



the campaign for
SUSTAINABLE Rx PRICING

Statement for the Record
U.S. House Committee on Energy & Commerce
Subcommittee on Health
Hearing: Health Care Affordability
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Committee Chairman Guthrie, Committee Ranking Member Pallone, Subcommittee Chairman Griffith, Subcommittee Ranking Member DeGette, and members of the U.S. House Committee on Energy & Commerce Subcommittee on Health, the Campaign for Sustainable Rx Pricing (CSRxP) thanks you for the opportunity to submit a statement for the record on our shared goal of improving healthcare affordability for all Americans. We particularly commend your efforts to reduce the unsustainable growth in prescription drug spending, which is the single largest contributor to the healthcare affordability crisis in the U.S. today.¹ CSRxP applauds your bipartisan leadership in seeking to address this critically important issue that impacts millions of American consumers and taxpayers.

CSRxP is a broad-based nonpartisan coalition of leaders committed to fostering an informed discussion on sustainable drug pricing. Our member organizations represent consumers, employers, health plans, hospitals, nurses, pharmacists, pharmacy benefit companies, and physicians. Our coalition is united behind one goal: to lower the cost of prescription drugs for patients. We are committed to developing bipartisan, market-based solutions that promote competition, improve affordability, and enhance list price transparency while maintaining patient access to innovative medications that improve health outcomes and save lives. We believe innovation and affordability must go hand in hand.

I. Big Pharma’s Abuse of the Patent System Keeps High-Priced Biologics on the Market without Competition

High-priced brand biologics drive much of the excessive spending on prescription drugs. **Brand biologics made up 5 percent of all prescriptions in the U.S., but comprised 51 percent of total spending on drugs in 2024.**² Spending on biologics grew 12.5 percent annually from 2017 to 2021 – a rate that far surpassed the 1.3 percent annual spending growth on traditional small molecule drugs over that same period.³ In Medicare Part D, prices for biologic medicines have grown more rapidly than

¹ AHIP. [Where Does Your Health Care Dollar Go?](#) October 24, 2024.

² *Ibid.*

³ IQVIA. [Biosimilars in the United States 2023 – 2027: Competition, Savings, and Sustainability.](#) January 31, 2023.



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traditional drugs, rising by more than 300 percent from 2006 to 2022.⁴ Similarly, biologics accounted for nearly 90 percent of spending growth on prescription drugs between 2008 and 2021 in Medicare Part B and accounted for 79 percent of all of Part B drug spending in 2021.⁵

Increasing the availability of lower cost biosimilars in the U.S. market will enhance competition for high-priced biologic medicines, thereby reducing prices and overall spending on prescription drugs. Indeed, a recent analysis from the FDA determined that **prices for biosimilars are on average 50 percent lower at launch than prices of their brand reference biologic products at that time.**⁶ Reflecting the price favorability of biosimilars, in 2024 alone use of biosimilars generated more than \$20 billion in cost savings and, since 2015, biosimilars have saved \$56 billion for patients and taxpayers.⁷ Along those lines, in Medicare Part B, beneficiary utilization of biosimilars decreased spending by \$12.9 billion, or about 31 percent, between 2018 and 2023.⁸ **Estimates suggest the potential for total healthcare savings of \$234 billion over the next 10 years if new biosimilar competition enters the market.**⁹

Despite the significant potential to improve healthcare affordability, many biosimilars and generic medicines have not been able to enter the market due to Big Pharma's anti-competitive abuse of the U.S. intellectual property system. Research suggests that the anti-competitive nature of the U.S. biologic market cost patients approximately \$5 billion from 2015 through 2020.¹⁰ Without action to combat Big Pharma's abusive tactics, patients needlessly will pay an estimated \$25 billion in excess drug spending through 2029.¹¹

One of the most common strategies that drug makers employ to abuse the patent system and delay competition from lower cost biosimilars is the construction of so-called patent thickets. Under this practice, drug companies apply for and obtain dozens or even hundreds of patents for their branded drugs *after* FDA approval to prevent and delay market entry from less costly generics and biosimilars. Secondary, often non-innovative, patents covering additional indications, dosing and delivery, manufacturing and packaging, and patient safety protocols are obtained to create a thicket of patents. These patent thickets create a nearly insurmountable barrier to competition from lower cost generics and biosimilars for years and, in some cases, decades due to the threat of lengthy, costly, and time-intensive litigation.

