PATIENTS FOR AFFORDABLE DRUGS NOW™

Statement of Merith Basey
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to the

Senate Judiciary Committee

for a hearing on

"Prescribing Sunshine: How Competition & Transparency Lower Prescription Drug Costs"

November 17, 2026

Chairman Grassley, Ranking Member Durbin, Members of the committee, thank you for the opportunity to testify today on the urgent need to lower prescription drug costs by increasing competition, improving transparency, and protecting genuine innovation.

Competition is one of the most effective tools we have to lower prescription drug prices. Yet, pharmaceutical companies routinely exploit weaknesses in our patent and regulatory systems to keep competitors off the market and preserve their monopolies, forcing patients to pay higher prices for longer. Congress has bipartisan solutions before it to address these abuses, ensure our laws work as intended, and deliver long-overdue relief to millions of Americans.

Section I. Background and Introduction

My name is Merith Basey, and I am the Chief Executive Officer of Patients For Affordable Drugs Now (P4ADNow), the only national patient advocacy organization focused exclusively on policies to lower prescription drug prices. We are bipartisan and 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.

Founded nearly a decade ago by David Mitchell, a multiple myeloma patient, our organization has collected more than 40,000 stories from patients struggling to afford their prescription drugs. Those stories span all 50 states, every congressional district, Puerto Rico, and the District of Columbia. We have built a community of hundreds of thousands of patients and allies advocating for 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: their prescription drugs are unaffordable. One in three Americans struggles to afford their prescription drugs.[1]

[1] (2023, March). *More than one-third of Americans haven't filled a prescription due to cost: survey*. The Hill. https://thehill.com/changing-america/respect/poverty/3893811-more-than-one-third-of-americans-havent-filled-a-prescription-due-to-cost-survey/

A major driver of this crisis is a patent and regulatory system that pharmaceutical companies have learned to manipulate to protect their profits at patients' expense.

Our patent system serves an essential purpose: rewarding genuine invention and encouraging the development of new treatments that can save lives. But that bargain depends on competition taking hold when legitimate monopoly protections end. Instead, drug companies have developed strategies to manipulate these protections to extend their market exclusivity, delaying competition and keeping more affordable alternatives out of reach.

Take Kevin, a young man from Eugene, Oregon, who relies on Rinvoq to treat his Crohn's disease. The drug carries a list price of more than $7,000 per month.

He told us:

"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 takes 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 who can't keep up with his friends."

Reforms to the patent system would reduce barriers to future competition for medicines like Rinvoq. But until then, Kevin will struggle to afford the treatments he needs.[2]

Every month competition is unnecessarily delayed is another month patients like Kevin are forced to pay unaffordable prices, sacrifice basic needs, or go without the medicines they depend on.

Kevin should be spending his twenties going to school, spending time with friends, and building his future, but his experience illustrates the consequences of a prescription drug market that too often puts corporate profits ahead of patients.

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

The U.S. prescription drug supply chain involves a complex web of corporate actors. And every actor in the chain makes a profit. Pharmaceutical manufacturers develop drugs and set their list prices, while pharmacy benefit managers (PBMs) serve as middlemen between drug makers and insurers, managing formularies and negotiating rebates. Historically, PBM practices have created incentives to favor high-list-price drugs. Increasingly, large conglomerates own insurers, pharmacies, and PBMs, allowing them to generate revenue at multiple points in the supply chain.[3] The current system prioritizes maximizing profits, not meeting patients' needs.

[2] (2026, June). *Rinvoq Price History*. Analysource. https://www.analysource.com/products/ndc/74231030
[3] (2024, July). *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies*. The Federal Trade Commission. https://www.ftc.gov/reports/pharmacy-benefit-managers-report

The three largest PBMs control more than 80 percent of the prescription drug market and are integrated with both pharmacies and insurers, giving them significant influence over which medicines patients can access and what they pay.[4]

But other actors in the supply chain must not obscure the central role manufacturers play in determining prescription drug prices. Drug companies alone set a medicine's launch price, and their efforts to delay competition allow them to preserve monopoly pricing far beyond what Congress intended.[5,6] According to America's Health Insurance Plans (AHIP), prescription drugs account for roughly 24 cents of every dollar spent on health insurance premiums.[7] A 2024 report by the Assistant Secretary for Planning and Evaluation (ASPE) of Health and Human Services (HHS) found that high list prices likely contribute to higher patient cost-sharing, meaning that reductions in net prices do not necessarily translate into lower out-of-pocket costs.[8] Polling consistently shows that Americans recognize drug companies' central role in driving high prescription drug prices.[9]

