

TESTIMONY

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“Addressing the Neglected Diseases Treatment Gap”

**Subcommittee on Africa, Global Health, Global Human Rights, and International
Organizations
Committee on Foreign Affairs
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Chairman Smith, Ranking Member Bass, and Members of the Subcommittee, it is my pleasure to come before you today to discuss the importance of U.S. investments in neglected tropical diseases (NTDs), the work of the Sabin Vaccine Institute (Sabin) and its academic partner, the new National School of Tropical Medicine at Baylor College of Medicine, and suggested ways the U.S. government could refine its strategy to more effectively help those who suffer most from these devastating diseases.

My name is Peter Hotez and I serve as both the President of the Sabin Vaccine Institute, which this year celebrates its 20th anniversary, and the founding Dean of the National School of Tropical Medicine at Baylor College of Medicine that was launched in 2011. After obtaining my MD and PhD degrees from the Rockefeller University and Weil Cornell Medical College, I have devoted the last 25 years my life to developing innovations to combat the NTDs, including new vaccines and drug packages. Together with colleagues in the United Kingdom we first put forward the concept of NTDs in the biomedical literature in 2005 and shaped the science and the policy leading to deployment of rapid impact packages of donated medicines for NTDs for more than 364 million people in 25 countries across the developing world through the support of the U.S. government and the U.S. Agency for International Development (USAID).

I like to call the NTDs “the most important diseases you have never heard of.” Today virtually every person on the planet who lives below the World Bank poverty figure – approximately 1.3 billion people, as well as most people who live on less than \$2 per day suffers from one or more NTD. For instance almost all of the children who live in extreme poverty have intestinal worms such as hookworms, which feed on blood and rob children of nutrients. Hookworms have actually been shown to reduce childhood intelligence and cognition – and as a result, reduce future wage earning by 40% or more. In this way, NTDs not only occur in the

setting of poverty, but they actually cause poverty. Moreover more than one-quarter of pregnant women in sub-Saharan Africa have hookworms and go into labor and delivery profoundly anemic infants. As my obstetrician colleagues point out, it's not that African women bleed more in childbirth, but that they begin the delivery process with two strikes against them because they start out with so little blood because of their hookworms. In this way, hookworm is a leading contributor to maternal morbidity in Africa.

Indeed the NTDs have a particularly horrific impact on girls and women. One of the worst problems just coming to light is female genital schistosomiasis – a parasitic infection that produces bleeding ulcers on the cervix, uterus and lower genital tract of as many as 100 million girls and women in sub-Saharan Africa. It's a cause of bleeding, pain, and terrible shame and grounds for spousal abandonment, as well as depression. I believe it is the most common gynecological condition of girls and women on the African continent. Can you imagine if 100 million girls and women in the U.S. had female genital schistosomiasis (FGS)? As a society we would never tolerate it, but because it affects girls and women who live in abject poverty, mostly in remote parts of Africa, they go untreated. Additional information indicates that FGS is also associated with a 3-4 increase in acquiring HIV/AIDS and may be Africa's most important co-factor in its HIV/AIDS epidemic you have never heard of, but I will come back to that in a minute.

One final example of the NTDs is the disfiguring and stigmatizing effects of cutaneous leishmaniasis – also known as “Aleppo Ulcer” or “Aleppo Evil” now affecting more than 100,000 people living in Syria and who have fled to refugee camps. In the Middle East, again its girls and women are permanently scarred and rendered unmarriageable or not allowed to hold their children as a result of this NTD.

These are the reasons that NTDs are so devastating. More often than not, nobody dies, but they are disfigured, stigmatized, stunted in their growth and mentally disabled. As a result, we now have an increasing body of evidence that the reason the poorest of the poor are trapped in poverty is because the NTDs block their ability to achieve their full mental and physical capacity and live a normal life.

The good news is that we can do something about seven of the most common NTDs, including hookworm and schistosomiasis (also known as snail fever), but also lymphatic filariasis (elephantiasis), trachoma, river blindness, ascariasis (roundworm) and trichuriasis (whipworm) for an extraordinary low cost – on average 50 cents per year or even less to prevent and in some cases eliminate these diseases. In 2005 and 2006 with colleagues from the UK and WHO and elsewhere we put forth in the Public Library of Science (PLOS) the concept of a rapid impact package, and now since 2006 this approach has been scaled up through support of USAID and with advocacy from our Global Network for Neglected Tropical Diseases, a Sabin initiative.

