value or innovative quality. This allows companies to invest in offshoots of drugs that they already know to be profitable, fend off regulation with disincentive defenses, and market themselves as innovators.[30]

II. CMS's grouping of products, as mandated by the Inflation Reduction Act, is a necessary response to market dynamics

The Inflation Reduction Act directs the Centers for Medicare & Medicaid Services to select at most ten products for price negotiation in the Negotiation Program's first year and bars selecting drugs that have not been approved and marketed for a requisite minimum number of years. Plaintiffs contend that CMS's decision to aggregate products that share the same active pharmaceutical ingredient violates that directive.

But, contrary to what Teva says, Congress in fact recognized the harms of "product hopping"—or marketing slightly different formulations of already-approved drugs to extend revenue streams on the same underlying active ingredients—when it passed the Inflation Reduction Act. Section 1192(d)(3)(B) directs CMS to "use data that is aggregated across dosage

[29] Richard G. Frank & Kathleen Hannick, *5 things to understand about pharmaceutical R&D*, Brookings (June 2, 2022).

[30] Increased competition and availability of generic drugs could be the answer. A review of pharmaceutical manufacturers with at least one FDA-approved product from 1985 to 2001 found that the most important predictor of new product introductions was the loss of exclusivity protection on a current product. *See* Stuart J.H. Graham & Matthew John Higgins, *The Impact of Patenting on New Product Introductions in the Pharmaceutical Industry* 29 (Apr. 4, 2007).

forms and strengths of the drug, including new formulations of the drug, such as an extended-release formulation, and not based on the specific formulation or package size or package type of the drug."[31] Likewise, section 1196(a)(2) of the IRA directs CMS to "compute and apply the [maximum fair price] across different strengths and dosage forms of a selected drug," preempting Novo Nordisk's concern that prices for aggregated products will lead to a single price on different dosages.[32] Not only do CMS's approach and guidance comply with Congress's directive in the Inflation Reduction Act, they are an explicitly mandated and necessary response to market dynamics.

In its June 2023 guidance on the Negotiation Program, CMS states that a single drug or biological product includes "all dosage forms and strengths" of the drug with the same active ingredient, including those forms that are "repackaged [or] relabeled."[33] But with the definition Teva proposes, drug companies would have full license to "product hop," introduce minimally different variations of their top-selling products to reset the clock on the negotiation timer, and push sales to the "new" drug. Leaving this unchecked would undermine the clear aim of the statute and harm consumers and taxpayers.

First, a systemic loophole in the Negotiation Programs would render Congress's directive in the Inflation Reduction Act toothless. If every company could reformulate and repackage its existing drugs to endlessly circumvent negotiation, there would be no reason to attempt price

[31] Inflation Reduction Act of 2022, Pub. L. No. 117-169, § 1192(d)(3)(B), 136 Stat. 1818, 1839.

[32] *Id.* § 1196(a)(2), 136 Stat. at 1849.

[33] Centers for Medicare and 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 11-12 (June 30, 2023).

negotiation in the first place. And without negotiation, drug prices would remain inflated at the expense of American consumers.

Second, the proposed loophole would exacerbate the existing problem of product-line extensions. Teva insists (at 3-4) that aggregation reduces incentives for innovation, but the opposite is true. As explained above, drug innovation is down and line extensions are up. Drug companies already repackage and relabel their products to avoid competition from generic drugs. These so-called line extensions are also less risky and less costly to develop than new truly innovative products. Therefore, they are likely to recuperate their development costs more rapidly than truly innovative products. If a further loophole promotes additional investment in line extensions, still more investment dollars would be diverted away from truly innovative products that offer advances in care or meet unmet medical need.

And *third*, the proposed loophole would create even greater barriers to entry for generic and biosimilar products, thereby furthering the anticompetitive effects that already impair consumer bargaining power in the prescription-drug marketplace.[34] Such a loophole should not be read into the statute.

Lastly, an analysis of financial filings submitted by Teva reinforce why enabling such a loophole would be improper. Teva has recouped its investment in AUSTEDO easily already—with cumulative revenues of $5.5 billion as of the second quarter of 2024, even applying very conservative estimates of flat sales for 2025 and 2026 would project to $8.7 billion in earnings by the time AUSTEDO is subject to negotiated prices.[35]

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[34] Byrski, *supra* note 28, at 2.

[35] See Teva, Investor Relations, SEC Filings (last accessed May 2, 2025), https://ir.tevapharm.com/financials/sec-filings/default.aspx.

Additionally, in Teva's most recent Form 10-K filing, when reporting revenues for products, the company does not differentiate between AUSTEDO and AUSTEDO XR.[36] Rather, Teva notes that the increase in revenue growth for AUSTEDO can mainly be attributed to "the launch of AUSTEDO XR."[37]

III. THE NEGOTIATION PROGRAM'S LEGISLATIVELY MANDATED STRUCTURE IS A FAIR PROCESS AND IS NOT UNIQUE TO THE MEDICARE MARKET.

