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THE CONTINUING THREAT OF NEGLECTED TROPICAL DISEASES

HEARING

BEFORE THE

SUBCOMMITTEE ON AFRICA, GLOBAL HEALTH, GLOBAL HUMAN RIGHTS, AND INTERNATIONAL ORGANIZATIONS

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THE CONTINUING THREAT OF NEGLECTED TROPICAL DISEASES

WEDNESDAY, APRIL 15, 2015

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON AFRICA, GLOBAL HEALTH,
GLOBAL HUMAN RIGHTS, AND INTERNATIONAL ORGANIZATIONS,
COMMITTEE ON FOREIGN AFFAIRS,
Washington, DC.

The subcommittee met, pursuant to notice, at 2:30 p.m., in room 2172 Rayburn House Office Building, Hon. Christopher H. Smith (chairman of the subcommittee) presiding.

Mr. SMITH. Pursuant to notice the subcommittee meets for our hearing on neglected tropical diseases.

Neglected tropical diseases, as I think many here know, or NTDs, are a group of 17 parasitic and bacterial diseases which blind, disable, disfigure, and sometimes kill sufferers among more than 1 billion of the world's poorest people, trapping the most marginalized communities in a cycle of poverty and pain.

The list ranges from Chagas to rabies to leprosy to dengue fever. However, there are others not on this list of 17 diseases that also receive far too little attention. These include diseases such as polio and small pox, which have been largely eliminated from the planet and often fatal—fortunately rare-NTDs such as kuru.

Prior to last year, that list of rare diseases included Ebola. Even though not immediately fatal, these diseases can keep children from attending school and their parents from working, as well as resulting in excessive loss of blood by mothers during birth and a resultant low birth weight babies as well.

These conditions constitute a significant hurdle to achieving economic growth and dilute the impact of foreign assistance programs. Last year, the world witnessed an Ebola disease pandemic that hit six African countries and spread to Spain, Scotland and the United States.

Furthermore, in recent years such diseases as dengue fever and chikungunya have spread into the United States. These and other tropical diseases most often victimize the poor who live in tropical climates whether in Africa, Latin America, or parts of the United States.

Even in the face of the worldwide challenges these tropical diseases pose, the administration has proposed cutting the budget in this area by 17 percent. Today's hearing will examine the problem of neglected tropical diseases and U.S. current and potential efforts to address this problem.

Eight NTDs account for almost all worldwide cases. Seven of them can be treated with low cost medication that could be dispensed by non-health workers irrespective of disease status. Nearly 80 percent of all NTD cases are comprised of people carrying intestinal worms.

On June 27th at our hearing in 2013, we learned the catastrophic nature of these preventable intestinal worm infections. So many of the problems we struggle with such as difficult births and malnourishment can be remedied without dealing with infections themselves.

You know, I am a great fan and I know the administration, both Bush and now President Obama, have done much on the nutrition side. We have a bill that will codify and expand Feed the Future.

It passed last year. It is going to be up on the docket we hope next week in the full committee. But we don't want to feed the worms. We want to feed people.

We want healthy children and mothers and families and to mitigate and eradicate these parasites. We can no longer look at photos of happy young children standing in muddy water without shoes and not think of the possibility that they are losing their future even as we see them enjoying a break from poverty in which they live because sometimes, of course, some of these diseases migrate through that means.

Yet we must understand that these are not merely diseases affecting people in faraway lands. Current U.S. law favors research in those diseases threatening the American homeland but in today's world diseases can cross borders as easily as those affected by them or the products imported into the United States.

For example, Chagas is most prevalent in Latin America but it has been identified in patients in Texas, and cases of dengue have been recently reported in Florida.

We cannot afford to assume that what may seem to be exotic diseases only happen to people in other countries, and I would note parenthetically, of course, even if that were true we have a moral obligation to aid and assist those who contract these diseases and to mitigate transmittal to the greatest extent possible.

Ten years ago West Nile virus, another rare disease, was not seen in the U.S. or anywhere else outside the east African nation of Uganda. But in less than a decade it has spread across this country and much of the rest of the world.

More than 10,000 people died of Ebola worldwide thus far. Although only one person died in this country due to that disease, we saw, clearly, how unprepared our medical services in the rest of the world were initially to deal with a rare disease that had previously been confined to isolated areas in central Africa.

There are other rare diseases, not to mention the recognized NTDs, that cause havoc if they find their way to populated international transit areas such as Ebola did last year.

Meanwhile, far too many people live lives of quiet suffering from diseases we must fight more effectively. That is why I have introduced today H.R. 1797, the End Neglected Tropical Disease Act.

Among other provisions, H.R. 1797 calls on the U.S. Agency for International Development to modify its NTD programming with respect to rapid impact packaging treatments, school-based NTD

programs which we know have been one of the most efficacious ways to date to deal with this, and new approaches to reach the goals of eliminating NTDs.

The bill also sets forth measures to expand USAID programs including by establishment of research and development programs.

One of the ideas that one of our distinguished panelists, Dr. Hotez, had suggested about a Centers of Excellence we include in the bill and I thank him again for that recommendation to combat what is happening here.

I know, parenthetically, that in 1997 when we saw an alarming spike in the prevalence in autism I wrote a law and have now written three laws including the Combating Autism Act and most recently Autism Cares that builds on Centers of Excellence at CDC and NIH to really combat that pandemic.

Although it is a developmental disease, a disability disease, the numbers are staggering worldwide as well as in the United States—one out of every 68.

So Centers of Excellence, I think, or such a center in the Southern part of the U.S., as Dr. Peter Hotez has recommended, included in the bill I think would make a significant difference for our efforts here in the United States.

In an effort to reach achievable and reachable goals to prevent and eliminate NTDs, the projected 70 percent cut in funding for such projects in the 2016 budget would pose a serious setback.

I have appealed and we plan on doing a letter to the members of the Appropriations Committee because we had a similar proposal last year that they, thankfully, in a bipartisan way ensured that we got to the $100 million level, but hopefully we can go even beyond that as we move forward in Fiscal Year 2016.

I would like to yield to any of my colleagues.

Okay. We will now welcome our first witness, the Honorable Ariel Pablos-Mendez, who is the Assistant Administrator for Global Health at USAID, a position he assumed in August 2011.

Dr. Pablos-Mendez joined USAID's leadership team with a vision to shape the Bureau for Global Health programmatic efforts to accomplish scalable, sustainable, and measurable impact in the lives of people in developing countries.

Prior to joining USAID, he worked on global health strategies and a transformation of health systems in Africa and Asia. He also served as director of knowledge management at the World Health Organization.

Dr. Pablos-Mendez is a board certified internist and until recently he was practicing as a professor of clinical medicine and epidemiology at Columbia University.

Doctor, welcome back.

We appreciate your previous testimonies before this subcommittee, always insightful and expert, and I thank you for being here. I yield.

STATEMENT OF ARIEL PABLOS–MÉNDEZ, M.D., ASSISTANT ADMINISTRATOR, BUREAU FOR GLOBAL HEALTH, U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT

Dr. PABLOS-MENDEZ. Thank you, Chairman Smith, and thank you to all the members of this subcommittee for highlighting this

important issue and I really appreciate the opportunity to discuss the U.S. Agency for International Development program to combat neglected tropical diseases.

You explained very well the realm of this space of diseases and the spectrum and the populations that it affects.

While Ebola is not technically classified as an NTD by USAID and the World Health Organization, the high profile outbreak of Ebola in west Africa in the past year has highlighted the risk of paying insufficient attention to diseases which typically occur in resource-limited settings.

And I take the opportunity to thank you, Chairman Smith, for the leadership role you played back in August when we were in recess and nonetheless it was just the right timing for mobilizing American people in the response against Ebola.

USAID is focused on its overall mission of partnering to end extreme poverty and promote resilient democratic societies while advancing our security and prosperity and our NTD program is making great progress toward ending diseases of extreme poverty.

Our global health programs include typical priorities—ending preventable child-maternal deaths and, again, I recognize the championing in this subcommittee for this cause, creating an AIDS-free generation working with PEPFAR, and protecting communities against infectious diseases under which our NTD program operates.

Still, even though we have made great progress, there are more than 1 billion people globally who suffer from NTDs and this disproportionally impacts poor and rural populations who often lack access to safe water, sanitation, essential services, and medicines.

NTDs take a very heavy human toll by creating sickness, disability, blindness, and severe disfigurement, contributing to childhood malnutrition and leading to an appreciable loss of productivity lifelong.

That is why I am very proud of the achievements in USAID's integrated NTDs program which began less than 10 year ago with a lot of support from the Congress and has accelerated success in what is really a historical scale.

With support from the Congress, the program has made solid advance in addressing the seven diseases we represent, approximately 80 percent of the global burden of NTDs and can be addressed through highly cost effective community and school-based distribution of preventive chemotherapy generally once or twice a year in these populations.

The integration of these programs has been the hallmark of the program in USAID and is now a global standard. With a budget of $100 million in the year 2014, USAID's program distributes 240 million treatments to 115 million people in 31 countries.

To date, the cumulative figure is over 1.2 billion treatments have been provided. In the year 2011, when I joined the U.S. Government, 7.7 million no longer required treatment for lymphatic filariasis in USAID-supported countries.

Last year, that increased from 7.7 to 92 million. By 2018, the number is predicted to jump to over 250 million. That is, half of the totality of the problem in the world will be managed.

In Latin America, onchocerciasis is close to elimination with transmission mainly remaining in the hard to reach border area between Venezuela and Brazil. It is a great success story in this continent.

I would like to highlight a few factors that have contributed to the success of the USAID's program and the global progress to date in addition to the support of the American people.

First, the success of USAID's NTD program would not have been possible without the partnership with the pharmaceutical sector. In 2014, USAID-supported countries benefited from over $2 billion in donated drugs.

To date, nearly $9 billion have been generously donated by Merck & Company, GSK, Pfizer, Johnson & Johnson, Merck Serono. We estimate that for every tax dollar spent by USAID, more than $26 in drugs are being donated for the countries we are supporting with USAID funding making critical investments in countries' systems to distribute the drugs and monitor progress.

Second, USAID partnership and coordination with the United Kingdom has allowed for a collective reach to almost 50 countries and the provision of 340 million treatments last year alone.

This has allowed for expansion in high burden countries including Ethiopia and Nigeria, which are very large, and ancillary global efforts to put trachoma elimination on track by defining the burden in countries throughout Africa and in Asia.

Third, USAID builds upon the existing infrastructure of national disease control and elimination programs to ensure sustainability. USAID and our partners coordinate with ministries to ensure that U.S. resources complement investment from other stakeholders and leverage local funding working with national NTD plans, and a lot of the work, of course, is based on the research, the science, and the advocates that have allowed us to come this far in the fight against NTDs.

Thanks to congressional support, progress made to date and available tools and partnerships, the elimination of these diseases of extreme poverty as a public health scourge is being—is really within our grasp. USAID is committed to working with countries and our global partners to reach the remaining 800 million people who still need treatment.

In order to ensure sustainability, we must maintain investments in research and development and monitoring and evaluation. For example, our partnerships with the Drugs for Neglected Diseases initiative just established last year and with a Coalition for Research on Neglected Tropical Diseases make important contributions toward new and much needed technologies to make it simpler initially to reach more people and to begin to consider additional diseases that today are very expensive to treat.

Part of USAID's commitment to all innovation that many of you have seen recently the work that our Center for Innovations has been doing on behalf of Ebola with new innovative personal protection equipment. I really just have to thank you for the leadership.

I think that progress has been impressive. We all need to work in maintaining support for these programs and we believe that with your support we will continue to do so.

Thank you very much.

[The prepared statement of Dr. Pablos-Mendez follows:]

Testimony of Ariel Pablos-Mendez
Assistant Administrator, Bureau for Global Health
U.S. Agency for International Development

House Committee on Foreign Affairs
Subcommittee on Africa, Global Health,
Global Human Rights, and International Organizations
"The Continuing Threat of Neglected Tropical Diseases"

April 15, 2015

Thank you, Chairman Smith, Ranking Member Bass, and Members of the Subcommittee for highlighting this important issue and providing me with the opportunity to discuss the U.S. Agency for International Development's (USAID) program to combat Neglected Tropical Diseases (NTDs).

Today, roughly one billion people live in extreme poverty. While that is still an overwhelming number of people, great progress has been made. Compared to 1990, today nearly 900 million fewer people live in extreme poverty. In 2010, the world achieved Millennium Development Goal 1 – to halve the poverty rate among developing countries – five years ahead of schedule. By 2011, the poverty rate in the developing world had fallen to 17.0 percent from 43.4 percent in 1990. And the aggregate poverty rates are now falling in every region, including sub-Saharan Africa. That is impressive progress in making the world a better place. Together with our allies, President Obama has identified Ending Extreme Poverty as an important goal and USAID has incorporated it into its overall mission of partnering to end extreme poverty and promote resilient, democratic societies while advancing our security and prosperity. USAID's NTD program is an exemplary program helping the world's most vulnerable people move from dependency to self-sufficiency and on the way to ending diseases of extreme poverty.

Today, there are still more than one billion people globally who suffer from one or more NTDs. These diseases disproportionately impact poor and rural populations, who often lack access to safe water, sanitation and essential medicines – the very people who make up those in extreme poverty. NTDs take a very heavy human toll by creating sickness, disability, blindness and severe disfigurement; contributing to childhood malnutrition; compromising the mental and physical development of children; and leading to an appreciable loss of productivity. While NTDs do not usually result in death, they clearly devastate individuals, families and the future of children.

But just like the tremendous progress that has taken place in reducing global extreme poverty, I am very proud of the substantial parallel achievements in USAID's integrated NTDs program – which started fewer than 10 years ago, with a modest mandate to demonstrate that programs could reach national scale in a handful of countries. With support from Congress, the program has made solid progress in addressing seven diseases – lymphatic filariasis, blinding trachoma, onchocerciasis, schistosomiasis and three soil-transmitted helminthes – which represent approximately 80 percent of the global NTDs burden and can be addressed through community and school-based distribution of preventive chemotherapy to all eligible individuals affected community at regular intervals, generally once or twice a year.

Some of the key achievements include:

- In the very first year of the program in 2006, USAID used $15 million to distribute 36 million treatments to 16 million people in four countries. Today, with a budget of $100 million in 2014, USAID's program distributes 240 million treatments to 115 million people in 31 countries. To date, over 1.2 billion treatments have been provided.
- In 2011, 7.7 million people no longer required treatment for lymphatic filariasis in USAID supported countries. In 2014, that increased to 92 million. And by 2018, the number is projected to jump to over 250 million, 50% of the target population.
- In Latin America, onchocerciasis is close to elimination with transmission only remaining in the hard-to-reach border area between Venezuela and Brazil.
- When compared to the World Health Organization's (WHO) reported data, the USAID NTD program accounts for over 35% of the treatments reported globally, when middle income countries like India that primarily finance their own programs are excluded.

