



Statement of

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before the

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

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Chairman Cummings, Ranking Member Jordan, and Members of the Committee, thank you for the opportunity to appear before you today. Drug affordability and access are critically important both to me personally and to Gilead, which is a longstanding leader in the prevention and treatment of, and race to cure, some of the most significant public health risks facing humanity, including HIV.

Gilead was founded in the late 1980s in the midst of the AIDS crisis, and was one of the first companies to focus on the discovery and development of antiviral medicines. Our first antiviral medication, Vistide, approved in 1996, addressed AIDS-defining illness, while our second, Tamiflu, was approved in 1998 for the treatment and prevention of influenza. Over the ensuing decades, Gilead innovation has made revolutionary contributions to transforming HIV from a death sentence to a chronic, manageable condition. Innovative HIV therapies have helped extend the average life expectancy of a person living with HIV from 40 to 78<sup>1</sup> years, an amazing life expectancy for a disease that 20 to 30 years ago was considered a death sentence. Today, more than 12 million people living with HIV around the world receive antiretroviral therapy provided by Gilead or one of our manufacturing partners. Every single Gilead employee is proud that we invented Truvada, a medicine that can both treat and prevent HIV. Truvada is just one of 11 lifesaving HIV drugs that we have successfully made available to patients and their healthcare providers.

Gilead has invested significantly in research and development (“R&D”), and we have taken bold scientific and financial risks in developing new HIV drugs and other groundbreaking products. For example:

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<sup>1</sup> Emily Land, *Life expectancies close to 80 years for young people starting HIV meds early*, San Francisco AIDS Foundation (Nov. 14, 2018), <https://www.sfaf.org/collections/beta/life-expectancies-close-to-80-years-for-young-people-starting-hiv-meds-early/>.

- Since 2000, Gilead spent an estimated \$25 billion on R&D, not including the cost of significant research-related acquisitions.
- Roughly a quarter of that R&D spending—more than \$6 billion—was devoted to HIV.
- We estimate that Gilead spent roughly \$1.1 billion on R&D related to Truvada.

Gilead holds multiple valid patents on Truvada. Gilead bore the risk and the vast majority of the cost of research and clinical studies to demonstrate Truvada’s efficacy and safety as part of combination HIV therapy. Our well-supported view is that the U.S. government does not hold valid patents on the use of Truvada for pre-exposure prophylaxis (“PrEP”), nor does it hold any patent for Truvada itself.

Like many Members of this Committee, we have always been concerned about access to HIV drugs for vulnerable populations. Working to ensure access to Truvada and other HIV drugs is, and has long been, a core mission for Gilead. We are proud of the wide range of programs we instituted and funded over the years to assist patients who seek access to all of our HIV medications, including Truvada. We took another significant step last week when we committed to provide up to 2.4 million bottles of Truvada per year to the federal government, free of charge—enough to meet the needs of 200,000 more uninsured patients annually for up to 11 years. All of us at Gilead are proud to join with the government in our collective national effort to end HIV in the United States by 2030. Gilead’s donation to this effort is among the largest pharmaceutical donations ever in U.S. history. Additionally, in 2014, Gilead reached an agreement to allow the early launch of a generic version of Truvada into the market in the United States in 2020, approximately one year before what is required under Gilead’s patents.

Throughout our history, Gilead has taken a number of affirmative steps to support affordability and expand access to our life-critical therapies. We priced Truvada, when it was originally approved, based on the price of its two component drugs, without adding a premium. We have increased its list price over the years at a rate consistent with average price increases in the industry. We did not increase the price of Truvada when it was approved for the additional use of PrEP, despite the considerable added value it provides to the U.S. healthcare system. Our ample spending on patient assistance programs has helped ensure that 98% of people who use our co-pay coupon program have no out-of-pocket costs. In addition, for uninsured or underinsured low- and middle-income Americans, our Medication Assistance Program (“MAP”) offers free Truvada for PrEP for those who need it. We also instituted a voluntary price freeze on Truvada for government-administered AIDS Drug Assistance Programs (“ADAPs”), the building blocks of community-based HIV care. As a result, ADAPs pay the same price for Truvada today as they did a decade ago.

