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June 4, 2021

Daniel O'Day
Chairman and Chief Executive Officer
Gilead Sciences, Inc.
333 Lakeside Drive
Foster City, CA 94404

Dear Mr. O'Day:

I invite you to appear before the U.S. Senate Committee on Finance's Subcommittee on Fiscal Responsibility and Economic Growth to testify at a hearing entitled "Promoting Domestic Competition and International Competitiveness." The hearing is scheduled to take place at 2:30pm on Wednesday, June 16, 2021. You have the option to participate in person or virtually. I request that you confirm your attendance at this hearing by Monday, June 7.

The hearing will examine the importance of competition policy and the role of the federal government in promoting competition. During the hearing, we will examine competition in the pharmaceutical industry and the impact of anti-competitive behaviors on consumer access, innovation within the industry, and the high prices that patients and taxpayers must pay for prescription drugs.

Gilead Sciences, Inc. can offer an important perspective on drug pricing and competitiveness within the pharmaceutical industry. In recent years, Gilead has sold revolutionary drugs for conditions like hepatitis C virus infection and HIV/AIDS. Harvoni and Sovaldi are so effective at treating hepatitis C that they were heralded as "miracle" drugs when they came on the market.[1] Patients described Truvada, when prescribed as a once-a-day HIV pre-exposure prophylaxis (PrEP), as "a revolution" in HIV/AIDS management.[2] During the early months of the coronavirus pandemic, Gilead's antiviral drug, remdesivir (Veklury), was identified as a useful treatment for severe COVID-19 at a time when few other effective therapeutics existed.[3]

[1] Politico, "Miracle cure, prioritized," Laura Nahmias, December 2, 2014, https://www.politico.com/states/new-york/albany/story/2014/12/miracle-cure-prioritized-017816.
[2] The Guardian, "'Honestly, it's a revolution. It's so great taking control.'" Lilah Raptopoulos, September 24, 2014, https://www.theguardian.com/society/2014/sep/24/truvada-hiv-aids-you-tell-us.
[3] New England Journal of Medicine, "Remdesivir for the Treatment of Covid-19—Final Report," John H. Beigel, M.D., et al., November 5, 2020, https://www.nejm.org/doi/full/10.1056/nejmoa2007764.

But the prohibitively high prices of Gilead's drugs have made it hard for patients to access the lifesaving treatments they need,[4] forced taxpayers to bear the brunt of high costs,[5] and inhibited competition.[6] When Sovaldi first came on the market, it cost $84,000 for a 12-week course of treatment; Harvoni cost between $63,000 for an 8-week treatment and $94,500 for 12 weeks.[7] Facing impossible budgetary constraints caused by these high prices, Medicaid programs across the country limited access to these extremely effective medications or have been forced to resort to novel purchasing programs.[8] Although US taxpayers paid for research (including pivotal clinical trials) showing that Truvada was effective for PrEP and hold some of the key patents on this use,[9] just a fraction of the U.S. patients that could benefit from Truvada for PrEP used it following the drug's approval for this indication—driven, in part, by its exorbitant price.[10] Similarly, even though a placebo-controlled trial publicly-funded through the National Institute of Allergy and Infectious Diseases showed that remdesivir was effective in severe COVID-19,[11] Gilead charged U.S. taxpayers some of the highest prices in the world for remdesivir.[12] That price remains extremely high, even though subsequent research has revealed that the drug does

[4] U.S. News & World Report, "Cost Puts HIV-Preventing PrEP Out of Reach for Many," Alan Mozes, September 10 ,2020, https://www.usnews.com/news/health-news/articles/2020-09-10/cost-puts-hiv-preventing-prep-out-of-reach-for-many.

[5] Washington Post, "An HIV treatment cost taxpayers millions. The government patented it. But a pharma giant is making billions." Christopher Rowland, March 26, 2019, https://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; Stat, "Pricey drugs overwhelm Medicare safeguard," Associated Press, July 25, 2016, https://www.statnews.com/2016/07/25/medicare-drug-prices-harvoni-solvaldi/.

[6] FiercePharma, "Gilead schemed with J&J, Bristol-Myers to keep their HIV combo monopoly, lawsuit claims," Eric Sagonowksy, May 15, 2019, https://www.fiercepharma.com/pharma/after-decades-activism-patients-hit-gilead-hiv-drug-antitrust-lawsuit.

[7] New York Times, "Harvoni, a Hepatitis C Drug From Gilead, Wins F.D.A. Approval," Andrew Pollack, October 10, 2014, https://www.nytimes.com/2014/10/11/business/harvoni-a-hepatitis-c-drug-from-gilead-wins-fda-approval.html?_r=0; U.S. Senate Committee on Finance, *THE PRICE OF SOVALDI AND ITS IMPACT ON THE U.S. HEALTH CARE SYSTEM* (Report), December 2015, https://www.finance.senate.gov/imo/media/doc/1%20The%20Price%20of%20Sovaldi%20and%20Its%20Impact%20on%20the%20U.S.%20Health%20Care%20System%20(Full%20Report).pdf.