USAID has developed, introduced and scaled-up an implementation package endorsed by WHO, which focuses on establishing policy in-country, conducting disease mapping to determine the disease burden and required drug package, distributing drugs through community and school-based platforms, and monitoring program performance and evaluating impact for the elimination or control of the targeted disease(s).

Integration of the treatment of diseases through community and school-based platforms has been a hallmark of the USAID program – increasing the number of people who can be reached and the number of diseases that can be addressed in the most cost-effective manner. Combining disease treatments for soil-transmitted helminthes and schistosomiasis in schools or multiple diseases during community distribution campaigns has streamlined and reduced the costs for program planning, training, education and monitoring. Integrated programs are considered the global standard, based on the success of USAID's program.

Integrated programming is just one example of USAID's leadership in developing cost-effective approaches that contribute to the global evidence base for tackling NTDs. All along, NTDs have relied on partnerships with communities, task shifting and public-private partnerships that have been models for other global health efforts. USAID has lead the way in developing monitoring and evaluation tools for national NTD programs to improve program monitoring across diseases, and is working with WHO and the NTD community to improve documentation of impact, especially for the elimination of lymphatic filariasis and trachoma. Country-level guidance on how to measure impact is being better defined and tested, along with the development of post-treatment surveillance systems to confirm that elimination has been achieved and no re-occurrence is taking place. Through an interagency collaboration the Centers for Disease Control and Prevention is working with USAID, WHO and our implementing partners to test various methods of post-treatment surveillance for lymphatic filariasis.

I would like to highlight a few factors that have contributed to the success of USAID's program and the global progress to date.

First, the success of USAID's NTD program would not have been possible without the partnership with the pharmaceutical sector. In 2014, USAID-supported countries benefited from over $2 billion in donated drugs. To date, over $8.8 billion has been generously donated from Merck & Co. Inc., GSK, Pfizer, Johnson & Johnson, and Merck Serono.

This represents an impressive leverage for our budget. We estimate that for every tax dollar spent by USAID, more than $26 in drugs is donated in-country. Conversely, the U.S. government funding plays a critical role in ensuring that systems are available to distribute the drugs. According to the *Task Force for Global Health*, fewer than 200 million tablets of albendazole and Mectizan, respectively, were distributed per year prior to 2006. Today, this has increased to over 800 million for albendazole and 600 million for Mectizan alone.

Second, USAID's partnership and coordination with the government of the United Kingdom, specifically the Department for International Development (DFID), has allowed for a collective reach to almost 50 countries and the provision of 340 million treatments in 2014. This has allowed for the expansion in high-burden countries, including Ethiopia and Nigeria, and accelerated global efforts to put trachoma elimination on track by defining the burden in countries throughout Africa and Asia. Both USAID and DFID are signatories to the "*London Declaration on Neglected Tropical Diseases*" and together represent the primary source of funding for country programs globally. The third annual WHO report on NTDs, released in February 2015, noted that USAID, along with DFID, have been the "stalwarts of Neglected Tropical Diseases funding among traditional donor nations."

Third, USAID builds upon the existing infrastructure of national disease control and elimination programs. USAID partners with ministries to complement existing funding, working within the context of the National Neglected Tropical Diseases Master Plans, and supporting coordination mechanisms to ensure that U.S. resources complement investments from other stakeholders and increasingly leverage domestic funding – which is a key to sustainability for diseases where the goal is disease control rather than elimination. Signs of progress are becoming visible in USAID-supported countries. Currently, eight countries have met the criteria to stop treatment for at least one disease. Further, 21 of the 31 USAID-supported countries are on track to meet the 2020 goals for one or more diseases.

Since the inception of the program, USAID has played a critical role in contributing to the global evidence for NTD programs, which has informed policy and implementation guidelines and produced new tools. Focusing on implementation is a comparative advantage of the program and fills a critical global gap. However, as the program has matured, the need to invest in new areas has arisen to ensure the WHO 2020 goals for NTDs can be achieved.

In 2014, thanks to the support of Congress, USAID expanded the NTD program to include two new components. The first programmatic change provides support for programs to address existing disability from NTDs, which leads to long-term suffering and traps individuals in poverty. Referred to as "Morbidity Management & Disability Prevention", support provided to national programs will result in increased access to services that address the disabling complications of lymphatic filariasis, such as the acute inflammation and extreme swelling of limbs more commonly referred to as elephantiasis, and provide eye surgeries to prevent further

blindness from trachoma. Approximately 40 million people have symptoms for lymphatic filariasis and four million people require surgery for trachoma. Additionally, some of these services are required for national programs to meet the WHO criteria for documenting elimination.

The second programmatic change supports research that addresses both the discovery of new drugs and operations research to accelerate progress toward elimination. USAID entered into a partnership with the Bill & Melinda Gates Foundation through the *Coalition for Research on Neglected Tropical Diseases* to strategically address the most pressing research questions. This collaboration includes a country-specific approach for addressing programmatic NTD issues in a timely manner. The Gates Foundation supports more early-stage research investments, while USAID support primarily focuses on programmatic or operational research needs. USAID efforts are improving monitoring and evaluation, introducing new diagnostics and developing program implementation tools. Additionally, this private sector collaboration compliments basic and clinical studies supported by the National Institutes of Health and academic institutions.

Complementing the operations research component is an investment with the Drugs for Neglected Diseases initiative (DNDi) to identify new or orphaned drugs or more effective drug combinations to accelerate progress toward elimination. This is also done in collaboration with the Gates Foundation, and seeks to complement the research efforts of other institutions. These investments fall in line with USAID's broader emphasis on sourcing and scaling innovations – as evidenced by the creation of the Agency's new U.S. Global Development Lab and the Bureau for Global Health's Center for Accelerating Innovation and Impact – that have the potential to leap frog conventional approaches and hasten the achievement of our development goals. The Saving Lives at Birth Grand Challenge, launched in March 2011, and the Fighting Ebola Grand Challenge, launched last fall, embody this new model of development – calling on the world's brightest minds to solve our biggest global challenges and swiftly providing them with the financial and technical support they need to bring their ideas to impact.

Effective treatment strategies have opened the door to strengthening cross-sector approaches. School-based deworming programs have brought the education sector in as a routine partner. The NTD and water, sanitation and hygiene community are working to find ways to influence national policy to better align investments for greater impact, particularly around trachoma and soil transmitted helminthes. Coordination between national malaria and lymphatic filariasis programs is evolving. Cross-sector approaches will be essential to ensuring the long-term sustainability for NTD programs, particularly with diseases that have a control goal and require long-term strategies.

Given that the tools are available and the drugs are being generously donated the elimination of these diseases of extreme poverty as a public health scourge is within our grasp. USAID is committed to achieving the WHO Neglected Tropical Diseases 2020 Goals and working with countries and our global partners to reach the remaining 800 million people who still need treatment. We must remain focused to ensure success. The progress to date, along with generous support from Congress, has made this program a clear success and continues to put the U.S. government in a position of leading the global effort to combat NTDs.

Mr. SMITH. Dr. Pablos-Mendez, thank you so much for your leadership and, you know, the materials, again, that you sent over to our office yesterday were very informative and encouraging and it is a great record and I want to thank you for your personal leadership.

I would like to yield to the vice chairman of the committee, Mr. Meadows.

Mr. MEADOWS. Thank you, Mr. Chairman, and for those of you that are here I think I would be remiss if I didn't say this. There are a number of times when the chairman has held hearings and there are not the cameras, there are not the reporters, because the actual thing that we are addressing is not necessarily newsworthy to the people on Main Street.

And yet the heart of this chairman has been not only diligent but tenacious and unyielding in his desire to be a voice for so many that have no voice. So I want to say thank you to the chairman for his work each and every day that is unrelenting.

Thank you, Doctor, for your work and your willingness to team up. It does come at a cost sometimes for some of us when you look at foreign aid and you look at helping other countries when there are so many needs here in the United States, and so it is imperative that you are efficient and focused with your money because it is every dollar that counts.

And so I know that a lot of USAID money in terms of this particular topic accounts for about 35 percent of the treatment is what I understand from what I have read. Who else is partnering with us or with you to address this particular medical concern?

Dr. PABLOS-MENDEZ. Thank you, Representative Meadows. Thanks for those kind words. I also want to recognize the chairman.

I did so in person earlier because you are right, you are also giving us your time and your political capital to support something to help the poorest people in the world and there is usually not a political pay for that.

It is just because it is the right thing and in particular in these diseases, and although some of them can sometimes spread and hit us, there is a security rationale. It is truly because it is the right thing and the American people support that.

You are right and I think that the partnership that we have had, particularly with the British Government, has been very important and it has been growing and it is allowing us to reach now 50 countries as opposed to the 30 countries that we were supporting directly.

DFID has committed $195 million UK pounds in the last period of 4 years or so and that is a very significant commitment. The Bill and Melinda Gates Foundation has stepped up to the plate as a big champion following that London partnership and declarations and so on and they have committed $363 million over 5 years.

They are particularly supporting research and innovation and that is a very important part of the overall global effort against these diseases.

So you are right, we are just about 40 percent of the total. But as I said before, it is the companies' historical willingness to work with the government in a public-private partnership to donate

these life-saving interventions and many of them from the beginning committed to do it for as long as it takes.

So we do have great partners and we also see many of the countries are now growing economically. So we are working to make sure those governments begin to invest more if the global investment is about $250 million outside the donations.

Now, the countries where the diseases are endemic are contributing maybe $100 million or $120 million a year. We expect this equation to evolve in the next 5 to 10 years for countries to begin to spend more, particularly those countries are already in the middle income category like Brazil or Nigeria, and we are working to mobilize those resources because that will be necessary to sustain the success of these programs.

Mr. MEADOWS. Right. One other area, and you mentioned Ebola, and the good success story that we are hearing today on the ground from many of those areas that were affected, one of the concerns I have is that this particular problem was one we knew about before it became the epidemic in the region that it was.

Samaritan's Purse had been there, as we know now, because of the highlighted newsreels that had been there. They had been there on the ground.

What vehicle is there, Doctor, that we can use with either USAID and primarily I guess it would USAID to bring that to the attention before it becomes a billion-dollar problem when it is a million-dollar problem?

Because what I feel like we did in this particular case is, whether it be bureaucratic, whether it be Congress or anything else, we looked the other way until it became such a big problem that it scared people in Texas and in New York and in Atlanta or wherever it may be and then we responded with big money when a few dollars wisely spent earlier on would have corrected the problem.

That may be simplistic. I am not a doctor. That is my take of it. What can we do to work closer with that so that it doesn't become a huge problem that the taxpayers have to bail out?

Dr. PABLOS-MENDEZ. Well, thank you very much. It is a very important point and it was the subject of that hearing that we had here last August.

It is the case that as you know there have been many, many Ebola outbreaks, particularly in central Africa. Each of them was successfully controlled and actually they were getting smaller and smaller because we learned in those geographical areas to respond quickly and control those outbreaks.

Although the virus was not new we have evidence that has been around west Africa for several years, it was the first time that the virus was recognized in west Africa.

Mr. MEADOWS. Okay.

Dr. PABLOS-MENDEZ. So those populations were not familiar with Ebola. In the cities their immune system may not have been familiar with the virus and the fact that it reached cities transformed this into something that was different than before even though the virus itself was similar to the virus that we know.

And the epidemic that began in December 2013 indeed was spreading through the spring, but by the end of May when I was at the World Health Assembly in WHO in Geneva there was a

sense that the numbers were coming down. And so in fact it was not even a major subject.

But we now know that even though we were paying attention and we were monitoring things, the virus reached in cities and spread in the ways that we saw in July and in August where I called it the summer of panic and because it was truly a scary time.

Now what to do? Because you are right, we have been successful with the response and the support of the Congress has been magnificent.

As someone who worked in global health and who was also talking to many others around the world in Africa and in other partners, the respect of that leadership and commitment has been quite palpable and important because it has been the right thing and it has worked in a quite dramatic way.

We are not out of the woods but it is pretty good. What to do? So we do have this neglected tropical diseases program that is focusing on all diseases of the poor for which simple treatments are the best way to prevent their damage on populations.

But we have a separate program, USAID's emerging pandemic stress programs, that, again, has been supported by the Congress as well, and the purpose of that program is to work precisely at the interface between humans and ecology and animals where all of these viruses are happening all the time.

I have to say that we hear about those viruses that breakout but there are many others, I am talking about hundreds—hundreds that we are detecting——

Mr. MEADOWS. Right.

Dr. PABLOS-MENDEZ [continuing]. And not happening. But as we know, it is not enough. In—we have——

Mr. MEADOWS. It is kind of like our job. We only hear about it when we don't do it right.

Dr. PABLOS-MENDEZ. Something like that.

Mr. MEADOWS. Yes.

Dr. PABLOS-MENDEZ. And in this case, the global community has recognized that preparedness of pandemics has been an area that has been under invested. In addition to some reform efforts from the World Health Organization to really call for help earlier and support the countries quicker, there had been a lot of discussion on the fact that the economic impact of these outbreaks will just grow because of the interconnectedness of society, and how we respond to that, clearly, we do not have yet in the world the right platforms.

The U.S. Government is now leading, as you know, with the Global Health Security Agenda——

Mr. MEADOWS. Right.

Dr. PABLOS-MENDEZ [continuing]. A process to reinvigorate the capacity of countries that are most vulnerable and creating with WHO, the World Bank, and others the mechanisms to respond in the human resources sense, in the financial sense, and also in the technology sense because we always come to try to do a vaccine when we are in the middle of the outbreak.

So we need to develop systems that will be there because now we know that these things do happen every 5 or 10 years.

Mr. MEADOWS. Very good. Well, that ends my questions. I am going to close with one personal request that comes way out of left field.

There is a hospital in Pakistan that is known as the American Hospital that is falling in somewhat of disrepair. If USAID could look at how we could partner with them on that particular facility from a health—global health standpoint, if you would personally look into that for me I would greatly appreciate it.

I think it would go a long ways in the region. I yield back. Thank you, Mr. Chairman.

Mr. SMITH. Thank you very much.

Mr. MEADOWS. I apologize. I have to leave. But we are monitoring it from my office.

Dr. PABLOS-MENDEZ. Thank you very much.

Mr. SMITH. Mr. Meadows, thank you very much and, again, for your leadership especially. Mr. Clawson?

Mr. CLAWSON. Thank you for coming. Thank you, Mr. Chairman, and full respect to those that work at USAID, and I have seen their work on a personal level in poor countries around the world and admire the sacrifice these folks make. That is my starting point.

I represent south Florida, southwest Florida. It is a great place. But when I think about the Caribbean I think about dengue fever and the chikungunya, and I think about my own population—large retiree base—and I have the impression that in the Caribbean and in South America lots of folks get dengue fever in particular and now more and more chikungunya when they are young and able to overcome.

I can't imagine having break bone fever at age 70. Can you? And so I am always worried about this epidemic that most Americans don't even know about.

I am worried about it invading my district and having a meaningful impact. Am I right about being worried about what I am worried—I mean, I am worried that, you know, you get a few mosquitoes going north on a year that we have a lot of rain and you have got a mixture for a really bad outcome. Do I view that correctly or am I being alarmist?