Today, Gilead focuses on the discovery and development of innovative therapies in areas of unmet medical need, with a particular focus on HIV/AIDS, liver diseases, hematology and oncology, and inflammatory diseases. My comments today will address the significant investments Gilead has made to create increasingly safe and more effective medications to treat and prevent the spread of HIV. This includes our years-long effort to develop Truvada; our support for clinical research that led to the approval by the Food and Drug Administration

(“FDA”) of the first and currently only biomedical HIV prevention tool, Truvada for PrEP; and our efforts to ensure that cost is not a barrier to access to Truvada and Truvada for PrEP. In addition, I would like to address the social and economic barriers that hinder further adoption of Truvada for PrEP in certain high-risk populations in the United States, and Gilead’s efforts to expand awareness of and access to PrEP in all communities throughout the country.<sup>2</sup>

### **Gilead Spent Years Developing the Breakthrough Drugs that Comprise Truvada**

For more than three decades, Gilead has led efforts to develop safer, more effective HIV treatment and prevention therapies. In the mid-1990s, a typical course of treatment for a patient living with HIV often involved a daily regimen of more than 20 pills that required some medications be taken twice daily and others three times daily.<sup>3</sup> With different storage requirements and usage instructions for each drug, strict adherence to an entire HIV “cocktail” was often difficult for patients to maintain. Further, the drugs included in these regimens presented serious, often debilitating, side effects that delayed patients from starting effective therapy and discouraged patients from continuing to take their medicines. For those patients who were able to maintain their daily regimen, the drugs offered a grim average life expectancy of less than 40 years.

In 1991, Gilead licensed the rights to a portfolio of compounds called nucleotides, including a compound called tenofovir that would go on to serve as the foundation of the company’s innovative HIV treatment and prevention development program. At the time, nucleotides were known to have notable antiviral activity. Concerns regarding toxicity, however, reduced interest in developing this class of compounds as a treatment method. Moreover, when Gilead licensed the compound, tenofovir could not be administered orally, limiting its potential utility as an alternative to existing HIV treatment therapies.

Aware of tenofovir’s potential as an antiviral medication, Gilead launched an extensive research and development effort to create a new drug that could be taken orally and would deliver tenofovir safely and efficiently into infected cells. As part of this effort, Gilead researchers worked over the course of 18 months to design and invent hundreds of new compounds. Through this process, Gilead invented tenofovir disoproxil fumarate (“TDF”) as a potentially useful antiretroviral medication and selected the drug for further development.

Following Gilead’s further pre-clinical and clinical trials demonstrating the safety and efficacy of TDF and FDA approval in 2001, Gilead began marketing TDF under the brand name Viread for use with other medications to treat HIV.

### **Gilead Developed Truvada to Make HIV Treatment More Effective and Patient-Friendly**

To prevent the HIV virus from developing a resistance to any one drug, HIV treatment has historically required the combination of at least three separate classes of drugs. This use of

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<sup>2</sup> Truvada, Truvada for PrEP, Viread, Emtriva, Atripla, Descovy, Odefsey, and Biktarvy are registered trademarks of Gilead.

<sup>3</sup> Michelle D. Furler et al., *Polypharmacy in HIV: Impact of Data Source and Gender on Reported Drug Utilization*, 18 AIDS Patient Care and STDs 568 (2004).

highly active antiretroviral therapy, or “HAART,” is still the standard of HIV treatment today. Although the three-drug regimens available at the time of Viread’s approval were far easier to maintain than the “cocktails” from the early 1990s, multi-tablet regimens continued to present complexity and a risk of non-adherence. Patients quickly realized which drugs did not make them feel well and would stop taking those pills, leading to viral resistance that rendered individual medicines and, in some cases, entire classes of medicines, ineffective.