Patients bear the consequences of our rigged prescription drug system. Americans pay, on average, at least four times more for the same brand-name prescription drugs than people in other high-income countries.[10] More than one in five Americans report taking on debt or declaring bankruptcy because of medication costs. Nearly half of U.S. adults were worried they would not be able to afford necessary health care services this year.[11]

Americans have been demanding relief for years. Nine in ten support congressional action to lower the price of prescription drugs, 80 percent support changes to patent laws to address high drug prices, and 90 percent support policies that lead to faster access to generic and biosimilar medicines.[12,13] Healthcare costs, including prescription drug prices, ranked among Americans' top concerns during the recent election cycle.[14]

Section III. Competition is one of the most powerful tools we have to lower prescription drug prices.

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[4] (2024, July). *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies.*The Federal Trade Commission. https://www.ftc.gov/reports/pharmacy-benefit-managers-report

[5] (2025, December). *Driven by GLP-1s, prescription drug spending explodes at major health insurers*. STAT News. https://www.statnews.com/2025/12/08/health-insurers-spending-more-on-prescriptions-glp-1-drugs-cited/

[6] (2024, April). *The impact of rising prescription drug costs on employers and employees.* Marsh & McLennan Agency. https://www.marshmma.com/us/insights/details/health-care-economics.html

[7] (2026, January). *Health Care Costs 101: What's Driving Premiums Higher and How to Make Coverage More Affordable*. America's Health Insurance Plans. https://www.ahip.org/news/articles/health-care-costs-101-whats-driving-premiums-higher-and-how-to-make-coverage-more-affordable

[8] (2024, November). *Prescription Drug Spending, Pricing Trends, and Premiums in Private Health Insurance Plans*. Assistant Secretary for Planning and Evaluation. https://www.dol.gov/sites/dolgov/files/ebsa/laws-and-regulations/laws/no-surprises-act/2024-report-to-congress-prescription-drug-spending.pdf

[9] (2025, April). *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

[10] (2024, February). *International Prescription Drug Price Comparisons*. RAND Corporation. https://www.rand.org/pubs/research_reports/RRA788-3.html

[11] (2025, November). *How Do Americans Experience Healthcare in Their State?* Gallup. https://news.gallup.com/poll/698042/americans-experience-healthcare-state.aspx

[12] (2025, April). *New Poll Finds Americans Agree, Drug Prices are Too High and Congress Needs to Act*, Arnold Ventures. https://www.arnoldventures.org/resources/national-targeted-cd-registered-voter-surveys

[13] (2025, October). *Understanding Americans' Top Concerns on Drug Pricing: Corporate Greed*. I-MAK. https://reports.i-mak.org/drug-pricing-concerns/

[14] (2026, March). *Healthcare Reclaims Top Spot Among U.S. Domestic Worries*. Gallup. https://news.gallup.com/poll/707732/healthcare-reclaims-top-spot-among-domestic-worries.aspx

While a drug is protected from competition, pharmaceutical companies have enormous, unilateral pricing power. When legitimate exclusivity ends, competition should begin — and the evidence shows just how much patients stand to gain.

The entry of a single generic competitor can lower the cost of a prescription drug by 39 percent (compared to the brand-name drug), while six or more generics can lower prices by up to 95 percent.[15] Biosimilars typically have a list price 15 to 35 percent lower than that of reference products, and evidence suggests a 10 to 13 percent decrease in brand-name price for every biosimilar that enters the market.[16,17] Over the past decade, generic medicines have saved patients and the U.S. health care system nearly $3 trillion, while biosimilars have generated $36 billion in savings since entering the market in 2015.[18]

Those savings explain why drug companies have such a powerful financial incentive to delay competition. Brand-name drug companies deploy a range of tactics to protect their blockbuster products from competition, including building patent thickets around existing medicines, shifting patients to slightly modified products through product hopping, entering into pay-for-delay agreements, and exploiting regulatory processes intended for other purposes. Each tactic operates differently, but the result is the same: competitors are kept off the market, monopoly pricing persists, and patients, employers, health plans, and taxpayers pay more.

