

**THE HIGH COST OF HIGH PRICES FOR HIV/
AIDS DRUGS AND THE PRIZE FUND ALTERNATIVE**

HEARING

BEFORE THE

SUBCOMMITTEE ON PRIMARY HEALTH AND AGING

OF THE

COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS

UNITED STATES SENATE

ONE HUNDRED TWELFTH CONGRESS

SECOND SESSION

ON

EXAMINING THE COST OF HIV/AIDS DRUGS AND THE PRIZE FUND ALTERNATIVE, INCLUDING S. 1137, TO PROVIDE INCENTIVES FOR INVESTMENT IN RESEARCH AND DEVELOPMENT FOR NEW MEDICINES, TO ENHANCE ACCESS TO NEW MEDICINES, AND S. 1138, TO DE-LINK RESEARCH AND DEVELOPMENT INCENTIVES FROM DRUG PRICES FOR NEW MEDICINES TO TREAT HIV/AIDS AND TO STIMULATE GREATER SHARING OF SCIENTIFIC KNOWLEDGE

MAY 15, 2012

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**THE HIGH COST OF HIGH PRICES FOR HIV/
AIDS DRUGS AND THE PRIZE FUND ALTER-
NATIVE**

TUESDAY, MAY 15, 2012

U.S. SENATE,
SUBCOMMITTEE ON PRIMARY HEALTH AND AGING,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The subcommittee met, pursuant to notice, at 10 a.m., in Room SD-430, Dirksen Senate Office Building, Hon. Bernard Sanders, chairman of the subcommittee, presiding.

Present: Senator Sanders.

OPENING STATEMENT OF SENATOR SANDERS

Senator SANDERS. We're going to begin the hearing, and I want to thank all of you very, very much for being here. In my view, the issue that we are discussing today is of monumental importance. And while it may be controversial within the halls of the U.S. Congress, I have the feeling that the more the American people understand this concept, the more support that there will be.

And I think it's fair for me to tell you that I do not expect the legislation that we'll be discussing today to be passed tomorrow or in the next few months. For the U.S. Congress, this is a fairly radical piece of legislation. We have many billions of dollars of opposition that will be out there from drug companies and other sources.

But I believe from the bottom of my heart that this issue is so important that discussion has got to begin as soon as possible, and that's what we're doing today. So the ideas that people may be hearing on C-SPAN today may sound fairly radical. In a few years, they're not, because I think what we're talking about is absolutely commonsensical, and it's absolutely in the best interest of the people of our country and people throughout the world. So I want to thank all of you for being here, not just for being here today, but for the work that many of you have done for many, many years on this subject.

I start my approach to healthcare from a very basic premise—and it's something that I have believed throughout my entire life—that health care is a right, not a privilege, and that poverty—the inability to pay for medicine or healthcare in general—should not be a death sentence, neither in the United States of America or anyplace else. And yet, to a significant degree, that is the case. Today, some 45,000 Americans die each year because they don't get

to a doctor when they should, and many, many others are suffering.

Now, to me, one of the great moral issues of our day is that there are people in our country suffering and in some cases dying because they are not able to afford a medicine that can be purchased for pennies per treatment. In other words, it is one thing—and I think we can all understand this—if somebody has an illness that is unable to be treated—we don't know how to treat it—that death is a tragedy, but it is a different type of tragedy.

It is a needless tragedy when somebody dies because they can't pay a few pennies for a drug that is out there that can cure them and ease their suffering. And that's what we're talking about today. The analogy would be if somebody were in the middle of a swimming pool and drowning, and somebody turned their back and said, "I'm not going to jump in that pool and save that child."

The United States has today, as I think most Americans know or should know, the highest prices in the world for prescription drugs. According to the Canadian Patented Medicines Prices Review Board's annual survey, average prices for patented medicines in the United States in 2009 were 85 percent higher in the United States than in Canada, and approximately 150 percent higher than in France, Italy, Sweden, and Switzerland.

Price differences on certain drugs are far greater, some of which I'll be talking about in a minute. The simple fact is that the prices of patented medicines are a significant barrier to access to health for millions of uninsured and underinsured Americans, let alone people in the developing world, and people die because of that.

Now, this is an enormously important issue, and it's an issue that says that our healthcare system is a system which allows significant numbers of people to die and suffer because they can't afford medicine. According to the Kaiser Family Foundation and the Harvard School of Public Health, 40 percent, 40 percent of Americans reported experiencing, quote,

"at least one of three cost-related concerns in their family: 16 percent say it is a serious problem to pay for prescription drugs; 29 percent say they have not filled a prescription in the past 2 years because of the cost; and 23 percent say they have cut pills in half or skipped doses in order to make a medication last longer."

I remember talking to a physician in northern Vermont, a primary care physician in a working class town in my State, and she said, "Yeah, I write out the prescriptions, but 40 percent of the people don't bother to fill them." Now, what sense does that make? What sense does that make, when people are unable to fill and pay for a prescription? It makes no sense. People then get sicker. They end up in the hospital, a great cost to the entire system, not to mention all of the suffering that is involved.

Stop and think for a moment what these numbers really mean. While we now take it for granted, one of the great advances of the 20th Century was the advent of modern medicines capable of treating a wide range of debilitating and fatal illnesses. But all of that research and all of that development doesn't mean a thing if somebody cannot afford to purchase that drug.

Now, the concept we are discussing today is relevant, of course, to all kinds of diseases, and we have introduced legislation based on the Prize Model for all kinds of diseases. But today, the legislation that we are discussing deals strictly with HIV/AIDS medicine.

Now, let me tell you why I have introduced separate legislation just to deal with HIV/AIDS. And the reason is that it simply blew me away—and I think would blow anyone's mind away—to understand that one drug, Atripla, costs over \$25,000 per person, per year, for a course of treatment, but that a generic, FDA-approved version of the very same drug is being purchased from a competitive supplier by a U.S. Government program—and that program is, of course, the President's Emergency Plan for AIDS Relief, PEPFAR, for under \$200 per patient for distribution in developing countries.

So let me repeat that again in case somebody in the C-SPAN world didn't get it. And that is that the same exact drug, which in a local pharmacy here in Washington, DC, will cost a patient \$25,000, is being purchased by the U.S. Government for distribution in the developing world for \$200—\$25,000—\$200.

Now, according to the CDC, approximately 1.2 million people are living with HIV in the United States. Each year, approximately 50,000 Americans are infected with HIV, and approximately 17,000 people with AIDS died in the United States in 2009. Globally, of course, the numbers are staggering.

According to the World Health Organization, there are more than 34 million persons living with HIV/AIDS worldwide, and 2.7 million more are infected each year. Ninety percent of the 34 million HIV-positive persons live in developing countries—over 30 million persons—yet only approximately 7 million of them are receiving treatment. So in the developing world, the vast majority of people who are struggling with HIV are not getting the therapy that they need.

Although medicines can slow or even halt the advance of HIV, many Americans—now we're back in the United States of America—diagnosed as HIV-positive are not taking the medicines they need because they simply cannot afford to buy them. The increased demand has overwhelmed Federal financial support for the AIDS Drug Assistance Program, ADAP, administered by the States. In fiscal year 2010, ADAP served a record 229,000 people, reflecting an increase of 24,000 people over fiscal year 2009, and a 40 percent increase since fiscal year 2007. However, during that same period, Federal funding only grew by 9 percent.

So here's where we are in the United States of America. I'm not talking about South Africa. We're not talking about the developing world. Funding shortages caused ADAP waiting lists that had been whittled down to 361 people nationwide in 2010 to grow to a high of 9,217 people in 12 States as of August 2011. And they are still at 2,700 people as of May 10, 2012. That's 2,759 Americans last week who need to be on treatment who are not.

And that, frankly, is only part of the story, because many more are simply being kept off or thrown off the waiting lists due to stiffer eligibility requirements. For example, if your income is just a little too high, or your State has a cap on the number of people who can enroll, you may not even get on a waiting list.

So, to summarize, all over the world, millions of people are suffering from HIV, not getting the treatment they need. In the United States of America, people are suffering with HIV, not getting the treatment they need, although the treatment is extremely inexpensive.

That's the challenge that we are going to address today. How do we deal with that? And the approach that we are offering today—and I'm so happy that our very distinguished panel is here to discuss it with us—is that in the case of AIDS, people can get the drugs that they need—should be able to get the drugs that they need at prices that they can afford.

That's the radical concept that we have. People should not be dying because they can't afford a rather small cost for drugs. And the solution that we are offering is a Prize Fund proposal targeted to HIV/AIDS medicine, S. 1138, and that's the legislation we're discussing today.

Now, under this bill, innovation would be rewarded annually from a \$3 billion Prize Fund for HIV/AIDS. The Prize Fund would make awards to developers of medicines, based primarily on the added therapeutic value a new treatment offers and the number of people it benefits.

Products would have generic competition immediately after FDA approval, that is—and here is the key point—the bill would eliminate today's high-priced marketing monopolies, where a company says, "We own the patent. Nobody else can have it. We can charge as much as we want for the medicine"—in the case of Atripla, \$25,000 a year for a patient.

As some of our witnesses will discuss, companies receive a prize today for bringing a new drug to market. They do receive a prize. But it's called a monopoly. That's the prize that they receive.

Under the legislation we are discussing today, instead of making their money by charging their patients outrageously high prices—in the case of Atripla, \$25,000 per year—innovative companies would be making their money by receiving Prize Fund payments for producing important medicines that ease suffering and save lives. Once that medicine is approved for sale, that company can receive prize payments, but the medicine goes to the market at an affordable price because of generic competition. Again, in the case of Atripla, instead of \$25,000, generic companies are making it for \$200.

There are many other aspects that we will discuss today. But, in essence, the concept is designed to accelerate innovation and expedite access to lifesaving medicines at the same time—more new ideas to tackle the serious health problems facing humanity, getting that product out to the market as inexpensively as we possibly can.

This legislation would reward true innovation, eliminate the market incentive for copy-cat drugs, and get all HIV/AIDS treatments to the people who need them at generic prices, which some have estimated to be under 1 percent, on average, compared to brand name prices for HIV/AIDS medicines.

I believe that by breaking the link between drug prices and the rewards for medical research and development, we can provide virtually universal access to medicines as soon as they are available

on the market. We can end rationing and restrictive formularies, and we can manage overall research and development incentives through a sanely administered fund that provides significant rewards, but only for new medicines that actually offer new value. The bottom line would be better products sooner and generic prices for all pharmaceutical products right away, not after 10 years of astronomical prices.

How do we pay for it? It pays for itself, and then some. While a \$3 billion per year fund for this may sound like a lot of money, when you compare it to the savings we would realize by paying generic prices for the approximately \$9.7 billion IMS Health estimates was spent in 2011 on the top 15 brand-name HIV/AIDS drugs last year, before rebates or discounts, it is a bargain.

So, in other words, the initial investment does cost money, but we save money long-term. That is why this bill would require all private health reimbursement and insurance programs to contribute to the Prize Fund in an amount proportionate to the number of HIV/AIDS patients covered by private plans.

To conclude, the bottom line is that the goal of our laws and policies for medicines must be to develop drugs as quickly as possible, drugs that are the most effective we can find for the diseases people are facing, and to get them out to every person who needs them as soon as possible. That is what I have tried to do with S. 1138 for HIV/AIDS treatments. We should reward innovators for developing these new medicines in a way that does not force any of those who need the drug to wait, suffer, and in some cases die.

I want to thank the panel that we have with us today. This is not only a distinguished panel, but it is a panel of folks who have been working, in some cases, on this issue and are very familiar with this issue. And I want to thank them again, not only for being here today, but for the work that they have done for so many years.

Let me begin with Dr. Mohammed Akhter. Dr. Akhter is the director of the DC Department of Health. Dr. Akhter has served as the executive director of the National Medical Association, the executive director of the American Public Health Association, and commissioner of Public Health for the District of Columbia. He has also been a professor at Howard University College of Medicine and the senior associate dean for Public and International Health at Howard. One of Dr. Akhter's stated goals for the DC Department of Health is expanding HIV services, including making them available on demand.

Dr. Akhter, thank you so much for being with us.

STATEMENT OF MOHAMMED N. AKHTER, M.D., MPH, DIRECTOR, DC DEPARTMENT OF HEALTH; EXECUTIVE DIRECTOR OF THE AMERICAN PUBLIC HEALTH ASSOCIATION FROM 1997-2002; WASHINGTON, DC

Dr. AKHTER. Good morning, Chairman Sanders. I appreciate the opportunity to be here. I want to thank you for holding these hearings, and I'm honored to be here to testify in support of your bill, S. 1138. We thank you for all the work that you have done in the past.

I know for many years that you have been always a tireless advocate for the American people's health and want to make sure

that people have the services available, accessible, and affordable to them. And I think this bill is a continuation of your lifelong effort in making sure that the people have the access to the medication that people so desperately need in order to live and live healthier lives.

I want to share with you this morning and the members of the committee the successes that we have in our Nation's capital, Washington, DC, in dealing with the HIV/AIDS epidemic. The District of Columbia has emerged as a leader in prevention. We've been doing the HIV testing and educational programs in the schools. We are testing in the clinics and the emergency rooms. But we are also testing for HIV in the DMVs, where people come to get their driver's license, or in social services centers, where people come to get social services, so that it's widely made available and accessible.

Last year, we tested 122,000 people, which means one out of five citizens in the District of Columbia had the chance to come and get tested and know their status. But that's not all. We've also been very active in connecting people once they've been tested to the treatment. Seventy-five percent of the people that tested positive were connected to the treatment within 3 months.

Our mayor, Mayor Gray, and the city council have been very actively in support of HIV/AIDS treatment, because treatment and prevention are now linked together. You can't do one without the other. And so we have made the treatment on demand available to all who test positive, so nobody in the District of Columbia is turned away.

In fact, we know in other States that the waiting lists—and sometimes people come to the District and register themselves so that they can get the free medication. And that's a shame, because everybody ought to be able to get the medication where they live and where they work.

Mr. Chairman, also, I want to say because of our work in prevention, in treatment, we've been very successful because we had a very close collaboration with the Federal Government, particularly with the Centers for Disease Control, Kevin Fenton, and also with the National Institutes of Health, where Tony Fauci has taken a personal interest in the District to make sure that we have the best research available to be able to act upon it.

So because of our work in the District, along with our community-based partners, since 2009 there has not been a baby born with HIV in the District of Columbia—since 2009. The number of cases of people dying from HIV has been reduced by more than 50 percent in the last 5 years. The number of persons—and also because of our good preventive work, the new cases have for the first time started to decline—the number of cases.

This is a tremendous success story. HIV/AIDS funding through HRSA played a big role in terms of providing us the ADAP drugs that we were able to provide to our residents. But despite all of this success that we talk about in the District of Columbia, it comes at a very high cost.

First, there are a lot more people living with HIV/AIDS today, and every day the number continues to increase. Second, more than half of our people living in the District of Columbia are now

in their mid-40s, so they are in need of additional medical care, which is very expensive. We've been very fortunate to move some of these patients over to Medicaid so they could get the other services that are available.

The cost in the District of Columbia for one patient per year is, right now, \$9,400 per person. And that cost is going to go up. This is the minimum cost, because we are now starting treatment earlier and earlier upon diagnosis. And I believe it's going to be a lot higher when everybody who needs the medication needs to be on the treatment.

In 2009, there were 755 cases in the District of Columbia, new cases, and they added \$228 million to the cost. And after all, at the end of the day, the taxpayers end up paying for these costs, and we all end up paying for these very exorbitant costs. So we are very encouraged with the bill that you have introduced, and we are looking forward to having a good discussion on the bill and hoping that it will eventually pass so that we can not only take care of the situation at home but also abroad.

Thank you very much, Mr. Chairman, for the opportunity.
[The prepared statement of Dr. Akhter follows:]

PREPARED STATEMENT OF MOHAMMAD N. AKHTER, M.D., MPH

Chairman Sanders, Ranking Member Paul and distinguished subcommittee members, I am honored to testify before you today on the Costs of HIV/AIDS Treatment in the United States, and the Medical Innovation Prize Fund Act: S. 1137, also referred to as the "prize bill" and the Prize Fund for HIV/AIDS Act: S. 1138, the "prize fund."

Thank you, Chairman Sanders, for convening this hearing and for your tireless work on behalf of the American people to make health care more accessible and more affordable. You have upheld for many years the belief that every American should be guaranteed comprehensive medical care as a right of citizenship so that they can live healthy lives. I believe that the prize fund concept will support and encourage innovations that will lead to better health outcomes.

I am very proud to share with this committee a success story for a Federal and local partnership that is truly making a difference in the lives of people living in our Nation's capital and in the fight against the HIV epidemic. Today, 30 years into the fight against the epidemic, we have the tools and experience to make a difference. Death rates in the District of Columbia due to AIDS have precipitously fallen, in part due to the generosity of Congress in the provision of medication and medical care. The number of deaths among persons with HIV/AIDS decreased by more than 50 percent from 326 in 2005 to 153 in 2009. Treatment is now also understood as prevention—an HIV-positive person successfully treated with antiretroviral is very unlikely to spread HIV to others. Along with our other highly successful prevention programs, we are beginning to see a slowing of new cases in the District of Columbia. This Federal-local partnership is paying off.

I am proud to report that DC is a national leader in HIV testing and set a new record for publicly funded HIV testing last year. Testing is done routinely in emergency rooms and in major clinics throughout the city. HIV testing is also administered in our Department of Motor Vehicles and in one of our Economic Security Offices, where city residents apply for TANF and other services. In 2011, we set a new record of 122,000 publicly supported HIV tests, up from 110,000 in 2010 and triple the total of 43,000 tests in 2007.

We are also very proud of our efforts to link people early into treatment to ensure healthy outcomes for people living with HIV. Over 75 percent of those who are diagnosed with HIV were connected to care within 3 months, which is also a new record for the District of Columbia.

We have also promoted successful large-scale prevention strategies. We distributed an unprecedented 5 million free condoms last year and made national news on a very successful female condom program. We are also proud of our award winning social marketing program that promotes condom use and protection against the spread of HIV.