In an effort to make HIV treatments simpler and more tolerable, Gilead began working in the early 2000s to develop a single-pill combination HIV treatment therapy. First, Gilead identified emtricitabine (“FTC”), a compound discovered by researchers at Emory University and licensed to Triangle Pharmaceuticals, as a potential partner drug for TDF. In January 2003, Gilead acquired Triangle Pharmaceuticals, along with the rights to FTC and the early-phase clinical trial data that Triangle had developed, and finished developing the compound for clinical use including by completing clinical trials. In July 2003, the FDA approved FTC for use in combination with other drugs to treat HIV. Gilead has since marketed FTC under the brand name Emtriva.

Within a year, Gilead invented a combination pill containing TDF and FTC and completed the research and clinical studies that would lead to the approval of Truvada in August 2004 as one of the first fixed-dose combination pills for HIV treatment. Since its release, Truvada has been an invaluable addition to the HIV treatment landscape, serving as the “backbone” medication in many patients’ HIV treatment plans.

The success of Truvada notwithstanding, Gilead has made continuous improvements to its TDF-based HIV treatment therapies. For instance, the company worked collaboratively with Bristol-Myers Squibb to develop Atripla, the first single-tablet regimen—a complete, once-daily combination antiretroviral therapy for the treatment of HIV. At the time of its development, Johns Hopkins University lauded Atripla as the “gold standard” and the “new standard of patient care” with respect to HIV treatment.<sup>4</sup> In particular, by enabling patients with HIV to suppress the virus with only one pill per day, Atripla further simplified the course of treatment for patients. As noted above, regimens with simple administration and that require fewer pills help improve patient adherence to treatment.

In the years that followed, Gilead continued to invent and develop new once-daily, single-tablet regimen therapies designed to improve upon existing products in the market and provide further options to meet patient needs. In April 2016, the FDA approved Descovy, a combination of a second tenofovir-based antiretroviral drug—tenofovir alafenamide (“TAF”)—and FTC, for treatment of HIV. The active ingredients in Descovy now serve as the backbone for other single-tablet HIV treatments developed and manufactured by Gilead, including Odefsey and Biktarvy. With modern treatment regimens, many patients living with HIV now experience a median life expectancy roughly equivalent to that of the general population. This is an

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<sup>4</sup> Johns Hopkins Medicine, *Study Sets New Gold Standard for Initial Antiretroviral Treatment of HIV Infection* (Jan. 18, 2005), [https://www.hopkinsmedicine.org/Press\\_releases/2006/01\\_18\\_06.html](https://www.hopkinsmedicine.org/Press_releases/2006/01_18_06.html).

incredible accomplishment that Gilead is proud to be part of and that our scientists and employees rightly view with great pride.

Gilead's central role in this transformation of HIV from a death sentence to a manageable, chronic condition shows the value of the risks the company took and the investments it made in cutting-edge science. It's an inspiration to our scientists today, as they now actively seek to cure HIV. Through both our own research and our support of other researchers through Gilead's HIV Cure scientific grants program, we continue to lead efforts to develop innovative treatments that would enable patients to control their virus without ongoing antiretroviral therapy.

### **Gilead Supported the Clinical Trials that Confirmed the Efficacy of Truvada for PrEP**

When Gilead created and launched Truvada, the company was focused on developing medications for the treatment of HIV. With patients dying daily from AIDS and HIV/AIDS-related complications, Gilead worked aggressively to create improved treatments that would prolong the lives of people living with the disease.

As early as the mid-1990s, however, Gilead recognized that tenofovir held potential promise as a prophylactic means of blocking the transmission of HIV to those not yet exposed to the virus. Most notably, prior to 1995, Gilead assisted in studies designed to assess the efficacy of tenofovir for PrEP. Gilead donated all of the drug used in these studies, collaborated in the study methodology design, provided dosing guidance, and participated in analysis of the study results. These studies demonstrated that tenofovir was effective as both a pre- and post-exposure prophylactic, with Gilead's head of research and development at the time credited as an author when one of the studies was published in *Science*.