These practices undermine a core purpose of our patent and regulatory systems. Our laws were designed to reward genuine inventions while allowing competition in the marketplace to drive down prices — not to give drug companies the tools to pursue strategies to extend their monopolies indefinitely. But when manufacturers can manipulate these systems to keep competitors out, the market cannot function as intended, and patients are denied the lower prices that competition should deliver.

Strong enforcement is also essential. We support continued Federal Trade Commission (FTC) action against anticompetitive practices that delay competition and keep prescription drug prices high.

Recent FTC settlements with PBM giants Caremark, Express Scripts, and OptumRx over practices associated with inflated insulin prices represent important steps toward addressing abuses throughout the supply chain. The FTC has also challenged improperly listed device patents that can obstruct generic competition, including through warning letters that led to the delisting of improper patents for QVAR RediHaler.[19,20]

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[15] (2019, December). *Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices*. The Food and Drug Administration. https://www.fda.gov/media/133509/download

[16] (2020, March) *FDA Officials Predict More Insulins Under New Biologics Pathway.* The Center For Biosimilars. https://www.centerforbiosimilars.com/view/fda-officials-predict-more-insulins-under-new-biologics-pathway

[17] (2025, May) *The Price Effects of Biosimilars in the United States.* Value in Health: Volume 28, Issue 5, Pages 742-750. https://www.sciencedirect.com/science/article/pii/S1098301525000865

[18] (2024, September). *The U.S. Generic & Biosimilar Medicines Savings Report*. The Association for Accessible Medicines. https://accessiblemeds.org/wp-content/uploads/2025/01/AAM-2024-Generic-Biosimilar-Medicines-Savings-Report.pdf.

[19] (2023, November). *Improper Orange Book-Listed Patents for QVAR RediHaler.* United States Federal Trade Commission. https://www.ftc.gov/system/files/ftc_gov/pdf/norton-orange-book.pdf

[20] (2026, November.) *Delisted Patents.* Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. The United States Food and Drug Administration. https://www.accessdata.fda.gov/scripts/cder/ob/search_patent.cfm?listed=delisted

For patients, these practices have real financial consequences. Charlene from Iowa shared that her family paid more than $500 per month for QVAR RediHaler. The cost placed such a significant strain on their finances that her husband delayed retirement.

Charlene's experience illustrates why enforcement matters. When companies use the patent and regulatory systems to obstruct competition, patients and families are left paying the price. Congress must strengthen the tools available to prevent these abuses and ensure that lower-cost medicines can reach patients without unnecessary delay.

Section IV. The Need for Patent and Regulatory Reform

Drug companies should earn profits by developing new and novel medicines—not by exploiting loopholes to extend monopolies on existing drugs. Congress must advance bipartisan reforms to restore the balance our patent system was intended to strike: rewarding genuine invention while allowing lower-cost competition to reach patients without unnecessary delay.

Exploitation of the patent system stifles both genuine innovation and competition while costing patients and taxpayers billions of dollars every year.[21]

Not every patent that is granted represents a discovery or meaningful innovation. Between 2005 and 2015, 74 percent of drug patents issued were for products already on the market.[22] A study of the ten top-selling drugs in 2021 found a similar conclusion, and another study determined that nearly 80 percent of the roughly 100 best-selling drugs obtained an additional patent to extend their monopoly period.[23] The industry's litigation strategies reflect this pattern: the majority of drug patents involved in litigation are continuation patents, often covering changes in formulation or new uses rather than entirely new medicines that patients need.[24]

Patent Thickets

One of the most consequential ways drug companies delay competition is building “patent thickets” around existing medicines.

Rather than relying solely on patents protecting a drug’s core innovation, manufacturers accumulate dozens, sometimes hundreds, of additional patents covering secondary features of the same product. Together, these overlapping patents create a legal fortress around blockbuster drugs, making it extraordinarily difficult for generic competitors to enter the market.

