IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MERCK & CO., INC.,
Plaintiff,

v.

XAVIER BECERRA, U.S. SECRETARY OF HEALTH & HUMAN SERVICES; CHIQUITA BROOKS-LASURE, ADMINISTRATOR OF CENTERS FOR MEDICARE & MEDICAID SERVICES; AND CENTERS FOR MEDICARE & MEDICAID SERVICES,
Defendants.

Case No. 1:23-cv-01615

BRIEF OF ECONOMISTS AND SCHOLARS OF HEALTH POLICY AS AMICI CURIAE IN SUPPORT OF DEFENDANTS AND IN OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

DEEPAK GUPTA
GUPTA WESSLER LLP
2001 K Street NW
Suite 850 North
Washington, DC 20006
(202) 888-1741
deepak@guptawessler.com

Counsel for Amici Curiae

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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. Because they are not lawyers, they do not directly address the parties' competing constitutional arguments. Instead, they submit this brief to provide the Court with 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; 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 Conti
Associated Professor,
Questrom Business School, Boston University

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[1] No party opposes the filing of this brief. 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

Merck's motion for summary judgment asserts (at 1–3) that the Inflation Reduction Act allows the government to "refus[e] to pay [the] true value" of medicines and "harms [] future innovation" under a pretense of "fair[ness]." This brief shows how Merck's contention reflects an overly simplistic and misleading account of the prescription-drug market.

The market for prescription drugs does not function like other markets. 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 its 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 recoups 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* 6 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 "true value" of the drug, the prices set during these periods reflect the market exclusivity under which drug manufacturers are operating.[2] This forces payors like Medicare to pay exorbitant prices for brand-name drugs without generic alternatives.

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

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 consumers a negotiating agent with enough clout to counter the pharmaceutical monopolist's excessive prices. The law now gives consumers a negotiating agent that has enough clout to counter the pharmaceutical monopolist in establishing a price. The harm to true innovation is negligible because any drug eligible for negotiation will almost certainly have already recuperated its investment many times over. This brief explains how, contrary to Merck's contention, the Inflation Reduction Act pushes the drug market's dynamics closer to competitive equilibrium, not further away.

ARGUMENT

I. Tensions between incentives for innovation and consumer protection frame the mechanics of the market for prescription drugs.

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

Research-and-development costs for new prescription drugs are high,[3] because the process to develop a prescription drug is long and clinical trials are expensive to organize. Research and development usually consists of early-stage basic science and pre-clinical proof-of-principle animal testing; clinical trials in humans (Phase 1); efficacy testing (Phases 2 & 3); and submission for FDA approval.[4] Early phases have high failure rates. Once a drug is submitted for approval, the chance that it will become a marketable product is greater than 50%.[5]

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[3] Richard G. Frank & Caitlin Rowley, *Much money to be made from developing drugs that will have negotiated prices*, Bloomberg (Sept. 5, 2023).

[4] Michael Hay et al., *Clinical development success rates for investigational drugs*, 32 Nature Biotechnology 1, 40–51 (2014); Chi Heem Wong et al., *Estimation of clinical trial success rates and related parameters*, 20 Biostatistics 2, 273–86 (2019); Katarzyna Smietana et al., *Trends in clinical success rates*, 15 Nature Revs. Drug Discovery 6, 379–80 (2017).

[5] Smietana, *Trends in clinical success rates*, at 379–80.

Although most new drugs are brought to the market by private companies, the federal government underwrites a substantial amount of costs, risk, and uncertainty. This mostly includes the cost of basic science and animal modeling but also can include proof-of-concept testing and, in rare cases, later-stage human clinical trials. The government invests in drug research primarily through the National Institutes of Health. 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 their development.[6] In contrast to private pharmaceutical companies, the federal government generally receives very limited royalties or financial return on these investments.[7]

Once a drug receives FDA approval, the industry's priority is to recuperate its investment costs and, ultimately, maximize its profits. The U.S. legal system aids this effort by providing manufacturers with two different types of market exclusivity for new drugs: patents and exclusivity periods. These measures block direct competition and provide a limited period of time to recuperate development costs and earn a profit.[8] 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

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[6] Ekaterina G. Cleary et al., *Contribution of NIH funding to new drug approvals 2010-2016*, 115 Proc. of the Nat'l Acad. of Scis. of the 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, 2010–2019*, 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] Richard G. Frank & Paul B. Ginsburg, *Pharmaceutical industry profits and research and development*, Brookings (Nov. 17, 2017).

other formulations, methods of use, and manufacturing 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 past the initial patent.