These early studies demonstrated the likelihood that tenofovir-based PrEP would prove effective. During this period, however, research regarding the use of antiviral medication for PrEP faced significant public opposition. Some were concerned that investments in PrEP might reduce support for research focused on developing an HIV vaccine or that availability of a medication for PrEP would undermine public health campaigns focused on safer sex practices.

Nonetheless, Gilead continued to develop innovative HIV treatment therapies while supporting PrEP-focused research led by others. In particular, after the FDA approved Truvada for treatment, Gilead provided free drugs and technical assistance to researchers exploring the drug's use for PrEP. Among other studies, Gilead provided such support for clinical trials funded by the National Institutes of Health and the Bill and Melinda Gates Foundation that ultimately confirmed the efficacy of Truvada for PrEP.

Following these successful trials, the FDA approved Truvada for PrEP in 2012. When taken daily as directed, Truvada for PrEP can reduce the risk of sexually acquiring HIV by more than 90%.<sup>5</sup> Although these trials led to FDA approval of the PrEP indication, it is important to

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<sup>5</sup> Press Release, U.S. Centers for Disease Control and Prevention, HIV prevention pill not reaching most Americans who could benefit—especially people of color (Mar. 6, 2018), *available at* <https://www.cdc.gov/nchhstp/newsroom/2018/croi-2018-PrEP-press-release.html>.

recognize that Truvada for PrEP was not a new drug. It was, and is, the same drug—Truvada—in the same dose, that is used for treatment of HIV in people who carry the virus.

### **Gilead Believes that the CDC’s PrEP Patents are Invalid**

As has been reported, after conducting a study focused on the efficacy of PrEP in monkeys, the Department of Health and Human Services (“HHS”), through the Centers for Disease Control and Prevention (“CDC”), sought and obtained three nearly-identical patents purporting to cover the use of Truvada for PrEP.<sup>6</sup> Although the agreement under which Gilead provided free drug for use in this study required the agency to notify Gilead if it intended to seek a patent on any invention, the CDC provided no such notice. As explained below, because the use of Truvada as prophylaxis was widely known at the time the CDC sought these patents, Gilead strongly believes that each of the patents is invalid.

At the outset, it is important to understand that Truvada works in exactly the same way in the human body whether it is administered after an infection has set in, shortly after someone has been exposed to HIV (*i.e.*, post-exposure prophylaxis, or “PEP”<sup>7</sup>), or before someone anticipates being exposed to HIV (*i.e.*, “PrEP”). Regardless of when Truvada is taken, these innovative compounds developed and brought to market by Gilead block the virus’s ability to replicate in the body’s cells.

Further, although CDC scientists claim that they conceived of the idea to use Truvada for PrEP by February 2006, the HIV community has known since the 1990s that antiretroviral drugs like TDF (a component of Truvada) suppress HIV replication. Because these drugs work the same regardless of when they are taken, scientists have long recognized that this technique of suppressing HIV replication could be used both to treat HIV and to prevent infection if administered properly.

Doctors and scientists first used this technique to prevent infection immediately after exposure to HIV, *i.e.* PEP. Well before the CDC monkey studies and the PrEP human clinical trials, PEP was shown to be effective in preventing infection after exposure in several populations, including HIV/AIDS caregivers exposed by needle-stick injuries and infants of HIV-positive mothers exposed during childbirth or through breastfeeding. In 2004, shortly after the approval of Truvada for treatment, scientists and HIV/AIDS organizations extended this technique to the prevention of HIV in individuals before exposures occur, *i.e.* PrEP.<sup>8</sup> They realized that the only meaningful difference between PEP and PrEP regimens is when the antiretroviral regimen begins—PrEP starts before an exposure to HIV, while PEP starts immediately after an exposure. As a result, they understood that the same antiretroviral agents used for HIV treatment and for PEP could be used for PrEP. During this period, some doctors

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<sup>6</sup> These include U.S. Patent Nos. 9,044,509, 9,579,333, and 9,937,191.

<sup>7</sup> Truvada has not been approved by the FDA for the PEP indication.

