Statement for Markup of Prescription Drug Bills

Submitted to the
Senate Judiciary Committee

June 27, 2019

We thank the committee for continuing its consideration of legislative proposals that address 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 and control 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.

In our previous statements to the committee, we have expressed strong support for legislation that would remove barriers to lower-cost generic drugs and promote competition in the pharmaceutical marketplace, including the "Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act" (S. 340) and the "Preserve Access to Affordable Generics and Biosimilars Act" (S. 64). These bipartisan bills take important steps toward providing the American people relief from out-of-control drug prices.

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.

In this statement, we highlight our support for several bills the committee is considering in today's markup:

Preserving Access to Cost-Effective Drugs (PACED) Act (S. 440)

This bill, which AHIP supports, would prevent patent owners from asserting sovereign immunity as a defense in certain actions before the United States Patent and Trademark Office (PTO). This legislation addresses concerns surrounding an attempt by Allergan, Inc. to circumvent the Inter Partes Review (IPR) process at the PTO—and thereby extend its monopoly power far beyond the time period intended by Congress—through a combination of patent transfer and tribal sovereign immunity.

While the Allergan case involves a specific approach to avoiding IPR review, it is part of a larger pattern of attempts by drug makers to extend their monopolies and avoid competition from generic products. By closing loopholes and combatting such sham transactions, this legislation would help spur the availability of more affordable generic drugs and promote patient affordability. Moreover, by preserving the IPR process to reconsider and challenge patents that should not have been granted, this bill can play an important role in promoting price competition while maintaining incentives that reward true medical advances and breakthroughs.

Stop Significant and Time-wasting Abuse Limiting Legitimate Innovation of New Generics (STALLING) Act (S. 1224)

This bill, which AHIP also supports, takes steps aimed at curbing abuses of the Food and Drug Administration's (FDA) citizen petition process that can cause unnecessary delays to the entry of less expensive generic drugs. By providing for stronger scrutiny and oversight of citizen petitions and by providing the Federal Trade Commission (FTC) with enhanced authority to take appropriate actions against "sham" citizen petitions, this legislation would help address tactics that delay patient access to more affordable generic drugs.

While the FDA petition process provides an opportunity to raise legitimate concerns about the safety and effectiveness of new drugs, it has also been exploited to delay or prevent the availability of more affordable generic drugs and biosimilars. This legislation takes a number of important steps in curbing abuses in the citizen petition process and removing barriers to generic and biosimilar availability.

Affordable Prescriptions for Patients Act (S. 1416)

AHIP supports this bipartisan legislation—which takes a number of steps to curb pharma company abuses that prevent or delay the availability of less expensive generic drugs and biosimilars. By providing enhanced authority to the FTC to address well-documented abuses of patent and exclusivity provisions, this legislation holds promise in promoting patient access to less expensive, but equally effective, generic drugs and biosimilars. Specifically, the legislation targets two tactics commonly used to forestall generic competition—product hopping and the creation of patent thickets. By empowering the FTC to challenge these tactics as anti-competitive, this legislation can help improve competition and promote patient access to more affordable medications.

Looking beyond the focus of today's markup, AHIP and our member health insurance providers support the following additional legislative and regulatory solutions for responding to out-of-control prescription drug prices:

- Preventing branded drug makers from exploiting Risk Evaluation and Mitigation Strategies (REMS) and limited distribution arrangements to restrict access to adequate samples of reference drugs and thereby impede the development of lower-cost generic and biosimilar competitors (S. 340);
- Prohibiting pay-for-delay settlements under which branded drug makers make payments to generic manufacturers to settle patent infringement claims and, in so doing, delay the availability of lower-cost generic drugs (S. 64);
- Preventing the "evergreening" of patent protections—a scheme through which drug makers make minor changes to a drug's chemical composition or delivery mechanism to extend patents that otherwise would have expired;
- Revisiting the incentives in the Orphan Drug Act to ensure that this law 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;
- Shortening the exclusivity period for biologics to allow for more biosimilar competition;
- 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 the Department of Health and Human Services' (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.