Statement for Hearing on "A Prescription for Change: Cracking Down on Anticompetitive Conduct in Prescription Drug Markets"

Submitted to the Senate Committee on the Judiciary Subcommittee on Competition Policy, Antitrust, and Consumer Rights

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Everyone should be able to get the medications they need at a cost they can afford. Rising drug prices impose a heavy burden on all Americans— a direct result of high list prices determined solely by drug companies. Too many hardworking Americans must choose between paying their bills and accessing life-saving medicines. AHIP appreciates the Subcommittee's attention on the problem of drug manufacturers' anticompetitive conduct in the prescription drug market. We look forward to working with the Subcommittee to advance market-based solutions that reduce drug prices by promoting competition and consumer choice, along with open and honest drug pricing.

The COVID-19 crisis has impacted all Americans and clearly illustrated the importance of access to convenient and affordable care, including lifesaving and life-sustaining medications and treatments. In a January 2021 survey conducted by Morning Consult and the Campaign for Sustainable Rx Pricing (CSRxP), 55% of Americans reported that the coronavirus pandemic has made them more concerned about prescription drug affordability.[1] However, this has not deterred drugmakers from raising their prices. In January 2021, drug companies raised prices for at least 582 brand-name drugs and so far in just this month, drug companies have hiked prices on another 52 brand name prescription drugs.[2] The conclusion is clear: Pharmaceutical companies alone set their prices—and they alone can lower them. Instead, they continue to raise prices year after year—even several times a year—making health care more expensive for everyone.

As a result of these exorbitant prices, more than 25% of Americans stated they, or both they and another family member, have been unable to afford a prescribed medication over the past year.[3] Americans should not have to choose between needed medications and other life essentials, such as housing or food.

While there are many factors that enable drugmakers to demand out-of-control prices, one of the most significant is their ability to engage in anti-competitive practices. While we all applaud true

[1] https://www.csrxp.org/wp-content/uploads/2021/01/CSRxP-Memo-Final.pdf
[2] https://www.goodrx.com/blog/january-drug-price-hikes-2021/
[3] https://www.csrxp.org/wp-content/uploads/2021/01/CSRxP-Memo-Final.pdf

innovations in care, including the recent successes in COVID-19 vaccine development, too many pharmaceutical innovations today also involve novel ways to extend patents beyond their intended terms. The cost of this kind of innovation takes dollars out of Americans' pockets, places care out of reach, and defers true innovation.

Prescription drugs comprise a very high percentage of medical costs, driving up Americans' health insurance premiums and the cost of health care delivered by providers whose care includes the administration of those drugs. Today, more than 21 cents of every dollar spent on health insurance premiums pays for prescription drugs—more than any other single category of expense.[4] At the same time, the largest drugmakers in the United States spend just 22 cents out of every dollar on research & development (R&D).[5] That means nearly 80 cents goes toward something other than R&D.

Research from the Congressional Budget Office confirmed that pharmaceutical R&D costs do not have a relationship to the prices drug companies set on their products.[6] The report states, "Importantly, when drug companies set the prices of a new drug, they do so to maximize future revenues net of manufacturing and distribution costs. A drug's sunk R&D costs—that is, the costs already incurred in developing that drug—do not influence its price."

In July 2021, the House Committee on Oversight and Reform released a report on drug pricing showing that leading drug companies have spent more on stock buybacks, dividends to investors, and executive compensation than on R&D.[7] In fact, from 2016 to 2020, the 14 leading drug companies spent $577 billion on stock buybacks and dividends—$56 billion more than they spent on R&D over the same period. This analysis therefore reveals that drug companies' claims that reducing U.S. prescription drug prices will harm innovation is overblown.

In September 2020, the Foundation for Research on Equal Opportunity released a study that found ballooning spending on American prescription drugs is being particularly driven by drugmakers' abuse of the patent system to undermine biologic and biosimilar competition.[8] The report finds that despite representing less than 1% of prescriptions in the United States, biologic drugs account for nearly half of all drug spending. Without action, the study estimates the anti-competitive nature of the biologic drug marketplace will cost American patients more than $30 billion from 2015-2029.

Drugmakers continue to command higher and higher drug prices for longer periods of time due to gamesmanship and other abuses of the monopoly power resulting from patent protection. Legislative and regulatory action is necessary to address drug manufacturer manipulation of existing laws. We welcome the opportunity to work with the Subcommittee to advance bipartisan solutions that end these abuses and lower drug costs, premiums, employer burdens, and taxpayer expenses.

