May 16, 2020

The Honorable Elijah E. Cummings
Chairman
House Committee on Oversight & Reform
U.S. House of Representatives
Washington, DC 20515

The Honorable Jim Jordan
Ranking Member
House Committee on Oversight & Reform
U.S. House of Representatives
Washington, DC 20515

Dear Chairman Cummings and Ranking Member Jordan:

Thank you for giving AVAC the opportunity to provide written testimony as part of the Committee's timely and important hearing on ***HIV Prevention Drug: Billions in Corporate Profits after Millions in Taxpayer Investments***.

Gilead's decision to donate Truvada (FTC/TDF), the drug registered for HIV prevention use as oral pre-exposure prophylaxis (PrEP) is a stark acknowledgment that there is a huge issue with PrEP access in America, as in many parts of the world.[1]

We welcome this indication that the company grasps the gravity of the situation. However, we urgently need a lower price for all, and it is disappointing that even this small step has taken so long.

Now, nine years since the safety and efficacy of oral PrEP was first demonstrated and seven years since the FDA approved the drug for use as PrEP, Gilead is making this announcement quite late in the process of trying to scale PrEP to achieve public health impact. And it is nowhere near enough. The donation offers PrEP to only 200,000 individuals, while the CDC estimates that 1.1 million Americans overall are at substantial risk for HIV and should be offered PrEP.[2]

Moreover, based on what we know about the generic costs of Truvada (FTC/TDF), this donation offers a mere $10 million per year in drug supply cost to Gilead – irrespective of the list price for the drug.

It is important to remember that PrEP is not merely a pill – it is a program that has to include regular HIV and STD testing, support to take the pills as prescribed, training providers in culturally competent care, and strategic demand creation effort.[3] The availability of more pills, while welcome, will never be enough to move PrEP to the public health intervention that is needed for it to have a real impact for individuals and communities. Medication costs are only one of the multiple barriers to PrEP uptake that have been identified in the United States.[4] Lack of a healthcare provider has been identified as barrier particularly

[1] https://www.avac.org/prevention-option/prep and https://www.prepwatch.org/in-practice/global-prep-tracker/.
[2] *Estimates of adults with indications for HIV pre-exposure prophylaxis by jurisdiction, transmission risk group, and race/ethnicity, United States, 2015.* Smith DK1, Van Handel M2, Grey J3. Ann Epidemiol. 2018 Dec;28(12):850-857.e9. doi: 10.1016/j.annepidem.2018.05.003. Epub 2018 May 18.
[3] See CDC Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2017 Update Clinical Practice Guideline; https://www.projectinform.org/wp-content/uploads/2019/01/PrEP_Flow_Chart-1.pdf; "PrEP is only one part of HIV prevention, so help paying for the pill is only one piece of the puzzle." Kaiser Health News Out-Of-Pocket Costs Put HIV Prevention Drug Out of Reach For Many At Risk July 3, 2018
[4] Parsons, JT H et al. Uptake of HIV pre-exposure prophylaxis (PrEP) in a national cohort of gay and bisexual men in the United States: The Motivational PrEP Cascade. J Acquir Immune Defic Syndr. 2017 Mar 1; 74(3): 285–292 (describing the multiple barriers to PrEP uptake); Gunn LH et al. Healthcare providers' knowledge, readiness, prescribing behaviors, and perceived barriers regarding routine HIV testing and pre-exposure prophylaxis in DeLand, Florida SAGE Open Med. 2019 Mar 11.

Accelerating the ethical development and global delivery of HIV prevention options as part of a comprehensive, integrated and sustained response to the epidemic

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for young people.[5] Sometimes distance to a clinic in rural settings is simply the most important factors.[6] Funding and support for innovative approaches to address these multiple barriers in different populations and jurisdictions would be at least as, if not more, beneficial to PrEP uptake than the Gilead drug donation on its own.

And, even after this donation and according to the CDC, nearly one million additional Americans would benefit from oral PrEP and will still be subject to the inflated price of Truvada (FTC/TDF) and, pending regulatory approval, Descovy (FTC/TAF) – which Gilead intends to focus on, based on their recent announcements.

Gilead's offer – and the announcement from Secretary of Health and Human Services Alex Azar – leave many open and important questions:

- How will the CDC distribute this additional oral PrEP?
- How will Gilead and CDC ensure the donation does not replace current PrEP access, but rather is additive?
- Who will pay for these distribution costs, as "free donations" often come with costs?
- Will Gilead continue its Truvada for PrEP Medication Assistance Program (MAP)?
- Will CDC and NIH – which, along with the Bill & Melinda Gates Foundation, funded the trials that demonstrated PrEP is safe and effective – still act on their intellectual property rights to Truvada for PrEP and reinvest any profits that could be realized into PrEP programs that work?

As Medecins Sans Frontieres and other global health experts have widely notes, donations of medical products and health technology are not sustainable for ensuring access for individuals and are difficult for both providers and health departments to manage effectively. Additionally, such programs can undermine long-term efforts to incentivize pharmaceutical corporations and other stakeholders to develop, market and deliver new and existing products at affordable prices.[7]

The bottom line is that the price of Truvada (FTC/TDF) – and Gilead's new, additional PrEP pill, Descovy (FTC/TAF) – is too high. We need sustainable price cuts, and clear strategic programs, that will support long-term access to and use of the medicines needed for PrEP. We cannot afford to lose any more time, or money, in translating PrEP's promise into public health impact.

We look forward to hearing how the Committee hearing goes and to providing additional input at any point if it would be helpful.

Yours sincerely,

Mitchell Warren
Executive Director

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[5] Marks S.J. et al., Potential Healthcare Insurance and Provider Barriers to Pre-Exposure Prophylaxis Utilization Among Young Men Who Have Sex with Men AIDS Patient Care STDS. 2017 Nov 1; 31(11): 470–478.
[6] Ojikutu BO et al. Spatial Access and Willingness to Use Pre-Exposure Prophylaxis Among Black/African American Individuals in the United States: Cross-Sectional Survey. JMIR Public Health Surveill. 2019 Feb
[7] MSF Policy for In-Kind Donations of Medical Products and Health Technology, Medecins Sans Frontieres (MSF), January 2018, and *Hidden Price Tags: Disease-Specific Drug Donations: Costs and Alternatives*, MSF, February 2001.