Consider the migraine drug Symbravo, which has more than 90 patents, the majority of which are non-innovative.[25] Two of the patents cover the same method of treatment, but one says it

[21] (2023, May). *The Costs of Pharma Cheating*, The American Economic Liberties Project. https://www.economicliberties.us/our-work/the-costs-of-pharma-cheating/
[22] (2022, September). *Overpatented, Overpriced: Curbing Patent Abuse*. I-MAK. https://drive.google.com/file/d/1sZP6oK9z6afFM9dUFRDGhWPTXw_imEnb/view
[23] (2017, November). *Most New Drug Patents Are for Old Remedies, Research Shows*. Bloomberg. https://www.bloomberg.com/news/articles/2017-11-01/most-new-drug-patents-are-for-old-remedies-research-shows
[24] (2023, September). *Why Pharmaceutical Patent Thickets are Unique*, Texas Intellectual Property Law Journal. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4571486
[25] (2026, May). *Patent thicket asserted by Axsome against Apotex.* Generation Patient. https://generationpatient.org/symbravo-patents

provides "pain relief" while the other offers "pain freedom."[26] In other words, the manufacturer has obtained separate patents for claims that appear to describe essentially the same benefit. That is not the kind of meaningful medical innovation the patent system was designed to reward. Yet each patent can become another obstacle a competitor must overcome before bringing a lower-cost alternative to patients.

The resulting litigation is extremely costly and time-consuming, and the prospect of defending against dozens of patents can delay market entry for years or discourage competition altogether. **For the brand-name manufacturer, every additional month without competition can mean millions in continued monopoly revenue. For patients, it means another month without access to lower-cost alternatives.**

Terminal disclaimers have become an increasingly important part of this strategy.

U.S. patent law generally prohibits a company from obtaining multiple patents on obvious variations of the same invention. When the U.S. Patent and Trademark Office (USPTO) rejects an application for this type of "double patenting," a manufacturer may overcome the rejection by filing a terminal disclaimer, agreeing that the later patent will expire at the same time as an earlier related patent.

Although terminal disclaimers do not extend the expiration date of the original patent, they create another patent that a generic or biosimilar competitor may have to address through litigation before entering the market. As these overlapping patents accumulate, they increase the density of the patent thickets, making competition substantially more difficult and expensive.

A recent report examining the Food and Drug Administration's (FDA) Orange Book found that 70 percent of drug patents filed between 2017 and 2021 had terminal disclaimers, compared with roughly 36 percent among patents filed between 2002 and 2006.[27] Research examining more than 7,000 drug patents filed between 2002 and 2022 and listed in the FDA's Orange Book found that half had both a double-patenting rejection and a terminal disclaimer approved by the USPTO.[28,29]

These patents are increasingly prominent in litigation. Sixty percent of district court pharmaceutical patent disputes between 2011 and 2020 involved at least one patent subject to a terminal disclaimer, with the share rising from 45 percent in 2011 to 74 percent in 2020.[30]

S. 2276, the ETHIC Act

Congress has a bipartisan solution to address this problem: The ETHIC Act.[31]

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[26] U.S. Patent No. 11,135,295, claim 1; U.S. Patent No. 11,207,328, claim 1. Both patents are listed in the Orange Book for NDA 215431 (Symbravo).
[27] (2026, May). Generation Patient published a new report finding terminal disclaimers on most drug patents, asserted in 74% of 2020 drug litigation. Generation Patient. https://generationpatient.org/blog/patent-thickets
[28] The Orange Book is the FDA's official publication of all FDA-approved drugs and their related patent and exclusivity information.
[29] (2026, May). *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
[30] (2026, May). *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
[31] Please see the bill text: https://www.congress.gov/bill/119th-congress/senate-bill/2276/text

The ETHIC Act would limit the number of patents a drug manufacturer could assert during litigation to one patent from each terminally disclaimed patent family. Brand-name manufacturers would retain the ability to enforce their genuinely innovative patents in court. But they could no longer weaponize duplicative patents to keep lower-cost competitors off the market, forcing patients to pay higher prices for longer.

This legislation would apply to both small-molecule drugs and biologics. An analysis of biologic patent litigation found that, had the ETHIC Act been in effect in 2010, the number of biologic patents subject to litigation would have fallen by 46 percent, from 271 to 147.[32] Significantly reducing the legal barriers facing biosimilar manufacturers interested in bringing a competitor to market. According to a preliminary Congressional Budget Office (CBO) estimate, the bill would save at least $4 billion over the next decade.[33]

Stelara, a blockbuster treatment for autoimmune diseases including plaque psoriasis and psoriatic arthritis, illustrates the potential consequences of delayed biosimilar competition. Biosimilar equivalents did not become available until 2025; had the ETHIC Act been law, competition for Stelara likely would have arrived sooner.[34]

Patricia from California described what monopoly prices have meant for her: “I can't afford Stelara at all. I live on $1,550 per month, and the cost is $2,000 a month.”

