Testimony Submitted for the Record

U.S. House Committee on Energy & Commerce Health Subcommittee

Hearing: ""Lowering the Cost of Prescription Drugs: Reducing Barriers to Market Competition"

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March 13, 2019

Chairwoman Eshoo, Ranking Member Burgess, and members of the House Committee on Energy & Commerce Health Subcommittee, the Campaign for Sustainable Rx Pricing (CSRxP) thanks you for the opportunity to submit testimony for the record on lowering the price of prescription drugs by enhancing market competition through reduction in barriers that impede generic drug and biosimilar competition. We very much appreciate your leadership in addressing this critically important issue that American consumers and taxpayers face every day.

CSRxP is a nonpartisan coalition of organizations committed to fostering an informed discussion on sustainable drug pricing and to developing bipartisan, market-based solutions that promote competition, transparency, and value to improve affordability while maintaining patient access to innovative prescription drugs that can improve health outcomes and save lives. Our members represent organizations including consumers, hospitals, physicians, nurses, pharmacists, employers, pharmacy benefit managers and insurance providers.

Prescription drug prices are needlessly high and continue to grow at unsustainable rates. Twenty-three cents of every health care dollar goes toward prescription drugs.[1] One in four Americans cannot afford their medications. Excessively high prices unfairly threaten the financial security, health and wellbeing of U.S. patients and their families every day, as well as strain Federal and state health budgets and the taxpayers who fund them. Too often patients are faced with the unfortunate and unfair choice of purchasing the medications they need to get well and stay healthy and paying their bills. Patients should never be presented with such a choice.

CSRxP thus strongly believes it is imperative to rein in out-of-control drug prices and welcomes the leadership of this Subcommittee in seeking to address this vexing problem that impacts Americans every day. In particular, we firmly believe that significant actions must be taken to address the root cause of the core problem: drug manufacturers – and drug manufacturers alone – set list prices too high and continue to raise them at unsustainably high rates.

CSRxP further believes that meaningful generic and biosimilar competition can place pressure on brand drug makers to lower list prices and reduce overall prescription drug costs. One study funded by the Pharmaceutical Research and Manufacturers of America (PhRMA) found, for example, that prices of oral generic medicines decline by 66 percent in the first 12 months after generic entry and cost 80 percent less than the brands they replace within five years.[2] Those individual product savings from generic

[1] AHIP. "Where Does Your Healthcare Dollar Go?" May 22, 2018.
[2] IMS Institute for Healthcare Informatics. "Price Declines after Branded Medicines Lose Exclusivity in the U.S." January 2016.

competition have reduced prescription drug costs for the U.S. healthcare system in aggregate, saving an estimated $265 billion in 2017 – including more than $80 billion in Medicare and $40 billion in Medicaid – and approximately $1.67 trillion over the last decade.[3] [4] Biosimilars also have the potential to generate substantial savings for consumers and taxpayers, particularly given that they can serve as meaningful competition to many of the high-cost specialty medications that are driving the increased and unsustainable U.S. spending on prescription drugs. One analysis, for instance, projected that the 11 biosimilars already approved for sale in Europe and elsewhere could generate approximately $250 billion in savings over 10 years if they were available in the U.S.[5]

Without significant legislative and administrative action, however, the potential savings for consumers and taxpayers from generics and biosimilars may not be realized. Therefore, CSRxP very much appreciates the Subcommittee's leadership and welcomes actions that will reduce barriers to generic and biosimilar competition. Below we offer our support and comments on many of the pieces of legislation under consideration by the Subcommittee that addresses patent listing barriers, drug development barriers, and market entry barriers to generic and biosimilar competition. In addition, we suggest certain refinements to better ensure that consumers can more quickly access these affordable products and lower their spending on prescription drugs.

CSRxP firmly maintains that without major actions by this Subcommittee and others, the pharmaceutical industry will continue to excessively profit from the anti-competitive and unsustainable pricing practices that make prescription drugs unaffordable and jeopardize access for the patients who need them. We look forward to our continued work with the Subcommittee to reduce barriers to generic and biosimilar competition, to thwart unfair drug company pricing practices, and to implement bipartisan, market-based solutions that curb the unsustainable growth in out-of-control prescription drug prices.

