Testimony Submitted for the Record
U.S. Senate Committee on the Judiciary
Hearing: "Ensuring Affordable and Accessible Medications: Examining Competition in the Prescription Drug Market"
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Chairman Durbin, Ranking Member Graham, and members of the U.S. Senate Committee on the Judiciary, the Campaign for Sustainable Rx Pricing (CSRxP) thanks you for the opportunity to submit testimony for the record on fostering competition in the prescription drug market to make medications more affordable and accessible for consumers. We commend your bipartisan leadership in seeking to address this critical issue that impacts far too many Americans today.

CSRxP is a broad-based nonpartisan coalition of leaders committed to fostering an informed discussion on sustainable drug pricing. Our members represent organizations including consumers, hospitals, physicians, nurses, pharmacists, employers, pharmacy benefit companies, and health plans. We are committed to the goal of lowering the cost of prescription drugs for patients. We support 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.

**Prescription Drug Prices are Unsustainable; Net Spending Increased 9.9 Percent in 2023**

Prescription drug pricing trends simply are not sustainable for U.S. patients, families, taxpayers, businesses, and our economy as whole. Twenty-two 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] The median annual list price among drugs newly approved by the Food and Drug Administration (FDA) in 2023 was more than $300,000 – a significant increase from 2022 when the median launch price was $220,000.[2] For one-time gene therapy treatments, list prices were even higher in 2023 ranging from $2.2 million to $3.2 million.[3]

Drug makers increased prices on 775 drugs to start 2024 even though many Americans cannot afford the medications they need to get well and remain healthy.[4] [5] The price increases implemented at the outset of the year follow years of unsustainable price increases imposed by Big Pharma on consumers and taxpayers. During the period of July 2021 to July 2022, for example, drug makers raised prices in

[1] AHIP. Where Does Your Health Care Dollar Go? September 6, 2022.
[2] Beasley, D. "Prices for new US drugs rose 35% in 2023, more than previous year." Reuters. February 23, 2024.
[3] *Ibid*.
[4] Calfas, J. Drug Makers Raise Prices of Ozempic, Mounjaro, and Hundreds of Other Drugs. *The Wall Street Journal.* January 18, 2024.
[5] Kirzinger A et al. Public Opinion on Prescription Drugs and Their Prices . Kaiser Family Foundation. August 21, 2023.

excess of inflation for 1,216 drugs, with an average price increase of 31.6 percent.[6] The average price increase was nearly $150 per drug (10.0 percent) in January 2022 and was $250 (7.8 percent) in July 2022.[7]

**Despite efforts from the branded pharmaceutical industry to suggest otherwise, drug makers – and drug makers alone – are the drivers of the unsustainable growth in drug prices and excessive spending on prescription drugs today.** In fact, net spending on prescription drugs increased 9.9 percent in 2023, excluding a decline in COVID-19 vaccines and therapeutics, rising to $435 billion and representing "a significant acceleration in spending growth," according to IQVIA's latest annual report.[8] Drug companies set excessively high list prices at launch for new drugs and raise those prices every year oftentimes at rates that far exceed inflation. Spending on high-priced drugs places significant strain on patients, federal health programs, and taxpayers. High-priced drugs also substantially burden the many small businesses and large employers who seek to offer affordable health insurance to their employees because, as prescription drug expenditures increase, cost-sharing and premium costs also rise.[9] 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.

**Patent Abuse Delays Competition and Patient Access to More Affordable Medicines**

Importantly, published research shows that the brand biopharmaceutical industry's abuse of the patent system to undermine competition particularly contributes to high drug costs and spending. The analysis found that, despite representing less than one percent of U.S. prescriptions, high-priced brand biologics account for nearly half of all drug spending largely because they face less competition from biosimilars due to differences in how the marketplace is regulated and how the brand industry games the patent system to undermine competition.[10] The study estimates that the anti-competitive nature of the U.S. biologic market cost patients approximately $5 billion from 2015 through 2020.[11] Without action, the study projects that patients needlessly will pay an extra $25 billion in excess drug spending through 2029.[12]

One of the most common strategies that drug makers employ to abuse the patent system 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

[6] U.S. Department of Health and Human Services Assistant Secretary for Planning and Evaluation Office of Health Policy. "Price Increases for Prescription Drugs, 2016 – 2022." September 30, 2022.
[7] *Ibid*.
[8] IQVIA. "The Use of Medicines in the U.S. 2024: Usage and Spending Trends and Outlook to 2028." May 2024.
[9] American Academy of Actuaries. "Prescription Drug Spending in the U.S. Health Care System." March 2018.
[10] Roy, Avik. "The Growing Power of Biotech Monopolies Threatens Affordable Care." Foundation for Research on Equal Opportunity. September 15, 2020.
[11] *Ibid*.
[12] *Ibid*.

