

PATIENTS FOR AFFORDABLE DRUGS NOW™

**Statement of Merith Basey
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to the

Subcommittee on Courts, Intellectual Property, Artificial Intelligence, and the Internet

of the

U.S. House Judiciary

for a hearing on

“Medicines and IP: Balancing Innovation and Access”

June 4, 2026

Section I. Background and Introduction

Thank you for holding this hearing to examine policies to lower prescription drug prices while continuing to spur innovation. My name is Merith Basey, and I am the Chief Executive Officer of Patients For Affordable Drugs Now (P4ADNow). We are the only national patient advocacy organization focused exclusively on policies to lower prescription drug prices. We are independent, bipartisan, and we do not accept funding from any organizations that profit from the development or distribution of prescription drugs—a position that distinguishes us from most patient advocacy groups.

Since our launch nearly 10 years ago, we have collected over 40,000 stories from patients struggling to afford their prescription drugs. Their stories span all 50 states and every congressional district. And we have built a community of over three-quarters of a million patients and allies supporting policies to lower prescription drug prices. Many patients in our community live with chronic, life-threatening, or rare conditions, but regardless of income, race, or zip code, they share a common experience: prescription drugs are unaffordable. One reason prices remain so high is that pharmaceutical companies increasingly exploit weaknesses in the patent system to extend monopolies beyond what Congress intended. One bipartisan solution before Congress today is the ETHIC Act, which would help restore balance by curbing patent thickets that block competition and keep prices high for patients.

Section II. The High Prices Americans Pay For Drugs and Need For Further Reforms

One in three people in the U.S. cannot afford to pay for their prescription drugs. On average, Americans pay at least four times more than people in other high-income nations for the same

brand-name drugs.¹ One survey found that over 20 percent of people took on debt or declared bankruptcy because of their medications. Nearly half of U.S. adults worry that they will not be able to afford necessary health care services in 2026.² Polling shows that the American public overwhelmingly understands that drug companies are responsible for high drug prices and that these corporations prioritize profits over patients.³

Americans have been demanding relief for years. A poll in July of 2023 found that three out of four Americans said there is not enough government regulation when it comes to limiting the price of prescription drugs.⁴ A 2025 poll found that roughly nine in ten Americans across the political spectrum want Congress to take action to lower the price of prescription drugs.⁵ In this election cycle, healthcare costs, including those for prescription drugs, top the list of Americans' economic anxieties.⁶

Prescription drug prices remain sky high in the U.S. because pharmaceutical corporations largely dictate what the health system—and patients—pay. Drug companies routinely abuse the patent system to block generic competition and to extend monopolies far beyond the intended period, all while extorting patients with annual price hikes, often even more than once per year. The entry of generic and biosimilar competition leads to lower costs for patients; a single generic can lower the cost of a prescription drug by 30 percent, and the entry of six or more generics can lower prices by nearly 85 percent.⁷ Recent polling shows that eighty percent of Americans across party lines support changes to patent laws to address high drug prices and ninety percent of Americans support policies that lead to faster access to generic and biosimilar drugs.⁸

Section III. The Need for Patent Reform

When a drug company makes a genuinely innovative discovery, it should be rewarded with a patent and receive a fair return for the risk and investment it undertook. The intention behind much of the patent system governing prescription drugs was to incentivize true clinical breakthroughs and inventions that bring meaningful benefits to patients. However, rather than solely prioritizing true innovation, drug manufacturers regularly find creative ways to abuse the patent system in order to strengthen their monopolies for existing drugs. Such action stymies market competition, costing patients and taxpayers billions of dollars annually.⁹

¹(2024, February 1). International Prescription Drug Price Comparisons. RAND Corporation.

https://www.rand.org/pubs/research_reports/RRA788-3.html

²(2025, November 18). How Do Americans Experience Healthcare in Their State?, Gallup.

<https://news.gallup.com/poll/698042/americans-experience-healthcare-state.aspx>

³(2025, April 22). Majority of Americans Support Lower Drug Prices, Demand Congress Act, Fabrizio Ward.