The synergy of our efforts has led to a decline in infant mortality in the District. While many factors have led to the decline in infant mortality, the contribution of the condom and safe sex program is clear. Access to condoms decreased our teen pregnancy rate by 10 percent, which further decreased our infant mortality rate, a double win for the District.

Through our efforts, no baby has been born HIV-positive in the District of Columbia since 2009. Likewise, through the leadership of our Mayor and city council, we have been able to ensure treatment on demand for HIV care and for drug treatment. The city has been an early adopter of the Affordable Care Act and as a result, now has the second highest insurance coverage level in the Nation, with 93 percent of adults insured. In addition, 96 percent of District of Columbia children are insured, which represents the highest level of children's health insurance coverage in the Nation.

In the District, like the rest of the Nation, we have focused on reducing disparities as part of our implementation of the National HIV/AIDS Strategy. As part of that effort, DC provided free Sexually Transmitted Disease (STD) testing for 4,300 youth, ages 15 to 19, through the school-based STD screening and community screening programs, up from 3,000 in 2010.

Under the National Strategy, we have also improved coordination and integration of services. I sent a letter to more than 4,000 doctors in DC, highlighting the District's policy of offering routine HIV tests to all adults and adolescents. The Department of Health is also collaborating with the Department of Insurance, Securities and Banking to enforce District law on insurance reimbursement of HIV testing in emergency rooms. The Mayor's Host Committee for the International AIDS Conference coordinates District government support for the AIDS2012 conference, which takes place in July 2012.

The District of Columbia government works in partnership with many fine community-based organizations such as Whitman Walker Health, La Clinica del Pueblo, Unity Health Care, and others. These groups have gained invaluable experience with our very diverse population in DC and more importantly, have gained their trust. Our many accomplishments are the result of strong partnerships and shared goals.

We also extend gratitude to our partners at the Centers for Disease Control and Prevention (CDC), particularly Dr. Kevin Fenton, for his leadership. Of note, our city has developed a significant research capacity to contribute to the fight against HIV and AIDS. We could not have done this without the leadership of Dr. Tony Fauci at the National Institutes of Health (NIH), who has taken a personal interest in our city.

I have emphasized our progress in prevention and care of HIV, but our work in health information, monitoring and evaluation has also improved. DC is one of three jurisdictions in the United States that has viral suppression data on a population basis. In partnership with the George Washington University School of Public Health and Health Services, the District has become a national leader in the epidemiology of HIV.

Despite our many successes, the District still has a serious HIV epidemic; in fact, all of urban America has a serious epidemic. Metropolitan DC is very much like other metropolitan areas in the United States in its high levels of the virus infecting the population. The composition of our epidemic is, however, a bit more complex than some cities. We actually have three epidemics: one among men who have sex with men, another among IV drug users and a third among African-American heterosexuals, making our challenge more complex even though DC rates, as a metropolitan area, are not as high as some.

In the District of Columbia, we had 755 new cases of HIV in 2009. Two or three persons are newly diagnosed in the District every day. The route of transmission has remained somewhat stable over the past years. In 2009, men who have sex with men (MSM) account for the greatest number of HIV/AIDS cases diagnosed each year. However, the number of MSM cases decreased by approximately 27 percent since 2005. Heterosexual contact was the second most common mode of transmission for HIV/AIDS cases diagnosed during the last 5 years. HIV/AIDS cases attributed to heterosexual contact declined from 335 cases in 2005 to 234 cases in 2009, a decrease of 30 percent. The number of newly diagnosed cases attributable to injection drug use decreased by 60 percent from 153 in 2007 to 62 in 2009. We credit the locally funded DC Needle Exchange Program, which started in 2008, for this significant decline.

We are very proud of the work we have done with our HRSA Ryan White program, where residents in our eligibility area have excellent access to life saving services. An important trend has been the transfer of clients from ADAP (AIDS Drug Assistance Program/HRSA) onto Medicaid, made possible by the expanded eli-

gibility of Medicaid. We are now able to offer full health insurance to residents, expanding coverage beyond HIV services. This is very important in the District, given the fact that our population of HIV-positive individuals is increasingly older. Well over half of the persons infected with HIV in the District are over 45 years of age, and that trend will continue. People with HIV are increasingly living with other chronic disease—diabetes and hypertension—like the rest of our population. The Affordable Care Act has made it possible for the District to move more than 1,000 persons from Ryan White CARE Act services to Medicaid, thereby decreasing some of the pressure on the Ryan White Program.

While there is much good news, it all comes at a huge cost. Medical care, specifically lifesaving antiretrovirals, is very expensive. Currently, our average cost per ADAP patient is about \$9,400 per year. (It is estimated that discounted drug costs for antiretrovirals are approximately \$303,100 per person¹ over the course of a lifetime for drugs alone). That estimate is low because new recommendations are for people to start on medication as soon as they are diagnosed, and not wait for their CD4 count to drop. This both preserves the health of the patient (protecting the immune system) and decreases the likelihood that a person will spread the virus, because the treatment suppresses HIV, making it undetectable in body fluids when taken properly. If there are two to three new diagnoses a day in the District, that means we are adding just under \$1 million to the long-term health expenditure in our city every day. A large part of that cost is taxpayer dollars. Though ultimately, we all pay into some insurance program or another. The increase in the number of people who were District residents at the time of their HIV diagnosis increased from 16,513 reported in 2008 to 16,721 in 2009. That increase adds over \$228 million to the long-term health care costs in the District of Columbia.

We need a cure and we need a vaccine. While we await those discoveries, the need for new treatments is clear. Our current medication, even if it was less expensive, creates a daunting challenge. To preserve life and to stop the transmission of the virus, patients need to take medication accurately every day for the rest of their lives. This is a major challenge for many of our residents, even if free drugs are available. So, we need new research into practical, patient-centered treatment approaches to fight the epidemic. We need to consider the affordability of new treatments, new drugs, and new approaches. To halt the HIV epidemic in the United States and around the world, we need a far more efficient approach. For generations, tuberculosis ravaged our country. Through combined effective medications and treatment protocols, the Nation eliminated the tuberculosis epidemic. We need to do the same for HIV.

We welcome discussion on the “prize bill” because it provides a fresh way to think about incentivizing innovations. New drugs and new treatments that are inexpensive from the outset are highly preferable. The inequitable situation we have faced for decades, in which new, high-priced medication and treatment are only available to those who can pay, makes our battle very difficult. We encourage any new incentives that will promote new treatment for HIV and other illnesses in the District of Columbia.

Senator SANDERS. Thank you very much for your presentation and for all of the extraordinary work you are doing.

Our next panelist is Frank Oldham, Jr. He is the executive director of the National Association of People with AIDS. He also serves on the board of directors for the National Minority AIDS Council. Mr. Oldham was the citywide coordinator for AIDS policy under Mayor Bloomberg, the assistant commissioner of the Chicago Department of Public Health Division on STD/HIV/AIDS Public Policy and Programs, and the deputy assistant commissioner of the Bureau of HIV Program Services for the New York City Department of Health.

He launched the “Faces of AIDS Project” in 1999, which spawned two books and a touring photo exhibit showcasing the stories of people living with AIDS. Mr. Oldham advises several planning and policy bodies for New York City, the Centers for Disease Control, LAMBDA Legal, and Washington, DC.

¹Medical Care: November 2006, Volume 44, Issue 11, PP. 990–997 doi: 10.1097/01.mlr.0000228021.89490.2a

Mr. Oldham, thanks very much for being with us.

**STATEMENT OF FRANK OLDHAM, JR., PRESIDENT AND CEO,
NATIONAL ASSOCIATION OF PEOPLE WITH AIDS, WASH-
INGTON, DC**

Mr. OLDHAM. Senator Sanders and distinguished members of the committee, thank you for providing us with the opportunity to share our thoughts with you on this subject that is so important to 1.2 million people living with HIV/AIDS in America. The National Association of People with AIDS, known as NAPWA, is the largest and oldest patient advocacy group for people living with HIV/AIDS. We're also seen as the most trusted voice of our community because of our longstanding independence.

Next year, NAPWA has a bittersweet milestone. We turn 30 years old. I say bittersweet because we'd like nothing better than to see an end to this epidemic which has already taken the lives of 620,000 Americans. On the other hand, we are thrilled to be alive to do the good work our organization needs to do to educate and inform about the needs of people living with HIV/AIDS. These are 30 years that dear friends of mine, lost in the early years of the AIDS epidemic back in the 1980s and 1990s, never had a chance to live.

So with this in mind, we thank the pharmaceutical industry, the FDA, and brilliant researchers for creating antiretrovirals. I'm living proof that they work. I've been positive for over 23 years. We are at a brilliant beginning in saving the lives of people living with AIDS.

However, according to recent studies from CDC, less than 25 percent of people prescribed antiretrovirals stay on the treatment. Some say it is because they get nauseous, especially when they first start them; others because of the barriers in access to the medication; and they have a potential to increase risk for long-term organ damage.

And while premature death at the age of 70 because of ART is preferable to premature death because of AIDS at age 30, NAPWA does believe we can work to support research that will find better treatments that will give those of us living with HIV/AIDS the same quality of life and expectancy as those who don't have HIV. One of my friends and colleagues who has been taking antiretrovirals for over 20 years is thrilled to be alive because of them. But he takes an additional 10 pills to manage the side effects of this class of medication. Please keep that in mind when factoring the cost burden of the status quo. Please keep this in mind.

So our 30th anniversary is not only bittersweet because the epidemic is still here. It's bittersweet because we are fortunate to have treatments that dramatically extend survival, but they are not an acceptable end-game. We can and must do better.

For the last 2 years at our major international conferences, NAPWA has hosted symposiums on functional cure research. This area of research involves creating triggers for the immune system to allow a patient's own natural self-defense to kick in and work against HIV. This involves creating therapeutic vaccines that could be given to people living with HIV after they are already infected.

To explain, very quickly, many children get chicken pox. Despite being treated for it, the virus lingers slowly in the background for the rest of the person's life. In most cases, it remains in check. But in some people, as adults, it emerges as shingles. Researchers are working on a shingles vaccine given, despite the presence of the virus in a person's body. The vaccine is designed to prevent further outbreaks within the person who is already infected.

So, too, would be the case for HIV therapeutic vaccines. Impressive results have been emerging recently. One company based in Gaithersburg, VIRxSYS, has shown that its therapeutic vaccine, when used in monkeys that were intentionally highly infected with the monkey version of HIV, was able to achieve a functional cure in some of the monkeys. At 2 years, no detectable—again, no detectable—viral load was recorded, even in the most hard to reach reservoirs of these animals. This represents significant progress.

Another company based in Norway, Bionor Pharma, has shown that its therapeutic vaccine reduced the viral set or baseline in patients significantly better than placebo. This could offer an insurance policy to all people living with HIV who either have no access, as you mentioned, to ART, can't afford the treatments, no longer respond to them, or who simply stop taking them. You can't stop taking a vaccine. Once it's in you, it's in you.

I want to make two other last points. Both of these cures, these beginning new cures, may fail because these companies do not have the money to really produce them. They do not have the money to produce them. The one in Norway is actually working in human beings, but they do not have the money to produce them. We need to rethink, as you said, as this bill says, how we actually get pharmaceutical companies to invest, and incentivize companies to find new treatments.

The National Association of People with AIDS will be here as long as there are people living with HIV/AIDS. We want to be partners with Senators, Members of Congress, and industry representatives who are prepared to roll up their sleeves and take an honest assessment of what does and what does not work when it comes to incentivizing drug development in HIV.

We applaud you, Senator Sanders, for thinking creatively to figure out new incentives that could result in faster results. We do not want to come back here 30 years from now without a cure. All possible incentive options should be put on the table for discussion if we are ever going to incentivize the type of breakthrough that can provide a bridge to a complete cure.

Thank you so much, Senator Sanders.

[The prepared statement of Mr. Oldham follows:]

PREPARED STATEMENT OF FRANK OLDHAM, JR.

The National Association of People with AIDS, known as NAPWA, is the largest and oldest patient advocacy group for people living with HIV/AIDS. We're also seen as the most trusted voice by the community because of our long standing independence.

Next year, NAPWA has a bittersweet milestone. We turn 30 years old. I say bittersweet because we'd like nothing better than to see an end to this epidemic, which has taken such a toll on the least fortunate of our society. On the other hand, we're thrilled to be alive to do the good work our organization needs to do to educate and inform about the needs of people living with HIV/AIDS. These are 30 years that

dear friends of mine, lost in the early days of the AIDS epidemic, never had a chance to live.

So with them in mind, we thank the pharmaceutical industry, the FDA, and brilliant researchers for creating antiretrovirals. I'm living proof that they work.

But these are far from perfect drugs. According to recent CDC studies, less than 25 percent of people prescribed antiretrovirals stay on the treatment.

Some say this is because they can make you nauseous, especially when one first starts taking them. Others stop because access to them has stopped. They do increase the risk of long-term organ damage. And while premature death at age 70 because of ART is preferable to premature death because of AIDS at age 30, NAPWA does believe we can work to support research that will find even better treatments that will give those of us living with HIV/AIDS the same quality of life and expectancy as those who don't have HIV.

One of my friends and colleagues who has been taking antiretrovirals for nearly 20 years is thrilled to be alive because of them. But he takes an additional 10 pills a day to manage the side effects of this class of medication. Keep *that* in mind when factoring the cost burden of the status quo.

So our 30th anniversary is not only bittersweet because the epidemic is still here. It's bittersweet because while we are fortunate to have treatments that dramatically extend survival, they are not an acceptable end-game. We can and must do better.

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To explain, many children get chicken pox. Despite being treated for it, the virus lingers slowly in the background for the rest of that person's life. In most cases it remains in check. But in some people, as adults, it emerges as Shingles. Researchers are working on a shingles vaccine—given despite the organism's presence already in the body. So too would be the case for therapeutic vaccines for HIV.

Impressive results have been emerging recently. One company based in Gaithersburg, VIRxSYS, has shown that its therapeutic vaccine, when used in monkeys that were intentionally highly infected with the monkey version of HIV, was able to achieve a functional cure in some of the monkeys. At 2 years, no detectable viral load was recorded, even in the most hard to reach reservoirs of these animals.

Another company based in Norway, Bionor Pharma, has shown that its therapeutic vaccine reduced the viral set point—or baseline—in patients significantly better than placebo. This could offer an insurance policy treatment for all of those people who either have no access to ART, can't afford the treatments, no longer respond to them, or who simply stop taking them. You can't stop taking a vaccine. Once it's in you, it's in you.

Our symposium featured many other vaccine candidates, but these two tell an interesting story. The Norwegian vaccine development will not move into phase 3, the final human test before presentation to FDA for approval, unless a pharmaceutical company steps forward. Costs of these trials are enormous, and the small biotech companies cannot do them alone. But the story of the first company, based here in Gaithersburg, is all too familiar to us. No funding was made available, and the technology now sits idle. We will never know if it is a breakthrough in humans unless something changes fast.

Many speculate why these—or any HIV therapeutic HIV vaccine candidate—have not been licensed by pharmaceutical companies. We don't know the answers and should be careful not to project. However, one prevailing thought is that eliminating a highly profitable daily treatment—one taken for years if not decades of a patient's life—is preferred to the sale of a significantly less expensive immune-based therapy.

Regardless of the reason, with over 30 HIV treatments on the market, but over 20 of these are antiretrovirals—a single class of therapy—we must do something to stimulate new innovation. Industry is not bringing us new breakthroughs—only mildly improved versions of the same class of treatment we first saw in 1987 when AZT was approved as the first antiretroviral.

Therapeutic vaccines are only one category of immune-based strategies that are underfunded and appear not to be the blockbuster-sized drug that industry embraces. There are others. We are eager to see these products reach the market—and for companies to make a fair profit for their brilliant research and investments—but under the current system, we're not seeing the advances despite good science.

The National Association of People with AIDS will be here as long as there are people living with HIV/AIDS. We want to be partners with Senators, members of Congress, and industry representatives who are prepared to roll up our sleeves and

take an honest assessment of what does and does not work when it comes to incentivizing drug development in HIV.

We applaud Senator Sanders for thinking creatively to figure out new incentives that could result in faster results. We do not want to be coming back to the Senate 30 years from now. We want a cure, and I'm here to tell you that the HIV community will not rest until we have one. All possible incentive options should be put on the table for discussion if we are ever going to incentivize the type of breakthrough that can provide a bridge to a complete cure.

Senator SANDERS. Thank you very much, Mr. Oldham.

Our next panelist is Dr. Suerie Moon, who is research director and co-chair of the Forum on Global Governance for Health, Harvard Global Health Initiative and Harvard School of Public Health. She is also the co-director of the Project on Innovation and Access to Technologies for Sustainable Development, Sustainability Science Program, Harvard Kennedy School of Government.

She previously worked for Médecins Sans Frontières/Doctors Without Borders and consulted on access to medicines policies for MSF, Oxfam, the Medicines Patent Pool, UNAIDS, UNITAID, and the World Health Organization. Dr. Moon is a member of the board of directors of MSF-USA, Drugs for Neglected Diseases Initiative-North America, the Proposal Review Committee of UNITAID, and the Global Advisory Committee of the World Health Organization project on local production for access to medical products.

Dr. Moon, thanks very much for being with us.

STATEMENT OF SUERIE MOON, MPA, Ph.D., RESEARCH DIRECTOR AND CO-CHAIR OF THE FORUM ON GLOBAL GOVERNANCE FOR HEALTH, HARVARD GLOBAL HEALTH INSTITUTE AND HARVARD SCHOOL OF PUBLIC HEALTH; CAMBRIDGE, MA

Ms. MOON. Thank you very much, Senator Sanders. It's a real honor to be here. And thank you for holding this hearing on this really crucial topic.

I'm going to focus my comments today on the link between drug prices here in the United States and the challenge of access to global access to medicines, two topics that are often discussed separately but are actually quite closely interlinked, as you pointed out this morning.

First, I'd like to provide a quick update on where we are today and how we got here. As you mentioned, global access to HIV medicines has increased dramatically over the last decade to reach a total of 7.4 million people as of 2010, about 90 percent of whom live in developing countries. I think this is an achievement that was unimaginable 10 years ago.