Dr. PABLOS-MENDEZ. No, I think you are correct. Dengue is a disease that can kill you although it rarely does so. Most of the time it is like a severe flu.

Mr. CLAWSON. But it would kill an 80-year-old?

Dr. PABLOS-MENDEZ. It could kill children and pregnant women, so vulnerable populations are the most at risk around the world. So it is a real threat. And you are also correct that dengue has been growing. Dengue is transmitted by mosquitoes that thrive in cities, unlike the malaria mosquitoes of the more rural areas.

Mr. CLAWSON. Yes.

Dr. PABLOS-MENDEZ. And because we are having this urban development in many places——

Mr. CLAWSON. It is an urban indoor mosquito?

Dr. PABLOS-MENDEZ. Correct.

Mr. CLAWSON. It is—so it is the inverse of malaria, if I understand it.

Dr. PABLOS-MENDEZ. That is correct.

Mr. CLAWSON. All right.

Dr. PABLOS-MENDEZ. And so because there has been so much urban growth in the tropical world, we are seeing now dengue really at unprecedented levels—Brazil, we hear in the news every day. So dengue is up and it also exists in Africa. We used to think it was all malaria.

Mr. CLAWSON. So do you agree we are vulnerable in Florida or—I mean, would we be vulnerable by this combination of a bad mosquito year and a bad rain year?

You know, if we had as much rain in my district as they get in some of the Caribbean Islands and get the wrong mosquitos, either chikungunya or dengue fever——

Dr. PABLOS-MENDEZ. Right.

Mr. CLAWSON [continuing]. Do we have a problem?

Dr. PABLOS-MENDEZ. Well, two things. One is that because you need to have reservoirs of water that stays there unattended, you have things that in poor settings are common—tires with water near the houses—that are less prevalent in the United States.

But that is important because we have better development. We are less at risk. In addition, even though you could get dengue and certainly you can get dengue in south Florida, the severity of the disease in better nourished populations and the ability to get medical care, which is general at this point, is also pretty good.

But I would say to you that there is a risk, of course, that dengue can spread. It had been growing. But I don't imagine something like Ebola spreading in the country as a risk in the mindset that we had in the fall. There is a different epidemiology, a different behavior in terms of the geography.

Now, for southern Florida being in the Caribbean it is certainly possible. There is no treatment, as you know, for dengue but there has been a lot of progress on the development of vaccines.

Because it is a large problem in the world and because it afflicts now many middle income countries, companies have been working with academia in developing vaccines for dengue.

Mr. CLAWSON. I have read that there is a dengue vaccine under development in Singapore but I have not read anything about chikungunya. Am I right about that?

Dr. PABLOS-MENDEZ. I am not following the vaccines for chikungunya but we will be happy to report back on chikungunya vaccines.

Mr. CLAWSON. All right.

[The information referred to follows:]

WRITTEN RESPONSE RECEIVED FROM ARIEL PABLOS-MÉNDEZ, M.D. TO QUESTION ASKED DURING THE HEARING BY THE HONORABLE CURT CLAWSON

Research and development of chikungunya vaccines is ongoing at the National Institutes of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health (NIH). A Phase I, open-label, dose-escalation study to examine the safety, tolerability, and immune response has been completed, but it will be years until all phases of studies have been completed and a decision can be made regarding licensure. Because chikungunya virus is transmitted by mosquitoes, wearing repellents is the best way to prevent infection. While there is no medicine for chikungunya, symptoms can be treated with plenty of rest, fluids to prevent dehydration, and taking fever and pain reducing medications.

Dr. PABLOS-MENDEZ. Dengue is a much bigger problem and the research attention—we have a lot of work that has been done in dengue. An effort that we have been particularly focused on is in making sure that the pediatric versions of the vaccines are developed soon because those are the people who die. It is usually kids. I mean, elderly could, but it is usually kids that are accounting for the deaths.

Mr. CLAWSON. Okay. Can I have a couple more minutes? Let me follow up on that and I appreciate your patience here. So I am not trying to pretend to be a doctor at all. It is just a topic that is important to me.

So monsoon season is in October in India. There are four or five different strains of dengue. Someone gets on the plane and flies to Florida.

He has been bit 2 or—you know, 2 or 3 days later, typically 6 or 7 days after being bit by the wrong mosquito you get a fever, right? And then he brings that—patient zero, so to speak, brings a different strain where we already have another strain, which increases the degree of danger. Am I right about that?

Dr. PABLOS-MENDEZ. Well, very interesting. You are right about some of the science there. Two things—first of all, because you don't transmit dengue person to person——

Mr. CLAWSON. But a mosquito can bite the sick person and transmit it?

Dr. PABLOS-MENDEZ. That is correct. So you would have to have been also in such conditions which make what you are saying possible. Unlikely, but possible. And you are right about the different types of the virus.

There used to be four. Now we have five, and immunity to one may protect you against that and may cross react with immunity against the other virus which has been one of the technical difficulties in vaccine development.

But they have been overcome and we are developing now that technology in the end. In addition to development, making sure you don't have pots and tires with water in your backyard or in your house, the development of vaccines probably holds the best promise for dengue, which is a real and growing problem in the world.

Mr. CLAWSON. I mean, I understand my bright researchers in our office say that there could be up to 500 million cases a year. I think I read in the New York Times a year or two ago that it maybe 10 percent of the population.

So it is a big number, which is why it worries me so much in south Florida. So let me ask—you know, I am taking more than my share of time here.

Are the right percentage of the resources that you all spoke about earlier being spent on this problem in general and this problem's prevention aspects in the United States within your organization?

Dr. PABLOS-MENDEZ. The investments in dengue and dengue vaccine, of course, are bigger than those that we have at USAID.

USAID's NTD program is currently focused on those simplest to treat and prevent diseases, the most cost effective of those interventions. We do not have a program devoted to dengue.

But I do hear you because the epidemiologists are asking us to consider doing that and we should certainly consider how we could add resources to do more on dengue. I would say that in addition to the strategies of prevention that I spoke of before, making sure that we get to a vaccine is the most important thing and supporting that is something that we should consider.

USAID invests close to $200 million in reasearch and development. Almost half of that is in the HIV space because that is where we get most of the resources. But we cover many of the other things as well based on burden of disease.

In the case of the dengue vaccine, we have now candidate vaccines that are close. It seems to us that although we may not need to put more money in developing the vaccines themself making sure that the pediatric formulations and making sure that those vaccines will be available in the future will be a very good and timely investment for us and we are going to be following closely with that.

That will happen. Until then, we only have these general measures I spoke of before and health systems strengthening too, to treat people because if you are untreated with severe dengue you may have 5 or 10 percent may have severe outcomes. With good treatment it is less than 1 percent.

Mr. CLAWSON. So with good treatment less than 1 percent are going to be hemorrhagic is basically what you are saying?

Dr. PABLOS-MENDEZ. Less than 1 percent of people with dengue will get severe disease.

Mr. CLAWSON. And so when this bill comes up or when we look at this even the appropriations process—look, I am a Republican, right, so we have a thing about debt and taking from future generations.

On the other hand, I also have a thing about poverty killing people and there is a lot of different ways that poverty kills people, right.

Well, this is one of them and all the world's needy aren't suddenly going to be middle class and therefore we are going to be fighting these infectious diseases. Tell me if you think I am wrong.

So it seems like the shortcut is the vaccine, which is a quick way to save a lot of lives, and then it also puts insulation on my state. I am glad to hear you say there is not enough tires with water sitting in them.

But, you know, we have all seen what happens in Santo Domingo and Hyderabad, for that matter. And so I would like, you know, a little vaccine in order to insulate my state from a southern invasion of the wrong mosquito would be a good idea for my developed state as well as the poor folk living across the world. Am I saying that the right way? I mean, you are——

Dr. PABLOS-MENDEZ. I am happy to hear you because you are right that more attention is needed, that even though we are focusing on those things that are the simplest for the poorest because then we can get the most bang in terms of life saving and preventing problems, that this is a problem that requires not only the U.S. Government but many more and then, of course, efforts, as I said before.

But I believe that we should explore how we could do more and with your support we could certainly look into that. I would say that——

Mr. CLAWSON. But are we more—we are more cost effective with a vaccine——

Dr. PABLOS-MENDEZ. Correct.

Mr. CLAWSON [continuing]. Than we are everybody in a poverty level existence digging a well, having shoes so they don't get worms and clean water and a clean septic.

That is—we all—we want all of that but that is a longer term, more expensive thing than giving somebody a vaccine. Am I right? You know, are you following?

Dr. PABLOS-MENDEZ. You are right, and vaccines have been one of the best things that we have done in public health in the last century and we are happy, as you know, with the Global Alliance for Vaccines and Immunizations recent replenishment.

The whole global community came together to put together $7.5 billion in vaccines because they are so important, and the U.S. Government has committed $1 billion to that. And vaccines are a great investment and, indeed, GAVI is open to look at how they can work in either support of the polio, as the polio eradication evolves. Ebola vaccines—there was one available. Once dengue vaccine will become available that also could be considered. We have a platform that we contribute to on vaccines that could pick this up.

But I think there are limitations to keep us thinking beyond any narrow particular programs and we do so, then choose where our dollars can have the most impact, and what you are saying is very important for us.

It is very important for the NIH. It is important for the CDC and globally with many of the other partners. So I will say to you that I will have this in mind, and the point you make about—we started with a humanitarian point as to why we do these things and you are making a very good point on the economics of this.

There has been a recent commission on investing in health. You should know because this is not a bad investment. It is actually one of the best investments that can be made today and I am not talking as an advocate. This is what the Commission on Investing in Health said; they looked at the payoff of investing in health, particularly in these types of things which are very cost effective.

You have a 10- to 25-fold leverage in terms of the economics of those countries. And you know at USAID we used to invest in Mexico, Brazil, South Korea when they needed help. Now they are our partners.

Actually, ten of the 15 largest trading partners used to be a recipient of USAID assistance. Now they are our partners. So it is in our interest also to help, as you have pointed out, because in the end it is good for America in more than just do the right thing or being safe. It is also a good investment.

Mr. CLAWSON. Well, as we go through the appropriations process, you know, anything I can do to help. I like free market solutions but there are gaps when it is poor people that can't pay for things and so this makes your role important, as far I can tell, in the breach and therefore I am supportive.

But I want to understand that it is, as you were discussing here, that it is money well spent and that others are paying their fair share, and then if that is the case we are all the same and we need to do what we can for everybody.

So thank you for what you are doing.

Dr. PABLOS-MENDEZ. Thank you.

Mr. SMITH. Mr. Clawson, thank you for your incisive questions and very compassionate comments.

Mr. CLAWSON. Sorry to take so much time.

Mr. SMITH. No, it was very well done. I thank you so very much.

I just have a few questions. We have been advised that we may have a series of votes that will go on for about an hour. So I will collapse all of my questions into one.

Mr. CLAWSON. I am sorry, Chris.

Mr. SMITH. No, no. I just got the word. First of all, on the gaps issue, Mr. Clawson, I think, brings a very good point up about gaps.

In his testimony, Dr. Hotez says that it is estimated that the annual global funding gap is over $220 million per year. He has recommended that—I think at a minimum that we put an additional $25 million on last year's number to bring it to $125 million.

Again, let the record note that we are all concerned that the administration's request suggested a $13.5 million decrease and my hope is that that will not have any traction and that we look to actually increase because of the work that it is doing.

And I think, as you point out in your own testimony, Doc, you know, that for every $1, $26 donated comes from the private sector, from the pharmaceuticals and the like.

That is leveraging the likes of which I have not seen and every dollar we put in we are getting back a huge impact on people's lives.

So if I could just ask all of our witnesses that follow will talk about public-private partnership being extraordinarily good.

The gap issue, $220 million—if you had additional dollars like $125 million how would you use it? Dr. Hotez makes a point about the horrific NTD outbreaks coming out of ISIS-occupied Syria and Iraq and possibly Libya and Yemen and in his testimony—and he has done this before—he talks about this being one of the consequences of war, very often under appreciated.

If you could speak to that. The integration with PEPFAR—our new bill has language and, again, I learned that having read his book—Dr. Hotez's book and his testimony last year that there is, again, an under appreciation of how—what NTDs—the role they play in making women especially more susceptible to HIV/AIDS and in his testimony he put it this way:

> "I am concerned that NTDs are still not a component of large-scale programs to combat HIV/AIDS such as PEPFAR and the Global Fund despite evidence that 20 million to 150 million girls and women in Africa suffer from female genital shistosomiasis, which increases susceptibility to HIV/AIDS and represents a major co-factor in Africa's AIDS epidemic."

Your view on that.

It seems to me that integration has to take place yesterday. The post-2015 goals, I have read them. I have read the targets. I am concerned that there doesn't seem to be the underscoring.

Our bill does that. It calls for those goals in effect since the year 2000, particularly goals three, ensuring healthy lives and, one, ending poverty in all its forms everywhere.

There needs to be, I think, a hyper sense of the disproportionately negative role that NTDs play and if you could—maybe not today but certainly soon—give your and the administration's view in supporting H.R. 1797, our new bipartisan bill that I just introduced today, the End Neglected Tropical Diseases Act, which incorporates so much of this, and hopefully will help take us to an even better level on this.

Dr. PABLOS-MENDEZ. Well, thank you very much, Congressman. Thank you very much.

Well, as you know, in terms of the overall budget we are making many critical investments across the spectrum of global health programs and you have been a champion of many of those, especially maternal and child health.

And as we have discussed, now half the kids who are dying are dying in the first month of life. Because of the success of the older kids it is now the babies who are dying or who are accounting for the greater proportion, and we are increasing our support for the newborns as one of the best ways to decrease total mortality.

But that calls for very difficult choices for us and since we are operating on a flat-line environment for budgets those choices are very difficult.

But I have to say that I fully support the funding level requested but, most importantly, I feel confident that the level of funds that will be available in Fiscal Year 2016 will allow us to continue the remarkable progress on NTDs and will also continue to save the lives of mothers and children.

If we had an additional $25 million, as you suggest, well, that would allow us to treat 30 million more people and, clearly, get sooner to the place in which we can get closer to elimination and control of many of these diseases. PEPFAR——

Mr. SMITH. Thank you for that——

Dr. PABLOS-MENDEZ. Yes.

Mr. SMITH [continuing]. That analysis. Perhaps elaborate that a little more so the rationale and the justification as we lobby our friends on the Appropriations Committee.

Because we will be doing a letter from our subcommittee and it will be, I am sure, bipartisan, it would be great if we could break that with as much exactness as possible——

Dr. PABLOS-MENDEZ. That is right. So——

Mr. SMITH [continuing]. And what good we can add.

Dr. PABLOS-MENDEZ [continuing]. Our teams will ready to expand in seven countries in Africa with—and we will send more details as needed.

On PEPFAR, because it is an important part of the program, clearly, PEPFAR is an incredible platform. It has helped especially in recent years to support the systems that can then help deal with other new problems.

