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Public Citizen Statement for the Record
Hearing: "Medicines and IP: Balancing Innovation and Access"

United States House of Representatives Committee on the Judiciary
Subcommittee on Courts, Intellectual Property, Artificial Intelligence, and the Internet

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Public Citizen is a nonprofit consumer advocacy organization with more than 1 million members and supporters around the country. For more than 50 years, Public Citizen has championed the public interest before federal agencies, Congress, and the courts. Over those five decades, we have focused especially on drug safety and affordability.

This statement will briefly describe the policy landscape that drives America's drug pricing crisis, how drug corporation monopoly abuses contribute, and reforms Congress can take to begin to rein in these harmful tactics.

The American Drug Pricing Crisis

Big Pharma price gouging of Americans is worse now than at any time in Public Citizen's more than 50 years of existence. It has, truly, become intolerable and unsustainable. In a very rough outline, here's how drug development, manufacturing, approval and sales work in the United States:

1) The U.S. government spends tens of billions on the most fundamental biomedical research, with a hand in the research for almost every prescription drug that reaches the market. It gives away the fruits of its research unconditionally.
2) The U.S. government confers 20-year patent monopolies on new drugs and bestows other marketing exclusivities on drug corporations.
3) The U.S. government is the world's largest drug purchaser, but with modest exceptions, it forbids its largest drug purchasing program from negotiating prices with drug companies.

In other words, there is no "free market" for the pharmaceutical industry. The industry relies on massive public subsidies; it exploits government-granted monopolies; and it leverages its political power to prevent its largest purchaser from exercising its negotiation power.

The result of this system is exactly the injustice one would predict: massive profits for drug companies, sky-high CEO pay, monopoly pricing and widespread rationing of important and sometimes life-saving medicines.

Consider these facts:

- More than 40 percent of Americans report that they have skipped drug treatments or otherwise haven't taken medicines as prescribed because of cost.[1]
- The median launch price of a new drug in the United States jumped from $2,115 in 2008 to $180,007 in 2021, a 20 percent annual inflation rate, according to researchers at Brigham and Women's Hospital in Boston.[2] Since 2021, the median launch price has more than doubled, to $370,000 in 2024.[3]
- The top 20 Big Pharma companies have reported more than $400 billion in profits over the last three years (2023-2025).[4]
- The top 20 Big Pharma CEOs take home more than $300 million in collective pay every year.[5]
- The United States pays 3-4 times more for prescription drugs than other rich countries.[6]

There's nothing natural, or market-based, about these facts. They are the result of Big Pharma leveraging its political power to impose and maintain subsidies, monopolies and manifold protections.[7,8]

Big Pharma's Monopoly Abuse

Exploiting government-granted monopolies to charge captive payers and patients unfathomable prices is central to Big Pharma's business model. Prescription drug corporations aggressively exploit legal loopholes to strengthen and lengthen their patent monopolies. When drug corporations engage in legal tricks to strengthen and lengthen monopolies, it exposes our health system and patients to higher costs, limits access, and weakens incentives for companies to make true therapeutic advancements. Ultimately, this leads to increased health spending and poorer health outcomes for American patients.

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[1] Audrey Kearney, Alex Montero, Julian Montalvo III, Isabelle Valdes, Ashley Kirzinger, and Liz Hamel, "Public Views on Prescription Drug Costs: Regulation, Affordability and TrumpRx," KFF, March 13, 2025, https://www.kff.org/public-opinion/public-views-on-prescription-drug-costs-regulation-affordability-and-trumprx/

[2] Robert Langreth, "New Drug Prices Soar to $180,000 a Year on 20% Annual Inflation," *Bloomberg*, June 7, 2022, https://www.bloomberg.com/news/articles/2022-06-07/new-drug-prices-soar-to-180-000-a-year-on-20-annual-inflation

[3] Deena Beasley, "Prices for new US drugs doubled in 4 years as focus on rare disease grows," Reuters, May 22, 2025, https://www.reuters.com/business/healthcare-pharmaceuticals/prices-new-us-drugs-doubled-4-years-focus-rare-disease-grows-2025-05-22/

[4] Public Citizen analysis based on company 10-K disclosures.

[5] Public Citizen analysis based on company 10-K disclosures.

