

**HIV PREVENTION DRUG:
BILLIONS IN CORPORATE PROFITS
AFTER MILLIONS IN TAXPAYER
INVESTMENTS**

HEARING
BEFORE THE
**COMMITTEE ON
OVERSIGHT AND REFORM
HOUSE OF REPRESENTATIVES**
ONE HUNDRED SIXTEENTH CONGRESS
FIRST SESSION

MAY 16, 2019

Serial No. 116-24

Printed for the use of the Committee on Oversight and Reform



Available on: <http://www.govinfo.gov>
<http://www.oversight.house.gov>
<http://www.docs.house.gov>

U.S. GOVERNMENT PUBLISHING OFFICE

36-660 PDF

WASHINGTON : 2019

COMMITTEE ON OVERSIGHT AND REFORM

ELIJAH E. CUMMINGS, Maryland, *Chairman*

CAROLYN B. MALONEY, New York	JIM JORDAN, Ohio, <i>Ranking Minority Member</i>
ELEANOR HOLMES NORTON, District of Columbia	JUSTIN AMASH, Michigan
WM. LACY CLAY, Missouri	PAUL A. GOSAR, Arizona
STEPHEN F. LYNCH, Massachusetts	VIRGINIA FOXX, North Carolina
JIM COOPER, Tennessee	THOMAS MASSIE, Kentucky
GERALD E. CONNOLLY, Virginia	MARK MEADOWS, North Carolina
RAJA KRISHNAMOORTHY, Illinois	JODY B. HICE, Georgia
JAMIE RASKIN, Maryland	GLENN GROTHMAN, Wisconsin
HARLEY ROUDA, California	JAMES COMER, Kentucky
KATIE HILL, California	MICHAEL CLOUD, Texas
DEBBIE WASSERMAN SCHULTZ, Florida	BOB GIBBS, Ohio
JOHN P. SARBANES, Maryland	RALPH NORMAN, South Carolina
PETER WELCH, Vermont	CLAY HIGGINS, Louisiana
JACKIE SPEIER, California	CHIP ROY, Texas
ROBIN L. KELLY, Illinois	CAROL D. MILLER, West Virginia
MARK DESAULNIER, California	MARK E. GREEN, Tennessee
BRENDA L. LAWRENCE, Michigan	KELLY ARMSTRONG, North Dakota
STACEY E. PLASKETT, Virgin Islands	W. GREGORY STEUBE, Florida
RO KHANNA, California	
JIMMY GOMEZ, California	
ALEXANDRIA OCASIO-CORTEZ, New York	
AYANNA PRESSLEY, Massachusetts	
RASHIDA TLAIB, Michigan	

DAVID RAPALLO, *Staff Director*

ALI GOLDEN, *Chief Health Counsel*

ELISA LANIER, *Director of Operations and Chief Clerk*

CHRISTOPHER HIXON, *Minority Chief of Staff*

CONTACT NUMBER: 202-225-5051

C O N T E N T S

Hearing held on May 16, 2019	Page 1
WITNESSES	
Dr. Robert M. Grant, Professor of Medicine, University of California, San Francisco Oral Statement	4
Dr. Rochelle Walensky, Professor of Medicine, Harvard Medical School, and Chief of Division of Infectious Diseases, Massachusetts General Hospital Oral Statement	6
Mr. Tim Horn, Director, Medication Access and Pricing, NASTAD Oral Statement	8
Mr. Stephen Ezell, Vice President, Global Innovation Policy, Information Technology and Innovation Foundation Oral Statement	9
Dr. Aaron Lord, PrEP Patient and Advocate Oral Statement	11
Daniel O'Day, Chairman and CEO, Gilead Sciences, Inc. Oral Statement	13
<i>The written statements of the witnesses are available at: https://docs.house.gov.</i>	

INDEX OF DOCUMENTS

The documents entered into the record during this hearing are listed below, and are available at: <https://docs.house.gov>.

- * Statement from New York City Council Speaker Corey Johnson; submitted by Ms. Ocasio-Cortez.
- * Yale Global Health Justice Partnership Statement dated 3-12-19; submitted by Ms. Ocasio-Cortez.
- * Peer Review Article from the New England Journal of Medicine dated 12-30-10; submitted by Mr. Jordan.
- * Washington Post Article from July 13, 2016, "The Drug Company that shocked the world with its prices dodged \$10 billion in taxes, report says;" submitted by Ms. Hill.
- * Letter from the Treatment Action Group; submitted by Mr. Cummings.
- * Letter from the AIDS Vaccine Advocacy Coalition; submitted by Mr. Cummings.
- * Letter from the HIV Medicine Association; submitted by Mr. Cummings.
- * Questions for the Record; submitted to Mr. O'Day.
- * Statement for the Record; submitted by Mr. Connolly.

**HIV PREVENTION DRUG:
BILLIONS IN CORPORATE PROFITS
AFTER MILLIONS IN TAXPAYER
INVESTMENTS**

THURSDAY, MAY 16, 2019
HOUSE OF REPRESENTATIVES
COMMITTEE ON OVERSIGHT AND REFORM
Washington, D.C.

The committee met, pursuant to notice, at 10:06 a.m., in room 2154, Rayburn House Office Building, Hon. Elijah Cummings (chairman of the committee) presiding.

Present: Representatives Cummings, Maloney, Norton, Connolly, Krishnamoorthi, Raskin, Rouda, Hill, Sarbanes, Welch, Speier, Kelly, DeSaulnier, Khanna, Gomez, Ocasio-Cortez, Pressley, Tlaib, Jordan, Amash, Foxx, Meadows, Hice, Grothman, Comer, Higgins, Norman, Roy, Miller, Armstrong, and Steube.

Chairman CUMMINGS. The committee will come to order. Without objection, the chair is authorized to declare recess of the committee at any time.

I now recognize myself for five minutes to give an opening statement.

Today is our committee's second hearing on the skyrocketing prices of prescription drugs. At our first hearing in January, the committee's very first witness, Ms. Antoinette Worsham, she was a compelling witness. Her 22-year-old daughter died because she could not afford the insulin she needed to control her diabetes. By the way, the insulin cost \$333 a month. Let that sink in. For \$333 a month, a 22-year-old college graduate died. Ms. Worsham's testimony was gut-wrenching, but unfortunately, she is not alone. We've heard other stories just like hers from our constituents, our friends, and our loved ones.

Today, we are examining the price of a drug called Truvada. Truvada is a phenomenal drug that prevents the transmission of HIV through a treatment called preexposure prophylaxis or PrEP for short.

At the outset, I want to recognize the efforts of our distinguished colleague, Congresswoman Ocasio-Cortez. She has been leading the charge on this issue, and it is because of her efforts that we are holding this hearing today. I want to thank her for her phenomenal leadership.

Think about this: We now have a drug that has the potential to end the HIV epidemic. This would have been unfathomable at the height of the HIV/AIDS crisis. This is an issue that I have been dealing with and working with communities on for more than 20-

some years. I have seen many people die. I have seen people who used to be on the choir at my church die. I have seen neighbors die. And we have made these phenomenal strides.

But this treatment was developed as a result of investments made by the American taxpayers through the National Institutes of Health and the Centers for Disease Control and Prevention. The problem is that Gilead, the company that now sells this drug, charges astronomical prices. When Truvada was first approved in 2004, Gilead charged about \$800 per month, again, for this life-saving drug. Since then, Gilead raised the price of this drug over and over and over and over and over again. It now charges about \$2,000 for just one month or about \$70 per pill. Think about that, lifesaving drug.

In the same period, Gilead has made massive windfalls on this treatment, more than \$36 billion in revenues. Let me say that one more time. They made more than \$36 billion on this drug alone. How can Gilead do this? How can our system allow a company to take a drug treatment that was developed with taxpayer funds and abuse this monopoly to charge such astronomical prices? This life-saving treatment would not exist but for the research funded by the CDC and NIH. So how can our system let a company charge prices that are so outrageous, making \$36 billion while there are literally hundreds of thousands of people who need this drug? We are better than that.

These are some of the hard questions we will ask Gilead's CEO Daniel O'Day, who is here today. And I am praying that you do not come and give us the normal rope-a-dope stuff that we usually hear about the various low programs you have got, the coupons you have got. We want the prices to come down. We want truth. We want to know why it is that the prices are going up astronomically. We want to know what this R&D is all about. We want to know if it is all about vacation, giving doctors vacations and encouraging them to prescribe certain things or not. We need to know all about that.

We appreciate that Mr. O'Day accepted our invitation to participate, and we anxiously look forward to his testimony.

The reason this is so critical is because the CDC estimates that there are 1.1 million people at high risk of contracting HIV who could benefit from this drug but that only a fraction, a fraction are getting it. Use is shockingly low among groups that are at particularly high risk, including communities of color that have been disproportionately impacted by this epidemic.

This treatment is available in other countries for much, much less. In Australia, patients pay less than \$7 a pill. Hello? Here, we are paying well over \$70. In other countries, patients pay even less. This is because Gilead charges less for its treatment overseas than it does in the United States. It is also because Gilead has generic competitors there but not here.

Finally, let me note that this is a bipartisan issue. HIV has no boundaries. It affects blacks and whites, rural, urban. It is a tough disease. President Trump recently announced an initiative to end the HIV epidemic within 10 years. This is a laudable goal. However, it relies on this particular drug treatment getting to everyone who needs it. Gilead recently agreed to donate millions of bottles

of its drugs but far short of what we need to save lives. Without addressing the fundamental problem of pricing, I am afraid that we simply may not get there.

And so we want to work with the President in addressing HIV, but we need to start right here, and we need to start right now.

Chairman CUMMINGS. So without further do, I want to recognize the distinguished ranking member Mr. Jordan for his comments.

Mr. JORDAN. Mr. Chairman, welcome back, and thank you for that and for this important hearing.

At the beginning of the HIV outbreak in the early 1980's, the outlook was just not good. In fact, it was pretty darn bleak. Early treatments were expensive and frankly not very effective, but advancements in medicine in the 38 years since the first reported incidence of AIDS in the United States have yielded hope for those afflicted with this virus. The most important development was Gilead creating and bringing Truvada to market in 2004.

Because of the invention of this, life expectancy for people with HIV is now effectively the same as life expectancy for people without it. I think we can all agree that Truvada is something of a miracle drug. It is the gold standard for preventing and treating HIV. Gilead's invention has been literally lifesaving.

Gilead of course made money based on its invention. My colleagues on the other side of the aisle and some of the witnesses they have invited seem to believe this is some sort of conspiracy. Rather than applaud Gilead for manufacturing this miracle drug, they wish to demonize a company for making a profit. The right to reap the rewards of your invention is so vital that our Framers included it in the Constitution. Our intellectual property protections are the crown jewel of the American economy and what makes our Nation the most innovative in human history. Article 1, section 8, clause 8, the Congress shall have power, quote "to promote the progress of science and useful arts by securing, for limited times, to authors and inventors the exclusive right to their respective writings and discoveries." The Framers knew that individuals would take risk and endeavor to make great things if they knew they would be rewarded.

Some would have you believe that Gilead did not invent this drug or discover its uses and that the Federal Government has equities here for which the company is not accounting. The evidence does not bear this out, and I hope we can use today to set the record straight. I fear that my colleagues are using today's hearing as a platform to strongarm private companies making breakthrough discoveries all because they are upset at how markets work.

The reality is that, while Gilead has made money on this drug, there do not seem to be genuine issues of access, and that is largely due, as the chairman talked about, to progress made by efforts of the Trump administration. The State of the Union address this year, President Trump announced his administration's initiative to eliminate new HIV infections in the U.S. within 10 years. This would be a remarkable breakthrough for public health. And to that end, just last week, HHS announced that, as a result of discussions between the Trump administration and Gilead, the company agreed to donate 2.4 million vials of its PrEP medication annually

to the CDC for distribution to treat individuals who are at risk and uninsured. The company has also agreed but was under no obligation to do so to allow generics to enter the market a year earlier to further help provide access.

Of course the cost of pharmaceuticals is a problem driven many factors that our committee and the Trump administration hope to tackle in a bipartisan fashion, as the chairman indicated. But we will never make real advancements in public health if the plan is to use false pretenses to attack and vilify those that are making game-changing scientific breakthroughs.

Thank you, Mr. Chairman. I look forward to the discussion from all our witnesses this morning, and I yield back.

Chairman CUMMINGS. Thank you very much.

I now want to welcome our witnesses. Dr. Robert Grant, professor of medicine at the University of California San Francisco, Dr. Grant led one of the clinical trials demonstrating that Truvada could be used to prevent the transmission of HIV; Dr. Rochelle Walensky, the chief of infectious diseases at Massachusetts General Hospital and professor of medicine at Harvard Medical School, who is an expert on cost-effectiveness in HIV treatment; Mr. Tim Horn, the director of medication access for the National Alliance of State and Territorial AIDS Directors, who has also worked in HIV treatment and advocacy; Stephen Ezell from the Information Technology and Innovation Foundation; Mr. Aaron Lord, a PrEP user and cofounder of PrEP4All. Dr. Lord's personal experience led him to advocate on behalf of others, and we are glad to have him with us today. And finally, Mr. Daniel O'Day, chairman and chief executive officer of Gilead Sciences Inc.

Now, if you all could please rise and raise your right hands, and I will now swear in the witnesses.

[Witnesses sworn.]

Chairman CUMMINGS. Thank you very much. Let the record show that the witnesses answered in the affirmative.

You may be seated. The microphones are quite sensitive, so please speak directly into them.

And without objection, your written statements will be made part of the record.

With that, Mr. Grant, you are now recognized to give an oral presentation of your testimony. Please note that I would ask that all of you stay within the five-minute limit.

And before you get started, Ms. Ocasio-Cortez, I mentioned before you got here that you were a main driver in making sure that this hearing happened today. I want to thank you for your leadership.

All right. Dr. Grant.

**STATEMENT OF ROBERT M. GRANT, PROFESSOR OF
MEDICINE, UNIVERSITY OF CALIFORNIA**

Dr. GRANT. Chairman Cummings—

Chairman CUMMINGS. Good morning.

Dr. GRANT [continuing]. Ranking Member Jordan, and members of the House Committee on Oversight and Reform, I'm pleased to testify today on how the promise of PrEP remains unfulfilled. 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 if proven. We have not kept that promise. I come today to ask for your help.

My PrEP research was funded by grants from the NIH starting in 2002. I later received supplemental funding from the Bill and Linda Gates Foundation. Our research was funded—other research was funded by NIH, CDC, and Gates. The U.S. Government provided the majority of funds for PrEP research, investing hundreds of millions of taxpayer dollars.

Furthermore, CDC scientists discovered that adding a drug called FTC to tenofovir increased protection, and it's the combination of those two medications which is FDA-approved today. The CDC scientists also demonstrated that preexposure dosing added substantially to the protective events, and it's these inventions that led to the CDC government patents that were awarded several years ago.

Gilead did not provide leadership, innovation, or funding for PrEP research. Gilead's role was limited to donating study drug and placebos. In my experience, Gilead proved to be a hesitant partner in PrEP research. For example, Gilead made public in 2005 that it would not seek FDA approval for PrEP no matter what the data showed.

Although not supporting the research with funding or innovation, Gilead took steps to limit research on alternative and competing PrEP agents. In particular, there was interest in 3TC, a competing drug because it was about to go off patent. Interest in 3TC PrEP dissipated with assurances that Gilead's Truvada would be generically available by the time efficacy trials were completed. Eight years after the completion of U.S. Government-funded efficacy trials, generic Truvada is still not available in the United States.

PrEP scale-up has failed. The PrEP demand in the U.S. hit a tipping point in 2013 and then plateaued in 2016. Currently, only 1 in 10 people who could benefit from PrEP are receiving it. What little access has occurred is not fairly distributed. For example, black people suffer 44 percent of new HIV infections while only 10 percent of PrEP users are black. Gilead has had seven years to get PrEP marketing right. It's time we try something else.

Our struggle against HIV is stuck. HIV is not stuck. HIV infects nearly 40,000 Americans every year, and there's been no decline since 2016. In my experience, the root cause of low PrEP access is the high price. Other barriers to PrEP access arise as consequences of the exorbitant drug prices. These factors may include fragmented insurance coverage, lack of awareness by providers and potential users, and stigma. At a competitive price, people would feel at ease to provide and use PrEP.

PrEP can be manufactured and distributed for \$6 per person per month, \$6 per person per month in manufacturing and distribution costs. Gilead charges more than \$2,100 per person per month, a 35,000 percent markup. Gilead's prices continue to increase every single year. The price of Truvada increased 76 percent since I published evidence of PrEP efficacy in 2010 using U.S. Government funding.

You might hear that no one pays list price. This is not true. The University of California Student Health Services pays full price for

PrEP, and it is their largest drug expense. All populations have multiple competing needs related to heart health, cancer prevention, mental health, substance use, productive health, and so much more. Should any public-health jurisdiction pay a 35,000 percent markup for a drug that addresses only one of these concerns? Hard choices have to be made in public health, and they are made.

However, PrEP becomes an easy choice if it is available at a competitive market price. For example, three states and Australia purchased generic PrEP for \$8 per person per month after a competitive process. That—what followed was the largest and fastest PrEP scale-up the world has ever seen.

I believe that there are actions that you could take, that this committee could take at this time that would make PrEP available. PrEP continues to be underutilized despite seven years of drug donations, community grants, and assistance programs. A market price would change the game. I ask you to consider three actions. This committee could insist that taxpayers benefit from U.S. Government intellectual property. Second, you could scrutinize agreements between originator and generic manufacturers for anti-competitive practices such as pay for delay. I believe that these actions would take PrEP off the shelf and stop HIV at a price that we all can afford.

Thank you.

Chairman CUMMINGS. Dr. Walensky.

T2STATEMENT OF ROCHELLE WALENSKY, PROFESSOR OF MEDICINE, HARVARD UNIVERSITY, ON BEHALF OF CHIEF OF DIVISION OF INFECTIOUS DISEASES, MASSACHUSETTS GENERAL HOSPITAL

Dr. WALENSKY. Good morning. Chairman Cummings, Ranking Member Jordan, and members of the committee, my name is Dr. Rochelle Walensky. I'm a 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 both in the U.S. and internationally.

In 1995, we told patients with AIDS they would, with certainty, die. AIDS plagued my internship. By the end of that year, we had an FDA-approved HIV cocktail, three drugs, up to 14 pills a day, which, if taken without fail, allowed AIDS patients to live. At the time, the three drugs of the cocktail cost a total of \$15,000 per person per year, and our research team reported its cost-effectiveness. We demonstrated it was good value for money.

Today, we definitively have the tools to end this epidemic. The HIV three-drug cocktail termed antiretroviral therapy is frequently 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 it to anyone else, but the cost of these drug regimens today is \$40–50,000 per person per year, a 300 percent increase in 25 years.

Truvada is a code formulation of two of these three drugs used for treatment, scientifically known as the combination of tenofovir

disoproxil fumarate and 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, much of which was led by Dr. Grant, the FDA approved the expanded indication of Truvada for preexposure prophylaxis or PrEP for HIV prevention. The cost of Truvada, when FDA approved in 2004, was \$7,800 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 I'm not proposing that this is what the price should be in the United States. I simply provide that benchmark for our national pricing to put it into 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 percent in five years and by 90 percent by 2030. Our research group has published work highlighting that even if we get 90 percent of people with HIV diagnosed, treated, and virologically suppressed, we can only decrease the number of new infections by 40 percent. In short, to end this epidemic, we need both treatment and prevention.

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 infection 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 United States are at high enough HIV risk to warrant PrEP. Fewer than 150,000 have ever received it. Over 75 percent of those are white gay men in the Northeast and the 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 one in two black gay men will be diagnosed with HIV in their lifetime. We need prevention tools like PrEP to reach these marginalized populations if we are ever even going to make a dent in this epidemic, never mind to reach the auspicious end-the-epidemic goals.