Some of the diseases are parasitic, which are not amenable to or targeted by the cost-effective programs that we have today—are expensive to treat, and I would like to say that their research and development efforts will be very important and if we have more resources we could someday also offer support for those diseases.

In terms of collaboration—we see also great opportunity and we leverage opportunity of working with our water, sanitation and health programs (WASH) because as we heard before many of these issues have to do with water that is a vector or water reservoirs.

So WASH programs are important. Our collaboration with malaria, some of this is to minimize mosquitoes and so the bed nets are helpful in lymphatic filariasis as much as they are helpful in malaria.

And in terms of the post-2015, I think you are making a good point. Maybe in part it is because the post-2015 agenda for the world is looking at a grand convergence in gains by 2030.

But in this case, we have to look at 2020 to eliminate many of these diseases. So we are almost ahead of the schedule in which the larger agendas are. But it is a good point that we should continue to maintain this ability and important——

Mr. SMITH. Well, and again, it is in goal three, target three but it is one line and it seems to be—maybe the indicators will expand and give it the weight that I think it just needs to get—it is not just one on a list of things.

Dr. PABLOS-MENDEZ. We will convey this to our negotiators. Thank you.

Mr. SMITH. I appreciate that. Thank you. Thank you very much. Just because of time, I do have other questions. I will submit them for the record. But I thank you so much, Doctor.

I would now like to welcome—look forward to working with you and please get back to us on supporting the End Neglected Tropical Diseases Act, any changes you think might be necessary to improve it, we are wide open for that and I think this is something that would get the whole Congress——

Dr. PABLOS-MENDEZ. Thank you.

Mr. SMITH [continuing]. Further on board on this important issue.

Dr. PABLOS-MENDEZ. Technical staff is happy to continue to do so.

Mr. SMITH. Thank you.

I would like to now invite our second panel, and I am only rushing because of the pending votes, beginning with Dr. Peter Hotez, who is president of the Sabin Vaccine Institute and leads the Texas Children's Hospital for Vaccine Development based at the Baylor College of Medicine.

He is also the founding dean of the National School of Tropical Medicine at Baylor College of Medicine. His academic research focuses on vaccine development for a wide range of neglected tropical diseases around the globe as well as studies to increase awareness about the neglected tropical diseases in the U.S. as well as other countries.

He created the Sabin Vaccine Institute Product Development Partnership and was instrumental in creating the Global Network

for Neglected Tropical Diseases. In 2014, President Obama named him as one of four U.S. science envoys with a mandate to explore the development of vaccine Centers of Excellence in North Africa and the Middle East and, again, he has also recommended such a thing, a Center of Excellence, for the United States.

We will then hear from Mr. Nicholas Kourgialis, who is the vice president for eye health at Helen Keller International where he provides programmatic direction and oversight for its eye health and neglected tropical disease programs worldwide.

Mr. Kourgialis joined Helen Keller in December 2003 and brings more than 13 years of related experience to his work at HKI, having spent his career specializing in public and global health interventions, addressing the needs of disadvantaged children.

Helen Keller International's integrated program includes several NTDs and they are actively supporting a number of programs across 14 countries in Africa and deworming in school children in the Asia Pacific and he is also, I am happy to say, from my state.

Dr. Hotez?

STATEMENT OF PETER J. HOTEZ, M.D., PRESIDENT, SABIN VACCINE INSTITUTE

Dr. HOTEZ. Good afternoon, and thank you, Chairman Smith, for inviting me and to members of the subcommittee, Congressman Clawson. I ask that my full written statement be added to the record.

Mr. SMITH. Without objection, so ordered.

Dr. HOTEZ. Thank you. My name is Peter Hotez. I am a physician scientist. As you pointed out, I am dean of the National School of Tropical Medicine and also president of Baylor College of Medicine, president of the Sabin Vaccine Institute where we make vaccines for neglected tropical diseases.

We make the vaccines that the drug companies can't make or won't make including vaccines for diseases that are affecting or will soon affect Congressman Clawson's district.

I would like to point out that I am the recent author of a paper called "The Gulf Coast: A New American Underbelly of Tropical Diseases and Poverty." And so that is very relevant, I think, to this committee.

Mr. SMITH. Without objection, I would like to add that to the record because there is a very keen interest. So without objection, if we could get a copy we will——

Dr. HOTEZ. Sure. We recently estimated that there are 12 million Americans living with one or more neglected tropical diseases, mostly affecting those in the Gulf Coast. I am on one end of the Gulf Coast. I am in Houston on the Texas side of the Gulf Coast. We are the bookends, Congressman.

Mr. CLAWSON. That is all right. I mean, you know, we got the better district but that is—it is all right. You are still on the Gulf. At least you didn't say ocean.

Dr. HOTEZ. And so—and then I would like to talk a little bit about my role as U.S. science envoy and some great concerns that we have for the next shoe that is going to fall after Ebola, which is going to be the Middle East and North Africa.

It won't be Ebola but I will tell you about that. So let me just briefly summarize the situation globally and then tell you about my concerns of what is happening in the Middle East and then fine tune it to disease and poverty here in the Gulf Coast and the United States.

Working with the Institute for Health Metrics in Seattle, we have just determined that practically every single person living in extreme poverty is affected by one or more neglected tropical diseases—these chronic and debilitating conditions.

The numbers we have just come up with are extraordinary—819 million people with ascariasis infection, 440 million with hookworm, 390 million with dengue, schistosomiasis 252 million, river blindness 30 million, Chagas disease 7 to 10 million—every single person living in poverty.

And the point is these diseases both occur in the setting of poverty and they cause poverty. We are about to publish at the end of next week a worm index for human development where you can actually show that there is this very inverse correlation between human development index and the level of neglected tropical disease burden and think this also applies to the United States as well, which I will point out.

Now, although Ebola virus infection is the best known neglected tropical disease, it remains one of the rarest. We have recently done an estimate of the three Ebola-affected countries in west Africa—Guinea, Liberia, and Sierra Leone—and while there are 20,000 cases of Ebola there, or what was 0.1 percent of the population, a third of the population is infected with either hookworm infection, schistosomiasis, or both.

So these are probably the major severe and incapacitating sequelae of the west African countries, and as I pointed out these diseases are not restricted to the poorest countries of Africa because poverty is the overriding determinant and can be found even among the extreme poor living in wealthy countries such as in the United States.

There are an estimated 20 million people who live in extreme poverty in the U.S. and now new numbers coming out of the University of Michigan Center for Poverty find that there are 1.65 million families in the U.S. that live on less than $2 a day.

So we could take that same benchmark for global poverty and apply it to the U.S. Now, throughout the month of October 2014 I appeared regularly on MSNBC or Fox News. Imagine appearing in the same day on MSNBC and Fox News. That was interesting.

And but the question I would get almost every time is Doctor, aren't you worried about Ebola virus coming to the United States and my answer was almost always no, and here is why—here is what we know—it is a difficult disease to transmit and only occurs in the setting of post-conflict when there is massive breakdown in public health infrastructure but we do have 12 million Americans living in extreme poverty, mostly in the Southern U.S., mostly on the Gulf Coast who are affected by at least one neglected tropical disease including Chagas disease, toxocariasis, and cysticercosis.

We have dengue in Houston. We have dengue in the west coast of Florida and chikungunya will surely follow. I predicted last summer but probably this coming summer.

What was interesting about that the anchors, whether from MSNBC or Fox, always responded the same way, which was, "Thank you, Doctor. We are out of time."

So the neglected tropical diseases continue to represent our nation's most glaring and ignored health disparity issues. Let me briefly summarize, if I may, what is working globally and what's not for the neglected tropical diseases.

First, a very important achievement has been the scale up of mass treatment packages of donated drugs, which we first proposed in partnership at the World Health Organization in 2005.

Today, this approach is in operation in more than two dozen less-developed countries which is leading to the elimination of two key neglected tropical diseases of major global importance, lymphatic filariasis and trachoma.

And I would like to thank Dr. Ariel Pablos-Mendez for his leadership on this issue and we are really thrilled with the fact that under his leadership and with the Administrator that over the past 8 years they have improved the lives of over 460 million people and delivered more than 1 billion neglected tropical disease treatments.

This successful public-private partnership with leading pharmaceutical companies has exceeded expectations in its ability to deliver treatments for the seven most common neglected tropical diseases which make up a bulk of the global NTD burden and leverage more than $6.7 billion worth of donated medicines in 25 target countries including Bangladesh, Indonesia, Nigeria, and Sierra Leone.

In addition, tremendous global progress has been made in tackling neglected tropical diseases since the announcement of the London Declaration on NTDs in 2012, partnerships which includes the United Kingdom and the Gates Foundation, 13 pharmaceutical companies and, of course, the U.S. Government.

In 2013, more than 1.35 billion treatments were supplied by pharmaceutical partners alone and by the end of 2014 more than 70 endemic countries had developed multi-year integrated NTD control plans, narrowly a 50-percent increase.

Despite the progress, as you pointed out, the funding gap remains. It is estimated that the global annual funding gap is over $220 million a year.

That is why we are disappointed to see the President's proposed budget request for USAID's NTD program for Fiscal Year 2016 at $86.5 million, which is actually a $13.5 million decrease from Fiscal Year 2015 enacted level of $100 million and urge Congress to increase funding for NTDs from $100 million to $125 million.

This additional $25 million will allow USAID to further maximize the benefits of increased drug donations received from pharmaceutical companies, conduct impact assessment surveys to measure progress and increase the impact of this successful public-private partnership.

The subcommittee should also consider the inclusion of additional NTD control and elimination measures within other USAID programs which are among broader U.S. Government and foreign assistant programming. This would include water, sanitation, and hygiene programs as well as food security or nutrition initiatives.

I am also concerned that NTDs are still not a component of large-scale programs to combat HIV/AIDS such as PEPFAR and the Global Fund, despite the evidence of tens of millions of girls and women suffer from female genital schistosomiasis and which increases their susceptibility to HIV/AIDS.

And parallel with these global public health measures there is an urgent need to support research and development for new drugs, diagnostics, and vaccines for NTDs. As the head of the nonprofit Sabin Product Development Partnership, we have developed two critically important neglected tropical diseases—one for hookworm infection, the other for schistosomiasis—which are now undergoing clinical testing in Brazil, Gabon, and the United States.

We also have new vaccines for Chagas disease, leishmaniasis, and other neglected tropical diseases in earlier stage of development. Greater U.S. investment in NTD related research and development are needed to support the introduction of these new technologies as a means to ensure the achievement of goals for control and elimination.

I would like to say that people who live in poverty deserve more than access to essential medicines. They also deserve access to innovation.

Previously, I proposed setting aside 1 to 2 percent of the U.S. commitment to global health for the development of new drugs, diagnostics and vaccines which would pump $100 million to $200 million new dollars into the system for NTD product development.

Yet, it is very important to point out that these research and development efforts must not come at the expense of accelerating the success of the NTD program at the USAID. We need to keep that program intact, otherwise, if you take it away—the research and development dollars—it would undercut the positive gains that resulted to date and put hundreds of millions of people at risk.

Now, we also need new vaccines for other countermeasures in preparation for new catastrophic NTD outbreaks such as the one that hit west Africa in 2014, and what I would like to say is the fact that we saw this catastrophic outbreak in west Africa last year and into 2015 was not because Guinea, Sierra Leone, Liberia are tropical.

It was because they emerged out of conflict and post-conflict settings, and when I had the time to point it out on television I would say Ebola's version 3.0 of a trend that we have seen for the last three or four decades, which is that you have a catastrophic conflict and then something terrible happens. It happened in Angola, the Democratic Republic of the Congo, in the 1970s, breakdown in infrastructure.

Half a million people died of African sleeping sickness after that conflict. So 20 times more than Ebola. It went unrecorded because there were no journalists there. Version 2.0 was in southern Sudan in the 1980s and 1990s with the conflict there. A hundred thousand people died of kala-azar—leishmaniasis transmitted by sand flies—Ebola's version 3.0.

So and the problem is the world reacts too slowly. So what happens is nobody is stockpiling vaccines to get ready for these diseases and when the crisis hits it is too late.

So what we saw now is even though the technology to make the Ebola vaccine was around for a decade, we sat around waiting for big pharma to pick it up and then it only happened after the 11th hour and only now are these vaccines going into clinical trials when there are no more cases around to really see if even the vaccines work.

So we need a new model and what I am particularly concerned about in my role as U.S. science envoy—and I would like to point out that the views in herein are my own and do not reflect those of the White House or the State Department—is that version 4.0, given the strong link between conflict and contagion, is going to be in ISIS-occupied zones of the Middle East, Iraq, Syria, Libya, and Yemen.

We don't have the World Health Organization working there because it is too dangerous. We are only getting glimpses of it from refugees spilling across the border into Jordan and Lebanon, into Turkey and to Egypt.

But what are we seeing? The resurgence of measles, the resurgence of polio, a horrific neglected tropical disease that the locals call Aleppo evil. It is a disfiguring disease of the face that particularly affects little girls and renders then unmarriageable.

The other name is cutaneous leishmaniasis, more than 100,000 new cases, and I am quite worried about the Middle Eastern Respiratory Syndrome virus. And the problem is big pharma will take on problems which have global importance but not regional importance.

Right now, there is no capacity to make vaccines or minimal capacity to make vaccines in the Middle East and North Africa. The Iranians do it on a good day, maybe a little bit of Israel Defense Forces, but that is about it.

So in my role as U.S. science envoy, I am trying to take the model of what we are doing for making vaccines in Houston in the nonprofit sector and reproducing that somewhere in a stable country in the Middle East and North Africa, one that has some underlying infrastructure for doing so, and I am happy to address that in more detail.

Finally, let me end by revisiting the NTDs in the United States. Twelve million Americans live with at least one neglected tropical diseases and most people have never heard of them. They include toxocariasis, a larval worm infection linked to deficits in cognitive development that affect almost one in five African-Americans living in poverty.

In a paper I wrote in JAMA Psychiatry, I asked whether toxocariasis could be partly responsible for the achievement gap noted among socioeconomically disadvantaged students. At our National School of Tropical Medicine in Houston, we are finding unique modes of transmission of diseases like toxocariasis as well as Chagas disease, a parasitic disease that causes debilitating and life-threatening heart defects among the poor and among hunters and campers in our state.

A key point is that many if not most of these neglected tropical diseases are not being imported through immigration, because that is usually the first response people have. Instead, we are finding

transmission among the poor, especially in the American South, especially in the Gulf Coast.

Throughout the Gulf Coast we have got two major species of mosquitoes, each capable of transmitting dengue, each capable of transmitting chikungunya.

So we need more comprehensive surveillance and to develop improved point of care diagnostics. One of the problems is physicians aren't trained to even recognize these diseases. When we had our outbreak in Houston we found that none of the cases were picked up by physicians because they are not trained in these diseases.

The other problem is we don't have point of care diagnostics. So, you know, when you go to your doctor you get a blood test and you see the little boxes checked off with your blood chemistries. There is no box for chikungunya.