The Inflation Reduction Act's Negotiation Program, which proposes a statutory limit on prices and conducts negotiation within those limits, mimics the decades-old negotiation process employed by federal agencies like the Departments of Defense and Veterans Affairs. These agencies purchase prescription drugs under the Federal Supply Schedule and the Federal Ceiling Price program, both of which establish prices available to agencies that purchase drugs directly from pharmaceutical companies.[38] The prices paid by agencies are set "through a combination of statutory rules, "negotiation," and "statutory caps," not unlike the process outlined in the Negotiation Program.[39] Prices sets by the Federal Supply Schedule and Federal Ceiling Price program are up to 40% lower than those paid by the federal government under Medicare Part D.[40] Manufacturers offer agencies like the Department of Defense, Department of Veterans Affairs, Bureau of Prisons, and state Medicaid entities additional concessions through negotiation.

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[36] Teva Pharm. Indus. Ltd. (Form 10-K) (Feb. 5, 2025), at 62 (Feb. 5, 2025).

[37] *Id.* at 63.

[38] Cong. Budget Off., A Comparison of Brand-Name Drug Prices Among Selected Federal Programs 1-2 (2021).

[39] *Id.*

[40] *Id.*

Those agencies pay prices that average between 31–59% less than the Federal Supply and Federal Ceiling rates, an effective 75% discount on the rates charged to Medicare.[41] Statutory rebate requirements like those found in the federal Medicaid statute further lower overall cost for state Medicaid programs, which pay 38% less for prescription drugs than the Department of Veterans Affairs.[42] If these options were disallowed, the federal government's expenditures for prescription drugs—for the Department of Defense, Department of Veterans Affairs, and Medicaid—would increase by tens of billions of dollars each year.

Concerns that the negotiation process is unfair are unfounded. The Inflation Reduction Act sets statutory discounts based on list prices (what companies choose to charge for the drug) instead of transaction prices (the price actually charged after rebates and discounts). A drug's list price almost always exceeds its transaction price.

The Negotiation Program also only applies to a small set of drugs sold in the United States, leaving most of industry's revenue entirely unaffected. The drugs selected for negotiation will have already recovered their initial investment many times over (as highlighted above specifically with respect to AUSTEDO) —they are products that have been on the market for at least 9 to 13 years and, for the drugs negotiated in the first year of the Program's existence, generated a revenue *surplus* ranging from roughly $15 to almost $57 billion during that time.[43] Incentives for the invention of such drugs are clearly not at risk from the Negotiation Program: large drug companies

[41] *See id.*; Cong. Budget Off., *Prices for Brand-Name Drugs Under Selected Federal Programs* (2005); Off. of the Inspector General, *Review of the Federal Bureau of Prisons' Pharmaceutical Drug Costs C Procurement* 26-27 (2020).

[42] Chris Park, *Medicaid Coverage of Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease* (Sept. 15, 2022), https://perma.cc/9M74-REFH.

[43] Richard G. Frank & Caitlin Rowley, *Much Money to be Made from Developing Drugs that Will Have Negotiated Prices*, Bloomberg (Sept. 5, 2023).

and venture capital firms have continued to invest in research and development at the same levels as before the Act.[44] And, contrary to assertions from opponents of the Negotiation Program, investment in oncology drugs remains strong, with more than 2,000 new oncology clinical trials started in 2023 alone.[45] The fact that these methods of negotiation have been employed in drug markets outside of Medicare for decades without complaint from the industry or any decline in supply should be dispositive.

Furthermore, drug companies stand to benefit from the Inflation Reduction Act. In 2025, the law limited annual out-of-pocket drug spending for Medicare Part D beneficiaries to $2,000. By making it easier for many Medicare beneficiaries to obtain and afford their medications, the Inflation Reduction Act will increase demand and boost sales. It would not be the first time this has happened. After Congress passed the Medicare Modernization Act of 2006, drug companies' revenues increased nearly 37 percent between 2001 and 2006 due to volume increases even though the average prices paid by Medicare were lower than before.[46]

IV. THE INFLATION REDUCTION ACT RESTORES BARGAINING EQUITY BETWEEN MANUFACTURERS AND CONSUMERS WHILE PROTECTING INNOVATION.

The hallmarks of a fair negotiation process include communication between parties, differences in interests, and alternatives to negotiation.[47] All of these hallmarks are present in the Negotiation Program established by the Inflation Reduction Act. There are various channels of communication available to the two parties, a clear difference in interests, and a number of

[44] *Id.*; Letter from Phillip L. Swagel, Director, Cong. Budget Off., to Committee on the Budget Chairman Jodey Arrington and Michael C. Burgess, U.S. House of Representatives (Dec. 21, 2023).

[45] IQVIA, *Global Oncology Trends 2024: Outlook to 2028* (May 28, 2024).