Patients like Patricia should benefit from lower-cost competition as soon as it is legally possible—not years later because of litigation over non-innovative, overlapping patents that only serve to benefit pharmaceutical corporations.

S. 1041, the Affordable Prescriptions for Patients Act

P4ADNow has also endorsed S. 1041, the Affordable Prescriptions for Patients Act, which addresses patent thickets in the biologic market before litigation begins.[35]

Under the current system, a biosimilar developer shares its application with the brand-name (reference) biologic manufacturer, initiating a process known as the “patent dance” to identify which patents may be litigated. S. 1041 would limit the number of patents that a brand-name company could select for assertion against a biosimilar competitor to 20, with restrictions on patents filed more than four years after FDA approval. This provision of the bill would help prevent manufacturers from using large numbers of later-filed, typically secondary patents to prolong litigation and delay biosimilar competition.[36]

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[32] (2025, August). *Combating Pharmaceutical Patent Thickets In The Trump Administration*, Health Affairs. https://www.healthaffairs.org/content/forefront/combating-pharmaceutical-patent-thickets-trump-administration
[33] (2026, November). *Letter to Senate Leadership on Patent Reform*, The ERISA Industry Committee. https://www.eric.org/wp-content/uploads/2026/11/11-10-26-Biosimilar_Patent_Reform_Leadership_Letter-ERIC_FINAL.pdf
[34](2024, December). *FDA Approves Steqeyma: The Seventh Stelara Biosimilar*, AJMC https://www.centerforbiosimilars.com/view/fda-approves-steqeyma-the-seventh-stelara-biosimilar
[35] Please see the bill text: https://www.congress.gov/bill/119th-congress/senate-bill/1041/text
[36] (2026, October). *Patent Thickets, Product Hops, and Skinny Labels: Congress Takes on Patent Reform,* R Street. https://www.rstreet.org/commentary/patent-thickets-product-hops-and-skinny-labels-congress-takes-on-patent-reform/

This Committee favorably voted on S. 1041 in 2025, and the bill passed the Senate unanimously this past summer.[37]

Product Hopping

Another tactic manufacturers use to preserve monopoly pricing is "product hopping," in which companies shift patients from a drug approaching generic competition to a slightly modified, newly patented version.

These changes may offer little or no meaningful clinical benefit. They can involve modifications as minor as changing a tablet to a capsule or altering the method of delivery. But even when the medical benefit is minimal, the financial benefit to the manufacturer can be enormous if the switch undermines competition from a lower-cost generic.

Companies generally use two approaches. In a "hard switch", the brand-name company removes the original product from the market, forcing patients onto the newer, patent-protected product. In a "soft switch", the original product remains available, but aggressive marketing encourages physicians and patients to adopt the newer product.[38]

Both strategies can thwart generic competition. Pharmacists can generally substitute a generic for its equivalent brand-name product, but if the reference product is pulled from the market, substitution becomes more difficult, and patients need a new prescription that specifically calls for the generic. In the event of hard and soft switches, generic firms often lack the resources and marketing power to compete with brand-name companies.

Namenda, a treatment for Alzheimer's disease, illustrates how product hopping can obstruct competition.

As generic competition for Namenda approached, its manufacturer introduced Namenda XR, an extended-release version, and announced plans to withdraw the original product from the market. The New York Attorney General challenged the strategy under antitrust law and secured a preliminary injunction preventing the withdrawal.[39, 40]

For years, patients were struggling to afford the treatment. Linda from Maryland shared that her family was paying $500 per month for Namenda to treat her husband's Alzheimer's Disease. "We couldn't afford this, so we stopped getting it."

Alzheimer's is a progressive, ultimately fatal disease. Losing access to a treatment intended to manage its symptoms can cause serious harm to a patient's cognitive function and daily life. Linda's family should never have been in a situation in which the cost of treatment put it out of reach.