<sup>8</sup> Michelle D. Furler et al., *Medicinal and Recreational Marijuana Use by Patients Infected with HIV*, 18 AIDS Patient Care and STDs 215 (2004).

even prescribed Truvada for off-label use as PrEP, despite the fact that the drug was not approved for this use by the FDA.

Indeed, soon after the approval of Truvada for treatment—and well before the CDC claims to have invented the concept of PrEP—publicly available resources made clear that others had conceived of using an antiretroviral treatment therapy, including Truvada, for PrEP. For example, two prominent California-based HIV/AIDS organizations published guidelines in November 2004 that recommended administering combination antiretrovirals—including Truvada—to certain categories of “high risk” individuals before an HIV exposure.<sup>9</sup> These organizations, the Center for HIV Identification, Prevention, and Treatment Services and AIDS Partnership California, published guidelines stating that Truvada could be used for prophylaxis, including PrEP, well before the CDC filed its patents. This means that the use of Truvada for PrEP was not a novel invention as of February 2006, a necessary condition to obtaining a valid patent.

Moreover, before CDC scientists claimed to have invented PrEP, the agency itself was aware of the use of Truvada for prophylaxis. In guidelines published in January 2005, the CDC explained that Truvada was the preferred drug for use in PEP. These guidelines encouraged use of PEP “as soon as possible”—and no later than 72 hours—after exposure, recognizing that the sooner a patient exposed to HIV began taking Truvada, the more likely the drug would be to interrupt replication of the virus. Further, in 2004 and 2005, the CDC was conducting surveys at Gay Pride events to document that gay men already were practicing PrEP with existing antiretroviral agents that had been approved for HIV treatment.<sup>10</sup>

Despite being obligated to provide this information when seeking to patent PrEP, the CDC did not alert patent examiners in the United States or Europe of this prior evidence of the effectiveness of Truvada for prophylaxis when the agency obtained its first PrEP patents. For these reasons, among others, Gilead is confident that the patents issued to the CDC are invalid.

### **Gilead’s Approach to Determining an Appropriate Price for Truvada and Truvada for PrEP**

As a general matter, in determining the appropriate price for its HIV treatment and prevention therapies, Gilead considers three primary factors: (1) the clinical and economic value of the product to patients and the market; (2) the price of comparable products in the market, including how the clinical attributes of those products compare to the safety and efficacy of our product; and (3) ensuring access to the product among different patient populations (for example, based on payer formulary coverage). Gilead also considers its overall portfolio of pipeline

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<sup>9</sup> Greg Zekeres et al., Ctr. for HIV Identification, Prevention, & Treatment Servs., *Anticipating the Efficacy of HIV Pre-Exposure Prophylaxis (PrEP) and the Needs of At-Risk Californians* (2004), available at [http://www.uclaisap.org/assets/documents/PreP\\_Report\\_FINAL\\_11\\_1\\_04.pdf](http://www.uclaisap.org/assets/documents/PreP_Report_FINAL_11_1_04.pdf).

<sup>10</sup> Scott E. Kellerman, *Knowledge and Use of HIV Pre-Exposure Prophylaxis Among Attendees of Minority Gay Pride Events, 2004*, 43 *Journal of Acquired Immune Deficiency Syndromes* 376 (2006).

products and the funding needs of its extensive ongoing research and development activities and investments in future breakthroughs.

*Clinical and Economic Value.* To assess the clinical value of a product, Gilead consults with healthcare providers and payers to compare the product's efficacy and safety profile to the existing standard of care and other products in the market. The economic burden of overall HIV healthcare costs is significant. Notably, a recent study concluded that the average lifetime cost of managing a patient's HIV was \$850,000 more than the average HIV-negative patient.<sup>11</sup>

*Market Analysis.* As an element of its review of the value of a product, Gilead also considers the price of other products on the market, including the price of the existing standard of care. For example, Gilead products offering an improved efficacy or safety profile over existing treatments may represent a higher value as compared to other therapies in the marketplace.