I. Drug Development Barriers

FDA uses the Risk Evaluation Mitigation and Strategy (REMS) program to allow products with potential safety issues to enter the market. When employed effectively and appropriately, REMS improves patient safety and makes accessible medicines that otherwise might not be available due to safety concerns. However, drug manufacturers often engage in abusive, anti-competitive behaviors that manipulate REMS to block generic drug companies from obtaining samples of brand drugs under the guise of addressing patient safety concerns, effectively preventing them from pursuing the research needed to bring less expensive generic drugs to market. Concern exists that manufacturers of reference biologic products have the potential to engage in similar REMS abuses as brand drug makers, causing developers of biosimilar and interchangeable biologics to face similar challenges in obtaining samples of reference biologics for testing.

To thwart this anti-competitive practice by brand manufacturers, CSRxP welcomes the Subcommittee's leadership and urges quick enactment of the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act or the Fair Access to Safe and Timely (FAST) Generics Act. Both of these important pieces of bipartisan legislation will help curb REMS abuses and better enable consumers to access more affordable generic drugs more quickly. We urge passage of either of these bills as soon as possible.

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[3] Gottlieb, Scott. "FDA Working to Lift Barriers to Generic Competition." *FDA Voice*. June 21, 2017.
[4] Association for Accessible Medicines. "2018 Generic Drug Access & Savings in the U.S.: Access in Jeopardy."
[5] Express Scripts. "The $250 Billion Potential of Biosimilars." April 23, 2013.

II. Patent Listing Barriers

Rather than only securing a patent for a drug's active ingredient or a biologic's composition of complex molecules, brand drug makers often obtain secondary patents for manufacturing, methods of production, or other aspects of a product to help extend its market exclusivity period and delay consumer access to generic and biosimilar competition. A study of secondary drug patents between 1985 found 2005 concluded that they were highly common, with supplemental formulation patents adding an average of 6.5 years of patent life and method-of-use patents adding an average of 7.4 years of patent life.[6] A separate study of the roughly 100 best-selling drugs between 2005 and 2015 found that, on average, 78 percent of drugs associated with new patents in the FDA's records were existing – not new – drugs coming on the market."[7] For example, Humira, the best-selling pharmaceutical product in the world today with nearly $20 billion in sales in 2018, has over 100 patents and obtained over 70 newer patents in recent years that potentially could extend its market protection as far as 2034, but likely at least through 2022.[8] [9] [10] [11]

Improvements to the Orange Book

Drug manufacturers list patent information in FDA's Orange Book to help generic manufacturers make drug development decisions. Recent research has shown that patent information included in the Orange Book by brand drug makers in certain cases may be of questionable validity or applied inappropriately as a way to delay generic competition.[12] "FDA does not scrutinize the company's representations, however, but merely records whatever the company submits in what is known as the 'Orange Book.' Thereafter, a competitor seeking approval of a generic drug must battle every patent listed in the Orange Book in relation to the drug. Thus, simply listing a patent in the Orange Book can operate to block or delay competition, even if the patent does not cover the drug," the researchers explained.[13] In addition, FDA requires that the drug company submit a short statement describing the approved use (or uses) claimed by the patent, which the agency then assigns a number and lists in the Orange Book as a "use code." Although FDA requires brand manufacturers to submit "use codes," researchers have found that manufacturers in certain instances submit "use codes" that are overbroad or inaccurate, potentially suggesting another means by which to delay generic competition.[14]

Given these potential anti-competitive manipulations of the FDA Orange Book process by brand manufacturers, the Orange Book Transparency Act of 2019 would assist generic drug manufacturers in product development and help remove barriers to generic competition in the marketplace. This

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[6] Feldman, Robin and Wang, Connie. "May Your Drug Price Ever Be Green." UC Hastings Research Paper No. 256. October 31, 2017.
[7] *Ibid*.
[8] Gonzalez, Richard. "Abbvie Long-Term Strategy." October 30, 2015. Slides 14 - 16.
[9] Pollack, Andrew. "Makers of Humira and Enbrel Using New Drug Patents to Delay Generic Versions." The New York Times. July 15, 2016.
[10] Slide presentation by Michael Carrier at FTC November 8, 2017 workshop. Slide 48.
[11] AbbVie. "AbbVie Reports Full-Year and Fourth-Quarter 2018 Financial Results." January 25, 2019.
[12] Feldman, Robin and Wang, Connie. "May Your Drug Price Ever Be Green." UC Hastings Research Paper No. 256. October 31, 2017.
[13] *Ibid*.
[14] *Ibid*.

