

Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM

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MEMORANDUM

May 13, 2019

To: Members of the Committee on Oversight and Reform

Fr: Majority Staff

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

On **Thursday, May 16, 2019, at 10:00 am in room 2154 of the Rayburn House Office Building**, the Committee will hold a hearing to examine Gilead Sciences, Inc.’s unreasonable price for an HIV prevention drug known as Truvada for pre-exposure prophylaxis (PrEP). The hearing also will examine taxpayer funding that led to approval by the Food and Drug Administration (FDA) of Truvada for PrEP and whether the public is receiving an appropriate return on its investment.

I. BACKGROUND AND HEARING PURPOSE

In 2012, the FDA approved the use of Truvada for PrEP, a daily pill that prevents the transmission of HIV. Gilead benefited from millions of dollars in taxpayer-funded research to obtain FDA approval. Since then, the company has received billions of dollars in sales revenues from the medication as it continues to raise its prices.¹

In the United States, Truvada is currently sold at a list price of approximately \$2,100 per month, generating \$3 billion in profit for Gilead in 2018 alone.² Generic Truvada is available in other countries at a fraction of the cost, but no generic version is offered in the United States.³

¹ National Institute of Allergy and Infectious Diseases, National Institutes of Health, *Pre-Exposure Prophylaxis (PrEP) to Reduce HIV Risk* (online at www.niaid.nih.gov/diseases-conditions/pre-exposure-prophylaxis-prep) (accessed May 9, 2019); *An HIV Treatment Cost Taxpayers Millions. The Government Patented It. But a Pharma Giant is Making Billions*, Washington Post (Mar. 26, 2019) (online at www.washingtonpost.com/business/economy/pharma-giant-profits-from-hiv-treatment-funded-by-taxpayers-and-patented-by-the-government/2019/03/26/cee5afb4-40fc-11e9-9361-301ffb5bd5e6_story.html?utm_term=.b4f73d6a8a54).

² Securities and Exchange Commission, *Gilead Sciences, Inc. 2018 Form 10-K Annual Report* (online at <http://investors.gilead.com/static-files/bee9e03b-34e8-452e-89f8-c8a3b0603b90>).

³ Australian Government Department of Health, *Pharmaceutical Benefits Scheme: Tenofovir + Emtricitabine* (online at www.pbs.gov.au/medicine/item/10347N-11276L) (accessed May 9, 2019); Government of

Although Gilead offers a patient and copay assistance program that helps some patients access the drug, the high price of Truvada limits access for at-risk communities that need it most and places significant financial strain on the United States health care system.⁴

During his State of the Union Address in 2019, President Trump unveiled the “Ending the HIV Epidemic” initiative, which seeks to reduce new HIV infections by 90 percent in the next ten years.⁵ A critical component of his plan is to expand the use of PrEP among at-risk populations. However, the high price of Truvada may hamper the federal government’s ability to achieve this objective.

On May 9, 2019, Health and Human Services Secretary Alex Azar announced that Gilead has agreed to donate up to 2.4 million vials of PrEP each year for up to 11 years. The medication will be distributed to approximately 200,000 individuals who are uninsured and at high risk of HIV transmission.⁶ However, there are approximately 1.1 million Americans who are “at substantial risk for HIV and should be offered PrEP,” according to the Centers for Disease Control and Prevention. It is unclear whether the Administration plans to secure additional amounts of the medication to address this shortfall and, if so, at what price.

II. WITNESSES

Daniel O’Day

Chairman and Chief Executive Officer
Gilead Sciences, Inc.

Additional Witnesses TBD

Staff contacts: Ali Golden, Jennifer Gaspar, Miles Lichtman, Amish Shah, or Theresa Chalhoub at (202) 225-5051.

Canada, *Ontario Drug Benefit Formulary/Comparative Drug Index: Emtricitabine & Tenofovir Disoproxil Fumarate* (online at www.formulary.health.gov.on.ca/formulary/interchangeable.xhtml?drugId=02274906) (accessed May 9, 2019).

⁴ *Rising Cost of PrEP to Prevent HIV Infections Pushes It Out of Reach for Many*, NPR (June 30, 2018) (online at 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); *Out-of-Pocket Costs Put HIV Prevention Drug Out of Reach for Many At Risk*, Kaiser Health News (July 3, 2018) (online at <https://khn.org/news/out-of-pocket-costs-put-hiv-prevention-drug-out-of-reach-for-many-at-risk/>).

⁵ Department of Health and Human Services, *What is ‘Ending the HIV Epidemic: A Plan for America’?* (online at www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview) (accessed May 9, 2019).

⁶ *Gilead Will Donate Truvada to U.S. for H.I.V. Prevention*, New York Times (May 9, 2019) (online at www.nytimes.com/2019/05/09/health/gilead-truvada-hiv-aids.html).