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[37] (2025, March). *The Affordable Prescriptions for Patients Act*, 119th Congress. https://www.congress.gov/bill/119th-congress/senate-bill/1041/all-actions

[38] (2016, March). *Strategies that delay or prevent the timely availability of affordable generic drugs in the United States*. NIH National Library of Medicine. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4915805/

[39] (2015, May). *New York ex rel. Schneiderman v. Actavis PLC*, Westlaw. https://1.next.westlaw.com/Document/I268e54df057611e5b4bafa136b480ad2/View/FullText.html?originationContext=typeAhead&transitionType=Default&contextData=(sc.Default)

[40] (2015, June). *Actavis Loses Namenda Appeal over "Hot Documents"*, JD Supra. https://www.jdsupra.com/legalnews/actavis-loses-nameda-r-appeal-over-hot-31293

P4ADNow has endorsed S.1040, the Drug Competition Enhancement Act, which would strengthen the FTC's authority to challenge product hopping more quickly and proactively.[41] Had this legislation been in effect during the Namenda case, the manufacturer's conduct would have constituted an antitrust violation on its face under the bill's provisions, rather than requiring prolonged litigation to establish the violation. The bill was favorably reported by the Senate Judiciary Committee in 2025 and is projected to save $1.2 billion.[42,43]

Sham Citizen Petitions

Drug companies also exploit regulatory processes intended to protect patient safety to delay generic and biosimilar competition. The FDA's citizen petition process allows individuals and organizations to raise concerns about a drug application, usually about a drug's safety. But manufacturers can misuse this process by submitting petitions that lack scientific merit, forcing the FDA to spend time reviewing objections to competing products. A sham petition does not need to prevent market entry altogether to benefit the brand-name manufacturer; it only has to delay the competitor.

Between 2011 and 2015, brand-name pharmaceutical companies submitted 92 percent of all citizen petitions seeking FDA action on generic drug applicants. The FDA denied approximately nine out of 10 of these industry "sham" petitions, which were without scientific merit. A significant share were filed against generic drugmakers in the final six months of a brand-name company's patent protection, further suggesting that the primary goal was to thwart competition.[44]

The industry's abuse of this mechanism not only delays generic market entry but consumes the FDA's time and funding. Research found that the agency spent an average of more than three years to process petitions against generic applicants seeking the most commonly assigned bioequivalence rating.[45]

The delayed entry of generic competition for EpiPen illustrates the consequences of these tactics. A citizen petition, alongside a settlement agreement, contributed to delaying a generic alternative.[46]

Bobbie from Indiana, who has severe allergies to bee stings and certain foods, paid approximately $500 per month for EpiPen. She told us, "The price of an EpiPen is too expensive, so I'm at risk of a reaction."

Filing a petition is free, while every month a generic competitor is kept off the market can generate millions of dollars in additional revenue for a brand-name pharmaceutical company.

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[41] Please see the bill text: https://www.congress.gov/bill/119th-congress/senate-bill/1040?hl=s.1040&s=1&r=1
[42] (2025, March). *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
[43] (2022, June). *Estimated Budgetary Effect of S. 1435 The Affordable Prescriptions for Patients Act*, The Congressional Budget Office. https://www.cbo.gov/system/files/2022-06/s1435.pdf
[44] (2017). *Citizen Petitions: Long, Late-Filed, and At-Last Denied*, American University Law Review. https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1956&context=aulr
[45](2022, June). *The FDA Could Do More to Promote Generic Competition: Here's How*, USC Schaeffer Institute. https://schaeffer.usc.edu/research/the-fda-could-do-more-to-promote-generic-competition-heres-how/
[46] (2017). *Citizen Petitions: Long, Late-Filed, and At-Last Denied*, American University Law Review. https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1956&context=aulr

P4ADNow supports S. 1095, the Stop STALLING Act, which would strengthen the FTC's authority to challenge baseless citizen petitions intended to interfere with generic and biosimilar competition.[47] The legislation would establish clearer enforcement authority and civil penalties for entities that abuse the petition process. This bill passed out of the Senate Judiciary Committee in 2025 and is projected to save $401 million.[48,49]

Pay For Delay Deals

Pharmaceutical companies also manipulate competition through "pay-for-delay" agreements.

