

Testimony Submitted for the Record

U.S. House Committee on Oversight and Reform

**Hearing on “HIV Prevention Drug: Billions in Corporate Profits
After Millions in Taxpayer Investments”**

**Mark Harrington, Executive Director
Jeremiah Johnson, HIV Project Director
Treatment Action Group (TAG)**

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Treatment Action Group thanks Chairman Cummings, Ranking Member Jordan, and members of the House Committee on Oversight and Reform for this opportunity to submit testimony regarding how the high monopoly price of Gilead Sciences’ Truvada brand coformulation of tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC) for HIV pre-exposure prophylaxis (PrEP) contributes to the unacceptably high annual rate of new HIV infections in the United States,¹ and what actions are necessary to reduce the price of PrEP and to substantially reduce the number of annual new HIV infections and related health disparities.

TAG is an independent, activist and community-based research and policy think tank fighting for better treatment, prevention, a vaccine, and a cure for HIV, tuberculosis, and hepatitis C virus. We have been leaders in HIV research and policy advocacy since 1992.

The two Gilead drugs which make up Truvada were separately approved as individual agents used for the combination treatment of HIV infection by the U.S. Food and Drug Administration (FDA) in 2001 (Viread brand TDF) and 2003 (Emtriva brand FTC).² The FDA approved Gilead’s fixed-dose combination of TDF and FTC for use in combination antiretroviral therapy (ART) regimens in 2004. Over the subsequent years, the TDF/FTC combination has been a mainstay of widely used and preferred antiretroviral therapy (ART) regimens in the United States and around the world, and the company has recorded billions of dollars in annual profits from the use of Truvada in ART regimens.

¹ U.S. Centers for Disease Control and Prevention. Estimated HIV incidence and prevalence in the United States, 2010-2016. HIV Surveillance Supplemental Report 2019;24(No. 1). <http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>. Published February 2019. “In 2016, the estimated number of HIV infections was 38,700; the rate [per 100,000 persons was 14.3 [per 100,000 persons aged 13 and above].” (p. 5).

² U.S. Food and Drug Administration (FDA). HIV/AIDS Historical Time Line 2000 – 2010. Last updated 5 January 2018. <https://www.fda.gov/patients/hiv-timeline-and-history-approvals/hivaids-historical-time-line-2000-2010>.

1. The high price of Truvada creates direct and indirect barriers to PrEP access, resulting in extremely low uptake of PrEP over the past seven years.

In 2012, the FDA approved a supplemental new drug application (sNDA) for Truvada to be used as PrEP for HIV negative individuals with data from two large-scale randomized controlled phase 3 efficacy trials: iPrEx,³ which was funded by the National Institutes of Health, and Partners PrEP,⁴ which was funded by the Bill and Melinda Gates Foundation. Later studies sponsored by publicly funded research groups in the U.K. and France showed that PrEP efficacy was over 86% among men who have sex with men (MSM).^{5,6} Evidence has shown that PrEP is capable of reducing sexual acquisition of HIV by upwards of 99% when taken as prescribed,⁷ making it among the most effective primary HIV prevention tools available to us at this time. In return for our nation's investment in this groundbreaking research, U.S. taxpayers have seen little benefit from PrEP due to slow and inequitable uptake, driven largely by Gilead's price gouging as well as by slow and inadequate federal and state investment in HIV prevention programming. In the U.S., Truvada is currently sold at a list price of over \$20,000 per person per year⁸ despite costing less than \$67 per person per year⁹ to manufacture.

The high drug cost of Truvada creates several direct and indirect barriers to PrEP access, resulting in extremely low uptake over the past seven years both in the U.S. and most other jurisdictions around the world. In 2018 the CDC estimated that, in the U.S., 1,444,550

³ Grant RM et al. "Preexposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex with Men." NEJM 2010; 363:2587-99.

⁴ Baeten JM et al. "Antiretroviral Prophylaxis for HIV Prevention in Heterosexual Men and Women." NEJM. 2012; 367:399-410. DOI: 10.1056/NEJMoa1108524.

⁵ McCormack S, et al. Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection (PROUD): effectiveness results from the pilot phase of a pragmatic open-label randomised trial. Lancet. 2016 Jan 2; 387(10013): 53–60. doi: 10.1016/S0140-6736(15)00056-2.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4700047/>

⁶ Molina J-M, et al. On-Demand Preexposure Prophylaxis in Men at High Risk for HIV-1 Infection. N Engl J Med 2015; 373:2237-2246. 3 December 2015. DOI: 10.1056/NEJMoa1506273.