The sale of Truvada has resulted in profits of \$36 billion, and Truvada, unchanged, has seen a price increase of 150 percent since 2004. That price tag is simply too high. We have the scientific tools to end this HIV epidemic, and we are fortunate that pharma has developed these drugs to get us there. They have already profited enormously.

Now, in the spirit of saving lives, of preventing new infections, of realizing a public health—of 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 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 that some of these companies, including Gilead, will begin to do the right thing. It's never too late for that. Thank you.

Chairman CUMMINGS. Thank you very much. Mr. Horn?

**STATEMENT OF TIM HORN, DIRECTOR, MEDICATION ACCESS
AND PRICING, NATIONAL ALLIANCE OF STATE AND TERRI-
TORIAL AIDS DIRECTORS**

Mr. HORN. Thank you, and good morning. Chairman Cummings, Ranking Member Jordan, and members of the committee, my name is Tim Horn, and I am director of medication access and pricing at NASTAD, which is the National Alliance of State and Territorial AIDS Directors. I am very pleased to be here today to offer testimony on PrEP access and pricing in the United States.

NASTAD is a nonpartisan, nonprofit association that represents public health officials who administer HIV and hepatitis programs in the U.S. and around the world. We represent public health officials in all 50 U.S. states, the District of Columbia, the U.S. territories, and several local jurisdictions. I'd like to focus my comments today on the intersection of the high cost of Truvada as PrEP and the need for effective, comprehensive, affordable, and, importantly, sustainable public health approaches to HIV prevention in the United States.

Now, our ability to respond to the needs of people who have been diagnosed with HIV is one of the greatest examples of effective public health in the United States. The Ryan White HIV/AIDS program ensures access to not only comprehensive state-of-the-art care but, importantly, low-or no-cost treatment made possible with significant discounting provided to AIDS drug assistance programs, or ADAPs. ADAPs insure treatment for nearly a quarter of all people living with HIV in the United States, the vast majority of whom are living at, below, or near the Federal poverty level.

Now, one thing I want to emphasize here is that there is no such comprehensive Federal medication program for people at risk for HIV. And I just want to be clear. The only difference between someone living with HIV and someone at risk for HIV is a diagnosis. Those vulnerable to HIV infection face the exact same barriers to affordable medication in the United States.

We are failing populations at high risk for HIV infection, including young black and Latino gay men, women, and transgender individuals. We are failing them because we have not built a payment and culturally appropriate delivery systems that are best able to reach them. There are many reasons for the low uptake of PrEP in this country, but financing and pricing, the subject of today's hearing, are undoubtedly among them. In order to end the HIV epidemic, we must build systems that provide access to PrEP for all populations.

Now, our current PrEP system particularly for uninsured and underinsured people vulnerable to HIV infection is essentially built on the back of Gilead's medication assistance program for those who are uninsured and meet strict financial eligibility criteria, along with the company's co-pay assistance program for individuals who are commercially insured. Now, while these programs have undoubtedly helped expand access to the medication component of comprehensive PrEP services, they have also succeeded in largely masking the impact of the high price of Truvada.

To be clear, these programs are not a substitute for functioning public health and healthcare systems. Partnerships with pharmaceutical manufacturers will always be important, but outsized dependency on their generosity, which in turn is dependent on their bottom line, is by no means an equitable and sustainable solution.

Now, the 340B drug pricing program has also played an important role in allowing public health programs and their community partners, including federally qualified health centers, to afford PrEP while extending Federal resources as far as possible. But it doesn't go far enough. Even if we assume that the price available to 340B entities in the U.S. is 75 percent to 80 percent below the list price, this still translates into approximately, you know, \$400 per month per person, a price that is at least four times higher than what we can reasonably expect with robust generic competition.

Additionally, 340B pricing of Truvada as PrEP is only available to some health departments and family planning clinics and is not available to other institutions where PrEP may be of significant benefit.

Gilead's assistance programs, the 340B program and discounting, and the recent announcement of donated PrEP will continue to expand access to PrEP. However, a long-term, sustainable approach to PrEP access requires a competitive generic market. To this end, we believe Federal, state, and community partners should be cautious not only to—not to allow the present and future of existing patchwork measures to build an artificial market for Gilead's Descovy, which is expected to be approved for PrEP by the end of this year. Doing so will undercut the ability of the generic market for generic versions of Truvada to bring down costs for our public payers, our commercial payers, and, most importantly, people vulnerable to HIV infection.

Importantly, a lower-cost form of PrEP would allow for more affordable procurement and expanded access across a variety of settings, including state and local health departments, family planning clinics, and STD clinics. And I want to underscore Dr. Grant's point. The list price of Truvada is the price of some of our most import programs do in fact pay.

Not only has the high cost of Truvada been a barrier in scaling up affordable access to PrEP by these programs, they have required some programs to reallocate funding from other public health initiatives to meet HIV prevention priorities.

So I do want to conclude by thanking the committee for the opportunity to testify today and for initiating a dialog that hopefully will be to the betterment of people vulnerable to HIV infection and to other intersecting conditions. Thank you.

Chairman CUMMINGS. Mr. Ezell?

STATEMENT OF STEPHEN EZELL, VICE PRESIDENT, GLOBAL INNOVATION POLICY, INFORMATION TECHNOLOGY AND INNOVATION FOUNDATION

Mr. EZELL. Good morning, Chairman Cummings, Ranking Member Jordan, and members of the committee. I'm Stephen Ezell, vice president of Global Innovation Policy at the Information Technology and Innovation Foundation. We're a nonprofit, nonpartisan

Washington, DC.-based science, technology, and economic policy think tank, and I appreciate the opportunity to testify in the panel this morning about the U.S. life sciences innovation system.

The United States clearly leads the world in life sciences innovation. For instance, in the 2000's, U.S.-headquartered enterprises generated more new-to-the-world drugs than enterprises from the next five nations combined. And over the past two decades, U.S. companies have accounted for almost half of the world's new drugs, including treatments such as for leukemia, skin cancer, inherited blindness, and a set of treatments for HIV/AIDS that have made a disease that was once a death sentence now treatable and hopefully will have a full cure in the years to come.

However, it was not always that way. In fact, in the 1970's, the United States was a global in life sciences innovation as European-headquartered companies invented twice as many new-to-the-world drugs as ours did in the 1970's.

What's changed over the past four decades has been a concerted and intentional set of policy choices designed to make America the world's leader in life sciences innovation. Those policies are anchored in three key tenants. First, robust and complementary public and private investment in life sciences R&D, effective mechanisms to facilitate the transfer of technology from universities and Federal laboratories to the private sector for commercialization, underpinned by strong intellectual property rights such as embodied in Bayh-Dole agreement, and a drug pricing system that allows companies to earn revenues that can be reinvested into future generations of biomedical innovation.

The U.S. invests by far more than any other nation in life sciences R&D. In fact, analysts estimate that the United States has invested 70 to 80 percent of global biomedical R&D investment over the past two decades. It's anchored by Federal Government investment of about \$39 billion a year into basic life sciences research that focuses on understanding fundamental processes by which diseases develop and transmit or identifying novel biomarkers indicating the presence of disease. This basic research creates a platform for innovation potentially leading to the discovery of new medicines, tests, or procedures.

The private sector complements this public-sector investment with, in some years, close to \$95 billion in annual R&D focused on the applied research and clinical trials necessary to bring safe and effective breakthrough drugs to market. The fact is this drug development process is lengthy, risky, and expensive. Studies vary, and I'm happy to share result of several with the committee. But research finds that, on average, developing a new pharmaceutical compound takes an average of 11.5 to 15 years at a cost of \$1.7–3.2 billion.

It's absolutely vital to recognize that public and private investments are complementary. A recent journal of Nature article estimates that, on average, biotechnology companies invest \$100 in development for every \$1 the government invests in research leading to a specific innovative drug.

If you take the case of the breakthrough anticancer prostate drug—or prostate cancer drug Xtandi developed primarily by Astellas and its partners, it's estimated that about \$2 million in

federally funded research conducted at UCLA was complemented by over \$900 million of private-sector investment required to bring Xtandi to market. That's a nice example of the almost 300 new drugs, vaccines, and devices that have been developed as a result of public-private partnerships facilitated in part by the Bayh-Dole Act since its enactment in 1980.

Just like semiconductors, movies, or music, life sciences is an innovation-based industry, meaning that companies incur extremely high upfront fixed cost of initial design and development that must be recouped and admits to failure rates that approach 95 percent. Moreover, these companies fundamentally depend upon the profits earned from one generation of innovation to finance investment in the next. Hopefully, Gilead's investment in HIV/AIDS drugs will generate profits that enable its ongoing efforts in areas like hemophilia and oncology to generate breakthrough treatments tomorrow.

This dynamic is why America's life sciences sector is the world's most R&D-intensive, investing 44 percent of its value added into subsequent R&D. The reality is that there's a direct link between pharmaceutical company revenues and their ability to reinvest in future generations of innovation. They are intimately and causally linked.

In conclusion, a key reason why the U.S. life sciences innovation system has been so successful is that we've created the framework for effective public-private partnerships where each party contributes what it does best. Public research to bring a stock of knowledge that can be innovated upon by the private sector and investing the hundreds of millions required to bring an innovative new drug to the market.

Thank you for your time today, and I look forward to answering your questions.

Chairman CUMMINGS. Thank you very much. Dr. Lord.

STATEMENT OF AARON LORD, PREP PATIENT AND ADVOCATE

Dr. LORD. Chairman Cummings, Ranking Member Jordan, and members of the committee, I thank you for inviting me here today to testify. My name is Aaron Lord. I am here today as a physician, as an HIV activist, and a cofounder of the PrEP4All collaboration, as well as a proud gay man.

I was born and raised in West Virginia. I attended Georgetown University on Federal scholarship. I then attended medical school at Columbia and am currently an assistant professor at NYU, but I am not here in my official capacity.

Since realizing I was a gay man in my early teens, like so many in my community, I lived in fear of acquiring HIV. The reality hit all too close to home when early on in our relationship my future husband, who I cherish and love dearly, was diagnosed with HIV.

In July 2012, the FDA announced the approval of Truvada as PrEP. It's the first drug approved to prevent rather than treat HIV. It is highly effective, reducing risk by over 99 percent when taken as prescribed. Since 2012, I have taken Truvada every day to protect my health and the health of my community. With this medication, I no longer have to live in fear.

Despite PrEP's remarkable efficacy, the number of new HIV infections in the U.S. remains the same today as when PrEP was approved in 2012 with one person becoming newly diagnosed every 15 minutes. We know it doesn't have to be this way. We know that when PrEP is made universally accessible at no cost, new HIV infections dramatically decrease. In Sydney, Australia, new HIV infections decreased by 25 percent statewide in one year when public health officials used low-or no-cost PrEP to reach all those at risk.

In the U.S., however, we are failing to reach those most vulnerable. With mere fractions of at-risk women and black and Latino men getting PrEP and rates and use in the South remain stubbornly low. Too many of us are still living in fear. A root cause of this problem is the price. Gilead Sciences, who makes the only PrEP available in this country, charges us over \$2,000 a month or over 400 times what FDA-approved generics cost internationally.

And while Mr. O'Day will certainly state that his company has earned the right to charge such exorbitant sums, Truvada as PrEP is not Gilead's invention. Truvada as PrEP is an invention of the U.S. Government whose research and development was funded exclusively by U.S. taxpayers and the Gates Foundation and is protected by multiple robust patents issued to the CDC. Even the very patents that Mr. O'Day currently uses to prevent the American people from accessing generic Truvada are themselves based on research funded by the U.S. taxpayer.

Price is not the only barrier preventing people from using PrEP. Stigma, racism, homophobia, transphobia, sexism, poverty, they all play a role. These barriers can and must be mitigated, but we cannot do it if our healthcare system spends over \$20,000 a year on Mr. O'Day's drug instead of spending it on precious programming to fight these barriers. Mr. O'Day, we are suffocating under the weight of your company's pricing.

Mr. O'Day, for a figure far less than \$2.6 billion, which is what we spend on your egregiously overpriced medication every year, we could have a national, far-reaching PrEP program that guarantees every person who needs PrEP can get it, including free medicine, clinical care, lab testing, and transportation. And we could still have half-a-billion left over for community organizations to fight these barriers. Mr. O'Day, you have given the American people a very bad deal for our money.

We have learned all too well from Gilead's past misdeeds what happens when they are left to their own devices. As the Wyden-Grassley's report so vividly showed, Gilead's pricing of their cure for hepatitis C at \$1,000 a pill was aimed to do one thing: maximize their profit. The consequences of that unmitigated greed resulted in a public health disaster. Despite spending \$50 billion of our hard-earned dollars buying overpriced medication, the number of new hepatitis C infections more than tripled.

I'm here today to say that HIV activists will not stand by and allow this to happen ever again. So ladies and gentlemen of the committee, I ask you as a representative of my community, as a proud American, as a scientist, and as a patient, to join me in asking Mr. O'Day what justification do you have for charging \$2,000 a month for Truvada as PrEP when the American people funded

the innovation of the molecule, invented its use as PrEP, and funded four clinical trials to prove its efficacy?

Mr. O'Day, we do not ask for your company's charity or for tax-deductible donations that meet your company's needs but fail to meet the needs of our communities. Rather, we ask Mr. O'Day, why not lower the price of Truvada to \$15 a month right here today at this hearing?

Members of Congress, the American people have invented a way to end the HIV epidemic, and that we should be very proud of. And we look to you today to ensure that every single person in this country can protect themselves from this plague. Thank you very much.

Chairman CUMMINGS. Thank you very much. Mr. O'Day?

STATEMENT OF DANIEL O'DAY, CHAIRMAN AND CEO, GILEAD SCIENCES, INC.

Mr. O'DAY. Good morning, Chairman Cummings, Ranking Member Jordan, and members of the committee. My name is Daniel O'Day. I recently joined Gilead as its new chief executive officer. Thank you for the opportunity to be here today.

Gilead is an American biotech company, but for the past three decades has been focused on creating therapies that prevent, treat, and cure some of the world's worst diseases. To name just a few examples, Gilead invented the first once-daily pill to cure hepatitis C, Tamiflu for influenza, and the first and currently only FDA-approved HIV prevention medication, Truvada, along with 10 other drugs used in the treatment of HIV.

When I decided to become CEO, I had long admired Gilead's remarkable contribution to health care and the high level of innovation behind their medicines. Importantly, I knew I was joining a company that was committed to the interest of patients and dedicated to pursuing scientific excellence to prevent and cure diseases. All of this is evident in Gilead's approach to HIV, the commitment to developing HIV medications that are safer, more patient-friendly, and more effective. Gilead researchers have made contributions that fundamentally changed the course of the HIV/AIDS epidemic, transforming the disease from a death sentence to a manageable chronic condition.

Gilead was founded in the midst of the AIDS crisis. At that time people living with HIV were required to take a cocktail of 20-plus pills each day to treat the disease. Many of these drugs lead to serious, often debilitating side effects. And even when taken as directed, the therapies offered an average life expectancy of less than 40 years of age with most people dying within just a few years of contracting the disease.

In the early 1990's, Gilead began working to invent a single-pill HIV treatment. Following nearly a decade of work and about \$6 billion invested in research, \$1.1 billion of which was devoted specifically to Truvada, Gilead launched Truvada as one of the first fixed-dose combination pills for HIV treatment in 2004. Today, Truvada and other Gilead medicines have contributed to nearly doubling the average life expectancy of people with the disease.

Although Truvada was initially approved to treat HIV, researchers and public health officials knew for years that antiretroviral

drugs like Truvada could also be used to prevent HIV infection, a technique referred to as PrEP. With this in mind, Gilead supported clinical trials that ultimately led to the approval of Truvada, the first and currently only medication approved for PrEP.

To be clear, despite some media suggestions otherwise, Gilead invented Truvada, no one else. Gilead developed the two drugs that are combined in Truvada, invented the combination that allowed these drugs to be taken as a single pill, and invented the drugs used to treat HIV in combination with other antiviral drugs.

I want to address the use patents on PrEP granted to the CDC. Using Truvada for PrEP was well-known in the scientific community long before CDC claimed it as an invention. We believe the CDC patents are invalid, but we've chosen not to challenge those patents because we value our collaborative relationship with the agency.

Finally, I want to address access to Truvada. Gilead is committed to ensuring that every American who needs Truvada can obtain it. We offer a wide range of programs to help ensure that people have access to Truvada when they need it. For example, 98 percent of people who use our co-pay assistance program have no out-of-pocket costs. In fact, according to the CDC's own estimates, when taking our programs into account, less than 1 percent of Americans who would benefit from PrEP are in need of a financial assistance to obtain Truvada.

Moreover, we continue to work with advocates, providers, and governments to remove the societal and other barriers to broader PrEP usage. Last week, we took another important step for expanding access by donating Truvada for up to 200,000 uninsured Americans each year.

We are committed to ending the HIV epidemic. We will work with Congress and others to further expand access to PrEP, and we will continue our scientific research in pursuit of a cure.

In representing Gilead, I can assure you that we take our responsibility in HIV extremely seriously and will ensure you that this is always evident in our actions.

Thank you for the opportunity to provide this testimony today, and I'd be pleased to answer your questions.

Chairman CUMMINGS. Thank you very much.

I now recognize Ms. Ocasio-Cortez, five minutes.

Ms. OCASIO-CORTEZ. Thank you. Thank you, Chair. Thank you for agreeing to hold this hearing. And while I appreciate your generosity in acknowledging the role our office played in this hearing, I also have to give credit to the countless advocates and activists that have been uplifting the issue of the price of Truvada and PrEP.

And I have to say that is not because of me we are having this hearing even in our office. It is because of a 23-year-old staffer Ms. Claudia Pagon Marchena, who first dug into—who first noticed this and first listened to the actual activists that raised this issue. She took the opportunity to pursue it, and if it wasn't for the openness and willingness of your leadership and committee staff to take her concerns seriously, we wouldn't be here today.

And so I just think it is an incredible testimony to—despite the powerlessness we often feel in this political moment, it shows that

everyday people, no matter your age or your identity, can make changes. And that is the reason why we are having this hearing today, so thank you.

I also, before I begin, would like to submit to the congressional record New York City Council Speaker Corey Johnson, who himself is HIV-positive, his testimony to the congressional record, so I seek unanimous consent to do so.

Chairman CUMMINGS. Without objection, so ordered.

Ms. OCASIO-CORTEZ. Thank you so much.

So let's get down to, you know, the core of this hearing. Dr. Grant, Truvada for PrEP is the only known drug that can prevent the transmission of HIV, correct?

Dr. GRANT. It's the only medication that's been approved by the FDA. It's also known that tenofovir alone is prophylactic—

Ms. OCASIO-CORTEZ. Okay.

Dr. GRANT [continuing]. for HIV—

Ms. OCASIO-CORTEZ. Thank you. And, Dr. Grant, it was your NIH-funded research on PrEP that built on the earlier research were patented by CDC researchers, is that correct?

Dr. GRANT. Yes. My clinical trial was informed by CDC research in two ways. One, the CDC demonstrated that the preexposure dose was—added to the efficacy of PrEP and—yes.

Ms. OCASIO-CORTEZ. Thank you. Thank you, Dr. Grant. And I would also like to seek unanimous consent to submit this Yale School of Law study into the congressional record, which concludes that the CDC's patents for PrEP were both valid and enforceable against Gilead.

Chairman CUMMINGS. Without objection, so ordered.

Ms. OCASIO-CORTEZ. Thank you very much.

Dr. Lord, thank you for your advocacy here today. Is it true that the public invested \$50 million to develop PrEP?