[8] Stat, "Some state Medicaid programs continue to restrict access to hepatitis C drugs," Ed Silverman, October 23, 2017, https://www.statnews.com/pharmalot/2017/10/23/medicaid-access-hepatitis-drugs/; NOLA.com, "Louisiana to announce details for 'Netflix'-style deal aimed at cutting cost of Hepatitis C treatment," Emily Woodruff, June 25, 2019, https://www.nola.com/archive/article_2d943333-8963-5a71-8080-1a63e190dbb4.html.

[9] Journal of American Medical Association, "US Sues Gilead, Alleging PrEP Drugs Infringe on HHS Patents," Rita Rubin, MA, December 24/31, 2019, https://jamanetwork.com/journals/jama/article-abstract/2757797.

[10] Annals of Internal Medicine, "National Trends in Drug Payments for HIV Preexposure Prophylaxis in the United States, 2014 to 2018," Nathan W. Furukawa, MD, MPH, et al., November 17, 2020, https://www.acpjournals.org/doi/10.7326/M20-0786.

[11] National Institute of Allergy and Infectious Diseases, "NIH Clinical Trial Shows Remdesivir Accelerates Recovery from Advanced COVID-19," press release, April 29, 2020, https://www.niaid.nih.gov/news-events/nih-clinical-trial-shows-remdesivir-accelerates-recovery-advanced-covid-19.

[12] Letter from U.S. Senators Elizabeth Warren, Tina Smith, Tammy Baldwin, Bernard Sanders, Chris Van Hollen, and Sherrod Brown, to HHS Secretary Alex Azar, July 16, 2020, https://www.warren.senate.gov/imo/media/doc/2020.07.16%20Letter%20to%20HHS%20re%20remdesivir%20pricing.pdf; NPR, "Remdesivir Priced At More Than $3,100 For A Course Of Treatment," Sydney Lupkin, June 29, 2020, https://www.npr.org/sections/health-shots/2020/06/29/884648842/remdesivir-priced-at-more-than-3-100-for-a-course-of-treatment.

not have a meaningful effect on survival, leading it to be dropped from the WHO list of COVID treatments.[13]

In response to public outcry, Gilead has taken some steps to expand access to these critical drugs.[14] But the company is set to hold on to its monopoly over its hepatitis C medications using "thickets" of questionable patents.[15] And though generic formulas of Truvada recently became available in the U.S.,[16] the company engaged in "product hopping," extending its revenue streams on older active ingredients by seeking FDA approval of patented alternative formulations that are not, in practice, substantially different from preexisting products. Descovy, a follow-on product similar to Truvada with a $16,600-a-year price tag and extended patent protection, was approved by the FDA in 2019.[17]

Gilead has also engaged in other behaviors that may have inhibited competition in the industry and increased prices for consumers, including allegations that Gilead colluded with rivals in certain HIV drug markets.[18]

Your testimony will provide you with an opportunity to offer context on pharmaceutical competition and the burden of high drug prices on patients and the American public. In your testimony, please provide the Committee with your assessment of the impact of Gilead's high drug prices on individuals in need of life-saving but expensive medications; the current state of innovation and competition in the pharmaceutical industry; and the steps Congress could take to increase competition and ensure drugs are priced at fair levels consistent with their value, taxpayer input in de-risking their development, and the limited healthcare budgets of public and private payors.

If you have any questions, please reach out to Evan Turnage (evan_turnage@warren.senate.gov) or Susannah Savage (susannah_savage@warren.senate.gov) in my office. Thank you in advance for your cooperation.

Sincerely,

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[13] World Health Organization, "WHO recommends against the use of remdesivir in COVID-19 patients," press release, November 20, 2020, https://www.who.int/news-room/feature-stories/detail/who-recommends-against-the-use-of-remdesivir-in-covid-19-patients.

[14] Gilead, "A perspective from our CEO: Gilead Subsidiary to Launch Authorized Generics to Treat HCV," press release, September 24, 2018, https://www.gilead.com/news-and-press/company-statements/authorized-generics-for-hcv.

[15] STAT, "European regulator amends some Gilead hep C patent claims," Ed Silverman, October 5, 2016, https://www.statnews.com/pharmalot/2016/10/05/gilead-sovalid-europe-invalidated/.

[16] POZ, "Cheaper Generic PrEP Now Available in the United States," Liz Highleyman, May 21, 2021, https://www.poz.com/article/cheaper-generic-prep-now-available.

[17] New York Times, "F.D.A. Approves New H.I.V.-Prevention Drug, but Not for Everyone," Apoorva Mandavilli, October 8, 2019, https://www.nytimes.com/2019/10/04/health/fda-descovy-truvada-hiv.html; Aidsmap, "Far fewer people would get PrEP in the US if generic TDF/FTC is replaced with Descovy (TAF/FTC), cost-effectiveness study finds," Gus Cairns, March 9, 2020, https://www.aidsmap.com/news/mar-2020/far-fewer-people-would-get-prep-us-if-generic-tdfftc-replaced-descovy-tafftc-cost#:~:text=The%20price%20charged%20by%20Gilead,a%20maximum%20of%20about%20%2420%2C000).

[18] Law360, "Gilead Tries To Shake Antitrust Suit Over Expensive HIV Drugs," July 16, 2020, https://www.law360.com/articles/1293009/gilead-tries-to-shake-antitrust-suit-over-expensive-hiv-drugs.

Elizabeth Warren
United States Senator