<https://www.arnoldventures.org/newsroom/new-poll-majority-of-americans-support-lower-drug-prices-demand-congress-act>

⁴(2023, August 4). KFF Health Tracking Poll July 2023: The Public's Views Of New Prescription Weight Loss Drugs And Prescription Drug Costs, KFF.

<https://www.kff.org/health-costs/kff-health-tracking-poll-july-2023-the-publics-views-of-new-prescription-weight-loss-drugs-and-prescription-drug-costs/>

⁵(2025, April 2022). *New Poll Finds Americans Agree, Drug Prices are Too High and Congress Needs to Act*, Arnold Ventures.

<https://www.arnoldventures.org/resources/national-targeted-ed-registered-voter-surveys>

⁶(2026, March 31). *Healthcare Reclaims Top Spot Among U.S. Domestic Worries*, Gallup.

<https://news.gallup.com/poll/707732/healthcare-reclaims-top-spot-among-domestic-worries.aspx>

⁷(2022, March 17). *The Generic Drug Approval Process*, Food and Drug Administration

<https://www.fda.gov/drugs/cder-conversations/generic-drug-approval-process>

⁸(2025, October). *Understanding Americans' Top Concerns on Drug Pricing: Corporate Greed*, I-MAK.

<https://reports.i-mak.org/drug-pricing-concerns/>

⁹(2023, May 16). *The Costs of Pharma Cheating*, The American Economic Liberties Project.

<https://www.economicliberties.us/our-work/the-costs-of-pharma-cheating/>

Patents do not always equal new innovation. Between 2005 and 2015, 74 percent of the new drug patents issued were for drugs already on the market.¹⁰ A second study of the ten top-selling drugs in 2021 corroborated that finding; of the roughly 100 best-selling drugs in another study, nearly 80 percent obtained an additional patent to extend their monopoly period.

One of the ways pharmaceutical manufacturers block competition is “patent thickets”. Manufacturers will file as many patents as possible on a drug to create a dense cluster of overlapping non-innovative patents to prevent market competition and maintain their monopolies – keeping prices high for as long as possible. U.S. patent law prohibits patent filers from receiving multiple patents on obvious variants of the same invention, but big drug companies avoid rejections by filing duplicative and non-innovative patents with a terminal disclaimer. A terminal disclaimer is the legal mechanism that allows these obvious iterations of the same patent to be filed as long as the secondary patent expires at the same time as the original patent. Collectively, they form a fortress on a single medication. Generic and biosimilar companies that intend to bring a competing product to market must overturn every individual patent in the thicket via expensive and time-consuming litigation. The process can be so cost-prohibitive that generic and biosimilar companies do not even attempt it.

Patent thicketing through terminal disclaimers is rampant in the industry. A report released last month shows that the share of drug patents with terminal disclaimers has risen steadily in the past two decades, from roughly 36 percent among patents filed between 2002 and 2006 to nearly 70 percent among those filed from 2017 to 2021.

The pharmaceutical industry is also abusing terminal disclaimers to file patents that should never have been granted. Research shows that of 7,836 drug patents filed from 2002 to 2022 and listed in any edition of the Orange Book,¹¹ 50 percent had both a double patenting rejection in their prosecution history as well as a terminal disclaimer approved by the United States Patent and Trademark Office (USPTO). The pharmaceutical industry is also increasingly relying on these noninnovative patents in patent litigation to block competition from generic or biosimilar companies, with 60 percent of all district court disputes between 2011 and 2020 involving at least one patent subject to a terminal disclaimer, rising from 45 percent of cases filed in 2011 to 74 percent in 2020.¹² In recent years, these secondary patents made up nearly half of all patents litigated on small-molecule drugs and one-third of those on biologics.¹³

H.R.3269, the ETHIC Act

The ETHIC Act would help curb the practice of patent thicketing by limiting the number of patents a drug manufacturer could assert during litigation to one per terminally disclaimed patent family. Brand-name manufacturers would still be able to sue over patent infringement, but they could not pursue litigation for multiple duplicative patents that pertain to the same feature of a

¹⁰(2022, September 15). Overpatented, Overpriced: Curbing Patent Abuse, I-MAK.
https://drive.google.com/file/d/1sZP6oK9z6afEM9dUFRDGhWPTXw_imEnb/view

¹¹ The Orange Book is the FDA’s official publication of all FDA-approved drugs and their related patent and exclusivity information.

