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Senate HELP Committee Hearing on S.1138: The Prize Fund for HIV/AIDS

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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 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 16-fold over seven 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% of the patented US 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 below).

Americans can be proud of these accomplishments, as the US 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 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). These contributions have strengthened the public image of the US overseas especially in the countries hardest hit by the

epidemic. Unfortunately, for the first time in five years it appears that US 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% (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

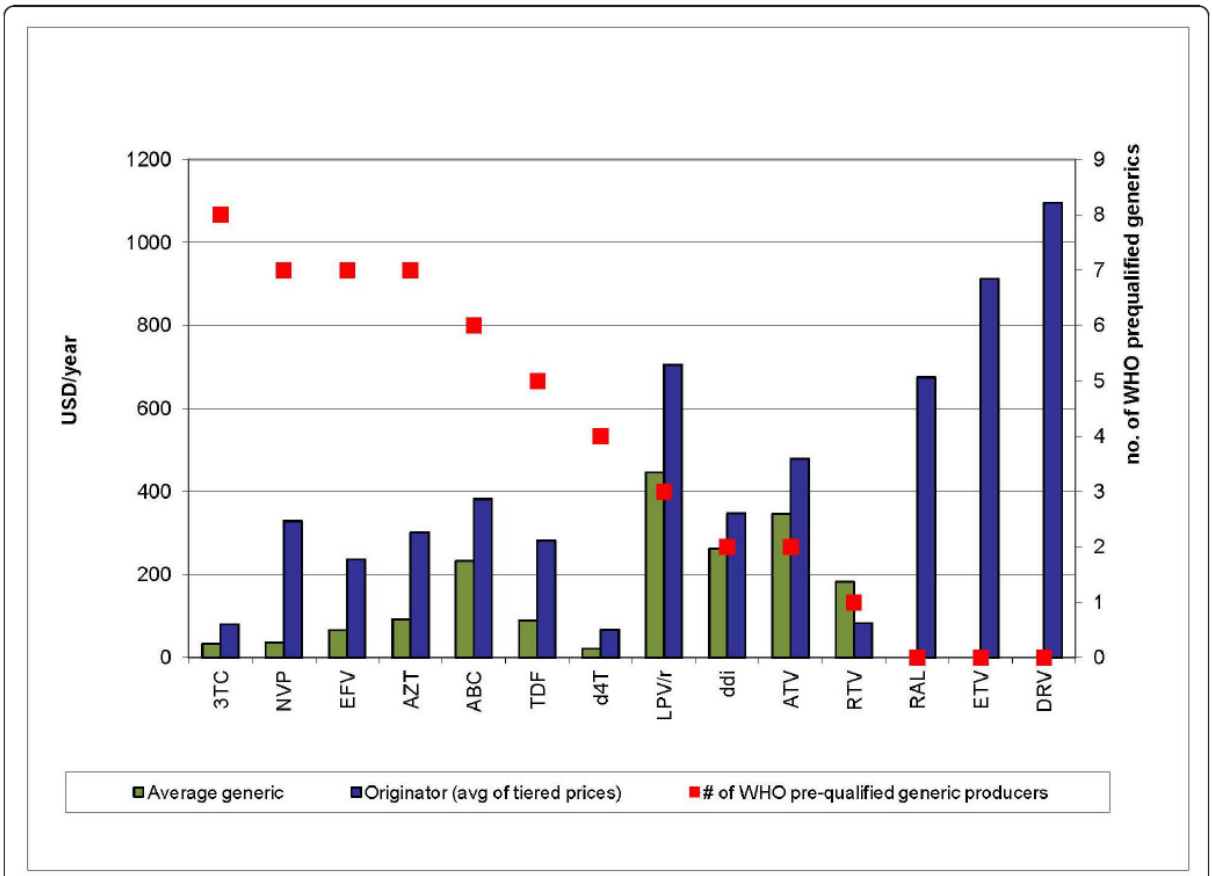

Figure 1 Number of competing WHO-prequalified suppliers by antiretroviral product. All prices are per patient/per year. 3TC = lamivudine 150 mg; NVP = nevirapine 200 mg; EFV = efavirenz 600 mg; AZT = zidovudine 300 mg; ABC = abacavir 300 mg; TDF = tenofovir 300 mg; d4T = stavudine 30 mg; LPV/r = lopinavir/ritonavir 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 $220 from a quality-assured generic producer in India cost over $25,000 in the US. 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 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 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 – 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 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% 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% 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, darunavir costs donors to the Global Fund over $6500 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 seven million people are still in immediate need of treatment worldwide, and unfortunately, here in the US 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 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. In putting forward the Prize Fund for HIV/AIDS Bill,

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

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 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. Thank you for this opportunity and for your attention, I look forward to your questions.

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