⁴ Medicare Payment Advisory Commission. [The Medicare prescription drug program \(Part D\): Status Report](#). Slide 15. January 11, 2024.

⁵ HHS ASPE. [Medicare Part B Drugs: Trends in Spending and Utilization, 2008 – 2021](#). June 9, 2023.

⁶ FDA. [Fact Sheet: Bringing Lower-Cost Biosimilar Drugs to American Patients](#). October 29, 2025.

⁷ Association for Accessible Medicines. [2025 U.S. Generic & Biosimilar Medicines Savings Report](#). September 2025.

⁸ HHS ASPE. [Medicare Part B Enrollee Use and Spending on Biosimilars, 2018 – 2023](#). January 15, 2025.

⁹ Association for Accessible Medicines. [2025 U.S. Generic & Biosimilar Medicines Savings Report](#). September 2025.

¹⁰ Roy, Avik. [“The Growing Power of Biotech Monopolies Threatens Affordable Care.”](#) The Foundation for Research on Equal Opportunity. September 15, 2020.

¹¹ *Ibid.*



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Patent thickets have contributed significantly to the “patient affordability crisis” that exists today: extensive patent thickets on just five brand drugs resulted in more than \$16 billion in excessive costs in the U.S. drug market in a single year, according to one analysis.^{12 13} Findings from a separate recent study published in *JAMA Health Forum* align with this study, as researchers determined that patent thickets on just four widely prescribed brand biologic products cost patients, taxpayers, and the U.S. healthcare system more than \$3.5 billion in excess spending over two years.¹⁴

Brand drug makers’ practice of constructing anti-competitive patent thickets has gained heightened prominence over the past two decades. According to an analysis published in *JAMA*, drug makers increased by 200 percent the number of secondary patent filings used to create anti-competitive patent thickets from 2000 to 2015; in stark contrast, they increased the number of patent filings for original patents by just 15 percent during that same period.¹⁵ Overall, the number of patents for each drug increased by 68 percent during those fifteen years, underscoring brand drug makers’ enhanced focus on pursuing secondary patents to form patent thickets for high-priced biologics that block competition from lower cost biosimilars.¹⁶

Big Pharma continues to deploy its aggressive pursuit of anti-competitive patent thickets today, making prescription drugs and healthcare more broadly unaffordable for far too many Americans. **Nearly three-quarters of all patents were filed for the top 10 selling drugs in the U.S. in 2021 after FDA approval,** according to a 2024 study published in *JAMA Internal Medicine*.¹⁷ Patent thicket density peaked 13 years following FDA approval of these top-10 selling medicines, at which time they were protected by a median of 42 (18 – 83) active patents, 66 percent of which were filed after FDA approval.¹⁸ Importantly, most of the 465 patents issued for applications filed after FDA approval for these top-10 selling drugs were for secondary, typically non-innovative, patents: 189 (41 percent) for method of use claims, 127 (27 percent) for formulation claims, and 103 (22 percent) for process or synthesis claims compared to 86 (19 percent) for chemical composition claims and 46 (10 percent) for device claims.¹⁹

In addition to patent thickets, brand name drug makers use other anti-competitive tactics commonly referred to as “evergreening” or “product hopping” to protect their product monopolies and prevent competition from lower cost biosimilars and generics. Under these practices, brand drug makers

¹² FDA. [Fact Sheet: Bringing Lower-Cost Biosimilar Drugs to American Patients](#). October 29, 2025.