[6] Office of Assistant Secretary for Planning and Evaluation (ASPE), "Comparing Prescription Drugs in the U.S. and Other Countries: Prices and Availability," January 31, 2024, https://aspe.hhs.gov/reports/comparing-prescription-drugs

[7] Public Citizen and the Groundwork Collaborative, "Protecting the Profiteer", November 3, 2022, https://www.citizen.org/article/protecting-the-profiteer/

[8] Mike Tanglis, "Mapping the PhRMA Grant Universe", Public Citizen, December 15, 2023, https://www.citizen.org/article/mapping-the-phrma-grant-universe/

Over the medium- and long-term, policymakers should advance alternative research and development systems that delink[9] the costs of biomedical innovation from the end prices charged to patients and health systems, through prize funds, more upstream grant funding, and a greater public role in later stage development.

In the short term, policymakers must rein in the worst of pharma's patent monopoly abuses that cost taxpayers and patients billions of dollars by preventing access to lower-cost alternatives through reforms including **the ETHIC Act, the Drug Competition Enhancement Act, the Preserve Access to Affordable Generics and Biosimilars Act, and the Stop STALLING Act**.

Beyond current proposals, Congress should pass legislation that goes further to combat common pharmaceutical company monopoly abuses, including through reforming patent law so a secondary patent claiming a method of use for an indication which has already been disclosed or claimed in a primary patent relating to a product is obvious and, therefore, unpatentable,[10] and preventing the pharmaceutical industry from unfairly extending exclusivity on drugs through crystalline/polymorph patents.[11]

Patent Abuses Cost Billions

Patent evergreening occurs when drug corporations make trivial or obvious modifications to medications in order to lengthen exclusivity on brand name medicines. Public Citizen analysis of the first 10 drugs selected for the Medicare drug price negotiation program found that four of the 10 drugs subject to negotiation would likely have faced competition before negotiated prices went into effect were it not for evergreening tactics and patent abuses.[12] Pharmaceutical company tactics to extend their monopolies on these drugs included obtaining patents for minor or obvious variations including on (1) standard processes for screening compounds across the drug industry and (2) previously known information publicly available or disclosed in prior patents.[13] In other cases, companies used recently acquired patents that had nothing to do with producing a branded drug to block competing products and patented methods of screening patients to ensure the drug's safety and efficacy.[14]

As a result, Medicare lost between $4.9 and $5.4 billion in savings that should have accrued from access to competing, lower-cost treatments.[15] These lost savings are nearly as much as what Medicare was projected to save from negotiated prices going into effect on all of the selected drugs

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[9] Knowledge Ecology International, "What Is Delinkage?", Accessed June 1, 2026, https://delinkage.org/overview/

[10] I-MAK, Addressing Patent Thickets to Improve Competition and Lower Prescription Drug Price: A Blueprint for Reform 5 (2023).

[11] Jishian Ravinthiran, "Using the Inflation Reduction Act to Rein in Patenting & Evergreening Abuses," Public Citizen, December 11, 2024, https://www.citizen.org/article/using-the-inflation-reduction-act-to-rein-in-patenting-evergreening-abuses/

[12] Ibid.

[13] Ibid.

[14] Ibid.

[15] Ibid.

in the first year of the program ($6 billion).[16] Evergreening practices were prevalent across the drugs selected for price negotiation in the first year of the program. Nine out of 10 drugs subject to negotiation show evidence of manufacturers engaging in blatant anticompetitive uses of patents to fend off generic or biosimilar competitors or evergreening abuses representing minor modifications or tweaks that unfairly lengthen monopoly protection on the drugs.[17] Patent protection on the branded drugs could extend well into the 2030s and possibly 2040.[18]

Patent Thicketing

Drug companies build patent thickets by filing numerous patent applications with small changes that build on a previously filed parent patent. These continuation patents are obvious variants of previously issued patents. Drug firms even admit that these are obvious variants. However, companies can use a procedural tool, called a 'terminal disclaimer' to prevent the patent office from rejecting these applications as obvious variations of previously patented inventions. The disclaimers shorten the protection period of the continuation patent to that of the parent patent. Though these weak patents may not extend the patent life for the product, when companies secure multiple patents with interlocking claims covering the same invention, it becomes more difficult and costly for generics and biosimilars manufacturers to mount legal challenges and bring competition to market While challenging a small number of patents may be manageable, requiring generic entrants to confront seven or eight patents imposes a substantially greater litigation burden.

For example, experts in pharmaceutical patent law and policy with Harvard Medical School's Program On Regulation, Therapeutics, And Law (PORTAL) noted that the patent thicket surrounding mega-blockbuster Humira, held by AbbVie, "consist[ed] of 105 patents connected by 436 terminal disclaimers."[19] The Humira patent thicket "helped AbbVie reach settlement agreements that delayed biosimilar market entry in the U.S. by five years compared to entry in Europe."[20] Were **ETHIC** in place, AbbVie would have only been able "to sue potential competitors to prevent market entry with a maximum of 24 patents instead of 105,"[21] potentially decreasing the cost of entry for Humira biosimilars.

