Statement for the Record
U.S. House Judiciary Committee
The Subcommittee on Courts, Intellectual Property, Artificial Intelligence, and the Internet
Hearing: "Medicines and IP: Balancing Innovation and Access"
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Chairman Issa, Ranking Member Johnson, Chairman Jordan, Ranking Member Raskin, and members of the U.S. House Judiciary Committee, the Campaign for Sustainable Rx Pricing (CSRxP) thanks you for the opportunity to submit a statement for the record on fostering biopharmaceutical innovation while at the same time advancing initiatives to make prescription drugs more affordable and accessible for all Americans. We appreciate your bipartisan leadership in seeking to address this critically important issue that impacts millions of U.S. patients and their families every day.

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. Skyrocketing Prescription Drug Prices Are Unsustainable

Prescription drug prices are not sustainable for U.S. patients, families, taxpayers, businesses, and our economy as a whole. Twenty-four cents of every health care dollar go toward prescription drugs – with prescription drugs contributing more to health care costs than any other type of health care service.[1] List prices for prescription drugs at launch have more than doubled since 2021 – with the median list price exceeding $370,000 in 2024 and representing a substantial increased over the median launch price of $300,000 in 2023 and $220,000 in 2022.[2] Median list prices increased by four percent at the start of 2026, consistent with price increases implemented in 2025.[3] List prices are even higher for many gene therapy treatments, with the highest one priced at

[1] AHIP. Where Does Your Health Care Dollar Go? October 24, 2024.
[2] Beasley, D. Prices for new US drugs doubled in 4 years as focus on rare disease grows. *Reuters*. May 22, 2025.
[3] Erman, M. Exclusive: Drugmakers raise US prices on 350 medicines despite pressure from Trump. *Reuters*. January 1, 2026.

$4.25 million for a single dose in 2025.[4] In total, prescription drug spending increased by 7.9 percent in 2024, reaching $467 billion.[5]

Manufacturers raised prices on at least 350 drugs to start 2026 even though many Americans still cannot afford the medications they need to get well and remain healthy.[6] [7] The price increases implemented at the outset of the year follow years of unsustainable price increases imposed by Big Pharma on consumers and taxpayers.[8] Across the U.S. market, for example, drug makers raised prices on more than 4,200 drug products by an average increase of 15.2 percent during the period of January 2022 to January 2023 –even faster than the prior year of 11.5 percent (January 2021 to January 2022).[9] Reflecting these unsustainable pricing trends, in Medicare Part D, the top 25 best-selling prescription drugs not selected for price negotiation have nearly doubled in price since entering the market, increasing by an average of 98 percent.[10]

Critically, high-priced brand biologics are driving much of the excessive pricing and 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.**[11] 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.[12] Indeed, list prices for biologic medicines covered under Medicare Part D have grown more rapidly than traditional drugs, rising by more than 300 percent from 2006 to 2022.[13] 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.[14]

II. "A Patient Affordability Crisis" Impacts Millions of Americans

Despite efforts from manufacturers to suggest otherwise**, pharmaceutical companies – and pharmaceutical companies alone – are the drivers of the unsustainable growth in drug prices and excessive spending on prescription drugs today**. Manufacturers set excessively high list prices at launch for new drugs and raise them every year, often at rates that far exceed inflation.

