

The Honorable Elijah Cummings
House Oversight and Reform Chairman
2157 Rayburn House Office Building
Washington, DC 20515

The Honorable Jim Jordan
House Oversight and Reform Ranking Member
2105 Rayburn House Office Building
Washington, DC 20515

May 16, 2019

Dear Chairman Cummings and Ranking Member Jordan,

The undersigned organizations represent health care providers, public health experts, and consumer and taxpayer advocates who work to advance public health and promote access to affordable medicines. We commend the Committee for investigating why Gilead Sciences has priced a publicly-funded HIV prevention drug out of reach for so many Americans. We urge the Committee to investigate the failure of the U.S. government to use its existing leverage, including its ownership of key patents on the drug and its government use authority, to negotiate lower prices. We request the Committee to recommend reforms to ensure that all Americans who need pre-exposure prophylaxis (PrEP) are able to receive it, and that the public always receives a fair return on its research and development investment.

I. The Public Largely Funded the Development of an HIV Drug that Remains Unaffordable.

Researchers at the Centers for Disease Control and Prevention (CDC) first discovered in monkeys that emtricitabine/tenofovir disoproxil (Truvada) could be used to prevent the spread of HIV.¹ Then researchers funded by the National Institutes of Health and the Bill and Melinda Gates Foundation showed Truvada's effectiveness in preventing HIV in two clinical trials.² The FDA approved the drug for PrEP based on the trials.³ Gilead contributed only by providing tablets and some travel support.⁴

Despite their substantial investment, taxpayers have not widely benefited from Truvada. Less than 10 percent of at-risk Americans are currently taking the drug.⁵ The number of new HIV infections has not significantly decreased since Truvada was approved for PrEP in 2012.⁶ The high price of Truvada is a major barrier to scaling-up access. Gilead charges over \$2000 a month for the drug, which could be manufactured for as a little as \$6.⁷ The high price precludes access for those without insurance, and results in unaffordable out-of-pocket costs for even those with insurance.⁸ Gilead earned \$3 billion from Truvada last year alone.⁹

¹ Garcia-Lerma et al., Prevention of Rectal SHIV Transmission in Macaques by Daily or Intermittent Prophylaxis with Emtricitabine and Tenofovir, PLoS Medicine (2008), available at <https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0050028>

² Emtricitabine/Tenofovir Disoproxil Fumarate for HIV Prevention in Men (iPrEx), <https://clinicaltrials.gov/ct2/show/NCT00458393> & Pre-Exposure Prophylaxis to Prevent HIV-1 Acquisition Within HIV-1 Discordant Couples (Partners PrEP), <https://clinicaltrials.gov/ct2/show/NCT00557245>

³ FDA, Application Number: 021752Orig1s030

⁴ PrEP4All, A National Action Plan for Universal Access to HIV Pre-Exposure Prophylaxis (PrEP) in the United States, https://breakthepatent.org/wp-content/uploads/2018/07/White_Paper_Final_Edits-PS-Version.pdf

⁵ *Id.*

⁶ CDC, HIV Incidence: Estimated Annual Infections in the U.S., 2010-2016 (2019), available at <https://www.cdc.gov/nchhstp/newsroom/2019/HIV-incidence.html>

⁷ Hill AM, Pozniak AL. How can we achieve universal access to low-cost treatment for HIV? Journal of Virus Eradication (2016)

⁸ KHN, Out-Of-Pocket Costs Put HIV Prevention Drug Out Of Reach For Many At Risk (2018), available at <https://khn.org/news/out-of-pocket-costs-put-hiv-prevention-drug-out-of-reach-for-many-at-risk/>

⁹ Gilead Sciences Inc., Form 10-K to the US Securities & Exchange Commission (2018), available at <https://tinyurl.com/y3pbtqnk>

II. **The Committee Should Investigate Whether the Trump Administration Has Taken Steps to Lower Prices for the HIV Drug, Including Potential Licensing Arrangements.**

The federal government holds patents on the method of preventing HIV in an HIV-negative individual with Truvada.¹⁰ Gilead has likely been infringing on these patents. The Trump Administration could leverage the government ownership of these patents to require Gilead to sell Truvada at a fair and affordable price, but to date it has failed to do so. The Trump Administration could also use its inherent government use authority to enable generic competition and increase affordable access.¹¹

In February, President Trump announced his plan to eliminate HIV transmission by 2030. Experts believe that his plan cost could tens of billions of dollars in medicine prices alone.¹² Achieving this goal would require either greatly increasing government spending or significantly reducing medicine prices. But the Administration has publicly neither signaled a willingness to substantially increase funding for HIV, nor to use its leverage to reduce medicine prices. Instead, it has celebrated a tax-deductible donation by Gilead for some Americans for a limited time. The donation will help Gilead provide cover for its exorbitant pricing.

