



Statement for Hearing on

“HIV Prevention Drug: Billions in Corporate Profits after Millions in Taxpayer Investments”

Submitted to the House Oversight and Reform Committee

May 16, 2019

We thank the Committee for focusing on the excessive list price set and controlled exclusively by Gilead Sciences, Inc. for Truvada, its HIV prevention drug, for pre-exposure prophylaxis (PrEP), and recognizing the need for bold solutions to address the pharmaceutical price and cost crisis.

For many Americans who have a high risk of contracting HIV, the rising price and cost of Truvada has created an affordability crisis that threatens their health and well-being. Out-of-control prices for Truvada—and innumerable other prescription drugs—are a direct consequence of drug makers taking advantage of a broken market for their own financial gain at the expense of patients.

We are deeply concerned about the lack of transparency in how drug makers set list prices and why drug prices go up on the same exact product year after year. The lack of competition, transparency, and accountability in the prescription drug market is a barrier to developing new

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.

solutions to lower drug prices. 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.

Our statement for today's hearing focuses on: (1) the importance of ensuring that PrEP is available to high-risk individuals at an affordable price; and (2) our support for 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.

Affordability of PrEP is Essential to Promoting HIV Prevention

Preventive services are critical to keeping people healthy over their lifetimes. Health insurance providers are committed to providing access to recommended, evidence-based preventive care as a strategy to improve health outcomes over time. Promoting preventive care is a fundamental part of our members' efforts to help the people and communities they serve stay healthy.

PrEP is a revolutionary HIV prevention strategy that has the potential to drastically reduce the incidence of HIV across the world. And the research shows that PrEP is highly effective in preventing HIV acquisition in those individuals who are at risk. Nearly 40,000 Americans are newly infected with HIV every year and, if used as directed, PrEP has the ability to reduce the risk of HIV transmission by more than 90%.

At this time, however, Truvada is the only prescription drug available and approved by the Food and Drug Administration (FDA) for PrEP. Since its FDA approval in 2012 for HIV prevention, the average wholesale price of Truvada has increased by 45%.¹ Today, the drug carries a list price approaching \$2,000 per month (or about \$70 per daily pill). Truvada is covered by most health insurance providers.² However, with no generic version and no FDA-approved therapeutic alternative currently available, the rising price and cost of Truvada are limiting access to lifesaving medications for some of our country's most vulnerable populations.

¹ <https://www.npr.org/sections/health-shots/2018/06/30/624045995/rising-cost-of-prep-a-pill-that-prevents-hiv-pushes-it-out-of-reach-for-many>

² <https://www.pbs.org/newshour/health/8-things-didnt-know-truvadaprep>

The United States Preventive Services Task Force (USPSTF) has issued a draft recommendation that clinicians should offer PrEP with effective antiretroviral therapy to persons who are at high risk of HIV acquisition.³ The USPSTF explains that it has found convincing evidence that PrEP is “of substantial benefit” in decreasing the risk of HIV infection in high-risk persons. Should these recommendations be finalized as an “A” recommendation, under the Affordable Care Act, patients will have access to these medications without cost sharing.

To assure that Truvada and other expensive PrEP medications are only made available under this requirement to patients for whom the treatment is clinically indicated, in December 2018, AHIP submitted comments to the USPSTF in which we offered suggestions for improving the draft recommendation. We recommended allowing health insurance providers the flexibility to implement clinically-appropriate prior authorization criteria to promote safe prescribing that is aligned with the FDA-approved indications. We emphasized that this is consistent with previous guidance released by the Center for Consumer Information & Insurance Oversight,⁴ which states that health insurance providers can use reasonable medical management techniques to determine the frequency, treatment, or setting for a recommended preventive health service.

Market-Based Solutions for Reducing Drug Prices

Truvada is just one example of how out-of-control drug prices are inflicting pain on patients, consumers, and taxpayers. A combination of bold legislative and regulatory steps is needed to hold drug makers accountable for high list prices and ensure that the American people have access to affordable medications.

With solutions that deliver real competition, create more consumer choice, and ensure open and honest drug prices, we can deliver more affordable pharmaceutical products—while at the same time protecting and supporting innovations to deliver new treatments and cures for patients.

There is no one silver bullet to reduce drug prices. Below we briefly identify key areas where we see opportunities for Congress and the Administration to provide relief to the American people from out-of-control prescription drug prices:

³ <https://www.uspreventiveservicestaskforce.org/Page/Document/draft-recommendation-statement/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis>

⁴ https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.html

- Stopping gaming by drug makers that limits the entry of new generic and biosimilar competitors—enactment of the “Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act” and the “Protecting Consumer Access to Generic Drugs Act” would be important steps toward achieving this goal;
- 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;
- Shortening the exclusivity period for biologics to promote greater price competition and help alleviate cost pressure for payers, patients and consumers for biologics;
- 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;
- 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 focusing on the serious problems raised by out-of-control prices for Truvada. We share your strong commitment to advancing solutions to address the pharmaceutical cost crisis. 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.