Two of the enabling factors that were key for increasing access in developing countries, in particular, was, first, the dramatic reductions in the price of antiretroviral medicines, and, second, the availability of international funding. In developing countries, the annual price of ARVs has dropped from \$10,000–\$15,000 per patient per year in the year 2000 down to as low as \$100 or less today, in other words, less than 1 percent of the patented U.S. price. These price reductions came about due to robust competition amongst generic producers that were enabled through a number of measures.

Americans can be proud of these accomplishments, because the U.S. Government has played a key role in at least three elements of this story. First were major investments by the NIH into HIV starting in the 1980s which enabled the major advances in antiretroviral treatment today.

Second is the fact that the United States is the largest single global funder of HIV treatment through PEPFAR as well as through the Global Fund, and these contributions have truly strengthened the public image of the United States overseas. Unfortunately, for the first time in 5 years, it seems that the United States will be decreasing its contributions, and I urge you to do everything that you can to prevent this reversal.

Third, most recently, as was alluded to earlier, the NIH-funded research last year demonstrated that ARV therapy can, in fact, reduce the risk of transmission of HIV by 96 percent. This research finding is the closest thing that we have to an HIV vaccine. We're still, unfortunately, far from a vaccine, as my colleagues have pointed out. But this is an amazing finding, and it could potentially bring benefits to millions more people and could potentially halt the epidemic.

Ironically—and it's a painful irony—just as the science shows that we need to find ways to reach more people with ART, both domestically as well as internationally, international funding for HIV is in crisis, and prices in the United States, as you pointed out yourself, are putting the drugs out of reach. Too many Americans living with HIV in our own backyard are unable to access treatment. And the same drugs that cost about \$220 overseas cost \$25,000 here.

The question is: What explains this difference? In my view, the availability of low-cost generic ARVs in developing countries is part of an unwritten global political bargain, and that bargain goes as follows. People living in the United States and in Europe will continue to pay higher prices for medicines in order to reward companies for their investments in R&D, while people living in the poorest countries, or the donors that support them, will essentially pay for generic drugs sold near the cost of production.

But that bargain is based on an assumption, and that assumption is that people living in rich countries will, in fact, be able to get access to care through government programs such as the ADAPs or private insurance. If this is no longer true and the prices are too high to ensure access, even in the wealthiest country in the world, then that bargain is not sustainable, and that is a problem for people everywhere, both in the United States as well as abroad.

As others have rightly pointed out, this crisis stems from the very way in which research and development for new medicines takes place and the fact that we recuperate R&D investments through high drug prices. Of course, this pricing system has terrible consequences, especially when we know that the drugs can be manufactured for less than 1 percent of the patented price.

But we also know that if everybody in the world paid that 1 percent generic price, then the incentives for R&D would evaporate. So is there a better system? What I find so promising about the HIV/AIDS Prize Fund bill that you've put on the table is that, in fact, it would try to achieve both. It would achieve both improved inno-

vation as well as ensuring the broadest possible access to the fruits of scientific research. And it's through a powerful concept called de-linkage which was recently endorsed by an independent international expert group of the WHO looking at new R&D mechanisms.

I'm going to leave it to other panelists to go into detail on how the Prize Fund would work. But I wanted to just highlight one key feature of de-linkage, which is that it would dramatically decrease the marginal costs of extending access to more people. And this is the critical principle that we need to keep in mind when we're thinking about how to give access to ART for millions more people so that we can actually use treatment both as prevention as well as to save lives.

Let me make one final comment regarding how this could function at the international level. At the end of your bill, you mention the possibility of a donor Prize Fund. And the way that the donor Prize Fund could function is to incentivize companies to share their patents with a new international initiative called the Medicines Patent Pool. The Patent Pool, in turn, out-licenses these patents to generic firms to encourage generic production to ensure the lowest sustainable prices for medicines everywhere.

The Patent Pool has been having difficulty getting all developing countries included in the scope of the Pool. And incentives such as those provided through your bill could make it easier to expand access to people living in all developing countries, not just in some of them.

So let me conclude my remarks there. And thank you very much for hosting this panel. I look forward to the other testimonies and to your questions.

[The prepared statement of Dr. Moon follows:]

PREPARED STATEMENT OF SUERIE MOON, MPA, PH.D.

INTRODUCTION

My name is Suerie Moon and I am the co-chair and research director of the Forum on Global Governance for Health at the Harvard Global Health Institute and the Harvard School of Public Health. I also co-lead the Project on Innovation and Access to Technologies for Sustainable Development at the Harvard Kennedy School of Government. The topic that brings us here today is the important issue of how to ensure equitable access to HIV treatment, an issue I have worked on for 13 years primarily at the international level but also at the national level in developing countries such as the Democratic Republic of the Congo and China. I have advised a number of intergovernmental and non-governmental organizations, published a number of articles, and am working on two books on this topic.

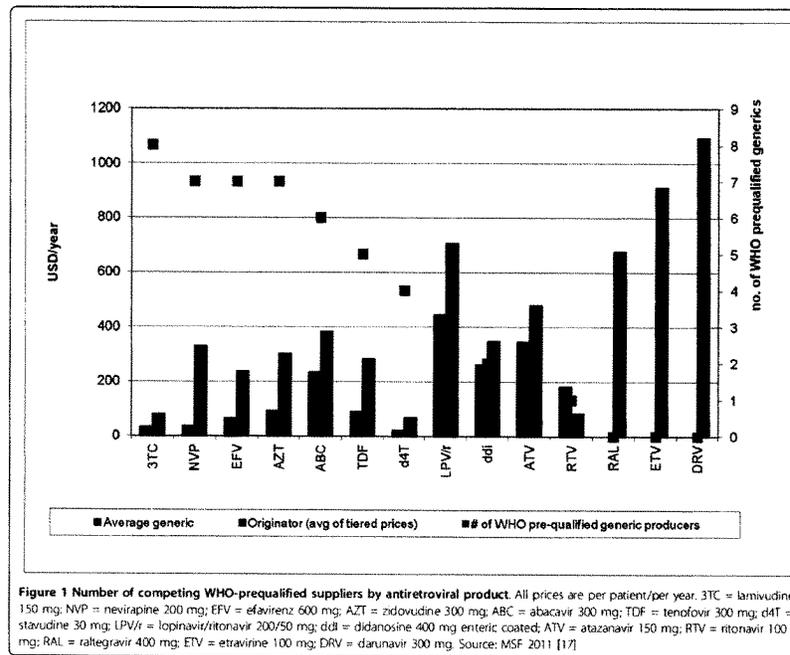
ACCESS TO HIV MEDICINES AT HOME AND ABROAD: PROGRESS AND SETBACKS

Global access to medicines for HIV/AIDS has increased dramatically over the past decade, increasing by sixteenfold over 7 years to reach 6.65 million people in the developing world by 2010; another approximately 750,000 people are on treatment in high-income countries (1). A key enabling factor for increasing access to treatment in developing countries was the combination of two things: first, the dramatic reductions in the price of antiretroviral (ARV) medicines and second, the availability of international funding. The price of a triple combination of ARVs has dropped from \$10,000–\$15,000 per patient/year in 2000, to as low as \$100 today (2)—in other words, less than 1 percent of the patented U.S. price. These price reductions were enabled by robust generic competition, as reflected in the chart below. What we have seen with ARVs is that the greater the number of competitors in the market, the lower the price (See Figure 1).

Americans can be proud of these accomplishments, as the U.S. Government has played an essential role in several elements of this story:

- First, major investment into HIV research by the National Institutes of Health (NIH) beginning in the 1980s enabled the scientific breakthroughs of antiretroviral therapy;
- Second, the United States is the single largest global funder of HIV treatment and care through the President's Emergency Plan for AIDS Relief (PEPFAR) and contributions to the Global Fund for HIV/AIDS, Tuberculosis and Malaria (3). These contributions have strengthened the public image of the United States overseas especially in the countries hardest hit by the epidemic. Unfortunately, for the first time in 5 years it appears that U.S. contributions will be decreasing.
- Third, most recently, NIH-funded research demonstrated that HIV transmission can be prevented by taking a "treatment as prevention" approach—that is, antiretroviral therapy (ART) can reduce the risk that an HIV-positive person will transmit the virus to their partner by 96 percent (4). This research finding is the closest we have come to an HIV vaccine, which remains elusive. It also means that potentially millions more people could benefit from getting access to ARVs, and that this could potentially end the epidemic.

Figure 1. Generic competition and prices of antiretroviral drugs



Source: Moon et al. 2011 (5).

But it is a painful irony that just as the science shows us that we need to find ways to reach more people with ART, international funding for HIV is in crisis and prices in the United States are putting the drugs out of reach. As we have heard from the other panelists, too many Americans living with HIV in our own backyard are unable to access the treatment they need, in part because of these high prices. The same drugs that cost about \$220 from a quality-assured generic producer in India cost over \$25,000 in the United States. Why?

The availability of low-cost generic medicines for HIV treatment in developing countries is part of an unwritten global political bargain. That bargain is that people living in high-income countries like the United States and Europe would continue to pay higher prices for medicines in order to reward companies for their in-

vestments in R&D, while people living in the poorest countries (or the donors that support treatment there) would essentially pay for generic drugs sold near the cost of production. But the political bargain was implicitly based on the assumption that people living in rich countries would have access through social protection mechanisms, such as government programs like the ADAPs or private insurance. If this is no longer true, and prices are too high to ensure access even in the wealthiest country in the world, then that political bargain is not sustainable.

Some may reply that the answer is to charge higher prices elsewhere in the world, and that this would lead to lower prices in the United States. But clearly this is unacceptable from an ethical and public health point of view—what we need to do to save lives and stop the epidemic is to expand the reach of ART to more people, not less, and we have fewer dollars with which to do it. It is also unlikely that increasing prices elsewhere would actually lower prices here—that’s not the way the pharmaceutical market works. So, what we have on our hands is the risk that the global political bargain will not hold—which is a problem that touches people everywhere, both in the United States and abroad.

This crisis reminds us of the drawbacks of the existing system for the research & development of new medicines (R&D)—that is, that we rely on high prices to recuperate private sector investments into R&D. These high prices mean that it costs society a significant amount of money (whether from government, insurance companies, or households’ out-of-pocket expenditure) for each additional person who needs a medicine. In other words, if it costs \$25,000 a year for ARV drugs, each additional person to be treated requires at least \$25,000 for the drugs alone. This seems quite simple and straightforward, but this pricing system can have terrible consequences, especially when we know that these drugs can be manufactured for less than 1 percent of that price. Yet, if everyone in the world only paid the generic price, the incentive for R&D would evaporate. So, is there a better system?

The promise of S. 1138 is that in establishing a prize fund, it would create a system that would separate the rewards for R&D from the price of the product—a powerful principle known as “de-linkage.” De-linkage was the central principle endorsed in a recent report by an independent expert group convened by the World Health Organization to examine new mechanisms for R&D (the Consultative Expert Working Group on Research & Development: Financing and Coordination [CEWG]) (6).

A SIMPLE ILLUSTRATION OF THE POTENTIAL OF DE-LINKAGE

Here is a simplified hypothetical example to illustrate the basic idea:

Imagine you have a budget of \$100. In the current system, let’s assume that the drugs are priced at \$10 per patient. Your budget allows you to cover 10 patients total. About 1 percent of the price covers the cost of producing the drug (about 10 cents), and the remainder goes to the drug company as a reward for innovation. That is, \$9.90 from each patient, or \$99 altogether. On average, out of this \$99 the industry will invest about 17 percent back into R&D, according to the industry association (7). So as a society we have now paid \$100 to get about \$17 worth of R&D in the future. The system is pretty inefficient both for generating R&D funding and for meeting priority public health needs, but that is a topic that I believe others on this panel will address.

Now imagine a system of de-linkage. In this system you create a prize fund to reward innovators, and in exchange for prize payments, the innovators allow competitive generic production of the drug from day 1. So, say you start with the same budget of \$100. You can begin by setting aside \$99 as a reward for the innovator. With the remaining \$1, you can cover treatment for the same 10 people by purchasing a generic version of the drug. The key difference is that you have separated the market for R&D from the market for drug production. So far, the results are the same between the current model and the de-linked model in terms of patient coverage and R&D incentives, for the same cost to society.

But then, what if more than 10 people need the drug? What if tomorrow the infectious disease has spread and 100 people need it? Or what if it turns out that more people need the drug than originally estimated? Or, what if the science shows the drugs can be used to prevent the transmission of a deadly disease? In the current system, to cover the additional 90 people would cost \$900. In the de-linked system, it would only cost \$9. The key difference here is that the marginal cost to get one more person access to the medicine under the de-linked system is \$0.10 not \$10.

This feature of the prize-fund system is particularly relevant when we consider the latest science on HIV. As I mentioned earlier, we know now that ARV treatment can function as prevention. WHO issued new guidelines just last month recommending that in couples where one partner is HIV-positive and the other HIV-negative, treatment begin immediately to reduce the risk of transmission (8). Here at

home, cities like New York are piloting this approach as well. The implications of the principle of treatment as prevention are that millions more people could potentially benefit from having access to ART. But achieving that requires big-picture thinking on how to get the drugs at the lowest possible cost while maintaining incentives for innovation.

Finally, let me offer a few thoughts on how this bill could operate to address access issues internationally. The U.S. Government is the largest funder, and therefore indirect *purchaser* of ARVs for use in developing countries. But sometimes, we pay more than we have to for these drugs. For example, darunavir costs donors to the Global Fund over \$6,500 per person/year in El Salvador, and this is just one drug required in a multi-drug combination.¹ There is an internationally supported initiative to help make HIV treatment more affordable, and therefore available and sustainable—its called the Medicines Patent Pool. It works by asking companies to make their patents available to the Pool in exchange for the payment of a royalty. The Pool then licenses those patents out to generic manufacturers, who compete to offer the lowest prices for quality-assured drugs for use in developing countries. Again, Americans have reason to be proud, as the NIH was the first to contribute patents to the Pool. One of the challenges facing the Pool is that a number of developing countries are unable to benefit from it, due to restrictions from patent-holders on geographic scope. In addition, a few outlier companies are not yet in negotiations with the Pool, including the American firms Abbott, Johnson & Johnson and Merck. The HIV Prize Fund could incentivize companies to collaborate with this international initiative and include all developing countries within its scope, by providing a prize payment to the developers of innovative medicines well-suited for use in resource-poor settings. In exchange, companies would make their patents available to generic firms so that medicines could be produced and sold at the lowest sustainable prices produced by robust competition in the market.

CONCLUSIONS

While progress has been impressive, we are far from defeating the HIV epidemic. Over 7 million people are still in immediate need of treatment worldwide, and unfortunately, here in the United States the sight of people waiting on long lists for access to lifesaving medicines is not foreign. In addition, in some developing countries, the prices of HIV medicines remain very high—in the thousands of dollars—particularly for the newer medicines needed to treat the virus once it mutates and becomes resistant to first-line drugs. Despite great progress, we are still far from resolving the access problem.

The United States has the opportunity to address a great moral challenge both at home and abroad by finding new ways to ensure that everyone gets access to the medicines they need, while providing improved incentives for R&D. In putting forward the Prize Fund for HIV/AIDS bill, Senator Bernie Sanders has reminded us that innovation in medicine will require innovation in public policy. Prizes are a promising new incentive mechanism for addressing the pressing public problem of high drug costs and declining rates of innovation. This bill merits serious consideration by anyone concerned about the affordability of healthcare, equitable access to medicines, or harnessing the potential of technological innovation to address our most important health challenges, both here in the United States and globally. Thank you for this opportunity and for your attention. I look forward to your questions.

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Senator SANDERS. Dr. Moon, thanks very much for your testimony.

Our next panelist is Dr. Joseph Stiglitz. He is a university professor at Columbia University and the winner of the 2001 Nobel Prize in Economics, as well as the 1979 John Bates Clark Medal. Dr. Stiglitz served in the Clinton administration as the chair of the President’s Council of Economic Advisers, followed by an appointment as senior vice president and chief economist of the World Bank.

He is a co-founder of the Initiative for Policy Dialogue, current president of the International Economic Association, chair of the U.N. Commission studying ways to reform the financial system, and a member of the CFTC–SEC Advisory Committee on Emerging Regulatory Issues. Last year, *Foreign Policy* magazine named him one of the Top 100 Global Thinkers.

Dr. Stiglitz, thanks very much for being with us.

STATEMENT OF JOSEPH E. STIGLITZ, PROFESSOR AT COLUMBIA UNIVERSITY; WINNER OF THE NOBEL PRIZE IN ECONOMICS; FORMER CHAIRMAN OF THE COUNCIL OF ECONOMIC ADVISERS; AND A CHIEF ECONOMIST FOR THE WORLD BANK; NEW YORK, NY

Mr. STIGLITZ. Thank you very much for holding these hearings. I welcome this opportunity to share with you my thoughts on Senate bill 1138 and on the broader subject of how we can best finance research on HIV/AIDS and for health more generally.

I should begin by saying that the approach taken by the bill is exactly right. It reflects an approach that I have been arguing for for years, including in my book, “Making Globalization Work,” in my academic writings, and in the various policy roles that I have been fortunate enough to play over the last two decades.

The timing of this hearing could not be better, coming soon after the release of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination at the World Health Organization. I was able to present a keynote address at the launch of the report in Geneva just over a week ago. Interestingly, but not surprisingly, its core recommendations concerning the organization and finance of research and development

coincide closely with this bill. The working group arrived at those conclusions after reviewing a wide range of alternative proposals.

I will not spend time reiterating the seriousness of the HIV/AIDS problem both in America and around the world. Medicines have made enormous progress in prolonging lives and alleviating some of the costs and suffering, and further research promises even bigger dividends.

The problem is that the medicines are very costly. Or, more accurately, the price charged for them is very high, but the cost of production is but a fraction of the price charged—the point that the Senator made earlier that the cost of production is less than 1 percent of the price charged.

This is the inherent consequence of our current innovation system. The curious aspect of our current system is that the government, directly or indirectly, finances most health R&D, directly through public support and indirectly through public purchases of medicine, both in the Medicare and Medicaid programs. Given that government is financing most of the research, it is especially important that it be done in a way that is efficient. There are many dimensions to efficiency, two of which I want to talk about today.

