# Statement for Hearing on

# "Intellectual Property and the Price of Prescription Drugs: Balancing Innovation and Competition"

## Submitted to the Senate Judiciary Committee

**May 7, 2019**

Thank you for examining concerns about prescription drug pricing and the importance of promoting both competition and innovation in the pharmaceutical market. AHIP and our members share your commitment to ensuring that Americans are able to get the medications they need at a price they can afford.

Drug prices are out of control, and hardworking American families shouldn't have to choose between paying their bills and getting the medications they need. The problem is the price: Drug makers set the prices for their medications, they alone increase prices, and they alone can decide to bring down their prices. By working together, we can find real solutions that will achieve both lower prices and innovation.

Our statement for today's hearing focuses on issues within the jurisdiction of the Senate Judiciary Committee, including two bills we support that would remove barriers to lower-cost generic drugs and promote competition in the pharmaceutical marketplace.

---

*America's Health Insurance Plans (AHIP) is the national association whose members provide coverage for health care and related services to millions of Americans every day. Through these offerings, we improve and protect the health and financial security of consumers, families, businesses, communities, and the nation. We are committed to market-based solutions and public-private partnerships that improve affordability, value, access, and well-being for consumers.*

**"Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act"**

We applaud Senator Leahy for introducing the Senate version of the "CREATES Act" (S. 340) and we appreciate that 11 other committee members have cosponsored this important legislation.

This bipartisan bill, which we strongly support, is needed to prevent the abuse of patient safety protocols and ensure the widespread availability of generic and biosimilar drugs. This will result in affordable, highly-competitive alternatives to high-priced brand name drugs and lower out-of-pocket costs for patients and consumers. The Congressional Budget Office (CBO) estimates that this legislation would save patients and taxpayers $3.9 billion over 10 years.[1]

Under the "CREATES Act," branded drug makers could no longer hide behind Risk Evaluation and Mitigation Strategies (REMS) and limited distribution arrangements to restrict access to adequate samples of reference drugs in order to impede the development of lower-cost generic and biosimilar competitors. By reducing barriers to the entry of generic drugs and biosimilars into the marketplace, this legislation takes an important step toward providing the American people relief from out-of-control drug prices.

**"Preserve Access to Affordable Generics and Biosimilars Act"**

We also applaud Senators Klobuchar and Grassley for introducing the "Preserve Access to Affordable Generics and Biosimilars Act" (S. 64), and we thank Senators Leahy, Durbin, and Ernst for cosponsoring this legislation.

This bill, which we strongly support, would prohibit "pay-for-delay" agreements under which branded drug makers make payments to generic manufacturers to settle patent infringement claims and not bring lower-cost generics to market. In return for some payment of money or other value, the generic competitor agrees not to research, develop, manufacture, market, or sell the branded product in question. These anti-competitive settlements create a barrier to competition. Halting them will expand the availability of lower-cost generic drugs and biosimilars. CBO estimates that this legislation would save patients and taxpayers $613 million over 10 years.[2]

---

[1] https://www.cbo.gov/system/files/2019-04/hr965.pdf
[2] https://www.cbo.gov/system/files/2019-04/hr1499.pdf

The U.S. Supreme Court has cautioned: "There is reason for concern that settlements taking this form tend to have significant adverse effects on competition."[3] Referring to the Court's comment on this issue, the Federal Trade Commission (FTC) states: "The core concern with agreements such as these—what the Court termed 'the relevant anticompetitive harm'—is that they will allow the branded manufacturer to 'prevent the risk of competition,' by sharing its monopoly profits, which are preserved by the agreement, with the prospective generic entrant."[4]

By enacting legislation to prohibit these anti-competitive "pay-for-delay" settlements and ensuring that the FTC has adequate resources to enforce the prohibition, Congress can make significant progress toward promoting competition and making life-saving prescription drugs more affordable for the American people.

**Curtailing Abuses of Patent Laws and Reforming Drug Market Exclusivity Provisions**

As the committee explores balancing patents and intellectual property protections and innovation, we want to highlight other policies that have significant implications for the affordability of prescription drugs:

- **Stop the "Evergreening" of Patent Protections:** We are concerned that some drug makers are gaming patent protections to artificially prolong the exclusivity period for some drugs and 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 meaningful enhanced clinical benefits to consumers. Instead, they are aimed at maintaining monopolistic pricing for products that are just as effective as their less expensive, generic counterparts. We look forward to working with the committee on legislative solutions to address this problem.

