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Remarks by R. Wolitski, PhD, Acting Director, HHS Office of HIV/AIDS and Infectious Disease Policy at the HIV Prevention Action Coalition and Congressional HIV/AIDS Caucus Briefing

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First I'd like to thank the **HIV Prevention Action Coalition** and the **Congressional HIV/AIDS Caucus** for inviting me to be here with you today to talk about pre-exposure prophylaxis—or PrEP—and what it means in the **war that we're** fighting against HIV.

We're about to cross a **historical milestone**. Next month will be 35 years since the first cases of AIDS were reported anywhere in the world. What started with just 5 cases that were reported in June of 1981, has exploded into a worldwide epidemic. Today, there are approximately **37 million** people living with HIV around the world, and **1.2 million** of those are living here in the United States.

It's clear that the **virus had the upper hand** in the very early days of the epidemic as it spread rapidly here and around the world, taking the lives of millions in their prime. In the US, since the beginning of the epidemic, **more than 670,000 people** with HIV have died. That's more deaths than the total number of American casualties in all of the wars and conflicts that the United States has been involved in over the last 100 years. More than WWI, WWII, the Korean War, the Vietnam War, Afghanistan, Iraq and all of the others over the past 100 years combined.

But we've made important progress. One of the first scientific breakthroughs came **in 1984 when HIV was discovered**. This was followed **the next year** by a test that could detect HIV antibodies, and we acted to **create a national network** of counseling and testing sites so that people could learn their HIV status. After HIV testing became available, **new infections started to drop for the first time**, and in **3 years**, they had **dropped by about a third**.

Another major breakthrough came in **1994**, when researchers found that giving HIV medication to pregnant women and their newborns could reduce the risk of mother to child transmission **by 67%**. In **3 years** the number of perinatally acquired AIDS cases **was cut in half**.

But the **biggest breakthrough of all** came toward the end of 1995 when highly active antiretroviral treatment first became available. **It changed everything**. People who were literally on their death beds came back to life. And the number of deaths among people with AIDS was **cut by more than half** in just **two short years**.

In each of these cases, **scientific advances made it possible** to alter the course of the epidemic. But **science alone wasn't responsible** for the infections that were averted or the lives that were saved. The impact of these advances was only made possible **because we as nation—government, advocates,**

health care providers, the legal system and many others—worked hard to ensure that these scientific breakthroughs were made available to those who needed them.

We made **HIV testing available for free**. And we made sure that **pregnant women and others living with HIV** had **access to HIV treatment** even if they could not afford it. This was possible in large part because of the **reauthorization of the Ryan White CARE Act in 1996**—just **one year** after effective treatments became available. The **reauthorization** funded the **AIDS Drug Assistance Program** as a **separate line item** and reflected our **national commitment** to ensure broad access to HIV treatment.

Treatment of persons with HIV infection is not only good for the health of people living with HIV; it reduces HIV transmission **by 96%**. But the success of that strategy depends on being able to reach those who are living with HIV, get them into care, and taking medication daily. Right now, we've accomplished that with **fewer than half** of people living with HIV in the US.

People who do NOT have HIV need to be able to protect themselves. Condoms are effective, but they have to be used each and every time in order to provide protection. Some people do use them consistently, but too many do not. As a result of testing, prevention, and treatment, we've seen **steady declines** in HIV diagnoses—**about 12%** over the past decade. But this rate of decline is much slower than it should be. We still have **about 40,000 new HIV diagnoses** each year in the United States.

Science has once again provided us with **another major opportunity** to change the course of the epidemic. Taking PrEP, which consists of a single daily pill, can reduce the risk of someone **acquiring HIV sexually by more than 90%**. And it reduces risk among **people who inject drugs by more than 70%**.

This figure [hold up] shows CDC estimates of what could be accomplished by expanding access to PrEP and getting more people with HIV into regular medical care. Expanding access to PrEP could prevent an estimated **48,000 new infections** by 2020 at current levels of viral suppression among people living with HIV. Improving access to PrEP and treatment for people living with HIV could prevent as many as **180,000** new infections.

Unlike condoms, it is somewhat forgiving. If a person forgets to take PrEP about once a week, they will still have about that same level of protection as someone who took it everyday. But with a condom, if you don't use it, you have no protection at all for that act. Of course, the effectiveness of PrEP drops substantially if people **miss 3 or 4 doses** a week. But **adherence has been better** than expected in the demonstration projects that have taken place after the first clinical trials. We are seeing real world effectiveness rates that are better than in the original trials in some cases because people **know they are taking** an effective medication rather than a placebo or an unproven medication that might work.

We know from multiple trials now that PrEP is **safe** and **does not pose any serious clinical risks**. A small minority of people experience problems with kidney function and bone loss, but these are reversed when the medication is stopped. Some people have gastrointestinal symptoms when they start PrEP, but these usually resolve after the first couple of weeks.

It was reviewed and approved by the **FDA in July of 2012**. Almost four years ago.

The **CDC** issued the first interim guidance for the use of PrEP among gay and bisexual men in **2011**. As studies in other populations were completed, CDC issued additional interim guidance. A comprehensive set of guidance for the use of PrEP in gay and bisexual men, people who inject drugs, and heterosexual women and men was published by **CDC and US Public Health Service in 2014**.

And the updated **National HIV/AIDS Strategy** that was released in July recognizes the importance of PrEP. The update was developed with input from experts across the federal government community stakeholders around the country. It makes increasing PrEP use one of the 4 pillars of our national response to fighting the epidemic.