The first is that once knowledge is acquired, it should be used efficiently. Thomas Jefferson described knowledge as being like a candle. When one candle lights another, it doesn't diminish the light of the first. Once produced, knowledge should be disseminated and used as widely as possible.

The desire to have knowledge used as widely as possible can run counter, however, to another concern. We have to have incentives to do research. Our patent system attempts to balance these concerns by providing a temporary monopoly power to innovators, the result of which is that there is restricted use of the knowledge for a limited period of time. This is a large inefficiency.

But, increasingly, we have become aware of some other limits of the patent system. While it provides incentives, it does not necessarily provide incentives that correspond to social returns. In the healthcare sector, it may be more profitable to devote research to “me-too” drugs than to the development of a drug that really makes a difference. The patent system may even have adverse effects on innovation, because the most important input into any research is prior ideas, and the patent system encourages secrecy, just the opposite of the openness that is the hallmark of successful universities and academia more generally.

There's ample ways to square the circle, which entail de-linking research and development incentives from drug prices, and that is precisely what S.1138 proposes to do in the context of new medicines to treat HIV/AIDS. It does this through a simple mechanism, prizes. The patent system is, of course, a prize. It awards to the first discoverer a temporary monopoly power, and that monopoly power results in the distortions I described above.

With the prize system, we use the power of competitive markets to ensure that once a drug is discovered, it is made available at the lowest possible price. Competition ensures that the knowledge is used as widely as possible. In contrast, with monopolies, prices are raised to restrict the benefits that accrue from the knowledge. Moreover, with the prize system, rewards can better reflect the so-

cial contribution of the innovation, the true marginal contribution, as opposed to the current system, where research efforts are directed at maximizing rents, often achieved by taking rents away from others.

What is particularly innovative about this bill is section 9 on the Open Source Dividend Prizes. It recognizes that there is an alternative, more open and collaborative approach to innovation that has proven itself enormously successful in a number of areas of research, and not just IT. Research builds on previous research, and by providing incentives to ensure that more knowledge is in the public domain, the bill will contribute to the advancement of knowledge in this vital area.

Finally, this bill has an important provision for a Donor Innovation Prize Fund. The United States has recognized that AIDS is a global problem and must be addressed globally. Our aid for AIDS is a humanitarian action, but it is also an action which is in our self-interest. The United States can play a leadership role in reforming the global system of financing and coordinating research and development to meet health needs, including and especially in the developing countries. With this bill, the United States does this.

I should emphasize, in closing, that especially in a time of budget stringency, the need to increase the efficiency of America's innovation system is compelling. The difference between what the drug companies charge the government and the cost of production is in the tens of billions of dollars a year. Dean Baker estimates the gap at \$270 billion a year.

Money that goes to "me-too" drugs could be far better spent. We need more of our health research budget to be spent on diseases that matter. Much of the difference between the cost of production and what is charged does not go into research, but into advertising and marketing, and much of that is not spent to transmit information that would lead to better health, but to decrease the elasticity of demand across products, thereby increasing monopoly power and profits. Moving from a patent system to an effective prize system, using the power of the competitive market place to ensure the efficient dissemination of medicines is a critical step in creating this more efficient innovation system.

America is the most innovative country in the world. It has the best universities, attracting the best minds from around the world. But America also has the least efficient healthcare system in the world, in the advanced industrial countries, spending more money per capita and a larger fraction of GDP on the healthcare sector than any other country, and getting far poorer outcomes than countries that spend much less.

We need to harness our innovation system to work to drive down the costs and to improve performance. It is not just a matter of economics. It is, in many cases, a matter of life and death. We can do it. An essential step in doing this is de-linking research and development incentives from drug prices and promoting greater sharing of scientific knowledge. This bill does this in an area that is of critical importance. It will provide a model for further reforms in our health innovation system.

Thank you.

[The prepared statement of Dr. Stiglitz follows.]

PREPARED STATEMENT OF JOSEPH E. STIGLITZ

I welcome this opportunity to share with you my thoughts on Senate bill 1138, and on the broader subject of how we can best finance research on HIV/AIDS, and for health more generally.

I should begin by saying that the approach taken by the bill is exactly right. It reflects an approach that I have been arguing for for years, including in my book “Making Globalization Work,”¹ in my academic writings,² and in the various policy roles that I have been fortunate enough to play over the last two decades.

The timing of this hearing could not be better, coming soon after the release of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination at the World Health Organization, “Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination.”³ I was able to present a keynote address at the launch of the report in Geneva just over a week ago. Interestingly, but not surprisingly, its core recommendations concerning the organization and finance of research and development coincide closely with this bill. The working group arrived at those conclusions after reviewing a wide range of alternative proposals.

I will not spend time here reiterating the seriousness of the HIV/AIDS problem, both in America and around the world, the suffering of those afflicted by the disease, the economic cost to them, their families, and our economy. Medicines have made enormous progress in prolonging lives and alleviating some of these costs and suffering, and further research promises even bigger dividends. The problem is that the medicines are *very* costly; or more accurately, the price charged for them is very high, though the cost of production is but a fraction of the price charged.

This is the inherent consequence of our current “innovation” system. The curious aspect of our current system is that the government, directly or indirectly, finances most health R&D—directly, through public support (National Institutes of Health, National Science Foundation), and indirectly, through public purchases of medicine, both in the Medicare and Medicaid programs. And even the part that is not so financed is not a “market” as we normally conceive of it; most individuals’ purchases of prescription medicines are covered by insurance. Further, their decision to use a particular medicine is largely determined by physicians, and not by patients themselves.

Given that government is financing most of the research, it is especially important that it be done in a way that is efficient. There are many dimensions to efficiency, two of which I want to talk about today. The first is that, once knowledge is acquired, it should be used efficiently. Thomas Jefferson described knowledge as being like a candle: When one candle lights another, it doesn’t diminish the light of the first. Once produced, knowledge should be disseminated and used as widely as possible.

The desire to have knowledge used as widely as possible can run counter, however, to another concern: we have to have incentives to do research.

Our patent system attempts to balance these concerns by providing a temporary monopoly power to innovators, the result of which is that there is restricted use of the knowledge for a limited period of time. This is a large inefficiency.

But increasingly, we have become aware of some other limits of the patent system. While it provides incentives, it does not necessarily provide incentives that correspond to social returns. In the health care sector, it may be more profitable to devote research to a “me-too drug” than to the development of a drug that really makes a difference. The patent system may even have adverse effects on innovation, because the most important input into any research is prior ideas; and the patent system encourages secrecy, just the opposite of the openness that is the hallmark

¹ Joseph E. Stiglitz, 2006, “Making Globalization Work,” New York: W.W. Norton. See chapter 4 for a discussion of intellectual property rights, including alternatives to the current system.

² Including “The Economic Foundations of Intellectual Property,” sixth annual Frey Lecture in Intellectual Property, Duke University, February 16, 2007, *Duke Law Journal*, 57(6), April 2008, PP. 1693–1724; “Intellectual Property, Dissemination of Innovation, and Sustainable Development,” with Claude Henry, *Global Policy* 1(1), October, 2010, PP. 237–251; “Two Ideas to Increase Innovation and Reduce Pharmaceutical Costs and Prices,” with Arjun Jayadev, *Health Affairs*, 28(1), January/February 2009, PP. 165–168; and “Medicine for Tomorrow: Some Alternative Proposals to Promote Socially Beneficial Research and Development in Pharmaceuticals,” with Arjun Jayadev, *Journal of Generic Medicine*, 2010, 7(3), PP. 217–226.

³ Published April, 2012, and available at http://www.who.int/phi/CEWG_Report_5_April_2012.pdf (accessed May 10, 2012).

of successful universities and academia more generally. (There are other adverse effects on innovation, related to the patent thicket and hold-up problems.)

There is a simple way to “square the circle,” which entails de-linking research and development incentives from drug prices, and that is precisely what S. 1138 proposed to do in the context of new medicines to treat HIV/AIDS. It does this through a simple mechanism—prizes.

The patent system is, of course, a prize. It awards to the first discover a temporary monopoly power, and that monopoly power results in the distortions I described above. In the case of HIV/AIDS, what is at stake is more than a distortion: it can become a matter of life and death. The high prices mean that those without insurance may not be able to afford medicines that could save their lives.

With the prize system, we use the power of competitive markets to ensure that, once a drug is discovered, it is made available at the lowest possible price. Competition ensures that the knowledge is used as widely as possible (in contrast, with monopolies, prices are raised to restrict the benefits that accrue from the knowledge.)

Moreover, with the prize system, rewards can better reflect the social contribution of the innovation—the true marginal contribution (as opposed to the current system, where research efforts are directed at maximizing rents, often achieved by taking rents away from others).

What is particularly innovative about this bill is section 9, on Open Source Dividend Prizes. It recognizes that there is an alternative, more open and collaborative approach to innovation that has proven itself enormously successful in a number of areas of research, and not just IT.⁴ Research builds on previous research, and by providing incentives to ensure that more knowledge is in the public domain, the bill will contribute to the advancement of knowledge in this vital area. The bill is correct in asserting that the prizes “would create a powerful economic incentive to open source knowledge, data, materials and technology, which should directly benefit product developers.”

Finally, this bill has an important provision for a Donor Innovation Prize Fund. The United States has recognized that AIDS is a global problem, and must be addressed globally. Our aid for AIDS is a humanitarian action, but it is also an action which is in self-interest. Global Health and Knowledge are both among the set of goods that have come to be called *Global Public Goods*, goods from which everyone can benefit. These goods have taken on increasing importance with globalization; as the world has become more interconnected, it has become increasingly imperative that there be cooperative actions to advance common interests.

The United States can play a leadership role in reforming the global system of financing and coordinating research and development to meet health needs, including and especially in the developing countries. As I noted before, the WHO Consultative Expert Working Group proposed the use of a prize fund to facilitate global innovation in this area.

In the critical area of HIV/AIDS research, the need to de-link research development incentives from drug prices for new medicines and to stimulate greater sharing of scientific knowledge is apparent and imperative. The economic costs of not doing so are huge, but so too may be the human costs, in terms of lives unnecessarily compromised or lost.

I should emphasize, in closing, that especially in a time of budget stringency, the need to increase the efficiency of America’s innovation system is compelling. The difference between what the drug companies charge the government and the cost of production is in the tens of billions of dollars a year. (Dean Baker estimates the gap at \$270 billion a year.) Money that goes to developing me-too drugs could be far better spent. We need more of our health research budget to be spent on diseases that matter. Moreover, much of the difference between the cost of production and what is charged does not go into research, but into advertising and marketing, and much of that is not spent to transmit information that would lead to better health, but to decrease the elasticity of demand across products, thereby increasing monopoly power and profits.

Moving from a patent system to an effective prize system, using the power of the competitive marketplace to ensure the efficient dissemination of medicines, is a critical step in creating this more efficient innovation system. We should think too about changing the balance between government-sponsored research (e.g., through the NIH, which has an impressive track record) and the patent system. The patent system encourages secrecy (and to some extent, so does the prize system, with the important exception of the open source prizes), and the hoarding of knowledge, rather than its efficient and full dissemination. (The patent, and to a less extent, the prize system has the further disadvantage of introducing high levels of uncertainty,

⁴Henry and Stiglitz, op. cit.

which is reduced, if not resolved, in government-funded research programs. In the patent there is often duplicative research. These costs of duplication and of risk are inevitably passed on to consumers, or in the case of medicines, largely to taxpayers.)

We should think too about reducing research and development costs and conflicts of interest in drug development by promoting public funding of clinical trials.⁵

We could also improve the efficiency of our research system by encouraging *real* innovations, those that make a difference for health, through value-based pricing for drugs (and since the government is such a large buyer of drugs, its use of such a system would help shape the entire marketplace.)⁶ The bill, in outlining the criteria for the award of the prizes, simultaneously outlines some of the principles that could guide a system of value-based pricing.⁷

America is the most innovative country in the world. It has the best universities, attracting the best minds from around the world. But America also has the least efficient health care system in the world, spending more money per capita, and a larger fraction of GDP, on the health care sector than any other country—and getting far poorer outcomes than countries that spend much less.

We need to harness our innovation system to work to drive down the costs and to improve performance. As I have said, it is not just a matter of economics. It is, in many cases, a matter of life and death. We can do it. An essential step in doing this is de-linking research and development incentives from drug prices and promoting greater sharing of scientific knowledge. This bill does this in an area that is of critical importance. It will provide a model for further reforms in our health innovation system.

Senator SANDERS. Thank you very much, Dr. Stiglitz.

Our next panelist is Lawrence Lessig, who is the Roy L. Furman Professor of Law at Harvard Law School, and director of the Edmond J. Safra Center for Ethics at Harvard University. Professor Lessig founded Creative Commons and The Center for Internet and Society at Stanford Law School and was previously on the faculty at the University of Chicago Law School.

Professor Lessig serves on the boards of Creative Commons, MAPLight, Brave New Film Foundation, The American Academy, Berlin, AXA Research Fund and iCommons.org, and is on the advisory board of the Sunlight Foundation. He is a member of the American Academy of Arts and Sciences and the American Philosophical Association, and has received numerous awards, including the Free Software Foundation's Freedom Award, Fastcase 50 Award, and being named one of Scientific American's Top 50 Visionaries.

Dr. Lessig, thanks very much for being with us.

STATEMENT OF LAWRENCE LESSIG, PROFESSOR AT HARVARD LAW SCHOOL; FOUNDER OF CREATIVE COMMONS AND THE STANFORD CENTER FOR INTERNET AND SOCIETY, CAMBRIDGE, MA

Mr. LESSIG. Mr. Chairman, thank you very much for the opportunity to testify.

As you know, since the beginning of this Republic, there has been a fierce debate about how best to create incentives for scientists and innovators to discover and to bring to market advances in science that address important public needs. On one side of that debate have been the supporters of exclusive rights, secured by the government. The Constitution gives Congress the power to secure such rights. And since the earliest days of the Republic, Congress

⁵ See, e.g. Stiglitz and Jayadev, 2010, op. cit.

⁶ See, e.g. Stiglitz and Jayadev, 2010, op. cit.

⁷ One of the key principles is to focus on “incremental therapeutic benefit ... as compared to existing drugs.”

has, by law, established mechanisms which secure exclusive rights to inventors.

On the other side of this debate have been skeptics about exclusive rights, at least within some domains of innovation. These skeptics have not doubted the need for incentives. They have instead worried that the costs of the system of incentives secured through government-granted monopolies sometimes outweigh the benefits. Such monopolies are, of course, just property rights.

But as another Nobel Prize winning economist, Ronald Coase, wrote in 1959,

“All property rights interfere with the ability of people to use resources. What has to be ensured is that the gain from interference more than off-sets the harm it produces.”

Now, these costs are many and, in my view, too often just simply ignored. They include not only the costs of administering any patent or copyright system, but also the costs imposed upon the environment of discovery itself.

Many have worried, for example, that one unintended cost of the Bayh-Dole Act has been to inhibit the sharing of scientific knowledge among academics, as technology transfer offices at universities have instructed researchers that secrecy is necessary to protect the patentability of inventions. Now, we have no way to be certain about the cost of such a change in incentives. But we need to worry about whether such costs outweigh the benefits of the system.

Now, my view is that the patent system, in general, has provided important support for innovation. But it is important that Congress innovate with alternatives and test alternatives to see whether it is the best system in all areas of innovation and whether there aren't better systems for particular areas of innovation.

Now, I've been asked to address one particularly important part of this bill, what's called the Open Source Fund in section 9. And this, of course, builds upon the insight that we've seen since the beginning of the Internet where scientists have been experimenting with alternative ways to share scientific knowledge. The traditional scientific journal provided an important service. But the process and constraints of journal publication were grounded in the technology of physical printing.

The significant investment in producing published work justified the strict control on distribution. And vigorous enforcement of copyright and access restrictions were essential tools to provide the revenue necessary to support even nonprofit journal production. Free access was simply not feasible.

But as the traditional mode of scientific publication has moved to the Internet, the temptation of at least some has been to exploit market power to radically increase the cost of access. In one study, for example, the Association of Research Libraries calculated that between 1986 and 2004, while the CPI increased just 73 percent, the unit cost for serial publications increased by close to 190 percent.

Likewise, in a study published in 2004, Theodore Bergstrom and R. Preston McAfee found that the average cost per page of a for-profit journal was 4.5 times the average cost of a not-for-profit journal, and the cost per citation was 9.2 times the cost of a not-for-

profit journal. Now, these differences don't reflect the relative inefficiency of for-profit journals. They reflect instead a business model that seeks to exploit the inelastic demand that at least some have for scientific journals. Whatever the price, Harvard University will pay it. And for many publications, the benefit from the increase in that price to elite universities more than outweighs the loss from institutions that can no longer afford access.

The Internet changes this dynamic dramatically by offering a free digital platform for distribution of creative work—and not just publications, data as well. But this work, too, needs revenue to support its provision. And so journals such as the Public Library of Science Medicine make published work available for free, but the authors must pay publication fees in order to make that work available initially. And while these fees are often subsumed within research budgets, these research budgets could benefit from the support that the Open Source Dividend Prize offers to make it so that more scientists can make their work available in this particular way.

Finally, let me just make one final comment about this hearing and your bill. I've spent the last 5 years of my career working on the cynical story of Congress. And the cynical story of Congress would predict that such a bill and such a hearing would never occur. And, indeed, it's not surprising that we have a bill with one Senator sponsoring it and a hearing with no Senator except the sponsor present.

So when Jamie asked me to come, my initial reaction was: Why waste my time? But I think it's extremely important—and I commend you, Senator—to give America a conception of how legislation could occur where it was sense and not campaign dollars that drove the bottom line of what Congress did. So I thank you for the opportunity to fling myself down here for this purpose, at least, and I strongly support the innovation you're trying to add to this field.

Thank you.

[The prepared statement of Dr. Lessig follows:]

PREPARED STATEMENT OF LAWRENCE LESSIG

INTRODUCTION

Mr. Chairman, and members of the committee, my name is Lawrence Lessig, and I am a professor of law at Harvard Law School. I also direct the University's Edmond J. Safra Center for Ethics. I am honored to testify in support of Senator Sanders' important legislation.