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.[9] During this time, generic versions of a drug cannot be sold and any profits from use are earned exclusively by the developer.[10] Various tactics are used by the large companies to extend exclusivity periods past the expiration of initial product patents—including settlements of patent challenges by generic firms, the late filing of patents, the refusal to provide samples to generic firms, filing of pretextual "citizen petitions" against competitors to delay market entry, and evergreening, when companies patent existing drugs with slight modifications.[11] Many of these tactics have been pursued by the FTC and DOJ as anticompetitive violations of antitrust laws, but they have been unsuccessful in halting the processes entirely.[12] As a result, the exclusivity for new drugs can extend anywhere from 7 to 35 years.[13]

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[9] Favour D. Makurvet, *Biologics vs. small molecules: Drug costs & patient access*, Med. in Drug Discovery, Nov. 23, 2020, at 1.

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

[11] 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).

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

[13] Benjamin Rome, *Market exclusivity length for drugs with new generic of biosimilar competition, 2012-2018*, 109 Clinical Pharmacology & Therapeutics 2, 367–71 (2021).

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

The protection of 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. The market is further complicated by the presence of insurance coverage.

In well-functioning markets, 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 ever seeing the true price of a drug because they only pay a small percentage of the cost, eliminating the drug companies' catalyst to set reasonable prices. Absent a mechanism to reel back such practices, like the Medicare negotiation program, companies can use unfettered market power to hike drug prices far past those that would be palatable to consumers.[14] While such temporary subsidization may be appropriate to aid in the recuperation of costs, pharmaceutical companies can hardly claim a right to perennial operation in such an imbalanced market.

Imagine a hypothetical drug that is worth $100 to consumers. Because people are insured — in part because of high drug prices — they pay only 20% of the cost of the drug at the time that the consumer buys it. Thus, the pharmaceutical company can price up to $500 per person without losing customers. The government notices this, and after *10 years* of this pricing model, passes legislation to bargain for lower prices (perhaps to $300). Merck's claim is equivalent to saying that any negotiated price below $500 violates free-market principles, and that the only acceptable

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[14] 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).

outcome is $500 pricing. The economic absurdity of this claim is self-evident.

The end of the exclusivity periods 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.[15] Once interchangeable products enter the market, competition between them and the brand naturally push prices down, making the drug more accessible to consumers.[16] This feature of the prescription-drug market has always been valuable to 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.[17] As state laws encourage the use of lower-cost generic drugs, spending on previously patent-protected drugs can often fall by as much as 80% within 24 months.[18] Insurance coverage, like that offered by Medicare Part D, also plays a crucial role in protecting consumers from the growing financial costs of prescription drugs and demand for pharmaceutical products. Health plans have implemented tiered benefit structures to steer patients and physicians to use generic versions of drugs whenever possible.[19] Such policies effectively reduce costs incurred by the consumer, especially considering that generic drugs are dispensed more than 90% of the time when they are available.[20]

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

[16] *Id.*

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

[18] 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).

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

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

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

Drug prices aren't the touchstone of innovation that pharmaceutical companies make them out to be. Empirical studies show that, on average, the expected number of patients and revenue of a drug cause more investment and entry than innovation.[21] Newer studies provide more insight, finding that much of the "innovation" marketed by drug companies is replication or rebranding. While the number of new drugs entering the market increased after the introduction of Medicare Part D, studies show that the new drugs were almost entirely in areas with five or more existing therapies, offering little by way of meaningful innovation.[22] A review for FDA approvals from 2007–2017 revealed that only about one-third of new drugs had "high therapeutic value," or in other words, offered more than a minimal improvement over drugs or other treatments already available.[23] Companies also advertise low therapeutic value drugs widely, [24] 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.[25] Further, drug companies took existing drugs that were viewed as insufficiently profitable prior to the creation of Medicare Part D and relaunched them as the market grew, while the market overall showed little evidence of increases in patenting or new

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[21] Pierre Dubois, Olivier de Mouzon, Fiona M. Scott Morton, et al., *Market Size and Pharmaceutical Innovation* 11 (TSE Working Paper, March 2014); Wesley Yin, *Market Incentives & Pharmaceutical Innovation*, 27 J. of Health Econ. 4, 1060–77 (2008).