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[4] Becker et al. Updated: Most expensive drugs in the US in 2025. *Fierce Pharma.* August 11, 2025.
[5] Hartman et al. National Health Care Spending Increased 7.2 Percent In 2024 As Utilization Remained Elevated. *Health Affairs.* January 14, 2026.
[6] Erman, M. Exclusive: Drugmakers raise US prices on 350 medicines despite pressure from Trump. *Reuters*. January 1, 2026.
[7] Kearney et al. Public Opinion on Prescription Drugs and Their Prices. KFF. March 31, 2026.
[8] U.S. Department of Health and Human Service Assistant Secretary for Planning and Evaluation. Changes in the List Prices of Prescription Drugs, 2017 – 2023. October 6, 2024.
[9] *Ibid*.
[10] Purvis, L. Prices for Top Medicare Part D Drugs Have Nearly Doubled Since Entering the Market. AARP Public Policy Institute. January 2025.
[11] FDA. Fact Sheet: Bringing Lower-Cost Biosimilar Drugs to American Patients. October 29, 2025.
[12] IQVIA. Biosimilars in the United States 2023 – 2027: Competition, Savings, and Sustainability. January 31, 2023.
[13] Medicare Payment Advisory Commission. The Medicare prescription drug program (Part D): Status Report. Slide 15. January 11, 2024.
[14] HHS ASPE. Medicare Part B Drugs: Trends in Spending and Utilization, 2008 – 2021. June 9, 2023.

Spending on high-priced drugs places a significant strain on patients, federal health programs, and taxpayers. High-priced drugs also substantially burden the many small businesses and large employers that seek to offer affordable health insurance to their employees because, as prescription drug expenditures increase, cost-sharing and premium costs also rise.[15]

The persistent skyrocketing prices of prescription drugs led the Food and Drug Administration to recently assert that a **"patient affordability crisis"** now exists in which **"biologic drugs can cost patients tens of thousands and upwards of hundreds of thousands of dollars annually, creating insurmountable financial barriers for many Americans who need these life-saving treatments**."[16] Indeed, far too often consumers experience the unfortunate and unfair choice of purchasing medications and paying their bills for food and housing. Patients and their families simply should never be presented with such a choice.

III. Biosimilar and Generic Competition Reduces Prescription Drug Prices

Biosimilar and generic medicines lower prices and total spending on prescription drugs. Savings totaled $467 billion in 2024 alone from use of these more affordable medicines and totaled $3.4 trillion over the past decade.[17] As stated at the outset, high-priced brand biologics are driving much of the excessive spending on prescription drugs – making up 5 percent of the prescriptions but 51 percent of the total spending on drugs in 2024.[18] Improved access to biosimilars can help to slow this trend: biosimilars generated more than $20 billion in cost savings in 2024 and, since 2015, have saved $56 billion for patients and taxpayers.[19] Estimates suggest the potential for total healthcare savings of $234 billion over the next 10 years if new lower-priced biosimilar competition enters the market.[20] Indeed, **prices for biosimilars are on average 50 percent lower at launch than prices of their brand reference biologic products at that time,** according to the FDA.[21]

Critically, affordability improves for patients when biosimilars and generic medicines are available. **Medicare Part B beneficiaries saved nearly $2,000 on average in potential out-of-pocket costs by utilizing biosimilars instead of brand biologics in 2023.**[22] In total, Part B beneficiaries had estimated out-of-pocket savings of $3.2 billion from 2018 to 2023 from use of biosimilars rather than high-priced brand biologics.[23] Likewise, in the broader commercial market, patients had 23 percent savings in out-of-pocket costs, or about $200 less on average, from selecting biosimilars rather than brand biologics, according to analysis published in *JAMA*.[24]

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[15] American Academy of Actuaries. "Prescription Drug Spending in the U.S. Health Care System." March 2018.
[16] FDA. Fact Sheet: Bringing Lower-Cost Biosimilar Drugs to American Patients. October 29, 2025.
[17] Association for Accessible Medicines. 2025 U.S. Generic & Biosimilar Medicines Savings Report. September 2025.
[18] FDA. Fact Sheet: Bringing Lower-Cost Biosimilar Drugs to American Patients. October 29, 2025.
[19] Association for Accessible Medicines. 2025 U.S. Generic & Biosimilar Medicines Savings Report. September 2025.
[20] *Ibid*.
[21] FDA. Fact Sheet: Bringing Lower-Cost Biosimilar Drugs to American Patients. October 29, 2025.
[22] HHS ASPE. Medicare Part B Enrollee Use and Spending on Biosimilars, 2018 – 2023. January 15, 2025.
[23] *Ibid*.
[24] Feng K, Russo M, Maini L. Patient Out-of-Pocket Costs for Biologic Drugs After Biosimilar Competition. *JAMA Health Forum.* 2024;5;(3):e235429. Doi:10.1001/jamahealthforum.2023.5429