*Broad-Based Access.* Finally, Gilead considers patient access to a product based on payer formulary coverage in determining a product's price. In so doing, Gilead looks to the likely patient segments that will be served by its product and identifies their payers. The company likewise considers approaches to promoting broad accessibility on payer formularies. Importantly, it is Gilead's policy not to consider its patient assistance programs, which are described in greater detail below, when it makes pricing decisions.

With respect to Truvada, Gilead's consideration of an appropriate wholesale acquisition cost ("WAC") centered on the drug's composition. As explained above, Truvada combines two compounds previously developed and marketed by Gilead: TDF (marketed as Viread) and FTC (marketed as Emtriva). Although treatment options that require patients to take fewer pills can help improve patient adherence and thus help prevent viral resistance, Gilead chose not to alter the price of the combination product (*i.e.*, we neither reduced the price because patients purchased both drugs at once, nor sought a premium in light of the benefits of the combined therapy). Rather, the initial launch price of Truvada reflected the sum of the then-current list prices for its component compounds.

Since launching Truvada, Gilead has increased the WAC price of Truvada by an average of 7% annually, with year-on-year increases typically ranging between 6% and 10%. These annual increases are consistent with single-digit year-over-year price increases in the pharmaceutical industry as a whole. Moreover, since its initial launch, Truvada's clinical value has been reaffirmed time and again as the drug has proven effective as a backbone treatment therapy across a broad range of patient populations. Most recently, Gilead announced a 4.9% increase to the Truvada WAC in March 2019. These increases notwithstanding, public payers and government programs such as Medicaid, 340B entities, ADAPs, the Department of Defense, and the Department of Veterans Affairs are entitled by law to significant rebates and discounts on Truvada. Moreover, in 2008, we instituted a voluntary price freeze on Truvada and our other HIV therapies for ADAPs, meaning that ADAPs pay the same price for Truvada today that they did more than a decade ago.

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<sup>11</sup> Cohen et al., HIV DART and Emerging Viruses 2018 (Nov. 2018).



After its approval for HIV treatment in 2004, Gilead joined efforts with the scientific and HIV advocacy communities to seek FDA approval for Truvada for PrEP, with the FDA approving the additional indication in 2012. While this newly approved indication for the drug provided additional value to the healthcare system, Gilead chose not to set a distinct price for Truvada for PrEP or to otherwise account for the new indication in pricing the product. Instead, because patients use the same product for all approved indications, and the Truvada list price was already established, Gilead chose to continue selling the drug at the then-current WAC and continued to offer steep discounts for public payers.

Finally, in 2014, Gilead entered into a settlement agreement with Teva Pharmaceuticals that will allow Teva to begin selling a generic version of Truvada beginning on September 30, 2020. This date is approximately one year before what would have been permitted under the patent on FTC.

### **Gilead's Patient Assistance Programs Help Ensure that Cost is Not a Barrier to Americans Who Need Truvada for PrEP**

As a guiding principle, Gilead is committed to ensuring that safe and effective HIV treatment and prevention medications are available to all who need them. Driven by this goal, Gilead has introduced patient assistance programs that offer targeted support to Americans who are prescribed Truvada. According to the CDC, when taking these programs into account, less than 1% of the estimated number of Americans at high risk for contracting HIV have an entirely unmet need for financial coverage for Truvada for PrEP.<sup>12</sup>

Gilead's Truvada for PrEP patient assistance programs include the following:

*Co-Pay Assistance for Americans with Private Insurance.* Gilead provides co-pay assistance for privately insured Americans prescribed Truvada for PrEP. In particular, Gilead provides up to \$7,200 per year to privately insured individuals who are prescribed Truvada, which recipients may apply toward their deductibles or monthly premiums if permitted by their insurers. Gilead's co-pay assistance benefit starts at the first dollar and does not require patients to pay a nominal, minimum co-pay before receiving co-pay assistance. As a result, in 2018, more than 170,000 Americans received co-pay assistance, 98% of whom had no out-of-pocket costs for Truvada for PrEP after using our co-pay coupon.