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[4] https://www.ahip.org/health-care-dollar/
[5] https://www.csrxp.org/wp-content/uploads/2019/05/CSRxP_One_pager_III_FINAL-SITERELEASE.pdf
[6] https://www.cbo.gov/system/files/2021-04/57025-Rx-RnD.pdf
[7] https://oversight.house.gov/sites/democrats.oversight.house.gov/files/COR%20Staff%20Report%20-%20Pharmaceutical%20Industry%20Buybacks%20Dividends%20Compared%20to%20Research.pdf
[8] https://freopp.org/the-growing-power-of-biotech-monopolies-threatens-affordable-care-e75e36fa1529

Identifying and Addressing Patent Abuses to Reduce Drug Prices

Americans broadly agree lowering drug prices is an urgent challenge, with 96% of Americans saying it is "very" or "somewhat" important among all the issues facing the nation.[9] That includes 71% of Americans who classify lowering drug prices as "very important."

Leveraging new patents to extend the life of existing patents. Pharmaceutical companies have a long history of engaging in anti-competitive patent abuse schemes to hinder generic competition and maintain high drug prices. This includes strategies to extend the patent life of their products without making clinically significant changes to the products. A recent study of prescription drugs on the market between 2005 and 2015 found that "78% of the drugs associated with new patents in the FDA's records were not new drugs coming on the market, but existing drugs."[10]

Product hopping describes a practice engaged in by brand drug manufacturer in which, when a product nears the end of its monopolistic patent life, the brand drug manufacturer works to move patients from the product nearing patent expiration to a patent-protected reformulation of the drug.[11] This practice takes two forms, through a "hard switch," where the older product is removed from the market, and a "soft switch," where the older product is kept on the market with the new product. In either case, this reformulation generally has no improved clinical result, does not fundamentally change the drug's therapeutic effect, and does not provide any additional benefits to consumers. It is a lifecycle management tactic that benefits only the manufacturer at the expense of patients and the health care system, as generic savings cannot be realized if patients have been moved to a protected drug before generic competitors can enter the market.

A recent example of product hopping can be seen with Gilead's two anti-retroviral HIV drugs—tenofovir disoproxil fumarate (TDF) and tenofovir alafenamide (TAF)—both critical therapies in treating and preventing transmission of that devastating disease. Manipulating intellectual property law and FDA regulations, Gilead was able to stagger exclusivity protections for each type of drug for the purpose of delaying the entry of generic versions of each drug and extend their patents despite both drugs having been discovered at roughly the same time. Moreover, the TAF drugs—introduced in 2016 after patent exclusivity for the TDF drugs expired—are potentially safer due to lower dosing requirements and fewer/less severe side effects, per research originally conducted by the company in 2002-2003.[12] Thus, HIV patients—and those at risk of contracting the virus who would be eligible to take the drug as a preventive measure—have been delayed access to a safer, more effective drug solely to extend the opportunity for Gilead to profit from their products over a greater length of time.

Patent thicketing serves a similar purpose to *product hopping* by effectively blocking cheaper generics or biosimilars from coming to market. Patent thicketing occurs when brand name drug companies create a "thicket" of patents that can dramatically extend exclusivity periods by

[9] https://www.csrxp.org/wp-content/uploads/2021/01/CSRxP-Memo-Final.pdf
[10] https://www.affordableprescriptiondrugs.org/resources/the-cost-of-brand-product-hopping/
[11] https://www.affordableprescriptiondrugs.org/resources/the-cost-of-brand-product-hopping/
[12] Intentionally Delayed Pharmaceutical Innovation Under Perverse Incentives: Gilead's HIV Pipeline As A Case Study | Health Affairs

seeking a multitude of patents for marginal aspects of the drug or biologic. A common example of this practice relates to Humira, a popular treatment for chronic inflammatory diseases such as rheumatoid arthritis and psoriasis made by AbbVie Inc. AbbVie has been granted 138 patents since Humira's approval by the Food and Drug Administration (FDA) in 2002.[13] Many of those patents were issued in the years close to the expiration of Humira's main patent. Even when the purpose of the patent acquisition was to harm competitors, courts have found that these thickets do not violate antitrust law.[14] But such court rulings have not helped hardworking American families, who lack access to biosimilars and thus are stuck paying high prices. Of note, Humira's price has almost doubled since 2012, from about $19,000 to $38,000[15] per year.[16]

Another way drugmakers maintain monopoly power is through *evergreening*. Evergreening occurs when a branded drugmaker makes minor changes to their drug, such as to their manufacturing process or the formulation of the drug in its injectable form, and receives approval for those changes from the FDA. As a result, drugmakers can gain new patents on the minor variations, extending their market exclusivity for an additional 20 years.[17]

These are just some of the anticompetitive tactics pharmaceutical companies employ to boost their profits. Market-based solutions will help crack down on drugmakers' egregious practices and increase biosimilar competition, lower prices, and enhance innovation.

