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U.S. House of Representatives
House Committee on Oversight and Reform

Chairman Cummings, Ranking Member Jordan, and members of the House Committee on Oversight and Reform, I am pleased to testify today on the topic of HIV pre-exposure prophylaxis, or PrEP, and the how the promise of PrEP remains unfulfilled.

I am a physician and a scientist at the the University of California, San Francisco. I have 35 years of experience with research and clinical care related to HIV. I pioneered research on PrEP that led to FDA approval in 2012, recommendations from the CDC in 2014, recommendations from the World Health Organization in 2016, and a grade A recommendation from the US Preventive Services Task Force in 2018. I helped start countless PrEP services. Some have called me the Father of PrEP; I prefer to think of myself as PrEP's midwife because I was there when thousands of research participants delivered proof that PrEP using a tenofovir based regimen was safe and effective. I now practice medicine. I devoted the last 20 years of my career to the development of PrEP. I am here today at my own expense because I promised that PrEP would become available to whoever could benefit from it.

I believe that your leadership is essential at this juncture, so I come to ask for your help.

I will describe how PrEP innovations developed, including roles played by public and private funding agencies and the drug manufacturer. I will review how scale up of PrEP services has occurred in well resourced jurisdictions where HIV transmission rates are now falling. In contrast, less well resourced jurisdictions have not made PrEP available and HIV rates continue to rise. I will describe how Australia has been able to roll out PrEP on a massive scale by acquiring generic medication at free market prices of approximately $8 per person per month, which includes fees for licensing both Gilead's and the US Government's patents.

My PrEP research was funded by investigator initiated research grants from the National Institutes of Health starting in 2002. I later received supplemental funding from the Bill and Melinda Gates Foundation. Similar research was funded by the NIH, CDC, and the Gates Foundation. The US Government is by far the majority funder of PrEP research. PrEP regimen selection was guided by research conducted by scientists at the CDC who demonstrated that adding emtricitabine to a tenofovir regimen increased protection. The CDC work nucleated my decision to use a combination tablet rather than tenofovir alone. The critically important research done by scientists at the CDC led to a US Government patent on the combined use of emtricitabine and tenofovir esters for PrEP. This is the only FDA approved product for PrEP today.

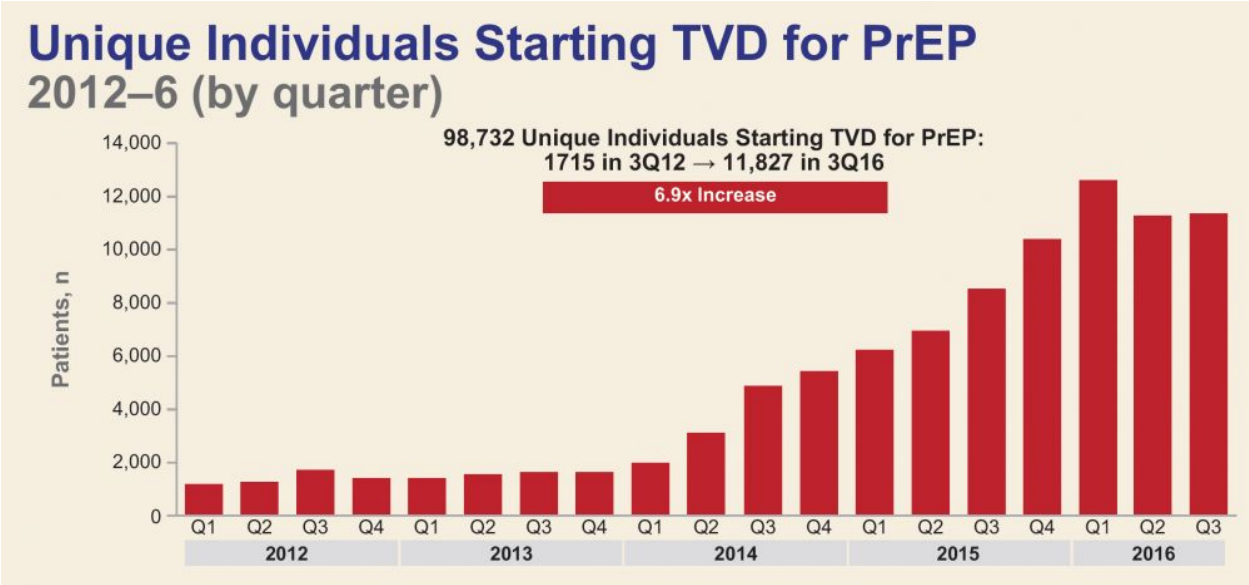
Gilead Sciences did not provide leadership, innovation, or funding for these projects; Gilead's role was limited to donating study medication and placebos. Our protocols were shared with Gilead, in accordance with an agreement between the NIH and Gilead; I do not recall receiving any comments. Indeed, Gilead proved to be a hesitant partner in PrEP research. For example, I submitted my grant application to the NIH without a letter of support from Gilead for drug donation. On the day before the application was due, I was informed by Gilead staff that I was requesting too much, that PrEP was too controversial, and Gilead's business was HIV treatment not prevention. It did not help that Gilead made public in 2005 that it would not be seeking FDA approval for PrEP, no matter what the data showed. Then there were challenges with drug