*Free Medication for Uninsured and Underinsured Americans.* Through our MAP program, Gilead provides free Truvada for PrEP to financially-eligible uninsured or underinsured Americans. Qualified individuals may enroll in the MAP program through an easy, online enrollment system or through a call to the MAP call center. Through the MAP program, Gilead provides free Truvada for PrEP to an estimated 20,000 Americans.

*Uninsured 24/7 Portal.* In February 2019, Gilead launched an online support portal available 24 hours a day, seven days a week, to facilitate further access to Truvada for PrEP.

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<sup>12</sup> Dawn K. Smith et al., *Estimated coverage to address financial barriers to HIV preexposure prophylaxis among persons with indications for its use, United States, 2015*, 76 *Journal of Acquired Immune Deficiency Syndromes* 475 (2017).

This portal provides access to the MAP program and free Truvada for PrEP that can be accessed from a pharmacy within hours. Through the program, individuals can receive immediate approval for free Truvada for PrEP for a 30-day period based on verbal confirmation of eligibility while the individual pursues the written MAP enrollment process.

Finally, on May 9, 2019, Gilead announced its intention to donate its PrEP products (Truvada and, if approved by the FDA, Descovy) to the CDC for distribution to as many as 200,000 uninsured Americans per year for up to 11 years. Gilead believes this donation will be instrumental in furthering HHS's goal of ending the HIV epidemic through diagnosis, treatment, protection, and rapid response. Representing one of the largest medication donations in American history, this donation is yet another example of Gilead's continuing commitment to ensuring that all Americans who can benefit from our products are able to access them.

Beyond the donation, Gilead's commitment to combating the HIV/AIDS epidemic includes the COMmitment to Partnership in Addressing HIV/AIDS in Southern States Initiative™ (“COMPASS”). Developed in response to the persistent racial and gender HIV-related disparities in the South, COMPASS is a 10-year, \$100 million commitment to address the HIV/AIDS epidemic in the South through capacity building, mental health and trauma-informed care, and awareness and anti-stigma education.

### **Gilead is Dedicated to Expanding Awareness and Access to Truvada for PrEP**

Today, more than 200,000 of the estimated 1.1 million Americans who are at risk for HIV currently receive Truvada for PrEP. While this reflects a significant increase in recent years, disparities in PrEP use persist across racial, ethnic, gender, and geographic populations. Mindful of these challenges, Gilead has worked closely with HIV advocates, providers, and others to expand its investments in outreach to communities most affected by HIV.

We are aware of media reports that suggest that the price of Truvada limits access to PrEP among at-risk communities. As previously noted, however, the CDC has found that less than 1% of the estimated 1.1 million Americans at high risk for contracting HIV are in need of financial assistance for the medication. Instead, broader usage of Truvada for PrEP among at-risk populations is hampered by a number of significant social and structural barriers, including:

*Limited access to affordable healthcare coverage.* Increased access to health insurance coverage is highly correlated with increased PrEP use. Truvada for PrEP is a chronic medication and requires quarterly testing for HIV and other sexually transmitted infections, as well as periodic monitoring of renal function. Even where out-of-pocket medication costs are low, people without health insurance may still have trouble obtaining a prescription for Truvada and accessing related services. As a result, Americans with insurance coverage are four times more likely to use PrEP than those without insurance. The expansion of Medicaid coverage as part of the Affordable Care Act resulted in insurance coverage for many Americans living with HIV or at risk for contracting the disease. Approximately 40% of people with HIV live in states that have not expanded Medicaid coverage under the Affordable Care Act.

*Low awareness of PrEP among medical providers and lack of experience to offer PrEP.* Medical providers who are most likely to care for HIV-negative patients—such as primary care

physicians—are often not aware of PrEP as an HIV prevention tool, nor are they trained to assess whether PrEP is appropriate for their patients. Provider education and training for non-HIV specialists has been part of Gilead’s support of Truvada for PrEP, but more is needed to increase the number of providers who are aware of and able to offer PrEP to eligible patients.