There is no box for dengue. There is no box for toxocariasis or Chagas disease. We have got to change that. We also need a new generation of drugs and vaccines.

So that is the whole point behind this Center of Excellence idea and the legislation that you just introduced and I am so grateful, again, for your tenacity, Chairman Smith, in making this happen.

So we just learned about the H.R. 1797. I assume it has similarities to what was H.R. 4847 and we are so grateful for this committee taking on this important issue which is devastating populations living in poverty and conflict everywhere, and I appreciate the opportunity the subcommittee has given me to speak on this issue.

Thank you.

[The prepared statement of Dr. Hotez follows:]

TESTIMONY

Peter J. Hotez MD, PhD
President, Sabin Vaccine Institute

"The Continuing Threat of Neglected Tropical Diseases"

Subcommittee on Africa, Global Health, Global Human Rights, and International Organizations
Committee on Foreign Affairs
United States House of Representatives

April 15, 2015

Good afternoon, Chairman Smith and Members of the Subcommittee. My name is Peter Hotez, I'm a physician-scientist, founding Dean of the National School of Tropical Medicine at Baylor College of Medicine, and President and head of the Sabin Vaccine Institute and Texas Children's Hospital Center for Vaccine Development, where we develop and test new vaccines for neglected tropical diseases. For this year I am also serving as United States Science Envoy, also focusing on neglected disease vaccines.

I appreciate the opportunity to speak with you today and will focus my remarks on the very important conditions known as the neglected topical diseases or "NTDs." Working with the Institute of Health Metrics in Seattle we have just determined that practically every single person living in extreme poverty is affected by at least one NTD, many of which are chronic and debilitating parasitic conditions such as ascariasis – which affects 819 million people, hookworm infection – 440 million, schistosomiasis – 252 million, river blindness 30 million, Chagas disease 7-10 million. Almost every person living in poverty has at least one of these NTDs, which I sometimes refer to as "the most important diseases you never heard of." We're about to publish a "Worm Index" for human development linking NTDs as an actual cause of poverty because it makes them too sick to go to work or because it reduces childhood cognition. The NTDs are one of the stealth reason why the bottom billion – the estimated 1.2 billion people living on less than a dollar a day - cannot escape poverty.

Although today Ebola virus infection is perhaps the best known infectious disease in fact it remains one of the rarest. For example in the three major Ebola-affected countries of West Africa – Guinea, Liberia, and Sierra Leone – where 22 million people live, there were

approximately 20,000 cases of Ebola, roughly 0.1% of the population. However, our numbers soon to be published in the *Public Library of Science* indicate that almost one third of the population of those three countries – more than five million people - are affected by either hookworm infection or schistosomiasis, or both, resulting in severe and incapacitating anemia and other sequelae.

NTDs are not restricted to the poorest countries of Africa. Because poverty is the overriding determinant, these diseases can also be found among the extreme poor living in wealthy countries, including the United States where an estimated 20 million people live in extreme poverty and 1.65 million families live on less than $2 per day. Throughout the month of October of 2014, I appeared regularly on MSNBC, Fox News, or Bloomberg TV for my opinion about if and when Ebola will spread throughout Texas and the United States. My answer was always, there is no risk of Ebola taking foothold in the US. But we do have 12 million Americans living in extreme poverty, mostly in the southern US (including Texas and the Gulf Coast) who are affected by at least one NTD, including Chagas disease, toxocariasis, and cysticercosis. The anchors would always respond by saying, "thank you doctor, but we're out of time." NTDs continue to represent our nation's most glaring and ignored health disparity issue.

Let me briefly summarize what's working and what's not working globally, but also here in the US, to control and eliminate the world's most serious NTDs.

First, a very important achievement has been the scale up of mass treatment packages of donated drugs, which we first proposed in partnership with the World Health Organization in 2005. Today, this approach is in operation in more than two dozen less developed countries, and

is actually leading to the elimination of two key NTDs of major global importance – lymphatic filariasis and trachoma.

We certainly applaud the commitment of the United States to the U.S. Agency for International Development (USAID) NTD Program, which over the past eight years has improved the lives of over 460 million people, delivered more than 1 billion NTD treatments, and trained over 500,000 community workers. This successful public- private partnership with leading pharmaceutical companies has exceeded expectations in its ability to deliver treatments for the seven most common NTDs (which make up the bulk of the global NTD burden) and leveraged more than $6.7 billion worth of donated medicines in 25 targeted countries, including Bangladesh, Indonesia, Nigeria, and Sierra Leone.

In addition, tremendous global progress has been made in tackling NTDs since the announcement of the London Declaration on NTDs in 2012—a partnership which includes the United Kingdom, the Bill & Melinda Gates Foundation, 13 pharmaceutical companies, the United States and many others. In 2013, more than 1.35 billion treatments were supplied by pharmaceutical partners alone and by the end of 2014, more than 70 endemic countries had developed multi-year integrated NTD control plans (nearly a 50% increase since 2012). NTD partners continue to use a comprehensive London Declaration Scorecard to promote accountability, transparency, and evidence-based prioritization. The 10 NTDs highlighted in the London Declaration should also remain as a main focal point in any future NTD legislation.

Despite the progress, however, significant funding gaps to implement comprehensive NTD control and elimination programs remain. And, without continued support by existing partners, like the United States, as well as redoubled efforts to attract new bilateral partners, a

major scale up of implementation efforts, and increased global resources, we will not achieve the WHO 2020 target goals endorsed by the London Declaration partners. **It is estimated that the annual global funding gap is over $220 million per year.**

That is why, we were disappointed to see the President's proposed budget request for USAID's NTD Program for fiscal year (FY) 2016 at $86.5 million (a $13.5 million decrease from the FY 2015 enacted level of $100 million) and urge Congress to increase funding for NTDs from $100 million to $125 million. This additional $25 million will allow USAID to further maximize the benefits of increased drug donations received from pharmaceutical companies, conduct impact assessment surveys to measure progress, and increase the impact of this successful public-private partnership.

The Subcommittee should also consider the inclusion of NTD control/elimination measures within other USAID programs or among broader U.S. government foreign assistance programming. Opportunities for cross-sectoral coordination may include maternal and child health services delivery platforms (e.g., childhood immunizations, vitamin supplements), water, sanitation and hygiene programs, as well as food security or nutrition initiatives. I am also concerned that NTDs are still not a component of large-scale programs to combat HIV/AIDS, such as PEPFAR and the Global Fund despite evidence that 20-150 million girls and women in Africa suffer from female genital schistosomiasis, which increases susceptibility to HIV/AIDS and represents a major co-factor in Africa's AIDS epidemic.

In parallel with these global public health control measures, there is an urgent need to support research and development (R&D) for new and improved drugs, diagnostics, and vaccines

for NTDs. As head of the non-profit Sabin product development partnership, we have developed two critically important NTD vaccines, one for hookworm infection and the other for schistosomiasis, which are now undergoing clinical testing in Brazil, Gabon, and in the United States. We also have new vaccines for Chagas disease, leishmaniasis, and other NTDs at earlier stages of development. Greater U.S. investment in NTD-related R&D is also needed to support the introduction of these new technologies as a means to ensure the achievement of the goals of disease control and elimination. People who live in poverty deserve more than the access to essential medicine, they deserve access to innovation. I previously proposed setting aside 1-2% of the US commitment to global health for the development of new drugs, diagnostics and vaccines, which would pump $100-200 million new dollars into the system for NTD product development. Yet, these R&D efforts must not come at the expense of accelerating the success of the existing integrated NTD Program at USAID. That approach would undercut the positive gains that have resulted from the millions of dollars the United States has invested in NTD treatment programs since FY2006, and risk condemning hundreds of millions of the world's poor to lives plagued by NTDs and a loss of economic potential.

We also need these new vaccines and other countermeasures in preparation for new catastrophic NTD outbreaks such as the one that hit West Africa in 2014-15. It is important to note that Ebola emerged in Guinea, Liberia, and Sierra Leone, not primarily because it was tropical, although maybe that was a component, but instead mostly it was because these countries have only recently emerged out of horrific civil wars lasting for years and completely depleting their public health infrastructure. I often point out that this link between conflict, post-conflict and cataclysmic NTDs is not new. We saw it during the 1970s in Angola and Congo when civil

wars there prevented sleeping sickness control measures that resulted in more than 500,000 people dying from that NTD, also known as African trypanosomiasis (50 times more than the recent Ebola epidemic), later in the 1980s when the civil war in Sudan forced human migrations that resulted in 100,000 deaths from an NTD known as kala-azar. In this sense Ebola is V.3.0 of a decades' long history of "conflict linked to contagion."

In my role as US Science Envoy I am preparing for V.4.0, which I believe will be horrific NTD outbreaks coming out of ISIS occupied Syria and Iraq, or possibly Libya and Yemen. We are already beginning to see glimpses of this through resurgence of polio and measles outbreaks among refugees spilling across the border into Jordan, Lebanon, and Turkey, as well as outbreaks of leishmaniasis, hepatitis, and others. Unfortunately, the Middle East and North African region has almost zero capacity for developing new vaccines for these diseases and I am working with the U.S. government to look at selected countries such as Morocco, Saudi Arabia, and Qatar, to potentially build a facility that resembles our Sabin-Texas Children's vaccine institute in Houston, in order to produce vaccines for NTDs such as leishmaniasis, and also the MERS coronavirus.

Finally, a comment about NTDs in the United States. Last year in the *Public Library of Science* I estimated that 12 million Americans live with at least one NTD. They include toxocariasis a larval worm infection linked to deficits in cognitive development that affect almost one in five African Americans living in poverty. In a paper I wrote in *JAMA Psychiatry* I asked whether toxocariasis could be partly responsible for the achievement gap noted among socioeconomically disadvantaged students. At our National School of Tropical Medicine in

Texas we are finding unique modes of transmission of Chagas disease - a parasitic disease that causes debilitating and life-threatening heart defects – among hunters and campers in our state. A key point is that many, if not most of these NTDs, are not being imported through immigration. Instead, we are finding transmission among the poor, especially in the American South. We urgently need to better determine the number of Americans at risk for these NTDs, through better and more comprehensive surveillance, and also develop improved and point-of-care diagnostics, as well as new drugs and vaccines. The U.S. needs a Center of Excellence based in the southern United States supported by the U.S. Department of Health and Human Services that will specifically address diseases such as Chagas disease and toxocariasis.

We, therefore, urge support for the re-introduction of H.R. 4847, the End Neglected Tropical Disease Act—legislation introduced by Congressman Smith and co-sponsored by Rep. Matt Salmon, Rep. Gregory Meeks, and Rep. Hank Johnson in the 113th Congress, which addresses both NTDs abroad as well as NTDs emerging in the United States. The NTDs are devastating populations living in poverty and conflict everywhere and I appreciate the opportunity this Subcommittee has given to speak on this issue. I now look forward to your questions. Thank you!

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Mr. SMITH. Dr. Hotez, thank you so very much. And again, many of the ideas that you recommended at our last hearing found a home in our legislation.

So I thank you for that guidance that you provided to the committee and to the legislation.

Mr. Kourgialis, please proceed.

STATEMENT OF MR. NICHOLAS KOURGIALIS, VICE PRESIDENT, EYE HEALTH, HELEN KELLER INTERNATIONAL

Mr. KOURGIALIS. Mr. Chairman, thank you for the opportunity to testify regarding the importance of continued funding for the U.S. Government's neglected tropical disease program and to highlight the enormous impact that it is having on the health and welfare of individuals living in the world's poorest communities.

I also want to thank you for your continued commitment to improving the lives of millions by helping to eliminate or control the seven most prevalent NTDs targeted by the U.S. Government.

Collectively, these parasitic and bacterial diseases blind, disfigure, and disable millions of people in the world's poorest communities and limit their ability to lead healthy and productive lives.

According to the World Health Organization, NTDs infect more than 1 billion people, a sixth of the world's population including an estimated 800 million children who, as a result, suffer from malnutrition, decreased school enrollment and diminished physical and intellectual development.

Eliminating NTDs can allow millions to climb out of poverty by increasing access to education and improving their ability to work. Since its inception, the U.S. Government's NTD program has supported the delivery of more than 1 billion treatments to approximately 470 million people in 25 countries.

The impressive reach and impact of the program would not be possible without the remarkable public-private partnership with the pharmaceutical sector. We commend the U.S. Congress and USAID for their global leadership on this issue.

Co-founded in 1915 by the deaf-blind crusader, Helen Keller, Helen Keller International offers programs in 21 countries in Africa and Asia as well as the United States. The prevention and treatment of NTDs is a key organizational priority and one of our most important and far-reaching programs.

HKI has been the recipient of integrated NTD program funding from USAID in Burkina Faso, Cameroon, Guinea, Mali, Niger, and Sierra Leone. Despite their many challenges, all six countries supported by HKI have made significant progress toward global NTD control and elimination targets.

In 2015, HKI will lead a new 5-year project aimed at managing morbidity and preventing disability related to trachoma and lymphatic filariasis.

HKI's approach and strength has been to partner with government ministries to provide technical assistance and support to national disease control teams and to build capacity within countries with the goal of scaling up and creating sustainable systems of care.

Our ultimate goal is for ministries of health and education to assume clear ownership over these programs and for national govern-

ments to commit the necessary human and financial resources needed to achieve control or elimination of the targeted diseases.

Trachoma offers a valuable example of what can be achieved through global cooperation. It also highlights the critical importance of continued funding for NTD program implementation activities.

Trachoma is the leading cause of infectious blindness in the world. This bacterial infection is transmitted by flies and through physical contact with eye and nose discharge of infected people, particularly young children who are often the principal reservoir of infection.

Repeated cycles of infection and inflammation can result in scarring of the inside of the eyelid, causing it to turn inward so the eyelashes scratch the cornea, ultimately causing blindness through a very painful condition called trichiasis.

To combat trachoma, HKI supports the distribution of antibiotics, increased face washing, and the use of latrines to reduce disease transmission. Surgery is also provided for those suffering from trichiasis.

Several HKI-supported countries have made notable progress in reaching specific disease control targets. For example, Burkina Faso is on track to stop mass drug administration for trachoma by the end of 2016.

Similarly, in Mali, despite the challenges posed by recent political instability and violence, more than 90 percent of districts that require trachoma treatment have been able to stop drug administration.

The U.S. Government's support of country-level implementation activities is essential to achieving the WHO goal of goal of eliminating trachoma as a public health problem by 2020.

Mr. Chairman, in order to sustain the accomplishments of the current NTD program I hope that the Congress will restore funding in Fiscal Year 2016 to at least the $100 million level provided in Fiscal Year 2015.

I also urge that the focus of the seven targeted diseases be continued. Enormous progress has been achieved over the past 8 years in combating these diseases. A decrease in USAID funding at this critical time would significantly undermine the ability of national NTD programs to continue their activities and to reach their control and elimination targets.

I am optimistic that funding levels for NTDs will be restored so I will conclude with the words of Helen Keller—"Optimism is the faith that leads to achievement. Nothing can be done without hope and confidence."