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

[23] 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).

[24] Neeraj G. Patel, Aaron S. Kesselheim, et al., *Therapeutic value of drugs frequently marketed using direct-to-consumer television advertising, 2015-2021*, 6 JAMA Network Open 1, 1–3 (2023).

[25] Alexander C. Eligman, et al., *Added therapeutic benefit of top-selling brand-name drugs in Medicare*, 15 JAMA 1283, 1283–89 (2023).

published science.[26] Development of line extensions is the subject of much of the present pharmaceutical research-and-development spending; 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 focusing on extensions of existing drug franchises.[27] This kind of prioritization is incentivized. 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.[28]

II. The Inflation Reduction Act restores bargaining equity between manufacturers and consumers.

The Inflation Reduction Act counters these effects by permitting the U.S. Department of Health and Human Services to select drugs for price negotiation under Medicare. Opponents argue that the provisions decrease incentives for research and development. But the Inflation Reduction Act includes several safeguards to make a significant reduction in innovation unlikely.

For starters, the Inflation Reduction 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 (depending on whether it is a biological or small-molecule drug).[29] This by no

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

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

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

[29] Meena Seshamani, Ctr. for Medicare & Medicaid Servs., *Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2026* 13 (June 30, 2023).

means limits the companies' ability to cover their research-and-development costs plus a healthy rate of return on their investment. In fact, recent data on the earnings of all ten of the drugs selected for negotiation by the federal government under the Inflation Reduction Act shows that every single drug has recuperated its initial research-and-development costs (including the cost of failed iterations) and generated a surplus revenue of at least $13.7 *billion* since its launch.[30] The Inflation Reduction Act's provisions neither cut the company off from future profits nor shorten the time that it retains exclusivity. Far from the "nuclear winter for innovation" prophesied by pharmaceutical companies, it will at a maximum result in a "small chill in their profit margins."[31] The Act also exempts several categories of drugs from the negotiation program. The excluded categories include (1) drugs for a single rare disease for which it 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 its 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).[32]

In addition to protecting certain new drugs through exclusion, the Inflation Reduction Act leaves in place important opportunities that promote innovation and increase revenues for large and small pharmaceutical companies. It includes no restrictions on launch prices. Further, it adds provisions that increase demand for drugs and generate new revenues for the industry. Specifically, its cap on out-of-pocket costs for high-cost products—particularly those like insulin—will increase

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[30] Frank & Rowley, *Much money to be made from developing drugs that will have negotiated prices*.
[31] *Id.*
[32] Rachel Sachs, Richard G. Frank, et al., *A holistic view of innovation incentives and pharmaceutical policy reform*, 1 Health Affs. Scholar 1, 2 (2023).

adherence to treatment regimens and likely boost sales. The Act goes one step further for vaccines, eliminating out-of-pocket costs entirely. 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 important for innovation since emerging biopharma companies produced two-thirds of all new drugs in 2022.[33] Finally, alongside the Inflation Reduction Act are whole government biotechnology innovation initiatives like ARPA-H, which funds cutting-edge medical research.[34]

These combined measures spur innovation and enable companies to recuperate their investment while protecting consumers from a market-wide overinflation of drug prices. The prescription-drug market has tipped in favor of manufacturers for decades, and the Inflation Reduction Act takes important steps to restore its balance.

CONCLUSION

This Court should deny the plaintiff's motion for summary judgment.

Respectfully submitted,

/s/ Deepak Gupta
DEEPAK GUPTA
GUPTA WESSLER LLP
2001 K Street, NW, Suite 850 North
Washington, DC 20006
(202) 888-1741
deepak@guptawessler.com

Counsel for Amici Curiae

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[33] IQVA, *Global Trends in R&D 2023: Activity, Productivity, and Enablers* (Feb. 15, 2023).
[34] Sachs, *A holistic view of innovation incentives and pharmaceutical policy reform*, at 2.