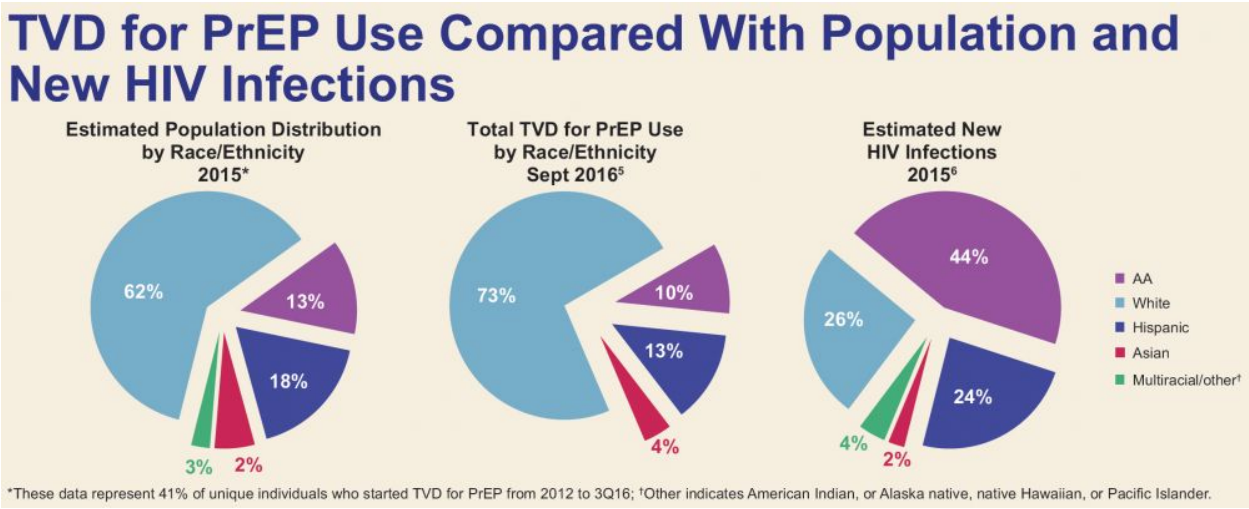
shipments. Gilead insisted on valuing drug shipments based on the commercial price in the United States, rather than the cost of manufacturing, which was at least 300 times less. The countries hosting the research would tax the importation according to the commercial price listed on the manifest. Administrative solutions to Gilead's excessive valuation of the donated product delayed the research. In hindsight, I wish that we had purchased generic medications for science, which eventually became a common practice outside the US. Such generic drug shipments would have been valued at the much lower purchase price, and would have established market parameters for sustainable and expanding access after the trial. Drug purchases are not allowable using NIH funds, so we were reliant on the donation from Gilead.

Throughout the PrEP research program, there was controversy from national governments and community leaders about whether PrEP could ever become available at an affordable price. The high price of HIV medications was the key controversy in all of PrEP research. I asked Gilead to establish plans in our host countries for post-trial access, if PrEP were found to be safe and effective. No agreements were pursued, and approvals for the study were delayed. Funding for post trial access came from the NIH until 2013. Gilead continued to be a reluctant partner in PrEP research until demand for PrEP in the USA hit a tipping point in that year.

Although not supporting the research with funding or innovation, Gilead employees took steps to limit research on alternative PrEP agents. Early in the development of PrEP research, I hosted a meeting in San Francisco to discuss whether 3TC, a medication manufactured by GSK, should be investigated as a PrEP agent. Present were employees from Gilead, GSK, and the Gates Foundation. 3TC and FTC are quite similar to each other and both medications were invented by academic chemists before they were purchased by GSK and Gilead respectively. The main advantage of 3TC, over FTC, appeared to be that the price of 3TC would be much lower, given that it was already off patent. I recall that we were assured by Gilead employees that Gilead's FTC would also be off patent by the time efficacy trials of PrEP were completed, and so the price advantage of 3TC would vanish. After that meeting, none of the public and philanthropic research sponsors requested proposals for research on 3TC PrEP. In hindsight, that was a mistake: we need competitively priced PrEP.