<https://www.nejm.org/doi/full/10.1056/NEJMoa1506273>.

⁷ Anderson PA, et al. for the iPrEx Study Team. Emtricitabine-Tenofovir Concentrations and Pre-Exposure Prophylaxis Efficacy in Men Who Have Sex with Men. Science Translational Medicine. 12 Sep 2012; Vol. 4, Issue 151, pp. 151ra125. DOI: 10.1126/scitranslmed.3004006.

<https://stm.sciencemag.org/content/4/151/151ra125>. "intracellular concentration of the active form of tenofovir, tenofovir-diphosphate (TFV-DP), of 16 fmol per million PBMCs was associated with a 90% reduction in HIV acquisition relative to the placebo arm. Directly observed dosing in a separate study, the STRAND trial, yielded TFV-DP concentrations that, when analyzed according to the iPrEx model, corresponded to an HIV-1 risk reduction of 76% for two doses per week, 96% for four doses per week, and 99% for seven doses per week. Prophylactic benefits were observed over a range of doses and drug concentrations, suggesting ways to optimize PrEP regimens for this population."

⁸ Medicaid NADAC Weekly Comparison as of 3.27.19. Each Truvada tablet cost \$56.77185 for an annual cost of \$20,721.73. <https://data.medicaid.gov/Drug-Pricing-and-Payment/NADAC-Comparison-as-of-2019-03-27/ekrz-99wm>.

⁹ Hill AM, Pozniak AL. How can we achieve universal access to low-cost treatment for HIV? J Virus Erad. 2016 Oct; 2(4): 193–197. Published online 2016 Oct 5. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5075345/>; see table 1, "Current prices for antiretrovirals in the USA, UK and low-income countries" where TDF/FTC cost \$67 per person per year in 2016 and the equivalent TDF/3TC cost just \$47.

Americans could potentially benefit from PrEP.¹⁰ Approximately “44% of people who could potentially benefit from are African American: approximately 500,000 people – but only 1% of these (7,000 African Americans) – were prescribed PrEP; and 25% of people who could potentially benefit from PrEP are Latino – nearly 300,000 people... but only 3% of those – 7,600 Latinos – were prescribed PrEP.”¹¹

Thus, a mere fraction of the 1.1 million Americans estimated by the U.S. Centers for Disease Control and Prevention (CDC) to be immediately in need of PrEP have successfully gained access.¹² While effective PrEP access could have dramatically reduced new infections in recent years, instead the U.S. has seen HIV incidence stagnate with over 240,000 new HIV infections since the 2012 FDA approval.¹³ Worse still, this uneven access to PrEP is furthering disparities for the most marginalized communities in America; while the epidemic disproportionately affects people of color, most PrEP prescriptions are among white people. A 2018 CDC analysis of PrEP prescriptions found that only 7,000 and 7,600 prescriptions were filled for African Americans and Latinos, respectively, whereas during the same time period 42,000 prescriptions were filled for whites.¹⁴ As a result, in 2016 new HIV infection rates were eight times higher among African Americans (49.6 per 100,000) than among whites (5.6); and four times higher (23.7 per 100,000) among Hispanic/Latinx persons than among whites.¹⁵ Disparities in access also persist for women, trans people, and people in the South.

2. Gilead’s unethical business practices have created direct financial barriers to PrEP for persons who need it.

Even for those who are insured, the systemic and individual burden of Gilead’s pricing of a taxpayer-funded intervention has been particularly insidious. Until July of 2018, Gilead kept the limit of its co-pay assistance program (CAP) at \$4,800 per year despite repeated calls by TAG and other advocates for the company to match the annual out-of-pocket maximum cost allowed for insured individuals under the Affordable Care Act, which at the time was set at \$7,350 for an individual and \$14,700 for a family.¹⁶ As such, individuals with inadequate insurance coverage for PrEP were set up to fall into a “donut hole” of \$2,550 or more once their co-pay assistance was maxed out, leading to increased risk of PrEP interruption and subsequent HIV infection. For years, Gilead was unmoved by these concerns – perhaps in part because new infections are not detrimental to the company’s bottom line. Gilead dominates the HIV treatment market with over

¹⁰ U.S. CDC. HIV prevention pill not reaching most Americans who could benefit – especially people of color. [press release] 6 March 2018. <https://www.cdc.gov/nchhstp/newsroom/2018/croi-2018-PrEP-press-release.html>.