¹³ Matrix Global Advisors. [Patent Thickets and Lost Drug Savings](#). January 26, 2023.

¹⁴ Hone D, Tu S, Beall R et al. [Estimating Costs of Market Exclusivity Extensions For 4 Top-Selling Prescription Drugs in the US](#). *JAMA Health Forum*. 2025;6;(8):e252631. Doi:10.1001/jamahealthforum.2025.2631

¹⁵ Tu S, Kesselheim A, Wetherbee K et al. [Changes in the Number of Continuation Patents on Drugs Approved by the FDA](#). *JAMA*. 2023;330;(5):469-470. Doi:10.1001/jama.2023.11525

¹⁶ *Ibid.*

¹⁷ Horrow et al. [Patent Portfolios Protecting 10 Top-Selling Prescription Drugs](#). *JAMA Intern Med*. Published online May 13, 2024. doi:10.1001/jamainternmed.2024.0836

¹⁸ *Ibid.*

¹⁹ *Ibid.*



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lengthen monopolies by seeking approval of "new" products that are essentially the same as original brand products – but with patents covering relatively minor changes like reformulations, such as an extended-release version of the medication, or a combination therapy that combines two existing drugs into one pill. One analysis determined that **consumers lose up to \$2 billion per year per each anti-competitive product reformulation produced by “evergreening” and “product hopping.”**²⁰

Big Pharma’s abuse of the U.S. intellectual property system harms consumers and taxpayers and makes prescription drugs unaffordable for millions of Americans. In Medicare, for example, a report from the House Oversight and Investigations Committee found that brand drug makers collectively raised prices on 12 top selling drugs more than 250 times reaching median prices that were nearly 500 percent higher than they were at the time of original market entry through by “product hopping” and constructing patent thickets.²¹ The patent thickets collectively comprised 600 patents and delayed competition for high-priced brand biologics from lower cost biosimilars for a total of nearly 300 years and, consequently, needlessly raised prices and spending for Medicare beneficiaries and taxpayers.²² Similarly, in the U.S. market more widely, a number of blockbuster drugs have not faced competition due to Big Pharma’s gaming of the system. For example:

- **Merck’s Keytruda for cancer:** Merck has filed nearly 300 patent applications for its anti-cancer biologic Keytruda and has been granted more than 100 patents as a result.²³ The drug maker filed the majority of those patent applications *after* FDA approved Keytruda to construct a patent thicket and delay competition from lower cost biosimilars, which the Initiative for Medicines, Access, and Knowledge (I-MAK) estimates could cost consumers and taxpayers at least \$137 billion.²⁴ ²⁵ This estimate notably does not account for the company’s latest product-hopping strategy aimed at switching patients from an IV infusion to a subcutaneous injection formulation in order to help protect the brand product – currently priced at more than \$200,000 per year – from competition from lower cost biosimilar IV infusion versions of the treatment once they enter the market.²⁶
- **Novo Nordisk and Eli Lilly’s GLP-1s for weight loss and diabetes:** Novo Nordisk has filed 320 patent applications and received 154 patents for semaglutide, the active ingredient in Ozempic, Rybelsus and Wegovy. Despite the fact that the main compound for semaglutide was set to expire in March 2026, the patent thicket constructed by the brand drug maker has lengthened

²⁰ Shadowen, Steve et. al. “[Anticompetitive Product Changes in the Pharmaceutical Industry.](#)” *Rutgers Law Journal*, Vol. 41, No. 1-2, Fall/Winter 2009.

²¹ House Committee on Oversight and Reform. [Drug Pricing Investigation.](#) December 2021.

²² *Ibid.*

²³ I-MAK. [May 2025: Merck’s Scheme to Product Hop Keytruda.](#) May 5, 2025.