Under these arrangements, brand-name manufacturers provide something of value to a potential competitor, such as a financial settlement, a side agreement, or a commitment not to launch an authorized generic. In exchange, the competitor delays entering the market. Rather than competing with a lower-cost product that would benefit patients, the companies reach an arrangement that preserves the brand-name manufacturer's monopoly. And patients and taxpayers pay the price. These agreements cost patients an estimated $3.5 billion per year.[50]

P4ADNow has endorsed S.1096, the Preserve Access to Affordable Generics and Biosimilars Act, which would strengthen enforcement against pay-for-delay agreements by changing the legal presumptions and penalties associated with these arrangements.[51]

The legislation would make FTC enforcement faster, less costly, and more effective.[52] It was favorably reported by the Senate Judiciary Committee in 2025, and the CBO projects that it would decrease the deficit by $1.646 billion.[53]

Earlier enactment of legislation like S. 1096 may have accelerated generic competition for Seroquel XR, a medication used to treat certain mental health conditions.[54]

Ainsley from Kentucky described the stakes: "One of my medications is $900 a month, and if I don't have it, I have to be hospitalized." For patients who depend on these medicines, delayed competition can mean years of unnecessary financial strain and difficult treatment decisions.

Section V. Other Key Reforms to Improve Competition

Patients For Affordable Drugs Now also supports several bipartisan reforms to close additional loopholes that pharmaceutical manufacturers exploit to delay competition.

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[47] Please see the bill text: https://www.congress.gov/bill/119th-congress/senate-bill/1095?hl=Stop+STALLING+Act&s=9&r=1
[48] (2025, March). *Senate Judiciary Committee Advances Grassley-Led Bills to Lower Prescription Drug Prices*. Senate Judiciary Committee. https://www.judiciary.senate.gov/press/rep/rhttps://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1956&context=aulreleases/senate-judiciary-committee-advances-grassley-led-bills-to-lower-prescription-drug-prices
[49] (2023, March). *Cost Estimate of S. 148, Stop STALLING Act*, Congressional Budget Office. https://www.cbo.gov/system/files/2024-03/s148.pdf
[50] (2010, January). *Pay-For-Delay: How Drug Company Pay-Offs Cost Consumers Billions*, The Federal Trade Commission. https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf
[51] Please see the bill text: https://www.congress.gov/bill/119th-congress/senate-bill/1096?hl=Preserve+Access+to+Affordable+Generics+and+Biosimilars&s=8&r=1
[52] (2025, March). *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
[53] (2024, March). *Cost Estimate of S. 142, Preserve Access to Affordable Generics and Biosimilars Act*, Congressional Budget Office. https://www.cbo.gov/system/files/2024-03/s142.pdf
[54] (2022, March). *The Price Tag of "Pay-For-Delay"*, Columbia University Science and Technology Law Review. https://journals.library.columbia.edu/index.php/stlr/article/view/9389

Within the Senate Judiciary Committee's jurisdiction, P4ADNow has endorsed:

- **S. 43, the Skinny Labels, Big Savings Act**, which would protect generic and biosimilar manufacturers from lawsuits involving uses of drugs that are no longer protected by patents, removing another barrier to lower-cost competition.[55]

- **S.1097, the Interagency Patent Coordination and Improvement Act of 2025**, which would establish a task force between the USPTO and FDA to improve coordination and information sharing on patent-related activities.[56]

P4ADNow also supports bills that recently advanced out of the Senate Health, Education, Labor, and Pensions (HELP) Committee, including:

- **S.2658, the Medication Affordability and Patent Integrity Act,** would help prevent drug manufacturers from improperly extending their monopolies by submitting incomplete or inconsistent information to the FDA and USPTO.[57] The bill would complement S.1097 by strengthening coordination between the two agencies.

- **S.1954, the Biosimilar Red Tape Elimination Act,** would codify existing FDA draft guidance on interchangeability, reducing barriers to biosimilar competition.[58]

Within the scope of the Senate Finance Committee, one of the relevant bills P4ADNow has endorsed is **S. 229, the Drug-price Transparency for Consumers Act of 2025**, which would require advertisements for pharmaceutical products to include pricing information.[59]

No single reform can address every tactic pharmaceutical companies use to delay competition. Patent thickets, product hopping, pay-for-delay agreements, evergreening, and abuse of the FDA's citizen petition process each exploit different weaknesses in our laws.