I have been asked to address section 9 of Senator Sanders' bill, concerning "open source dividend prizes." My work studying innovation and creativity on the Internet, especially as it relates to "open source" and "free software" licensing, provides the background that informs my view of this provision. In light of that work, I am strongly supportive of the effort to experiment in alternatives to create the necessary incentives for scientists and researchers to produce the knowledge that progress in science requires.

INCENTIVES TO DISCOVER

Since the beginning of the Republic, there has been a fierce debate about how best to create incentives for scientists and innovators to discover and bring to market advances in science that would address important public needs.

On one side of that debate has been supporters of exclusive rights, secured by the government, in the form of patents and copyrights. The Constitution, for example, expressly gives Congress the power to secure to "Inventors" and "Authors" such ex-

clusive rights. Since the earliest days of the Republic, Congress has by law established mechanisms by which such exclusive rights can be secured.

On the other side of this debate have been skeptics about exclusive rights, at least within some domains of innovation. These skeptics have not doubted the need for incentives. They have instead worried that the costs of the system of incentives secured through government-granted monopolies would outweigh the benefits. Such monopolies are, of course, just property rights. But as Nobel Prize winning economist Ronald Coase wrote in 1959,

All property rights interfere with the ability of people to use resources. What has to be ensured is that the gain from interference more than off-sets the harm it produces.

These costs are many, and too often simply ignored. They include not only the costs of administering any patent or copyright system, but also the costs imposed upon the environment of discovery itself. Many have worried, for example, that one unintended consequence of the Bayh-Dole Act has been to inhibit the sharing of scientific knowledge, as technology transfer offices at universities have instructed researchers that secrecy is necessary to protect the patentability of inventions. We have no certain way to measure the significance of this effect, or its prevalence. But skeptics of an exclusive rights strategy for creative incentives worry that we systematically ignore these important costs, and thereby interfere with crucial discoveries.

It is my own view that the patent system has provided essential and critical support to drug development in particular, and innovation more generally. But it is also my view that Congress should experiment with alternatives to the traditional patent system, and evaluate more carefully the conditions under which those alternatives might create more incentives at less overall cost.

The idea of a “prize fund” as an alternative to an exclusive reliance on patents has a long historical pedigree. From the birth of the Republic, both private and public institutions have experimented with prizes as a less costly way to induce important innovation. In the 18th Century, both in Britain and in the United States, private societies “for the Encouragement of Arts, Manufacturers, and Commerce” were established to offer prizes for named innovations. Sometimes these prizes were given in lieu of patents. Sometimes they complemented patents. But the urge to experiment was driven by the recognition that no single, simple system of incentives would produce the optimal amount of innovation. And that innovation about the system of incentives is just as important as the innovation those incentives create.

The innovation contemplated by this bill would, at a minimum, teach us a great deal about the utility of the prize fund alternative to patents in the context of medical research. More importantly, it would incentivize discoveries that then would be available cheaply to patients in desperate need. I strongly support this limited experimentation, both because of this important benefit to patients, and because it might well promote the progress of understanding about how best to induce this class of medical innovation more generally.

THE OPEN SOURCE FUND

Senator Sanders’ bill also includes a critical innovation to create incentives to support “open sourced” knowledge. This too is an important change which I strongly agree with.

Since the birth of the Internet, scientists have been experimenting with alternative ways to create and share scientific knowledge. The traditional scientific journal has no doubt served science well. But the process and constraints of traditional journal publication were grounded in the technology of physical printing. The significant investment in producing published work justified the strict control on its distribution. Vigorous enforcement of copyright and access restrictions were thus essential tools to create the revenue necessary to support even non-profit journal production. “Free access” was simply not feasible.

But as this traditional mode of scientific publication has moved to the Internet, the temptation of at least some has been to exploit market power to radically increase the cost of access. In one study, for example, the Association of Research Libraries calculated that between 1986 and 2004, while the CPI increased just 73 percent, the unit cost for serial publications increased by close to 190 percent. Likewise, in a study published in 2004, Theodore Bergstrom and R. Preston McAfee found that the average cost per page of a for-profit journal was 4.5 times the cost of a not-for-profit journal, and that the cost per citation in a for-profit journal was 9.2 times the cost in a not-for-profit journal. These differences do not reflect the relative inefficiency of for-profit journals. They reflect instead a business model that seeks to exploit the inelastic demand that at least some have for scientific journals. What-

ever the cost, Harvard University will pay it. And for many publications, the benefit from increasing the price to elite institutions more than outweighs the loss from institutions that can no longer afford access.

The Internet could change this dynamic dramatically. By offering a free digital platform for distributing creative work of any kind, the Internet enables “open source” models of scientific publication. Journals such as those supported by the Public Library of Science produce high quality publications, licensed freely on the Internet, with the same rigorous peer-review that marks traditional scientific publications.

Because this work is licensed freely, it is accessible to any researcher around the world. And because it is licensed freely, innovative technologies for “machine processing” the work and extracting data for further scientific analysis can occur without any cloud of illegality. While the business model of many artists is restricted access to their work—so as to secure, rightly and properly, the necessary revenue to support their creativity—the business model of scientists is free access to their work. Open source models of publication support this business model of scientists, and advance the spread of knowledge and innovation generally.

It is important to emphasize that such open source methods do not reject the idea of intellectual property in general, or copyright in particular. Indeed, to the contrary: “open source” publication properly understood depends upon intellectual property. When PLOS licenses its articles under a Creative Commons Attribution license, it is relying upon the copyright that the law automatically gives to authors of creative work, but it is deploying those rights in a way that fits with the business model of the creator—here, the scientist who wants her work distributed freely. This desire is not inconsistent with copyright. It is instead a perfect manifestation of the objectives of copyright: to secure to authors a benefit that helps them achieve their creative objective, and thereby helps the public too. It is for this reason that the late Jack Valenti, former president of the Motion Picture Association of America, endorsed the Creative Commons project upon its launch in 2002. *As he said then*, the licenses simply secure to the author more easily the freedom the law of copyright intends the author to have. They do not deny the freedom of other authors to restrict access to their work. Neither does the existence of “open source” models of publication deny the freedom of others to license their work in a more restricted way.

But open source publication does not eliminate the need for revenue. It simply shifts the source of revenue, so as to secure free and open access to research results. Journals such as PLOS Medicine make the published work available for free. But authors are asked to support the publication of the work by paying a publication fee. And while these fees are often subsumed within the research budget of the scientists whose work is being published, they point to a more general need to secure alternative sources of revenue to support this more freely accessible mode of publication.

The “Open Source Dividend Prize” described in section 9 of Senator Sanders’ bill is an innovative way to support this more general need. By creating a fund and a mechanism for rewarding scientists who make their work freely accessible, the bill could increase dramatically the range of work accessible freely. Most scientists prefer that their work is easily accessible. Giving them even a chance at a fund that might compensate for that free access is likely to induce many more to make their work freely accessible.

This is especially valuable for HIV/AIDS research, and for those who depend upon it. The burden of this disease is not exclusively born by those who can afford the high cost of journals. It is instead primarily born by people living in the regions with the least access to medical information. Creating incentives for free distribution of HIV/AIDS-related research will have a dramatic impact on those regions most heavily burdened by this disease, and could provide a model for further innovation in research incentives for other critical diseases.

The same point is true of other open source resources in science—including data, materials necessary to replicate funded research (cell lines, model animals, DNA tools, reagents, and the like), and patents. These resources too can all be licensed in a manner consistent with the principles of open science. For the same reasons such licensing of publications would benefit HIV/AIDS research, open licensing of these resources would as well. Between 2000 and 2011, for example, the USPTO granted more than 2,000 HIV/AIDS related patents to universities, colleges, and foundations. Incentives to free access to these inventions might be incredibly important to new discoveries.

THE IMPORTANCE OF THIS LEGISLATION NOW

The importance of this bill is that it would create incentives for scientific innovation where insufficient incentives exist right now. But in a critical way, the bill itself represents an innovation in legislation where there are insufficient legislative incentives existing now.

It is commonplace to note Congress' attention to matters that involve significant gains or losses to well-funded special interests. But it is likewise rare for Congress to act in contexts in which there is no clear, well-funded interest that benefits from Congress' intervention.

This bill contradicts that cynical rule. There is no "open source" industry that would support, either through lobbying or campaign contributions, the experiment that this bill envisions. There is no well-funded interest group that is likely to make this its No. 1 cause. Instead, this bill is a response to a type of market failure in government policymaking—the tendency to legislate only when strong private interests push—by proposing a substantive reform that responds to a market failure in the translation of scientific discovery—the failure to price innovations close to their marginal cost.

Much of my own work over the past 4 years has pointed to, and criticized, this cynical rule about the behavior of Congress. But I am happy to testify in support of a bill that weakens my own argument for that cynical rule. I don't know of anyone who would predict that a bill such as this could pass a Congress whose elections are funded as this Congress' is. But it would be wonderful for such a prediction to be proven wrong.

Senator SANDERS. Thank you very much.

Last but certainly not least of our panelists is Jamie Love. James Love is the director of Knowledge Ecology International (KEI), the winner of a MacArthur Award—you see, I get a little bit intimidated standing up here with all you smart people. I've got Nobel Prize winners, MacArthur—for Creative and Effective Institutions.

Mr. Love is also the co-chair of the Trans Atlantic Consumer Dialogue Intellectual Property Policy Committee and chairs the Essential Innovations board of directors. He serves as an advisor to U.N. agencies, national governments, intergovernmental organizations, and nongovernmental organizations on innovation and intellectual property rights, and has been working on the potential for Prize Funds for medical innovation for at least a decade. And Jamie is somebody I've known for a long time and much admire.

Jamie, thanks very much for being with us.

STATEMENT OF JAMES PACKARD LOVE, DIRECTOR OF KNOWLEDGE ECOLOGY INTERNATIONAL; CO-CHAIR OF TRANS ATLANTIC CONSUMER DIALOGUE INTELLECTUAL PROPERTY POLICY COMMITTEE, WASHINGTON, DC

Mr. LOVE. Thank you. I'd like to start by saying my prepared statement is 14 pages long, and rather than attempt to read it in 5 minutes, I will provide a summary.

Today, we are asking that the Congress should undertake a radical and transformative change in our incentive system for HIV/AIDS. This is a big ask, of course. So why should Congress consider something as radical and transformative as it relates to AIDS?

Part of the answer is that the current system is flawed in important ways, many of which were referred to by the other speakers. But these flaws would be acceptable if there was no other feasible way to stimulate innovation. I'm here today to echo the views of several of the other witnesses and to say that the Prize Fund approach is better than the existing system and, indeed, so much better that logic, evidence, and duty compel the Congress to make the change.

As elected representatives, we ask you to improve our lives and to find better ways to solve old problems. The Prize Fund is a reform that builds on everything that is well-known about the economics of innovation. It eliminates the artificial scarcity of new medicines and addresses well-known flaws in the current system of granting product monopolies.

The current system places a crushing financial burden on patients and the broader public, often at the expense of access itself. The current system does not appear to be sustainable or appropriate for dealing with the HIV pandemic which requires high levels of access to new drugs, not only in the United States but throughout the world.

Others have referred to a number of basic facts that the United States, for example, has 1.2 million persons living with HIV. And with new infections, that number is growing every year. I can remember when the size of the community was considered 200,000 people, and now it's 1.2 million people. And 5 years from now, it will be more than 1.2 million people.

You mentioned the cost of Atripla—the average wholesale cost of Atripla being \$25,000 a year. That's actually a fairly inexpensive calculant in the current environment in the United States. Some of the more expensive regimes, even for treatment of naive patients, could be as much as \$35,000, and for people that have developed drug resistance, which a lot of patients will—that will happen to them over the period of their treatment. It's a lifelong treatment at present. The treatments could be \$50,000 to \$75,000 per year.

I don't see how you take a country with 1.2 million people that have that condition and impose those kinds of astronomical costs. The CDC currently says that 64 percent of the people living in the United States that are HIV-positive are not receiving drugs. Recent studies also show that people—when they are taking drugs that the risk of re-infection goes down by as much as 95 percent.

Some of the companies are now trying to encourage people that are not even HIV-positive to take drugs in order to prevent retransmission if they are high-risk groups. There's no way you can do that at the current prices.

Now, the bill proposes a \$3 billion reward fund for innovation split into three different types of innovations. It has an end-product prize, which is similar to the economic incentive you have out of the monopoly at present. But it's better, because it rewards innovations based upon the improvement of health outcomes benchmarked against existing drugs, and it stops the rewarding of products which are just comparable to existing drugs.

I will note that of the 15 largest selling products in the United States today for AIDS, 13 of the 15 were registered by the FDA after 2003. I'm sorry—before 2003. They're like 9-year-old products in terms of the underlying drugs that are used in them. I mean, some of them are fixed-dose combinations that have come on the market earlier, but they're made up of older drugs, basically.

We spend probably easily about \$8 billion a year more every year than we have to for AIDS drugs at current prices right now to support the cost of the monopoly. With that, you've gotten approximately one drug a year out for the last 25 years, of which most of them are no better than the existing drugs and are just minor vari-

ations on the same drug, just as FTC is almost an identical drug to 3TC, a product that was first registered in 1995.

So the Prize Fund would reform that incentive by—instead of just saying that you get money if you replicate what these other drugs do with minor improvements, it would say that—it would look at what you do to improve health outcomes benchmarked against existing drugs. So it would de-incentivize copycat drugs, but it would incentivize things that actually did something that is medically new and would benefit the patients the most.

So that's the reform of the end product. And it's calibrated, by the way, at about three times what the industry says it costs to produce a single drug on a risk-adjusted cost-to-capital basis just for the U.S. market, which is only 24 percent or 25 percent of the world's GDP. So it's actually a fairly generous allocation.

It also adds an Open Source Dividend of \$150 million a year to incentivize people to open source access to libraries, to data, to materials, and to patented inventions, of which there are thousands in the HIV area, to make it easier for drug developers to get the kind of research that Professor Stiglitz and Professor Lessig referred to that is necessary for the R&D process.

And, finally, it opens the door for the development of competitive intermediaries to fund upstream research further on through a competitive system where employers and insurance companies would choose the manager of their money for dealing with this issue that's referred to as a so-called valley of death in the development area, but in an open source manner. Taken together collectively, this is like a nuclear option for the pharmaceutical sector.

Instead of one sector in the AIDS sector—if it would work in the AIDS sector, which is a completely dysfunctional market right now, where things are completely unsustainable, where you have literally the inability at the present to deal with the population, the growing demand, and you have tens of millions of people outside the United States right now who are suffering—a huge crisis in funding right now and sustainability for AIDS treatment outside the United States. It would take this market, and if it would work here, it would create enormous pressure to rethink the rest of the problem for cancer drugs, for diabetes, and for all sorts of other areas.

Senator SANDERS. Not so loud. Somebody may hear you.

[Laughter.]

Mr. LOVE. And so the challenge is the government. If you have a system that doesn't work, and it's about innovation, can you innovate, and can you do something different?

Thank you very much.

[The prepared statement of Mr. Love follows:]

PREPARED STATEMENT OF JAMES PACKARD LOVE

My name is James Packard Love. I am pleased to testify today in support of S. 1138, the Prize Fund for HIV/AIDS.

I am the Director of Knowledge Ecology International (KEI), a non-profit organization that is concerned with the management of knowledge and human rights. A significant part of our work focuses on the development of and access to new medicine technologies, including in particular new medicines, vaccines and diagnostic devices. KEI was created as a new corporation in 2006 to carry out the work done earlier by the Consumer Project on Technology (CPTech) and the Taxpayer Assets Project (TAP), two projects of the Center for the Study for Responsive Law (CSRL).

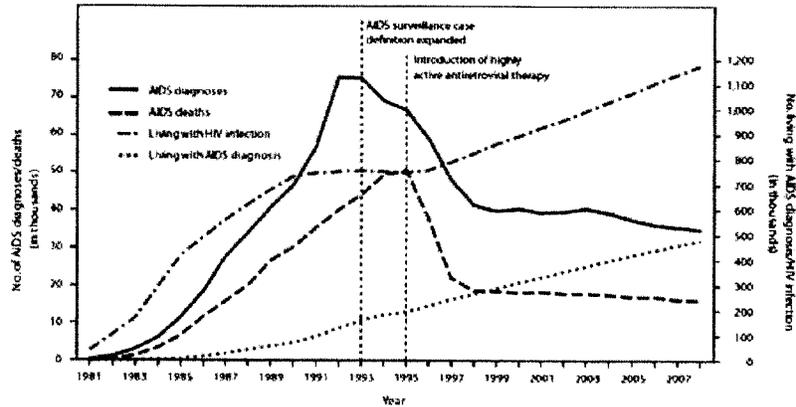
Including the work for KEI, CPTech, and TAP, I have worked extensively on issues relating to medical innovation since 1991, when I was asked to review an agreement between Bristol Myers Squibb (BMS) and the National Institutes of Health (NIH) for the commercial development and sale of Taxol, a drug for cancer invented by the NIH.¹ Since 1991, I have been involved in more than two decades of research and analysis into various aspects of the drug, vaccine, and medical device industries, including, for example, the economics of discovery and commercial development, the efficacy, efficiency, and fairness of various incentive mechanisms to stimulate investments in private sector R&D, the pricing of medicines and vaccines (including products developed with government support), the setting of research and development priorities, intellectual property right policies, and new approaches to supporting research and development, including those that encourage more open systems of innovation. A list of several publications on these topics is available at <http://keionline.org/jamie>.

Since 1994, I have worked on both domestic and international aspects of these issues. Since 2000, I have been a consultant, advisor, or expert for the World Bank, the United Nations Development Program (UNDP), the World Health Organization (WHO), UNICEF, the U.N. Human Rights Council, the World Intellectual Property Organization (WIPO), the Global Fund for HIV/AIDS, Tuberculosis and Malaria (TGF), regional intergovernmental bodies including the European Parliament, the European Patent Office (EPO), the African Union (AU), and several national governments and NGOs. I am the U.S. co-chair of the Trans Atlantic Consumer Dialogue (TACD) Policy Committee on Intellectual Property, the Chairman of Essential Inventions, the Chairman of the Union for the Public Domain, and a member of a number of committees, and task forces, such as the 2.3(c) Committee (to implement paragraph 2.3c of the WHO Global Strategy on Public Health, Innovation and Intellectual Property).

