



Statement for Subcommittee Markup of Health Legislation

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

March 27, 2019

We thank the subcommittee for considering legislative proposals that would help to stabilize the individual health insurance market and reduce out-of-control prescription drug prices for the American people.

Every American deserves affordable, comprehensive coverage—regardless of their income, health status, or pre-existing conditions. This has been a core principle for health insurance providers and remains a continuing commitment by our industry. The health insurance provider members of AHIP work every day to promote health, wellness and prevention; address the significant drivers of chronic disease and poor health; give consumers the power to choose the care and coverage that works best for them; and improve patient care and the consumer experience with innovative tools, treatments, and technologies.

Our members work hard every day to improve the purchasing power of the consumers and employers that we serve, negotiating the best possible price from pharmaceutical manufacturers in order to deliver lower costs to the people who need their products. These savings are delivered to patients and consumers through lower premiums and out-of-pocket costs. 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. But the lack of transparency in how prices are set and why they increase, sometimes multiple times a year, creates a barrier to developing new solutions to lower 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.

Below we outline our comments on numerous bills the subcommittee will consider in today's markup.

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 in order to offer consumers affordable alternatives to high priced brand name drugs and to 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.²

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 and biosimilars into the marketplace, this legislation takes an important step toward providing the American people relief from out-of-control drug prices.

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 which agrees, after receiving something “of value”, not to research, develop, manufacture, market, or sell the 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.

² <https://www.cbo.gov/system/files/2018-09/s974.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 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.

H.R. 1520, “Purple Book Continuity Act” and H.R. 1503, “Orange Book Transparency Act”

Both of these bills propose changes to pharmaceutical and biologics 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.

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

H.R. 1425, “State Health Care Premium Reduction Act”

The “State Health Care Premium Reduction Act” (H.R. 1425) would provide \$10 billion annually to support state reinsurance programs and other approaches to making health care more affordable for individuals enrolled in qualified health plans. AHIP supports this legislation, consistent with our past support for federal funding of state-based initiatives to stabilize insurance markets.⁵

State-based reinsurance programs are an effective, proven way to stabilize premiums in the individual health insurance market. Building on our experience in the states, a federally-funded reinsurance program would offset some of the costs of patients who have the most complex health conditions and need the most care. In the last three years, several states have adopted reinsurance arrangements through the use of Section 1332 state innovation waivers with notable success in reducing premiums.

Enacting measures like these can help significantly lower premiums for millions of individuals who rely on the individual market to access care, as long as they are adequately funded and designed to ensure that consumers in all states benefit. This approach also can reduce federal spending on premium tax credits.

H.R. 1386, “ENROLL Act”

The “Expand Navigators’ Resources for Outreach, Learning, and Longevity (ENROLL) Act” would provide \$100 million annually for the Navigator Program to support outreach and education activities focusing on the annual open enrollment period for the Affordable Care Act (ACA) Exchanges. AHIP supports this legislation, consistent with our past support for these activities.

Our members believe it is important for the federal government to devote adequate resources to marketing, outreach, and education before and during open enrollment to help consumers understand their coverage options and encourage broad market participation. Moreover, even with improved availability and functionality of online tools to help consumers, the process of

⁵ Similar proposals AHIP supported in the 115th Congress include the Patient and State Stability Fund that was approved by the House in May 2017 as part of the American Health Care Act, and a bipartisan Senate proposal announced in October 2017 that would have given states more funding flexibility to establish reinsurance, high risk pools, invisible high-risk pools, insurance stability funds, and other programs.

choosing and enrolling in coverage along with understanding eligibility for different programs and federal assistance can still be complicated. Marketing, outreach, and education activities help reduce the number of uninsured Americans by ensuring that consumers are aware of the products available to them and the timing of the annual open enrollment period including the enrollment deadline. In addition, by encouraging continuous coverage and promoting enrollment of a broad mix of both healthy and less healthy individuals, these activities help to stabilize the risk pool and promote more affordable premiums.

H.R. 1385, “SAVE Act”

The “State Allowance for a Variety of Exchanges (SAVE) Act” would provide \$200 million to support the planning and establishment of state-based Health Insurance Exchanges in states that currently are participating in the federally-facilitated Exchange. AHIP also supports this legislation.

In 2019, 11 states and the District of Columbia are offering ACA coverage options through their own state-based Exchanges. The other 39 states are using the federally-facilitated Exchange. Both approaches are currently working well for millions of Americans. However, to the extent that additional states may wish to transition to state-based Exchanges, we agree that federal funding should be available to support this transition. In states that want to administer their own marketplaces, such funding would help state officials provide a shopping experience that is tailored to meet the specific needs and circumstances of their residents.

H.R. 986, “Protecting Americans with Pre-existing Conditions Act”

The position of health insurance providers is clear: Every American deserves affordable, comprehensive coverage—regardless of their income, health status, or pre-existing conditions. No one should be denied or priced out of affordable coverage because of their health status.

AHIP supports protections for all Americans with pre-existing conditions. As we said in our testimony to the subcommittee for its February 6th hearing, we believe that pre-existing conditions protections alone are not enough to assure access to quality, affordable care for all Americans.

H.R. 987, “Marketing and Outreach Restoration to Empower Health Education Act”

We believe it is important for the federal government to devote adequate resources to marketing, outreach, and education before and during open enrollment to help consumers understand their coverage options and encourage broad participation. Marketing, outreach, and education activities are critical to ensure that all consumers are aware of the annual open enrollment period and enroll by the deadline. These activities help reduce the number of uninsured Americans. In addition, by encouraging continuous coverage and promoting enrollment of a broad mix of both healthy and less healthy individuals, these activities help to stabilize the risk pool and promote more affordable premiums.

H.R. 1010, Overturning Final Regulations for Expanding Short-Term Plans

Consumers deserve access to more choices, particularly those who do not qualify for federal subsidies and must pay the full premium on their own. While we believe it is essential that consumers who rely on short-term, limited duration insurance (STLDI) policies clearly understand what their plan does and does not cover, we believe they play an important role for many consumers. AHIP submitted detailed comments in April 2018 on the proposed version of the Trump Administration’s regulation for expanding short-term plans.⁶

Conclusion

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.

We appreciate that the subcommittee has made it a priority to reduce drug prices for all Americans, and we join them in this commitment. We applaud their pursuit of common-sense policy solutions, like the CREATES Act and legislation to eliminate pay-for-delay arrangements, that will help Americans fight back against Big Pharma’s gaming of a broken system for their own financial gain.

⁶ <https://www.ahip.org/wp-content/uploads/2018/04/AHIP-Comments-NPRM-on-STLDI-4-20-18FINAL.pdf>

As consumers' bargaining power, AHIP's members will continue to fight for lower drug costs for patients. And we will continue to work to ensure that every American gets the medications they need at a price they can afford.

We similarly applaud the subcommittee's efforts to assure that every American has access to affordable, comprehensive coverage—regardless of their income, health status, or pre-existing conditions and to encourage broad-based consumer participation in the individual health insurance market in order to assure that it remains stable and that consumers have a broad range of affordable health insurance options. We look forward to continuing our work with consumers, providers and the subcommittee to protect the health and financial security of all Americans.