Thank you, Mr. Chairman.

[The prepared statement of Mr. Kourgialis follows:]

STATEMENT BY
NICHOLAS KOURGIALIS
VICE PRESIDENT FOR EYE HEALTH
HELEN KELLER INTERNATIONAL

BEFORE THE

SUBCOMMITTEE ON AFRICA, GLOBAL HEALTH, GLOBAL HUMAN RIGHTS,
AND INTERNATIONAL ORGANIZATIONS
COMMITTEE ON FOREIGN AFFAIRS
U.S. HOUSE OF REPRESENTATIVES

APRIL 15, 2015

Mr. Chairman,

My name is Nick Kourgialis; I am the Vice President for Eye Health Programs at Helen Keller International (HKI). Thank you for the opportunity to appear before the Committee this afternoon to testify regarding the importance of continued funding for the U.S. government's Neglected Tropical Diseases (NTD) Program, and to highlight the enormous impact that it is having on the health and welfare of individuals living in the world's poorest communities. I also want to thank you for the Committee's continued commitment to improving the lives of millions by helping to eliminate or control the seven most prevalent NTDs targeted by the U.S. government – lymphatic filariasis, onchocerciasis, schistosomiasis, soil transmitted helminths (hookworm, roundworm, whipworm), and trachoma.

Collectively, these parasitic and bacterial diseases blind, disfigure, and disable millions of people in the world's poorest communities, and limit their ability to lead healthy and productive lives. According to the World Health Organization (WHO), NTDs infect more than one billion people - a sixth of the world's population – including an estimated 800 million children who, as a result, suffer from malnutrition, decreased school enrollment and diminished physical and intellectual development. Research has shown that eliminating NTDs can allow millions to climb out of poverty, particularly by increasing access to education and improving their ability to work.

Since its inception, the U.S. government's NTD Program has supported the delivery of more than one billion treatments to approximately 470 million people as part of large scale, integrated disease control and elimination programs in 25 countries. The impressive reach and impact of the program would not be possible without the remarkable public-private partnership with the pharmaceutical sector and the donation of over $6 billion worth of NTD drugs by

GlaxoSmithKline, Johnson & Johnson, Merck & Co, Inc., Pfizer, Inc. and Merck Serono to countries receiving support from the U.S. Agency for International Development (USAID). We commend the U.S. Congress and USAID for the leadership that has been demonstrated over the past eight years by focusing the attention of the global public health and corporate community on this vital public health issue and for their steadfast commitment to achieving the global control and elimination targets for these debilitating diseases.

Helen Keller International currently offers programs in 21 countries in Africa and Asia, as well as the United States. Co-founded in 1915 by the deaf-blind crusader Helen Keller, HKI is a leading nonprofit organization dedicated to preventing blindness and reducing malnutrition worldwide.

Our programs serve tens of millions of vulnerable people each year. The prevention and treatment of NTDs is a key organizational priority, and one of our most important and far-reaching programs. HKI's early work in NTD control dates back to the mid-1950s, supporting the elimination of blinding trachoma in Taiwan.

HKI also played a pivotal role in the development of the SAFE strategy (**S**urgery for trichiasis, **A**ntibiotics to treat infections, **F**acial cleanliness and **E**nvironmental improvement) in trachoma control and the Community Directed Treatment with Ivermectin strategy in onchocerciasis control. More recently, with USAID funding, HKI has supported integrated control activities focusing on all seven targeted NTDs in six countries in Africa.

HKI has been the recipient of integrated NTD Program funding from USAID in Burkina Faso, Cameroon, Guinea, Mali, Niger and Sierra Leone. These funds have provided crucial technical, programmatic, and financial support to the Ministries of Health in these countries to

develop integrated approaches and to achieve their NTD control and elimination goals for the targeted diseases.

In 2015, with support from USAID, Helen Keller International will lead a new five-year project aimed at managing morbidity and preventing disability related to blinding trachoma and lymphatic filariasis in Burkina Faso, Cameroon and Ethiopia. Support for trichiasis and hydrocele surgery along with treatment for the painfully swollen limbs caused by lymphatic filariasis is critical to the achievement of the elimination criteria for these disabling diseases by the WHO designated target date of 2020. Without this support, these countries would not have adequate resources to address these needs.

HKI's approach and strength has been to partner with government ministries, particularly of Health and Education, to provide technical assistance and support to the national disease control teams, and to build capacity within countries with the goal of scaling up and creating sustainable systems of care. Throughout this work, HKI emphasizes the ownership of the integrated disease control programs by the country and communities themselves. Our ultimate goal is for Ministries of Health and Education in the countries in which we work to assume clear ownership over these programs. We want to assure that national governments also commit the necessary human and financial resources needed to achieve control or elimination of the targeted diseases.

Several HKI supported countries have made notable progress in reaching specific disease control targets. For example, in Burkina Faso, fifty two percent of endemic districts have already reached the criteria to stop mass treatment for lymphatic filariasis, and eighty three percent of endemic districts have stopped treatment for trachoma. Burkina Faso is on track to stop mass drug administration (MDA) for lymphatic filariasis in all districts by 2018 and by the

end of 2016 for trachoma. Considerable progress has also been made in significantly reducing the prevalence of schistosomiasis and soil transmitted helminths.

Similarly, in Mali, despite the challenges posed by recent political instability and violence, more than ninety percent of districts that required trachoma treatment at baseline have been able to stop drug administration and significant progress is being made in addressing the trichiasis backlog. Due to insecurity in the North of Mali, five out of the six remaining trachoma districts have not been able to be assessed to determine if they have reached elimination criteria.

Trachoma offers a valuable example of what can be achieved through global cooperation. It also highlights the critical importance of continued funding for NTD program implementation activities. Trachoma is the leading infectious cause of blindness in the world. This bacterial infection is transmitted through contact with eye and nose discharge of infected people, particularly young children who are often the principal reservoir of infection. It is also spread by flies which have been in contact with the eyes and noses of infected people. Repeated cycles of infection and inflammation can result in scarring of the inside of the eyelid, causing it to turn inward so the eyelashes scratch the cornea, ultimately causing corneal opacity and blindness through a very painful condition called trichiasis.

According to the most recent WHO report on NTDs, an estimated 232 million people live in areas where trachoma is endemic. More than 21 million people have active trachoma, 7.2 million require surgery for trichiasis, and 1.2 million are irreversibly blind. As primary caregivers, women are far more likely to be repeatedly infected with trachoma, to develop trichiasis, and to lose their sight.

Many of the key components needed to achieve the elimination of trachoma as a global public health problem by 2020 are already in place.

- The Global Trachoma Mapping Project, supported by UK government's Department for International Development (DFID) and managed by Sightsavers is seeking to complete a comprehensive global mapping of trachoma prevalence to guide disease elimination efforts.
- The International Coalition for Trachoma Control has developed critical tools and identified best practices that support the implementation of WHO-endorsed SAFE strategy.
- The International Trachoma Initiative, with support from Pfizer, ensures that the antibiotic Zithromax® is provided to countries seeking to achieve trachoma control and elimination.
- The WHO Alliance for the Global Elimination of Blinding Trachoma by 2020 (GET2020) provides the global advocacy platform and support for country implementation of the SAFE strategy.

The U.S. government's support of country level implementation activities serves as an essential complement to the important commitments outlined above, and is critical to achieving the WHO goal of eliminating trachoma as a public health problem by 2020. Despite their many challenges, all six countries supported by HKI have made significant progress towards global NTD control and elimination targets. Each of these countries has strong National NTD Programs with capable and committed staff, as well as dedicated technical partners. A decrease in USAID funding for the targeted NTDs at this critical time would significantly undermine the ability of the National NTD Programs in these countries to continue their activities and to reach their control and elimination targets.

Furthermore, additional investments in epidemiological assessment and surveillance are also required. As criteria for ending drug administration are met for various diseases on a district-by-district basis in each of these countries, surveillance systems will need to be put into place to ensure that countries are able to identify incident cases or identify recrudescence of transmission. This is particularly true along border regions where countries that have made

significant progress in achieving their elimination targets are linked to countries where the scale-up of drug distribution is far less advanced, and where cross border transmission poses a significant risk.

Mr. Chairman, in your letter inviting me to testify at this hearing you indicated that you would like me to address the funding level for Neglected Tropical Diseases included in the Administration's fiscal year 2016 budget request. In fiscal year 2014 and 2015, the Congress appropriated $100 million for Neglected Tropical diseases. However, in the fiscal year 2016 budget request the Administration has only requested funding for NTD's at a level of $86.5 million.

In order to sustain the current NTD program, I hope that the Congress will restore funding in fiscal year 2016 for the targeted NTD program to at least the level provided in fiscal year 2015. I also urge that the emphasis on the seven-targeted NTD diseases be continued. Enormous progress has been achieved over the past eight years in combatting these diseases, but much work remains to be done during this critical phase when elimination goals are within sight.

I am optimistic that funding levels for NTDs will be restored and on that I turn to the words of our organization's founder, Helen Keller, "Optimism is the faith that leads to achievement. Nothing can be done without hope and confidence."

I thank the Committee for your ongoing commitment to global health and especially to the challenges posed by Neglected Tropical Diseases.

Mr. SMITH. Thank you so very much for your leadership, for those insights as well, and so many lives that have benefitted because of your work.

Just a few questions, if I could, beginning with Dr. Hotez and perhaps both of you might want to address this. In your testimony you said it is estimated that the annual global funding gap is over $220 million per year.

In the 1980s, I was on this committee and I remember I contacted WHO and asked them what it would take to make the meaningful difference in neglected tropical diseases, and I think we just called it tropical diseases then, and I got back a time line, numbers and I worked every year to try to get those numbers as close as possible both on the authorizing and the appropriation side.

We never actually got there but it was far less than this, I can tell you, and I am just wondering if you could for the committee and for us, all of us here, break that out either here or by way of a written submission.

You suggested $125 million, Dr. Hotez, as, I guess, our additional. You know, we are always constrained by the doable versus what really would make all the difference in the world.

Whatever you could do to provide, I asked Dr. Pablos-Mendez earlier. He said 30 million people would be positively impacted and said he would get back. The more detailed the better in terms of making our case to the leadership and to the appropriators on this because it seems to me, again, the sustainable development goals—post-2015 their goal is to eliminate it by 2030.

Talk of 2020 is always in the mix. For the person dying or suffering from this they want it now, as we all know. So if you could speak to that, if you would. Yes?

Dr. HOTEZ. Thank you, and I appreciate that question. I guess just to give it some perspective let us remember the budget of PEPFAR is around the order of $8 billion a year so we are talking about $25 million.

Remember what you get for that $25 million. This package we helped design is 50 cents a person per year. It is probably the single most cost effective public health control measure out there.

I mean, where else are you going to treat 50 million people for $25 million? Maybe it won't get quite to 50 but those are the numbers we are talking about.

And so, when we—the neglected tropical disease people are always grateful for any crumbs that anyone can throw at us and so we think $25 million is a very modest amount but look what you get for it. So USAID is currently operating in more than two dozen countries.

We have the opportunity to take on a whole additional country with that, just to give you a perspective on what that money can do.

Mr. SMITH. I thank you for that.

Mr. Kourgialis, would you want to speak to that?

Mr. KOURGIALIS. Certainly, the needs for services far exceed the available resources. So any additional resources that can be brought to bear would be very valuable.

Mr. SMITH. You spoke, Mr. Kourgialis, very, I think, eloquently about the importance of pushing ownership. I am sure, Dr. Hotez, you believe the same thing, as does USAID.

How receptive have you found the ministries of health and political leaders to say we do want to take this over and more of our resources are going to be devoted to ending neglected tropical diseases?

Mr. KOURGIALIS. I can only speak to the countries in which we work. But, certainly, we couldn't do our work without the support of the ministries. They are a critical player in all this and we must have their cooperation and support in order to conduct any activities at this scale.

We are functioning at a national scale. We face enormous challenges in reaching people at the end of the road, these are the poorest of the poor. Without the ministries' support that wouldn't be possible.

So it is critical and in most of the countries the support is. They certainly see the effect that these diseases have on their populations. They want to address that.

The support is there on the part of the global community at this point on a very broad scale. So I think they are taking advantage of that opportunity, accomplishing it as much as they can with the resources that are available.

Dr. HOTEZ. Yes, I would agree with that and just to say that because the packages of medicines are so low cost—50 cents a person per year—a Minister of Health and a Minister of Finance for a country can look at that and say yes, we can do this—we can help with this.

So, for instance, Burkina Faso, when I last looked was paying for 69 percent of its NTD bill. So and as opposed to something like PEPFAR where you are talking about hundreds of dollars a person to put a person on anti-retro viral drugs for a year, this is 50 cents.

So it is not so daunting for a lot of these disease-endemic countries to help take this on and assume a lot of ownership.

Mr. SMITH. Can I ask you, Dr. Hotez, how receptive has USAID and the PEPFAR program leaders, especially the czar, been to your recommendation that it be integrated—the neglected tropical diseases component—to the PEPFAR fight?

Dr. HOTEZ. Well, I have not approached PEPFAR recently. The last time I approached PEPFAR Ambassador Goosby was still in charge and, you know, in principle they thought it was a great idea but there was—there was just too much inertia to make it happen.

So I haven't had the opportunity to meet with the new Global AIDS Coordinator to discuss it. You know, we have had this conversation with Mark Dybul, head of the Global Fund, and there was some initial push back.

But then we understood that Mark Dybul was visiting the schistosomiasis people at WHO. So maybe we are getting some movement.

Mr. SMITH. I was there when you had that phone call.

Dr. HOTEZ. Yes.

Mr. SMITH. Your very persuasive case. As you know, we did include in the bill that kind of direction to integrate into work in a partnership. So thank you.

You mentioned NTD vaccines for hookworm and for schistosomiasis there at the clinical testing level in Brazil, Gabon, and United States. How soon before something might be available?

Dr. HOTEZ. So we are in the phase one testing now for safety and immunogenicity and now we are going to be moving to look at the efficacy.

So I am hoping within 5 years we will be able to be well advanced on the way, and the idea behind it is the package of medicines has been great for eliminating lymphatic filariasis and trachoma.

The problem was that for hookworm and schistosomiasis they keep coming back. So they knock down the bioburden, there tends to be reinfection and that is the idea behind the vaccine. Thank you for that question.

Mr. SMITH. Quick, the issue that you have raised repeatedly about the consequences of war and you did it in your testimony and I did ask our previous witness about that, could you elaborate on that?

I mean, you just came back from a visit some weeks ago to the Middle East.

Dr. HOTEZ. Yes. I don't have to tell this committee the situation in the Middle East is dire with an ever expanding territory now over four countries—Syria, Iraq, Libya, and Yemen—and the first thing that happens, of course, is all public health control measures pretty much stop.

All access to medicine stops, and my point in my testimony was that when we have seen this before where, again, calling them tropical diseases it is a bit of a misnomer.