legislation would better ensure that information in the Orange Book is accurate and up-to-date, providing generic manufacturers with improved information to make drug development decisions. In addition to the provisions in H.R. 1503, CSRxP further suggests that FDA work with the U.S. Patent and Trademark Office (USPTO) to increase scrutiny of patents and "use codes" listed in the Orange Book so that patents lists are valid and applied appropriately. This will help guard against any anti-competitive listing of inappropriate or invalid patents of brand drugs by drug makers that delays or prevents generic competition.

Improvements to the Purple Book

FDA's Purple Book includes certain limited information about reference biologics, but not the same level of information as is available for small molecule drugs in FDA's Orange Book. For example, the Purple Book does not include any information related to the patents of brand biological products.[15] Moreover, the limited information available in the Purple Book is not easily accessible and searchable online. Researchers have suggested that lack of sufficient and easily accessible information in the Purple Book has the potential to hinder development and consumer accessibility of biosimilar and interchangeable biological products.[16]

The Purple Book Continuity Act of 2019 would help foster increased development of biosimilar and interchangeable biologics and prevent unnecessarily delayed development and entry of biosimilar and interchangeable biologic products. This legislation would mandate that the Purple Book follow the general format and include information similar to that in the Orange Book, as well as require FDA to publish the Purple Book on its website with routine updates. Indeed, at a minimum, the Purple Book should list, for example, the patents and their expiration dates that protect reference biological products, the dosage, the route of administration, and exclusivity periods (e.g., pediatric and orphan exclusivities) so that manufacturers of biosimilar and interchangeable biologic products can have a better understanding of product development. Moreover, in addition to the provisions included in the legislation, CSRxP further suggests that FDA collaborate with the USPTO to increase scrutiny product patents listed in the Purple Book to limit any potentially invalid or inappropriately applied patents. This will better protect against any anti-competitive tactics by brand biologic manufacturers to delay or prevent competition from interchangeable or biosimilar biologic products through listing of invalid or inappropriate patents.

III. Market Entry Barriers

Prohibition on "Pay-for-Delay" Settlements

Brand and generic drug manufacturers are able to enter into patent dispute settlements – often referred to as "pay-for-delay" settlements – that result in the generic manufacturer agreeing to refrain from marketing its product for a specific period of time in return for compensation (often undisclosed) from the branded company. The Federal Trade Commission (FTC) estimated that these anti-competitive agreements cost consumers and taxpayers $3.5 billion in higher drug costs every year.[17] Of significant concern is that, more recently, these "pay-for-delay" settlements have extended to biologics, delaying

[15] *Ibid*.
[16] *Ibid*.
[17] FTC. "Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions." January 2010.

the entry of less costly biosimilars into the market. The Protecting Consumer Access to Generic Drugs Act of 2019 may reduce barriers to generic market entry that result from "pay-for-delay" agreements, improving competition and lowering costs for consumers and taxpayers.

Refining Generic Exclusivity Provisions

CSRxP strongly supports policies that promote increased availability of generic drugs and we welcome the opportunity to work with the Subcommittee on policies that will help expedite the availability of generic drugs to consumers. As Congress considers policies to achieve these goals it is imperative that we increase competition in the prescription drug market and maintain important incentives for manufacturers to develop generic drugs.

Conclusion

In conclusion, CSRxP again thanks the Subcommittee for the opportunity to submit testimony for the record to reduce barriers to generic and biosimilar competition in the U.S. prescription drug marketplace so that can consumers can more quickly access these more affordable medicines. We very much appreciate the leadership from the Subcommittee in addressing this critically important issue that affects American patients and their families every day. CSRxP looks forward to working with the Subcommittee to implementing these and other bipartisan, market-based policies that promote transparency, foster competition, and incentivize value to make prescription drugs more affordable for all consumers while at the same time maintaining access to the treatments that can improve health outcomes and save lives.