¹¹ CDC NCHHSTP Newsroom. 2018 Conference on Retroviruses and Opportunistic Infections. March 6, 2018 – A new CDC analysis suggests HIV prevention pill is not reaching most Americans who could benefit – especially people of color. <https://www.cdc.gov/nchhstp/newsroom/2018/croi-2018.html#Graphics>.

¹² <https://www.cdc.gov/nchhstp/newsroom/2018/croi-2018-PrEP-press-release.html>

¹³ CDC 2019; see note 1.

¹⁴ CDC 2018; see note 11.

¹⁵ CDC 2019. Table 1. Estimated HIV incidence among persons aged ≥ 13 years, by year of infection and selected characteristics, 2010-2016 – United States [for 2016], p. 20.

¹⁶ Fair Pricing Coalition. Fair Pricing Coalition Pleased with Steps by Gilead to Increase Access to PrEP, but More Actions Needed. 31 July 2018. <https://fairpricingcoalition.org/2018/07/31/fair-pricing-coalition-pleased-with-steps-by-gilead-to-increase-access-to-prep-but-more-actions-needed/>.

80% of treatment-naive HIV-positive patients starting on a Gilead product.¹⁷ It wasn't until a July 2018 *New York Times* op-ed highlighted pricing and access concerns that Gilead finally made any concession and raised its maximum assistance to \$7,200.¹⁸ The consequences of Gilead's intransigence may never be fully documented; however, we know that cost has been a significant factor in discontinuance of PrEP prior to the 2018 CAP increase. A study of young gay and bisexual men in Chicago between 2015 and 2017 found that 1/3 of those who started PrEP discontinued it within a six-month period, with 9% of those individuals listing cost and 20% listing insurance coverage as their reason for dropping PrEP.¹⁹

While Gilead and some stakeholders may claim that the newly expanded co-pay and medication assistance programs will cause cost to no longer be a barrier, simply having a separate coverage program does not mean that individuals, particularly those from marginalized communities, know about the program and are accessing it. On July 23, 2018, after years of advocacy by TAG and others to get Gilead to disclose enrollment in its medication assistance program, Advancing Access, the company finally revealed in an emailed statement that in the years “[s]ince 2014, a total of 146,329 unique individuals have received support through the co-pay assistance program. So far this year, 15,264 unique individuals have received free drug through the Truvada for PrEP MAP [Medication Assistance Program].”²⁰ This is shockingly low number that is perhaps indicative of the severe limitations of these sorts of assistance programs.

3. The high price of Truvada creates several systemic and indirect barriers and inhibits PrEP scale up.

In addition to years of creating direct financial barriers, we also know that the cost of Truvada as PrEP exacerbates existing healthcare coverage barriers, leads to perceptions of PrEP being too expensive for individuals to access or for population scale up, and significantly burdens publicly-funded initiatives to increase access. High prices disincentivize both public and private insurers from providing PrEP coverage, and we have seen several publicized examples of private insurers attempting to limit access. Lack of insurance²¹ and geographic distance to PrEP-providing health services²² are each associated with lower uptake of PrEP. Gilead's business practices and high

¹⁷ <http://investors.gilead.com/static-files/ead8235f-ab4e-4d0e-b354-453b3d6820a2>

¹⁸ Krellenstein J, Lord M, Staley P. Why Don't More Americans Use PrEP? *The New York Times*. July 16, 2018. <https://www.nytimes.com/2018/07/16/opinion/prep-hiv-aids-drug.html>.

¹⁹ <http://www.aidsmap.com/Many-young-MSM-discontinue-PrEP/page/3276627/>

²⁰ Gilead Sciences. Advocacy at Gilead Sciences. [Email from advocacy@gilead.com] Changes to Gilead Advancing Access Program. 23 July 2018.

²¹ Patel RR, et al. Impact of insurance coverage on utilization of pre-exposure prophylaxis for HIV prevention. *PLoS One*. 2017 May 30;12(5):e0178737. doi: 10.1371/journal.pone.0178737. eCollection 2017. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5448799/>. “After adjusting for Medicaid-expansion and individual socio-demographics, insured patients were four times as likely to use PrEP services compared to the uninsured (OR: 4.49, 95% CI: 1.68–12.01; p = 0.003).”