In the United States, PrEP demand hit a tipping point in 2013 and then plateaued in the first quarter of 2016 with only small increases since. Currently, only 1 in 10 people who would benefit from PrEP are receiving it in the United States. What little PrEP access has occurred is not fairly distributed. For example, black people suffer 44% of new HIV infections in the United States, while only 10% of PrEP users are black. I am disappointed that 9 years after we proved that PrEP was safe and effective, and 7 years after the FDA awarded exclusive marketing rights to Gilead, they have failed to get this product out to where it is needed. Instead, we hear of next generation agents offering few advantages. In 2019, our struggle against HIV is stuck. HIV is not stuck - nearly 40,000 americans become infected every year and the rate of new infections has not declined since 2016.





Robertino Mera Giler et al, Changes in truvada (TVD) for HIV pre-exposure prophylaxis (PrEP) utilization in the United States: (2012-2016). IAS Paris 2017

I believe that the root cause of low PrEP access is the high price of the medication. PrEP can be manufactured and distributed, including a profit, for about $6 per person per month. Gilead charges more than $2100 per person per month, a 35000% markup. Gilead's prices continue to increase: Gilead has increased the price of truvada 76% since I published evidence of PrEP efficacy in 2010, using US government funding.

You might hear that "no one pays" the list price after discounts. This is not true. The University of California student health services pay full price. They were among the first to offer PrEP to their students. I recall a medical director saying that the legacy of a college education should never be HIV infection. It helped that PrEP was developed by University of California faculty. Our commitment to the student body comes at a high cost: Truvada PrEP is the largest drug cost paid by the student health service. Keep in mind that college students have multiple compelling health care needs, related to mental health, sexual health, substance use, and

management of chronic diseases like diabetes. Should any organization afford a 35000% markup for medications related to only one of these health care needs?

In my experience, public health officials are reluctant to promote PrEP in their jurisdictions because of the high price of PrEP medications. Public health officials have to weigh the burden of HIV with many other priorities, including cancer prevention, maternal health, tobacco cessation, mental health, opiate addiction, other substance use, and so much more.

Promoting and providing PrEP is an easy decision when it is available at a free market driven price. For example, three states in Australia purchased generic FTC/TDF PrEP in a competitive process. What followed was the fastest growing PrEP scale up the world has ever seen, and HIV transmission rates dropped. I hear that the price paid by Australian state governments was $8 per person per month; that price included a licensing fee for the US Government's patent and for Gilead's patent on the active pharmaceutical ingredient.

What can we learn from Australia? Price matters and government leadership matters. In contrast, the US price of PrEP at $2100 per person per month keeps PrEP out of the reach of all but the wealthiest jurisdictions, or diverts funds from other compelling health care needs. Small discounts and donations are small and do not matter enough. What matters is political leadership needed to assure market competition and respect for government intellectual property.

Drug pricing practices in the United States are byzantine. Price reductions negotiated by large payers are kept confidential. Government mandated drug discount programs, like 340B, are complicated, partly because industry has resisted the development of regulatory procedures; 340B covered entities typically have to hire consultants and legal representation. Industry programs for patient assistance and copayment assistance change frequently and require paperwork. Ad hoc drug donations, like the one recently announced, may duplicate these existing patient assistance programs. Moreover, drug donations may create greater confusion and shift administrative burden from industry to public organizations. To sort through these complexities, PrEP clinics in wealthy jurisdictions pay benefits navigators to help clients obtain coverage for PrEP. Poor jurisdictions pass on PrEP entirely. Some clients still do not find a way to pay for PrEP, and some may resort to importing generic drug for personal use. Our way of pricing drugs are no way to control an epidemic, and it shows in the United States.

PrEP continues to be massively underutilized despite 7 years of drug donations, community grants, and assistance programs. A market driven price of $8 per person per month for PrEP changes the game. It starts with this committee choosing to defend US government intellectual property and innovation. You may also stand up for free market pricing by scrutinizing agreements between originator and generic manufacturers for evidence of anti-competitive practices, such as "pay for delay" and market access given to only one generic source. Approval of marketing rights to 3 or 4 generic manufacturers is the key to price competition. Your actions could take PrEP off the shelf, and stop HIV, at a price we can afford.

Thank you.