THE CURRENT AND LOOMING CRISIS IN THE MARKET FOR NEW DRUGS FOR HIV/AIDS

My earliest work on treatments for HIV/AIDS drugs was focused on the pricing of AIDS drugs in the United States, including cases where the U.S. Government had played an important role in funding the research and development. One insight was that the pricing of drugs invented with extensive public support was at least as aggressive as the pricing of products developed without such support, and indeed, often the government supported inventions were more expensive. Another insight was that the pricing of a product had almost no relationship to actual private sector outlays on research and development for that product, or to its costs of manufacturing. In the absence of competition, typically due to some type of government enforced monopoly such as the exclusive rights associated with patents, orphan drug designations, pediatric testing, or regulatory test data reliance, prices were set according to the seller's perception of the patient's willingness to pay. For treatments for AIDS, a potentially lethal disease, the better the drug, the higher the price, moderated only by the unwillingness of insurance companies, employers and governments to reimburse high-priced drugs. In the early days of the HIV/AIDS pandemic, the combination of a politically influential patient community and a relatively small number of persons receiving treatment made it possible for drug companies to be very aggressive in terms of prices, as the costs of the drugs were absorbed by the larger population. In the United States, after 1996, when effective three-drug antiretroviral therapy (ART) was first introduced, the number of AIDS-related deaths plummeted. With fewer deaths and but thousands of new infections each year, there was a steady rise in the number of persons living with HIV, which today the Centers for Disease Control and Prevention (CDC) estimates to be more than 1.2 million persons in the United States.

¹Subcommittee on Regulation, Business Opportunities, and Energy, of the Committee on Small Business, U.S. House of Representatives. *Exclusive Agreements between Federal Agencies and Bristol-Myers Squibb Co. for Drug Development: Is the Public Interest Protected?* July 29, 1991. Hearing Record. Serial No. 102-35.



At present, CDC estimates there are roughly 50,000 new infections per year, many of them relatively young, and 16 thousand AIDS-related deaths. Depending upon assumptions regarding deaths from other causes, the number of persons living with HIV continues to grow by several thousand per year.

THE COST OF ANTIRETROVIRAL DRUGS

Since 1987, the FDA has approved 25 new molecular entities in six classes of antiretroviral drugs, or roughly one new product per year. These drugs are normally taken in 3 or 4 drug combinations, according to the relevant treatment guidelines. Over time, patients may develop resistance or suffer from the side effects of a particular regime. Given the advantages of some of the newer drugs, and the continued monitoring of treatment, the standard of care is periodically revised. Some of the older AIDS drugs have gone off patent, and are available from generic suppliers, but as the standard of care has evolved, there is a focus on the newer drugs that are still protected by patents or other intellectual property rights.

For U.S. consumers, the cost of commonly used AIDS drug regimes has increased significantly. In 2000, the combination of d4T+3TC+NVP was available at just over \$10,000 per year. Today the four recommended regimes for treatment naïve patients range have an average wholesale price of \$25,000 to \$35,000 per year, and “salvage” regimes for patients that have developed resistance to several drugs are often far more expensive.

Table 1: Average Wholesale Prices (March 2012), selected Antiretroviral Therapy regimes

| Products | Brand names | Monthly | Annual |
|--|---|------------|-------------|
| <i>Preferred, treatment naive patients</i> | | | |
| EFV/TDF/FTC | Atripla | \$2,080.97 | \$24,971.64 |
| ATV/r + TDF/FTC | Reyataz, Norvir(100), Truvada | \$2,865.17 | \$34,382.04 |
| DRV/r + TDF/FTC | Prezista, Norvir(100x2), Truvada | \$3,238.85 | \$38,866.20 |
| RAL + TDF/FTC | Isentress, Truvada | \$2,562.75 | \$30,753.00 |
| LPV/r + ZDV/3TC | Kaletra + Combivir | \$1,906.48 | \$22,877.76 |
| <i>Alternative Regimes</i> | | | |
| EFV + ABC/3TC | Sustiva, Epzicom | \$1,808.42 | \$21,701.04 |
| RPV/TDF/FTC | Complera | \$2,195.83 | \$26,349.96 |
| RPV + ABC/3TC | Isentress, Epzicom | \$2,290.20 | \$27,482.40 |
| ATV/r + ABC/3TC | Reyataz, Norvir(100), Epzicom | \$2,603.73 | \$31,244.76 |
| DRV/r + ABC/3TC | Prezista, Norvir(100x2), Epzicom | \$2,966.30 | \$35,595.60 |
| FPV/r + TDF/FTC | Lexiva (700x2), Norvir(100x2), Truvada | \$2,914.99 | \$34,979.88 |
| FPV + TDF/FTC | Lexiva(700x4), Truvada | \$3,204.13 | \$38,449.56 |
| LPV/r + TDF/FTC | Kaletra + Truvada | \$2,262.79 | \$27,153.48 |
| TPV/r + TDF/FTC | Aptivus, Norvir(100x4), Truvada | \$3,959.99 | \$47,519.88 |
| T20 + TPV/r + TDF/FTC | Fuzeon, Aptivus, Norvir(100x4), Truvada | \$7,208.71 | \$86,504.52 |

The AWP of the products bears no relationship to the costs of manufacturing. The range of prices for products varies considerably, particularly when expressed as the price per formulated active pharmaceutical ingredient (API). (See Table 2)

In the United States, the leading HIV drug Atripla (TDF/FTC/EFV) sells for more than \$57,000 per formulated kilo of active pharmaceutical ingredient (API). Pfizer and GSK sell Maraviroc in both 150 and 300 mg tablets, for the same price. Depending upon the dose, the price ranges from \$63,000 to \$126,000 per kilo of API. J&J's drug rilpivirine is sold for \$9,653 per year in the United States, or \$1.058 million per formulated kilo of API. In contrast, outside of the United States, the best prices for the most commonly used generic AIDS drugs are between \$212 and a \$1,101 per kilo of API.² If rilpivirine, a drug with a daily dose of only 25 mg per day, was available from competitive suppliers as a generic drug in large quantities, it would likely be available for less than \$10 per year from manufacturers.

With efficient procurement and distribution, it would not be difficult to obtain generic supplies of many AIDS drugs from manufacturers for 1 to 3 percent of the U.S. prices, or less than \$1,000 per formulated API.

²Prices for generic drugs outside the United States depend upon economies of scale and the number of generic suppliers. Because of the complicated intellectual property rights for AIDS drugs, the number of patients who were treatment naive, and the severe resource constraints in most developing countries with significant incidence of HIV infections, only a handful of the current set of antiretroviral drugs are manufactured in large quantities in developing countries, and all of these products are now available at less than \$1,000 per kilo of API. If the United States was to adopt the HIV/Prize Fund legislation, the number of affordable generic antiretroviral drugs would be expanded, and include more of the products registered by the FDA since 2005, the year the WTO required patents be granted for pharmaceutical products.

Table 2: US Average Wholesale Price Compared to MSF best global generic price, annual and per kilo of API

| Brand Name | Daily dose in mg | US Average Wholesale Price, March 2012 | | MSF UTW, best global generic price, July 2011 | | Percent of US AWP |
|--------------------------------|------------------|--|--------------|---|--------------|-------------------|
| | | Annual | Per Kilo API | Annual | Per Kilo API | |
| Single drugs | | | | | | |
| Abacavir (ABC) | 300 x 2 | \$7,698 | \$35,151 | \$195 | \$890 | 2.5% |
| Atazanavir (ATV) | 300 | \$13,981 | \$127,684 | \$250 | \$2,283 | 1.8% |
| Darunavir (DRV) | 600 x 2 | \$14,762 | \$33,704 | | | |
| Efavirenz (EFV) | 600 | \$8,274 | \$37,782 | \$52 | \$237 | .6% |
| Efuvirtide (T20) | 90 x 2 | \$38,985 | \$593,374 | | | |
| Emtricitabine (FTC) | 200 | \$6,052 | \$82,910 | \$61 | \$836 | 1% |
| Etravirine (ETV) | 100 x 4 | \$11,744 | \$80,436 | | | |
| Fosamprenavir (FPV) | 700 x 2 | \$10,876 | \$21,284 | | | |
| Maraviroc (MVC) | 150 x 2 | \$13,778 | \$125,826 | | | |
| Maraviroc (MVC) | 300 x 2 | \$13,778 | \$62,913 | | | |
| Nevirapine (NVP) | 200 x 2 | \$8,677 | \$59,431 | \$31 | \$212 | .4% |
| Raltegravir (RAL) | 400 x 2 | \$14,056 | \$48,136 | | | |
| Rilpivirine | 25 | \$9,653 | \$1,057,815 | | | |
| Ritonavir (r) | 100 | \$3,703 | \$101,458 | \$183 | \$2,507 | 2.5% |
| Tenofovir (TDF) | 300 | \$10,479 | \$95,702 | \$83 | \$758 | .8% |
| Tipranavir (TPV) | 250 x 4 | \$16,022 | \$43,895 | | | |
| Fixed dose combinations | | | | | | |
| ABC/3TC | 600/300 | \$13,427 | \$40,873 | \$112 | \$341 | .8% |
| AZT/3TC | 300/150 x 2 | \$12,421 | \$37,813 | \$101 | \$307 | .8% |
| | 200/50 x 4 | | | | | |
| Lopinavir/ritonavir (LPV/r) | 25/300/200 | \$10,456 | \$28,647 | \$402 | \$1,101 | 3.8% |
| Rilpivirine/TDF/FTC | 25/300/200 | \$9,653 | \$50,372 | | | |
| TDF/FTC | 300/200 | \$16,697 | \$91,493 | \$116 | \$636 | .7% |
| | 300/300/600 | | | | | |
| TDF/FTC/EFV | 300/300/600 | \$24,972 | \$57,013 | \$219 | \$500 | .9% |

LACK OF PRICE COMPETITION IN U.S. MARKET

Even with the extensive intellectual property rights protection in the United States for antiretroviral drugs, one might expect more price competition, particularly for similar drugs within the same therapeutic class, available from eight different manufacturers. The U.S. FDA has approved 8 Nucleoside Reverse Transcriptase Inhibitors (NRTIs), 11 protease inhibitors (PIs), 5 Nonnucleoside Reverse Transcriptase Inhibitors (NNRTIs), and drugs in three new classes of drugs (fusion inhibitors, entry inhibitors—CCR5 co-receptor antagonists, and HIV integrase strand transfer inhibitors). Even though these products have medical differences, there is enough similarity and substitutability to expect some price competition, but prices are still quite high, and have increased over time, despite the growth of registered products and the expiration of patents for some older products. There are several explanations for the paucity of price competition among manufacturers, including the fact that end users are often insulated from price differences by third party reimbursement agents, and because the medical differences can be important for some patients, and it is unwise to frequently switch drug regimes, among and between classes of antiretroviral drugs. However, another reason is that there is a great deal of collusion between drug manufacturers, both for AIDS drugs and treatments for other diseases. BMS, Gilead, Merck, Pfizer, J&J, GSK and Abbott all cross license products from each other. Pfizer and GSK recently combined their HIV products to be managed by ViiV Healthcare. For several products, global rights for the same drug are split among companies in different parts of the world. For example, BMS sells EFV in the United States as a stand-alone product under the brand name Sustiva, and combines EFV with two other drugs in Atripla, a combination product sold by Gilead. Merck sells EFV outside of the United States under the brand name Stocrin. Roche sells Viracept in Europe, and ViiV sells the drug elsewhere, including in the United States. The fixed dose combination Complera includes rilpivirine, a J&J product, with the Gilead drugs TDF and FTC. GSK and

Gilead have an agreement to commercialize TDF for chronic hepatitis B in several Asian countries. Abbott, Pfizer, GSK and Merck recently announced various collaborations to develop diagnostic tests for cancer. These are just a few of the cross licensing and marketing agreements between the companies that “compete” in the U.S. antiretroviral market.

RATE OF GROWTH OF MARKET FOR ANTIRETROVIRAL DRUGS

In 2011, IMS reported sales of \$9.782 billion for the top 15 antiretroviral drugs for HIV/AIDS, based upon average wholesale receipts, before off invoice discounts and rebates. This is up from \$8.799 billion in 2010, an increase of 11.2 percent in 1 year, following a trend of double digit increases in national outlays on antiretroviral drugs.

Rate of Increase in U.S. ARV Sales

| Year | Percent increase |
|------------|------------------|
| 2007 | 10.7 |
| 2008 | 14.5 |
| 2009 | 15.5 |
| 2010 | 12.2 |
| 2011 | 11.2 |

Assuming 1.2 million persons living with HIV, and 36 percent of the current HIV+ population receiving ARV drugs, this amounts to \$8,151 per HIV+ person, and \$22,643 per person receiving ARV drugs. Any effort to implement treatment as prevention would dramatically change the rates of increase.

PATIENTS RECEIVING TREATMENT

Historically, several factors have influenced the numbers of persons on treatments. In the past, given the high cost of drugs and the side effects from taking drugs, the primary considerations were the patient CD4 count or other measures of patient health, as well as patient awareness of infections. Over time, there have been stronger arguments for beginning ART earlier, both to improve patient outcomes, and also lower rates of reinfection. New “treatment as prevention” norms may lead to a dramatic increase in the numbers of patients who would be using drugs, including in some scenarios, patients who are not HIV+ themselves, but: who are having sex with persons who are HIV+.

Estimates of the number of patients actually receiving treatments in the United States vary. CDC estimates that more than one in five persons living with HIV do not even know they are infected. One recently published study estimated that only 24 percent of persons living with HIV in 2006 were regularly receiving ART.³ The CDC recently estimated the number of persons receiving ART to be about 36 percent of the HIV-positive population.⁴ The Kaiser Foundation puts the percent of persons “not in regular care” at 50 percent of those diagnosed with HIV,⁵ or about 40 percent of persons who are HIV+.

Some health experts are calling for dramatic increases in the numbers of persons receiving antiretroviral drugs.

One obvious factor in access to treatment is the availability of insurance or reimbursements for the many persons living with HIV that have low incomes. Many of those patients now seek to obtain treatment from various federally funded or subsidized programs, including the State-run and co-funded AIDS Drug Assistance Programs, known as ADAPs.

ADAP COST-CONTAINMENT

In recent years, the ADAP programs have faced a difficult crisis in funding. One aspect of the crisis has been waiting lists in several States. According to the National ADAP Monitoring Project, in 2011, 14 States reported waiting lists for treatment, reaching 9,298 individuals by September 1, 2011. Since then, special Federal appropriations were made available which helped at least temporarily lower the

³ Gardner EM, McLees MP, Steiner JF, Del Rio C, Burman WJ., The spectrum of engagement in HIV care and its relevance to test-and-treat strategies for prevention of HIV infection. Clin Infect Dis. 2011 Mar 15;52(6):793–800.

⁴New Hope for Stopping HIV, CDC VitalSigns, December 2011. <http://www.cdc.gov/VitalSigns/HIVtesting/index.html>.

⁵Fact Sheet: The HIV/AIDS Epidemic in the United States, March 2012.

numbers on waiting lists. As of May 3, 2012, there were 2,704 individuals who have registered and qualified for treatments, but are on waiting lists in 10 States.

Since September 2009, six State ADAP programs have lowered the standards for financial eligibility, in order to control costs. Illinois, North Dakota, Ohio and South Carolina lowered the eligibility level to 300 percent of the Federal Poverty Level (FPL). Utah now uses 250 percent of FPL, and Arkansas uses 200 percent. The previous standard was 400 percent of the FPL. The changes led to the disenrollment of 445 individuals in Arkansas (99), Ohio (257), and Utah (89). Illinois, North Dakota, and South Carolina grandfathered existing clients, and will only apply the new income standards to new applicants.

As demand “has not dwindled,” *ADAP Watch* predicts “the waiting lists will likely plateau and grow again in the coming months,” and more cost containment measures are anticipated.

In addition to wait lists and lowered standards for incomes, *ADAP Watch* reports the following cost control strategies have been implemented from April 1, 2009, to April 11, 2012:

- Alabama: reduced formulary, capped enrollment.
- Arkansas: reduced formulary.
- Florida: reduced formulary, transitioned 5,403 clients to Welvita from February 15 to March 31, 2011.
- Georgia: reduced formulary, implemented medical criteria, participating in the Alternative Method Demonstration Project.
- Illinois: reduced formulary, instituted monthly expenditure cap (\$2,000 per client per month); disenrolled clients not accessing ADAP for 90-days.
- Kentucky: reduced formulary.
- Louisiana: discontinued reimbursement of laboratory assays.
- Nebraska: reduced formulary.
- North Carolina: reduced formulary.
- North Dakota: capped enrollment, instituted annual expenditure cap.
- Puerto Rico: reduced formulary.
- Tennessee: reduced formulary.
- Utah: reduced formulary.
- Virginia: reduced formulary, restricted eligibility criteria, transitioned 204 clients onto waiting list.
- Washington: instituted client cost sharing, reduced formulary, only paying insurance premiums for clients currently on antiretrovirals.
- Wyoming: capped enrollment, reduced formulary, instituted client cost sharing.
- ADAPs Considering New/Additional Cost-containment Measures (before March 31, 2013***).
- Alaska: reduce formulary.
- Arizona: instituting client cost sharing.
- California: instituting client cost sharing.
- Georgia: instituting client cost sharing.
- Virginia: enrolling clients into PCIPs.

At present, the USA faces a growing crisis in treatment for HIV/AIDS, and it is directly associated with the intellectual property right system. What was once a relatively small population of persons with a “rare” disease is now a health condition for more than 1.2 million persons. As the population of persons living with HIV grows, and the prices for products rise, patients face increasing barriers to access, and society as a whole finds it harder to bear the cost. It is highly unlikely that the United States will achieve adequate coverage of patients, at best standards of care, unless we try something radically different.