²⁴ *Ibid.*

²⁵ I-MAK. [Overpatented, Overpriced: Keytruda’s Patent Wall.](#) May 2021.

²⁶ I-MAK. [May 2025: Merck’s Scheme to Product Hop Keytruda.](#) May 5, 2025.



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market exclusivity for these GLP-1s until December 2031 and will result in excess cost of \$166 billion, according to I-MAK.²⁷ Similarly, Eli Lilly has filed 53 patent applications and received 16 patents for its GLP-1 products, Mounjaro and Zepbound. The main patent compound for these two products is set to expire in 2036, but the patent thicket is expected to extend patent protection for these blockbuster drugs through 2041.

- **AbbVie’s Humira for autoimmune diseases:** AbbVie and its former parent company applied for more than 300 patents for Humira and was granted more than half of those patents over the course of the more than 20 years the drug was on the market without competition.²⁸ Ninety-four percent of the patents filed on Humira came after initial approval from the FDA. Humira’s extensive patent thicket blocked competition helped to generate an excess of \$114 billion for AbbVie at the expense of consumers and taxpayers.²⁹

Without Congressional action to thwart anti-competitive tactics by Big Pharma such as patent thickets, product hopping and evergreening, drug makers will continue to delay and block competition from lower cost biosimilars and impose billions in excess drug costs on patients, taxpayers, and the U.S. healthcare system overall. The excessive spending on prescription drugs will continue to contribute significantly to the healthcare affordability crisis in the U.S. today. Hence, CSRxP respectfully urges the Committee and the Congress to enact legislation quickly that combats the abuses of Big Pharma in order to reduce unsustainable growth in drug prices and spending.

II. Recommended Policies to Improve Affordability by Enhancing Biosimilar Competition

Given the outsized impact of prescription drugs on healthcare affordability, **CSRxP applauds the Administration and Congress for taking steps to increase competition in the U.S. marketplace with lower cost biosimilars and reduce drug prices and spending.** In particular, CSRxP applauds the recent enactment of bipartisan provisions from the Increasing Access to Generic Drug Applications Act (H.R. 1843), which will reform the Q1/Q2 sameness requirements from the FDA that Big Pharma abuses to extend market exclusivity for high-priced brand medicines. CSRxP also supports the new FDA draft guidance³⁰ to eliminate comparative efficacy study requirements and streamline biosimilar approvals, as well as the Administration’s demonstrated support for automatically designating all biosimilars as interchangeable with their reference products and increasing domestic biosimilar manufacturing.³¹ The

²⁷ I-MAK. [The Heavy Price of GLP-1 Drugs: How Financialization Drives Pharmaceutical Patent Abuse and Health Inequities for GLP-1 Therapies](#). April 2025.

²⁸ Robbins, R. [How a Drug Company Made \\$114 Billion by Gaming the U.S. Patent System](#). *The New York Times*. January 28, 2023.

²⁹ *Ibid.*

³⁰ FDA. [Scientific Considerations in Demonstrating Biosimilarity to a Reference Product: Updated Recommendations for Assessing the Need for Comparative Efficacy Studies](#). Draft Guidance. October 2025.

³¹ FDA. [FDA News Release: FDA Moves to Accelerate Biosimilar Development and Lower Drug Costs](#). October 29, 2025.



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new law combined with recent administrative actions should encourage the development of additional lower cost biosimilars.