IV. Big Pharma's Anti-Competitive Tactics Delay Patient Access to More Affordable Generic and Biosimilar Medicines

Big Pharma deploys a variety of strategies to prevent and delay competition from generic and biosimilar medicines and needlessly raise prices and costs for patients, taxpayers, and the U.S. healthcare system overall. CSRxP thus appreciates and strongly supports efforts by the Committee and the Congress to address two key anti-competitive tactics Big Pharma uses to maintain market monopolies for brand products and thwart competition from lower cost generics and biosimilars: (1) the construction of extensive "patent thickets" for brand biologics; and (2) the weakening of the "skinny label pathway" for generic drugs.

1. *Patent Thickets:* Effective and Costly Tactic That Prevents Biosimilar Competition for High-Priced Biologics

To construct patent thickets, manufacturers apply for and obtain dozens or even hundreds of patents for their branded biologic medicines *after* FDA approval to prevent and delay market entry from less costly biosimilars. Patent thickets are typically built through large numbers of late-stage, secondary patents covering minor modifications of a drug, including new methods of use, dosing regimens, manufacturing processes, formulations, delivery mechanisms, and packaging changes, rather than the original active ingredient itself. Patent thickets create a nearly insurmountable barrier to competition from more affordable biosimilars for years and, in some cases, decades due to the threat of lengthy, costly, and time-intensive litigation.

Patent thickets enable drug companies to maintain market monopolies for brand products and keep prices needlessly high for consumers and taxpayers. **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.[25] Along similar lines, **patent thickets on 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**, according to a separate study published in September 2025 in *JAMA Health Forum*.[26]

Notably, the building of patent thickets by brand biologic manufacturers has gained heightened prominence over the past two decades. According to an analysis published in *JAMA*, manufacturers increased by 200 percent the number of secondary patent filings used to create anti-competitive patent thickets from 2000 to 2015 – while at the same time, in stark contrast, they increased the number of patent filings for original patents by just 15 percent.[27] More recently, **nearly three-quarters of all patents were filed for the top 10 selling drugs in the U.S. in 2021**

[25] Matrix Global Advisors. Patent Thickets and Lost Drug Savings. January 26, 2023.
[26] 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
[27] 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

***after* FDA approval**, according to a 2024 study published in *JAMA Internal Medicine*.[28] 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.[29] 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.[30]

2. *Weakened Skinny-Label Pathway:* Brand Drug Companies' Strategy to Delay Competition from Lower-Cost Generic Drugs

Under the Hatch-Waxman Act, generic manufacturers can bring lower-cost drugs to market using the "skinny-label pathway," seeking approval only for non-patented uses while carving out patented indications. This pathway allows patients to benefit from earlier generic competition without waiting for all patents to expire, helping to lower drug costs. However, recent court decisions have created legal uncertainty and created new risks for generic manufacturers, suggesting that they still may be liable for patent infringement.[31] This legal uncertainty has discouraged use of the skinny-label pathway and delayed market competition from lower cost generic drugs.

Published data indicate that skinny-label generics enter the market earlier and generate substantial savings for patients and taxpayers. In a study of 15 brand-name Medicare Part D drugs with skinny-label generics that first came to market between 2015 and 2019, skinny-label generics led to a median of 2.5 years of earlier competition from lower-cost generics.[32] Average prices in the final year of skinny-label generic competition were a median of 34 percent less than the year before competition.[33] **Earlier competition and lower prices from skinny-label generics resulted in an estimated $14.6 billion in savings to Medicare over the five-year period.**[34] Hence, the legal uncertainty for skinny-label generics created by recent litigation creates new costs for patients and taxpayers by discouraging generic manufacturers from using the pathway.