Dr. LORD. That is correct.

Ms. OCASIO-CORTEZ. Is it also true that Gilead relied on publicly funded trials to obtain FDA approval?

Dr. LORD. Yes. If you look at their supplementary new drug application, you'll see that every sponsor of Truvada as PrEP was a non-Gilead sponsor.

Ms. OCASIO-CORTEZ. So the public invested to develop the drug. The public invested and funded the trials for FDA approval. Is it true that the pharmaceutical companies force the public to pay twice first when investing in drug discovery, but then it looks like these patient assistance programs that they tout very often also have a public investment piece as well, right? How are these public assistance programs funded?

Dr. LORD. Yes, so, you know, I think as far as like the co-pay assistance program goes, it's important to also note that it's—it only exists in its current state due to the work of activists. We have worked for years to get them to increase from initially a \$300 a month co-pay assistance, which left people with hundreds if not thousands of dollars of co-pay per month. And then they really only increased it to \$4,800 after additional years of activist pressure, and that still left thousands of dollars of donut hole potential for some patients. And then it only took a New York Times op-ed that

we published, you know, to threaten march-in rights on this drug in order to get them to raise it to the \$7,200—

Ms. OCASIO-CORTEZ. Thank you.

Dr. LORD [continuing]. which is still not enough.

Ms. OCASIO-CORTEZ. Thank you. And even when it comes to when folks can't access PrEP because it is so expensive and, you know, the HIV epidemic continues, that also comes at a public cost, right? So the public is paying—we pay to develop PrEP, we paid to finance the publicly funded trials to develop this drug, we also pay and foot the bill with patient assistance programs. Also, as you noted, the existence of these programs happen because of the public, and also we pay when the HIV epidemic gets spread as well.

Very quickly, Mr. O'Day, you are the CEO of Gilead. Is it true that Gilead made \$3 billion in profits from the sales of Truvada in 2018?

Mr. O'DAY. Three billion in revenue.

Ms. OCASIO-CORTEZ. Oh, yes, in revenue, thank you. And, very quickly, the current list price is \$2,000 a month in the United States, correct?

Mr. O'DAY. The current list price is \$1,780 in the United States.

Ms. OCASIO-CORTEZ. Okay.

Mr. O'DAY. And just to correct, the \$3 billion was a global figure—

Ms. OCASIO-CORTEZ. Okay. I see.

Mr. O'DAY.—for Truvada for PrEP—

Ms. OCASIO-CORTEZ. So the list price is almost \$2,000 in the United States. Why is it \$8 in Australia?

Mr. O'DAY. Truvada still has patent protection in the United States, and in the rest of the world it is generic. I can't comment on the price in Australia of the generic medicines, but it is generically available in other parts of the world and will be generically available in the United States as of September in 2020 based upon Gilead agreeing to support—

Ms. OCASIO-CORTEZ. Thank you.

Mr. O'DAY.—generic entries one year earlier.

Ms. OCASIO-CORTEZ. So I think it is important that we notice here that we the public, we the people developed this drug, we paid for this drug, we led and developed all of the grounding patents to create PrEP, and then that patent has been privatized. Despite the fact that the patent is owned by the public, we refuse to enforce it. There is no reason this should be \$2,000 a month. People are dying because of it. And there is no enforceable reason for it. We own the core intellectual property for it. And, as a result, people are dying for no reason, for no reason—

Chairman CUMMINGS. The gentlelady's time is—

Ms. OCASIO-CORTEZ [continuing]. to develop this drug. Thank you very much.

Chairman CUMMINGS. The gentlelady's time is expired. Mr. Armstrong?

Mr. ARMSTRONG. Thank you, Mr. Chairman. And I agree. I believe that prescription drug pricing, it is a conversation that I get, it is one of the biggest ones we get in our office both in D.C. and back in our offices in North Dakota, and it should be a bipartisan endeavor. And in fact, we have had a package of prescription drug

bills that have come through two committees here, and I know in at least one they passed unanimously.

But unfortunately, we are in D.C. and, never allowing a political opportunity to go to waste, they are going to get marked up in Rules Committee, and we are going to vote on bills this week that just quite frankly have no chance of becoming law. So when we talk about bipartisanship, we had two sets of packages that could come to the floor clean this week that would pass, they pass the Senate, the President could sign them by the end of the month, but that is not going to happen.

So, Mr. O'Day, it has been said that NIH spent \$51 million on clinical trials for PrEP, is that correct?

Mr. O'DAY. Thank you, Congressman. Yes, it's important to point out that Gilead has spent \$1.1 billion developing this medicine. Gilead has the patents on this medicine. And in the course of the PrEP indication, it's also important to take us back to that period of time of history with the HIV/AIDS epidemic. It was a time when prevention of AIDS was actually something that was highly controversial both from a scientific standpoint, resistance, but also from public advocacy because there were questions around the morality of providing a preventive medicine that could take away from safe-sex practices in others. So this was a public-health question that needed to be answered.

And we partnered with several members of the community. It's a very complex topic. For the PrEP indications, we supported it with medicines. We have two of our Gilead scientists that are co-authors on the fundamental—one of the fundamental trials, the iPrEx trial that Dr. Grant has spoken to before and to be an author on these trials in a highly regarded 30-party publication—medication—publication, you need to have sufficient involvement in those trials. So Gilead had sufficient involvement in those trials. The NIH provided \$50 million in grant. The Gates Foundation supplied \$17 million in grants. And the Gates Foundation also independently funded the second trial that was used for this indication with \$70 million as well. So it was a partnership amongst public and private institutions to get this indication.

Mr. ARMSTRONG. And you said in your opening statement you provide financial assistance to uninsured patients. How does that work?

Mr. O'DAY. So we have two basic programs to help with patients. One is the co-pay assistance program. So patients that have commercial insurance that have a high deductible cost for their medicines, we have a program that supports them. In fact, patients that access our co-pay programs during the life of the patent that we have on the product, 98 percent of people take nothing out of their pocket when they go to the pharmacy, zero.

The other end of the spectrum we have deep discounts to government programs that allow patients in Medicaid, Medicare, ADAP programs to access our medicines at 70 to 80 percent discounts for the list prices that we've discussed here today.

Finally, for the uninsured patient population that is truly not met by these needs, we've been working with CDC and announced the—one of the largest-ever donations of medicine last week in conjunction with HHS and CDC for—by the CDC's own estimates,

they've estimated that out of the 1.1 million patients that are susceptible to HIV, 200,000 are uninsured. We have donated as a result of the announcement last week for all 200,000 of those patients to receive free Truvada for the next 10 years.

Mr. ARMSTRONG. And I grew up in the early 1980's, and we have come a long way since then and we have a long way to go. But, I mean, particularly when we are talking about the uninsured population as it relates to HIV and access to drugs, I mean, it is a debilitating, crippling disease. We are working toward prevention, we are working toward cure, but those factors to that uninsured population are unique to this healthcare crisis, are they?

Mr. O'DAY. Well, yes, this is quite a unique circumstance because of the fact that, at the end of the day, there are so many things that are getting in the way of people that require PrEP getting PrEP. There's access to the healthcare system for sure, but there's also education, education for physicians, education for patients, and there's a tremendous amount of stigma associated with this disease, what comes into play for the underserved communities. And this is something that Gilead has been focused on, provided hundreds of millions of dollars and supporting community associations to try to get at these other root causes of PrEP, and it's absolutely what's required to help eliminate the disease. I completely agree that we have to attack it from both a prevention as well as a treatment standpoint to eliminate this disease, and we're a big part of that.

Mr. ARMSTRONG. Thank you, sir.

Chairman CUMMINGS. Thank you very much. I recognize myself now.

Mr. O'Day, other drug companies sat in the very seat, that very seat that you are sitting in like Martin Shkreli, and all offer the same excuses and justifications, same thing. They claim they have patient assistance programs to help those who cannot access the drug, but the truth is that someone, somebody is paying for these exorbitant prices. And that impacts everybody in the system. That is one reason health care now is so expensive. At the end of the day, it is the taxpayers who bear the cost of these skyrocketing prices through government programs like Medicaid.

Dr. Lord, isn't it true that in some countries the generic version of this treatment is sold for a fraction of the U.S. price? Is that right?

Dr. LORD. That is correct.

Chairman CUMMINGS. And how much is it sold for overseas?

Dr. LORD. According to the Global Fund, you can purchase this medication for under \$5 a month.

Chairman CUMMINGS. That is astonishing. Yet Gilead is charging around 17, close to \$1,800 a month?

Dr. LORD. Yes.

Chairman CUMMINGS. Mr. O'Day, in your written statement, you claim that your company spent \$1.1 billion on research and development related to Truvada. But you made \$36 billion in revenue on Truvada since it was approved in 2004. That is according to your own company's SEC filings. Mr. O'Day, do you believe that that is appropriate, and do you believe it is moral?

You know, somebody said over here I guess it is a thing of choices. One of my first employees died from AIDS, and I will never forget it. And I described it, his dying on installment. It is a mother. It is rough to watch somebody die from AIDS. But anyway, you can answer my question.

Mr. O'DAY. Mr. Chairman—and, you know, I'm very sorry to hear about your—

Chairman CUMMINGS. Employee.

Mr. O'DAY. Employee.

Chairman CUMMINGS. It was a person.

Mr. O'DAY. Yes.

Chairman CUMMINGS. An African-American young male about 25 years old, dead.

Mr. O'DAY. I'm very sorry to hear that. The answer to the question is that we have spent more than \$6 billion over the past—since 2020 on HIV research in general. And in fact, we've taken the disease from a death sentence to a manageable chronic condition with one pill once a day, but we're not done yet. We still have medicines—because of the fact that we now have the average life expectancy out to 78 years from 40 years, we never anticipated that people would be taking these medicines for decades. And some of the current generations of medicines have kidney and bone effects that now our next generations that we're launching will be able to have less of those effects and allow people to live longer healthier lives.

And yet we're not done because we have to get to a stance where people aren't taking a daily pill, where they're taking it once a month, once every two months, or we hope we can get to a cure where people can take a limited course of therapy like in HCV, 12 weeks, and never have to worry about medicines again. In order to do that, we have to continue to invest in research for the patent life of our medicines. And, of course, when a patent ends, generics come on like they are in other parts of the world.

But during that patent period time, we also have a responsibility to make sure that Americans get our medicines when they're priced at a level that allows us to reinvest in research. And that's where our access programs, co-pay assistance, the donation to the CDC come in to allow us to make sure the price doesn't get in the way during this period of time of patent exclusivity.

Chairman CUMMINGS. Can you tell me quickly about the timing of the donation that you all are making of medication? I think you said 200,000.

Mr. O'DAY. Yes, Mr. Chairman. So it's 2.4 million bottles a year, which equates to around—the PrEP treatments for around 200,000 patients for up to 10 years.

Chairman CUMMINGS. All right.

Mr. O'DAY. And this includes both our current generation product Truvada, as well as our advancement, which may come to market as early as later this year, which allows that better safety profile if you like for patients.

Chairman CUMMINGS. And how did you all come up with this 200,000? That is what I was trying to get to.

Mr. O'DAY. Oh, that was a number that was requested and discussed with the CDC. They acknowledged that in the 48 hotspot

communities, District of Columbia; San Juan, Puerto Rico; and the seven rural states, that that would be where—the number of patients that would not qualify for Federal programs or be involved in commercial insurance. So that number came from the CDC, and we were happy to support them with that.

Chairman CUMMINGS. And so if they had come up with a higher number, it is quite possible you would have given more. Is that a reasonable assumption?

Mr. O'DAY. That's a reasonable assumption, yes.

Chairman CUMMINGS. All right.

Mr. O'DAY. We were trying to solve a gap that isn't currently covered by our current access programs.

Chairman CUMMINGS. You know, Mr. O'Day, something was said here earlier, and I want you to be real clear. I have said this to many of the witnesses in the pharmaceutical industry. I have no problem with you all making a profit. I want you to make a profit. I want you to make a profit because I have seen what research can do. I have relatives that went, say, for example, from a chronic condition with cancer—I mean, from a terminal condition to chronic. I have seen it in a few years. And I also serve with Dr. Gallo on the Human Virology Board in Maryland, so we have been dealing with this a long time.

But, at the same time, I am talking about the people who cannot get it, you know, the one who is getting ready to die and will not be able to attend his daughter's wedding, that one, or the mother who won't be there to see her children grow up, that lady. And what I am saying to you is that, you know, I want to work, we all want to work with the industry, but it is kind of hard.

I mean, you can imagine when we hear about the \$36 billion or the \$3 billion—and I know it is global, I got that—\$3 billion, and then we go back to our districts and we see people, and they see the cure. They know the cure is out there. They know there is something out there called Truvada. They don't know you, they don't know who makes it. All they know is that it is something that could save their life. And they are reaching, trying to get it. And then they hear about these figures and they say—they just can't get there. They cannot reach it. And I don't know whether those kind of things are taken into consideration in the board rooms. Are they?

Mr. O'DAY. Absolutely. I can assure you that if there is a patient out there that cannot access Truvada because of financial means, our programs are designed to capture them. I mean, again, we have the co-pay assistance for people with insurance. People without insurance that, you know, make less than five times the poverty level, are provided with medicine for free through our medication assistance program.

Chairman CUMMINGS. And who pays for that?

Mr. O'DAY. Gilead pays for that.

Chairman CUMMINGS. So that cuts into your profit. Is that what you are saying?

Mr. O'DAY. It's important to us to make sure that every patient can have access to the medicines, and it's absolutely part of our responsibility.

Chairman CUMMINGS. All right. I now recognize Mr. Jordan.

Mr. JORDAN. Thank you, Mr. Chairman.

Mr. O'Day, what is the difference between Truvada and PrEP?

Mr. O'DAY. Truvada is a medicine that's used for HIV treatments and for prevention. It was discovered many years ago.

Mr. JORDAN. I guess my question is is it the exact same drug; it is just used at a different time and in a different way?

Mr. O'DAY. No, PrEP is an indication—one of the indications that Truvada is approved for.

Mr. JORDAN. Right, but—so the drug is Truvada. It is used—and when we say—because Dr. Lord talked about Truvada as PrEP.

Mr. O'DAY. Oh—

Mr. JORDAN. It is the same drug?

Mr. O'DAY. Yes, it's the same drug, is the same mechanism, the same dose, it's the same—

Mr. JORDAN. It is a different use?

Mr. O'DAY.—frequency.

Mr. JORDAN. Different use, different timing—

Mr. O'DAY. What Truvada does is it reduces viral replication of HIV, and that can be effective for—

Mr. JORDAN. I just want to be clear for everyone, though, that—

Mr. O'DAY. Yes.

Mr. JORDAN [continuing]. I think there can be some confusion that Truvada and PrEP are somehow some different drug. It is the same drug?

Mr. O'DAY. Truvada is the drug. PrEP is one of the indications—

Mr. JORDAN. Right.

Mr. O'DAY.—that the drug is used for.

Mr. JORDAN. Got it. Got it. Okay. And, earlier, Dr. Grant said Gilead did not provide leadership or funding for PrEP in the studies at CDC. Is that true?

Mr. O'DAY. No, that's not true. I mean, we have nine scientists that were involved in the iPrEx trial itself, was one of the two trials that went to the FDA to seek approval. And of those, we have two scientists. Both are still with the company actually that were authors in the primary New England Journal article that is the iPrEx study.

Mr. JORDAN. Okay.

Mr. O'DAY. And to be an author on the New England Journal of Medicine, you must have—

Mr. JORDAN. So—

Mr. O'DAY.—involvement in the trial—

Mr. JORDAN. So—

Mr. O'DAY.—in addition to the free medicine we provided and the—

Mr. JORDAN. So, Mr. O'Day, Gilead developed Truvada?

Mr. O'DAY. Correct.

Mr. JORDAN. You guys did that all on your own. Gilead participated with CDC on Truvada as PrEP, right?

Mr. O'DAY. Correct.

Mr. JORDAN. And your drug has made a difference for millions of people all over the world, right?

Mr. O'DAY. That's correct.

Mr. JORDAN. How many folks do you think have been impacted—I would say people are alive today because of your drug. Is that true?

Mr. O'DAY. Oh, absolutely. And with 10 other medicines that Gilead makes, absolutely millions of people living with AIDS and preventing AIDS.

Mr. JORDAN. And how long did it take to develop Truvada?

Mr. O'DAY. Truvada was a long story. It goes back to the early 1990's with—Truvada is a combination of two different medicines. One is called, for the sake of simplicity, TDF, and the other one is FTC. So this goes back to the early 1990's and then into the early 2000's when FTC was evaluated by our scientists, and it's the combination of these two medicines that led to the first approval for Truvada in 2004 after a good decade to 15 years of research and lots of failures, by the way. I mean, 90—

Mr. JORDAN. So over a decade of research and trials and all kinds of effort to develop this miracle drug that has saved millions of people all over the planet, my guess is that costs a few dollars. What did it cost you to develop the drug?

Mr. O'DAY. Well, in this case it cost \$1.1 billion.

Mr. JORDAN. So billions of dollars to develop this amazing drug—

Mr. O'DAY. Yes.

Mr. JORDAN [continuing]. that saved all kinds of folks. And no what are you doing with those profits? I think you said you are trying to find a cure, right?

Mr. O'DAY. We're—absolutely. We're investing them back into research. We—our scientists and the colleagues—I'm so inspired by Gilead. They will not rest. They will not rest. Good enough was never good enough for them when we had this generation of medicines that had these kidney and bone toxicities, and we're now launching medicines that are much more tolerable for patients today. But they're not stopping. So we're looking at long-acting medicines that—

Mr. JORDAN. Just last week you said for folks who can't afford it, folks who don't have insurance, you are going to give it to them free?

Mr. O'DAY. Absolutely.

Mr. JORDAN. Okay. So just let me get this straight. Over a decade of research, over \$1 billion into that research, you develop a drug that saved millions of people, now can be used as PrEP prior to, not just as something after the fact that when people have been diagnosed with HIV. The profits you have made from that you are now working on developing a cure and, just last week, you announced folks who can't get the access to the medication right now, you are going to give it to them free?

Mr. O'DAY. Yes, Congressman.

Mr. JORDAN. But you are a bad guy. You are a bad guy. I mean, that is what we heard from the other side.

Mr. Ezell, isn't that exactly how it is supposed to work under the Constitution? People come up with a great idea, they go to the Patent and Trade Office, they get a patent for it, they get that patent for certain length of time to recoup the billions of dollars it cost to make the product or the idea or whatever they did that has helped

millions of people, that has been great for our—this is one of the things that makes America the greatest place ever. Isn't that supposed to be how it is supposed to work

Mr. EZELL. That's exactly right, Representative Jordan. And, you know, it's interesting to hear the questions about, well, how much cheaper is this drug in other countries of the world. Well, part of the problem is that other countries of the world are not as effective in innovating drugs because they did not—

Mr. JORDAN. They didn't make it. These guys made it.

Mr. EZELL. That's exactly right. We've put in place systems to—

Mr. JORDAN. Oh, I forgot to add one thing. I forgot another thing. They are going to go off patent year early. Isn't that right, Mr. O'Day?

Mr. O'DAY. Yes, and generics will enter one year early.

Mr. JORDAN. I mean, so one year early is going to go to a lower cost. They don't have to do that, but somehow, they are the bad guy, right? I just fail to—I appreciate what you have done and the thousands of people that are being impacted as we speak, the millions of people whose lives have been impacted, the folks who are alive today because of the work you have done. And we are going to beat you up.

So, Mr. Chairman, I appreciate this hearing, and I yield back my time.