THE HIV/AIDS PRIZE FUND APPROACH

The HIV/AIDS Prize Fund Approach is a radical change from the existing system, and for HIV/AIDS, that is a good thing. By de-linking R&D costs from drug prices, the Prize Fund makes it possible to eliminate price sensitive drug formularies and other ADAP cost-containment measures, dramatically reduce the burden on employers and others who pay for AIDS drugs, and make the new “treatment as prevention” strategies feasible. The Prize Fund would also dramatically reform and improve the economic incentives for drug developers, including by providing new incentives to open source and share research on new treatments for AIDS.

THE OLD INCENTIVE SYSTEM

At present, we grant time limited legal monopolies to make, sell, distribute and use new drugs and vaccines. Following extensive lobbying by drug developers, the time limits on these monopolies continues to grow, as do the many ways that such

monopolies can be claimed. For AIDS drugs, patents on new compounds, new uses of old compounds, methods of heat stabilization, the use of gel tabs and enteric coatings on pills, fixed dose combinations, and countless minor improvements in products receive patent protection, exclusive rights to test data, orphan drug exclusive marketing rights, and other legal monopolies. Collectively these monopolies lead, very predictably to high prices, aided by both tacit and explicit collusion among leading AIDS drug developers. Faced with aggressive monopolies on the selling side, reimbursement agencies either shift huge costs to others, or find ways to limit access to treatment. The cost of legal monopolies for AIDS drugs in the United States was probably well over \$8 billion in 2011. Despite the huge outlays, only about one new drug per year has been registered, and most of these have been medically unimportant me-too products. If the annual cost of the monopoly is currently more than \$8 billion, and growing, this is an expensive way to pay for innovation.

THE NEW INCENTIVE SYSTEM

The Prize Fund for HIV/AIDS proposes more than \$3 billion per year in prize fund rewards. This would provide ample incentives for the development of new products, and also implement a much more efficient reward design, by tying innovation rewards to improvements in patient outcomes, when benchmarked to existing medicines. This single change in the incentive system would dramatically refocus private sector R&D toward projects that were medically more important.

The \$150 million in open source dividends would dramatically enhance the speed at which we introduce medically superior treatments.

If implemented in the United States, the prize fund would dramatically expand access, allowing us to reverse the rate of growth in infections, stimulate development of better products, and potentially save taxpayers and employers more than \$5 billion per year.

The size of the prize fund for HIV/AIDS would be 0.02 percent of the gross domestic product of the United States. The money for the prize fund would come from governments and health insurance providers, according to:

- The ratio of the number of persons receiving treatments for HIV/AIDS that are insured in the private sector to the number of persons receiving treatments for HIV/AIDS who received insurance or reimbursements or care from the public sector.

PRIZE DESIGN

The prize fund money would be used to pay for:

End product prizes. These are rewards for products that receive FDA approval and which are used to market. To be eligible to receive an end product prize a person shall be:

- (1) in the case of a qualifying treatment for HIV/AIDS that is a drug or biological product, the first person to receive market clearance with respect to the drug or biological product;
- (2) in the case of a manufacturing process for a qualifying treatment for HIV/AIDS, the holder of the patent with respect to such process;

Section (b) of the bill sets out a number of criteria for such prizes. Among them:

- A new product or process is eligible to receive such prizes for 10 years.
- The prizes would be based upon the number of patients using products, and the “incremental therapeutic benefit of the qualifying treatment,” benchmarked against existing therapies, or for the benefits of the new process.
- There would be a cap on the amount that any single product could receive.

Open Source Dividend Prizes. At least 5 percent of the prize money will be allocated to “open source dividends,” to reward “the persons or communities that openly shared knowledge, data, materials, and technology on a royalty-free and non-discriminatory basis.” The system for managing the open source dividends would include “time-limited period of nominations for persons or communities whose contributions were considered useful, including the evidence to support such nominations to describe the significance of the contribution.” These prizes, which would be greater than \$150 million per year at current levels of GDP, would create a powerful economic incentive to open source knowledge, data, materials and technology, which should directly benefit product developers.

Decentralized management of upstream prizes, by competitive intermediaries. The prize fund will have the possibility of authorizing multiple non-profit entities to manage parts of the prize fund, to either manage some of the funds for the open source dividend prizes, or to give prizes for upstream R&D projects. This money will be given to “communities that provide open, nondiscriminatory, and royalty-free licenses to relevant intellectual property rights.”

The competitive intermediaries would be funded by private sector employers.

- Section 10(a). Such intermediaries shall compete for funding from non-Federal entities that co-fund the Fund.

BACKGROUND ON THE PRIZE FUND APPROACH

The ideas presented in S. 1138, for rewarding innovation with cash prizes rather than monopolies, is both old and new. KEI has a web page with extensive background on the use of innovation inducement prizes here: <http://www.keionline.org/prizes>. While prizes have been used to stimulate and reward innovation both before and after the patent system was developed, interest in prizes as a mechanism has increased sharply in recent years.

Academic work on innovation prizes was reinvigorated by the work by Brian Wright in 1983, and Michael Kremer, Steven Shavell and others in the 1990s,⁶ as well as by the pioneering efforts of Michael Kremer and his collaborators to fashion new prize type mechanisms (the Advance Purchase Commitment and Advanced Marketing Commitment models) to reward development of new treatments for malaria and other diseases. Also, following interest in the crisis in the AIDS market, Dean Baker began to question the economic efficiency of monopoly rewards for new drug development—proposing as an alternative expanded direct government funding of drug development.

In 2002, Tim Hubbard and I were invited by Aventis, the pharmaceutical and life sciences company now owned by Sanofi, to meet with top level executives to develop scenarios for drug development that did not depend upon patents or other legal monopolies. By the end of 2002, Tim Hubbard and I developed, with the collaboration of several Aventis executives, a new paradigm for drug development that included three major features—a global R&D treaty to address the need to address the sustainable sharing of R&D costs, the use of innovation inducement prize funds to reward successful innovations, and the creation of new “competitive intermediaries” funded by employers, insurance companies, or individuals (under mandates), to provide funding for various open source and upstream R&D projects or achievements. This was meant to co-exist and complement existing government grant and contract programs, like those administered by the NIH. This work was further developed in articles and research papers and presented at a series of workshops and seminars from 2002 to 2004, including two at Columbia University with Jeffrey Sachs.

The notion of de-linking drug development incentives from product prices was independently being developed by others, such as the economist Burton Weisbrod, who wrote an editorial in the *Washington Post* on the topic in August 2003.⁷ Will Masters was also developing similar prize fund models to reward innovations in agriculture.

The key challenges in developing the prize fund approach were to address the sources of sustainable funding for the prize fund, and to explain how prize payments were set when the path to innovation was uncertain, the risk-adjusted costs of development was unknown and/or variable, and the true value of the products are unknown at the time of product development.

Hubbard and I proposed a competitive model, where the amount of the prizes themselves would be determined by the supply and demand for innovation, by competing for shares of a prize fund of a fixed size. Anticipating that valuation of innovations was difficult when products were new, Hubbard and I proposed a system whereby innovations were eligible to compete for prize fund shares every year for 10 years, adjusting claims each year on the basis of best evidence of utilization and benefits of innovations.

The valuation of the “end product” prizes would be based upon the incremental impact of the innovations on health outcomes, compared to older benchmarked products, subject to the flexibility to have non-linear payoffs, caps on rewards, the use of option pricing models to capture the benefits of redundancy for products that might fail or be held in stockpiles, and other nuances. Given the stochastic nature of innovation, and the ability of developers to pool risks, the system would work if

⁶1983. Brian Wright. *The Economics of Investment Incentives: Patents, Prizes, and Research Contracts*. *American Economic Review*. 73: 691–707, 1998. Michael Kremer. “Patent Buyouts: A Mechanism for Encouraging Innovation.” *Quarterly Journal of Economics* 113: 1137–67, 2001. Steven Shavell and Tanguy van Ypersele. “Rewards versus Rights.” *Journal of Law and Economics*. 44: 525–547. Previously published as “Rewards versus Intellectual Property Rights.” 1998 Harvard Law School, Olin Center for Law, Economics & Business, Discussion Paper No. 246. Also, see: <http://keionline.org/prizes/cites>.

⁷Burton Weisbrod. “Solving The Drug Dilemma.” *Washington Post*, August 22, 2003.

the size of the prize fund was large enough, and if the *anticipated* payoffs were closely enough correlated to social values of innovation.

To address the challenges of valuing pre-commercial innovations, Hubbard and I proposed systems of competitive intermediaries, that need only justify their valuations to entities (employers, insurers or individuals) that choose the intermediary.

In 2004, Representative Sanders expressed interest in drafting a bill to implement a version of the prize fund approach for the U.S. market. H.R. 417 was subsequently introduced in the 109th Congress. The Sanders bill included several of the basic ideas that have been incorporated in several subsequent proposals on prize fund.

- The bill did not eliminate the patent system, but did eliminate the patent monopoly once products were registered for sale with the FDA. Patents still could be used to establish claims on the prize fund rewards, and drug developers could also receive rewards even without patents.
- The valuation was based upon the incremental value of the innovation, benchmarked against older products.
- Products participated in the prize fund for 10 years, competing against each other for shares of a fund of fixed size.

Subsequent to the development of the Sanders bill, there was a proliferation of various prize fund proposals, including several in 2008 and 2009 in the context of the work of the World Health Organization (WHO) on public health, innovation and intellectual property rights, a 2004 proposal by Aidan Hollis for a voluntary mechanism that was later transformed into the 2009 Health Impact Fund proposal with Thomas Pogge, and a growing literature on medical prizes from a diverse group of other academics, practitioners and journalists, including, for example, Joe Stiglitz, Carl Nathan, Thomas Erren, Ron Marchant, Joseph DiMasi and Henry Grabowski, Stan Finkelstein, Peter Temin, Sara E. Crager, Matt Price, Jorn Sonderholm, Paul Hynek, Talha Syed, Terry Fisher, Thomas Erren, Adam Mann, Hafiz Aziz ur Rehman, Paul Wilson, Amrita Palriwala, Richard Bergstrom, A. Gandjour, N. Chernyak, Jan Keunen, Evert van Leeuwen, Gert-Jan van der Wilt and Tina Rosenberg, to mention a few.

Among the several papers on this topic that I have co-authored, particularly relevant are:

- 2009. James Love and Tim Hubbard. “Prizes for Innovation of New Medicines and Vaccines.” 18 *Annals of Health Law*. 155.
- 2007. November. James Love and Tim Hubbard. “The Big Idea: Prizes to Stimulate R&D for New Medicines.” *Chicago-Kent Law Review*. Volt. 82, no. 3.
- 2005. James Love and Tim Hubbard. “Paying for Public Goods.” In *Code: Collaborative Ownership and the Digital Economy*. Edited by Rishab Aiyer Ghosh. MIT Press, Cambridge. 207–229.
- 2004. James Love and Tim Hubbard. “A New Trade Framework for Global Healthcare R&D.” *PLOS Biology*. 2(2): e52.
- 2003. A New Trade Framework for Global Healthcare R&D, Access to Medicines and the Financing of Innovations in Health Care, Paper presented at Workshop Hosted by the Program on Science, Technology, and Global Development, The Earth Institute at Columbia University, and the Consumer Project on Technology, Washington, DC, December 4.
- 2003. James Love. “From TRIPS to RIPS: A Better Trade Framework to Support Innovation in Medical Technologies.” Paper for the Workshop on Economic issues related to access to HIV/AIDS care in developing countries, Agence nationale de recherches sur le sida, Marseille, France, May 27.

The 2009 articles in the Annual of Health Law provide the most concise explanation of the evolution of the core prize fund design features that are found incorporated the S. 1138, including the bill’s open source dividend and competitive intermediaries proposals. The rationale for competitive intermediaries is also discussed in the article in *Code*.

I also highly recommend the new April 2012 report by the World Health Organization’s Consultative Expert Working Group on R&D, which discusses the issue of de-linkage at some length.

THE INTERNATIONAL DIMENSION

While my testimony has focused on the domestic aspects of S. 1138, the international dimension is quite important. There are tens of millions of poor people living in developing countries who are HIV+ and who will die without sustainable access to treatment. Since the WTO rules on drug patents were enforced in 2005, it has become increasingly difficult to obtain affordable generic versions of AIDS drugs in developing countries. Not only would S. 1138 greatly benefit people living in the

United States, but it would radically transform the market for AIDS drugs throughout the world, and make a vast contribution to the struggle to make treatment for HIV/AIDS sustainable for tens of millions of poor people living outside the United States.

Senator SANDERS. Well, thank you very much.

Let's do this informally. Let me start off with an ethical question.

And I noticed, Dr. Lessig, in your biography, among many other achievements, you deal with ethics. I think the average American would be extremely upset to know that people are dying, not because we don't know how to treat those people—that's one sad aspect of life—but that they can't afford what is, in fact, a minimal cost in terms of the real production of the product to save their lives. It's like somebody over there dying and nobody's going out and reaching out a hand and bringing them in. They're drowning in a swimming pool.

What are the ethical implications of that?

Mr. LESSIG. Of course, I agree that there's a significant ethical question raised by the problem you describe of somebody not voluntarily stepping forth and saving a drowning child. But I think this problem is actually worse, because as Jamie was just emphasizing, the government is intervening in this market already. Its intervention is in the form of an exclusive right called a patent. The consequence of that intervention is to produce a market where only a tiny slice of those who are affected by the disease can actually get access to the drug.

There's a different way for the government to intervene. The government could intervene, as Professor Stiglitz has described and as your bill has made possible, in a way that would facilitate a wide range of people being able to have access to the drug.

So I think the precise ethical question is when you have two modes of intervention, and you select one that certainly will exclude the vast majority of people who need access to this drug, what possible justification could there be for that? And I don't think there is.

Senator SANDERS. In other words, the government is proactively preventing people from getting the treatment.

Mr. LESSIG. By choosing one mode of intervention over the other.

Senator SANDERS. Other comments on the ethical implications of what we're talking about?

Mr. STIGLITZ. I would just add one thing, which is the government winds up paying for the research, anyway. So it's the public's money. The effect and the way the system is designed, the public's money is not being used in an equitable way.

Senator SANDERS. Well, let me add to that. And tell me what I'm missing here. Ideally, I think what medicine is about is providing the treatment when people need it. And we've got a couple of physicians up here, at least.

And, Dr. Akhter, if somebody does not get the medicine that they need, and their illness continues, and they end up in the hospital, at a huge expense, are we saving money as a system by not providing the medicine when somebody needs it? What are the financial implications of this?

Mr. STIGLITZ. Mr. Chairman, we see this every day. I mean, it's obviously a lot more expensive when somebody gets to the hospital and then has to be in the intensive care unit. And then you spend

hundreds of thousands, if not millions of dollars, to really no avail. There's no good outcome at that point.

And so it is basically foolish to be in that position when you could do some preventive work up front, when you could provide the medication. Not only do you save the person's life, but also you prevent the transmission of the disease to the others. So you are not only providing a treatment to the individual, but you're also protecting the society, and I think that is the bigger question for us to discuss.

Senator SANDERS. So for \$200, roughly speaking, for the HIV/AIDS cocktail—by not providing that \$200, somebody will end up at the hospital, suffer—a great financial cost to the society. That does not make a whole lot of sense, I think.

Mr. STIGLITZ. That does not make economic sense. It does not make professional sense, from a medical standpoint. But that also does not make public health sense—

Senator SANDERS. Right.

Dr. STIGLITZ [continuing]. When you are leaving this individual untreated, and the person continues to spread the disease to others.

Senator SANDERS. All right. Other thoughts on that general subject?

Mr. Oldham.

Mr. OLDHAM. Yes. I think that—one of the things we mentioned was that we're living in a time of treatment as prevention. Well, if the treatment is going to be \$25,000 as opposed to \$200—300,000 people of the 1.2 million don't know they're infected. So if we increase testing, if we go by the national AIDS strategy, and try to get them in treatment, we have to be able to afford to do that. So this legislation would make that more possible.

Senator SANDERS. OK. Other thoughts—yes.

Mr. Love.

Mr. LOVE. We've been told of cases where—some jurisdictions where people are not tested to see if they're HIV-positive while they're inmates in prison until they're released, because the institution doesn't want to bear the high cost of paying for the drugs.

Senator SANDERS. I mean, it really would be—responding to that would be—I mean, it really is laughable if it wasn't so tragic, isn't it? Imagine that—not diagnosing somebody because you can't afford to pay for their treatment.

Ms. Moon.

Ms. MOON. Thank you. I think the point that the—the importance of prevention and the huge positive externalities of preventing new infections both in this country as well as worldwide has been well emphasized. And if we imagine how the public would react if an AIDS vaccine was developed and it was priced at \$25,000 or \$35,000 per person per year, I think that really drives home some of the ethical quandaries that we're facing, some of the big challenges.

But I wanted to get back to the point that Professor Lessig raised regarding the fact that IP systems are, in fact, government interventions in the market. The U.S. Government does intervene in the market here in the United States. But we also know that the U.S. Government has been pushing for more stringent IP standards

worldwide, including in developing countries, starting in the 1980s with the negotiation of the TRIPS agreement, and, more recently, through demanding certain types of provisions in free trade agreements that are being negotiated, demanding higher and higher and higher IP standards, knowing full well what the implications are for access to medicine. So I think the ethical questions reach far beyond the damages to our own society here at home and stretch really worldwide.

Senator SANDERS. All right. Let me ask you, Dr. Moon, a dumb-bunny question of which I know the answer, but some people watching this on TV may not know. Why is that? What are the economic forces involved here? Is it an accident that the U.S. Government is telling poor people around the world and their governments essentially what you're saying, that they're going to have to pay more for drugs to keep people alive? How does that happen?

Ms. MOON. Well, I think there are others on this panel who can speak more regarding—speak more on the problems with the way our own government is functioning and the way that our own trade policies are designated—sorry—are decided upon. But I think one rationale that has been put forward for why it is in the U.S. interest to push for stronger IP standards abroad is the idea that we want other countries to pay higher prices for medicines to, therefore, contribute more to research and development. That's the rationale that's been given.