The **ETHIC Act** would help combat this monopoly abuse by allowing branded drug companies to assert only one patent per family of patents linked by terminal disclaimers in litigation. This would

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[16] Ctrs. Medicare & Medicaid Servs., Fact Sheet: Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026 (Aug. 14, 2024), https://www.cms.gov/newsroom/fact-sheets/medicare-drug-price-negotiation-program-negotiated-prices-initial-price-applicability-year-2026

[17] Jishian Ravinthiran, "Using the Inflation Reduction Act to Rein in Patenting & Evergreening Abuses," Public Citizen, December 11, 2024, https://www.citizen.org/article/using-the-inflation-reduction-act-to-rein-in-patenting-evergreening-abuses/

[18] Ibid.

[19] Chao B, Whalen R, Kesselheim AS, Tu SS. Clearing Dense Drug-Patent Thickets. N Engl J Med 2024; 39(23): 2180-2182 https://www.nejm.org/doi/full/10.1056/NEJMp2412999

[20] "Combating Pharmaceutical Patent Thickets In The Trump Administration", Health Affairs Forefront, August 13, 2025. DOI: 10.1377/forefront.20250811.410352

[21] Chao B, Whalen R, Kesselheim AS, Tu SS. Clearing Dense Drug-Patent Thickets. N Engl J Med 2024; 39(23): 2180-2182 https://www.nejm.org/doi/full/10.1056/NEJMp2412999

make it less onerous and costly for generics and biosimilars firms to challenge originator patents and bring price-lowering competition to market.

Product Hopping

Product hopping occurs when a drug corporation introduces a follow-on product with no significant therapeutic benefit over its predecessor and makes efforts to switch patients onto the new product to prevent potential generic or biosimilar competitors from gaining market share. This effectively prolongs monopoly pricing and profits for the drug corporation engaging in the abuse. Product hops of just five drugs have been estimated to cost the United States $4.7 billion annually.[22]

As proposed through the **Drug Competition Enhancement Act**, enacting a prohibition on product hopping and empowering the Federal Trade Commission (FTC) to enforce this prohibition would stop drug corporations from taking advantage of these unfair monopoly extensions.

Pay-for-Delay Reverse Patent Settlements

Pay-for-delay deals, also known as reverse payment settlements, occur when a brand-name drug corporation provides something of value to a generic or biosimilar manufacturer in exchange for that manufacturer delaying the launch of a competing product. In 2013, the Supreme Court took a small step forward. Through the Actavis decision, the Supreme Court decided that while not presumptively illegal, pay-for-delay deals could be contested under antitrust principles,[23] but many types of pay-for-delay arrangements have persisted. Pay-for-delay deals post-Actavis decision are estimated to cost taxpayers and patients from $6.2 to $37.1 billion dollars per year.[24]

As proposed through the **Preserving Access to Affordable Generics and Biosimilars Act**, making pay-for-delay reverse patent settlement deals presumptively anticompetitive and providing the FTC sufficient resources for aggressive enforcement would help put an end to this practice.

Citizen Petition Abuse

Citizen petition abuse occurs when a brand drug corporation formally raises with the Food and Drug Administration (FDA) safety concerns of a generic drug application to delay the launch of competition, and thereby inappropriately prolong the monopoly period for a brand-name drug. Drug corporations that file spurious petitions[25] raise drug prices for consumers and taxpayers and hamper the FDA with the burden of reviewing sham filings.

As proposed through the **Stop STALLING Act**, empowering the FDA to dismiss sham petitions filed with the primary purpose of delaying competition and the FTC to pursue suits against such

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[22] Brill, Alex. “The Cost of Brand Drug Product Hopping”, Matrix Global Advisors, September 2020, https://getmga.com/wp-content/uploads/2022/04/CostofProductHoppingSept2020.pdf

[23] Feldman, R. (2022). The Price Tag of "Pay-for-Delay". *Science and Technology Law Review*, *23*(1), 1–49. https://doi.org/10.52214/stlr.v23i1.9389

[24] Ibid.

[25] Michael A. Carrier, “Five Actions to Stop Citizen Petition Abuse”, Columbia Law Review Online, March 6, 2018, https://columbialawreview.org/content/five-actions-to-stop-citizen-petition-abuse-2/

petitioners would support more timely generic competition and lower prices for patients and consumers.

Conclusion

Public Citizen thanks the subcommittee for its exploration of prescription drug corporation monopoly abuses and how they contribute to the U.S. drug pricing crisis. We are grateful for the opportunity to comment on policies to rein in these abuses, lower drug prices, and improve access to medicines.