[46] Duggan & Scott Morton, *supra* note 22.

[47] Roger Fisher & William Ury, *Getting to Yes: Negotiating Agreement Without Giving In* 20-84 (2d ed. 1991).

alternatives or off-ramps if companies choose not to negotiate.

The Inflation Reduction Act counters the imbalanced market by permitting the Department of Health and Human Services to select a limited set of older drugs for price negotiation under Medicare. Opponents argue that the Act decreases incentives for research and development, suggesting for example, that the law will discourage investment in the development of post-approval indications. But this assertion conflicts with well- established evidence that most successful follow-on indications are investigated early on in the drug development cycle.[48] For instance, one study of cancer drugs approved between 2005 and 2022 found that the majority of first and second post-approval indications occurred within five years of each drug's launch.[49] Drugs would not be subject to the Negotiation Program until long after this five-year window has passed, and there is no evidence to suggest that the prospect of future negotiation affects a company's incentives to pursue post-approval indications.

The Inflation Reduction Act rather includes several safeguards to make a significant reduction in innovation unlikely. For starters, the Act limits the drugs that can be considered for price negotiation. To be considered, a product must be a single-source drug that has been on the market for at least 9–11 years.[50] Recent data on the earnings of all ten drugs initially selected for negotiation shows that every single drug has recouped its initial research-and-development costs

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[48] Benjamin Carlisle, et al., *Benefit, Risk, and Outcomes in Drug Development: A Systematic Review of Sunitinib*, J. Natl. Cancer Inst. 2015;108(1); Nora Hutchinson et al., *Probability of Regulatory Approval Over Time: A Cohort Study of Cancer Therapies*, JCO Oncology Practice 2023;20(2); Patrick Crotty, et al., *Assessing Patient Risk, Benefit, and Outcomes in Drug Development: A Decade of Lenvatinib Clinical Trials: A Systematic Review*, Targeted Oncology 2024;19.

[49] Jelle Stoelinga, et al., *Comparing Supplemental Indications for Cancer Drugs Approved in the US and EU*, Eur. J. Cancer 2024;212.

[50] Centers for Medicare and Medicaid Services, *supra* note 33, at 13.

(including the cost of failed iterations) and generated a surplus revenue of at least $13.7 *billion* since its launch.[51] The Act neither cuts the company off from future profits nor shortens the time that it retains exclusivity. Far from the "nuclear winter for innovation" prophesied by drug companies, the Act will at a maximum result in a "small chill in their profit margins."[52] Indeed, drug company executives have largely shrugged off the negotiation results in public earnings calls, and a leading investment analyst said "the industry as a whole seems to be managing this fine so far."[53] The Act also exempts several categories of drugs from the Negotiation Program. The excluded categories include (1) drugs for a single rare disease that might take longer to recuperate initial investment; (2) drugs soon to be subject to biosimilar competition, since the lower price for the negotiated drug will provide an advantage relative to generic competitors and thus deter their entry into the market; (3) drugs from small biotech firms, where those drugs bring in over 80% of the company's Medicare revenue; and (4) plasma-related products, because their prices reflect fluctuating costs (as opposed to up-front research-and-development investment).[54]

The Inflation Reduction Act also preserves important opportunities that promote innovation and increase revenues for large and small pharmaceutical companies. The law includes no restrictions on launch prices. As discussed above, the Act adds provisions that increase demand for drugs and will likely boost sales. It also doubles the research-and-development tax credit for small businesses and expands the conditions under which it can be used, which is especially

[51] Frank & Rowley, *supra* note 43.

[52] *Id.*

[53] Nathaniel Weixel & Joseph Choi, *5 Takeaways from First Medicare Drug Price Negotiations*, The Hill (Aug. 16, 2024).

[54] Rachel Sachs, et al., *A Holistic View of Innovation Incentives and Pharmaceutical Policy Reform*, 1 Health Affs. Scholar 1, 2 (2023).

important for innovation since emerging biopharma companies produced two-thirds of all new drugs in 2022.[55]

The prescription drug market has favored manufacturer profits for decades. For this reason, Congress has regularly stepped in to mandate lower prices for government buyers. Each of those changes was resisted by industry because shareholders do not wish to diminish their profit. Those objections are understandable. What is not understandable is the contention that the U.S. drug market is not a highly regulated environment in which many aspects of a firm's business are dictated by regulations and consumer interests. Instead of ignoring this environment, the Inflation Reduction Act works within the confines of this highly regulated market to preserve incentives for valuable innovation while protecting consumers from overinflation of drug prices.

CONCLUSION

This Court should grant defendants' motion for summary judgment.

DATED: May 5, 2025

Respectfully submitted,

/s/ Joseph J. Wardenski

Joseph J. Wardenski
WARDENSKI P.C.
134 West 29th Street, Suite 709
New York, NY 10001
(347) 913-3311
joe@wardenskilaw.com

Attorney for Amici Curiae

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