They are diseases of poverty and disease of poverty in conflict. So you bring in those social forces of poverty conflict and with it comes human migrations, trafficking of animals, which transmit zoonotic diseases, deforestation.

All of these create the perfect storm to allow a catastrophic neglected tropical disease. That is why Ebola arose in west Africa, and from my point of view in my role as dean of National School of Tropical Medicine all those same forces are in place now in ISIS-occupied zones and therefore we need to be ready.

Mr. SMITH. Before going to Mr. Clawson, just let me conclude by quoting from your testimony, I don't know if you said this orally but it bears repeating if you did.

Dr. Hotez, you said, "NTDs continue to represent our nation's most glaring and ignored health disparity issue" and I think they are called neglected tropical diseases for a reason. The "neglected" has to fall out of that phrase.

Mr. Clawson?

Mr. CLAWSON. Well, I am thinking about everything you are saying. Most of the time you are saying it and I am tapping my foot but once in a while I am not understanding exactly.

So since none of my colleagues showed up I guess I get to ask you some more questions and I appreciate you all's patience. I believe in a strong military because it creates leverage.

But I wish our country was more judicious in where we send bombs because it feels like bad wars create bad outcomes, one of which I hear you saying is not just the bombs killing people but

far more people probably die from the secondary unintended impacts of refugee camps whether they are in Kurdistan, or on the Thai-Cambodian border 30 years ago.

Am I hearing you right on that? Is that right?

Dr. HOTEZ. That is correct. I call it the link conflict and contagion and but it is conflict in the areas where we have had a lot of intense poverty for years as well. Those two forces combined are synergistic to create this.

Mr. CLAWSON. So it is odd to me, really, that therefore that given that the Ebola thing also rose out of conflict, which wasn't nearly as bad as some other countries in central Africa, right, that when we speak about ISIS and our own propensity to go to war that we don't talk enough about this outcome. Am I right about that?

Dr. HOTEZ. That is right. It is not a sexy topic and it just doesn't get a lot of time either in the news media or elsewhere.

But it is—and it is something that not a lot of people appreciate that there is this link between conflict and disease. And so it is something we need to create better awareness of because remember, we are not talking small numbers.

Five hundred thousand people died of sleeping sickness as a consequence of the wars in Angola and the Democratic Republic of the Congo, and that is a lowball estimate.

Mr. CLAWSON. I don't think you are going to venture to predict how many people could die in the Middle East because of disease as a result of war? I am not trying to get——

Dr. HOTEZ. Right. Right.

Mr. CLAWSON [continuing]. Make you get wet here but I am—what is your worst case scenario?

Dr. HOTEZ. Well, it is a two-step process because the first step is you have to accurately predict what the diseases are going to be and so some of them are not even lethal diseases, like cutaneous leishmaniasis is disfiguring, it is ruining people's lives but it is not killing.

But something like—I am worried about MERS—the Middle Eastern Respiratory Syndrome corona virus—that we know it is a high rate of mortality.

You add it to the mix of conflict and animal trafficking and the numbers could go very high. And so the point is we need to be flexible in being ready to make vaccines for these diseases.

Mr. CLAWSON. Could I have another minute, Chairman? Is that all right? Okay. Thank you for your patience.

Mr. SMITH. Sure.

Mr. CLAWSON. So let us change gears a little bit. That is all new learning for me so it is on the shelf and I plan to think about it in my duties in Foreign Affairs Committee as well as Homeland Security.

Dr. HOTEZ. Great. Thank you for that.

Mr. CLAWSON. Well, I am pretty new around here so I wouldn't overrate that. So somebody gets off a plane. He has got chikungunya or dengue fever. The emergency room goes through their checklist.

They think about malaria because they know he came from a tropical country. They think about influenza. They probably don't think about dengue fever or chikungunya, even in a very good clin-

ic, even though the person has got a high fever and is coming from one of those infected countries. Am I right or wrong about that?

Dr. HOTEZ. Well, we can actually prove you are right because we did this exercise. Kristy Murray, who is a faculty member in our National School of Tropical Medicine, found that dengue, when she did this through retrospective records, emerged in Houston, which has got a pretty good medical center, which I am from, one of the best health care facilities in the world, dengue emerged in 2003 with an epidemic, again, from people who never left Houston—people who have been living there the whole time, and it occurred again in 2004 and 2005. Not a single case was diagnosed by a physician.

Mr. CLAWSON. So then the conclusions that I am drawing from everything I have heard so far today are——

Dr. HOTEZ. Which, by the way, is the reason why we have now created a unique certificate program—a diploma in tropical medicine, an 8-week concentrated course that we are now giving to physicians, medical students, residents to actually teach them how to recognize these diseases.

Mr. CLAWSON. And what percentage of doctors in the Gulf Coast states that you have talked about earlier have had that course?

Dr. HOTEZ. Well, we have probably graduated about six classes with maybe 20 physicians each. So it is a small number—a very small number.

Mr. CLAWSON. So right now on vaccines, mosquito nets and not letting the water pool up and our diagnosis is about 20 doctors that know enough to have an idea what they are seeing. I don't want to overstate the negative but tell me if I am——

Dr. HOTEZ. No, I think you are reading between the lines of my testimony which is that it is not clear to me that we have adequate public health preparedness for neglected tropical diseases affecting the Southern part of the United States.

We need to step it up and part of the problem is we are not even—we are doing almost nothing in regard to active surveillance of many of these diseases. Dengue may actually be an exception because there is a dengue branch of the Centers for Disease Control based in Puerto Rico.

But, certainly, for the other diseases, I mean, again, they mimic other conditions. So Chagas disease mimics heart disease or toxocariasis——

Mr. CLAWSON. Nonspecific symptoms?

Dr. HOTEZ. Right. So unless you are actively looking for it and going into the affected communities, you are going to miss it.

Mr. CLAWSON. I got it. I guess I would then draw the conclusions that as—to the chairman's point, as we see the funding for appropriations, given that I am from a Gulf state I am going to be interested in how much prevention and how much diagnosis is going to be a part of the program.

Dr. HOTEZ. Yes. I mean, the key, from my perspective, is we have to figure out how to walk and chew gum at the same time because USAID has now launched this mass treatment program, which in my estimate is one of the most effective and most cost effective public health control programs out there globally.

But and so we need to keep that going, even increase it. But at the same time we have got to pay attention to our neglected populations here in the Southern part of the United States.

Mr. CLAWSON. And then I guess my final point is a little bit from left field, as Mr. Meadows might have said. At some point, our employers have got to understand this, too.

I mean, if I was operating a resort in southern Florida I would want to know a little bit about dengue fever. Am I missing something or would you agree with that?

Dr. HOTEZ. Yes. We will certainly know it if we see chikungunya hit the Southern part of the United States. Dengue is a febrile illness.

It could mimic other diseases even though it is called break bone fever. Chikungunya can cause excruciating joint symptoms and that is going to be a show stopper if and when it hits over the summer.

Mr. CLAWSON. Well, then my main message is we need to win.

Dr. HOTEZ. We sure do.

Mr. CLAWSON. Okay. Anything I can do to help you all let me know.

Dr. HOTEZ. Thank you. I do appreciate it.

Mr. CLAWSON. Thanks for your patience with all of these questions.

Dr. HOTEZ. Great questions. Thank you.

Mr. SMITH. So thank you very much. I will just conclude with a couple of final questions. The surgeries that sometimes are required how often do they occur? When medicines are not up to the task?

Mr. KOURGIALIS. Trichiasis surgery—can you clarify your question? In terms of how frequently they——

Mr. SMITH. Yes, do they get—do individuals get the surgeries? I think—did you have the 4 million number?

Mr. KOURGIALIS. Okay. There is a considerable trichiasis backlog though it is being addressed now. Certainly, the recent USAID grant will help to address that in a significant way in many of the countries where we work.

Certainly, there is a broader commitment on the part of the global community to address morbidity management. A lot of resources have been invested in preventative chemotherapy and distribution of drugs.

But dealing with the later consequences of diseases, both for lymphatic filariasis and for trichiasis, there haven't been the comparable investments made in the past. But they are being made now and a lot of progress is being made as we speak.

But, certainly, it is going to take some time to address that backlog. It has been a longstanding commitment of Helen Keller International to address this need and it is something that the global community has committed to do, too.

In order to achieve the elimination criteria that WHO has set, these issues have to be addressed: Hydrocele, lymphedema management, and trichiasis. So that is why this investment is being pushed in order to achieve these elimination targets.

Mr. SMITH. Thank you. Finally, in his statement, Dr. Pablos-Mendez mentioned that there are 800 million people who still need treatment.

Does that comport with your estimations as well? And it seems when we are talking about this, it is almost like money that falls off the table in terms of magnitude versus what we could be doing.

A $25-million increase from the current levels at a time when a cut was recommended is not all that much money when you have such an overwhelming pool of people not getting the help they need.

Dr. HOTEZ. So that is based on WHO. I believe that number is based on WHO estimates. They just came out with new numbers this month which says that 1.7 billion people require treatment for neglected tropical diseases on our planet, which is somewhere between a little more than the number of people that live on no money in the world, that live less than the World Bank poverty figure of a $1.25 a day.

We got a few people living on less than $2 a day who also have that problem. Of that I think it was 1.7 billion there are about 717 million people who have received access to essential medicine.

It is pretty good and a pretty amazing program. But that still leaves a gap and, of course, the United States cannot be expected to do all of this.

We need the United Kingdom, of course, to continue their commitments. Also, some of the disease-endemic countries can do more than they are doing.

So our global network for neglected tropical diseases, which is headed by Neeraj Mistry, is going into some of the wealthier emerging economies to say, you have got to step up also and do better at treating your own NTDs.

So he is leading efforts in India for this purpose, in Nigeria for this purpose. These guys should be able to support their own NTDs and I think that is going to be a big step forward as well.

And then Neeraj, which Michelle Brooks, who is with me here today, is also working on the German Government to start stepping up. We need to have some of the other European countries step up as well.

So the whole point is the United States should not be going alone on this. Other countries need to weigh in as well.

Mr. SMITH. Section 202 of our new bill would require a report on neglected tropical diseases in the U.S. To your knowledge, has that been done before?

And secondly, the Centers of Excellence idea, the establishment of such a center—how much do you think that would cost? You know, do you have any kind of ballpark estimate of what such a center would require in terms of appropriation?

And when you spoke earlier about when we get a blood test—that box and having to check the box—do you perceive that that is something that might emanate out of these centers—that the unmet need would be or the lack of surveillance on an individual basis would manifest and they would say, this is what we need to do now?

Dr. HOTEZ. It does, Congressman, and we are looking at what we are doing here in Houston as a model for what needs to be done.

So we are focusing on developing new diagnostics and new vaccines.

I think the key point of having a Center of Excellence is not only on the surveillance component but you want to see tangible deliverables. We need products for this and they are going to have to come out of the public's—of the nonprofit sector jointly with pharma.

But we can't count on pharma alone to do this. In terms of level of funding, it depends on the extent of the deliverables.

I think it is unrealistic to expect anything more than $3 million or $4 million a year at most and probably less than that.

Mr. SMITH. Mr. Clawson, anything before we conclude?

Anything you would like to add before we conclude the hearing, either of you?

Mr. KOURGIALIS. Thank you.

Dr. HOTEZ. No, again, thank you for this opportunity.

Mr. SMITH. Oh, thank you. One of the things we do with this committee is that we do take information and it is all about what is actionable, and we will follow up and use what you have provided as effectively as we can.

So I thank you for your leadership but also for sharing your valuable time with the subcommittee to make your very, very valid points and to give guidance on these issues.

Dr. HOTEZ. Congressman, thank you for your leadership and yours, Congressman Clawson, as well. Thank you.

Mr. SMITH. Thank you.

The hearing is adjourned.

[Whereupon, at 4:06 p.m., the committee was adjourned.]

APPENDIX

Material Submitted for the Record

SUBCOMMITTEE HEARING NOTICE
COMMITTEE ON FOREIGN AFFAIRS
U.S. HOUSE OF REPRESENTATIVES
WASHINGTON, DC 20515-6128

Subcommittee on Africa, Global Health, Global Human Rights, and International Organizations
Christopher H. Smith (R-NJ), Chairman

April 15, 2015

TO: MEMBERS OF THE COMMITTEE ON FOREIGN AFFAIRS

You are respectfully requested to attend an OPEN hearing of the Committee on Foreign Affairs, to be held by the Subcommittee on Africa, Global Health, Global Human Rights, and International Organizations in Room 2172 of the Rayburn House Office Building (and available live on the Committee website at http://www.ForeignAffairs.house.gov):

DATE: Wednesday, April 15, 2015

TIME: 2:30 p.m.

SUBJECT: The Continuing Threat of Neglected Tropical Diseases

WITNESSES:

Panel I
Ariel Pablos-Méndez, M.D.
Assistant Administrator
Bureau for Global Health
U.S. Agency for International Development

Panel II
Peter J. Hotez, M.D.
President
Sabin Vaccine Institute

Mr. Nicholas Kourgialis
Vice President, Eye Health
Helen Keller International

By Direction of the Chairman

The Committee on Foreign Affairs seeks to make its facilities accessible to persons with disabilities. If you are in need of special accommodations, please call 202/225-5021 at least four business days in advance of the event, whenever practicable. Questions with regard to special accommodations in general (including availability of Committee materials in alternative formats and assistive listening devices) may be directed to the Committee.

COMMITTEE ON FOREIGN AFFAIRS

MINUTES OF SUBCOMMITTEE ON *Africa, Global Health, Global Human Rights, and International Organizations* HEARING

Day *Wednesday* **Date** *April 15, 2015* **Room** *2172 Rayburn HOB*

Starting Time *2:32 p.m.* **Ending Time** *4:06 p.m.*

Recesses [*0*] (____ to ____) (____ to ____) (____ to ____) (____ to ____) (____ to ____) (____ to ____)

Presiding Member(s)

Rep. Chris Smith

Check all of the following that apply:

Open Session [✓]
Executive (closed) Session [ ]
Televised [✓]
Electronically Recorded (taped) [✓]
Stenographic Record [✓]

TITLE OF HEARING:

The Continuing Threat of Neglected Tropical Diseases

SUBCOMMITTEE MEMBERS PRESENT:

Rep. Curt Clawson, Rep. Mark Meadows

NON-SUBCOMMITTEE MEMBERS PRESENT: *(Mark with an * if they are not members of full committee.)*

HEARING WITNESSES: Same as meeting notice attached? Yes [✓] **No** [ ]
(If "no", please list below and include title, agency, department, or organization.)