Recommendations
AHIP is committed to advancing policies that increase choice, competition and end this anti-generic/biosimilar patent gaming pursued by pharmaceutical companies. Those policies include:

1. Shortening the Exclusivity Period for Biologics to Increase Biosimilars Competition.
Biosimilars offer great promise for generating cost savings and increasing patient access to needed treatments and therapies. Just as with generic medications, a truly competitive biosimilars market will mean greater use of these products which, in turn, will drive down costs and increase patient access. As drugmakers are preventing competition from biosimilars by gaming the 12-year exclusivity period for biologics, Congress should consider shortening this exclusivity period to allow for earlier biosimilar competition. Non-partisan experts, such as those at the Federal Trade Commission (FTC), have concluded that the current 12-year exclusivity period is "unnecessary to promote innovation by pioneer biologic manufacturers" and could actually harm innovation in this space. By reducing the exclusivity period from 12 years to 7 years, Congress could promote greater price competition and help alleviate cost pressure for payers, patients, and consumers for biologics, which often carry extraordinarily high price tags. Moreover, a shorter exclusivity period could facilitate earlier and greater availability of biosimilars in the marketplace.

[13] https://www.healthaffairs.org/do/10.1377/hblog20210126.820337/full/
[14] https://www.natlawreview.com/article/abbvie-s-enforcement-its-patent-thicket-humira-under-bpcia-does-not-provide
[15] https://www.csrxp.org/big-pharma-earnings-watch-abbvie-3/
[16] A Humira Prescription Costs $38,000 A Year Because Our Patent System Is Being Abused | HuffPost
[17] https://freopp.org/the-growing-power-of-biotech-monopolies-threatens-affordable-care-e75e36fa1529

2. Prohibit Anti-Competitive "Pay-For-Delay" Settlements that Hinder Competition in the Generics and Biosimilars Markets.

Currently, drugmakers offer patent settlements that pay generic drug companies not to bring their lower-cost alternatives to market for a certain amount of time. "Pay-for-delay" settlements block generic competitors from entering the market, allowing brand name drugmakers to continue to obtain monopoly profits and avoid competition. The FTC indicates that these "pay-for-delay" tactics by drugmakers cost Americans $3.5 billion in higher drug costs each year.[18] Fully halting these anti-competitive settlements will remove a barrier to competition and expand the availability of lower-cost generic drugs and biosimilars.

3. Stop the "Evergreening" of Patent Protections.

Some drugmakers game the patent system to artificially prolong the exclusivity period for certain drugs and to prevent less costly generic versions from reaching the market. By making minor changes to a drug's chemical composition or delivery mechanism (*e.g.*, an extended-release version of a previously patented drug that had to be taken twice daily), manufacturers can extend patents that otherwise would have expired. These evergreening schemes do not typically provide any meaningfully enhanced clinical benefits to patients. Instead, they are aimed at maintaining monopolistic pricing for products that are no more effective than their less expensive, generic counterparts. We look forward to working with the Subcommittee to address this issue.

4. Limit Product Hopping that Does Not Benefit Patients

Product hopping is frequently used in combination with Evergreening to hold patients captive to a higher-cost drug. Drugmakers using this strategy redesign a drug in a way that allows a new version to be patentable even though it does not fundamentally change the drug's therapeutic effect. Those minor changes present an opportunity for the brand-name manufacturer to extend its monopoly potentially decades into the future. We look forward to working with the Subcommittee to address this issue.

Conclusion

Americans deserve bold actions, at both the legislative and regulatory levels, to hold drugmakers accountable for the high list prices they set. The impact of high drug prices and patent abuses is felt directly by American families and businesses in the form of higher costs for needed drugs, higher premiums for health plans that pay for them, and fewer treatment choices for patients. With solutions that deliver real competition, create more choices, and ensure open and honest drug prices, the private market will have the tools it needs to deliver more affordable pharmaceutical products— while protecting and supporting innovations to deliver new treatments and cures for patients.

[18] https://www.ftc.gov/news-events/media-resources/mergers-competition/pay-delay