V. Recommended Actions to Thwart Big Pharma's Abuses and Improve Patient Access to More Affordable Medicine

[28] 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
[29] *Ibid*.
[30] *Ibid*.
[31] Congressional Research Service. "Skinny Labels" for Generic Drugs under Hatch-Waxman. Accessed May 21, 2026.
[32] Joszt, L. Competition From Skinny-Label Generics Saved Medicare Nearly $15B Over 5 Years. AJMC. April 29, 2024.
[33] *Ibid*.
[34] *Ibid*.

Put simply, Big Pharma deploys anti-competitive and costly strategies to delay and prevent competition from lower-cost biosimilar and generic medicines for their high-priced brand products. These practices needlessly raise spending on prescription drugs and contribute significantly to the patient affordability crisis that exists today. Thus, to lower drug prices and reduce spending for patients and taxpayers, **CSRxP respectfully urges the Committee and Congress to swiftly adopt bipartisan pieces of legislation that address two of Big Pharma's most abusive tactics – (1) patent thickets, and (2) weakening of the skinny-label pathway**:

1. **ETHIC Act (H.R. 3269):** One method drug manufacturers deploy to construct extensive patent thickets that block biosimilar competition is obtaining multiple closely related patents covering obvious variations of the same invention for their brand products – a practice known as "obviousness-type double patenting" (OTDP). Oftentimes managed through "terminal disclaimers," the practical result of OTDP is that brand companies typically obtain dozens of related formulation, dosing, polymorph, method-of-treatment, or manufacturing patents surrounding one drug product, thereby extending and expanding the patent thicket for the brand product well beyond the original patent expiration date.

   The ETHIC Act weakens the ability of Big Pharma to build patent thickets by linking terminal disclaimers into a "Patent Group" and treats them as a single patent cluster for enforcement purposes, such that, if a court invalidates one of the patents in the "Patent Group," then all of the duplicative patents in that patent group also will be invalidated. Further, the legislation bars follow-on lawsuits based on other patents in the same "Patent Group." CSRxP strongly supports and respectfully urges enactment of this bipartisan legislation introduced in the 119th Congress by Rep. Arrington (R-TX) with co-sponsors Reps. Doggett (D-TX), Issa (R-CA), Jayapal (D-WA), Pfluger (R-TX), Dingell (D-MI), Tlaib (D-MI), Harshbarger (R-TN), and Garcia (D-IL).

2. **Skinny Labels, Big Savings Act (H.R. 6485):** The Skinny Labels, Big Savings Act restores certainty to the skinny-label pathway that has been created under recent Federal court decisions by establishing a new statutory safe harbor for generic manufacturers, which clarifies that FDA-approved carved-out patent indications alone cannot form the basis for induced infringement liability absent active promotion of patented uses by the generic manufacturer. By restoring certainty to the skinny-label pathway, the legislation helps ensure timely generic entry, increased competition, and lower prescription drug costs for patients. CSRxP thus strongly supports and respectfully urges enactment of this bipartisan, bicameral legislation introduced by Rep. Cline (R-VA) with co-sponsors Reps. Lofgren (D-CA), Kiggans (R-VA), Suozzi (D-NY), and Pfluger (R-TX).

VI. Conclusion

In conclusion, CSRxP thanks you for your bipartisan leadership in seeking to address the skyrocketing prices of prescription drugs that impact millions of Americans every day. We thank you for the opportunity to submit a statement for the record on preserving innovation while at the

same time better guarding against the abusive tactics of Big Pharma that delay and limit access to affordable generic and biosimilar medications. Without taking major actions to combat the unsustainable growth in prescription drug prices and spending, the brand pharmaceutical 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.