Chairman CUMMINGS. I appreciate you, but let me say something. Let me make this clear, and listen up. Nobody is coming here to beat you up. I want to make that clear. I applaud Gilead. But it is nothing like holding the hand of somebody who is dying from AIDS. I am sorry. And all we are trying to do is represent our constituents and help them stay alive. When you are dead, you are dead. And when I think about the fact that Truvada for PrEP is only getting to 10 percent of the people that need it, what about the other 90 percent? What about their families? I am not knocking you. I am just trying to figure out how we can help you get to the people who are dying as we speak, as we speak.

And we can holler, we can play all these games, but let me be clear. Let me be clear. I speak for the dead and the living, we are simply trying to get, again—I don't know who he is talking about, but I applaud Gilead. I have been dealing with this issue for 20-something years, so I know about it, and I know the problems, and I know the pain. And I know about the death by installments. So I want to be clear. Who is next?

Mr. JORDAN. Well, can I respond, Mr. Chairman?

Chairman CUMMINGS. No.

Mr. JORDAN. You got like nine minutes and you just went after me—

Chairman CUMMINGS. Mrs. Maloney. Mrs. Maloney.

Mr. JORDAN. Oh, that is wonderful. Thank you.

Mrs. MALONEY. Thank you, Mr. Chairman.

Mr. JORDAN. You had seven, eight minutes. I had—

Mrs. MALONEY. Thank you, Mr. Chairman. I deeply appreciate the passion—

Mr. JORDAN. Would the gentlelady yield just for 1 second?

Mrs. MALONEY. No, I will not.

Mr. JORDAN. I wasn't playing games——

Mrs. MALONEY. I appreciate the leadership and passion of the chairman of this committee, Mr. Cummings, and I want to thank the advocates who advocated for it and my colleague from New York who——

Mr. JORDAN. Get the——

Mrs. MALONEY [continuing]. negotiated this hearing. And I want to ask a question about the 90 percent that the chairman talked about, the 90 percent of Americans that want to get access to this drug. And I want to ask Mr. Horn because how they get access is through the local healthcare system in our cities and in our states that are dealing with people hands-on every day.

But first I have to say that I find it a national scandal that we are paying in this country \$70 a pill while Australia pays \$7 a pill. How fair is that? And, Mr. O'Day, you say that is because Australia negotiated a lower price. Well, we in America are going to pass a law that allows our government to negotiate a better price going forward.

And today, we have two bills on the floor that will strike at this problem. It will end the abusive practice of drug companies where they pay to delay the development of generic drugs, a terrible abusive practice, keeping affordable drugs from our people. And the other will stop the practice where drug companies pay to block, they literally pay to block the development of lifesaving drugs here in America where it was pointed out it is the American taxpayer that puts the money in on the ground and starts the research that then moves forward. And then our people don't have access to it.

So, Mr. Horn, I want to ask you, how does this high cost of PrEP limit the ability of states and local health departments and clinics from scaling up and providing the drugs and support to the 90 percent of people who need it that the chairman mentioned?

Mr. HORN. Thank you, Representative Maloney. I—first, I just want to sort of piggyback on one of your points and just—something that's really important to recognize is when we consider where we have the highest number of new infections in the United States, if you overlap that map with another map of like where we have not expanded Medicaid, for example, we definitely see where there is a tremendous disparity.

So when we're thinking about those jurisdictions in particular, this is where we find a number of people who are vulnerable to HIV infection really do become increasingly dependent on this incredibly complex patchwork in order to access not just PrEP but all of the services that are required to support PrEP, lab testing, supported services, counseling, you know, engagement in care, access to a care provider, so on, and so forth.

So—and I also just do want to reference that just with respect to, you know, that cost certainly isn't our own issue. We do have issues of stigma, discrimination, so on, and so forth. But when we do take a look at what's happening with health departments, I would just reiterate that for many of our health departments—and we do have a number of states have actually implemented state, you know, PrEP, your drug assistance programs.

The one thing I will point out about that is that these are state-funded programs, but they're not federally funded programs. There—

fore, they do not have access to 340B discounting. Therefore, they are reliant on leveraging the very complex system in order to guarantee access to PrEP and the various services that are required.

Mrs. MALONEY. I want to say that I have the privilege of resenting New York, which has been at the forefront in combating the AIDS epidemic. And, according to the city of New York, we have been making some progress. New AIDS/HIV infections in the city decreased by 36 percent between 2013 and 2017, but by increasing access to PrEP and making it affordable, they believe that they can bring new infections to less than 700 cases a year. This would be a dramatic, dramatic improvement. And I am afraid that by basing our public health response largely on the generosity of a private company that says they are going to make it affordable, it should be affordable to everyone. It should be affordable to everyone. They shouldn't have to negotiate having access to this drug. It is just putting the whole program in quicksand. It is not there to serve the people.

So I want to ask what do we need to do to make this affordable to people in our public health system, in our cities, in our states, in our clinics, in our local areas, Mr. Horn?

Chairman CUMMINGS. The gentlelady's time is expired. You may answer the question.

Mr. HORN. Okay. We just need to be conscious of cost at all point—I mean, we just need to make sure that we are able to procure both PrEP and the services that are required for PrEP at an equitable price and that we are moving in that direction. We're moving toward generics. And we just need to keep an eye on that. That really is the great unifier in terms of ensuring access to everyone who requires preexposure prophylaxis. Thank you.

Mrs. MALONEY. Thank you for your service.

Chairman CUMMINGS. Mr. Meadows.

Mr. MEADOWS. Thank you, Mr. Chairman. Thank each of you for your testimony.

I would want to point out since my colleague from New York talked about voting on bills today, candidly, those bills today are nothing more than a political statement. There are both Republicans and Democrats—

Mrs. MALONEY. Will the gentleman yield?

Mr. MEADOWS. No, I will not. You didn't offer the same courtesy to my friend from Ohio, so—I will say this. I am dead serious on actually lowering prescription drug prices and making sure that availability is here. I am willing and have worked with my Democratic colleagues for us to put bills on the floor that actually are not a product of bipartisanship. It is not going to solve this problem. And so it is critically important that we allow for the R&D that happens that has groundbreaking drugs that come to market, that they continue, and that we make sure that availability for all Americans and indeed globally are there.

But with that, I am going to yield the balance of my time to the gentleman from Ohio, Mr. Jordan.

Mr. JORDAN. I thank the gentleman for yielding.

The chairman talked about playing games. I am not playing games. I just want to thank a company who has developed a drug that has saved millions of people and not beat them up for that

fact. I mean, you can look at—on one hand, you go after them, and then you say, oh, but I am not really going after them. Look at the title of the hearing, “billions in corporate profits after millions in”—you are going after them right in the title of today’s hearing.

Dr. Grant in his opening testimony said that Gilead had nothing to do with it. I have gotten article, a peer-reviewed article from the New England—in fact, I would ask unanimous consent, Mr. Chairman—

Chairman CUMMINGS. Without objection, so ordered.

Mr. JORDAN [continuing]. Gilead signed this, participated in this. I don’t remember any member thanking them for what they have done.

Chairman CUMMINGS. I did.

Mr. JORDAN. Not till after I did, that is for darn sure.

So, look, as my colleague said, we want prescription drug—we want all drug prices to come down. We want that to happen, so let’s figure out a way to do it. But I don’t know that you do it by going after a company who has developed an amazing drug that has helped so many people, and they are taking the profits from that now, working on a cure. I don’t see where that helps us.

So, anyway, Mr. Chairman, I would—or, excuse me, I will yield back to the gentleman from North Carolina.

Mr. MEADOWS. I thank the gentlemen.

So, Mr. Ezell, let me come to you. Really at this particular point what we have got is one of the greatest R&D abilities in terms of pharmaceuticals on the globe. In fact, most of the world looks to the United States for those groundbreaking drugs. Is that correct?

Mr. EZELL. That is correct. The U.S. truly leads the world in both investment in life sciences R&D and commercializing drugs that come out of that R&D.

Mr. MEADOWS. And why do we lead the world in that? Is it just that we have the greatest brainpower or why would we lead the world and be able to do that? Why does that come from here and not from some other country?

Mr. EZELL. It’s a combination of factors, as I tried to indicate. First, a really strong complementarity between private and public investment. A lot of cases of public-private partnerships bring innovative new drugs to market.

Mr. MEADOWS. So it is our coordination between the pharmaceutical industry, NIH, other areas where we have this to come up and have groundbreaking pharmaceuticals that actually meet the needs of not just the United States but certainly the world at large. Is that correct?

Mr. EZELL. That’s a large part of it, also a wonderful STEM talent and pipeline, some of the best scientists in the world, and a system broadly that enables innovators to undertake the risky process of investing hundreds of millions if not billions into a drug and earned for a temporary period of time revenues from those innovations that can then be reinvested into future generations—

Mr. MEADOWS. So strong patents that actually help the proprietary investment that many companies make, is that correct?

Mr. EZELL. That’s correct.

Mr. MEADOWS. So if we look at that, one of the number-one complaints I get, though, is with the rise of prescription drug prices

and why can I get it cheaper, you know, in the E.U. and other areas? Is it our delivery system at times, the way that we have done this, and for me, a lot of this has come on in the last five decades as we have had a number of competing things that have happened with regards to the delivery system. Is there a way that we can still protect the patents, allow for research and development, and yet make sure that what both the ranking member and the chairman are talking about is that availability to underserved populations? Is there a way to do that without having it a government-owned entity?

Mr. EZELL. I think there—yes, there is certainly a way to do that without having a government-owned entity. The private sector remains the best engine of innovation in the life sciences.

I think there are interesting things we should do. One thing, for instance, is we can think more thoughtfully about how to increase R&D efficiency. The biggest problem in the broader drug development system is so many drugs get to like phase three clinical trials and then fail, and that's a massive cost for both the companies and the system. If we could focus on public-private partnerships like around translational research that would focus on how we can bring more efficiency to the R&D drug discovery process, that would be a very important way that we could broadly illuminate some of the cost in the drug discovery system.

Mr. MEADOWS. All right. I look forward to working with my colleagues opposite, and I yield back. I thank the gentleman.

Chairman CUMMINGS. Ms. Norton.

Ms. NORTON. Yes, thank you very much, Mr. Chairman. This is a very important hearing, particularly for people who represent districts like mine, the District of Columbia. I am interested in PrEP because it is of course the cornerstone of the administration's HIV plan, so it plans to increase the use of PrEP from a paltry 10 percent today to 50 percent within the next 10 years, so everything is riding on PrEP.

I can't resist asking you a question, Mr. O'Day. It is kind of a John Q. Public question. Instead of the donations you are offering, even some of the reductions, why not simply lower the price of PrEP?

Mr. O'DAY. Thank you, Congresswoman. And obviously, your district is extraordinarily important in terms of HIV elimination and a part of the CDC program that we just agreed for the donation of medicine.

So the answer to the question is that if we had lowered the price of our medicines even a decade ago, we wouldn't be sitting here today with the innovations that are changing the face of HIV/AIDS.

Ms. NORTON. Mr. O'Day, I think you testified that your company earned \$36 billion in revenue, and you are telling me that at that rate of revenue, we just wouldn't have PrEP at all?

Mr. O'DAY. Without the investment back in research, we wouldn't have PrEP today, and we wouldn't also have the advances that we have with the talented scientists at Gilead looking at long-term—

Ms. NORTON. And so that price is justified?

Mr. O'DAY. That price—

Ms. NORTON. In order to get back any return on what you have invested in order to develop PrEP. Otherwise, you would be at a loss?

Mr. O'DAY. Yes. The revenues are invested to a large percent back into R&D, and I just point out that everything that we start in early phase R&D trial has a 97 percent chance of failing. So exactly to Mr. Ezell's point, this is a very complex iterative process that requires a lot of investment, but, more importantly, requires no——

Ms. NORTON. But this one didn't fail—just reclaiming my time. So I would like to go on and find out the feasibility of the use of PrEP by asking Ms. Walensky how feasible is this goal I mentioned to get from 10 percent to 50 percent within 10 years, after which you have heard Mr. O'Day testify, how feasible that we will get there?

Dr. WALENSKY. Thank you. We aspire to laudable goals. This one's going to be hard, and I will tell you——

Ms. NORTON. Will reducing the price be necessary?

Dr. WALENSKY. I think we need to put PrEP in the water is what I think we need to do in order to get this epidemic under control and the places that don't have access to PrEP. I think, you know, the data from South Wales that said that they were able to decrease incidence by 25 percent, they essentially give it to almost everybody. They did everything that they could to get PrEP to a lot of people, and so we need to do everything that we can.

We know that since PrEP has been available, there has been no dent in incidents. It's been unchanged, and so if that's going to be the case, we need to sort of figure out—that 10 percent access hasn't done anything to the incidents.

Ms. NORTON. No effect. Mr. Horn, does it trouble you that the administration's plan relies so heavily on the donation of free drugs from Gilead? We are going to get there with these kinds of donations?

Mr. HORN. Donations help. They don't solve anything. I'll give you the example. When we have looked at the U.S. response and I think the response globally, when we took a look at what happened when we had our major innovator manufacturers who were donating drug to low-income countries, that only got us so far. What was really required there was a reduction in price. Really that was spurred by robust generic competition to ensure equitable access and affordability to our programs.

And so let me be clear. I think the donation will help, but it is not the panacea that we require.

Ms. NORTON. I just want Mr. O'Day to know that everybody affords your donations and charity, but I think we would actually prefer you to go back to old-fashioned capitalism and reduce the price.

Thank you, Mr. Chairman.

Chairman CUMMINGS. Mr. Norman?

Mr. NORMAN. Thank you, Mr. Chairman.

Mr. O'Day, I appreciate you justifying and coming up here. You know, you are being put in a position of being a bad guy, I mean, by the questions you are asked. Your company competes with other drug companies. You are not the only company that took the inno-

vation and the time and the effort to go after a treatment, which, as Congressman Jordan said, you are having the people that ordinarily would not have a chance to live, they are living now.

Now, I am all for lowering prices. You do that through competition, through capitalism, so I want to thank you for doing that and really for taking some of these questions, which is really amazing to me.

You know, Australia, the drug that has been quoted for \$8, where were they when the innovation—where were they—why didn't they invent the drug? Why didn't they go through the trials and the studies that you did over time?

But, Mr. Ezell, you are in a good position to I guess answer questions as far as the many times that this country has led an innovation and putting drugs on the market that other countries either couldn't or wouldn't or didn't do. What effect if—go through the trials that failed and who foots the bill for that with different companies, yours particularly?

Mr. EZELL. I'm sorry, could you restate the question? I didn't—could you restate the question? I didn't entirely understand what you are asking.

Mr. NORMAN. Could you—well, my question is, you know, part of the reason—you are in a unique perspective on the innovation that is occurring in this country. The U.S. is a leader in innovation, as I have said. You succeed in bringing lifesaving drugs to the market. And you improve the lives of Americans who desperately need them, as has been said today. I think part of the reason is because when a drug fails in the pipeline, it is the company primarily who suffers the financial loss. Could you elaborate on this point?

Mr. EZELL. Well, essentially—and that's exactly right. The simple reality is that the process of bringing an innovative new drug to market is risky and extremely expensive. I could quote studies, the most recent one from Deloitte estimating that—that study shows that over six of the past eight years the cost to bring an innovative new drug to market has risen. Now the average in 2018 was about \$2.1 billion.

It really is the private sector of the United States. That's the only entity at a large scale in the world who's willing to undertake these incredibly risky and expensive investments and be willing to accept failure rates that, as Mr. O'Day has said, can exceed 95 percent. We have a system in place to bring talent and capital to the world's most innovative companies, to bring breakthrough solutions to market.

And I would also ask the committee to understand that their deliberations today importantly about the price of Truvada will also have implications for a number of other drugs because we care not only—although we care deeply about those patients who suffer from HIV/AIDS, we care about those who are affected by maladies that we currently do not have solutions to. And the genius of America's life science innovation system is that we're able to put in place a system that enables us to invest to try to solve challenges that are currently unsolved by the frontiers of medical science, and we're the best country in the world doing that.

Mr. NORMAN. You are planning for the future and you are reinvesting to help the lives that you are saving already, making it better.

Dr. Walensky, some of my colleagues are advocating for breaking the patent system in the United States as a way to address drugs. Would this work?

Dr. WALENSKY. Well, you know, one of the things I want to get to is the fact that several people have described that with an earlier patent—an earlier-going generic, a year earlier, I want to just emphasize that the only way drugs prices come down in the generic market is if there's generic competition. So the fact that this is going to be—the patent is going to be broken a year earlier and there will be one company making a generic drug is not going to decrease the price of Truvada. Maybe it'll decrease it by five or 10 percent, but we're not going to get the discounts that we need such that the patients who need to access it will be able to access it.

I do think that—you know, it's not that I don't believe that the companies need to profit. I do believe that companies need to profit. I do believe we need new drugs. We certainly need them in HIV, we need them in antimicrobials, we need them in a lot of different places. But I do believe that Gilead has already profited enough, especially in the context of a Presidential call to end the epidemic here. So I think that that would work here.

Mr. NORMAN. You think they have profited enough, and that is your opinion.

Dr. WALENSKY. Certainly on this drug for this indication, I do. I do. I think this is a public health mandate. Not all—

Mr. NORMAN. Thank you. Thank you so much. I yield back.

Chairman CUMMINGS. Mr. Connolly.

Mr. CONNOLLY. Thank you, Mr. Chairman.

My friend from Ohio, the ranking member, has attempted to discredit the purpose of this hearing and in the process discredit those of us who raise questions, legitimate questions about the pricing of a lifesaving drug.

I am here because of one of my best friends. His name was Rick. He developed AIDS in the late 1980's when there was no cure. He died when my daughter was just a few months old in 1991. I spent a lot of time with him during the illness. I saw its progression. I saw his suffering, terrible symptoms. It ultimately went to his brain, and he started hallucinating. Maybe there was a blessing there because he was not any longer aware of his suffering.

He lost his job because of the illness and was uninsured, and he didn't have access to health care. He went to a homeopathic clinic because he was hopeful maybe that would work. It seemed to only make his suffering worse.

So, Mr. Jordan, I am not here to discredit an American company or Mr. O'Day. I am here for my friend Rick. I am here to make sure no American has to go through what Rick went through and that drugs are available to people who are suffering. And I would say to you, Mr. Jordan, that is a legitimate source of inquiry.

I am not going to yield because I am going to run out of time unless the chairman grants me more time.

So I just want to make that really clear. Most of us absolutely subscribe to the thought that a drug company has to recover profits

because it recovers cost and legitimate R&D that can produce more lifesaving drugs. But the question in front of us is how much is enough? How high do you go to the point where it becomes a barrier to access? It may help your bottom line, but it doesn't help people like Rick.

And I think that is a legitimate form of inquiry. And given that, one notes that, right now, the cost of Truvada is about \$70 per day if you are paying full freight. Is that correct, Mr. O'Day?

Mr. O'DAY. That's correct.

Mr. CONNOLLY. In Canada, it is \$5 a day. In Australia, it is \$7 a day. And, to be fair, in Canada, that is generic. For the branded product, it is \$20 a day, not \$70. Now, they have different systems, but it is the same drug.

Mr. O'Day, when Truvada was first approved as a treatment in 2004, you had a list price of \$800 per month. By 2012 when you were approved for preventing HIV transmission, that price had almost doubled to \$1,400 a month. In your statement today you claim you did not increase the price of Truvada when it was approved in July 2012, correct? That is in your statement.

Mr. O'DAY. The—there was no—there was an increase in 2012—

Mr. CONNOLLY. Yes.

Mr. O'DAY.—so it was—over the past—since 2004, the average increase has been around—

Mr. CONNOLLY. But in your statement you said today you did not increase the price of Truvada when it was approved. And I would suggest respectfully that is a little misleading because you had just raised the price six months earlier, and you raised it again six months later.