---

[3] *Federal Trade Commission v. Actavis, Inc*., 133 S.Ct. 2223, 2231; 570 U.S. 756, ___ (2013)

[4] Federal Trade Commission testimony for hearing in House Judiciary Subcommittee on Regulatory Reform, Commercial and Antitrust Law, July 27, 2017. https://www.ftc.gov/system/files/documents/public_statements/1234663/p859900_commission_testimony_re_at_concerns_and_the_fda_approval_process_house_7-27-17.pdf

- **Preserve the Inter Partes Review Process:** It is important to preserve the Inter Partes Review (IPR) process at the U.S. Patent and Trademark Office. The IPR process plays an important role in invalidating patents that do not represent true innovation and should not have been issued in the first place. Weakening this process would effectively extend the original patent monopoly for pharmaceutical and biological products and result in significantly higher prices for consumers. We urge the committee to hold back in considering legislation (S. 344) that would place new restrictions on the ability of generic and biosimilar companies to challenge non-meritorious pharmaceutical patents through the IPR process.

- **Shorten the Exclusivity Period for Biologics to 7 Years:** Congress should consider shortening the exclusivity period for biologics to allow for more biosimilar competition. Non-partisan experts, such as those at the 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.[5] 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 some of the highest price tags. Moreover, a shorter exclusivity period could facilitate earlier and greater availability of biosimilars in the marketplace.

- **Revisit and Revise Orphan Drug Incentives:** Among its provisions to incentivize the development of drugs developed to treat rare diseases, the Orphan Drug Act provides a 7-year market exclusivity period. This period begins on the date of the Food and Drug Administration's (FDA) approval of the orphan indication, during which time the FDA cannot approve another similar drug for the same orphan indication. Many drugs classified as orphan drugs are being used to treat common medical conditions. In fact, an AHIP analysis of 45 orphan drugs available from 2012 to 2014 found that almost half of the utilization of these drugs (44%) was for non-orphan diseases.[6] We also found that drugs having little to no orphan utilization increased their prices during this time period by 180% more than those orphan drugs used almost exclusively to treat orphan diseases, making such medications more expensive for patients and the health care system. Congress should revisit the

---

[5] "Emerging Health Care Issues: Follow-on Biologic Drug Competition," Federal Trade Commission, June 2009. https://www.ftc.gov/sites/default/files/documents/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report/p083901biologicsreport.pdf

[6] "Orphan Drug Utilization and Pricing Patterns (2012-2014)," AHIP, October 2016. Orphan drugs are defined as those intended to treat rare diseases that affect fewer than 200,000 people in the United States. https://www.ahip.org/wp-content/uploads/2016/10/OrphanDrug_DataBrief_10.21.16.pdf

incentives within the Orphan Drug Act to ensure the Act is used as intended by those developing medicines to treat rare diseases—not as a gateway to premium pricing and blockbuster sales and profits beyond orphan indications.

Looking beyond the focus of today's hearing, there are many other areas where AHIP and our members support legislative and regulatory solutions for responding to out-of-control prescription drug prices:

- Ensuring that federal rules promote the availability of interchangeable biosimilars;
- Providing more transparency and timely information about drug and biologic patents to promote greater generic drug and biosimilar competition;
- Requiring drug makers to publish true research and development costs and explain price setting and price increases;
- Mandating that drug maker coupons and/or co-pay cards cover a patient's entire out-of-pocket expenses for the duration of the drug therapy;
- Disclosing list prices in direct-to-consumer advertisements;
- Informing patients and physicians on the effectiveness and value of drugs;
- Eliminating barriers to value-based pricing; and
- Exercising HHS' authority to introduce market competition when manufacturers fail to engage in reasonable, good-faith negotiations with payers.

**Conclusion**

Thank you for considering solutions to address the pharmaceutical cost crisis. We look forward to working with the committee to make prescription drugs more affordable. Everyone deserves access to the medications they need at a price they can afford. We should not have to choose between innovation and affordability. With the right solutions and genuine collaboration, we can have both.