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on

The High Cost of High Prices for HIV/AIDS Drugs and the Prize Fund Alternative

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Introduction:

Thank you for the opportunity to testify before you today. It is both an honor and serious responsibility to speak on a topic as critical as access to lifesaving medicines. 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, in the Sustainability Science Program at the Harvard Kennedy School of Government.

I will focus my comments on the link between drug prices here in the US, and the challenge of ensuring global access to medicines, especially in developing countries. I have worked on this issue for 13 years at the international and national levels, have advised many intergovernmental and non-governmental organizations, published a number of peer-reviewed articles, and am currently working on two books on this topic.

Access to HIV Medicines at Home and Abroad: Progress and Setbacks

First, a quick update on where we are and how we got here.

Global access to HIV medicines has increased dramatically over the past decade to a total of 7.4 million people in 2010, about 90% of whom live in developing countries (1). Two enabling factors were key for increasing access to treatment in developing countries: first, the dramatic reductions in the price of antiretroviral (ARV) 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 in the year 2000, to as low as $100 today (2) – in other words, less than 1% of the patented US price. These price reductions came about due to robust competition among generic producers, 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 US government has played an essential role in three key 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 US 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); through our contributions to these two initiatives combined, we are involved in supporting treatment for an estimated 5.6 million people living with HIV.[1] These contributions have strengthened the public image of the US overseas. Unfortunately, for the first time in five years it appears that US contributions will be decreasing – a trend that I urge you to do everything in your power to reverse.
- Third, most recently, NIH-funded research demonstrated that antiretroviral therapy (ART) can reduce the risk of HIV transmission by 96% (4). This research finding is the closest we have come to an HIV vaccine. It also means that potentially millions more people could benefit from getting access to ARVs, and that this could potentially halt the epidemic.

[1] See PEPFAR's estimates of support for treatment at: http://www.pepfar.gov/results/index.htm

Figure 1. Generic competition and prices of antiretroviral drugs

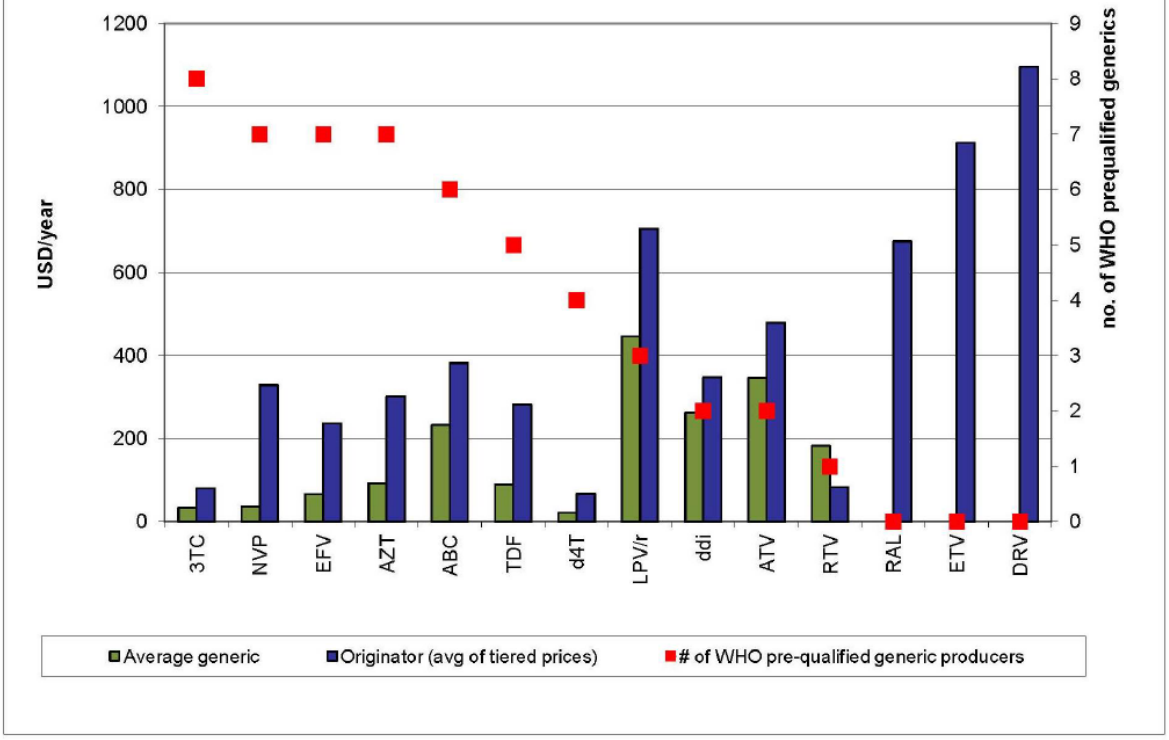

Figure 1 Number of competing WHO-prequalified suppliers by antiretroviral product. All prices are per patient/per year. 3TC = lamivudine 150 mg; NVP = nevirapine 200 mg; EFV = efavirenz 600 mg; AZT = zidovudine 300 mg; ABC = abacavir 300 mg; TDF = tenofovir 300 mg; d4T = stavudine 30 mg; LPV/r = lopinavir/ritonavir 200/50 mg; ddI = didanosine 400 mg enteric coated; ATV = atazanavir 150 mg; RTV = ritonavir 100 mg; RAL = raltegravir 400 mg; ETV = etravirine 100 mg; DRV = darunavir 300 mg. Source: MSF 2011 [17]

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 US 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 $200 from a quality-assured generic producer in India cost over $25,000 in the US. What explains this difference?

The availability of low-cost generic ARVs in developing countries is part of an unwritten global political bargain: people living in the US and Europe would 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 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 AIDS Drug Assistance Programs (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 US. But clearly this is unacceptable from an ethical and public health point of view – particularly when we are talking about populations that live on less than $1-$2 per day. 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 US and abroad.

This crisis stems from 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% 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 the HIV/AIDS Prize Fund bill S.1138 is that it would create a system that would separate the rewards for R&D from the price of the product – a powerful concept called "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% 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% 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 US 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, the HIV drug darunavir costs donors to the Global Fund over $6500 per person/year in El Salvador, or about twice the average annual income ($3380) in that country – and this is just one drug required in a multi-drug combination.[2] If we want to make HIV treatment truly sustainable, and make our donor dollars go further, we have to find ways to lower the prices of these medicines.

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

To conclude, we are far from defeating the HIV epidemic. Over eight million people are still in immediate need of treatment worldwide (1). Unfortunately, even here in the US, the sight of people waiting on long lists for access to lifesaving medicines is not foreign. Despite great progress, we are still far from resolving the access problem. By

[2] Price data from the WHO Global Price Reporting Mechanism, available: http://apps.who.int/hiv/amds/price/hdd/index.aspx

dramatically reducing the price of ARV drugs both at home and abroad, while maintaining strong incentives for innovation, the Prize Fund could create the solid foundation for a new global political bargain.

The US 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. With this bill, Senator 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 drugs 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 US and globally. I urge the Committee to seriously consider supporting this legislation. Thank you for this opportunity.

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