Mr. O'DAY. So, Congressman, I understand your point. What I was trying to assert was there was no additional increase to the price as a result of the additional indication.

Mr. CONNOLLY. So let me ask a question in terms of corporate deliberations. I worked in the corporate world for 20 years. When you look at pricing and when you looked at pricing, did you have a discussion about, okay, corporate profit, we want to maximize our profit, but on the other hand, we also understand our, you know, community obligation to suffering people and so we have to strike a balance here? Does that factor into the pricing of the drug?

Mr. O'DAY. Absolutely, Congressman. And there are four things that we look at critically when we price a medicine. First of all, what's the value of the medicine to the patient and society? The most recent figure associated with the disease HIV/AIDS that it can cost on average \$880,000 per patient to treat that disease, so that's given into context.

The second thing is what the comparable treatments that are on the market today?

The third and potentially most important is exactly to your point. What are the access limitations that might be created by setting that price, and we anticipate that in advance.

And then the fourth one is our commitment to reinvest back in research not just for this medicine and not just for this disease but for other terribly devastating diseases that inflict Americans and the globe.

Mr. CONNOLLY. Well, Mr. O'Day, I appreciate that, and I just want to say I hope today's hearing is something that will give you thought and is something that maybe you will take back to the corporate boardroom to reevaluate the pricing of a drug that so many people need access to.

And I want to thank the chairman for having this hearing on behalf of my deceased friend Rick, your deceased employee, and the millions of Americans who have succumbed to this terrible virus. Thank you.

Chairman CUMMINGS. Mr. Hice?

Mr. HICE. Thank you, Mr. Chairman.

Mr. Ezell, could you explain in basic terms the law that addresses intellectual property that comes from federally funded research?

Mr. EZELL. Yes, Congressman. It's called the Bayh-Dole Act. It was introduced on a bipartisan basis in 1980, but what it does is it gives universities and public research institutions the rights to innovations that stem from federally funded research at their institutions.

Mr. HICE. And before 1980, before that law, do you have any idea how many patents the U.S. Government owned?

Mr. EZELL. Yes, so in 1978 the Federal Government had licensed less than five percent of the 30,000 patents owned at the time. There was a massive underutilization and a lack of commercialization of intellectual property and knowledge that was sitting in laboratories across the United States.

Mr. HICE. So before the law, then, there were approximately 30,000 patents that the U.S. Government owned, only about five percent of which, however, had commercial licensing. Is that correct?

Mr. EZELL. That is correct.

Mr. HICE. All right. And why is that? It is a lot of patents, a lot of potential great benefits out there, only five percent in the commercial market to go out to the public.

Mr. EZELL. Well, that's right because, well, first, government institutions and universities were not equipped or expected or it wasn't their intent to incur the risk that would be required to, you know, take those technologies or inventions and bring them to the market as commercializable—

Mr. HICE. And neither is the government?

Mr. EZELL. In fact, an interesting story was from the year 1968 when President Johnson asked Elmer Staats, who was then the comptroller general of the United States, to analyze how many drugs had been developed from NIH-funded research, and Johnson was stunned when Staats' investigation came back and said that not a single drug had been developed when patents were taken from universities for commercialization by the Federal Government. Staats' report from 1969 found that—we found hundreds of new compounds developed at university laboratories that had not been tested and screened by the pharmaceutical industry because the manufacturers were unwilling to undertake the expense without some possibility of obtaining exclusive rights for further development. It was not until they put in place the Bayh-Dole Act of 1980 that we—led to an explosive growth of innovations stemming from federally funded research.

Mr. HICE. That is my point exactly where I want to go with this. And so you had the Federal Government pretty much in charge of all the patents until Bayh-Dole. Then things started changing and actually patents were able to get into the hands of commercial licensing and thereby get to the needs of the population.

Can you briefly explain what the march-in provision is in Bayh-Dole?

Mr. EZELL. Yes, so the march-in provision is language that would in very specific limited cases give a government agency the ability to, quote, "march in" and compel the divulsion of the intellectual property or force additional licenses on an innovation that was a result in part from some degree of Federal—

Mr. HICE. And, real briefly, what would be—I am assuming that would be like an emergency?

Mr. EZELL. Yes, so when the architects of the Bayh-Dole Act, Bob Dole and Birch Bayh, designed the legislation in the early 1980's, the reason they conceived of putting in the march-in rights was primarily to ensure that a licensee took the steps to commercialize the—

Mr. HICE. The whole point was to get it to the public when there was a need?

Mr. EZELL. That's correct.

Mr. HICE. So has the march-in provision ever been used by the Federal Government?

Mr. EZELL. No, not—no, it has not.

Mr. HICE. All right. So what kind of impact would using the march-in impact have on research and development?

Mr. EZELL. I think there's a real risk that, if you ever used march-in rights, it would substantially stifle the potential of research and development. If the government ever had the capacity to march in decades later and compulsory license the IP on a pending pharmaceutical drug on the grounds that some of it was contributed by federally funded research and now some number of decades later the government declares that that price is unreasonable, that will give enterprises serious pause about investing the enormous sums required to bring innovative new drugs to the marketplace.

Mr. HICE. So—

Mr. EZELL. It would stifle innovation.

Mr. HICE. So, in other words, there would be a great disincentive for research and development in various companies if they spent the billions of dollars, if they assumed the risk to develop drugs, and then all the while knowing that the Federal Government could march in and take that patent away from them, you are saying that would massively disincentivize R&D?

Mr. EZELL. That's correct, Congressman. There was a great case from 1995, something called CRADAs, cooperative research and development agreements, in 1989 the NIH inserted a reasonable-pricing clause into those CRADAs. The amount of collaboration between industry and government subsequently cratered. And when that requirement for original pricing of a subsequent innovation was repealed, the number of CRADAs instantaneously rebounded in 1995 and we again stimulated effective public-private partnerships toward developing new drugs.

Mr. HICE. Thank you. Thank you, Mr. Chairman.

Chairman CUMMINGS. Mr. DeSaulnier?

Mr. DESAULNIER. Thank you, Mr. Chairman. Thank you for having this hearing. Thank you to everybody who has been behind this.

As somebody who has a pill in my pocket that I will take at three o'clock that keeps me alive that in Australia costs \$6, here in the United States it costs \$400, Johnson & Johnson distributes it. I am told it is going to \$500, but it keeps me alive, so I am happy that I have health insurance that pays for it.

So I have spent a good deal of time in the last four years since I was diagnosed with chronic lymphocytic leukemia trying to figure this out. And what is a good reasonable rate of return to get people from private sector to invest and what do we get as taxpayers? NIH has a figure that shows since 1974 the NIH's research has contributed \$77 trillion to the U.S. GDP.

So having gone out there now multiple times and Dr. Grant having—Mr. O'Day, as somebody who is a resident of the bay area I take it now, as somebody who lives in the bay area, moved to San Francisco in the 1970's, went into the restaurant business, I sit here and think of the friends, the coworkers, the people who worked for me when I owned restaurants who passed away and what that did to the culture in San Francisco having moved there from the west end of Boston—not a bad facility, by the way, but it is no UCSF—and having one of my oncologists be one of your colleagues, Dr. Kaplan at UCSF, who put some work into this as well.

The numbers that I have from the Washington Post article is the research that you got or the grants you received was \$50 million, as has been said, \$50 million from NIH and then about \$17 million from the Gates Foundation. Were there other significant contributions from this company or others to your research?

Dr. GRANT. Gilead did not provide funding. They did donate medications, and it was that donation that justified their listing as authors on the publication cited before. Importantly, my study was not the only study done in PrEP. The CDC funded and performed its own study in Botswana and in Thailand, and the NIH also funded a study in—called VOICE in Africa. The total U.S. Government investment in PrEP is much more than the \$50 million from my project. It's in the hundreds of millions of dollars paid by the U.S. Government for the development of PrEP.

Mr. DESAULNIER. So, Dr. Grant—and actually, Mr. O'Day, I think your career is a similar—I remember reading a book *Our Daily Meds* years ago, and that reporter from the New York Times did a wonderful job of doing an investigation of the influx of venture capital into this pharmaceutical industry that traditionally, 40, 50 years ago, the CEO of pharmaceutical companies were researchers like yourself who went to work for the private sector and moved up the chain of command. And they weren't driven by the market forces that are currently driven.

So my question is—and I have an amendment on the floor today that I would like to get bipartisan support, and it goes to a little bit of the history that Mr. Ezell was talking about. In her investigation, she says that investors looked at professions that people trusted, and people with white smocks people trusted. And that

changed the culture. It brought a lot of pressure to get return on investment.

Mr. O'Day is somewhat legendary, as I read your history, about managing pharmaceutical industries. You are on the board of Genentech. You are on the board of California Life Sciences, which I have great respect for.

So my question is—my amendment is actually to get the Academy of Sciences to do a study that does the history but helps us understand what is the best investment and what is the base that we get from NIH, which I believe is underestimated. And then, to my Republican colleagues, what is a reasonable rate of return that will bring investors in to do what they do?

So when you look back on your career, how much better would it be now if we had that information and you could do the base? And maybe it would be more efficient when we argue about patent controls in the CDC and this company. Maybe there is a more efficient way to do this for the consumer, for the shareholder, but mostly, importantly, for the person whose life is being extended, as they do in Australia, as I understand.

They have a discussion about, for instance, this drug or my drug in Australia is \$6 when it is subsidized when they go through the process, and the risk to the client. If it is fully loaded, it is like \$35 a day, so I don't understand why it is \$500 a day here.

Dr. GRANT. I don't understand that either, sir.

Mr. DESAULNIER. But we need to find that out to have a rational conversation. And I invite my colleagues on the Republican side for a more efficient look at how do you attract these investments and get what we want, longer and higher-quality lives for American citizens?

Dr. GRANT. You know, I think you're raising all the right points. And it's important to realize that both components of Truvada, tenofovir and emtricitabine, were developed in academic centers using public funding.

Mr. DESAULNIER. Right.

Dr. GRANT. And then those property rights were purchased by Gilead. And, you know, people at Gilead will say that they invented those products, but in fact they were invented in academic centers using public funds and then purchased by Gilead, who then co-formulated, meaning mixed it into a single tablet. And the mixture in the single tablet is what allowed them to extend their patent rights beyond 2017.

And so when we look at innovations, the CDC brought us preexposure dosing, they brought us information that the mixture of two drugs was much more important than one drug and, you know, Gilead's invention was really buying products developed with public funding in the academic sector. So this synergy between academics and private industry is important, but I think that we need to be more honest, as you've proposed, about who is doing what in all of this and how much should be charged later.

Mr. DESAULNIER. Thank you, Mr. Chairman. I really hope we continue to pursue this question because it clearly is a life-determining question that needs to be answered by the American people. Thank you, Mr. Chairman.

Chairman CUMMINGS. Mr. Grothman.

Mr. GROTHMAN. Thank you. Mr. Ezell, I kind of want to talk to just in general an overview because I think the hearing today touches not just on a particular drug but things across the board. And we talk about the interaction between the private drug companies and NIH funding. And really not till we have this hearing that, you know, it occurred to me that we are putting billions and billions of dollars a year into the NIH, and I don't know whether we are getting bang for the buck or we should be, you know, getting some other way to get cures for these diseases.

Of the \$37 billion we put into NIH, how much of that do you think goes into pharmaceutical development if you had to guess? We are not going to fact-check you.

Mr. EZELL. I'm not an expert on the share of the allocation of the NIH's budget across its 27 research institutes. Their funding of the NIH goes to a number of activities from training future scientists to looking into very basic research trying to understand the basic molecular processes of how diseases work, trying to identify biomarkers that can single future targets for innovation opportunities. But certainly the majority of NIH's research is going into this basic science trying to understand fundamental molecular activities, and a much smaller portion of their research is going toward development-oriented activities.

Mr. GROTHMAN. Okay. As far as drug development, not just what we are talking about today but collectively, do you feel—or could you describe the different—well, do you know how much is spent every year on what we will call drug development by the private pharmaceutical industry? If you can't give me an answer, we will ask Mr. O'Day.

Mr. EZELL. In the year 2013 there was \$96.5 billion, as I understand. The average over the past three years has been about \$80 billion per year.

Mr. GROTHMAN. How many?

Mr. EZELL. Eighty billion dollars.

Mr. GROTHMAN. Eighty, so we are going about 80 billion. So, in other words, far and away most of the research in this country done on drug development is done by private industry, and what we get out of NIH is a small fraction?

Mr. EZELL. That's exactly right.

Mr. GROTHMAN. Okay. Could you give me an example of other success stories coming out of NIH?

Mr. EZELL. Well, there are a number. We can look at the invention of Gleevec, treatments for chronic myelogenous leukemia. That was a nice set of case studies that the original research was conducted by Dr. James Allison I believe at the University of UCLA I believe, and then some of his basic discoveries into how genes work gave rise to a new form of treating cancers called checkpoint blocking that we were able to identify specific antigen growth factors in the body, and then that set of basic research was ultimately licensed to the private sector, and Bristol-Myers Squibb invested the hundreds of millions required to now turn that into a first-in-the-world—

Mr. GROTHMAN. Do you feel overwhelming—and I don't mean to put words in your mouth—overwhelming the number of pharmaceuticals that are having an effect on our lives or extending lives

with people with various diseases? I suppose there is a difference in the type of things that are financed by NIH and the private industry. Could you comment on the differences between which type of drugs each sector goal was after or any reasons why you would feel one does a better or worse job than the other?

Mr. EZELL. Well, it is the private sector that is primarily incurring the risk of doing the applied research and in conducting the grueling set of three stages of clinical trials that are proving the safety and efficacy of that drug. And the private sector is the one who is assuring that the formulation is effective and works in the human body, and then of course the FDA is working with the private sector to validate that fact.

But the system we've put in place is now responsible for the fact that there are 7,000 new-to-the-world drugs under development globally, and it's estimated that at least 3,600 of those are being led primarily by U.S.-headquartered enterprises.

There's a lot to do. I'm not satisfied, as wonderful as Mr. O'Day's drug is. We need a cure for HIV/AIDS. We need a cure for various forms of cancer. It's wonderful that there's competition in the workplace Mr. O'Day's—O'Day's company faces the loss of competitiveness. It faces existential threats hopefully from the innovators out there who are trying to build a better solution, and I think it's important that we broadly focus on the system we have in place in America that enables competition and enables innovation so that we can try and come up with some of these cures.

Mr. GROTHMAN. Can I give you just one broad question? Does the chairman mind?

Chairman CUMMINGS. The gentleman's time is expired, but you may answer this question.

Mr. GROTHMAN. Okay. My disease of interest is Alzheimer's. Do you feel, as far as we look for a cure there, that will more likely come from the private sector or from NIH, or could you comment on that?

Mr. EZELL. My organization actually did a study looking at the economic impact if we were able to come up with a cure for mental diseases. We estimated that the value to society would be as much as \$1.5 trillion. I would support an all-of-the-above solution to innovate for cures like Alzheimer's. It's estimated that the real-time net present value of curing Alzheimer's alone would be about \$50 trillion for the U.S. economy. So these are massive numbers we're talking about over a period of time, so I applaud research that's being supported by nonprofit and foundational actors like the Gates Foundation toward that end. That may be a pathway to innovating such a drug.

But I note that there are hundreds of clinical trials ongoing even now to solve various forms of mental diseases being led by the private sector, and that's, I think, probably a—I mean, historically, that—historically across a broader set of disease states that's been a more likely pathway to getting toward a solution toward a breakthrough cure.

Chairman CUMMINGS. Mr. Rouda.

Mr. ROUDA. Thank you, Mr. Chairman.

I would like to talk about two different issues. One is just the government's commitment under the President's stated objectives

to addressing HIV infections and then also talk after that a little bit about the balance between innovation and drug pricing.

So, Mr. Horn, I will start with you. The President has stated that he wants to reduce infections by 75 percent in the next five years and 90 percent in the next decade, yet we have seen systematic attacks on the ACA and funding for community institutions and Medicare and so on. What kind of impact is that going to have in our ability to address HIV infections?

Mr. HORN. It has a profound effect. We rely on these systems, and we fight very hard for these systems. And I will say that we actually fight very hard against these systems sometimes just to ensure that.

But in order to do this—and I think that we realize this. When we're just beginning to think about, you know, just getting—just maximizing the number of people who are living with HIV to getting them biologically suppressed. What is making that possible, what is getting us there is the Affordable Care Act, as all of the systems under the Affordable Care Act. And I think when we do think about this in the context of primary prevention or PrEP or just the prevention for those who are vulnerable to HIV infection, the same holds true. We absolutely need the ACA and, frankly, we need Medicaid expansion to make that happen.

Mr. ROUDA. And actually, if we had universal healthcare, much of the issues that we are having when talking with Gilead about and any other drug manufacturer about those costs, many of those disagreements would go away because we would have properly funded, systemwide care for all Americans.

Mr. HORN. That is correct.

Mr. ROUDA. And, Mr. Ezell—and hopefully I pronounced that correctly—you made the comment earlier that the NIH plays such an important role in the development of new drugs, yet the President has three straight years tried to make massive cuts to the NIH. Wouldn't that diminish our opportunity to continue to have innovation in the development of drugs through that public-private partnership?

Mr. EZELL. Absolutely, Congressman. In fact, this is perhaps the most fundamental threat to the U.S. innovation economy. If the United States—essentially, today, the U.S. invests the least it has in federally funded R&D as a share of GDP since 1995—1955. To match our investment on average in the 1990's—

Mr. ROUDA. Sixty-five years roughly, 64 to be exact.

Mr. EZELL. Correct. On average, to match the Federal Government's investment in R&D that we averaged in the 1990's, we would have to invest 80 percent more per year today. And we're seeing that manifest itself within NIH even. The average age of first NIH ROI grant has increased from 34 to 42 years, eight years later in life. The average success rate has declined from close to 60 percent in 1962 under 20 percent today. And if we don't make that right, we risk losing our—

Mr. ROUDA. I understand.

Mr. EZELL [continuing]. international competitiveness.

Mr. ROUDA. Thank you. And, Dr. Walensky, I am not sure if this is the appropriate question for you, but I am just curious. When we look at the societal cost of not doing anything to making sure

that we have proper medication and putting a number on that versus the cost of providing these drugs to all those, has that analysis been done, and if so, is there any indication as to what it would do?

Dr. WALENSKY. I think—we haven't done what the status quo is. We know that if we invest in this, it will be a cost-effective investment. I want to just comment on something Mr. Ezell said, and that is that, currently—and I've screened every infectious disease fellow who comes in the door at Massachusetts General Hospital. Nationally, we have .7 applicants for every infectious disease position in the country. That is—the Indiana HIV outbreak that occurred, there was no infectious disease doctor in that county. And if we don't invest in the NIH to do——

Mr. ROUDA. Right.

Dr. WALENSKY [continuing]. these things, we will not have those physicians.

Mr. ROUDA. Mr. O'Day, I heard testimony that the list price is \$1,780 to approximately \$2,000. That list price, let's just assume for simple math, \$2,000. If you sell a monthly prescription for \$2,000, does that go to your revenue line?

Mr. O'DAY. The \$2,000 would go to the revenue line, that's correct.

Mr. ROUDA. And then the pharmacy benefit managers, PBMs, about roughly what percentage of that \$2,000 would be paid to them?

Mr. O'DAY. Well, actually, the discounting in the commercial sector is actually quite small because the cost-effectiveness of this medicine has not required that discounting. When you look into the public sector, however, we have very deep discounts, so 70 to 80 percent discounts, for instance, for Medicaid, for ADAP, and for all the government programs.

Mr. ROUDA. And, one last question, the billion dollars of investment that you noted earlier, is that an ordinary or a capital expense on your income statement?