²² Siegler AJ, et al. Location location location: an exploration of disparities in access to publicly listed pre-exposure prophylaxis clinics in the United States. *Ann Epidemiol*. 2018 Dec;28(12):858-864. doi: 10.1016/j.annepidem.2018.05.006. Epub 2018 May 26. <https://www.ncbi.nlm.nih.gov/pubmed/30406756>. “The Southern region accounted for over half of all new HIV diagnoses but only one-quarter of PrEP-providing clinics. [...] PrEP-providing clinics are unevenly distributed compared to disease burden, with poor coverage in the Southern divisions and areas with higher poverty, uninsured, and larger minority populations.”

Truvada prices further exacerbate these structural barriers to access to effective prevention and care. While this is also a sign of the limitations of the American healthcare coverage system overall, and while TAG has played a significant role in calling out coverage entities for limiting access,²³ we cannot only hold payers accountable; the indefensible cost of PrEP must also be addressed. Although the recent draft “A” rating from the U.S. Preventive Services Task Force (USPSTF)²⁴ will, if finalized, require insurers to provide PrEP to those who need it without cost sharing, these barriers will not be fully mitigated without a dramatic price reduction for PrEP across all contexts. Insurers will still be pushed to find other ways to limit use such as through the use of prior authorization requirements and even more rigid evaluation methods to ensure that someone “needs” PrEP. Furthermore, many people in need remain uninsured.

The cost also likely has a chilling effect on individuals trying to access PrEP and incorporation of this essential intervention into population-level initiatives to end HIV as an epidemic. Community members may not even attempt to access the medication because they believe that it is too expensive. While some advocates have tried to counteract this perception, public education will not be nearly as effective as a dramatic price reduction. Since FDA approval, several articles have been published saying that PrEP may not be a cost-effective intervention based upon the price,^{25,26,27,28} and surveys of providers have shown that cost may be a deterring factor in prescribing PrEP.²⁹ In conversations with numerous public health officials, we have experienced a notable lack of enthusiasm for scale up due to a combination of price and inadequate coverage programs for comprehensive primary prevention services. This phenomenon has clearly been at play outside of the U.S. as well. A 2016 European Centre for Disease Prevention and Control (ECDC) survey of 32 European health ministries found that cost was the number one barrier to scale up, with 31 countries listing it as an issue and 24 countries rating it as an issue of high

²³ Treatment Action Group. Advocacy organizations celebrate results as UnitedHealthcare swiftly reverses discriminatory PrEP practices. August 2017. <http://treatmentactiongroup.org/content/advocacy-organizations-celebrate-results-unitedhealthcare-swiftly-reverses-discriminatory>.

²⁴ U.S. Preventive Services Task Force. Draft Recommendation Statement. Prevention of Human Immunodeficiency Virus (HIV) Infection: Pre-Exposure Prophylaxis. November 2018. <https://www.uspreventiveservicestaskforce.org/Page/Document/draft-recommendation-statement/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis>.

²⁵ Bernard CL, et al. Cost-Effectiveness of HIV Preexposure Prophylaxis for People Who Inject Drugs in the United States. *Ann Intern Med*. 2016;165(1):10-19. DOI: 10.7326/M15-2634
Published at www.annals.org on 26 April 2016. <https://annals.org/aim/article-abstract/2517406>.

²⁶ Juusola JL, et al. The Cost-Effectiveness of Preexposure Prophylaxis for HIV Prevention in the United States in Men Who Have Sex With Men. *Ann Intern Med*. 2012;156(8):541-550. DOI: 10.7326/0003-4819-156-8-201204170-00001. <https://annals.org/aim/article-abstract/1103892/cost-effectiveness-preexposure-prophylaxis-hiv-prevention-united-states-men-who>.

²⁷ Chen A, Dowdy DW. Clinical Effectiveness and Cost-Effectiveness of HIV Pre-Exposure Prophylaxis in Men Who Have Sex with Men: Risk Calculators for Real-World Decision-Making. *Published: October 6, 2014. PLOS ONE*. <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0108742>.