Despite this consensus about the safety and effectiveness of PrEP, it has not been scaled up like earlier scientific innovations.

CDC estimates that **1.2 million Americans** who are at the highest risk for contracting HIV could benefit from taking PrEP. This includes gay and bisexual men, people who inject drugs, and heterosexual women and men. Of these groups, the largest percent who can benefit are gay and bisexual men. CDC estimates that 1 in 4 gay and bisexual men are at sufficiently high risk that they should be offered PrEP.

It has been nearly **4 years since the FDA approved PrEP**, yet too few of the people who need it are taking it. We are seeing this change and PrEP use has now begun to increase rapidly. Our best estimate is that about **18,000 people started** taking PrEP in the most recent year's worth of data, which covers most of 2015. This number is incomplete and an underestimate, but it shows how far we still have to go.

Why aren't more people using PrEP?

There are **multiple barriers**. Some high-risk persons **do not know** about it or have misinformation about it. Sadly, some health care providers are not much better informed. A national survey conducted in 2015 found **that 1 in 4 health care providers** were unaware of PrEP. Some of those who know about it are **reluctant** to prescribe it because they think of HIV medications as being **difficult to prescribe** and monitor. Some providers think that their patients should **just stop** having sex or use condoms instead of PrEP. When PrEP first became available, some in the **community perceived** early adopters to be promiscuous. That has changed a great deal, but some of the judgment and stigma toward people who are taking responsibility for their own health remains.

But, like with many other medical advances today, the biggest barrier is **cost**. The retail cost of Truvada is about \$1,200 a month, but most Medicaid and some private insurance plans cover it, and the manufacturer (Gilead Sciences) offers financial assistance programs for persons who cannot afford the medication or the copays. But many patients do not know how to, or do not have the time and energy to, navigate these payment and reimbursement systems.

These barriers are having a **devastating impact**. This is especially frustrating because PrEP is cost effective for some high-risk populations and can even cost saving when it is provided to those whose immediate risk of HIV infection is greatest.

As a society we can either pay up front for preventing the infections in the first place. Or we can pay for the costs of medical care down the road. The lifetime medical costs for someone with HIV infection add up to about **\$380,000**. If you multiply that by the 40,000 people who are newly diagnosed with HIV, we are adding about **\$15 billion** in costs for medical care each year that HIV infections continue at their current level.

The burden of HIV doesn't affect us all equally.

One of the sobering realities of this epidemic is that people of color, the poor, and the marginalized have been hit the hardest. These handouts show CDC's estimates of the current lifetime risk of HIV infection in various groups. The CDC estimates that 1 in 2 black men who have sex with men will be diagnosed with HIV in their lifetime. Half of them. The number is 1 in 4 for Hispanic men who have sex with men. Overall, 1 in 6 gay and bisexual men will become infected if things don't change. This compares to 1 in 473 for heterosexual men.

Access to PrEP is not just a public health issue. It's also a social justice issue. We are likely to see these disparities widen if the ability to PrEP is limited to those with the most resources or the best insurance. ACA certainly has, and will, improve access for many. But we're likely to see disparities get worse in the south, where infections and deaths are already greatest, because fewer southern states expanded Medicaid. And we're likely to see disparities grow along socioeconomic lines because the medication co-pays can be too high for some to afford.

We saw this very thing happen when effective HIV treatments became available in the 1990s. The numbers of deaths dropped in all racial/ethnic groups, but we also saw racial/ethnic disparities in survival get larger because whites had better access to the new medications compared to racial/ethnic minorities.

Important work to increase PrEP use is already being done. But it's not yet occurring at the scale that is needed to dramatically change the course of the domestic epidemic.

- NIH and CDC are conducting demonstration projects that look at efforts to improve PrEP awareness and access among gay and bisexual men. For example, the Secretary's Minority AIDS Initiative Fund supporting a 4-year project with a total investment of \$63 million project to improve comprehensive prevention and care services, including PrEP, for gay and bisexual men of color who are at-risk for or living with HIV.
- CDC is providing capacity building assistance and training to community-based organizations to improve their ability to educate their clients about PrEP and to help their clients navigate the approval and reimbursement processes.
- And HHS supports a physician hotline that is available nationwide to support and advise physicians on prescribing PrEP and monitoring their patients who are taking it.

We are also working across agencies to improve our federal response.

- Federal Interagency Workgroup that is responsible for implementing the National HIV/AIDS Strategy has established a subgroup that is focused specifically on improving access to PrEP through federal programs. HHS has a similar group that is working to improve communication and coordination on PrEP-related issues within the Department.

The President's FY17 budget recognizes the need to further improve our efforts and calls for \$20 million pilot program at CDC to increase availability and improve use of PrEP. Up to 30% of these funds could be used to pay for PrEP medication as payer of last resort.

This pilot program reflects the work of states that have been leading the way on improving access to PrEP like Washington and New York that have used state funds to establish PrEP Drug Assistance Programs that help people obtain insurance, navigate approval and reimbursement processes, and cover co-pays and act as payer of last resort when necessary.

These activities represent real progress, but it has been almost 4 years since the FDA approved PrEP for prevention. We still have a **long way** to go before we achieve the same level of uptake as we did for HIV testing, perinatal prevention and HIV treatment for those who would benefit the most from PrEP. We have the tools to realize the vision of an AIDS free generation. We just have to use them.

Thank you.