P4ADNow urges Congress to pass all of these bills before the end of the 119th Congress, to address the multitude of anti-competitive tactics deployed by big drug companies at the expense of American patients.

Section VI: Conclusion

These bipartisan reforms before Congress would preserve the integrity of the patent system to incentivize genuine innovation while closing loopholes that pharmaceutical companies exploit to delay lower-cost competition and maintain monopoly pricing.

The pharmaceutical industry continues to defend a system that allows corporations to preserve monopoly power and dictate exorbitantly high prices to Americans long after lower-cost competitors should have entered the market.

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[55] Please see the bill text: https://www.congress.gov/bill/119th-congress/senate-bill/43
[56] Please see the bill text: https://www.congress.gov/bill/119th-congress/senate-bill/1097?hl=Interagency+Patent+Coordination+and+Improvement&s=6&r=3
[57] Please see the bill text: https://www.congress.gov/bill/119th-congress/senate-bill/2658/text?s=1&r=26
[58] Please see the bill text: https://www.congress.gov/bill/119th-congress/senate-bill/1954/text?s=2&r=2&hl=S.1954
[59] Please see the bill text: https://www.congress.gov/bill/119th-congress/senate-bill/229

Rather than confront its role in driving high prices, the industry frequently shifts blame to other actors in the prescription drug supply chain. While there are legitimate concerns about PBMs, insurers, and pharmacies, pharmaceutical manufacturers enjoy substantially higher profit margins than these other industries and retain enormous power over the prices patients pay.[60]

The industry also routinely argues that reforms to promote generic and biosimilar competition threaten innovation. But protecting genuine innovation and protecting manipulation are not the same thing.

Taxpayers help underwrite pharmaceutical innovation, with more than 99 percent of drugs approved by the FDA between 2010 and 2019 benefiting from federal research support.[61] A West Health analysis found that major brand-name pharmaceutical companies could lose a trillion dollars over a decade and remain one of the most profitable industries.[62] Another analysis found that the ten largest pharmaceutical companies spend three times as much on advertising, overhead, and profits as they do on research and development.[63]

These findings challenge the industry's claim that stronger competition would undermine its ability to develop new treatments. In fact, allowing companies to preserve monopolies on existing medicines can weaken incentives to invest in the next generation of breakthrough drugs. When companies can continue generating billions from older products by delaying competition, they face less pressure to develop genuinely new treatments.

Our founder, my friend and colleague, David Mitchell, understood why patients need both innovation and affordability.

David lived with multiple myeloma for 15 years. During the last decade of his life, he regularly spent more than $20,000 out-of-pocket each year for his cancer medicines alone. He relied on scientific breakthroughs to stay alive, even as he fought to change a system that made those treatments unaffordable for so many others.

In January of this year, David died because, ultimately, there were no more treatments available to stop his cancer as it became more aggressive.

David understood that patients need the next generation of breakthrough medicines, but those medicines must also be affordable to the people whose lives depend on them. That conviction drove his work and continues to drive ours.

Congress has the opportunity to honor that principle by advancing the bipartisan solutions before it today that would address abuses of the patent and regulatory systems that undermine competition while preserving protections for genuine innovation.

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[60] (2024, November). *Drug patent reform advocates make their lame-duck pitch*. POLITICO. https://subscriber.politicopro.com/article/2024/11/drug-patent-reform-advocates-make-their-lame-duck-pitch-00190537?

[61] (2023, April). *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/

[62] (2019, November). *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/

[63] (2026, August). *The Big Pharma Dollar Tells a Story on Priorities*, The Campaign for Sustainable Drug Pricing. https://www.csrxp.org/wp-content/uploads/2026/09/CSRxP_Pharma-Dollar-One-Pager.pdf

Our laws should reward the development of new medicines, not allow pharmaceutical companies endless opportunities to protect their monopolies.

Patients shouldn't have to choose between paying rent and filling a prescription. They should not have to ration medications or take on debt because drug companies have found a way to keep lower-cost alternatives off the market.

We urge Congress to pass these bipartisan reforms before the end of the 119th Congress and ensure that our laws work as intended. Every American should be able to get the prescription drugs they need at prices they can afford.

Thank you.