CSRxP further respectfully urges the Committee and the Congress to build on these actions to foster enhanced competition in the prescription drug marketplace and improve healthcare affordability. To that end, we strongly support and urge the Committee to advance the following pieces of legislation:

1. **Biosimilar Red Tape Elimination Act (H.R. 5526 and S. 1954):** The bipartisan, bicameral legislation introduced by Reps. Pfluger (R-TX), Landsman (D-OH), Auchincloss (D-MA), Crenshaw (R-TX), Vasquez (D-NM), and Owens (R-UT) in the 119th Congress would eliminate outdated FDA requirements to expedite biosimilar substitution and increase competition from more affordable alternatives to high-priced brand name products.
2. **The Drug-price Transparency for Consumers (DTC) Act (H.R. 3789 and S. 229):** The bicameral bill introduced in the 119th Congress by Reps. Taylor (R-OH), Schakowsky (D-IL), Begich (R-AK), Quigley (D-IL), Bresnahan (R-PA), Nunn (R-IA), Vindman (D-VA), and Hinson (R-IA) and Del. Norton (D-DC) would require direct-to-consumer (DTC) advertisements to include price information.

CSRxP further respectfully urges lawmakers to enact additional bipartisan and bicameral legislation under the jurisdiction of other committees that would thwart Big Pharma's anti-competitive behavior and promote competition from lower cost biosimilars and generics:

3. **The Skinny Labels, Big Savings Act (H.R. 6485 and S. 43):** The bill introduced in the 119th Congress would preserve the skinny label pathway for generic drug applicants.
4. **The Eliminating Thickets to Increase Competition (ETHIC) Act (H.R. 3269 and S.2276):** The bill introduced in the 119th Congress would streamline drug patent litigation and help remove barriers to generic and biosimilar market entry.
5. **The Interagency Patent Coordination and Improvement Act (H.R. 1717 and S.79):** This bicameral legislation advanced out of the Senate Judiciary Committee in April 2025 would improve coordination and communication between the FDA and the U.S. Patent and Trademark Office (USPTO) on prescription drug-related issues.
6. **The Affordable Prescriptions for Patients Act (S.1041):** This bill advanced out of the Senate Judiciary Committee in April 2025 would target anti-competitive patent thickets by placing limits on the number of patents a biologic manufacturer can use to prevent competition from lower cost biosimilars.



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7. **The Preserve Access to Affordable Generics and Biosimilars Act (S.1096):** This bill advanced out of the Senate Judiciary Committee in April 2025 would ensure that patent settlement agreements facilitate timely competition from more affordable alternative medicines.
8. **The Drug Competition Enhancement Act (S.1040):** This legislation advanced out of the Senate Judiciary Committee in April 2025 would address anti-competitive “product hopping” that involves making small changes to a brand name drug to extend product monopolies.
9. **The Stop STALLING Act (S.1905):** This legislation advanced out of the Senate Judiciary Committee in April 2025 would provide the Federal Trade Commission (FTC) with enhanced authority to stop brand drug companies from exploiting FDA’s “citizen petition” process to file sham petitions that delay and prevent FDA approval of more affordable generic and biosimilar medicines.
10. **Medication Affordability and Patent Integrity Act (S.2658):** This bill reintroduced in the 119th Congress would help to prevent abuses of the patent system by requiring biopharmaceutical manufacturers to provide consistent and additional information to the FDA and the USPTO on newly submitted or approved drug applications.
11. **Reforming Evergreening and Manipulation that Extends Drug Years (REMEDY) Act (S.2620):** This legislation reintroduced in the 119th Congress would help to thwart anti-competitive “evergreening” practices in which brand drug manufacturers make minor modifications to existing drugs to maintain market dominance and limit competition from more affordable generic therapies.

III. Conclusion

In conclusion, CSRxP again applauds the bipartisan leadership of the Committee in seeking to tackle the U.S. healthcare affordability crisis. High-priced prescription drugs make healthcare unaffordable for millions of Americans. Without taking major actions to combat the abuses of Big Pharma, the brand drug industry will continue to excessively profit from its anti-competitive pricing practices that needlessly increase drug costs and make healthcare unaffordable for the very people who depend on it most. CSRxP looks forward to our continued work with the Committee and the Congress to develop bipartisan, market-based policies that promote transparency, foster competition, and incentivize value to lower costs for consumers and taxpayers while at the same time maintaining access to the treatments that can improve health outcomes and save lives.