²⁸ Paltiel DA, et al. HIV Preexposure Prophylaxis in the United States: Impact on Lifetime Infection Risk, Clinical Outcomes, and Cost-Effectiveness. *Clinical Infectious Diseases*, Volume 48, Issue 6, 15 March 2009, Pages 806–815, <https://academic.oup.com/cid/article/48/6/806/286632>.

²⁹ Karris MY, et al. Are We Prepped for Preexposure Prophylaxis (PrEP)? Provider Opinions on the Real-World Use of PrEP in the United States and Canada. *Clinical Infectious Diseases*, Volume 58, Issue 5, 1 March 2014, Pages 704–712. <https://academic.oup.com/cid/article/58/5/704/365749>.

importance.³⁰ Cost greatly overshadowed any other potential barrier, including concerns about adherence, potential risk compensation, and feasibility of scale up. We are unaware of a comparable survey of American private and public coverage entities, however, we can assume that if cost is considered a major barrier and disincentive to scale up among European payers, it is probably also a disincentive to American coverage entities.

This delay in population-level scale up is particularly disappointing in light of the recent progress seen in New South Wales (NSW), Australia. Treatment availability and testing in NSW has remained consistently high, but it wasn't until a government-funded program provided PrEP to over 9,000 gay and bisexual men that true progress was achieved. A recent study out of the Kirby Institute at the University of New South Wales found that following the 2016 PrEP scale up, NSW saw a 25% decline in risk of new HIV diagnosis.³¹

4. Gilead's refusal to work with publicly funded PrEP programs robs taxpayers a second time.

Where state and local programs have stepped in to support PrEP scale up through public funding, there has been little assistance from Gilead. An innovative immediate PrEP access program in New York City's publicly funded sexual health and wellness clinics has proven to be a blockbuster, particularly for communities of color and LGBTQ New Yorkers. Truvada's high price has resulted in enormous drug-related costs to the program, causing vital community services to be delayed, and the program is unlikely to continue unless there is a dramatic reduction in the price of PrEP for the clinics.

5. Gilead uses funding and board positions to strategically silence significant community advocacy.

Although the cost of Truvada is undeniably a major factor in slowing PrEP scale up, pricing has, unfortunately, been insufficiently addressed by many advocates due to Gilead's undue influence in the field of HIV advocacy. The company has strategically placed itself in such a way as to virtually eliminate criticism from community advocates and federal HIV/AIDS policy organizations. Gilead employees hold board positions on many major HIV/AIDS organizations, and the company has become the number two funder of HIV prevention programs in the United States, just behind the U.S. government.³² After years of declines in HIV prevention funding, community organizations are under significant pressure to avoid alienating a significant funder.

³⁰ European Centre for Disease Prevention and Control (ECDC) Evidence Brief. Pre-exposure prophylaxis for HIV prevention in Europe: Monitoring implementation of the Dublin Declaration on partnership to fight HIV/AIDS in Europe and Central Asia – 2016 progress report. October 2016. <https://ecdc.europa.eu/sites/portal/files/media/en/publications/Publications/pre-exposure-prophylaxis-hiv-prevention-europe.pdf>.

³¹ McCormack S. What happens when PrEP is scaled up? Results from EPIC-NSW. *The Lancet HIV* 5:11;PE607-E608, November 1, 2018. Published: October 17, 2018. [https://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018\(18\)30253-4/fulltext](https://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018(18)30253-4/fulltext).

³² Funders Concerned About AIDS. Philanthropic Support to Address HIV/AIDS in 2017. December 2018. https://www.fcaids.org/wp-content/uploads/2018/11/FCAA_2017RT_FINsingles.pdf.

The \$125 million that Gilead invested in U.S. philanthropy in 2017,³³ equaling less than 6% of their \$2.3 billion in sales for Truvada in 2017 alone,³⁴ is a small price to pay for silence. Additionally, reimbursements for community organizations with 340B pharmacies create a perverse incentive to keep prices high, undercutting efforts to improve PrEP access on a national level through drastic price reductions.

6. Donation programs benefit drug companies, are anti-competitive, and fall far short of providing medications at affordable prices for all.