STATEMENTS FOR THE RECORD: *(List any statements submitted for the record.)*

Questions for the record from Rep. Chris Smith
Article by Dr. Peter Hotez, submitted for the record by Rep. Chris Smith

TIME SCHEDULED TO RECONVENE _____
or
TIME ADJOURNED *4:06 p.m.*

Gregory B. Simpkins
Subcommittee Staff Director

QUESTIONS FOR THE RECORD OF THE HONORABLE CHRISTOPHER H. SMITH

AFRICA, GLOBAL HEALTH, GLOBAL HUMAN RIGHTS, AND INTERNATIONAL ORGANIZATIONS SUBCOMMITTEE HEARING, COMMITTEE ON FOREIGN AFFAIRS, U.S. HOUSE OF REPRESENTATIVES (#1) "THE CONTINUING THREAT OF NEGLECTED TROPICAL DISEASES" April 15, 2015

Question:
You have testified about the success of USAID's NTD program and stated that "the elimination of these diseases of extreme poverty as a public health scourge is within our grasp." However, the drastic cut in NTD funding in the Administration's FY 2016 budget proposal would seem to undercut any prediction of continued success. What is being planned to cope with this reduction in funding?

Answer:

The Administration's FY 2016 budget request for USAID's Neglected Tropical Disease (NTD) program reflects difficult choices amongst competing budgetary demands. We are confident that with the funding to be provided in FY 2016, USAID's NTD program will continue making great strides in helping the world's most vulnerable people move from dependency to self-sufficiency and on the way to ending diseases of extreme poverty.

USAID's NTD program is the largest public-private partnership collaboration in USAID's 50-year history, contributing to the goal of:

- eliminating of onchocerciasis in the Americas by 2016;
- eliminating of lymphatic filariasis globally by 2020; and
- eliminating of blinding trachoma globally by 2020.

Over the past seven years, the U.S. Government has leveraged $8.8 billion in donated medicines, resulting in the delivery of more than 1.2 billion treatments to approximately 554 million people, cumulatively.

QUESTIONS FOR THE RECORD OF THE HONORABLE CHRISTOPHER H. SMITH

AFRICA, GLOBAL HEALTH, GLOBAL HUMAN RIGHTS, AND INTERNATIONAL ORGANIZATIONS SUBCOMMITTEE HEARING, COMMITTEE ON FOREIGN AFFAIRS, U.S. HOUSE OF REPRESENTATIVES (#2) "THE CONTINUING THREAT OF NEGLECTED TROPICAL DISEASES" April 15, 2015

Question:

In addition to the proposed 17% reduction in NTD funding, the global health security budget is being recommended for a 31% cut. Is the emergency funding created for the Ebola pandemic being counted on to meet the needs for other potential pandemics in this fiscal year and the next?

Answer:

The Ebola emergency supplemental appropriation that Congress included in the FY 2015 appropriations focused on getting to zero cases, aiding recovery from the devastating effects of Ebola, and establishing the capacity to prevent, detect, and respond to future Ebola outbreaks and similar threats in the region. Congress' decisive action in appropriating the needed funds allowed our nation to be a leader in an aggressive international response that has yielded impressive results, as demonstrated by the dramatic decline in new cases across the three primary Ebola-affected countries in West Africa.

The Administration's FY 2016 request of $50 million for the Global Health Security in Development program (formerly known as Pandemic Influenza and Other Emerging Threats) is a straight line from the FY 2015 request and will allow USAID to implement the Global Health Security Agenda beyond the Ebola response in affected regions. This will reduce the risks to Americans through the establishment of capacity for vulnerable countries to prevent disease outbreaks, provide early detection (particularly before viruses transition from animals hosts to humans), and respond before they become epidemics that threaten our national security. This includes urgent needs to monitor for viruses in animals that could be future threats; understand where risk of emergence of new public health threats is greatest; provide equipment and training needed to test patients and report data in real-time; establish safe and secure laboratory capacity; develop and prepare a trained workforce to track and end outbreaks; and develop risk-mitigation strategies. These activities are essential for global health security beyond Ebola – to stop future infectious disease outbreaks early to reduce the negative health, economic, social, and development impacts.

QUESTIONS FOR THE RECORD OF THE HONORABLE CHRISTOPHER H. SMITH

AFRICA, GLOBAL HEALTH, GLOBAL HUMAN RIGHTS, AND INTERNATIONAL ORGANIZATIONS SUBCOMMITTEE HEARING, COMMITTEE ON FOREIGN AFFAIRS, U.S. HOUSE OF REPRESENTATIVES (#3) "THE CONTINUING THREAT OF NEGLECTED TROPICAL DISEASES" April 15, 2015

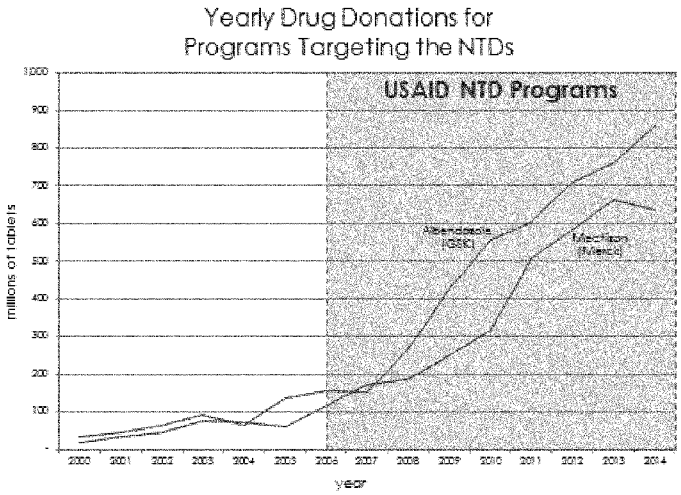
Question:

U.S. Government NTD programming is dependent, as you describe it, on the donation of drugs by pharmaceutical companies. What is being done or what should be done to encourage the continuation or even expansion of such donations?

Answer:

The current drug companies supporting the USAID Neglected Tropical Disease (NTD) Program have been expanding their donation programs for decades. The Merck Co. Inc. and GSK drug donations for onchocerciasis and lymphatic filariasis are the two longest programs dating back to 1987 and 1998, respectively. Both companies have expanded their programs to incorporate other diseases. Merck expanded from supporting onchocerciasis to lymphatic filariasis and GSK added soil-transmitted helminths to their original lymphatic filariasis donation of albendazole. In addition, other companies have joined the NTD donation efforts and have continued to meet commitments and expand output in line with country-level demands. This commitment was restated publically at the London Declaration on NTDs in 2012.

The pharmaceutical sector has consistently taken the position that for the donation programs to continue, country programs need to be in a position to use the regular supply of donated medicines, which includes having sufficient funding to implement Mass Drug Administration, conduct monitoring and evaluation, and improve human and physical infrastructure – all in a coordinated effort to achieve control and elimination. When the countries are in a position to use donated medicines, the industry donation supplies have been made available. The table below shows the dramatic increase in the drug donations through Merck and GSK as a result of the increased funding to distribute drugs provided by the U.S. Government since 2006.



Data courtesy of the Task Force for Global Health, Secretariat for the Merck and GSK drug donation programs.

MATERIAL SUBMITTED FOR THE RECORD BY THE HONORABLE CHRISTOPHER H. SMITH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY, AND CHAIRMAN, SUBCOMMITTEE ON AFRICA, GLOBAL HEALTH, GLOBAL HUMAN RIGHTS, AND INTERNATIONAL ORGANIZATIONS

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PLOS | NEGLECTED TROPICAL DISEASES

Viewpoints

The Gulf Coast: A New American Underbelly of Tropical Diseases and Poverty

Peter J. Hotez[1,2,3]*, Kristy O. Murray[1]*, Pierre Buekens[4]*

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The recent finding that dengue fever has emerged in Houston, Texas—the first major United States city in modern times with autochthonous dengue—adds to precious evidence indicating that the Gulf Coast of the Southern US is under increasing threat from diseases thought previously to affect only developing countries.

Extreme poverty and a warm, tropical climate are the two most potent forces promoting the endemicity of neglected tropical diseases in Africa, Asia, and Latin America. Now, these same forces are also widely prevalent in the five states of the US Gulf Coast—Texas, Louisiana, Mississippi, Alabama, and Florida (Figure 1). Poverty is rampant: ten million Gulf Coast residents currently live below the US poverty line, with Mississippi topping the list of all states in terms of percentage of people who live in poverty (22%) [1]. Texas alone has almost five million poor people [1]. Of particular concern is the level of extreme poverty—defined as less than one-half of the federal poverty level—in the region, especially among minorities. One in ten black children living in Louisiana and Mississippi live in such near-developing-nation-level conditions [2]. Superimposed on this pervasive extreme poverty are frequent and periodic exposures to climate and environmental hazards, including hurricanes, floods, droughts, and oil spills [3,4], which in some cases can further exacerbate financial hardships in the region. Thus, today the Gulf Coast is currently considered America's most vulnerable and impoverished region [4,5].

One of us (PJH) previously noted in 2011 how neglected tropical diseases could emerge in this mixing bowl of poverty and hardship in the Gulf (Table 1) [6]. At that time, the key factors linking poverty with disease on the Gulf Coast included housing with inadequate or absent plumbing, air conditioning, and/or window screens, and it was predicted that the region faces imminent threats from dengue fever and other vector-borne tropical infections [6]. Now, a new retrospective study of almost 4,000 sera samples has revealed that Houston, Texas, suffered from a seasonal outbreak of dengue fever caused by dengue virus type 2 (DENV-2) from May until September of 2003, with transmission (by *Aedes* mosquitoes) also occurring in the two subsequent years [7]. No information beyond this period is available, so it remains a possibility that dengue emerged prior to 2003 and might still be causing seasonal epidemics. Moreover, it was also reported that in 2004–2005 an outbreak of DENV-2 dengue fever occurred in Cameron County, more than 300 miles to the south on the Texas Gulf Coast [8,9]. Additional news reports indicate that dengue returned to Cameron and Hidalgo Counties late in 2013. In both the Houston and South Texas outbreaks, the poorest communities were most affected [7–9].

In light of the locally acquired cases of dengue fever caused by DENV-1 in Florida in 2009–2010 [10], an added concern is whether the phenomenon of viral immune enhancement that could result from the presence of two different dengue serotypes (previous exposure to one serotype followed by infections with a different serotype) on the Gulf could place populations living there at future risk for dengue's most serious complications: severe dengue and dengue shock syndrome.

Beyond dengue, Texas previously suffered from regular St. Louis encephalitis summer outbreaks [11] and currently has had the largest number of cases of West Nile virus (WNV) infection (transmitted by *Culex* mosquitoes) of any state, with periodic spikes in the number of cases occurring at three-year intervals [12]. Possibly unique to WNV strains in Texas [13] is the observation that chronic persistent infection and prolonged immunoglobulin M (IgM) seropositivity is a common occurrence and is associated with several major clinical sequelae [14], including depression [15] and chronic kidney disease associated with viruria [16].

The US Gulf Coast is also considered vulnerable to the introduction of Chikungunya fever, an alphavirus infection transmitted by *Aedes* mosquitoes that clinically resembles dengue, with the possibility of year-round transmission in the warm Gulf climate [17]. Still another mosquito-transmitted viral infection—Venezuelan equine encephalitis (VEE)—spread rapidly from Guatemala and into Gulf coastal regions of Mexico and South Texas during the late 1960s and early 1970s, resulting in the deaths of 1,500 horses and several hundred human illnesses on the US side [18]. The VEE virus continues to actively circulate in areas of Mexico bordering the US [18].

Important neglected bacterial infections also stand out. Both murine and epidemic typhus have emerged among the homeless in Houston [19]. *Vibrio vulnificus* is a gram-negative bacterium of estuarine and coastal habitats of the northern Gulf of Mexico, where it has become an important opportunistic pathogen that can cause serious wound infections and primary septicemia among individuals who come into contact

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Figure 1. Gulf Coast of the US (original prepared by Nathaniel Wolf).
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with seawater or contaminated seafood [20].

Among the parasitic infections now considered widespread in the Gulf Coast, trichomoniasis was shown to be the leading sexually transmitted infection and an important cofactor in the HIV/AIDS epidemic in New Orleans, Louisiana [6,21]. Human autochthonous Chagas disease transmission has been confirmed in Texas and Louisiana [6,22,23]. Canine Chagas has also been found in these states. A recent economic analysis reveals that Chagas disease incurs almost $900 million in costs in the US [24], although the percentage of these costs for the Gulf region has not been specified. Similarly, toxocariasis, a soil-transmitted helminthic zoonosis, disproportionately occurs in the South, affecting as many as one in five non-Hispanic blacks and linked to low education levels and cognitive delays [25], but its prevalence in the Gulf is not known.

To date, the major social determinants of the neglected tropical diseases are poverty and also race or ethnicity. The actual biomedical underpinnings for these connections are poorly understood, although, with respect to poverty, in some cases poor housing may increase exposure to medically relevant vectors while lack of sanitation and access to clean water in impoverished areas, as well as lack of access to health care, would further promote disease. These diseases also disproportionately occur among non-Hispanic blacks and Hispanics, but this relationship may also be based mostly on links to poverty.

Still another observation is the association between some of these neglected tropical diseases and maternal and child health. There are an estimated 40,000 pregnant North American women who are *Trypanosoma cruzi* seropositive and at risk of transmitting the parasite to their babies [26]. Thus, there is an urgent need to measure the frequency of congenital Chagas disease and to evaluate the need for screening and treatment. Dengue in pregnancy is also increasingly recognized for its associations with increased risks of postpartum hemorrhage and preterm birth [27].

Some of the urgent needs in addressing the neglected tropical diseases in the Gulf have been summarized previously and include specific recommendations for greatly expanded disease surveillance and studies to determine exactly how these diseases are transmitted [6,28,29]. Currently, such studies are not being actively pursued across the Gulf region for any major neglected tropical disease. Mosquito control programs are often well organized, but there is a need to seriously investigate different control strategies for vector-borne diseases in order to reduce vector populations and host exposure [17]. For many neglected tropical diseases, diagnostic tests are cumbersome or not widely available. There is a severe lack of physician awareness about how

Table 1. Actual or potential neglected tropical disease threats to the US Gulf Coast.

Disease	Previous 20th-century outbreaks or endemicity	Current 21st-century outbreaks or endemicity	Gulf Coast states known to be affected
Viral Infections			
Dengue fever	+	+	Texas and Florida
West Nile virus infection	+	+	All
St. Louis encephalitis	+	+	All
Chikungunya			None as of yet
Venezuelan equine encephalitis	+	-	Texas
Bacterial Infections			
Murine typhus	+	+	Texas
Vibrio vulnificus	+	+	All
Parasitic Infections			
Trichomoniasis	+	+	All
Toxoplasmosis	+	+	All
Chagas disease	+	+	Texas and Louisiana
Cutaneous leishmaniasis	+	+	Texas
Toxocariasis	+	+	All
Cysticercosis	+	+	Texas

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to manage and treat neglected tropical diseases and an equally urgent need to develop new or better drugs and vaccines.

The stakes are high. The Gulf Coast remains vitally important to the American economy because of its key role in petrochemicals [3] and shipping [4]. Today, Houston and New Orleans represent two of the largest American ports [4], with expectations that these ports will continue to expand significantly with the imminent widening of the Panama Canal. Enhanced measures to detect, treat, and prevent neglected tropical diseases are important steps to promote the health of populations living on the Gulf and ensure the region's economic vitality.

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