# Statement on
# "Lowering the Cost of Prescription Drugs: Reducing Barriers to Market Competition"

## Submitted to the
## House Energy and Commerce Committee
## Subcommittee on Health

**March 13, 2019**

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.

We thank the Committee for focusing on solutions that will help to reduce out-of-control prescription drug prices for the American people. Outrageous drug prices harm patients who cannot afford life-saving medications, consumers who pay higher and higher premiums because of higher and higher drug prices, employers who have fewer resources to devote to employee wages, and hardworking taxpayers who fund public programs like Medicaid and Medicare.

AHIP's health insurance provider members—along with their pharmacy benefit manager (PBM) partners—are the bargaining power of the American people. Leveraging competition among prescription drugs with generic or therapeutic alternatives, they negotiate with drug makers for lower costs, encourage enrollees to use the most cost-effective, therapeutically appropriate drugs, and pass the savings along to consumers through lower premiums and out-of-pocket costs.

Drug makers alone set the prices for their products. They alone increase prices and they alone have the ability to reduce their prices. The monopoly power of drug makers allows them to set prices for their own financial gain at the expense of patients and taxpayers. To address this reality—that **"The Problem Is the Price"**—additional legislative and regulatory actions are needed to make prescription drugs more affordable for everyone.

Our members support market-based solutions that hold drug makers accountable for high list prices and put downward pressure on prescription drug prices through competition, consumer choice, and open and honest drug pricing. This includes solutions that would: (1) promote competition by removing barriers to the availability of generic drugs; (2) create a robust and competitive marketplace for biosimilars; and (3) increase transparency around pharmaceutical prices.

We appreciate this opportunity to comment on several bills the Committee will consider in today's hearing, including proposals that take important steps to reduce barriers to competition in the pharmaceutical marketplace.

**H.R. 965, "Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act"**

We strongly support the "CREATES Act." This bipartisan bill is needed to prevent the abuse of patient safety protocols and ensure the widespread availability of generic and biosimilar drugs to promote affordability and lower consumers' out-of-pocket costs. The Congressional Budget Office (CBO) estimates that this legislation would save patients and taxpayers $3.9 billion over ten years by allowing lower-priced generic drugs to enter the market earlier.[1]

Enactment of the "CREATES Act" would discourage brand name drug makers from blocking the availability of generic drugs by abusing Risk Evaluation and Mitigation Strategies (REMS) that are otherwise required by the Food and Drug Administration (FDA) to promote patient safety. Under this bill, branded drug makers could no longer hide behind REMS and limited distribution arrangements to restrict access to adequate samples of reference drugs and impede the development of lower-cost generic competitors. By reducing barriers to the entry of generic drugs into the marketplace, this legislation takes an important step toward providing the American people relief from out-of-control drug prices.

[1] https://www.cbo.gov/system/files/2018-09/s974.pdf

**H.R. 985, "Fair Access for Safe and Timely (FAST) Generics Act"**

The "FAST Generics Act," which we also support, proposes another approach to preventing the abuse of REMS protocols and ensuring that generic drug makers have access to adequate samples of approved drug products for the purpose of testing and developing generic versions.

Enactment of this bipartisan bill would increase competition in the pharmaceutical market and help drive down out-of-control prescription drug costs. Similar to the CREATES Act, it closes a loophole in federal law that has too often been exploited by certain brand name drug makers to keep generic and biosimilar competitors out of the market. We agree that this legislation should be approved by Congress as part of a broad-based strategy for halting anticompetitive behavior by drug makers and lowering drug prices for the American people.

**H.R. 1499, "Protecting Consumer Access to Generic Drugs Act"**

We strongly support H.R. 1499 and other legislative proposals that would prohibit "pay-for-delay" agreements under which prescription drug patent infringement claims are settled with a potential generic competitor agreeing (after receiving something "of value") not to research, develop, manufacture, market, or sell the product in question. Halting these anti-competitive settlements will remove a barrier to competition and expand the availability of lower-cost generic drugs and biosimilars.

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."[2] 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 to 'prevent the risk of competition,' by sharing its monopoly profits, which are preserved by the agreement, with the prospective generic entrant."[3]

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

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

significant progress toward promoting competition and making life-saving prescription drugs more affordable for the American people.

**H.R. 1520, "Purple Book Continuity Act" and H.R. 1503, "Orange Book Transparency Act"**

Both of these bills propose changes to pharmaceutical reference compendia (e.g., the Purple and Orange Books) as a way to promote greater generic and biosimilar competition and reduce drug costs for patients. By including more information about approved biological products, H.R. 1520 can help stakeholders have access to more timely and updated information on biologics and biosimilars via enhancements to the Purple Book. Moreover, making available such information—including critical information related to biologic patents and bioequivalence studies—can help biosimilar developers in bringing their products to market and increasing the availability of more affordable treatment options for patients.

Likewise, legislation to improve the transparency of patents for brand name drugs—via updates and changes to the Orange Book—can also help fulfill the goals of greater generic availability and lower drug costs. For example, by requiring brand name drug makers to remove invalidated patents from the Orange Book, H.R. 1503 can spur greater generic competition and entry when patents are invalidated by a court or patent appeals board decision.

**Conclusion**

Thank you for considering solutions to address the pharmaceutical cost crisis. We look forward to continuing to work 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.