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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"

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Chairman Cummings, Ranking Member Jordan, and members of the House Committee on Oversight and Reform, the Health Global Access Project ("Health GAP") thanks you for the opportunity to submit testimony for the record on tenofovir/emtricitabine (TDF/FTC) pre-exposure prophylaxis (PrEP) access and pricing in the United States.

Over the past two decades, Health GAP has successfully helped reduce the cost of antiretroviral medicines to treat HIV in resource-poor countries around the world by as much as 99%. Health GAP played a key role in winning new donor initiatives to support HIV treatment and prevention scale-up – such as the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) and the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) – and worked shoulder-to-shoulder with scores of organizations in the Global South to increase access to quality HIV treatment, prevention, and other related services that meet the needs of people living with and affected by HIV. We believe that the human right to life and to health must prevail over drug companies' excessive profits, expanding patent rights, and other harmful monopolistic approaches.

Seven years ago the HIV prevention landscape changed. For the first time in decades, people had the opportunity for a choice in prevention—PrEP—that gave them control. While we do not believe that a single strategy will end this epidemic, PrEP meets people at substantial risk for HIV infection *where they are*—and provides an option other than relying on condom use alone. However, this promise of high-impact prevention has stalled, in part because of Gilead's high pricing and relentless pursuit of monopolies that put a stranglehold on cost-cutting generic competition. This combined with inequities in access to prevention services that are exacerbated by price gouging, means reaching the estimated 1.1 million people in the U.S. in need for PrEP's is in doubt. While under-utilization of PrEP is caused by multiple factors, it is clear that price is a barrier that inhibits broad access. Each additional barrier for accessing healthcare makes life more challenging for people most at risk of HIV infection including people of color, men-who-have-sex-with-men, transgender women, sex workers, and people who inject drugs.[1][2]

[1] Bauermeister, Jose A et al. "PrEP awareness and perceived barriers among single young men who have sex with men." *Current HIV research* vol. 11,7 (2013): 520-7.

Especially given the significant investment made by the United States Federal Government and private charities to conduct all the studies that proved the effectiveness and safety of TDF/FTC in preventing HIV acquisition, it is frankly outrageous that Gilead has waited so long to take any meaningful steps to increase affordable and equitable access to PrEP and that its current offers are so inadequate to the task. For years, Gilead delayed introduction and promotion of TDF/FTC for PrEP while it made billions on efavirenz combined with TDF/FTC for HIV treatment at home and abroad. This tactic of the company has become a habitual practice seen not only in TDF/FTC but also its other HIV and HCV medicines produced by Gilead. Gilead cynically delayed patenting of tenofovir alafenamide (TAF) and research and development (R&D) on TAF/FTC for PrEP in order to extend its period of patent/marketing exclusivity and monopoly profits. (By delaying TAF patenting, the 20 years of additional patent protection extended longer, and the same is true for TAF/FTC for PrEP as a second use beyond treatment.) Furthermore, steps such as these are part of distributing patterns that incentivizes doing harm to public health in pursuit of higher profit margins.

Initial research on TDF and FTC received considerable support from the Centers for Disease Control and Prevention (CDC) and the Bill and Melinda Gates Foundation in particular. The pivotal trial that supported the approval of TDF/FTC for PrEP was also funded by the federal government, meaning that Gilead has a cognizable duty to price reasonably, which it has refused to do. Even though the Trump Administration (and prior administrations) have refused to recognize excessive pricing as grounds for exercising march-in rights, a permissible interpretation of federal law would permit the federal government to do so. As further evidence of federal government R&D and early-stage contributions to this regimen, the federal government actually holds three patents on TDF/FTC for PrEP that have been consistently violated by Gilead without any acknowledgment of government's right to royalties or other concessions, including arguably generic licensing. This issue remains outstanding today.

Gilead has taken further steps that leave people vulnerable and risk the nation's health. For example, Gilead's license to Teva Pharmaceuticals Industries, operational only 6 months before the expiration of the formal period of patent exclusivity, is not a good faith effort to allow for generic competition for two reasons. First, it is sufficiently delayed to allow Gilead to establish TAF/FTC as a preferred second generation PrEP, meaning that Teva might have only a limited market. Second, we don't know how robust generic competition will be because Gilead has kept its pay-for-delay settlements with other generic companies confidential. The company's effort at remediation pales in comparison to the difference significantly lower price could make on the overall market.

Gilead's donation program is deceptive and insufficient in several ways. First, it provides free TDF/FTC and subsequent TAF/FTC for 200,000 uninsured people, which is admittedly useful,

[2] Goparaju, Lakshmi et al. "Stigma, Partners, Providers and Costs: Potential Barriers to PrEP Uptake among US Women." *Journal of AIDS & clinical research* vol. 8,9 (2017): 730. doi:10.4172/2155-6113.1000730

but Gilead will continue to charge full price for the remaining 800,000 to 900,000 eligible for PrEP (note: only 200,000 are already on PrEP). In essence, in terms of potential market earnings, Gilead has offered a 20% price reduction off its list price of $20,000 per patient per year. **The net price for all PrEP users, especially after they have been switched to the patent- and data-protected TAF/FTC will be $16,000 per person per year times 800,000 users equals $12.8 billion per year.**

Additionally, Gilead will most certainly receive a major tax break on the donation value of the donated PrEP, which might also add as much as $1 billion a year to their bottom line. After early donations of TDF/FTC, the donation program will quickly product-switch to second generation PrEP (AAF/FTC), locking patients and programs into the evergreened Gilead monopoly, keeping its PrEP earnings high. The high cost of PrEP will continue to burden insured patients, who will pay high co-pays and deductibles (especially as some insurers continue to discriminate against PrEP), and to payors who will raise premiums because of increased PrEP coverage and costs.

Although these hearings are focused primarily on domestic access to PrEP, Gilead's patent exclusivity extends to many middle-income countries that are excluded from Gilead's ARV (antiretroviral) license with the Medicines Patent Pool. This includes some countries that are served by Global Fund and PEPFAR programming. Excluded countries, such as Brazil, are limited to negotiating discount prices that can be quite high and that limit country uptake of PrEP, taking away a key prevention tool in the campaign to end AIDS.

In our opinion, seeking price concessions from Gilead is a weak response and leaves Gilead in the driver's seat. Likewise, seeking royalties for the U.S. patents do not impact the cost of antiretroviral drugs and, in fact, could paradoxically increase prices.

By far the best solution for increasing access is in pushing Gilead to issue broad generic licenses that allow competitive sourcing of first- and second-generation PrEP in the U.S. and abroad. Gilead has already earned billions off of TDF and FTC – there is no R&D recapture or market dynamics justification for further monopoly rewards. TAF/FTC is likely to be even cheaper than the $60 per year generic price for quality assured TDF/FTC that is available from India generic companies (mainly because the quantity of TAF needed is much smaller than TDF). **Although competitive costs of TAF/FTC at economies of scale have not been fully calculated, assuming an eventual cost of $40 per patient per year, the U.S. could provide PrEP to 1,000,000 Americans at a cost of $40 million a year instead of the $12.8 billion Gilead stand to charge under the existing self-serving arrangement!**

Health GAP thanks to the Committee for the opportunity to submit testimony for the record on pre-exposure prophylaxis (PrEP) access and pricing in the United States. We thank the Committee for its leadership in the important area of access to preventative medicines for those in need.