Developments in the past few weeks might appear at first to alleviate some of the financial barriers to PrEP, however in reality these changes are far too little, too late. TAG is skeptical over the recent announcements from the Department of Health and Human Services³⁵ and Gilead³⁶ that they will collaborate on providing free Truvada – and, if approved by the FDA, Gilead’s new oral PrEP, a fixed-dose combination of tenofovir alafenamide and emtricitabine (TAF/FTC) sold under the brand name Descovy – for prevention of HIV in 200,000 uninsured Americans each year. This agreement was made without consultation or input from those affected by HIV. Leading experts in drug access, including Médecins Sans Frontières (MSF), have for years discouraged the use of such donations as a band aid for pricing issues, because these deals fall far short of the systems-level changes required for broader access while benefiting companies by providing tax breaks, improving public perceptions, and absolving the corporation of responsibility for ongoing gaps.³⁷

The announced donation will assist with some PrEP scale up and allows Gilead to reap good will, not to mention millions in tax breaks – but it is not an acceptable substitute for sustainable, equitable, affordable access to PrEP. It falls far short of the estimated 1.1 million Americans in need of PrEP, meaning that it will still remain out of reach for the many taxpayers who footed the bill for this innovation. The donation is also only focused on the small subset of 57 U.S. jurisdictions named in the new federal plan to end HIV as an epidemic named by President Trump in his State of the Union address,³⁸ leaving the rest of the country without any benefit from this deal. It also has the potential to serve as a vehicle for promotion of Gilead’s new

³³ Ibid.

³⁴ Gilead Sciences Press Release. Gilead Sciences Announces Fourth Quarter and Full Year 2017 Financial Results. February 6, 2018. <https://www.gilead.com/news-and-press/press-room/press-releases/2018/2/gilead-sciences-announces-fourth-quarter-and-full-year-2017-financial-results>.

³⁵ U.S. Department of Health and Human Services. Trump Administration Secures Historic Donation of Billions of Dollars in HIV Prevention Drugs. May 9, 2019. <https://www.hhs.gov/about/news/2019/05/09/trump-administration-secures-historic-donation-of-billions-of-dollars-in-hiv-prevention-drugs.html>.

³⁶ Gilead Sciences Press Release. Gilead Sciences to Provide Free Truvada for PrEP® to Support U.S. Initiative to End the HIV Epidemic. May 9, 2019. <https://www.gilead.com/news-and-press/press-room/press-releases/2019/5/gilead-sciences-to-provide-free-truvada-for-prep-to-support-us-initiative-to-end-the-hiv-epidemic>.

³⁷ Médecins Sans Frontières. MSF policy for in-kind donations of medical products and health technology. January 2018. <https://www.msf.org/sites/msf.org/files/msf-policy-in-kind-donations-medical-products-health-technology-2018.pdf>.

³⁸ U.S. Department of Health and Human Services. HIV.gov. What is ‘Ending the HIV Epidemic: A Plan for America’? May 10, 2019. <https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview>.

Descovy as PrEP, which has no demonstrated clinical or efficacy benefit over TDF/FTC,³⁹ but may remain on patent for several years after both medications in Truvada go off patent. While this may look like some sort of corporate largesse, the donation will be once again a self-serving maneuver by Gilead to avoid real accountability and to continue its dominance in the HIV space.

7. Gilead’s announcement that it will allow Teva to enter the U.S. PrEP Market a year early is not a victory for marginalized communities.

Recent reports indicate that generic manufacturer Teva will enter the U.S. PrEP market in October 2020 – a year earlier than anticipated thanks to a settlement Gilead reached back in 2014 as part of a pay-for-delay scheme.^{40,41} While at first glance this looks like affordable PrEP is around the corner, Teva will still have six months of exclusivity under the deal, meaning that the price will not drop quickly without additional competition from other generic manufacturers. Thus, the U.S. faces another two years of price gouging that may contribute to as many as 80,000 new infections at current rates.

8. Gilead has an extended history of anticompetitive and unethical business practices that prioritize profits over access.

Gilead has an extensive history of unethical business practices, indicating that without sufficient oversight it will continue to act contrary to the interests of people in need of accessing PrEP. On Tuesday, May 14, 2019, advocates filed a lawsuit in San Francisco, alleging that, similar to its pay-for-delay scheme with Teva, Gilead has colluded with several of its main competitors in HIV treatment to ensure the company’s continued dominance in that space.⁴² Gilead has also delayed research on potentially safer compounds in order to extend its dominance in the HIV space. The newer version of tenofovir, TAF, contained in Gilead’s Descovy, was actually shelved for a decade in order to avoid potential competition with Truvada.

CONCLUSION: Without intervention from Congress, Gilead will repeatedly undercut access in favor of amassing profits.