The Committee should investigate whether the Trump Administration has taken steps to lower Truvada prices, including potential licensing arrangements. Analyzing CDC records—including internal communications and communications with Gilead—could help elucidate why the Administration has thus far failed to protect the American taxpayer.

III. **The Committee Should Propose Reforms to Increase Access to PrEP and Take Steps to Ensure the Public Always Receives a Return on its Investment.**

The Committee should recommend that the Trump Administration protect the American taxpayer by using its leverage to negotiate lower prices. This could include entering into a licensing agreement that requires Gilead to decrease its price and compensate the American taxpayer with royalties used to develop a National PrEP Access Program.

We applaud the Committee for holding this hearing. But while the Truvada story is troubling, it is not anomalous. The Senate Finance Committee already investigated the very same company for another exorbitantly-priced, publicly-funded medicine in 2016.¹³ Taxpayers continue to pay twice for prescription drugs: first, for the knowledge base fundamental to their development, and then for the monopoly prices charged by manufacturers who piggyback on federal investment. For example, all 210 medicines approved by the Food and Drug Administration from 2010–2016 were associated with research funded by the National Institutes of Health.¹⁴ Of the 210 medicines, the 77 first-in-class products with new molecular targets benefited on average by as much as \$839 million in public investment. U.S. taxpayers are compensated for this investment by being charged the highest medicine prices in the world.¹⁵

¹⁰ Yale GHJP, Summary of Statement on CDC's Patents for PrEP (2019), available at https://law.yale.edu/system/files/area/center/ghjp/documents/ghjp_2-page_statement_on_cdc_patents_-_final.pdf

¹¹ 35 U.S.C. § 200-212.

¹² NY Times, Trump's Proposed Budget Undermines His H.I.V. Plan, Experts Say, March 12, 2019, available at <https://www.nytimes.com/2019/03/12/health/trump-hiv-aids-costs.html>

¹³ Wyden-Grassley Sovaldi Investigation Finds Revenue-Driven Pricing Strategy Behind \$84,000 Hepatitis Drug (2015), available at <https://www.finance.senate.gov/download/the-price-of-sovaldi-and-its-impact-on-the-us-health-care-system-full-report>

¹⁴ Ekaterina Cleary et al., Contribution of NIH funding to new drug approvals 2010–2016, 115 PNAS 10 (2018).

¹⁵ Aaron Kesselheim et al, The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform, 316 JAMA 858 (2016)

Since the enactment of the Bayh-Dole Act¹⁶, the federal government has given away the fruits of the tens of billions of dollars of research it funds annually, granting corporations exclusive rights to commercialize government-funded inventions, with little commensurate benefit. Bayh-Dole was introduced, under intense lobbying pressure, because valuable inventions were supposedly languishing in laboratories, and incentives were needed for commercialization. But this assumption was always questionable, and much evidence has emerged disputing the need to provide additional incentives.¹⁷ The government has further sweetened the deal for pharmaceutical companies by repeatedly failing to enforce its authority to demand reasonable pricing on federally-funded inventions.¹⁸ This year, the Trump Administration sought to further weaken these protections.¹⁹ The Committee should investigate the role of public funding of medical inventions, including the failure of the government to exercise its existing pricing authority, the Administration's proposal to undermine these public interest protections under Bayh-Dole, and what steps may be taken to ensure the public always gets a fair return on public investment.

Sincerely,

Public Citizen

Center for Popular Democracy Action

Doctors for America

End AIDS Now

Health GAP

Housing Works

Social Security Works

Treatment Action Group

cc: Members of the House Oversight and Reform Committee

For further information, contact:
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¹⁶ 35 U.S.C. § 200-212.

¹⁷ See A So et al., Is Bayh-Dole Good for Developing Countries? Lessons from the US Experience, 6 PLoS Biology 10 (2008).

¹⁸ Robert Weissman, The Role of Federally-Funded University Research in the Patent System, Testimony Before the Committee on the Judiciary US Senate (2007), available at <https://tinyurl.com/ya5x3nh7>

¹⁹ NIST, Return on Investment Initiative, Final Green Paper (2019), available at <https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.1234.pdf>. See Comment on the NIST Green Paper on Bayh-Dole technology transfer recommendations regarding march-in and government use rights, available at <https://www.keionline.org/30451>