



Congressional Committee on Oversight and Reform

***HIV Prevention Drug: Billions in Corporate Profits
After Millions in Taxpayer Investments***
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Testimony of:
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Good morning.

My name is Dr. Rochelle Walensky. I am Professor of Medicine at Harvard Medical School, Chief of the Division of Infectious Diseases at Massachusetts General Hospital, a practicing clinician and a researcher on the cost-effectiveness of HIV care in the United States and globally. In 1995 we told patients with AIDS that they would, with certainty, die from the disease; AIDS plagued my internship. By the end of that year, we had an FDA-approved HIV cocktail: 3 drugs, up to 14 pills a day, which if taken without fail, allowed patients with AIDS to live. At the time, the 3 drugs of the cocktail cost a total of \$15,000 per person per year, and our research team reported its cost-effectiveness -- the cocktail demonstrated good value for money.

Today, we definitively have the tools to end this epidemic. The HIV 3-drug cocktail – termed antiretroviral therapy -- is frequently co-formulated into a single daily pill; the regimens have high resistance barriers (that's good); they have low toxicity profiles (that's also good) and projections suggest a normal life expectancy for adherent patients with HIV. We also know that people who take these drugs and effectively suppress their virus cannot transmit the disease to anyone else. But, the cost of these drug regimens today is \$40,000 to \$50,000 per year, a 300% increase in 25 years.

Truvada is a co-formulation of two of the three-drugs used for treatment – scientifically known as the combination tenofovir disoproxil fumarate/emtricitabine. It was FDA approved for HIV treatment in August 2004 and has, since then, been a mainstay of HIV care. In 2012, following remarkable scientific work – some of which was led by Dr. Robert Grant – the FDA approved the expanded indication of Truvada for pre-exposure prophylaxis or PrEP, for HIV prevention. The cost of Truvada when approved in 2004 was \$7800 per year; today, it costs \$20,000 per year. A similar drug combination is available internationally at a cost of \$60 per year. Please understand that I am not proposing that this is what the price should be in the US; I simply use that as a benchmark to put our national pricing in a global context.

In his February State of the Union address, the President announced his initiative to “End the HIV Epidemic.” *This will not be easy.* The benchmarks for the “End the Epidemic” initiative are a decrease in the number of new HIV infections by 75% in 5 years and 90% by 2030. Our research group has published work highlighting that even if we get 90% of people with HIV diagnosed, treated and virologically suppressed, we can only decrease the number of new infections by 40%. In short, to end this epidemic, we need both treatment and prevention interventions.

Aside from treatment, PrEP offers the most efficacious prevention intervention known. Make no mistake, even if it was free -- PrEP is difficult. In addition to drug adherence, it requires *quarterly doctor visits* for HIV testing, sexually transmitted infections screening and laboratory monitoring. But right now, the biggest problem with PrEP is access. The CDC estimates that more than 1.1 million people in the US are at high enough HIV risk to warrant PrEP; fewer than 150,000 people have ever received it, and over 75% of those are white gay men in the Northeast or West Coast. But, today’s uncontrolled HIV epidemic is rampant among black gay men and continues to disproportionately affect women of color, especially in the South. In 2016, it was estimated that 1 in 2 black gay men would be diagnosed with HIV in their lifetime. We need prevention tools, like PrEP, to reach these marginalized populations if we are ever to make a dent in HIV incidence, never mind reach the auspicious End the Epidemic goals.

The sale of Truvada has resulted in profits of over \$36 billion, and Truvada, unchanged, has seen a price increase of 150% since 2004. This price tag is simply too high.

We have the scientific tools to end the HIV epidemic; we are fortunate that pharma has developed the drugs to get us there; and they have already profited enormously. Now, in the spirit of saving lives, preventing infections, putting forth a cohesive public health response, and realizing a presidential call to action, I simply ask that these drugs be reasonably priced so that those most marginalized and at risk can also reap their benefit.

And finally, I would like to applaud Congress for holding this hearing and bringing this issue to the forefront in the public dialog. I hope to see that some companies – including Gilead -- will begin to do the right thing. It’s never too late for that.

Thank you