What is really needed in order to make PrEP available for the estimated 1.1 million Americans who are most vulnerable to HIV infection is a dramatic reduction in price, combined with a robust public sector commitment to provide primary care – including PrEP, HIV testing, testing and treatment for sexually transmitted infections, as well as mental health, substance use, and housing services when needed. # # #

³⁹ Treatment Action Group, PrEP4All Collaboration. Letter to FDA Regarding Application for Descovy as Pre-Exposure Prophylaxis for HIV. April 16, 2019. <http://www.treatmentactiongroup.org/content/letter-fda-regarding-application-descovy-pre-exposure-prophylaxis-hiv>.

⁴⁰ Fitzsimmons T. Generic HIV prevention drug coming in 2020, Gilead says. NBC News. 8 May 2018. <https://www.nbcnews.com/feature/nbc-out/generic-hiv-prevention-drug-coming-2020-gilead-says-n1003391>.

⁴¹ Gilead Sciences. Form 10-Q quarterly report, U.S. Securities and Exchange Commission. 9 March 2019, p. 35; “Pursuant to a settlement agreement relating to patents that protect Truvada and Atripla, Teva Pharmaceuticals will be able to launch generic fixed-dose combinations of emtricitabine and TDF and generic fixed-dose combinations of emtricitabine, TDF and efavirenz in the United States on September 30, 2020.”

⁴² Silverman E. Gilead struck anti-competitive deals to bolster profits on an HIV drug, lawsuit says. STAT News. May 14, 2019. <https://www.statnews.com/pharmalot/2019/05/14/gilead-hiv-anticompetitive-lawsuit/>.

Annex: Further considerations on accelerating universal access to PrEP for all Americans who need it.

The urgent need for universal and equitable access to affordable HIV pre-exposure prophylaxis (PrEP)

- Over 1.1 million Americans could urgently benefit from PrEP which, when used properly, can prevent over 85% of new HIV infections;^{43,44}
- The Centers for Disease Control and Prevention (CDC) estimates that at least 240,000 new HIV infections have occurred in the U.S. since taxpayer-funded research led to U.S. Food and Drug Administration (FDA) approval of the PrEP indication for TDF/FTC (Truvada) in 2012;⁴⁵
- Over the past seven years, PrEP scale-up in the U.S. among those most vulnerable to HIV – including young gay men of color, young black women, people who inject drugs, and transgender women and men – has been dismal.⁴⁶

The harms of monopolistic drug pricing

- Gilead’s monopoly on TDF/FTC has allowed the drug’s price to rise to over \$20,000 per person per year – a price that rivals that of precious metals;
- The estimated manufacturing cost for a year’s supply of TDF/FTC is as low as \$67;⁴⁷
- Notably, in other developed countries such as Canada, cheaper generic PrEP is already available, and it is being used successfully along with rapid antiretroviral treatment initiation in places such as London, U.K.⁴⁸, and New South Wales, Australia,⁴⁹ to drive down new HIV infection rates among gay men;
- If Gilead is able to deduct the full market value of the donated PrEP doses, the company may realize U.S. income tax deductions as high as \$4 billion per year for this program – an amount significantly higher than the \$3 billion Gilead made on Truvada in 2018 alone.

⁴³ PROUD study – see ref 5, IPERGAY – see ref 6.

⁴⁴ Anderson PA, et al; see ref 7.

⁴⁵ CDC 2019; see ref 1.

⁴⁶ CDC 2018; see refs 10, 11.

⁴⁷ Hill AM, Pozniak AL, see ref 9.

⁴⁸ Public Health England. Progress towards ending the HIV epidemic in the United Kingdom – 2018 report. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/759408/HIV_annual_report_2018.pdf “The progressive implementation of combination HIV prevention is the principal explanation for the fall in HIV incidence in gay and bisexual men since 2012.” [p. 9]; “The estimated number of new infections acquired per year rose from around 2,300 infections (95% credible interval (CrI) (CrI 2,200 to 3,200) in 2012, before falling to 1,200 (CrI 600 to 2,100) in 2017 (Figure 4).” [pp. 19-20]; “In England, the greatest fall in diagnoses from 2015-17 was in the London large fall clinics(46%, 1,073 to 575).” [p. 20].