Thanks to the generous drug donations from leading pharmaceutical companies, including Merck & Co. Inc., GlaxoSmithKline, Eisai, Johnson & Johnson, Merck Serono, and Pfizer, and the efforts of the USAID a unique and innovative public/private partnership was formed to efficiently and cost effectively address NTD control and elimination. To date, USAID's NTD Program has improved the lives more than 364 million people, delivered nearly 820 million NTD treatments, and trained over 500,000 community workers. It has exceeded expectations in its ability to deliver treatments for the seven most common NTDs, leveraging more than \$4 billions of donated drugs, and operated in 25 countries such as Cambodia, Haiti, Indonesia, Nigeria, and Senegal.

We applaud USAID's NTD Program and the U.S. government's steadfast and vital dedication to this fight, which has been instrumental in inspiring similar efforts by partner countries to initiate control programs and allocate funding. It is important to note that, if funding for USAID's NTD Program does not at least match FY 2013 levels, the capacity to deliver these medicines to those who need them most will be significantly reduced and we may see a resurgence of many of these NTDs. Furthermore, the momentum generated over the past few years could well stall if the United States steps back from its global leadership role in NTD control and elimination efforts.

In fact, the time is right for the U.S. government, through USAID and NIH/NIAID, to establish one or more Centers of Excellence for Neglected Tropical Diseases. The Centers of Excellence concept -- investing in multi-faceted research and development and the scientific infrastructure needed to support it -- is very effective in many different areas of therapeutic, vaccine and diagnostic research. For instance, NIAID currently supports 11 Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases (RCEs), focused on countering threats from bioterror agents and emerging infectious diseases. I hope we can find the resources, even in this difficult fiscal climate, to fund at least one Center of Excellence for NTDs.

However, while the USG commitment to NTDs must remain strong, we must also increase support from other sources, including the private sector. The Global Network for Neglected Tropical Diseases and our END7 campaign are hard at work raising awareness and support to address these diseases.

I would like to play for you a short promotional video that brings in the celebrity community and explains the urgency for supporting the NTDs.

PLAY VIDEO

Given the recently revealed links between snail fever and female genital schistosomiasis and HIV/AIDS, as well as malaria and hookworm, I think we now need to look to Version 2.0 of NTD control and elimination which better links the USAID NTD Program to other USG global health initiatives such as PEPFAR as well as the Global Fund to Fight AIDS, TB, and Malaria. A recent victory published in PLOS found that when Global Fund support is used for NTDs it can actually lead to the elimination of an NTD in Africa, with the example being lymphatic filariasis – elephantiasis in Togo.

We also need to encourage other government support beyond the U.S. We are grateful to the UK Government, which has also been a stalwart supporter of NTD control, while other European governments have supported R&D efforts, but the other G20 countries have been underachievers when it comes to global NTD control and elimination support. This finding is ironic given my new analysis published a few weeks ago in *Foreign Policy* that more than half of serious NTDs actually occur among the poor living in G20 countries, especially India, Indonesia, and China. I believe that a potentially important role of the new State Department Office of Global Health Diplomacy could include stepping up diplomatic pressure on the G20 to support NTD control and elimination.

Along the theme of NTDs among the poor in wealthy countries is new information coming to light from the U.S. census that 20 million Americans live in extreme poverty and University of Michigan Center for Poverty finding that 1.46 million families with almost 3 million children live on less than \$2 per day. Although we call them neglected *tropical* diseases – the truth is that poverty (more than climate) is the overwhelming determinant of these unique

infections. At our National School of Tropical Medicine, we have turned the global health lens inward to find a previously hidden burden of NTDs among the poor in the U.S. In a paper published in PLOS in 2008, I identified a group of NTDs now afflicting at least five million Americans living in poverty, mostly in the American South. They include:

- Millions of African Americans with toxocariasis a larval worm infection of the lungs and the brain linked to pulmonary dysfunction and asthma and developmental delays and seizures, respectively;
- Millions of African Americans with trichomoniasis linked with HIV/AIDS
- Hundreds of thousands of Hispanics with Chagas disease, a debilitating heart condition
- Tens of thousands of Hispanic Americans with cysticercosis a parasitic worm infection of the brain.
- Widespread arbovirus infections including dengue fever in Texas and Florida.

It's important to emphasize that these are not rare diseases. Scientists at our National School of Tropical Medicine are finding that these diseases are widespread in Texas and elsewhere in the American South, and we are now investigating the basis for their links to being extremely poor. Of interest is our finding that we have actual transmission of many of these NTDs within U.S. borders. This is not a primarily a problem of immigration – it is a problem of extreme poverty, extraordinary magnitude and simultaneous neglect. We urgently need to expand our local and national surveillance efforts for these diseases and to investigate how they are transmitted, as well as to conduct R&D for new tools, i.e., drugs, diagnostics, and vaccines.