¹² (2026, May 6). *Patent Thickets Increase Costs and Delay Access to Medicines for Young Adult Patients*, Generation Patient.
<https://static1.squarespace.com/static/5c11eb6ab40b9daef16158a9/t/69fb5f42d6db837b19d38e9c/1778081607804/Patent+Thicket+Report.pdf>

¹³(2024, August 12). *Extent of Drug Patents with Terminal Disclaimers and Obviousness-Type Double Patenting Rejections*, JAMA.
<https://jamanetwork.com/journals/jama/fullarticle/2822181>

drug. This would lower the barrier to entry for generics and biosimilars and allow market forces to bring down prices for consumers. Importantly, the ETHIC Act does not shorten a single patent term or revoke a single valid patent. Brand-name companies would retain every patent protection Congress intended them to have. The bill simply prevents companies from asserting multiple duplicative patents covering the same invention in order to delay competition. If the ETHIC Act had been law in 2010, the number of biologic patents subject to litigation would have dropped 46 percent from 271 to 147.¹⁴ As a result, biosimilar companies would have faced fewer legal barriers to market entry and could have offered affordable versions to patients more readily.

Continuing to allow abuse of the patent system not only keeps drug prices artificially high at the expense of American patients but also harms bona fide innovation. Innovation should be rewarded. Manipulation should not. When big drug companies can block competition and raise prices at will on existing drugs, they face less pressure to invest in the development of the next generation of breakthrough treatments.

Section IV. Other Reforms to Improve Competition

Patent thicketing is just one of a number of strategies and tactics used by drug corporations to abuse the patent system and further entrench monopolies. Other practices include product hopping, evergreening, pay-for-delay deals, and abuse of the U.S. Food and Drug Administration (FDA)'s citizen petition process.

In addition to supporting the ETHIC Act, Patients for Affordable Drugs Now supports additional reforms to improve competition in the prescription drug market. All have bipartisan support. Each of these bills passed favorably out of the Senate Judiciary Committee in March 2025.¹⁵ In addition, the Congressional Budget Office (CBO) has found that this package of policies would reduce federal spending by billions of dollars due to increased competition. P4ADNow supports:

- [S.1041](#), the Affordable Prescriptions for Patients Act, which cracks down on patent thickets in the biologic market and would bring biosimilars to market faster.
- [S.1040](#), the Drug Competition Enhancement Act, which would address product hopping. This tactic occurs when a brand-name company switches a patient population from an older product whose patent is coming to an end and facing imminent competition to a different formulation that has a later-expiring patent and therefore, is not facing competition. The “new” drug typically offers little or no new clinical benefit; it may even be as simple as changing a product from a tablet to a capsule.
- [S.1096](#), a bipartisan bill to curb pay-for-delay agreements. This tactic occurs when brand-name drug companies provide something of value to a potential competitor to induce them to delay selling a generic version of a drug, therefore keeping it off the market in order for the brand-name drug to maintain a monopoly for longer.

¹⁴(2025, August 13). *Combating Pharmaceutical Patent Thickets In The Trump Administration*, Health Affairs. <https://www.healthaffairs.org/content/forefront/combating-pharmaceutical-patent-thickets-trump-administration>

¹⁵(2025, March 3). *Senate Judiciary Committee Advances Grassley-Led Bills to Lower Prescription Drug Prices*, Senate Judiciary Committee. <https://www.judiciary.senate.gov/press/rep/releases/senate-judiciary-committee-advances-grassley-led-bills-to-lower-prescription-drug-prices>

- [S.1095](#), the Stop STALLING Act, which would reform the citizen petition process and promote generic competition. This process at the FDA was designed so that patients could raise safety concerns about drug approvals. However, research has revealed that the citizen petition process has been co-opted by corporations looking to block competition. Brand-name drug makers were behind 92% of all citizen petitions filed between 2011 and 2015. But they were not raising legitimate safety concerns, which is why the FDA threw out nine of every 10 of the industry’s “sham” petitions, which were without scientific merit and filed for the sole purpose of delaying generic competition, keeping prices high for patients.
- [S.1097](#), which would establish a task force between the USPTO and FDA in order to improve communication in the implementation of each agency's patent-related activities.