*Low awareness of PrEP among at-risk HIV-negative individuals.* Although public awareness of PrEP has increased, there are many people who could benefit from PrEP who are not aware of it. Studies have found lower awareness of PrEP among Black and Latino men who have sex with men, as well as among women and young people of color. Additionally, many individuals do not identify as being at risk for HIV or in need of prevention tools like PrEP.

*Stigma and discrimination associated with PrEP.* PrEP has been associated with “promiscuity” and the encouragement of “risky” behaviors, particularly among men who have sex with men, which has contributed to stigma tied to its use. Individuals seeking PrEP may also experience stigma in healthcare settings, which impedes people’s willingness to disclose sexual behaviors or ask about PrEP.<sup>13</sup>

*Insurance benefit design that places a significant cost-sharing burden on patients.* Although most insurance plans currently cover Truvada for PrEP without restriction, they vary in terms of patient cost-sharing requirements. While Medicaid has minimal to no coinsurance requirements, private and Medicare Part D plans are increasingly shifting cost-sharing responsibilities onto patients, with some plans requiring patients to pay as much as 50% of the cost of Truvada for PrEP.

Further, Gilead supports federal and state healthcare programs that serve vulnerable populations, including many of the people at highest risk of HIV infection, like Medicaid and the 340B Program. Gilead’s PrEP community grants have provided more than \$28 million in funding to more than 120 organizations working to raise awareness about HIV prevention and PrEP among at-risk populations and their providers, and we have actively supported research efforts to identify optimal public health strategies to encourage PrEP use.

Lastly, in recent years, Gilead has greatly expanded its investment in educating consumers and healthcare providers about HIV prevention strategies, including PrEP. Most notably, working with HIV advocates and the LGBT community, Gilead has launched a PrEP awareness campaign across TV and digital media to help educate individuals with high need for, but low awareness of, HIV prevention and Truvada for PrEP.

Gilead also supports congressional and administrative actions to address challenges that restrict access to PrEP, including stigma, provider education, and health benefit design. Along with a broad coalition of HIV advocates and providers, Gilead supports the inclusion of additional funding to support these efforts in the fiscal year 2020 appropriations legislation approved by the House Labor-HHS-Education Appropriations Subcommittee. This funding will

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<sup>13</sup> Lenny Bernstein, *This HIV pill saves lives. So why is it so hard to get in the Deep South?*, The Washington Post (Mar. 11, 2019), available at [https://www.washingtonpost.com/national/health-science/this-hiv-pill-saves-lives-so-why-is-it-so-hard-to-get-in-the-deep-south/2019/03/11/a221a784-354a-11e9-854a-7a14d7fec96a\\_story.html?utm\\_term=.b7472880cfbc](https://www.washingtonpost.com/national/health-science/this-hiv-pill-saves-lives-so-why-is-it-so-hard-to-get-in-the-deep-south/2019/03/11/a221a784-354a-11e9-854a-7a14d7fec96a_story.html?utm_term=.b7472880cfbc).

support Ending the HIV Epidemic Initiatives through the Health Resources and Services Administration's Health Centers and the Ryan White HIV/AIDS Program, along with the CDC Division of HIV/AIDS Prevention. We also support efforts to restrict the ability of health plans to use prior authorization requirements and step therapy in ways that create barriers to access to PrEP. In particular, Gilead applauds proposed regulatory changes included in the recent Centers for Medicare and Medicaid Services 2020 Notice of Benefit and Payment Parameters requiring drug manufacturers' financial assistance to count towards beneficiaries' annual cost-sharing limits. These proposed changes will help ensure that cost is not a barrier for patients with private health insurance who rely on PrEP.

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Gilead is committed to providing people with HIV and at risk for HIV with effective, safe, and patient-friendly medication options that will help them live longer, healthier lives. As the Committee considers proposals to increase the use of Truvada for PrEP by individuals at risk for HIV, we urge you to build on the efforts Gilead has already undertaken to expand awareness of the risk of HIV and the steps Americans can take to protect themselves against infection. We look forward to continuing to work together with HIV advocates, patients, healthcare providers, and our federal partners to identify creative solutions to this critically important challenge.