Mr. O'DAY. That's ordinary, yes. I mean, there could be capital components to that, but the vast majority is recurring expenses, year-on-year invested in R&D, into people, and into costs that support our research and development.

Mr. ROUDA. Thank you, Mr. Chairman.

Chairman CUMMINGS. Before we go to Mr. Comer, Dr. Walensky, you said something about .7 percent. Can you say that again? I think I misheard you.

Dr. WALENSKY. Unfortunately, you probably didn't.

Chairman CUMMINGS. I hope I did.

Dr. WALENSKY. For every infectious disease fellowship slot that we have in this country, we have 0.7 applicants. There has been a New York Times editorial in the last week that—or in the last month by Matt McCarthy that demonstrates that we are going to have a shortage of infectious disease doctors. We know we are anticipated a shortage of infectious disease doctors. Some of the counties that have had HIV outbreaks, there have been no infectious disease doctors in them. And so, yes, I think we have a public health problem. Part of that is related to NIH funding and seeing—

because we are what we call a cerebral field, we rely on NIH dollars to recruit applicants into the field.

Chairman CUMMINGS. Mr. Comer?

Mr. COMER. Thank you, Mr. Chairman. And we have already hit on the important roles of private-sector versus public sector in the R&D process and also the role of having strong patents and the consequences if the government breaks patents on drugs like Truvada. We have also hit on the major scientific and regulatory risks and hurdles you have had to take in to market Truvada.

Overall, though, I just want to reiterate the great role that Gilead has played in innovations in antivirals, and I hope we can continue to save lives because that is something that we agree on in a bipartisan way.

Switching gears, I want to talk about the President's initiative to eradicate HIV. From what I understand, the bulk of the Trump administration's plan to eradicate HIV is the ability to locate every American susceptible to HIV and provide a drug and provide help adhering to the daily regime for the rest of their lives. That is no easy task. The cost of doing that will be daunting. About 1.1 million Americans have the virus, and about 1 million are at risk of contracting it. Finding, treating, and keeping them all on treatment experts estimate would be more than the administration currently is devoting, even in addition to the \$20 billion the Federal Government already spends on HIV prevention and treatment. There are criticisms that if the patent on Truvada remains, the Trump administration's plan to eradicate HIV would cost over \$20 million.

So, Mr. O'Day, let me start with a few questions. How many bottles of Truvada has your company Gilead donated to the U.S. Government?

Mr. O'DAY. So our commitment is to donate 2.4 million bottles per year for up to 10 years.

Mr. COMER. Okay. I think Mr. Jordan asked this question. When is a generic version coming onto the market? Do we know?

Mr. O'DAY. A generic version of this medicine Truvada comes out into the market in September of next year, 2020, and other generics will come on six months later.

Mr. COMER. And you did, as I understand, voluntarily release the patent early?

Mr. O'DAY. That's correct. In discussions with—and it was a legal decision at the end of the day and an important decision to avoid the cost of litigation and to bring this medicine sooner to patients. It's important to note that when the patent expires for Truvada, the next most safe, most effective medicine will take its place in the donation—

Mr. COMER. Right.

Mr. O'DAY.—for 2.4 million bottles for the next 10 years. We want to make sure that the uninsured patient population in America has access to state-of-the-art care at all times over this decade.

Mr. COMER. With those developments, how much closer are we to eradicating HIV?

Mr. O'DAY. Well, I think, as has been mentioned, the—you know, it's—I think it's within our grasp. It's clearly challenging. It's, as I've tried to articulate, based upon the Gilead programs. You know,

it's really not about drug pricing. It's about—in this particular case is about the wraparound care. I think the administration and CDC and HHS' efforts to, you know, reduce by 70 percent in five years and 90 percent in 10 years is within our grasp, but it does require a holistic approach to the wraparound care.

Many people have talked about Australia here, which I think is interesting to look at in some regards. In Europe, generics have been available for three years, and even with the lower cost of medicines in Europe, we've seen very little increase in HIV PrEP, which goes to show you that there are many, many elements of this system—

Mr. COMER. Right.

Mr. O'DAY.—that have to be invested in.

Mr. COMER. Right. What proposals currently would hinder the progress of eradicating HIV or any prospect of a cure or vaccine to HIV? What proposals have you heard out there that would hinder that?

Mr. O'DAY. Well, I think that's—I mean, the current initiative is focused on the available antiretrovirals, which are very effective but have drawbacks in terms of getting them into the hands of the patients at the right time. So what our scientists are doing is they're working on longer-term medicines. Those could be delivered once a month, once every three months, long-acting, which I think could help us desperately with this solution of HIV elimination and eventually the cure. And the cure is still—it's I wouldn't say within our grasp today. There'll need to be a lot of failures to get there, but we're firmly committed at Gilead to investing in that research, to keep having the 90 percent failure rates and finding eventually that 3 percent cure, which we're firmly committed to. We won't rest until we get there.

Mr. COMER. Right. Thank you. Mr. Chairman, I yield back.

Chairman CUMMINGS. Ms. Hill?

Ms. HILL. Thank you, Mr. Chairman. I ask unanimous consent to enter into the record a Washington Post article from 2016 entitled "The drug company that shocked the world with its prices dodged \$10 billion in taxes," report says.

Chairman CUMMINGS. Without objection, so ordered.

Ms. HILL. Thank you. We have talked about saving lives, but, as a corporate executive, Mr. O'Day, let's talk about money. Just as you are responsible for your budget, I am responsible for our taxpayers' money, and in this case our worlds collide. Mr. O'Day, how much does Gilead spend per year in direct costs for patient care for people with HIV and AIDS?

Mr. O'DAY. I don't have the exact figure, Congresswoman, but it's in the tens of millions of dollars.

Ms. HILL. You pay for direct care?

Mr. O'DAY. We pay—we fund community support groups that support patients in a variety of different ways. We're the largest corporate donor to community funding—

Ms. HILL. That's great. Is it true that you get a tax break for those corporate donations?

Mr. O'DAY. Yes.

Ms. HILL. Okay.

Mr. O'DAY. Yes, it is.

Ms. HILL. Okay. So, effectively, you don't spend money on direct patient care. But do you know how much the U.S. Government does?

Mr. O'DAY. No, we do spend money on patient care. We may get some tax benefits of that, just to correct—

Ms. HILL. Okay. Okay, but—

Mr. O'DAY.—but absolutely spend, and we have an outflow in our P&L that's—

Ms. HILL. Okay.

Mr. O'DAY.—associated with those costs—

Ms. HILL. Do you know how much the U.S. Government spends on that treatment for patients with HIV or AIDS?

Mr. O'DAY. I—what I know is that the current plan for HHS and CDC has earmarked for the 2020 budget somewhere around \$290 million for the HIV elimination program. Now, the fact that Gilead will donate all of—

Ms. HILL. Well, hold up. Hold up. So what the U.S. Government pays in direct care—this is through Medicaid and Medicare—is \$21.5 billion, so it is a much higher number than what we are adding to the budget for research and elimination.

But, anyway, it is estimated that \$470,000 in lifetime costs is what it takes to treat someone with HIV infection, and now we have 40,000 people with new HIV diagnoses in the country each year, and so that cost to our taxpayers is going to continue to rise.

So, as you heard from the title of the article I submitted, Gilead is notorious for not even paying its fair share in taxes that go toward HIV treatment. Gilead reported its 2018 financial performance to the SEC on February 26. It showed that the company had revenue of about \$22 billion—that number sounds familiar—in 2018 with about \$31 billion in cash available. So I want to take a look at how Gilead is using some of its profits.

Mr. O'Day, you just joined Gilead Sciences earlier this year. Is that right?

Mr. O'DAY. That's correct.

Ms. HILL. Your initial compensation package was reportedly worth about \$30 million, including both cash and stock options. So the company agreed to pay you \$30 million just for taking the job. Is that right?

Mr. O'DAY. That's correct. I mean, I should articulate that half of that was for compensation that I gave up from my previous assignment and have—

Ms. HILL. Okay. But it is \$30 million for taking the job. So, just out of curiosity, do you know what the median income is for a U.S. worker according to the BLS?

Mr. O'DAY. I do not offhand.

Ms. HILL. It's \$46,800 or one-sixth of 1 percent of what your signing bonus was, just thought you would want to know that.

And Gilead has a long history of paying windfall amounts to its corporate executives. In 2013 Gilead's former CEO John Martin earned almost \$180 million. His salary for the year was \$15.4 million, but he cashed out almost \$160 million in stock options that year. Mr. Martin appears to have timed his pay well. According to Gilead's 2013 annual report to shareholders, Gilead had, quote, "record total revenues" in 2013 of \$11.2 billion. Twenty 13 was the

year that Gilead's blockbuster drug Sovaldi received FDA approval, correct?

Mr. O'DAY. I believe so.

Ms. HILL. Sovaldi is a hep C drug that also made headlines for costing \$1,000 per pill.

I want to turn to another Gilead executive, your direct predecessor John Milligan. He made a little less than you, just \$15 million. I understand Mr. Milligan resigned in 2018, but he didn't lose his salary. In fact, he received what is called a golden parachute, meaning that the company paid him extra just for resigning. Mr. Milligan had previously received stock options that were not worth anything because the company's stock had gone down, but thanks to a separation agreement between Mr. Milligan and the company, he was paid an additional severance that earned him a total of \$26 million just for resigning from the company. That is true, right, Mr. O'Day?

Mr. O'DAY. As far as I understand. Those decisions are made by the board of directors.

Ms. HILL. Of course. Gilead is a private company and it can pay its corporate executives whatever it likes, but Gilead also makes a lifesaving drug that it has kept a U.S. monopoly on. We have heard today about people who are not accessing this drug because they cannot afford it. We have heard about local public health officials that are straining under the financial burden of providing this drug to everyone else that needs it to stay healthy, and this drug, which has generated billions of dollars for Gilead, was developed using tens of millions of dollars of Federal funds.

So what Gilead chooses to do with its profits really does matter to all of us. And I will say that the millions and millions of dollars to corporate executives I take some issue with. Thank you.

Chairman CUMMINGS. Mr. Roy.

Mr. ROY. Thank you, Mr. Chairman.

You know, I came to this hearing hoping that we might have a hearing where we spent some time diving into some of the tough questions instead of preening and posturing for cameras, attacking people for making profit in a capitalist society, but that is what I just heard in rants for the last five minutes.

Now, Mr. O'Day, do you make Brentuximab? Do you know what Brentuximab is?

Mr. O'DAY. I do not. I'm sorry, Congressman. Brentuximab vedotin is the drug that I took when I was suffering from Hodgkin's lymphoma, a drug that was created, built, manufactured, developed, designed, created by a private company that made a lot of money. And I am really glad they did. I hope they make a lot more, and I hope they make a lot more drugs to save a lot more people and distribute a lot more drugs around the world to save a lot more people.

Now, it is a reasonable question when patents expire, when they should expire, when they shouldn't expire. It is a reasonable question, how much money that NIH has and is investing and how much we should factor that into the patent life. But to sit here and attack the capitalistic system that produces and distributes medicine to saving lives around the world, I mean, it is just offensive.

I mean, I just cannot possibly understand why we are spending time sitting here while I listen to people lecturing companies about making money. I hope you make a lot of money. It is a reasonable question what patent length should be. I would like to have that conversation and dialog. I don't know whether it should be one year, five years, 17 years. I don't know. Let's have that debate. I don't know how much we should factor in that NIH puts in \$400 million, \$50 million, I don't know what it is, whatever the number is that has gone into the production of this drug. I don't know how much went into merging these two putting them together and then you guys distribute it versus how much NIH has done. Fine. Let's have this conversation.

But this absurd attack on profit being evil is undermining the entire ability for us to have a rational conversation about the serious questions that are actually before us here. We don't go down—how much cash on hand does Apple have? Two hundred and forty-five billion dollars. How much has Apple done to go cure health? Is Apple in the business of providing direct health care, Mr. O'Day?

Mr. O'DAY. Not to my knowledge, no.

Mr. ROY. Right. Are you in that business?

Mr. O'DAY. Yes, we are.

Mr. ROY. Do you provide medicine or do you run hospitals?

Mr. O'DAY. Our role is to bring breakthrough medicines to patients with devastating diseases.

Mr. ROY. Right. Do you hire doctors to go out and provide care, or do you, for the most part, design, develop, and manufacture medicine?

Mr. O'DAY. My colleagues and I at Gilead are exclusively focused on the design and development of medicines and getting them in the hands of patients.

Mr. EZELL. And, if I may, Mr. O'Day, you employ 10,000 people at Gilead. There are some of the 1.2 million individuals in America's—who are employed by America's pharmaceutical companies who earn an average salary of \$122,000. This is an industry that supports over 5.5 million workers across the U.S. economy considering direct and indirect effects, and it's an industry that supports a high-value-added sector of the economy, high-value exports—

Mr. ROY. Yes, but whatever, profit is evil, right? Making money is apparently evil because never mind all those people you just talked about who are making money and able to pay for their jobs, their salaries, and be able to send their kids to school and be able to buy their houses in our system. This is somehow the wrong thing for us to do?

I mean, again, can we have a roundtable discussion? I am happy to sit down with my colleagues on the other side of the aisle and this side of the aisle and let's have two hours, three hours. Let's get whiteboards up and let's go through all of this stuff and come to a reasonable consensus on some of these tough questions about patents. It is a real concern.

But can we dispense with the ridiculousness of hostility toward profit. It is a good thing that Apple makes a crap-ton of money making these things so that we can have them and distribute them and use them and use them for great additions and benefits to the world. And it is the same thing in medicine.

Chairman CUMMINGS. Before we go on to—Mr. Raskin, just a moment.

Mr. Roy, I have been here—oh, he is gone.

Mr. Roy, I have been here since quarter of 10. I have heard every syllable that has been stated here, and I am sorry you had to leave, but I think the committee on both sides have asked reasonable questions. And I am not beating up on anybody for profit. We are just trying to make sure we understand what the American tax dollars are paying for. We want to understand why the price is so high, and we are trying to understand how we can get the 90 percent of people who need this lifesaving medication, how we can get it to them.

And, as a matter of fact, I have applauded Gilead for their research and what they have been able to accomplish. Now, we are just trying to expand it. And Mr. O'Day has made it clear that they are trying to figure out how to expand treatment and the number of people also who will have access to this medication. So in fairness to the committee, I just wanted to make that clear to my colleague.

Now, we will hear from Mr. Raskin.

Mr. RASKIN. Mr. Chairman, thank you for that thoughtful comment. And I want to followup on Mr. Roy's very interesting and provocative statement there because I think what we are trying to figure out is precisely what are the various public and private ingredients that go into our pharmaceutical system. My friend Mr. Roy doesn't have to look across the aisle to find people who are upset with big pharma. President Trump himself has said that the pharmaceutical industry is getting away with murder. Pharma has a lot of lobbies, a lot of lobbyists, and a lot of power, and there is very little bidding on drugs. So I think that it is not just members of this side of the aisle that have noted some problems in the current system.

But, Mr. O'Day, let me come to you because we know that the taxpayers, through the NIH, which is proudly in my district, in the Eighth congressional District in Maryland, put in \$49 million, and the Gates Foundation put in tens of millions of dollars more into funding the development of Truvada as a method for preventing HIV. And I think a lot of the discussion here is about the fact that tens of billions of dollars have been earned by your company. But how much did Gilead spend on researching and developing Truvada as PrEP specifically as a prevention drug?

Mr. O'DAY. Thank you, Congressman. So it's hard to tease out some of the PrEP activities with the other activities because, at the end of the day, this medicine reduces the viral replication. It's the same mechanism if you like for treatment as it is for PrEP.

Mr. RASKIN. Okay. So how much did you guys put into that part of the process then?

Mr. O'DAY. One point one billion over the course of Truvada's development, which was really for all indications associated.

Mr. RASKIN. Okay. And then the infusion of money that came from the taxpayers and the NIH was essential for the development, I think you would agree, of Truvada for the purpose of preventing HIV?

Mr. O'DAY. Yes. The know-how and knowledge that Gilead put in, the investment from the NIH and the \$50 million, the greater

than \$80 million donation from the Gates Foundation, all of this was important to provide the body of evidence——

Mr. RASKIN. Terrific. Okay. So while we can't imagine this is some kind of Ayn Rand fantasy where the private sector did it all on its own, right? Would you agree with me about that?

Mr. O'DAY. I would agree, absolutely.

Mr. RASKIN. Okay. But what has been the total revenue from Truvada as PrEP?

Mr. O'DAY. The total revenue for Truvada as PrEP is difficult to kind of tease out. Again, we've talked about the number of \$36 billion globally for the entire medicine, but it's very hard because the medicine is prescribed by physicians——

Mr. RASKIN. Got you.

Mr. O'DAY—who often don't know whether it's PrEP or treatment.

Mr. RASKIN. When you set the price for it for U.S. payers, did you take into account the role of taxpayer funding in the development of the drug?

Mr. O'DAY. When we set the price for Truvada originally, we took into account a variety of things, including the impact upon the healthcare system, the ability to make sure we get access to——

Mr. RASKIN. All right. But you didn't take into account the fact that the public was one of the investors in the research?

Mr. O'DAY. Well, at the time we priced the medicine, the public had very little to do with the invention of this medicine.

Mr. RASKIN. Okay. And you are choosing now to donate some drugs rather than reduce drug prices. Will you claim the donation as a tax deduction, as you testified that you did habitually? There is nothing wrong with it, but it will be claimed as a tax deduction presumably?

Mr. O'DAY. I would—that's been my understanding is that at a cost-of-goods level.

Mr. RASKIN. Okay. But one of the shocking revelations from the Senate Finance Committee's investigation into the pricing of your hepatitis C product was that the \$1,000-a-day price you settled on was based on seemingly extraneous or arbitrary factors like the likelihood of a public outcry at a certain price point or the likelihood of receiving a letter from a Member of Congress or the likelihood of facing a congressional committee and a hearing like this. Did you use those same political factors in setting the price for Truvada?

Mr. O'DAY. So, Congressman, again, I was not at the company at the time, but I've looked into those details. I think the overriding factors for the setting of the price for the HCV medicine were based upon both the cost of current treatment at the time and the innovation of bringing this together in a curative setting for 12 weeks of therapy to cure the disease, a huge step up from what was done in the past. Those were the—those are the prevailing means that go into account when we priced——

Mr. RASKIN. Okay. And then finally, last question, just to follow through on the point Mr. Roy raised—and I am sorry he is not here for it—but do you think it is inappropriate in a constitutional democracy where the public invests in scientific and medical research and helps to produce pharmaceutical drugs that the public relies

on, for that factor to be taken into account in the pricing and distribution of pharmaceutical drugs?

Mr. O'DAY. Well, I think it's very important that you consider the access question. Will the medicine get to the patients that need it, including in the government sector and the government-funded healthcare sector, as well as the private sector. So absolutely I think you need to take a variety of things into account in pricing.

Mr. RASKIN. Okay. Thank you. And I wish I could ask you about that access, maybe if we get another round, but I yield back to you, Mr. Chairman.

Chairman CUMMINGS. Thank you very much. Ms. Miller?

Mrs. MILLER. Thank you, Chairman Cummings and Ranking Member Jordan, and thank all of you all for being here today.

In my home county of Cabell County, there has been an increase in HIV cases. In March there were 28 confirmed cases, and in April that number has risen to 44. This number is a sharp uptick from the case where we only had the eight cases annually over the last five years.

Unfortunately, those most impacted are intravenous drug users, which is a terrible result of the opioid crisis that has devastated so many communities across the United States. I am very glad that President Trump is taking the issue of HIV seriously and has secured the donation of the 2.4 million from Truvada for the Centers of Disease Control, and thank you for doing that.

Mr. O'Day, if a patient cannot afford Truvada, are there precautions in place to ensure access?