Indeed, greater investment in NTD-related R&D for NTDs both globally and here in the U.S. is needed to support the introduction of new technologies (e.g., drugs, vaccines and

diagnostics); to ensure the achievement of the goals of disease control and elimination, as noted earlier, and address the urgent needs of particularly neglected patient populations.

Our work in R&D includes the development of novel, low-cost vaccines for NTDs – ironically for both developing countries and the U.S. Vaccines against NTDs are considered to be cost-efficient if not cost-saving with the potential to avert the suffering of millions and hundreds of thousands of deaths annually. Although the pharmaceutical sector has the knowledge base and resources to create therapies or possible vaccine candidates, there is little potential market for these new technologies and we are forced to use alternative market mechanisms to spur research and development. Sabin Vaccine Institute’s non-profit product development partnership (PDP) based at the National School of Tropical Medicine at Baylor College of Medicine is helping to fill this gap. The Sabin’s PDP focuses on creating safe, effective, and low-cost vaccines for human hookworm, schistosomiasis, Chagas disease and leishmaniasis – among the NTDs that are ravaging communities in developing countries and in the U.S. in the case of Chagas disease and leishmaniasis. Drawing on over a decade of experience, the Sabin PDP has created a comprehensive, relatively low-cost model that serves as a blueprint for vaccine development and ongoing efforts to fight public health threats that adversely impact more than one billion people worldwide. Three of Sabin’s vaccine candidates are either currently undergoing clinical testing or moving into clinical testing this year.

Over the last two decades there has been a growing recognition that the existing system for stimulating research and development has failed to deliver needed health technologies, particularly for diseases that disproportionately affect the world’s poor. Currently the vaccine pipeline is largely concentrated on the pre-clinical through phase II stages of clinical development. Projections suggest that up to a handful of new neglected disease vaccines will be

approved in the coming years because of the impressive work coming out of the PDPs. As later stage clinical trials are much more costly than earlier stage development, increased costs remain an important obstacle. While strong support has come from the Bill & Melinda Gates Foundation during the last decade, the Foundation does not have sufficient resources available to cover the needs that lie ahead. Consequently, other sources of funding will be necessary to support product development for the world's poor. Sustained investments in NTD R&D are critical to ensure the progress made is not squandered and to keep the momentum needed to ensure these new products reach those in need. The U.S. government has a significant role to play in this, as both a world leader with influence over other country investments and as a strong investor in neglected diseases R&D that help create a new generation of tools to eliminate NTDs, support U.S. foreign policy, and spur the U.S. economy both through job creation, but also to cure and prevent NTDs that now trap at least five million Americans living in extreme poverty. While the U.S. government invests in early stage neglected disease research and development through the National Institutes of Health and several other agencies, new and sustained funding is needed to enable continued progress.

We urge you, therefore, to vigorously support public/private partnerships that will benefit not only the developing world, but will ultimately benefit the economic prosperity and national security of the United States by helping to lift millions across the globe out of a vicious cycle of poverty and disease.

We, at Sabin and the National School, appreciate that global health issues have been a bipartisan priority for the United States for more than 50 years. Relatively modest financial investments have not only saved lives, but also improved the economic growth and regional stability of developing nations, and bolstered public perceptions of the United States. Since

national borders do not stop the spread of diseases and indeed many of the NTDs are widespread in the United States, addressing global health issues is vital for the protection of America's health and security. And, we certainly believe that U.S. investments must continue to support efforts to develop, implement, and adapt health tools that are culturally, financially, and technologically suited for impoverished communities.

In May 2013, the World Health Assembly passed its first comprehensive NTD resolution recognizing the progress made in combating NTDs, noting the diversity of these 17 diseases—from leishmaniasis, dengue, and Chagas disease to leprosy and schistosomiasis—advocating for predictable long-term, international financing, urging stronger commitments to research, and calling on nations to expand and implement, as appropriate, interventions against NTDs. The U.S. has clearly shown extraordinary leadership on NTDs, but the U.S. investment needs to continue if the WHA hopes to meet its goals and targets.

Mr. Chairman and Members of the Subcommittee, this concludes my testimony. I thank you, again, for your interest in furthering U.S. engagement in neglected diseases and global health and the opportunity to address you this afternoon. I am now happy to answer any questions you may have.

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