Of course, whether or not that's effective, and whether or not that is acceptable in countries where people are living on \$100 per year, \$200 per year, is another issue altogether, but what I think is quite interesting to consider today is that there are, in fact, interesting alternatives that have been put on the table. Next week at the World Health Assembly, 193 member States will come together and debate the recommendation that governments come together and start to negotiate a binding convention for R&D which would set more predictable, sustainable, and fair methods for sort of calculating contributions for every country to contribute to R&D so that we don't have to rely on high prices.

Senator SANDERS. Anyone want to add to the question of how it just so happens that the U.S. Government goes around the world telling developing countries that they have to pay, in some cases, prices for drugs that their people simply cannot afford?

Dr. Stiglitz.

Mr. STIGLITZ. First, let me just highlight the seriousness of this issue. We have bilateral trade agreements with a number of countries and propose them with others. One of the developing countries that we had proposed an agreement with was—the president was a doctor, and he had given the Hippocratic oath to do no harm. And I explained to him that it was inconsistent with that for him to sign the bilateral trade agreement with the United States, because by doing that, it would deny access to lifesaving medicine to his people.

The reason these provisions are included is obviously clear. The U.S. special interest—these are not free trade agreements that we have. They're managed trade agreements—if they were free trade agreements, they would be a couple of pages long—we get rid of all our trade barriers; you get rid of all your trade barriers; all our

subsidies; their subsidies. These go on, as you know, for hundreds of pages, because they are really special interest pieces of legislation.

And a special interest that has played a very important role in shaping trade negotiations are intellectual property interests—entertainment industries and the drug companies, particularly. And their concerns have been more to maximize the rents that they get out of their drugs than maximizing innovation or maximizing the health of the world.

An example of a provision of particular concern goes well beyond issues of patents—goes to issues like data exclusivity, which means that in other countries, they cannot use data, even when it's partly financed by the U.S. Government, to license generic drugs that would provide the basis—that are equivalent and that would enable poor people in their countries to get access to drugs, as you pointed out, at as little as 1 percent of the cost of the patented drugs. The whole structure of many of these agreements is to discourage generic medicines and, therefore, to make medicine less accessible, which means to hurt health.

Senator SANDERS. Well, let me jump from—yes.

Mr. Love.

Mr. LOVE. To answer that, the policy of really going after medicine really took off in the 1980s, initially. But then toward the end of resident Clinton's term, there was this activism by AIDS activists particularly about access to AIDS drugs in Africa. And Vice President Gore and President Bush—they moderated their position. President Clinton issued an Executive order.

And to the surprise of a lot of people, George Bush kept a lot of those reforms in the early part of his Administration. He endorsed the Doha Declaration on TRIPS and Public Health in 2001. And on May 10, 2007, he entered into an agreement with the Democrats in the House of Representatives to protect access to medicine in developing countries that it dealt with by eliminating the requirement for data exclusivity in developing countries. That was the agreement they reached to moderate their demands on patent extensions and other issues.

Now, the Obama administration is in a new trade agreement, called the Trans-Pacific Partnership Agreement, right now. They're meeting this week in Dallas—they're meeting in Dallas as we speak on this issue. The Obama administration is now renegeing on the May 10 agreement. They're now re-upping the demands for data exclusivity and patent extensions. Vietnam is part of that negotiation. Peru is part of that negotiation. You know, it's designed to affect very poor countries.

The new proposal the U.S. Government has is called the TEAM proposal, something or other, on access to medicine. It's secret, except if you're a drug company lobbyist, then you can be on a cleared advisory board and you have access to that information. And they refused to present the text that the United States is proposing on this to ordinary citizens and taxpayers. It's only available if you can find yourself on one of these cleared advisory groups that the U.S. Government has.

I had one other point, and that is that India recently issued a compulsory license on a patent for a cancer drug called Nexavar.

The drug was priced at \$69,000 per year for cancer patients for kidney and liver cancer in India, a country that recently had a per capita income of \$1,300 a year. The government said that \$69,000 a year in India was not reasonably affordable. And I certainly agree with that conclusion.

Now, subsequently, the Secretary of Commerce of the United States traveled to India a few weeks ago and met to complain about this, and then Ron Kirk, the U.S. trade representative, listed this issue on the recent May 1–April 30 version of the new Special 301 Report. So, yes, it's a huge problem.

And I think one way I'd sort of think about this is in the United States, we're increasing the IPR protection, and we're raising the prices—internationally, we do it. Nobody thinks it's enough to do anything about. It's like we're a frog that's being put in a pot of water where it's being turned up 1 degree at a time, and we're just going to be cooked.

If you look at where we're going to be 20 years from now, the IPR system today for drugs is worse than it was 5 years ago. It's worse than it was 10 years ago. You have to ask yourself where is it going to be 20 years from now? This bill is an attempt to build a bridge for the future so the future is something that's consistent with human rights, consistent with universal access, consistent with our values.

Mr. LESSIG. Can I just add one point? As Jamie's intervention makes clear, it's a problem that doesn't afflict one party in this government. So let me amend my comments about the uniqueness of this event. It's also significant that this is an independent Senator raising this issue, because, obviously, the need to keep the IP interests—both pharmaceutical companies and Hollywood—happy is something that both the Democrats and the Republicans are addicted to. And there's no way out of that particular addiction so long as we have this structure of funding.

Senator SANDERS. Let me just pick up on that. A number of years ago, when I was in the House of Representatives, I went on a congressional delegation to South Africa, and it was bipartisan, tripartisan. And I will never forget sitting in a room with the president of South Africa—that was after Mandela—and he was being berated, berated, for standing up to the pharmaceutical industry at that time and suggesting that the people in his very, very poor country needed drugs that they could afford. And he was being attacked by Democrats and Republicans.

So you're right. I think this is very much a bipartisan concern.

I want to jump to another issue. I speak now as a member of the Budget Committee and a former mayor of a city.

Dr. Akhter, when we talk about very, very expensive treatments for HIV/AIDS at a time when we know the same treatment is available abroad because of U.S. funding, by the way, at 1 percent of the cost, what does it mean—DC has—you have educational problems, you have infrastructure problems, and every State in the country—virtually every State is feeling serious financial constraints right now. What does it mean to be paying very, very high prices for medicine when you know that it should be available at a much lesser price?

Dr. AKHTER. Mr. Chairman, with the current prices, they are neither affordable nor sustainable, not only in Washington, DC, but any other State. This is a major cost driver for us, as over the number of years, the number of patients will continue to increase, and the cost will continue to increase. And if the current way continues, who knows where it will end up?

Ultimately, we will end up rationing in this country. Where we're seeing, right now, 9,000 people don't get it, maybe 100,000 people will not get it. And that's where things are. But speaking strictly from the budgetary standpoint, it busts the budget. It's a budget buster. And unless the Federal Government does something—the city governments don't have much control over it.

We have gone through every avenue that I know to get the discount prices, and that's how 9,400 came to be. We go through the Defense Department. We buy in bulk. We do this. But for a private citizen to go buy the drugs, a person who is uninsured, it could be \$25,000 or \$35,000 a year. This is not sustainable. And if you look at the lifetime cost, a minimum lifetime cost of \$300,000, it is equivalent to the equity that people have in their homes—the average American living in Vermont or in Missouri will have in their homes. And so this is really not affordable, not sustainable.

There's another issue, also. When costs are so high, people who have no health insurance or people who can't afford it—they then go and try to buy it from other countries, try to smuggle it in, or try to come and register in Washington, DC, where the thing may be available, and end up doing something that's illegal. So we are asking people who are otherwise law-abiding—they've been paying their taxes, they've been working very hard—we are asking them to do these illegal things because we don't have the medications available to them. And I think that's really a very fundamental human question in addition to the budget question.

Senator SANDERS. Let me jump to another issue. We have been talking about the impact of high costs on individuals, people dying because they can't afford the artificially high price. We talked about the problems facing city and State and Federal Government budgets.

But let me go back to a question or an issue that Jamie Love raised as well, and that is, not only is the current system forcing—in some cases, mandating that people die because they can't afford the treatment, and cities to bear undue financial burden because of the high prices, but, apparently, the system isn't doing all that well in terms of new research and innovation. We are not seeing the kinds of breakthroughs—and I think others have mentioned—I think Dr. Stiglitz and others have mentioned that in many instances, drug companies could make more money from doing me-too products or investing in this, that, and the other thing, rather than investing in the most important health crisis facing Americans and people all over the world.

Dr. Love, do you want to say a word on that? Or anybody else?

Mr. LOVE. Well, I'm not a doctor, so I'll just set the record straight on that. But the good news is that there's been about 25 different new chemical entities that have come on the market in the last 25 years. That's a positive thing, because I think patients need a complicated mixture of products. They need a minimum of

three in a highly active antiretroviral treatment. A lot of them use four products, and then some people use more than that.

The feasible combinations are complicated, and people have resistance. And so it's a positive thing, you know, that there's been a pipeline of drugs. So I think everyone that works on these issues, at a very minimum, wants to protect the fact that there continues to be innovation, products with fewer side effects. The reality is, as I mentioned, 13 of the 15 largest selling products are based on drugs that are at least 9 years old.

So given the fact that we're spending \$8 billion a year to support the monopoly system on this, you know, and you maybe have two drugs on this thing that have come on the market since 1999, I'd have to say the only way you could justify the economics of this is if you didn't really try and justify it compared to anything else. It has to be compared to flat earth. It has to be compared to absolutely nothing at all.

It cannot possibly be compared to this prize system. And I know that the National Academies has been asked to look at this, and we're hoping that they'll take a deep look at it. But in terms of the thing—the most profitable products for companies are the chronic products that you take every day for the rest of your life. That's sort of the goal for a company, and they just try to get the total maximum—you mentioned lifetime earnings. It's exactly right. I mean, they want to look at what is a lifetime cap on insurance for somebody or something like that.

But, obviously, with 1.2 million people that are HIV-positive, a number that's headed north, you know, it just isn't really feasible to get the number of patients on here that you want. Now, what you want to have is products which—you want the money that you are spending, which is probably less than a half—I don't know what the exact numbers are.

If you ask people how much is being actually spent on AIDS drugs, you'd say—if we're spending \$9 billion in the United States on drugs or \$10 billion on drugs or whatever the number is, you'd have to say, then, how much money are the companies reinvesting in R&D? Is it a billion dollars? Is it a half billion dollars?

Senator SANDERS. Do we know that?

Mr. LOVE. No, you don't know. I mean, I think you could make some estimates based on the number of people in clinical trials and make some informed estimates about what's spent on these clinical trials.

Senator SANDERS. In other words, what you're saying is, at least, theoretically, what we would like is the drug companies to be investing in trying to find solutions to the most serious illnesses that we face.

Mr. LOVE. Well, they do make investments. What we don't know, given the high cost of the system, is how much they do.

Senator SANDERS. Right.

Mr. LOVE. In other words, if prices are higher by \$8 billion, how much of that trickles down into R&D, and is——

Senator SANDERS. Dr. Stiglitz, you are a doctor, right? So why don't you——

Mr. STIGLITZ. Not a real doctor, but——

Senator SANDERS. Not a real doctor, but it'll do for this committee.

Mr. STIGLITZ. The fundamental problem is that the incentives provided by our intellectual property system do not direct attention to the areas that are the most socially productive. And that's the fundamental problem. So if the returns are highest for a me-too drug that doesn't add any real value or very little value, that's what they're going to do. It's been proven successful. It divides somebody else's profits by half. And we know we can do it, because it's been proven.

So the incentives for the direction of research do not accord in any way with social returns. It's particularly true if we look at this from a global point of view, because many of the diseases are diseases of poor people, and one of the attributes of poor people is they don't have money. And when you don't have money—

Senator SANDERS. Do you need to be an economist to know that? That's my question.

Mr. STIGLITZ. And the result of that is that they aren't going to be a profit center for—but we're all affected by that, because in world globalization, viruses and bacteria don't carry passports and don't know about visas to go across boundaries. So we can all be exposed to diseases that originate—that are, at one time, a disease of the poor, and they become diseases in the more advanced industrial countries.

The broader point which Jamie has emphasized is if you look at the difference between what we pay—government, or we as a nation pay for drugs and the cost of production, that's a huge amount. I mentioned in my oral testimony studies that showed that the gap for the government alone is something like a quarter of a trillion dollars a year. Over 10 years, that's, you know, over \$2 trillion. We're talking about how do we make up for our budgetary—this is a big potential.

If all that money went into productive research, you might say, well, it was money well spent. But, in fact, a relatively small fraction of that money goes into productive research. More money is spent on advertising and marketing. And, as I again pointed out, much of that goes to trying to reduce the elasticity of demand, i.e., to increase market power, to increase monopoly profits, rather than to disseminate information to make sure our healthcare system is working better.

Senator SANDERS. Mr. Oldham.

Mr. OLDHAM. Well, I just wanted to reiterate something, and that was that, you know, these two companies that have the therapeutic vaccines—they don't have the money to produce it. One of them now, Bionor in Norway, actually has a way—this works in human beings. But you have to have enough money to get through the second level of trials at FDA so that they could actually say that we have something that actually works, because some of these medications where you have to take such complicated regimens—and it's worth it, because it does save your life or it prolongs life.

But with the vaccine, it may fit into being more realistic in people's lives, because if I'm feeling healthy and I have HIV, even at a high level, I'm not going to—I have to take care of family, raise money, do things like that. You may not adhere to your regimen.

The therapeutic vaccine is a breakthrough that can make that kind of difference, and we don't have enough money to develop it.

Senator SANDERS. OK. Thank you.

Yes, Dr. Moon.

Ms. MOON. I think Mr. Oldham raises a very important point about prizes which we've not really touched on today, which is that the benefit of the prize mechanism is that, in fact, it opens up a problem to be solved to a much broader population of potential solvers than other methods. And I think what he has reminded us of is that despite the major advance that antiretroviral therapy does offer, it's far from perfect—it's difficult to maintain—and that there are, in fact, lots of other areas of scientific inquiry that could, in fact, yield benefits, and that mechanisms for innovation that are, in fact—that encourage risk taking, that encourage breakthrough innovation, are needed. And one of the strengths, really, of the Prize Fund, I think, is the possibility of encouraging solvers from everywhere, from every corner, to come forward and put their ideas on the table.

Senator SANDERS. OK. Does anybody—we've been here for an hour and a half, and I don't want to keep you longer than necessary. Is there anything that anyone wants to add or raise that we haven't touched upon?

Jamie.

Mr. LOVE. In my written statement, on pages 5 and 6, I made some reference to the cross-licensing agreements between the companies that sell AIDS drugs. On the face of it, you'd think you'd have a lot of competition in the AIDS drugs market. There's eight different manufacturers that are among the leading people that have antiretroviral drugs. And you have a lot of me-too drugs that suggest maybe you'd have competition within the same therapeutic class. You have, in some classes, eight or nine products that are in the same therapeutic class.

Why is it you don't observe much price competition? And part of it is the legal collusion that you observe between companies. Bristol Myers and Gilead, Merck, Pfizer, GSK, Abbott, and Roche all cross-license their products in various ways in the HIV area, or outside of the HIV area.

And they're so often in bed with each other, back and forth, and, in some cases, one company will sell the drug in the United States, another company will sell it in Europe or other countries. Or there might be a fixed-dose combination, like Atripla, the leading one, that involves products from both—in the United States, Bristol Myers and Gilead. So it's hard to know. Are they partners, or are they competitors? And the prices would suggest that they're more like partners than competitors.

Senator SANDERS. All right. Let me—yes.

Dr. Stiglitz.

Mr. STIGLITZ. Just two comments I want to add. You, I think, were right in thinking about this as an experiment, an innovation in innovation, and thinking about how we can develop a better innovation system, not just for AIDS, but for health and beyond health for research more broadly.

And I just want to reiterate that in thinking about the innovation system, there are a couple of other parts. I mean, the patent

system will continue to play some role in, for instance, ideas that we haven't even thought about. In health, the prize system is particularly well suited, because we have a more well-formulated notion of what we need, and, therefore, it is particularly effective in that area.

Some other areas where—for instance, in climate change, it can be particularly effective. We know what we need in terms of more efficient batteries. So there are certain areas where the prize system is very well-suited, other areas where the patent system may still play a role.

The third and really important part is government-funded research itself. That has been very effective in the area of health—NIH, NSF. And in thinking about allocation of resources to prizes and across innovation, one has to balance all three of these components of our innovation system.

And then more particularly in the area of health, one of the points that was referred to earlier was that our system of testing is a very costly one. Drugs to be made available have to go through a set of tests. There's a lot of belief that that testing system is inefficient. And it certainly raises problems of conflicts of interest, because, typically, the drug company does its own testing, and we know some very dramatic stories of that conflict of interest playing out in ways that led to probably the death of other people.

So I think one thing to consider going forward is thinking through more deeply reform of the ways that our system of testing is conducted. And that system of testing is one of the mechanisms by which the drug companies exercise monopoly power and act as a barrier to entry—to making R&D and the drug market less competitive.

So I think that one wants—this is a really important bill in opening the door. And I do hope that you'll pursue trying to push that door further in other ways.

Senator SANDERS. We sure will. But let me just say this in thanking all of you for being here. I am more than aware that there is only one name on the piece of legislation. I'm also more than aware that I have been the only Senator at this hearing today.

But I believe—and I think you will all agree with me—that the time is long overdue for us to place that flag down and to move forward vigorously in a concept that can save millions of lives around the world, that could open up huge vistas of new research and development, and make our health system much stronger and much more cost-effective. All of us—nobody here is naïve. We know the obstacles that stand in front of us. We know the very, very powerful special interests that spend huge amounts of money on lobbying and campaign contributions who do not want us to proceed.

But I think we have an idea, and that as a result of the work all of you are doing in your separate areas, it is an idea that is spreading, not only in this country but around the world. And I think as more and more people learn about what we together are trying to do, the day in which legislation like this is passed will come sooner. And when it comes sooner, it will be of profound importance to people in our country and around the world.

So I just want to thank you, not just for being here, because I know each and every one of you has spent perhaps a lifetime or many, many years working on this issue and issues like this. We very much appreciate you coming here to the Senate today and thank you very much for your contributions.

Thank you. The hearing is adjourned.

[Whereupon, at 11:35 a.m., the hearing was adjourned.]