Mr. O'DAY. Yes, absolutely. So we—if there are—if they have private insurance and they can't afford their co-pay, they can apply to our co-pay assistance programs, and 98 percent of patients that have done that pay nothing out of pocket. And then if they're uninsured or struggle with their medicine, we have a medicine assistance program, which essentially evaluates their financial needs and provides it for free.

Mrs. MILLER. Thank you. Can you explain how the new version of tenofovir if that is how you pronounce it—

Mr. O'DAY. Tenofovir, right.

Mrs. MILLER [continuing]. was—tenofovir was an improvement to patients, and what new benefits does it provide?

Mr. O'DAY. Well, thank you, Congresswoman. So what you are referring to is actually a completely separate medicine from tenofovir. It's a medicine that's called—or abbreviated as TAF. And this is now to—you know, the advancement that we've seen in both treating and preventing HIV/AIDS is that people living with AIDS or people subject to AIDS have the ability to take these medicines now for decades. Tenofovir, when taken that long, a certain subset of patients have issues with their kidney or with bone disease on such a chronic basis because we've essentially transformed the disease to such a long-term illness.

So the new medicine, so-called TAF, which will be combined again with FTC and other agents, has a much lower incidence of these side effects and is really designed for, if you like, the new generation of medicines that will allow patients to be on this longer-term without having to worry about other debilitating side effects that they could get from their medicines. We've launched

this now into the treatment of HIV setting with a medicine called Biktarvy, and we'll be bringing this innovation—it's right now filed with the FDA, and we will—hope to have a positive approval by the end of this year for patients that are eligible for PrEP. So this innovation, this new medicine that was completely discovered and developed by Gilead scientists, is now kind of the next evolution of care for HIV patients.

Mrs. MILLER. How long did it take you to do that?

Mr. O'DAY. Oh, my gosh, well, this was back in the 1990's that we started this, so it's been more than two decades and part of that \$6 billion investment that we've had so far in HIV.

Mrs. MILLER. Wonderful. Would any new patents prevent generics from being created against the original version?

Mr. O'DAY. No, it's a completely separate medicine. It has nothing to do with the patents of Truvada. It's patent-protected from this new innovation that took decades to produce.

Mrs. MILLER. Thank you. Mr. Ezell, do you foresee a future where the NIH could take on the entire of the drug development process from start to finish?

Mr. EZELL. I simply do not think that would be the case. First, the capacities are not there. The NIH focuses on basic scientific research. What industries really bringing to the table is the development aspect of it, doing the applied research, conducting the clinical trials.

Now, this has been proposed. Dean Baker, for instance, has written that, quote, "We could expand the public funding going to NIH or other public institutions to extend their charge beyond basic research to include developing and testing drugs and medical equipment." But Baker estimates that, were we to try to do that, we would likely—quote, "It would be necessary to increase the amount going to NIH by at least \$60 billion a year" in order to, quote, "replace the funding currently supported through patent monopolies. So no, I don't think that's tenable. I don't think we're going to increase NIH funding by \$60 billion a year, especially if we can't increase the—we pass a gas tax.

And more beyond that point, I think there is very little reason to make that dramatic of a change to a system that, as I've tried to say today, is in fact the world's most effective and productive at generating new-to-the-world cures.

Mrs. MILLER. Thank you.

Chairman CUMMINGS. Mr. Khanna.

Mr. KHANNA. Thank you, Mr. Chairman, and thank you to Representative Alexandria Ocasio-Cortez for working to have this hearing.

Mr. O'Day, I want to try to be constructive and not score political points or embarrass you but just get some facts and see if we can make some progress of your commitment. The New York Times wrote that Truvada was developed significantly by taxpayers. Is that a true statement?

Mr. O'DAY. I think that's really inadequate—inaccurate I should say.

Mr. KHANNA. So you disagree with The New York Times editorial board?

Mr. O'DAY. Yes.

Mr. KHANNA. And why is it not a true statement?

Mr. O'DAY. Because the medicine was developed and discovered within Gilead. Some of my colleagues have mentioned that we licensed some initial compounds on this. That's important. Those were very early stage ideas on the product. In the case of TDF, which is one of the components of Truvada, it was not a drug that—at the time, and it went through many iterations before it got there.

Mr. KHANNA. Did you benefit at all from the study that was funded, \$49 million by NIH and the Gates Foundation in terms of understanding the drug could be used for preventing HIV?

Mr. O'DAY. Absolutely. Of the \$1.1 billion we invested, I think that was an important contribution to supporting the HIV—

Mr. KHANNA. And did you—

Mr. O'DAY.—story at the time, and I'm grateful for Dr. Grant's—

Mr. KHANNA. And—

Mr. O'DAY.—leadership.

Mr. KHANNA [continuing]. grateful is good. Have you paid them anything?

Mr. O'DAY. Well, I think there's different ways to look at contribution to society. I mean, we have—

Mr. KHANNA. Right. I mean, I am sure they appreciate the compliments, but, you know, usually if I get something, I pay something for it. I am just curious. It is a simple answer, yes or—usually I don't like yes or no questions, but this one is pretty yes or no. Did you pay them money or not?

Mr. O'DAY. The donations that were provided by NIH and the Gates Foundation did not come with terms suggesting that—

Mr. KHANNA. No, I am not saying that they required it. I'm just asking—so you didn't pay them anything for that?

Mr. O'DAY. No, I think it's in the interest of public health to advance a foundational medicine for additional—

Mr. KHANNA. And it absolutely is. The difference is 99.9 percent of us don't get to profit when it is in the interest of public health. You know, you have acknowledged that this is something that you used to profit, and you haven't paid them back. I mean, that is your decision. I just want to get the facts.

One thing I want to get, are you—I appreciate that you are going to donate these 200,000 drugs. Can you assure us that you are not going to claim a tax write-off for those?

Mr. O'DAY. You know, those will show up on our P&L balance sheet—

Mr. KHANNA. So you will claim a tax write-off. Can you assure us that you will only deduct the manufacturing cost—

Mr. O'DAY. Yes, I can assure you of that.

Mr. KHANNA. So you are going to deduct \$6. You are not going to deduct—

Mr. O'DAY. The \$6 figure is not accurate.

Mr. KHANNA. Okay. But you aren't going to deduct the \$2,000? You are going to deduct something closer to—

Mr. O'DAY. That's correct.

Mr. KHANNA [continuing]. \$6?

Mr. O'DAY. That's correct.

Mr. KHANNA. So it is inaccurate that you would try to get a billion-dollar tax deduction?

Mr. O'DAY. Absolutely not.

Mr. KHANNA. Okay. So let me ask you this. One thing that I think you could commit to that would go a long way, there is some misunderstanding on the 200,000 that you have pledged to the President, and they are saying that that also includes people who are already on your financial aid programs. Can you commit that those 200,000 drugs are going to be in addition to the ones of people who are already part of your financial aid programs?

Mr. O'DAY. Yes, absolutely. I mean, I think it's important to note—

Mr. KHANNA. So you are making that commitment. So in addition to the people you have on financial aid, you are going to do 200,000 new ones, and you are committing today that you are not going to deduct anything beyond the cost on your deductions?

Mr. O'DAY. That's correct. We'll continue to serve patients through our medical assistance program. Today, we have 20 to 30,000 a year. This is an additional 200,000, plus we continue to support all the co-pays. So back to, you know, do we give back, you know, to, you know, inventions that are supported in us? I mean, the answer is yes, in different forms—

Mr. KHANNA. Well, I am glad you have made a commitment because in The New York Times editorial, you know, they will be happy to know. I mean, there was legitimate concern about what tax deduction you are going to take. It seems you are not going to take that. You are going to do 200,000 in addition. Now, if you would just commit to paying back something to the CDC, I think it would go a long way.

Any final thoughts?

Mr. O'DAY. Well, I think, you know, we are collaborating with the CDC on the entirety of the program, so I think this is a partnership. It's one where we provide resources, intellectual know-how, medicine. The government provides funding to support—we're all in this together to get to the HIV elimination, so I think there's give-and-take on a variety of sides, Congressman. Thank you.

Chairman CUMMINGS. Mr. Higgins.

Mr. HIGGINS. Thank you, Mr. Chairman. Madam and gentlemen, thank you for being here today.

Mr. Horn, has Gilead invested approximately \$1.1 billion in developing Truvada? Is that an accurate number?

Mr. HORN. I'm sorry?

Mr. HIGGINS. Approximately did Gilead spend \$1.1 billion developing Truvada?

Mr. HORN. I can't confirm or deny that.

Mr. HIGGINS. Can you answer that, Mr. Ezell?

Mr. EZELL. I would defer to Mr. O'Day, who's from the company. I do not know myself how much—

Mr. HIGGINS. Okay. I was wondering if this was common knowledge. Mr. O'Day, can you clarify?

Mr. O'DAY. I can—

Mr. HIGGINS. According to our research, it costs \$1.1 billion—

Mr. O'DAY. Yes, I can—

Mr. HIGGINS [continuing]. to develop Truvada?

Mr. O'DAY. I can confirm that, yes.

Mr. HIGGINS. And that drug has been quite successful at treating HIV and AIDS, correct?

Mr. O'DAY. It's been a cornerstone of HIV treatment, yes.

Mr. HIGGINS. Thank you. The drug Descovy, are you currently investing a great deal of money perhaps on a similar level to develop Descovy? Is that at phase three right now?

Mr. O'DAY. The phase three trials ran out. They represented at the AIDS meeting in March. It's now been submitted to the FDA for the—

Mr. HIGGINS. How much money are you making on Descovy right now?

Mr. O'DAY. I don't have that number on the top of my head. I apologize, but I can get back to you.

Mr. HIGGINS. Is it being sold?

Mr. O'DAY. It is being sold for the treatment indication, but the prevention indication will be new later this year.

Mr. HIGGINS. Very well. And that is because it is in phase three right now—

Mr. O'DAY. Yes, it finished phase three.

Mr. HIGGINS. And GS-9131, is that an HIV/AIDS drug?

Mr. O'DAY. I believe so. I'm still getting the numbers down.

Mr. HIGGINS. It is in phase two. Is money being spent to develop that drug for HIV and AIDS?

Mr. O'DAY. I'm just not familiar with this particular number, Congressman, so I apologize. But we have a variety of medicines in phase two right now.

Mr. HIGGINS. According to my research, you have four—including Descovy, you have five HIV/AIDS drugs being developed, three in phase one, one in phase two—

Mr. O'DAY. Yes.

Mr. HIGGINS [continuing]. one in phase three.

Mr. O'DAY. Yes, that sounds right.

Mr. HIGGINS. Is that reflective of—so the drugs that are in phase one, these three drugs that are in phase one and treat HIV and AIDS, is there money, tremendous amounts of money being invested in the development of those drugs?

Mr. O'DAY. Well, we spent about \$3.5 billion U.S. a year on R&D and around 40 percent of that goes into HIV/AIDS at this stage. So yes, there's significant—

Mr. HIGGINS. And—

Mr. O'DAY.—investment in—

Mr. HIGGINS. And prior to these drugs that are in development right now being sold and marketed including levels that are being questioned by this oversight committee, I think appropriately so—we must protect the American people. We wouldn't want to gouging, would we? And yet this clearly indicates—our research indicates that you are investing a tremendous amount of money right now into drugs being developed to treat HIV and AIDS, which are not being sold, so you are not making money on these drugs, you are spending money—

Mr. O'DAY. Yes.

Mr. HIGGINS [continuing]. on these drugs?

Mr. O'DAY.—Congressman, and many of those will fail unfortunately.

Mr. HIGGINS. Thank you.

Mr. O'DAY. But it's the nature of innovative research.

Mr. HIGGINS. The ones that succeed and they go to market and they help Americans, perhaps millions of Americans, as Truvada has, is that the corporation's only window to recoup and retain moneys to invest in further research and development? Is that not—

Mr. O'DAY. Yes.

Mr. HIGGINS [continuing]. a logical formula to—

Mr. O'DAY. Absolutely. That's basically our contract with society. We invest a tremendous amount in R&D at a high failure rate. Those that succeed we have a limited patent life to recoup the investment back into investing it and finding cures for devastating diseases. And then it becomes generic and broadly available to society.

Mr. HIGGINS. In the interest of time—thank you for clarifying, but I have limited time. According to our research, besides the five HIV/AIDS drugs that are in development and which you referred to as in the pipeline, you have 28 other drugs that are in the pipeline at various phases of development. Of those 28 additional drugs, would it be fair to say that scores of millions of Americans could be helped with diseases that currently suffer?

Mr. O'DAY. Well, we're certainly hoping, yes. We're working on some of the most devastating diseases—

Mr. HIGGINS. And when a drug is under development, is there any guarantee that it will become a profitable drug for the company?

Mr. O'DAY. Quite the contrary. In phase one, 95 percent failure rates; phase two, 85 percent failure rates; phase three, 50 percent failure rates are the average. In fact, we just had a phase three trial for a devastating disease called NASH that failed.

Mr. HIGGINS. Thank you for clarifying, sir. I think it is clear that this is a worthwhile hearing that should be reflected upon in a balanced measure.

Thank you, Mr. Chairman.

Chairman CUMMINGS. You mentioned African Americans not getting the medication at a far disproportionate rate. Did you mention that?

Dr. WALENSKY. I did.

Chairman CUMMINGS. Can you tell me about that?

Dr. WALENSKY. Well—

Chairman CUMMINGS. Because I am listening to you, Mr. O'Day, and I am wondering—when I first got to Congress 20-some years ago, one of the first issues that we addressed with Maxine Waters was AIDS. And back then the treatment went to gay white males. The African-American community was pretty much left out. And so I am trying to figure out—when I heard those numbers, I am just trying to figure out who is going to cover the African-American communities and whether when you all make those decisions, you know, about distribution, where does that go? I mean, in other words, where do the drugs go and what role do you all play in making sure that there is some equitable distribution?

And I want you to understand I have heard a lot of talk here this morning about how people are beaten up—it is not about beating up. It is about being thankful that we have a medication that can do just about everything but finally cure it, AIDS, and wanting it to get to everybody that it can get to. I mean, it is as simple as that.

So Ms.—Dr. Walensky. I am sorry.

Dr. WALENSKY. Great. Yes, so a couple of comments on that. We know there are about 39,000 new HIV infections in the United States per year. This past—the most recent data that we have we know 80 percent of those new infections were on persons of color. We know that—

Chairman CUMMINGS. Eighty percent?

Dr. WALENSKY. Eighty percent were in persons of color. We know that, of the new infections in 2017, 43 percent were in African Americans. African Americans make up 13 percent of this population. We know that African Americans suffered over 53 percent of the deaths of HIV and AIDS. And we know that PrEP is getting to largely gay white men, which it needs to get to, and about 75 percent, but only about 10 percent of its consumers are people of color.

Chairman CUMMINGS. Now, Mr. O'Day, what can we do about that?

Mr. O'DAY. This is a dire need. We completely agree. And part of the program we've just agreed to with the CDC is focused on 48 hotspot counties, seven rural states, you know, District of Columbia and San Juan, Puerto Rico. These are areas predominantly in the southern United States where the African-American incidence is—we're not reaching and getting to. So we've had programs that are continually focused on supporting the communities, support services that are underway. Now—but we have much more we have to do to get to these communities.

It's make sure that the medicine is not the barrier in these communities, but beyond that, it's making sure we provide the services to both address the issues relative to inequalities in the healthcare system, lack of education, stigma associated with the minority and African-American communities. We need to do more. We're fully committed to rolling up our sleeves to be a part of that.

In fact, I just received an email overnight from an incredible organization in Jackson, Mississippi, that supported 400 patients to get PrEP over the past six years. It's a small start. There's so much more to do. And when they started, they were the only organization in Mississippi that did this. And, fortunately, they have a system there where, once they identify patients—and they're now using telemedicine to try to identify patients—built into their protocols are the ability to access the Gilead support services. And I'm pleased to say that they said, of the 400 patients, none of the 400 had a financial problem with getting the medicine.

But we need to do this in so many other communities, and that's why we're rolling up our sleeves and hoping—and not just hoping but committing to the CDC initiative and others to get to this community.

Chairman CUMMINGS. Ms. Pressley. Ms. Pressley.

Ms. PRESSLEY. Thank you, Mr. Chairman, and thank you, Representative Ocasio-Cortez and all the advocates who made this hearing possible.

And, Mr. Chairman, just picking up on some of your commentary and the comments of our colleague across the aisle who is very impassioned, and I have an equitable amount of outrage about the fact that people are dying. This is not about the vilifying of profit. This is about the vilifying of choosing profit over people. And if we know that a new person is infected every 15 minutes and we have been here two and a half hours, that is 10 more people who have been infected.

And so we have an administration, the occupant of this White House, who sets an aspirational and achievable goal to end this epidemic, and yet we don't have enough infectious disease doctors. We have a cost-prohibitive lifesaving drug, and it is not equitably being accessed. So that sounds like an unfunded mandate. And we have been here before.

And this is the Oversight and Reform Committee, and so it is our job to hold everyone from—you know, I served on the city council before, but any time profit over people, whether it is developers or pharmaceutical companies are engaging in those practices, we are here to shine a light on that and to keep us all accountable. So that is the role of this committee.

So, you know, we should be furious about what we have heard here today. This is the world's wealthiest Nation. There are 40,000 new HIV diagnoses each year. In my home state of Massachusetts, there have been over 140 new HIV cases since 2015, eight new cases in Boston over the last six months.

Now, we have heard a lot of sobering and damning statistics here, but I don't want us to get lost in the numbers and allow that to dominate the conversation because this is about people, our family members, our neighbors, our friends, our constituents like my constituent Matthew. He lives in Somerville. He is a gay man. And Matthew knows he is at higher risk of getting HIV, and for three years, he has been fortunate enough to be on PrEP. His insurance coverage gives him access to the drug at an affordable rate. However, he lives in constant fear that a job change will push it out of reach for him.

There are millions of Matthews in our country for whom PrEP allows them to stand in their truth, safety, and unencumbered by the fear of contracting HIV, but unlike Matthew, there are millions more who need it and still cannot afford it.

It has been 40 years since the first HIV case in the U.S., and this disease still remains a global public health challenge and, as reminded to all of us by our chair in your earlier commentary, particularly for women and queer people of color.

It is my opinion that, Gilead, you have used your power to manipulate our patent systems, monopolized the marketplace to line your shareholders' pockets, and I think that is shameful.

Dr. Walensky, you have studied HIV transmission closely, and, as a physician at Mass General Hospital, you are on the frontlines of this epidemic. Since we are short on time, yes or no, do you agree that by failing to get PrEP in the hands of those most at risk,

including people who inject drugs, we undercut our ability to eradicate this disease?

Dr. WALENSKY. Yes.

Ms. PRESSLEY. Thank you. Can you speak to how substance abuse disorders specifically for those who inject drugs with needles, have heightened the need for greater access to PrEP?

Dr. WALENSKY. Our hospital is full of injection drug users right now. We have double our consult volume in the last decade much due to injection drug use. And there's been an outbreak in Lawrence and Lowell, as you know, in Massachusetts that was reported in the MMWR by the CDC. So yes—an HIV outbreak I should say. So yes, we need PrEP for all people at risk.

Ms. PRESSLEY. Mr. O'Day, Gilead plans to donate millions of bottles of PrEP and bring a generic product to the market in the next few years. At face value, this seems like a good idea, although, you know, two years is two years too long. But the CDC estimates only a fraction of the 1.1 million people who need PrEP have access to it. The donation your company announced would reach even less people.

Now, I recognize your company's efforts to provide financial assistance for people without insurance who can't afford it, but given the uptick in HIV infection, these efforts simply don't keep pace. They don't go far enough. Mr. O'Day, can you guarantee that the donated medications will go to people who do not already have access to the drug?