Industry criticizes the aforementioned bills, including ETHIC, as threats to innovation. Patients want and need innovation. In fact, innovation matters to no one more than it does to patients. Lives depend on it. The notion, however, that pharmaceutical research and development (R&D) necessitate astronomical list prices is disingenuous. Taxpayers underwrite innovation, with over 99 percent of drugs that received approval by the FDA between 2010 and 2019 benefiting from federal support.¹⁶ And a West Health analysis found that major brand-name pharmaceutical companies could lose a trillion dollars over a decade and still remain the most profitable industry.¹⁷

Section VI: Conclusion

Let’s be clear: Big Pharma is not fighting for the interest of patients or because lowering its prices will cripple innovation. It’s fighting to preserve its economic power to dictate and maintain exorbitantly high prices of brand-name drugs—a power it does not hold in any other country. The head of the powerful trade association, PhRMA, acknowledged this reality in a moment of candor when he said in an interview that his industry is “particularly adept at ... rolling the tanks, if you will, to push back against policy proposals *adverse to the industry’s interests.*”

Rather than confront its role in driving high prices, the industry seeks to shift blame and distract from its central role in making drugs unaffordable. But we cannot overlook the harm that patients experience. These harms are not abstract. They are experienced every day by people across the country.

Drugs don’t work if people can’t afford them. To achieve true innovation at prices that are affordable for patients, we must reform our patent system so that it is once again focused on driving innovation that saves lives, not driving high prices that make lifesaving drugs unaffordable to those whose lives depend on them.

¹⁶ (2023, April 28). *Comparison of Research Spending on New Drug Approvals by the National Institutes of Health vs the Pharmaceutical Industry, 2010-2019*, NIH National Library of Medicine. <https://pmc.ncbi.nlm.nih.gov/articles/PMC10148199/>

¹⁷(2019, November 14). *New Analysis Finds Large Drugmakers Could Lose \$1 Trillion in Sales and Still Be the Most Profitable Industry*. West Health. <https://westhealth.org/news/new-analysis-finds-large-drug-makers-could-lose-1-trillion-in-sales-and-still-be-the-most-profitable-industry/#:~:text=Adjusting%20the%20analysis%20to%20apply,61>

Kevin from Eugene, Oregon, takes Rinvoq, which has a list price of \$7,090.41 and would likely see a lower-cost generic alternative under ETHIC. He struggles to afford Rinvoq along with the rest of his regimen.¹⁸

“The insane cost of these medications, which is about \$2,000 out of pocket for me, has tremendously affected my life. I have to choose between food and medication or even take more extreme measures to make sure I don’t get sick. In addition, I spend approximately three hours on the phone trying to order medications, which take away from my time in class, with friends, and loved ones. Due to the difficulty in getting these medications, I have never experienced a full remission, meaning that I am significantly weaker than those my own age. It is indescribable being a twenty-something that can’t keep up with his friends.”

Kevin's experience is exactly why patent reform matters. Every year competition is delayed means another year patients face unaffordable prices and impossible choices.

Congress must not only protect the recent policy wins that are already delivering savings for patients and taxpayers but must also advance reforms to make the prescription drug system work for the people it is meant to serve. Patients are rationing medications and deciding between paying rent and paying for prescriptions. We cannot wait for competition. Congress must act now to pass the bipartisan ETHIC Act and lower drug prices for Americans. Every American should be able to get the prescription drugs they need at prices they can afford.

Thank you.

¹⁸ (2026, June 2). *Rinvoq Price History*, Analysource. <https://www.analysource.com/products/ndc/74231030>