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.

Newly published research illustrates how brand drug makers construct patent thickets to prevent and delay competition from lower cost generic and biosimilar medicines. The study found that **nearly three-quarters of all patents were filed for the top-10 selling drugs in the U.S. in 2021 *after* FDA approval.** 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.[13] Critically, 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. Notably, research from the Initiative for Medicines, Access, and Knowledge (I-MAK) reached similar conclusions.[14]

Anti-competitive patent thickets impose substantial and unnecessary costs on consumers and taxpayers**: patent thickets on just five brand drugs resulted in more than $16 billion in excessive costs in single year.[15]** For example, Merck's blockbuster cancer drug *Keytruda* attained $25 billion in sales in 2023.[16] Merck filed 129 patent applications for *Keytruda* and 53 have been granted; 50 percent were filed after *Keytruda* approval and reporting suggests that Merck is seeking a new formulation of the drug to protect it from competition expected as soon as 2028.[17] [18] I-MAK estimates the cost of delayed competition for *Keytruda* could be at least $137 billion.[19]

**Patent Thickets, Evergreening and Product Hopping are Anti-Competitive and Distort the Market**

In addition to patent thickets, brand name drug makers abuse the U.S. intellectual property system through other anti-competitive tactics that keep drug costs needlessly high. Under practices commonly referred to as "evergreening" or "product hopping," for instance, brand drug makers 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 concluded that **consumers can lose up to $2 billion per year per each anti-competitive product reformulation**.[20] Critically, "product hopping" practices not only lead to higher costs, but also can harm patients: an investigation from the *New York Times* found, for example, that

[1313] 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

[14] I-MAK and the American Economic Liberties Project. The Costs of Pharma Cheating. May 16, 2023.

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

[16] Dunleavy, Kevin. Who's No. 1? With $25B in sales, Merck's Keytruda looks to be the top-selling drug of 2023. Fierce Pharma. February 1, 2024.

[17] I-MAK. Overpatented, Overpriced: Keytruda's Patent Wall. May 2021.

[18] Erman, Michael. Focus: Merck could keep its patent edge by shifting Keytruda cancer drug to a simple shot. *Reuters*. December 2, 2022.

[19] I-MAK. Overpatented, Overpriced: Keytruda's Patent Wall. May 2021.

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

drug maker Gilead employed an egregious "product hopping" strategy around a pair of blockbuster HIV treatments to maximize profits while blocking access to newer versions of those treatments proven to be safer for patients.[21]

Importantly, a report from the House Committee on Oversight and Reform demonstrates the significant cost to taxpayers and the Medicare program of Big Pharma's abuse of the U.S. intellectual property system. Upon reviewing the price histories of 12 of the best-selling drugs in Medicare, the Committee found that more than 600 patents were obtained for these 12 drugs, effectively blocking competition from more affordable alternative therapies for decades.[22] Patents already secured for these 12 drugs could potentially extend their monopoly periods to a combined total of nearly 300 years.[23] Moreover, the manufacturers collectively raised prices more than 250 times on the top-selling Medicare drugs using strategies including "product hopping" to maintain product monopolies – leading to median prices almost 500 percent higher than when they were brought to market.[24]

Thus, put simply, the brand biopharmaceutical industry is engaging in a variety of anti-competitive practices that abuse the U.S. intellectual property system to inappropriately prolong market monopolies for costly brand name drugs. These practices needlessly raise drug costs for consumers and taxpayers and significantly contribute to the overall unsustainable growth in prescription drug prices and spending that exists today. **Given today's critical prescription drug pricing crisis and the substantial contribution of Big Pharma's abuse of the intellectual property system to this crisis, CSRxP welcomes actions from the Committee and the Congress to foster greater competition and access to more affordable medications in the prescription drug marketplace.** To that end, we commend the Senate Judiciary Committee for its bipartisan efforts to advance the Affordable Prescriptions for Patients Act, the Stop STALLING Act, the Preserve Access to Affordable Generics and Biosimilars Act, and Interagency Patent Coordination and Improvement Act in February 2023. CSRxP respectfully urges enactment of these bills and other bipartisan legislation as outlined below:

**Thwart Patent Abuse**

1. **Affordable Prescriptions for Patients Act (S.150):** This bill introduced in the 118th Congress would target abusive "product hopping" practices, as well as address anti-competitive patent thickets by placing limits on the number of patents a biologic manufacturer can use to prevent competition from lower cost biosimilars. CBO estimated savings of $1.1 billion in 2022.[25]

2. **Legislation to Address Patent Thickets (S.3583 and H.R.6986):** This bill introduced in the 118th Congress would streamline patent litigation by limiting the number of patents per patent thicket that a pharmaceutical company can assert in litigation to one.