Mr. O'DAY. Yes.

Ms. PRESSLEY. Thank you. In Canada and Australia Truvada is sold for less than \$10 a pill. It seems to me if your company wanted to, you can make the drug affordable for everyone. What has stopped your company from lowering the price to a comparable rate in the U.S.?

Mr. O'DAY. The patent exclusivity ends, as you know, in September of next year, and we will, you know—the pricing between the countries is very different. It's a very heterogeneous systems between the United States and in other countries, and the pricing, as set in the United States, takes into account the innovation it brings, the cost of the health care of treating an HIV patient, the ability to invest back in research and development, and then also to make sure our access programs are effective and that patients in America do not go without receiving this lifesaving medicine.

Ms. PRESSLEY. Well, it's—

Dr. LORD. It's greed.

Ms. PRESSLEY. Yes. Okay. So I was going to say just, you know, respectfully, in that every 15 minutes a new person is infected, the more time we waste, the more lives that we are losing. And again, this is an aspirational and achievable goal, and so it is really infuriating. There are clearly many barriers people are facing in accessing this lifesaving medication, and price should not be one of them. Gilead could make PrEP more affordable in the U.S. and therefore more accessible if you want to, if there is the moral courage and the fortitude and the commitment to do so. Your failure to do so is indefensible. Your company brings in record-level profits while holding hostage a drug that could end this epidemic. There isn't a

country in this world where this type of greed and conduct will be tolerated, so I am not sure why we tolerate it in this one.

Thank you, Mr. Chairman, and I yield back.

Chairman CUMMINGS. Thank you very much. Ms. Tlaib.

Ms. TLAIB. Thank you, Mr. Chairman. And, Mr. Chairman, thank you so much for always supporting us, especially us new class of women that have come in to this U.S. Congress. It speaks volumes to your character.

I also want to thank my sister from New York, Congresswoman Alexandria Ocasio-Cortez, and the incredible advocates that are behind her and making sure that we always speak truth to power.

What is evil, Mr. Chairman? And I talked with you about this. What is evil is that people are dying a painful death all because of corporate greed. How much profit is enough, Mr. O'Day? When does it become immoral? And in my district I have the third-largest population of those infected in the state of Michigan. And as I think about you saying you are helping folks, I look at numbers because it is important. And when you say you are going to provide assistance, 200,000 people when 1.1 million people need your assistance, it is baffling.

And I agree with Dr. Lord. I agree that Truvada belongs to all of us. And it is our responsibility in this chamber to make sure that we are putting people before profit. And it is really absurd that, as I hear my colleagues defending this practice over the American people that brought us here, it is disheartening because in the last five months, I don't care which committee I go to, corporate greed is the issue always. It is always about the money and about profit. And as Mr. Chairman has constantly always said, there is no problem with that, but when does it become immoral? When does it become so unjust that we are seeing our neighbors die, die because drugs are just not accessible to them, drugs that we created, the Federal Government on behalf of the people?

And so I just want to urge Mr. O'Day to please take Dr. Lord's recommendations. This is your time to do what is right for the people and do what is right for our country.

And with that, I want to yield to my sister from New York, who is, again, such a shed of light in this time of darkness in our country, that is constantly always putting people before profit, and that is Alexandria Ocasio-Cortez.

Ms. OCASIO-CORTEZ. Thank you. That is incredibly too generous. Thank you.

And I would like to thank my sister and colleague from Michigan because, you know, I see you go home every weekend and connecting with your community and really bringing yourself to hold that space and feel what your constituents feel.

Mr. O'Day, I just want to clarify and let you know that this isn't about you, and I am not here to vilify the work that you have done because you are responding to a set of incentives. And you could, you know, resign today, there would still be someone that would come up and occupy this seat, responding to those same incentives, making the same decisions that you make. So this isn't about you as an individual or who you are or your character. This is about the system of incentives that we have set up.

And when it comes to who to blame for this, I don't blame you. I blame us. I blame this body because every single developed country in the world guarantees health care as a right except us, except the United States because we can't get it together, because we don't have the fortitude to kick pharmaceutical lobbyists outside of our congressional offices.

We have a leader here, Mr. Sarbanes, who has led in the role of money and politics. We can't even reform our own political system to make sure that we are more responsive to the people and the electorate that we seek to lead and whose votes we ask for.

And so this isn't your fault. This is our fault because for some reason, for some reason the conclusion that every single other Western or rather developed country in the world has come to, we haven't been able to come to. In Australia, PrEP is \$8 a month. In the United States, it is almost \$2,000 a month because we have legislated a set of incentives, and we have legislated a system that allows that to happen.

Out of every 10 people that need PrEP, nine of them cannot access it, and that is largely due to the price. We heard earlier today an impassioned plea about profits and about how a corporation like Apple should be able to enjoy that. Well, I know a woman, her name is Amy Vilela and her daughter died because she went to a hospital and told them that she wasn't insured and they said come again in a month when you do have insurance. Well, her blood clot didn't wait a month. Her daughter died at 22 years old. And the rub of it was that her daughter, I believe, might have actually been insured and just didn't know it because she was in between jobs.

And so what Amy says, what Ms. Vilela says is this is a commodity. Her daughter's life was not. People's lives are not commodities. When we talk about economics, there is something known as a demand curve with elasticity. And with every other commodity, you can say how much is this phone worth to you and you can say \$100, \$200. You can buy a Nokia phone. You cannot have a phone at all, but you cannot ask the question how much will you pay to be alive? How much will you pay to live? Because the answer is everything. The answer is you will pay \$10, you will pay \$1,000, you will go into debt, you will do anything to live. And that is what makes the price of medicine different than the price of an iPhone.

Thank you very much.

Chairman CUMMINGS. The gentlelady's time is expired.

Mr. SARBANES.

Mr. SARBANES. Thank you, Mr. Chairman. I am tempted to just say amen and stop talking, but I do have a couple of questions I would like to—

Chairman CUMMINGS. Me, too.

Mr. SARBANES. Yes, I would like to get on the record. Mr. O'Day, this new drug that is going through the process, Descovy, is that how you say it?

Mr. O'DAY. That's correct, Congressman.

Mr. SARBANES. Yes, that is based on this component that has TAF as opposed to TDF.

Mr. O'DAY. Correct.

Mr. SARBANES. Is that something you are going to pursue exclusivity on in terms of the patent around that? What is—

Mr. O'DAY. It's a brand-new medicine.

Mr. SARBANES. Yes, brand-new—

Mr. O'DAY. It has a patent life, as granted to it under the patent statutes.

Mr. SARBANES. I know there are some questions being raised out there. I think it has found its way into litigation as to whether Gilead knew back when it was developing TDF that the TAF opportunity might be a safer one. And I am curious as to whether you were aware of the safety benefits associated with TAF at the time when TDF was being developed.

Mr. O'DAY. Absolutely not. I mean, TAF was still in the very early stages.

Mr. SARBANES. Okay.

Mr. O'DAY. We pursued the development of that for treatment and for prevention in line with the natural course of development.

Mr. SARBANES. Dr. Lord, did you want to say something?

Dr. LORD. We know that Gilead in 2011, the ex-CEO actually said that they stopped the development of the safer TAF drug because they knew—they knew it was not as safe, and when they were trying to launch Truvada versus another drug Epzicom at the time—and this is a quote, they said “and to have our own studies suggesting that Viread”—which is part of Truvada—“wasn't the safest thing on the market, which it certainly was at the time, it didn't seem like the best.” So we have evidence from their CEO that they purposely delayed—

Mr. SARBANES. Well, that—

Dr. LORD [continuing]. development of the safer drug.

Mr. SARBANES. I appreciate that. And it is obviously going to play itself out. I mean, we will—

Dr. LORD. See you in court.

Mr. SARBANES [continuing]. the courts will decide, I guess, whether these allegations are well-founded or not. But it is interesting that the effect of this is that with the new Descovy TAF-based drug that is coming, you are going to get another period of exclusivity. So am I right that essentially what is being achieved there is that by first pursuing the TDF-based Truvada with apparently the safety risk and now pursuing the safer TAF-based drug of Descovy, basically Gilead is going to reap the benefit of two periods of exclusivity rather than one, correct? I mean, that is just factual.

Mr. O'DAY. Well, these are two completely different medicines.

Mr. SARBANES. Right, but—

Mr. O'DAY. This is a step—

Mr. SARBANES. I got you—

Mr. O'DAY. This is a step change in innovation—

Mr. SARBANES. That is going to be subject to debate and whatever, but you are going to get a period of exclusivity, which you are still in for the TDF-based Truvada, and then you are going to get another period if this all works out for you of exclusivity for the TAF-based Descovy. That is how it looks to me.

I have got to move on real quick to one other series of questions I wanted to ask you. I understand that Teva Pharmaceutical got FDA approval for a generic equivalent for its Truvada back in June 2017. And so it raises the question if that generic drug was ap-

proved in 1917, why did it not enter the market in 1917? And apparently, the answer is that three years previously in 1914 Gilead had entered into a settlement agreement with Teva under the terms of which Teva agreed not to challenge Gilead's patents in court. And so in exchange, Gilead allowed Teva to come to the market in 2020, which is a year earlier.

So you made this deal with them that basically said we will let you come in a year earlier if you, I gather, don't sue us on the patent. And maybe you saw some weakness there, and this was a good deal to make, but is that true that there is some agreement that was made there with Teva where they are going to be able to come in a year earlier in return for something that was done? Is that true?

Mr. O'DAY. So this is a fairly normal process of generics coming in, challenging patents—

Mr. SARBANES. Yes.

Mr. O'DAY.—and then a determination is eventually made on the cost of litigation, the potential litigation. We believe strongly in the Truvada patents. At the end of the day—

Mr. SARBANES. It is pretty typical. You are right about that. And you have done it in I think nine other instances, the effect of which—there are all these ways to extend your patent control. One is pay for delay. This is a little bit different. This is making a deal basically so people won't challenge the patent, which to me signals maybe some concerns about the weakness of the patent, but you have figured out a way to push that off. So it just makes me concerned about how you are conducting the business because the bottom line is these generics don't get to the market as quickly as they could. And I understand from Dr. Walensky that the benefits of that in terms of the pricing may not be as much as we fantasize about. But nevertheless, it is important that the generics be able to get to market quickly or as quickly as they can. And we are seeing some maneuvers on your part I believe that keeps that from happening.

With that, I would yield back my time, Mr. Chairman.

Chairman CUMMINGS. Ms. Speier.

Ms. SPEIER. Thank you, Mr. Chairman. Thank you all for being here.

At the outset, it is important for me to disclose that Gilead is a company in my district with 9,000 employees around the world, many of them in my district.

Having said that, Mr. O'Day, I am glad that you are here. I am glad that you have participated in the manner that you have. I think you do have a responsibility to your shareholders. I also think you have a responsibility to our country. And you are doing what you are doing in large part—and I agree with Ms. Ocasio-Cortez—because the system allows you to do it. And we have got to take responsibility for the fact that when Medicare part D was created, we tied our hands behind our backs and did not allow Congress or the government to negotiate prescription drug discounts.

Now, I am deeply concerned about the 1.1 million people that Dr. Walensky talked about who warrant PrEP right now. They are those most susceptible to potentially getting HIV. But only 150,000 of those 1.1 million people actually do, and of those, they are 75

percent white. So the people that desperately need this drug are African-American gay men. One in two black gay men will be diagnosed with HIV in their lifetime.

So knowing all this, I want to know—and here I am negotiating with you in public over something frankly the government should have been doing a long time ago. Are you willing to provide P.R. ads—you put lots of ads on TV, I see them all the time for your drugs. Will you put ads on TV that are targeted at the African-American gay men who should be getting this drug and who are not and make them also aware of the fact that you are making available this drug for free to those who need it?

Mr. O'DAY. Thank you, Congresswoman. Just to clarify, the numbers that we have are around 200,000 people are on—of the 1.1 million are on the Truvada today. There's clearly a huge unmet medical need to your point, and again, the CDC's own studies suggest that, with the Gilead support programs, there's only 1 percent that aren't on it for financial means.

We are firmly committed to working in a number of ways to outreach—

Ms. SPEIER. Okay. Mr. O'Day, I don't have a lot of time.

Mr. O'DAY. Right.

Ms. SPEIER. Will you commit to developing a P.R. campaign for TV to target the African-American population that is most susceptible to getting HIV and making them aware that the drug is available and it will be made available to them for free?

Mr. O'DAY. We do do television advertising today for this community. We do digital advertising. We commit to—

Ms. SPEIER. That is not working.

Mr. O'DAY. We commit to a variety of programs that are getting at this community today. And it is increasing, but there is much, much more to do, which is why the CDC initiative, which it is their numbers that suggest that 200,000 people are uninsured of those 1.1 million, and we are providing the total amount to make sure that we get that to patients, and we'll continue to work—

Ms. SPEIER. But if people don't know about it, it doesn't matter that you are making 200,000 doses or enough for 200,000 people. If they don't know about it, they are not going to access it. So—

Mr. O'DAY. Right.

Ms. SPEIER [continuing]. I feel that you have a moral obligation to inform that population. We have to save these lives. We do know that HIV is increasing because young gays, particularly in my district, are feeling immortal now, and since this disease is becoming chronic, that they can engage in unprotected sex, and so HIV is on the increase. So, as the biggest provider of the drug that protects these individuals, I believe you have to do more, and I am asking you to do more.

Mr. O'DAY. Yes, and we will continue to do more. We spend more than \$100 million over a 10-year period on a compass program that specifically targets the southern states in the United States that focuses on education, that focuses on access to health care, and we'll continue to roll up our sleeves and work with the community and work with other organizations to be able to increase this presence. Absolutely we commit to that.

Dr. LORD. It's obviously not working, though, and this donation really is not anything meaningfully different than their medication access program, which they already have, which, as you say, is not working. It's only reaching, as Mr. O'Day said, 20,000 people—

Ms. SPEIER. Okay. So, Dr. Lord, what would you recommend?

Dr. LORD. I would recommend that they lower the price—that they lower the price so that Mr. Horn's organizations can get drugs to the people that need them. Instead of spending \$2.6 billion, which is the domestic spend on Truvada, I say we spend that money to develop programs for Mr. Horn's agencies to get drugs to these people that need it. They don't just need a free drug. They need programs, and we're not going to do that with a donation. We're going to do that when we spend serious money, instead of sending it to Gilead, to giving it to the states, to the counties and municipalities that need it.

Mr. O'DAY. And Gilead is spending hundreds of millions of dollars on these programs.

Dr. LORD. We're spending \$2.6 billion, so, yes, you give us a few hundred million back, but we're giving you the vast majority of that to begin with.

Ms. SPEIER. All right. My time is expired, but, Mr. O'Day, I hope that you will take my request seriously and come back to us with a campaign that will engage the whole community that is not aware that your program exists. I yield back.

Chairman CUMMINGS. We want to be effective and efficient. Is there any agency that can identify who these people are that need this treatment, Dr. Walensky? In other words, can we pinpoint them, I mean, who they are? Do you follow me?

Dr. WALENSKY. Yes, I do.

Chairman CUMMINGS. And that way you can go straight to them.

Dr. WALENSKY. Yes, thank you for that question. I want to go back to a number that keeps getting cited that is 98 percent of people get access and 1 percent of people don't have—don't—cite cost as the issue. Less than 1 percent of people don't cite cost as the issue. That was a study that was funded by the CDC, it was conducted by the CDC. It was a household survey. So we know that—so we know that adults who are surveyed in the household don't think that they have a problem accessing PrEP. Well, I can tell you what, those are not the people who actually need access to PrEP.

We know that of our youth that are—that about 10 percent of our youth are gay. We know that of our homeless youth, 40 percent of them are gay. And you know what, they're not filling out household surveys. So I think part of the challenge with access to PrEP is that these folks are not easily coming forward.

When we talk about gay black men, they don't have a good reason to come forward. And I can promise you that teenagers and 20-year-old gay men are not accessing health care. They just don't come to the doctor. So—

Chairman CUMMINGS. And how can we reach them? How do you—

Dr. WALENSKY. I think we needed to decrease stigma. I think we need to have advertising. I think we need to open our doors to these people so that they will come, welcomed and loved, and access these drugs and come quarterly. So I know the other statistics

that's been thrown out is 200,000 people are currently on PrEP. Two hundred thousand people have ever been on PrEP. We learned at the HIV meetings in March 34 percent of people don't take it for longer than a year.

Chairman CUMMINGS. And, Mr. Horn?

Mr. HORN. Thank you. So we've been really discussing cost as a considerable factor here, and cost does remain, you know, a key issue here. But I think when we sort of open it up a little bit, we really have to talk about really sort of financing sustainable healthcare systems, you know, for the individuals that we're trying to reach here.

And I just do want to circle back on one thing here. I think that, you know—I think the—you know, the hearings, it's sort of just centers around acrimony around like, you know, that—we're against profit, that Gilead is the enemy. Neither is true. Neither is true in that. And I am surrounded by activists, by clinicians, by academics, by policymakers who have all fought tooth and nail with health insurance companies, with Medicaid to make sure that Truvada was covered.

However, what that comes back to is the issue of cost. And even with the co-pay assistance program, again, that has been—that has really been elementary in just ensuring access there, but it really does come down to an issue of cost as to why those programs are even necessary in the first place.

So we're all in this together. We're all looking for solutions here. We're just not—we don't have one good guy, we don't have one enemy. We really have to think about our entire system and how costs manifest across that entire system and what are we going to do about that going forward? Thank you.

Chairman CUMMINGS. Mr. O'Day, do you all—your board—I know it may be out of the ordinary, but does your board ever hear from people like Dr. Walensky and Mr. Horn?

Mr. O'DAY. Well, as you know, I just joined a couple of months ago—

Chairman CUMMINGS. Right.

Mr. O'DAY.—so I don't know the past practices of the board, but—

Chairman CUMMINGS. No, I was just wondering.

Mr. O'DAY. But I think the voice of the patient and voice of the community is represented in the company in very, very meaningful and serious ways. There's many, many community leaders that have joined Gilead, many HIV top physicians that are now part of Gilead. It is a part of the fabric of Gilead in my—if you'll allow me—in my two and a half months, Mr. Chairman, that you feel very connected with all aspects of the continuum of care here. And people take it very seriously. I mean, our role is to develop the next transformational medicine, but it's also to work as a member of this community in a very responsible way, and we take that seriously.

Chairman CUMMINGS. Finally, where are the negotiations with the CDC? Where are they right now? I mean, you did the 200,000. Is that ongoing? Do you follow me?

Mr. O'DAY. Well, yes, I mean, the details of the program, how to implement it, those are all now ongoing. The commitment is clear.

And, as you said before, I mean, I think we would respond to other requests for the commitment. But now we're working through the details and trying to get it implemented as quickly as we can.

Chairman CUMMINGS. Mr. Jordan?

Mr. JORDAN. I would just thank our panel and again thank Gilead for the amazing drug they developed and the difference it has made for, as I said earlier, millions of people around the world.

Chairman CUMMINGS. Without objection, letters the committee has received about this issue are entered into the hearing record from a number of organizations, including the Treatment Action Group, the AIDS Vaccine Advocacy Coalition, and the HIV Medicine Association. All of these groups have written to express their concerns about the impact that the high price of Truvada is having on their members, their communities, and the American healthcare system.

Chairman CUMMINGS. I would also like to thank our witnesses for testifying today.

And without objection, all members will have five legislative days within which to submit additional written questions for the witnesses, and they should be submitted to the chair, which will be forwarded to the witnesses for their response. I ask our witnesses to please respond as promptly as you possibly can when you receive those written questions.

With that, the hearing is adjourned.

[Whereupon, at 1:30 p.m., the committee was adjourned.]