⁴⁹ Grulich AE, et al. Population-level effectiveness of rapid, targeted, high-coverage roll-out of HIV pre-exposure prophylaxis in men who have sex with men: the EPIC-NSW prospective cohort study. *The Lancet HIV*. Published: October 17, 2018DOI:[https://doi.org/10.1016/S2352-3018\(18\)30215-7](https://doi.org/10.1016/S2352-3018(18)30215-7). [https://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018\(18\)30215-7/fulltext](https://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018(18)30215-7/fulltext). “Over 4100 person-years, two men became infected with HIV (incidence 0.048 per 100 person-years, 95% CI 0.012–0.195). Both had been non-adherent to PrEP. HIV diagnoses in MSM in New South Wales declined from 295 in the 12 months before PrEP roll-out to 221 in the 12 months after (relative risk reduction [RRR] 25.1%, 95% CI 10.5–37.4). There was a decline both in recent HIV infections (from 149 to 102, RRR 31.5%, 95% CI 11.3 to 47.3) and in other HIV diagnoses (from 146 to 119, RRR 18.5%, 95% CI –4.5 to 36.6).”

- Although it has been reported that generic PrEP will enter the U.S. in October 2020⁵⁰ – a year earlier than anticipated thanks to a settlement Gilead reached with generic manufacturer Teva back in 2014 as part of a pay-for-delay scheme – Teva will have six months of exclusivity.⁵¹ Without competition, the price will not quickly drop substantially. Thus, the U.S. faces another two years of price gouging that could contribute to as many as 80,000 new infections.
- TAF/FTC has no demonstrated clinical or efficacy benefit over TDF/FTC, but may remain on patent for the next decade making it substantially more burdensome for the U.S. healthcare system compared to generic TDF/FTC once two or more generic manufacturers enter the market in 2021.

Multiple political, systemic failures that have contributed to the persistence of HIV and grave health disparities

- Poorly-performing primary health systems are fundamental to the epidemic and its continued spread – particularly in the South and in other states where Medicaid expansion under Affordable Care Act has been rejected by state governments;
- A coherent, comprehensive federal plan to scale-up PrEP and associated services among all those who need them is lacking;
- The U.S. failed to reach incidence reductions proposed under the 2010 and revised 2015 National HIV/AIDS Strategies during the previous administration;⁵²
- The current Administration’s plan to “End the HIV Epidemic” in the U.S. by 2030 also fails to provide the resources to achieve this goal;⁵³
- The current administration’s other actions – such as extending discrimination against LBGTQ people, migrants, and immigrants in the health system will make it harder to reach and properly serve the needs of these and others who remain at high risk for HIV exposure, infection, and progression – work in direct opposition to a coherent national commitment and adequately funded and coordinated effort to end the U.S. HIV epidemic.

Key questions on the recently announced donation program

- How will this deal improve upon Gilead’s existing medication assistance program, Advancing Access?
- How do we ensure that this does not become another promotional program for Gilead’s Descovy following the potential FDA approval of the fixed dose combination of TAF/FTC as a second oral PrEP?

⁵⁰ Fitzsimmons T. Generic HIV prevention drug coming in 2020, Gilead says. NBC News. 8 May 2018.

<https://www.nbcnews.com/feature/nbc-out/generic-hiv-prevention-drug-coming-2020-gilead-says-n1003391>.

⁵¹ Gilead Sciences. Form 10-Q quarterly report, U.S. Securities and Exchange Commission. 9 March 2019, p. 35; “Pursuant to a settlement agreement relating to patents that protect Truvada and Atripla, Teva Pharmaceuticals will be able to launch generic fixed-dose combinations of emtricitabine and TDF and generic fixed-dose combinations of emtricitabine, TDF and efavirenz in the United States on September 30, 2020.”

⁵² CDC 2019; ref. 1.

⁵³ Treatment Action Group. Statement on the President’s Fiscal Year 2020 Budget Proposal. 13 March 2019.

<http://www.treatmentactiongroup.org/content/treatment-action-group-statement-presidents-fiscal-year-2020-budget-proposal>.

- How was the 200,000 figure calculated, and will it actually meet the demand within even the small subset of 57 U.S. jurisdictions where half of new U.S. HIV infections occur and which are the focus of this current donation?
- How will the CDC reinvest the anticipated savings on medication into community-based programs that can help marginalized communities navigate the stigma, social, and structural barriers that keep them from accessing PrEP?

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