[21] Robbins R and Stolberg S. How a Drugmaker Profited by Slow-Walking a Promising H.I.V. Therapy. *The New York Times.* July 23, 2023.
[22] *Ibid*.
[23] *Ibid*.
[24] House Committee on Oversight and Reform. "Drug Pricing Investigation: Majority Staff Report." December 2021.
[25] Congressional Budget Office. "Estimated Budgetary Effects of S. 1435, the Affordable Prescriptions for Patients Act of 2021." June 2022.

3. **Interagency Patent Coordination and Improvement Act (S.79 and H.R.1717):** This legislation introduced in the 118th Congress would improve coordination and communication between the FDA and the U.S. Patent and Trademark Office (USPTO) on prescription drug-related issues.

4. **Patent Examination and Improvement Act (S.4704):** This bill from 117th Congress would help to improve the quality of patents issued and improve the overall USPTO patent examination process.

5. **Medication Affordability and Patent Integrity Act (S.2780 and H.R.5429):** This legislation introduced in the 118th 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.

6. **Restoring the America Invents Act (S.2891):** The American Invents Act established the USPTO's Patent Trial and Appeal Board (PTAB) inter partes review (IPR) process with the goals of improving patent quality and serving as a quicker and less expensive alternative to district court patent litigation. Since enactment of the AIA, certain administrative actions have created new challenges for generic and biosimilar developers. This bill from the 117th Congress would make reforms to the PTAB process and other USPTO procedures to promote generic and biosimilar competition as originally intended by the AIA.

7. **Biologic Patent Transparency Act (S.659 and H.R.4850):** This legislation from the 116th Congress would improve the quality of patent information available to biosimilar developers.

8. **Reforming Evergreening and Manipulation that Extends Drug Years Act (S.1209):** This bill from the 116th Congress would help to thwart anti-competitive "evergreening" practices in which brand name drug manufacturers make minor modifications to existing drugs to maintain market dominance and limit competition from more affordable therapies.

**Promote Biosimilar and Generic Competition**

9. **Stop STALLING Act (S.148):** This legislation introduced in the 118th Congress would provide the Federal Trade Commission (FTC) with enhanced authority to stop brand name 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. CBO estimated savings of $401 million in 2024.[26]

10. **Ensuring Timely Access to Generics Act (S.1067):** This bill from the 118th Congress would give FDA new oversight authority to reject sham citizen petitions from drug makers.

[26] Congressional Budget Office. "S. 148, Stop STALLING Act." March 2024.

11. **Increasing Transparency in Generic Drug Applications Act (S.775 and H.R.3839):** This legislation introduced in the 118th Congress would streamline the FDA approval process for generic drugs. CBO estimated savings of $871 million in 2023.[27]

12. **Preserving Access to Affordable Generics and Biosimilars Act (S.142):** This bill introduced in the 118th Congress would give the Federal Trade Commission (FTC) more authority to ensure patent settlement agreements facilitate timely patient access to more affordable generic and biosimilar medicines. CBO estimated savings of $1.6 billion in 2024.[28]

13. **Retaining Access and Restoring Exclusivity (RARE) Act (S.1214):** While FDA has approved hundreds of orphan drugs that have helped patients suffering from rare diseases, drug companies have abused the Orphan Drug Act in many instances to generate billions of dollars in sales for orphan drugs with "non-orphan" indications.[29] This legislation introduced in the 118th Congress would help prevent drug makers from exploiting the Orphan Drug Act.

14. **Reduce the market exclusivity period for brand biologics.** The overly generous 12-year market exclusivity period that brand name biologics currently have should be reduced to 7 years to better reflect the appropriate balance of incentives for pharmaceutical companies to continue innovating while also improving access to biosimilar drugs that will help alleviate cost pressures for consumers and taxpayers. Bipartisan legislation – the PRICED Act – has been introduced in previous sessions to do so.

**Conclusion**

In conclusion, CSRxP again thanks the Committee for your bipartisan leadership in aiming to enhance competition in the prescription drug marketplace to lower drugs costs and improve affordability for consumers. CSRxP firmly believes that without major actions by this Committee and others, the brand name pharmaceutical industry will continue to excessively profit from their unsustainable pricing practices that increase drugs costs and risk access for the patients who need them. 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 improve affordability for consumers while at the same time maintaining access to the treatments that can improve health outcomes and save lives. We look forward to continuing to work with you to address the drug pricing problem and advance solutions to rein in high drug prices.

[27] Congressional Budget Office. "Estimated Direct Spending and Revenue Effects of H.R. 5378, the Lower Costs, More Transparency Act." December 2023.
[28] Congressional Budget Office. "S. 142, Preserve Access to Affordable Generics and Biosimilars Act." March 2024.
[29] Tribble S and Lupkin S. Drugmakers Manipulate Orphan Drug Rules To Create Prized Monopolies. *KFF Health News*. January 17, 2017.